INFLIXIMAB HOME INFUSION DRAFT STANDARD OPERATING PROCEDURE

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DEDICATION

In memory of the person who inspired me to pursue project work on infliximab home infusion treatment. Your spirit, and memories of you and your family, are embedded in my heart.

ABSTRACT

The research indicates that infliximab home infusion treatment is complex and requires careful consideration of various aspects of patient care and coordination of services. The literature clarifies that standardization is needed to foster quality and safety in infliximab infusion home-based care. Patient care and clinical outcomes will continue to be jeopardized in the absence of a standard operating procedure (SOP) for home infusion nurses (RNs) to access, consult with, and inform infliximab home infusion care. Within Alberta, Canada, home-based infliximab infusions have become a service offered to patients and families. However, there is no evidence suggesting that an SOP related to infliximab infusion home-based care exists, specifically within the Canadian INVIVA McKesson organization. I developed an evidence-based draft SOP for infliximab home infusion treatment tailored to the INVIVA McKesson Canada organization through this project. I engaged with stakeholders from varying professional backgrounds to validate and improve the draft SOP.

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SECTION 1: INTRODUCTION

An infliximab infusion, used to treat various autoimmune diseases, is traditionally administered in hospitals and physicians' clinics; however, it is also now infused within patients' homes (Fenster et al., 2020). Infliximab is commonly administered intravenously within a vein in the hand or arm by a qualified healthcare provider (e.g., physician, licensed practical nurse, and registered nurse). Registered nurses (RNs) use various documents, such as guidelines, policies, procedures, and infusion therapy product monographs, to guide their nursing practice in infliximab infusion administration. Infusing infliximab in the home setting is a complex healthcare service that requires consistency and standardization to foster patient safety and quality of care (Giese-Kim et al., 2020). However, there is a lack of a detailed and robust standard nursing practice in the form of a standard operating procedure (SOP) to guide RNs while infusing infliximab in the home setting.

Nursing Practice Problem

RN-administered infliximab home infusion treatment is becoming a service offered in Canada. Within the Canadian INVIVA McKesson organization, no single standardized practice exists for RNs to guide patient care. Lavelle et al. (2015) proclaim that standardized nursing and organizational practices have been shown to improve the quality of care and reduce unnecessary variations in practice. Barfield et al. (2018) further recommend that an evidence-based standard of care must be developed for biologic therapy, such as infliximab, to maximize the benefit and sustainability of treatment before initiating this service in the home.

Administering infliximab within any setting, including the hospital, clinic, or home, is associated with risk. The lack of a standardized practice for home infliximab infusion treatments jeopardizes safety and quality of care within the home setting. Since home infusion service providers are external to the prescribing physician's office, fragmented care may threaten the quality of infliximab infusion care in the home setting (Barfield et al., 2018). Risks must be mitigated, and efforts made to prevent issues arising in terms of safety and quality of care. In the absence of a clear, evidenced-based SOP, it is challenging for RNs and organizations to mitigate risks, potentially compromising the quality of care and patient safety. Without an evidence-based SOP to guide RNs in their practice, critical aspects of care may be omitted or overlooked, performed incorrectly, or not considered at all.

Purpose of the Project

The purpose of this Master of Nursing (MN) project was to develop a standardized practice in the form of a draft SOP regarding infliximab infusion treatment in the home setting, tailored to the INVIVA McKesson Canada organization. The project was successfully developed and implemented by accomplishing the goals, objectives, and short-term outcomes described in the project's logic model (Appendix A).

I based the draft SOP on both evidence and best practices related to infliximab infusion treatment and considered implications for safe and quality-driven nursing practice in the home setting. I did this by incorporating nursing theory and utilizing the nursing metaparadigm concepts to foster comprehensive patient care in the context of infliximab home infusion treatment. My strategic method of gathering the best evidence involved using a systematic process of developing evidence-based recommendations for

infliximab infusion treatment in the home setting. The following chapter highlights the review of the literature related to the project.

SECTION 2: LITERATURE REVIEW

I performed a literature review regarding infliximab home infusion treatment using the 6S pyramid (McMaster University, 2021), starting at the top and working downward. Journal article searches were conducted using BMJ, PMC – NCBI, PubMed, Science Direct, EBSCO, Web of Science, ProQuest, and CINAHL. Only English-language, peer-reviewed research articles were included. Other sources of information included evidence-based research and documents published by nursing organizations. The reviewed literature consisted of articles published within the last five to 10 years; however, some relevant literature published earlier was also deemed valuable and reliable since infliximab has been administered in homes for at least two decades.

Scope of Guiding Nursing Documents

Product monographs, organizational policies and procedures, and evidence-informed guidelines have been developed and implemented in nursing practice to standardize nursing actions and influence positive patient outcomes.

Product Monographs

Manufacturer product monographs are scientific documents that contain information about a medication's purpose, indications, clinical pharmacology, and classification, as well as any safety considerations required for effective, optimal, and safe use of the medication (Government of Canada, 2020). Over the years, infliximab therapy has been developed by multiple pharmaceutical manufacturers, including, but not limited to, Amgen Canada (2020), Janssen (2019), Merck Canada (2020), and Pfizer

Canada (2018), who have developed their manufacturer-specific administration guidelines (e.g., product monographs). The efficacy of infliximab is based on randomized control trials, and the safety and effectiveness of the medication in treating various diseases have been widely established. Organizations utilize manufacturer product monographs to inform their organizational policies, procedures, and monographs for staff, such as RNs, to inform care. According to the College & Association of Registered RNs of Alberta (CARNA, 2013), RNs are expected to use resources and appropriate sources of information to inform safe patient care.

Organizational Policies and Procedures

Policies and procedures in health care promote consistency in day-to-day operational activities and processes associated with health and safety, regulatory requirements, and accreditation standards (Accreditation Commission for Health Care [ACHC], 2020). In brief, organizational policies tell staff what to do and identify the reasons for doing. The World Health Organization (WHO, 2017) states that compliance with such policies is typically mandatory and enhances organizational accountability. Procedures focus on when and how a routine should be carried out to accomplish the desired outcome. Organizations, including those in the healthcare sector, develop organizational policies and procedures specific to their respective companies and services. The Infusion Nurses Society (INS, 2016) states, organizational policies and procedures that emphasize infusion-related care are essential in delivering high-quality patient care in this area of healthcare.

Guidelines

Evidence-informed guidelines optimize the safety and quality of patient care, improve patient outcomes, and are used in nursing practice to inform care. Infliximab is a standard treatment found within evidence-informed clinical practice guidelines regarding the treatment of Crohn's disease (Lamb et al., 2019; Panaccione et al., 2019), ulcerative colitis (Feuerstein et al., 2020; Lamb et al., 2019), and rheumatoid arthritis (Bykerk et al., 2012; Mian et al., 2019), to name a few. Clinical practice guidelines are explicitly developed to assist physicians in making optimal decisions regarding disease management. However, nursing best practice guidelines (BPGs) are specific to nursing and assist RNs in applying best evidence in practice (Registered Nurses' Association of Ontario (RNAO, 2012). Among the BPGs that RNs may consult to inform care related to infliximab administration are those concerning vascular access. The Canadian Vascular Access Association (CVAA, 2019) and the RNAO (2008a, b) has created guidelines for facilitating central venous access device best practices to promote positive patient outcomes.

SOPs

In addition to product monographs, policies, and procedures, SOPs are implemented to establish work standards related to performance, are presented in the form of a written process (i.e., a set of stepwise instructions), and may serve as a reference material (Singh, 2019). An SOP synthesizes the best available evidence in the form of a single guiding document and incorporates organizational policies and standardized processes, which can subsequently be put into action.

Several authors, including Amare (2012), da Rosa Walter et al. (2016), and Feuerstein et al. (2020), cite the benefits of a standardized set of practices, procedures, and actions, as they provide clarity and minimizes variation in clinical practice. Chen et al. (2016) advise that as long as SOPs are implemented consistently and correctly, additional benefits of utilizing SOPs in clinical practice include increased employee adherence to guidelines and improved patient outcomes. Ausserhofer et al. (2016) and Rao et al. (2011) have determined that nursing care is positively influenced when standardized practices are implemented and consistently used for every patient in ordinary clinical care. Upon reviewing the literature, no formal SOP related to infliximab home infusion treatment exists.

The Impact of the Problem

SOPs are useful tools intended to ensure both quality and safety (Ausserhofer et al., 2016; Drake et al., 2021; Feuerstein et al., 2020). Kredo et al. (2016) and Leotsakos et al. (2014) agree that SOPs assist in standardizing nursing performance and activities when implemented into nursing practice, which reduces both risks to patients and the likelihood of adverse events. A fundamental benefit of SOPs is that they bridge the gap between evidence-based practice and frontline clinical care (Rao et al., 2011).

Chiu et al. (2015) reports that SOPs have been shown to reduce variations in nursing practice, direct standardized nursing care following established policies, and prevent complications and patient harm. The use of multiple supporting documents to guide care is paramount. SOPs integrate multiple supporting documents, describe in sequential order the essential steps on how to carry out nursing care and, Rao et al. (2011)

assert that SOPs integrate aspects of care into clinical practice that may not be included in guiding documents that staff, including RNs, consult to inform patient care.

Currently, there are no SOPs available to RNs for infusing infliximab in the home setting in the INVIVA McKesson Canada organization, which poses the risk of variations in nursing practice, potentially leading to suboptimal patient outcomes. High-quality nursing and organizational best practice require consolidation and consideration of various aspects of infliximab home infusion research in the form of an SOP that will guide this type of complex patient care.

The following sections highlight the complexity of infliximab home infusion treatment and various aspects of quality care in this context. A whole literature review will lay the foundation for broadly acquiring and applying the knowledge concerning the complex nature of infliximab home infusion treatment to develop the content of the draft SOP.

Infusion Treatment in the Home Setting

While in a patient's home setting, RNs do not have immediate or in-person access to other support staff, physicians, and resources that would be readily available in the hospital. In contrast to the stability and certainty of the hospital setting, Markkanen et al. (2017) maintain that the home setting is unpredictable, isolated from the hospital and hospital staff, and dynamic. Unanimously noted by Barfield et al. (2018), Gorski et al. (2021), Kelly et al. (2019), McElroy (2018), National Home Infusion Association (NHIA, 2017), Finney et al. (2015), and Petroff and Johnson (2016), interdisciplinary team collaboration, communication, and coordination of care facilitate optimal quality-driven patient care when infliximab home infusion services are offered in the home setting. On

the other hand, Giese-Kim et al. (2020) point out that poor communication between an RN and the interdisciplinary team may result in suboptimal patient care outcomes, such as discontinuation of treatment and poor quality of life.

To ensure seamless nursing care and coordination of patient services, RNs must communicate and collaborate with patients, their families, and the interdisciplinary healthcare team members. Barfield et al. (2018) emphasize that since home infusion service providers are external to the prescribing physician's office, fragmented patient care is a potential risk of infliximab home infusion treatment. However, cited by Gorski and Alexander (2017), the risk may be mitigated by ensuring direct and open lines of communication with the external members of the patient's healthcare team, such as the prescribing physician. An SOP that includes collaborative and communicative actions may facilitate patient safety, satisfaction, and high quality of care needed to achieve efficiency and coordination of infliximab home infusions.

According to the Canadian Nurses Association (CNA, 2017), RNs are obligated to advocate for conditions that support quality practice settings to benefit patients who receive care. Like the CNA, the Australian Primary Health Care Nurses Association (APHCNA, 2015) believes that healthcare organizations should implement processes to determine the home setting's appropriateness (e.g., safety) to reduce risk to both patients and nursing staff. To ensure the safety and suitability of the patient's home for home infusion treatment, the NHIA (2020) has recommended using a patient home environment screening similar to a safety hazards checklist developed by Gershon et al. (2012). Additionally, the APHCNA (2015) recommends using a patient and RN safety screening tool or checklist when caring for patients in the home. Gorski (2020) and Schultz et al.

(2019) ascertain that the home setting must be appropriate for home infusion administration. For example, the cleanliness of the home and the ability to safely prepare and administer the infusion must be assessed by the RN before initiating home-based care to evaluate patient and nursing safety considerations related to infliximab infusion treatment in the home setting.

Several authors, including ACHC (2020), Barfield et al. (2018), and Gorski et al. (2021), state that to provide quality care in the home setting, home infusion service providers and their employees (RNs) must engage in quality improvement activities. Both Gupta et al. (2019) and the INS (2016) believe that when home infusion RNs participate in their employers' performance improvement practices, such as reporting adverse and quality events, their employers can assess and track the safety and quality of care provided in patients' homes. RNs are in direct contact with each patient and family and must regularly question and inquire about organizational practices to ensure consistent, safe, and quality-driven patient care outcomes (Gorski et al., 2021).

With all the recommendations and available resources for organizations and nursing staff to inform safe and quality-driven patient care, it is evident that an SOP to guide home-based infusion safety and quality can assist RNs in providing the best care possible in this setting.

Person- and Family-Centred Care

Quality nursing care is achieved in partnership with patients and their families when making infliximab home infusion care decisions (Gupta et al., 2019). Specifically to infliximab home infusion treatment, Bohra et al. (2020) reinforce the importance of including patient and family values, preferences, needs, and overall satisfaction

throughout care provision. Furthermore, Barfield et al. (2018), Gorski et al. (2021), and Kokorelias et al. (2019) believe that patients and families are best supported by encouraging ongoing collaboration, respect, communication, education, and participation regarding treatment in the coordination of infusion services. An SOP that incorporates person- and family-centred care during infliximab home-based treatment will aspire to place the patients and families at the centre of quality and safe home-based care and that clinical care decisions are based on patient and family perspectives.

Nursing Skills and Competency

In addition to using a person- and family-centred care approach, RNs who provide individualized care to patients receiving home-based infliximab intravenous therapy, must have appropriate nursing knowledge, skills, experience, and training. According to the INS (2016) and Schultz et al. (2019), nursing skills and competency are essential for maintaining patient safety when providing infusion treatment in the home. Additionally, Barfield et al. (2018), Gupta et al. (2019), and the Royal College of Nursing (RCN, 2015) agree that nursing competency and skill contribute to high-quality and safe care. There is overwhelming evidence in the literature to suggest that patient and family satisfaction and quality of care delivered is high when healthcare providers are skilled and competent in home-based infliximab services (Checkley et al., 2019; Choquette et al., 2015; Condino et al., 2005: Goodoory et al., 2019).

Planning, Assessment, and Monitoring

RNs must employ strategies and interventions that facilitate patient care planning, assessment, and monitoring, all of which lead to high-quality patient care when administering infliximab in patients' homes (Checkley et al., 2019). Multiple authors,

including Gorski et al. (2016), Gorski (2020), Gorski and Alexander (2017), assert that home infusion care is determined by selecting appropriate patients for the home setting. Bohra et al. (2020), Condino et al. (2005), and Gupta et al. (2019) further highlight the importance of carefully selecting appropriate patients as determined by the prescribing physician for infliximab home infusion care. However, the CVAA (2019), Gorski (2020), and Gorski et al. (2021) proclaim that appropriate patient selection is best determined in collaboration with the patient and the prescribing physician to ensure patient safety and that high-quality care is delivered in the home setting.

Appropriate patient selection is not unique to infliximab home infusion treatment. Schultz et al. (2019) underscored the importance of proper patient selection within their model of care for natalizumab used to treat multiple sclerosis when administered in patients' homes. Like infliximab home infusion care, Schultz et al. (2019) found that natalizumab home infusion care requires appropriate patient selection, effective patient education, and comprehensive patient care assessment and monitoring.

Nursing strategies used to assess or confirm appropriate patient selection have been significantly noted in the literature, signaling the importance of proper patient selection. Barfield et al. (2018) and Kuin et al. (2016) found that patients with no prior history of reaction to infliximab are ideal candidates for the home setting. However, Condino et al. (2005) and the INS (2016) report that patients who have had a minimum number of infusions in the clinic setting without prior history of infusion reaction are most appropriate for receiving infliximab in the home. Mosadeghi and Taleban (2019) slightly differ from Condino et al. (2005), Kuin et al. (2015), and the INS (2016) perspectives on appropriate patient selection in that they believe that patients must have

had first or induction infliximab doses in the hospital or clinic before transferring to the home setting.

Additionally, RNs may also consider the patient's disease stability (Bohra et al., 2020; Condino et al., 2005; Kuin et al., 2015) and loss of response to infliximab therapy (McElroy, 2018). Disease stability and loss of response to infliximab therapy may pose a lower and higher risk, respectively, of an acute infusion reaction to infliximab infusion treatment.

The selection of patient vascular access further compounds appropriate patient selection for infliximab home infusion. According to Gorski et al. (2021) and the RNAO (2008a, b), home infusion RNs must be competent in vascular access selection and aware of associated complications. The RN must advocate in the patient's best interest for optimal vascular access methods selected by the prescriber and educate the patient in making decisions regarding appropriate, patient-specific vascular access options, including alternative options if required (CVAA, 2019, Gorski et al., 2021, RNAO, 2008b). Making inquiries concerning a patient's vascular access before each infliximab home infusion treatment will assist the RN in anticipating the patient's vascular access needs. In collaboration with the patient, the RN must communicate vascular access issues to the patient's prescribing physician and, if applicable, an advanced vascular access team for assessment and consultation. Vascular access safety and quality are achieved when home infusion RNs are competent, knowledgeable, collaborative, and use best practices to inform care.

Additional nursing strategies and interventions include comprehensive patient care planning upon initial and ongoing assessment of each patient (Gorski, 2020).

Prescreening practices assist RNs in identifying contraindications to treatment (Hamlin et al., 2011; Janssen, 2019; Merck Canada, 2020; Pfizer Canada, 2018; RCN, 2015). According to the American College of Rheumatology (2019), Janssen (2019), and Panaccione et al. (2004), infliximab infusion administration and infusion titration protocols are strongly recommended strategies. RNs use infliximab infusion titration rates to slowly and incrementally increase infusion rates to reduce the severity of an acute infusion reaction should a patient experience one. Vital signs monitoring before, during, and in some cases, after infliximab infusion treatment allow the RN to safely monitor patients throughout each treatment for potential adverse reactions to infliximab (Caon et al., 2015; de Vries et al., 2011; Gorski & Alexander, 2017; Mazzuoli et al., 2016).

Acute Infusion Reactions

Infliximab is traditionally administered in the hospital setting by RNs who have immediate access to physician support if an acute infusion reaction occurs. Symptoms of an acute infusion reaction may develop during or within one hour after the infusion and may include fever, chills, chest pain, hypotension, hypertension, dyspnea, pruritis, urticaria, headache, rash, flushing, and, in severe cases, anaphylaxis (Janssen, 2019; Merck Canada, 2020; Pfizer Canada, 2018). Studies have shown that the incidence of infliximab-associated infusion reactions is low and uncommon (Checkley et al., 2019). Authors such as Choquette et al. (2015), Lee et al. (2011), Markatseli et al. (2013), Van Schie et al. (2017), and Vultaggio et al. (2008) affirm that infliximab-associated acute infusion reactions are typically mild to moderate in severity; therefore, infliximab infusion treatment can be safely infused within the home. Within the home setting, Checkley et al. (2019)'s study found that the majority of infliximab-associated acute

infusion reactions were noted as mild to moderate in severity and accounted for only 2% of the total infliximab infusions administered.

However, infusion reactions occurring within the home setting may pose a risk to patient safety because there is no onsite physician or support staff to assist the home infusion RN. To mitigate risk, Checkley et al. (2019), Lichtenstein et al. (2015), and Mosadeghi and Taleban (2019) firmly state that early recognition and timely acute infusion reaction management are paramount in preventing worsening of reaction and controlling reactions once they occur.

Furthermore, antibody development is linked to lower infliximab trough levels and loss of response to infliximab, leading to an acute infusion reaction in patients (McConnell et al., 2012; McElroy, 2018). Several studies have demonstrated that when physicians proactively monitor patient antibody levels, this leads to optimizing infliximab dosage and therapeutic benefits (Bendtzen et al., 2019; Lichtenstein et al., 2015; Vaughn et al., 2015). Infliximab antibody testing is critical in determining the appropriate infliximab dosages for patients because dose increases in the presence of antibody development are linked to an increased risk of infusion-related reactions. Therefore, RNs must consider and assess patients' infliximab trough and antibody level results. These are metrics that RNs can use to inform patient care in the context of infliximab home infusion treatment (e.g., by assessing potential infusion reaction risk to the patient). Notably, RNs play a crucial role in facilitating infliximab- and disease-related laboratory bloodwork testing since they are directly involved in patient care.

Acute Infusion Reaction Nursing Competency

Nursing competency and skill regarding infliximab acute infusion reaction management are crucial elements for healthcare organizations to consider when employing RNs in the home. RNs responsible for infliximab infusion administration in the home setting must possess the skill and knowledge required to promptly assesses the severity of acute infusion reactions and manage them accordingly (Cáceres et al., 2019). Using a standardized protocol to prevent, monitor, and manage infusion reactions has contributed to quality nursing interventions that facilitate safe patient care. The use of organizational protocols and flowcharts intended to inform the quality of nursing care and guide RNs in making decisions during infliximab infusion administration in the home setting reduces risk to patients.

Organizational protocols and flowcharts include (a) grading the severity of anaphylaxis (Cáceres et al., 2019; Gülsen et al., 2020); (b) anaphylaxis algorithms used in infliximab infusions (Akarsu et al., 2020; Cáceres et al., 2019; Gülsen et al., 2020; Lichtenstein et al., 2015; McElroy, 2018; Sandborn & Hanauer, 2002); (c) infliximab infusion titration recommended protocols (American College of Rheumatology, 2021; Bohra et al., 2020; Hamlin et al., 2011; McConnell et al., 2012); (d) monitoring vital signs while administering infliximab (Cáceres et al., 2019; Caon et al., 2015; Checkley et al., 2019; Gorski et al., 2021; Mazzuoli et al., 2016; Panaccione et al., 2004); (e) standardized medical directives (Ducharme et al., 2010; Madden et al., 2018); and (f) reporting adverse events according to organizational policy (INS, 2016).

In summary, there is no evidence of an SOP for infusing infliximab in the home setting, which poses the risk of variations in nursing practice and omits the multifaceted

pertinent aspects of care, potentially leading to poor patient outcomes, experience, and satisfaction with care. A comprehensive, evidence-based SOP will account for the complexity of infliximab infusion home-based care.

Gaps in the Literature

SOPs specifically related to infusion nursing care are not commonly found in the scientific literature, representing a primary gap in the evidence base. Furthermore, the majority of infliximab home infusion literature has been conducted using retrospective and prospective cohort studies, such as Bohra et al. (2020), Checkley et al. (2019), Choquette et al. (2015), Condino et al. (2005), Ducharme et al. (2010), Fenster et al. (2018), Giese-Kim et al. (2020), Goodoory et al. (2019), Gupta et al. (2019), and Kuin et al. (2015), concluding the need for more rigorous studies in the home-based infliximab literature.

Of the literature reviewed, only one research article evaluated a hospital-based SOP specific to infliximab administration related to pediatric care was located (Kelly et al., 2019). In the study, Kelly et al. (2019) employed a literature review, focus group nursing discussions, and expert opinions to develop an SOP. The SOP was intended to standardize infliximab infusion administration that included a preinfusion safety checklist, monitoring vital signs parameters, laboratory testing, appropriate infliximab infusion administration, and standardized preinfusion medications to prevent infusion-related reactions.

Kelly et al. (2019) indicated that using an SOP increased the use of a preinfusion safety checklist and the collection of standard laboratory testing. The authors also conducted focus groups among RNs and physicians to gather feedback regarding the use

of the SOP. The RN focus group responses indicated that communication, quality of care, and efficiency had increased and improved the quality of care. The physician focus group results were similar to that of the RNs; however, an additional theme emerged, safety. Physicians agreed that overall communication, the efficiency of care, safety, and quality of care had improved with the implementation of the SOP. The findings of this study highlight the potential benefits associated with the development and implementation of an SOP regarding infliximab infusion care; however, the study is limited to the hospital setting and pediatric care. Further studies specifically related to the home setting that includes adult and pediatric patient populations are needed to evaluate the benefit of an infliximab home infusion SOP.

Patient care is undoubtedly jeopardized by the absence of standardized organizational and nursing practices regarding infliximab home infusion treatments (Barfield et al., 2018; Bohra et al., 2020; Fenster et al., 2018). However, the evidence suggests that when RNs and organizations use standardized infliximab infusion-related practices, the quality of patient care is improved, and patient satisfaction is high. Currently, there is no clearly defined and comprehensive SOP related to infliximab home infusion treatment. A lack of an SOP may confuse RNs who provide care and prove detrimental to organizations that provide the service. There is ample and varied evidence in the literature to support the development of an SOP related to infliximab home infusions. The development of an SOP that considers the multifaceted nature of infliximab home infusion treatment will be explored.

SOP Development

Core concepts and content are essential in drafting and creating SOPs that staff can use to make their work consistent, efficient, quality-driven, and safe. An SOP should be written stepwise and in chronological order, and from the end user's perspective (The FDA Group, 2017). The FDA Group (2017) recommends that SOP developers avoid dense paragraphs and use bullet formatting and lists where applicable.

Organizations have access to various SOP templates or may choose to develop their own. In the context of business operations and processes, SOP development is best understood by examining the entire lifecycle of SOPs (Beadle, 2015). To help end-users and creators understand SOP development, Beadle (2015) has crafted a diagram of the SOP lifecycle. I looked to Beadle's (2015) SOP lifecycle for direction when developing the SOP (Appendix B).

Additionally, the WHO (2018) has created a process to develop an SOP through an SOP implementation toolbox. Within the toolbox, it is suggested that organizations draft SOPs using a standardized format to facilitate the intended use of these procedures (WHO, 2018). Recommended SOP template content includes an identification section, purpose, scope, definitions, responsibilities, lists of equipment and supplies, procedures, references, and appendices, as applicable (WHO, 2018). Organizations may then draft SOP templates specific to their institution to inform the development of their SOPs (WHO, 2018).

In conclusion, I considered the FDA Group's (2017) core concepts, and I compared the WHO's (2018) suggested template format with that of the INVIVA organization and identified similarities summarized in Table 1. I used INVIVA's SOP

template to serve two purposes: to follow an evidence-based, standardized format and use a template that best suits the organization's needs and interests.

Table 1

The WHO's (2018) SOP Template Versus INVIVA's SOP Template

Content	WH0 (2018) SOP Template	INVIVA SOP Template
Identification Section	X	X
Purpose	X	X
Scope	X	X
Definitions	X	X
Responsibilities	X	X
Equipment and Supplies	X	X
Procedure	X	X
References	X	X
Appendices	X	X
Review/Revision Section		X

SECTION 3: PROJECT DESCRIPTION

The following section describes aspects of the project, including the background and planning and the project's primary goal and objectives, audience, and associated ethical considerations. Methods and strategies for developing and implementing the project are also identified.

Background and Planning

Studies have demonstrated the overall safety of infliximab in the home setting and indicated that standardized, evidence-based practices inform quality nursing and patient care. Improving the quality of the care provided to patients and their experiences is a universally identified goal that both organizations and RNs aim to achieve. The development of this draft SOP may inform system-wide uptake of infliximab home infusion quality-driven nursing best practices in the INVIVA McKesson network by reducing variations in nursing practice and enhancing patient quality of care, should the organization choose to adopt it. A review of INVIVA documents indicated no SOP related to infliximab home infusion treatment exists; in discussion with the organization, it was

determined that there was an interest in developing one. A collaborative decision among the INVIVA organization and I was made to draft an SOP as my MN project.

Project Goal and Objectives

The project's primary goal was to establish a standardized practice, in the form of an SOP, for infliximab infusion treatment in the home setting that aims to:

1) Use evidence-based research to develop recommendations for an SOP related to infliximab infusion treatment in the home setting; and
2) Reduce variations in nursing practice by developing an evidence-based SOP (draft) for infliximab home infusion treatment.

A project logic model supported the project's development, including the project's goal and objectives, and outlined details such as inputs, audience, activities and outputs, deliverables, and the project's short-, medium-, and long-term outcomes. Only the short-term outcomes of the project's logic model were attainable during the time allotted for the project; however, medium- and long-term outcomes were established should the SOP be implemented in the future by the INVIVA McKesson Canada organization and determine the long-term vision of the SOP.

Target Population and Stakeholders

The project's target population is the INVIVA McKesson Canada organization. Clinics and the home nursing department exist within the INVIVA network to serve and care for patients requiring infusion treatments. The INVIVA Home Nursing Department is Canada-wide, and, in Alberta, it is independent of the publicly funded healthcare system. INVIVA McKesson Canada's National RN Educator is the primary stakeholder for this project and served as an expert consultant in policy development and infliximab infusion

administration, and home nursing practices. As the development of the MN project progressed, other stakeholders included the INVIVA Home Nursing Department RN Manager, the INVIVA Home Nursing Department Patient Care Coordinator, an INVIVA Home Nursing Department frontline RN, the Director of INVIVA McKesson Canada, and the McKesson Canada Senior Operating Officer in Customer Service.

Stakeholder Engagement

Stakeholder engagement has occurred from the inception of the project idea. I invited the National RN Educator to attend my project proposal presentation in March 2021. Open lines of communication and ongoing collaboration with the primary stakeholder contributed to developing a meaningful, impactful, and quality-focused project. Engaging with the other stakeholders included a stakeholder review of the draft SOP in the form of an individual feedback questionnaire and an informal interview held via Microsoft Teams at a date and time that was mutually agreed upon during June 2021. Before the Microsoft Teams meeting, the draft SOP and an individual feedback questionnaire were emailed to stakeholders to provide individual perspectives on the draft SOP.

Ethical Considerations

To move forward in the project development and implementation, I addressed ethical considerations. I used the ARECCI Ethics Screening Tool (Alberta Innovates, 2017) to assess, mitigate, and navigate potential ethical risks; the proposed draft SOP does not require an ethical review by a research ethics board. The ARECCI Ethics Screening Tool was completed, signifying that the proposed project is likely a quality

improvement or program evaluation. Upon determining the risk category to participants, the score received was zero, indicating that the project involves minimal risk.

To identify ethical implications related to the proposed project, I completed the ARECCI Ethics Guideline Tool developed by the A pRoject Ethics Community Consensus Initiative (Alberta Innovates, 2017). I used the tool to assess knowledge generation and its usefulness and to address data-specific ethical processes. The project did not involve patients or staff as participants; however, other stakeholders, also referred to as subject matter expert (SME) reviewers, were identified. Stakeholders agreed to be part of the project evaluation of their own free will to evaluate the draft SOP for home-based infliximab tailored to their organization.

Project Development and Implementation

The theoretical concepts of the nursing metaparadigm were used as the foundation for broadly acquiring and applying the knowledge generated in the literature review regarding infliximab home infusion treatments and initiated the first step in the project's development. The primary purpose of using the theoretical concepts was to ensure that the generated knowledge addressed the complex nature of infliximab administration in the home setting. The nursing metaparadigm's four interrelated theoretical concepts are fundamental to nursing and care provision. The concepts served as a holistic framework for determining the type of nursing knowledge to be included within and inform the development of the draft SOP based on a review of the relevant literature, including the concepts person, environment, health, and nursing (Fawcett, 1978).

In the context of this MN project, the person refers to the patient or client who is receiving care (e.g., infliximab home infusion treatments); the environment is the

patient's home setting, in which the care is provided; health is viewed as the degree of patient wellness and quality of care received; and nursing refers to the attributes, qualities, and actions of the RN providing care. The metaparadigm concepts were applied and integrated into the draft SOP through the lenses of multiple nursing theorists' perspectives described in Appendix C.

Evidence-Based Recommendations Methods for SOP Development

I used the concepts from the nursing metaparadigm as a framework to account for the complexity of infliximab home infusion treatments to develop a tangible document based on best evidence in the form of recommendations. Similar to evidence-based guidelines, the draft SOP is based on evidence-based recommendations stemming from a systematic literature review.

The Infusion Nursing Society's committee has developed a method of determining the strength of the body of evidence in the form of a chart to develop practice recommendations found within the Infusion Therapy Standards of Practice. The GRADE Working Group method for categorizing the strength of the recommendations is used internationally and by various organizations (e.g., within the RNAO's Best Practice Guidelines development program) and was used to classify recommendations as strong or conditional. To develop evidence-based recommendations for infliximab home infusion treatment, I applied the Infusion Nursing Society's and the GRADE Working Group's methods of drafting systematically developed statements (e.g., recommendations).

The evidence-based recommendations were developed to establish an evidence-informed starting point for the draft SOP. To develop evidence-based recommendations, I used the Infusion Nurses Society's method (Appendix D) in determining the strength of

the body of evidence by assigning an evidence rating. The recommendations were then categorized as strong or conditional as defined by the GRADE Working Group (2013) (Appendix E). To classify each recommendation as either strong or conditional, I considered the strength of the body of evidence and the key criteria adapted from the RNAO (2019c) (Appendix E). The key criteria adapted from the RNAO (2019c) were used to ensure that the patient is at the centre of care and fostering the patient perspective.

Both the Infusion Nurses Society and the GRADE Working Group permitted me to use their methods in developing evidence-based recommendations for the project's main deliverable (e.g., the draft SOP). Each evidence-based recommendation incorporated nursing standards found in the Infusion RNs Society Infusion Therapy Standards of Practice (Gorski et al., 2021) for infusion nursing specialty care. The standards are critical in upholding safe patient care practices, preventing patient harm, and facilitating optimal patient outcomes related to intravenous therapy. In addition to the Infusion Therapy Standards of Practice, the Canadian Community Health Nursing Standards of Practice (Community Health Nurses of Canada, 2019) and the Canadian Home Care Association Principles (Canadian Home Care Association, 2019) were used to enhance the evidence-based recommendations by accounting for the complexity of infliximab infusion treatment in the home setting.

During the project's development and implementation phases, I used multiple methods to create the deliverable and validate the draft SOP with SME reviewers. First, I created evidence-based recommendations for the infliximab home infusion treatment SOP through a systematic literature review. A total of nine evidence-based recommendations were developed for the infliximab home infusion treatment SOP

tailored to the INVIVA organization that included (a) knowledge, skill, experience, and competency; (b) acute infusion reaction competency; (c) patient selection; (d) planning, assessment, and monitoring; (e) vascular access; (f) the home environment; (g) person- and family- centred care; (h) interdisciplinary team collaboration and communication; and (i) quality assurance and improvement.

Next, I compiled the recommendations into a PowerPoint document titled "Evidence-Based Recommendations for Infliximab Home Infusion SOP (draft): Implications for Nursing Practice in the INVIVA Network" (Appendix F). I shared the evidence-based recommendations document with the primary stakeholder before using the recommendations to build the draft SOP. Sharing the evidence-based recommendations document and collaborating with the primary stakeholder served as an opportunity for her to ask questions regarding the literature review, provide feedback to enhance relatability to the INVIVA organization, and communicate the next step in building the draft SOP.

RNAO BPG Five Phases in the Project's Development and Implementation

I used the five phases of the RNAO's (2019a) BPG program, consisting of planning, development, pilot implementation, evaluation, and dissemination/uptake and in consideration to Beadle's (2015) SOP lifecycle, to develop and implement the draft SOP. The RNAO's BPG phases were used as a guide to inform optimal decision-making throughout the entirety of this project in a step-by-step and sequential fashion. Should the draft SOP be formalized for use in the future, the five phases may be repeated and used in monitoring and updating the SOP in actual and current practice. The details of the project development and implementation are presented in Appendix G.

Evaluation Design

During the RNAO's BPG development process, BPGs undergo a stakeholder review to refine each guideline before implementation (RNAO, 2019b). To align with the RNAO best practices related to BPG development, I specifically chose a formative evaluation method to validate the SOP.

The evaluation focused on formative feedback to develop and improve the draft SOP. McKenzie et al. (2017) describe formative evaluation as "the measurement of the process used to improve the quality of the effort" (p. 254). Similarly, Windsor (2015) implies that feedback retrieved from formative evaluation aids in assessing the feasibility of implementation and interventions (as cited in McKenzie et al., 2017). Since the SOP is in draft form and the pretesting phase, a formative evaluation method was solely used to validate and improve the SOP.

SME reviews are conducted with a small group of professionals who are not associated with the intervention in question but have expertise in the topic and are asked to analyze, critique, and provide recommendations upon review of the intervention (McKenzie et al., 2017). Informal interviews are a standard formative evaluation method, and McKenzie et al. (2017) describe them as brief interviews in the form of a casual conversation.

To align with formative evaluation best practices, I sought stakeholder feedback on the draft SOP by using multiple methods before implementation by the organization. "Inclusion" is an element used in formative evaluation that ensures that the right partners are involved in the project (McKenzie et al., 2017). To foster inclusion, step one of the formative evaluations of the first draft involved a preliminary review by one SME who is

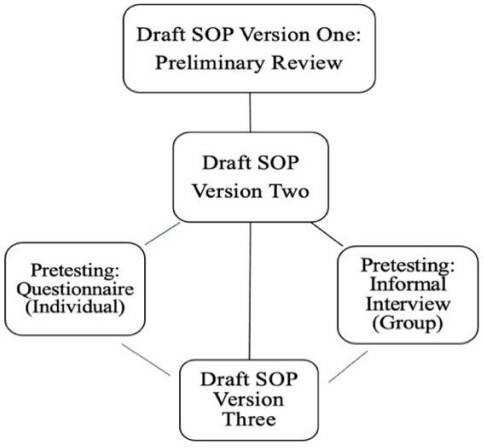
the key stakeholder supporting this project, is an expert in INVIVA policy development, and a previous home nursing department RN.

First, the key stakeholder's initial review of the draft of the SOP (version one) was designed to gather preliminary formative feedback to validate the SOP was evidence-informed, assess accountability (staff roles and responsibilities outlined in the document and safety) satisfaction with the overall design, and adjust the draft, as necessary, before pretesting (McKenzie et al., 2017). Using the key stakeholder's initial feedback, I revised the draft SOP (version two) to best suit INVIVA's SOP procedural format and language used within the document; although, all content remained unchanged.

Second, I used a two-step formative evaluation design (pretesting) by acquiring SMEs to review the draft SOP individually (questionnaire) and within a group setting (informal interview) to further revise the SOP to its third and final version. The formative evaluation and stakeholder feedback methods used to improve the draft SOP are conceptualized in Figure 1.

Figure 1

Process of Formative Evaluation and Stakeholder Feedback Methods



Data Collection

I collected data by using two formative evaluation methods during the project's implementation (pretest) period consisting of a survey (questionnaire) and an informal interview (McKenzie et al., 2017). The individual feedback questionnaire was crafted considering the project's primary goal: establishing a standardized nursing practice for infliximab home infusion treatment in the home setting. I incorporated the adapted key criteria (RNAO, 2019c) used in the evidence-based recommendations document to develop questions one to five. Questions 6, 7, 9, and 10 evolved by referring back to the SOP core concepts, and question eight was used to assess whether the SOP was evidence-informed. The individual feedback questionnaire was further developed to target the project's short-term outcomes: to validate and improve the draft SOP using stakeholder feedback.

Ponto (2015) asserts that quantitative strategies (e.g., questions that are numerically rated), qualitative strategies (e.g., asking open-ended questions), or both (e.g., mixed methods) are used in survey research. As Creswell and Hirose (2019) stated, a mailed questionnaire is the most common mixed methods design used in survey research. The questionnaire sent to the SME reviewers via email encompassed a mix of both quantitative (eight) and qualitative (three) questions. I chose a mixed-methods approach when designing the questionnaire because quantitative data alone may limit feedback to measurable data only; therefore, the qualitative data was used to gain context about the quantitative questions that may be better understood using open-ended questions.

In May 2021, version two of the draft SOP was emailed to the SME reviewers (n=5) along with the individual feedback questionnaire (Appendix H) and the evidence-based recommendations document, which served as supporting material should the SME reviewers wish to review it. SME reviewers were given approximately two weeks to review the draft SOP and were asked to email their feedback questionnaire along with their responses to me by June 7, 2021. Two staggered reminder emails were sent to the SME reviewers within the two weeks. All (100%) SME reviewers appraised the draft SOP and individually provided feedback using the feedback questionnaire. Following the individual feedback questionnaire, all SME reviewers were invited to attend a 45 minute to one-hour informal interview via Microsoft Teams to gather additional group formative feedback.

Stakeholder review is a best practice and key element of BPG development and implementation. I strategically chose SME reviewers from varying healthcare professional backgrounds within the INVIVA organization to gain feedback from multiple perspectives on the draft SOP. Two stakeholder feedback methods were used to improve the draft SOP. Initially, stakeholders shared their thoughts freely and without influence from others by completing the individual feedback questionnaire. The informal interview allowed stakeholders to share ideas casually in a group setting without the pressure of a structured format.

Data Analysis

Using the questionnaire, the SME reviewers were asked to rate their responses by using a 4-point Likert scale including choices “strongly disagree,” “somewhat disagree,” “somewhat agree,” and “strongly agree.” In my effort to create a valid feedback

questionnaire, I integrated McKenzie et al.'s (2017) formative evaluation elements, such as "evidence," "accountability," "adjustment," and "satisfaction," to validate, improve, and revise the draft SOP in its final version. As such, the questions were formed by (a) using the adapted key criteria (RNAO, 2019c) from the evidence-based recommendations document that informed the development of the draft SOP; (b) inquiry into safety and quality; (c) the use of scholarly research and evidence; (d) evaluating ease of readability; (e) determining logical flow; and (f) overall satisfaction.

The SME reviewer questionnaire results were initially examined individually. All individual results were entered into Excel, and response types were coded as (1) strongly disagree; (2) somewhat disagree; (3) somewhat agree; and (4) strongly agree. Quantitative questions were assessed by the overall rating assigned to questions. For the quantitative questions in the questionnaire, all stakeholders responded with "somewhat agree" or "strongly agree," demonstrating a general agreement for the draft SOP with some variation in the degree of agreement (somewhat or strongly). Stakeholders' responses from questions 1 to 5 and 8 to 10 within the feedback questionnaire generally averaged 3.7 and 3.9/4; however, one averaged response to question nine was slightly lower at 3.3/4. The comments in the individual feedback questionnaire and the informal interview provided a richer understanding of why this rating is lower than the rest.

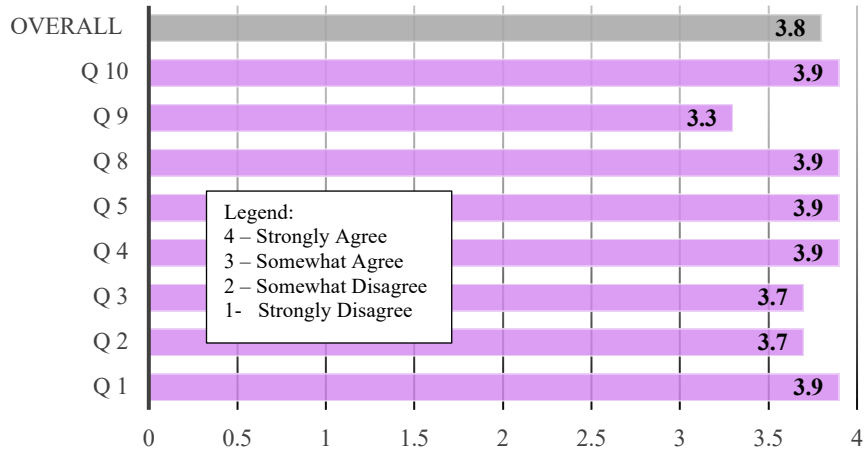
However, all stakeholder responses to the quantitative questions averaged 3.3/4 or greater, with all quantitative questions averaging 3.8/4. Response of two or less would indicate that the draft SOP lacked in areas found within questions 1 to 5 and 8 to 10. Although stakeholder responses from question 9 returned a positive result with an

average rating of 3.3/4 on a scale of 1 – 4, the qualitative questions identified a gap in the draft SOP further explored in the informal interview.

To aggregate individual SME reviewer results, the sum of all responses to each quantitative question was averaged and represented in graph form (Figure 2).

Figure 2

SME Feedback Questionnaire Aggregated Results



Note. n=5. 100% stakeholder response rate. Stakeholder aggregated results based on questions 1 to 5 and 8 to 10.

The qualitative questions were used to explore the SME reviewers' perspectives by asking open-ended questions. Qualitative questions six and seven and the general comments section allowed the SME reviewers to provide feedback using their own words. The SME reviewer responses were categorized into two themes, positive (strengths of the draft) and negative (areas for improvement). Table 2 highlights the qualitative responses by theme.

Table 2

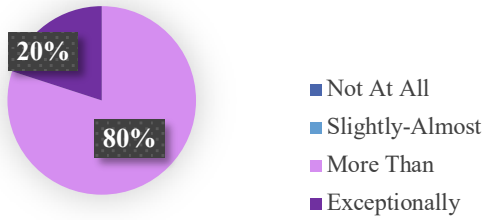
Questions 6, 7 and General Comments: Positive and Negative Themes

Themes	Qualitative Responses
Positive	Easy to understand
	Relevant information
	Integral steps
	Promoted comprehensive patient care and patient perspective
Negative	Lengthy
	Lack of specific relevant information

All positive themes were perceived as validating the formative evaluation results of the second draft. Negative themes were further explored in the informal interview, and areas of improvement were addressed in the final revision of the draft SOP. Last, question 11 of the questionnaire aimed to evaluate the SME reviewers' overall satisfaction with the second draft of the SOP. The results are shown below in Figure 3 and concluded that four out of five SME reviewers were "more than" satisfied with the second draft of the SOP, with one SME reviewer being "exceptionally" satisfied.

Figure 3

SME Level of Satisfaction with the Second Draft of the SOP



Note. n=5.

The final step in the formative evaluation process for the project included a SWOT (strengths, weaknesses, opportunities, threats) analysis. The SWOT analysis (Gürel & Tat, 2017) was used during the second phase of the formative evaluation

process in a Microsoft Teams meeting group discussion (e.g., informal interview with SME reviewers).

Appendix I summarizes the SWOT analysis used during the informal interview with the SME reviewers. Three out of five SME reviewers attended the informal interview and may impact the overall results of the SWOT analysis used to improve the draft SOP. Three principal threats were identified using the SWOT analysis within the draft SOP such as (1) INVIVA RNs do not typically have direct communication with the prescribing physician; (2) the RN's lack of access to bloodwork results; and (3) the need for a standardized infliximab home infusion supplies list.

Regarding the first threat listed, home infusion service providers are generally external to the patient's prescribing physician's office; therefore, fragmented care and suboptimal patient outcomes are potential risks. Increased communication and collaboration with the patient's entire healthcare team, internal and external to the home infusion service organization, may mitigate risk and improve patient outcomes. Therefore, I chose to leave direct communication among the RN and physician in the draft SOP; this facilitates best practices related to infliximab home infusion treatment and reduces risk to patients. INVIVA RNs do not have access to laboratory bloodwork results such as the therapeutic drug monitoring (TDM) and antibody level results regarding the second identified threat. Research suggests that the patient's TDM and antibody blood level results are metrics that RNs may use to assess for potential acute infusion reaction to the patient. The RN's lack of access to bloodwork results identified a gap in the draft SOP that may signify the need for an organizational change of practice in the future. Lastly, developing a standardized supplies list is beyond this project's scope; however,

INVIVA may choose to develop one formally and include it as a referenced document within the SOP in the form of a standardized checklist. The identified threats pertain to organizational matters outside this project's scope but may impact the organization's potential for approval and implementation.

The SWOT analysis allowed me to gain a richer understanding of the data obtained from the individual feedback questionnaires, particularly the rating (3.3/4) from question 9 and the themes identified from the qualitative questions. Following the informal interview, a third and final draft of the SOP was completed. In addition to the data obtained from the individual feedback questionnaire, the SWOT analysis allowed me to make specific changes made to the draft SOP summarized in Appendix J.

To validate the draft SOP, I sought feedback from several stakeholders from varying professional backgrounds within the organization, INVIVA McKesson Canada, to evaluate and improve the draft SOP to include within the final MN report. The final version of the Infliximab Infusion Administration in the Home Setting draft SOP may be reviewed in Appendix K.

SECTION 4: REFLECTION

Reflection is an aspect of registered nursing practice highlighted in critical inquiry and quality improvement (CARNA, 2013). Critical inquiry, from my perspective, is linked to quality improvement practices and initiatives. RNs play a vital role in quality improvement practices that lead to improvements in nursing practice and quality patient care.

RNs are professionally and ethically obligated to self-reflect on nursing practice and engage in dialogue with other RNs and healthcare professionals to improve the

quality of patient care and practice issues in healthcare (CNA, 2017). This MN project has emphasized my desire to use the knowledge and skill gained throughout my MN journey to improve nursing practice issues through its development and implementation. I aspire to strive for quality and safe nursing practices not only for the benefit of patients and families but for RNs and organizations who provide the service.

For this MN project, I used guiding principles found within the Canadian Association Schools of Nursing (CASN, 2015) National Nursing Education Framework as a guide to engaging in self-reflection to assess growth throughout this MN project journey and the project development process.

Application and Integration of Theory and Knowledge

I learned that applying nursing theory to the MN project process is vital to generating valuable and useful nursing knowledge and its applicability to improving nursing practice and practice-related issues in healthcare. I integrated a breadth and depth of knowledge by performing a comprehensive literature search and strategically using nursing's metaparadigm theoretical concepts to cover the complexity of infliximab infusion treatment services in the home setting. In addition to the concepts, I used nursing standards of practices and principles to create and inform evidence-based recommendations for the draft SOP content. I used a systematic approach to gather evidence and to plan, implement and evaluate the project. I regularly engaged in professional autonomous decision-making and applied the RNAO's BPG program's five phases in consideration to Beadle's (2015) SOP lifecycle throughout the project's entirety to plan, implement (pretest), and evaluate the project that aimed to address the identified practice problem.

Autonomy, Confidence, and Competence

Autonomy is central to professional nursing practice (Oshodi et al., 2019; Rouhi-Balasi et al., 2020). Highlighted by Bissett et al. (2016), evidence-based practice is a critical aspect of quality patient care, decreases variations in practice, and strengthens nursing autonomy. Through developing and implementing my project, I improved my ability to gather, analyze, critique, and synthesize literature to develop an evidence-based SOP that may someday promote safe and quality organizational and nursing practices in infliximab home infusion treatment. I gained confidence and used leadership skills to convey my literature findings through individual and group methods across various settings (e.g., email communication, informal interview, final project presentation). Owens and Keller (2018) recognize confidence as an influential element related to performance, also referred to as competency (Fukada, 2018). I am confident I will promote positive change in my current and future practice as a nursing leader by using skills gained throughout this MN project. This newly found confidence has strengthened my abilities to competently fulfill advanced practicing nursing roles in my future career as an RN leader.

Leadership and Evidence-Based Practice

I identified a practice problem within the INVIVA Network that is part of the McKesson Canada organization by pursuing and fulfilling the role of the project lead. I used evidence-based research to address the practice problem and formulated a rigorous method of developing a draft SOP for infliximab home infusion treatment. A standardized practice related to infliximab infusion treatment care is vital to patient and RN safety and quality nursing and organizational best practices. Identifying a practice issue, using skills

and knowledge acquired throughout the MN project, and translating knowledge in the form of an evidence-based SOP have instilled confidence in my ability to convey practice-related issues to healthcare professionals from varying backgrounds through an expert and nursing leadership lens.

Evaluation and Collaboration

Finally, I used strategies, such as formative evaluation skills and interprofessional collaboration, to create a culture of learning and a spirit of collaboration among healthcare professionals to improve the practice issue that the project (draft SOP) aimed to address. I sought and gained stakeholder feedback to revise and improve the draft SOP, which may someday facilitate positive change and improve practice in infliximab home infusion treatment in the INVIVA organization. Reflecting on my experience evaluating the data from the individual feedback questionnaire, I initially questioned whether enough RN stakeholder feedback was collected to improve the draft SOP. However, I reoriented my perspective and redirected myself back to the RNAO BPG stakeholder review process. The RNAO strategically uses stakeholders from varying healthcare and organizational backgrounds to gain feedback and input to improve BPGs before they are implemented into practice. The draft SOP was improved through multi-stakeholder lenses, which contributed to the overall success of the project deliverable, the draft SOP.

Further, I used a SWOT analysis to gather feedback which allowed a richer understanding of gaps identified in the individual feedback questionnaires. Stemming from the SWOT analysis, I identified three potential barriers to the successful uptake of the draft SOP. Alatawi et al. (2020) declare that by identifying barriers, the organization (INVIVA) can form solutions that will best suit their needs to facilitate successful uptake

and implementation of the SOP in the future. By effectively collaborating with stakeholders, I collected valuable formative data that validated the SOP and may someday promote organizational best practice changes. I felt empowered in the project lead role to offer solutions based on best evidence to promote positive organizational change and best practices.

Major Lessons Learned

Practice-related issues are problems that RNs and healthcare organizations face in their work. To address practice problems, guiding nursing documents, such as SOPs, are used to standardize practice to improve patient care and reduce variation in practice. Major lessons learned from identifying a practice problem within the INVIVA Network and developing and evaluating a solution to the problem, such as the draft SOP, are described in the following section.

Key Major Lesson Learned: Collaborative Practice

I developed the draft SOP content independently, and, in reflection, the first and significant lesson learned is that policy development is enhanced through collaboration among staff and work teams. The CNA (2019) proclaims that when learning occurs in silos, the spirit of interprofessional collaboration is undermined. Thinking about BPG development, one person alone does not develop BPGs. However, even though I acquired knowledge, synthesized research, and created the draft SOP content independently, I identified and collaborated with strategically selected stakeholders to review and provide feedback on the draft SOP. Collaborating with stakeholders from different healthcare roles allowed me to see areas of improvement from multiple perspectives. The

collaborative practice allowed me to improve the final project deliverable, the draft SOP, aligned with BPG development processes.

Second Major Lesson Learned: Ethics in Project Development

A second major lesson learned emerged from reflecting on ethical considerations during the project's implementation phase (stakeholder review). I learned the importance of ethical implications during project management, specifically related to confidentiality. Maintaining privacy and confidentiality and safeguarding personal information collected during professional interactions is outlined in the CNA's (2017) Code of Ethics for registered RNs who practice within Canada. Hall et al. (2020) state that "upholding the ethical principles of autonomy, beneficence, non-maleficence, and justice in quality improvement projects should be as stringent as what is expected in clinical research" (p. 3-4). As a project management lead, I am held to high standards during data collection and reporting stakeholder results to broad audiences. A critical insight learned in project management ethics was my role in upholding trust, respect, and confidentiality related to stakeholder interactions and data collected. The stakeholders' ongoing motivation to participate in this MN project will always be near and dear to my heart. Attributed to the success of the project was their valuable input and recommendations to improve the draft SOP.

Third Major Lesson Learned: Evidence-Based Practice

RNs play a vital role in providing quality patient care and healthcare service delivery (Aiken et al., 2014). Therefore, nursing practices that support quality care will improve patients' care and experiences with the healthcare system. To foster quality care in infliximab home infusion treatment, I developed an evidence-based SOP (in draft

form) to account for the complexity of infliximab home infusion care and standardize care to reduce variations in nursing practice. Stemming from the evidence-based literature, I developed and tailored the draft SOP to standardize care in infliximab home infusion treatment within the INVIVA Network. There is no formal SOP for infliximab home infusion treatment that is established within the Canadian INVIVA Network. Therefore, the draft SOP will result in a change of practice within the organization as INVIVA plans to use the draft SOP in the future formally.

Lastly, through this experience, I mobilized evidence-based research to influence organizational policy that may someday shape patient care and nursing practices (CNA, 2021). I am confident in my ability as a master's prepared RN to influence new and current policy development and implementation and promote positive change within my nursing practice and the organizations I work for.

Future Research

There is no clearly defined standardized practice for infliximab home infusion care. The studies that evaluated infliximab infusion home-based care identify the need for standardization, consistency, and comprehensive nursing care required to support quality nursing and organizational care in this area of healthcare. However, further research is needed to evaluate infliximab home infusion treatment globally, particularly within Canada, since limited research has been conducted from a Canadian perspective. Further, the infliximab home-based studies are restricted to mainly retrospective and prospective cohort studies, and more rigorous inquiry into patient care and nursing and organizational infliximab home infusion practices are critical to inform quality and safety in this context.

Inquiry into patient and family experiences, however, cannot be underscored enough. The majority of the literature review studies collected patient feedback and assessed patient satisfaction with care through surveys. Even though patient feedback and satisfaction are captured in routine organizational practice, it is questionable whether healthcare service delivery is improved (Asprey et al., 2013; Boiko et al., 2015). Qualitative research studies into patients' and families' perspectives on infliximab home infusion treatment may shed light on further insights into the complex nature of infliximab home infusion care and improvements needed to facilitate quality nursing and organizational practices stemming from the patient and family perspective.

Additionally, there is evidence, however scarce, to suggest that SOPs for some biologic therapies exist (UNC Health, 2020). On the other hand, there is very little evidence to suggest that an SOP related to infliximab infusion treatment has been studied. There are no studies associated with the development, implementation, and effectiveness of an SOP specifically related to infliximab infusion administration within the home setting. Future inquiry and research on the development, implementation and use of an SOP related to infliximab home infusion treatment are justified.

Implications for Nursing and Organizational Practice

The project's primary goal was to establish a standardized practice, in the form of an SOP, for infliximab home infusion treatment in the home setting. Overall, the project was successful as the short-term outcomes related to validating and improving the draft SOP outlined in the project's logic model were achieved. Since the project's medium- and long-term outcomes were outside the time allotted to complete the project, more time is required to assess these outcomes in the future.

The project validated that an SOP for home infusion treatment is warranted, and the organization that offers this service is motivated to establish a standardized practice in the form of an SOP. The INVIVA organization plans to use the draft SOP for possible implementation in the future. However, to assess the overall effectiveness of the draft SOP, the organization will need to test it in real practice. Pilot testing the draft SOP before actual implementation with a small number of nursing staff will prove or disprove the viability of the draft SOP. Pilot testing will allow the organization to make final revisions and adjustments to the SOP to best suit the needs of patients and families, nursing staff, and the organization. Additionally, trialing the SOP before implementation will allow end-users, such as the frontline nursing staff, to use the SOP and provide feedback to the organization to ensure usability solely from the end-user's perspective, which the FDA Group (2017) affirms is a key aspect of SOP development. Also, assessing nursing staff satisfaction with the SOP will facilitate compliance with the SOP (Haile et al., 2017).

Upon implementing the SOP in the Canadian INVIVA McKesson organization, the SOP will be disseminated (e.g., formal policy approval, nursing staff education and training, and Infusion RNs Society and National Home Infusion Association conferences, 2022) and used across Canada to inform and standardize infliximab home-based nursing and organizational practices.

Conclusion

Infusion treatment has been administered in the home dating back to the 1980s (Cannon, 2013). The NHIA (2017) firmly states that biologic infusion treatment has been safely infused in the home over the last three decades. However, Canada has been slow to

adopt this service, with infliximab home infusion treatments emerging in Alberta. The research indicates that infliximab infusion patient care in the home setting is complex and requires careful consideration of various aspects of patient care and coordination of services. The literature clarifies that standardization is needed to foster quality and safety in infliximab infusion home-based care. As such, there is a need for a standardized and comprehensive practice in this context. Patient care and clinical outcomes will continue to be jeopardized in the absence of an SOP for home infusion staff, such as RNs, to access, consult with, and inform infliximab home infusion care.

Within Alberta, home-based infliximab infusions have become a service offered to patients and families. However, there is no evidence suggesting that an SOP related to infliximab infusion home-based care exists, specifically within the Canadian INVIVA McKesson organization, which now provides infliximab infusion treatment in the home. I developed an evidence-based draft SOP for infliximab home infusion treatment tailored to the INVIVA McKesson Canada organization through this project. I engaged with stakeholders from varying professional backgrounds to validate and make meaningful improvements to the draft SOP.

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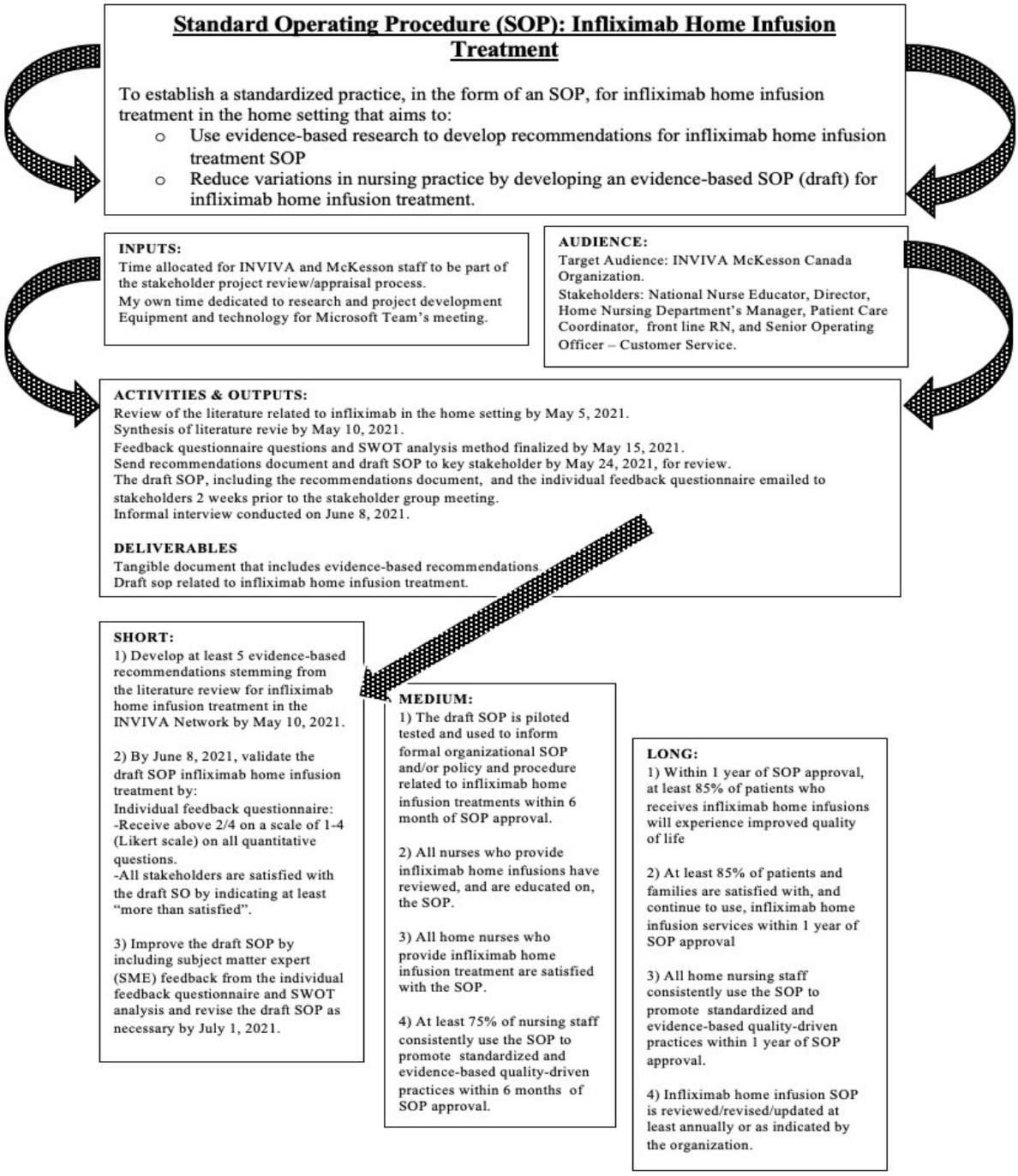
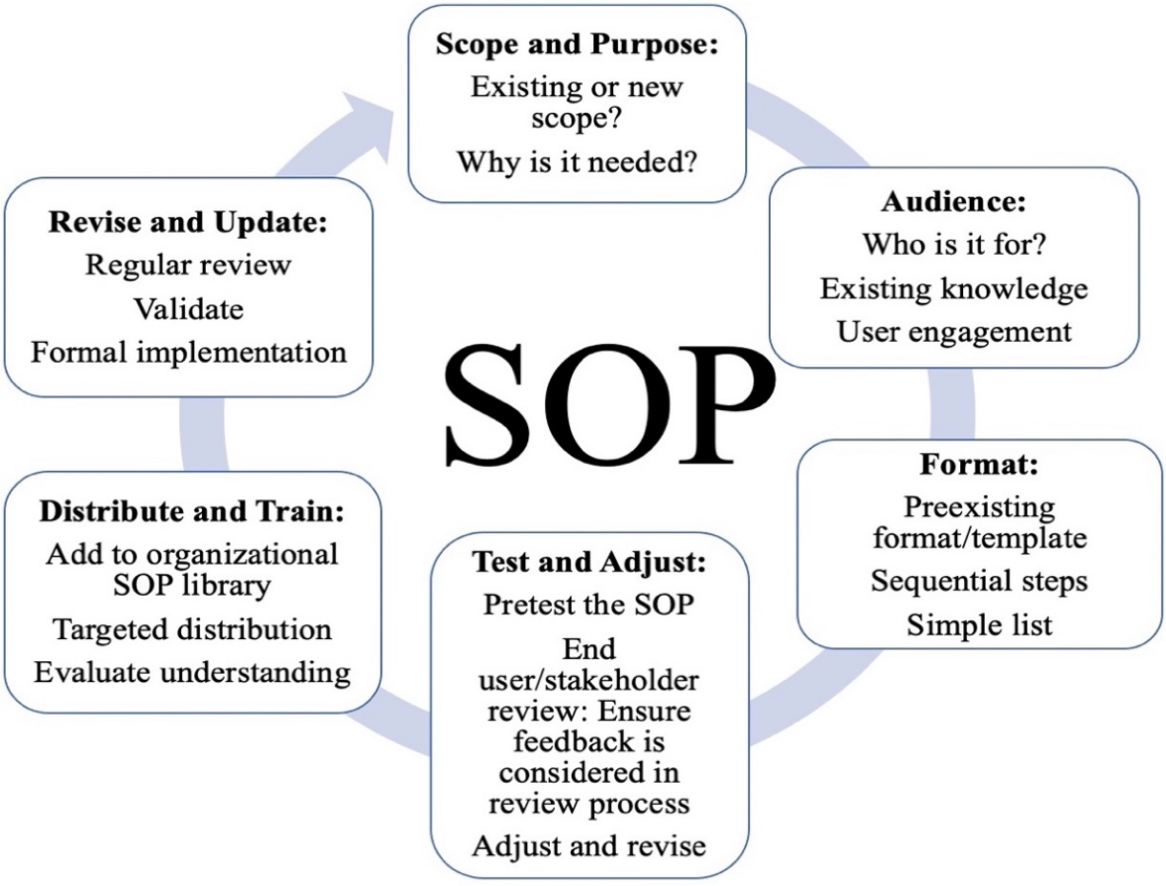
Appendix A: Project Logic Model



Appendix B: SOP Lifecycle



Note. Aspects found with the distribute and train and revise and update sections were beyond the project's scope but helped me align the project with the long-term vision of the SOP.
Adapted from Beadle, F. (2015). *Standard operating procedures - A complete guide!* https://www.collaboris.com/standard-operating-procedures-a-complete-guide/

Appendix C: Integration of Nursing's Metaparadigm Concepts

Concepts	Description	Application
Person	The person: "a valued person in and of him- or herself to be cared for, respected, nurtured, understood and assisted; in general a philosophical view of a person as a fully functional integrated self. The human is viewed as greater than, and different from, the sum of his or her parts" (Watson, 1988, p. 14).	The patient, viewed as nursing's metaparadigm's person, will be incorporated by prioritizing patient safety and satisfaction at the forefront of the draft SOPs development.
Environment	The environment: "Environment is the umbrella concept in the Nightingale theory of nursing. It was her contention that the environment could be altered in such a manner as to improve conditions so that the natural laws would allow healing to occur" (Selanders, 2010, p. 84).	Nursing's metaparadigm concept, environment, will consider the patient's home environment and how it affects nursing services provided.
Health	Health: life experiences of a human being are dynamic, which "implies continuous adjustment to stressors in the internal and external environment through optimum use of resources to achieve maximum potential for daily living" (King, 1981, p. 5).	Regarding the concept of health, patients' quality of life (health) may be impacted should home-based infliximab therapy be poorly executed. Coordination of services and communication among the interdisciplinary team are perceived to positively impact the person's overall quality of life.
Nursing	Nursing: the application of science in nursing practice to care for and improve patient outcomes, serving as the theoretical structure to guide patient care through integration and application of the patient, environment, and RN relationship (Creasia et al., 2007).	The concept nursing will include nursing practices and implications for practice: this aspect refers to " how to" perform nursing-related actions during care provision.

Appendix D: Evidence Rating Method

Strength of the Body of Evidence

Evidence Rating	Evidence Description
I	May include: Systematic reviews, meta-analyses, and guidelines based on randomized control trials (RCTs). May also include at least 3 well-designed RCTs.
II	May include: 2 well-designed RCTs, 2 or more well-designed non-randomized clinical trials, or systematic reviews of varying prospective study designs.
III	May include: 1 well-designed RCT, several well-designed non-randomized clinical trials, or multiple studies with quasi-experimental designs based on the same question.
IV	May include: 1 well-designed quasi-experimental study, case control, cohort, correlational, time series study, systematic review of qualitative and descriptive studies, narrative literature review, or psychometric study. May include 1 well-designed laboratory study.
V	May include: Journal article, clinical/professional book, report, guideline based on consensus, descriptive study, quality improvement project (well-designed), accrediting bodies and professional organizations recommendations, or manufacturer recommendations and guidelines. This also includes a standard of practice that is generally accepted but does not have a research basis (e.g. patient identification)
Committee (Stakeholder) Agreement	Review of literature: Discussion and committee (stakeholder) agreement for a recommendation. May be used when there is insufficient or low-quality evidence to draw upon a conclusion.

Note. Chart adapted from Gorski, L. A., Hadaway, L., Hagle, M. E., Broadhurst, D., Clare, S., Kleidon, T., Meyer, B. M., Nickel, B., Rowley, S., Sharpe, E., & Alexander, M. (2021). Infusion therapy standards of practice, 8th Edition. *Journal of Infusion Nursing*, *44*(1S), S1–S224. https://doi:10.1097/NAN.0000000000000396

Appendix E: Categorizing Strength in the Recommendations Method

Determining Strong or Conditional Recommendations

Recommendations are formulated as *strong* or *conditional* by considering the *strength of the body of evidence* and the following key criteria adapted from the Registered RNs' Association of Ontario (2019c, p. 11):

- Benefits versus harms and balancing the two.
- Values and preference in terms of patient satisfaction.
- Potential impact on access to care and health equity.

A *strong* recommendation: confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention).

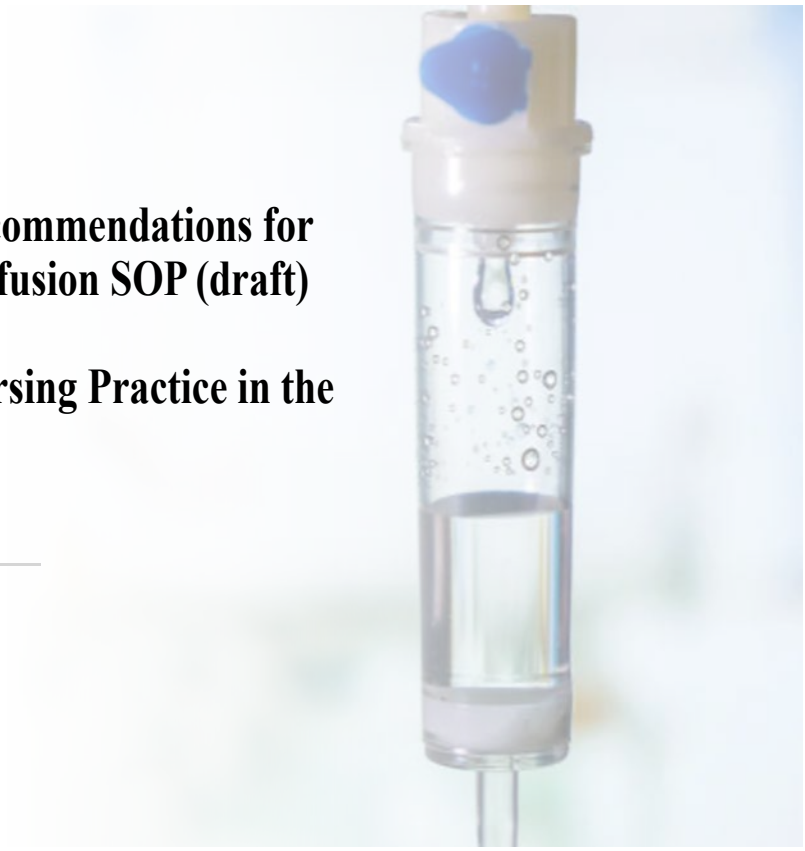
- A strong recommendation implies that most or all individuals will be best served by the recommended course of action.

A *conditional* recommendation: the desirable effects probably outweigh the undesirable effects (weak recommendation for an intervention) or undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists.

- A conditional recommendation implies that not all individuals will be best served by the recommended course of action. There is a need to consider more carefully than usual the individual patient's circumstances, preferences, and values.

Note: Definitions adapted from the GRADE Working Group. (2013). *Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach.* (para 40-41). https://gdt.gradepro.org/app/handbook/handbook.html

Appendix F: Evidence-Based Recommendations for Draft SOP



Evidence-Based Recommendations for Infliximab Home Infusion SOP (draft)

Implications for Nursing Practice in the INVIVA Network

Developed by Nicole A. Gibson
University of Lethbridge
Master of Nursing Degree
May 2021

Table of Contents

Strength of the Body of Evidence

Content is categorized according to strength (evidence rating) and displayed explicitly.

Evidence Rating	Evidence Description
I	May include: Systematic reviews, meta-analyses, and guidelines based on randomized control trials (RCTs). May also include at least 3 well-designed RCTs.
II	May include: 2 well-designed RCTs, 2 or more well-designed non-randomized clinical trials, or systematic reviews of varying prospective study designs.
III	May include: 1 well-designed RCT, several well-designed non-randomized clinical trials, or multiple studies with quasi-experimental designs based on the same question.
IV	May include: 1 well-designed quasi-experimental study, case control, cohort, correlational, time series study study, systematic review of qualitative and descriptive studies, narrative literature review, or psychometric study. May include 1 well-designed laboratory study.
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Committee (Stakeholder) Agreement	Review of literature: Discussion and committee (stakeholder) agreement for a recommendation. May be used when there is insufficient or low-quality evidence to draw upon a conclusion.

Chart adapted from Gorski, L. A., Hadaway, L., Hagle, M. E., Broadhurst, D., Clare, S., Kleidon, T., Meyer, B. M., Nickel, B., Rowley, S., Sharpe, E., & Alexander, M. (2021). Infusion therapy standards of practice, 8th Edition. *Journal of Infusion Nursing*, *44*(1S), S1–S224. https://doi:10.1097/NAN.0000000000000396

Categorizing Strength in the Recommendations

Recommendations are formulated as ***strong*** or ***conditional*** by considering the strength of the body of evidence and the following key criteria adapted from RNAO (2019c, p. 11).

- Benefits versus harms and balancing the two.
- Values and preference in terms of patient satisfaction.
- Potential impact on access to care and health equity.

A ***strong*** recommendation: confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention).
A strong recommendation implies that most or all individuals will be best served by the recommended course of action.

A ***conditional*** recommendation: the desirable effects probably outweigh the undesirable effects (weak recommendation for an intervention) or undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists.
A conditional recommendation implies that not all individuals will be best served by the recommended course of action. There is a need to consider more carefully than usual the individual patient's circumstances, preferences, and values.

Definitions adapted from the GRADE Working Group. (2013). *Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach.* (para 40-41). https://gdt.gradepro.org/app/handbook/handbook.html

4

Document Definitions

Definitions specific to this document include:

1. Acute Infusion Reactions: a hypersensitivity reaction to infliximab that develops shortly after initiation of or during administration of infliximab. Acute infusion reactions are classified as mild, moderate and severe based on patient symptoms.

1.a. **Mild**: transient pruritis, mild flushing, myalgia, fever.
1.b. **Moderate**: pruritis, mild flushing, myalgia, fever, chest tightness, urticaria, hypo/hypertension, palpitations, diaphoresis, headache, dizziness.
1.c. **Severe**: bronchospasm, angioedema, hypo/hypertension.
1.d. **Anaphylaxis**: severe, rapid-onset, systemic, and potentially life-threatening hypersensitivity (allergic) reaction managed with Epinephrine as first line treatment.

2. Asymptomatic Disease: a patient who does not experience negative symptoms from their disease.

3. Central Venous Access Device (CVAD): a short- or long-term intravenous catheter inserted into a centrally located vein with the tip residing in the lower one third of the superior vena cava (SVC).

4. Disease Stability: a patient's disease is stable over time such as in absence of disease symptoms, is in disease remission, has absence of disease flair ups, and/or has good disease self-management (e.g., follows suggested diet and exercise plan to lessen disease symptoms, adheres to medication regimen, participate in routine follow-up appointments with disease specialist).

5. Infliximab: a drug classified as a monoclonal antibody; a tumor necrosis factor inhibitor (anti-TNF) drug; also referred to as immunotherapy, and it is indicated for both children and adults for treatment of various autoimmune diseases (e.g., Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis). Infliximab is given Infliximab is both a biologic therapy (REMICADE®) and biosimilar therapy (INFLECTRA® and RENFLEXIS®). Infliximab is commonly given intravenously (into a vein) through an infusion, usually inside the hand or arm administered by a qualified healthcare provider, such as a registered nurse.

6. Interdisciplinary Team: includes all healthcare team members internal and external to the organization involved in each patient's care, as appropriate. May include health care team members internal to the organization (patient care coordinator, nursing staff, pharmacist, nursing manager, national nurse educator) and external healthcare team members external to the organization (prescribing physician and office staff, auto-immune disease nurse specialist, nurse practitioner, advanced vascular access team, and program support team).

7. Loss of Response: where a patient does not respond to initial (induction) infliximab therapy and/or where a patient does not respond to infliximab therapy during on-going (maintenance) treatment. A common way to measure response to infliximab therapy is through therapeutic drug monitoring (measurement of medication in blood levels) and presence or absence of anti-infliximab antibodies.

5

Knowledge, Skill, Experience, and Competency

All home infusion nurses must have acquired and demonstrated knowledge, skill, experience, and competency regarding adult and/or pediatric intravenous **infliximab** infusion care. (Evidence Rating IV)

Implications for Nursing Practice:

Home infusion nurses who provide individualized care to adults and children receiving home-based infliximab intravenous treatment must have appropriate nursing knowledge, experience, and training in order to deliver quality, safe, ethical, and excellent patient care. Nurses providing care to children age 12 years or younger must have previous pediatric nursing knowledge and experience. Patient and family satisfaction and quality of care delivered is high when healthcare providers are skilled and competent in home-based infliximab services.

The research supports a ***strong*** recommendation.

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This Recommendation and the Implications for Nursing Practice are Based on these Practice Standards and Principles:

Canadian Harmonized Home Care Principle: Accountable Care.
Infusion Therapy Standards of Practice: 1.5; 2.1; 3.1; 5.1; 5.2; 5.3; 5.4.
Community Health Nurses of Canada Standards of Practice: Professional Responsibility and Accountability.

Evidence used to Inform the Recommendation and Implications for Nursing Practice: (Knowledge, Skill, Experience, and Competency)

Barfield, E., Sockolow, R., Hoffenberg, E., Saeed, S., Kim, S., Siebold, L., Picoraro, J., Moses, J., Dykes, D., Grossman, A., Wahbeh, G., & Park, K. T. (2018). Assuring quality for non-hospital-based biologic Infusions in pediatric inflammatory bowel disease: A clinical report from the north American society for pediatric gastroenterology, hepatology and nutrition. *Journal of Pediatric Gastroenterology and Nutrition*, *66*(4), 680–686. https://doi.org/10.1097/MPG.0000000000001890

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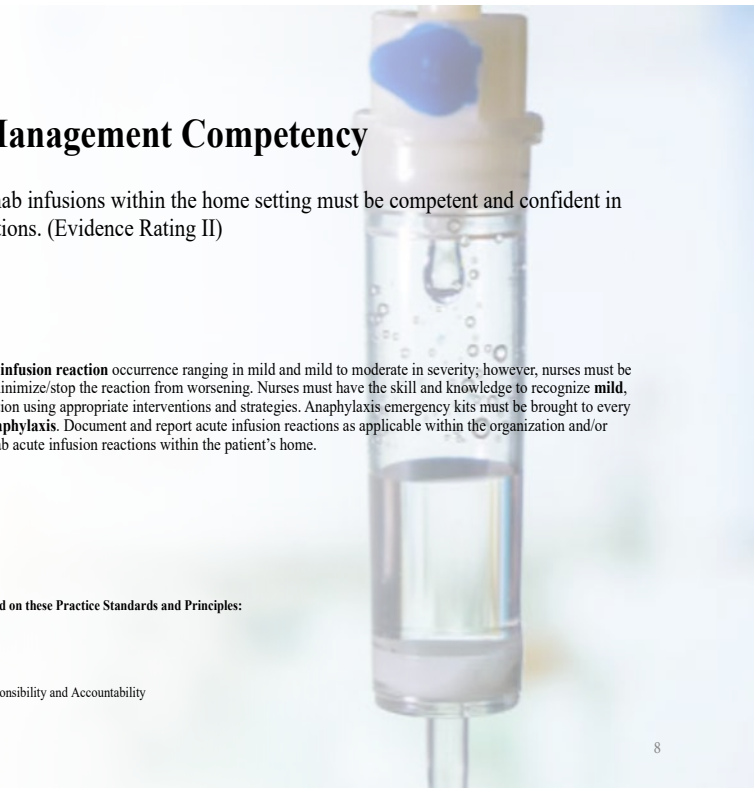
Schultz, T. J., Thomas, A., Georgiou, P., Cusack, L., Juaton, M., Simon, L., Naidoo, K., Webb, K., Karnon, J., & Ravindran, J. (2019). Developing a model of care for home infusions of natalizumab for people with multiple sclerosis. *Journal of Infusion Nursing*, *42*(6), 289–296. https://doi.org/10.1097/NAN.0000000000000343



Acute Infusion Reaction Management Competency

Home infusion nurses who administer infliximab infusions within the home setting must be competent and confident in recognizing and managing acute infusion reactions. (Evidence Rating II)

Implications for Nursing Practice:

Infliximab home-based infusions are safe with low rates of **acute infusion reaction** occurrence ranging in mild and mild to moderate in severity; however, nurses must be able to recognize and respond promptly to infusion reactions to minimize/stop the reaction from worsening. Nurses must have the skill and knowledge to recognize **mild**, **moderate**, and **severe** infusion reactions and respond to the situation using appropriate interventions and strategies. Anaphylaxis emergency kits must be brought to every patient appointment to rapidly reverse signs and symptoms of **anaphylaxis**. Document and report acute infusion reactions as applicable within the organization and/or manufacturer's methods of communicating and tracking infliximab acute infusion reactions within the patient's home.

The research supports a ***strong*** recommendation.

This Recommendation and the Implications for Nursing Practice are Based on these Practice Standards and Principles:

Canadian Harmonized Home Care Principle: Evidence-Informed Care.
Infusion Therapy Standards of Practice: 3.1; 7.2; 11.1; 61.1; 61.2.
Community Health Nurses of Canada Standards of Practice: Professional Responsibility and Accountability

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Evidence used to Inform the Recommendation and Implications for Nursing Practice: (Acute Infusion Reactions)

Barfield, E., Sockolow, R., Hoffenberg, E., Saeed, S., Kim, S., Siebold, L., Picoraro, J., Moses, J., Dykes, D., Grossman, A., Wahbeh, G., & Park, K. T. (2018). Assuring quality for non-hospital-based biologic Infusions in pediatric inflammatory bowel disease: A clinical report from the north American society for pediatric gastroenterology, hepatology and nutrition. *Journal of Pediatric Gastroenterology and Nutrition*, *66*(4), 680–686. https://doi.org/10.1097/MPG.0000000000001890

Bohra, A., Rizvi, Q.-A.-A., Keung, C. Y. Y., Vasudevan, A., & van Langenberg, D. R. (2020). Transitioning patients with inflammatory bowel disease from hospital-based to rapid home-based infliximab: A stepwise, safety and patient-orientated process towards sustainability. *World Journal of Gastroenterology*, *26*(36), 5437–5449. https://doi.org/10.3748/wjg.v26.i36.5437

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Choquette, D., Faraawi, R., Chow, A., Rodrigues, J., Bensen, W. J., & Nantel, F. (2015). Incidence and management of infusion reactions to infliximab in a prospective real-world community registry. *Journal of Rheumatology*, *42*(7), 1105–1111. https://doi.org/10.3899/jrheum.140538

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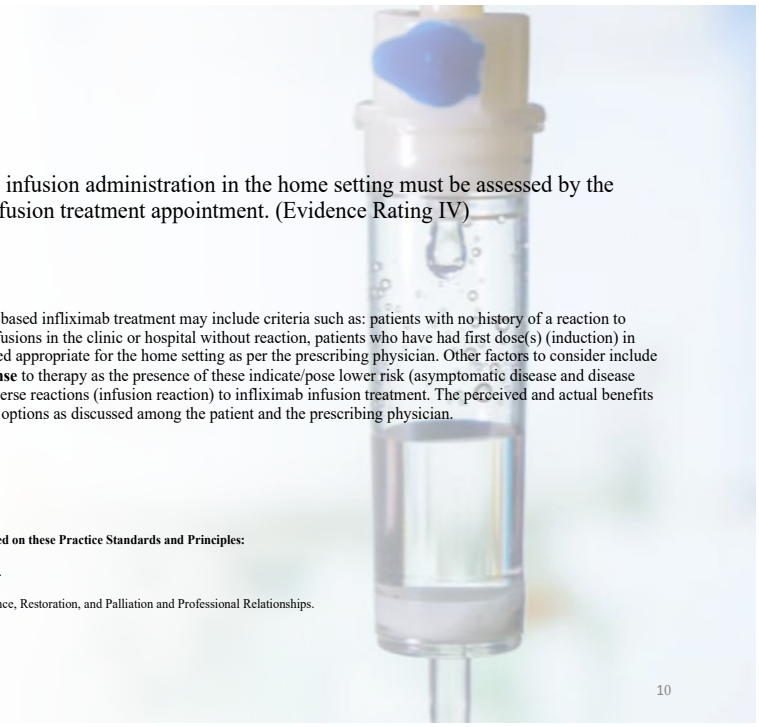
9



Patient Selection

Appropriate patient selection for infliximab infusion administration in the home setting must be assessed by the home infusion nurse prior to every home infusion treatment appointment. (Evidence Rating IV)

Implications for Nursing Practice:

Appropriate patient selection to identify readiness for home-based infliximab treatment may include criteria such as: patients with no history of a reaction to infliximab, patients who have had a minimum number of infusions in the clinic or hospital without reaction, patients who have had first dose(s) (induction) in clinic or hospital prior to the home setting, or patients deemed appropriate for the home setting as per the prescribing physician. Other factors to consider include **asymptomatic disease**, **disease stability**, and **loss of response** to therapy as the presence of these indicate/pose lower risk (asymptomatic disease and disease stability) and higher risk (loss of response to therapy) of adverse reactions (infusion reaction) to infliximab infusion treatment. The perceived and actual benefits of infliximab home infusion treatment outweigh alternative options as discussed among the patient and the prescribing physician.

The research supports a ***conditional*** recommendation.

This Recommendation and the Implications for Nursing Practice are Based on these Practice Standards and Principles:

Canadian Harmonized Home Care Principle: Sustainable and Accessible Care.
Infusion Therapy Standards of Practice: 1.4; 61.2.
Community Health Nurses of Canada Standards of Practice: Health Maintenance, Restoration, and Palliation and Professional Relationships.

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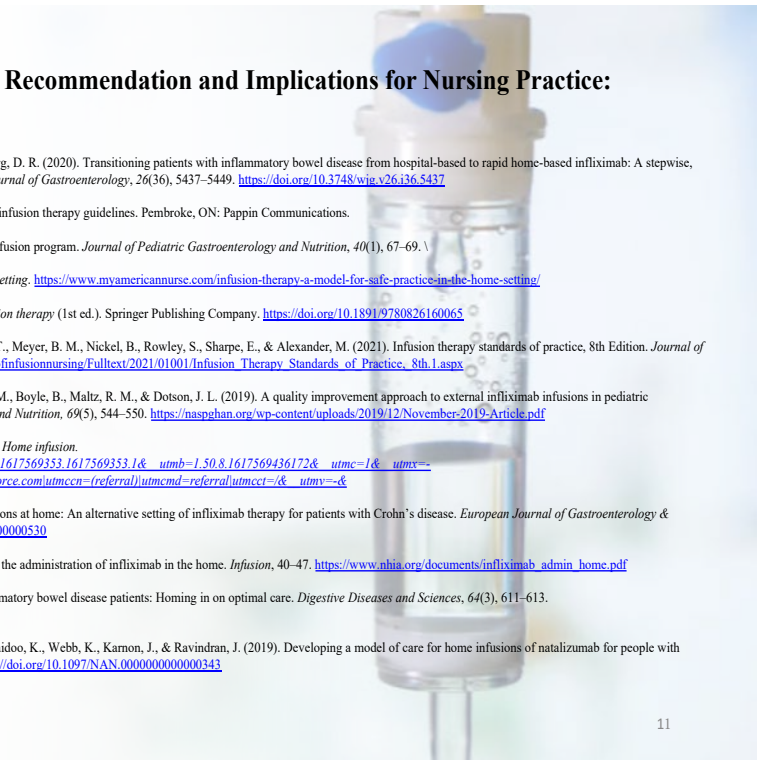

Evidence used to Inform the Recommendation and Implications for Nursing Practice: (Patient Selection)

Bohra, A., Rizvi, Q.-A.-A., Keung, C. Y. Y., Vasudevan, A., & van Langenberg, D. R. (2020). Transitioning patients with inflammatory bowel disease from hospital-based to rapid home-based infliximab: A stepwise, safety and patient-orientated process towards sustainability. *World Journal of Gastroenterology*, *26*(36), 5437–5449. https://doi.org/10.3748/wjg.v26.i36.5437

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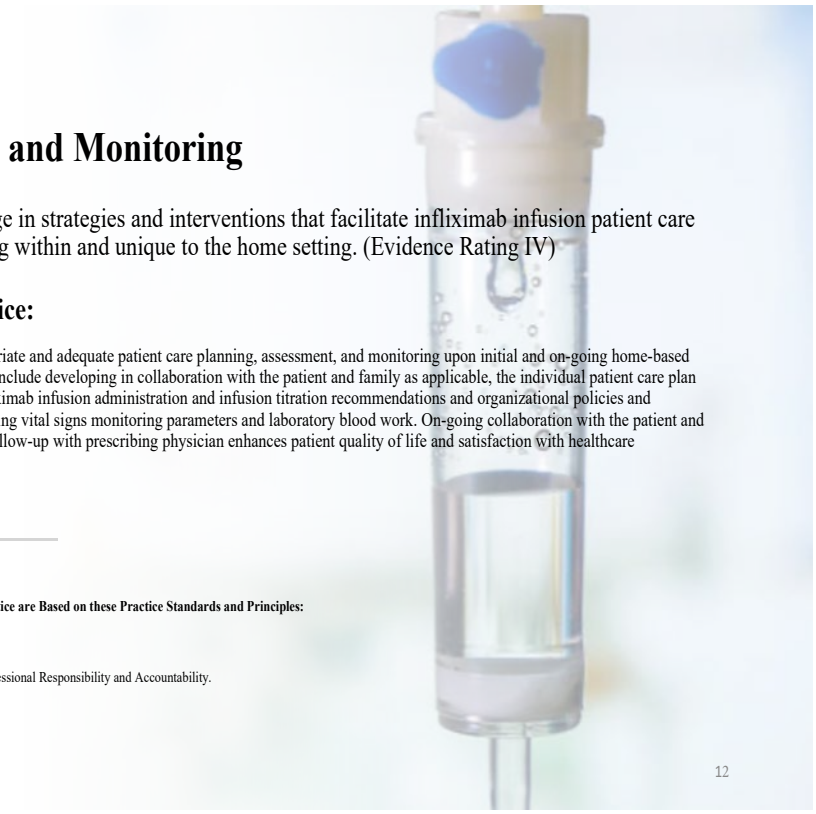

Planning, Assessment, and Monitoring

The home infusion nurse must engage in strategies and interventions that facilitate infliximab infusion patient care planning, assessment, and monitoring within and unique to the home setting. (Evidence Rating IV)

Implications for Nursing Practice:

The home infusion nurse is responsible for appropriate and adequate patient care planning, assessment, and monitoring upon initial and on-going home-based infliximab infusions. Strategies and interventions include developing in collaboration with the patient and family as applicable, the individual patient care plan assessment, pre-screening practices, utilizing infliximab infusion administration and infusion titration recommendations and organizational policies and procedures, appropriate patient monitoring, including vital signs monitoring parameters and laboratory blood work. On-going collaboration with the patient and patient care coordinator to facilitate patient care follow-up with prescribing physician enhances patient quality of life and satisfaction with healthcare services/nursing care.

The research supports a ***strong*** recommendation.

This Recommendation and the Implications for Nursing Practice are Based on these Practice Standards and Principles:

Canadian Harmonized Home Care Principle: Accessible Care.
Infusion Therapy Standards of Practice: 1.4; 2.1; 61.1; 61.2.
Community Health Nurses of Canada Standards of Practice: Professional Responsibility and Accountability.

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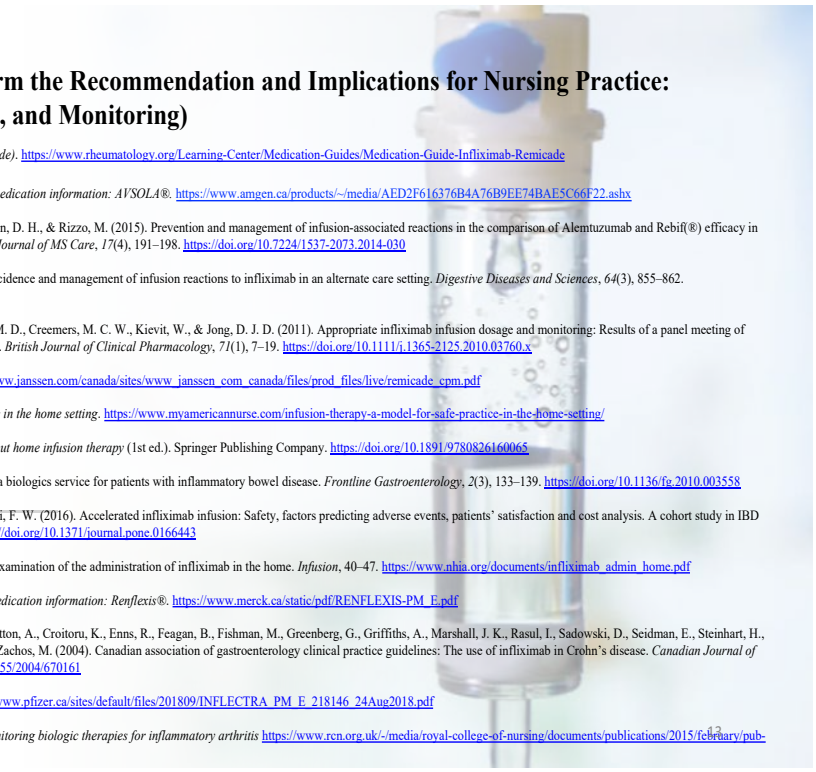

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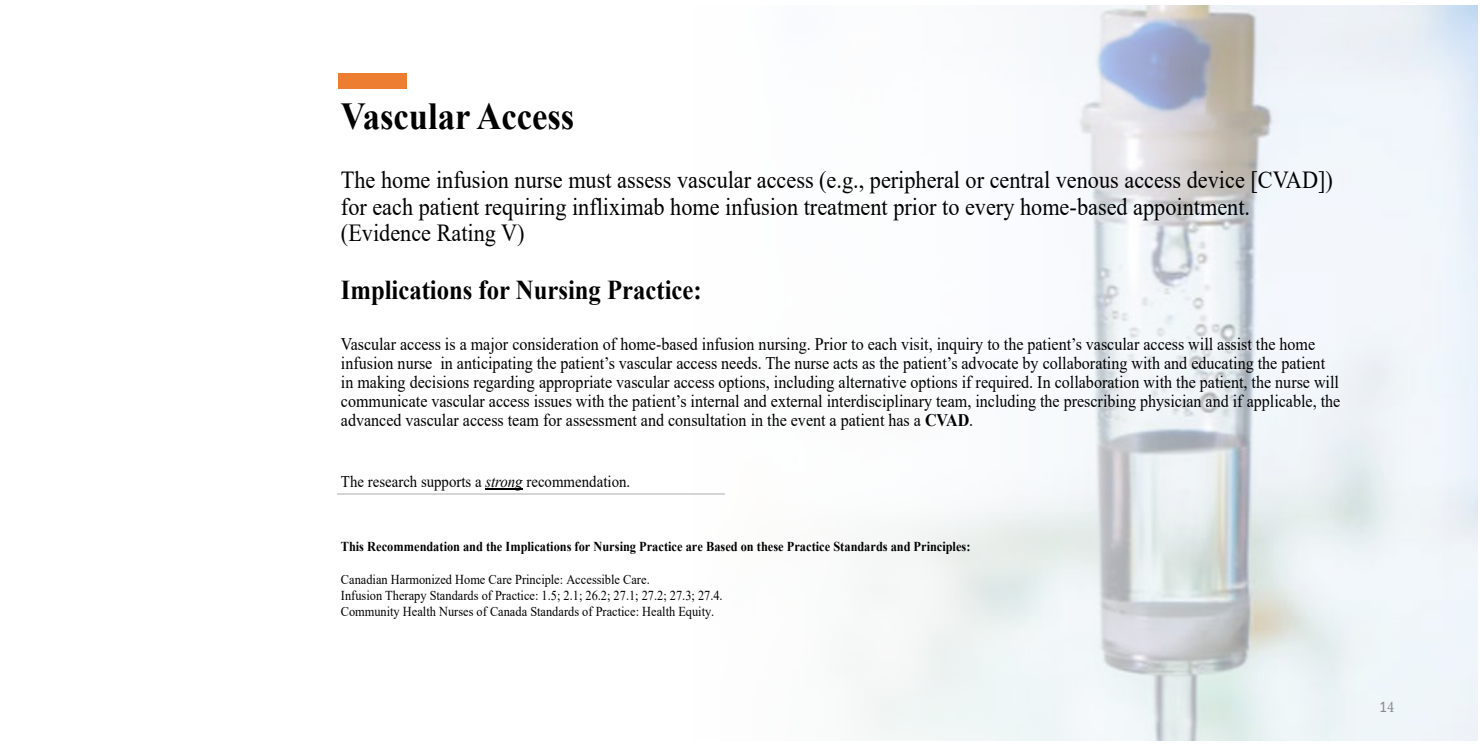

Vascular Access

The home infusion nurse must assess vascular access (e.g., peripheral or central venous access device [CVAD]) for each patient requiring infliximab home infusion treatment prior to every home-based appointment. (Evidence Rating V)

Implications for Nursing Practice:

Vascular access is a major consideration of home-based infusion nursing. Prior to each visit, inquiry to the patient's vascular access will assist the home infusion nurse in anticipating the patient's vascular access needs. The nurse acts as the patient's advocate by collaborating with and educating the patient in making decisions regarding appropriate vascular access options, including alternative options if required. In collaboration with the patient, the nurse will communicate vascular access issues with the patient's internal and external interdisciplinary team, including the prescribing physician and if applicable, the advanced vascular access team for assessment and consultation in the event a patient has a **CVAD**.

The research supports a ***strong*** recommendation.

This Recommendation and the Implications for Nursing Practice are Based on these Practice Standards and Principles:

Canadian Harmonized Home Care Principle: Accessible Care.
Infusion Therapy Standards of Practice: 1.5; 2.1; 26.2; 27.1; 27.2; 27.3; 27.4.
Community Health Nurses of Canada Standards of Practice: Health Equity.

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Evidence used to Inform the Recommendation and Implications for Nursing Practice: (Vascular Access)

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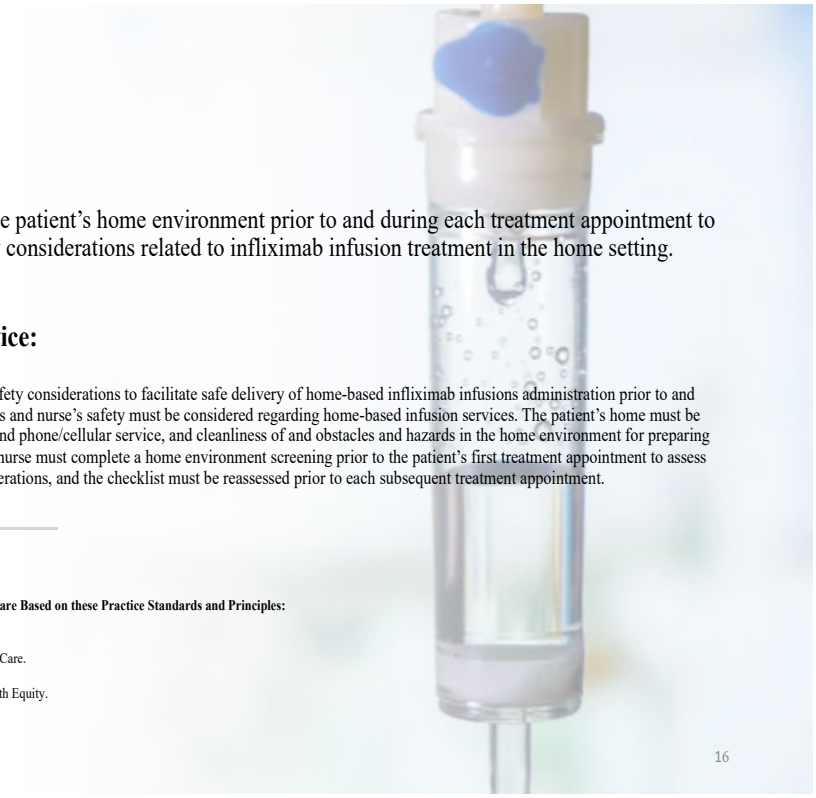


Home Environment

The home infusion nurse assesses the patient's home environment prior to and during each treatment appointment to determine patient and nursing safety considerations related to infliximab infusion treatment in the home setting. (Evidence Rating IV)

Implications for Nursing Practice:

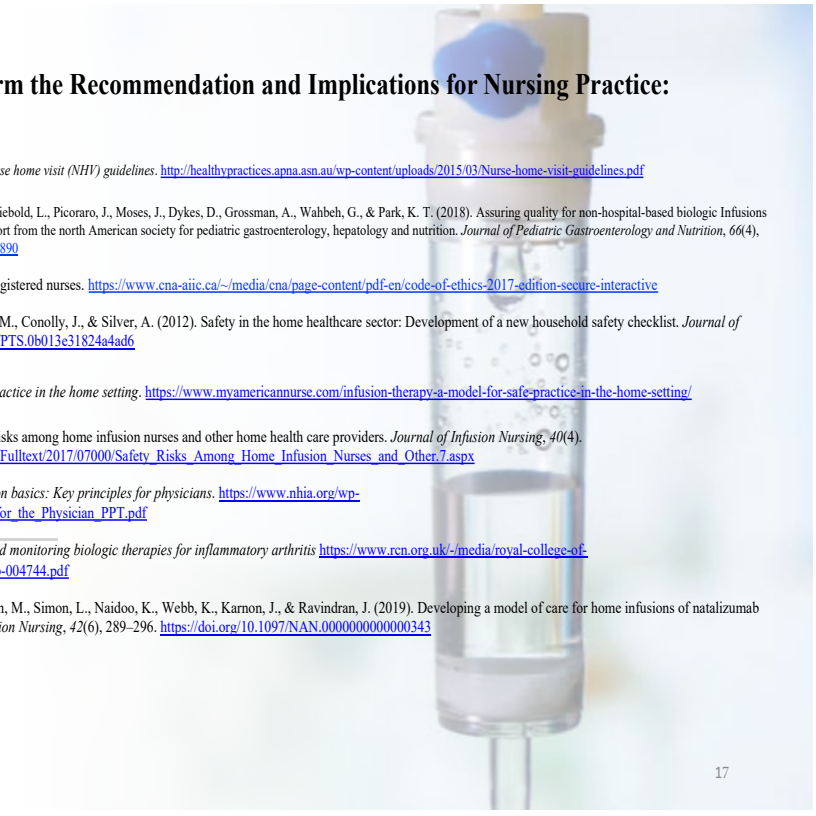
The patient's home environment is assessed for safety considerations to facilitate safe delivery of home-based infliximab infusions administration prior to and during each patient appointment. Both the patient's and nurse's safety must be considered regarding home-based infusion services. The patient's home must be assessed for: accessibility to emergency services and phone/cellular service, and cleanliness of and obstacles and hazards in the home environment for preparing and administering infliximab. The home infusion nurse must complete a home environment screening prior to the patient's first treatment appointment to assess for the above-mentioned safety and hazard considerations, and the checklist must be reassessed prior to each subsequent treatment appointment.

The research supports a ***strong*** recommendation.

This Recommendation and Implications for Nursing Practice are Based on these Practice Standards and Principles:

Canadian Harmonized Home Care Principle: Evidence-Informed Care.
Infusion Therapy Standards of Practice: 61.1.
Community Health Nurses of Canada Standards of Practice: Health Equity.

16



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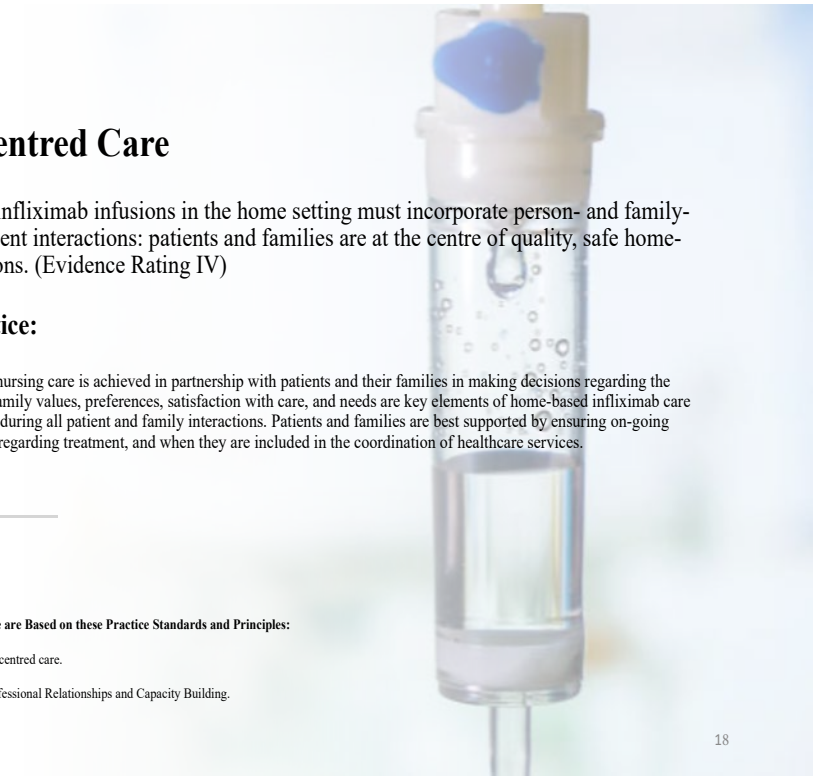

Person and Family-Centred Care

Home infusion nurses who provide infliximab infusions in the home setting must incorporate person- and family-centred care practices during all patient interactions: patients and families are at the centre of quality, safe home-based care that guide clinical decisions. (Evidence Rating IV)

Implications for Nursing Practice:

Quality and safe home-based infliximab infusion nursing care is achieved in partnership with patients and their families in making decisions regarding the patient's care and services provided. Patient and family values, preferences, satisfaction with care, and needs are key elements of home-based infliximab care provision that nurses must take into consideration during all patient and family interactions. Patients and families are best supported by ensuring on-going collaboration, respect, communication, education regarding treatment, and when they are included in the coordination of healthcare services.

The research supports a ***strong*** recommendation.

This Recommendation and Implications for Nursing Practice are Based on these Practice Standards and Principles:

Canadian Harmonized Home Care Principle: Person and family-centred care.
Infusion Therapy Standards of Practice: 7.1.
Community Health Nurses of Canada Standards of Practice: Professional Relationships and Capacity Building.

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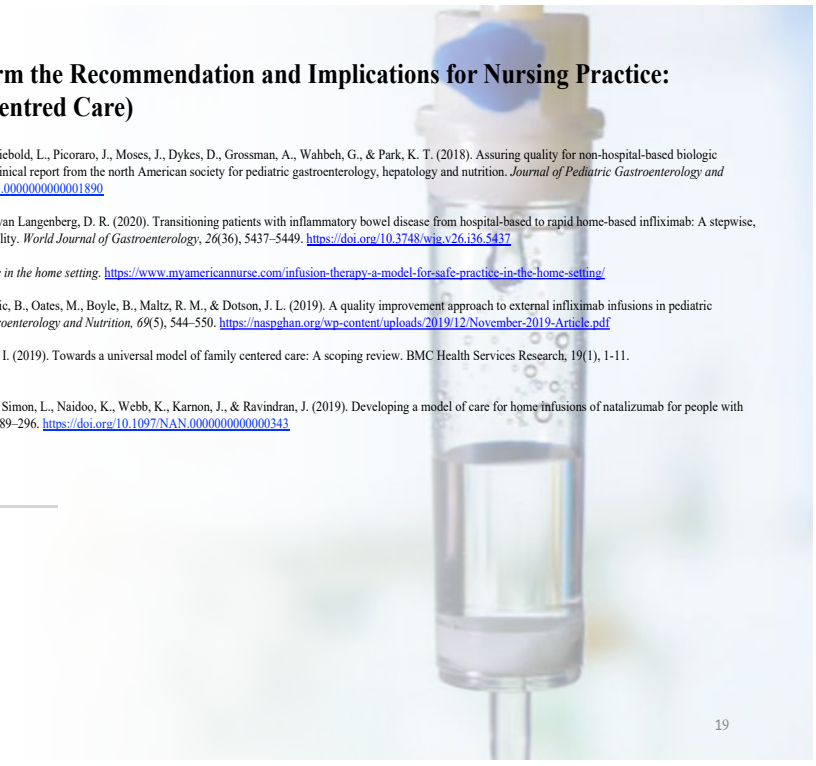

Evidence used to Inform the Recommendation and Implications for Nursing Practice: (Person and Family-Centred Care)

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Interdisciplinary Team Collaboration and Communication

The home infusion nurse communicates and collaborates with patients, patients' families, and members of the internal and external **interdisciplinary team**, as needed, to promote patient safety, quality of care, patient satisfaction, and that efficiency and coordination of home-based services are maintained for all infliximab home infusion treatment appointments. (Evidence Rating IV)

Implications for Nursing Practice:

In addition to using a person- and family-centred care approach, the nurse collaborates with the patient's entire healthcare team (interdisciplinary team) to facilitate quality driven patient care. Poor communication between nurse and members of the interdisciplinary team internal and external to the organization (e.g., prescribing physician, pharmacist, patient care coordinator, auto-immune disease nurse specialist, etc.) may result in suboptimal patient care outcomes, such as discontinuation of treatment and poor quality of life.

The research supports a ***strong*** recommendation.

This Recommendation and Implications for Nursing Practice are Based on these Practice Standards and Principles:

Canadian Harmonized Home Care Principle: Integrated Care.
Infusion Therapy Standards of Practice: 1.4; 4.1.
Community Health Nurses of Canada Standards of Practice: Professional Responsibility and Accountability.

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Evidence used to Inform the Recommendation and Implications for Nursing Practice: (Interdisciplinary Team Collaboration and Communication)

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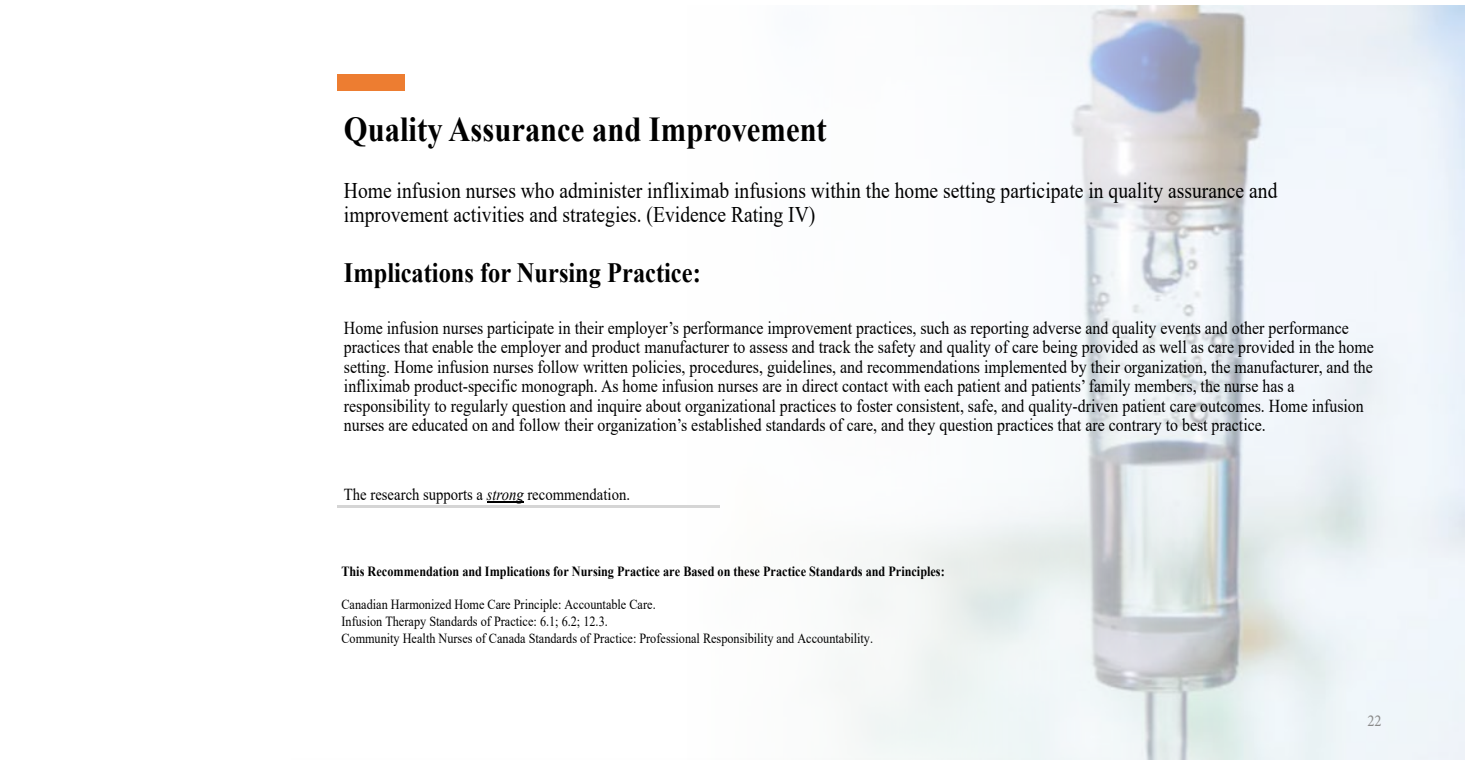

Quality Assurance and Improvement

Home infusion nurses who administer infliximab infusions within the home setting participate in quality assurance and improvement activities and strategies. (Evidence Rating IV)

Implications for Nursing Practice:

Home infusion nurses participate in their employer's performance improvement practices, such as reporting adverse and quality events and other performance practices that enable the employer and product manufacturer to assess and track the safety and quality of care being provided as well as care provided in the home setting. Home infusion nurses follow written policies, procedures, guidelines, and recommendations implemented by their organization, the manufacturer, and the infliximab product-specific monograph. As home infusion nurses are in direct contact with each patient and patients' family members, the nurse has a responsibility to regularly question and inquire about organizational practices to foster consistent, safe, and quality-driven patient care outcomes. Home infusion nurses are educated on and follow their organization's established standards of care, and they question practices that are contrary to best practice.

The research supports a ***strong*** recommendation.

This Recommendation and Implications for Nursing Practice are Based on these Practice Standards and Principles:

Canadian Harmonized Home Care Principle: Accountable Care.
Infusion Therapy Standards of Practice: 6.1; 6.2; 12.3.
Community Health Nurses of Canada Standards of Practice: Professional Responsibility and Accountability.

22

Evidence used to Inform the Recommendation and Implications for Nursing Practice: (Quality Assurance and Improvement)

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Appendix G: The Five Phases of the RNAO's BPG Cycle

- Identification of the topic/problem, purpose/scope, and intended audience of the draft SOP. Review of SOP development processes and templates. Define key stakeholder and SME reviewers.
- Systematic literature search: evaluation and synthesis of best evidence in the form of recommendations for best practice informed the content development of the draft SOP. Based on nursing's metaparadigm concepts; building on the Infusion Therapy and Canadian Community Health Nursing Standards of Practice and the Canadian Home Care Association Principles; and existing organizational policy. Decision to use the INVIVA SOP template. Feedback from key stakeholder to improve version one of the draft SOP prior to pretesting and revised into version two.
- Pretesting the draft SOP was conducted prior to any formal use by the organization. Pretested via a SME review appraisal process. Two phase formative feedback: individual feedback questionnaire and informal interview. Version two draft SOP is evaluated using feedback and input received from stakeholders via individual questionnaire and group discussion informal interview using SWOT Analysis.
- Review of SME reviewers' feedback from the aggregated results from the individual feedback questionnaires and the data retrieved from the SWOT analysis used during the informal interview. Feedback used to improve and revise the draft SOP prior to its final version.
- Version three and finalized draft SOP. Project targeted dissemination: Infusion Nurses Society and National Home Infusion Association conferences, 2022. The draft SOP may be formalized and used by the organization.

Note. Adapted from RNAO (2019a)

Appendix H: Feedback Questionnaire

Draft Standard Operating Procedure (SOP):
Infliximab Administration in the Home Setting

My name is Nicole Gibson, and I am a Master of Nursing (MN) student at the University of Lethbridge. The draft SOP you are about to review is part of my MN project. Please review the draft SOP and use this individual feedback questionnaire to provide feedback. ***Your voice will be used to improve the draft SOP.*** The time needed to review the draft SOP and provide feedback will take approximately one hour. Please email your completed individual feedback questionnaire to me by June 7, 2021. Please reach out to me if you have any questions (nicole.gibson@inviva.ca).

Please indicate strongly disagree, somewhat disagree, somewhat agree, or strongly agree and provide answers to the questions below or indicate if no additional information is needed:

		Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree
1.	Overall, there is a balance between the benefits and harms that are addressed in the draft SOP.	1	2	3	4
2.	Overall, the draft SOP considers patients' values, preferences, and satisfaction with care.	1	2	3	4
3.	The draft SOP fosters patient access to infliximab infusion care in the home setting.	1	2	3	4
4.	The draft SOP supports safe infliximab infusion treatment practices in the home setting.	1	2	3	4
5.	The draft SOP supports quality driven infliximab infusion treatment practices in the home setting.	1	2	3	4

6. Under section 3.0 Referenced Documents and Definitions and Abbreviations:

   Are there any documents listed that are not appropriate or excessive? Are there any documents missing?

   Are there any definitions or abbreviations missing? Are the definitions easy to understand?

7. Under section 4.0 Procedure:

   Are there any steps that are unnecessary? What additional steps and/or actions are needed to enhance the draft SOP?

8.	It is evident that the draft SOP is evidence informed.	1	2	3	4
9.	Overall, the draft SOP is easy to read.	1	2	3	4
10.	Overall, the draft SOP has a logical flow in accordance with other INVIVA documents.	1	2	3	4

11. How satisfied are you with the draft SOP?

o Not at all o Slightly-almost o More than o Exceptionally

Please use this space to explain your responses or provide additional feedback to improve the draft SOP.

Appendix I: SWOT Analysis

Strengths:	Weaknesses:
1. The draft Sop is detailed and relevant. 2. Comprehensive patient care is evident. 3. The patient perspective is included throughout. 4. Easy to understand. 5. The evidence-based recommendations document and rationales enhanced understanding of the content.	Draft SOP: 1. Too many definitions; tailer to your "audience." 2. Document is long. 3. Condense the rationales. 4. Check for overall redundancy and language used. Content: 1. Nursing home safety considerations for the "day of." 2. Extra supplies unclear 3. Anaphylaxis supplies 4. Step 4.3 focuses too heavily on the patient and family. 5. Nursing documentation is not made explicit
Opportunities for further improvements:	Threats (barriers) to approval and implementation:
1. Enhance nursing communication (documentation) paragraph regarding RN, PCC, and PSP caseworker collaboration (used in the absence of direct communication with the physician). 2. Increase clarification of information and steps when an appointment is not completed the "day of." 3. Amend referenced documents section formatting in the INVIVA SOP template to improve readability. 4. Amend the anaphylaxis section. 5. Make the extra supplies section explicit. 6. Condense sections to reduce the overall page length possibly.	1. INVIVA home RNs do not generally have direct contact with the prescribing physician; however, it is stated in the SOP. INVIVA home RNs use documentation as their main form of communication with the prescribing physician and the patient support program. 2. Stated in the draft SOP, the RN is to review relevant bloodwork results such as the TDM and antibodies level results. However, the organization does not currently provide RNs with access to relevant bloodwork results such as the therapeutic drug monitoring (TDM) and antibody level results. 3. A standardized supplies list is stated in the draft SOP; however, the organization does not currently have one developed.

Note. Chart adapted from Gürel and Tat (2017)

Appendix J: Description of Changes Made to the SOP: Third and Final Draft

1. Documents listing put in table form.
2. Shortened, deleted and separated abbreviations and definitions.
3. Patient and family changed to patient and family/caregiver. Added to abbreviations section.
4. Enhanced instructions for nursing communication by making it more explicit within the draft SOP.
5. Refocused step 4.3 and removed patient and family/caregiver focus.
6. Amended step 4.4.
7. Condensed the rationales within the document.
8. Removed anaphylaxis supplies as these are listed in the Medical Directives
9. Recommended the use of a standardized supplies checklist to draw attention to the reader so that it is made more explicit. *The organization may want to create a formalized standardized supplies checklist developed into a FORM listed within the document. A standardized supplies checklist labeled FORM "X" is listed within the document because INVIVA currently does not have one.
10. Added information regarding "day of" patient appointments and when appointments are not completed. Also, a notation was added regarding nursing home safety considerations for the "day of" the patient appointment.
11. Checked for overall redundancy.
12. Overall page length reduced to 8 from 11.

Appendix K: Infliximab Infusion Administration in the Home Setting SOP (Draft)

STANDARD OPERATING PROCEDURE

Title: Infliximab Infusion Administration in the Home Setting

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to outline the procedures for administering infliximab infusions in patients' home setting for the INVIVA Network.

2.0 SCOPE

This SOP applies to all nurses who are employed and who provide care to patients enrolled in the Home Nursing program within the INVIVA Network.

3.0 REFERENCED DOCUMENTS

FORM/OTHER	POLICY	REFERENCE	SOP	WORK INSTRUCTION
FORM-INF-NURS-0003 – Patient Care Plan **FORM**-INF-OPS-0016 – Offsite Nursing Visit Safety Assessment **FORM** "X" – Standardized Supplies Checklist Janssen Standard Infusion Protocol Molecule-specific Product Monograph	**POL**-INF-0001 – Visitors in the INVIVA Network **POL**-INF-0002 – Patient Safety **POL**-INF-0003 – Cardio-Pulmonary Resuscitation Certification **POL**-INF-0004 – Good Documentation Practices **POL**-INF-0011 – Infection Prevention and Control **POL**-INF-0020 – Home Nursing Safety Consideration **POL**-INF-0021 – Pediatric Patients in the INVIVA Network	**REF**-INF-0008 – Emergency Contact List **REF**-INF-0027 – Management of Mild to Moderate Reactions - Home Nursing **REF**-INF-0028 – Management of Anaphylaxis - Home Nursing	**SOP**-INF-BUS-0007 – Patient Experience Management **SOP**-INF-CLIN-0001 – Handling and Disposal of Biomedical and Pharmaceutical Waste **SOP**-INF-NURS-0002 – Home Nursing Equipment and Environmental Cleaning **SOP**-INF-OPS-0004 – Adverse Event and Product Quality Complaint Reporting for Nurses	**WI**-INF-CLIN-0003 – Hazardous Medication Cleaning and Spill Management **WI**-INF-IXB-0001 – Infliximab Infusion and Injection Administration **WI**-INF-NURS-0006 – Peripheral Intravenous Insertion **WI**-INF-NURS-0007 – Administration of Medications in the INVIVA Network **WI**-INF-NURS-0008 – Accessing a Central Venous Access Device WI-INFNURS-0013 – Falls Prevention in the INVIVA Network

ABBREVIATIONS		
AIRs: Acute Infusion Reactions	**BLS:** Basic Life Support	**IXB:** Infliximab
AE: Adverse Event	**CVAD:** Central Venous Access Device	**PCC:** Patient Care Coordinator
AID: Auto Immune Disease	**F/C:** Family/Caregiver	**PQCs:** Product Quality Complaints
		TDM: Therapeutic Drug Monitoring

DEFINITIONS

- **Anaphylaxis:** severe, rapid-onset, systemic, multiorgan involvement, and potentially life-threatening hypersensitivity (allergic) reaction managed with Epinephrine as first line treatment.
- **Asymptomatic Disease:** a patient who does not experience negative symptoms from their disease.
- **Delayed Infusion Reactions:** a range of symptoms associated with hypersensitivity reaction occurring 24 hours to 14 days post IXB infusion administration.
- **Disease Stability:** a patient's disease is stable over time such as in absence of disease symptoms, is in disease remission, has absence of disease flair ups, and/or has good disease self-management (e.g., follows suggested diet and exercise plan to lessen disease symptoms, adheres to medication regimen, participate in routine follow-up appointments with disease specialist).
- **IXB:** a drug classified as a monoclonal antibody; a tumor necrosis factor inhibitor (anti-TNF) drug; also referred to as immunotherapy, and it is indicated for both children and adults for treatment of various autoimmune diseases (e.g., Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis). IXB is given IXB is both a biologic therapy (REMICADE®) and biosimilar therapy (AVSOLA®, INFLECTRA®, and RENFLEXIS®). IXB is commonly given intravenously (into a vein) through an infusion, usually inside the hand or arm administered by a qualified healthcare provider, such as a registered nurse.
- **Interdisciplinary Team:** includes all healthcare team members internal and external to the organization involved in each patient's care, as appropriate. May include health care team members internal to the organization (patient care coordinator, nursing staff, pharmacist, nursing manager, national nurse educator) and external healthcare team members external to the organization (prescribing physician and office staff, auto-immune disease nurse specialist, nurse practitioner, patient support program, advanced vascular access team).
- **INVIVA Patient Scheduling Application:** is an online software information center accessible to INVIVA staff. Includes patient and INVIVA specific data used to facilitate patient care and streamline communication and collaborative processes.
- **Loss of Response:** where a patient does not respond to initial (induction) IXB therapy and/or where a patient does not respond to IXB therapy during on-going (maintenance) treatment. A common way to measure response to IXB therapy is through TDM and presence or absence of anti-IXB antibodies.
- **TDM:** the measurement of medication in blood level to maintain clinically appropriate serum drug concentrations in the blood. TDM is ordered by the prescribing physician or nurse practitioner and may be performed at regular intervals or on a as needed basis.

4.0 PROCEDURE

STEP	ACTION [Responsibility]
4.1	**Nurse Competency [Nurse]** • The nurse administering IXB infusions in the home setting must have: – Experience administering IXB infusions in alternate care areas (e.g., INVIVA clinic or hospital). – Completed all required trainings (e.g. INVIVA new-hire onboarding, molecule-specific curricula, mandatory policies and procedures, etc.). – Competency and proficiency in peripheral IV and CVAD insertion, initiation, and management. Refer to WI-INF-NURS-0006 and WI-INF-NURS-0008. – Nurses providing care to children age 12 years or younger must have previous pediatric nursing knowledge and experience. – BLS certification at minimum, but both ACLS and PALS are recommended. Refer to POL-INF-0003. ***Rationale:*** *Nurse skill and competency are vital for maintaining patient safety in home IXB infusion treatment that contributes to high-quality patient care. Patient and F/C satisfaction with care and overall quality of care received is high when healthcare providers are skilled and competent in IXB infusion home-based care.*
4.2	**Appropriate Patient Selection [Nurse]** • The nurse must assess for appropriate patient selection for IXB home infusion treatment to identify readiness for treatment in the home setting. Use the following criteria to assist in determining/confirming: – Patients with no history of AIRs to IXB; – Patients who have had induction doses in a clinic/hospital setting before transferring to the home environment; – Patients who have had a minimum number of infusions in the clinic or hospital without reaction; and – Patients deemed appropriate for the home setting as per the prescribing physician. • Other factors to consider: – The perceived and actual benefits of IXB home infusion treatment outweigh alternative options as discussed among the patient and the prescribing physician; – Asymptomatic disease and disease stability; and – Loss of response to therapy. ***Rationale:*** *Asymptomatic disease and disease stability may pose lower risk and loss of response to therapy linked to antibody development may pose higher risk of an adverse reaction (infusion reaction) to IXB infusion treatment.* • Advocate in the best interest of patients by considering appropriate patient selection and patients' values, needs, preferences, and satisfaction with care to foster patient safety and quality care. • Communicate concerns related to appropriate patient selection to the PCC, nurse manager, and prescribing physician. • AE reporting and documentation in patients' charts regarding appropriate patient selection concerns and suboptimal patient outcomes as indicated.
4.3	**Communication and Collaboration [Nurse]** Communicate and collaborate with members of the interdisciplinary team as applicable regarding safety, quality of care, patient satisfaction, the efficiency of treatment, and coordination of home-based services. Communicate and collaborate with the PCC regarding first and subsequent patient appointments.

	• Communication among the nurse and interdisciplinary team includes: direct contact with the prescribing physician, detailed nursing documentation, and e-mail and verbal communication (e.g., telephone call). ***Rationale:*** *Poor communication between the nurse and members of the interdisciplinary healthcare team may result in suboptimal patient care outcomes, such as discontinuation of treatment, dissatisfaction with care, and poor quality of life. Refer to SOP-INF-BUS-0007.*
4.4	**Person and Family-Centred Care Approach [Nurse]** • Patient and F/C values, needs, preferences, and satisfaction with care are key elements of IXB home infusion treatment that the nurse must consider. • Use patient care nursing strategies and interventions applicable to the patient's age and developmental needs. Collaborate with the patient's F/C to improve and tailor nursing care provided. If applicable, refer to POL-INF-0021. • Consider patient care needs and preferences when scheduling, coordinating, and planning initial and on-going IXB home infusion treatment appointments. Collaborate with the patient and F/C in scheduling appointments mutually agreed upon by the patient, the patient's F/C, and the nurse. • Complete the initial patient assessment in consultation with the patient, and F/C as applicable. Document patient health history and special considerations upon initial and on-going IXB infusion treatment appointments. Refer to FORM-INF-0003. Include the patient and the patient's F/C in making decisions regarding care. • Listen to and address patient and F/C concerns regarding aspects of care, intervene and assist where appropriate and within the nurse's scope of practice, or refer the patient and F/C to the right healthcare provider for further assistance. **NOTE:** The home environment differs from the clinic setting and F/C members are deemed authorized persons of care in the patient's home unless otherwise deemed unauthorized by the patient. ***Rationale:*** *Quality and safe IXB home infusion care is achieved in partnership with patients and their families/caregivers in making care decisions and when they are included in the coordination of healthcare services.*
4.5	**Patient Care Planning, Assessment, and Monitoring [Nurse]** • The nurse is responsible for appropriate and adequate patient care planning, assessment, and monitoring upon initial and on-going IXB home infusion treatment appointments. • Review FORM-INF-NURS-0003 prior to and at each patient appointment and update the patient care plan as patient care needs change. – Assess vascular access (e.g., peripheral or CVAD) for each patient requiring IXB home infusion treatment before every home infusion treatment appointment. – Act as the patient's advocate by collaborating with and educating the patient in making decisions regarding appropriate vascular access options, including alternative options if required. – Communicate vascular access issues with the patient's interdisciplinary team, including the prescribing physician and, if applicable, an advanced Vascular access team for assessment and consultation. – Educate the patient on strategies that promote successful IV initiation. ***Rationale:*** *Inquiry to the patient's vascular access will assist in anticipating the patient's vascular access needs before and during each patient appointment. Communicate vascular access issues to improve patient care and home IV treatment experience and prevent and manage CVAD complications and adverse events.* – The nurse must familiarize her/himself with each patient home environment by performing a scan of the home setting and remove clutter and identified hazards (e.g., patients' pets) that may pose a risk to patient and nurse safety during IXB infusion preparation, administration, and patient monitoring.

NOTE: A patient's pet deemed a service animal shall remain with the patient as needed and as preferred by the patient. Refer to POL-INF-0001.

- Determine, in collaboration with the patient and F/C, the most appropriate preparation and treatment area (e.g., cleanliness, comfort, and safety). Consider how comorbidities, including physical ailments and mental health, and other medications impact the patient's mobility level and care received in the home setting. Perform a falls risk assessment to assess and manage patient mobility issues. Refer to FORM-INF-NURS-0003. Report patient mobility concerns to the home nursing manager should care received in the home setting appear unsafe.

- Assess the patient's home environment prior to and during each treatment appointment to determine patient and nursing safety considerations related to IXB administration in the home setting. At any point when the nurse feels unsafe, terminate the appointment and report concerns to the home nursing manager and PCC. Refer to FORM-INF-OPS-0016 and POL-INF-0020.

- Should an appointment not be completed the day of the appointment due to patient or nurse safety or quality considerations, document and report the situation, and if possible, reschedule the patient's appointment. Possible reasons for not completing the patient appointment the day of the appointment 9e.g., safety considerations related to the patient's home, the patient failing the pre-infusion screening checklist, inadequate access to supplies and medications to safely complete and perform patient care).

- Gather and prepare adequate supplies (e.g., applicable PPE and IXB infusion administration supplies) needed to successfully complete each patient's home infusion appointment. Bring additional supplies to account for possible contamination of sterile supplies. Refer to INVIVA's standardized supplies checklist FORM "X" so that adequate and appropriate supplies are accessible during IXB home infusion treatment.

Rationale: *The home must be accessible to emergency services and phone/cellular service. The cleanliness of and obstacles and hazards in the home setting must be addressed when preparing and administering IXB infusion treatment in the home setting to prevent adverse outcomes related to home infusion medication administration.*

- Clarify concerns with members of the interdisciplinary team, such as the PCC, prescribing physician, pharmacist, and AID Nurse Specialist, as needed to accept IXB home infusion patient referrals.

- Follow, review, download to an electronic device, or print off as needed the most current version of this SOP and WI-INF-IXB-0001, confirm printed copies are the most current.

- Must have quick/easy access to AIR flowcharts and protocols during each patient appointment.
Rationale: *Patient care is jeopardized in the absence of standardized nursing and organizational practices regarding IXB home infusion treatments.*

- Assess appropriateness of patient selection for IXB home infusion treatment. Review relevant laboratory bloodwork results (e.g. last TDM with antibody screen laboratory test). See step 4.2.
Rationale: *Nurses must consider patients' IXB trough and antibody level bloodwork results as these are metrics that nurses can use to assess for potential infusion reaction risk to the patient. Consider changes in dosage regimen (e.g., dose increases in the presence of IXB antibody development are linked to a high risk of infusion-related reactions).*

- Bring appropriate supplies to safely prepare, administer, and manage infusion medications in the home setting, as well as proper cleaning supplies to disinfect home nursing equipment. Refer to SOP-INF-CLIN-0001, SOP-INF-0002, and WI-INF-CLIN-0003.
- Prepare/administer IXB infusion treatment patient care by referring to WI-INF-IXB-0001 and molecule-specific product monograph. Adhere to INVIVA and manufacturer IXB patient care practices (e.g., individual patient care planning, pre-screening practices, IXB infusion administration and infusion titration guidelines, vital signs monitoring, nursing documentation and

	organizational policy and procedure). **NOTE:** All applicable INVIVA and manufacturer forms required for infusion administration of IXB are listed within WI-INF-IXB-0001 and accessible to the nurse on the INVIVA Patient Scheduling Application. • Educate the patient by referring to the product monograph's consumer/patient medication information section, including signs and symptoms of acute and delayed infusion reactions. Provide effective patient and F/C education regarding IXB home infusion treatment. • Assess for on-going patient follow-up appointments with prescribing physician and laboratory bloodwork testing, such as routine bloodwork and TDM. Communicate concerns with the PCC regarding patient's follow-up appointments and bloodwork, such as prolonged intervals since the patient's last follow-up appointment and missed/late/prolonged/unknown bloodwork testing. ***Rationale:*** *Patients are best supported during IXB home infusion treatment by facilitating and ensuring follow-up physician appointments and completing routine and TDM laboratory bloodwork* as indicated.
4.6	**Recognizing and Managing IXB Acute Infusion Reactions [Nurse]** • Acquire and apply previous AIR knowledge, experience, and training related to IXB infusion administration such as previous experience gained in the clinic or hospital setting. • The nurse must be competent and confident in early recognition and respond to mild, moderate, and severe AIRs using appropriate interventions and strategies during IXB home infusion administration. Nurses are responsible for rapidly assessing and reassessing the severity of AIRs and prompt management and prevention of AIRs from worsening. Refer to REF-INF-0027 and REF-INF-0028 for descriptions of acute infusion reactions signs and symptoms. • Obtain knowledge regarding: INVIVA network emergency contacts (e.g., Home Nursing Manager). Refer to REF-INF-0008. INVIVA specific AIR references and flow charts. (e.g., *Janssen Standard Infusion Protocol*, REF-INF-0027, or REF-INF-0028). • Request additional training and support if nursing roles and responsibilities are unclear. • Anaphylaxis kits must be brought to every patient appointment. Anaphylaxis kits must be within the expiry range. Replace all expired medications and products. • Refer to and print the Medical Directives found in REF-INF-0027 and REF-INF-0028 and bring adequate supplies and medications to manage mild to moderate reactions and anaphylaxis. • AIRs must be documented as per INVIVA and manufacturers' requirements. Refer to WI-INF-IXB-0001 and SOP-INF-OPS-0004.
4.7	**Participate in Quality Assurance and Improvement Activities and Strategies [Nurse]** • Participate in INVIVA performance improvement practices such as manufacturer reporting AEs and PQCs. ***Rationale:*** *Reporting adverse and quality events helps assess and track the safety and quality of care provided in the patient's home and to comply with manufacturer guidelines regarding IXB administration. Refer to SOP-INF-QA-0005.* • Follow and adhere to quality and safety written policies, procedures, guidelines, and recommendations implemented by the INVIVA network to foster consistent, standardized day-to-day operational activities and nursing actions. • Nurses are educated on and follow INVIVA's established standard of care and question practices contrary to best practice as identified by the nurse. ***Rationale:*** *Nurses are in direct contact with each patient and F/C and must regularly question and inquire about INVIVA organizational practices to foster consistent, safe, and quality-driven patient care outcomes.*

5.0 REVISION HISTORY

Rev	Author	Description of Changes
00	Nicole Gibson	Release.

6.0 APPENDICES

NA

7.0 REFERENCES

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