ATHABASCA UNIVERSITY

CHARACTERISTICS OF PATIENT EDUCATION IN SELF-ADMINISTRATION OF HOME INTRAVENOUS ANTIMICROBIALS: A MULTIPLE CASE STUDY and LOGIC MODEL

BY

DAPHNE BROADHURST

A THESIS

SUBMITTED TO THE FACULTY OF GRADUATE STUDIES

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF NURSING

FACULTY OF HEALTH DISCIPLINES

CENTRE FOR NURSING AND HEALTH STUDIES

ATHABASCA, ALBERTA

MAY, 2020

Athabasca University
FACULTY OF GRADUATE STUDIES

Approval of Thesis

The undersigned certify that they have read the thesis entitled

CHARACTERISTICS OF PATIENT EDUCATION IN SELF-ADMINISTRATION OF HOME INTRAVENOUS ANTIMICROBIALS

Submitted by

Daphne Broadhurst

In partial fulfillment of the requirements for the degree of

Master of Nursing

The thesis examination committee certifies that the thesis and the oral examination is approved

Co-Supervisors:
Dr. William Diel-Jones
Athabasca University

Dr. Sharon Moore
Athabasca University

Committee Member:
Dr. Beth Perry
Athabasca University

External Examiner:
Dr. Nicole Harder
University of Manitoba

December 4, 2019

1 University Drive, Athabasca, AB, T9S 3A3 Canada
P: 780.675-6821 | Toll-free (CAN/U.S.) 1.800.788.9041 (ext 6821)
fgs@athabascau.ca | fgs.athabascau.ca | athabascau.ca

Dedication

This work is inspired by and dedicated to:

- My daughter, Cassie, who just wanted to get to the cottage with her IV antimicrobials to celebrate her Sweet 16th Birthday;
- My incredibly courageous and precious nephew, Matthew, and sister, Diana, through their steadfast determination to fit healthcare into their family life, despite the all-consuming struggles of a tragic healthcare journey (performing Matthew's infusion therapy care, dare I say, safer and more diligently than most any nurse); and
- All patients striving to fit healthcare into the demands of their hectic lives in their journey to wellness.

Thank you for inspiring me.

Acknowledgements

It is with a grateful heart that I extend my sincere thankfulness for the scholarly and loving guidance that acted as a shining beacon to find my way through this thesis journey. Dr. William Diehl-Jones- thank you for your incredibly patient wisdom and confidence in me, steering the winding pathway, encouraging my strengths and working with my limitations. Dr. Sharon Moore- your expertise as a qualitative scholar stretched my epistemological approach to query knowledge through a more pragmatic lens- beyond empiricism. Dr. Beth Perry and Dr. Nicole Harder-your expertise as reviewers strengthened the rigour of my thesis. Dr. Gwen Rempel- thank you for meeting me in Toronto to help me find my way, sharing your vast insight and expertise. Your Athabasca Graduate Studies Program leadership has inspired my burgeoning love for research.

To my loving family, you all were so patient with Mom as she sat at her desk seeking higher knowledge. Scottie- thank you for your love, patience, and understanding, keeping the family running, and motivating me to cross the finish line. Shannon, Sean, and Cassie- thank you for patiently championing my research.

This work was dependent upon the dedication and expertise of the generous nurses and patients who welcomed me into their world- helping me learn how they teach/learn self-administration. It is my sincere hope that achieving and sharing this knowledge gleaned through the lens of these participants will help strengthen community nurses as strong supporting coaches and patients as active and keen participants in their path to wellness.

Abstract

Self-administration of intravenous antimicrobials has been designated as a healthcare innovation practice; however, there has been limited national uptake. The aim of this descriptive-explanatory multiple case study is to describe the characteristics of a self-administration patient education program and to explain the mechanisms used to activate learning. Data was triangulated from two cases of home infusion programs, including direct observations of 18 nurse-patient teaching sessions, three focus groups of 18 nurses and four patient interviews. Results are synthesized as a program theory logic model and toolkit for patient education in self-administration, which includes program inputs (e.g., willing and able patients, competent and patient nurse coaches, easy-to-use supplies and personalized patient education materials) applied to tailored patient education which triggers mechanisms such as patient self-efficacy and empowerment to perform self-administration which fits their lifestyle, leading to outcomes such as patient satisfaction, adherence to therapy, and improved healthcare resource utilization.

Keywords: Self-administration, patient education, home care, case study, program theory, critical realism

Table of Contents

Dedication iii
Abstract v
List of Tables viii
List of Figures ix
List of Abbreviations x
Chapter 1. Introduction 1
Traditional Nurse-Administration Home Care Model 1
Shifting to a Self-Administration Model 4
Statement of the Problem 6
Chapter 2. Review of the Literature 7
Self-administration: Is it Safe, Effective and Acceptable? 7
Characteristics of Patient Education for Self-Administration 11
Mechanisms of Patient Education 16
Summary 16
Research Questions 17
Chapter 3. Conceptual Framework 19
Purpose of the Study 20
Self-Care 20
Patient Activation 21
A Realist Program Theory of Self-Administration 22
Significance of Research 24
Chapter 4. Study Methods 27
Case Study Methodology 27
Operational definitions 32
Ethical Considerations 33
Study Participants 34
Data Collection 38
Data Analysis 44
Role of the Researcher 46
Chapter 5. Results 48
Description of the Cases 48
Characteristics of Patient Education 51
Mechanisms (Outputs) of Patient Education 74
Synthesis of Finding 79
Chapter 6. Discussion 86
Comparison of Findings with Literature 86
Methodological considerations 96
Implications of Findings 101
Chapter 7. Conclusion 106
References 110
Appendix A: Athabasca University Certification of Ethical Approval 129
Appendix B: University of Manitoba Research Ethics Certificate 130
Appendix C: Winnipeg Regional Health Authority Letter of Approval 131
Appendix D: Email Recruitment (for case sites) 132

Appendix E: Letter of Information/Informed Consent Form (for case sites) 133
Appendix F: Letter of Information/Informed Consent Form (for Nurses in Observation Study) 138
Appendix G: Letter of Information/Informed Consent Form (for Nurses in Focus Groups) 142
Appendix H: Email Recruitment (for Case Sites)..... 147
Appendix I: Letter of Information/Informed Consent Form (for Patients in Observation Study) 148
Appendix J: Letter of Information/Informed Consent Form (for Patient Interviews) 152
Appendix K: Observation Grid..... 156
Appendix L: Focus Group Interview Guide 157
Appendix M: Patient Interview Guide..... 158
Appendix N: Baseline Case Site Data Interview Questions 159
Appendix O: Certificates of Ethical Approval..... 161

List of Tables

Table 1 Characteristics of Educational Interventions for Self-administration of Outpatient Antimicrobial Parenteral Therapy …… 13

Table 2 Community Infusion Program Characteristics ……... 49

Table 3 Initial Logic Model of Patient Education in Self-administration of Home IV Antimicrobials - *Case A* ……..... 54

Table 4 Initial Logic Model of Patient Education in Self-administration of Home IV Antimicrobials- *Case B* …… 55

Table 5 Characteristics of Observed Self-Administration Patient Education Programs ……..... 58

Table 6 Plain Language Terms for Self-Administration of Home IV Antimicrobials …… 71

Table 7 Visit Schedule Exemplar for Teaching Self-Administration in One Session ……. 85

List of Figures

Figure 1 Conceptual framework of patient education for self-administration ……. 19

Figure 2 Mechanisms (outputs) of patient education in self-administration ……... 75

Figure 3 Logic model for self-administration of home IV antimicrobials ……... 80

Figure 4 Strategies for Successful Patient Education in Self-Administration of Home IV ……. 86

List of Abbreviations

IHI	Institute for Healthcare Improvement
IV	Intravenous
PICC	Peripherally inserted central catheter

Chapter 1. Introduction

The Institute for Healthcare Improvement (IHI) has designated patient-administered self-care of infusion therapy as a healthcare innovation practice (Martin & Anderson, 2017). Self-administration of home intravenous (IV) antimicrobial therapy ('self-administration') implies the patient or informal care partner can independently administer the infusion of antimicrobial agents in the patient's home. This model has been shown to increase patient autonomy, satisfaction, and self-efficacy, as well as optimizing healthcare resource utilization, while demonstrating similar or improved patient outcomes to nurse administration (Barr, Semple & Seaton, 2012; Kieran, O'Reilly, Parker, Clarke & Bergin, 2009; Martin & Anderson, 2017; Mitchell et al., 2017; Stiver, Trosky, Cote & Oruck, 1982; Subedi, Looke, McDougall, Sehu & Playford, 2014).

Stiver and colleagues (1978) recognized the capacity of patients to self-administer in the 1970s; however, there has been slow global uptake of this approach (Mackenzie, Rae & Nathwani, 2014). As Nazarko states, "the number of people who have the ability to self-administer IV therapy is probably much greater than most professionals realize" (2013, p.165). There is significant potential to promulgate this practice, engaging and empowering patients in this resource-protective model of care (Martin & Anderson, 2017; Nazarko, 2013).

Traditional Nurse-Administration Home Care Model

Parenteral administration of medications, such as antimicrobial agents and hydration therapy, in the home setting has become a standard of practice. Patients receive infusions of antimicrobials at home for the treatment of infections such as muscle, bone, skin and soft tissues infections (e.g., osteomyelitis and cellulitis) (Kieran et al., 2009). Supporting patients in their natural environments has been shown to improve patients' quality of life (Nathwani, 2000).

The appropriateness of infusion therapy in the home care setting, in terms of efficacy, safety and cost-effectiveness, has been well-supported by the extant literature (Corwin et al., 2005; Cote, Oruck & Thickson,1989; Fried, van Doom, O'Leary, & Drickamer, 2000; Harris, Ashton, Broad, Connolly & Richmond, 2005; MacKenzie et al., 2014; Marra et al., 2005; Stiver et al., 1978; Stiver et al., 2000). A systematic review of home infusion therapy literature concluded that home infusion patients "were no more likely to experience adverse drug events or side effects (all $p > .005$)" than infusion in an outpatient medical facility or hospital (Polinski, Kowal, Gagnon, Brennan, & Shrank, 2017, p. 68). Clinical outcomes "were as good or better" and costs significantly lower, with savings between $1828 and $2974 per treatment course (Polinski et al., 2017, p. 68). Patients allocated to care in the home generally reported higher levels of satisfaction than hospital-based care patients (Corwin et al., 2005; Fried et al., 2000). Polinski and colleagues reported that "patients overwhelmingly preferred receiving infusions at home" as opposed to medical facilities (2017, p. 79). This practice provides freedom for the patients to return to work or school, reducing pressure on hospital bed utilization and decreasing the risk of developing nosocomial infection (Corwin et al., 2005; Fried et al., 2000; Harris, Ashton, Broad, Connolly & Richmond, 2005; Seetoh et al., 2013; and Subedi et al., 2015; Wilson et al., 2002). A Canadian study confirmed patient preference to receive parenteral antimicrobial therapy at home as opposed to hospital, by demonstrating patients' willingness to pay to for treatment at home as opposed to receiving publicly funded care in the hospital (Marra et al., 2005). As there has been a significant shift of care from the hospital to the community since the 1970s (Laupland & Valiquette, 2013), home infusion programs strive to ensure sustainability of home infusion therapy within an economically sustainable manner, while still achieving high quality care.

Currently, home care patients in Ontario receive nurse-administered infusion therapy in the home care or clinic setting, with nursing services supported by public funds. In this system, referred to by Orem as a 'wholly compensatory system' (Orem, 2001), nurses are the primary healthcare providers responsible for the administration of this therapy, with typically minimal patient input into these procedures. The nurse is responsible for the preparation of the intravenous medication, management of infusion pumps and tubings to deliver the medication through the patients' intravenous catheters, flushing the catheter to prevent catheter blockage, and monitoring for complications. This complex process may necessitate frequent nursing services (e.g., daily or more frequent nursing visits in either the home or clinic setting).

This nurse-administration model places both financial and human resource burdens on the healthcare system, in an era of healthcare sustainability concerns. "Health care providers are aging, resources are scarce and it is predicted that demand for health care service will exceed human resource supply in the very near future" (Canadian Home Care Association [CHCA], 2008).

Moreover, Johanson (1984) argues that this nursing system places the patient in a position of dependence upon others (as cited in Hanucherunka & Vinya-nguag, 1991). This ironically counters a core harmonizing principle of home care, which is to foster autonomy and self-sufficiency (CHCA, 2013; Greenfield & Pace, 1985; Johanson, 1984, as cited in Hanucharurnkui & Vinya-nguag, 1991). Furthermore, it has been reported that having care providers come in to the home may be viewed by some as an invasion of their privacy or intrusion of their space (CHCA, 2016) and discontinuity of nurses (i.e., multiple nurses over the course of the therapy) a source of frustration for some patients.

Shifting to a Self-Administration Model

Self-administration of home infusion therapy, however, is a model of care which is designed to promote patient autonomy while optimizing healthcare resource utilization (Martin & Anderson, 2017). Much of the self-administration literature primarily focuses empirically on self-administration outcomes (Mackenzie et al., 2014; Mitchell et al., 2017). Mitchel et al.'s systematic review of community intravenous antimicrobial programs concluded that the duration of treatment, drug-related side effects, venous access complications, hospital readmission rates and deaths were no different across the models of care (outpatient [home or clinic setting] by nurse or patient versus inpatient treatment). The rate of cure or improvement was superior in the self-administration model versus inpatient treatment.

Self-administration of home parenteral antimicrobial therapy refers to the patient or their care provider (e.g., family member, significant other) being taught by nurses to administer the infusion of antimicrobial agents, such as antibiotics and anti-fungals, in the patient's home, as opposed to the traditional nurse-administration model in the home setting (Barr, et al., 2012). Nursing supervision may continue to monitor the patient during the therapy and provide additional care (such as vascular access device placement and management and blood sampling); however, the patient is responsible for the administration of the therapy (Stiver et al., 1982).

With appropriate and supportive education, tasks such as medication administration can be delegated to patients and family caregivers (College of Nurses of Ontario, 2015) alleviating some of the current costly roles of nurses. This supportive-educative nursing system highlights the nurse as a coach, and supporter of patients, and the patient no longer a passive recipient of care (Orem, 2001). Having the patients engaged in their own care in their home fosters autonomy and self-sufficiency, leading to better health outcomes, care experiences, and lower healthcare

costs (Hibbard & Greene, 2013). Patients require complex knowledge and skills to safely administer and monitor their prescribed IV medication therapy.

Eaves and colleagues (2014) emphasize the necessity of a formal, well-designed patient training program to support education of patients to safely administer antimicrobial therapy in the home. In a scoping review of the literature in preparation for this thesis, minimal evidence describes the design of self-administration patient education programs (e.g., patient recruitment, teaching format, duration, and competency validation processes) to explain how nurses teach patients these complex concepts and skills (Eaves et al., 2014; Kieran et al., 2009; Matthews et al., 2007; Subedi et al., 2015). A grounded theory study (Cox & Westbrook, 2005) provided insight into the educational process- from the care partner perspective only. Grimes-Hoslinger (2002) was the sole author to describe the home as the setting of patient teaching, as opposed to the hospital (Cox & Oakes Westbrook, 2005; Eaves *et. al*, 2014; Kieran et al., 2009; Matthews et al., 2007; Subedi et al., 2015). (It was unclear if the teaching setting in the Cox and Oakes Westbrook study was solely the infusion clinic.) In these studies, the only reported intensity of the training sessions was 1-3 days of 1 to 2 hours of patient training sessions per patient (Eaves et al., 2014; Subedi et al., 2015). The time required for patient and family education and patient compliance with this modality have been reported as concerns related to self-administration as this requires an active role in their care and use of sophisticated infusion devices (Tice, 2000). Examination of patient adherence, that is whether patients comply with the therapy as prescribed and taught is beyond the scope of this research; however, a review of patient outcome literature related to self-administration may provide insight whether adherence is an issue.

Furthermore, the self-administration literature fails to describe well how these programs are designed to activate patients to engage in self-administration, particularly in regions in which

nurse administration has been the expectation of both nurses and patients. A grounded theory study examined the teaching-learning experience with self-administration from the care partner perspective (Cox & Oakes Westbrook, 2005). The authors describe increased self-efficacy and satisfaction in learning difficult tasks as motivational factors for care partners. The lack of explanation of mechanisms which trigger patient activation may be a factor contributing to the slow uptake of self-administration.

Statement of the Problem

Transitioning care to the patient as an active participant and involving the nurse in more a supportive role is a paradigm shift. Patients and care providers must have confidence that this is effective and acceptable, and nurses must be effective coaches to teach and support patients to safely achieve self-administration of home intravenous antimicrobials. Evidence describing how nurses engage and teach patients to safely administer their own IV antimicrobials is limited, with studies primarily describing program outcomes, with nominal details of the patient education program and its processes (Cox & Oakes, 2007; Eaves et. al, 2014; Kieran, et al., 2009; Matthews et al., 2007; Subedi et al., 2015). This lack of description of patient education processes provides little guidance for healthcare organizations and healthcare professionals interested in implementing this self-administration model of care, nor for nurses to better understand how to effectively teach self-administration to their patients.

Chapter 2. Review of the Literature

Self-administration of home IV antimicrobial agents is a shift in the paradigm of care, with patients assuming an active role in the care and nurses, a supportive-educative role. In this review of the literature, I further examine the safety, efficacy and acceptability of self-administration. This will help provide evidence to support nurses recruiting patients for self-administration and help determine patient adherence to the prescribed therapy and training. Characteristics of self-administration programs will then be described to better understand what is known about the structure of these programs. Principles of patient activation applied to self-administration will be reviewed to understand the mechanisms of the training-learning process of patients and nurses. To conclude, a summary of this literature will lead to a reveal of research questions arising from this review.

Self-administration: Is it Safe, Effective and Acceptable?

One of the earliest published reports of self-administration therapy was by Stiver and colleagues, with a Manitoba based infectious disease home care program (Stiver et al., 1978; Cote et al., 1989). There is also evidence of this practice in Vancouver, BC (Stiver et al., 2000). Self-administration is practiced widely in the United States (MacKenzie, Rae & Nathawani, 2014). An American outpatient parenteral antimicrobial registry analysis demonstrated 53% self-administration in the home setting (Tice, 2000), while 32% used an infusion centre and 16% received visit nurse administration in the home (Tice, 2000). In the UK and Asia, 7% of patients participated in self-administration which is mirrored in a large Asian cohort (Hitchcock, Jepson, Main, & Wickens, 2009; Seetoh et al., 2013). In Australia, Htin et al.'s retrospective cohort study (2013) of patients with infective endocarditis received 100% nurse-administered home antimicrobial therapy. Mitchell's recent systematic review (2017) of outpatient parenteral

antimicrobial therapy suggests the shift to self-administration is evolving as self-administration was the most frequently reported (52%) model of the 106 studies, followed by specialist nurse visits in the home (34%), outpatient treatment in clinics (34%) and home visits from a general nurse (11%). Most of the studies included were North American-based (35%), followed by Europe (41%), in which two-thirds were UK-based.

Emerging outcome data validating the safety and efficacy of this model of delivery may help shift the pendulum of care. Subedi et al. (2015) concluded in their analysis of self-administration that this modality of therapy is safe and effective, based on an overall cure rate of 93%. Chapman and colleagues' (2009) retrospective analysis of 62 patients with skin and soft tissue infection showed a 98.4% cure/improvement rate of patients receiving self-administered intravenous antimicrobial therapy. Seetoh and colleagues (2013) demonstrated that self-administration and hospital-administration had similar clinical deterioration outcomes, while home care (nurse) administration was a significant risk factor for clinical deterioration, hazard ratio of 2.5, 95% CI [1.7-3.8], $p < .001$. The authors suggested this risk may be indicative of patients' multiple co-morbidities or poorer functional status, older age and possibly the need for more extensive care. Barr, Semple and Seaton (2012) investigated the risk of intravenous catheter adverse events with self-administration in a retrospective cohort study of 2,766 patient episodes and 42,238 patient days. The authors found that patients self-administering had non-significantly lower rate of line infections (i.e., phlebitis, external leakage, extravasation, collusion, dislodgment), OR 1.3171; $p = .2215$. Patients self-administering home IV antimicrobial therapy had a non-significantly lower rate of line infections, OR 0.84; $p = 0.7181$. The researchers concluded that there is no evidence that self-administration is associated with higher rates of catheter-related complications. Matthews et al., (2007) also concluded that

complication rates for self-administration are comparable to healthcare professionals-administered therapy (p=.07). Results of a retrospective review of 944 patients receiving self-administered outpatient parenteral antimicrobial therapy demonstrated that self-administration is not associated with a compensatory increase in emergency department visits related to antimicrobial therapy (Ganguly, Agrawal, Brown & Bhavan, 2018).

Mitchell et al.'s systematic review (2017) reported that self-administration was the model of care with the highest mean cure/improvement rate (91.3%), followed by specialist nurse (90.6%), general nurse (90%) and lastly, the outpatient treatment model (88.3%). No difference was found in deaths, hospital admissions, improved lung function (in cystic fibrosis), drug side effects, or vascular access complications in self-administration versus inpatient treatment. Most of the studies (67%) examined in the systematic review were not experimental or quasi-experimental as they were primarily case-series and involved retrospective data collection.

Demonstration of the acceptability of self-administration may help advance uptake of this modality of care by changing the perception that infusion therapy is solely a nursing intervention. Self- administration of home infusion therapy has been shown to promote patient autonomy, patient and family well-being, and high patient satisfaction levels in a cost-effective manner (Barr, Semple & Seaton, 2012; Kieran et al., 2009; Saillen, 2017; Stiver et al., 1982; Subedi et al., 2015;). Reported factors contributing to the acceptability of and transition towards self-administration include:

- improved intravenous technology (e.g., portable infusion pumps),
- decreased antimicrobial dosing frequency (e.g., intravenous antimicrobials required only once or twice daily rather than four to six times daily), and

- patient preference for autonomous care at home due to the quiet and increased home comfort, familiar environment, ability to resume daily activities and choice of activities, and feelings of improved self-esteem or greater freedom and control (Corwin et al., 2005; Czoski Murray et al., 2015; Mitchell, et al., 2017; Seetoh et al., 2013; Subedi et al., 2015).

Kieran et al.'s satisfaction survey results (2009) of patients performing self-administered home IV antimicrobial therapy indicated "strongly positive results." No patients felt that they had inadequate training in administering the antimicrobials prior to discharge. No patient felt that their infection took longer to be treated because they were treated at home and all patients (n=12) indicated being able to return to work/caregiving. Chapman et al. (2009) also reported strong satisfaction with this mode of therapy, indicating the patient's flexibility, control and ability to fit the therapy around their work and commitments, as sources of satisfaction.

Bhavan and colleagues (2015) demonstrated an annual $10 million dollar savings to the hospital and 47% lower 30-day hospital readmission rate upon introduction of a self-administration of intravenous antimicrobials program. The program enabled patients who lacked sufficient coverage for outpatient care to be discharged home to self-administer their therapy, with supplies provided by the hospital. Tice (2000) reports self-administration presents the advantage of reduced staffing costs (due to reduced nursing visits) and reduced facility costs (as these patients do not necessarily travel to clinic).

Reported disadvantages include the administrative support and nursing time required for patient and family education (Tice, 2000). It may be perceived to be quicker and easier for the nurse to perform the tasks than teach the patient. A Scottish outpatient parenteral antimicrobial therapy clinic found a decrease in uptake of self-administration from 53% in 2006 to 15% in

2013 and 24% in 2015 (Tonna et al., 2019). The author's qualitative study of patients who do not self-administer home IV antimicrobials posited that a lack of resources makes it difficult for the nurse to provide the relatively intense patient training. Tice also cites patient adherence as a potential disadvantage. It is possible that patients may not administer the therapy as prescribed because of the unsupervised administration and use of sophisticated infusion devices, with little training or knowledge of medicine. However, the improvement in cure/improvement rates and not difference in vascular access device complications associated with self-administration (Mitchell et al., 2017) suggest adherence may not be a significant issue.

In summary, extant literature suggests that self-administration is safe, effective and acceptable to patients/care partners and healthcare professionals. It should be noted however that the evidence is of lower quality due to the lack of experimental studies.

Characteristics of Patient Education for Self-Administration

Self-administration requires patients or their care partner to have complex knowledge and skills to safely administer the therapy. Patient education is defined as "any set of planned educational activities, using a combination of methods (teaching, counseling and behaviour modification), that is designed to improve patients' knowledge and health behaviours" (Friedman, Cosby, Boyko, Hatton-Bauer & Turnbull, 2011, p. 12). The goal of patient education is for patients to assume maximum responsibility for their care (Phillips, 1999). The nurse's role is mentoring the patient who is in the process of changing their behaviour, knowledge, attitudes and skills to achieve this. Eaves and colleagues (2014) emphasize the necessity of a formal, well-designed patient training program. The nurse's role is to support the patient/care partners' self-efficacy and capability to achieve this successfully, while minimizing adverse events, such as drug (i.e., toxicity) or catheter-related (i.e., infection) complications.

Evidence describing how nurses teach patients to safely administer their own IV antimicrobials is limited, with studies primarily describing program outcomes, with nominal details of the patient education process (e.g., teaching format, duration, and competency validation) (Cox & Oakes Westbrook, 2005; Eaves et. al., 2014; Kieran et al., 2009; Matthews et al., 2007; Subedi, et al., 2015). Cox and Oakes Westbrook qualitatively explored characteristics of the education process- from the care partner's point of view (not the patient's). These authors emphasized the need to focus on the needs of the learner, assessing their motivation and self-efficacy to influence how the nurse conducts the teaching in an interpersonal caring supportive manner. They applied principles of adult learning theory, Bandura's concept of self-efficacy and the Swanson's middle range of theory to explicate how nurses teach patients new skills.

The Workgroup for Intervention Development and Evaluation Research (WIDER) methodology for reporting of knowledge translation interventions was used to describe published educational interventions of self-administration programs for this paper, with results described in Table 1 (Albrecht, Archibald, Arseneau & Scott, 2013). Although the WIDER recommendation guides authors to provide access to intervention protocols, none of the studies reviewed met this recommendation which hinders description of these education programs. Grimes-Holsinger (2002) described the use of a checklist as a delivery format.

Table 1

Characteristics of Educational Interventions for Self-Administration of Outpatient Antimicrobial Parenteral Therapy

Lead Author, Year, Country	Participant	Provider	Setting	Intensity	Content*	Delivery Format+
Subedi 2015, Australia	Patient/ Carer	N/A	Hospital	1-2 days 1-2hours	N/A	N/A
Eaves 2014, UK	Patient	Nurse	Hospital	3 days	A B C D E F G H	N/A
Kieran 2009, Ireland	Patient	OPAT team	N/A	N/A	B	N/A
Matthews 2007, UK	Patient/ Carer	Nurse	Hospital	N/A	C D F G	1 2 4
Cox 2007, USA	Patient/ Carer	Nurse	Hospital	N/A	C	N/A
Grimes-Holsinger 2002, USA	Patient	Nurse	Home	N/A	A B C D E F	1 3 4

Note: Absence of data indicates no reporting of the data and is not intended to denote program does not provide a content topic or delivery method.

* Content topics:
(A) Asepsis (i.e., handwashing, verifying integrity of solutions and supplies, supplies and medication storage)
(B) Medications (i.e., purpose, side effects, preparation)
(C) Infusion (i.e., priming, gravity/ pump infusions)
(D) Vascular access device care (i.e., flushing, dressing change)
(E) Self-monitoring and complications (i.e., recognition/management/prevention of infection, adverse drug events, catheter occlusion or damage)
(F) Home safety (i.e., emergency plan, waste disposal)
(G) Resources (i.e., who to contact in case of emergency, for supplies…)
(H) Schedules (i.e., nursing visits, deliveries, OPAT clinic follow-up/ bloodwork)

+ Delivery format methods:
(1) Verbal
(2) Demonstration
(3) Return demonstration
(4) Written material
(5) Computer
(N/A) Data not available

Only one of the retrieved studies (Grimes-Hoslinger, 2002) described the home as the setting of patient teaching (as opposed to the hospital) (Cox & Oakes, 2007; Eaves et. al, 2014; Kieran et al., 2009; Matthews et al., 2007; Subedi et al., 2015). The minimal data which are available describe the intensity of the training sessions as being 1-3 days of 1 to 2 hours of patient training sessions per patient (Eaves et al., 2014; Subedi et al., 2015).

Only three studies discussed the training content in detail, with the common topics across these studies being infusion delivery, vascular access device care, and home safety (Eaves et al.,

2014; Grimes-Holsinger, 2002; Matthews et al., 2007). Although the WIDER recommendation guides authors to provide access to intervention manuals/protocols, none of the six studies investigating self-administration met this recommendation (although Grimes-Holsinger [2002] included a checklist), which hindered data analysis. Verbal and written communication of the patient education material with return demonstration were the most common format of education delivery (Grimes-Hoslinger, 2002; Matthews et al., 2007). No studies reported the use of electronic computer and video teaching materials. A systematic review of patient teaching strategies in general concluded that teaching strategies that increased knowledge, decreased anxiety and increased satisfaction included computer technology, audio and videotapes, written materials and demonstration, as well as a combination of strategies (Friedman et al., 2010). Cox and Oakes Westbrook's grounded theory (2005) cautions that outdated, lengthy written instruction materials can cause confusion, frustration and feeling overwhelmed.

Grimes-Holsinger's quasi-experimental study (2002) demonstrated that the use of a standardized teaching checklist for self-administration of infusion therapy leads to less nursing visits, $p < .0001$, and less total time of instruction, $p = .0024$. The strongest correlation, Pearson's $r = .572$; $p < .0001$, occurred between the number of nursing visits and the total teaching time, indicating that controlling the number of visits is a key factor in limiting instruction time. The standardized approach supports Friedman et al.'s systematic review (2010) recommendation for structured teaching. However, the review's authors concluded that use of culturally appropriate and patient-specific teachings targeted to the individual rather than providing only general information were found to be better than ad hoc teaching or generalized teaching. They also caution that the use of verbal teaching and discussion alone were found to be the least effective teaching methods.

Patients' retention of learning self-administration has been shown to be high in a prospective direct observational study of 38 patients nearing completion of intravenous antimicrobial therapy (Eaves et al., 2014). Thirty-five of 38 patients demonstrated strong retention and application of their initial training, with 92% fully competent in all areas evaluated. The authors emphasized the necessity of a formal, well-designed training program to support education of patients to safely administer antimicrobial therapy in the home. Factors that have been identified to support care partner competency in administering infusion therapy at home included knowledgeable resources for problems, sufficient supplies, organized home and access to ongoing follow-up by healthcare providers (Cox & Oakes Westbrook, 2005). These authors emphasize that transfer of care from the nurse to the care partner should occur only when the nurse has assessed a competent return demonstration and the care partner has self-assessed their capability or self-efficacy and there is a mutual agreement of competency.

Evidence is minimal in terms of the intensity (length and duration of session), the teaching method (format) and the application of the home setting for patient teaching (see Table 1). In addition, technology used to administer the infusion therapy may influence the complexity of patient education of self-administration; however, none of the studies cited above explicated the type of infusion device used to facilitate self- administration (e.g., elastomeric infusion device, electronic infusion pump). Transitioning care to the patient as an active participant and the nurse in a supportive role is a shift in care archetype. However, this limited description of patient education programs provides little guidance for organizations interested in developing such a program.

Overall, results from published studies demonstrated the safety, efficacy, and acceptability of self-administration. The literature was moderately useful in identifying

educational content and the hospital as the common setting for teaching, due to the similarity in population across the studies and with the review target population. However, evidence is minimal in terms of the intensity (length and duration of session), the teaching method (format) and the application of the home setting for patient teaching.

Mechanisms of Patient Education

While the literature presents a limited description of patient education programs for self-administration, it does not delve into how nurses in these programs specifically engage patients to participate in self-administration, nor how they tailor their education to the patient's needs, as recommended by Friedman et al. (2011). Cox and Oakes Westbrook's grounded theory of the educational process of home infusion therapy for patient's care partners (2005) suggests that most of the care partners experience negative emotions at the prospect of learning home infusion therapy, ranging from apprehension to anxiety and extreme stress. The nurses' demonstrated competence, reassurance and personalized support was helpful to their learning. Nurses' knowledge and expertise and caring attitudes as "their teacher, coach and chief cheerleader partnering with the learner" helped ensure success (p. 103). Assessing the motivation of the care partner can help the nurse to tailor the education to the needs of the person. They recommend supporting self-efficacy by providing empathy, positive feedback and encouragement, in an unhurried, non-disruptive environment, with opportunity for return demonstration. Care partners reported an increased self-efficacy and satisfaction in learning difficult tasks that enabled their family member to remain at home as outcomes of their learning.

Summary

Self-administration of home intravenous antimicrobial therapy appears to be safe and effective and associated with high patient satisfaction, based on retrospective and observational

data. This review presents a synthesis of the limited extant evidence of the characteristics of patient education in self-administration, using the WIDER methodology, which has not been previously well elucidated in self-administration of home infusion therapy literature. However, evidence describing how self-administration is achieved is limited, with studies primarily describing program outcomes, with little described detail of the patient education process (Cox & Oakes, 2007; Eaves et. al, 2014; Kieran et al., 2009; Matthews et al., 2007; Subedi et al., 2015). Further research guiding the design and implementation of education programs may further the pendulum swing from nurse-administration to self-administration.

Research Questions

The aim of this research is to explain how patient education in self-administration of home IV antimicrobial agents is achieved. We seek to answer the research questions:

1. **What are the characteristics of patient education for self-administration?**
2. **What are the mechanisms which facilitate patient activation to perform self-administration?**

These questions are designed to describe the process of patient education in self-administration and explain why, how, and under what conditions the patient education occurs.

The objectives of this study are to:

- Describe the characteristics of patient education for self-administration of home IV antimicrobial therapy (including patient eligibility criteria; education content, format, intensity, duration, setting).
- Explain how a nurse tailors the teaching to guide effective patient-centric learning.

- Determine how a nurse evaluates patient learning.
- Identify how nurses can help motivate patients to learn self-administration.
- Describe technology (i.e., infusion flow control device types) used in home infusion programs for self-administration.

Chapter 3. Conceptual Framework

This research is guided by a pragmatic and realist theoretical approach, integrating concepts from nursing, psychology and evaluation science. (Turner & Danks, 2013). A realist approach will be used to determine how patient education is achieved. The tenet of realism holds that it is not the intervention itself (patient education) that makes complex interventions work, but people, through their reasoning and reactions (or mechanisms) (Hewitt, Sims & Harris, 2012). Principles of patient activation (such as self-efficacy and skill mastery) will guide the exploration of mechanisms which may trigger patient learning (Hibbard & Mahoney, 2010). This study is underpinned by Orem's theory of nursing systems, in which the goal of a supportive-educative system is to enable patients to be an agent of their own care through nursing support (Vasquez, 1992; Orem, 2001). I have depicted my conceptual framework guiding this research in Figure 1. Baxter and Jack (2008) advise that conceptual frameworks identify subjects, relationships and constructs to be included in the study.

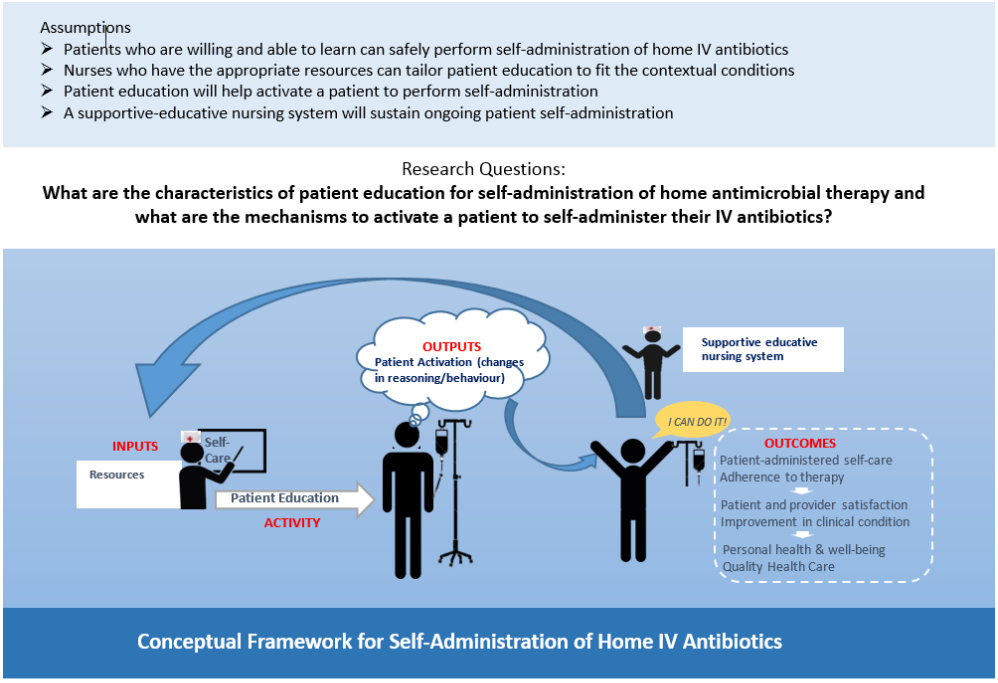


Figure 1. Conceptual framework of patient education for self-administration. This figure depicts the logic model framework concepts underpinning the study (resources, activity, and outputs). (White shapes are the foci of the research; outcomes in box [derived from the literature review] are outside the scope of this study.

Purpose of the Study

The purpose of this research is to explain the process of patient education practiced in self-administration of home IV antimicrobial programs. I seek to explain: (1) how patient education for self-administration of home IV antimicrobials is achieved and (2) what the mechanisms are which facilitate patient activation to perform self-administration. I will describe how patient education is achieved- in which I will strive to describe not just the content (or what is taught) but explain how it is taught, exploring the following elements of patient education:

- the participant (i.e, patient or carer),
- the provider (i.e., pharmacist or nurse),
- the format or method of teaching (e.g., written, computer, video),
- the setting (i.e., clinic, home or hospital),
- the intensity (e.g., how many sessions and how long), and
- the mechanisms to trigger patient learning (e.g., self-efficacy).

The aim of the project is to propose a theory-based logic model to systematically explicate the components of patient education for self-administration and contextual factors, such as patient eligibility criteria, program educational resources and technology used, which impact patient education. The intent is to provide a framework, underpinned by nursing theory, to help inform nurses, service providers and policy makers in developing, implementing and/or evaluating a self-administration patient education program.

Self-Care

Orem posits that people have a natural ability for self-care and nursing should focus on affecting that ability (Simmons, 2009). A goal of nursing intervention is to enable the person to

be an agent of his or her own care, in which the person is less dependent on others and can enhance the patient's sense of personal, diminishing the patient's role as "victim" (Greenfield & Pace, 1985; Johanson, 1984, as cited in Hanucherunka & Vinya-nguag, 1991). Orem's theory of nursing systems proposes that nurses are needed to develop a plan of care for patients whose demands for self-care exceed their ability to perform required actions designed to achieve or improve one's health and well-being (Cox & Taylor, 2005). The nurse's actions are directed towards assisting the patient to assume responsibility for self-care. The aim of my research is to help build the capacity of a supportive-educative nursing system for self-administration of home IV antimicrobials, for those patients willing and able. The patient learns to perform self-administered care, with nursing support, guidance and teaching (Vasquez, 1992). (I acknowledge that the nursing system used across the spectrum of care for a patient receiving infusion therapy in the home setting may be more of a partially compensatory system as patients may still require nursing care for the management of the vascular access device).

Patient Activation

Patient activation refers to the patients' "willingness and ability to take independent actions to manage their health and care" (Hibbard & Greene, 2013, p. 207). Studies have demonstrated that patients who are more highly activated (willing and able to perform self-care) are more likely to engage in healthcare activities, have better healthcare experiences, have better health outcomes and have lower rates of costly healthcare (Hibbard & Greene, 2013). The authors report interventions shown to increase activation include: changing beliefs about a patient's roles, skill development, problem solving and peer support, tailoring support to the person's activation level and changing the social environment to facilitate peoples' changes in beliefs and opportunities to engage in the behaviour (Hibbard & Gilburt, 2014). Patient

activation theory recommends adjusting interventions in alignment with the levels of activation (moving from small steps to build confidence, to helping them build their knowledge and skills, thus building a sense of mastery and efficacy by experiencing a series of small successes, to supporting the implementation of the skills to monitoring and, finally supporting the patient for problem solving and planning for difficult situations) (Hibbard & Mahoney, 2010; Hibbard & Tusler, 2007). My proposition is that if clinicians tailor their teaching to the patient's level of willingness and ability, this tailored coaching will trigger patient activation in performing self-administration by improving the patient's self-efficacy knowledge and skills. The IHI also proposed patient activation as a key component of patient-administered self-care (Martin & Anderson, 2017).

A Realist Program Theory of Self-Administration

To explore the complex intervention of a patient education program, a realist inquiry approach was used throughout the study processes. Realism attempts to make sense of real life, rather than attempting to control for real life events (Rycroft-Malone et al., 2012). Pawson and Manzano-Santaella describe realist evaluation as a method to explain program effectiveness, striving to answer "what is it about a program that works for whom, in what circumstances… over which duration… and why?" (2012, p. 178). They explain that realist philosophy purports that a program works by providing resources (context) designed to trigger a person's reasoning or response (mechanism) which cause the change in action, all of which are dependent upon the person's characteristics and their circumstances (context).

The realist approach is appropriate for providing propositions or explanations of how an intervention works and what change agency mechanisms are effective (Kastner, Antony, Soobiah, Straus, & Tricco, 2016). Other healthcare studies have also used realist inquiry to

understand what works, for whom, and under what circumstances in complex programs (Dalkin, Jones, Lhussier, & Cunningham, 2015; Mukumbang, van Belle, Marchal, & van Wyk, 2016; Vareilles, Marchal, Kane, Petric, Picket, & Pommier, 2015).

Using a realist approach, the research explores the elements of a program which explain how the program works, through an investigation of the underlying mechanisms (M) of an intervention which under certain conditions or context (C) lead to an outcome (presented as the equation: C + M → O) (Pawson & Manzano Santaella, 2012). The case study extends the evidence explaining the patient education characteristics and delve further into 'how' the resources and context influence the patient or nurse's reasoning during the patient education intervention which leads to performance of self-administration. Exploring the explicit link between all explanatory mechanisms and outcomes is beyond the scope of this research. The intention is not to provide a prescription for elements of a self-administration programs that must be provided to achieve desired outcomes but to enlighten or make sense of how programs work. Individual, institutional and wider contexts and mechanisms will vary with every program; however the goal of realist inquiry and program theory is that there is a "family resemblance" across programs that may guide other programs (Pawson, Greenhalgh, Harvey & Walshe, 2004, p 34).

Yin states that an explanation should also include an "emerging taxonomy of contextual conditions with which the programme operates" (Yin, 1992, p. 135). As previously mentioned, I use the WIDER definitions of interventions to describe contextual conditions describing patient teaching (e.g., teaching format, intensity, location, etc.). The taxonomy also includes mechanisms of education (e.g., self-efficacy).

Significance of Research

Extant research suggests that self-administration is an effective, safe and acceptable model (Mitchell et al., 2017). My findings describing patient education programs and mechanisms which trigger patient learning may facilitate further uptake of this model of care, as well as support literature describing the acceptability of this mode of therapy. The data describing program resources, characteristics, and outcomes are presented through realist inquiry to explain how patient education programs work, under what circumstances and for whom. The strength of the study is the rich description of self-administration programs gleaned from this realist case study approach. The observations and insight of a group of nurses and patients within two established self-administration training program explain not only the objective characteristics of patient education for self-administration, but also how mechanisms of participant's behaviour interact with the context and resources of the program (Masso, MCarthy & Kitson et al., 2014). While previous studies have demonstrated the safety and efficacy of this program, few have attempted to probe how patients are trained in this mode of therapy.

Results of the case study are synthesized as a program theory which clinicians and policy makers may apply in developing or evaluating similar programs. Statistical generalization of results to the general population is not possible with case study research (Yin, 2009, 2012). Yin explains that the external validity of the case study instead refers to generalizing results to a theory, whereby the logic of the theory may be applicable to other situations (rather than a population). It is the theory, therefore, that may be transferrable to other situations. The use of multiple cases helps to enhance this study's external validity (Kohn, 1997; Yin, 2009). If the results are replicated in multiple cases, they are considered more robust. A detailed description of strategies to enhance study rigour is further explained in Chapter Four, Study Methods.

Anticipated outputs of this work also include: 1) a program theory logic model describing how patient self-administration programs work and are structure, 2) a taxonomy of education interventions not commonly used in the self-administration literature which will hopefully inspire researchers to better describe educational interventions in this field, 3) qualitative information about how to trigger patient activation to promote successful self-administration patient education, and 4) a patient-centric focus extending knowledge beyond patient satisfaction. Combined, these outputs may help transform home care practice in infusion therapy, supporting a paradigm shift from nurse-led to patient-led care, with the nurse acting as a supportive-educative resource. This new knowledge may be integrated across the healthcare spectrum, from the individual level to organizational levels (restructuring of outpatient parenteral antimicrobial programs) to the wider home healthcare system, in the form of policy development, program implementation and quality improvement (Dalkin et al., 2012).

Specifically, these data may provide tangible evidence to guide healthcare organizations to develop policies, education resource material, including patient competency assessment. The data describing content, format and intensity of patient education may also aid organizations to identify patient education criteria which they may use to evaluate existing programs. Patients may experience a significant impact of this work. Effective communication of the benefits of this model of care and supporting resources required is crucial for patients to understand how this model will enhance their autonomy, knowledge and skills, safety and well-being, as demonstrated in published studies. Nursing providers require procedures and education to not only assess patient eligibility and enable their coaching of patients, but also to change their philosophy of care from “doing” to a more supportive-educative role in “teaching and coaching.” Providers (including physicians) must “view their patients as enabled partners in care delivery

and trust that patients are willing and capable of increasing the control that have over their own care delivery" (Martin & Anderson, 2017, p. 6). Administrators are required to provide administrative support to develop this model to ensure the desired outcomes are achieved.

For those programs still practicing nurse-administration of home infusion therapy, the generated theory will help program administrators to understand the need to explore how their patient education program incorporates inputs, activities and mechanisms which support patient autonomy. The theory should also provide impetus for nurses practicing education of self-administration to patients to pause and reflect on how they are activating mechanisms which may optimize the teaching-learning experience. Understanding of these mechanisms will also help my journey in developing a patient-centered self-administration program. In my local practice, policy and procedures will require modification and supplies and equipment provided may require slight adjustments to implement technology which reduces the complexity of teaching and use.

It is my aim that strengthening the body of evidence of patient education programs supporting self-administration of home infusion therapy will enhance the capacity of Canadian healthcare systems (as well as internationally) to transition to a resource-protective and supportive-educative nursing system in which patients gain autonomy by administering their own IV therapy at home.

Chapter 4. Study Methods

Through a mixed methods multiple-case descriptive and explanatory case study, I aim to describe the characteristics of education programs for this patient population and explain mechanisms which facilitate patient education. Study methods include:

a) Direct observation of patient education of nurse-patient dyad interactions in the Community IV Program clinic/home or inpatient unit which will describe the content, duration, format of patient education;

b) Focus group interview performed with 6-10 nurses to refine the program theory logic model of patient education developed during the observation period;

c) Telephone interviews with 3-5 patients observed during the direct observation phase to determine mechanisms facilitating or hindering patients learning;

d) Document analysis of available organization nursing policies, care plans, checklists, etc., related to self-administration patient education;

e) Informal interviews with patients and nurses.

In this chapter, the rationale for selection of the case study methodology is explained. Participant recruitment, data collection and data analysis methods are described. Ethical considerations, the role of the researcher, strategies to optimize study rigour and the study dissemination plan are then elucidated.

Case Study Methodology

The study of multiple cases was chosen to enable the examination of more than one program to determine if similar findings may be replicated to describe program characteristics

and mechanisms of patient learning (Cope, 2015). The case study approach is appropriate for this study as case studies enable "in-depth complex health service research" (Crowe et al., 2011, final para.). Smith (2018) affirms that case study is ideal for studying a process—in this case, investigating the process of patient education.

Yin's methodological approach to case study research directs the design, application, and analysis of this study. Yin (2009) describes case study research as appropriate for developing "a theory of how a program works, enabling investigation of the richness of a phenomenon [i.e., patient education for self-administration] in a real-life context [i.e., infusion clinic/home]… retaining the holistic and meaningful characteristics" (p.4) of the phenomenon, looking at it from many angles (Thomas & Magilvy, 2011). The purpose of a case study is "to get in-depth details as much as possible about an event, person or process" (Njie & Asimiran, p. 36). This case study explains the process of patient education and the influence of various contextual elements or characteristics of patient education (e.g., resources, patient characteristics, pedagogical techniques) and what mechanisms (decisions or behaviours) are activated to lead to program outcomes (Hewlitt, 2012; Wong et al., 2013;). As Yin (2012) contends, explanatory case study research seeks to explain how and why a series of events occurred.

Yin (2009) defines case study research as "an empirical inquiry about a contemporary phenomenon (e.g., a 'case'), set within its real-world context—especially when the boundaries between phenomenon and context are not clearly evident" (p. 18). The integral nature of context in this methodology fits well with the study of patient education and contextual inputs identified in the program theory which affect education and related outcomes. As patient education is influenced by context, case study methodology's focus on the real world is suitable (Casey & Houghton, 2010). Casey and Houghton contend that case study research "captures the holistic

and meaningful characteristics of events," (p.41), which is appropriate to examine complex elements which influence nursing practice. The case study will explain patients' and nurses' understanding of contextual elements and mechanisms which affect patient education.

Yin (2012) further states that cases studies are particularly relevant for research questions addressing 'what is happening' (i.e., 'what are the characteristics of patient education' in my study) and 'how did something happen' (i.e., 'how is education achieved'). According to Yin's case study research design, frameworks provide "direction, reflect the theoretical perspective and guide the search for relevant evidence" (Ridder, 2017, p. 287). Yin is a proponent of program logic models as a framework for use with the case study approach as they attempt to explain the presumed causal links in real-life intervention (Yin, 2009). The four main categories of a logic model explication the theory of how a program works (resources, activities, outputs and outcomes), form the framework for both data collection and analysis. The program logic model evolving from the data will be a visual representation or road-map of the resources, activities, outputs and short and long term outcomes related to self-administration. This model is a program theory- a theory of how a program works. It is founded on the concepts of self-care, patient activation and program logic model constructs. As Ridder indicates, "case study research has its strength in creating theory by expanding constructs and relationships within distinct settings" (Ridder, 2017, p. 282).

Yin's realist- postpositivist approach (Harrison, Birks, Franklin & Mills, 2017) to case study research was purposely selected over Stake's constructivist methodology. Harrison et al. explain that "postpositivist qualitative researchers conduct research that embraces the ideals of objectivity and the generalizability of results" (3.4.1 section, para. 2). The empirical orientation of Yin's approach with an emphasis on observations and "highly structured analytic guidelines"

(Yazan, 2015, p. 144) aligns well with my experience in the empirical realm and my desire for linear structure. Yin also permits the use of quantitative data with the qualitative and quantitative collection of data, which is opposed to Stake's preference for the use of strictly qualitative data, impressions and reflectively finding meaning and non-structured, intuitive approach to data collection and analysis (Stake, 2008; Yazan, 2015). The postpositivist researcher attempts to remain an impartial observer who objectively observes actions or process but does not apply moral judgments or subjective opinion (Cahier, 2001). As an individual who is more a concrete thinker, this detachment from the phenomena and non-interpretive approach better fits with my current comfort level and ability in performing qualitative research (Cahier, 2001; Harrison et al., 2017).

In addition, the use of the realist lens fits well with Yin's methodology (Easton, 2010), as both seek to understand what caused something to happen in real-life situations. As Easton states, a critical realist case study should ask the question "What caused events associated with the phenomenon to occur?" (p. 121). Both Yin and Easton reinforce that the goal of case study research is not statistical generalization, as the case does not represent a 'sample.'

Defining the Case. Yin describes a case as being a "real-life phenomenon" which is the main unit of analysis in a study (2009, p. 32). Examples of cases include an individual, event, program, organization or process (Baxter & Jack, 2008; Yin, 2009). A multiple-case study design is used in which two home infusion nursing programs in North America are bounded by the programs' patient education processes. The multiple case approach was adopted to enable the selection of more than one case to attempt to determine if findings are similar across findings, thus achieving literal replication and enhancing the external validity/credibility of the study (Harrison et al., 2017; Houghton et al., 2013; Kohn, 1997; Yin, 2009). Yin describes a multiple

case study as containing more than a single case, which provides more compelling evidence than from a single case, leading to a more robust study (Yin, 2009).

Each case in this study is defined as a nursing program of patient education of self-administration of home intravenous antimicrobials at the case study site in the community care setting. I have adopted Bergen and While's case study identification of a case in which they described the case management *practice* as the case, rather than the individual practitioner. Their rationale aligns with mine, in that the focus revolves around professional theory and practice, rather than the individual. As Bergen and While explained, the nurses "are the vehicles for this practice" (2000, p. 929). The subjects of the case are the nurses who perform patient education and the patient/ care partner learning the procedures. The object, or analytical frame of the case --is the process of patient education (Thomas, 2011). An embedded study design is used, in which the main unit of analysis is the collective practice of patient education by nurses in the community IV program while the subunits of analysis are the characteristics of patient education (e.g., content, duration, format, location), and mechanisms triggering patient learning.

The Canadian case organization was purposively selected due to their extensive experience, as this program has practised self-administration in Canada since the 1970's (Cote, et al., 1989; Stiver et al., 1978). The second case organization, located in Virginia, U.S.A., was purposively selected as a typical case and because of the expertise of the program director, currently a President of an authoritative American infusion nursing association. Another factor making this an appealing case to study is their protocol to teach most patients in one visit (making care more cost-effective than multiple visits), contrary to the first case which uses multiple visits for patient education. These cases were also selected in part due to the ease of access (McDonnell, Lloyd Jones, & Read, 2000). Due to the private status of the second

organization, logistics were a factor as minimal resources were required to obtain institutional research ethics approval (e.g., local primary investigator not required) and due to geographic proximity to the primary researcher.

To further define a case in case study methodology, boundaries of the study are determined. Boundaries are like the inclusion and exclusion criteria for sample selection in quantitative studies as they indicate what will and will not be included in the study (Baxter & Jack, 2008). These pre-defined boundaries help set the time, location, social group or organization, activities, definitions and context and data collection in a study (Baxter & Jack, 2008; Crowe et al., 2011). Yin cautions that it may be difficult to define a case which is a process or program, in terms of the "beginning or end points of the 'case' " (2009, p. 28). This case is bound by the process of patient education on the continuum of training sessions with patients first starting to learn how to self-administer to final training sessions in which nurses inform patients they have completed the training sessions.

The goal of this binding of cases is to define the scope of the project and help direct the data collection, analysis and reporting of study findings (Yin, 2009, 2012). A detailed description of the cases and contextual description is included in the report of findings to ensure the reader understands the setting and context which will better equip the reader to determine if analytical generalization to their situation is appropriate (Crowe et al., 2011).

Operational definitions

The operational definition of *home IV antimicrobials* is adapted from the Infectious Diseases Society of America Guidelines (Tice et al., 2004). Home IV antimicrobials refers to the provision of antimicrobial medications (including antibiotics, antifungals and antiviral medications) in at least 2 doses on different days without intervening hospitalization. The

medications are administered in the patient's residential home, work or other site in the community (excluding care facilities such as hospitals, retirement homes or long term care facilities). The medication is administered through a patient's *intravenous device*, which may include a peripheral vascular access device, peripherally inserted central catheter, tunneled catheter or implanted vascular access device. Patients requiring more complex instruction for infusion therapies such as parenteral nutrition, blood products and hemodialysis therapies are excluded. *Care partner,* also known as an informal caregiver, is defined as "a family member, friend or paid non-professional individual with the ability and willingness to administer treatment and to observe and report significant events" (Tice et al., 2004, p.1653).

Ethical Considerations

All research was conducted in compliance with local Personal Health Information policies/acts and the Canadian Tri-Council Policy Statement. Research ethics board and institutional approval has been acquired for the case study from the Athabasca University Research Ethics Board (see Appendix A), University of Manitoba Health Research Ethics Board (see Appendix B) and Winnipeg Regional Health Authority (see Appendix C). Patients, nurses and case site administrators were provided with letters of information and consent for study participation. All participants were assured of the confidentiality and security of data. Once transcribed, digital audio recordings were deleted.

Due to the practical nature of this research, I did not anticipate the emergence of significant situational or relational ethics issues (Tracy, 2001). There was no anticipated harm from participation in this study, apart from perhaps some discomfort of the participant in sharing their experience and thoughts regarding teaching or learning self-administration. I maintained principles of relational ethics, being mindful of my character and consequences on others,

maintaining values of mutual respect and dignity. If there was potential for the results to be harmful in any way (e.g., lack of adherence to best practice), I would disclose and discuss the results with the cases and thesis supervisor prior to publication.

Study Participants

The settings for this study were community nursing clinics, patient homes, and possibly acute care units, in which the teaching was provided by the case organizations. Only nurses working in the acute care setting would be included if the nurses was a community nurse employed by the case, initiating teaching in hospital. The participants for this study were nurses employed in home infusion therapy programs and patients receiving home IV antimicrobials in these programs. All study participants were adults who were able to comprehend written and/or oral English (due to the language limitations of the researcher) and provide consent to participate.

Inclusion criteria for registered nurses and licensed or registered/licensed practical nurses also included those who were employed by the case site organization and actively participated in patient education of self-administration of home antimicrobial infusion at the case site. Self-administration patient education had to be identified as a primary role of the nurse. Nurses who did not provide patient education for this patient population would be excluded. To recruit participants, the case site manager/delegate provided the letter of information to unit nurses providing this care with the instruction that participation was strictly voluntary and that the manager would not be told which nurses participated.

Patients were those diagnosed with a severe infection who required home administration of intravenous antimicrobial therapy and opted to be trained for self-administration during the observation period. Patients participating in the patient interviews were those who required home

administration of intravenous antimicrobial therapy and opted for self-administration during the observation period. If a patient was not able to participate, however, a care partner (defined as a family member or friend) who had been trained in self-administration of the home antimicrobial therapy would be included. Patients were purposively selected from the case site clinic visits for telephone interviews. Patients had to receive infusion therapies which include intravenous antimicrobial therapies. Patients requiring more complex instruction for therapies such as parenteral nutrition, blood products and hemodialysis therapies were excluded. Competence to consent was determined by the nurses observed in the nurse-patient dyad.

Sampling. Sequence sampling was used for direct observation, whereby the focus of observation was the nurse-patient interaction sequence to capture teaching and outcomes of teaching respectively (Altmann, 1974). The sample period began when an interaction started and the behaviours were studied in order of sequence until the interaction process terminated (Altmann, 1974), at which time the next nurse-patient/ care partner interaction was observed. More than one nurse, if present, could be observed (although not simultaneously). The benefit of this approach was that "time is seldom spent without available data" (Altmann, 1974, p.251), moving from one nurse's interaction to another," as opposed to focal sampling in which one provider is followed.

Focus group interviews of 5 -10 participants (nurses) is recommended by Polit and Beck (2014) to solicit the opinions of participants simultaneously. These were conducted at each case site. An over-recruitment rate of 20-50% of participants was to be used to account for persons not able to attend on the designated day (Onwuegbuzie, Dickinson, Leech & Zoran, 2009). Purposive sampling was used whereby I asked a program leader to identify potential participants who had experience and interest in this topic (Plummer-D'Amato, 2008a). If focus groups were

not feasible, due to geographic or scheduling limitations, individual interviews would be held instead. Selection of participants strove for homogeneity, a key principle of focus group methodology (Halloran & Grimes, 1995). The goal was to gather a group of individuals with similar experience, in this case being patient education of self-administration.

Purposive sampling was used for the patient population. A purpose sampling criterion for the interviews was the ability to reflect on and articulate what the individual's experience was with the infusion therapy, with the goal of obtaining a diversity of individual experiences (Polit & Beck, 2014). A total of 3-5 patients was estimated, following Malterud, Siersma and Guissora's model for sample size of qualitative research, the narrow aim of the patient interviews, the focused theoretical foundation directing the type of data required, and the strong background of the primary investigator in interview and the subject area. However, assessment of the sample size needed would continue during the data collection and analysis until there was strong data saturation (Malterud, Siersma & Guiassora, 2016; Polit & Beck, 2014). To reduce the sample size required, during the recruitment of patients, I would seek assistance from nurses` personal judgments to help identify patients during the nurse-patient direct observation period who may informative and be more articulate in sharing their insights (Polit & Beck, 2014).

Participant Recruitment. The following procedures describe the recruitment processes for the case sites, nurses and patients.

Case organizations. The settings proposed for this study were nursing clinics and patient homes, in which the teaching was occurring, in the community settings of the Winnipeg, Manitoba, Canada and Chantilly, Virginia, U.S.A. Administrators of each case site infusion program were approached initially by email (see Email Recruitment Script- Appendix D) and subsequently by telephone to determine eligibility and willingness to participate in the study.

Participating sites were requested to identify a study site administrator. A letter of support from the Department Head at each site was requested for site research ethics board approval, where applicable. I requested case site administrators to sign the Letter of Information and Informed Consent for Case Sites (see Appendix E). Institutional Research ethics board approval was obtained from the University of Manitoba and Winnipeg Regional Health Authority as required by the case (see Appendix B and C).

Nurses. I provided a Letter of Information and Consent for Observation Study (see Appendix F) and Focus Group Interviews (see Appendix G) to the study site administrator/designate, to share with nurses working in the location of the direct observations of patient education sessions during the observation period. Purposive sampling was used whereby I asked the site administrator/designate to identify potential participants who have experience and interest in this topic (Plummer-D'Amato, 2008a). I provided an email recruitment letter (see Appendix H) to the unit manager who distributed the message to nursing staff requesting participation in the focus group. I asked the administrator/designate to identify nurse-patient dyads during the observation periods which were appropriate for observation, as defined by willingness of nurse and patient to be observed.

Patients. The site administrator/delegate provided the Letter of Information and Consent form (see Appendix I) to nurses working in the clinic/unit during the observation period to recruit patients for the direct observation and patient interviews research. Nurses were requested to provide this letter to the patients attending the clinic/unit during the observation. They were informed by the nurse that a study was underway to describe how patients are taught to manage their home infusion therapy. They were asked by the nurse if they were willing to have a researcher quietly observe how the patient was being taught and that I would not be collecting

any private information at that time. Nurses were also requested to recruit patients/ care partners from this sample population who were articulate in sharing their insight for the patient interviews at the end of the teaching session, providing them with the Letter of Information and Consent for the Patient Interview (see Appendix J). This form requested the telephone number of patients interested in participating in the interview. Nurses did not obtain patient/ care partner consent; they simply asked patients and/or care partners if they would like to learn more about participating in the research. I obtained informed consent. If the patient/care partner was interested in participating in the direct observation, I obtained informed consent. Patients/ care partners not interested in the interview were not contacted. Potential participants who expressed interest in the telephone interview were telephoned by me. The nursing team was not informed of who had/had not agreed to participate in the telephone interviews.

Data Collection

Case study research requires detailed data on the case to provide "a rich picture- with many kinds of insights coming from different angles, from different kinds of information" (Thomas, 2011, p. 21). Multiple data sources (data triangulation) were used to provide a greater breadth in understanding and "a more 'convincing and accurate' case study" (Cope, 2015; Houghton, Casey, Shaw & Murphy, 2013, p. 12; McGloin, 2008: Yin, 2009). Triangulating both data collection methods and data sources facilitates a "convergence of data around the framework [or proposed theory] constructed from the literature" (Bergen & While, 2000, p.932). Therefore, data were collected by direct non-participant observation, focus group and informal interviews, and document analysis. Yin contends that interviews are one of the most important data sources, thus the inclusion of both patients and nurses in interviews, to gain a deeper understanding of both group's perspectives (Ridder, 2017). To enhance cross-case analysis, I

used a consistent data collection protocol for each case (Hyett, Kenny, & Dickson-Swift, 2014). In keeping with case study methodology in which research design remains flexible throughout the data collection process, data collection instruments, information sheets and preliminary interview schedules could developed but revised during the fieldwork process (none were altered however) (McDonnell, Lloyd Jones, Read, 2000). Unlike case study approaches of Stake which focus on data which will yield rich thick descriptions, Yin's approach is "a more construct- and variable- oriented collection of data" (Ridder, 2017, p. 292). Therefore, the preliminary interview schedules were designed to capture at least the four main constructs of a logic model.

To uphold the principle of enquiry in a natural setting, the data collection occurred in the nurse's workplace (Corbin & Strauss, 1990). Socio-demographic data describing each case was collected, providing details such as the clinic/unit physical environment, staffing mix, to help the reader and researchers understand the setting or context in which the study was conducted, without divulging any participant identifiers (Hyett, Kenny, & Dickson-Swift, 2014). Details of the case site program will help readers determine applicability of results to their organization.

Data was collected by direct non-participant observation, focus group and informal interviews, and document analysis.

Direct Observation. Yin (2012) states the direct observation is one of the most common methods of data collection in case studies. I observed nurses teaching patients how to self-administer home antimicrobial infusion therapy at the case. Field notes captured salient observations in which the nurse was interacting with patients, to describe the characteristics of the education and to explore mechanisms employed to direct the change and their impact on the patient.

Yin advises that a formal observational instrument may be used. An Observation Grid (see Appendix K) guided collection of patient education components to standardize recording of observations (Jersild & Meigs, 1972). The observational data allowed me to identify what was being taught in a given context, who the recipients and providers were, where the education occurred, how much education was provided, how it was taught and how nurses are supported the behaviour change of the patient, as well as what the patient response was to the education. It also allowed links and comparisons to be made between data gleaned from interviews and that which occurs in practice (Hewitt-Taylor, 2002).

The teaching delivery formats and duration were collected as neutral and factual data; however, data representing the views of the field participants and my interpretation of the observations were also captured (Yin, 2012). To determine the temporal process of patient education, quantitative data was also gathered. Time information (onset and offset) was be recorded and analyzed to determine the duration of patient education topics. Non-participant observations were expected to occur over three to four days in either the clinic, home or hospital setting for each case to gain full understanding of the phenomenon of this patient education (Houghton et al., 2013). The external validity of the study would be strengthened by the collection of data over several days (Pegram, 2000). This enabled data points to be collected over several points in time which enable pattern matching of events within the case (McGloin, 2008; Pegram, 2000).

To reduce the Hawthorne effect (in which people tend to perform better under observation), I attempted to help the observed become less aware of the observation by making the role of the observer clear, not interacting with those observed and sitting in an unobtrusive manner.

Focus Groups. Krueger defines focus groups as "a carefully planned discussion designed to obtain perceptions on a defined area of interest in a permissive, non-threatening environment" (Massey, 2011). Halloran and Grimes (1995) describe their application of focus group methodology as an effective means for educational program development.

Focus group interviews of 5-10 nurses (as recommended by Polit & Beck, 2014) were sought to solicit simultaneously the opinions of participants on how education is achieved at the case site. (In the event that focus groups were not feasible, due to geographic or scheduling limitations, individual interviews would have been held instead.) The interviews allowed interpretation of the significance of concepts emerging from the direct observations and allowed nurses to discuss their experiences. This technique was selected to meet time limitations of the study and as a method to encourage insightful data collection. Focus groups are "an economical, fast and efficient method for obtaining data from multiple participants" (Onwuegbuzie et al., 2009, p. 2), and commonly used in program theory development (Ryan, Gandha, Culbertson & Carlson, 2014). The group interaction helps participants to develop and refine their ideas, building upon responses from other members, generating ideas which may not have been elicited in one-to-one interviews (Plummer-D'Amato, 2008a). This method allowed informants to build on the answers of others in the group and stimulate thoughts and comments.

An interview question guide (see Appendix L) was used to help elicit data, using a triangular prepared question approach (Plummer-D'Amato, 2008a). The group started with personal introductions, which provided the moderator with clues about the backgrounds of the participants and set a response model, as well as provide the moderator with information to draw upon to elicit a quiet participant's participation (Plummer-D'Amato, 2008a). A broad opening question introduced the topic of interest and serve as a means to start stimulating discussion.

Participants were asked to generate a paper case of a theoretical patient who would be trained to self-administer parenteral antimicrobials. This vignette acted as a stimulus for exploring the process of patient education (Holloway & Wheeler, 2013). Hyett and colleague's critical review of published case studies found that vignettes or vicarious experiences enhanced contextual description (2014). Each participant, in round robin fashion, was asked to contribute an element of the vignette, to further stimulate each participant's contribution. Transition questions gleaned more detailed information, which then led into the key interview questions (Plummer-D'Amato, 2008a). Question items were derived from concepts of the conceptual framework (e.g., resources, patient education strategies, outputs and outcomes) and Young, Hudson, Clarke, Dungey, Feehally, Buron & Smiths' focus group study interview guide for exploration of patient and staff perceptions of intradialytic exercise (2015). I paraphrased and summarized key thoughts at various intervals, writing key points on flip charts (Hernandez, 2011). These served to spark further conversation or refer back to for constant comparison, in addition to facilitating transition to the next question (Plummer-D'Amato, 2008a). Flip charts also functioned as a means for participants to review and refer to during the discussion, acting as a form of member-checking to ensure the data was summarized to the group's satisfaction (Millar, Maggs, Warner & Whale, 1996).

To avoid censoring (i.e., silence of participants, in which they withhold their views), I attempted to obtain trust from the group members, with introductory comments describing my background in the field, allaying apprehension regarding the future use of data by ensuring anonymity to protect their identities, and providing reassurances that there were no 'right' or 'wrong' answers, and lastly requesting confidentiality at the conclusion of the meeting, to

ensuring protection of confidentiality of each person's contributions (Plummer, D'Amato, 2008b).

A prepared question guide helped elicit data (Plummer-D'Amato, 2008a). I served as group facilitator and scribe, with my thesis advisor (W.D.J.) functioning as the field note taker in one session with Case A. Holloway & Wheeler (2013) indicate that in a small health research project, a single interviewer usually facilitates the group.

Patient Interviews. Patient interviews were performed to investigate the patient's explanation of facilitators, barriers and mechanisms (motivation) of patient education of self-administration of home IV antimicrobials. Three to five patients observed in the direct observation study would be recruited to participate in a 10-20 minute telephone interview, guided by a Patient Interview Guide (see Appendix M), which was audio-recorded and transcribed.

Documents. Documentary evidence in the form of nursing policies, care plans, documentation templates and educational materials were requested to understand contextual resources which may guide the educational process (Yin, 2009). This data helped the understanding of the patient education process, educational philosophies and use of technology in teaching.

Baseline Case Site Data. Details of each case site program were captured to provide a rich description of the structure of each program. Data collected included the number of years of provision of self-administration, number of patients, location of patient education, staffing complement, types of educational materials provided, nursing policies, outcomes measurement (if available), and program conceptual framework if applicable. This information will help

readers to determine the generalizability of results with their organization. Each case site administrator/delegate was asked to answer 11 questions in a telephone or in-person interview. See Appendix N for Baseline Data questions.

Field Notes. Field notes were maintained to capture salient observations in which the nurse was interacting with patients to describe and interpret experiences observed and her response to these events, and any response or beliefs which may have affect her interpretation of the event. The notes were used to reflexively help identify and develop meanings and themes to help answer the research question (Hewitt-Taylor, 2002).

Data Analysis

Within-case analysis using directed content analysis was used, performing first a within-case analysis, followed by a cross-case analysis (Miles, Huberman, & Saldana, 2014). This analysis was integrated with a combined case-oriented and variable-oriented approach. First, data were analyzed within each case using a predetermined set of variables gleaned from the conceptual framework, with leeway for new variables as they emerged. The variable-oriented approach was guided by deductive direct content analysis (Hsieh & Shannon, 2005). Categories (e.g., resources, activities, outputs, and outcomes) were identified prior to development of the data collection tools. A meta-matrix was then generated to summarize and compare findings across cases in a tabular display (Miles et al., 2014).

Data analysis was iterative and simultaneous with data collection. The characteristics of the patient education program were described primarily qualitatively, with minimal descriptive quantitative statistics for data obtained during direct observations in the field to quantify the intensity of education content. Descriptive statistics (e.g., frequency and average) were used to

measure the time spent for each education domain, the setting and formats of patient education. To aid in the transferability of findings, rich detail of the patient education setting was described (Noble & Smith, 2015).

Yin (2009) advises that a researcher develop the analytic strategy prior to data collection. Analysis consists of "examining, categorizing, tabulating, testing, or otherwise recombining evidence, to draw empirically based conclusions (Yin, 2009, p. 126). This explanatory case study focused on process variables, more than outcome variables (due to the lack of monitoring of program outcomes at the case site).

Yin's two-phased approach to data analysis was adopted: codes, identified in the conceptual framework, were applied to the data and then be sorted by code to permit interpretation (Crabtee & Miller, 1999). As Ridder describes, the final analysis using Yin's case study approach, "concentrates on the matching of the framework… with patterns from the data" (Ridder, 2017, p. 292). The goal was to "extend conceptually a theoretical framework" (Hseih & Shannon, 2005, p. 1281). Examples of categories to be analyzed included resources, patient education, mechanisms or outputs and outcomes. However, as Crowe *et al*. caution, data were not "forced to fit" the theoretical framework (2011, p. 7).

If during the study, a significant discovery was made (i.e., the case did not suit the original design- which did not occur), the study's propositions, design, or protocol would have been reconsidered (Yin, 2009). Yin endorses the use of logic models as an analytic technique "to match empirically observed events to theoretically predicted events" (2009, p. 149). This is similar to the technique of pattern matching in which an empirically based pattern is compared with a predicted one. The data was analyzed to help determine both confirmation (replication) and completeness, to help "build up" the theory (Bergen & While, 2000; Houghton et al., 2013).

If data gathered from multiple methods is consistent, this increases the confidence in the credibility of the study (Houghton et al., 2013). Obtaining data through the perspectives of the multiple observed and interview nurses and patients helped ensure "as complete a picture as possible of the phenomena can be portrayed… [through] in-depth insight" (Houghton et al., 2013, p. 13). Analysis of the observational data helped me to identify gaps or areas requiring data clarification during the focus groups and patient interviews. This in turn helped enhance the completeness or accuracy of information collected (Smith, 2018).

To increase dependability or consistency of the findings, I coded the initial data set, with thesis advisor checking the accuracy of the coding and then meeting to come to consensus on the emerging codes and categories (Baxter & Jack, 2008). Results were then synthesized as a program theory logic model to explicate resources, context, interventions and mechanisms which lead to effective self-administration patient education programs.

Role of the Researcher

Hyett and colleagues' critical review of case studies (2014) indicates that few researchers provide sufficient detail of the relationship of the researcher with the case and how this may have influenced the study. Declaration of the researcher's beliefs, preconceptions and previous experience enhances a study's inter-subjectivity (Malterud, 2001). My own assumption entering into the development of the study protocol was that with the appropriate resources in the right context nurses can teach patients to perform self-administration, through the triggering of generative mechanisms (such as self-efficacy and autonomy) that lead to effective patient self-administration and patient satisfaction and health outcomes, cost efficiencies and thus achievement of the triple aim of healthcare. It is the intent of this paper to elicit these contextual

conditions and mechanisms (although resources preclude the investigation of the outcomes in any detail).

In the focus group, I functioned as the moderator, facilitating the group process to ensure the topic of interest is discussion, while unobtrusively establishing an environment in which all participants are able to share their views, whilst being careful to not share my personal point of views to prevent moderator bias (Plummer-D'Amato, 2008b). My evolving experience in co-leading consensus groups for the development of published algorithms and guidelines (Broadhurst, Moureau & Ullman, 2016; Canadian Vascular Access Association, 2019; & Hill et al., 2013) strengthened my ability to steer the discussion, without directing the debate. Attention was given to not imposing my own biases or assumptions in the interviews (Holloway & Wheeler, 2013).

Chapter 5. Results

A case study approach was used to determine how patient education in self-administration is achieved. The study sought to answer the following research questions: 1) "What are the characteristics of patient education for self-administration?" and 2) "What are the mechanisms which facilitate patient activation to perform self-administration?"

This chapter begins with a description of the two cases to familiarize the reader with the cases. Findings are then presented in the four domains of the conceptual framework to build a logic model: inputs, activities, outputs and outcomes. Inputs, or resources, identified as essential for patient education are identified for each case. A description of the activity of interest and patient education depicts each cases' characteristics (patient eligibility criteria, education content, format, intensity, setting and fidelity). Strategies to tailor education to patients are explored. The outputs of patient education are used to explain how the activity of patient education may lead to patient engagement in self-administration. An attempt to describe short-term outcomes of patient education will then be addressed. Finally, an overview of the study findings are synthesized as a cross-case analysis, depicting results as a logic model representing the characteristics of patient education in self-administration of home infusion of antimicrobials, as identified in these two cases.

Description of the Cases

Two home and community infusion programs in North America were the cases under investigation. Each study case was bounded by the process of patient education in self-administration of home IV antimicrobials. Characteristics of each program are detailed in Table 2.

Table 2

Community Infusion Program Characteristics

	CASE A	**CASE B**
Program type	Community IV Program	Home Infusion Pharmacy
Location	Winnipeg, MB, Canada	Chantilly, VA, US
Ownership	Government	Independent
Funding for medications/supplies	Public	Insurance provider; private (non-Medicare)
Year of opening	2008	2016
Care settings	Clinic (2) Urban (5 patient chairs and 5 private exam rooms) Suburban (6 patient chairs) Home Hospital	Clinic (1) Home Hospital
Staff	Registered Nurses Clinic and home (52) Hospital (4) Infectious Diseases MD (7) Manager (1) Nursing coordinator (2) Pharmacists (7) Clinical assistants (9)	Registered Nurses Home: full-time (2), per-diem (3) Hospital liaison (1) Transitional care liaison (1) Nursing manager (1) Pharmacists (3) Pharmacy technicians (2) Clinical intake (2)
Hours	Clinic 07:30-23:30 Intake 0830-4:45 On-call 23:30-07:30	0830-5:00 Monday-Friday Saturday- pharmacy team only On-call 1700-07:30
Referral source	Hospital IV and respiratory clinics Physician offices	Hospitals (electronic bidding system), physician offices, insurance companies, patients
Referral response time	"a few hours to days"	NR
RNs per shift	Days (4 and 5 at the 2 sites) Evenings (2 and 3 at the 2 sites)	Days (2-5)
Therapies compounded	Antimicrobials 80%; other 20%	Antimicrobials 80%; other 20% (e.g., inotropes and biologics)
Administration of IV therapy	Clinic Self-care and limited-care (18%) Nurse-care (72%) Home (145*) Self or limited care (40*) Nurse-care (105*)	Nurse-care (N/A) Self-care (100%) Total: 60-70 visits per week
Outcome Tracking	No	Yes
Conceptual framework	No	No

* Data collected June-December 2017

Case A is a large Canadian Community IV Program, in practice for 11 years (although providing home infusion services through the acute care setting since approximately 1978). The government-funded public program has two outpatient clinics, both of which are free-standing facilities separate from the acute care facilities. Both are part of the regional healthcare program, governing clinics and acute care settings. One clinic is in a suburban setting, while the other is an urban centre adjacent to a community centre. All patients are assessed and followed by onsite Infectious Disease physicians and pharmacists review serum drug therapeutic levels, collaborating with prescribers to adjust therapies as needed. Medications and supplies are funded and provided by the program, at no cost to patients. The nurse discharging the patient from nurse-administration to self-care creates a weekly standing supplies order in the electronic supplies platform.

Six community infusion patients and 10 community IV registered nurses were observed in the two Case A clinics, for a total of 15 nurse-patient teaching sessions, over a course of six days in December 2017. No home or hospital visits for patients learning self-administration occurred during the observation period; all occurred in clinic. Fourteen clinic registered nurses participated in two nursing focus groups in December 2017 (six nurses in the first 115-minute session and another eight nurses in the second 90- minute interview). Five home infusion patients initially agreed during the observation period to the phone interviews; however, only two were able to be contacted by phone in January 2018. Two patients failed to return voice mail messages and a third did not have voice mail messaging.

Case B is a small American independent home infusion pharmacy, in practice for three years. Funding for patient medication and supplies is dependent upon private insurance providers, as the pharmacy does not provide services to patients with federally funded Medicare.

Reimbursement is based on a per diem model. The pharmacy is reimbursed a set fee per patient, to cover all expenses related to supplies, equipment rentals, and pharmacy compounding and professional (nursing and pharmacist) services. The pharmacy operates out of one suburban facility, comprised of a compounding room (two negative pressure laminar flow hoods), two private patient clinic rooms, a warehouse and office stations for pharmacists, clinical intake, reimbursement officers and management. The majority of prescriptions are for antimicrobial therapy, with a smaller portion for inotropes and biologics.

Two home infusion registered nurses were observed at home visits over two days in April 2019 and four registered nurses (three home infusion nurses and one manager) participated in the 75 minute focus group for Case B. Three patient education sessions were observed over the four planned observation days. The remaining home visits were related to non-antimicrobial therapies or maintenance care, rather than patient education, and thus did not meet study inclusion criteria and thus were not observed. No hospital or clinic patient visits were scheduled during the observation period.

Characteristics of Patient Education

Self-administration of home intravenous antimicrobials requires nurses to teach patients complex information and skills and motivate patients to change their behaviours and sometimes attitudes to safely and independently administer their medication. Study findings are presented first describing the characteristics of patient education to describe the ‘what’, ‘when’, ‘where’ and ‘how much’ of patient education. The mechanisms, or the ’how’ patients are activated to engage in self-administration, is then explained.

Due to the complexity of this educational process, data were collected at each case through a triad of sources, including non-participatory direct observation, focus groups and

patient interviews. A within-case analysis of the data is summarized in Tables 3 and 4 to provide the reader with an opportunity to identify similarities and disparities across the two cases, in terms of program resources and inputs, activities, outputs and outcomes and to compare these programs to their own when considering applying results to their own context. An in-depth comparison of each of these logic model components follows. It should be noted, however, that the shorter, smaller and single focus group held with Case B generated less data.

Resources/Inputs. Prior to the provision of care, program inputs must be in place to support program interventions. These resources may be human, physical, and/or financial in nature. Participants felt that having the inputs described below enhance the teaching/learning experience. The nurses found that having those resources helped them be organized, efficient and competent in their teaching, increasing their self-efficacy and empowering them to confidently advocate for patients. As one nurse stated, "If you know they can't come to clinic for six weeks, you can provide another alternative to ensure they can get treatment." Another nurse stated "it's fun" teaching patients, which promotes job satisfaction amongst nurses.

Willing and able participants. In both cases, the programs only provided care for adult patients. Inclusion criteria for participation in self-administration were similar between cases. Participants in the learning process had to be either the patient and/or care partner (e.g., family member or friend) who are both willing to learn and able to perform the procedures for the duration of treatment. Both programs required the patient or family member speak English/French or English/Spanish. They acknowledged, however, that they have accepted patients as exceptions who speak neither language through use of a translating service or an online translation program. One nurse reported carrying an English/Spanish dictionary to

facilitate difficult discussions, while another has effectively used an online translation website for keyword translation.

While one nurse expressed that it would be preferable to offer services in any language, they stated that the reality is that it has proven difficult to obtain these services particularly for teaching complex material over frequent visits. Neither site reported using a formal tool or checklist for assessment of participant ability and willingness. The goal is to select patients who are able and motivated to learn.

Capacity to learn and do. Upon referral to the program at both sites, the nurse assessed the physical and mental capacity of the participant to perform self-administration procedures. No overt assessments were observed; however, nursing focus group members described several techniques used to assess capacity. The following are relative contraindications to self-administration identified by participants:

- Physical impairment (e.g., severe arthritis, neuropathy, confined to bed and unable to access supplies, upper limb paralysis). To assess manual dexterity (and thus ensure a participant is able to manipulate the supplies and equipment), one member indicated she asks the participant to remove the cap from a syringe, while another reported asking patients if they have any difficulty unscrewing a medicine bottle lid or toothpaste cap;
- Visual impairment. Nurses assessed ability to see supplies in relation to procedures in various manners, such as if participant is able to see the gravity drips and see device connections or read a newspaper (one participant noted that the had successfully trained a blind patient over many visits);

Table 3

Initial Logic Model of Patient Education in Self-administration of Home IV Antimicrobials- Case A

Resources/Inputs	**Activities**	**Outputs**	**Outcomes**
Patients Adults English (translator available) Willingness to learn and do Ability Physical (manual dexterity, visual acuity) Cognitive/ mental Lifestyle Home environment Nursing care needs Central venous access device	Learn self-administration Therapy adherence Self-monitoring Participate in follow-up appointments	Self-administration New knowledge and skill Physical well-being Enhanced wound healing Decreased risk of falls Sense of control/autonomy Freedom to live life on their own schedule Sense of privacy Sense of family Financial gain	Efficient, effective and safe self-care in administration of medications Patient satisfaction
Registered Nurses Knowledge and experience in vascular access devices and pharmacology Total patient care nursing Orientation- mentorship; no formal patient education training Policies and procedures	Patient assessment (patient condition, adherence to therapy) Patient recruitment (assessment of eligibility for self-care) Tailored patient education (multiple sessions) Medication administration Venipuncture/ blood sampling Vascular access device care Wound care	Organization Efficiency Competency Empowerment Appropriate selection of patients willing and able to learn Self-efficacy Enhanced patient advocacy Social norm	Provision of and effective education and supportive care Job satisfaction
Pharmacists Knowledge and experience	Therapeutic serum monitoring Counselling	Prescriptions adjusted to patient needs	Appropriate prescription of medications
Clinical assistants (phone contact)	Patient scheduling Assessment of patient eligibility for self-assessment Order and store supplies	Timely clinic visits Supplies delivered	Patient satisfaction Appropriate treatment delivery Clinic efficiency
Technology Syringe drivers preferred; gravity most common; electronic infusion devices; no elastomerics; Prefilled saline syringes Extension sets Smart phone apps (drip counts) Electronic documentation	Medication administration by patients and nurses	Ease of learning and use Accuracy	Patient acceptance of self-administration and satisfaction
Organizational Setting: primarily clinic; some home; multi-chair and private rooms Patient education material (written)	NR	NR	Improved healthcare resource utilization

NR= Not reported

Table 4

Initial Logic Model of Patient Education in Self-administration of Home IV Antimicrobials- Case B

Resources/Inputs	**Activities**	**Outputs**	**Outcomes**
Patients Adults English-Spanish only Willingness to learn and do Ability Physical (manual dexterity, visual acuity) Cognitive/ mental Lifestyle Home environment Nursing care needs Peripheral or central venous access device	Learning self-administration Therapy adherence Self-monitoring Participate in follow-up appointments	Self-administration Physical well-being Enhanced wound healing Decreased risk of falls Sense of control/autonomy Freedom to live life on their own schedule Sense of privacy Sense of family Financial gain	Efficient, effective and safe self-care in administration of medications Patient satisfaction
Nurses Knowledge and experience in home care, vascular access devices, and pharmacology Primary nursing Orientation- mentorship; no formal patient education training Personality: independent, patient, creative, strong listening skills Policies and procedures Pharmacists Knowledge and experience	Patient assessment (patient condition, adherence to therapy) Patient education Medication administration Venipuncture/ blood sampling Vascular access device care Wound care Therapeutic serum monitoring Counselling	NR	NR
Clinical intake staff (phone contact)	Patient scheduling Supplies	NR	NR
Technology Primarily elastomeric and direct push infusion Prefilled saline syringes Extension sets Electronic documentation Organizational Setting: primarily home; Patient education material (written)	Medication administration by patients and nurses	Ease of learning and use Accuracy	Patient acceptance of self-administration and satisfaction Improved healthcare resource utilization

NR= Not reported

- Hearing impairment. While not an absolute contraindication, nurses suggested severe hearing impairments may be a difficult challenge; one participant reported successful education with the use of a sign language interpreter combined with patient-tailored directions;

- Cognitive impairment. Some nurses expressed assessing participant's conversation, memory (orientation to date and time), although this tended to be more of an intuitive process and two focus group members indicated this can be difficult to identify short-term impairment until into the education;
- Lifestyle. Nurses assessed for signs of lifestyle suggesting potential non-adherence to therapy (e.g., intravenous drug use, alcoholism, addictions); Case B accepted those with IV drug use history if they are in a rehabilitative program and have a care partner and they assess the type of use and duration of no usage.

Willingness and readiness to learn and to do. In addition to ability, the nurse also assessed the willingness and readiness of the participant to learn and perform self-administration. This assessment was performed either at the hospital prior to discharge by the program's hospital liaison nurse, in the clinic by the nurse, or by the clinical intake team by telephone. While some Case A focus group members indicated they ask participants outright if they are willing; however, others suggested they have found this to be a deterrent as many initially perceive it to be either too difficult to learn or the role of the nurse to perform these tasks. To avoid these challenges, it was suggested by nurses at both sites, that they have had more success in recruiting patients whom they feel have the ability by setting the expectation of self-care, rather than asking if they would like to participate. As one participant stated:

If you present it as "Do you want to do self-teaching?" they will say "No," as opposed to positioning it as a goal. If they say no, explore their rationale (too nervous, too weak) and address that limitation, saying "For the first few days you can just watch me and gradually we'll add in a few tasks for you to do (come to clinic for a week and we'll see how you feel about it)."

Let them know that if they change their mind, if during teaching they are overwhelmed or not well enough, they can go back to nurse-care [so they don't feel locked-in to self-administration].

A nurse at Case B indicated she would often "walk through the steps" if the patient is hesitant, and they would often then agree to self-administration "once they see how simple it is." Focus group participants advised nurses need to be non-judgmental, of either the patient's environment or the patient- "sometimes patients thought to be unteachable do well." Nurses also reinforced that support is available 24/7 should they run into complications. Another motivation for patient willingness, noted by a patient, was peer influence. Having observed other patients in clinic learning how to self-administer helped him to realize that he could learn to do this as well.

A Case A nurse recommended judging the correct timing to approach the patient. If the patient is overwhelmed on admission, the suggestion for self-care would be delayed until the patient is feeling stronger. Nurses at Case A also reported frustration of patients who are receiving nurse-care or limited –care and are repetitively asked to learn self-administration. They now place a note on these patients' charts indicating "do not ask about self-care."

Safe home environment. Both sites required a refrigerator (for storage of compounded IV medications) and telephone or email access. Case A did not accept patients for self-administration if the patient does not have a fixed address or lives in a shelter, due to numerous problems in the past with deliveries and adherence. Nurses reported that those living remotely from the clinic location tend to be more receptive to self-administration to avoid the transportation to clinics. Weather is another factor, with an increase noted in self-administration during inclement weather due to transportation barriers. There tends to be a peak in self-administration as well during summer weather, to facilitate patient's vacations.

Duration and mode of treatment. Treatment less than 6 days (due to length of time required to train patients) and peripheral vascular access devices were generally not accepted for self-administration at Case A, while Case B accepted patients with both peripheral (including midline catheters) and central vascular access devices.

Concomitant nursing care. At Case A, if the patient required other nursing care (such as wound care) during the infusion period, the patient would be placed on nursing care and the nurses administer the medication during the concomitant nursing care.

Table 5

Characteristics of Observed Self-Administration Patient Education Programs

	Case A	**Case B**
Provider	Registered Nurse	Registered Nurse
Participant	Patient (9), care partner (0), both (6) (Only participant[s] allowed in clinic to minimize distraction)	Patient (1), care partner (1), both (1)
Format	Verbal, written (occasionally personalized), demonstration/return demonstration, teach-back	Verbal, written (occasionally personalized), demonstration, return demonstration, teach-back
Setting, intensity and procedure	Hospital: 1 session if inpatient; self-care introduction; patient-eligibility; minimal teaching Phone: Clinical intake assesses home/clinic visits Clinic (home less often): 3-7 sessions (average 26 min. teaching per session) Session 1 (approx. 10-20 min.) Patient assessment and recruitment for self-care Nurse administration with demonstration and verbal explanations of medication administration Infection prevention Vascular access device assessment Session 2 (approximately 20-60 min.) Return demonstration with verbal cueing throughout (patient not expended to know how to do it) Start to add in complication management if learning progressing well Session 3 (approx. 20-60 min.) Patient performs procedure with verbal cueing as needed Discuss complication management and vascular access device care if learning progressing well Session 4-7 (occasionally up to 2 weeks) Patient performs procedures, adding tasks progressively	Hospital: 1 session if inpatient; self-care introduction; patient-eligibility; minimal teaching Phone: Clinical intake assesses patient eligibility for self-administration Home (rarely clinic): 1 session (average 36 min. teaching) in the following sequence: Infection prevention (1 min.) Flush (7 min.), medication administration (2 min.), deaccess (4 min.) by nurse demonstration with immediate return demonstration by participant Patient assessment (10 min. during infusion) Complication management (6 min.) Vascular access device care (2 min.) Supplies and medication management and follow-up appointments (3 min.) Resources (contacts) (3 minutes)

Fidelity (adherence to teaching)	Final session- informal competency validation Patient able to perform procedures independently without error (or recognizing and correcting errors) up to 3 times with verbal confirmation of self-efficacy Review supplies management, resources (contacts), complication management, medication schedule and vascular access device care Weekly follow-up clinic visits for assessment of patient response to therapy and therapy adherence, bloodwork and vascular access device assessment and care, complication management, care plan adjustment	End of session- informal competency validation Return demonstration with verbal confirmation of patient self-efficacy Weekly follow-up home visits for assessment of patient response and adherence to therapy, bloodwork and vascular access device assessment and care, complication management, care plan adjustment

Competent, caring and patient nurse coaches. Providers of self-administration patient education had to be registered nurses at both sites. They were required to have strong knowledge and experience in the infusion therapy procedures, vascular access devices and pharmacology, and, for case B, experience in home care. At both sites, nurses are trained to teach patients through nurse mentorship and adhering to policies and procedures. Neither case provides formal patient education training to staff. One nurse reported that principles of adult learning are a resource they don't have access to that would enhance their ability to teach. It was suggested that a nurse can increase her self-efficacy as a coach through observation of skilled nurses, practice and knowledge of best practice in infusion therapy and vascular access. When questioned what skills or resources a nurse requires to teach patients, the following personality characteristics were reported: patient, extroverted (ability to adapt and speak to strangers, critical thinking (as the nurse is working alone), confidence, creativity, willingness to go into the unknown and willingness to be around animals.

Quiet non-distractive setting. Case B uses a primary nursing model approach. The nurses expressed their preference for the home as the teaching setting. Continuity of care and teaching was facilitated with the patient being assigned primarily one nurse for the duration of treatment whenever possible. They felt being in their natural setting at home increased the

patient's comfort level, and was less hectic than in the clinic setting, usually creating a quieter environment conducive to learning. Alternatively, Case A nurses primarily preferred the clinic setting, although acknowledged that the home is more optimal in terms of the quite relaxed environment to facilitate focusing on teaching and learning. Most patients in the home at Case A received nurse-care due to their complexity of care or lack of well-being. Some patients receive 'limited care', in which the nurse starts the infusion and the patient learns how to discontinue their infusion, thus facilitating a shorter visit. However, nurses preferred clinic setting due to the cleanliness and reduced safety risk factors. To reduce distractions in the clinic, during the high anxiety preliminary sessions, when feasible, nurses and a patient indicated a preference for the quiet private rooms, affording patients more privacy and less distractions. As the training progressed, they would then continue the training in the busier clinic room with multiple patients.

Easy-to-use supplies. Both case sites preferred to use infusion technology and supplies which are easy to teach and easy for patients to use. Case A nurses preferred syringe driver pumps as they are "much easier to teach the patient to use" than gravity or electronic infusion devices. As the medication is already admixed in the syringe by the pharmacy, there are less steps for administration and it's perceived to be safer due to accuracy than gravity flow. However, due to the high loss of these pumps in the home setting, gravity infusions were the most common at Case A, although nurses acknowledge gravity infusions are "much harder to teach." In 12 of the observed teaching episodes, gravity was the mode used, while in three episodes, an electronic pump was used. Nurses at Case B preferred the elastomeric infusion devices due to ease of use, less manipulation of device and hence perceived enhanced safety, followed by IV push technique. Elastomeric devices, which are disposable, single-use, non-

electronic infusion devices, were not used at Case A (due to cost implications). A patient described how easy it was to use an elastomeric pump:

> …when you stop and think about it, that ball [the elastomeric infusion device] - all I had to do was screw the end onto the line. That was it. It's not like, you know, I had to- in the hospital when you watch the nurse, they stick a needle or something up into the line and squirt the stuff in. I just had to screw it on and I would put it on the back of my chair and sit for 30 minutes. And that's it. I didn't have to do anything but screw it on. And then unscrew it, flush it and put the heparin in.

The electronic infusion pump was least preferred at both sites, due to the complexity of teaching and required mental capacity and dexterity to manage the device and accessories. Other products which the nurses expressed simplify teaching and patient use are prefilled saline and heparin syringes, needle-free connectors and extension sets added to the vascular access device. One patient stressed that having a peripherally inserted central catheter (PICC) was a valuable resource for her. "This PICC line was so much easier than getting stuck and you know having blood drawn from your arm. She could draw vials and vials of blood. I did not get stuck. It did not hurt when they put it in. If I ever, I hope I don't have to ever be hospitalized, but it's like, a PICC line-- give it to me." All patients observed at both Case A and B had PICCs.

Current tailored patient education materials. Case A provided a comprehensive training manual to patients in the hospital (although I did not have the opportunity to review it). Participants indicated they do not use this in clinic due to the overly extensive information, with some content being outdated. In the clinic setting, a "cheat sheet" with an overview of the steps is provided to patients at the first session. Case B staff provided an 11-page booklet written in plain language, large font and much white space. Content includes overview of visit schedule,

supplies, hand washing, “line-flushing”, IV care and troubleshooting, pump instructions, and patient monitoring log. Pamphlets specific to the patient’s mode of administration (e.g., slow IV Push and elastomeric) instructions were also provided.

Neither site provided electronic training material, such as videos or online material. Three patients recommended the availability of a video, such as on YouTube®, would be helpful. Smart phone apps were aids recommended by several nurses during observation and focus groups. During observation, one patient took a photo of the supplies set-up to aid his memory, while another reported taking a photo of the cheat sheet and referring to it the first few days of self-administration at home. A stopwatch app was used to time the rate if IV push injection in one episode, while another used a phone alarm to time when the elastomeric infusion would be finished (as some patients have forgotten to disconnect, causing catheter occlusions) and another recommended using a metronome app to time the drip rate of a gravity infusion. Another recommendation to set the gravity drip rate was for the patient to tap their leg to the rhythm. In two sessions, nurses were observed writing patient-specific instructions for the patients.

Activities (Patient Education). The following elements of the primary activity, patient education, were observed during the study.

Participants. Nurses felt the preferred number of care partners learning is one (two maximum). “The whole family does not need to learn.” Some patients once independent would start to teach their care partners and have them come into clinic to assess competency. Nurses indicated that family conflict can increase the burden of teaching, particularly if the patient wants self-care, but the family doesn’t or if the care partner refuses to learn, despite the patient’s preference for self-care. A lack of confidence in the learner can be addressed through positive reinforcement for both the learner and the patient. In the 18 nurse-patient teaching sessions

observed, most learning participants were the patients (56%), followed by care partner (spouse) only (39%) and both patient and care partner (0.06%). All were young or middle age adults, with the exception of one older adult. Case A reported one incident of a 12-year old child as the participant learning to perform self-care for her parent.

Providers. Primary nursing was the model of care employed at Case B. A nurse follows the patient throughout the duration of their treatment, lending to consistency of teaching. In the clinic setting of Case A, total patient care was the model of care, in which a nurse is assigned patients sequentially in order of appearance in clinic to provide all care for that patient during that particular visit. This leads to patients receiving care from multiple nurses across their treatment regimen. Nurses described this lack of continuity in nursing as contributing to a potential lack of consistency in patient education content (as discussed below). However, two patients and a focus group participant both suggested that having more than one provider may be beneficial, to learn techniques or topics that another nurse had not mentioned or "if a patient relates better to a particular nurse."

Content and intensity. Table 5 describes the patient education content taught, which seemed generally consistent amongst nurses and across sites. The content discussed for complication management varied. Infection and medication side effects were most commonly addressed, with some discussing occlusions, Red Man Syndrome, phlebitis and thrombosis. There was some consistency at Case A in how some procedures were to be completed by patients. A patient expressed frustration when his performance (the number of saline syringe flushes) was corrected by a nurse, despite being given a different message the previous visit. As he stated, "If a nurse doesn't know the right way, how am I going to?" which may also serve to undermine the trusting nurse-patient relationship. A discrepancy in the number of flushes and

duration of alcohol swab use and dry time were observed more than once in the patient educations sessions. This was not observed at Case B, in which a patient is taught by their primary nurse.

The most significant difference between the two sites in their approach to patient education is the intensity, or duration, of teaching. Case A reported 3-7 visits being required before patients are typically able to independently self-administer. During my observations, the number of training sessions a patient participated in prior to the session I observed was an average of 3.3 sessions. Only 3 of the 6 patients completed the self-administration, transferring to self-care, while the reminder required further training beyond the observation period. During the observation period, each patient visit was of an average duration of 57 minutes, with an average of 26 minutes per session dedicated to patient education. Contrastingly, Case B nurses teach their patient in one visit (largely due to the private funding model). The average duration of each of the three visits was 51 minutes, with 36 minutes spent on patient education and resulting in progressing to self-administration. To achieve this short time-frame, the nurse would promptly begin the visit demonstrating the medication administration, with the patient immediately performing each step before advancing to the next step in the procedure. During the infusion, the nurse then performed the patient assessment and any vascular access device care and bloodwork. Upon completion of the infusion, the nurse would cue the participant how to disconnect and repeat the flush and have the patient perform the procedure. The visit was completed with a review of complication and supplies/medication management, supporting resources, and follow-up appointments. During the single visits in Case B, the most common complications briefly discussed were infection, drug side effects and occasionally signs of thrombosis or malposition.

A factor that extended the intensity of training in Case A was the use of gravity infusions, whereby patients had to learn how to admix their antimicrobials and prime the administration set. On average, 7 minutes per visit (range 2-10 minutes) was spent on medication preparation and 6 minutes (range 3-15 minutes) on priming, neither of which was required in Case B with the use of syringes for direct IV (push) administration and elastomeric devices, both of which were prefilled with medication by the compounding pharmacy.

Another difference in the content taught was the inclusion of rationales for the content being taught. While several nurses were much more task-oriented in teaching the skill, others explained the purpose of the task (e.g., to prevent infection). One patient commented that a nurse he was working with was a "great teacher." The patient felt she was very patient with him, focusing first on the task to ensure the patient was grasping it and then explaining the purpose to reinforce the learning.

Delivery Format. The most common teaching delivery method observed was nurse demonstration with patient return demonstration for the skills related to hand washing, and medication administration. Two patients described the immediate return demonstration of each step progressively as being very effective methods of learning. At Case A, occasionally a nurse offered new patients the opportunity to practice with expired medications and sample end caps and syringes while the infusion was running to enable them to feel comfortable with attaching a syringe to a device. Patient education materials were rarely used during the observed sessions at Case A. Nurses suggested that the detailed patient binder wasn't used "as patients would be overwhelmed by the volume of information." Although every patient received the checklist, known as a "cheat sheet," the nurses stated that few patients brought it to clinic (which was reflected in my observations). One patient was observed to review the cheat sheet when the nurse

left the room and then put it away as soon as the nurse returned. When I asked the patient after the visit about this, he was worried that he "would fail" if he had to use the cheat sheet. A nurse mirrored this stating "some patients feel they have to know it by heart but I tell them it's okay to follow." One nurse on two occasions used the cheat sheet to summarize resources and supplies, circling and highlighting the key points for quick patient reference once independent at home. At all three visits with Case B nurses, the written material was referred to for teaching patients the set-up of supplies, flushing technique and complications. One nurse stood the booklet up adjacent to the patient's work area, for ease of reference during the teaching, pointing to the text and images with verbal instruction concurrently. Another visual aid used by several nurses at both sites was to set up supplies in the sequence of use on the work surface (e.g., alcohol swab, flush, alcohol swab, elastomeric device, alcohol swab, and flush). One patient at each case site found taking a photo of how they personally set up their supplies on their work surface in the sequence of use to be a useful resource to refer to, to help ensure they were organized and used the appropriate supplies in the correct sequence. Complications and supplies management were predominantly taught verbally.

Tailoring patient education. Several strategies were observed and/or discussed to adjust the teaching to the patient's learning needs:

- Plain language. Use non-medical and short words and sentences in the active tense (see table 6 for examples of plain language terms used by these cases); For example: "Look at the drops. Count the drops for 15 seconds. Too slow? Move the roller up."
- Frequent positive reinforcement. Praise often; a nurse praised each step (e.g., "good cleaning to kill any germs" and "good- you're pushing and stopping to rinse your IV"), reinforcing both the correct technique, while also reinforcing the rationale; in another

situation, when a nurse praised a patient “your technique is very good,” the patient was beaming and his wife said “I am so proud of you.”

- Teach-back:
    - After teaching a topic, pause and evaluate the teaching and patient understanding. (Nurses rarely employed this during topics which are taught verbally, rather than tasks in return demonstration, making it difficult to know if the patient truly understood by simply asking if there are any questions). One nurse frequently used teach-back during didactic learning. Rather than simply asking, “Do you understand?” or “Any questions?” as this doesn’t really provide data to assess their comprehension, after verbally teaching IV site assessment, she asked “Tell me what you see… What might be worrisome? What do you need to do to keep the dressing clean?” Another nurse seeking to assess the teaching, questioned, “How do you know the pump is running?” Another nurse asked the patient to speak aloud the steps he was doing to get an understanding of his thought processes and was able to intercept to problem solve before committing an error.
    - Teach in “small chunks,” one step at a time and validate, reteaching if necessary before proceeding to next step. Verbalize/demonstrate one topic and then validate that teaching (through either return demonstration or questions) prior to moving on to the next section (e.g., show patient how to expel air from prefilled syringe and do return demonstration, prior to showing how to flush the catheter); if patient makes error, reteach the task/topic, adjusting teaching to facilitate learning and revalidate learning; one nurse explained the entire procedure to the patient which seemed to intimidate the patient (breaking it down into small sections might have been more effective).

- Keep it simple at first. Start with basic tasks and minimal descriptions and explanations. A nurse indicated she starts her patient education with just the facts or tasks and then builds on the task with explanations once they can perform the task.
- Explanations. Provide rationale for the task (one nurse in particular excelled at first teaching the task and once the patient is more comfortable, bringing in explanation of the rationale during the return demonstration- e.g., a nurse praised the patient while she was scrubbing the catheter hub, “good cleaning to kill any germs so they don’t get into your body” or while the patient was washing hands (return demonstration), asking “Why is it so important to wash your hands well?”
- Review informal learning plan at start/end of visit: Discuss learning goals for the session and at the end, evaluate the learning progress, collaboratively reviewing what was done well and what should be focused on at next session. For instance, at the second last teaching session, the nurses stated you’re 90% there” and reviewed the accomplishments (e.g., preparing the medicine, flushing and scrubbing the hub) and then discussed the areas for improvement (hand washing, counting drips and priming). “One more time and you’ll be good to go.” Document learning progress (facilitates mutually setting goals for next leaning session, if multiple sessions required and cues the next coach of patient’s learning status).
- Adjust to patient’s learning style and be flexible: One nurse suggested some nurses are rigid in their teaching but advised not using a rote message, teaching it in the same pattern to all patients; however not all patients learn the same way, “so you need to switch up the message;” another patient emphasizes the need to focus on the learning style of the patient. As one patient stated, “I’m a hand’s on learner- when I see someone do it, I learn faster than if you tell me to read about it.”

- Problem-solving: Ask lots of questions, particularly if the teaching is progressing well. Rather than always telling the patient what to do, cue the patient to critically think by asking questions to allow the patient to think the issue through and problem solve on their own (e.g. “you did a great job disconnecting, now what do you need to do?”).
    - Encourage the patient to recognize and correct errors, rather than immediately stopping the patient and informing them what to do; when questioned what helped a person learn, the first strategy a patient reported was “Just- they watch. Let you make your own mistakes and then they correct you before you do anything;” In one case, a patient forgot to flush the catheter prior to connecting the tubing. The nurse purposely didn’t intercept the error to see if the patient would catch the mistake and then correct it.
    - As errors can be intimidating to some, consider sandwiching the constructive criticism/problem-solving with praise and encourage the patient to problem-solve (e.g., when a patient forgot to swab the catheter, a nurse stopped the patient, and started with “You did a great job priming the air out of the syringe. Before you connect it to your IV, what do you need to do?” After the correct response, praise was provided. If the incorrect response was given, the patient would be prompted to critically solve the problem (e.g., “How would you keep the germs from getting in your line?”).
    - Provide visual or tactile cueing, in addition to verbal. (When a patient forgot to scrub the hub, rather than just redirecting her verbally, she touched the syringe to visually cue the patient.)
- Use and personalize patient education material: One patient indicated he found the written material provided a quick reference guide of the set-up of supplies, stating, “Here

are the materials you're going to need- to kind of lay them out." One nurse had personalized the material by highlighting and circling information pertinent to the patient. Another nurse, noting the learner's difficulties, wrote out instructions for priming a pump administration set using plain language. Focus group participants at Case A recommended encouraging patients to look at written material while teaching (although this was rarely observed), stating that the information doesn't need to be memorized.

- Ensure consistent messaging. "Patients will pick up on inconsistencies;" as one patient stated, "Every day I was there, it was a different nurse who'd show me/tell me different techniques;" "it was a little confusing." For instance, one nurse taught a patient to aspirate blood when flushing the catheter, which he stated no other nurses had showed him (which created confusion for him) (with no patient-aspiration being the organizational protocol).
- Use alternate technology: If the patient is struggling, consider a change of mode of administration (e.g., if the patient is unable to count gravity drips, use a syringe driver).
- Provide culturally sensitive training. One nurse indicated she may permit a visitor to remain with the patient, regardless of whether they are a participant in care; not teaching a wife if the culture prohibits it.
- Minimize distractions- avoid extraneous noise during a session to allow the participant to focus on the learning material. Strategies employed included avoiding social discussions during training, remaining silent during a patient's return demonstration whenever possible, closing the curtain between patient chairs or using a private room. I observed one patient repetitively looking up at the nurse while she was talking, distracting his concentration on the task he was performing.

- Address dexterity issues (e.g., stabilize arms on table if patient has tremours; use a tourniquet to loosen connections).

Other strategies to optimize the learning experience include providing breaks, particularly if the learner is anxious, use of humour and creativity and providing motivation if the teaching is progressing slowly.

Table 6

Plain Language Terms for Self-Administration of Home IV Antimicrobials

Medical Term	**Plain language**	**Medical Term**	**Plain language**
Administration set	Tubing	Occlusion	Blocked, plugged
Aseptic technique	Sterile, keep it clean, no-touch	Phlebitis	Redness, soreness, irritation, sore vein
Bacteria	Germs	Plunger end of syringe	Tail (e.g., "hold the tail up to keep air at top of flush")
Cap (tubing)	Butterfly cap	Prime	Prime, fill the tubing
Catheter	IV (regardless of type) or PICC, port, line	Rate	Pace, speed
Complications	Problems	Roller clamp	Roller
Dressing	Dressing, bandage	Start infusion	Start IV, hook-up, connect
Hand hygiene	Wash hands, use sanitizer	Stop infusion	Stop IV, unhook, disconnect, take-off
Medication	Medicine		
Monitor	Watch	Thrombosis	Clot
Needlefree connector	End cap, injection port	Turbulent flush	Push-stop; squirt/squirt/squirt

Competency Validation and Adherence. A non-structured process to validate patient competency was most commonly used with both cases. During the observations in the field, three patients in Case A and three patients in Case B had successfully completed the training and were transitioned to self-administration at home. No patients had reverted to nurse-administration during the observation periods. Validation of patient understanding of verbal content was primarily achieved simply by asking if they understood or had any questions, rather than using teach-back to ensure patient teaching was appropriate and comprehension was achieved. Only one nurse at Case A was observed using the electronic documentation record, which includes a teaching checklist and narrative field.

When a patient was nearing completion of teaching, nurses would attempt to simply observe, cueing only when necessary (e.g., “I’m going to sit back and just let you do this and help you if you need to”). One Case A nurse indicated the patient must be able to perform the procedures independently without error or must recognize and correct the error three times before they are transitioned to self-care. If that nurse has to cue them, it is considered a failed attempt. However, this requirement of an absence of errors in the return demonstration was not the case with the other 2 patients who were transitioned to self-administration. Other nurses judge a patient’s readiness to self-administer by when “the client starts asking the right questions” or “interprets errors” or through their response to “How do you feel about doing this on your own?” One nurse used how often the patient must refer to the sheet as a guide to deciding if the patient was ready for self-administration. This contrasts with the three patients observed in Case B, in which patients required cueing throughout the single visit and referring to the written material was encouraged.

In all cases observed in Case A, the nurse asked the patient how they assessed their performance at the visit. One nurse informed the patient of their progress, without seeking patient input; however, most collaboratively evaluated the patient’s progress. One nurse who appeared to be a confident and effective patient educator, reviewed the learning progress at the end of each visit, starting with tasks performed well and moving to those that should be focused on at the next visit, thus setting a learning plan for the next session. She would then review their progress of the previous session and set learning goals for that episode. Others would use questions to promote critical thinking (e.g., “How many swabs should I set out?”). At some of the final teaching sessions, patients were asked to explain, or “walk-through” what they would do to prepare/start/stop their infusion, at what time(s), how they would get more

supplies/medication and who and when they would call for problems. This teach-back approach served as a good summation of their responsibilities and evaluation of the teaching/understanding.

A disadvantage of self-administration, as expressed by study participants, is the inability of nurses to assess the patient's progress daily and perhaps promptly recognize delayed healing or complications, when the patient is self-administering at home. However, to compensate, patients are taught how to recognize and respond to complications. As well, the weekly clinic/home visits provide opportunities to assess patient condition and adherence to the therapy. These may be assessed by improvement in the underlying infection or wound, therapeutic drug serum levels and vascular access device patency and site condition. To assess their adherence to medication administration, they assessed for missed appointments, supplies inventory (e.g., excels supplies or expired medications or not picking up medication in the clinic) and patient verbalization of progress and performance. The patient's ongoing ability to perform self-administration and care partner fatigue are also evaluated. One nurse indicated she reminds patients of where, in their IV booklet, they can locate instructions for managing problems should they experience a complication.

To maintain a supportive-educative system, nurses also emphasized the importance of an interprofessional health team, collaborating with physicians and infectious disease or general practice physicians for the follow-up assessment of patients, therapeutic serum monitoring, counselling, and treatment adjustment to reflect patient condition or medication regime (e.g., pharmacy consultation re drug compatibility or drug adverse events). A program manager emphasized the importance of quality improvement initiatives to ensure the provision of quality services. Case A expressed a strong goal of outcome measurement, although not feasible with

current resources. Case B maintains outcome data (not authorized to share data with this researcher), which is used to identify opportunities for quality improvement. The program manager indicated that their central line associated bloodstream infections rates are within national benchmarks.

Mechanisms (Outputs) of Patient Education

Changes in behaviour, knowledge and attitudes of patients (mechanism) are triggered by the resources and contextual conditions which in turn elicit the desired outcome. Figure 2 depicts the contextual conditions and resources identified by participants which trigger a nurse's skill mastery and empowerment leading to a nurse able to teach, motive and encourage patients.

In Case B, before the patient was visited by the nurse, the expectation was set by the clinical intake team (telephone contact) that the patient will self-administer. Self-administration was explained to the patient as part of the patient's role in their therapy- the patient is expected to engage in self-administration. If the patient is unable/unwilling to participate, alternate levels of care are discussed with the patient. Nurses stated that this role clarification greatly facilitates their accomplishment of teaching in one visit. Within Case B's region, there is a cross-sector culture of safety, efficacy and acceptability of self-administration. The referral sources (e.g., hospitals and physician offices) are aware of the goal of self-administration, thus setting this expectation. Nurses at Case A, indicated that often the expectation (both patients and many healthcare professionals) is that administration of self-administration is the role of the nurse, creating a strong barrier to engaging patients in self administration.

The nurses in turn are a human resource who help trigger a patient's self-efficacy and sense of autonomy to elicit patient self-administration. Two participants expressed an initial anxiety and lack of self-confidence on their first episode of self-administration without nursing

presence. "Well the first day I was nervous. I didn't think I would be able to do it." This fear was echoed by a patient at the second case site as well: "I was a little fearful, thinking that this was something I really should have a nurse or somebody do." This patient had indicated a preference for nurse-administration but was not given that option. However, both described quickly coming to the realization of the ease of the procedures which contributed to a sense of self-efficacy. The latter patient expressed her sense of self-efficacy and pride in performing self-administration despite her initial reticence. "But I did exactly what they said and it went really easy and fast. That was the first day and then it was no problem." "It was easy to learn and was very easy to do…After the first time, it was ok. It was not that hard at all… it was very easy… It felt good." "Initially I was a little fearful, like 'Oh my God' but after the second and third time- piece of cake… like I'm a pro- I got it!" In this case, not being provided with an option for nurse-administration proved to be an effective mechanism as she had no choice but to learn.

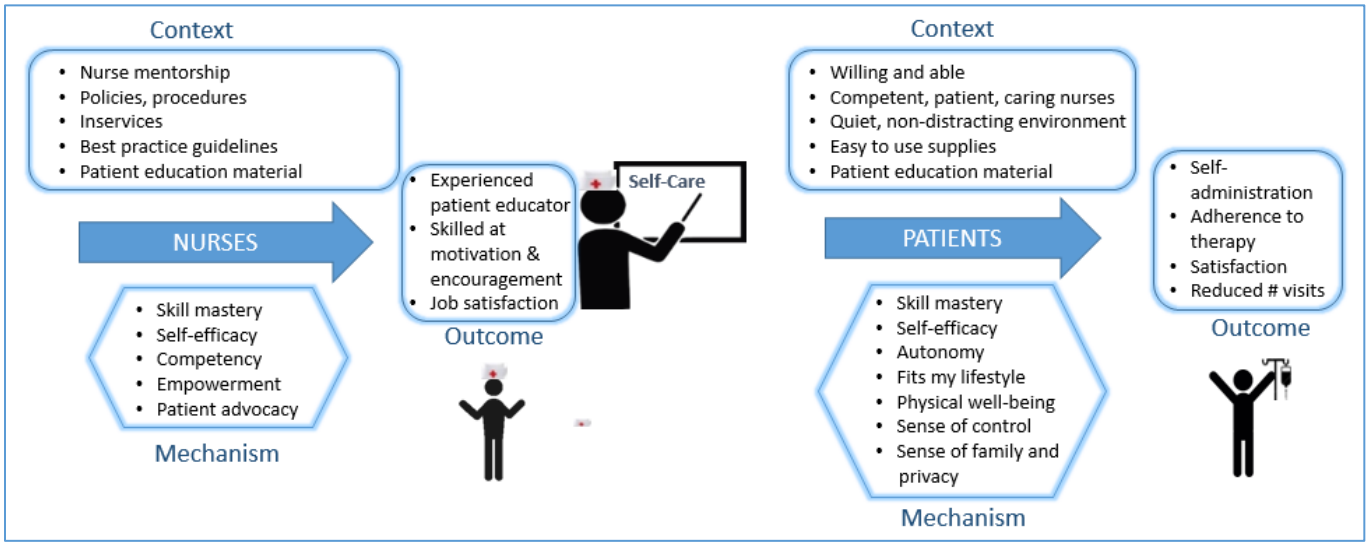


Figure 2. Mechanisms (outputs) of patient education in self-administration. (Configuration adapted with permission from Mukumbang, F.C., van Belle, S., Marchal, B., & van Wyk, B. 2016. Towards developing an initial programme theory: programme designers and managers assumptions on the antiretroviral treatment adherence club programme in primary health care facilities in the metropolitan area of Western Cape Province, South Africa. PLOS ONE 11(8): e0161790. https://doi.org/10.1371/journal.pone.0161790)

Nurses and patients elucidated changes in patients' behaviour, attitudes and knowledge which supported their learning journey and on-going adherence or fidelity to the training:

- *Physical well-being*
    - Increased safety (at home, not driving on winter roads or ambulating, especially if patient is at risk while ambulating);
    - Healing (Keep feet up (keep feet elevate, no ambulation if lower limb wounds);
    - Reduced pain due to lack of need to ambulate to clinic;
    - Adherence to prescribed therapy (if on for osteomyelitis, cellulitis for 6 weeks of treatment twice a day they start skipping visits and it doesn't take much for an excuse- oh I'm tired today);
    - Able to adhere to schedule regardless of weather (in poor weather, policy is if buses stop running, they don't send nurses to the home);
    - No missed doses (adherence);
    - Increased time to rest.
- *Fits their lifestyle.* Freedom to live life on their own schedule; patients expressed relief at not having to travel to clinic, or take time off from work or school to go to clinic or make parenting plans during clinic time; freedom and travel while self-administering; "It was great… It gives you a little more freedom…I got up at 4 in the morning and I did it. So at least I could go to work and stuff. I didn't have to miss time, going when they [the clinic] opened;" "It was so much easier because that way I'm not working around somebody else's schedule;" "I can go to the cottage while giving myself my medicine."
- *Previous exposure to infusion therapy.* Reinforce any learnings the patient may have observed already from previous experiences or exposures to infusion therapy while in

hospital/clinic or with family members. A patient stated, “I saw other patients doing it in the clinic and knew I could do it.”

- *Sense of self-efficacy and accomplishment*. One patient expressed “pride in learning a new skill and knowledge” while another expressed joyfully “I got this!” Explore other learning activities they may have been exposed to in which they were successful. A nurse indicated she will sometimes ask a reticent patient, “What new skill or piece of equipment have you learned recently, that you thought at first might be difficult?” in an effort to demonstrate patient’s capacity to learn and do new skills.
- *Sense of privacy*. Some patients expressed a desire to not have nurses in their home: “Not everyone wants to be surrounded by people or have nurses in their home.”
- *Sense of family*. One person expressed being at home with family rather than “sitting in the clinic for hours” motivated him to learn.
- *Increased sense of control and autonomy.* Patients are less dependent on nurses; patient participates, takes part and ownership in their care plan, giving the patient a sense of control when the feel like things are spiraling out of control.
- *Financial gain*. Patients and nurses reported reduced costs of transportation (including parking costs) to clinic, reduced childcare costs (during clinic visits) and reduced time off from work as mechanisms to trigger acceptance of self-administration.

Supportive care system. Once a patient has transitioned to self-administration at home, a supportive care system provides patients with the resources necessary to support their ongoing and effective self-administration therapy. This includes: a) follow-up nursing visits (weekly and prn at clinic or home); b) assessment of patient status and serum therapeutic monitoring; c) weekly and prn vascular access device care; d) infectious disease and pharmacist consultation

prn; e) complication management; f) monitoring of patient's adherence to therapy and protocols; g) medication and supplies provision; and h) 24/7 telephone support service. A supporting care system provides reassurance to the patient that they are not on their own- help is available and reassuring them that they are doing a great job in taking care of themselves. "You know the nurse came out every Monday to check which was nice." "It was nice to know that if something ran amuk, it was nice to know that if- like- it was extremely painful or it started looking bad in my opinion that I could call a 24 hour number and either somebody there would answer my question or they would contact [my nurse][to answer my question."

At any time with both Cases, a patient may be transitioned to an alternate care pathway should a risk be identified or at the request of the patient. In Case A, the patient may move from self-care to partial-care or nursing-care, while in Case B, the patient would have to be transferred to a skilled nursing facility or seek care from a nursing agency (due to the private funding structure).

Outcomes. Due to the short observation period, patient outcomes were not observed (except for completion of training) and outcome monitoring data were not available. Patients and nurses expressed intermediate outcomes of adherence to the prescribed therapy, satisfaction for both the provider and recipient of the teaching and long-term effect of patient health and well-being. At the healthcare level, nurses suggested self-administration was more cost-effective due to fewer nursing visits and some patients are keener for earlier discharge from hospital if they know they can do this themselves, increased case load (able to increase the number of patients to service when patients are independent). This enhanced resource utilization is suggested to lead to quality of care. Case A nurses also suggested that the limited care model enables them to be more efficient. By teaching patients to disconnect at the end of the infusion, the nurses can see other

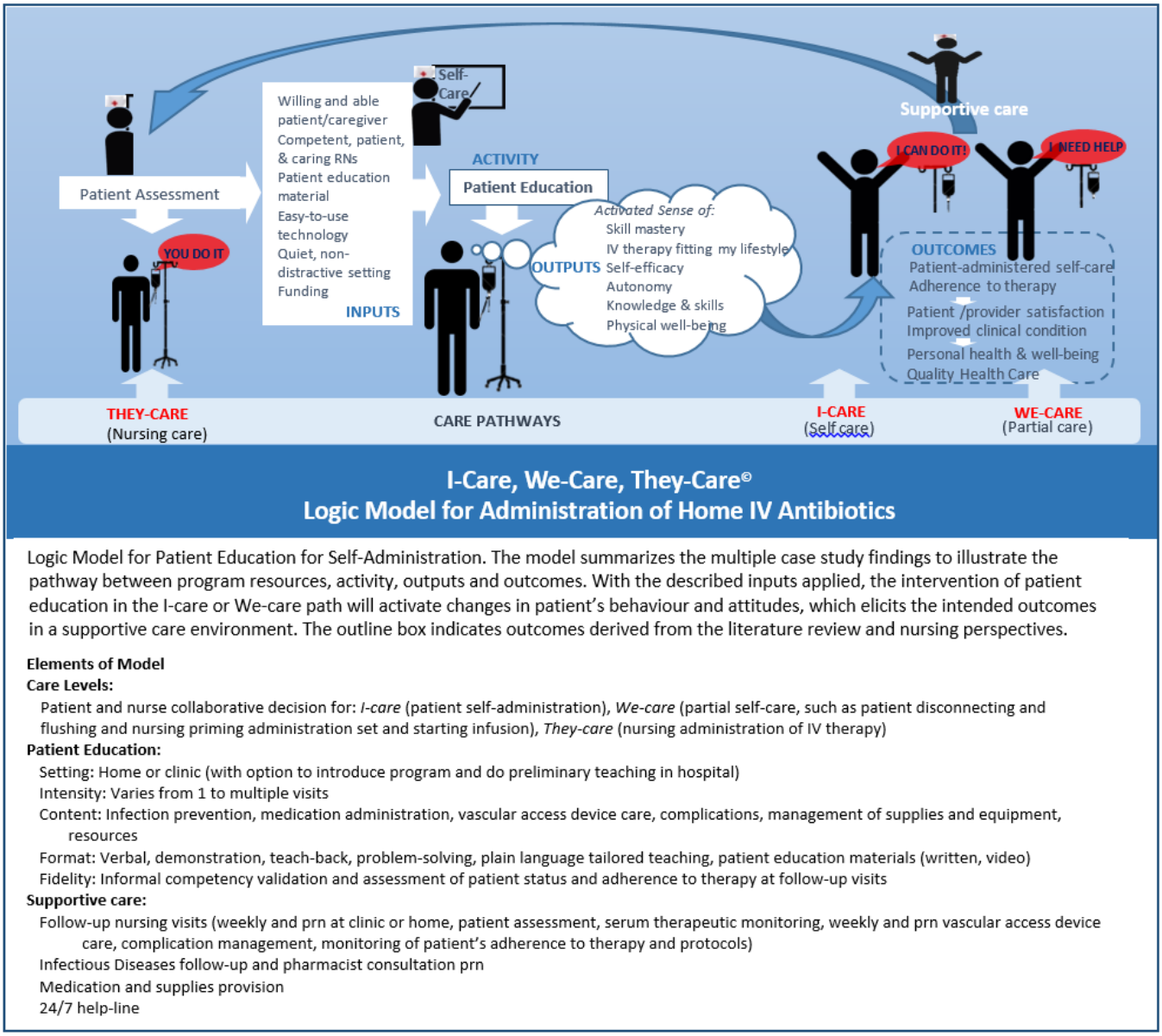
patients, indicating that limited care can reduce a visit from 2 hours down to 15 minutes (for instance a patient on a BID dose may come in the morning for the am dose and take the primed tubing home for self-administration in the evening).

Synthesis of Finding

The aim of this study was to describe and explain how patient education in self-administration of home IV antimicrobials is achieved. The triad of data sources obtained from studying two cases of self-administration of home IV antimicrobials has provided a wealth of data. To visually frame the concepts of patient education in self-administration, a logic model is presented as Figure 3, summarizing these data as a program theory. This "I-Care, We-Care, They-Care©" logic model provides a visual depiction of the program theory derived from this cross-case synthesis. The original conceptual model depicted in Figure 1 has been expanded to the logic model in Figure 3 to reflect the elements observed in these 2 cases. The model provides a framework or road map, describing the self-administration program resources/inputs, activities, outputs and outcomes identified while studying the two cases. A key adjustment to the conceptual model is the addition of the option of partial nursing care, as described below.

The goal of home IV antimicrobial programs is to ensure the patient receives the medication as prescribed in the most effective, efficient, and acceptable manner. The resources and process of teaching patients depicted in the logic model describe the characteristics of patient education programs observed in these two cases (thus addressing the primary research question of this study, "What are the characteristics of patient education for self-administration?"). Upon admission to the home infusion program, the patient is assessed, in collaboration with either the clinical intake team or the admitting clinic/visit nurse to determine which care pathway is appropriate for the patient. The three options include: 1) nursing administration of therapy

(described as "They Care" in the model); 2) partial nursing care ("We-care" or limited care as described in Case A) in which the patient is taught how to perform some of the infusion tasks while the nurses performs the remaining tasks in clinic or at home visits; and 3) self-care or self-administration ("I-care", as performed in both cases).



Logic Model for Patient Education for Self-Administration. The model summarizes the multiple case study findings to illustrate the pathway between program resources, activity, outputs and outcomes. With the described inputs applied, the intervention of patient education in the I-care or We-care path will activate changes in patient's behaviour and attitudes, which elicits the intended outcomes in a supportive care environment. The outline box indicates outcomes derived from the literature review and nursing perspectives.

Elements of Model

Care Levels:

Patient and nurse collaborative decision for: *I-care* (patient self-administration), *We-care* (partial self-care, such as patient disconnecting and flushing and nursing priming administration set and starting infusion), *They-care* (nursing administration of IV therapy)

Patient Education:

Setting: Home or clinic (with option to introduce program and do preliminary teaching in hospital)
Intensity: Varies from 1 to multiple visits
Content: Infection prevention, medication administration, vascular access device care, complications, management of supplies and equipment, resources
Format: Verbal, demonstration, teach-back, problem-solving, plain language tailored teaching, patient education materials (written, video)
Fidelity: Informal competency validation and assessment of patient status and adherence to therapy at follow-up visits

Supportive care:

Follow-up nursing visits (weekly and prn at clinic or home, patient assessment, serum therapeutic monitoring, weekly and prn vascular access device care, complication management, monitoring of patient's adherence to therapy and protocols)
Infectious Diseases follow-up and pharmacist consultation prn
Medication and supplies provision
24/7 help-line

Figure 3. Logic model for self-administration of home IV antimicrobials.

To support the target activity of patient education for I-care or We-care, the following resources are required: willing and able patients/ care partners; competent, patient and caring nurses; personalized patient education material; easy-to-use supplies; and a quiet setting (either home or clinic) with minimal distractions. It is the nurse or clinical intake's responsibility to assess patient willingness and readiness to learn and physical, cognitive, psychosocial and environmental capacity to perform self-administration. Neither program provided formal patient education to nurses.

Patient education is then performed over one or multiple sessions, depending on the type of funding model. Single visits are used in the private-pay model, while 3-7 visits are the norm in the government-funded model. A registered nurse teaches the participants, usually a patient or patient and care partner, over an average of 26-36 minutes per visit. Content appears consistent across cases (with some minor differences), including infection prevention, medication administration, vascular access device care, complications, management of supplies and equipment and available resources (contacts). Consistency of messaging to patients avoids patient frustration with conflicting teaching.

Return demonstrations are the most commonly used delivery format for task-oriented topics, while verbal instruction is commonly used for didactic topics, such as complication management. Case B tended to support discussion of complications with written patient education material, while Case A rarely used written material. Neither site used videos as a delivery format, although this was recommended by three patients. Pedagogical strategies included plain language, positive reinforcement, teach-back, explanations, learning plans, tailored teaching, problem-solving, and adjusting to cultural expectations. Validation of patient understanding is predominantly informal with both Cases, although some nurses use electronic

documentation to cue validation. A typical nursing visit in which a patient is trained self-administration in one visit is depicted in Table 7, as derived from observations at Case B. Due to the time constraint of one 60-minute visit, the nurse must be well-organized and focused on the visit plan to achieve patient competency by the end of the visit. Contact from the home infusion team prior to the visit to explain self-administration appears crucial to activating a patient to learn and perform self-administration in this short time frame.

Table 7

Visit Schedule for Teaching Self-Administration in One Session

Content	**Teaching technique**	**Duration**
Greeting; explain program*; review plan of care (while setting supplies out)	N/A	3 min.
Handwashing, infection prevention	Demonstrate; verbal; teach back	2 min.
Add extension set to vascular access device	N/A	2 min.
Flush vascular access device	Demonstrate; teach back	7 min.
Initiate infusion	Demonstrate; teach back	3 min.
Care of elastomeric pump	Verbal; teach back	1 min.
Patient assessment	N/A	10 min.
Care of vascular access device	Verbal; teach back	2 min.
Complications	Written; teach back	4 min.
Supplies; resources; review medical appointments	Verbal; teach back	10 min.
Social	N/A	3 min.
Handwashing	Teach back	1 min.
Disconnect infusion and flush vascular access device	Verbal; teach back	5 min.
Review plan, document, socialize, end visit	Verbal; N/A	7min.

* Note: Patient is contacted by home infusion team prior to visit to explain program and obtain consent to self-administer

Effective education triggers changes in the patient's behaviour, knowledge and skills to support desired outcomes. These changes are the mechanisms which facilitate patient activation to perform self-administration (the second research question guiding this study). It is worth reinforcing that activation of patients' willingness to engage in self-administration, ideally begins before the training session. To optimize the successful completion of training in one visit at Case

B, the Clinical Intake team ensures the patient is engaged in self-administration prior to the nurse visit, which. Gaining knowledge and skills to competently perform self-administration enables the patient to administer the therapy in the safety and comfort of their home (or at least reduce the burden of clinic visits, as with Case A). An overview of mechanisms which may engage patients to adopt and maintain participation in self-administration are described in Figure 4.

Successful patient education can activate a patient's sense of acceptance of this treatment modality, providing a sense of freedom and autonomy with the IV therapy fitting into their schedule (rather than vice versa). The patient also enhances their self-efficacy through the new knowledge and skills learned. Figure 4 provides a toolkit or synthesis of strategies identified in this multiple case to successfully teach patients and promote a supportive-education system to ensure optimal program and patient outcomes of self-administration of home infusion of antimicrobial agents.

Supportive care is crucial to the success of self-administration. The patient is reassured to know that help is just a phone call away 24/7. Nursing visits (at home or in clinic) are scheduled at least weekly for patient assessment, therapeutic serum monitoring, vascular access device care (e.g., dressing changes), patient education, and monitoring of adherence to therapy and protocols and identification of any complications. In Case A, all patients receive follow-up appointments with the Infectious Diseases team and in Case B, the nurse reviews scheduled follow-up appointments with their health care teams. Supplies are provided by both programs and patients are informed of this process. At any time, patients may be reassessed to determine if a patient should be reassessed to transition to an alternate care pathway, such as partial care or nursing care to maintain optimal outcomes.

Due to the short observation period of this study, intermediate and long term outcomes were not able to be observed. The literature review performed prior to this study and focus group feedback suggests self-administration is safe and effective, with completion of therapy as prescribed, leading to patient satisfaction and avoidance of hospital admissions and personal well-being for patients and improved quality healthcare with enhanced resource utilization.

In summary, competent, caring, and patient nurse coaches can effectively teach patients by triggering patients' senses of skill master, self-efficacy, autonomy, physical well-being and control and using pedagogical techniques such as teach-back and problem-solving, particularly if teaching occurs in quiet, non-distractive settings with easy-to use supplies and current tailored patient education materials.

All patients interviewed indicated they would recommend self-administration to other patients: "It was great. I'd rather sit at home for three hours, than twice a day there [clinic];" "Learning was pretty easy;" and "…it gave me the chance to do it whenever… I had time… I didn't have time to run to the clinic all of the time." "Self-care was perfect for me."

Toolkit for Successful Self-Administration (S-A)

Patient Engagement

- Mentor competent, caring, patient nurse coaches
- Create culture (patient and healthcare professionals) of safety, efficacy and acceptability of S-A
- Assess patient/ care partner capacity and willingness to learn and perform S-A
- Set expectation of patient as an active participant in their treatment, performing S-A. If patient reticent, identify mechanisms to promote patient willingness:
  - Explain benefits of S-A, as relevant to patient: Physical well-being and safety (reduce travel/ambulation to clinic [and resultant improved rest, healing, comfort, and adherence to therapy]; treatment fits their lifestyle (e.g. administering at home, work or on vacation and avoidance of requiring childcare during clinic visits); increased senses of control and autonomy, self-efficacy /accomplishment, privacy, family; and financial gain (reduced child care/transportation/parking costs and time off from work); experiential learning (previous exposure to infusion therapy in clinic/hospital)

Effective Patient Learning

-Teach in a quiet non-distractive setting
- Set supplies out in sequence of use (e.g., antiseptic swab and saline syringe, antiseptic swab and pump, antiseptic swab and saline syringe); consider photo of set-up
- Use current tailored patient education materials- personalize materials to patient (e.g., underscoring, highlighter, notes)
- Tailor teaching to patients needs:
  - Assess patient learning style and adjust teaching accordingly
  - Apply principles of teach-back (lots of it!) throughout learning journey:
  - Use plain language (non-medical short words and sentences in the active tense)
  - Break content into small chunks (one step at a time) and validate teaching; reteach (adjusting teaching method if necessary) and validate again before advancing
  - Keep it simple at first (consider starting with basic tasks and minimal descriptions and explanations and build on these)
  - Frequently provide positive reinforcement; sandwich criticism in between praise, using positive, rather than negative phrasing
- Encourage problem-solving- ask questions, encourage identification and management of errors during learning
- Set learning goals and review progress/ learning plan at start and end of visit
- Ensure consistent messaging
- Culturally sensitive training
- Use easy-to-use supplies/equipment (e.g., prefilled syringes and elastomeric pumps)

Supportive-educative system

- 24/7/7 clinical support
- Written clinical information (including complication management)
- Weekly and prn nursing visits (clinic/home):
  - Assessment of patient condition and response and adherence to therapy (e.g., missed appointments, supplies usage, improvement in therapy indicator, patient satisfaction), vascular access device care, blood sampling, wound care, complication management; assessment of adherence to therapy and adjustment of care plan accordingly;
- Provision of positive reinforcement of patient's self-efficacy and accomplishments
- Collaborative inter-professional health team: pharmacist/Infectious Disease follow-up for assessment, therapeutic serum monitoring, counselling and treatment adjustment
- Outcome monitoring; quality improvement initiatives

Figure 4. Strategies for Successful Patient Education in Self-Administration of Home IV

Chapter 6. Discussion

The purpose of the study was to explore how patient education in self-administration of home IV antimicrobials is achieved, using case study methodology. The data provide insight into the characteristics of this education and how patients become activated to practice self-administration. A discussion of the results related to characteristics and mechanisms of patient education in relation to published evidence is presented, followed by methodological considerations to help the reader interpret the study results. Lastly, the significance of these findings provides insight to how the program theory logic model way impact clinical and administrative practice, with opportunities for further research identified.

Comparison of Findings with Literature

Self-administration is safe and effective, as revealed by a systematic review examining different modalities of delivery of care in this population (Mitchell et al., 2017). A recent retrospective review found that outpatient parenteral antimicrobial therapy was judged to be a full/partial success in 93% of episodes, although self-administration was associated with a higher rate of catheter-related events in the program with a high use of midline catheter usage (HR 9.4, 95% CI 2.4-51.9, p<.004) (Underwood, Marks, Collins, Logan, & Pollara, 2019). A retrospective review of medical records of patients who self-administer IV antimicrobials found that self-administration is not associated with an increase in emergency department visits related to their therapy (Ganguly, Agrawal, Brown & Bhavan, 2018). A study of patients who receive outpatient parenteral antimicrobial therapy found that 97% of patients would choose self-administration again and had a statistically higher overall satisfaction rate (96%; n=68/71) than patients treated at the outpatient unit or by home care nurse (80%; n=32/40) (Saillen et al., 2017). My findings extend the knowledge base related to self-administration, identifying how self-

administration is achieved. A comparison of the study findings to published literature will help the reader to interpret the position of the logic model against extant evidence.

Characteristics of patient education.

Typically studies examining the outcomes of self-administration provide minimal description of the study's educational interventions used to achieve these outcomes (Cox & Oakes Westbrook, 2005; Grimes-Holsinger, 2002; Kieran, O'Reilly, Parker, Clarke, & Bergin, 2009; Rickard et al., 2015; Subedi, Looke, McDougall, Sehu, & Playford, 2015). Yet, patients expected to self-administer their home IV antimicrobials are challenged with learning complex skills and knowledge. Results of this study provide greater insight into how patient education is achieved. Eaves and colleagues (2014) call for self-administration programs to have formal, well-designed patient education programs. The logic model provides a visual synthesis of the requisite inputs of a patient education program, outputs and outcomes employed by two robust home infusion programs to achieve self-care.

As described in Chapter Two, in the literature, and in these two case programs, the recipient of the education may be the patient, care partner or both and the provider of the education is the nurse. An Irish program indicated it was a member of the outpatient parenteral antimicrobial team (not specifically a nurse) responsible for the training (Kieran et al., 2009). As part of the supportive care for the patient, pharmacists and clinical intake staff (not necessarily healthcare professionals) also provide tele-support to patients. A study of care partners receiving self-administration education described a range of negative emotions, expressing apprehension to extreme stress related to learning (Cox & Oakes Westbrook, 2005). Few participants in this case study expressed these emotions, although two patients were initially anxious, but found it easy to learn as the teaching progressed.

Although most of the studies identified in Chapter Two described the hospital as the location of patient education, both case study sites recommended the hospital primarily for introduction of self-administration, with perhaps high-level introductory information to the procedures. The sites recommended the clinic or home as the preferred site. In contrast, a quality improvement initiative studying 60 patients receiving pre-discharge self-administration education by a community liaison nurse versus 37 patients receiving teaching at home, found an overall 20% improvement in outcomes, 48% decrease in after-hours calls or interruptions in therapy and 28% reduction in readmission/emergency room visits with the pre-hospital discharge teaching (Bondi & Stancil, 2017). In this case, the home infusion team positioned a liaison nurse in hospital, which helps ensure consistency in teaching across the sectors. This model of pre-discharge education, in which patients understand they will be expected to self-administer at home may serve to reduce the barrier of patient expectations once at home of nurse-administered therapy.

Tonna et al. (2019) identified social/professional role and identity as a barrier, with some patients believing that it was not appropriate for patients to self-administer as it was the role of healthcare professionals. The authors also recommended further research to explore the views and perceptions of health professionals towards self-administration. A small U.S. study suggested the hesitancy of healthcare professionals to promote self-administration to be a major barrier, more so than patient reluctance (Agrawal, Ganguly, & Bhavan, 2017). The authors suggest that widespread adoption of self-administration requires physicians to initiate self-administration. However, seventy-six percent of physicians reported that they would not feel comfortable sending the patient home to self-administer, citing the complexity of self-administration, patients' inability to care for their PICCs, low patient health literacy and medico-

legal concerns. Educating healthcare professionals on the concepts of patient self-efficacy and engagement to support self-administration should be encouraged to promote uptake of self-administration.

Educational content was fairly consistent between the case sites and those described in the literature in Table 1. An exception is neither site discussed an emergency plan with patients. Both programs discussed catheter-related complications with patients, which is supported by Underwood's study (2019) which found that catheter-related adverse events (extravasation, blockage and displacement) occurred significantly more frequently than drug-related adverse events, although it should be noted that the rate was highest for non-radiologically guided midline catheters (n=23, 59% at 15.6 [95%CI 10.3-23.4). Midline catheters were rarely placed at Case B and not used at Case A. The type of infusion device technology was identified by participants to impact the ease of learning and administration. Nurses and patients at Case B cited the ease of use of the elastomeric (balloon-type, disposable pump). Saillen and colleagues (2017) found a high level of satisfaction in patients performing self-administration with elastomeric pumps, reporting it easier to use than expected, which mirrors the report of one patient at Case B, who was initially fearful, but pleasantly surprised by the ease of use.

The delivery format of patient education was not described in 67% of the reviewed studies described in Table 1, with the remaining two studies describing verbal teaching, demonstration/return demonstration and written material as the methods of delivery, similar to this case study's findings. Print materials should be prepared at a reading level appropriate for the general population, with pictures and illustrations particularly useful for those with low literacy skills (Friedman et al., 2010). As well, none of the studies reported the use of electronic media (e.g., videos), although three patients recommended this format. A systematic review of

patient teaching strategies concluded that computer technology (particularly interactive programs), audio and videotapes and written materials and demonstration and a combination of media increases knowledge, and satisfaction and decreases anxiety (Friedman et al., 2010).

The intensity of patient education varied greatly between the two cases. Reducing the number of educational sessions to one visit could have significant potential to optimize the value of healthcare, in terms of financial, human and physical resources. Table 7 provides a snapshot of how teaching in one visit may be accomplished, which to my knowledge has not yet been explicated in the literature. Tonna et al. (2019) recommend an investment in nursing resources to ensure adequate staff to provide the intensive teaching, which would ideally commence while in hospital. Additionally, enabling patients to understand they have the self-efficacy to learn and perform this prior to initiating teaching and thus setting the expectation for self-administration appeared to be a strong mechanism for patient engagement, particularly with Case B.

It is of interest that the case program that achieved patient education in one visit used written material consistently and more so than the site which required multiple sessions. A systematic review found that knowledge is significantly improved when verbal health information is combined with written material in comparison to verbal information alone (Johnson & Sandford, 2005). Verbal teaching was found to be the least effective, and hence not-recommended as a patient education strategy (Friedman et al., 2010). This may be a key strategy for self-administration programs to employ when teaching non-kinesthetic topics such as complication management, supplies and medication management and available resources. A nurse may point to the written material while verbalizing the content and circle or highlight key points to increase the likelihood of retention (Sustersic, Gauchet, Goote, & Bosson, 2016).

Tailoring the teaching to the patient's individual leaning needs, as identified by participants, is a key strategy for effective patient education (Hronn Svavarsdottir, 2015; Inott & Kennedy, 2011). Inott and Kennedy caution that neglecting to understand the particular patient's learning needs and style and setting learning goals and expectations is common. Using a rote generic teaching plan can impair learning and the educational outcome for the patient. Participants recognized the importance of cultural sensitivity, which Inott and Kennedy advise includes assessing and adjusting the teaching to the patient's perceptions of illness, health beliefs, family roles and communication. One patient participant in this study referred to his learning style as being kinesthetic. Inott and Kennedy also advise assessing and adjusting the learning plan to the patient's learning style: visual (written and technological instructions and images), reader (written materials and suggested readings), auditory (verbal repetition, audio recordings) or kinesthetic learner (hands-on, return demonstrations). They also recommend learning the patient's motivation to learning. This study identified several mechanisms eliciting patient learning and performance of self-administration. These mechanisms can be used to help incentivize the reticent learner through the training to achieve their intrinsic goal (Inott and Kennedy, 2011).

Dr Carmona, former U.S. Surgeon General, cautions "Heath care professionals do not recognize that patients do not understand the health information we are trying to communicate" (Agency for Healthcare Research and Quality, 2017). This is alarming given that 60% of Canadian adults, including 88% of seniors are reported to have low health literacy (Canadian Public Health Agency, 2014). We need to ensure that patients understand our health teaching. Patients with low literacy may have difficult recall and comprehending information (Negarandeha, Mahmoodib, Noktehdanb, Heshmatc & Shakibazadehd, 2013). One very

effective patient educator in Case A used teach-back frequently and Case B used written materials with images and teach-back. A randomized controlled trial exploring the impact of pictorial images and teach back as educational strategies found these two educational strategies to statistically significantly increase knowledge and adherence to medication among patient with diabetes and low health literacy (Negarandeha et al., 2013). These authors indicated that teach back is recommended as a top patient safety practice by the National Quality Forum. Teach-back incorporates the use of plain language, avoiding medical jargon or vague terms and asking open-ended questions for the patient to restate or teach back the information to confirm patient understanding after teaching a few key points. It is hoped Table 6 will provide a useful tool to help clinicians transition to the use of plain language. Rather than simply asking if they have any questions, as many of the case study nurses were observed to use, a more effective approach may be the following exemplar from the randomized control trial protocol:

> 'I always ask my patients to repeat things back to make sure I have explained them clearly. I'd like you to tell me how you're going to take the medicine that we talked about today' or: 'When you get home, your [husband/wife] will ask you what the nurse said. What will you tell them?' If the answers were wrong or incomplete, I explained the issue again to ensure the patients finally understood the matter (Negarandeha et al., 2013, p.3).

Mechanisms of patient education.

In addition to the use of pedagogical techniques to optimize the learning experience, understanding what motivates the patient to learn and do self-administration will help the clinician teaching these patients. The data describing the outputs of patient education, the mechanisms of how patient's behaviour, knowledge and attitudes change, provide insight into why they adopt this mode, despite its complexity. Achieving a sense of self-efficacy, autonomy

and skill development as revealed in the logic model, align with the principles of Bandura's concepts of self-efficacy and patient activation, applied to home infusion therapy (Hibbard & Greene, 2013). These mechanisms serve as triggers for patient learning and ongoing adherence to self-administration, acting as motivators for the change in behaviour. Tonna et al. (2019) identified patients' perceptions of being sufficiently knowledgeable, skillful and competent as main determinants of potentially encouraging patients to self-administer IV antimicrobials.

The self-efficacy model depicts that an individual's self-efficacy is based on the mastery of skills, often modelled on observation of the behaviour of others, social persuasion that the person is capable and arousal of emotions (Syx, 2008). When patients view themselves as capable, they are more likely to adhere to the treatment plan. This aligns with study participant's views that the tasks of self-administration should be broken down into manageable steps to master the skills through observing nurses with the support of nurses and family reinforcing the skills mastery, bringing the patient from self-doubt and perhaps anxiety to confidence in his or her abilities. Tonna and colleagues (2019) recommend the used of graded tasks (building up from easy-to-perform tasks to more complex tasks) when teaching patients self-administration as a strategy to address patients' lack of belief in their capabilities. The authors also recommend the use of verbal persuasion, providing reassurance of success to help patients overcome self-doubt and increase self-belief.

Study participants' beliefs that intrinsic mechanisms such as autonomy, freedom and fitting their IV therapy into their lifestyles motivates patients to learn and perform self-administration fits with Knowles' adult learning theory (Syx, 2008). Patients' perceptions that self-administration supports the potential to work while receiving treatment has been identified as a key determinant of uptake of self-administration (Tonna, 2019). Knowle's research also

emphasizes the importance of the learning environment. Participants preferred the less hectic pace of the home and clinic private rooms to the hospital environment which can be fast paced, distracting and full of interruptions (Syx, 2008).

The Institute for Healthcare Improvement recommends patient activation as a key strategy in patient-administered self-care (Martin & Anderson, 2017). Central to patient activation is a tailored approach in the levels of activity at which a patient participates, which aligns with the logic model's care pathways. Although the focus of the study was originally self-administration, the tiered approach of Case A supports adjusting the training to the ability of the participant, thus not requiring an 'all-or nothing' approach. The care pathways of I-care, We-care and They-care© align both with Case A's self-care, limited care and nurse-care paths. These also are in accordance with Orem's theory of nursing systems (Cox & Taylor, 2005). Orem purported that patients have an innate ability for self-care yet require assistance when their demands for self-care exceed their ability. The logic model's 'They-care' pathway mirrors Orem's wholly compensatory nursing system in which the patient is unable to meet self-care demands, and thus requires clinical care to meet these needs. The 'We-care' pathway aligns with Orem's partially compensatory system in which patient require some nursing care (such as priming of tubing if they have physical impairments) yet can meet some self-care demands independently. The 'I-care' pathway aligns with the supportive-educative nursing system in which patients are able to perform self-care, yet take confidence in having nursing support, guidance and teaching available (Vasquez, 1992). The logic model has adopted the term "supportive care," rather than "nursing support" to reflect the inter-professional support services provided by nursing, pharmacy, infectious diseases physicians and phlebotomy staff.

The study also identified mechanisms which enable a nurse to be a successful coach. Nurses and patients reported that a nurse who exhibits confidence, patience, and expertise facilitates a patient's burgeoning skill set and knowledge base. A grounded theory of care partners' educational process to learn home infusion therapy also found that nurse's knowledge, expertise, personalized support and caring attitude helped ensure success (Cox & Oakes Westbrook, 2005). Those authors also concluded that the participant's increasing self-efficacy and satisfaction in learning a new task was a mechanism for their successful administration of therapy, which supports the findings of my study that these are mechanisms for patients as well.

A qualitative study described an expert patient educator as a health professional with subject matter expertise, confidence and excellent communication skills to share the information in an interesting method clearly understood by the patient (Hronn Svavarsdottir, Siguroardottier & Steinsbekk, 2015). These attributes echo the study participant's views of an effective patient coach, including the need to tailor the education to the patient's needs and context of the situation. Neither program in my study provided formal training in patient education to nursing staff. These authors also reinforced the need for educators to have a supportive learning environment for the staff, in the forms of continuing education, mentoring and peer support, supportive educational resources such as evidence-based clinical guidelines, standardized educational sessions. They also encourage educators to take an active role in knowledge seeking and training to further develop their competency. I also found building experience through observation and experiential training as an effective tool, which mirror this study's participants who found this to be the primary method of learning how to be a coach. Hronn Svavarsdottir and colleagues found that observation of expert educators increases awareness of effective communication skills, including appropriate language, providing explanations and responding to

questions. They also suggested roleplaying and rehearsing to enhance a novice educator's training and evaluations of one's performance as an educator.

The proposed mechanisms are not intended to be prescriptive elements as prerequisites for self-care, particularly as individual, institutional and wider contexts vary across programs. It is the goal of realist inquiry and program theory that there is a "family resemblance" across programs that may guide other programs (Pawson, Greenhalgh, Harvey & Walshe, 2004, p 34). Programs may recognize features of these two case sites which are similar to theirs. This enhances transferability of findings, in which the reader may investigate whether these finding may be applied in their context, whether it is another home infusion program, or a program promoting self-administration of other therapies (such as home parenteral nutrition, home dialysis, wound care or ostomy care).

Methodological considerations

A high-quality study employs strategies which helps persuade readers that they can trust and act on study findings (Tracy, 2010). Perhaps the greatest strength of this study is the use of Yin's approach of multiple case study methodology (2009). I applied Yin's methodology throughout the research process as adherence to well-known case study methodology enhances study authenticity (Anthony & Jack, 2009). Hyett and colleagues (2014) emphasise the importance of the novice researcher adhering to traditional methodology, rather than deviating from the methodological procedures which may cause unforeseen issues. I have strived consistently to apply Yin's approach to case-study methodology throughout the research process of this study.

Positioning the research in its real-world context enabled me to capture the holistic characteristics of the complex process of patient education, which enhances the credibility of the

study (Casey & Houghton, 2014; Houghton et al., 2013). Data were collected in the natural setting, facilitating my interpretation of the data in practice. The non-participative direct observations in the field afforded the capture of a plethora of pedagogical techniques in action and applied to infusion therapy domain. The use of multiple cases was advantageous in being able to replicate results across the cases, thus adding to the rigour of the study by enhancing the study's external validity (Kohn, 1997; Yin, 2009). The use of two cases with disparate approaches to patient education (single versus multiple patient visits and self-care only versus self-care and limited-care) introduced alternative interventions for consideration.

In addition to the use of two cases to strengthen data collection, the use of triangulation of data sources (direct observation of nurse-patient education dyads, nursing focus groups and patient interviews) strengthens the trustworthiness of the findings (Houghton et al., 2013; McGloin, 2008; Mukumbang et al., 2016). Specifically, observation yielded rich data on pedagogical strategies, while the focus groups presented a greater understanding of the resources and outputs of patient education, and the patient interviews ensured inclusion of the patient perspective throughout the education process. Observing and interviewing the same participants permits comparisons between reported and actual behaviour and developing a complete picture (Casey & Houghton, 2010). Spending sufficient time in the field, observing nurses and patients in the home infusion settings helped achieve a full understanding of this phenomenon (Houghton et al., 2013). The multiple data sources helped to a) ensure the findings are grounded in the data, rather than my interpretation; and b) confirm agreement among the different sources of data to increase the validity of the study (Malterud, 2001; McGloin, 2008). In positioning the nursing focus group after the direct observations, the relationship built with the nurses while in the clinic helped to establish a rapport with the nurses over multiple days which likely contributed to

robust discussions during the focus groups. This may have been a factor, in addition to the smaller sample size, yielding less data from the focus group at Case B (as the only available time for the focus group meeting was prior to the observations).

The use of the logic model framework was particularly useful to operationalize the research process, as recommended by Yin (1999). Using the categories of inputs/resources, activity, outputs and outcomes helped in the development of the interview guides to ensure key elements of patient education were collected and provided a semi-structured format for directed content analysis (Kohn, 1997; Yin, 2009). The logic model proved to an effective visual display method to present the data synthesis in a cohesive manner.

Yin's realist-positivist approach aligned well with my novice experience in qualitative research and my comfort level in the empirical realm. Yin's inclusion of both qualitative and quantitative data as appropriate approaches enabled me to collect descriptive statistical data to better describe the intensity of the education sessions, not previously described in the literature (Yazan, 2015).

My extensive experience and expertise as a subject matter expert enable her to focus more intensely on the nuances of patient education, rather than focusing strictly on the content. It also helped ensure the overall study had a strong evidence-based foundation underpinning the research. To increase transparency and transferability of results, I have declared my role and preconceptions as a researcher (Houghton et al., 2013; Malterud, 2001). Despite this, it is conceivable as a novice that bias has been introduced. To enhance the quality rigour of the study, the data were subjected to peer review in which my thesis advisors reviewed the data, analysis and synthesis for accuracy and consistency. In addition, participation of a thesis advisor in the data collection, permitted an in-depth understanding of the method and type of data collection.

Remaining a silent, non-obtrusive observer during the nurse-patient dyads helped to reduce the risk of social desirability responses during the observations (Baxter & Jack, 2008). My ability to check personal assumption and understanding by using flip charts was valuable as a means to member check but also to have visual cues to refer back to previous discussions to spark new topics of discussion.

There were limitations to this study that should be considered when interpreting results. First, there was limited time for observation as the case sites were geographically remote to me and many patients scheduled during the observation period received therapies not meeting study inclusion criteria. Unfortunately, no initial visits at Case A were observed to better explore patient recruitment and assessment, although the documents provided by the program provided some insight. The potential limitation was lessened through the use of multiple data sources. Second, the sample size of the patient interviews and the Case B nursing focus group were small. It proved to be very difficult to reach patients for a telephone interview, due to unanswered calls and voice mail messages. However, observation of patients strengthened incorporation of the patient perspective in this study. The small focus group really hindered the richness of data collection at this site; however having two groups at Case A provided an additional dataset. Critics of case study argue that the small number of study participants in case studies may lead to circumstantial findings, rather than fact (McGloin, 2008). However, as McGloin asserts, Yin's rebuttal is that "focusing on such a small sample results in the generation of 'deep data' and thus sample size is not a limitation of transferability or trustworthiness of findings" (McGloin, 2008, p.52).

To interpret these results, the reader is encouraged to situate the findings in the context of the described cases to determine similarity or differences to their practice. To enhance the

transferability or application of findings beyond the limits of the study, a detailed description of each case was presented and depicted in a logic model. The goal of this study was not to create a generalizable or universal truth of patient-administered self-care but to help explain how patient education might work, for whom, in what circumstances and why. Yin explains that the external validity of the case study instead refers to an analytical generalizing results to the program theory depicted in the logic model, as the cases do not represent a sample (Crowe et al., 2011; Easton, 2010; Yin, 2009 & 2012). Therefore, the logic of the theory may be applicable to other situations (rather than a population). The reader is encouraged to assess whether the logic resulting from this study's findings are applicable within the context of their setting (Yin, 2012). A review of the description of the programs and the programs' characteristics will guide the reader to help determine the fit of the model with their own program. To further enhance transferability, I am confident that the logic model and pedagogical strategies will resonate with reader, by feeling that the logic model "overlaps with their own situation and they intuitively [will] transfer the research to their own action" (Tracy, 2010, p. 845).

The use of the logic model framework may be perceived to introduce bias in the collection and interpretation of the data. It is acknowledged that this account of characteristics and mechanisms of patient education is not exhaustive. Nor has there been an attempt to determine causation. It was beyond the scope of this research to trace causal connections among the inputs, activity, outputs and outcomes of self-administration (Strahan, Kronenberg, Burgner, Doherty & Hedt, 2012). The arrows in the logic model are used as process directors to indicate the flow of the process and how the elements are linked to each other.

Third, this study spanned two years, with the second case site enrolled late due to resource limitations. It is possible that characteristics of Case A may have changed in the

interim. Fourth, a threat to the legitimacy of the research is my own bias. This threat was controlled through the use of member-checking by using flow charts for the focus groups and providing an audit trail as a chain of evidence to ensure transparent decision making, so the reader is assured of the dependability or consistency of the data (McGloin, 2008; Yin, 2009). As a novice researcher, unintentional bias may have been introduced into generating and analyzing the data. However, the analysis remained close to the data due to my inexperience in interpretive research. Examples of raw data (direct quotes) were frequently provided in the presentation of results to help the reader to consider alternative interpretations (Houghton et al., 2013).

Lastly, limitations were imposed by constraints of time and resources, hindering case and sample size, as well as seeking a skilled realist researcher (Wong, Greenhalgh, Westhorp, Buckingham & Pawson, 2013). I concede the vulnerability of the program theory due to the inability to explore the myriad context-mechanism-outcome configurations which may explain patient education.

Implications of Findings

This logic model of patient education advances the understanding of patient education in the context of the community and homecare setting. The study was conducted to answer the question of how patient education in self-administration of home IV antimicrobials is achieved. There are valuable insights for patients, clinicians, administrators and researchers about the characteristics and mechanisms of patient education in this specialty which could contribute to optimizing the practice of self-administration of home infusion therapy.

Patients. Patients want to be well and enjoy the comfort and safety of their homes. Offering self-administration provides them with the opportunity to do their own care on their own schedule-- at work, home or even on vacation. Tailoring their education to their health

literacy and learning needs makes this a more effective and less stressful learning journey for them. Understanding how this education triggers their willingness and skillful behaviour will help optimize their adherence to the prescribed regimen, through the ongoing supportive care of the program.

Clinical Practice. Nurses participating in this study expressed a strong sense of satisfaction in teaching, rather than just providing the care. This is despite not having received formal training in the principle so patient education. The study findings, supported by extant literature results and synthesized as a toolkit provide strategies which the clinical nurse may employ when teaching patients, which would be applicable not only to self-administration teaching but other patient teaching topics as well. It is hoped that nurses will pause and reflect on their current practice and adopt the lexicon of plain language terms to optimize patient health literacy. Armed with these strategies, the nurse may have a stronger sense of self-efficacy in teaching, which as a study participant portrayed, strengthens the patient's confidence in the nurse and the teaching. Exemplars related to infusion therapy will hopefully help cue the clinician to better apply these principles to their practice, empowering them to advocate for self-administration. It is possible that further tailoring of patient education to patients' learning styles and increased availability and use of multi-media patient education materials may reduce the number of nursing visits required to teach a patient (with less cognitive memory burden associated with patient education materials). A systematic review of found that patient information leaflets improve patients' knowledge and satisfaction and recommend providing them at the same time as verbal information is provided, only if the patients wants the written material to and tailor the material to the patient's needs (e.g., underscoring key items) (Sustersic et al., 2016).

Administrators. The logic model holds strong implications for nurse leaders and healthcare organizations who are either planning or evaluating a home infusion program. The Institute for Healthcare Improvement recommends a "whole-system approach is required to build the support infrastructure and operational reality of patient-administered self-care" (Martin & Anderson, 2017). Based on my literature review, it appears that there has been a slow uptake of this model of care. For those seeking to develop a patient education program for self-administration, a care pathway has now been proposed, providing 3 options for care. The option of partial care ("We-care" as I have termed it) was an unexpected revelation gleaned from the study. This presents an alternative which opens the door to self-care while providing efficiencies to the healthcare system and introducing more autonomy for the patient. Results also encourage organizations to review their current supplies and equipment inventory, to identify opportunities to provide products which are easy to teach and to learn.

As nurses become more confident and effective patient educators and organization support the resources to support this model of care, hopefully we will see a paradigm shift from nurse-led to patient-led care, with a strong supportive system for the patient. A communication plan should be implemented to promote and support uptake of this program. This will help ensure that both patients and healthcare professionals are aware of and confident in this model of care.

Neither case had a formal patient education nursing orientation program. This study provides strategies for organizations to include in nursing orientations, policies and procedures, and patient education material to help ensure clinicians are effective patient coaches. The strategies and logic model also provide potential data points for organizations to consider as variables for evaluation of their program. As well, neither program had a formal competency

validation process to ensure a strong health literacy related to self-administration, providing a potential research opportunity.

As a case study, the results are not transferable to another population. However, the program theory presented as a logic model may be transferable to other situations. The reader is encouraged to review the characteristics of each case to consider the similarities and dissonance with their program. Is it sincerely hoped that this new knowledge may be integrated across the healthcare spectrum, from the individual level to organizational levels (acute care and community) and incorporated into outpatient antimicrobial programs, and beyond to other types of therapies which may be appropriate for self-administration.

Research. The study findings contribute to the breadth of evidence supporting self-administration. The synthesis of the findings in a logic model creates a program theory for novice or existing programs to consider. However, hopefully programs implementing the model or components of it will do so as either a quality improvement or research initiative to evaluate and share the impact of the model. A deeper exploration of the patient experience of self-administration may help to further tailor programs to patients' learning needs and lifestyles. Stronger clinical studies evaluating outcomes related to self-administration may also bolster uptake and identify gaps in programs, including the optimal site for patient education (hospital, clinic or home). Health economic studies demonstrating the financial impact on both the patient and health system levels may help promote further uptake of the program. By presenting the characteristics of patient education using the WIDER definitions of interventions, this may provide guidance for researchers of self-administration to incorporate more in-depth details of the intervention using this taxonomy (e.g., education setting, delivery format, intensity and fidelity).

I have recently been awarded and completed two Registered Nurses Association of Ontario Advanced Clinical Practice Fellowships to design a framework for self-administration in my local region. Much of that work was based on this thesis work. My goal is to publish the results of successful implementation of a pilot of this program, although it was based on self-care. A pilot will be developed with the I-care, We-care, Nurse-care© approach with metrics to test the model.

Chapter 7. Conclusion

This multiple-case descriptive and explanatory case study offers considerable insight into patient education in self-administration of home IV antimicrobials. My study of patient education in the real-world clinic and home settings advances the knowledge gleaned from self-administration empirical studies of safety, efficacy and acceptability to understanding how these outcomes are actually achieved. Two cases of community/home infusion programs deliver comprehensive and effective patient education to empower patients to self-administer their IV antimicrobials in the safety and comfort of their home. The main conclusions of this thesis are as follows:

- **Program inputs** (human, physician and financial) are requisites for effective patient education. These resources support nurses to be organized, efficient and competent in their teaching, increasing their self-efficacy and empowering them to confidently advocate for patient. Requisites include:
    - Willing and able patients and/or care partners with a safe home environment,
    - Competent, caring and patient nursing providers,
    - Easy-to-use supplies,
    - Personalized patient education materials, including the addition of videos;
- **Patient education characteristics** include:
    - Content is consistent across cases, including infection prevention, medication administration, vascular access device care, complications, management of supplies and equipment, resources;
    - Preferred setting is quiet and non-distractive (primarily the patient's home or clinic);

  - Most commonly used delivery formats are verbal and return demonstration;
  - Intensity is affected by the funding model. The publicly funded model takes 3-7 sessions, with an average of 26 minutes teaching per session), while the privately-funded model accomplishes the visit in 1 visits, with an average of 36 minutes teaching per session; a template to accomplish this is provided;
  - Fidelity is assessed through informal competency validation and weekly follow-up appointments to assess patient status and adherence to therapy;
  - Tailored patient education is used to adjust the teaching to the patient's learning needs:
    - Adjust to learning style
    - Review informal learning plan
    - Plain language
    - Teach back
    - Frequent positive reinforcement
    - Personalized patient education material
    - Problem-solving
    - Explanations
    - Consistent messaging
    - Cultural sensitivity
    - Minimize distractions

- **Mechanisms or outputs** which motivate a patient to learn include motivation and encouragement and to perform self-administration include physical well-being, IV therapy fits their lifestyle, giving them freedom to attend work or school, provides a sense of control, privacy and family, empowers the patient to be an active participant in their care.
- **A supportive care system** provides patients with the resources necessary to support their ongoing and effective self-administration therapy, including a) follow-up nursing visits (weekly and prn at clinic or home; b) assessment of patient status and serum therapeutic

monitoring; c) weekly and prn vascular access device care; d) complication management; e) monitoring of patient's adherence to therapy and protocols; and f) a 24/7 telephone support service. At any time a patient may be transitioned to an alternate care pathway (e.g., from self-care to limited or nursing care) should a risk be identified or at the request of the patient;

- **Program outcomes** were not collected; however, literature review findings and participant feedback suggest self-administration is safe and effective, with completion of therapy as prescribed leading to patient satisfaction and avoidance of hospital admissions and personal well-being for patients and improved quality healthcare with enhanced resource utilization.

The program theory logic model and accompanying toolkit synthesizing the study's findings provides a comprehensive visual display or roadmap of the characteristics of the patient education programs supporting self-administration of home IV antimicrobials in these two cases. The theory suggest that that the program inputs or resources (e.g., competent nurses and willing and able patients with the support of patient educational material and easy-to-use supplies) support the delivery of effective patient education using a myriad of pedagogical strategies, which affects the resulting behaviour, or output (e.g., skill mastery and autonomy), leading to outcomes such as patient and provider satisfaction, patient well-being and improved healthcare resource utilization.

For those programs still practicing nurse-administration of home infusion therapy, the generated theory will help program administrators to understand the need to explore how their patient education program incorporates resources and mechanisms which optimize patients success in the strive towards patient autonomy. The theory also provide impetus for nurses

practicing education of self-administration to patients to pause and reflect on how they are activating patients to master the complex skills and knowledge. This program theory provides insight into strategies to help shift the paradigm to the patient as an active participant in care. In the words of a patient who has mastered self-administration, “Learning was pretty easy;” and “…it gave me the chance to do it whenever… I had time… I didn’t have time to run to the clinic all of the time…Self-care was perfect for me.”

References

Agency for Healthcare Research and Quality. (2017). *Health literacy: Hidden barriers and practical strategies,* Rockville, MD. Retrieved from: https://www.ahrq.gov.professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/tool3a/index.html

Agrawal, D., Ganguly, A., & Bhavan, P.B. (2017). *Capturing the patient voice. Patients Welcome IV Self-care; Physicians Hesitate.* Retrieved from http://catalyst.nejm.org/patients-welcome-iv-antibioitcs-self-care/

Albrecht, L., Archibald, M., Arseneau D., Scott, S. D. (2013). Development of a checklist to assess the quality of reporting of knowledge translation interventions using the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations. *Implementation Science, 8*(52), 1-5. Retrieved from http://www.implementationscience.com/content/8/1/52

Altman, J. (1974). Observational study of behavior: sampling methods. *Behaviour, 49*(3), 227-266.

Anthony, S., & Jack, S. (2009). Qualitative case study methodology in nursing research: An integrative review. *Journal of Advanced Nursing; 65*(6), 1171-1181.

Barr, D. A., Semple L., Seaton R. A. (2012). Self-administration of outpatient parenteral antibiotic therapy and risk of catheter-related adverse events: a retrospective cohort study. *European Journal of Clinical Microbiology and Infectious Diseases, 10*, 2611-2619.

Baxter, P., & Jack, S. (2008). Qualitative case study methodology: study design and implementation for novice researchers. *The Qualitative Report, 13*(40), 544-559. Retrieved from http://nsuworks.nova.edu/tqr/vol13/iss4/2

Baxter S. K., Blank L., Buckley Woods, H., Payne, N., Rimmer M. & Goyder E. (2014). Using logic model methods in systematic review synthesis: describing complex pathways in referral management interventions. *BMC Medical Research Methodology*, 14-62. doi:10.1186/1471-2288-14-62.

Baxter, S., Killoran, A., Kelly, M. P., Goyder, E. (2010). Synthesizing diverse evidence: the use of primary qualitative data analysis methods and logic models in public health reviews. *Public Health, 124*, 99-106.

Belanger, E., Rodriguez, C., & Groleau, D. (2011). Shared decision-making in palliative care: a systematic mixed study using narrative synthesis. *Palliative Medicine, 25*(3), 242-261.

Bergen, A., & While, A. (2000). A case for case studies: exploring the use of case study design in community nursing research. *Journal of Advanced Nursing, 31*(4), 926-934. doi: 10.1177/0269216219289248

Bhavan, K. P. Brown, L. S., & Haley, R.W. (2015). Self-administered outpatient antimicrobial infusion by uninsured patients discharged from a safety-net hospital: a propensity-score-balanced retrospective cohort study. *PLOS Medicine, 12*(2): e1001922. doi: 10.1371/journal.pmed.1001922

Bondi, N. & Stancil, H. (2017). Hospital pre-discharge education improves home infusion outcomes. *Business Wire.* Retrieved from https://www.businesswire.com/news/home/20170713005783/en/Hospital-Pre-discharge-Education-Improves-Home-Infusion-Outcomes

Broadhurst, D., Ullman, A. J., Moureau, N. (2016). Central venous access devices site care practices: an international survey of 34 countries. *Journal of Vascular Access, 17*(1), 78-86. doi: 10.5301/jva.5000450

Canadian Home Care Association (CHCA). (2008). *Home care- the next essential service. Meeting the needs of our aging population.* Retrieved from www.cdnhomecare.ca.

Canadian Home Care Association (CHCA). (2013). *Portraits of home care in Canada. Executive Précis*. Retrieved from http://www.cdnhomecare.ca/media.php?mid=3394

Canadian Home Care Association, Canadian Nurses Association and The College of Family Physicians of Canada. (2016). *Better home care in Canada: A national action plan.* Retrieved from http://www.thehomecareplan.ca/wp-content/uploads/2016/10/Better-Home-Care-Report-Oct-web.pdf

Canadian Public Health Agency (2014). *Examples of health literacy in practice.* Ottawa, ON. Retrieved from: www.cpha.ca

Canadian Vascular Access Association. (2019). *Canadian vascular access and infusion therapy guidelines*. Pembroke, ON: Pappin Communications.

Casey, D., & Houghton, C. (2010). Clarifying case study research: examples from practice. *Nurse Researcher*, *17*(3), 41.

Chapman, A. L. N., Seaton, R. A., Cooper, M. A., Hedderwick, S., Goodall, V., Reed, C., Sanderson, F., & Nathwani, D. on behalf of the BSAC/BIA OPAT Project Good Practice Recommendations Working Group. (2012). Good practice recommendations for outpatient parenteral antimicrobial therapy (OPAT) in adults in the UK: a consensus statement. *Journal of Antimicrobial Chemotherapy*, 67(5), 1053-1062. doi: 10.1093/jac/dks003

College of Nurses of Ontario. (2015). *Practice standard*: *Medication.* Retrieved from https://www.cno.org/globalassets/docs/prac/41007_medication.pdf

Cooksy, L. J., Gill, P., & Kelly, P. A. (2001). The program logic model as an integrative framework for a multimethod evaluation. *Evaluation and program planning*, *24*(2), 119-128.

Cope, D. G. (2015). Case study research methodology in nursing research. *Oncology Nursing Forum*, *43*(6), 681-682.

Corbin, J., & Strauss, A. (1990). Grounded theory research: Procedures, canons and evaluative criteria. *Zeitschrift fur Soziologie*, *19*(6), 428-427.

Corwin, P., Toop, L., McGeoch, G., Than, M., Wynn-Thomas, S., Wells, J. E., & . . . Richards, D. (2005). Randomised controlled trial of intravenous antibiotic treatment for cellulitis at home compared with hospital. *British Medical Journal*, *330*, 129. doi:http://dx.doi.org/10.1136/bmj.38309.447975.EB

Cote, D., Oruck, J., Thickson, N. (1989). A review of the Manitoba home i.v. antibiotic program. *Canadian Journal of Hospital Pharmacy*, *42*, 137-142.

Cox K. R., & Taylor S. G. (2005). Orem's self-care deficit nursing theory: pediatric asthma as exemplar. *Nursing Science Quarterly*, *18*(3), 249-57.

Cox, J. A., & Oakes Westbrook, L. J. (2005). Home infusion therapy: Essential characteristics of a Successful education process: Grounded theory study. *Journal of Infusion Nursing*, *28*(2), 99-107.

Crabtree, B., & Miller, W. (1999). Using codes and code manuals: A template organizing style of interpretation. In B. F. Crabtree & W. L. Miller (Eds.), *Doing qualitative research* (2nd ed.) (pp. 163-177). Thousand Oaks, CA: Sage Publications.

Crowe, S., Creswell, K., Robertson, A., Huby, G., Avery, A., & Sheikh, A. (2011). The case study approach. *BMC Medical Research Methodology, 11*, 100. Retrieved from http://www.biomedcentral.com/1471-2288/11/100.

Dalkin, S. M., Jones, D., Lhussier, M., & Cunningham, B. (2015). Understanding integrated care pathways in palliative care using realist evaluation: A mixed methods study protocol. *BMJ Open, 2*, e001533. doi: 10.1136/bmjopen-2012-001533.

Dooley, L. M. (2002). Case study research and theory building. *Advances in Developing Human Resources, 4*(3), 335-354

Durham, J., & Blondell, S. J. (2014). Research protocol: A realist synthesis of cross-border patient mobility from low-income and middle-income countries. *BMJ Open, 4*, e006514. doi: 10.1136/bmjopen-2014-006514

Easton, Geoff. (2010). Critical realism in case study research. *Industrial Marketing Management, 39*, 118-128.

Eaves, K., Thornton, J., & Chapman, A. L. (2014). Patient retention of training in self-administration of intravenous antibiotic therapy in an outpatient parenteral antibiotic therapy service. *Journal of Clinical Nursing*, *23*(9-10), 1318-22. doi: 10.1111/jocn.12376.

Fried, T. R., van Doom, C., O'Leary, J.R., Tinetti, M. E., Drickamer, M. A. (2000). Older person's preferences for home vs hospital care in the treatment of acute illness. *Archives of Internal Medicine, 160*(10), 1501-6.

Friedman, A. J., Cosby, R., Boyko, S., Hatton-Bauer, J., & Turnbull, G. (2011). Effective teaching strategies and methods of delivery for patient education: a systematic review and

practice guideline recommendations. *Journal of Cancer Education, 26*(1), 12-21. Retrieved from https://www.researchgate.net/publication/49686490_Effective_Teaching_Strategies_and_Methods_of_Delivery_for_Patient_Education_A_Systematic_Review_and_Practice_Guideline_Recommendations

Ganguly, A., Agrawa, D., Brown L, S., & Bhavan, K.P. (2018). Emergency department utilization during self-administered outpatient parenteral antimicrobial therapy. *Ann Med Health Sci Res*, *8*:45-46.

Greenfield, E., & Pace, J.C. (1985). Orem's self-care theory of nursing: Practical application to the end stage renal disease (ESRD) patient. *Journal of Nephrology Nursing*, *2*(4), 187-193.

Grimes-Holsinger, V. (2002). Comparing the effect of a skills checklist on teaching time required to achieve independence in administration of infusion medications. *Journal of Infusion Nursing*, 25(2), 109- 120.

Halloran, J. P., & Grimes, D. E. (1995). Application of the focus group methodology to educational group development. *Qualitative Health Research*, 5(4), 444-453.

Hanucharurnkui, S., & Vinya-nguag, P. (1991). Effects of promoting patients' participation in self-care on postoperative recovery and satisfaction with care. *Nursing Science Quarterly*, *4*(1), 14-20.

Harris, R., Ashton, T., Broad, J., Connolly, G., & Richmond, D. (2005). The effectiveness, acceptability and costs of a hospital-at-home service compared with acute hospital care: a randomized controlled trial. *Journal of Health Services Research & Policy, 10*(3), 158-166.

Harrison, H., Birks, M., Franklin,R., & Mills, J. (2017). Case study research: foundations and methodological orientations. *Forum: Qualitative Social Research, 18*(1, Art 19). Retrieved from www.qualitative-research.net/index.php/fqs/article/view/2655/4079#g341

Herber, O. R., Schnepp, W., & Rieger, M. A. (2008). Developing a nurse-led education program to enhance self-care agency in leg ulcer patients. *Nursing Science Quarterly, 21*(2), 150-5.

Hernandez, C. (2011). Developing grounded theory using focus groups. In V. B. Martin & A. Gynnild (Eds), *Grounded theory: The philosophy, method, and work of Barney Glaser* (pp. 117-132). Boca Raton: Brown Walker Press.

Hewitt, G., Sims, S., & Harris, R. (2012). The realist approach to evaluation research: An introduction. *International Journal of Therapy and Rehabilitation, 19*(5), 250-259.

Hewitt-Taylor, J. (2002). Case study: An approach to qualitative enquiry. *Nursing Standard, 16*(20), 33-37.

Hibbard, J., & Gilburt, H., (2014). *Supporting people to manage their health: An introduction to patient activation*. The King's Fund. Retrieved from *https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/supporting-people-manage-health-patient-activation-may14.pdf*

Hibbard, J. H., & Greene, J. (2013). What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. *Health Affairs, 32*(2), 207-214. doi10.1377/hlthaff.2012.1061 Retrieved from http://www.healthynh.com/images/PDFfiles/partnership-for-patients/PFE/Ninth/What_the_evidence_shows_about_pt_activation.pdf

Hibbard, J. H., & Mahoney, E. (2010). Toward a theory of patient and consumer activation. *Patient Education and Counselling, 78,* 377-381.

Hibbard, J., & Tusler, M. (2007). Assessing activation stage and employing a "next steps" approach to supporting patient self-management. *Journal of Ambulatory Care Management, 30*(1), 2-8.

Hitchcock, J., Jepson, A. P., Main, J., & Wickens, H. J. (2009). Establishment of an outpatient and home parenteral antimicrobial therapy service at a London teaching hospital: A case series. *Journal of Antimicrobial Chemotherapy, 64*, 630-634. doi: 10.1093/jac/dkp212.

Hill, J., Broadhurst, D., Miller, K., Cook, C., Dumanski, J., Friesen, N., … Whynot, A. (2013). Occlusion management guidelines for central venous access devices (CVADs). *Vascular Access, 7*(S1).

Holloway, I., & Wheeler, S. (2013). *Qualitative research in nursing and healthcare* (3rd ed). Somerset, BG: Wiley-Blackwell.

Houghton, C., Casey, D., Shaw, D., & Murphy, K. (2013). Rigour in qualitative case-study research. *Nurse Researcher, 20*(4), 12-17.

Hronn Svavarsdottir, M., Siguroardottier, A.K., & Steinsbekk, A. (2015). How to become an expert educator: A qualitative study on the view of health professionals with experience in patient education. *BMC Medical Education, 15,* 87. doi10.1186/s12909-015-0370-x.

Hsieh, H., & Shannon, S. E. (2005). Three approaches to qualitative content analysis. *Qualitative Health Research, 15*(9), 1277-1288. doi: 10.1177/1049732305276687

Hyett, N., Kenny, A., & Dickson-Swift, V. (2014). Methodology or method? A critical review of qualitative case study reports. *International Journal of Qualitative Studies on Health and Well-Being, 9:* 23606 Retrieved from http://dx/doi.org/10.3402/qhw.v923606

Inott, T., & Kennedy, B.B. (2011). Assessing learning styles: Practical tips for patient education. *Nurs Clin N Am, 46,* 313-320. doi.10.1016/j.cnur.2011.05.006

Jamshed, S. (2014). Qualitative research method- interviewing and observation. *Journal of Basic Clinical Pharmacy,* 5(4), 87-88.

Jersild, A. T., & Meigs, M. F. (1972). Direct observation as a research method. *Reviews of Educational Research,* 9 (5), 472-482. (Original work published 1939)

Johnson, A., & Sandford, J. (2005). Written and verbal information versus verbal information only for patients being discharged from acute hospital settings to home: Systematic review. *Health Educ Res, 20*(4), 423–429.

Kastner, M., Antony, J., Soobiah, C., Straus, S. E., Tricco, A. C. (2016). Conceptual recommendations for selecting the most appropriate knowledge synthesis method to answer research questions related to complex evidence. *Journal of Clinical Epidemiology, 73,* 43-49. doi:10.1016/j.jclinepi.2015.11.022

Kieran, J., O'Reilly, A., Parker, J., Clarke, S., Bergin, C. (2009). Self-administered outpatient parenteral antimicrobial therapy: A report of three years' experience in the Irish healthcare setting. *European Journal of Clinical Microbiology and Infectious Disease, 28*(110), 1369-74. doi: 10.1007/s10096-009-0794-5

Kneale, D., Thomas, J., & Harris, K. (2015). Developing and optimising the use of logic models in systematic reviews: Exploring practice and good practice in the use of programme theory in reviews. PLoS ONE, *10*(11): e0142187. doi:10.1371/journal.pone.0142187

Kohn, L.T. (1997). Methods in case study analysis. *The Center for Studying Health System Change. Technical Publication No. 2,* June 1997.

Lalor, J. G., Casey, D., Elliott, N., Coyne, I., Comiskey, C., Higgins, A., ... & Begley, C. (2013). Using case study within a sequential explanatory design to evaluate the impact of specialist and advanced practice roles on clinical outcomes: The SCAPE study. *BMC medical research methodology*, *13*(1), 55. Retrieved from http://www.biomedcentral.com/1471-2288/13/55.

Laupland, K. B., & Valiquette, L. (2013). Outpatient parenteral antimicrobial therapy. *Canadian Journal of Infectious Disease Medicine and Microbiology*, *24*(1), 9-11.

MacKenzie, M., Rae, N., & Nathwani, D. (2014). Outcomes from global adult outpatient parenteral antimicrobial therapy programmes: A review of the last decade. *International Journal of Antimicrobial Agents*, *43*, 7-16.

Malterud, K. (2001). Qualitative research: Standards, challenges, and guidelines. *The Lancet, 358,* 483-488.

Malterud, K., Siersma, V., D., & Guassora, A. D. (2016). Sample size in qualitative interview studies: guided by information power. *Qualitative Health Research; 26*(13), 1753-1760. doi: 10.1177/1049732315617444

Marra, C. A., Frighetto L, Goodfellow, A. F., Wai, A. O., Chase, M. L, Nicol, R. E., … Jewesson, P. J. (2005). Willingness to pay to assess patient preferences for therapy in a Canadian setting. *BioMed Central Health Services Research, 5:*43. doi:10.1186/1472-6963-5-43

Martin, L., & Anderson, A. (July 2017). *Patient-administered self-care.* Massachusetts: Institute for Healthcare Improvement. IHI Innovation Report. Cambridge. Retrieved from http://www.ihi.org/resources/Pages/Publications/Patient-Administered-Self-Care.aspx

Massey, O. T. (2011). A proposed model for the analysis and interpretation of focus groups in evaluation research. *Evaluation and Program Planning, 34,* 21-28. doi:10.1016/j.evalprogplan.2010.06.003

Masso, M., McCarthy, G., & Kitson, A. (2014). Mechanisms which help explain implementation of evidence-based practice in residential aged care facilities: a grounded theory study. *International Journal of Nursing Studies, 51,* 1014-1026.

Matthews, P. C., Conlon, C. P., Berendt, A. R., Kayley, J., Jefferies, L., Atkins, B. L., & Byren, I. (2007). Outpatient parenteral antimicrobial therapy (OPAT): Is it safe for selected patients to self-administer at home? A retrospective analysis of a large cohort over 13 years. *Journal of Antimicrobial Chemotherapy, 60,* 357–362.

McDonnell, A., Lloyd Jones, M., & Read, S. (2000). Practical considerations in case study research: The relationship between methodology and process. *Journal of Advanced Nursing, 32*(2), 383-390.

McGloin, S. (2008). The trustworthiness of case study methodology. *Nurse Researcher, 16,* 45-55.

Millar, B., Maggs, C., Warner, V., & Whale, Z. (1996). Creating consensus about nursing outcomes. An exploration of focus group methodology. *Journal of Clinical Nursing, 5,* 193-197.

Mitchell, E. D., Czoski Murray, C., Meads, D., Minton, J., Wright, J., & Twiddy, M. (2017). Clinical and cost-effectiveness, safety and acceptability of community intravenous antibiotic service models: CIVAS systematic review. *BMJ Open, 7:* e013560. doi: 10.1136/bmjopen-2016-013560

Mukumbang, F. C, van Belle, S., Marchal, B., & van Wyk, B. (2016). Towards developing an initial programme theory: programme designers and managers assumptions on the antiretroviral treatment adherence club programme in primary health care facilities in the metropolitan area of Western Cape Province, South Africa. *PLoS ONE, 11*(8): e0161790. doi:10.1371/journal.pone.0161790

Nathwani, D., Zambrowki, J. J. on behalf of the AdHOC Workshop. (2000). Advisory group on Home-based and Outpatient Care (AdHOC): an international consensus statement on non-inpatient parenteral therapy. *Clinical Microbiology and Infection*, *6*(9), 464-476. http://dx.doi.org/10.1046/j.1469-0691.2000.00113.x

Nazarko L. (2013). Outpatient parenteral antimicrobial therapy: its delivery in the community. *British Journal of Community Nursing*, *18*(4), 163-167.

Negarandeha, R., Mahmoodib, H., Noktehdanb, H., Heshmatc, R., & Shakibazadehd, S. (2013). Teach back and pictorial image educational strategies on knowledge about diabetes and medication/dietary adherence among low health literate patients with type 2 diabetes. *Primary Care Diabetes,* 7(2), 111-118. doi.10.1016./j.pcd.2012.11.001.

Njie, B., & Asimiran, S. (2014). Case study as a choice in qualitative methodology. *ISOR Journal of Research & Method in Education, 4*(3), 35-40.

Noble, H., & Smith, J. (2015). Issues of validity and reliability in qualitative research. *Evidence Based Nursing*; *18*(2), 34-35.

Onwuegbuzie, A. J., Dickinson, W. B., Leech, N. L., & Zoran, A. G. (2009). A qualitative framework for collecting and analyzing data in focus group research. *International Journal of Qualitative Methods, 8*(3), 1-21. Retrieved from http://journals.sagepub.com/doi/pdf/10.1177/160940690900800301

Orem, D. (2001). *Nursing: Concepts of practice* (6th ed.). St. Louis, MO: Mosby.

Pals, R. A. S., Olesen, K., & Willaing, I. (2016). What does theory-driven evaluation add to the analysis of self-reported outcomes of diabetes education? A comparative realist evaluation of a participatory patient education approach. *Patient Education & Counselling, 99*(6), 995-1001.

Pare, G. (2001). *Using a positivist case study methodology to build and test theories in information systems: Illustrations from four exemplary studies.* École des Hautes Études Commerciales de Montréal. Cahier du GReSI no 01-09.

Pawson, R. (2002). Evidence-based policy: The promise of 'realist synthesis.' *Evaluation, 8*(3), 340–358.

Pawson, Greenhalge, T., Harvey, G., & Walshe, K. (2004). *Realist synthesis: An introduction*. Manchester: ESRC Research Methods Programme, University of Manchester.

Pawson, R., & Manzano Santaella, A. (2012). A realist diagnostic workshop. *Evaluation, 18*(2), 176-191. doi: 10.1177/1356389012440912

Pegram, A. (2000). What is case study research? *Nurse Researcher, 7*(2), 5-16.

Petersen D., Taylor E.F., & Peikes D. (2013). *The logic model: The foundation to implement, study and refine patient-centered medical home models*. Rockville, MD: Agency for Healthcare Research and Quality. AHRQ Publication No. 13-0029-EF. Retrieved from https://pcmh.ahrq.gov/page/logic-model-foundation-implement-study-and-refine-patient-centered-medical-home-models

Phillips, L. D. (1999). Patient education: Understanding the process to maximize time and outcomes. *Journal of Intravenous Nursing, 22*(1), 19-35.

Polinski, J. M., Kowal, M.K., Gagnon, M., Brennan, T.A., & Sharankd, W.H. (2017). Home infusion: Safe, clinically effective, patient preferred, and cost saving. *Healthcare*, *5*(1-2), 68-80. Retrieved from: http://dx.doi.org/10.1016/j.hjdsi.2016.04.004i

Plummer-D'Amato, P. (2008a). Focus group methodology part 1: Considerations for design. *International Journal of Therapy and Rehabilitation, 15*(2), 69-73.

Plummer-D'Amato, P. (2008b). Focus group methodology part 2: Considerations for analysis. *International Journal of Therapy and Rehabilitation, 15*(3), 123-129.

Polit, D.F., & Beck, C. T. (2014). *Essentials of nursing research: Appraising evidence for nursing practice* (8th ed.). Philadelphia PA: Wolters Kluwer, Lippincott Williams & Wilkins.

Ridder, H. (2017). The theory contribution of case study research designs. *Business Research, 10*, 281-305. doi: 10.1007/s40685-017-0045-z

Rindflesch, A. B. (2009). A grounded-theory investigation of patient education in physical therapy practice. *Physiotherapy Theory and Practice*, *25*(3), 193-202.

Ryan, K. E., Gandha, T., Culbertson, M. M., & Carlson, C. (2014). Focus group evidence: Implications for design and analysis. *American Journal of Evaluation, 35*(3), 328-345. doi: 10.1177/1098214013508300

Rycroft-Malone, J., McCormack, B., Hutchinson, A.M., DeCorby, K., Bucknall, T.K., Kent, B., … Wilson, V. (2012). Realist synthesis: Illustrating the method for implementation research. *Implementation Science, 7,* 33. Retrieved from http://www.implementationscience.com/content/7/1/33

Saillen, L., Arensdorff, L., Moulin, E., Cochet, C., Boillat-Blanco, N., Gardiol, C., & de Valliere, S. (2017). Patient satisfaction in an outpatient parenteral antimicrobial therapy (OPAT) unit practising predominantly self-administration of antibiotics with elastomeric pumps. *Eur J Clin Microbiol Infect Dis, 36,* 1387-1392. doi:10.1007/s/10096-017-2944-5

Seetoh T., Lye, D. C., Cook, A. R., Archuleta S., Chan M., Sulaiman, Z., Zhong L., Llorin R. M., Balm, M,. & Fischer, D. An outcomes analysis of outpatient parenteral antibiotic therapy (OPAT) in a large Asian cohort. *International Journal of Antimicrobial Agents, 41,* 569-573. http://dx.doi.org/10/1016/j.ijantimicag.2013.01.015

Smith, P. R. (2018). Collecting sufficient evidence when conducting a case study. *The Qualitative Report, 23*(5), 1043-1048. Retrieved from https://nsuworks.nova.edu/tqr/vol23/iss5/2

Stake, R. E. (2008). Qualitative case studies. In N.K. Denzin, & Lincoln, Y. S. (Eds), *Strategies of qualitative inquiry* (pp. 119-149). Los Angeles, CA: SAGE Publications.

Simmons, L. (2009). Dorothea Orem's self-care theory as related to nursing practice in hemodialysis. *Nephrology Nursing Journal, 36*(4), 419-421.

Stiver G., Wai A., Chase L., Frighetto, L., Marra, C., & Jewessen, P. (2000). Outpatient intravenous antibiotic therapy: the Vancouver Hospital experience. *Canadian Journal of Infectious Diseases, 11 Suppl. A*, 11A-14A.

Stiver, H. G., Telford, G. O., Mossey, J. M., Cote, D. D., van Middlesworth E. J., Trosky, . . . Mossey, W. L. (1978). Intravenous antibiotic therapy at home. *Annals of Internal Medicine, 89*, 690-595.

Stiver, H. G., Trosky, S. K., Cote, D. D., & Oruck, J. L. (1982). Self-administration of intravenous antibiotics: an efficient, cost-effective home care program. *CMA*, 127, 207-211.

Strahan, D., Kronenberg, J., Burgner, R., Doherty, J., & Hedt, M. (2012). Differentiation in action: Developing a logic model for responsive teaching in an urban middle school. *RMLE Online, 35*(8), 1-17. doi: 10.1080/19404476.2012.11462091

Subedi S., Looke, D. F. M., McDougall, D. A., Sehu, M. M., Playford, E. G. (2015). Supervised self-administration of outpatient parenteral antibiotic therapy: A report from a large tertiary hospital in Australia. *International Journal of Infectious Diseases, 30*, 161-165. Retrieved from: http://dx.doi.org/10.1016/j.ijid.2014.11.021

Susteric, M., Gauchet, A., Goote, A., & Bosson, J. (2016). How best to use and evaluate patient information leaflets given during a consultation: A systematic review of literature reviews. *Health Expectations; 20*, 531-542.

Syx, R. L. (2008). The practice of patient education: The theoretical perspective. *Orthopeaedic Nursing, 27*(1), 50-54.

Taylor, R., & Thomas-Gregory, A. (2015). Case study research. *Nursing Standard, 29*(41), 36-40.

Thomas, G. (2011). *How to do your case study: A guide for students and researchers.* Thousand Oaks, CA: SAGE Publications.

Thomas, E., & Magilvy, J., K. (2011). The rigor or research validity in qualitative research. *Journal for Specialists in Pediatric Nursing;* 16, 151-155.

Tice, A. D. (2000). Outpatient parenteral antibiotic therapy (OPAT) in the United States: Delivery models and indications for use. *Canadian Journal of Infectious Disease, 11* (Suppl A), 17A-21A.

Tice, A. D., Rehm, S. J., Dalovisio, J. R., Bradley, J. S., Martinelli, L. P., Graham, D. R., … Williams, D.N. (2004). Practice guidelines for outpatient parenteral antimicrobial therapy. *Clinical Infectious Diseases, 38,* 1651-1672.

Tonna, A., Anthony, G., Tonna, I., Paudyal, V., Forbes-McKay, K., Laing, R., … Stewart, D. (2019). Home self-administration of intravenous antibiotics as part of an outpatient parenteral antibiotic therapy service: A qualitative study of the perspectives of patients who do not self-administer. *BMJ Open; 9*; e027475. doi:10.1136/bmjopen-2018-027475

Tracy, S. J., (2010). Qualitative quality: Eight "big-tent" criteria for excellent qualitative research. *Qualitative Inquiry*, *16*(10), 837-851. doi: 10.1177/1077800410383121

Turner, J.R., & Danks, S. (2014). Case study research: A valuable learning tool for performance improvement professionals. *Performance Improvement, 53*(4), 23-31. doi: 10.1002/pfi.21406

Underwood, J., Marks, M., Collins, S., Logan, S & Pollara, G. (2019). Intravenous catheter-related adverse events exceed drug-related adverse events in outpatient parenteral antimicrobial therapy. *Journal of Antimicrobial Chemotherapy, 74* : 787-790. doi.10.1093/jac/dky474

Vareilles, G., Marchal, B., Kane, S., Petric, T., Pictet, G., & Pommier J. (2015). Understanding the motivation and performance of community health volunteers involved in the delivery of health programmes in Kampala, Uganda: A realist evaluation. *BMJ Open, 5,* e008614. dos: 10.1136/bmjopen-2015-008614

Vasquez, M. A. (1992). From theory to practice: Orem's self-care nursing model and ambulatory care. *Journal of Post Anaesthetic Nursing, 7*(4), 251-5.

Wilson, A., Parker, H., Wynn, A., Jagger, C., Spiers, N., Jones, J., & Parker, G. (1999). Randomised controlled trial of effectiveness of Leicester hospital at home scheme compared with hospital care. *BMJ, 319*(7224), 1542-1546.

Wong, G., Greenhalgh, T., Westhorp, G., Buckingham J., Pawson R. (2013). RAMSES publication standards: Realist synthesis. *Journal of Advanced Nursing, 69*(5), 1005-1021. doi: 10.1111/jan12095

Yazan, B. (2015). Three approaches to case study methods in education: Yin, Merriam, and Stakes. *The Qualitative Report, 20*(2), 134-152. Retrieved from http://nsuworks.nova.edu/tqr/vol20/iss2/12

Yin, R. K. (1992). The case study method as a tool for doing evaluation. *Current sociology, 40*(1), 121-137.

Yin, R. K. (1999). Enhancing the quality of case studies in health services research. *Health Services Research, 34*(5 Pt II), 1209-1224.

Yin, R. K. (2009). *Case study research, design and method* (4th ed.). London, UK: Sage Publications.

Yin, R. K. (2012). *Applications of case study research.* (3rd ed.). Thousand Oaks, CA: Sage Publications.

Young, H. M. L., Hudson, N., Clarke, A. L., Dungey, M., Feehally, J., Burton, J. O., & Smith, A. C. (2015). Patient and staff perceptions of intradialytic exercise before and after implementation: a qualitative study. *PLOS ONE, 10*(6). Retrieved from http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0128995

Appendix A: Athabasca University Certification of Ethical Approval

Athabasca University
RESEARCH ETHICS BOARD

The future of learning.

CERTIFICATION OF ETHICAL APPROVAL

The Athabasca University Research Ethics Board (AUREB) has reviewed and approved the research project noted below. The AUREB is constituted and operates in accordance with the current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* and Athabasca University Policy and Procedures.

Ethics File No.: 22593

Principal Investigator: Daphne Broadhurst, Faculty of Health Disciplines/Master of Nursing

Supervisor (if applicable): William Diehl-Jones, Faculty of Health Disciplines, Centre for Nursing & Health Studies

Project Title: 'A Multiple Case Study of Patient Education for Self-Administration of Home Antimicrobial Infusion Therapy'

Effective Date: May 17, 2017 **Expiry Date**: May 16, 2018

Restrictions:

- Recruitment and/or data collection cannot begin until approvals have been received from Vancouver Coastal Health and Winnipeg Regional Health Authority
- Any modification or amendment to the approved research must be submitted to the AUREB for approval.
- Ethical approval is *valid for a period of one year*. An annual request for renewal must be submitted and approved by the above expiry date if a project is ongoing beyond one year.
- A Project Completion (Final) Report must be submitted when the research is complete *(i.e. all participant contact and data collection is concluded, no follow-up with participants is anticipated and findings have been made available/provided to participants (if applicable))* or the research is terminated.

Approved by: **Date: May 17, 2017**
Sherri Melrose, Chair
Faculty of Health Disciplines, Departmental Ethics Review Committee
Athabasca University Research Ethics Board

Athabasca University Research Ethics Board
University Research Services, Research Centre
1 University Drive, Athabasca AB Canada T9S 3A3
E-mail: rebsec@athabascau.ca
Telephone: 780.675.6718

Appendix B: University of Manitoba Research Ethics Certificate

UNIVERSITY OF MANITOBA | Research Ethics - Bannatyne
Office of the Vice-President (Research and International)

P126-770 Bannatyne Avenue
Winnipeg, Manitoba
Canada, R3E 0W3
Telephone : 204-789-3255
Fax: 204-789-3414

HEALTH RESEARCH ETHICS BOARD (HREB)
CERTIFICATE OF FINAL APPROVAL FOR NEW STUDIES
Delegated Review

PRINCIPAL INVESTIGATOR:	INSTITUTION/DEPARTMENT:	ETHICS #:
Dr. William Diehl-Jones	U of M/Medicine/Biological Sciences and Nursing	HS21105 (H2017:297)
APPROVAL DATE: October 31, 2017	**EXPIRY DATE:** October 31, 2018	
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable): NA		

PROTOCOL NUMBER:	PROJECT OR PROTOCOL TITLE;
NA	A Multiple Case Study of Patient Education for Self-Administration of Home Antimicrobial Infusion Therapy
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: NA	

Submission Date of Investigator Documents:	HREB Receipt Date of Documents:
August 8 and October 26, 2017 (Received)	August 8 and October 26, 2017

THE FOLLOWING ARE APPROVED FOR USE:

Document Name	Version(if applicable)	Date
Protocol:		
Protocol including Clarifications as per Letter received October 26, 2017 and Revised REB Submission Form submitted October 26, 2017	V. 2.0	2017.09.21
Consent and Assent Form(s):		
Letter of Information/Informed Consent Form (Case Site)		September 21, 2017
Letter of Information/Informed Consent Form (For Focus Groups)		September 21, 2017
Letter of Information/Informed Consent Form (For Nurses' Participation in Observational Study)		September 21, 2017
Letter of Information/Informed Consent Form (For Patient Interviews)		September 21, 2017
Other:		

Appendix C: Winnipeg Regional Health Authority Letter of Approval

Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg
Caring for Health / À l'écoute de notre santé

George and Fay Yee Centre for Healthcare Innovation
4th Floor, Chown Building
753 McDermot Avenue, Winnipeg, Manitoba, R3E 0T6

November 21, 2017

Dr. Bill Diehl-Jones
University of Manitoba Bannatyne Campus
Room 561 – 750 McDermot Avenue
Winnipeg, MB R3E 0T5

Dear Dr. Diehl-Jones:

Re: Letter of Approval – "A Multiple Case Study of Patient Education for Self-Administration of Home Antimicrobial Infusion Therapy"

Reference No: RAAC 2017-050 **UofM REB: HS21105(H2017:297)**

We are pleased to inform you that your request for the above-named study has been approved by the Winnipeg Regional Health Authority (WRHA) Research Access and Approval Committee (RAAC).

Access and approval are pending confirmation that the following conditions are met or agreed to:

1. No Personal or Personal Health Information (PHI) will be disclosed from the WRHA during the undertaking of the above-named study;
2. Submit any significant changes in your proposal prior to implementation, or any significant changes during the course of the study;
3. You agree to be accountable for the appropriate storage, disposal and/or destruction of material;
4. Appropriately acknowledge the role of the WRHA and/or affiliated organizations in any peer-reviewed publications resulting from this study;
5. Submit a summary of the final results of the study to the WRHA and provide the RAAC with a copy of any publications arising from the study;
6. Give the WRHA a minimum of five working days advance notice of the publication or presentation of results with policy implications, in order for the WRHA to be prepared for a public response.

Thank you for selecting the Winnipeg Regional Health Authority as the site to conduct your research. Please let us know should you encounter any site-related difficulties during the course of your study.

We extend best wishes for successful completion of your study.

Yours sincerely,

Dr. Paul Beaudin, MSc-SLP, PhD
Researcher, Evaluation Platform, George and Fay Yee Centre for Healthcare Innovation
Chair, Research Access and Approval Committee, WRHA

cc. Mr. Réal Cloutier, Interim President and CEO, WRHA
Ms. Christina Von Schindler, Chief Privacy Officer, WRHA
Dr. John Arnett, Chair, HREB

Appendix D: Email Recruitment (for case sites)

Email Recruitment Script
Daphne Broadhurst, RN, BScN, CVAA(c)

A Study of Patient Education of Self-Administration of Home Infusion Antimicrobial Therapy

---

E-mail Subject line: Invitation to participate in Research Study – Patient Education of Self-Administration of Home Infusion Antimicrobial Therapy

I am inviting you to participate in a case studies research study in the month of June 2017. As part of a graduate program in Nursing at Athabasca University, I am carrying out a study to learn about patient education in self-administration of home infusion therapy. I'm interested in learning how nurses teach patients to self-administer their therapy, including describing the structure of patient education programs and patient- identified barriers and facilitators to learning Your organization has been selected as one of 2-3 Canadian case sites for the study due to a publication indicating your program's work in self-administration of home infusion therapy. I will be requesting permission to: a) observe nurses teaching patients how to self-administer home antimicrobial therapy in the clinical or home setting for approximately 3-5 days; b) review program written material to support patient education; c) hold a focus group interview with 6-10 nurses; and d) perform telephone interviews with approximately 3-4 patients who are taught how to self-administer their infusion therapy, preferably during the observation period.

.

There are no known risks for participating in this study, other than sharing your experience and opinions.

You can withdraw your participation or that of your program at any time. I have attached a copy of a letter of information and consent form about the study that gives you full details. This project has been reviewed by the Athabasca University Research Ethics Board. Should you have any comments or concerns regarding your treatment as a participant in this project, please contact the Research Ethics Office by e-mail at rebsec@athabascau.ca or by telephone at 1-800-788-9041, ext. 6718.

We would like to thank you in advance for your time and consideration. After a week, we will send you a one-time follow-up reminder.

Daphne Broadhurst RN, BScN
Masters Student
Faculty of Health Disciplines
Athabasca University, Calgary ON
Tel: 613.244.4560 ext. 22383
dbroadhurst@oms.ca

Appendix E: Letter of Information/Informed Consent Form (for case sites)

University of Manitoba

LETTER OF INFORMATION / INFORMED CONSENT FORM (Case Site)

Athabasca University

Self-Administration of Home Infusion of Antimicrobial Therapy: Characteristics of Patient Education

Nov. 30, 2017

Co- Investigator:
Daphne Broadhurst, RN, BScN
Faculty of Health Disciplines
Athabasca University
Ottawa, ON
(613) 244-4560 ext. 22383
daphne.broadhurst@medicalpharmacies.com

Principal Investigator:
Dr. William Diehl-Jones (Supervisor)
Center for Nursing and Health Research
Athabasca University
wdiehljones@athabascu.ca
Department of Biological Sciences
University of Manitoba

Dear Kathleen and Tatyana,

Your organization is invited to take part in a multiple case study research project entitled '**Self-Administration of Home Infusion of Antimicrobial Therapy: Characteristics of Patient Education.**'

This form is part of the process of informed consent. The information presented should give you the basic idea of what this research is about and what your organization's participation will involve, should you choose to participate. It also describes your organization's right to withdraw from the project. In order to decide whether you wish to participate in this research project, you should understand enough about its risks, benefits and what it requires of you to be able to make an informed decision. This is the informed consent process. Take time to read this carefully as it is important that you understand the information given to you. Please contact the investigator, Daphne Broadhurst, if you have any questions about the project or would like more information before you consent to participate.

It is entirely up to you whether or not you take part in this research. If you choose not to take part, or if you decide to withdraw from the research once it has started, there will be no negative consequences for you now, or in the future.

Introduction
My name is Daphne Broadhurst and I am a Master of Nursing student at Athabasca University. As a requirement to complete my degree, I am conducting a research project about how nurses teach patients to self-administer their home intravenous antimicrobial therapy. I am conducting this project under the supervision of Dr. William Diehl-Jones.

Why are you being asked to take part in this research project?
Your organization, one of 2-3 Canadian sites, has been invited to participate in this project because, your program has been identified from a literature search as a Canadian health care program who is actively teaching patients how to self-administer their home intravenous antimicrobial therapy.

What is the purpose of this research project?

From this research, we wish to describe and explain how patient education of self-administration of home infusion of antimicrobial therapy is achieved. The information will be used to develop a conceptual model of patient education programs for self-administration of home antimicrobial infusions. This information may help programs in which nurses administer the patient's medication to transition to a model of self-administration by the patient.

What will you be asked to do?
It is my hope to gain insight into the characteristics of the patient education through the following study methods within your program. I am requesting permission to: a) observe nurses teaching patients how to self-administer home antimicrobial therapy in the clinical or home setting for approximately 3-5 days; b) review program written material to support patient education; c) hold a focus group interview with 6-10 nurses from your program; and d) perform telephone interviews with approximately 3-4 patients who are taught how to self-administer their infusion therapy.

The observations of nurse-patient interactions during the patient education will require no effort on the part of the nurse or patient, other than essentially permitting a research nurse to observe them in the clinic/hospital/ or home setting teaching patients how to self-administer home antimicrobial infusions. The observer will take notes during the observations and may ask some informal interview questions to clarify observations; however a participant may opt not to respond. The researcher will be observing nurse-patient interactions during a 3-5 day period in September 2017.

At the conclusion of the observation period, 6-10 nurses who teach patients how to self-administer antimicrobial infusion will be invited to participate in a 2-hour focus group interview to further discuss the structure of a patient education program.

Lastly, during the observations, patients will be provided with a letter of information/consent seeking participation of 5-7 patients in a follow-up telephone call. The researcher will ask approximately 5 questions over a 15-30 minute period to better understand what helped the patient to learn how to self-administer their therapy.

What are the risks and benefits?
There are no known risks associated with this research study; however, a possible inconvenience may be the fact that a research is observing the nurse and patient and the inconvenience participating in the focus group and patient interviews. The researcher will attempt to be as unobtrusive as possible, not speaking during the observations.

There are no personal benefits for taking part in this research, with the exception of perhaps of nurses self-reflecting on their practice of patient education of home infusion therapy. Your insights and those of other participants may be helpful to contribute to a better understanding of the structure and mechanisms of patient education programmes to understand how nurses facilitate patient learning. As a token of appreciation for the inconvenience of the longer focus group interview, participants in the nursing focus group interview will be entered into a draw for a Littman stethoscope, to be drawn at the end of the session. Participants will be required to answer a skill question to participate in the draw and will have a 1/6 chance of winning if 6 participants attend the session.

Do you have to take part in this project?
As stated earlier in this letter, involvement in this project is entirely voluntary. Your organization and participating nurses and patients may withdraw from the study at any time and/or refuse to answer any questions, without suffering any negative consequences. If a participant chooses to withdraw during the observations or interviews, the researcher will stop the

observation/interview and delete field notes. This information can be deleted and permanently destroyed during data collection (i.e., the months of October-December 2017).

How will your privacy and confidentiality be protected?
The ethical duty of confidentiality includes safeguarding participants' identities, personal information, and data from unauthorized access, use or disclosure. We will collect your organization's name and those participating in the focus group/phone interview on a separate data log only, in the event that the participant later requests withdrawal from the study. However, there will be no data with any personal information on the data records to be analyzed, nor in the final published report. All information will be held confidential, except when legislation or a professional code of conduct requires that it be reported. Although focus group participants will be requested to respect and maintain participant confidentiality, due to the nature of focus groups, it is not possible for the researchers to guarantee that everyone will do so.
Your personal information will not be used or disclosed for other purposes, unless permitted by *The Freedom of Information and Protection of Privacy Act (FIPPA)*. If you have any questions about the collection of your personal information, contact the Access & Privacy Office (tel. 204-474-9462), 233 Elizabeth Dafoe Library, University of Manitoba, Winnipeg, MB, R3T 2N2.

How will my anonymity be protected?
Anonymity refers to protecting participants' identifying characteristics, such as name or description of physical appearance. Every reasonable effort will be made to ensure your organization's anonymity and will not be identified in publications without your explicit permission.

How will the data collected be stored?
All paper-based data (i.e., consent forms) will be scanned electronically and the paper subsequently shredded. All electronic copies of signed consent forms, digital audio recordings and transcriptions will be kept in a secure manner on the Principal Investigator's password-secured network in Ottawa for 5 years at which time it will be destroyed. The research team, indicated above, and a research assistant will be the only individuals who will have access to these files. An executive summary of the results will be shared with the organizations participating in the study. A manuscript describing the study and results will be submitted for publication in a peer-reviewed journal. Phase two of the study will explore the development and evaluation of a self-administration patient education program. Data collected from this focus group study may be archived for use in the phase 2 study.

Who will receive the results of the research project?
An executive summary of the results will be shared with your organization, for you to share with your site's participants if requested. Direct quotations may be included; however no personally identifying information will be reported. A manuscript describing the study and results will be submitted for publication in a peer-reviewed journal. The existence of the research will be also be listed in an abstract posted online at the Athabasca University Library's Digital Thesis and Project Room and the final research paper will be publicly available.

Who can you contact for more information or to indicate your interest in participating in the research project?
Thank you for considering this invitation. If you have any questions or would like more information, please contact me, (the co-investigator) by e-mail at daphne.broadhurst@medicalpharmacies.com , mail to 1100 Algoma Rd, Ottawa ON, K1B0A3) or phone at 1.800.267.1069.22383 or my supervisor by email at *wdiehljones@Athabascau.ca* .
If you are ready to participate in this project, please complete and sign the attached Consent Form and return it the researcher when she is at your worksite for the observations.

Thank you.

Daphne Broadhurst

This project has been reviewed by the Athabasca University Research Ethics Board and the local University of Manitoba Health Research Ethics Board. Should you have any comments or concerns regarding your treatment as a participant in this project, please contact the Research Ethics Office:

Athabasca University
Research Ethics Board
rebsec@athabascau.ca
1-800-788-9041, ext. 6718

University of Manitoba
Health Research Ethics Board
bannatynereb@umanitoba.ca
1-204-789-3389

Informed Consent:

My signature on this form means that:

- I have read the information about the research project.
- I have been able to ask questions about this project.
- I am satisfied with the answers to any questions I may have had.
- I understand what the research project is about and what I will be asked to do.
- I understand that I am free to withdraw my participation in the research project without having to give a reason, and that doing so will not affect me now, or in the future.
- I understand that if I choose to end my participation **during** data collection, any data collected from me up to that point will be destroyed.
- I understand that my data is being collected anonymously, and therefore cannot be removed once the data collection has ended.
- I allow data collected (de-identified) from the research group to be archived in the researcher's case study database for phase 2 of this study.

My signature confirms:

- I have read what this research project is about and understood the risks and benefits. I have had time to think about participating in the project and had the opportunity to ask questions and have those questions answered to my satisfaction.
- I understand that participating in the project is entirely voluntary and that I may end my participation at any time without any penalty or negative consequences.
- I understand that my signing of this document does not waive any of my legal rights.
- I have been given a copy of this Informed Consent form for my records.
- I agree to participate in this research project.
- I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Health Research Ethics Board or Athabasca Research Ethics Board for quality assurance purposes.

_____ _____
Signature of Participant Date

_____
Printed name of Participant

Investigator's Signature:

I have explained this project to the best of my ability. I invited questions and responded to any that were asked. I believe that the participant fully understands what is involved in participating in the research project, any potential risks and that he or she has freely chosen to participate.

_____ _____
Signature of Investigator Date

Appendix F: Letter of Information/Informed Consent Form

(for Nurses in Observation Study)

University of Manitoba

Athabasca University

LETTER OF INFORMATION / INFORMED CONSENT FORM
(For Nurses' Participation in Observation Study)

Self-Administration of Home Infusion of Antimicrobial Therapy:
Characteristics of Patient Education (Nurse's Form)

September 21, 2017

Co-Investigator
Daphne Broadhurst, RN, BScN
Faculty of Health Disciplines
Athabasca University
Ottawa, ON
(613) 244-4560 ext. 22383
daphne.broadhurst@medicalpharmacies.com

Principal Investigator
Dr. William Diehl-Jones (Supervisor)
Center for Nursing and Health Studies
wdiehljones@athabascau.ca
Department of Biological Sciences
University of Manitoba

You are invited to take part in a research project entitled '**Self-Administration of Home Infusion of Antimicrobial Therapy: Characteristics of Patient Education.**'

This form is part of the process of informed consent. The information presented should give you a clear idea of what this research is about and what your participation will involve, should you choose to participate. It also describes your right to withdraw from the project. In order to decide whether you wish to participate in this research project, you should understand the risks, benefits and requirements of you to be able to make an informed decision. Take time to read this carefully as it is important that you understand the information given to you. Please contact the co-investigator, Daphne Broadhurst, if you have any questions about the project or would like more information before you consent to participate.

It is entirely up to you whether or not you take part in this research. If you choose not to take part, or if you decide to withdraw from the research once it has started, there will be no negative consequences for you now, or in the future.

Introduction
My name is Daphne Broadhurst and I am a Master of Nursing student at Athabasca University. As a requirement to complete my degree, I am conducting a research project about how nurses teach patients to self-administer their home intravenous antimicrobial therapy and what helps a patient to perform these procedures. This project is under the supervision of Dr. William Diehl-Jones.

Why are you being asked to take part in this research project?
You are being invited to participate in this project because, as a member of your organization's home infusion program, you are have experience and insight into teaching patients how to self-administer their home intravenous antimicrobial therapy.

What is the purpose of this research project?
From this research, we wish to describe and explain how patient education of self-administration of home infusion of antimicrobial therapy is achieved. The information will be used to develop a conceptual model (and related resources) of patient education programs for self-administration

of home antimicrobial infusions. This information may help programs in which nurses administer the therapy to transition to a model of self-administration.

What will you be asked to do?
Your participation will require not effort on your part beyond your normal work, other than essentially permitting a research nurse to observe you in the clinic/hospital/ or home setting teaching patients how to self-administer home antimicrobial infusions. The observer will take notes during the observations. You may be asked some informal interview questions to clarify observations; however you may opt not to respond. The researcher will be observing nurse-patient interactions during a 3-5 day period in September or October 2017.

You may also be invited to participate in a focus group interview, if you are interested, to further discuss the structure of a patient education program. A separate information letter and consent form will be used for the focus group portion of the study, which will be audio-recorded.

What are the risks and benefits?
There are no known risks associated with this research study; however, a possible inconvenience may be the fact that a research is observing you and your patient. The researcher will attempt to be as unobtrusive as possible, not speaking during the observations.

There are no personal benefits for taking part in this research, with the possible exception of enabling self-reflecting on your practice of patient education of home infusion therapy. Your insights and those of other participants may be helpful to contribute to a better understanding of the structure and mechanisms of patient education programmes to understand how nurses facilitate patient learning. You will receive no payment or reimbursement for any expenses related to taking part in this study.

Do you have to take part in this project?
As stated earlier in this letter, involvement in this project is entirely voluntary. You may withdraw from the study at any time and/or refuse to answer any questions, without suffering any negative consequences. If you choose to withdraw during the observations, the researcher will stop observation of your interaction and delete observation notes. This information can be deleted and permanently destroyed during data collection (i.e., the months of October-December 2017).

How will your privacy and confidentiality be protected?
The ethical duty of confidentiality includes safeguarding participants' identities, personal information, and data from unauthorized access, use or disclosure. We will collect your name on a separate data log only, in the event that you later request your observational data be withdrawn from the study. However, there will be no data with any of your personal information on the data records to be analyzed, nor in the final published report. All information will be held confidential, except when legislation or a professional code of conduct requires that it be reported.
Your personal information will not be used or disclosed for other purposes, unless permitted by *The Freedom of Information and Protection of Privacy Act (FIPPA)*. If you have any questions about the collection of your personal information, contact the Access & Privacy Office (tel. 204-474-9462), 233 Elizabeth Dafoe Library, University of Manitoba, Winnipeg, MB, R3T 2N2.

How will my anonymity be protected?
Anonymity refers to protecting participants' identifying characteristics, such as name or description of physical appearance. Every reasonable effort will be made to ensure your anonymity; you will not be identified in publications or presentations without your explicit permission.

How will the data collected be stored?
All paper-based data (i.e., consent forms) will be scanned electronically and the paper subsequently shredded. All electronic copies of signed consent forms, digital audio recordings and transcriptions will be kept in a secure manner on the Principal Investigator's password-secured network in Ottawa for 5 years at which time it will be destroyed. The research team, indicated above, and a research assistant will be the only individuals who will have access to these files. An executive summary of the results will be shared with the organizations participating in the study. A manuscript describing the study and results will be submitted for publication in a peer-reviewed journal. Phase two of the study will explore the development and evaluation of a self-administration patient education program. Data collected from this focus group study may be archived for use in the phase 2 study.

Who will receive the results of the research project?
An executive summary of the results will be shared with the organizations participating in the study. Direct quotations may be included; however no personally identifying information will be reported. You will be able to receive a copy from your administrator. A manuscript describing the study and results will be submitted for publication in a peer-reviewed journal. The existence of the research will be also be listed in an abstract posted online at the Athabasca University Library's Digital Thesis and Project Room and the final research paper will be publicly available.

Who can you contact for more information or to indicate your interest in participating in the research project?
Thank you for considering this invitation. If you have any questions or would like more information, please contact me, (the co-investigator) by e-mail at daphne.broadhurst@medicalpharmacies.com or my supervisor by email at *wdiehljones@athabascau.ca*. If you are ready to participate in this project, please complete and sign the attached Consent Form and return it the researcher when she is at your worksite for the observations.

Thank you.

Daphne Broadhurst

This project has been reviewed by the Athabasca University Research Ethics Board and the local University of Manitoba Research Ethics Board. Should you have any comments or concerns regarding your treatment as a participant in this project, please contact the Research Ethics Office:

Athabasca University
Research Ethics Board
rebsec@athabascau.ca
1-800-788-9041, ext. 6718

University of Manitoba
Health Research Ethics Board
bannatynereb@umanitoba.ca
1-204-789-3389

Informed Consent:

My signature on this form means that:

- I have read the information about the research project.
- I have been able to ask questions about this project.
- I am satisfied with the answers to any questions I may have had.
- I understand what the research project is about and what I will be asked to do.

- I understand that I am free to withdraw my participation in the research project without having to give a reason, and that doing so will not affect me now, or in the future.
- I understand that if I choose to end my participation **during** data collection, any data collected from me up to that point will be destroyed.
- I understand that my data is being collected anonymously, and therefore cannot be removed once the data collection has ended.
- I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Health Research Ethics Board or Athabasca Research Ethics Board for quality assurance purposes.

	YES	NO
I agree to the use of direct quotations	○	○
I allow data collected (de-identified) from the research group to be archived in the researcher's case study database for phase 2 of this study	○	○
I am willing to be contacted following the interview to verify that my comments are accurately reflected in the transcript.	○	○

My signature confirms:

- I have read what this research project is about and understood the risks and benefits. I have had time to think about participating in the project and had the opportunity to ask questions and have those questions answered to my satisfaction.
- I understand that participating in the project is entirely voluntary and that I may end my participation at any time without any penalty or negative consequences.
- I have been given a copy of this Informed Consent form for my records.
- I agree to participate in this research project.

_____ _____

Signature of Participant Date

_____

Printed name of Participant

Investigator's Signature:

I have explained this project to the best of my ability. I invited questions and responded to any that were asked. I believe that the participant fully understands what is involved in participating in the research project, any potential risks and that he or she has freely chosen to participate.

_____ _____

Signature of Investigator Date

Appendix G: Letter of Information/Informed Consent Form

(for Nurses in Focus Groups)

University of Manitoba

Athabasca University

LETTER OF INFORMATION / INFORMED CONSENT FORM
(For Focus Groups)

Self-Administration of Home Infusion of Antimicrobial Therapy: Characteristics of Patient Education

September 21, 2017

Co- Investigator:
Daphne Broadhurst, RN, BScN
Faculty of Health Disciplines
Athabasca University
Ottawa, ON
(613) 244-4560 ext. 22383
daphne.broadhurst@medicalpharmacies.com

Principal Investigator:
Dr. William Diehl-Jones (Supervisor)
Center for Nursing and Health Research
Athabasca University
wdiehljones@athabascu.ca
Department of Biological Sciences
University of Manitoba

You are invited to take part in a research project entitled '**Self-Administration of Home Infusion of Antimicrobial Therapy: Characteristics of Patient Education.**'

This form is part of the process of informed consent. The information presented should give you the basic idea of what this research is about and what your participation will involve, should you choose to participate. It also describes your right to withdraw from the project. In order to decide whether you wish to participate in this research project, you should understand enough about its risks, benefits and what it requires of you to be able to make an informed decision. This is the informed consent process. Take time to read this carefully as it is important that you understand the information given to you. Please contact the co-investigator, Daphne Broadhurst, if you have any questions about the project or would like more information before you consent to participate.

It is entirely up to you whether or not you take part in this research. If you choose not to take part, or if you decide to withdraw from the research once it has started, there will be no negative consequences for you now, or in the future.

Introduction
My name is Daphne Broadhurst and I am a Master of Nursing student at Athabasca University. As a requirement to complete my degree, I am conducting a research project about how nurses teach patients to self-administer their home intravenous antimicrobial therapy and what helps a patient to perform these procedures. I am conducting this project under the supervision of Dr. William Diehl-Jones.

Why are you being asked to take part in this research project?
You are being invited to participate in this project because, as a member of your organization's home infusion program you are have experience and insight into teaching patients how to self-administer their home intravenous antimicrobial therapy.

What is the purpose of this research project?
From this research, we wish to describe and explain how patient education of self-administration of home infusion of antimicrobial therapy is achieved. The information will be used to develop a conceptual model of patient education programs for self-administration of home antimicrobial

infusions. This information may help programs in which nurses administer the therapy to transition to a model of self-administration.

What will you be asked to do?
Your participation will consist essentially of participating in a focus group interview, with 5-9 other nurses, during which you will be asked to respond to questions in response to a case study, which will take approximately 1.5-2 hours to complete. The focus group session will be arranged at a location convenient to your workplace, in the month of September or October 2017.

What are the risks and benefits?
There are no known risks associated with this research study; however, a possible inconvenience may be the fact that a research is observing you and your patient. The researcher will attempt to be as unobtrusive as possible, not speaking during the observations.

There are no personal benefits for taking part in this research, with the exception of perhaps self-reflecting on your practice of patient education of home infusion therapy. Your insights and those of other participants may be helpful to contribute to a better understanding of the structure and mechanisms of patient education programmes to understand how nurses facilitate patient learning. You will receive no payment or reimbursement for any expenses related to taking part in this study. Participants will be entered into a draw for a Littman stethoscope, to be drawn at the end of the session. You will be required to answer a short skill-testing question (as per Federal regulations) and will have a 1/6 to 1/10 chance of winning.

Do you have to take part in this project?
As stated earlier in this letter, involvement in this project is entirely voluntary. You may withdraw from the study at any time and/or refuse to answer any questions, without suffering any negative consequences. If you choose to withdraw during the focus group session, you may leave the session. The researcher will strive to remove my comments from any transcriptions (recognizing, however, that this may not be entirely possible due to the difficulty of discerning individual voices on the recording).

How will your privacy and confidentiality be protected?
The ethical duty of confidentiality includes safeguarding participants' identities, personal information, and data from unauthorized access, use or disclosure. We will collect your name on a separate data log only, in the event that you later request your observational data be withdrawn from the study. However, there will be no data with any of your personal information on the data records to be analyzed, nor in the final published report. All information will be held confidential, except when legislation or a professional code of conduct requires that it be reported. I understand that the contents will be used only for the purposes of the research. The session will be audio recorded to ensure that the researches have captured the comments of each individual. Only the research team will have access to the recording. The nature of focus groups, however, prevents the researchers from guaranteeing confidentiality amongst members. The researchers would like to remind participants to respect the privacy of fellow participants and not repeat what is said in these discussions to others.
Your personal information will not be used or disclosed for other purposes, unless permitted by *The Freedom of Information and Protection of Privacy Act (FIPPA)*. If you have any questions about the collection of your personal information, contact the Access & Privacy Office (tel. 204-474-9462), 233 Elizabeth Dafoe Library, University of Manitoba, Winnipeg, MB, R3T 2N2.

How will my anonymity be protected?
Anonymity refers to protecting participants' identifying characteristics, such as name or description of physical appearance. Every reasonable effort will be made to ensure your anonymity; you will not be identified in publications without your explicit permission.

How will the data collected be stored?
All paper-based data (i.e., consent forms) will be scanned electronically and the paper subsequently shredded. All electronic copies of signed consent forms, digital audio recordings and transcriptions will be kept in a secure manner on the Principal Investigator's password-secured network in Ottawa for 5 years at which time it will be destroyed. The research team, indicated above, and a research assistant will be the only individuals who will have access to these files. An executive summary of the results will be shared with the organizations participating in the study. A manuscript describing the study and results will be submitted for publication in a peer-reviewed journal. Phase two of the study will explore the development and evaluation of a self-administration patient education program. Data collected from this focus group study may be archived for use in the phase 2 study.

Who will receive the results of the research project?
An executive summary of the results will be shared with the organizations participating in the study. Direct quotations may be included; however no personally identifying information will be reported. You will be able to receive a copy from your administrator. A manuscript describing the study and results will be submitted for publication in a peer-reviewed journal. The existence of the research will be also be listed in an abstract posted online at the Athabasca University Library's Digital Thesis and Project Room and the final research paper will be publicly available.

Who can you contact for more information or to indicate your interest in participating in the research project?
Thank you for considering this invitation. If you have any questions or would like more information, please contact me, (the co- investigator) by e-mail at daphne.broadhurst@medicalpharmacies.com or supervisor by email at *wdiehljones@athabascau.ca*. If you are ready to participate in this project, please complete and sign the attached Consent Form and return it the researcher when she is at your worksite for the observations.

Thank you.

Daphne Broadhurst

This project has been reviewed by the Athabasca University Research Ethics Board and the local University of Manitoba Health Research Ethics Board. Should you have any comments or concerns regarding your treatment as a participant in this project, please contact the Research Ethics Office:

Athabasaca University
Research Ethics Board
rebsec@athabascau.ca
1-800-788-9041, ext. 6718

University of Manitoba
Health Research Ethics Board
bannatynereb@umanitoba.ca
1-204-789-3389

Informed Consent:

My signature on this form means that:

- I have read the information about the research project.
- I have been able to ask questions about this project.
- I am satisfied with the answers to any questions I may have had.
- I understand what the research project is about and what I will be asked to do.
- I understand that I am free to withdraw my participation in the research project without having to give a reason, and that doing so will not affect me now, or in the future.
- I understand that if I choose to end my participation **during** data collection, any data collected from me up to that point will be destroyed.
- I understand that my data is being collected anonymously, and therefore cannot be removed once the data collection has ended.
- I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Health Research Ethics Board or Athabasca Research Ethics Board for quality assurance purposes.

	YES	NO
I agree to maintain the confidentiality of the information discussed by all participants and researchers during the focus group session	○	○
I agree to the use of direct quotations	○	○
I agree to be audio-recorded		
I allow data collected (de-identified) from the research group to be archived in the researcher's case study database for phase 2 of this study	○	○

My signature confirms:

- I have read what this research project is about and understood the risks and benefits. I have had time to think about participating in the project and had the opportunity to ask questions and have those questions answered to my satisfaction.
- I understand that participating in the project is entirely voluntary and that I may end my participation at any time without any penalty or negative consequences.
- I have been given a copy of this Informed Consent form for my records.
- I agree to participate in this research project.

_____ _____

Signature of Participant Date

_____

Printed name of Participant

Investigator's Signature:

I have explained this project to the best of my ability. I invited questions and responded to any that were asked. I believe that the participant fully understands what is involved in participating in the research project, any potential risks and that he or she has freely chosen to participate.

_____ _____

Signature of Investigator Date

Appendix H: Email Recruitment (for Case Sites)

Email Recruitment Script
Daphne Broadhurst, RN, BScN, CVAA (c)

A Study of Patient Education of Self-Administration of Home Infusion Antimicrobial Therapy

---

E-mail Subject line: Invitation to participate in Research Study – Patient Education of Self-Administration of Home Infusion Antimicrobial Therapy

I am inviting you to participate in a focus group interview that will take about 1.5- 2 hours in June, with some of your team members. As part of a graduate program in Nursing at Athabasca University, I am carrying out a study to learn about patient education in self-administration of home infusion therapy. I am interested in learning how nurses teach patients to self-administer their therapy.

Your organization has been selected as a case site for the study due to a publication indicating your program's work in self-administration of home infusion therapy.

There are no known risks for participating in this study, other than sharing your experience and opinions.

You can stop being in this study any time during the focus group. I have attached a copy of a letter of information and consent form about the study that gives you full details. This project has been reviewed by the Athabasca University Research Ethics Board. Should you have any comments or concerns regarding your treatment as a participant in this project, please contact the Research Ethics Office by e-mail at rebsec@athabascau.ca or by telephone at 1-800-788-9041, ext. 6718.

We would like to thank you in advance for your time and consideration. After a week, we will send you a one-time follow-up reminder.

Daphne Broadhurst RN, BScN
Masters Student Candidate in Nursing
Faculty of Health Disciplines
Athabasca University, I would change to 1 University Drive, Athabasca
Tel: 613.244.4560 ext. 22383
dbroadhurst@oms.ca

Appendix I: Letter of Information/Informed Consent Form

(for Patients in Observation Study)

University of Manitoba

Athabasca University

LETTER OF INFORMATION / INFORMED CONSENT FORM
(for Patient's Participation in Observation Study)

Self-Administration of Home Infusion of Antimicrobial Therapy: Characteristics of Patient Education

September 21, 2017

Co- Investigator:
Daphne Broadhurst, RN, BScN
Faculty of Health Disciplines
Athabasca University
Ottawa, ON
(613) 244-4560 ext. 22383
daphne.broadhurst@medicalpharmacies.com

Principal Investigator:
Dr. William Diehl-Jones (Supervisor)
Center for Nursing and Health Research
Athabasca University
wdiehljones@athabascu.ca
Department of Biological Sciences
University of Manitoba

You are invited to take part in a research project entitled '**Self-Administration of Home Infusion of Antimicrobial Therapy: Characteristics of Patient Education.**'

This form is part of the process of informed consent. The information presented should give you the basic idea of what this research is about and what your participation will involve, should you choose to participate. It also describes your right to withdraw from the project. In order to decide whether you wish to participate in this research project, you should understand enough about its risks, benefits and what it requires of you to be able to make an informed decision. This is the informed consent process. Take time to read this carefully as it is important that you understand the information given to you. Please contact the co-investigator, Daphne Broadhurst, if you have any questions about the project or would like more information before you consent to participate.

It is entirely up to you whether or not you take part in this research. If you choose not to take part, or if you decide to withdraw from the research once it has started, there will be no negative consequences for you now, or in the future.

Introduction
My name is Daphne Broadhurst and I am a Master of Nursing student at Athabasca University. As a requirement to complete my degree, I am conducting a research project about how nurses teach patients to self-administer their home intravenous antimicrobial therapy and what helps a patient to perform these procedures. I am conducting this project under the supervision of Dr. William Diehl-Jones.

Why are you being asked to take part in this research project?
You are being invited to participate in this project because your nurse is teaching you how to manage your antibiotic infusion.

What is the purpose of this research project?
From this research, we wish to describe and explain how patients are taught to run their intravenous (IV) antibiotics at home. The information will be used to develop a model, describing

this patient education. This information may help programs in which nurses usually administer the therapy to move towards teaching patients how to manage this with some help from nurses.

What will you be asked to do?
Your participation will require no effort on your part. The researcher will watch you and your nurse to see how you learn how to manage your infusions. The research nurse will take notes during the observations of how your nurse is teaching you and how you are learning the information. You may be asked a few informal interview questions to clarify observations at the end of the teaching session; however you may opt not to respond. The researcher will be observing nurse-patient interactions during a 3-5 day period in September or October 2017.

You may also be invited to participate in a 15-30 minute telephone interview with someone from the research team. You do not have to participate in the phone interview. If you would like to, however, you will be asked approximately 5 questions about your experience with learning how to manage your infusions. The interview will be audio recorded. A separate information letter and consent form will be used for the phone interview portion of the study.

What are the risks and benefits?
There are no known risks associated with this research study; however, a possible inconvenience may be the fact that a researcher is observing you and your nurse. The researcher will attempt to be as unobtrusive as possible, not speaking during the observations. There are no personal benefits for taking part in this research. You will receive no payment or reimbursement for any expenses related to taking part in this study.

Do you have to take part in this project?
As stated earlier in this letter, involvement in this project is entirely voluntary. You may withdraw from the study at any time and/or refuse to answer any questions, without suffering any negative consequences. If you choose to withdraw during the observations, the researcher will stop observation of your interaction and delete observation notes. This information can be deleted and permanently destroyed during data collection (i.e., the months of October-December 2017).

How will your privacy and confidentiality be protected?
The ethical duty of confidentiality includes safeguarding participants' identities, personal information, and data from unauthorized access, use or disclosure. We will collect your name on a separate data log only, in the event that you later request your observational data be withdrawn from the study or consent to a telephone interview. However, there will be no data with any of your personal information on the data records to be analyzed, nor in the final published report. All information will be held confidential, except when legislation or a professional code of conduct requires that it be reported.
Your personal information will not be used or disclosed for other purposes, unless permitted by *The Freedom of Information and Protection of Privacy Act (FIPPA)* and the *Personal Health Information Act (PHIA)*. If you have any questions about the collection of your personal information, contact the Access & Privacy Office (tel. 204-474-9462), 233 Elizabeth Dafoe Library, University of Manitoba, Winnipeg, MB, R3T 2N2.

How will my anonymity be protected?
Anonymity refers to protecting participants' identifying characteristics, such as name or description of physical appearance. Every reasonable effort will be made to ensure your anonymity; you will not be identified in publications without your explicit permission.

How will the data collected be stored?

All paper-based data (i.e., consent forms) will be scanned electronically and the paper subsequently shredded. All electronic copies of signed consent forms will be kept in a secure manner on the Principal Investigator's password-secured network in Ottawa for 5 years at which time it will be destroyed. The research team, indicated above, and a research assistant will be the only individuals who will have access to these files. An executive summary of the results will be shared with your healthcare team participating in the study. A manuscript describing the study and results will be submitted for publication in a peer-reviewed journal. Phase two of the study will explore the development and evaluation of a self-administration patient education program. Data collected from this study may be archived for use in the phase 2 study.

Who will receive the results of the research project?
An executive summary of the results will be shared with the organizations participating in the study. Direct quotations may be included; however no personally identifying information will be reported. You will be able to receive a copy from your health care team at this site. A manuscript describing the study and results will be submitted for publication in a peer-reviewed journal. The existence of the research will be also be listed in an abstract posted online at the Athabasca University Library's Digital Thesis and Project Room and the final research paper will be publicly available.

Who can you contact for more information or to indicate your interest in participating in the research project?
Thank you for considering this invitation. If you have any questions or would like more information, please contact me, (co-investigator) by e-mail at daphne.broadhurst@medicalpharmacies.com or my supervisor by wdiehljones@athabascau.ca. If you are ready to participate in this project, please complete and sign the attached Consent Form and return it the researcher when she is at your worksite for the observations.

Thank you.

Daphne Broadhurst

This project has been reviewed by the Athabasca University Research Ethics Board and the local University of Manitoba Health Research Ethics Board. Should you have any comments or concerns regarding your treatment as a participant in this project, please contact the Research Ethics Office:

Athabasca University	**University of Manitoba**
Research Ethics Board	**Health Research Ethics Board**
rebsec@athabascau.ca	bannatynereb@umanitoba.ca
1-800-788-9041, ext. 6718	204 789-3389

Informed Consent:

My signature on this form means that:

- I have read the information about the research project.
- I have been able to ask questions about this project.
- I am satisfied with the answers to any questions I may have had.
- I understand what the research project is about and what I will be asked to do.
- I understand that I are free to withdraw my participation in the research project without having to give a reason, and that doing so will not affect I now, or in the future.
- I understand that if I choose to end my participation **during** data collection, any data collected from me up to that point will be destroyed.

- I understand that my data is being collected anonymously, and therefore cannot be removed once the data collection has ended.
- I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Health Research Ethics Board or Athabasca Research Ethics Board for quality assurance purposes.

	YES	NO
I agree to the use of direct quotations	○	○
I allow data collected (de-identified) from the research group to be archived in the researcher's case study database for phase 2 of this study	○	○
I am willing to be contacted to discuss my participation in a 20-30 minute telephone interview about my learning experience. *Please write your phone number is you replied "Yes" to the interview.* My phone # is (_____) _____	○	○

My signature confirms:

- I have read what this research project is about and understood the risks and benefits. I have had time to think about participating in the project and had the opportunity to ask questions and have those questions answered to my satisfaction.
- I understand that participating in the project is entirely voluntary and that I may end my participation at any time without any penalty or negative consequences.
- I have been given a copy of this Informed Consent form for my records.
- I agree to participate in this research project.

_____ _____
Signature of Participant Date

_____
Printed name of Participant

Investigator's Signature:

I have explained this project to the best of my ability. I invited questions and responded to any that were asked. I believe that the participant fully understands what is involved in participating in the research project, any potential risks and that he or she has freely chosen to participate.

_____ _____
Signature of Investigator Date

Appendix J: Letter of Information/Informed Consent Form

(for Patient Interviews)

LETTER OF INFORMATION / INFORMED CONSENT FORM
(For Patient Interviews)

Self-Administration of Home Infusion of Antimicrobial Therapy: Characteristics of Patient Education

September 21, 2017

Co-Investigator
Daphne Broadhurst, RN, BScN
Faculty of Health Disciplines
Athabasca University
Ottawa, ON
(613) 244-4560 ext. 22383
daphne.broadhurst@medicalpharmacies.com

Principal Investigator
Dr. William Diehl-Jones (Supervisor)
Center for Nursing and Health Research
Athabasca University
wdiehljones@athabascu.ca
Department of Biological Sciences
University of Manitoba

You are invited to take part in a research project entitled '**Self-Administration of Home Infusion of Antimicrobial Therapy: Characteristics of Patient Education.**'

This form is part of the process of informed consent. The information presented should give you a clear idea of what this research is about and what your participation will involve, should you choose to participate. It also describes your right to withdraw from the project. In order to decide whether you wish to participate in this research project, you should understand enough about its risks, benefits and what it requires of you to be able to make an informed decision. This is the informed consent process. Take time to read this carefully as it is important that you understand the information given to you. Please contact the co-investigator, Daphne Broadhurst, if you have any questions about the project or would like more information before you consent to participate.

It is entirely up to you whether or not you take part in this research. If you choose not to take part, or if you decide to withdraw from the research once it has started, there will be no negative consequences for you now, or in the future.

Introduction
My name is Daphne Broadhurst and I am a Master of Nursing student at Athabasca University. As a requirement to complete my degree, I am conducting a research project about how nurses teach patients to self-administer their home intravenous antimicrobial therapy and what helps a patient to perform these procedures. I am conducting this project under the supervision of Dr. William Diehl-Jones.

Why are you being asked to take part in this research project?
You are being invited to participate in this project because your nurse is teaching you how to manage your antibiotic infusion at home. We will be asking about 15 patients in 2 or 3 Canadian home infusion programs to participate.

What is the purpose of this research project?
From this research, we wish to describe and explain how patients are taught to run their intravenous (IV) antibiotics at home. The information will be used to develop a mo this patient education. This information may help programs in which nurses usuall the therapy to move towards teaching patients how to manage this with some hel

What will you be asked to do?
You are being asked to participate in one phone interview. We will ask you about 5 questions to learn what helped you to learn how to manage your own antibiotic infusion. You may opt not to answer a question. The call will last from 15 to 30 minutes. We will be recording the call to analyze the data.

What are the risks and benefits?
There are no known risks associated with this research study; however, a possible inconvenience may be the time it takes to answer the questions. If you feel uncomfortable with any of the questions you may opt not to respond or to withdraw from the call. There are no personal benefits for taking part in this research. You will receive no payment or reimbursement for any expenses related to taking part in this study.

Do you have to take part in this project?
As stated earlier in this letter, involvement in this project is entirely voluntary. You may withdraw from the study at any time and/or refuse to answer any questions, without suffering any negative consequences. If you choose to withdraw during the call, the researcher will stop the interview and delete any notes and audio recordings. This information can be deleted and permanently destroyed during data collection (i.e., the months of October-December 2017).

How will your privacy and confidentiality be protected?
The ethical duty of confidentiality includes safeguarding participants' identities, personal information, and data from unauthorized access, use or disclosure. We will collect your name on a data log only, separate from notes about your interview. However, there will be no data with any of your personal information on the data records to be analyzed, nor in the final published report. All information will be held confidential, except when legislation or a professional code of conduct requires that it be reported.
Your personal information will not be used or disclosed for other purposes, unless permitted by *The Freedom of Information and Protection of Privacy Act (FIPPA)* and the *Personal Health Information Act (PHIA)*. If you have any questions about the collection of your personal information, contact the Access & Privacy Office (tel. 204-474-9462), 233 Elizabeth Dafoe Library, University of Manitoba, Winnipeg, MB, R3T 2N2.

How will my anonymity be protected?
Anonymity refers to protecting participants' identifying characteristics, such as name or description of physical appearance. Every reasonable effort will be made to ensure your anonymity; you will not be identified in publications without your explicit permission.

- I am satisfied with the answers to any questions I may have had.
- I understand what the research project is about and what I will be asked to do.
- I understand that I are free to withdraw my participation in the research project without having to give a reason, and that doing so will not affect I now, or in the future.
- I understand that if I choose to end my participation **during** data collection, any data collected from me up to that point will be destroyed.
- I understand that my data is being collected anonymously, and therefore cannot be removed once the data collection has ended.
- I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Health Research Ethics Board or Athabasca Research Ethics Board for quality assurance purposes.

	YES	NO
I agree to the use of direct quotations	○	○
I agree to be audio-recorded	○	○
I allow data collected (de-identified) from the research group to be archived in the researcher's case study database for phase 2 of this study	○	○
I am willing to be contacted following the interview to verify that my comments are accurately reflected in the transcript	○	○

My signature confirms:

- I have read what this research project is about and understood the risks and benefits. I have had time to think about participating in the project and had the opportunity to ask questions and have those questions answered to my satisfaction.
- I understand that participating in the project is entirely voluntary and that I may end my participation at any time without any penalty or negative consequences.
- I have been given a copy of this Informed Consent form for my records.
- I agree to participate in this research project.

_____ _____

Signature of Participant Date

_____

Printed name of Participant

Investigator's Signature:

I have explained this project to the best of my ability. I invited questions and responded to any that were asked. I believe that the participant fully understands what is involved in participating in the research project, any potential risks and that he or she has freely chosen to participate.

_____ _____

Signature of Investigator Date

Appendix K: Observation Grid

Observation Grid for Self-Administration of Home Antimicrobial Therapy Study				
Date yy/mm/dd	**Case** ***(circle)*** Winnipeg Vancouver	**Setting** ***(circle)*** Home Community clinic Outpatient clinic Hospital	**Provider** *(circle)* RN LPN	**Recipient** *(circle)* Patient Caregiver Both
Activity/ Teaching Content	**Time (start/stop)**	**Teaching Format** C=computer; D= demonstration; I= internet; T= teach-back; V= video; V=verbal (didactic); W= written	**Patient Response/ Competency Validation** C= Competent P= Partial competence; further training required U= unsuccessful; nursing to perform task NA= Not applicable/not performed	**Thoughts/Insights**
Patient Assessment				
Program Description				
Infection prevention				
Medication Administration				
Infusion (*Circle*: Direct Push; Gravity; Electronic; Elastomeric)				
Vascular access care				
Dressing changes				
Complication management				
Supplies & equipment handling				
Self-monitoring				
Resources				
At the end of each observation, ask[1]: 1. Do you think you said or did anything differently because I was with you today? ___ [If yes] How so? 2. Do you think you said or did anything differently because of anything we discussed today? ___ [If yes] How so?				
[1]Adapted from Goldman, R., Parker, D. R., Brown J., Walker, J., Eaton, C.B., & Borkan, J.M. (2015). Recommendations for a mixed-methods approach for evaluating the patient-centered medical home. *Annals of Family Medicine*, 13, 168-175. doi: 10.1370/afm.1765.				

Appendix L: Focus Group Interview Guide

Organization	# Nurses Invited	# Nurses Participating	Date of Interview	Location

Topic	*Minutes*
Welcome. Introduce research team.	5
Purpose. While some areas in Canada are practicing self-administration of home infusions, many do not. This requires patients to either attend clinic appointments or await home nursing visits, supporting a nurse-dependence model. The purpose of this study is to describe and explain how patient education of self-administration of outpatient parenteral antimicrobial therapy is achieved. Study results will be published in a peer-reviewed journal, with the goal that the information will be used to develop a conceptual model that programs may use to guide the development and/or implementation of a self-administration patient education program. We will provide your administrator with a copy of the executive summary for your review. You were each invited because your program lead recommended you as being knowledgeable and/or well-experienced in this patient education.	5
Meeting Guidelines (things that will help our conversation flow better). • We're audio recording • We're on a first name basis. No names attached. • It will help if only one person talks at a time. If several of you are talking at the same time, the recording gets garbled and we'll miss your comments. • No wrong answers, only differing points of view. You don't need to agree with others, but you must listen respectfully as others share their views • Please silence your phones. If you must respond to a call, please do so as quietly as possible and rejoin us as quickly as you can. • We are going to be informal here tonight, so feel free to get up for more coffee or refreshments. • My role is to guide the discussion and to listen to you talk to each other. We want to hear your thoughts and experience. • I may need to interrupt to get through all the questions. I apologize ahead of time if I need to do this.	5
Broad Opening Question Let's develop a fictional case of a typical patient, 'Mary." requiring self-administration of home intravenous antimicrobial therapy. We'll then use this case to guide the rest of our discussion.	5
Transition Questions *(to explain the structure of self-administration patient education programmes)* How would you assess Mary's eligibility for self-administration? What knowledge does Mary have to gain to safely self-administer her therapy? What skills does Mary have to learn how to safely self-administer her therapy? Which of these skills and knowledge items are critical (a "must have")? What infusion therapy technology would make Mary's learning easier? Where should Mary be taught and how many sessions? What resources would you use to teach Mary and which do you find more effective? How do you evaluate Mary's learning and competency? What are the short-term and long-term outcomes of Mary self-administering her OPAT?	50
Key Questions *(to explore mechanisms of learning??)* How can a nurse effectively teach a patient how to self-administer infusion therapy? How can a nurse tailor teaching to guide patient-centric learning? How do you motivate a patient to learn self-administer her therapy? How did you learn to teach patients self-administration? *(Prompt: courses, certification)*	30
Conclusion	15

Appendix M: Patient Interview Guide

Organization	Date/Time	Interview Location	Person Interviewed Patient/spouse/ child/ parent/ friend/ other

---

I. **Introduction:** Introduce self and explain "This study was initiated to understand how patients are taught how to administer their IV medication on their own. This interview is part of the information that we are collecting to better understand this patient education. I'll be asking you 5 questions for about 15-20 minutes. I'll be audio-recording this interview to ensure that I don't miss or misconstrue any statements you make. Before we start, please review the consent form we sent you that explains your participation in this interview."

II. **Informed Consent**: Explain and read consent form. Ask for and answer questions. Obtain verbal consent. Sign 1 copy and send to participant

III. **Interview Questions**: "OK, thanks, Let's get started"

1. What motivated you to learn how to self-administer your IV medications?
2. What was most helpful for you to learn how to self-administer your IV medication?
3. Have there been any barriers or challenges to your learning?
4. What would you change or improve about the teaching you received?
5. My last question, would you recommend self-administration of IV therapy to other patients? Please elaborate.

Adapted from Goldman, R., Parker, D. R., Brown J., Walker, J., Eaton, C.B., & Borkan, J.M. (2015). Recommendations for a mixed-methods approach for evaluating the patient-centered medical home. *Annals of Family Medicine*, 13, 168-175. doi: 10.1370/afm.1765.

Appendix N: Baseline Case Site Data Interview Questions

PROGRAMME DEMOGRAPHICS

1. Enter the following information about your programme:
    a. Organization Name:
    b. Department:
    c. Address:
    d. City: Province Postal Code
    e. E-mail:
    f. Phone:
    g. Website:
2. Number of years programme has been in practice:
3. Please choose one of the following that best describes your setting:
    a. Home Infusion Clinic
    b. Outpatient parenteral antimicrobial program
    c. Hospital
4. Please complete the following regarding the number of staff in your practice and their FTEs

	# Staff	FTE
RNs		
LPNs		
Program Manager		
Educator		
Pharmacist		

PROGRAMME CHARACTERISITICs

5. Please indicate approximately the number of patients who are seen in a typical week in the following categories:
    a. Hospital, clinic visits: _____
    b. Hospital, inpatient: _____
    c. Inpatient: _____
6. Please indicate the approximate percentage of your patients that fall into the following categories:
    a. Self-administration of outpatient antimicrobial therapy (no nursing support):____
    b. Self- administration of outpatient antimicrobial therapy (excluding dressing and connector changes) :____
    c. Partial nursing support of administration of outpatient antimicrobial therapy:____
    d. Nursing administration of outpatient antimicrobial therapy:____
7. Which patient education materials are available:

   a. Written
   b. CD/DVD
   c. Online interactive programme
   d. Online video

   Please share copies of your education material for assessment of content to guide this study. Email to dbroadhurst@oms.ca

8. Does your organization track outcomes related to self-administration of parenteral antimicrobial therapy?
   a. Yes
   b. No
   c. Unsure
9. If yes, please check all outcomes that are measured:
   a. Catheter-related bloodstream infection
   b. Patient satisfaction
   c. Adverse events/complications
   d. Completion of therapy as prescribed
   e. Hospital readmissions
   f. Cure or improvement
   g. Quality of life
   h. Other, please describe
10. Please describe how patients are referred to your programme?
11. Does your programme use a conceptual framework or theory to guide teaching of self-administration?
   a. Yes, please describe
   b. No
   c. Unsure

Appendix O: Certificates of Ethical Approval

Athabasca University
RESEARCH ETHICS BOARD

The future of learning.

CERTIFICATION OF ETHICAL APPROVAL

The Athabasca University Research Ethics Board (AUREB) has reviewed and approved the research project noted below. The AUREB is constituted and operates in accordance with the current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* and Athabasca University Policy and Procedures.

Ethics File No.: 22593

Principal Investigator: Daphne Broadhurt, Faculty of Health Disciplines/Master of Nursing

Supervisor (if applicable): William Diehl-Jones, Faculty of Health Disciplines, Centre for Nursing & Health Studies

Project Title: 'A Multiple Case Study of Patient Education for Self-Administration of Home Antimicrobial Infusion Therapy'

Effective Date: May 17, 2017 **Expiry Date**: May 16, 2018

Restrictions:

- Recruitment and/or data collection cannot begin until approvals have been received from Vancouver Coastal Health and Winnipeg Regional Health Authority
- Any modification or amendment to the approved research must be submitted to the AUREB for approval.
- Ethical approval is *valid for a period of one year*. An annual request for renewal must be submitted and approved by the above expiry date if a project is ongoing beyond one year.
- A Project Completion (Final) Report must be submitted when the research is complete *(i.e. all participant contact and data collection is concluded, no follow-up with participants is anticipated and findings have been made available/provided to participants (if applicable))* or the research is terminated.

Approved by: **Date: May 17, 2017**
Sherri Melrose, Chair
Faculty of Health Disciplines, Departmental Ethics Review Committee
Athabasca University Research Ethics Board

Athabasca University Research Ethics Board
University Research Services, Research Centre
1 University Drive, Athabasca AB Canada T9S 3A3
E-mail: rebsec@athabascau.ca
Telephone: 780.675.6718

Athabasca University
RESEARCH CENTRE

CERTIFICATION OF ETHICAL APPROVAL - RENEWAL

The Athabasca University Research Ethics Board (AUREB) has reviewed and approved the research project noted below. The AUREB is constituted and operates in accordance with the current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) and Athabasca University Policy and Procedures.

Ethics File No.: 22593

Principal Investigator:
Mrs. Daphne Broadhurst, Graduate Student
Faculty of Health Disciplines\Master of Nursing

Supervisor:
Dr. William Diehl-Jones (Supervisor)

Project Title:
A Multiple Case Study of Patient Education for Self-Administration of Home Antimicrobial Infusion Therapy

Effective Date: May 14, 2018 **Expiry Date**: May 13, 2019

Restrictions:

Any modification or amendment to the approved research must be submitted to the AUREB for approval.

Ethical approval is valid *for a period of one year*. An annual request for renewal must be submitted and approved by the above expiry date if a project is ongoing beyond one year.

A Project Completion (Final) Report must be submitted when the research is complete *(i.e. all participant contact and data collection is concluded, no follow-up with participants is anticipated and findings have been made available/provided to participants (if applicable))* or the research is terminated.

Approved by: **Date:** May 14, 2018

Joy Fraser, Chair
Athabasca University Research Ethics Board

Athabasca University
RESEARCH CENTRE

CERTIFICATION OF ETHICAL APPROVAL - RENEWAL

The Athabasca University Research Ethics Board (AUREB) has reviewed and approved the research project noted below. The AUREB is constituted and operates in accordance with the current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) and Athabasca University Policy and Procedures.

Ethics File No.: **22593**

Principal Investigator:
Mrs. Daphne Broadhurst, Graduate Student
Faculty of Health Disciplines\Master of Nursing

Supervisor:
Dr. William Diehl-Jones (Supervisor)

Project Title:
A Multiple Case Study of Patient Education for Self-Administration of Home Antimicrobial Infusion Therapy

Effective Date: May 3, 2019 **Expiry Date**: May 02, 2020

Restrictions:

Any modification or amendment to the approved research must be submitted to the AUREB for approval.

Ethical approval is valid *for a period of one year*. An annual request for renewal must be submitted and approved by the above expiry date if a project is ongoing beyond one year.

A Project Completion (Final) Report must be submitted when the research is complete *(i.e. all participant contact and data collection is concluded, no follow-up with participants is anticipated and findings have been made available/provided to participants (if applicable))* or the research is terminated.

Approved by: **Date:** May 3, 2019

Carolyn Greene, Chair
Athabasca University Research Ethics Board

Athabasca University Research Ethics Board
University Research Services, Research Centre
1 University Drive, Athabasca AB Canada T9S 3A3
E-mail rebsec@athabascau.ca
Telephone: 780.675.6718