Understanding the Determinants of Critical Care Nurses' Use of Sedation Interruptions for Adult Mechanically Ventilated Patients.

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A thesis submitted in partial fulfillment of the requirements for the Doctorate in Philosophy degree in Nursing.

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Dedicated to my growing family for their encouragement and support throughout this journey:
Peter, Isla, Margot, Mom, Papa, Wendy, and Sandy.

Preface

Approvals to Conduct the Research

This dissertation was initially approved by my thesis committee members (Appendix A), followed by ethical approval from the Research Ethics Boards for the study site and the University of Ottawa (Appendix B and C). Following a letter to the Vice-President Clinical and Chief Nursing Executive (Appendix D), the participating organization's Administration (e.g., corporate, and unit-level administration) approved obtaining access to medical records for auditing purposes and recruiting participants for interviews. Information about the study was then emailed to potential participants in the organization's critical care unit (Appendix E). Volunteers were sent additional information and provided written informed consent before participating (Appendix F).

Authors' Contribution to the Dissertation

This doctoral dissertation was conceived with my supervisor and co-supervisor in collaboration with the committee members. As the primary researcher, I was responsible for identifying the research focus and conducting all research activities. As such, I accept full responsibility for each manuscript and the dissertation. The main collaborators made up the thesis committee, which included Dr. J. E. Squires RN, Ph.D. (supervisor), Dr. I. D. Graham Ph.D. (co-supervisor), Dr. B. Vanderspank-Wright RN, Ph.D. (committee member) and Dr. D. Fergusson Ph.D. (committee member). All thesis committee members participated in the design of the individual research studies, the proposal's development, and the research plan's approval. All members also provided methodological and content expertise during the deployment of each study and offered significant contributions of intellectual insight. Each member of the thesis

committee provided feedback before approving the final version of each manuscript for publication. Additional researchers (Letitia Nadalin-Penno and Melissa Demery-Varin) participated in the investigation and analysis of specific studies further described in Table i.i. Authors' Contribution to Prepared Manuscript.

Table i.i Authors' Contribution to Prepared Manuscripts

Element	**Chapter 1**	**Chapter 2 Study 1 (Published)**	**Chapter 3 Study 2 (Peer-review revisions required)**	**Chapter 4 Study 3 (Accepted for publication)**	**Chapter 5**
Title	Introduction	A systematic review and critical appraisal of guidelines and their recommendations for sedation interruptions in adult mechanically ventilated patients	Preparing for an implementation study: lessons learned conducting an implementation needs assessment	A local critical care unit's perspective of the factors that influence the use of sedation interruptions: the results of a descriptive qualitative study using semi-structured interviews	Integrated Discussion
Conceptualization and design	NDG, JES, IDG, BV-W, DAF	NDG, JES, IDG, BV-W, DAF	NDG, JES, IDG, BV-W, DAF	NDG, JES, IDG, BV-W, DAF	NDG, JES, IDG, BV-W, DAF
Investigating	NDG	NDG, MDV, LNP	NDG, LNP	NDG, LNP	NDG
Data analysis and synthesis	NDG	NDG, LNP	NDG, LNP	NDG, NLP	NDG
Original draft preparation	NDG	NDG	NDG	NDG	NDG
Manuscript revisions and significant intellectual insights	NDG, JES, IDG, BV-W, DAF	NDG, JES, IDG, BV-W, DAF	NDG, JES, IDG, BV-W, DAF	NDG, JES, IDG, BV-W, DAF	NDG, JES, IDG, BV-W, DAF
Approval of final version of manuscript	NDG, JES, IDG, BV-W, DAF	NDG, JES, IDG, BV-W, DAF, LNP	NDG, JES, IDG, BV-W, DAF	NDG, JES, IDG, BV-W, DAF, LNP	NDG, JES, IDG, BV-W, DAF
Responsible for overall content	NDG	NDG	NDG	NDG	NDG

NDG – Nicole D. Graham; JES – Janet E. Squires; IDG – Ian D. Graham; BV-W – Brandi Vanderspank-Wright; DAF – Dean A. Fergusson; LNP – Letitia Nadalin Penno; MDV – Melissa Demery Varin.

Dissertation Abstract

Purpose. The purpose of this dissertation is to understand the state of recommended practice for sedation interruptions (SI) and to discover factors that hinder or facilitate critical care nurses' use in practice. To garner insight about why this evidence-informed intervention is not being used as recommended to improve mechanically ventilated patient outcomes.

Methods. A series of studies using a multi-methods design and guided by the Knowledge to Action Framework: study 1) a systematic review and critical appraisal examined the quality and reporting of all available guidelines and care bundles with recommendations related to SI for mechanically ventilated adults in critical care; study 2) a needs assessment included an environmental scan of the study site and gap-analysis using a retrospective chart audit to measure the nature and magnitude of the evidence-practice gap; study 3) a descriptive qualitative study used semi-structured theory-based interviews to deepen our understanding of the determinants that influence SI use in preparation for a future implementation study.

Findings. Study 1 included 11 guidelines and care bundles with 15 recommendations about SI. Deficiencies in the methodological quality of the current guidelines and care bundles may impact overall credibility and applicability of the recommendations, though SI is currently recommended best-practice. Study 2 confirmed the existence of an evidence-practice gap related to SI and affirmed the need to discover barriers and drivers to best practice implementation (study 3). We identified nine facilitators and 20 barriers to SI use by nurses. Facilitators were associated with the innovation (e.g., the importance of protocols) and the potential adopters (e.g., SI are specific to the nurse's role). The barriers were associated with the potential adopters (e.g., nurses' knowledge gaps and variable goals of SI) and the practice environment (e.g., lack of availability of extra staff and multidisciplinary rounds).

Conclusion. Before adequately implementing SI and evaluating uptake by nurses, we need to address modifications to existing guidelines and recommendations, even though SI is considered best practice. A theory-informed implementation study can further activate the use of SI for mechanically ventilated adults in critical care.

Acknowledgments

The findings from this thesis would not be possible without the willing participation of the medical records department staff and the sincerity of the nurses, respiratory therapists, pharmacist, and physician who participated in the qualitative study. Thank you to the unit Manager and Nurse Clinicians for your assistance with recruitment and for allowing me to attend multiple unit huddles to speak directly with the critical care team. I hope this research will help promote awareness of the complexities of sedation interruption implementation and lead to a more straightforward path toward innovative approaches for supporting nurses using this essential evidence-informed intervention. Also, thank you to Karine Allard and Stephanie Spencer for offering their critical care expertise in identifying the clinical relevance of the interview findings. Together, we endeavor to improve the outcomes of patients who endure a period of invasive mechanical ventilation.

I am grateful to my esteemed supervisor, Dr. Janet Squires and co-supervisor, Dr. Ian Graham for their infinite wisdom and support throughout my thesis journey, it was a privilege to receive your mentorship and learn from your excellence in implementation research. Dr. Squires, your commitment to research is truly inspiring and has motivated me during the more challenging moments in developing this thesis. Thank you for your guidance and for fostering my involvement in other research projects. These were undoubtedly invaluable learning opportunities contributing to my professional growth as an aspiring researcher. Dr. Graham, you inspired a greater depth of meaning to this thesis by illuminating the study findings' utility and practicality. I want to thank you for sharing your brilliance and your steady kindness with me through this journey. To my thesis committee members, Dr. Brandi Vanderspank-Wright, whose clinical expertise, and relations with the critical care community were essential to

this thesis, and to Dr. Dean Fergusson for your expertise on systematic reviews and commitment to this thesis, I thank you.

My sincere appreciation to my colleagues at work for cheering me on or offering wise-words of advice and encouragement, you know who you are. I am deeply grateful for the patience that my immediate and extended family has shared with me as I pursued this achievement. To Mom and Papa for their unwavering encouragement. Peter, Isla, and Marot thank you for understanding when I needed to work late into the evening or before sunrise to keep progressing, and always greeting me with open arms and a smile when I finished. I hope the dedication that I have shown in this pursuit inspires my daughters to achieve their goals.

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Abbreviations

AACTT	**A**ction, **A**ctor, **C**ontext, **T**arget, **T**ime Framework
ABCDEF bundle	**A**ssessment, prevention and management of pain; **B**oth spontaneous awakening and spontaneous breathing trials; **C**hoice of analgesia and sedation; **D**elirium assessment, prevention, and management; **E**arly mobility and exercise, and **F**amily engagement and empowerment
AGREE-II	**A**ppraisal of **G**uidelines for **Re**search & **E**valuation **II**
AGREE-REX	**A**ppraisal of **G**uidelines for **Re**search & **E**valuation: **R**ecommendation **Ex**cellence
CBG	**c**linical **p**ractice **g**uideline
CCU	**C**ritical **C**are **U**nit
CINAHL	**C**umulative **I**ndex to **N**ursing and **A**llied **H**ealth **L**iterature
CNO	**C**ollege of **N**urses of **O**ntario
COVID-19	coronavirus disease 2019
DSI	**d**aily **s**edation **i**nterruption
EMR	**e**lectronic **m**edical **r**ecord
EMS	**e**lectronic **m**edical **s**ystem
iKT	**I**ntegrated **K**nowledge **T**ranslation
K2A Framework	**K**nowledge-**to**-**A**ction Framework
REB	**R**esearch **E**thics **B**oard
SI	**s**edation **i**nterruptions
SOP	**s**tandard **o**perating **p**rocedure
SoR	**s**trength **o**f **r**ecommendation
SV	**s**edation **v**acation
LoE	**l**evel **o**f **e**vidence
MEDLINE	Ovid MEDLINE, National Library of Medicine
MRN	**m**edical **r**ecord **n**umber
NE	**n**eurological **e**valuation
OMRU	**O**ttawa **M**odel of **R**esearch **U**se
PHIPA	**P**ersonal **H**ealth **I**nformation **P**rotection **A**ct

PICAR framework	**P**opulation, clinical indication, and condition; **I**ntervention; **C**omparator, comparison, and content; **A**ttributes of eligible guidelines; and **R**ecommendation characteristics.
PRISMA	**P**referred **R**eporting **I**tems for **S**ystematic **R**eviews and **M**eta-**A**nalyses
PROSPERO	The International Prospective Register of Systematic Reviews
RCT	**R**andomized **C**ontrolled **T**rial
RN	**r**egistered **n**urse
RNAO	**R**egistered **N**urses **A**ssociation of **O**ntario
RT	**r**espiratory **t**herapist

Glossary

Critical care: The World Federation of Societies of Intensive and Critical Care Medicine have suggested that critical care is synonymous with intensive care and is, "a multidisciplinary and interprofessional specialty dedicated to the comprehensive management of patients having, or at risk of developing, acute, life-threatening organ dysfunction. [Critical care] uses an array of technologies that provide support for failing organ systems, particularly the lungs, cardiovascular system, and kidneys" (Kayambankadzanja, et al., 2022; Marshall et al., 2017).

Evidence-practice gap: Also known as the 'know-do gap', which is the difference between what is known from the best available research and what is practiced. It refers to the failure of clinicians to adopt evidence-informed practices that improve patient outcomes (Medical Dictionary, 2009).

Evidence-informed practice: The point of overlap whereby practitioner expertise, and client values are influenced by, rather than based-on, the best available evidence (Shlonsky & Mildon, 2014). Evidence-informed practice and evidence-based practice (terms often used interchangeably), espouses the interconnectedness of various factors and elements that enable a professional to use evidence in support of their clinical decision-making within complex environments (Kumah et al., 2022).

Environmental scan: A process designed to gather information to inform and direct organizational change. The external environment includes elements outside the boundaries of an organization (i.e., technological, sociocultural environments) and internal environment may include elements of an organization (i.e., budget, workforce capacity, leadership, policies, and standard operating procedures) (Charlton et al., 2021).

Implementation needs assessment: A systematic process for determining the size and nature of the gap between current and more desirable knowledge, skills, attitudes, behaviors, and outcomes. The strategies for needs assessment depend on the purpose of the assessment, the type of data and the available resources (Chapter 3.1 Kitson & Straus in Straus, Tetroe & Graham, 2013).

Sedation interruption: Interruption of continuous infusions of sedative and analgesic medications simultaneously daily until the patient is awake and can follow instructions or until they become uncomfortable or agitated and deemed to require the resumption of sedation (Kress et al., 2000).

Chapter 1 Introduction

1.1 Personal Impetus

I became interested in sedation interruptions (SI) for mechanically ventilated adults while working as a Registered Nurse in the critical care unit at a tertiary hospital in Northeastern Ontario. At that time, I observed inconsistent use of sedation interruptions amongst my nursing colleagues despite having an order to perform it from the attending physician. At this time, I had limited understanding of the field of research concerned with SI but felt motivated to understand why nurses were not using the intervention consistently. During my Master of Science in Nursing (MScN) degree, I started exploring the field of research related to SI and mechanically ventilated adults and understood that SI was an evidence-informed recommendation that was becoming more prevalent globally. Interestingly, the inconsistent use of SI was not unique to my critical care unit (CCU), it was, in fact an issue that had been identified across Canada and in other countries. Near the end of my MScN, I fast-tracked to the Doctorate in Philosophy (PhD) Nursing program to further understand SI use as an evidence-informed practice. Within the Ph.D. program, my preliminary literature exploration of SI and conceptualization of the thesis to better understand the determinants of SI use by nurses grew in depth and scope. I also gained considerable insight into implementation research after completing the Special Topics in Epidemiology: Turning Health Services, Public Health, and Policy into Action course in my MScN, which turned out to be instrumental in my understanding of knowledge mobilization theories and processes and had a profound influence on the development of this thesis. Later, the Systematic Review course in my PhD coursework also contributed significantly to the growth of this PhD thesis.

1.2 Background

Using the best available evidence is a fundamental aspect of providing high quality nursing and health care and clinical practice guidelines are an essential tool to inform evidence-informed practices (Harrison et al., 2013). Over two decades ago, as much as 30-40% of patients did not receive healthcare according to clinical evidence and up to 25% of care provided was unnecessary or even harmful (Grol, 2001; McGlynn et al., 2003). Back in 2009, participants of the Institute of Medicine Roundtable on Evidence-Based Medicine set a goal that, by the year 2020, 90 percent of clinical decisions would be supported by accurate, timely, and up-to-date clinical information and will reflect the best available evidence. Unfortunately, there is still work to be done to shift the evidence-practice gap pendulum to meet the goal set by the Institute of Medicine. A 2023 systematic review identified 174 Canadian studies from 2007 to 2021, representing 228 clinical practices and found large evidence-practice gaps, highlighting that 30% of the care received by people in Canada was considered inappropriate (Squires et al., 2022). Inappropriate health care for this review was defined as "inappropriate clinical practices that may harm the patient, or when health care risks exceed the benefits" (Squires et al., 2022, p.5).

Moreover, significant evidence-practice gaps continue to surface in healthcare across the globe (Falster et al., 2022). Despite having high-quality evidence available to practitioners and purposeful dissemination through clinical practice guidelines, many critically ill patients still do not receive recommended care, contributing to their morbidity, mortality, and higher costs of care (Kahn, 2017; Levy et al., 2018; Rhodes et al., 2017). Collaborative efforts are needed across sectors, including clinical, research and academic arenas, to improve the use of knowledge and evidence from guidelines. Sedation interruptions for mechanically ventilated adults cared for in the critical care environment is one important example of an evidence-practice gap that requires

a multi-pronged research approach to move closer to improved use by clinicians.

1.3 Review of the Literature

I reviewed the literature to identify the extant knowledge related to sedation interruptions. I conducted a preliminary CINAHL search of the literature using the term 'sedation interruption' to get a sense of the language used to describe the primary concept and focus of the thesis. This identified several papers and the keywords used to index them. The search terms sedation vacation, sedation interruption, daily sedation interruption, interruption of sedation and spontaneous awakening trial were combined using Boolean phrasing to generate similar and relevant results. The following databases accessed through the University of Ottawa's omni–Academic Search Tool: Medline (Ovid), CIHNAL, and EBM Reviews. Search terms, Boolean phrases, inclusion, and exclusion criteria are available in Appendix G. Other relevant literature was identified through an iterative process based on journal papers citations of key studies. Total articles returned was 328; reasons for exclusion include not relating to sedation interruptions, pediatric population, abstracts only, and randomized control trials published before 2015. The number of articles used to inform the review of the literature in this Chapter is 51.

1.3.1 Sedation Interruptions

Mechanically ventilated patients in critical care often require sedative medications that are run continuously to facilitate the work of the ventilator and effective breathing in addition to providing patient comfort, treating agitation, and patient tolerance of necessary lines and tubes (Vagionas et al., 2019). Sedative medications, such as Propofol, do not have analgesic properties, so they are often used in conjunction with opioids. High doses of analgesics can also have a sedative effect and are known to have potentially dangerous side effects (Stephens et al., 2017; Vagionas et al., 2019). In fact, early deep sedation during the first 48 hours of mechanical

ventilation was associated with decreased in-hospital and two-year follow-up survival (Balzer et al., 2015).

A common definition for deep sedation has not been well described in the literature, though deep sedation was described when 85% of documented Richmond Agitation Sedation Score during the study period equalled or were below -3 (Balzer et al., 2015). The definition of deep sedation aligns with that of light sedation, which is a RASS score (or its equivalent using other scales) of -2 to +1 (Devlin et al., 2018). Short-term complications that are linked to continuous sedation are microaspiration, gastrointestinal motility disturbances, microcirculatory and immunomodulatory effects (Kress & Hall, 2006; van Diepen et al., 2017). Yet, delirium is one of the most common sequalae associated with continuous infusions and other corresponding treatments delivered in the CCU (Mart et al., 2021). Duration of delirium is the major risk factor for cognitive impairment after critical illness also known as a form of Intensive Care Unit-acquired dementia that is especially debilitating (Sakusic et al., 2018) but also leads to posttraumatic stress disorders, and reduced quality of life (Pandharipande et al., 2014). Cognitive impairment was identified in 100% of survivors at hospital discharge and up to 56% of survivors several years after discharge from critical care (Davidson et al., 2015). Over the past 30 years, increased attention has been given to this field of research, specifically related to the impact that the ‘front-end’ of critical care imposes on the ‘back-end’ of survivorship.

A paradigm shift is emerging in the field of research concerned with care, management, and recovery of critically ill patients (Ely, 2017; Kress, 2013). Care and management primarily refer here to the front-end of care, which is the processes for re-establishing physiological homeostasis in a moment of crisis, and the end goal is discharge from the intensive care unit (ICU) (Ely, 2017). Recovery of a patient, or the back end of care, constitutes the rehabilitation

phase beyond the ICU doors (Ely, 2017). Critical care has moved from a biased focus on the front-end of care toward making deliberate efforts to reduce modifiable risk factors during the care and management phase of a critically ill patient. This can be achieved through the implementation of evidence-informed interventions aimed at optimizing the recovery phase.

Excessive sedation is one of the many modifiable factors that contribute to the manifestations of post-intensive care syndrome; this includes physical and cognitive impairments, mental health morbidities such as acute stress disorder, anxiety, depression, and post-traumatic stress disorder (Davidson et al., 2015; Elliott et al., 2014). Prevention and management of post-intensive care syndrome requires an integrated multidisciplinary approach with standardized care processes (Balas et al., 2022; Barnes-Daly et al., 2017). Early mobilization is one strategy to modify risk and is often precipitated by a cessation of the sedative infusion, which is also a strategy for reducing sedation exposure, and thereby minimizing the risk of over-sedation (Vagionas et al., 2019). Despite showing that early deep sedation in critically ill patients has a negative impact on health outcomes, up to two thirds of patients on mechanical ventilators are deeply sedated (Nassar et al., 2019; Stephens et al., 2017). Ventilator associated pneumonia, for example, is one of the most common infections in patients requiring invasive mechanical ventilation and is reported to affect 5-40% of patients receiving mechanical ventilation for more than 2 days with estimated mortality rate around 10% (Papazian et al., 2020). Ventilator-associated pneumonia has since expanded into a category belonging to a much broader definition, now termed ventilator associated events (CDC, 2014) which can affect about 5% of ventilated patients. Ventilator associated events are strongly associated with increased duration of mechanical ventilation and increased hospital mortality risk.

To address concerns about prolonged exposure and over-sedation from continuous

sedative infusions, evidence-informed guidelines recommend daily sedation interruptions (SI) together with other evidence-informed interventions as part of routine care for adults requiring invasive mechanical ventilation in critical care (Barr et al., 2013; DAS-Taskforce 2015 et al., 2015; Ouellette et al., 2017). Several National and International associations also endorse the use of SI, including the Society of Critical Care Medicine, German Society of Anaesthesiology and Intensive Care Medicine and the German Interdisciplinary Association for Intensive Care and Emergency Medicine. There are several terms used in the literature that refer to the same concept of interrupting sedative infusions, and these include: daily sedation interruption (DSI), daily interruption of sedation, sedation-vacation, spontaneous awakening trial (SAT) and sedation interruption (SI).

The term SI will be used going forward. An attempt was made for this thesis to create a comprehensive definition of SI from various sources of literature. SI is a short-term suspension, hold, discontinuation, cessation, or interruption of intravenous sedatives as well as analgesics if pain is judged as adequately treated. A patient is considered ‘awake’ or having ‘passed an SI’ if he or she is able to perform at least three of the following four actions, which could be assessed objectively: 1) open the eyes in response to a voice, 2) use the eyes to follow the investigator on request, 3) squeeze a hand on request, and stick out the tongue on request, 4) opened their eyes to verbal stimulus without meeting any failure criteria. Failure criteria are evidence of ventilator asynchrony or signs of potential or real threat to patient safety, or the patient has tolerated the SI for more than 4 hours despite not opening their eyes (Burry et al., 2014; Jackson et al., 2010; Kress et al., 2000; Kress & Hall, 2006).

1.3.2 Evidence for Sedation Interruptions

Evidence for SI has evolved over time since the landmark study by (Kress et al., 2000)

when they demonstrated a shorter duration of mechanical ventilation by 2.4 days (P = 0.004) and ICU length of stay by 3.5 days (P = 0.02) in sample of patients that received daily SI. The authors concluded that SI was a safe, practical, and cost-effective clinical intervention to include in the care of mechanically ventilated patients (Kress et al., 2000). Evidence for SI continued to grow over the years with several randomized control trials having been published and the popularity of SI in practice becoming more widespread (Girard T.D. et al., 2008; Mehta, 2012). The results of a meta-analysis of trials comparing daily SI with no interruption showed that SI was not associated with a significant reduction in duration of mechanical ventilation, length of stay in critical care, mortality, or an increase in self-extubation but was associated with a reduced risk of requiring tracheostomy (Augustes & Ho, 2011). Burry et al., (2014) published a prominent Cochrane Review highlighting the heterogeneity of the evidence available related to the benefits of SI by comparing daily SI with other sedation strategies, including sedation protocols, usual care, and targeting sedation to a sedation assessment scale in mechanically ventilated adults. Findings revealed a lack of strong evidence that daily SI reduced the duration of mechanical ventilation, length of stay in the critical care or hospital, death, or the amount of drug used (Burry et al., 2014). These findings were initially surprising, but the study also indicated a need for more homogeneous trials examining daily SI in combination with other evidence-informed interventions (for example spontaneous breathing trials) to better understand the impact on health outcomes.

Later Vagionas et al. (2019) conducted a literature review of three online databases to assess whether there was a correlation between daily SI and weaning from the mechanical ventilator. The review was inclusive of all randomized control trials from inception to 2019 resulting in nine studies that either compared SI with usual practice or with another sedation

protocol (Vagionas et al., 2019). The authors report an overall moderate quality of evidence due to study vulnerability to performance and detection bias (using the Cochrane Risk of Bias tool) underlying SI. The authors conclude, SI is safe and beneficial for the facilitation of weaning from the mechanical ventilator (Vagionas et al., 2019).

1.3.3 Recommendations for Sedation Interruptions in Guidelines

Recommendations for SI have been presented in numerous guidelines, one influential example is from the Pain, Analgesic and Delirium (PAD) guideline published by Barr and colleagues published in 2013. The goal of the guideline is to recommend best practices for managing pain, analgesics, and delirium to improve clinical outcomes in adults in the critical care unit (CCU) (Barr et al., 2013). Support for the recommendation was from five moderate quality unblinded randomized controlled trials involving 699 adult ICU patients (Anifantaki S et al., 2009; de Wit M & Devlin JW, 2008; Girard T.D. et al., 2008; Kress et al., 2000; Mehta S. et al., 2008).

Barr and Pandharipande (2013) identified a reduction of time spend on the ventilator (or increases ventilator-free days in survivors) and ICU length of stay as an outcome of SI use. Given the identified benefits of SI and supporting evidence, the panel recommendation was strongly ‘in favor’ of SI indicating that the benefits of the intervention significantly outweighed the risks (Barr et al., 2013). Since the influential PAD guideline, several guidelines and care bundles were published and are easily accessed in the extent literature (i.e., Devlin et al., 2018; Health Protection Scotland, 2012). The results of the systematic review and critical appraisal presented in Chapter 2 further elaborate on the available guidelines and care bundles related to SI.

1.3.4 Evidence for Sedation Interruptions in Care Bundles

Clinical protocols are often a stepwise, linear, concise narrative tool that are designed to be used at the bedside in practice by front-line healthcare providers as a guide for implementation of evidenced-informed care (Dols et al., 2017; Prasad et al., 2010). Evidence-informed care practices known to improve patient outcomes are often 'bundled' into protocols to facilitate a standard of care that can be used at the discretion of critical care physicians and nurses, referred to in this thesis as care bundles. Care bundles in critical care typically contain three to five evidence-informed clinical recommendations that when standardized in a protocol format have the capacity to facilitate use of best practices. A bundle is a structured way of improving the processes of care and facilitating a concise presentation of the delivery of evidence- informed interventions that when performed collectively and reliably, have shown to improve patient outcomes (Barnes-Daly et al., 2017).

A common example of a bundle is the awakening and breathing coordination, delirium monitoring/management, early exercise/mobility, and family engagement/empowerment (ABCDEF) which is an evidence-informed critical care management strategy for reducing sedation exposure, duration of mechanical ventilation, and critical care-acquired delirium and weakness (Balas et al., 2014). The ABCDEF bundle is applicable to every critically ill patient that is admitted to the ICU and is focused on symptom assessment, prevention, and management rather than disease processes (Pun et al., 2019). The goal of the ABCDEF bundle is to establish patient wakefulness to promote cognitive engagement and physical activity lending to a more holistic approach to patient care (Pun et al., 2019). Care bundles can take other forms as well. For example, the assess, prevent, and manage pain; both spontaneous awakening trials (SATs) and spontaneous breathing trials (SBTSs); choice of analgesia and sedation; delirium: assess, prevent, and manage; early mobility and exercise; and family engagement and empowerment

(ABCDEF) bundle. Regardless of the chosen nomenclature, the ABCDEF bundle is an integrated, interprofessional approach to optimizing CCU team performance and patient- and family centered outcomes (Barnes-Daly et al., 2018; Ely, 2017).

SI are an essential component of the ABCDEF bundle because of its utility in facilitating other aspects of the bundle, such as spontaneous breathing trials and early mobilization, in addition to individual known benefits described earlier. Together with other practices, for example allowing the patient to practice breathing without assistance from the ventilator (spontaneous breathing trials) and early mobilization, critically ill patients spend three more days breathing without assistance, experience less delirium, and are more likely to be mobilized during their CCU stay than patients that receive usual care (Balas et al., 2014). A large prospective study reported complete ABCDEF bundle performance to be associated with lower likelihood of seven outcomes: hospital death within 7 days (adjusted hazard ratio, 0.32; CI, 0.17–0.62), next-day mechanical ventilation (adjusted odds ratio [AOR], 0.28; CI, 0.22–0.36), coma (AOR, 0.35; CI, 0.22–0.56), delirium (AOR, 0.60; CI, 0.49–0.72), physical restraint use (AOR, 0.37; CI, 0.30–0.46), ICU readmission (AOR, 0.54; CI, 0.37–0.79), and discharge to a facility other than home (AOR, 0.64; CI, 0.51–0.80) (Pun et al., 2019). Another key finding from this study and others is a clear dose-response relationship between daily ABCDEF bundle performance and patient outcomes (Barnes-Daly et al., 2017; Pun et al., 2019).

1.3.5 Evidence-Practice Gap

The use of evidence in practice is important for the nursing profession because it improves patient outcomes and quality of care (Emparanza et al., 2015), it also helps the nurse build their own body of knowledge and minimize the gap between nursing education, research, and practice (Abu-Baker et al., 2021). Failure to implement evidence-informed practice can

threaten these benefits. Despite the well documented benefits and recommendations to include SI as a strategy for modifying risk in the CCU population, the reported and observed uptake of the intervention have been inconsistent and sub-optimal at best (Balas et al., 2014; Carrothers et al., 2013; Klompas M., 2015; Mehta S. et al., 2008; Smith, 2013). A reported 62% of respondents used daily SI in Australian and New Zealand intensive care units, and 23% used daily SI for more than 75% of patients (O'Connor et al., 2010). Of 212 hospital representatives in Michigan, including nurses, only 45% reported that more than three-quarters of their patients undergo SI every day (Miller et al., 2015). There are challenges with consistent use of SI by nurses, physicians, and other members of the critical care team over the years with only some improvement in adherence to recommendations for SI (Balas et al., 2014; Carrothers et al., 2013; Klompas, 2015; Mehta et al., 2008; Smith, 2013). Nurses have been attributed to implementing daily SI on average only one-fifth of the expected time (Smith, 2013). When SI is bundled within a protocol, similar gaps have been reported. A retrospective study based in Detroit, Michigan determined rates of 'compliance' with ventilator bundle components at a tertiary care hospital (Mendez et al., 2013). Use of SI, which was determined to be a predominantly nurse-driven function, was significantly higher ($P < .001$) for the ventilator bundle rounding team (62%) than for the regular CCU rounding team (54%) (Mendez et al., 2013). In both cases, adherence to SI had significant room for improvement.

1.3.6 Known Determinants to Sedation Interruption Use

Known factors that inhibit the use of SI are frequently reported as related to knowledge and attitude deficiencies (Balas et al., 2014; Carrothers et al., 2013). Time constraints, interdisciplinary coordination, and communication issues, staffing turnover, and lack of resources have also been reported as barriers (Balas et al., 2014; Carrothers et al., 2013).

Forty-four percent of attendees of the yearly Keystone Intensive Care Unit meeting in 2011 reported being afraid to perform sedation interruptions (Miller et al., 2013). Results from a Statewide survey discovered a lack of shared understanding for why SI is necessary and varied reasons for electing to implement a SI between members within a critical care team (Miller et al., 2013). Despite apparent consensus of the utility of SI in improving patient health outcomes, lack of shared understanding of the rationale for the intervention may lead to divergent practice patterns and failure to implement this evidence-based practice (Miller et al., 2012). Furthermore, a different web-based survey geared toward health professionals revealed a lack of nursing acceptance (22%) of the protocol or evidence to support the recommendation. Possible reasons were offered, including a perception that SI compromises patient safety and comfort, it demands one-to-one attention, or SI is not perceived to contribute to improve patient outcomes. Concerns about increased risk of patient-initiated device removal (19%), and other unintended consequences such as respiratory compromise (26%) or patient discomfort (13%) have been cited as perceived barriers to implementation of SI (Tanios et al., 2009).

Amongst factors suggested to facilitate the use of SI in practice, educational strategies that illustrate the benefits of SI and interdisciplinary rounds at the bedside positively influence implementation and standardization of these protocols (Balas et al., 2013; Carrothers et al., 2013). The existence of a quality improvement culture is also associated with more consistent implementation of SI (Carrothers et al., 2013; Miller et al., 2013). While contradictory to measured performance rates, 89.4% of nurses self-reported either strongly agreeing or agreeing that sedation protocols are effective in achieving their care goals and allowed them to use their clinical assessment skills (Fry C et al., 2009). The Pinto and Biancofiore (2016) questionnaire revealed 71% of responders judged sedation interruptions to be easy to follow.

1.4 Problem Statement

Literature to date about SI use in nursing is informed primarily by survey data (Burns, 2012) which has a limited capacity to uncover the depth of understanding of a topic that open discourse would otherwise foster. This limits our depth of understanding about the factors that influence SI use by nurses. A literature review by Burns (2012) identified twelve studies from 1998 to 2011 from Sweden, Australia, Netherlands, and North America. Most of these studies used survey or questionnaire methodology and their purpose was to determine nurses' and physicians' perceptions of sedation adherence and/or actual sedation withdrawal adherence. Although numerous studies examine the impact of implementing guidelines and care bundles, to the best of our knowledge, none focus specifically on nurses' use of SI from a qualitative descriptive lens (for example, Bounds et al., 2016). To augment what is known in existing literature, descriptive knowledge about the factors that hinder or facilitate SI use in practice is needed. The purpose of this dissertation is to understand the state of recommended practice for SI and to discover factors that hinder or facilitate critical care nurses' use of SI in practice. All of which will garner insight into why this evidence-informed intervention is not being used as recommended. To complete that, we draw from Dissemination and Implementation Science for guidance about the process of conducting research to further activate SI use in practice.

1.5 Conceptual Framework

1.5.1 Theoretical and Epistemological Location

As a researcher, I situate myself within a Social Constructivists lens that knowledge is created through intentional discourse between subjects and is influenced by the contextual circumstances that surround them. A Social Constructivist lens supports identification of determinants to SI use by nurses through social interactions between the researcher and

participants in qualitative interviews. The Social Constructivists view reconciles the chart audit methodology and the knowledge generated from abstracting data from clinical records because of the human interaction that first produced the data (i.e., nursing documentation of perceived experiences with patients within the contextual environment).

Lev Vygotsky (1896-1934) was one of the first theorists to emphasize the importance of culture and social interaction and the intrinsic development of knowledge. From this perspective, knowledge is not considered an inert object, rather knowledge is created when people interact with one another and within a dynamic environment. Knowledge use can be considered an active learning process whereby knowledge is a fluid set of understandings shaped by those who produce it and those who use it (Thomas et al., 2014). There are two autonomous realms of activity at work in any societal sector, the state of the science (what the research community knows) and the state of the art (what clinicians collectively do) (Thomas et al., 2014). Implementation science seeks to understand the processes and factors that augment successful uptake of evidence-based and evidence-informed knowledge from the research community into clinical practice and is concerned with what happens prior to and after adoption of best practices. Implementation science is distinguished from other forms of enquiry because it is uniquely focused on optimizing the use of evidence-informed methods through the development and testing of tailored implementation strategies (Curran, 2020). The benefits of conducting implementation studies are demonstrated in a recent systematic review and meta-analysis showing a consistent positive effect of guideline implementation on the health outcomes (i.e., clinical condition, remission rate and satisfaction with care) of patients experiencing mental health concerns (Girlanda et al., 2017). Dissemination science is the study of how evidence-based or evidence-informed practices, programs, and policies can best be communicated to a

person or group of people who will decide whether to adopt an innovation or practice (Shelton et al., 2020). Together, dissemination and implementation sciences merged the study and objectives of diffusion of innovation with those of organizational change geared toward generating practical means of moving the state-of-the- science (empirical research) into art form (application or use by clinicians at the bedside) (Dearing, 2009). There is an underlying assumption that use of evidence is used judiciously by clinicians in conjunction with sound clinical judgment and for practical purposes, or when appropriate. Furthermore, the use of evidence by clinicians is best achieved when the organization's readiness for change is understood and a climate and culture for supporting evidence-informed practice use is present (Turner et al., 2018; Williams et al., 2018; Yoo et al., 2019). As such, implementation of knowledge in practice must be thoughtfully and holistically approached and to do so various frameworks have been conceptualized, formalized, and published to help guide knowledge mobilization efforts (Skolarus et al., 2017).

1.5.2 Knowledge-to-Action Framework

The epistemological stance for this thesis project aligns with the Social Constructivist perspective posited by the Knowledge-to-Action (K2A) framework (Harrison & Graham, 2021). The K2A framework (I. D. Graham et al., 2006, 2007; Straus et al., 2013) informed the overarching theoretical design of this dissertation and the development of a series of studies to better understand the determinants of SI use in clinical practice. The K2A framework is one of the most frequently published and well-respected frameworks used for implementation research (Skolarus et al., 2017). As an overarching framework, it comprises two processes to inform synthesis, dissemination, and exchange of evidence-informed knowledge into practice both of which are presented in this thesis (Straus et al., 2013). The framework depicts a cycle of activities that interconnect in an iterative manner to help guide planning and implementation of

evidence into practice (I. D. Graham et al., 2006), also termed knowledge translation.

Knowledge translation is a term defined by the Canadian Institute of Health Research [CIHR] (2015) as a "dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health care system". Illustrated in the center of the K2A framework is the knowledge creation funnel which represents the phase of knowledge creation with the underlying epistemological assumption that the result or 'product' will be user friendly knowledge. Emphasis is given to the importance of synthesizing results of individual studies within the appropriate context of global evidence leading to a greater potential for solutions to identified evidence-practice gaps (Tricco et al., 2018). All three studies of this thesis can be situated within the knowledge creation funnel considering new knowledge is created within each study, all of which contributes to SI literature in a broader sense. Though, studies 2 and 3 are also akin to the next phase of knowledge translation in accordance with the framework. The outside of the K2A framework is known as the action cycle which is a high-level depiction of the essential activities for implementation and sustainment of evidence in practice. The action cycle is represented as a circular shape with arrows indicating the back-and-forth or iterative nature of the cycle, or the cyclical nature of the pre-implementation and implementation phases (Straus et al., 2013). There are eight activities that can occur sequentially or simultaneously (Harrison & Graham, 2021), whereby the knowledge creation phase can have an impact at any point (Straus et al., 2013).

The design of this dissertation was focused on one stage of the knowledge creation funnel (Chapter 2, Study 1) involving knowledge synthesis of available guidelines and care bundles with recommendations related to SI. Also, the design exploits four activities from the action

cycle: first is Chapter 2 (Study 1) which supported identification, review, and selection of knowledge to provide a solution to the problem; second, Chapter 3 (Study 2) involved identifying and clarifying the practice problem or issue to be addressed; third, Chapter 4 (Study 3) focused on adapting or customizing the knowledge (solution) to the local context (i.e., practice and system), together with the fourth activity of assessing local determinants to knowledge use (i.e., barriers and facilitating factors).

1.5.2.1 Knowledge synthesis and identifying, reviewing, and selecting knowledge that provides a solution to the problem (Chapter 2 Study 1). The first study in this dissertation relates to the identification, review, and selection of knowledge (knowledge synthesis) that constitutes best practice to be implemented. Affirming recommended best practice for SI and getting a sense of the guidelines and recommendations that are available for implementation in practice is a critical first step in knowledge translation. Study 1 was a systematic review and critical appraisal to identify and appraise recommended practice for SI, to understand current best practice. In this phase of the K2A, knowledge is created and refined through various levels of synthesis (from randomized controlled trials to systematic reviews into clinical practice guidelines), which becomes more useful for practical use by clinicians (Straus et al., 2013). In some cases, knowledge synthesis about a particular care practice has been conducted and can be used at this stage. In our case, a systematic review of guidelines with recommendations related to SI was not available in the literature which became the stimulus to conduct Study 1 a systematic review and critical appraisal of recommendations related to SI for mechanically ventilated adults.

1.5.2.2 Identifying and clarifying the practice problem or issue to be addressed (Chapter 3 Study 2). The second study of this dissertation relates to identifying the problem to be addressed in nursing practice, founded on the introduction of SI as an intervention that contributes to

improved outcomes for mechanically ventilated adults. The call to action occurred after first recognizing that SI use was inconsistent amongst my nursing colleagues and later identified in the literature as an evidence-practice gap elsewhere (Balas et al., 2014; Carrothers et al., 2013; Klompas M., 2015; Smith, 2013). Identification of the evidence-practice gap ultimately led to the design of a series of studies to investigate the use of SI. Determining the 'know-do' gap involved comparing current practice with presumed best practice. We refer to this process as a gap-analysis, a necessary first activity in the action cycle (I. D. Graham et al., 2006). To fully appreciate current practice, the K2A framework emphasizes the importance of obtaining a strong understanding of the environmental context for implementation. As such we designed Study 2 an implementation needs assessment with two components: first, an environmental scan that facilitated our understanding of the environmental context more broadly (e.g., the nature of the setting: historical context, size, number and types of providers and patients, etc.) before the conduct of a gap-analysis. Environmental scans are an efficient and organized means of identifying and collecting information about the setting, the individuals (staff and patients) and activities of the unit. The second component was a gap-analysis and, although there are several alternatives to conducting a gap-analysis, we used a retrospective chart audit as the method provided the opportunity to measure use of SI objectively.

1.5.2.3 Adapting or customizing the knowledge (solution) to the local context (i.e., practice and system), together with the fourth activity of assessing local determinants to knowledge use (i.e., barriers and facilitating factors) (Chapter 4 Study 3). Study 3 was a descriptive qualitative study and aligns with the action cycle of the K2A framework. Understanding the barriers and facilitators (determinants) that contribute to or inhibit the use of evidence is necessary for tailoring interventions to effectively implement evidence into clinical practice.

Understanding the determinants that influence evidence use within a particular setting is necessary to avoid jumping to erroneous conclusions and attempting to implement best practice before addressing barriers to implementation.

The dissertation was supplemented with other frameworks and models to inform data collection and analysis. A full description of each framework or model is further elaborated within each respective chapter. For example, the Appraisal of Guidelines for Research & Evaluation II (AGREE-II) instrument (Brouwers et al., 2010) as well as the Appraisal of Guidelines for Research and Evaluation – Recommendations Excellence (AGREE-REX) instrument were used in the systematic review and critical appraisal of guidelines and care bundles with recommendations related to SI (Chapter 2 Study 1) (AGREE-REX Research Team, 2019). The Action, Actor, Context, Target, Time framework informed the analysis of determining best practice for SI from guidelines and care bundles (Chapter 2 study 1) (Presseau et al., 2019). The Action, Actor, Context, Target Time framework outlines common domains that can identify the necessary elements needed to specify a behaviour and is often used for clarifying who needs to do what differently in clinical interventions (Presseau et al., 2019). The Theoretical Domains Framework (TDF) informed development of the interview guide and analysis of semi-structured interviews with nurses, allied health professionals and a physician. The Ottawa Model of Research Use (OMRU) informed synthesis of the descriptive qualitative study findings (Chapter 4 Study 3) (Logan & Graham, 1998). The Implementation Roadmap, which is a comprehensive implementation planning framework that is based on the K2A framework, gave us insight into how to categorize the essential phases for activating evidence in practice (Chapter 5 Integrated Discussion). The underlying assumption of the Implementation Roadmap is solutions focused rather than problem-based and prioritizes the collaboration and commitment

from experts working in the clinical setting of interest (Harrison & Graham, 2021). Although we identified the evidence-practice gap and described the barriers to implementation of SI in this thesis, the end- result was also a demonstration of how to follow the Implementation Roadmap for building solutions to the SI evidence-practice gap.

1.6 Research Objectives and Aims

There was limited knowledge about what determinants impact nurses' decisions or ability to use a SI daily when it is ordered by a physician or as part of an established local protocol. Behavior change theory to inform qualitative interviews had not been used to examine the determinants that contribute to SI use by nurses in critical care. Therefore, comprehensive knowledge about current SI practice and the determinants influencing critical care nurses' use of recommendations for SI found in protocols and guidelines was needed to improve the delivery of this clinical intervention. A theory informed multiple-methods study added value to the current state of information about SI use and contributes practical knowledge to the study of nursing SI practice.

This dissertation followed a multiple methods research design, which is appropriate for understanding a complex concept in the real world setting that could not otherwise be fully understood using one approach within a project (Morse, 2003). Where a mixed method study design involves one study (e.g. a qualitative study) informing another study (e.g. a quantitative study) and data points are combined in the research process (Anguera et al., 2018) (e.g. the qualitative findings being further explored by a survey study). A multiple methods study design involves each study having its own sub-question that is answered by either using a quantitative or qualitative approach (focusing on different pieces of the research puzzle) (Morse, 2003). Based on this premise, there are three individual studies in this dissertation: first, a systematic

review and critical appraisal to examine the quality and reporting of all available guidelines and care bundles with recommendations related to SI for mechanically ventilated adults in critical care. Second, a needs assessment consisting of an environmental scan of the organization with potential for a future implementation study. In conjunction with a formal analysis of the nature and magnitude of the evidence-practice gap related to SI using a retrospective chart audit. Third, a descriptive qualitative study using semi-structured and theory-based interviews to deepen our understanding of the determinants that influence SI use at the study site. The individual study research objectives or aim are displayed in Table 1.1.

Table 1.1 Individual study research objectives or aim.

Study	Chapter	Study Type	Research Objectives or Aim
1	2	Systematic review and critical appraisal	The objectives of this review were to (i) assess the methodological quality of all accessible and published guidelines and care bundles that offer a recommendation related to sedation interruptions, using the AGREE-II instrument, to (ii) determine what is the recommended best practice for sedation interruptions from the available guidelines, and then to have (iii) a closer inspection of the overall credibility and applicability of the recommendations using the AGREE-REX instrument.
2	3	Needs assessment and gap-analysis	The objectives of this study were to (i) describe the methods used in conducting an implementation needs assessment at a tertiary hospital, and to present the

			needs assessment findings, (ii) highlight the value of doing a needs assessment and the associated implications for undertaking future implementation research at this setting, (iii) provide advice for conducting a needs assessment in less research-intensive hospitals.
3	4	Descriptive qualitative	The aim of this study was to understand critical care nurses, physicians and allied health professionals' perceptions of factors that support, inhibit, or limit the use of sedation interruptions by nurses.

1.7 Structure of the Thesis

In accordance with the doctoral dissertation regulations of Graduate and Postdoctoral Studies at University of Ottawa, this thesis is article based. The dissertation is composed of an introductory chapter, three original scholarly articles, and a final integrated discussion. A description of each proceeding article follows:

1.7.1 Chapter 1 Introduction

An introduction was provided for the justification of this research which described the background for SI including evidence for its use in practice and in conjunction with other evidence-informed practices. The research problem was summarized followed by a guiding theoretical framework. This is a thesis by article and the structure and purpose of each chapter is outlined next.

1.7.2 Chapter 2 Study 1: knowledge synthesis and identifying, reviewing, and selecting

knowledge that provides a solution to the problem.

We conducted a systematic review and critical appraisal guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) reporting standards (Page et al., 2021) a 27-item checklist. The objectives of this review were to (i) assess the methodological quality of all accessible and published guidelines and care bundles that offer a recommendation related to SI, using the AGREE-II instrument, to (ii) determine what is the recommended best practice for SI from the available guidelines, and then to have (iii) a closer inspection of the overall credibility and applicability of the recommendations using the AGREE-REX instrument. This review identified benefits for critical care community, including critically ill patients, nurses, physicians, and other members of the multidisciplinary team responsible for caring for mechanically ventilated adults with a clear inference about best practice and the current methodological quality of available recommendations. Also, findings include a synthesis of the recommended action(s), actor(s), contextual information, target(s), and timing related to SI from all the available guidelines and care bundles that can be leveraged by clinicians in practice. International guidance on SI is only useful when it is customized to a particular setting because implementation of best practice(s) is most successful when the barriers to the innovation (best practice recommendations) are addressed using tailored implementation interventions. To contribute valuable knowledge about SI use for bridging the evidence-practice gap evident in the literature, we needed to focus our attention on one CCU.

1.7.3 Chapter 3 Study 2: Identify and clarify the practice problem or issue to be addressed

We focused our attention on the hospital in Northeastern Ontario prompting the personal impetus of this dissertation because the issue related to SI use has yet to be addressed. We

conducted an implementation needs assessment starting with an environmental scan of the organization's website and preliminary discussions with key informants. To understand the nature and magnitude of the evidence-practice gap related to SI a formal gap-analysis was conducted using a retrospective chart audit. Our specific objectives for the study were to (i) describe the methods used in conducting an implementation needs assessment at a tertiary hospital, and to present the needs assessment findings, (ii) highlight the value of doing a needs assessment and the associated implications for undertaking future implementation research at this setting, (iii) provide advice for conducting a needs assessment in less research-intensive hospitals. Electronic medical reports were used to abstract data for the gap-analysis, and we reviewed 28 records with 82 eligible sedation interruption days.

1.7.4 Chapter 4 adapting or customizing the knowledge (solution) to the local context (i.e., practice and system), together with the fourth activity of assessing local determinants to knowledge use (i.e., barriers and facilitating factors)

To determine critical care nurses', physicians' and allied health professionals' perspectives of the factors that support, inhibit, or limit the use of SI by nurses we conducted 13 semi-structured interviews in the same CCU as study 2. Understanding the determinants that influence SI use was necessary for tailoring implementation interventions to local barriers to address the evidence-practice gap in a future implementation study. The interview guide and data analysis were informed by the Theoretical Domains Framework. The interviews were conducted either in person, by phone or online using videoconferencing software. Using a thematic analysis approach, common belief statements were generated, and three criteria were applied in the identification of specific beliefs or themes: 1) frequency of specific beliefs and/or themes; 2) presence of conflicting beliefs; and 3) evidence of strong beliefs that may affect the target

behaviour.

1.8 Conclusion

A Social Constructivist perspective was needed to gain a deeper understanding of the determinants that influence SI use by nurses in critical care. This perspective is important because social discourse revealed more detail about the realities of SI use within a complex environment. The processes posited by the K2A framework supports research efforts to activate evidence in practice. Improved activation of SI use in practice will contribute positively to evidence-informed practice implementation of care bundles and lead to improving patients' outcomes after experiencing mechanical ventilation in critical care. Our understanding of SI use by nurses has improved with the rigorous application of a multi-methods study design, more details of which are presented in the following chapters of this dissertation.

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Chapter 2

A Systematic Review and Critical Appraisal of Guidelines and their Recommendations for Sedation Interruptions in Adult Mechanically Ventilated Patients

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Review paper

A systematic review and critical appraisal of guidelines and their recommendations for sedation interruptions in adult mechanically ventilated patients

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ABSTRACT

Objective: The objectives of the review were to (i) assess the methodological quality of all accessible and published guidelines and care bundles that offer a recommendation related to sedation interruptions, using the AGREE-II instrument, to (ii) determine what is the recommended best practice for sedation interruptions from the available guidelines, and then to have (iii) a closer inspection of the overall credibility and applicability of the recommendations using the AGREE-REX instrument. This review will benefit the outcomes of critically ill patients and the multidisciplinary team responsible for the care of mechanically ventilated adults with continuous medication infusions by providing a synthesis of the recommended action(s), actor(s), contextual information, target(s), and timing related to sedation interruptions from current best practice.

Review method used: We conducted a systematic review.

Data sources: We applied a peer-reviewed search strategy to four electronic databases from 2010 to November 2021—MEDLINE, CINAHL, Embase, and The Cochrane Database of Systematic Reviews—and included grey literature.

Review method: Findings are reported in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analyses checklist. We assessed overall quality using the validated Appraisal of Guidelines for Research and Evaluation II and AGREE Recommendation Excellence tools.

Results: We identified 11 clinical practice guidelines and care bundles comprising 15 recommendations related to sedation interruption. There are three key findings: (i) deficiencies exist with the methodological quality of included guidelines, (ii) sedation interruption is recommended practice for the care of adult mechanically ventilated patients, and (iii) the current evidence is of low quality, which impacts overall credibility and applicability of the recommendations.

Conclusions: Sedation interruptions are currently best practice for adult mechanically ventilated patients; however, the available guidelines and recommendations have several deficiencies. Future research is needed to further understand the role of the nurse and other actors to enact this practice.

1. Introduction

Continuous sedation infusions are often necessary for patients that are mechanically ventilated to help mitigate anxiety associated with being intubated and on a ventilator, to assist with physical compliance with the ventilator, and to facilitate nursing care.[1] To

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avoid the adverse effects and risk of over sedation, a more recent philosophical approach to care adopts 'less is best' strategies for the use of continuous intravenous sedation in mechanically ventilated patients.[2] Oversedation is known to cause negative sequelae during the acute and recovery phases of critical illness.[3,4] For example, altered mentation is a likely occurrence from the sedation and analgesic infusions, which make the identification of delirium more challenging.[5] Intensive care unit delirium is only one example of adverse events that are linked to worse outcomes in this patient population; other negative sequelae include post-traumatic stress disorder[6] and an increased risk of having no recall which was associated with a longer stay in intensive care.[7]

In response to concerns about prolonged exposure to sedative infusions, recommendations related to sedation interruption (SI) continue to surface in many clinical practice guidelines (CPG)[8] and care bundles.[9] Despite some well-documented benefits of SI, with the practice now recommended by national (e.g., Institute for Health Improvement) and international (e.g., Society of Critical Care Medicine) associations, the reported and observed uptake of SI are inconsistent and suboptimal at best.[10–13] There are multifaceted clinician and guideline factors that influence uptake of recommendations in practice. For example, studies suggest it is more difficult for clinicians to adopt a guideline when there are several different guidelines to choose from,[14] and when they address the same condition, guidelines can confuse healthcare providers and confound implementation of best practices.[15,16]

Currently, the number of available recommendations related to SI is unknown, as is the methodological quality of these guidelines. Providing greater transparency and accessibility to the quality and content of the recommendations is relevant to all clinicians involved in implementing sedation strategies in critical care, especially nurses and physicians,[17] and will improve consensus amongst critical care clinicians about the impetus and approach for SI.[18] The purpose of this systematic review was to identify and appraise recommended best practice for SI. The objectives of this review were to (i) assess the methodological quality of all CPGs and care bundles that offer a recommendation related to SI, using the Appraisal of Guidelines for Research & Evaluation II (AGREE-II) instrument, then to (ii) determine recommended best practice for SI from the available guidelines, and then to 3) have a closer inspection of the overall credibility and applicability of the recommendations using the Appraisal of Guidelines for Research and Evaluation – Recommendations Excellence (AGREE-REX) instrument.

2. Methods and materials

2.1. Design

We conducted a systematic review of the published literature. The protocol was registered with The International Prospective Register of Systematic Reviews (PROSPERO), registration number: CRD42021239699. We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[19] statement to guide reporting of the findings in the PRISMA checklist (Supplemental Table 1)

2.2. Data sources and searches

We developed a search strategy in consultation with a librarian from the University of Ottawa. The PICAR framework, defined as P: population, clinical indication(s), and conditions(s); I: intervention(s); C: comparator(s), comparison(s), and content; A: attributes of eligible guidelines; and R: recommendation characteristics,[20] illustrates the search strategy: P- mechanically ventilated adults (18 years of age or older) in a critical care environment with a continuous sedative infusion; I- sedation interruption; C- none; A- guidelines published from 2010 to November 2021, written in English, regional, national, or international scope; R- recommendations must discuss sedation interruption. The following four electronic databases were searched: MEDLINE, CINAHL, Embase, and The Cochrane Database of Systematic Reviews. Known grey literature sources including 11 guideline repository websites and 15 professional association websites were also searched. Reference lists of all included CPGs and care bundles were hand searched. Only open-access guidelines or guidelines published in journals requiring subscription were included. If a guideline required payment to a company/organisation, it was excluded. Specific search terms, search strings, the full search strategy, as well as a list of the searched repositories and professional organisations are in Supplemental File 2.

2.3. Inclusion/exclusion criteria

All accessible CPGs and care bundles published between January 2010 and November 2021 that provided at least one explicit recommendation related to SI for mechanically ventilated adult patients, over the age of 18 years, in the ICU, and written in English were included. We only included guidelines and/or care bundles that were published within the past 10 years as best practice should be determined from the best and most recent research evidence. Reviews, letters, editorials, commentaries, reports of all studies, institutional recommendations/policies, and recommendations resulting from a single study were excluded.

2.4. Screening and data extraction

Covidence evidence synthesis software[21] was used to facilitate title and abstract screening, as well as full-text screening, data extraction, and the quality appraisal phases of the review. All phases were conducted in duplicate by two independent reviewers with any disagreements resolved through discussion. A third investigator was consulted to adjudicate unresolved discrepancies. When necessary, the corresponding author was emailed for supplemental material.

3.1. Methodology and required data elements for answering the objectives

3.1.1. Objective 1: methodological quality of the CPGs and care bundles

The Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument was used to complete the quality appraisal of the methodological development of each included guideline.[22] This instrument has quickly become an internationally accepted standard for evaluation of the methodological quality of guidelines[23] and has good validity and reliability in its application to CPGs.[24] The instrument is designed to assess the quality of guidelines, which is defined "as the confidence that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid and are feasible for practice".[25] Two independent reviewers completed the AGREE training prior to conducting the review.[25] AGREE II has six domains: (i) Scope and Purpose (items 1–3), (ii) Stakeholder Involvement (items 4–6), (iii) Rigour of Development (items 7–14), (iv) Clarity of Presentation (items 15–17), (v) Applicability (items 18–21), and (vi) Editorial Independence (items 22–23). Each of the 23 items was scored on a seven-point Likert scale from 1 = strongly disagree to 7 = strongly agree. In addition to the primary guideline, we attempted to locate and retrieve supporting documents to inform our appraisal of the guideline, for example, executive summaries and data summary tables identified as supplemental to

the guideline and directly reported on the methodological development of the guideline or recommendation for SI.

The AGREE II domain scores were then calculated by summing the consensus item scores within domains and scaling the total as a percentage of the maximum possible score for that domain,[22] using the following formula:

$$\text{Scaled domain score} = \frac{\text{Obtained consensus score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}} \times 100$$

The scaled domain scores were used to determine which CPGs or care bundles are of high quality. Guidelines were considered to have high methodological quality if they had at least four or more AGREE II domain scores ≥60%, similar to thresholds reported in previous reviews.[26–28]

3.1.2. Objective 2: best practice for SI in CPGs and care bundles

Information was abstracted from all recommendations directly related to SI. Any supplemental documents or live links to material that offered additional explanation about SI were also included. For example, data were abstracted from definitions found in the supporting rationales for the recommendations and also decision aids when available. The Action, Actor, Context, Target, Time (AACTT) framework was used to organise the content across recommendations.[29] This framework outlines common domains that can be used to identify the necessary elements needed to specify a behaviour. Data were extracted and organised according to the domains: the action (clinical practice/behaviour recommended); actor (who is to perform the behavior); context (related to SI); target (to whom the practice is to be done); and timing of sedation interruptions. Similar to how the AACTT framework can be used to uncover evidence–practice gaps in care,[29] we used the framework to identify if the foundational elements for implementation (i.e., someone, somewhere, needs to do something differently) are present in the recommendations for SI.

3.1.3. Objective 3: clinical applicability, values and preferences, and implementability of the recommendation(s) related to SI

The AGREE-REX tool was used in this study to assess the methodological quality of each CPG and care bundle's recommendation(s) related to SI.[30] The AGREE-REX was designed to assess the quality of recommendations and to inform their development and reporting.[25] It differs from the AGREE II instrument in that it is used to assess the quality of the recommendation(s) rather than the overall guideline.[31] A high-quality recommendation, using AGREE-REX, is one that is (i) clinically credible, (ii) trustworthy, and (iii) implementable.[30] The instrument is based on these three high-quality factors which are represented by three domains that contain a total of nine quality items. Each of the recommendations in our study was scored according to these nine items. The three domains are as follows: (i) Clinical Applicability is concerned with the evidence used to formulate the recommendation and its applicability to target users, patients, or populations (1–3 items); (ii) Values and Preferences considers the inclusion of the values and preferences of target users, patients and populations, policymakers and decision-makers, and guideline developers in the formulation of the recommendation (4–7 items); (iii) Implementability examines whether the overall purpose of the guideline was achieved in the development of the recommendation as well as the provision of materials and resources to facilitate local application and adoption by users (8–9 items). Each of the items contains a definition and quality criteria for that item, as well as one question related to quality and another focused on suitability for use in a particular setting. Both questions are scored using a seven-point response scale, where 1 = strongly disagree and 7 = strongly agree.[30] The question about suitability was omitted as we did not implement the recommendations. Studies have been conducted to test the validity, reliability, and usability of the AGREE-REX instrument.[31,32] Three hundred and two individuals applied the AGREE-REX to a CPG and completed the AGREE-REX usability survey; the results indicated the instrument is useful for assessing factors related to CPG credibility and implementability.[32] Another study demonstrated how the instrument produced most favourable scores in items related to the quality of the evidence and clinical relevance.[31]

While using the AGREE-REX Manual,[30] two independent reviewers appraised each guideline, specifically focussing on the recommendation(s) related to SI. When the CPG or care bundle contained more than one recommendation related to SI, the recommendations were clustered and appraised together because each recommendation within a particular guideline or care bundle followed the same development process. Consensus was reached for each question.

Scores are reported for each individual item, and average scores were computed by domain to compare the quality of the recommendation(s) in terms of clinical credibility, trustworthiness, and implementability. Additionally, overall AGREE-REX scores were calculated by adding all item scores for each individual CPG and care bundle. The value was then inputted into the following formula to scale the total as a percentage of the maximum possible score:[30]

$$\text{Scaled overall AGREE} - \text{REX score} = \frac{\text{Obtained consensus score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{minimum possible score}} \times 100$$

Overall AGREE-REX scores were used to identify the quality of each individual or cluster of recommendations. In this review, recommendations with overall AGREE-REX scores >70% are considered high quality, while those with overall quality scores <30% are lower quality, and all others are moderate quality (approach suggested by AGREE-REX Research Team[30]).

3.2. Data summary and synthesis

To summarise the strength and direction of recommendations across guidelines, a simple narrative account of the grading of evidence reported by the authors is presented. Further synthesis of the strengths was not possible due to the limited number of guidelines that appraised the evidence in formulation of the recommendation. All of the content data pertaining to the SI recommendation(s) are organised using the AACTT framework elements. The data were then synthesised in a recommendation matrix. Matrices are commonly used to group together similar recommendations from various guidelines to ease the comparison of content and use of evidence to develop the recommendations and their clinical relevance.[33]

4. Results

4.1. Literature search

Fig. 1shows the flow of article selection and reasons for exclusion. We screened 6873 titles and abstracts, of which 542 were potentially relevant, and 11 were included in the systematic review.

4.2. Characteristics of the included CPGs and care bundles

The characteristics of the included guidelines are displayed in Table 1. Eight out of the 11 guidelines were open access,[34–40] of which

one required registration at no charge[41] and, three were in subscription journals.[8,9,42] The authors reported their documents were a 'consensus"—evidence-informed recommendation (n = 1),[35] a systematic review and evidence-based guideline (n = 1),[36] a CPG (n = 4),[8,37–39] a care bundle of evidence-based interventions (n = 4),[9,34,40,41] or taskforce consensus recommendations developed by an expert panel.[43] Development teams were from the US (n = 3),[34,38,41] North America, Europe, Australia,[37] Italy/United Kingdom/United States of America,[42] Columbia,[8] Germany,[39] Scotland,[40] Spain[9], Latin America,[35] and Ethiopia.[36] All were endorsed by a formal institute, organisation, or society, except for one developed by a Pan-European Committee of 12 participants representing different disciplines.[9]

4.3. Objective 1: methodological quality of the CPGs and care bundles

Table 2 depicts the overall AGREE II domain scores by guideline. None of the included CPGs and care bundles scored well on the AGREE-II instrument, indicating there are varying deficiencies in the methodological development of guidelines that contain a recommendation related to SI. For example, four guidelines address domain I (Scope and Purpose) by clearly articulating the health questions addressed by the guideline and to which patient population the guideline applies to (89%;[35] 89%;[8] 78%;[37] 72%[38]). Two guidelines satisfy most of the criteria in domain 5 (Applicability) by providing an a higher amount of guidance for implementing the guideline (79%;[34] 71%[41]). No guidelines addressed both of these domains completely, nor did any of the guidelines score >60% on four or more domains.

4.4. Objective 2: best practice recommendation for sedation interruptions

The 15 recommendations identified across the 11 guidelines, along with their respective strength and level of evidence as reported by the authors, are displayed in Table 3. Thirteen recommendations support the use of SI, and two recommendations are against performing SI specifically in patients with intracranial hypertension. All 15 recommendations were deconstructed using the

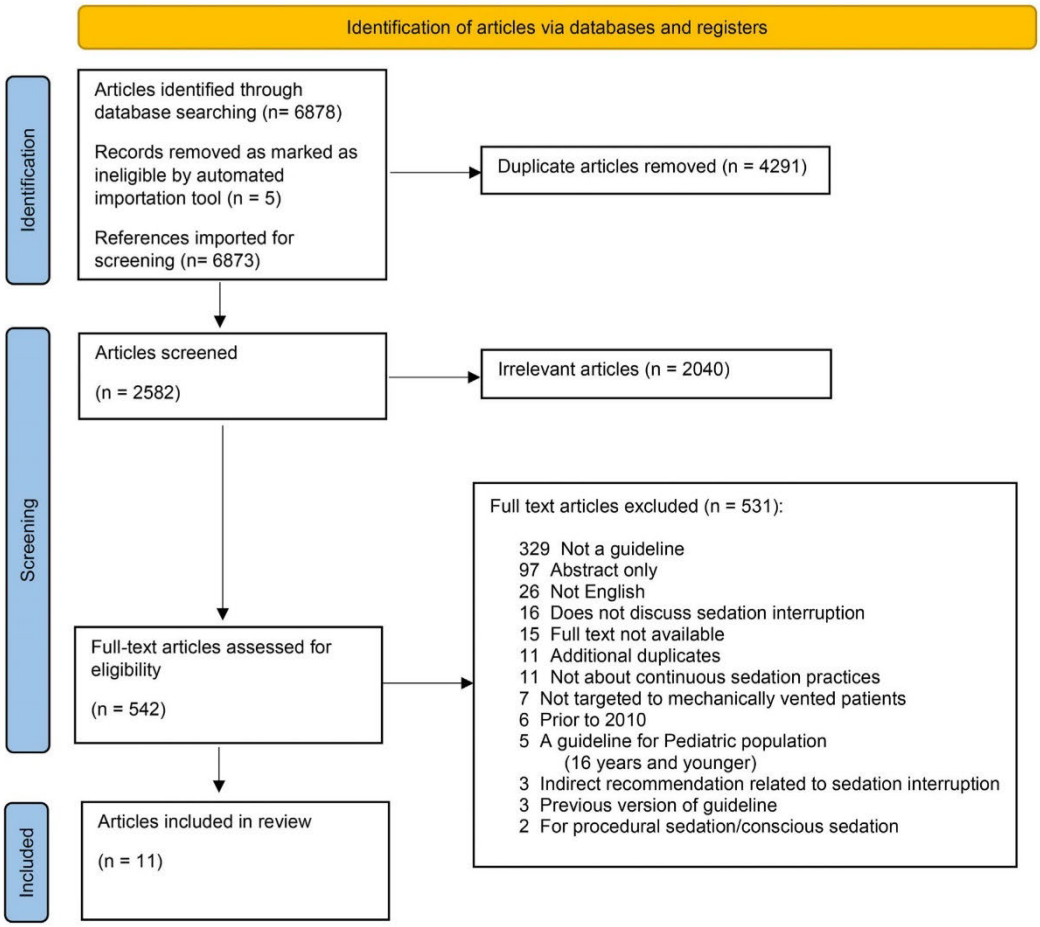

Figure 1. PRISMA flow diagram for the selection of the guidelines and care bundles. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Table 1
Characteristics of included guidelines and care bundles.

Author (year) guideline title *Guideline type*	Country	Institution/guideline development group *Composition of development group*	Guideline health outcome	Target population	Intended users	Method used to collect or select the evidence	Method used for quality appraisal of the evidence	Method used to formulate and/or select the recommendations
Donato et al. (2021) Consensus for the management of analgesia, sedation and delirium in adults with COVID-19-associated acute respiratory distress syndrome *'Consensus' - evidence informed recommendations*	Argentina – Latin America	On behalf of the Committee for Analgesia, Sedation and Delirium of the Sociedad Argentina de Terapia Intensiva *Intensivist physicians, pharmacists and kinesiologists who addressed a protocol for managing ASD in adults with ARDS caused by COVID-19.*	Initial approach to the airway, to mechanical ventilation approaches in the different phases and to the withdrawal process	Critical patients that require systematic assessment of analgesia, sedation and delirium (ASD) in adults with ARDS caused by COVID-19	Argentinian health professionals caring for critical patients with ARDS caused by COVID-19	Non-systematic review of the scientific evidence, added to the judgement and clinical experience of the group of participating experts and other groups throughout the world	Not reported	For each stage, the mentioned sources of bibliographic information were analysed, and recommendations were established through nominal group consensus
Temesgena et al. (2021) Adult sedation and analgesia in a resource limited intensive care unit – A systematic review and evidence based guideline *Systematic review and evidence based guideline*	Ethiopia	Netsanet Temesgen, Bsazinew Chekol, Tadesse Tamirie, Denberu Eshetie, Nigussie Simeneh, Abatneh Feleke *Unknown*	Up-to-date perspective on procedures for the treatment of mechanically ventilated adult ICU patients in terms of sedation and analgesia	Mechanically ventilated patients in ICU	Not clear	Systematically reviewed 16 SR and MA, 8 RCTs, 3 evidence-based recommendations, 11 cohort studies, 5 cross-sectional studies, and 1 case report	LoE and SoR determined using criteria from WHO Evidence of Good Clinical Practice (GCP)	Finally conclusions and recommendations are made by balancing the benefits and drawbacks of alternative treatment options for sedation and analgesia protocols in ICU. WHO Evidence of Good Clinical Practice (GCP) used to categorise the recommendations based on level of evidence
Celis-Rodríguez et al. (2019) Evidence-based clinical practice guidelines for the management of sedoanalgesia and delirium in critically ill adult patients *Clinical practice guideline*	9 countries in the Americas and the Iberian Peninsula	Pan-American and Iberian Federation of Societies of Critical Medicine and Intensive Therapy *24 specialists in critical care medicine, with epidemiological and literature research support*	Management of sedation, analgesia, and delirium in the intensive care units	Critically ill adult patients	Physicians, nurses, clinical pharmacologists and professionals in the numerous disciplines that form part of the multidisciplinary team in the ICUs	Systematic search of all relevant studies related to the proposed topic	GRADE	Those recommendations with a voting rate of over 80% were included by consensus
Devlin et al. (2018) Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult *Clinical practice guideline*	North America, Europe, Australia	Society of Critical Care Medicine *Thirty-two experts from five countries, across five topic-specific sections; four methodologists, two medical librarians, four critical illness survivors, and two Society of Critical Care Medicine support staff.*	Assessment, prevention, and treatment of pain, agitation/sedation, delirium, immobility (mobilisation/ rehabilitation), and sleep (disruption) in critically ill adults	Critically ill, intubated adults/adult patients in the ICU	1) clinicians who provide patient care; 2) critically ill patients (and their families); 3) methodologists and other CPG developers; and 4) researchers	Systematic search of five databases	GRADE	Evidence and consensus based; graded recommendations and ungraded statements derived from actionable PICO questions and nonactionable descriptive ungraded statements
AHRQ (2017) Daily Care Processes Guide for Reducing Ventilator-Associated Events in Mechanically Ventilated Patients *Care bundle*	US	Prepared by Johns Hopkins Medicine/Armstrong Institute for Patient Safety and Quality *VAP Prevention committee of 155 healthcare experts in the care of patients on mechanical ventilation.*	Eliminates VAEs, including VAP.	Mechanically ventilated patients in intensive care units (ICUs)	Staff in intensive care units	Unclear	Unclear	Committee members participated in a modified Delphi process to determine the most important interventions

(*continued on next page*)

Table 1 (*continued*)

Author (year) guideline title *Guideline type*	Country	Institution/guideline development group *Composition of development group*	Guideline health outcome	Target population	Intended users	Method used to collect or select the evidence	Method used for quality appraisal of the evidence	Method used to formulate and/or select the recommendations
Schmidt et al. (2017) Liberation From Mechanical Ventilation in Critically Ill Adults: An Official American College of Chest Physicians/ American Thoracic Society Clinical Practice Guideline *Clinical practice guideline*	US	American Thoracic Society (ATS) and the American College of Chest Physicians (CHEST) *Six co-chairs, eight pulmonary/critical care physicians, four critical care physicians, one critical nurse, one physical therapist, and one critical care pharmacist. There were also two methodologists, one of whom is also a critical care physician.*	Liberation from the ventilator	For acutely hospitalised patients ventilated more than 24-h	Clinicians	Systematic review that included six unblinded randomised trials	GRADE	Evidence and consensus based; Evidence to Decision (EtD) framework was to facilitate the discussion and to ensure that all important categories were discussed before formulating the recommendation
DAS-Taskforce (2015) Evidence and consensus based guideline for the management of delirium, analgesia, and sedation in intensive care medicine *Clinical practice guideline*	Germany	German Society of Anaesthesiology and Intensive Care Medicine (DGAI) and the German Interdisciplinary Association for Intensive Care and Emergency Medicine (DIVI) *The guideline task-force consisted of 49 voting members nominated by 17 participating national societies.*	Delirium, anxiety, and agitation, as well as for the protocol- based analgesia, sedation, and sleep management	Critically ill patients of all age groups and severity of illness, regardless of comorbidities	All professions working in the intensive care unit (ICU)	Systematic search of the literature; no details in English	LoE determined using the Oxford System approved of by representative from 17 National Societies	Evidence and consensus based using a DELPHI approach
Sharshar et al. (2014) Neurological examination of critically ill patients: a pragmatic approach. Report of an ESICM expert panel *Clinical practice guideline*	Italy, UK, US	European Society of Intensive Care Medicine *The members of the expert panel were nominated at a meeting of the NIC in March 2010. Participants are senior academic intensivists with training in anesthesiology, critical care medicine, and neurology.*	A pragmatic approach to neurological examination (NE) of the critically ill patient	Patients admitted to the intensive care unit (ICU) that have pre-existing or acquired neurological disorders (delirium or coma)	Critical Care providers	Systematic search of the literature using one database	Because of the lack of robust studies, this group elected to not undertake a formal evidence-based consensus process	Pragmatic approach
HPS (2012) VAP Prevention Bundle Guidance for Implementation *Care bundle*	Scotland	Health Protection Scotland (HPS): NHS National Services Scotland *Experts in intensive care and infection control, from around Scotland.*	Prevention of VAP, primarily aimed at the prevention of Healthcare Associated Infections (HAI)	Patients with respiratory failure and especially those who require invasive ventilation	Those who manage patients with respiratory failure and especially those who require invasive ventilation	Initial rapid literature search; main public health websites; followed by a targeted systematic search of the literature	SIGN checklists	Evidence and expert opinion

IHI (2012) How-to Guide: Prevent Ventilator-Associated Pneumonia: Prevent ventilator-associated pneumonia (VAP) by implementing the five components of care called "the ventilator bundle" *Care bundle*	US	Institute for Health Improvement *IHI Faculty in collaboration with VHA in the Idealised Design of the Intensive Care Unit (IDICU), including intensivists and improvement leaders.*	Prevention of ventilator-associated pneumonia (VAP), venous thromboembolism (VTE), and stress-induced gastrointestinal bleeding	No specific exclusion criteria exist, clinical judgement should be exercised	Multidisciplinary team: intensive care physician, intensive care nurses, respiratory therapists, and pharmacists	Unclear	Unclear	Unclear	Unclear
Rello et al. (2010) A European care bundle for prevention of ventilator-associated pneumonia *Care bundle*	Spain	None *A pan-European committee of 12 participants representing different disciplines (microbiology, infectious diseases, infection control, epidemiology, nursing, pneumology and critical care).*	Reduce the incidence of clinical complications in patients with VAP	Mechanically vented patients	Those who manage care in VAP treatment settings	Evidence derived from European HAP guidelines produced between 2002 and 2006	Unclear (used the multi-criteria decision analysis (MCDA) framework to decide which interventions were most applicable for the care bundle)	Multi-criteria decision analysis (MCDA) following a process of weighting and scoring

GRADE, Grading of Recommendations Assessment, Development and Evaluation; HICPAC, Healthcare Infection Control Practices Advisory Committee; IHI, Institute for Health Improvement; PICO, Patient, Intervention, Comparator, Outcome; VAP, ventilator-associated pneumonia; WHO, World Health Organization.
Composition of the development team is reported here verbatim from the original authors of the paper.

AACTT framework for specifying a sedation interruption. For complete information on how each guideline mapped to the AACTT framework, please see supplemental file 3. All of the foundational requirements were present to varying extents, with the exception of the *Actor* element. None of the recommendations identified which healthcare professional (Actor) should be responsible for completing the action.

None of the recommendations were explicit or detailed about what actions were being recommended. Devlin et al. offered a description of SI but not directly in the recommendation itself, rather it can be found in the remarks associated with the recommendation. The act of performing an SI is when "[p]atients can wake up and achieve arousal and/or alertness, defined by objective actions such as opening eyes in response to a voice, following simple commands, and/or having a Sedation–Agitation Scale (SAS) score of 4–7 or a Richmond Agitation Sedation Scale (RASS) score of −1 to +1"[37](p. e838). The only other guideline to specify a recommended action was the Institute for Healthcare Improvement's (IHI) (2012) care bundle; their description of SI originated from Kress et al. which defines and speaks to the positive clinical outcomes of SI use: "[i]nterrupt sedation until the patient is awake and follows instructions, or becomes uncomfortable or agitated. The sedative infusions are started again after the patient [is] awake or, if agitation prevents successful waking, at half the previous rates and adjust according to the need for sedation"[43](as cited by IHI, 2012). Only one guideline[39] states to pair SI with a spontaneous breathing trial, and one states to perform a neurological assessment at the time of SI.[41]

There was a significant gap in who (*Actor)* should perform the action (a sedation interruption) across all guidelines. This information can only be deduced by considering the target users of the guideline as a whole, but no details are provided at the level of the SI recommendations. Collectively, the guidelines give a generalised idea of the target users of the guidelines by referring to critical care unit staff, clinicians, and/or physicians, nurses, respiratory therapists, and pharmacists.

Information on *Context* is more common in the recommendations; however, the elements significantly vary in their wording and complexity, yet compliment and at times contradict one another. All 11 included guidelines recommend including SI in the plan of care for critically ill, intubated, and mechanically ventilated adults. Schmidt et al. specify that SI should occur in patients mechanically ventilated for greater than 24 h, a practical inclusion criterion, as SIs are typically completed daily. Four guidelines[9,36,39,41] indicate SI should be included within the context of a weaning protocol. We have assumed that this is in reference to a mechanical ventilation weaning protocol. Three others[8,34,37] conversely recommend that SI should be part of an ABCDEF protocol which is, a wholistic approach to implementing evidence-informed strategies for patients on a mechanical ventilator. The elements of the protocol promote the assessment, prevention and management of pain; both spontaneous awakening and spontaneous breathing trials; choice of analgesia and sedation; delirium assessment, prevention, and management; early mobility and exercise, and; family engagement and empowerment.[37] One guideline in particular addressed implications associated with COVID-19, specifying that SI is to be used only if clinical conditions specific to the patient allow and proper protection by the health team can be ensured.[35]

The *Target* of an SI is directed at critically ill, intubated, and mechanically ventilated adults, a notion shared across 10 guidelines,[8,9,34,36–42] with some important and unique specifications. Firstly, SIs are reported to be performed only in patients that are mechanically ventilated for more than 24 h[38] and only in patients with the RASS less than or equal to −2,[39] and not in patients

Table 2
Overall AGREE-II scores by guideline.

AGREE II domain (scaled % scores)	Guideline author	Donato et al. (2021)	Temesgena et al. (2021)	Celis-Rodríguez et al. (2019)	Devlin et al. (2018)	Schmidt et al. (2017)	AHRQ (2017)	DAS-Taskforce (2015)	Sharshar et al. (2014)	HPS (2012)	IHI (2012)	Rello et al. (2010)
1. Scope and purpose		89	33	89	78	72	39	67	61	44	33	56
2. Stakeholder Involvement		22	0	50	89	44	17	28	17	22	28	11
3. Rigour of Development		38	6	63	69	69	6	58	25	17	10	15
4. Clarity of Presentation		78	11	72	39	50	78	56	56	33	33	22
5. Applicability		58	8	8	25	4	79	4	0	33	71	17
6. Editorial Independence		33	50	50	42	75	50	83	50	0	8	100
High quality (yes/no)		No	No	No	No	No	No	No	No	No	No	No

*High methodological quality (at least four domains with scores ≥60%).

Table 3
Recommendations for sedation interruptions with reported evidence appraisal.

Guideline and recommendation	Strength of the recommendation and level of evidence as reported by the author
Donato et al. (2021)	
1. We recommend daily sedation "breaks" or interruptions in adults with COVID-19 ARDS only if clinical conditions specific to the patient allow and proper protection by the health team can be ensured.	1. Not reported
Temesgen et al. (2021)	
2. Light sedation is recommended so that patients are responsive and able to communicate and daily interruption of sedation is stimulated.	2. Level 1 a.
3. Protocolised sedation or daily sedation interruption is recommended.	
Celis-Rodríguez et al. (2019)	
4. The recommendation is to apply the ABCDEF protocol in critically ill patients to increase the number of days without delirium and the days without coma, and to reduce the duration of ventilatory support, intensive care stay and mortality.	4. SoR = Strong; LoE = Low 5. SoR = Conditional; LoE = Low 6. SoR = Conditional; LoE = Low
5. If needed, continue sedation with dexmedetomidine as maintenance for over 7days, since there is not enough evidence to recommend a maximum time. It is advisable to alternate with periods of drug suspension and to monitor the appearance of adverse effects.	
6. The daily interruption of sedation in patients with intracranial hypertension is not recommended.	
Devlin et al. (2018)	7. Ungraded Statement
7. In critically ill, intubated adults, DSI protocols and NP-targeted sedation can achieve and maintain a light level of sedation.	
AHRQ (2017)	8. Not reported
8. Minimise sedative use and perform a daily sedation interruption or vacation, or SAT.	
Schmidt et al. (2017)	9. Conditional Recommendation, Low Quality of Evidence
9. For acutely hospitalised patients ventilated for more than 24 h, we suggest protocols attempting to minimise sedation. Example of protocols is provided in rationale (eg, bedside nursing sedation algorithms, daily sedative interruption).	
DAS-Taskforce (2015)	10 LOE = [a] 1a, [b] 1b; GoR = A (strong recommendation (we recommend/one shall))
10. If there are no contraindications, we recommend daily SAT and SBT only in patients with a RASS less than or equal to −2.	
Sharshar et al. (2014)	11. Moderate evidence, strong recommendation
11. Daily interruption or reduction of sedation is recommended in mechanically ventilated patients to enhance NE and improve short- and long-term outcomes.	12. Moderate evidence, strong recommendation
12. Sedation interruption is not recommended in patients with intracranial hypertension.	
HPS (2012)	13. Category 1B: strong recommendation based on low quality of evidence which suggest net clinical benefits or harms or an accepted practice.
13. Sedation is reviewed and, if appropriate, stopped each day.	
IHI (2012)	14. Not reported
14. Include a sedative interruption strategy in your overall plan to wean the patient from the ventilator; if you have a weaning protocol, add sedative interruption to that strategy.	
Rello et al. (2010)	
15. The incorporation of sedation vacation and weaning protocols into patient care.	15. Not reported

AHRQ, Agency for Healthcare Research and Quality; DAS, Delirium, Analgesia, and Sedation; DSI, daily sedation interruption; Level 1 a., strongly recommended and directly applicable; LoE, level of evidence; NE, neurological evaluation; RASS, Richmond Agitation Sedation Scale; SAT, spontaneous awakening trial; SBT, spontaneous breathing trial; SoR, strength of recommendation.

DAS -Taskforce LoE using the Oxford System: [a] - Burry L, Rose L, McCullagh IJ, Fergusson DA, Ferguson ND, Mehta S. Daily sedation interruption versus no daily sedation interruption for critically ill adult patients requiring invasive mechanical ventilation. Cochrane Database Syst Rev. 2014 Jul 9;7:CD009176. https://doi.org/10.1002/14651858.CD009176.pub2. [b] - Mehta S, Burry L, Cook D, Fergusson D, Steinberg M, Granton J, Herridge M, Ferguson N, Devlin J, Tanios M, Dodek P, Fowler R, Burns K, Jacka M, Olafson K, Skrobik Y, Hébert P, Sabri E, Meade M; SLEAP Investigators. Canadian Critical Care Trials Group. Daily sedation interruption in mechanically ventilated critically ill patients cared for with a sedation protocol: a randomised controlled trial. JAMA. 2012 Nov;308(19):1985-92. https://doi.org/10.1001/jama.2012.13872.

with intracranial hypertension.[8,42] Finally, 10 out of 11 guidelines recommend that SI should be performed daily (*Time*).[8,34–42]

4.4. Objective 3: clinical applicability, values and preferences, and implementability of the recommendation(s) related to SI

Table 4 illustrates the results of the AGREE-REX individual item consensus scores, the scores by domain, as well as a final overall score by guideline for the specific recommendation related to SI. The overall AGREE-REX scores range from 9%[42] to 76%.[37] We identified that most SI-related recommendations are formulated using poor to moderate guideline development methods. Only one recommendation was considered to be of high methodological quality[37](overall AGREE-REX score = 76%). Four guidelines contained recommendations of moderate quality (44%;[8] 41%;[35] 37%;[34] and 33%[38]), and six were of low quality (24%;[39] 22%;[41] 20%;[36] 19%;[9] 11%;[40] and 9%[42]).

A closer inspection of the individual AGREE-REX domains illustrates the strengths and inadequacies of the available recommendations:

4.4.1. Domain 1. Clinical Applicability

The average score across guidelines ranged from 11%[34] to 94%.[37] Overall, the evidence base reportedly used in the formulation of the recommendations for SI was derived from low-quality trials,[8,38–40] with the exception of Sharshar et al. who reported a moderate evidence base. Notably, one guideline offered an ungraded statement,[37] despite having considered the evidence base available for SI. Five others did not report having undertaken a formal evidence appraisal.[9,34–36,41] Only two guidelines, Celis-Rodriguez et al. (83%) and Devlin et al. (94%), provided a comprehensive report of the analysis of evidence and how the anticipated outcomes of SI are relevant to *target patients*. Although, these same two guidelines could be more transparent about the target user's scope and role in performing an SI.

4.4.2. Domain 2. Values and preferences

The average score across guidelines ranged from a low of zero[39,40,42] to only a modest 54%.[37] Overall, most of the guidelines do not provide a detailed description of the methods or approaches used to address the values and preferences of target users, patients, policymakers and decision-makers, or guideline developers in the formulation of the recommendation. The notable exception is Devlin et al. which described having critical illness survivors along with the 32 experts from five countries, four methodologists, and two librarians having participated in the development of the recommendations. This guideline received only moderate scores because the target users or Actor(s) needed to complete an SI were not well described.

4.4.3. Domain 3. Implementability

The average scores ranged from 0%[42] to 92%.[31] Devlin et al. (92%) and the Agency for Healthcare Research and Quality (AHRQ) (2017) (75%) scored the highest for achieving the purpose of the guideline with provision of advice and tools for implementation. This domain is focused on whether or not the guideline addresses implementation factors, such as system level changes, resources, and strategies needed for uptake of SI at the bedside. Both Devlin et al.'s

Table 4
AGREE-REX Clinical Applicability, Values and Preferences, and Implementatbility of the Recommendation(s) related to SI.

	Donato et al. (2021)	Temesgena et al. (2021)	Celis-Rodríguez et al. (2019)	Devlin et al. (2018)	AHRQ (2017)	Schmidt et al. (2017)	DAS-Taskforce (2015)	Sharshar et al. (2014)	HPS (2012)	IHI (2012)	Rello et al. (2010)
AGREE-REX items clustered by domain	Consensus scores by recommendation cluster for each guideline										
Domain 1 Clinical Applicability (% out of 100)	*67*	*28*	*83*	*94*	*11*	*67*	*56*	*33*	*28*	*22*	*22*
1 Evidence	2	2	6	7	1	7	4	2	3	2	2
2 Clinical Relevance/ Applicability to target users	6	3	5	6	2	6	5	3	2	3	3
3 Relevance and Applicability to patients or population	7	3	7	7	2	2	4	3	3	2	2
Domain 2 Values and Preferences (% out of 100)	*13*	*0*	*21*	*54*	*38*	*17*	*0*	*0*	*0*	*8*	*8*
4 Values and Preferences of target users	2	1	2	4	4	2	1	1	1	2	1
5 Values and Preferences of patients or population	1	1	1	6	1	2	1	1	1	1	1
6 Values and Preferences of policymakers and decision-makers	3	1	4	3	6	2	1	1	1	2	3
7 Values and Preferences of guideline developers	1	1	2	4	2	2	1	1	1	1	1
Domain 3 Implementability (% out of 100)	*53*	*50*	*33*	*92*	*75*	*17*	*25*	*0*	*8*	*50*	*33*
8 Purpose	6	6	4	6	6	3	2	1	2	3	3
9 Local application and adoption	3	2	2	7	5	1	3	1	1	5	3
Recommendation for use in appropriate context	No	No	No	Yes	No	No	No	No	No	No	No
Overall AGREE-REX score (% out of 100)	*41*	*20*	*44*	*76*	*37*	*33*	*24*	*9*	*11*	*22*	*19*

Each of the items contain a definition of that item, quality criteria for that item, one question related to quality, as well as one question that focused on suitability for use in a particular clinical setting. Both questions are scored using a seven-point response scale, 1 = strongly disagree and 7 = strongly agree.[25] In this review, recommendations with overall AGREE-REX scores >70% are considered high quality, while those with overall quality scores <30% are lower quality, and all others are moderate quality (approach suggested by AGREE-REX Research Team, 2019).

guideline and AHRQ's care bundle offered generalised guidance for implementing the guideline in its entirety or as appropriate portions of the guideline/care bundle. Devlin et al.'s guideline did get more specific about SI implementation and aligned this practice with other recommendations that should be bundled together as part of the ABCDEF protocol.

Although there are significant methodological deficiencies noted in this review, even within the highest scoring guideline, one guideline does meet a quality threshold that has been commonly used in other reviews. The guideline that met most of the criteria for guideline development was from Devlin et al., which has moderately addressed the values and preferences of key stakeholders, and is the most applicable and implementable of the nine included guidelines. The Devlin guideline offers a 'good practice statement' related to SI, "In critically ill, intubated adults, [daily sedation interruption] (DSI) protocols and [nursing-protocolised] NP-targeted sedation can achieve and maintain a light level of sedation" (2018, p. e838). As the highest overall AGREE-REX scoring guideline, the recommendations were based on a thorough review and analysis of the available evidence related to SI; however, the recommendation was not graded. The recommendation is defined by the authors to be a 'good practice statement' because "… there is an unequivocal belie[f] that the benefit of the intervention outweighs the risk but no available direct evidence that could be summarised or evaluated"[37](Supplemental Digital Content 1, http://links.lww.com/CCM/D733, p. 10).

5. Discussion

Sedation interruptions are an important component of care that has been identified as necessary for mitigating negative sequelae associated with the treatments received in the critical care environment.[44] In this review, we have systematically identified, appraised, and synthesised 15 recommendations related to SI from 11 published guidelines. We have developed a summary table with current best practices for SI recommendations derived from existing guidelines and present three key findings. (i) There are important deficiencies with the quality of the methodological development of all available guidelines that contain a recommendation related to SI. (ii) Best practice is in favour of performing a SI for adult mechanically ventilated patients, but there are key elements missing in the formulation of the recommendation. (iii) The evidence for the SI recommendations are generally weak.

To the best of our knowledge, our review is the first to appraise CPGs as well as care bundles with recommendations directly related to SI using the AGREE-REX as a compliment to the AGREE II instruments. Prior to this review, the AGREE II instrument has been used to appraise CPGs on pain, agitation, and delirium management in the ICU to identify high-quality guidelines appropriate for clinical use.[27] The use of the AGREE II instrument in this review adds a novel perspective in the literature about the overall quality of the methodological development of the guideline while AGREE REX adds transparency to the quality of the recommendations themselves. Three of the eight included guidelines in Rosenthal et al.'s systematic literature search and quality appraisal of guidelines on pain, agitation, and delirium management are also included in this review.[8,39,44] There were differences in the AGREE-II appraisal scores for Celis-Rodriguez et al. and the Delirium, Analgesia, and Sedation (DAS)-Taskforce. The reason for the discrepancy in scoring may reflect Rosenthal et al.'s inclusion of Celis-Rodriguez past guideline from 2013. The Celis-Rodriguez et al. version included in our review is an update of the 2013 version. The older version from 2013 contains a more detailed account of the methodological approaches which could impact AGREE-II scores. Similarly, Rosenthal et al. also included DAS-Taskforce (2015) extended version published in German only, which again would impact AGREE-II scores. Three of the authors on the Rosenthal et al. review are also contributing members on the DAS-Taskforce (2015) guideline, and they may have had access to additional methodological information for that review.

Clinicians need to be aware of certain considerations when they are trying to decide whether to incorporate guidelines and in particular, recommendations related to SI, into unit-specific policies. Being aware of the methodological quality of the formulation of the guideline and individual recommendation itself is important when trying to weigh the options that are available in the literature. This review provides a synthesised view of the available evidence about recommendations related to SI in all available guidelines written in English and may be of particular interest to the individuals developing polices for the critical care clinicians. This review can also help clinicians and policy developers alike to interpret the available recommendations related to SI.

5.1. Guideline quality

There were 11 guidelines identified in this review, none which were of high methodological quality after applying the AGREE II instrument. None of the included guidelines in this review scored ≥60% on at least four AGREE-II domains, which reflects overall poor methodological quality at the level of the guideline as a whole. Clinicians looking to implement the recommendations from these guidelines should be aware that these recommendations are a more practical option for improving the quality of care that this patient population receives rather then being a product of high-quality evidence. The recommendations continue to surface in guidelines despite this lack of high-quality evidence to support their use. This may be because maintaining the ideal minimal level of sedation to keep a patient cooperative enough on the ventilator and also be able to participate in spontaneous breathing trials and early ambulation is not always possible or practical.

Guideline developers would benefit from using more rigorous methodology in guideline development by addressing the domains and criteria detailed by instruments, such as the AGREE II. Despite this finding, the guidelines do offer some valuable information about SI and can serve to inform a clinician or policy developer's knowledge about the elements needed to enact this practice, albeit they do require some modifications. Optimistically, researchers have begun to address the issue of needing higher quality clinical trials evaluating the safety and effectiveness of sedation medications used in mechanically ventilated patients.[45]

5.2. Current best practice for SI

Despite the low methodological quality of the guidelines, the foundational elements for SI that are presented are of value to clinicians. Clinicians are faced with the need to make decisions everyday about patient care, one of these decisions is whether or not to perform SI. Thirteen out of 15 recommendations support the use of SI in practice, and the remaining two only recommend not performing SI on patients with intracranial hypertension. This indicates that including a daily SI can generally be considered current best practice. As best practice, it is important for the recommendation to contain enough detail for clinicians to be able to use it in practice. Currently, the existing recommendations provide some instruction about how to perform SI (action) but lack detail about who is responsible for performing SI (actor), the circumstance(s) when SI should or should not be performed (context) (assuming that a patient may not be eligible for a SI for more reasons than intracranial hypertension) and lastly the goal of performing a SI

(target); there is, however, agreement across recommendations that SI should be performed daily (time).

Overall, there is agreement from the results of this review that the benefits of including a SI in the plan of care out weigh the potential risks. SIs are recommended for patients that are deeply sedated but not recommended for those with diagnosed intracranial hypertension. Indeed, after having deconstructed the foundational requirements (AACTT) for implementing a SI across all 11 guidelines, we can appreciate why it is challenging for clinicians to understand the what, who, when, and under what circumstances a SI should be performed. Guideline developers can ameliorate the current state of recommended practices related to SI by working together to reach consensus on the precise actions required to complete an SI clarity on who is/are the actor(s) and what is/are their role(s), as well as under what contextual circumstances that SI should be performed.

Nomenclature is also important as, arguably, a weaning protocol for mechanical ventilation can be considered to be different from the ABCDEF protocol.[44] A weaning protocol aims to actively discontinue mechanical ventilation, while the ABCDEF protocol is a holistic approach to patient management.[44] More consistency with terminology and specificity about what actions are required to be taken, under what conditions, when, and will likely improve guideline recommendation adherence and patient outcomes. Clinicians and policy-developers need to come together and look at this synthesis of recommendations related to SI and decide what is most appropriate and implementable for their unique context, given the variability that exists.

5.3. Quality of SI recommendation formulation

According to the thresholds set in this review, only the recommendation from Devlin et al. is considered to be of high methodological quality, although the same guideline failed to meet the quality threshold for overall guideline methodological development. The poorest scoring domains for AGREE-REX in this review were Domains 2 (Values and Preferences) and 3 (Implementability). If guideline developers attend to these items in future recommendation formulation, more detailed recommendations could influence the uptake of SI practice at the bedside. This finding is congruent with a study that appraised 161 CPGs using the prototype of the AGREE-REX (draft) tool and the AGREE II tool.[31] The results suggest the least favourable (defined as ratings below the mid-point of the 7-point Likert scale, < 4.0) are more commonly found for *patients/population values, policy values, alignment of values, local applicability* and *resources, tools, and capacity* items.[31] Furthermore, our results reveal the applicability of SI recommendations has the greatest potential for improvement. This finding is consistent with Rosenthal et al.'s appraisal of similar delirium guidelines. To inform the development of recommendations related to SI, it is plausible that recommendations are intentionally left ambiguous since the quality of the evidence to draw from is generally of low quality.[37,38]

5.4. Practice implications

As a potential consumer of guidelines and recommendations related to SI, caution should be taken when deciding to implement these recommendations in practice. In general, the quality of SI recommendation formulation is low, and furthermore, the evidence base in support of these recommendations is mostly of low quality. The heterogeneity of the small number of studies that examine patient outcomes and SI management can explain the low-quality evidence base. Some of the guidelines in this review cite Burry et al.'s systematic review from 2014 in support of the recommendations. Burry et al.'s review examined SI versus no SI in terms of total duration of invasive mechanical ventilation and the influence on mortality, ICU length of stay, adverse events, the total doses of sedative medication required, as well as quality of life.[46] Burry et al advise caution when interpreting their findings given they are based on a small number of heterogenous RCTs and that these results are unstable rather then negative for SI.[46] Inconsistency in the findings on the effects SI recently spurred Chen et al. to conduct a systematic review and meta-analysis of 45 RCTs (i.e., 49 effect size) from different countries. Conversely, Chen's review revealed there is a need to include SI as routine care to reduce the mechanical ventilation duration, especially in higher disease severity populations.[47] The implications of these inconsistencies are reflected in the current state of recommendations related to SI. Clinicians should be aware, whether they continue to implement SI either as a stand-alone intervention or paired with others, research is ongoing about the benefits and risks of SI, and a recent review[47] has demonstrated favourable results.

Furthermore, there is a lack of consensus across recommendations about the *actors*, the *action*, and the *context* by which SI is best performed, with notable absence of specificity about the actor. Although not specified in recommendations related to SI, nurses are primarily responsible for the management of sedative infusions and have self-reported using SI in practice.[17,48] The lack of specificity in recommendations about how to perform SI likely led to variation in SI practice. In 2012, Milller et al. conducted focus groups with intensive care unit physicians, nurses, and respiratory therapists and found a pervasive lack of consensus within and across disciplines about the reason for performing an SI and, most importantly, confusion about the end-points or goals of the intervention.[18]

The recommendation matrix presented in this review can be used by clinicians, policymakers, and guideline developers to make decisions about adopting one of the guidelines or recommendations for local use. The matrix can serve as a starting point for refinement of existing local protocols that include SI. This review also brings increased awareness of two appraisal instruments that can be used during guideline development and/or recommendation formulation. More trustworthy and implementable recommendations alongside structured and multifaceted knowledge translation interventions will increase the likelihood of SI uptake at the bedside. Notably, there is a global need for strengthened guideline quality that is not unique to this field of research.[49]

5.5. Limitations

This study has limitations. It is possible that some CPGs and care bundles were missed during the search. Four databases and 15 critical care associations from around the world and all 11 guideline repositories were hand searched to find guidelines. A selection bias may exist from inadvertently neglecting to include search terms that may result in additional relevant guidelines or ignorantly missing relevant associations or repositories. Also, the authors accept the possibility of a language bias considering only articles published in English were considered for full-text review. Despite the possibility of a selection and/or language biases, countries from around the world are represented here. We had originally planned, as noted in our protocol, to assess the quality of the evidence supporting each guideline recommendations using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.[50] The GRADE system differs from the AGREE instruments, which do not specifically rate and categorise the quality of evidence and the strength of the recommendations. We were unable to undertake the GRADE analysis because some guidelines

did not assess the evidence in support of their recommendations or reported on this.

6. Conclusion

In this review, we identified 11 CPGs and/or care bundles with a total of 15 recommendations related to SI for adult mechanically ventilated patients in the critical care setting. Thirteen recommendations are in favour of SI, and two recommend not performing SI in patients with intracranial hypertension. This review provides greater transparency of the quality and formulation of recommendations related to SI for clinicians policy-, and guideline developers. Nurses and other critical care clinicians can compare the recommendations related to SI to better facilitate application in their local context. Future research should focus on understanding the more technical aspects of completing a SI (e.g., explicating recommended procedural steps) to better assist nurses and other clinicians with the implementation of this practice.

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CRediT authorship contribution statement

Nicole Graham: conceptualisation, methodology, formal analysis, investigation, writing - original draft preparation. **Ian Graham:** conceptualisation, methodology, writing - review and editing, supervision. **Brandi Vanderspank-Wright:** conceptualisation, review and editing, supervision. **Melissa Demery Varin:** investigation, validation, writing - review and editing. **Letitia Nadalin Penno:** investigation, validation, writing - review and editing. **Dean Fergusson:** methodology, writing - review and editing, supervision. **Janet Squires:** conceptualisation, methodology, writing - review and editing, supervision.

Conflict of interest

The authors declare that they have no competing interests.

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Appendix A. Supplementary data

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Chapter 3

Preparing for an Implementation Study: Lessons Learned Conducting an Implementation Needs Assessment

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Involved in drafting the manuscript or revising it critically for important intellectual content;	NDG, IDG, BV-W, DAF, JES
Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content;	NDG, IDG, BV-W, LNP, DAF, JES
Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.	NDG, IDG, BV-W, LNP, DAF, JES

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Ethical approval. The Research Ethics Board (REB) of the research site approved this project (file no. 2108-026). The principal investigator of this study was a Doctoral student conducting research under the auspices of the University of Ottawa and as such received ethics approval from the University REB prior to the start of this project (file no. H-12-21-7555).

3.1 Abstract

Aim To 1) describe an implementation needs assessment at a less research intense tertiary hospital and present the findings 2) highlight the value of doing a needs assessment and the associated implications for future implementation research 3) provide advice for conducting an implementation needs assessment in a less research-intensive hospital.

Design and Methods A needs assessment was conducted that included: 1) an environmental scan of the organization's website and preliminary discussions with key informants to learn about the implementation context, and 2) a formal analysis of the evidence-practice gap (use of sedation interruption) using a chart audit methodology using electronic medical reports.

Results The implementation needs assessment study was conducted from November 2021 to March 2022. The environmental scan revealed valuable information that informed the conduct of an evidence-practice gap analysis. We reviewed 28 records with 82 eligible sedation interruption days. The gap-analysis revealed adherence to the local protocol recommendation for sedation interruption ranged from 65% (n=53) of the time to as high as 84% (n=69) when all failure to document cases were assumed to be either appropriate-use or appropriate non-use of SI.

Conclusions Implementation needs assessments should include an environmental scan to understand the local context and be designed to identify current recommended best practice for the intervention of interest in addition to local best practice. Evidence-practice gap analyses should be designed to quantify the magnitude of the gap between local practice and desired, or best practice.

Impact Evidence-practice gaps are a nursing concern and needs assessments are a feasible approach to understanding the nature and magnitude of these gaps. Access to information can be a major challenge in conducting an implementation needs assessment at less-research intensive hospitals. Our example of a systematic and rigorous approach to conducting a needs assessment demonstrates how even small samples can lead to meaningful results and can be a resource for nurses to understand how to conduct implementation studies.

No Patient or Public Contribution No engagement with patients occurred in this study.

Keywords Evidence-practice gap, know-do-gap, environmental scan, implementation needs assessment, sedation interruption, critical care.

3.2 Background

Evidence-informed practice is the point of overlap whereby practitioner expertise, and client values are influenced by, rather than based-on, the best available evidence (Shlonsky & Mildon, 2014). Evidence-informed practice and evidence-based practice (terms often used interchangeably), espouses the interconnectedness of various factors and elements that enable a professional to use evidence in support of their clinical decision-making within complex environments (Kumah et al., 2022). There is increased attention and support for the incorporation of evidence into nursing practice by researchers, organizations, and professional bodies around the world (e.g., the Registered Nursing Association of Ontario). According to one literature review, there were at least 60 associations around the world (from Canada, United-States of America, New Zealand, Finland, and Switzerland) that were undertaking 'evidence-based' activities (Holleman et al., 2006). The current Canadian Nurses Association position advocates that all nurses, including clinicians, educators, researchers, administrators, and policymakers must collaborate with other health-care stakeholders to facilitate evidence-informed decision-making in practice (CNA, 2018) because of the potential benefits and improved patient outcomes.

Well-developed evidence-informed guidelines support this initiative and are readily available around the globe. However, despite the availability of high-quality clinical practice guidelines, many critically ill patients still do not receive the recommended care, contributing to their morbidity, mortality, and higher costs of care (Kahn, 2017; Levy et al., 2018; Rhodes et al., 2017). A reported 17-years is the average time it takes for evidence to make it into practice (Morris et al., 2011). "Evidence to practice," or "know-do" gaps result in possible suboptimal care or a delay in benefits associated with unsuccessful implementation (Grimshaw et al., 2012).

Pre-planning before implementation allows the researcher or clinician to gather critical information that informs future steps and phases of the project. Gaining a sense of the context is a principal step in the pre-planning phase of any implementation project or study and needs to be done rigorously to provide meaningful information. To accomplish this step, Kitson and Straus (2013) describe an implementation needs-assessment as "a systematic process for determining the size and nature of the gap between current and more desirable skills, attitudes, behaviors, and outcomes" (p. 100). The strategy(ies) used to conduct a needs assessment depends on the purpose of the assessment, the type of data and the available resources (Kitson & Straus, 2013). An implementation needs assessment can be conducted as research, and when appropriate require research ethics board approval, or can be considered part of a quality improvement initiative and not be undertaken as research. At the care provider level, chart audits, observational studies, competency assessments and reflective practice are common approaches to assessing implementation needs.

3.2.1 *Context for a Needs Assessment and Future Implementation Study*

Sedation interruptions (SI) is an evidence-informed intervention that has demonstrated positive outcomes for mechanically ventilated adults in critical care. Since introduction of SI in the literature nearly 24 years ago (Kress et al., 2000), a gap continues to exist between recommended practice and actual practice (Carrothers et al., 2013; Darby, 2020; Smith, 2013; Sneyers B., Laterre P.-F., Perreault M.M., et al., 2014). SI is an important evidence-informed strategy used to minimize the bioaccumulation of sedative medications and facilitates the completion of a proper neurological assessment amongst other known benefits (Vagionas et al., 2019). SI are one of several bundled recommendations for mitigating post intensive care

syndrome that can impact survivors of critical illness (DAS-Taskforce 2015 et al., 2015; Ely, 2017b).

According to a recent review, there are 11 guidelines with 13 recommendations for the use of SI for adult mechanically ventilated patients and two offer recommendations to not use SI in patients with increased intracranial pressure (N. D. Graham, Graham, Vanderspank-Wright, Demery Varin, et al., 2022). Despite evidence that suggests important deficiencies with the quality of the guidelines' methodological development, best practice favors SI (N. D. Graham, Graham, Vanderspank-Wright, Demery Varin, et al., 2022).

Adherence to SI was noted as a topic of interest to staff (nurses and physicians) in a critical care unit (CCU) in Northeastern Ontario and that a related implementation study may be warranted to improve SI use (to be referred to as the future implementation study). To plan for an implementation study, we selected a planned action framework and developed a strategy for how to undertake the first phase of the framework which was an implementation needs assessment.

3.3 Purpose and Objectives

Little is known about the real-world challenges of conducting an implementation needs assessment especially in smaller less-research intensive hospitals or social organizations. Our specific objectives for the paper were to 1) describe the methods used in conducting an implementation needs assessment at a tertiary hospital, and to present the needs assessment findings; 2) highlight the value of doing a needs assessment and the associated implications for undertaking future implementation research at this setting; 3) provide advice for conducting a needs assessment in a less research-intensive hospital. What follows is a description of our

approach to an implementation needs assessment in a small tertiary hospital, which was comprised of an environmental scan followed by an evidence-practice gap analysis.

3.4 Guiding Conceptual Framework

The Knowledge to Action Framework (KTA) was derived from a synthesis of more than 30 planned action theories, frameworks and models and is one of the most used to inform the conduct of implementation projects and studies (Azer, 2015; Moore et al., 2022; Skolarus et al., 2017). The KTA comprises two processes: knowledge creation and an action cycle (I. D. Graham et al., 2006; Straus et al., 2013). The action cycle comprises seven phases that should be addressed for successful implementation of evidence into practice. The first phase involves identifying the clinical problem, selecting the evidence to be implemented to assess the problem, and determining the know-do gap between current and best practice. This phase involves understanding the implementation environment or context (e.g., the nature of the setting: historical context, size, number and types of providers and patients) and the nature and magnitude of the know-do gap (e.g., current practice and how it reflects (or not) best practice) Understanding the context for implementation accelerates activation of evidence in practice. Determining the know-do gap has similarities to the planning phase of the Plan-Do-Study-Act which is a commonly used tool in quality improvement activities (Christoff, 2018), however, our purpose and objectives necessitated more in-depth guidance about understanding the translation of SI into practice rather than improving the current process. To supplement the KTA, we used a second planned action framework.

Our approach was also informed by Implementation Roadmap (Harrison & Graham, 2021) a more detailed planned action framework based on the KTA framework, and is comprised of planning and implementation phases: 1) issue identification and clarification, 2) build

solutions and field test them, and 3) implement, evaluate, and sustain. The two steps under phase 1 correspond to the KTA action phase of determining the know-do gap and comprise: i) identifying the problem of concern and potential best practice for it (including identifying best practice and identifying indicators of best practice) and ii) assembling local evidence on context and current practices (including determining the magnitude of the problem, determining current practice, and measuring the evidence-practice gap).

3.5 Implementation Needs Assessment Methodology

Our approach to conducting the implementation needs assessment started with an environmental scan of the hospital and gathering information specific to the critical care unit; then, conducting an evidence-practice gap analysis.

3.5.1 *Methods for Environmental Scan*

We conducted an environmental scan to better understand the context for the gap-analysis study. Environmental scans in the health care sector are gaining popularity for examining the current state of programs, services, or policies (Charlton et al., 2021) and can cover everything from casual discussions, observations, analysis of organizational documents (e.g. policies and procedures) and a secondary analysis of organizational databases (e.g. the electronic health record, and other micro-data storage systems). The purpose of the environmental scan in this study was to understand and document the structure of the organization (hospital), specific setting (the CCU) and those who work there. The environmental scan was composed of two components, during which information was gathered to better understand 1) the gap-analysis setting, and 2) the organization's readiness for research.

Component 1 Understanding the Study Setting Scanning the Environment. We scanned the organization's website to identify documents that described the hospital context

(e.g., number of beds, staffing arrangement, relationships with academic centres, etc.). We had preliminary informal discussions with key individuals. For example, we spoke with the clinical nurse educator in CCU to understand more about the internal staffing structure, the Chief Nursing Executive Officer to elicit support for the ethical conduct of nursing research in CCU, and an electronic medical record system analyst to become familiar with the documentation procedures in CCU. We asked for relevant policies and procedures related to the prescription for SI practice at this organization and the CCU's standardized order set for mechanically ventilated patients. We also asked for any examples of related electronic medical system documentation screens that nurses and other multidisciplinary team members used for charting about SI.

Identifying Best Practices and Determining Indicators of Best Practice. To determine best practice for the use of SI and how it compares with what was considered local best practice for SI, we conducted systematic review and appraisal of SI guidelines (N. D. Graham, Graham, Vanderspank-Wright, Demery Varin, et al., 2022). The systematic review used the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument (Brouwers et al., 2010) to appraise the methodological development of 11 identified guidelines with 15 recommendations related to SI (N. D. Graham, Graham, Vanderspank-Wright, Demery Varin, et al., 2022). This was useful for determining best practice for SI from an international perspective rather than limiting the benchmark for best practice to one recommendation from one guideline. The review also provided the needed comparator for determining how closely the local CCU protocol reflected international recommendations. We sought the hospital's SI policy to determine what the hospital considered local best practice. The CCU had a standard order set applied to all adult mechanically ventilated patients admitted to CCU that corresponded with a regional protocol

(Sedation and Analgesia Protocol). Once a physician orders the protocol, the nurse has the authority to implement the treatments and interventions included in the order.

The next step was to create indicators of SI use based on the standard order set for mechanically ventilated patients, the CCU's Sedation and Analgesia Protocol, as it did not already include indicators that could be used to assess adherence to the protocol. Following the local protocol, if the patient was stable (e.g., blood pressure stable, no neuromuscular blockades in use, not difficult to ventilate), all sedation was to be turned off until the Richmond Agitation Sedation Scale was between 0 and -1 (meaning alert and calm to not fully alert but has sustained awakening to voice). We reviewed the electronic medical system documentation templates to see the available data and modified the proposed indicators to align with what we anticipated in the documentation screens.

Component 2 Understanding the Local Research Ethics and Data Access Processes. The need to obtain approval from a research ethics board is common to all research involving human participants and secondary use of information within personal health records. We searched the organization's website using keywords related to research ethics (e.g., 'research ethics' and 'Research Ethics Board (REB)') to locate documents and information about the local process for seeking approval to access secondary data and the conduct of research. Informal, preliminary discussions were had with representatives of the REB to learn about the current processes and policies for conducting research at this organization.

3.5.2 *Methods for Evidence-Practice Gap Analysis*

The evidence-practice gap was determined using a retrospective chart audit to compare current practice to performance indicators developed for this study. The unit of analysis for measuring SI use was the number of *days* when a patient would be eligible for an SI. Eligibility

was defined as having a physician's order for a sedation interruption, the absence of neuromuscular blockade, and/or prone positioning. The local protocol's definition of 'stable' was also used to determine eligibility for SI. Based on the local protocol we developed two indicators that described 1) the adherence to the local protocol recommendation and, 2) the evidence-practice gap. Table 1 illustrates the indicators for analyzing the evidence-practice gap in using SI. We summarized the types and sources of information that we found useful for conducting a gap-analysis.

Chart Audit Setting and Sample Selection. We used a purposive sampling strategy to obtain a sample of charts from patients admitted to CCU from October 2019 to January 2021 who were mechanically ventilated for at least 24 hours and were 18 years of age or older at the time of admission. Sample size was calculated using a benchmark for estimating the expected proportion within the population that will have the clinical intervention of interest. In one large study, adherence with *daily SI* was reported to be 72.2% of all eligible study days for an average patient (Mehta et al., 2012). If the proportion of the population expected to have the characteristic is over 50%, then the sample size calculation should be based on the proportion without the characteristic (Patient Safety-Quality Improvement, 2016). The estimated proportion of patients not receiving SI was estimated to be 27.8%. With a confidence interval of 0.20 and a confidence level of 95%, the sample needed was 81 patients' electronic charts. We requested 200 unique patients' charts to be pulled to account for the possibility that further exclusion would occur at the level of abstraction (Vassar & Holzmann, 2013). The clinical records department generated a worklist of all the electronic charts that met the inclusion criteria from October 2019 (the launch of the new online EMR) to the commencement of the chart audit,

which was January 2021. We decided to use this timeframe as it was not feasible to undertake a manual chart audit of paper charts.

Chart Audit Data Collection. For ease of data collection, the data abstraction tool was developed following the flow of information presented in the electronic medical record documentation screens. We consulted an analyst to validate that the information we were seeking would be available in the documentation screens. Reliability of the data abstraction tool was assessed independently by two reviewers on 5% (n=4 charts) of the total desired sample (n=81 charts) (Allison et al., 2000). Minimal modifications to the instrument were made during the pilot. After consensus was achieved on 5% of the sample of charts by two independent reviewers, one reviewer went on to complete data abstraction of the remaining charts. In addition to the indicators for 1) adherence to the local protocol recommendation and, the 2) evidence-practice gap, we collected data using a data-minimization approach to protect the patients' identity which included their month and year of admission, admitting diagnosis, age in weeks, length of stay, and any other demographic information that we could use to describe the population.

Gap Analysis. Frequencies were tallied and the data were categorized as four distinct observations that described the use of SI: 1. appropriate use, 2. appropriate non-use, 3. overuse, and 4. underuse. The indicator for adherence was the magnitude of appropriate use and appropriate non-use, summed together. While the evidence-practice gap was defined as the magnitude of overuse and underuse, together.

3.6 Ethical Considerations

As the implementation needs assessment was undertaken as a research project, the REB of the research site approved this project (file no. 2108 - 026). The principal investigator of this study is a Doctoral student conducting research under the auspices of University of Ottawa and

as such received ethics approval from the University REB prior to the start of this project (file no. H-12-21-7555).

3.7 Findings from the Environmental Scan

Component 1

Understanding the Organization

The environmental scan began in November 2021 approximately three months prior to the commencement of the chart audit (January 2022 – March 2022) with some overlap between its end and the beginning of the evidence-practice gap analysis. The environmental scan revealed valuable information about the clinical setting that informed the conduct of the evidence-practice gap analysis. Examples of information gathered during the environmental scan were number of beds, Registered Nurses, Respiratory Therapists, Anesthesiologists, Pharmacists, CCU patient admissions per year, average length of stay, the history of the hospital, and information about the electronic medical record system or platform, etc. Table 2 displays a summary of the types and sources of information included in the environmental scan and used to plan the evidence-practice gap analysis. For example, the annual reports that were published on the organization's public domain website were used to understand the hospital's administrative structure which helped us identify the Chief Nursing Officer. The facility hosts both district acute care services and regional mental health care services and operates under one Chief Executive Officer and one senior team. The hospital is designed to accommodate up to 57,000 annual visits and facilitates quicker access (by land or air) to larger metropolitan area hospitals within the geographical region. The information gathered shaped the context of the implementation setting which was not

only important for interpreting the data but also understanding the organization's administrative structure for approval of a future implementation study.

The environmental scan was valuable in setting up the SI evidence-practice gap analysis as it provided the researchers with insight into the key stakeholders and gatekeepers that would have an influence on decision-making and access to secondary data. There was stakeholder engagement throughout the needs assessment, starting with the Chief Nursing Officer who approved of the conduct of nursing related research and expressed ongoing support for the advancement of knowledge related to SI in this CCU. The CCU clinical nurse educator agreed that SI were relevant to their unit and facilitated access to the local protocol. Engagement of the Manager of the clinical records department was essential for enabling REB approval to conduct a retrospective chart audit.

Understanding the Gap Analysis Setting

We found that the Level 3b CCU had 16 beds and operates as a closed unit run by an Internist. There were approximately 22 full-time Registered Nurses (RN), 19 part-time RN, 10 Internists, 9 CCU Anesthesiologists, 17 Respiratory Therapist employed by the hospital, and one assigned to CCU each shift, also one Pharmacist. We understood that it was considered a general admissions CCU and received approximately 220 to 400 admissions per year.

Component 2

Understanding the Setting's Readiness for Implementation Research

Informal discussions with senior leaders revealed that the hospital had experience with routine chart reviews for internal quality improvement initiatives, however, a formal retrospective chart audit had never been conducted at this facility by an external researcher. To access patient level data, we needed research ethics approval from the hospital. The ethics

application process took approximately three months from the application's submission to receiving final ethics approval for the chart audit. Confidentiality agreements needed to be signed by anyone on the research team that may potentially view the raw data or Medical Record Number (MRN) list, identifying these individuals in advance of the application helped mitigate delays. Personal Health Information Protection Act (PHIPA) Research Agreements also needed to be signed by all principal and co-investigators. Completing this early was important because the same form had to be signed by the Chief of Staff before approval. Mandatory signatures were required from the Clinical Record department Manager, and the Privacy Officer prior to ethics approval.

We encountered a high turnover of mid-level and senior-level staff during the ethics application process. During the period from when the ethics application was submitted to when we were given access to the electronic chart, the Clinical Records department Manager, and Privacy Officer changed. Our ethics application was delayed during the management transition period as it was deemed inappropriate for the interim Manager to sign off on the research ethics application.

Issues with Data Access

The process for creating research accounts to access the facility’s electronic records took more than two weeks. In our case, this new type of account was less familiar to the staff in the Information Technology department and the technician required additional time and guidance from another hospital staff to create them. In addition, more than two weeks was required for the patient MRN worklist to be created and procured by a clinical records department staff member and approved by the Manager.

The chart audit took place between January 2021 and March 2021. Despite receiving REB approval to access the electronic medical record, the clinical record department provided access to a different source of data for the chart audit. This unanticipated change led to an approximate 4-week delay to the commencement of the chart audit and necessitated changes to the method for data collection. We were only given access to information from the legal electronic report and once we started to abstract data it became apparent that the audit from this type of document would take considerably more time than directly from the electronic medical record. These reports were a synchronous account of multidisciplinary documentation (assessment order sets, ventilator settings and vital signs, with narrative notes clustered at the end of the report) which were presented in chronological order from the first to last day of admission. The reports were often between 100 and 700 pages in length per patient, so we were unable to use a search data function to locate key words and clinical interventions. The team discussed options for how to move forward in a feasible way. It took over 3 weeks (approximately 32-hours) to extract data from 28 randomly selected charts from the purposive sample. We decided this number of charts would be adequate to get a sense of the SI evidence-practice gap even though we would not have the power to state conclusions with statistical certainty. The 28-chart sample satisfied the objectives of the practice-gap analysis as our intent was to get a sense of the current state of SI use, confirming there was a gap that warrants a future implementation study.

3.8 Findings from the Evidence-Practice Gap Analysis

There was a total of 156 records identified by the Clinical Records Department of mechanically ventilated patients admitted to CCU from the time of the new EMR system launch to the time of record retrieval. After closer inspection of the records, 86 met eligibility

Criteria: 51 records were excluded for having a ventilation time less than 24-hours, 7 were excluded because the patient was transferred to another facility in less than 24-hours, 4 patients expired, 2 patients had an order not to perform SI, 1 patient did not have a sedation infusion ordered, 1 record was not available.

Of the final abstracted sample of 28 patient records, the total number of eligible SI days was 82. The sample contained a range of patients with a variety of admitting diagnosis and reasons for mechanical ventilation, including respiratory failure, pneumonia (including COVID-19 positive patients), polysubstance overdose, and brain injury. All these data contributed to the environmental scan data allowing us to describe the CCU patient population.

Of the total 82 eligible SI days, SI occurred on 51 days in accordance with recommended practice; SI did not occur for an inappropriate reason on 2 days; SI was documented to not have occurred but no reasons for not providing SI were documented on 13 days, and there was a failure to document SI on 16 days (e.g., it was not documented whether it was done or not done). Table 3 displays the results of the evidence-practice gap analysis. Depending on the scenario, the rates of adherence ranged from a low of 64.6% (51+2/82) to a high of 84% (51+2+16) of cases when it was assumed the 16 undocumented cases all represented appropriate use or appropriate non-use of SI. Depending on the scenario, non-adherence rates ranged from a low of 16% (13/82) to a high of 35% (13+16/82) of days, again when it was assumed the 16 undocumented cases all represented overuse or underuse of SI, respectively, leaving considerable room for improvement and providing justification for conducting an implementation study to improve the use of SI.

There was also an unanticipated finding related to documentation which has implications for the future implementation study. For approximately 20% of the days, there was no

documentation about whether SI was performed or not. We also noticed that at times nurses were not selecting an approved reason for not performing a SI (n=11 occurrences); free text was inputted into the 'other' category. All 11 reasons (100%) that were documented in the 'other' category did not align with the rationales offered by the protocol for not performing SI nor did they align with exclusionary criteria that can be found in the literature (Sneyers B., Laterre P.-F., Perreault M.M., et al., 2014; Society of Critical Care Medicine, n.d.).

3.9 Discussion

The Value of an Implementation Needs Assessment

The value of the implementation needs assessment was two-fold. First, the environmental scan provided valuable information about the study setting. At the hospital level, we gained a sense of the organizational structure and were able to identify relevant gatekeepers. Engagement of gatekeepers can be invaluable to the research process; having an impact on what data is accessed and the facilitation of research activities to completion. Furthermore, identifying individuals within different departments early in the process will ease the work of engaging champions later to oversee or promote and advocate for best practice and evaluation of implementation activities within an organization (Harrison & Graham, 2021; Santos et al., 2022). The unit level information was necessary for the gap analysis study and later, the interpretation of the data. Contextual details, such as number of beds, staffing structure, types of admissions were important for situating the data within boundaries when interpreting the data. For example, knowing the types of patients that are typically admitted to the unit helped the researchers recognize appropriate reasons for non-use of SI, which include increasing intra-cranial pressure, prone positioning, or concurrent use of neuromuscular blockade. A significant contextual finding

from the environmental scan was that the unit is run by an Internist, primarily, while staff Anesthetists manage the care of mechanically ventilated patients. This has implications on the continuity of care that is received by the mechanically ventilated patients and possibly the degree of involvement from the multi-disciplinary team with SI. Multidisciplinary rounds are commonly known to be an effective method for discussion and identification of clinical concerns (Ganesan et al., 2017). Lack of teamwork and organizational support have been frequently identified as barriers to implementing evidence-informed guidelines in other settings (McArthur et al., 2021; Wolfensberger et al., 2018). Secondly, identifying the CCU's internal policies related to SI was essential for understanding what was expected of clinicians working in this CCU in relation to SI practice. The policy and corresponding electronic documentation screens were the basis for the development of appropriate indicators that would help us understand how SI was being used in the unit.

We categorized the implications of the implementation needs assessment into three stages of work: 1. before you measure – understanding the environment for implementation, 2. what to measure – determining indicators to measure the gap, 3. how to measure – conducting a gap analysis. Table 4 illustrates these stages of work and important questions to ask when preparing for an implementation needs assessment. An initial set of questions were obtained from Straus, Tetroe and Graham (2013) and additional questions were added based on our experience with the implementation needs assessment.

Before Conducting a Gap Analysis- Understand the Implementation Context

It is important to understand the internal structure of the hospital and separately, the target setting (e.g., CCU). Knowing how a department is run and who the gatekeepers are (e.g., the Clinical Records department Manager and Privacy Office) can impact access to information.

Unanticipated findings can be revealed during the process that have implications for future work relevant to improving practice. For example, we encountered some delays and challenges undertaking the chart audit because the organization was less experienced with external researchers and were rightfully concerned about protecting personal information and abiding by privacy legislation. At the time of this implementation needs assessment, the hospital had not yet been developed a Corporate Standard Operating Procedures (SOP) for secondary use and disclosure of electronic data whereas larger researcher-intensive organizations often have SOP governing access and secondary use of the information in personal health records. This type of SOP outlines the criteria and process for researchers with the appropriate authority to access personal health information for research purposes. We advise that researchers ask in advance about all SOP that might be relevant to conducting an implementation needs assessment. Researchers should be aware that processes for research may be in development. This may be an opportunity for the researcher to connect the smaller hospital with the privacy officer at a larger research-intensive organization to share knowledge related to how legislation and regulatory requirements can be incorporated into SOP.

What to Measure with the Gap Analysis– Determine Indicators for Measuring the Gap

Researchers should begin by developing gap analysis research questions that can generate results that are actionable. This can be achieved by asking a question that directly relates to observations of a particular clinical practice setting. Sometimes the research questions may not be obvious at first, and in this case conducting an implementation needs assessment beginning with an environmental scan gave the researcher a sense of where research efforts should be focused. Once the practice issue becomes clearer and before embarking on a gap-analysis, identify the evidence to be implemented. Start by searching for relevant systematic reviews and

meta-analysis of clinical practice guidelines related to the practice issue. Consider conducting a review of guidelines if one is not already available in the literature. Local protocols, clinical pathways, decision-aids, electronic documentation systems (relevant order sets and nursing documentation screens) can also serve as a source for understanding local best practice. If not already available in the literature or from local policy, indicators of best-practice use will need to be developed. Consider all possible permutations of best-practice use of an evidence-informed practice to develop indicators describing the magnitude and nature of the evidence-practice gap.

In our case, the evidence-practice gap was measured regarding the disparity between desired practice (appropriate use of SI) from the protocol or policy and current practice. Indicators of the gap needed to be developed to measure the magnitude and nature of adherence to the desired practice. This was thought of as four distinct observations that described the use of SI: 1. appropriate use, 2. appropriate non-use, 3. overuse, and 4. underuse. The indicator for adherence was considered the magnitude of appropriate use and appropriate non-use, together. While the evidence-practice gap was defined as the magnitude of overuse and underuse.

How to Measure the Evidence-Practice Gap– Conduct a Gap Analysis

Sample size is important and to have generalizable findings and must be large enough to conduct statistical inferences. Other researchers agree (Etchells et al., 2016) that smaller sample sizes, however, can provide a sense of the current state of practice and inform future implementation projects, sometimes serving as baseline data for the implementation study. It may not always be possible to access the full EMR and alternative strategies will need to be developed to obtain the desired data. For example, our work around not gaining access to the EMR involved working collaboratively with the clinical record department staff to obtain screen shots of the desired EMR documentation screens to answer our implementation

needs assessment questions. If using additional measures to obtain the needed data, ensure that the process is also piloted. In our case, we needed to revise the data abstraction tool to match the available information in the legal electronic reports. As a result of only having access to the lengthy electronic reports (pages ranged from 100 to 700) and having a limited timeframe (this study is a component of a PhD dissertation), we decided to stop data abstraction early. Despite the smaller than anticipated sample, the rates of SI adherence were still comparable to other studies. For example, a large study done in six ICUs in Zurich, Switzerland, examined several different evidence-informed interventions and reported SI adherence to be 81% (Wolfensberger et al., 2018). Also, a study conducted as part of a doctoral dissertation used a single-paged post-shift questionnaire and described charting "compliance" for sedation vacations to have increased from 68% to 80% when documentation was bundled together with other practices (Darby, 2020).

At times nurses were not performing SI for appropriate reasons that aligned with the local protocol. Furthermore, the documented rationales often did not align with frequently cited reasons for not performing SI in randomized control trials (Mehta et al., 2012; Sneyers B., Laterre P.-F., Perreault M.M., et al., 2014) and the sedation awakening trial safety screen described by the Society of Critical Care Medicine. This finding demonstrated an evidence-to-practice gap between recommended and current practice and provides justification for pursuing a future study to reduce the evidence-to-practice gap related to the use of SI in this CCU.

Importantly, it became evident during the gap-analysis that there was an issue related to accurate and timely documentation (the College of Nurses of Ontario (2008) standards for documentation) that needed to be addressed by the site, potentially in a future implementation study.

3.10 Limitations and Strengths

This implementation needs assessment was designed to increase our understanding of the research context and provided justification for a future implementation study at a tertiary-care hospital. The setting for our research may not reflect all small tertiary hospitals, however, we believe that many of the lessons learned during this study can benefit other researchers attempting to understand evidence- practice gaps. The generalizability of the findings from this study is limited but the lessons learned, and advice formulated because of the needs assessment process are likely transferable. As with all environmental scans, our understanding of the context was limited to the information that was available. Informal discussions with senior leaders and an analyst facilitated the development of relationships with key individuals in the organization that likely helped us move forward with the gap-analysis and possibly improved willingness to support the work of our future implementation study.

Our chart audit was limited by virtue of potential, and at times unavoidable, challenges associated with this methodology. These include incomplete or missing data within the medical record, records lacking specific information, difficulty in interpreting or verifying documented information, and variability in documentation quality among health care professionals (Gearing et al., 2006). Although the small sample size limited capacity for more complex statistical analysis, the 28 reports and resulting 82 days used for analysis gave us useful and actionable information with implications for our future implementation study.

3.11 Conclusions

An implementation needs assessment is a practical approach to gathering key information upon which to plan an implementation project or study. Our experience reveals that an implementation needs assessments should include an environmental scan to get a wholesome picture of the local context and some of the factors that might influence implementation. The lessons learned are particularly relevant to researchers working with a center with less research experience or a limited understanding of the ethics process because the logistics of getting REB approval and the time this takes can be impacted. The scan should also be designed to identify the current state of recommended best practice for the intervention of interest in addition to what the local site considers best practice to be. Local best practice may or may not align with the international guidelines or literature but knowing this is important for measuring the 'know-do' gap.

Any evidence-practice gap analyses should be designed to quantify the magnitude of the gap between local practice and desired, or best practice. An important aspect of our approach was the development of indicators used to measure the evidence-practice gap as such indicators are often not included in either local policy or published best practice recommendations. The four distinct categories that describe the use of a practice are 1) appropriate use, 2) appropriate non- use, 3) overuse, and 4) underuse. Each of the four categories gives different useful information from an implementation perspective. Indicators of evidence-practice gaps can be thought of as the magnitude of the combined overuse and underuse of a practice. Knowing the extent of over and underuse has implications for selection of possible implementation strategies as the factors that influence overuse of a practice may differ from those influencing the underuse of it. We found access to information needed to conduct an implementation needs assessment at a smaller less-research intensive hospital to present some challenges.

Nonetheless, we encourage implementation researchers and practitioners to work with clinical and organizational stakeholders to obtain as much data as possible and that even smaller than desired samples can still generate meaningful implementation insights and potentiate change.

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Table 3.1 Indicators for analyzing an evidence-practice gap of an intervention

Indicators	Indicator calculations	Sub-indicators	
1. Adherence to the local protocol's recommendation	A+B/total*100	A.	Appropriate use
		B.	Appropriate non-use
2. Evidence-practice gap	C+D/total*100	C.	Overuse
		D.	Underuse of SI

A. Appropriate use: Sedation interruption performed when indicated by the local policy
B. Appropriate non-use: Sedation interruption not performed when not indicated
C. Overuse: Sedation interruption is performed when not indicated
D. Underuse: Sedation interruption not performed when it was indicated

Table 3.2 Types and sources of information for the environmental scan

Category	Type of Information	Access or Source for Information	Use for the Information
Hospital Operations	Published Annual Reports	Institution Public Domain Website	Brief history about the organization Annual updates related to operations Partnerships with other organizations External and internal structures
	Policy and Procedures	Access through permission from unit educator and administration	Clinician guidance and prescription for the intervention of interest
	Electronic Medical System	Access through permission from unit educator and administration	Templates of mandatory and optional multidisciplinary documentation for the intervention of interest
Research Ethics	Research Ethics Board documentation	Institution Website - Public Domain	Research policy (general information) Submission form Instructions for completing the REB Research Project Annual Renewal Form Amendment form Final Report Participant Adverse/Unanticipated Event Notification Form Research Agreement
	Ministry of Health and Long-Term Care	www.health.gov.on.ca	Ontario's personal health information privacy legislation for the health sector (Health Sector Privacy Rules) The Personal Health Information Privacy Act (PHIPA) is the legislation tat describes the permit and collection, use, and disclosure of personal health information for secondary purposes. See section 37 (1) Permitted Use and subsection 3.
	Government of Canada – Panel on Research Ethics	www.ethics.gc.ca	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2
	Information and Privacy Commissioner of Ontario	www.ipc.on.ca	Privacy by Design approach to using personal health information in a way that is safe for the individuals and at the same time amenable to high quality research
Gatekeepers	Clinical Nurse Educator	Email	Internal resource for: policies and procedures, documentation, and internal structure of the unit.
	Clinical Records Manager or Supervisor	Email consider cc' REB administrator	Signature is required for the REB application
	Privacy Officer	Email consider cc' REB administrator and Clinical Records Manager	Signature is required for the REB application
	Chief Nursing Executive (CNE) officer	Email	Signature strengthens the REB application but not required

	Manager Risk	Email, consider cc'd CNE office	Internal resource for ethical conduct of research involving human participants

Gatekeeper: an individual that is key for gaining approval and access to the personal health records for a chart audit. Secondary gatekeeper: individual that is key for access to information about the process and structure of the organization and unit of interest.

Table 3.3 Results of the evidence-practice gap analysis

		Local best-practice use		
		Adherent	**Non-adherent**	**Total**
Sedation Interruption	**Performed**	A. appropriate use (n=51) 62% (82% if *all undocumented cases included)*	C. overuse (n=0) 0% to 19.5% (if *all undocumented cases included)*	**51**
	Not performed	B. appropriate non-use (n=2) 2.4 (22% (if *all undocumented cases included)*	D. underuse (n=13) 16% to 35% (if *all undocumented cases included)*	**15**
	Failure to document	E. failure to document n=16 (20%)		**16**
	Total	(n=53) 65% or as high as (n=66) 80% (when all failure to document cases included)	(n=13) 16% or as high as (n=29) 35% (when all failure to document cases included)	**82**

Legend
A. Appropriate use: Sedation interruption performed when indicated by the local policy
C. Overuse: Sedation interruption performed when not indicated
B. Appropriate non-use: Sedation interruption not performed when not indicated
D. Underuse: Sedation interruption not performed when it was indicated
E. Failure to document *(undocumented cases)*: Not documented whether sedation interruption was done or not done

Unit of analysis is days when a patient is eligible for a sedation interruption. Eligibility was defined here as having a physician's order for a sedation interruption, the absence of neuromuscular blockade and/or prone positioning. An appropriate reason non-use of SI is increasing intra-cranial pressure, prone positioning, or concurrent use of neuromuscular blockade.

Table 3.4 Important questions to ask when preparing for an implementation needs assessment.

Questions about comparing actual and desired practice	Yes / No / Unsure
1. before you measure – understanding the environment for implementation	
• Is the setting where research is to take place a research-intensive hospital or other?	
• Has the institution or agency granted permission in the past for external research?	
• Does the institution or agency have existing Corporate Standard Operating Procedure (SOP) for Secondary Use and Disclosure of Electronic Data? Does this SOP apply to research conducted by external researchers?	
• Are there existing Clinical Record Department policies or procedures developed for chart audits? Do they apply to external researchers?	
• Have you reached out to key stakeholders and are they willing to assist with the provision of documents/information/contacts?	
• Do you have someone with the right experience and skill to assist you with the pilot of the chart audit?	
• Have you gathered all the documentation relevant to applying for Research Ethics Board approval? (See Table 2)	
2. what to measure – determining indicators to measure the gap	
• What is/are the research question(s) that you are trying to answer?	
• What is the evidence from which the gap is being measured?	
• Do you require a benchmark to compare your findings or to establish a threshold to know the extent of the gap?	
• What are the indicators that the intervention/action is or is not occurring? Do they need to be created?	
• *Do your indicators have sufficient impact to lead to improvements in care, if addressed?	
• What will you measure and how will you measure it? Will this information answer your research question(s)?	
• Will you have access to the information that you used to create the indicators to measure?	
3. how to measure – conducting a gap analysis	
• *How are you identifying a representative sample?	
• How big does your sample need to be to get a sense of the extent and nature of the evidence-practice gap?	
• Is your sample from the same medium? Will you have different types of documents in your sample that change over time?	
• *How will you collect the information?	
• Do you have a data extraction sheet developed that reflects the documents that you reviewed and created indicators for?	
• Is the information that you need for data extraction available in the format that you anticipated?	
• If your access to documentation has changed, is it still possible to abstract the indicators developed a priori?	
• *How will you interpret the information?	

* - The initial set of questions were obtained from Tetroe and Graham (2013) and additional questions were added based on our experience with the implementation needs assessment: in Sharon ES, Tetroe J, Graham ID. Knowledge Translation in Health Care: Moving from Evidence to Practice, Second Edition (2013). Harrison, MB…Chapter 3.2 Adapting knowledge to local context. John Wiley & Sons, Lt.

Chapter 4

Factors influencing nurses' use of sedation interruptions in a Level 3 Basic critical care unit: a descriptive qualitative study.

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Declarations: The current study was conducted in partial completion of a Doctorate in Philosophy Nursing at the University of Ottawa, Faculty of Health Sciences, School of Nursing. The corresponding author previously worked in the same unit that the participants were sampled from. She did not have a current working relationship with any of the participants.
Ethics approval and consent to participate: This study received research ethics approval from the University of Ottawa (REB file no. H-12-21-7555) together with approval from the Research Ethics Board at the participating site (REB file no. 2108 – 026).

Consent for publication: all authors have consented to publication.
Availability of data and materials: The interview guides are available upon request from the corresponding author.

Competing Interest: The authors declare that they have no competing interests.

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4.1 Abstract

Introduction and Aims: More knowledge about the factors that influence the use of sedation interruption practice is needed to improve the use of this integral component of care for mechanically ventilated patients. The aim of this study was to understand critical care nurses', physicians', and allied health professionals' perceptions of factors that support, inhibit, or limit the use of sedation interruptions.

Method: We conducted a theory-based descriptive qualitative study using semi-structured interviews with critical care registered nurses, respiratory therapists, a pharmacist, and a physician from a hospital in Northeastern Ontario. The interviews were conducted either in person, by phone, or online using videoconferencing software. The interview guide and analysis were informed by the Theoretical Domains Framework and transcripts were analyzed using content analysis.

Results: Interviews were conducted with 12 participants: eight registered nurses, two respiratory therapists, and one pharmacist and physician. The findings from the study were synthesized into overarching themes with sub-themes encompassing 9 facilitators and 20 barriers to sedation interruption use by nurses. Facilitators were the innovation (the importance of protocols) and the potential adopters (specific to the role of the nurse and comfort with the skill increases its use). The barriers were the potential adopters (nurses' knowledge gaps related to the performance and goal of sedation interruptions) and the practice environment (lack of time and availability of extra staff and lack of multidisciplinary rounds).

Conclusion and relevance to clinical practice: This study identified important facilitators and barriers to sedation interruption use for mechanically ventilated patients. A well-designed clinical protocol is an essential precondition for the uptake by potential adopters, but it alone is insufficient. Implementation efforts must address the barriers associated with the nurses (potential adopters) as well as the environment and contextual factors that impact the use of sedation interruption (practice environment).
Support for a team-based approach is essential, and the absence of interprofessional rounds is a significant barrier to the appropriate use and non-use of sedation interruption. Based on these findings, future research can focus on understanding more about the indications, contraindications, and goals of sedation interruption use, emphasizing establishing a shared appreciation for these across disciplines. Nursing capacity to manage a patient waking up from sedation is necessary for point-of-care adherence and improved patient outcomes; future research should focus on the best ways to do so. Implementation study designs should use theory and evidence-based determinants of sedation interruption to mend the evidence-practice gap.

Keywords: critical care nursing, evidence-based, implementation, multi-disciplinary, nursing, Ottawa Model of Research Use, sedation interruption, Theoretical Domains Framework.

Manuscript Highlights

1. What is known about the topic?
    - Sedation interruptions are an important component of a combination of evidence- informed interventions used to minimize the negative impact of life-sustaining therapies in critical care.
    - Research is needed to further understand both the role of the nurse and other actors in enacting this practice and the determinants that influence the use of sedation interruptions.
    - Sedation interruptions require coordination and collaboration between members of the critical care team.
2. What does this paper add?
    - The use of the Theoretical Domains Framework enhanced the opportunity to tailor behaviour change techniques to a greater number of determinants of behaviour.
    - This study identified nine facilitators and twenty barriers to sedation interruption use.
    - A well-designed sedation interruption protocol is an important precondition for uptake of sedation interruption by potential adopters but alone is not sufficient. Implementation efforts need to address the barriers associated with the nurses (potential adopters) as well as the environment and contextual factors that impact adherence to sedation interruptions (practice environment).

Introduction

There are several strategies for mitigating the post-intensive care syndrome that are now recognized in critical care survivors around the globe (DAS-Taskforce 2015 et al., 2015; Ely, 2017). Sedation interruptions (SI) are an important component of a combination of evidence-informed interventions for minimizing the negative impact of life-sustaining therapies in critical care and, when effectively performed together, can positively impact patient outcomes (Miller et al., 2015). According to Burry et al (2014), the aim of daily SI is to prevent drug accumulation, reduce overall drug exposure, and permit assessment of neurological status, patient tolerance of drug discontinuation, and readiness for endotracheal extubation. There are 11 guidelines or care bundles with 13 recommendations supporting the use of SI in practice (N. D. Graham et al., 2022). However, the reported and observed uptake of SI as a stand-alone intervention is sub-optimal (Carrothers et al., 2013; Klompas M., 2015; Mehta S et al., 2009; Smith, 2013) and when SI is combined with other evidence-informed practices adherence is also low (Miller et al., 2015; Sneyers B. et al., 2017)

Sedation interruptions require coordination and collaboration between members of the critical care team. In fact, the foundation of the Awakening and Breathing Coordination, Delirium monitoring and management, and Early mobility (ABCDE) bundle depends on communication among members of the ICU team, standardizing care processes, and breaking the cycle of over-sedation (Vasilevskis EE et al., 2010). A review to systematically identify the barriers to each component of the ABCDE bundle confirmed that further research is needed to understand the barriers to the use of SI, among other components (Costa et al., 2017). Specifically, there is a need for research to further understand the role of the nurse and other actors in enacting this practice (N. D. Graham et al., 2022; Miller et al., 2012). A deeper understanding of the factors that influence the use, misuse, and non-use of SI in clinical practice is important for improving the uptake of recommendations within guidelines and for practical implementation by clinicians. The aim of this study was to understand critical care nurses, physicians, and allied health professionals' perceptions of factors that support, inhibit, or limit the use of sedation interruptions by nurses.

Methods

Design

We conducted a qualitative study (Sandelowski, 2000) using semi-structured interviews with registered nurses (RN), respiratory therapists (RT), pharmacists, and physicians employed at a tertiary hospital's critical care unit. A multi-disciplinary perspective was sought because disciplines other than nursing have a role in the consistent delivery of SI (Girard T.D. et al., 2008; Kallet et al., 2018; Stollings et al., 2015). As nurses are predominantly at the point of care initiating, managing, and evaluating the practice, they were the primary focus of this study. The consolidated criteria for reporting qualitative research (COREQ) checklist (Tong et al., 2007) were followed to ensure transparent reporting, available in the additional file.

Study site

The study was conducted in a Level 3 Basic, 16-bed Critical Care Unit (CCU) in Northeastern Ontario, Canada (Critical Care Services Ontario, 2020). At the time of this study, there were approximately 22 full-time RNs, 19 part-time RNs, 10 internists, 9 CCU anesthesiologists, 17 respiratory therapists, and one pharmacist assigned to the CCU rotation. The CCU had a local protocol for SI as part of the Sedation and Analgesia order set that required a physician's order for a nurse to initiate (see Table 1).

<insert Table 1 about here>

Recruitment and participants

Purposive sampling occurred with the support of the CCU's clinical nurse educator and unit manager (J. Devers, Richard M. Frankel, 2000), and information about the study was distributed to all those working in the CCU through the intra-departmental email list. The Principal Investigator conducted four brief presentations to the CCU staff during unit-specific huddles. Each participant was emailed a $20 electronic gift card in appreciation for participating.

Interview guide

The development of the interview guide for the nurse participants was informed by the theoretical domains framework (TDF) (Michie et al., 2005) which contains 14 theoretical domains grounded in psychological theory (see Table 2). The TDF was developed jointly by health psychology theorists, health services researchers, and health psychologists and comprises 14 theoretical domains derived from 128 constructs from 33 different health, behavioral, and social psychology theories that explain health-related behavior change (Cane et al., 2012). The TDF represents an agreed-upon set of key theoretical constructs that can be used to identify all possible barriers and facilitators to healthcare professional

practices, thereby explaining implementation challenges that could be used to inform implementation interventions (Cane et al., 2012). The framework has been used to identify the determinants of a wide range of healthcare professionals and participants' behaviors, such as hand hygiene by nurses (Squires et al., 2014), participant retention in trials (Newlands et al., 2021), and nurses' perceived barriers to the delivery of person-centered care to complex patients (Younas et al., 2023).

A team member (JES) with expertise using the TDF reviewed the interview guide to ensure adequate coverage and accurate representation of the psychological constructs. Two pilot interviews were conducted to test the guide to avoid redundancy in the questions and for the researcher to gain experience with the guide. After piloting, minor changes were made to the wording of two interview questions and additional prompts were included to ensure that questions were understood by the participant. The interview guide was later adapted for the allied health and physician sample to account for the possibility that participants may have only a peripheral role in enacting SI, rather than direct involvement in the target behaviour. Also, the allied health interview guide included questions that asked about the allied health perspective of what influences nurses' use of SI. The interview guide is available upon request from the corresponding author.

<insert Table 2 about here>

Data collection

Interviews were conducted by one researcher (NDG) either in person, by telephone, or via videoconferencing software, between May 2022 and January 2023. Two in-person interviews were conducted in a private, closed room for personnel in the critical care unit during work hours at a convenient time for the participant. Interviewer field notes were included in memos after conducting the interview. The interviews were digitally audio recorded, transcribed using an automated transcription software, and manually de-identified prior to analysis. The participants' identities remained confidential and were known by one researcher (NDG), aside from the two in-person interviews whose identities were known by the covering nurse. Participants' names corresponded with a unique study code and were maintained on a master list; the master list was stored on an encrypted USB separate from the encrypted USB that stored the transcribed interviews, both stored in a locked cabinet in a locked office. In

concordance with the research site's data storage policy, all the de-identified transcripts will be digitally stored for 10 years after the termination of the study, after which will be deleted.

Analysis

Data were managed in NVivo 12, a qualitative data analysis software for researchers to efficiently conduct analysis. The data were first analyzed deductively, using the TDF domains as the framework for the content analysis (Hsieh & Shannon, 2005) and, then inductively, generating overarching themes across theoretical domains (Atkins et al., 2017):

1. Coding. Two researchers (NDG, LNP) deductively coded the first two interviews into the 14 TDF domains and a code description was developed based on the utterances that were grouped within each respective domain. This process resulted in the development of a codebook to guide the coding of the remaining transcripts; the codebook comprised a set of explicit statements of how the TDF was to be applied to the remaining data set (Atkins et al., 2017). The two researchers then went on to code each transcript independently; all utterances that related to SI in each transcript were deductively coded into one or more of the TDF domains by considering their relevance to the codebook description of the domain. In instances where a single domain allocation agreement could not be reached, the researchers agreed the response could be placed in both domains. Consensus was reached for each segment of coded text after coding the remaining transcripts.

2. Generation of specific belief statements. Specific belief statements were inductively developed for each specific coded text by one researcher (NDG) and the other researcher (LNP) interrogated and confirmed the accuracy of the statement. Specific belief statements were developed for each coded text (within each TDF domain) by abstracting the underlying meaning and writing it in a concise statement in preparation for merging belief statements, the next step in the analysis.

3. Generation of merged belief statements. A merged belief statement is a grouping of specific belief statements, from coded text, with a similar underlying belief (Atkins et al., 2017; Francis et al., 2012). Merged belief statements were created by clustering specific belief statements with a common meaning within a single TDF domain by examining all specific belief statements in that domain. This process was completed independently for all 14 TDF domains. A frequency count of the number of participants who mentioned the belief was calculated for each merged statement in each TDF domain; each participant

was only counted once. Frequency counts were generated separately for the nursing sample and the allied health and physician sample. In anticipation of a future implementation study, we identified relevant theoretical domains that can be focused on when selecting implementation interventions to improve adherence to recommendations for SI:

Identifying relevant theoretical domains. The following two criteria were applied to the merged belief statements in the identification of relevant theoretical domains: 1) frequency of merged beliefs and 2) evidence of strong beliefs that may affect the target behaviour (Michie et al., 2005). Frequency of merged belief statements were tallied as described in the analysis process. Later, a critical care nurse expert (KA) was consulted for the second criterion, to interpret the importance of the merged beliefs from a clinical perspective. Finally, both criteria were considered concurrently by three researchers (NDG, IDG, JES) to judge the relevance of the domains in terms of influencing the use of SI. Theoretical saturation was sought and reached for the nursing sample when the participants revealed no new information, but not from the physician and allied health sample as they were not the primary focus of the study.

4. Generation of overarching themes. To create a comprehensive overview of all barriers and enablers of SI, we inductively generated overarching themes from the merged belief statements across all theoretical domains. This process entailed repeated review and examination of the merged belief statements within each theoretical domain and identifying common threads in the merged belief statements across theoretical domains. One researcher (NDG) generated the overarching themes, while the other researcher (LNP) verified and confirmed those.

5. Specifying categories and identification of determinants to SI. We used a pragmatic model to specify categories for the overarching themes. The Ottawa Model of Research Use (OMRU) is a planned action model designed to prescribe the action steps to guide the implementation of best practices (I. D. Graham & Logan, 2004; Logan & Graham, 2010, 1998). The overarching themes were categorized into the key elements of the model: the innovation (guidelines); the potential adopters (nurses); and the practice environment (setting and context). The key elements together influence the uptake of best practices and can be used to specify areas in which barriers and supports to SI use should be assessed in a future implementation study. The overarching themes were divided into facilitators or barriers that suggest a problem and/or influence on SI adherence (Atkins et al., 2017).

Ethical considerations

This study received research ethics approval from the University of Ottawa together with support from the Research Ethics Board at the participating site. Participants were given both written and verbal information about the study, informed that participation was voluntary, and they could terminate their participation at any time without consequence.

Results

The recruitment email was sent to all 78 employed staff on the CCU emailing list, and each volunteer participated in an interview. Interviews were conducted with 12 participants: eight RNs, two Respiratory Therapists, one Pharmacist, and one Physician: 77% were women. Six out of 12 responded returned by email responses to the participant information survey; ages ranged from less than 30 to over 50 years of age and practice experience ranged from 6 to over 20 years. The interviews ranged in duration from 13 minutes to 1 hour and 7 minutes, with a mean interview time of 23 minutes. Interviews with nurses were conducted sequentially as participants volunteered and sampling ceased after multiple recruitment efforts were exhausted. Interviews with the physician and allied health professionals ended once we obtained one or two representatives from each discipline because nurses were the focus of this study.

Theoretical Domains Framework

Utterances from all participants were coded within one or more of the 14 domains. A total of 545 utterances from 12 interviews were subsequently synthesized into 86 merged beliefs across the 14 domains. Data from both groups were considered together for identifying relevant domains because beliefs were shared across both groups. Seven of the 14 domains, consisting of 52 merged beliefs were deemed relevant to improving adherence to recommendations for SI. The following TDF domains should be the focus when mapping determinants to implementation interventions: *Social influence, Environmental context and resources, Beliefs about consequences, Skills, Goals, Knowledge,* and *Reinforcement*. The relevant theoretical domains, the belief statement with frequencies (i.e., the number of interviews in which the belief was mentioned), and an illustrative quote from the participants are available in the additional file.

<insert Table 3 about here>

Facilitators of the use of SI by nurses

Table 3 displays the overarching themes and sub-themes of facilitators (n = 9) of SI use by nurses. Facilitators were identified within two key elements from the OMRU: the *innovation* and the *potential adopters*.

The Innovation. Awareness of the local protocol for SI is essential for use by nurses and allied health professionals, yet only two nurses were aware of the protocol and knew where to access it. Nurses, physician, and allied health professionals believed that the recommendation for SI was easy to perform under certain conditions and that having a clear protocol inclusive of the indications and contraindications of using SI was important for practice. Reasons for not performing SI were different between nurses and between disciplines, for example, one nurse said they would not perform SI on “patients that are delirious already…that aren't really able to follow commands…”. Compared to another nurse who said, “In our unit…there is this unwritten rule if somebody has a really poor prognosis”.

Potential Adopters. Participants agreed that SI was an expected skill of critical care nurses. A nurse must feel comfortable and have experience with SI to implement the intervention effectively, which can impact their attitudes and intentions to perform the skill. Nurses reported being influenced by knowing the positive impact of SI on patient outcomes. Participants reported terminating an SI quickly or deciding not to perform one at all because of concerns about adverse events, patient safety, or personal safety. For example, one nurse stated, “It's the nurse’s feeling that they would be in danger if the patient was to wake up because they have a very aggressive history… self-extubating as well”. Nurses were motivated by being aware of the negative consequences on health outcomes when the intervention was not performed.

<insert Table 4 about here>

Barriers to the use of SI by nurses

Table 4 displays the overarching themes (n=2) and sub-themes of barriers (n = 20) to SI use by nurses. Barriers were identified within two key elements from the OMRU: the *potential adopters* and, the *practice environment*.

Potential adopters. An important barrier that was identified was a lack of awareness of the local protocol for SI (*n*=6 nurses and *n*=2 allied health). Nurses and allied health professionals alike were not aware of the unit’s protocol for SI or, thought there was likely a protocol but had never reviewed it. Nurses alluded to making most of the decisions about the conduct of SI independently and with little guidance from other

team members, although input from physicians was ideal. There were also several biased perspectives held by nurses and allied health professionals that the use of sedation was needed and ultimately beneficial in many patient-centered circumstances. As one participant from the physician and allied health sample said “There's an ease of care around sedating. That is probably the principal impediment to me for sedation vacation…”. It became apparent that other important knowledge gaps and inconsistencies in what nurses thought the goal of SI was and how it should be performed could contribute to the misuse of the intervention. For instance, a nurse said, “We have to wake these people up to make sure that…their brain is OK and just so that we can get them off”, yet most did not mention the need to minimize the amount of sedation the patient receives.

Practice environment. The nurses identified a lack of time and the need for extra staff to assist if needed as a barrier to SI use. Furthermore, the lack of formal multidisciplinary rounds for mechanically ventilated patients was identified as a predominant barrier, separately, inconsistent support and buy-in from the physician was also reported by both the nursing, physician, and allied health samples. Conversely, the influence of the physician was also considered to hinder SI use by nurses when the point-of-view from one physician to the next did not align. Even amongst nurses, there were inconsistent points of view that could negatively influence the use of SI, for example, family involvement. One nurse said “Family is a big one. I wouldn't want to do it when the family is there”, while other nurses consider the family to be a catalyst to SI. Nurses and allied health professionals agree that SI is challenging for nurses given the multitude of environmental resources (for example, one-to-one nursing; physician buy-in, advanced knowledge and skill) and patient factors (for example, variability in underlying diagnosis and clinical presentation) that influence the safety of the skill. Critically ill patients on mechanical ventilators are complex. As one nurse stated “I'm not always excited to do it. I don't know that any nurses are…”, the challenges associated with SI can be demotivating for some nurses.

Discussion

This study used the TDF (Michie et al., 2005) to better understand the determinants of SI use in a small Northeastern Ontario critical care unit, from the perceptions of nurses, respiratory therapists, a pharmacist, and a physician. To the best of our knowledge, this is the first study to identify determinants of SI use using the TDF and then further categorize the barriers and facilitators using the OMRU. The

findings reveal six overarching themes comprised of nine facilitators and 20 barriers to SI use; the most common facilitators and barriers to SI use were found in a single study. The facilitators are associated with the innovation (the guideline or protocol) as well as with the potential adopters (nurses). The barriers are associated with the potential adopters and separately, the practice environment (environmental resources and contextual factors).

Importantly, we did not identify barriers associated with the attributes or characteristics of the recommendation for SI (*innovation*) and we speculate two possible reasons. Some nurses and allied health professionals were not aware of the local protocol, while others knew there was a local protocol but had not reviewed it. It is reasonable to speculate that without awareness of the protocol's content, it is understandable that clinicians did not report related issues. Another reason could be the recommendation itself is not difficult to perform, rather the factors related to potential adopters and the environmental context were considered challenging. Considering SI as a technical skill is relatively simple given that it involves simply turning off the infusion pump.

Potential adopters

Knowledge and skill. Important knowledge and skill development gaps related to SI continue to exist in some ICUs (Carrothers et al., 2013). Participants from our study expressed a need for a unit-specific orientation that includes purposeful education about SI, the implications of sedation on the brain's ability to recover from a critical illness, and the construct of targeted sedation strategies to minimize exposure to sedation. In 2013, sustained and diverse educational efforts were believed to facilitate the implementation of bundled evidence-informed practices, which included SI (Balas et al., 2013). The participants from this study suggested routine learning opportunities could promote discussions about different patient case scenarios and the opportunity to develop strategies to customize SI to the complex nature of the critically ill patient population. Specifically, knowledge development could target the basic principles of SI (how and when to initiate the intervention) while recognizing that the sequence of how it is done is less important if the goal of SI is clear.

The goal of SI. The findings from this study add more granularity to the current understanding of the barriers to SI use (Borkowska et al., 2018; Carrothers et al., 2013; Miller et al., 2013; Tanios et al., 2009). Our findings were similar to Miller et al.'s (2013) in terms of divergent reasons or *goals* for SI

across professions (nurses, physicians, RTs). We confirm that continued challenges still exist in practice related to a lack of consensus about the goal of SI within CCUs previously identified over the past 10 years (Vagionas et al., 2019). Moreover, our findings identified the presence of divergent goals between nurses and not only across professions (Vagionas et al., 2019). Miller et al. (2012) reported five perceived reasons why SI is performed: (i) minimized dose of sedation, (ii)neurological examination, (iii) ventilator weaning, (iv) reduced length of stay, and (v) assessment of pain and discomfort, all of which were also mentioned by one or more of the participants in this study. Divergence of goals between nurses is a concern because the least amount of sedation exposure overall should always be the primary focus. Otherwise, important opportunities for assessing the patient's neurological status and preparing them for recovery could be jeopardized. Without the least sedation in mind, a nurse may be inclined to resume the sedation until the desired effect without consideration of the impact of cumulative sedation. A shift needs to occur in the mindset of clinicians toward a better understanding of the impact of continued sedation given the more sedation a person is exposed to the harder it will be for the patient to wake up with their highest neurological potential. Waking a patient up after hours and days or weeks of sedation will "unmask the delirium that we have created" (Wolpaw, 2023) (18.18). Nurses and allied health need to have a unified understanding of the goal of SI because only then can its benefits contribute to an overall improvement in patient outcomes. Fortunately, the reasons for doing a SI are motivating factors and generally agreed upon by all clinicians.

Nurses' attitudes and intentions toward SI. There is a way of thinking or a unit-culture mentality that is unique to the critical care community that breeds misinformation (Wolpaw, 2023). Misinformation was identified in this study, including a belief that the agitation or anxiety that nurses witness during awake periods directly correlates with a patient's lack of tolerance for SI or patient discomfort. Similar findings have been identified in physicians, the strongest predictor of underuse of a daily SI was the perception that it impairs patient comfort (Sneyers B. et al., 2017). It could be argued this is not always true as reported in a prospective study; 50% of the sample (n=16) agreed or strongly agreed that they were comfortable while mechanically ventilated and half agreed or strongly agreed that they preferred to be kept awake (Prime et al., 2016). The idea that a patient needs some level of sedation to maintain comfort while mechanically ventilated is accurate for some patients, but not all.

Practice Environment

Environmental and contextual factors. While there was consensus that SI is the nurse's role and an expected skill of a critical care nurse, this study highlights the necessity for physician buy-in and a team-based approach. In this study, nurses expressed wanting consistent access to clinical guidance from physicians and the provision of one-to-one care to perform SI safely. Previous studies have identified staff attitudes, buy-in, and lack of interprofessional team support (Costa et al., 2017) as barriers to SI use and that sedation goals discussed on rounds increase nurses' willingness to perform SI (Miller et al., 2013). In this study, buy-in from all members of the team was perceived as necessary for SI use, and the lack of consistency amongst physicians was a focal barrier. Nurses were being held responsible for making consequential decisions about the appropriateness of SI in the absence of multi-disciplinary rounds and without foundational education about SI. Not having multi-disciplinary rounds for mechanically ventilated patients was identified as a barrier to promoting team-based decision-making about SI. High-quality interprofessional rounds are associated with improved communication amongst CCU team members and enhanced care coordination leading to reduced risks for errors, prevention of harm, shared decision-making, and several other benefits (Stollings et al., 2019). Furthermore, interprofessional rounds can serve as a team-based checkpoint for validating nursing rationales for not performing SI. Alternatively, explanations for the non-use of SI may be refuted by the team leading to greater rates of SI. Team rounds could also facilitate an opportunity to foster cohesive goal setting and establish a tailored approach to waking the patient up.

Future Implications

Better education for nurses about the implications of continuous sedation and the purpose of SI can address misinformation and the current way of doing things that are more harmful than good for our patients. Also, researchers and policymakers should reach a consensus about the goal of SI and generate a more explicit goal statement that clinicians can incorporate into their care plans. Using the TDF in this study added a deeper understanding of psychological capability and reflective motivational processes (Atkins et al., 2017) inherent to SI practice which can contribute to a tailored approach for addressing the evidence-to-practice gap in critical care. The determinants identified in this study serve as a platform for clinicians to further examine their own unique needs within their ICUs. The next steps

include mapping determinants to behaviour change techniques that could be pre-tested in the critical care unit where the interviews were conducted. For example, in designing interventions, investigators can select behaviour change techniques using the linkages to the Behaviour Change Wheel (Michie et al., 2011). The links could guide selecting intervention functions, policy categories, and behaviour change techniques (Atkins et al., 2017).

Strengths and Limitations

Credibility and Dependability. Strategies used to ensure confirmability are a detailed description of our research methods, including a systematic data analysis approach used in similar research studies deploying the TDF. A critical care nurse expert was deliberately included to complement the initial analysis steps by adding an overall judgment of the clinical relevance of theoretical domains. The reliability and validity of the results were strengthened by having two independent researchers conduct coding and analysis, and a third TDF expert validated the coding structure. The heterogeneous sample of participants with variable ages, genders, disciplines, and years of work experience was a strength of our study sample.

Confirmability. During a previous needs assessment study, we ensured confirmability by learning about the staffing structure and CCU environment (Graham et al., 2023). The researcher conducting the interviews (NDG) previously worked in the unit from which the sample was drawn, and previously worked with some of the participants. Enrolment of volunteer participants was done through email from the CCU clinical nurse educator and brief presentations of the study during unit huddles, minimizing recruitment bias. The interviewer remained non-directive during the interviews to minimize imposing bias on the participants' responses. All other authors had no previous knowledge of the participants or staff at the research site. The strengths of the study were the use of the TDF to enhance opportunities to tailor behaviour change techniques to a more significant number of determinants of behaviour (Michie et al., 2005). A defined domain structure and a shared coding scheme for the interview transcripts reduced the subjectivity in interpreting interview data. Multiple lengthy discussions between two researchers (NDG and LNP) about the underlying theme of the utterances and their relevance to the domains also enhance confirmability in this study. However, a step-by-step repetition of the study to identify similarities would improve the confirmability of our findings.

Limitations. Though a thorough description of the research process, including data collection with theory-informed interview guides, enhances our findings' credibility and dependability. A limitation of our study was the absence of member checks or data triangulation. We decided not to return the transcripts to the participants for confirmation of the accuracy of the dictations out of respect for the CCU staff's time, given the difficulties we encountered with recruitment. However, collecting data from multiple perspectives in four disciplines and consistently using a codebook enhanced the credibility of the findings. Limitations of the study include the limited number of participants other than nurses (physicians, respiratory therapists, and pharmacists). However, recruitment was challenging because of high administrative turnover and poor staffing morale related to the COVID-19 pandemic. Participants were sampled from one site, and transferability could have been increased had we sampled from more than one organization or more countries.

Conclusion and relevance to clinical practice

This study identified important facilitators and barriers to SI use for mechanically ventilated patients. A well-designed clinical protocol is an essential precondition for the uptake by potential adopters, but it alone is insufficient. Implementation efforts must address the barriers associated with the nurses (potential adopters) as well as the environment and contextual factors that impact the use of SI (practice environment). Support for a team-based approach is essential, and the absence of interprofessional rounds is a significant barrier to the appropriate use and non-use of SI. Based on these findings, future research can focus on understanding more about the indications, contraindications, and goals of SI use, emphasizing establishing a shared appreciation for these across disciplines. Nursing capacity to manage a patient waking up from sedation is necessary for point-of-care adherence and improved patient outcomes; future research should focus on the best ways to do so. Implementation study designs should use theory and evidence-based determinants together with a thoughtful selection of implementation interventions to mend the evidence-practice gap and improve patient outcomes.

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Table 4.1 Sedation interruption local protocol

QAM If target RASS different from 0 to -1, reconfirm RASS target with MRP each morning If utilizing infusions, re-evaluate infusion requirements DAILY each morning once stable Stable = i.e. BP stable, no neuromuscular blockades in use, not difficult to ventilate Turn off all sedation until RASS 0 to -1 If patient becomes restless or agitated (RASS 2+ or higher) use bolus doses to sedate Resume infusions at one half previous rate and titrate infusions to achieve target RASS Notify MRP if unable to achieve target RASS Once stable, aim for target RASS of 0 to +1 during day and -1 to -2 at night

Table 4.2 Theoretical Domains Framework[†]

Theoretical domain	Definition[†]	Sample interview question Knowledge
	An awareness of the existence of something	Does your CCU have a local protocol or policy about sedation vacations? If yes; can you tell me about it/those?
Skills	An ability or proficiency acquired through practice	How do you perform a sedation vacation? Can you walk me through the steps?
Social or professional role and identity	A coherent set of behaviors and displayed personal qualities of an individual in a social or work setting	Are sedation vacations an intervention that is specific to nursing? What is your discipline's role for this intervention?
Beliefs about capabilities	Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use	How easy or difficult is it for you to perform a sedation vacation? Why?
Optimism	The confidence that things will happen for the best or that desired goals will be attained	What do you think will happen if you do not perform a sedation vacation on an eligible patient?
Beliefs about consequences	Acceptance of the truth, reality, or validity about outcomes of a behavior in a given situation	What are the benefits of a sedation vacation?
Reinforcement	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus	Have your views toward sedation vacations evolved from your time in your orientation to the unit or any other specialty course up until now?
Intentions	A conscious decision to perform a behavior or a resolve to act in a certain way	Do you intend to perform a sedation vacation for all mechanically ventilated patients who are sedated and eligible?
Goals	Mental representations of outcomes or end states that an individual wants to achieve	In what situations do you want or not want to perform sedation vacations?
Memory, attention, and decision making	The ability to retain information, focus selectively on aspects of the environment, and choose between 2 or more alternatives	Is performing or not performing a sedation vacation ever a conscious decision?
Environmental context and resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behavior	What aspects of your work environment influence whether you perform a sedation vacation?

Social influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviors	Do other team members influence your decision to perform a sedation vacation?
Emotion	A complex reaction pattern involving experiential, behavioral, and physiological elements, by which the individual attempts to deal with a personally significant matter or event	Does practicing or not practicing sedation vacation ever evoke worry or concern in you?
Behaviour regulation	Anything aimed at managing or changing objectively observed or measured actions	What do you think is needed in your work environment to ensure that you consistently perform sedation vacations?

† Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implement Sci. 2012 Apr 24;7:37.

Table 4.3 Overarching themes and sub-themes of facilitators (N = 9) to sedation interruption use organized according to OMRU.

Overarching theme Sub-themes	**Illustrative quote from a participant**	**Domains in which overarching theme was identified**
Innovation		
Perceptions of SI (guideline)		
1. Local protocols are important for consistency in use and need to be used in conjunction with clinical judgment.	The other thing that I think would help a lot is to have some sort of clear protocol about the indication versus contraindication of performing sedation vacation, and widely available. Again, making an appropriate protocol for nurses who are looking after intubation patients, is a very important part. (nurse)	Behaviour regulation Knowledge Memory, attention, decision process
Potential Adopters		
Nurses' awareness of SI		
2. Awareness of the local protocol and of the existence of national recommendations for SI.	I believe there is a policy like a protocol…on our Meditech there's an intervention and there's a little 'P' You click on it. It kind of tells you the RASS score and to follow the RASS score and sort of thing. (nurse)	Beliefs about capabilities Knowledge
Nurses' knowledge and skill to perform SI		
3. Nurses and allied health professionals know that SI is an expected skill of a critical care nurse.	It needs to be done; it has to be done, is pretty much my just of things. If you are an ICU nurse sedation vacations need to happen, and that's ICU. (nurse)	Skills Social professional role and identity Emotion
4. The goal of sedation vacation is to get the patient's brain as close to a pure state as possible and this should be a priority of care for the critically ill patient.	They have much shorter intubation periods, and much less complications and less delirium. I definitely see the importance of it and I always try to keep the least amount of sedation as possible. (nurse)	Goals
Nurses' attitudes and intentions towards SI		
5. Feeling comfortable, having experience performing SI, and colleagues can positively influence attitudes toward SI.	Depends on the staff working. There are some staff that will directly ask; "have you vacationed your patients? How did they do? You should turn the sedation off. Hey, you should vacation, make sure you don't forget to vacation them". (nurse)	Social influence Renforcement Social professional role and identity
6. Knowing the benefits of SI for the patient, or the consequences of not performing SI reaffirms its use by	The narrative approach might be helpful to people like publishing narrative accounts of people who have had to have sedation vacations. (allied health)	Reinforcement Beliefs about consequences Knowledge

Overarching theme Sub-themes	**Illustrative quote from a participant**	**Domains in which overarching theme was identified**
nurses and allied health professionals.		
Nurses' role in SI		
7. Nurses and allied health professionals know that SI is specific to the nurse role.	The nurses' bias dictates everything…because you are the person who has to actually interact with this patient. (allied health)	Skills Social professional role and identity Emotion
8. It is the nurse's role to make important decisions about SI, including: the appropriateness of SI and providing a rationale for when it is not done, the start time and how long it should last.	I think really you are managing the day-to-day activity for any patient, so I think it is nursing that would decide it. (nurse)	Social professional role and identity
Nurses' use of SI		
9. Perceived adherence to SI for every approximate 10 eligible patients, is anywhere from 50% to 100% of the time that it should occur.	I would say for respiratory related intubated patients I would say maybe 80 to 85% of the time we do sedation vacation. (nurse)	Memory, attention, decision making process

OMRU – Ottawa Model of Research Use. *Source:* Graham, I. D. & Logan J. (2004) Knowledge transfer and continuity of care research, (p.94). Canadian Journal of Nursing Research, 36(2), 89-103. Licensed under CCBY 4.0.
Allied health = physician and allied health sample

Table 4.4 Overarching themes and sub-themes of barriers (N = 20) to sedation interruption use organized according to OMRU.

Overarching theme Sub-themes	**Illustrative quote from a participant**	**Domains in which overarching theme was identified**
	Potential Adopters	
Nurses' awareness of SI		
1. Unaware of the local protocol or national/international guidelines with recommendations related to SI.	There's probably a protocol on there. But honestly, I couldn't tell you what it says. We certainly don't push it. (nurse)	Knowledge
Nurses' knowledge and skill to perform SI		
2. Nurses use their judgment to decide when a SI should be used or not.	I don't think we have clear inclusion, exclusion criteria for performing the intervention. (nurse)	Knowledge
3. There is a biased perspective held by clinicians about the benefits of sedation in mechanically ventilated patients.	I think that the effect of sedation, the subjective effects of sedation on patients are sometimes overestimated or even largely unproven…that's…been the bias towards sedation. (allied health)	Beliefs about consequences
4. There are several knowledge gaps that need to be addressed, including the impact of sedation on recovery, targeted sedation strategy and the best practice approach for implementing SI and contraindications for its use.	There's not really a lot of education or training about that when you come in here, or when you start. It was the first time that I had ever heard of it was even after doing my critical care course and I came in here, they were like "so how do you want to do it?". And I was like "what is that, I don't know anything about it". (nurse)	Beliefs about consequences Knowledge Skills Behaviour Regulation Goals
5. Peer-to-peer education is not sufficient for consistent implementation of SI.	We need to have more guidance and, like maybe even more focus in our orientation. (nurse)	Skills
6. Lack of Physician leadership in educating nurses and allied health professionals to reinforce SI use.	There should be a 30-minute round around each week by the internist and even by… if necessary, where the nurses take a topic and the physician can talk about it. (allied health)	Behaviour regulation Reinforcement
7. The long-term goals of sedation vacations are not typically considered.	I have never looked at it as the long-term solution to anything…as a long-term assessment for whether they could walk or whether they could be extubated sooner or later. (nurse)	Goals
Nurses' attitudes and intentions towards SI		

Overarching theme Sub-themes	**Illustrative quote from a participant**	**Domains in which overarching theme was identified**
8. The challenges associated with SI can be demotivating for nurses.	I'm not always excited to do it. I don't know that any nurses are but. (nurse)	Goals Optimism
9. There is a false belief that mechanically ventilated patients require sedation and other common missuses of sedation.	There is a feeling still pervasive in our ICU, probably all ICUs…It's better to have something going in those patients because surely, they must be uncomfortable. (allied health)	Beliefs about consequences Social professional role and identity
10. There is a perceived ease of care with the use of sedation.	There's an ease of care around sedating. That is probably the principal impediment to me for sedation vacation…The patient looks better, everything, vital signs are better, it's way easier to care for your patient. You go from a very difficult busy shift to a very easy shift just by sedating. (allied health)	Environmental context and resources Beliefs about capabilities
11. There is a perception out there that sedation vacations are only necessary when a patient is being extubated.	There's a perception out there that sedation vacation is only necessary when you're extubating. (allied health)	Goals Beliefs about consequences
Nurses' use of SI		
12. Half of the nurses turn off sedative medications completely while the other half either turn off the longest acting medication or only wean down the sedative.	I think when you first started that consistency in your sedation vacation across the board, if you ask for help, if you ask three different nurses for help, you'll get three different answers, likely. (nurse)	Intentions Skills Social professional role and identity
Concerns about performing SI		
13. Often, nurses will terminate a sedation vacation prematurely or decide not to perform one at all because of concerns about adverse events, patient safety or personal safety.	It's the nurses feeling that they would be in danger if the patient was to wake up because they have a very aggressive history and they be at risk to themselves of self extubating as well. (nurse)	Beliefs about capabilities Social professional role and identity Beliefs about consequences Reinforcement
Practice Environment		
Environment and contextual factors influencing use of SI by nurses		

Overarching theme Sub-themes	**Illustrative quote from a participant**	**Domains in which overarching theme was identified**
14. At times there is a lack of time and availability of extra staff to manage a SI safely.	The time and do it and keep the patient safe…and maybe having more one to one support, if a sedation vacation is happening. Having a staff member that's maybe designated to watch the patient…because it's really tough. (nurse)	Environmental context and resources Beliefs about capabilities Optimism
15. There is a lack of multidisciplinary rounds for mechanically ventilated patients that would otherwise support the use of SI by promoting a shared responsibility across disciplines for decisions about indications, contraindications, and goals.	1. …there's not a great vent round. We have the anaesthesiologist just popping in… sometimes before cases, sometimes between cases. (nurse)	1. Environmental context and resources
	2. Really having a more formal rounding would help…what their goals for the day across the board would be nice. (allied health)	2. Reinforcement Behaviour regulation Social professional role and identity Social influence Memory, attention, decision process
16. There is a lack of consistent support and buy-in from the physicians.	…advocating a little bit more for physician interaction. Maybe discussions in the morning like so I could certainly advocate a little bit better for that. (nurse)	Social influence Behaviour regulation Environmental context and resources
17. Physician's can influence the use of sedation and sedation vacations depending on their point-of-view.	…depending on who the physician is. They are not always too eager to encourage nursing to use a sedation vacation…there is a wide variation, some are very involved with it and some others are just not at all. (nurse)	Social influence
18. Nurses do not share the same opinion about the importance of family involvement in SI.	Family is a big one. I wouldn't want to do it when the family is there. (nurse)	Social influence
19. SI are believed to be a challenging for nurses because of the need for one-to-one care, physician buy-in, advanced nursing knowledge and skill required to complete the intervention and lack-of guided support for SI.	The whole process probably takes anywhere from half an hour to …2 hours. You're in the room with them nearby while they're awake and appropriate…but they have the restraints on still. And then work from there and start de-restraining the patient. (nurse)	Reinforcement Beliefs about consequences Skills

Overarching theme Sub-themes	**Illustrative quote from a participant**	**Domains in which overarching theme was identified**
20. There are multiple patient factors that negatively influence the use of SI. For example, the admitting diagnosis or the reason for mechanical ventilation, acuity, past medical history, treatments, and the patient's disposition.	When it comes to the patient factors, I think the past medical history is plays a very important role in deciding how easy or not easy doing the sedation vacation. (nurse)	Beliefs about capabilities

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Allied health = physician and allied health sample

Chapter 5

Integrated Discussion

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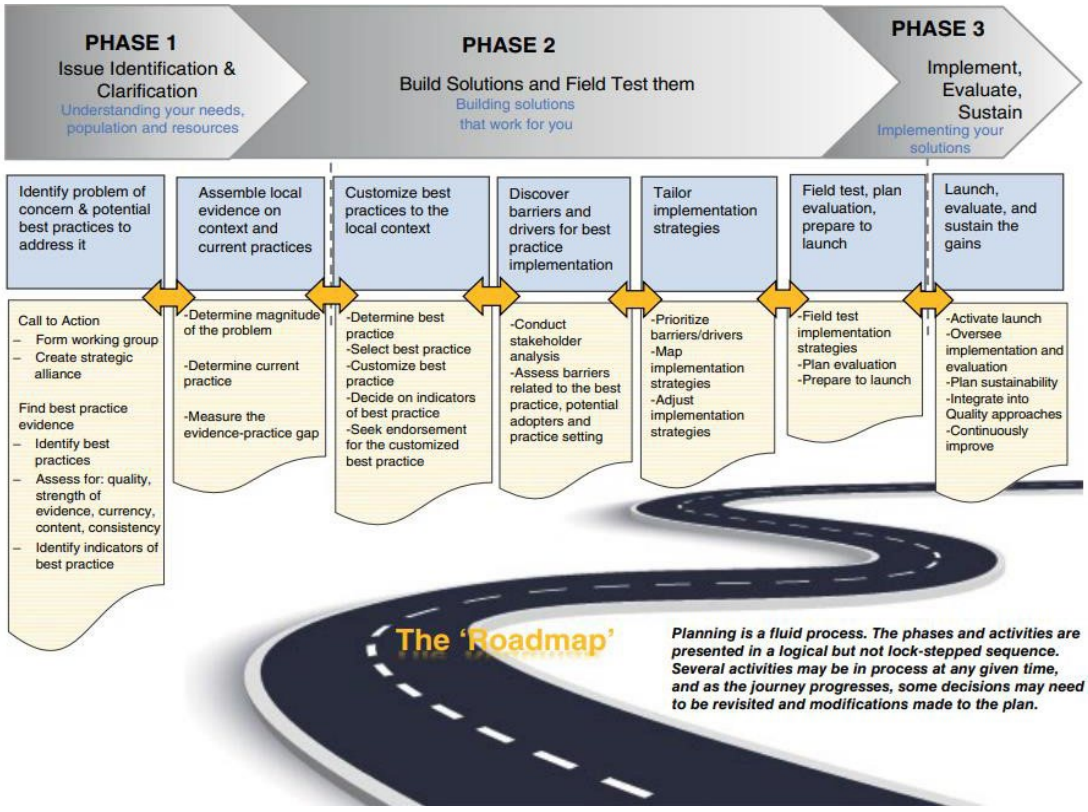
Chapter 5 Integrated Discussion

5.1 Introduction

Sedation interruptions (SI) are a component of bundled evidence-informed practice interventions that have been successful in improving patient outcomes (Chen et al., 2022; Klompas et al., 2015; Levy et al., 2010; Pronovost et al., 2006) yet adherence to specific components, specifically SI, continues to be a challenge (Klompas et al., 2015; Mehta S et al., 2009; Miller et al., 2012). My dissertation focused on understanding current SI practice and the determinants influencing critical care nurses' use of recommendations for SI to ultimately contribute to optimizing SI use. This Chapter is organized around the first two of three phases and steps of the Implementation Roadmap (Harrison & Graham, 2021): Phase 1 issue identification and classification, Phase 2 build solutions and field test.

Figure 5.1 Implementation Roadmap



Note: The Implementation Roadmap. Reprint from *Knowledge Translation in Nursing and Healthcare* (p.44), by M. B. Harrison & I. D. Graham, 2021, Wiley Blackwell. Copyright 2021 by John Wiley & Sons, Inc. Reprinted with permission from John Wiley & Sons, Inc.

In this Chapter, I summarize and integrate the findings from my three studies, reflect and discuss how they contribute to the existing literature and then reflect on my experiences following the Implementation Roadmap. I then discuss implications for implementation planning, implications for practice (nursing and multidisciplinary), offer suggestions for future research and then implications for guidelines developers.

Study Site and Context for the Dissertation

Study 1 was a systematic review of international literature while studies 2 and 3 were conducted at a tertiary care hospital in Northeastern Ontario hosting a Level 3b critical care unit (CCU) (Critical Care Services Ontario, 2020) with 16 beds and operated as a closed unit run by Internists rather than Intensivists. It is a general admissions CCU with approximately 220 to 400 admissions per annum. The unit employs 22 full-time RNs, 19 part-time RNs, 10 internists (three nephrologists, one respirologist, 1 cardiologist, 1 endocrinologist), 9 CCU anesthesiologists, 17 respiratory therapists, and one pharmacist assigned to the CCU rotation. The electronic medical record software, Meditech Expanse, was implemented in the unit in 2019, almost 3-years prior to studies 2 and 3.

5.2 Summary of Study Findings Following the Implementation Roadmap

What follows is a summary of the findings from three studies, categorized using the Implementation Roadmap.

Phase 1: Issue identification and classification

Step 1: Determining International Best Practice. The first step of the Implementation Roadmap is focused on identifying the issue and being able to describe the issue in relation to implementation of best practices. This step has been described as largely 'exploratory' and conceived of as the time at which a working group is assembled and will work to understand what is known and if more information is needed to understand the issue (Harrison & Graham, 2021). In phase 1, step 1 the focus is on establishing or understanding the best practice for the issue. In some cases, best practice and the quality and consistency of the recommendations for best practice are available and leveraged at this point to identify or develop (if needed) indicators of best practice to measure and evaluate in a future implementation study. Harrison and Graham (2021) recommend starting with a critical review and quality assessment of the available guidelines to understand the best available evidence related to the practice intervention. A synthesis of all the available recommendations for an intervention is likely more thorough than relying on a single guideline to establish a broader perspective of recommended implementation practices. In other instances, as was the case for SI, a synthesis of all the available evidence-informed recommendations was not available in the literature, in which case it is prudent for clinicians or researchers to complete a synthesis to identify evidence-informed best practice (Harrison & Graham, 2021).

For this reason, we wanted to establish best practice for SI from an international perspective using a systematic review and critical appraisal of all available guidelines and care bundles containing recommendations related to SI (Chapter 2 - Study 1). We identified 11 guidelines and care bundles globally that provided 15 recommendations related to SI. Our synthesis helped us understand the limitations within individual recommendations which are reflected within internal protocols for SI (Chapter 3 - Study 2). In Chapter 4 Study 3, we propose

addressing the limitations in local protocols to optimize the context for a future implementation study to improve use of SI in practice (Chapter 4 - Study 3). However, when the recommendations were considered all together, there was sufficient information to guide practice in a more fulsome manner. Essentially, there were three key findings from Study 1: (i) sedation interruption is recommended practice for the care of adult mechanically ventilated patients, (ii) deficiencies exist with the methodological quality of included guidelines, and (iii) the current evidence is of low quality, which impacts overall credibility and applicability of the recommendations.

More specifically, 13 recommendations supported the use of SI, and two recommendations opposed performing SI in patients with intracranial hypertension. Although best practice supports performing SI for adult mechanically ventilated patients, it is important to recognize that the recommendations are mostly from guidelines of low methodological quality. Indeed, none of the guidelines met our threshold for high quality (which was at least 4 AGREE II domains with scores > 60%) for methodological development. As a result of this finding, we did not endorse any of the guidelines in their entirety. Other authors have identified significant limitations in critical appraisals of guidelines for critical care settings (Cattani et al., 2023). Like our findings, the AGREE-II domains Stakeholder Involvement and Applicability were infrequently addressed in eleven guidelines about critical care nutrition (Noyahr et al., 2022). The Stakeholder Involvement domain examines stakeholder involvement (including patients) in the development of the guideline (Brouwers et al., 2010). The absence of patients' perspective may inadvertently dismiss their perspective of values and experiences of SI in the recommendations. When patients and other stakeholders were involved in the development of the guideline (for example Devlin et al., 2018) an account of their influence on the individual

recommendations were often not explicitly stated. The Applicability domain explores whether guidelines describe facilitators and barriers to uptake, consider resource implications of uptake, and provide tools or advice to support application and monitoring (Brouwers et al., 2010). The identification of barriers and facilitators is crucial for anticipating and mitigating challenges associated with implementation of the recommendations and would serve as a point-of-reference for clinicians in the conduct of a local needs assessment (Tricco et al., 2018). The quality of guidelines common to the CCU community (for example, pain, agitation, and delirium management guidelines) vary significantly, and it is vital that clinicians exercise caution when selecting a guideline to implement in daily practice (Bush et al., 2017; Rosenthal et al., 2020). There is room for improvement in critical care guidelines, including those for SI, with regard explicit involvement of patients and families in the development process and addressing the need for advice or tools and resources to facilitate the implementation of the recommendations.

Only one out of 15 recommendations met the high-quality threshold using the AGREE-REX instrument for methodological development of the recommendation for SI (the Pain, Agitation/sedation, Delirium, Immobility (rehabilitation/mobilization), and Sleep (disruption) (PADIS), AGREE REX score = 76% (Devlin et al., 2018)). Similar overall quality results were found in twelve recommendations specific to energy expenditure determination in critical illness using the AGREE-REX tool, noting the ‘values and references’ domain had scored the lowest and the ‘clinical applicability’ domain had scored the highest (Noyahr et al., 2022) which is like our findings. The recommendation for SI in the PADIS guideline (Devlin et al., 2018) is the most robust and implementable in an appropriate setting out of the nine included guidelines.

We can presume that SI as an intervention is simple enough to perform in terms of the physical skill that is required (turning off the infusion pump), yet the realities of conducting the intervention are far more complex. Nonetheless, the individual recommendations alone lack some of the necessary components to enact the behaviour according to the Action, Actor, Context, Target, Time framework (Presseau et al., 2019). Indeed, after having deconstructed the foundational requirements across all 11 guidelines of the Action Actor Context Target Time framework for implementing SI, we can appreciate why there is inconsistent practices amongst clinicians. Variation in practice was evident in the findings from Chapter 4 Study 3 demonstrating differences amongst nurses with how SI is initiated and what the intended goal of SI is, more specifically what the endpoints were, and which professionals needed to be involved and their role(s). Recommendations for SI need to describe the goal that everyone should be aiming for (action), who are the professionals responsible for enacting SI and their roles (actor) and in what context it is/is not to be performed. Chapter 4 Study 3 further elaborates on the variations in practice as reported by the participants in the study. Researchers in Implementation Science agree there is a need for recommendations to be actionable (Brouwers et al., 2019) and we argue that the available recommendations for SI are not actionable enough for clinicians. Similarly, Michie and Johnston, (2004) proposed that when behaviours are described in terms of what, who, when, where and how, they are more actionable and hence more likely to be performed. Though, authors from the PADIS guideline acknowledge the recommendations are brief and direct so that clinicians can quickly understand the bottom-line guidance (Balas et al., 2018).

It is important to recognize the definition or description of SI in the PADIS guideline is from a landmark RCT from the year 2000 (Kress et al., 2000), at which time daily SI was

implemented for the first time. Since that time, there has been important advancements in our understanding of the use of SI recognizing the need for coordination of other evidence-informed interventions using a multidisciplinary approach (Barnes-Daly et al., 2018; DeMellow et al., 2020; Mion et al., 2023; Pun et al., 2019), and to account for the wide array of clinical diagnoses of patients. Findings from studies 2 and 3 confirmed the local hospital protocol prescribed SI practice in accordance with definitions found within guideline recommendations. Gaining an understanding of best practice had a secondary utility in the series of studies as we were then able to compare the description or definition of SI (as part of the international recommendations in Study 1) to the local protocol's recommendation for SI (Studies 2 and 3) and determine alignment between the two, which set us up for the next step in the Implementation Roadmap.

Step 2: Establishing the Evidence-Practice Gap. The second step of Phase 1 (*Issue identification and classification*) in the Implementation Roadmap entails finding the best practice evidence and assembling the local evidence on the issue and context which may or may not occur concurrently (Harrison & Graham, 2021). Early identification of evidence-informed best practice can inform the type of information about current practice that should be collected during a chart audit or type of gap-analysis (Harrison & Graham, 2021). Doing so will facilitate ease of the development of indicators of best practice for the purpose of comparing current practice to best practice. We selected knowledge about best practice for SI from Study 1 as this was the most comprehensive synthesis of guidelines with recommendations about SI available in the literature.

After concluding that SI is indeed the best practice according to guideline recommendations, we felt confident it is a necessary clinical intervention for mechanically ventilated adults at the study site. At this point, we were able to proceed with an implementation

needs assessment (Chapter 3 – Study 2). Our approach to conducting the implementation needs assessment started with an environmental scan of the hospital and gathering information specific to the critical care unit; then, conducting an evidence- practice gap analysis. The needs assessment facilitated understanding the context for a future implementation study and a gap-analysis to identify the nature and magnitude of the local evidence-practice gap for SI using a retrospective chart audit. The purpose of the environmental scan in this study was to understand and document the structure of the organization (hospital), specific setting (the CCU) and those who work there. The environmental scan was composed of two components, during which information was gathered to better understand the gap-analysis setting, and the organization's readiness for research. The gap-analysis study confirmed the existence of an evidence-practice gap related to SI and the magnitude of the gap was significant enough to warrant efforts to optimize SI use.

Our retrospective chart audit revealed an evidence-practice gap between recommended and actual practice indicating that adherence to SI continues to be a challenge. From our sample of 28 electronic charts, non-adherence was present over 1/3 of the recommended time (in days) that SI should have been performed on mechanically ventilated patients. Table 3 in Chapter 3 displays the descriptive results of the evidence-practice gap analysis. In summary, depending on the scenario, the rates of adherence ranged from a low of 64.6% (51+2/82) to a high of 84% (51+2+16) of cases when we assumed the 16 undocumented cases all represented appropriate use or appropriate non-use of SI. Depending on the scenario, non-adherence rates ranged from a low of 16% (13/82) to a high of 35% (13+16/82) of days, again when the 16 undocumented cases all represented overuse or underuse of SI, respectively, leaving considerable room for improvement and providing justification for conducting an implementation study to improve the use of SI.

Similar low-end adherence rates have been identified in other critical care units after the implementation of a local protocol for evidence-informed interventions commonly used in the treatment of mechanically ventilated patients. For example, after initial implementation of the Pain, Agitation, Delirium (PAD) protocol (Barr & Pandharipande, 2013), the unit's leadership noted inconsistent compliance, with an estimated utilization of less than 50% (Yan et al., 2019). Likewise, similar high-end adherence rates for SI use were observed in two Australian ICUs reporting a mean of only 78.8% of patients had SI over 3-days of mechanical ventilation (Madhuvu et al., 2021). Rates of adherence are often obtained retrospectively from medical records which is dependent on the thoroughness and accuracy of clinical documentation (Madhuvu et al., 2021; Soltani et al., 2023).

Issues with documentation was an important finding in our gap-analysis because of the significant impact missing documentation (16 days) made on the range of adherence rates. We also noticed that, at times, nurses were not selecting a pre-defined reason for not performing a SI from a drop-down menu (n=11 occurrences); rather free text was inputted into the 'other' category. The issue with this is that all 11 reasons (100%) that were documented in the 'other' category did not align with the rationales offered by the protocol for not performing SI nor did they align with exclusionary criteria that can be found in the literature (Sneyers B. et al., 2014; Society of Critical Care Medicine, n.d.).

Phase 2: Build Solutions and Field Test

Step 3: Customize Best Practices to the Local Context & Step 4: Discover Barriers and Drivers for Best Practice Implementation. Phase 2 of the implementation roadmap is about customizing and aligning the best practice to the local context, discovering the barriers and drivers (facilitators) to implementing the best practice, and selecting and tailoring

implementation strategies. It also involves developing an evaluation plan (including identifying measures of best practice use and impact), and field testing the customized best practice (Harrison & Graham, 2021). The first activity involves making decisions about possible customization or tailoring of recommendation(s) chosen for adoption in the local setting. Customizing may involve changing the wording of a recommendation to make it more user friendly or adapting the recommendation to suit the local context (Harrison & Graham, 2021). Once a best practice has become a customized best practice for local use, attention can turn to identifying barriers and drivers to implementation of the adapted best practice (Harrison & Graham, 2021).

By this point in the Implementation Roadmap process, we identified best practice (Phase 1, Step 1), determined the methodological quality of recommendations (Phase 1, Step 1), and identified an evidence-practice gap that is suitably wide to justify addressing it (Phase 1, Step 2). The next steps were focused on discovering the determinants of current and best practice for SI as doing so is among the most important elements to consider when preparing to implement knowledge (Chapter 3.3a Legare & Zhang in Straus, Tetroe & Graham, 2013). To accomplish these steps, we conducted a descriptive qualitative study using individual semi-structured interviews with nurses, allied health professionals and a physician from the same unit in which we identified the gap (Chapter 4 – Study 3). Findings from this study revealed nine facilitators and twenty barriers to SI use by nurses. Facilitators were associated with the innovation (e.g., the importance of protocols) and the potential adopters (e.g., SI are specific to the role of the nurse and, comfort with the skill increases its use). The barriers were associated with the potential adopters (e.g., nurses' knowledge gaps related to the performance and goal of SI) and the practice environment (e.g., lack of time and availability of extra staff and, lack of

multidisciplinary rounds). Participants in our study discussed their perceptions of best practice and current practice, which we could compare to international best practice that we identified in Chapter 2 (Study 1 – Systematic Review).

Participants' Perceptions of Best Practice. The components to enact a behaviour (Action, Actor, Context, Target, Time) (Presseau et al., 2019) were abstracted from the participants' descriptions of their perceptions of best practice. An observable *action* for SI was described by the nurses and from this we identified at least three approaches to initiating SI: 1) completely turning off only the sedative medication, 2) completely turning off the sedative and analgesic medications, 3) weaning down the sedative and analgesic medications. One nurse summarized the variation in practice: "I think when you first started that consistency in your sedation vacation across the board, if you ask for help, if you ask three different nurses for help, you'll get three different answers, likely". Interestingly, variation in practice was described by (Miller et al., 2012) highlighting that a lack of consensus about why to do a SI was relatively unexplored as a barrier to using multidisciplinary interventions. This lack of shared understanding encourages the potential for different patients being selected and diverse approaches to carrying out the SI (Miller et al., 2012), or errors in clinical judgment about process and termination of SI.

All participants consider the nurses to be the primary *actors* of SI, which is appropriately within their scope of knowledge, skill, and judgment, making nurses important drivers of SI use. The intersection between the role of the nurse and the role of the other allied health professionals and physician were less well defined and considered a barrier to SI use. The specification of each person (actor) that has a role in the action (SI) needs some thoughtful consideration which also aligns with our findings from Study 1 (Chapter 2). In Study 1, the recommendations were not

explicit about which clinician(s) is/are responsible for enacting SI, limited information about the professionals involved with SI had to be inferred from the additional text associated with the recommendation(s). Overall, there was limited description of the roles of the various members of the CCU team, including the nurses. CCU guidelines serve several purposes that generally fall into the assessment, management, and treatment of certain critical illnesses. For clinicians to assess, manage and treat patients in accordance with the recommended best practice, there should be alignment between the target user's scope of practice and recommended actions (AGREE-REX Research Team, 2019). An important inference from the findings of this thesis is the lack of identification of *actors* to enact the recommended action (SI practice) and the manifestation of a lack of multidisciplinary support as an identified barrier to SI.

Much like the action and the actor, the *context* can explain multiple scenarios for the physical location, emotional context, or social setting (Presseau et al., 2019) and in this case the clinical indicator(s) or contraindicator(s) for SI. Some nurses identified specific patient diagnosis that would warrant a SI, for example, patients with respiratory related diagnosis would receive a SI. An allied health professional added "there's a perception out there that [SI] is only necessary when you're extubating". Another nurse confirmed the lack of guidance related to context in the local protocol by stating "I don't think we have clear inclusion, exclusion criteria for performing the intervention".

Overall, the participants' perceptions of the *target* and *time* of SI were relatively aligned with best practice recommendations. These indicate that SI are intended to be performed daily for adult mechanically ventilated patients with continuous medication infusions apart from patients with increased intracranial pressure. The nurses confirmed that "ventilated patient[s] need to have a [SI] early in the morning between 7:00 to 8:00" which aligns with the international

recommendation of daily. Knowledge of and a shared understanding of the action associated with SI, along with the actor, context, target, and time, are vital to the successful implementation of the intervention itself and more importantly in conjunction with the other components of a multidisciplinary bundle. Overall, the nurses' perceptions of best practice aligned with what is recommended in the guidelines but as we learned in Study 2 (Chapter 3), non-adherence to SI recommendations is still identifiable. We also found that on average participants' perceptions of adherence to SI within the unit were similar or overestimated (depending on the scenario) to measured adherence rates from Study 2 (Chapter 3). As one nurse stated, "I would say for respiratory-related intubated patients I would say maybe 80 to 85% of the time we do sedation vacation", suggesting a perceived 15 to 20% of the time SI is not performed daily for each patient.

Participants' Perceptions of Current Practice. Nurses agreed that they were introduced to SI during their unit specific orientation and only some of the time had the opportunity to perform a SI under the supervision of a more senior nurse. Ongoing skill development was largely through experience and knowledge about SI was reinforced by either other nurses or a physician some of the time. Only one participant reported having completed a formal critical care course through an external institution and specifically noted that SI was not a component of the curriculum. In fact, several knowledge gaps were identified and warrant further consideration for any future implementation study. Examples of knowledge gap findings from our study relate to indications for sedative and analgesic medication especially in the presence of delirium, the impact of sedation on short and long-term recovery, as well as indications and contraindications for SI use. We can infer from the data that peer-to-peer education is not sufficient for consistent implementation of SI and other studies have identified similar inferences highlighting the need

for multidimensional, multidisciplinary education interventions to improve adherence to evidence-informed protocols (Yan et al., 2019). In a recent quality improvement study at a hospital in the United States, key barriers to the Pain, Agitation, and Delirium protocol were reported by staff (mostly nurses, nurse practitioners and one physician) to include a lack of education or understanding of the protocol along with some knowledge deficits about the value of the protocol (Yan et al., 2019). Participants in the study largely agreed that education was needed on a regular basis and that reminders of the protocol usage, benefits, and risks would all contribute to increasing adherence to the protocol (Yan et al., 2019).

A frequent barrier reported by all participants in Study 3 (Chapter 4) was the need for more leadership by physicians in educating nurses and allied health professionals to reinforce SI use. Physicians' influence on the use of sedation and SI has been identified in previous studies. A systematic review of the barriers to the ABCDE bundle delivery identified staff attitudes and buy-in and lack of interprofessional team support to be important barriers to the ABCDE bundle (Costa et al., 2017). Importantly, consensus amongst physicians about sedation goals and having these discussed during multidisciplinary rounds increased nurses' willingness to perform SI (Miller et al., 2012). Nassar et al. (2019) suggested having an intensivist on the morning and afternoon shifts was the only organizational factor associated with achieving target sedation levels in patients on mechanical ventilation 48 hours after ICU admission. A recent study highlights the importance of multidisciplinary collaboration in care bundle implementation, which includes SI (Balas et al., 2022). There is a considerable amount of practice change, interprofessional communication, and teamwork needed to deliver all the elements in care bundles (ABCDEF). This was illuminated in a study that evaluated the effectiveness of a quality improvement collaborative approach to implementing the bundle in 68 CCU in the United States

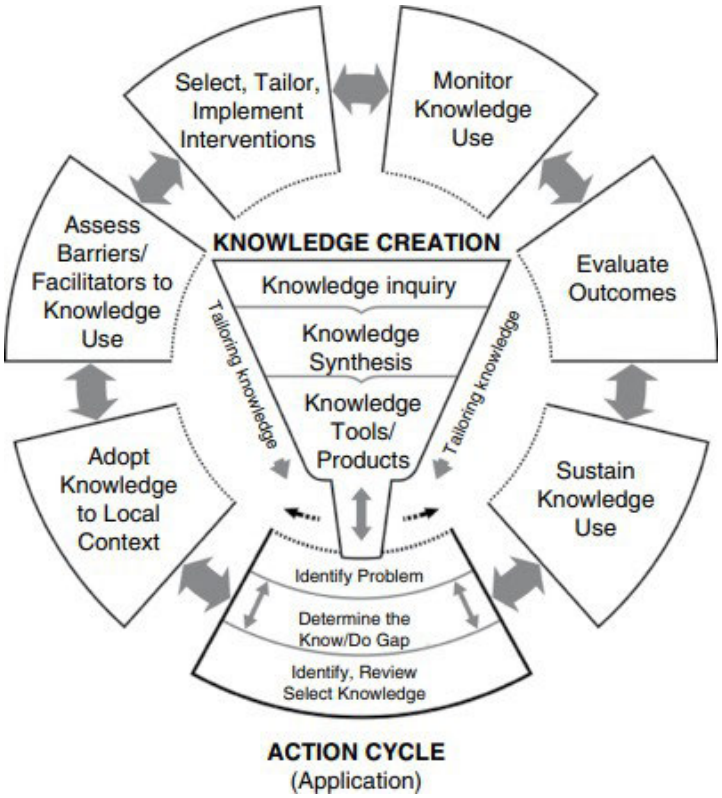
(Balas et al., 2022). This study reported low complete performance of bundle elements and was related to limited delivery of daily SI (Balas et al., 2022), highlighting its cascade of influence on other elements of the bundle.

Lastly, an important misconception was identified in Chapter 4 (Study 3) about needing to sedate mechanically ventilated patients for comfort, which stems from an older philosophical approach to care when heavy sedation was accepted practice (Ely, 2017; Petty, 1998). Guttormson et al., (2019) explored nurses' self-reported attitudes and practices related to sedation to determine whether they changed in the past decade. Nurses' attitudes toward sedating patients receiving mechanical ventilation have shifted in the past decade, with fewer nurses now believing that all patients should be sedated. However, more than half of the nurses in our study still agree that sedation is needed for patients' comfort, highlighting the need to consider nurses' attitudes when seeking to optimize sedation practices during mechanical ventilation.

5.3 Discussion

The Knowledge-to-Action (K2A) framework guided this work, from the appraisal and selection of evidence for SI to the confirmation of an evidence-practice gap followed by the discovery of determinants that impact SI use. The findings in this thesis are needed for a future implementation study to fully realize the remaining implementation and sustainment activities described by the K2A framework.

Figure 5.2 Knowledge to action framework



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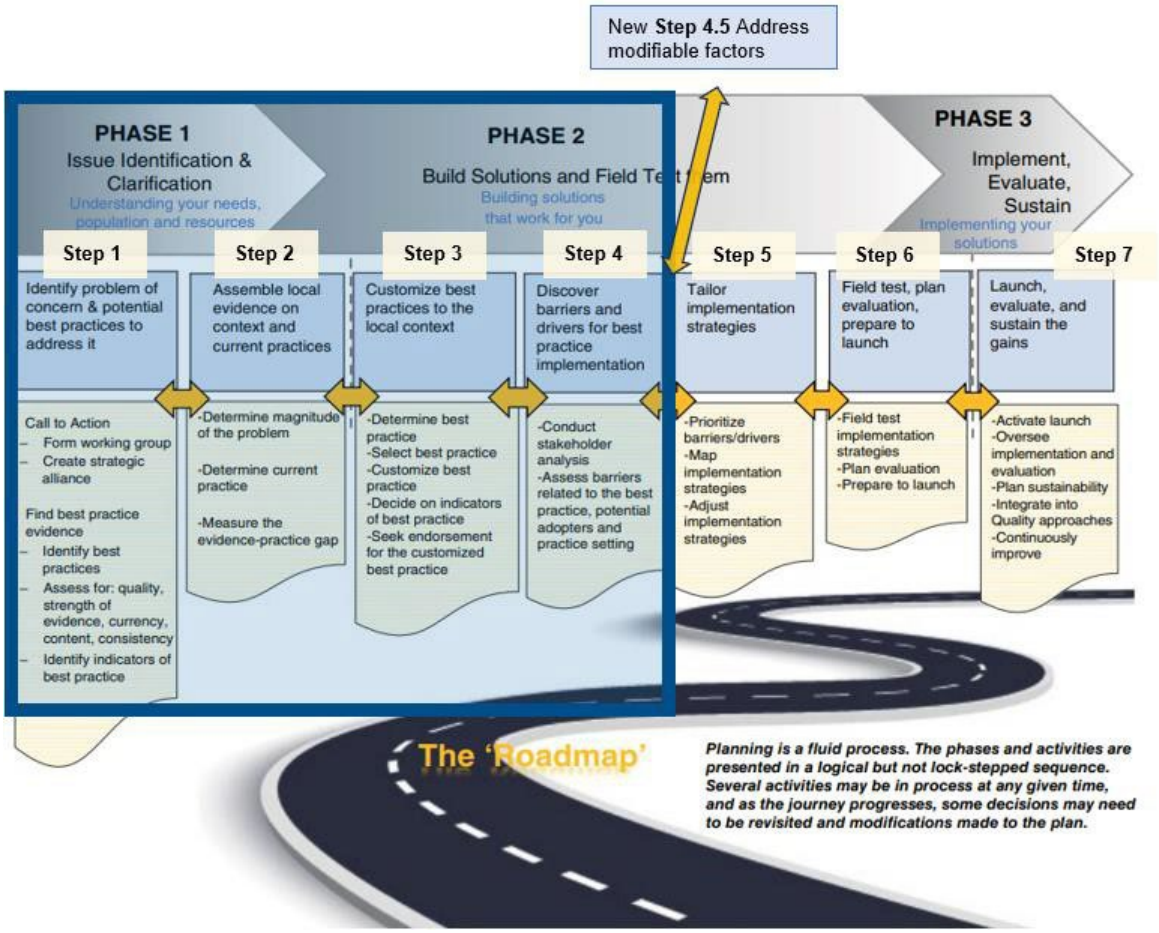
An important reflection on using the K2A is the recognition of how knowledge can be created at any point within either of the two cycles. Knowledge is formally examined, synthesized and/or selected in the *knowledge creation funnel* and new or identified knowledge is created and operationalized within the *action cycle*. We have created knowledge in each of the individual studies but the contribution across studies is what can drive change in practice. This thesis is an example of how effective a planned action model can be at guiding research to implement evidence in practice. Using the Implementation Roadmap with the K2A framework

offers a more practical approach to conducting and organizing knowledge translation research (Harrison & Graham, 2021). Our overall impression of using the Implementation Roadmap as a means for organizing our findings is that it is a user-friendly and practical guide for understanding the necessary steps for optimizing the use of evidence by clinicians. Preconceptions of what contributes to adherence issues can distract clinicians and lead to wasted implementation efforts when modifiable barriers are unknown and not addressed or ignored. The Implementation Roadmap is useful for keeping clinicians and researchers on track with the necessary preceding steps to activating evidence in practice without jumping to an erroneous solution.

While significant gains were made in this series of studies more work is needed to fully realize the activities of the Implementation Roadmap in forthcoming investigations. We successfully identified indicators of best practice to measure the evidence-to-practice gap using findings from the systematic review and critical appraisal in Study 1 (Chapter 2) together with the knowledge gained from the environmental scan component of the implementation needs assessment (Chapter 3 - Study 2). While critical activities in Phase 2 of the Implementation Roadmap were achieved such that we started tailoring knowledge to the local context through the identification of barriers and drivers to SI use by nurses (Step 5), this phase also involves developing an evaluation plan and field testing the customized best practice (Step 6) (Harrison & Graham, 2021). A working group will need to be established at the study site before proceeding to the roadmap's final steps and phases. Further work includes the completion of implementation strategy mapping (step 5) and the development of an evaluation plan and field test of the customized best practice (or the local protocol for SI) (step 6) before the launch of the implementation study (step 7). Before steps 5 through 7 can be accomplished, we propose a

newly identified step 4.5 *pre-implementation modifications* that should be intentionally planned for when following the Implementation Roadmap.

Figure 5.3 Implementation Roadmap and New Step 4.5 to Address Modifiable Factors



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Phase 2 Build Solutions and Field Test Continued

New Proposed Step 4.5 Address Modifiable Barriers. It became apparent that some modifiable factors should be resolved before planning an implementation study. This intermediate step is

somewhat less well defined in the Implementation Roadmap, and we suggest addressing modifiable barriers purposefully before implementing the practice intervention.

Doing so will optimize aspects of the environment in preparation for implementation. We postulate that if we first act on some of the modifiable findings from the initial study of determinants impacting the use of SI (Chapter 4 - Study 3), the study site will be better prepared to effectively use SI. First, given that greater awareness of the local protocol is needed in this unit, it is also reasonable to suggest that the limitations in the protocol be addressed first. From what we gathered in Study 1 (Chapter 2) the recommendations from guidelines and care bundles that form our understanding of best practice for SI lack certain components to guide the enactment of the behaviour. We also know from Study 2 (Chapter 3) that the local protocol for SI aligns with current best practice in that it prescribes SI like the recommendation in the PADIS guideline (Devlin et al., 2018) which was limited concerning behaviour components to enact SI. We propose updating the current local protocol to include all the components of the Action Actor Context Target Time framework to ensure coverage of the Action (SI) including the goals of SI, the roles of the nurses, physicians, respiratory therapists, pharmacists involved in the behaviour (Actors) with the goal for each stakeholder explicitly described, and the patients' condition(s) that may be excluded from SI (Targets) in the setting, and the time/date/frequency (Time) that SI should occur. Doing so would require engagement and input from key stakeholders in the CCU. The K2A framework supports an integrated knowledge translation approach where the producers and users of evidence work collaboratively (Harrison & Graham, 2021). The individuals needed for this type of change are, for example, CCU nurses, CCU physicians, CCU respiratory therapists, and those with authority to change the organization's protocols. Second, the Actors must be made aware of the protocol, where and how to access it before we can effectively expect

the innovation (SI) to be used by clinicians. Purposeful dissemination and orientation to the policy is needed so that every nurse and allied health professional in the unit knows what it is and where to access it. After foremost awareness of a protocol, clinical knowledge about the protocol needs to be assessed. Lack of knowledge about protocols was previously identified as a barrier to evidence use in critical care (Yan et al., 2019). Thirdly, we need to minimize missing documentation and support nurses by keeping an accurate and timely record of daily SI. The nurses will need to do their due diligence with documentation related to SI for professional and legal reasons, and this will also facilitate evaluation of the effectiveness of any implementation interventions.

After resolving the modifiable factors, we need to follow up with a second barriers assessment to learn if additional determinants influence the use of SI. With newly established awareness for some professionals (nurses, allied health, and physicians) of the local protocol, new insights about barriers associated with the innovation (SI) may be exposed. We will then be ready to map the first and second set of barriers to implementation strategies, tailor the strategies and later launch the implementation intervention(s). There are 3 remaining steps in the Implementation Roadmap. This thesis has begun to address step 5 and our findings can be further applied to a future implementation study that will entail steps 6 and 7 (phase 3).

Step 5 Tailor Implementation Strategies. The findings from Study 3 (Chapter 4) can be leveraged in a future implementation study through the prioritization of facilitators (primarily associated with the innovation (SI) and the potential adopters) and barriers (primarily related to the potential adopters and the environmental context) to SI use. We identified seven Theoretical Domains Framework (TDF) domains most relevant to modifying SI behaviour in practice. The seven identified TDF domains from Study 3 (Chapter 4) can be leveraged by the study site to

guide the development of tailored implementation interventions designed to improve the use of SI. The 29 identified barriers and facilitators from Study 3 (Chapter 4) can be used to design the building blocks of an implementation intervention, which should also include input from various stakeholders' (researchers and clinicians) experiences, and empirical evidence in support of SI (French et al., 2012). Suppose a theory-based approach to barriers mapping is taken. In that case, the Behaviour Change Techniques matrix can be used to narrow down some candidate implementation interventions given we use the TDF for the identification of barriers (Cane et al., 2015; Harrison & Graham, 2021; Michie et al., 2008). For example, techniques judged to be effective in changing behaviour within the TDF motivation and goals domain (we identified four barriers associated with the motivation and goals domain) can include specifying the goal of SI for clinicians and increasing clinicians' problem-solving, decision-making and goal setting skills (Michie et al., 2008). Six barriers were identified within the TDF beliefs about consequences domain, some of which can be addressed using persuasive communication and/or information about evidence-informed use of SI in clinical practice (Michie et al., 2008).

Step 6 Field Test, Plan Evaluation and Prepare to Launch. Harrison and Graham (2021) offer guiding questions and advice for planning an evaluation, which will be useful for planning the future implementation study. A preliminary test of indicators for both an outcome evaluation (measuring best practice(s) uptake or knowledge use) and an impact evaluation (measuring the impact of using best practice(s)) will assure that the measures are appropriate before the actual launch of the solution. A field test of the solution(s) will give us a sense of how the implementation strategies for SI fit with the current structures of the CCU and facilitate an opportunity to address potential issues that may arise before going full scale.

Phase 3 Implement, Evaluate, and Sustain

The next and final phase of the Implementation Roadmap is focused on implementation of best practice(s), evaluating their use and impacts, and concurrently tending to strategies for sustaining the practice change (Harrison & Graham, 2021).

Step 7 Launch, Evaluate and Sustain the Gains. At this point the implementation study can be activated and launched while overseeing the operation and evaluation plan and concurrently planning to sustain the implementation interventions. Integration of the implementation study monitoring and evaluation can be integrated into existing quality approaches at the study site. For example, the Plan-Do-Study-Act (PDSA) approach, which is a different implementation process, may be advantageous because the healthcare organization described in Chapters 2 and 3 already leverage these cycles in their quality improvement portfolios. PDSA cycles can be used to elicit input from key stakeholders into prioritizing the most relevant determinants and later assessing these approaches' effectiveness using rapid feedback and evaluation cycles. In this case, we suggest integrating some of the rigor of the Implementation Roadmap phases with the PDSA approach.

Whether the PDSA approach or another guiding framework is used, continuous improvement is the persistent goal of the implementation, sustainment, and evaluation phase of the Implementation Roadmap. This necessitates reflection on requisite findings from the series of studies. Completing a systematic review and critical appraisal of SI guidelines was an essential step in the Implementation Roadmap. Identifying best practice assured us that SI is the appropriate practice intervention for this patient population and should be included in the standard of care for adult mechanically ventilated patients at the study site. Comparing best practice (Chapter 2 - Study 1) to current practice (the environmental scan in Chapter 3 - Study 2) was essential for developing indicators of best practice that we used in a subsequent gap-analysis

(Chapter 3 - Study 2). The evidence-practice gap between recommended and current practice that we identified justifies pursuing an implementation study in the future to reduce the gap in SI use at the study site, which was started in Study 3.

The findings from studies 1 (Chapter 2) and 2 (Chapter 3) helped us understand that the local protocol for SI was aligned with international guideline recommendations in prescribing daily SI. Similarly, the local protocol had some but not all the needed behaviour components to enact SI. We speculate that if guideline recommendations and thus local protocols contained all the components to enact a behaviour and the tools/resources (for example the Choosing Wisely For Critical Care daily care rounding checklist) offered by the higher scoring guidelines were leveraged in a formal implementation study, we may see greater impact on clinician uptake of SI. Notably, the complexity of the recommendation for SI (the innovation) did not pose an important barrier to the participants in the descriptive qualitative study (Chapter 4 - Study 3). Most of the participants were not aware of the local protocol or if they were aware, they had not reviewed the content. Generally, the nurses felt that SI was expected of them, and they learned about this during their peer-mentorship to CCU rather than being informed by best practice recommendations. Lack of awareness of the local protocol is an important finding that needs to be addressed so that barriers to the innovation (both the use of SI and adherence to the protocol's recommendation for SI) can be properly assessed.

Another important finding to consider early in the design of an implementation study is the importance of the physicians' consistent buy-in and support for SI use. Nurses believed that multidisciplinary rounds would have a positive impact on SI use; thus, highlighting the need to activate buy-in and support from relevant critical care physicians in the design of the implementation study. Engaging members of the multidisciplinary team in co-creating tailored

implementation interventions and subsequent measures for monitoring uptake is a form of integrated knowledge translation that the K2A Framework supports. Clinicians working at the site of implementation need to be full partners in the research from the study design through to analysis considering the aim is to assess and actively intervene to change their structures in which the clinical intervention is used, notably, where they are experts (Bauer & Kirchner, 2020). Insights about the implementation context from the needs assessment (Chapter 3 - Study 2) were valuable for planning a future implementation study, for example identification of key working experts (CCU physicians), gaining a sense of the organization's readiness for research, and laying the foundation for future working relationships with the staff. Accurate documentation of SI can influence the results of an evidence-to-practice gap analysis and should be considered when analyzing these results. Moreover, missing documentation can impose legal implications for nurses. It should be addressed by the study site and other units with this same issue before proceeding to an implementation study.

5.4 Implications

Practice

Importantly, SI is best practice and should be prioritized as a necessary component of care for mechanically ventilated patients with continuous sedative and analgesic medications. Yet, clinicians need to be aware of certain factors about SI guidelines and care bundles when selecting one for local use. In general, the evidence base supporting these recommendations is mostly of low quality, and the quality of SI recommendation formulation is low. This has two important implications for practice. First, as a clinical intervention, SI does not have a strong supporting evidence base to suggest that it produces strong positive outcomes in clinical trials. Meaning, conflicting studies, low methodological quality studies, or studies with insufficient or

limited populations form our understanding of the outcomes of SI (Balas et al., 2018). But SI is considered safe and is a reasonable choice for reducing exposure to harmful sedative and analgesic medications. It is also a prerequisite to other evidence-informed interventions, for example spontaneous breathing trials, found in ABCDEF bundles. Second, although there are 13 recommendations in favor of SI, only one recommendation is sufficiently developed to be useful for clinical practice (Devlin et al., 2018). Clinicians are still tasked with addressing limitations within recommendations until researchers and guideline developers improve the methodological quality in future recommendations. We suggest clinicians modify recommendations for local use to include consistent behavioural components (action, actor, context, target, and time) of SI to inform clinical decision-making and promote multidisciplinary collaboration. Often guideline developers intend to offer "examples of pedagogical problem- solving and should be used by critical care clinicians as examples to further discussion, debate, and application of the guideline recommendations to real-life clinical scenarios" (Balas et al., 2018, p. 9) which is not always sufficient for guiding practice.

There are also additional implications for practice. Our findings highlight the need for more collaboration among nurses and joint responsibility by nurses and multidisciplinary team members (notably, the physicians and the respiratory therapist) to carry out SI as many of the barriers that we identified (Chapter 4 – Study 3) were associated with potential adopters and the environmental context. Multidisciplinary rounds for mechanically ventilated patients would support the use of SI by promoting a shared responsibility across disciplines for decisions about indications, contraindications, and goals of SI. The roles of all members of the team must be defined so that everyone can work together to reach the same goal instead of the current trend of nurses being the primary drivers for SI. The data collected for Study 2 (Chapter 3) by the

retrospective chart audit was from nursing documentation, and the primary focus of the data and analysis of the semi-structured interviews was on the nursing perspective. Nurses play a pivotal role in implementing SI for mechanically ventilated patients and this thesis confirms nursing is central to the concept. However, the findings from this thesis also highlight the need to address several shortcomings in current practice to improve implementation of both SI as an evidence-informed practice and as a necessary component of a multidisciplinary care bundle. Improvements to the recommendations for SI (innovation) can support the use of SI by nurses as potential adopters, but not without providing environmental and contextual structures that promote consistent deployment of the recommendations.

As autonomous leaders in the healthcare system, nursing work is best supported within the context of the health care team. However, where the environment is not conducive, either by lack of managerial support, lack of resources, lack of education, or lack of the necessary information (or a combination of these), sustained use of evidence-informed practice by nurses is not possible (Engström et al., 2015). These realities will continue to challenge the nursing profession and impose barriers to the nurse's role. Nevertheless, nurses have autonomy which gives them privilege of control over some outcomes in practice and these need to be reflected accurately in documentation. Accurate documentation of nursing practice is essential for not only continuity of care and continued quality improvement (for example the Practice Standard, Documentation from the College of Nurses of Ontario) but also for the legal justification of nursing work. In our Study 2 (Chapter 3), missing documentation about SI was documented on approximately 20% of the days that SI should have been performed, which has legal and implementation implications. Concerns about documentation accuracy have been noted by other studies reporting that user friendly electronic-health-record platforms that are easily adaptable

would better support ongoing quality improvement and research around care bundle implementation (Barnes-Daly et al., 2018; Costa et al., 2017; Eakin et al., 2015).

Finally, we want clinicians to be aware that current knowledge about the contraindications for SI is limited which has implications for guiding practice. A recent study concluded diversity in (and in some cases the lack of) 'safety screen criteria' or a defined list of contraindications for SI, precluded determination of when a daily SI was appropriately not performed (Balas et al., 2022). Those responsible in practice for developing local protocols, much like the site for our studies, will need to develop unit specific procedures to address inconsistent non-use of SI amongst nurses by explicitly stating and disseminating absolute contraindications for use and other more obscure scenarios should be explored in routine educational updates or multidisciplinary rounds. It is also pertinent for clinicians to be aware of another limitation that researchers and guideline developers need to address, which has implications for practice. The definition or description of SI in existing guidelines is largely informed by the original definition presented in a landmark RCT from over 20 years ago and does not consider advances in our understanding of the use of SI in combination with other interventions. This may be misleading to those not already aware that SI is a prerequisite to other bundled practice and when all the components are implemented patients experiences the greatest improvements in outcomes (Balas et al., 2022; Barnes-Daly et al., 2018; Pun et al., 2019b).

Educators

Education about SI can begin in undergraduate advanced medical and surgical nursing curricula where future nurses potentially endeavor to work in CCU. At this juncture, it will be helpful for those designing educational material or content to initially focus on the prevalence and consequences of post intensive care syndrome and the importance of family-centred care

(Registered Nurses' Association of Ontario, 2015). Nurses' attitudes about sedative use generally in this population and during mechanical ventilation should be addressed in undergraduate nursing education and be a required component of any critical care certification in ongoing education. Other topics that should be addressed and demystified include the idea that a sedated mechanically ventilated patient is easier to care for, (termed previously as *an ease of care*) and the misconception that sedation is a requirement for the comfort of all mechanically ventilated patients.

Within the clinical setting, there is considerable room for improvement in education about SI for nurses and the multidisciplinary team. Foremost, interprofessional education was favorable for the uptake of complex interventions amongst 54 CCU professionals in a qualitative evaluation study, and especially beneficial when the content addresses professional roles (Rak et al., 2021). The approach to educating the CCU team about SI should also target interprofessional and use educational strategies and mediums that have been developed for other critical care topics involving nurses (Devlin et al., 2008; Roberts et al., 2010; Weinert & Mann, 2008). For example, simulation-based education demonstrated improved competency of cardiovascular critical care nurses (Abe et al., 2013). Peer-to-peer mentorship at the bedside is important (Roberts et al., 2010) but alone, is not sufficient to optimize the enactment of SI at the bedside. Mentorship has been shown to decrease annual staff turnover rates and increase staff satisfaction (Vergara, 2017) yet in the age of profound staffing shortages with an all-time high of 136,800 job vacancies (Statistics Canada, June 2023) CCU orientations are limited to the resources and time that are readily available, though expert nurses are limited. Education about SI should target the interprofessional team using existing validated tools and approaches to learning about

complex, evidence-informed interventions used in CCU, and although important, have less dependence on one-to-one peer-to-peer mentorship.

Educators can promote engagement of nurses as drivers for SI use with support from the multidisciplinary team using other means as well. Champions were not specifically identified as a potential facilitator to SI use in this study, however, champions have successfully propagated sustained use of evidence-informed practices in other CCUs (Aitken et al., 2011) and specifically sustained uptake of a ventilator-associated pneumonia bundle six-years after implementation (Robinson et al., 2018). Champions are individuals who have a dedicated role supporting, promoting, and leading implementation and overcoming barriers to SI use, alone or in conjunction with other bundled practices. CCU Champions should be identified, and willing volunteers should be supported by leadership in this role to augment evidence-informed practices, which is advocated for in the PADIS guideline (Balas et al., 2018). Champions can provide clear direction and support for timely documentation of SI and drive the work to tailor the local protocols for SI use.

Suggestions for Researchers

Researchers are responsible for conducting trials to increase understanding about the benefits, risks, and potential outcomes of practice interventions. There is a continued need for research around SI, and, in that research, those responsible need to be clear about the definition of the intervention(s) and the behaviour components that they are evaluating. SI is generally supported by low quality evidence as identified in Study 1 (Chapter 2). The quality rating stems from the clinical heterogeneity of a small number of trials available that evaluate the outcomes of SI (i.e., the trials are not uniform in terms of methods, patients studied, and clinical management) (Burry et al., 2014). Though, essential research to solicit input from critical care clinicians about

what is needed for evidence-informed care bundle implementation (Mion et al., 2023), and evaluations of care bundle performance and patient-centered outcomes (Pun et al., 2019) is ongoing. Perhaps, research needs to scale back to also focusing on the most effective Actions, Actors, Context, Target, and Time components of SI and how they work best in conjunction with the ABCDEF bundle elements.

Implementation research can focus on generating more synthesis of available evidence-informed recommendations to ease the process of knowledge translation. It is important for clinicians and implementation researchers to understand what best practice is before expecting to incorporate these into routine care. Ideally, this is derived from a synthesis of all the available recommendations for an intervention, however, it is suitable to rely on a single high-quality guideline when needed. Though there were limitations within individual recommendations for SI, when considered all together we could discern enough information to guide practice in a more fulsome manner. Conducting our systematic review and critical appraisal was a laborious process but worth the effort and we encourage clinicians to do the same if a systematic review of guidelines is not available in the literature. Users of systematic reviews of guidelines are still limited to what guideline developers report and publish within guidelines which emphasizes the importance of producing high quality guidelines using valid methodological guides like the AGREE instruments (Brouwers et al., 2010, 2019).

We give advice for working with less research-intensive hospitals in Chapter 3 that others may find useful when planning an implementation study in similar settings. We also stress the importance of establishing indicators of the magnitude of the evidence-practice gap. The indicators that we established in Study 2 (Chapter 3) may be transferrable to other evidence-practice gap analysis studies and may also be used in the evaluation plan of a future

implementation study. Our findings indicate that even small samples from retrospective chart audits can reveal meaningful findings when conducted using rigorous standards which may be more feasible in rapid-cycle quality improvement studies. Future implementation research can examine the usefulness of deploying indicators of recommendation *use*, *non-use*, and *underuse,* like those that we developed for measuring adherence to SI, on other types of best practices.

Regarding SI in particular, researchers in collaboration with clinicians can focus on reaching a consensus on a modern definition for SI. Considering there is emphasis in the literature to include SI as a necessary component of care in bundled protocols, a review of the definition of SI seems warranted, like the transformation that the clinically significant definition of pain underwent years ago (Williams & Craig, 2016). There is also a need to reach consensus on the behaviour components (Action, Actor, Context, Target, Time) that are necessary to enact SI, specifically more clarity about what action is to be taken, in what context SI is not to be performed, and what are the targets or intended goal(s) of each SI.

Suggestions for Guideline Developers

When these areas of research are addressed, guideline developers will be better situated to improve the quality of their guidelines and recommendations related to SI. The benefits of guidelines will only be realized if the recommendations are used by clinicians which is best achieved when there is alignment between the actual recommendation and the goal(s) of the guideline (Brouwers et al., 2019). The purpose of a guideline is most useful when the definition is clear to clinicians and relevant to the current state of practice. For this reason, guideline developers are responsible for incorporating up-to-date definitions of the practice intervention and if the definition is old, which is the case for SI, a disclaimer or modification should be included with the recommendation. Further improvements in the use of SI may be achieved with

a clearer understanding of the contraindications or context for appropriate non-use of SI. Consistent terminology within the recommendations is also important as, arguably, a weaning protocol for mechanical ventilation can be different from the ABCDEF protocol (Pun et al., 2019b) and having a variety of nomenclature to describe the elements of care bundles can be confusing for clinicians (i.e., spontaneous awakening trials and sedation vacation versus sedation interruption).

Guideline developers should also be providing implementation guidance (domain 5 *applicability* of the AGREE-II instrument, and domain 3, item 9 *local application and adoption* of the AGREE REX instrument) to augment clinicians ability to implement the recommendations. Guideline developers need to focus on providing and disseminating decision-making tools for nurses to better facilitate informed decision-making and improve application and adoption at the bedside. Indicators to support evaluation and monitoring of recommendation implementation is a necessary element of high-quality guideline recommendations (Brouwers et al., 2019) which is supported by domain 3, item 9 *local application and adoption* in the AGREE REX instrument (AGREE-REX Research Team, 2019). These, however, will only benefit implementation and sustainability when clinicians use the indicators to monitor SI uptake in practice. Guidelines should inform clinicians of the indicators of use, non-use, and underuse of SI and how to use these in quality improvement efforts.

When the evidence is being translated to practice, leaving too much room for interpretation and extrapolation of the recommended practice, i.e., when the recommendations lack the necessary components to enact the behaviour (Action, Actor, Context, Target, Time) or do not include indicators of use, significant variability in the enactment of the clinical intervention can ensue. Sometimes these differences are suitable and appropriate while at other

times it may lead to non-adherence to best practice. Guideline developers should think about how each recommendation can be observed and measured in practice. Indicators of recommendation use should include instruction for how to measure *use*, *underuse*, and *non-use* of a recommended action which in practical terms will change the way recommendations are defined and presented in guidelines.

5.5 Limitations and Strengths of the Thesis

Limitations

There are potential limitations to this thesis that need to be acknowledged. There were limitations in our capacity to follow through with all the potential activities described by the Implementation Roadmap at the study site. Although we accomplished a critical component of Phase 1, for example identifying knowledge for local use (Chapter 2 - Study 1) and understanding the nature and magnitude of the evidence-practice gap (Chapter 3 - Study 2), some aspects will need to be accomplished in a more fulsome manner outside the constraints of a PhD dissertation. We had limited opportunity to maintain the working group relationships of both researchers and clinical experts and carry the partnership forward into the design and deployment of an implementation study, but the environmental scan gave us insight into the organizational structure which will be useful again in the future.

We used multiple methods to gain a better understanding of the determinants that influence SI use in clinical practice, including a systematic review and critical appraisal, a needs assessment that involved an environmental scan and gap analysis (retrospective chart audit), and an implementation barriers assessment qualitative descriptive study using semi-structured individual interviews. We could have used alternative approaches to conduct implementation research and recognize that other methods could lead to different findings. Using focus groups

versus semi-structured interviews, for example, may have led to different information being shared as the interviewer has less control over the direction of the dialogue (Edley & Litosseliti, 2010). Limitations within the chosen methods were minimized, when possible, for example by allowing participants to speak freely if desired and interview questions were only asked if the participant had not yet addressed the topic. Another example, in the systematic review and critical appraisal (Chapter 2 - Study 1) we may have missed guidelines or care bundles that were not readily available, though, we conducted a peer-reviewed systematic search of the literature and followed PRISMA reporting of systematic reviews. In Study 2 (Chapter 3), the final sample size for the chart audit was not what we initially set out to obtain, yet we had enough data in the end to generate meaningful findings, but a larger sample may result in different ranges of adherence to SI. In Study 3 (Chapter 4), we conducted a qualitative study and would have liked more diversity in the sample, still the participants offered important information that enhanced our understanding of SI use. The data collected from study 2 (Chapter 3) were limited to one small tertiary hospital, which limits its generalizability. Though, our adherence results are consistent with those of larger studies (Madhuvu et al., 2021; Yan et al., 2019). To compensate for potential to under or overestimate adherence rates due to missing documentation, we provided three possible scenarios to explain the adherence rates. The determinants to SI use (Chapter 4 - Study 3) may not be transferable to other critical care units in larger, more research-intensive metropolitan centres where the environmental context is likely different than the study site. While adherence rates and the barriers and drivers to SI use may not be transferable, the implementation roadmap process and methodologies used to collect and analyze data are certainly transferable to other critical care settings.

Strengths

Faced with several models, frameworks, and theories available in the literature (Skolarus et al., 2017) this thesis could have different theoretical approaches which could have influenced the knowledge discovery about SI. The K2A framework is based in implementation science and theoretically supports the chosen methodologies for answering the research questions (Graham et al., 2006, 2007). Our multi-method study design aligned with the K2A framework and created a robust foundation for advancing knowledge about SI use. The thesis is a good example of how addressing each step in the Implementation Roadmap is necessary to produce valuable information for making change within our clinical setting. The K2A framework is one of the most frequently cited frameworks used for implementation and dissemination research (Skolarus et al., 2017) and emphasizes social interaction and adaptation of research within the local culture and context to effectively address an evidence-practice gap (Harrison & Graham, 2021). From a theoretical standpoint, the K2A framework was the ideal framework to guide this work. It specifies steps in the process of translating research into practice and emphasizes the impact that social interactions together with contextual and environmental factors have on knowledge creation which contributed to the validity of our findings. Furthermore, each study has deeper theoretical underpinnings from a variety of theories and frameworks (AGREE II, AGREE-REX, Action Actor Context Target Time framework, Ottawa Model of Research Use) that guided data collection and analysis. We used the TDF framework for assessing the determinants of SI which is the preferred approach when developing a knowledge-to-action project (Legare & Zhang, 2013).

The studies in this thesis follow systematic and rigorous inquiry using validated research methods. The insights we gained from following the Implementation Roadmap are transferable to other evidence-practice gaps in clinical practice. Researchers or clinicians conducting

implementation studies may benefit from knowing about our experience using the Implementation Roadmap when preparing for an implementation study in either a smaller tertiary centre or a less research-intensive settings. Additionally, we have contributed 29 determinants of SI use (Study 3) to the current literature that can serve as a point of reference for those conducting quality improvement projects or studies. Once clinicians or researchers assess for local barriers and drivers to SI or care bundle use, a comparison can then be made to our barriers or facilitators which are linked to TDF domains, easing the process of mapping determinants to corresponding behaviour change techniques. Studies 2 and 3 are anchored in a particular case scenario which strengthens the cohesiveness of the findings and relevance to practice change at the study site.

5.6 Conclusions

This thesis offers one example of a rigorous approach to implementation planning using valid theoretical underpinnings (K2A framework) together with a robust implementation planning framework (Implementation Roadmap) for categorizing the findings (I. D. Graham et al., 2006, 2007; Harrison & Graham, 2021). Critical Care Unit-specific modifiable factors that influence the innovation, potential adopters, or the environmental context and implementation interventions need to be field tested prior to proceeding with further customization of best practice to the local context. Specifically, we determined SI to be best practice, yet there remains a gap between best practice and actual practice. Modifications are needed to existing guideline recommendations that include modernization of the definition of SI to consider its use in care bundles and to harness a multidisciplinary focus. Future recommendations need to include an up-to-date definition of SI together with a fulsome description of the necessary components to enact SI (actor, action, context, target, time). This alone will not change practice as there needs to be a

shift from nurses working in silos to implement SI to a greater emphasis on taking a collaborative approach. Similar improvements to local protocols together with other local changes to modifiable factors related to the potential adopters (for example, awareness, knowledge, documentation) will better prepare the CCU for a future implementation study. Integration of end users (nurses, allied health professionals and physicians) in the design of implementation interventions will support activation of SI in practice.

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Appendices

Appendix A: Approval of Dissertation Proposal by Thesis Committee

ÉCOLE DES SCIENCES INFIRMIÈRES
Programmes des études supérieures

uOttawa
Faculté des sciences de la santé
Faculty of Health Sciences

SCHOOL OF NURSING
Graduate Programs

APPROBATION DU PROJET DE THÈSE
THESIS PROPOSAL APPROVAL

DATE	NOM DE L'ÉTUDIANT/E – *NAME OF STUDENT*	Nº D'ÉTUDIANT/E – *STUDENT NO.*
	Nicole Graham	[redacted]

Graduate Program: ☐ NSG 7999 (M.Sc.Inf. / MScN) ☑ NSG9999 (Doctorat / Ph.D)

Thesis Title / Titre de la thèse: UNDERSTANDING THE DETERMINANTS OF ADULT INTENSIVE CAR

Directrice de these / Thesis Supervisor	Dr Janet Squires (Nom/Name)	[redacted]
Co-directrice de these/ Thesis Co-supervisor (s'il y a lieu / if applicable)	Dr Ian Graham (Nom/Name)	[redacted]

Autres membres du comité de direction de thèse / Other Thesis Committee Members

Dr Brandi Vanderspank-Wrigh (Nom/Name)	Assistant Professor/Univ of Ottawa (Position/Institution)	[redacted]
Dr Dean Fergusson (Nom/Name)	Professor/Univ of Ottawa (Position/Institution)	
(Nom/Name)	(Position/Institution)	(Signature)
(Nom/Name)	(Position/Institution)	(Signature)

Rapport d'évaluation / Evaluation Report

☒ La proposition est acceptée / Proposal accepted.

☐ La proposition devra être soumise à nouveau aux membres du comité, avec révisions, avant d'obtenir l'approbation finale / Proposal must be resubmitted to Committee members, with revisions, to obtain final approval.

☐ La proposition est rejetée. L'étudiante doit refaire le processus d'approbation à nouveau / Proposal is rejected. The student must complete the thesis proposal approval process again.

[redacted] Signature de l'étudiante / Student signature — Date

Approuvé par / Approved by : Directrice adjointe, études supérieures / Assistant Director, Graduate Programs — Date

V: 07/2018

Appendix B: Approvals for Conducting Studies 2 and 3 from the Research Site

[redacted]

APPROVAL FOR CONDUCTING RESEARCH INVOLVING HUMANS
Research Ethics Board (REB) - [redacted]

November 26, 2021

Nicole Graham
[redacted]

Dear Ms. Graham

This letter serves to inform you that the [redacted] Research Ethics Board (REB) has reviewed and approved the research protocol and other documents identified below for the research which is to be conducted by the qualified investigators named in the approval letter.

Type of Approval	New	X	Amendment	☐	Renewal	☐

Name of Principal Investigator	Student Investigator: Nicole Graham - PhD Thesis Supervisor: Dr. Janet Squires
Name(s) of Co-Investigator(s)	Dr. Ian Graham Dr. Brandi Vanderspank Dr. Dean Fergusson
Program/School/Department	Faculty of Health Sciences, School of Nursing, Ottawa University.
Title of Project:	Understanding the Determinants of Adult Intensive Care Unit Nurses' Use of Daily Sedation Interruption for Mechanically Ventilated Patients
REB File Number	**2108 - 026**
Initial Study Approval Date:	**November 15, 2021**
Annual Renewal/Final report due on:	**November 15, 2022**

Submission Documents:

- Research Project Submission Application
- Thesis Proposal
- Data Extraction Form for the Chart Audit Study (study tool)
- TCPS certificates for N. Graham, Dr. J. Squires, Dr. I. Graham
- Curriculum Vitea for N. Graham

[redacted]

If, during the course of the research, there are any adverse/unanticipated events, confidentiality concerns, deviations in the approved protocol/consent form/recruitment material, or any new information that must be considered with respect to the project, these should be brought to the immediate attention of the Board and the appropriate REB form completed.

All projects must submit an annual renewal or final report to the REB before their project's approval expires. You are responsible for ensuring the study receives re-approval by completing the appropriate REB form prior to the expiry of your approval.

The [redacted] operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS2, The International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice, and Part C, Division 5 of the Food and Drug Regulations of Health Canada.

If you have any questions, please do not hesitate to contact the REB Administrator [redacted] or REBoffice@[redacted]on.ca

Best wishes for the successful completion of this study.

[redacted]

Dr. Robert Butcher, Chair

[redacted] esearch Ethics Board

[redacted]

RB/kh

cc: Dr. Janet Squires, Thesis Supervisor

[redacted]

APPROVAL FOR CONDUCTING RESEARCH INVOLVING HUMANS
Research Ethics Board (REB) - [redacted]

April 4, 2022

Nicole Graham
[redacted]

Dear Ms. Graham,

This letter serves to inform you that the [redacted] Research Ethics Board (REB) has reviewed and approved the amended protocol identified below for the research, which is to be conducted by the qualified investigator named in the approval letter.

Type of Approval	New ☐	Amendment X	Renewal ☐

Name of Principal Investigator	Student Investigator: Nicole Graham - PhD Thesis Supervisor: Dr. Janet Squires
Name(s) of Co-Investigator(s)	Dr. Ian Graham Dr. Brandi Vanderspank Dr. Dean Fergusson
Program/School/Department	Faculty of Health Sciences, School of Nursing, Ottawa University
Title of Project:	Understanding the Determinants of Adult Intensive Care Unit Nurses' Use of Daily Sedation Interruption for Mechanically Ventilated Patients
REB File Number	**2108 - 026**
Amendment Approval Date:	**April 4, 2022**
Initial Study Approval Date:	**November 15, 2022**
Annual Renewal/Final report due on:	**November 15, 2022**

Submission Documents:

- Request for Ethics Approval of Amendment to an Approved Protocol Form
- Research Ethics Board Research Project Submission Form - Changes Highlighted
- Supplemental Files

If, during the course of the research, there are any adverse/unanticipated events, confidentiality concerns, deviations in the approved protocol/consent form/recruitment material, or any new information that must be considered wth respectto the project, these should be brou ghtto the immediate attention of the Boa rd and the appropriate REB form completed.

All projects must submit an annual renewal or final report to the REB before their project's approval expires. You are responsible for ensuring the study receives re-approval by co mp leting the appropriate REB form prior to the expiry of your approva l.

The [redacted] operates in compliance wth the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans - TCPS2, The Internati onal Council for Harmonisation (ICH) Guide lines for Good Clinical Practice, and Part C, Division 5 of the Food and Drug Regulations of Health Canada.

If you have any questions, please do not hesitate to contact the REB Administrator [redacted] or REBoffice@[redacted]on.ca

Best w shes for the successful completion of this study

[redacted]

Dr_ Robert Butcher; Chair

[redacted] Hhfcs 'Board

[redacted]

RB/kh

[redacted]

APPROVAL FOR CONDUCTING RESEARCH INVOLVING HUMANS
Research Ethics Board (REB) - [redacted]

November 7, 2022

Nicole Graham
[redacted]

Dear Ms. Graham

This letter serves to inform you that the [redacted] Research Ethics Board (REB) has reviewed and approved your request for annual renewal for the research named in this approval letter.

Type of Approval	New ☐	Amendment ☐	Renewal x
Name of Principal Investigator	Student Investigator: Nicole Graham - PhD Thesis Supervisor: Dr. Janet Squires		
Name(s) of Co-Investigator(s)	Dr. Ian Graham Dr. Brandi Vanderspank Dr. Dean Fergusson		
Program/School/Department	Faculty of Health Sciences, School of Nursing, Ottawa University		
Title of Project:	Understanding the Determinants of Adult Intensive Care Unit Nurses' Use of Daily Sedation Interruption for Mechanically Ventilated Patients		
REB File Number	**2108-026**		
Initial Study Approval Date:	**November 15, 2021**		
Annual Renewal/Final report due on:	**November 15, 2023**		
Submission Documents:	• REB Annual renewal form		

If, during the course of the research, there are any adverse/unanticipated events, confidentiality concerns, deviations in the approved protocol/consent form/recruitment material, or any new information that must be considered with respect to the project, these should be brought to the immediate attention of the Board and the appropriate REB form completed.

All projects must submit an annual renewal or final report to the REB before their project's approval expires. You are responsible for ensuring the study receives re-approval by completing the appropriate REB form prior to the expiry of your approval.

The [redacted] operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS2, The International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice, and Part C, Division 5 of the Food and Drug Regulations of Health Canada.

If you have any questions, please do not hesitate to contact the REB Administrator [redacted] or REBoffice@[redacted]ca

[redacted]

Dr. Robert Butcher, Chair
[redacted]Research Ethics Board
[redacted]

RB/kh

Appendix C: Certificate of Ethics Approval for Study 2 and 3 from the University of Ottawa

16/12/2021

Université d'Ottawa
Bureau d'éthique et d'intégrité de la recherche

University of Ottawa
Office of Research Ethics and Integrity

CERTIFICAT D'APPROBATION ÉTHIQUE | CERTIFICATE OF ETHICS APPROVAL

Numéro du dossier / Ethics File Number	H-12-21-7555
Titre du projet / Project Title	Understanding the Determinants of Adult Intensive Care Unit Nurses' Use of Daily Sedation Interruption for Mechanically Ventilated Patients.
Type de projet / Project Type	Thèse de doctorat / Doctoral thesis
Statut du projet / Project Status	Approuvé / Approved
Date d'approbation (jj/mm/aaaa) / Approval Date (dd/mm/yyyy)	16/12/2021
Date d'expiration (jj/mm/aaaa) / Expiry Date (dd/mm/yyyy)	15/11/2022

Équipe de recherche / Research Team

Chercheur / Researcher	Affiliation	Role
Nicole GRAHAM	École des sciences infirmières / School of Nursing	Chercheur Principal / Principal Investigator
Janet Elaine SQUIRES	École des sciences infirmières / School of Nursing	Superviseur / Supervisor
Ian GRAHAM	Département d'épidémiologie et santé publique / Department of Epidemiology and Public Health	Co-superviseur / Co-supervisor
Brandi VANDERSPANK	École des sciences infirmières / School of Nursing	Co-chercheur / Co-investigator
Letitia NADALIN-PENNO	Canadore College	Co-chercheur / Co-investigator

Conditions spéciales ou commentaires / Special conditions or comments

NOTE: The expiry date of November 15th, 2022 was set in accordance with the [redacted] Research Ethics Board (REB) ethics certificate approval dates.

550, rue Cumberland, pièce 154 Ottawa (Ontario) K1N 6N5 Canada
550 Cumberland Street, Room 154 Ottawa, Ontario K1N 6N5 Canada

613-562-5387 • 613-562-5338 • ethique@uOttawa.ca / ethics@uOttawa.ca
www.recherche.uottawa.ca/deontologie | www.recherche.uottawa.ca/ethics

16/12/2021

Universite d'Ottawa
Bureau d'ethique et d'integrite de la recherche

University of Ottawa
Office of Research Ethics and Integrity

Le Comite d' ethique de la recherche (CER) de l'Universite d'Ottawa, operant conformement a *l'Enonce de politique des Trois conseils* (2014) et toutes autres lois et tous reglements applicables, a examine et approuve la demande d'ethique du projet de recherche ci-nomme.

L'approbation est valide pour la duree indiquee plushaut et est sujette aux conditions enumerees clans **la** section intitulee "Conditions Speciales ou Commentaires". Le formulaire « Renouvellement ou Fermeture de Projet)} doit etre complete quatre semaines avant la date d'echeance indiquee ci-haut afin de demander un renouvellement de cette approbation ethique ou afin de fermer le dossier.

Toutes modifications apportees auprojet doivent etre approuvees par le CER avant leur mise en place, sauf si le participant doit etre retire en raison **d'un** danger immediat ou s'il s'agit d'un changement ayant trait a des elements administratifs ou logistiques du projet. Les chercheurs doivent aviser le CER dans les plus brefs delais de tout changement pouvant augmenter le niveau de risque aux participants ou pouvant affecter considerablement le deroulement du projet, rapporter tout evenement imprevu ou indesirable et soumettre toute nouvelle information pouvant nuire a la conduite du projet ou a la securite des participants.

The University of Ottawa Research Ethics Board, which operates in accordance **vVith** the *Tri-Council Policy Statement* (2014) and other applicable laws and regulations, has examined and approved the ethics application for the above-named research project.

Ethics approval is valid for the period indicated above and is subject to the conditions listed in the section entitled "Special Conditions or Comments". The "Renewal/Project Closure" form must be completedfour weeks before the above-referenced expiry date to request a renewal of this ethics approval or closure of the file.

Any changes made to the project must be approved by the REE before being implemented, except when necessary to remove participants from immediate endangerment or when the modification(s) only pertain to adininistrative or logistical components of the project. Investigators must also promptly alert the REE of any changes that increase the risk to participant(s), any changes that considerably affect the conduct of the project, all unanticipated and harmful events that occur, and new information that may negatively affect the conduct of the project or the safety of the participant(s).

Riana MARCOTTE
Responsable d'ethique en recherche / Protocol Officer
Pour/For Daniel LAGAREC President(e) du/ Chair of the Co mite d'ethique de la recherche en sciences de la sante et sciences/ Health Sciences and Sciences Research Ethics Board

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Ottawa (Ontario) K1 N 6N5 Canada

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www.recherche.uottawa.ca/deontologie | www.recherche.uottawa.ca/ethics

Appendix D: Letter to the Vice-President Clinical and Chief Nursing Executive for Studies 2 and 3.

Dear [redacted], Vice-President Clinical & Chief Nursing Executive

RE: Request for your approval and signature for PhD thesis study at [redacted].

Introduction and Request: My name is Nicole Graham, and I am currently enrolled in the PhD Nursing Program at the University of Ottawa, studying under the supervision of Dr. Janet Squires, Dr. Ian Graham, Dr. Brandi Vanderspank-Wright, and Dr. Dean Fergusson. I am in the process of reaching out to key individuals at [redacted], such as yourself to finalize my research ethics board (REB) proposal submission. I kindly request that you consider signing the department/division/program head support and awareness form located on page 32-3. By signing you will be indicating your approval and awareness of the proposed research activities, notably the semi-structured interviews with nurses and other critical care staff, and the impact the study will have on the resources of your Nursing Department/Division.

Research Aim: To quantify and qualify an evidence-to-practice gap identified in the literature pertaining to the use of sedation interruptions for adult mechanically ventilated patients. Sedation interruptions are the pausing of continuous sedative infusions once per day to allow for proper neurological assessment and to decrease the bioaccumulation of the medication.

Study Design and Methods: My PhD thesis research proposal involves a mixed-methods research design with three components. The first component is a systematic review that identified and assessed the quality of all published and available guidelines and care bundles with recommendations related to sedation interruptions. This manuscript has been prepared and submitted for publication. The second component consists of a retrospective chart audit of clinical charts from patients admitted and mechanically ventilated in the critical care unit at [redacted] to determine the prevalence rate of sedation interruption uptake. REB approval from both [redacted] as well as the University of Ottawa have been obtained for this study. I am now seeking your approval to conduct semi-structured interviews with a sample of nurses from the critical care unit, as well as other willing members of the critical care team at REDACTED (for example an Intensivist, an Anesthesiologist, a Respiratory Therapist, or a Pharmacist). The third component of my thesis will be based on the results of the previous three studies and consists of the design of a knowledge translation intervention aimed at augmenting facilitators or limiting barriers to sedation interruption uptake.

Ethics: I want to reassure you; several steps will be taken to protect the privacy and confidentiality of participants to be interviewed and the organization's identity will not be released or published. The details of which can be found in the REB submission package included on this email. Participants will receive a token of appreciation in the form of a $20 gift card to Indigo/Chapters for participating in this study. Individuals may also benefit from knowing that they contributed to the development of knowledge aimed at improving the quality of care for critically ill adults.

I thank you for your consideration of this letter and at your request, I look forward to connecting with you soon to further discuss the possibility of exploring the factors that influence the use of sedation interruptions at your facility.

Sincerely

Nicole Graham RN, BScN, PhD (c)

Attachments include:

1. REB submission package
2. Approval letter from [redacted] for conduct of the chart audit study
3. Approval letter from the University of Ottawa for conduct of the proposed research

Appendix E: Email to Participants for Study 3

uOttawa

Université d'Ottawa
Faculté des sciences de la santé

École des sciences infirmières

University of Ottawa
Faculty of Health Sciences

School of Nursing

April 19, 2022

Re: Sedation Vacation Study in the Critical Care Unit at [redacted]

Dear Critical Care Staff,

I would like to inform you of an opportunity to participate in a research study entitled, ***Understanding the Determinants of Adult Intensive Care Unit Nurses' Use of Daily Sedation Interruption for Mechanically Ventilated Patients.*** This research is being conducted in partial completion of a PhD in Nursing.

The research study is about the use of sedation interruptions for adult mechanically ventilated patients in the critical care unit and consists of short individual interviews. The interview questions are focused on understanding the barriers and facilitators to implementing sedation interruptions. I am looking for 8-10 Registered Nurses and approximately 1-2 individuals from each of the following disciplines currently working in CCU at [redacted] Medicine, Pharmacy, Respiratory Therapy.

Please see the **Participant Information Letter and Consent Form** that is attached to this email. If you are interested in being a participant in this study, I kindly ask that you read the information carefully and please returned a signed copy to [redacted]

Thank you in advance for considering this request.

Yours Sincerely,

[redacted]

Nicole Graham, RN, BScN, PhD candidate
[redacted]

613 562-5473
613 562-5443
451 Smyth
Ottawa ON K1H 8M5 Canada

www.uOttawa.ca

Appendix F: Participant Information Letter and Consent Form for Study 3

Participant Information Letter and Consent Form

Title of the study: Understanding the determinants of sedation interruption implementation for mechanically ventilated adults.

Principal Investigator:
Nicole Graham RN, PhD candidate
Tel.: [redacted]
Email: [redacted]

Thesis Supervisors:
Janet E. Squires, PhD
University of Ottawa, Faculty of Health Sciences, School of Nursing, 451 Smyth Road, Ottawa, Ontario, K1H 8M5, Canada.
Clinical Epidemiology Program, Ottawa Hospital Research Institute, 501 Smyth Road, P.O. Box 201-B, Ottawa ON, Canada, K1H 8L6
janet.squires@uottawa.ca

Ian D. Graham, PhD
Clinical Epidemiology Program, Ottawa Hospital Research Institute, 501 Smyth Road, P.O. Box 711, Ottawa ON, Canada, K1H 8L6
Faculty of Medicine, School of Epidemiology and Public Health, University of Ottawa, Ottawa, ON, Canada
University of Ottawa, Faculty of Health Sciences, School of Nursing, 451 Smyth Road, Ottawa, Ontario, K1H 8M5, Canada.
igraham@ohri.ca

You are invited to participate in the abovementioned research study conducted by Nicole Graham, Dr. Janet Squires and Dr. Ian Graham. Participation in this study is voluntary. This study has not been funded by any internal or external sources. This study has been reviewed and received ethics approval through [redacted] ([redacted] Research Ethics Board (REB) as well as the University of Ottawa's REB.

Please read this Information Sheet and Consent Form carefully and feel free to reach out to the Principal Investigator before deciding whether to participate in this research study.

Purpose of the Study
The purpose of the study is to explore factors that influence the use of sedation interruptions (SI) in the daily care of mechanically ventilated adults in the critical care unit (CCU). The impetus for the study originates from an evidence-to-practice gap that has been well documented in literature. Recommendations to include sedation interruptions in the management of critically ill adults continue to surface in clinical practice guidelines, yet the uptake of sedation interruptions is inconsistent according to research studies from across the globe. Participants from the critical care team (nurses, physicians, respiratory therapists, and pharmacists) at [redacted] are needed to help increase the understanding of the factors that influence the use of this practice. The knowledge gained from this study will help inform the design of a knowledge translation intervention to augment facilitators and limit barriers to the consistent use of SI in practice.

Participation
Your participation will consist of an individual interview. The interview will be conducted on a date and time that is convenient to you. The interview will be conducted using Microsoft Teams online conferencing software, or if you prefer, over the phone or face-to-face at a location that is most suitable for you. The interview will last approximately 20 minutes and will not exceed 30 minutes. You have the right to end the interview at any time. Each interview will be audio-recorded and transcribed to help the researchers interpret the information accurately.

Risks
Your participation in this study will entail you talking about your experiences and opinions of using sedation interruptions in your clinical practice and/or your thoughts about the intervention generally. There are no known or anticipated risks to participating. You can stop the interview at any time and for any reason. Please note that if you feel emotionally upset during or subsequent to the completion of the interview, you may contact the following services to discuss your feelings and to locate appropriate support services in your community. Both of these services are confidential and are available 24 hours/day, 7 days/week: Ontario Mental Health Hotline: http://www.mentalhealthhelpline.ca/ or 1 (866) 531-2600; and Telehealth Ontario: 1 (866) 797- 0000.

Benefits and Compensation
Direct incentive will be provided to each participant via their preferred email address after the completion of the interview in the form of a $20 gift card to Indigo. An indirect benefit for each of the participants is having contributed to the advancement of knowledge that may lead to improved outcomes for adult mechanically ventilated patients. You may also gain satisfaction from knowing that you are helping a PhD in Nursing student with her thesis.

Confidentiality and anonymity/Conservation of Data
The interview will be digitally audio-recorded. At the first opportunity the audio-recordings will be transcribed and verified, once this is complete the recordings will be erased. All transcripts will be assigned a unique number, and your name will not appear on the transcripts.
The audio-recordings and electronic transcripts will only be accessed by the Principal Investigator, Nicole Graham. All transcriptions will be digitally stored for 10 years after the termination of the study. At the end of the 10-year retention period, all electronic records will be deleted. The participants' involvement will remain confidential, only the Principal Investigator will be privileged to the participants' name and email address. Names of the participants will not be included on the electronic transcripts, rather a unique study code will be assigned to the file. Each audio-recording will be transcribed immediately after the interview and as soon as this is complete, the audio-recordings will be deleted.

You will not be identifiable in any publications or presentations resulting from this study.

Voluntary Participation
You are under no obligation to participate. The researcher will respect your wish to stop the interview. If you choose to withdraw, all data from this point forward will be excluded from the study and destroyed. There are no known risks involved with this study. However, please note that in signing this form you have not waived any rights to legal recourse in the event that research-related harm is experienced. Please note that you are under no obligation to participate in the study, and that you are free to withdraw from the study at any time by simply contacting the Principal Investigator, Nicole Graham, by email. There will be no penalty or negative consequence of any kind for withdrawing from the study. If at any point during the interview you feel uncomfortable with a question being asked, please be reminded that you have the right to not answer any given question, and the right to withdraw from the study at any time.

Questions about the Study
If you have any questions regarding the ethical conduct of this study, you may contact the Protocol Officer for Ethics in Research at the University of Ottawa, phone 613-562-5800 ext. 1379, or email ethics@uottawa.ca. You may also contact the **Research Ethics Board Assistant,** [redacted] **or REBOffice@** [redacted] **on.ca**

If you have any questions or concerns about the research, please feel free to contact the Principal Investigator, Nicole Graham, by phone at [redacted] or by email [redacted]

Participant Consent

As a participant in this research project, I understand that I am agreeing to participate in a 20-30-minute individual interview and that I am free to decline or withdrawal involvement from the project at any time, and for any reason. I have read the 2-page Participant Information Letter and all of my questions have been answered to my satisfaction. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

I_____voluntarily agree to participate in this study.

X_____

Volunteer Participant

Date:

Participant's email address:

Your email will only be used by the principal investigator to schedule a date and time for the interview, and later to send you an electronic gift card.

Please forward a signed copy of this form to [redacted] or copy-n-paste the information from this form directly into a return email with your electronic signature.

Appendix G: Chapter 1 Review of the literature search terms Boolean phrases, inclusion, and exclusion criteria

Search terms	Sedation interruption Sedation vacation Daily sedation interruption Interruption of sedation Spontaneous awakening* Critical care Intensive care Nursing
Boolean phrases	Each term searched using the corresponding MESH term or key term and combined using Boolean 'OR' and 'AND' For example, sedation* OR sedation vacation AND critical care OR nursing
inclusion	exclusion

• Qualitative studies
• Quantitative studies
• Randomized control trials
• Pilot studies
• Secondary analysis
• Books
	• Abstracts (1)
	• Author's replies (1)
	• Editorials (1)
	• Opinion papers (2)
	• Results exploring or testing:
	  ○ Patients aged less than 18 years (15)
	  ○ Analgesic or sedative medication comparisons (8)
	  ○ Spontaneous breathing trials alone (3)
	  ○ SATs* and one disease process (for example, severe head injury, myasthenia gravis) (14)
	  ○ Dexmedetomidine trials (3)
	• Studies greater than or equal to ten years old (162)
	• Sedation in general: (54)
	  ○ Communication with ventilated patients
	  ○ Assessing pain
	  ○ SATs for mobilization only
	  ○ Sedation monitoring scales alone
	  ○ Reflexology
	• Grey literature (0)
	• Duplicates (64)

Note. *spontaneous awakening trials

Appendix H: Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement to guide reporting of the findings in the PRISMA checklist.

Chapter 2 Study 1 Supplemental Table 1

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Title page lines 1-2
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Pg. 1 lines 1 to 24 and Pg. 2 lines 1 to 4.
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Pg. 2 lines 4 to 10
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Pg. 4 lines 18 to 24.
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Pg. 5 lines 1 to 5..
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Two example full search strings in Supplemental File 2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Pg. 5 lines 8 to 15.
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study	Pg. 5 lines 16 to 21.

Section and Topic	Item #	Checklist item	Location where item is reported
		investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Pg. 5 line 22 to Pg. 9 line 7.
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Pg. 5 line 22 to Pg. 9 line 7.
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Pg. 5 line 22 to Pg. 9 line 7.
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	N/A
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Pg. 12 lines 8 to 16.
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Pg. 12 lines 8 to 16.
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	

Section and Topic	Item #	Checklist item	Location where item is reported
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Pg. 9 lines 20 to 22 & Figure 1.
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Pg. 15 lines 14 to 19.
Study characteristics	17	Cite each included study and present its characteristics.	Pg. 9 lines 24 to pg. 10 line 8, & Table 1.
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Tables 2 and 4
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Tables 1, 2, 3 & 4
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Pg. 10 lines 9 to 18. Pg. 12 line 20 to pg. 14 line 20.
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Tables 1, 2, 3 & 4
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Pg. 19 lines 4 to 18.
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Table 3
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pg. 15 lines 7 to 24.
	23b	Discuss any limitations of the evidence included in the review.	Pg. 18 lines 9 to 23.

Section and Topic	Item #	Checklist item	Location where item is reported
	23c	Discuss any limitations of the review processes used.	Pg. 20 lines 11 to 24.
	23d	Discuss implications of the results for practice, policy, and future research.	Pg. 18 to pg. 20 line 10.
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Pg. 4 lines 13 to 15.
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Pg. 4 lines 13 to 15.
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Pg. 20 lines 18 to 24.
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Pg. 1 with author contributions
Competing interests	26	Declare any competing interests of review authors.	Pg. 1 with author contributions
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	N/A

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

Appendix I: Search Terms, Databases and Grey Literature (Study 1)

Supplemental File Chapter 2 Study 1

Concepts A, B, and C combined with Boolean operator AND	**Related, surrogate and MESH terms search using wildcards* when appropriate, then combined using Boolean operator OR**
A. Sedation interruption	Sedation interruption Sedation* Sedation-vacation Spontaneous awake* Analgesia
B. Evidence-based clinical guidelines	Clinical Practice Guideline string.
C. Intensive Care Unit	Intensive Care* Critical* CCU* ICU*
Bibliographic Databases and Grey Literature (January 2010 – November 2021)	
Databases • MEDLINE (OvidSP) • Cumulative Index to Nursing and Allied Health (CINAHL)(EBSCO) • EMBASE (OvidSP) • The Cochrane Effective Practice and Organization of Care (EPOC) Review Group specialized register Grey literature **Critical Care Associations:** • Critical Care Associations/societies/federations · Canadian Critical Care Trials Group · Canadian Association of Critical Care Nurses · Intensive Care Society · Canadian Anesthesiologists society · Canadian Society of Respiratory Therapist · Australian and New Zealand Intensive Care Society · European Society of Intensive Care Medicine · American Thoracic Society · Neuro Critical Care Society • Registered Nurses Association of Ontario (RNAO) **http://rnao.ca/bpg** • Canadian Medical Association (CMA) Clinical Practice Guidelines CPG InfoBase **https://joulecma.ca/cpg/homepage**	

- American Medical Association (AMA) Guideline Central **https://www.guidelinecentral.com**
- Society of Epidemiology
- Centre for Disease Control
- World Federation of Intensive and Critical Care

Guideline Repositories:

- Guideline International Network (GIN) – need membership access
- The National Guideline Clearinghouse
- TRIP database
- The Cochrane library https://www.cochranelibrary.com
- The Joanna Briggs Institute (Australia) http://connect.jbiconnectplus.org/Default.aspx
- National Health and Medical Research Council of Australia (NHMRC) Clinical Practice Guidelines Portalwww.clinicalguidelines.gov.au
- National Institute for Health and Care Excellence (NICE)http://www.nice.org.uk/about
- NHS Evidence https://www.evidence.nhs.uk/
- Scottish Intercollegiate Guidelines Network (SIGN) http://www.sign.ac.uk/index.html
- Danish Society of Anesthesiology and Intensive Care Medicine
- AHRQ
- https://sporevidencealliance.ca/resources/other-resources/

Appendix J: Search String Examples (Study 1)

Supplemental File

Example 1 from EMBASE database

1. deep sedation/
2. sedat*.ti,ab.
3. (spontaneous* adj3 awak*).ti,ab.
4. 1 or 2 or 3
5. intensive care/
6. intensive care unit/
7. (critical adj2 care).ti,ab.
8. (intensive adj2 care).ti,ab.
9. ICU*.ti,ab.
10. CCU*.ti,ab.
11. 5 or 6 or 7 or 8 or 9 or 10
12. practice guideline/
13. exp clinical pathway/
14. exp clinical protocol/
15. exp consensus/
16. exp consensus development conference/
17. exp consensus development conferences as topic/
18. critical pathways/
19. guidelines as topic/
20. exp practice guideline/
21. practice guidelines as topic/
22. health planning guidelines/
23. (guideline or practice guideline or consensus development conference or consensus development conference, NIH).pt.
24. (position statement* or policy statement* or practice parameter* or best practice*).ti,ab,kw.
25. (standards or guideline or guidelines).ti,kw.
26. ((practice or treatment* or clinical) adj guideline*).ab.
27. (CPG or CPGs).ti.
28. consensus*.ti,kw.
29. ((critical or clinical or practice) adj2 (path or paths or pathway or pathways or protocol*)).ti,ab,kw.
30. recommendat*.ti,kw.
31. (care adj2 (standard or path or paths or pathway or pathways or map or maps or plan or plans)).ti,ab,kw.
32. (algorithm* adj2 (screening or examination or test or tested or testing or assessment* or diagnosis or diagnoses or diagnosed or diagnosing)).ti,ab,kw.
33. (algorithm* adj2 (pharmacotherap* or chemotherap* or chemotreatment* or therap* or treatment* or intervention*)).ti,ab,kw.
34. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33
35. 35. 4 and 11 and 34 = 1952

Example 2 from Medline database

Sedation/CCU/CPG for SR

1. Deep Sedation/
2. sedat*.ti,ab.
3. (spontaneous* adj3 awak*).ti,ab.
4. 1 or 2 or 3
5. Critical Care/
6. Intensive Care Units/
7. (critical adj2 care).ti,ab.
8. (intensive adj2 care).ti,ab.
9. ICU*.ti,ab.
10. CCU*.ti,ab.
11. 5 or 6 or 7 or 8 or 9 or 10
13. exp clinical pathway/
14. exp clinical protocol/
15. exp consensus/
16. exp consensus development conference/
17. exp consensus development conferences as topic/
18. critical pathways/
19. exp guideline/
20. guidelines as topic/
21. exp practice guideline/
22. practice guidelines as topic/
23. health planning guidelines/
24. (guideline or practice guideline or consensus development conference or consensus development conference, NIH).pt.
25. (position statement* or policy statement* or practice parameter* or best practice*).ti,ab,kf,kw.
26. (standards or guideline or guidelines).ti,kf,kw.
27. ((practice or treatment* or clinical) adj guideline*).ab.
28. (CPG or CPGs).ti.
29. consensus*.ti,kf,kw.
30. consensus*.ab. /freq=2
31. ((critical or clinical or practice) adj2 (path or paths or pathway or pathways or protocol*)).ti,ab,kf,kw.
32. recommendat*.ti,kf,kw.
33. (care adj2 (standard or path or paths or pathway or pathways or map or maps or plan or plans)).ti,ab,kf,kw.
34. (algorithm* adj2 (screening or examination or test or tested or testing or assessment* or diagnosis or diagnoses or diagnosed or diagnosing)).ti,ab,kf,kw.
35. (algorithm* adj2 (pharmacotherap* or chemotherap* or chemotreatment* or therap* or treatment* or intervention*)).ti,ab,kf,kw.

36. 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35
37. 4 and 12 and 36 = 757

Appendix K: Action, Actor, Context, Target, Time Framework for specifying a sedation interruption (Study 1)

Supplemental File Chapter 2 Study 1

Domain	Recommendation	a. Donato et al. (2021)	b. Temesgena et al. (2021)	c. Celis-Rodríguez et al. (2019)	d. Devlin et al. (2018)	e. AHRQ (2017)	f. Schmidt et al. (2017)	g. DAS-Taskforce (2015)	h. Sharshar et al. (2014)	i. HPS (2012)	j. IHI (2012)	k. Rello et al. (2010)
Action	Interrupt sedation until the patient is awake and follows instructions or becomes uncomfortable or agitated. The sedative infusions are started again after the patient was awake or, if agitation prevents successful waking, at half the previous rates and adjust according to the need for sedation (Kress et al., 2000).										X	
	Patients can wake up and achieve arousal and/or alertness, defined by objective actions such as opening eyes in response to a voice, following simple commands, and/or having a Sedation-Agitation Scale (SAS) score of 4–7 or a RASS score of –1 to +1.				X							
	Perform a neurological assessment at the time of SI										X	
	Pair with spontaneous breathing trial							X				
Actor	Not specified directly in the recommendation.	X	X	X	X	X	X	X	X	X	X	X
Context	Include as part of a weaning protocol		X					X			X	X
	Part of ABCDEF protocol			X	X	X						
	Sedation scales are <u>not</u> a reasonable substitute for the interruption of sedation										X	

	SI should not be used to justify the use of deep sedation for the rest of the day				X							
	Only if **clinical conditions* specific to the patient allow and proper protection by the health team can be ensured	X										
Target	Critically ill, intubated and mechanically vented adults		X	X	X	X	X	X	X	X	X	X
	Ventilated for more than 24-hours						X					
	Not in patients with intracranial hypertension			X					X			
	Only in patients with RASS less than or equal to -2							X				
	Patients receiving dexmedetomidine			X								
	Critical patients that require systematic assessment of analgesia, sedation, and delirium (ASD) in adults with ARDS caused by COVID-19	X										
Time	Daily	X	X	X	X	X	X	X	X	X	X	
	Not specified											X
Tools	Motor Activity Assessment Scale (MAAS)										X	
	Riker Sedation Agitation Scale (SAS)				X	X					X	
	Richmond Agitation Sedation Scale (RASS)		X		X	X		X			X	

* *Clinical conditions*: all the following criteria should be met: Partial Pressure of Oxygen (PaO2)/Fraction of Inspired Oxygen (FiO2) > 175mmHg, final positive end-expiratory pressure (PEEP) < 10cm H2O, FiO2 < 50%, supine for at least 4 hours, seizure-free, free of NMBs for at least 2 hours, and without extracorporeal membrane oxygenation (ECMO) (Donato et al., 2021); NMB = Neuromuscular Blockade.

a. Donato et al. (2021) Consensus for the management of analgesia, sedation and delirium in adults with COVID-19-associated acute respiratory distress sundrome
b. Temesgen et al. (2021) Adult sedation and analgesia in a resource limited intensive care unit – A systematic review and evidence based guideline
c. Celis-Rodríguez et al. (2019) Evidence-based clinical practice guidelines for the management of sedoanalgesia and delirium in critically ill adult patients
d. Devlin et al. (2018) Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult

e. AHRQ (2017) Daily Care Processes Guide for Reducing Ventilator-Associated Events in Mechanically Ventilated Patients
f. Schmidt et al. (2017) Liberation from Mechanical Ventilation in Critically Ill Adults: An Official American College of Chest Physicians/American Thoracic Society Clinical Practice Guideline
g. DAS-Taskforce (2015) Evidence and consensus-based guideline for the management of delirium, analgesia, and sedation in intensive care medicine
h. Sharshar et al. (2014) Neurological examination of critically ill patients: a pragmatic approach. Report of an ESICM expert panel
i. HPS (2012) VAP Prevention Bundle Guidance for Implementation
j. IHI (2012) How-to Guide: Prevent Ventilator-Associated Pneumonia: Prevent ventilator-associated pneumonia (VAP) by implementing the five components of care called "the ventilator bundle."
k. Rello et al. (2010) A European care bundle for prevention of ventilator-associated pneumonia

Kress JP, Pohlman AS, O'Connor MF, Hall JB. Daily interruption of sedative infusions in critically ill patients undergoing mechanical ventilation. N Engl J Med. May 18, 2000;342(20):1471-1477

Appendix L: Interview Guides for Study 3

Understanding the Determinants of Adult Intensive Care Unit Nurses' Use of Daily Sedation Interruption for Mechanically Ventilated Patients: Interview Guide

Introduction

Thank you for agreeing to speak with me today about sedation vacations for adult mechanically ventilated patients. It is important to note that there are no right or wrong answers to the questions and that no one will know what your specific answers were. The interview should take approximately 20-30 minutes and will be audio-recorded to ensure that all key points are accurately documented. Any identifying information (for example the names of individuals) that you use during our discussion will be removed from the interview transcripts. If you wish to end the interview before I have asked all of the questions or if you wish to withdraw from the study, you are free to do so.

I am conducting these interviews as part of a PhD dissertation. For the purposes of this interview sedation vacations are the act of pausing continuous infusions of sedative type medications for a certain period to promote clearing of the medication from the patient's body. The sedation vacation can last different lengths of time depending on the patient's clinical picture, it sometimes includes a neurological assessment at the end, and resumption of the sedative at half of the previous rate.

Opening Discussion *(all participants will be asked the following two questions)*

1. Before beginning, can you please tell me what term you use to describe this intervention?

To answer the questions in this interview, I want you to think about your experiences here in the CCU at [redacted]

2. How common are sedation vacations in your unit? If you could estimate for approximately 10 eligible patients, how many would receive a sedation vacation?

3. What types of patients will or will not get a sedation vacation? (Prompts: are there any diagnoses that automatically make a patient not eligible; do you assume that all mechanically ventilated patients with continuous sedation infusions will receive a sedation vacation; age limitations; anticipated length of ventilation; types of procedures; other).

The following are all the potential questions and prompts that may be asked during the interview. The selection of prompts for each participant will be based on the information that is provided as the interview unfolds. Some participants may elaborate on a question and provide enough information to satisfy several other potential prompts. In this case, fewer questions will be posed.

A. Interview Discussion Questions for Registered Nurses

Research questions for the interviews with the Nurses:

Research question 1: *What are the nurses' perceptions of SI/sedation vacation practices generally?*

Research question 2: *What are the nurses' perceptions of the factors that facilitate, inhibit or limit the consistent uptake of internationally recognized recommendations for SI/sedation vacation practice in adult mechanically ventilated patients?*

Theoretical Domains Framework	
Domain 1: Knowledge	Does your CCU have a local protocol or policy about sedation vacations? If yes. Can you tell me about it/those? Is there a standardized approach to sedation monitoring and goals? (For example, the use of SAS or RASS)
	Are you aware of any provincial, national, or international recommendations about sedation vacations? • Can you tell me about the recommendation(s)? • How evidence-based is/are the recommendation(s) for sedation vacations?
Domain 2: Skills	Have you received any training related to sedation vacations? If yes. • Can you tell me about the training?
	How do you perform a sedation vacation? Can you walk me through the steps? (Prompt: Can you tell me about who performs it, when it is done and how it is done? How do you know when a sedation vacation is over? Do you turn the sedation infusion off all together or slowly turn the infusion down? What action do you take with any analgesic medication infusions, if applicable?
Domain 3: Social/professional Role and Identity	Are sedation vacations a standard part of the care that you provide to adult mechanically ventilated patients?
	What is your impression of the adherence of others in your profession with performing sedation vacations? Do you feel as though the way you perform a sedation vacation is in line with your peers?
	Are sedation vacations an intervention that is specific to nursing? What is your discipline's role for this intervention?
Domain 4: Beliefs about capabilities	How easy or difficult is it for you to perform a sedation vacation? Why?
	What would make performance of a sedation vacation easier, or

	harder for you?
	Do you believe that what you consider to be a 'sedation vacation' fits with the current recommendations in guidelines that are external to your hospital? Do believe that what you consider to be a sedation vacation is in line with [redacted] CCU protocol?
	Are you confident that you are following the recommended practice when performing a sedation vacation?
Domain 5: Beliefs about Consequences	What are the benefits of a sedation vacation? (Prompt: patients/families, yourself)
	What are the negative aspects when a sedation vacation is performed? (Prompt: patients/families, yourself, documentation, adverse events)
	In what situations do you think a sedation vacation is necessary/unnecessary?
Domain 6: Optimism	What do you think will happen if you do not perform a sedation vacation on an eligible patient?
	In your opinion, how likely is it that performing a sedation vacation will lead to an adverse event? (For example, it is suggested in the literature that clinicians sometimes believe that sedation vacations can lead to self-extubation).
Domain 7: Intentions	Do you intend to perform a sedation vacation for all mechanically ventilated patients who are sedated and eligible? • If not, why? • If yes, do you anticipate any problems?
Domain 8: Memory, attention, and decision processes	Are sedation vacations automatic or do you need to remember or be reminded to do them?
	Is performing or not performing a sedation vacation ever a conscious decision?
	Are there certain situations where you find yourself forgetting to perform a sedation vacation?
	Do you have any triggers for remembering to perform a sedation vacation? What would make it easier to remember to perform a sedation vacation? Would a reminder to perform a sedation vacation be helpful? How so? What would be the best way to remind you?

*Will cross several TDF domains.	In what situation(s) might you find it difficult to follow the sedation vacation recommendations?
Domain 9: Environment context and resources	What resources would make it easier for you to perform a sedation vacation? (Prompt: other nurses or clinicians; sedation vacation how-to guide; technology; documentation)
	What aspects of your work environment influence whether you perform a sedation vacation? (Prompt: staffing, technology)
	Are there any competing tasks or time constraints that might influence whether you perform a sedation vacation? What would help you overcome these problems/difficulties?
Domain 10: Social influences	Do other team members influence your decision to perform a sedation vacation? • If yes, how? • If no, prompt (co-workers/team lead/multi-disciplinary rounds)
	Do the expectations of the patients' families influence you to perform a sedation vacation? • If yes, how?
Domain 11: Emotion	Do your emotions or mood ever influence whether you perform a sedation vacation?
	Does practicing or not practicing sedation vacation ever evoke worry or concern in you?
	Do you have any strong feelings about sedation vacations that you haven't already mentioned and would like to share?
Domain 12: Goals	In what situations do you want or not want to perform sedation vacations?
	Considering your other priorities, on a scale of 1 to 10 with 10 being very important, how important do you think it is for you to perform sedation vacations? • (If not 10), what is a higher priority?
	Thinking about all the ventilated patients that come and go from your unit, are there ever times when a sedation vacation is not performed when you feel it should or could have been performed?
	Out of every 10 eligible mechanically ventilated patients you have cared for, how many to you think received a sedation vacation?
Domain 13: Behavioural regulation	What could you personally do to increase your sedation interruption practice? (Prompt: within your everyday practice) ask about personal adherence to local protocol.
	What do you think is needed in your work environment to ensure that you consistently perform sedation vacations?

Domain 14: Reinforcement	In the past, are there any personal or external incentives that you have experienced to be effective to improve the use of sedation vacations? (Prompt: for example, the documentation process, any anticipated outcomes, for example, knowing that you may be able to decrease the sedation infusion rate; other reasons that would benefit you directly?)
	Have your views toward sedation vacations evolved from your time in your orientation to the unit or any other specialty course up until now? • If so, how?

Interview Discussion Prompts for the Multidisciplinary Participants (Physicians, Respiratory Therapist, Pharmacist)

Research question 3: *What are the perceptions from various key informants of the multidisciplinary team in critical care of the factors that influence sedation vacation practices at* [redacted]

1. What do you consider to be the benefits and negative aspects of SV?

- Patients, families, yourself, documentation process, adverse events

2. Can you please tell me about the use of SV in your CCU?

- What guides your practice?
- In general, how is it performed?
    - Can you tell me about who performs it, when it is done and how it is done?
    - Is the sedation infusion turned off all together or slowly turned down?
    - What happens to any analgesic infusions during a sedation vacation?

3. What is your role related to SV?

4. I understand that the unit has a SV protocol, What is your impression of the adherence to the unit's protocol?

- Yourself, other professionals
- Out of every 10 eligible mechanically ventilated patients, how many do you think receive a sedation vacation on each day that they should receive one; how come?
    - What would it take to get it closer to 10?

5. When thinking about the multidisciplinary team, what factors inhibit daily sedation vacations?

- Can you think of factors that might promote it?
- Can you think of something that can be done to…*address the issue that is presented by the participant*?

6. Thinking about the multidisciplinary team in the CCU, what could be done to ensure SV are performed more consistently?

- local protocol

Research question 4: *What are the perceptions of various key informants of the factors that influence nursing practice at the point-of-care with respect to SI?*

7. From your perspective as a [discipline], what do you think may influence nurses' decisions to perform SV on a patient?

    - What influences nurses' decisions to not perform SV?

8. From your perspective, what do you think are other factors that inhibit or promote the use of SV by nurses in the CCU?

9. In your opinion, what makes it easier or harder for nurses to perform SV?

    - Other clinicians, patients, family, practice setting factors.

Appendix M: Participant Information Form for Study 3

Study Title: Understanding the Determinants of Adult Intensive Care Unit Nurses' Use of Daily Sedation Interruption for Mechanically Ventilated Patient. Protocol File Number: 2108 – 026.

Personal Information *Please select your age category*		**Education / training** *Please indicate the program that you received your education and training*
20 yrs. - 25 yrs.	❒	**Diploma (RN, RNP)** ❒
26 yrs. – 30 yrs.	❒	**University Bachelor (BScN)** ❒
31 yrs. – 35 yrs.	❒	**Other** ❒_____
36 yrs. – 40 yrs.	❒	**Following your initial training did you complete any other education program(s)?**
41 yrs. – 45 yrs.	❒	
46 yrs. – 50 yrs.	❒	**No** ❒ **Yes**❒ **If yes please indicate the type:**
51 yrs. – 55 yrs.	❒	**Baccalaureate** ❒
More then 56 yrs.	❒	**Post RN program** ❒
		Please specify_____
		Master's in nursing ❒
		Other ❒
		Please specify_____

Work Experience *Please indicate how many years of experience you have in your field of study*		**What is your position?**	
↗2 years	❒	**Registered Nurse**	❒
2-5 years	❒	**Registered Practical Nurse**	❒
6-10 years	❒	**Team/Clinical Leader**	❒
11-15 years	❒	**Educator/APN**	❒

16-20 years	❒	**Program Manager**	❒
Over 20 years	❒	**Other (specify)_____**	

Appendix N: Identification of relevant theoretical domains and illustrative quotes from participants

Chapter 4 Study 3 Supplemental File 1

Identification of relevant theoretical domains and illustrative quotes from participants

	Criteria (Michie et al., 2005)				
	1		**2**	**3**	
	Relative frequency of responses by participant group		**Presence of conflicting beliefs**	**Evidence of strong beliefs that may affect the target behaviour**	
# Theoretical Domains Framework Merged Beliefs Statements (barrier or facilitator - overarching theme)	***Nurse*** **N=8**	***Physician and allied health*** **N=4**			**Illustrative quotes from participants**
1. Social Influence					
Decisions about sedation and sedation vacations need to be team driven. (B – env. and contextual factors)	6	2	✓	✓	The physician support level I feel from them is important, so if I don't feel like a physician's going to support my assessment if I vacation them, I would be less reluctant to do it. (nurse)
Physicians can influence the use of sedation and sedation vacations positively or negatively, depending on their point-of-view. (B – env. and contextual factors)	5	1			I'm very much on the extreme advocacy side, I don't think the rest of my colleagues are. (allied health) I would say it is shared, depending on who the physician is. They are not always too eager to encourage nursing to use a sedation vacation…there is a wide variation, some are very involved with it and some others are just not at all. (nurse)

Family members do not influence decisions to use SI. (B - env. and contextual factors)	3	1			Most of the time in conjunction with the physician not with the family. (nurse)
Nursing colleagues influence use of SI. (F – nurses' attitudes and intentions towards SI)	3	2			Depends on the staff working. There are some staff that will directly ask; "have you vacationed your patients? How did they do? You should turn the sedation off. Hey, you should vacation, make sure you don't forget to vacation them".
Families can influence use of SI. (B - env. and contextual factors)	2	1			I feel like in general, patients with active families probably get more attention and are more likely to get a station vacation. (allied health)
Nursing colleagues do not influence my use of SI. (B- env. and contextual factors)	1	0			Whether or not we did a sedation vacation or not or attempted it, yeah there are some that enquire about it. But it is always something that I cover anyways even if it is not brought up. (nurse)
Some nurses do not perform SI when family present. (B - env. and contextual factors)	1	0			Family is a big one. I wouldn't want to do it when the family is there. (nurse)
Clinicians need to be more accountable for the cumulative impact of sedation. (B – env. and contextual factors)	0	1			Accumulation is somebody else's problem. And that's often actually, unfortunately, that's a human nature problem with the ICU. As a rule. I mean every team member goes it's somebody else's problem. (allied health)
2. Environmental context and resources					
The nurse-to-patient ratio and workload influences SI use. (B – env. and contextual factors)	7	3			Adequate staffing. If you have less staff, you might have to forgo a sedation vacation because its just unsafe. So, I think adequate staffing wherever you go. (nurse)
SI are best performed in the morning, at a set time, when all the staff are available to help if needed. (B – env. and contextual factors)	4	1	✓	✓	But the morning is the optimal time because they have had a full rest and then you just go from there. (nurse)

Support and access to the anaesthesiologist would make SI easier for nurses. (B- env. and contextual factors)	3	1			Maybe if there was a little more support from the physician. I mean, that's their area. If the physicians were around a little bit more, but of course as you know in our unit, they're not dedicated to us and they're in the OR all of the time. (nurse)
Including mechanically vented pts in multidisciplinary rounds would support SI discussions. (B – env. and contextual factors)	1	3			As for as an actual good vent rounds, there's not a great vent round. We have the anaesthesiologist just popping in whenever they feel like it, sometimes before cases, sometimes between cases. (nurse)
More human resources are needed to optimize the use of sedation vacations, for example a sedation champion and extra staff. (B – env. and contextual factors)	2	1			The time and do it and keep the patient safe and that sort of thing. A lot of it does have to do with that, and maybe having more one to one support, if a sedation vacation is happening, maybe having a staff member that's maybe designated to watch the patient or something like that because it's really tough. (nurse)
Biases among ICU clinicians, impact pt outcomes i.e. the perceived ease of sedation. (B – nurses' attitudes and intentions towards SI)	0	1			That is probably the principal impediment to me for sedation vacation. It's the ease of sedating. (allied health)
Sedating during COVID-19 caused regression in progress towards use of sedation vacations. (B - nurses' attitudes and intentions towards SI)	0	1			Well, there's been a lot of progress in the last decade. We went through COVID where sedation was just a necessary part of so many people's cares. So that's kind of the eroded back to the world of let's just sedate like crazy. (allied health)
3. Beliefs about consequences					
Nurses consider the safety of performing a SI and some experience anxiety about the risks. For example, the risk of self-extubation, increased ICP or patient and clinician well-being related to agitation and	8	1	✓	✓	Once I've kind of evaluated my patient, if it's kind of safe to do so, like they're not, you know intubated for their airway or whatever reason they can. You know, I feel like they're lungs can handle if they can handle it. (nurse) (concerns about performing SI)

aggression. (B - concerns about performing SI)					
Knowing either the consequences of not doing SI and/or, the benefits of doing SI motivate nurses to use the intervention. (F - nurses' attitudes and intentions towards SI)	6	1			You might miss that window to get them off life-support and it could also lead to possibly their demise if you don't. (nurse)
The contraindications for SI are not clear and the rationales for not performing SI are highly varied across nurses and physicians. (B – nurses' knowledge and skill to perform SI)	6	2			Patients that are delirious already, they that aren't really able to follow commands, that sort of thing. (nurse)
The benefit of sedating a mechanically ventilated patient is overestimated and even unproven; it predisposes to an unanchored state-of-mind that comes across as delirium making it harder for the brain to recover. (B – nurses' knowledge and skill to perform SI)	0	1			I think that the effect of sedation, the subjective effects of sedation on patients are sometimes overestimated or even largely unproven, so there's a feeling that, you know that people need to be asleep through their critical illness, essentially. And the less they remember it the better. That's kind of been the bias towards sedation. (allied health)
The beneficious use of sedation for the relief of potential discomfort experienced during a critical illness is a biased perspective clinicians hold. (B – nurses' knowledge and skill to perform SI)	0	1			OK, sedation can be harmful in recovery and no sedation may be not as people think. (allied health)

The benefits of sedation vacations are not always obvious to nurses because the initial work can be challenging. (B - env. and contextual factors)	0	1			So initially there is a lot of cost to the nurse for sedation vacation and there seems to be very little benefit, literally practical downside and for their day their workload, everything goes ugly when they do a sedation vacation. It seems semi pointless. (allied health)
There is a perception out there that sedation vacations are only necessary when a patient is being extubated. (B - nurses' attitudes and intentions towards SI)	0	1			There's a perception out there that sedation vacation is only necessary when you're extubating. (allied health)
Post COVID-19 patients experienced ICU psychosis, illuminating the need for post delirium treatment plans. (B - nurses' knowledge and skill to perform SI)	0	1			The post COVID world will be full of people who recovered, and they couldn't do sedation vacations because they were on ventilators had difficulty being ventilated. We had some people in deep sedation for a long time. This would be an interesting study because many of them had ICU psychosis. (allied health)
4. Skills					
Standardized SI training is needed for nurses. (B - nurses' knowledge and skill to perform SI)	7	0			We need to have more guidance and, like maybe even more focus in our orientation. (Nurse)
Nurses learn about SI through informal peer to peer training/mentorship implemented during orientation (B - nurses' knowledge and skill to perform SI)	5	0	✓	✓	In my mentorship to CCU, my lovely mentor did discuss with me that any ventilated patient needs to have a sedation vacation early in the morning between 7:00 to 8:00.
Nurses must conduct multiple system assessments during SI (i.e., mentation, cognition, musculoskeletal, neurological, vital signs. (F - nurses'	5	0			It's just like a constant evaluation of the patient and how they're handling it, so. Are they starting to wake up? Are there vital signs spiking that kind of thing? Are they tolerating it with their lung capacities and whatnot, meaning like their settings on their ventilator. Umm, are

knowledge and skill to perform SI)					they still getting volumes? Are they still, you know, tolerating that? (nurse)
Nurses turn off all sedative and analgesic medication(s). (B - nurses' use of SI)	4	0			So, I would pause all of my infusions, Fentanyl, Propofol, Versed, anything that has a sedative effect. (Nurse)
Nurses will turn down the longest acting medication first, or only wean down the sedative medication(s). (B - nurses' use of SI)	4	0			OK in the mornings, turn your sedation down or off. For me, it's sort of depends on the patient. (Nurse)
Nurses will assess and monitor patients during the complex and lengthy steps of a SI. (B - env. and contextual factors)	4	0			The whole process probably takes anywhere from half an hour could be like 2 hours. You're in the room with them nearby while they're awake and appropriate, and they have, but they have the restraints on still. And then work from there and start de-restraining the patient. (nurse)
Initial SI education is done through peer-to-peer training and then through independent study. (B - nurses' knowledge and skill to perform SI)	2	0			I received my training from my clinician and then after that, my own training, like my own studies with my Critical Care certificate and conferences and stuff. P7RN
Nurses need to be taught targeted sedation approaches and agents that optimize the patients' ability to recover. (B - nurses' knowledge and skill to perform SI)	0	1			I just don't know why people at night especially don't just use sedation in an intermittent fashion, and even during the day. That's my standard approach. And extend the sedation vacation by just largely you know, instead of just turning your back on. Turn it on for an hour then turn it off again and see what happens. Because sometimes people in the delirious state, they get very agitated as they're coming out of the sedation vacation. But you have to control their agitation and distress. But once it's time to come out of it, the less sedation you are on then you're actually better off.
5. Goals					

The goal of SI is to assess the patient's status, move toward extubation and decrease negative outcomes. (F - nurses' knowledge and skill to perform SI)	6	1			We have to wake these people up to make sure that they're their brain is OK and just so that we can get them off. (nurse)
We aim for the least amount of sedation as possible. (F - nurses' knowledge and skill to perform SI)	2	0			They have much shorter intubation periods, and much less complications and less delirium. I definitely see the importance of it, and I always try to keep the least amount of sedation as possible. (nurse)
The goal of sedation vacation is to get the patient's brain as close to a pure state as possible and this should be a priority of care for the critically ill patient. (F - nurses' knowledge and skill to perform SI)	1	1	✓	✓	The value of a sedation vacation to me is to get the brain as close to pure state as possible to see whether they're delirious or not, and if they're not then you've made substantial progress in their care. (allied health)
The challenges associated with SI can be demotivating for nurses. (B - nurses' attitudes and intentions towards SI)	0	1			Why am I doing this, they're going to be back on a massive dose of Propofol IV? So there's no real desire to put yourself through this. (allied health)
Educating nurses about targeted sedation is, unfortunately, not a priority in our ICU. (B - nurses' knowledge and skill to perform SI)	0	1			There's a targeted sedation approach teaching that I think would be very helpful in our ICU and it's of the many things that need to be taught to the nurses. I don't think that has been the priority. That's the issue. (allied health)
The long-term goals of sedation vacations are not typically considered. (B - nurses' knowledge and skill to perform SI)	1	0			I have never looked at it as the long-term solution to anything. Sedation vacations, I never thought of it as a long-term assessment for whether they could walk or whether they could be extubated sooner or later. (nurse)
6. Knowledge					

Nurses and allied health professionals are not aware of the existence the local protocol for SI. (B - nurses' awareness of SI)	6	2			There's probably a protocol on there. But honestly, I couldn't tell you what it says. We certainly don't push it. (Nurse)
Standardization of education about the importance of SI and a protocol on how to perform it is needed for nurses and allied health professionals during their orientation or mentorship to CCU with booster sessions. (B - nurses' knowledge and skill to perform SI)	5	3			There's not really a lot of education or training about that when you come in here, or when you start. It was the first time that I had ever heard of it was. Even after doing my critical care course and I came in here, they were like "so how do you want to do it?". And I was like "what is that I don't know anything about it". (Nurse)
Nurses use their judgment to decide when a SI should be used or not. (B - nurses' knowledge and skill to perform SI)	4	1	✓	✓	I don't think we have clear inclusion, exclusion criteria for performing the intervention. (Nurse)
Nurses are aware of the local protocol for SI and know where to access it. (F - nurses' awareness of SI)	2	0			I believe there is a policy like a protocol attached to the, like intervention on our, Meditech there's an intervention and there's a little 'P' You click on it. It kind of tells you the RASS score and to follow the RASS score and sort of thing. (Nurse)
Nurses are not aware of guidelines with recommendations related to SI. (B - nurses awareness of SI)	3	0			Are you aware of any provincial, national, or international recommendations about sedation vacations? No. (nurse)
Nurses are aware of the existence of national recommendations for SI and believe that the intervention is based on evidence. (F - nurses' awareness of SI)	3	0			As personal desire, when I started my ICU career, I tried to look into that and, if I remember correctly, it's been a long time, I remember that the first ever recommendation was in 2000. I sent this paper around, and I believe one of them is, let's say, well that this is the

					main reason now it's a nationwide practice to do sedation vacations. (nurse)
Clinician knowledge deficits about the impact of sedation on recovery need to be addressed to improve the use of sedation vacations. (B – nurses' knowledge and skill to perform)	0	1			There's a targeted sedation approach teaching that I think would be very helpful in our ICU and it's of the many things that need to be taught to the nurses. I don't think that has been the priority. That's the issue. (allied health)
Sedation vacations are necessary to properly monitor for delirium and the benefits of this intervention significantly out way the risks. (F - nurses' attitudes and intentions towards SI)	0	1			It's been well shown to me that delirium is definitely bad and so we should be monitoring to try to treat it. And you can't monitor it if you keep them on sedation. P12MD
Protocols alone are not sufficient to guide sedation vacation practice. (F - perceptions of SI (guideline))	0	1			The protocols have to recognize that there is a certain amount of decision to be made in the morning, what is the gain the value? (allied health)
7. Reinforcement					
A patient's known history of agitation or aggression has a negatively influences on SI use. (B - concerns about performing SI)	2	1			It's the nurses feeling that they would be in danger if the patient was to wake up because they have a very aggressive history and they be at risk to themselves of self extubating as well. (nurse)
Multidisciplinary collaboration is needed and would positively influence the use of SI. (B – env. and contextual factors)	2	2		✓	Really having a more formal rounding would help. In the morning. You know what their goals for the day across the board would be nice. (allied health)
Experience performing SI reinforces its importance. (F – nurses' attitudes and intentions towards SI)	2	0			I knew it was important, but I think its even more so with time you gain the knowledge, skill, expertise or what's best, and what's best practice so I think I just have more of understanding of it. (nurse)

Case reviews and rounds by physicians would enhance clinician knowledge of impact of sedation vacations. (B – nurses' knowledge and skill to perform SI)	2	1			And reviewing the cases because some cases are complicated. Those used to be the most valuable thing for nurses to me. Just go over the patients that everybody has treated at least once. (allied health)
The critical care unit needs champions to promote protocol implementation and re-educate regarding misconceptions about sedation vacations. (B - env. and contextual factors)	0	1			I think in the nursing world you need a few champions in the unit that largely say the same thing. You need champions largely who largely talk to nurse just around and other colleagues around how they approach it. (allied health)
Publishing patient experiences will reaffirm benefits of sedation vacations and reinforce its use. (F - nurses' attitudes and intentions towards SI)	0	1			The narrative approach might be helpful to people like publishing narrative accounts of people who have had to have sedation vacations. (allied health)
8. Social professional role and identity					
It is the nurse's role to make important decisions about SI, including: the appropriateness of a SI and providing a rationale for when it is not done, the start time and how long it should last. (F - nurses' role in SI)	8	3	✓		The nurses' bias dictates everything…because you are the person who has to actually interact with this patient. (allied health)
Nurses and allied health professionals know that SI is specific to the nurse role and is an expected skill of a critical care nurse. (F - nurses' knowledge and skill to perform SI)	7	4			It needs to be done; it has to be done, is pretty much my just of things. If you are an ICU nurse sedation vacations need to happen, and that's ICU. (Nurse)

SI is performed differently among nurses in this unit. (B – nurses' use of SI)	6	0			I think when you first started that consistency in your sedation vacation across the board, if you ask for help, if you ask three different nurses for help, you'll get three different answers, likely. (Nurse)
The nurse and the RT work collaboratively together to assess the patient's readiness for extubation and the plan for the day. (B – env. and contextual factors)	2	2			We chat with the RTs about what our plans are for the day. (nurse)
Comfort with SI influences its use. (F – nurses' attitudes and intentions towards SI)	2	0			Staff members that maybe aren't as comfortable turning off sedation, or even just being able to wean. (nurse)
Some nurses believe SI is a shared responsibility between nurses and physicians. (B – env. and contextual factors)	1	0			I would say it is shared, depending on who the physician is. (nurse)
There is a misconception among nurses that mechanically ventilated patients who are delirious require more sedation. (B – nurses' attitudes and intentions towards SI)	0	1			But we don't do it great for the brain. So, people do the Cam-ICU score and it's terrible, the person is obviously delirious. But what do you do with that? I think a lot of people think we got to give more sedation, which is the last thing you need to do. (allied health)
Often, nurses will terminate a sedation vacation prematurely or decide not to perform one at all because of concerns about adverse events and or patient safety. (B – concerns about performing SI)	0	1			And I think that there's a really quick bailout that happens very fast on nurses. (allied health) (concerns about performing SI)
Clinicians need to be accountable for the bioaccumulation of sedative	0	1			Unfortunately, that's a human nature problem with the ICU. As a rule, I mean every team member goes it's somebody else's problem.

medications on the brain. (B – env. and contextual factors)					
9. Beliefs about capabilities					
There are multiple patient factors that influence the use of SI. For example, the admitting diagnosis or the reason for mechanical ventilation, acuity, past medical history, treatments, and the patient's disposition. (B-env. and contextual factors)	4	0			And when it comes to the patient factors, I think the past medical history is plays a very important role in deciding how easy or not easy doing the sedation vacation. (nurse)
Nurses believe SI are managed best with 1:1 nursing care and experience increases a nurse's capability of performing SI. (B - env. and contextual factors)	4	0			Yes, sedation vacations require one-to-one nursing care. (nurse) I think it there's a difficult skill to learn because there's so many factors and variables you have to consider when performing your sedation vacation. (nurse)
I try to follow the best guidelines. (F – nurses' awareness of SI)	2	0	✓		I feel like I certainly try to follow the best guidelines. (nurse)
I experience anxiety, uncertainty, and concerns about personal safety when performing a SI. (B – concerns about performing SI)	1	0			It's a lot of work. Yeah, yeah, there's a lot of anxiety for me. It's it provokes a lot of anxiety, personally. (nurse) (concerns about performing SI)
The presence of another person makes performing SI easier for the nurse (i.e., either an allied health care professional (RT) or a familiar face of a family member). (B – env. and contextual factors)	1	0			Yeah, I guess having an RT is always a plus in the room. And another staff member around just in case there is the agitation. (nurse)
The biggest barrier to sedation vacations is the ease of care that	0	1			There's an ease of care around sedating. That is probably the principal impediment to me for sedation vacation. It's

comes with sedating a patient; the belief that it is easier to keep a patient sedated in the busy ICU environment. (B – nurses' attitudes and intentions towards SI)					the ease of sedating. The patient looks better, everything, vital signs are better, it's way easier to care for your patient. You go from a very difficult busy shift to a very easy shift just by sedating. (allied health)
There is a false belief that mechanically ventilated patients require sedation. (B – nurses' attitudes and intentions towards SI)	0	1			There is a feeling still pervasive in our ICU, probably all ICUs, with patients not progressing any way on the ventilator, whole bunch of lines stuck in them, you know, maybe has a few bed sores or not, a fracture here, there, not, recovering from surgery. Whatever the pain issues that person, because they're just lying there, not moving is better sedated than not, this is the bias. It's better to have something going in those patients because surely, they must be uncomfortable. (allied health)
Delirium and sedation vacations can be managed easier when we have the time to talk people through it and involve them in their care. (B - env. and contextual factors)	0	1			And it's not all about pharmacology. A lot of it is nonpharmacological. You have to talk people through it, keep people active and getting them engaged in their care.
10. Memory, attention, and decision processes					
For every approximate 10 eligible patients, SI occurs anywhere from 50% to 100% of the time that it should occur. (F – nurses' use of SI)	8	2			I would say for respiratory related intubated patients I would say maybe 80 to 85% of the time we do sedation vacation. (nurse)
The standard order set for adult mechanically ventilated patients is a reminder to perform SI. (F – perceptions of SI (guideline))	5	0	✓		With the E[MR] platform, there is no way you can't remember because it's right there in front of you. If you don't do it, it will keep showing up and it will keep reminding you that you need to do it. (nurse)
There is an important decision-making process that needs to	0	1			If you're going to sedate them…appreciate that the brain is going to have to recover from whatever you give it.

occur about the type of sedation that is used, keeping in mind that the patient will need to recover from what is given to them. (B – env. and contextual factors)					Let's just appreciate that and use the necessary things to get the brain back. And that can be part of our care plan. I don't even know whether you need a protocol but just the awareness of how the agents work, which ones are not as delirium provoking and then how you manage it. (allied health)
11. Behaviour Regulation					
Advocating for a daily discussion about SI with the anaesthesiologist would positively influence use of this intervention. (B - env. and contextual factors)	3	2			Sometimes, maybe organizing my day better would be a little bit, might obviously of course always help. Maybe advocating a little bit more for physician interaction. Maybe discussions in the morning like so I could certainly advocate a little bit better for that. (nurse)
Having a standard time for SI when all staff are available to help during a SI would help address some safety concerns about this intervention. (B - env. and contextual factors)	3	0			If we had a time during the day like, you know, in my opinion, like at 10:00 AM like everybody gets on in their day. (nurse)
Modifications to the existing SI protocol are needed to ensure consistency in use and gaps in knowledge. (F – perceptions of SI (guideline))	3	0			The other thing that I think would help a lot is to have some sort of clear protocol about the indication versus contraindication of performing sedation vacation, and widely available. Again, making an appropriate protocol for nurses who are looking after intubation patients, is a very important part. (nurse)
Education about targeted sedation would improve SI use. (B - nurses' knowledge and skill to perform SI)	0	1			There's a targeted sedation approach teaching that I think would be very helpful in our ICU and it's of the many things that need to be taught to the nurses. (allied health)
Physician led case review. (B – nurses' knowledge and skill to perform SI)	0	1			There should be a 30-minute round around each week by the internist and even by anesthesia, if necessary, where the nurses take a topic and the physician can talk about it. (allied health)

12. Emotion					
My feelings toward sedation vacations motivate me to be a strong advocate. (F – nurses' attitudes and intentions towards SI)	1	1			I think it's both, but its really something I have always done. I really feel like I am going against the grain when I don't. (nurse)
13. Optimism					
SI are easier to perform under certain conditions. (B - env. and contextual factors)	2	1			Those two situations are likely to result in a unplanned exhibition for the most part, they're quite controlled if the nurse is close by and paying attention and the patient is properly restrained. (nurse)
Nurses are not always excited to perform a SI. (B - nurses' attitudes and intentions towards SI)	1	0			I'm not always excited to do it. I don't know that any nurses are but. (nurse)
14. Intentions					
Sedation is turned back on when the patient is not being extubated. (B - nurses' use of SI)	1	1			For me, I want to do it when the anesthesiologist…depending on what the goal is. If the goal is extubation, I would have to wait till the anesthesiologist is there to assess them themselves and they're readiness. (nurse)

HCP – allied health care provider; B – barrier; F – facilitator; env. and contextual factors – Environmental and contextual factors influencing use of SI by nurses.

Appendix O: Consolidated Criteria for Reporting Qualitative Research (COREQ) Checklist

Additional File Chapter 4 Study 3

Table 1. Consolidated criteria for reporting qualitative research (COREQ) checklist.

No.	Item	Applicability to this study	Location in thesis
	Domain 1: Research team and reflexivity		
	Personal Characteristics		
1.	Interviewer/facilitator	NDG	Authors, Methods
2.	Credentials	• Nicole D. GRAHAM, RN, BScN • Ian D. GRAHAM, PhD • Brandi VANDERSPANK-WRIGHT, RN, PhD • Letitia NADALIN PENNO, RN, PhD • Dean A. FERGUSSON, PhD • Janet E. SQUIRES, RN, PhD	Authors, affiliations
3.	Occupation	Corresponding author: PhD student, Registered Nurse, Professor	-
4.	Gender	Female	-
5.	Experience and training	The current study was conducted in partial completion of a Doctorate in Philosophy Nursing at the University of Ottawa, Faculty of Health Sciences, School of Nursing	Declarations
	Relationship with participants		
6.	Relationship established	The corresponding author previously worked in the same unit that the participants were sampled from. She did not have a current working relationship with any of the participants.	Declarations
7.	Participant knowledge of the interviewer	Respondents were briefed on the purpose of the study and understood that it was the graduation study for NDG.	-

No.	Item	Applicability to this study	Location in thesis
8.	Interviewer characteristics		
	Domain 2: Study design		
	Theoretical framework		
9.	Methodological orientation and Theory	Theoretical Domains Framework and the Ottawa Model for Research Use. Analysis was conducted using content analysis (Hsieh & Shannon, 2005).	Method – Analysis
	Participation selection		
10.	Sampling	Theoretical sampling.	Method – design, recruitment, and participants
11.	Method of approach	The CCU's clinical nurse educator and unit manager, information about the study was distributed to all those working in the CCU through the intra-department email list. The Principal Investigator conducted four brief presentations to the CCU staff during unit specific huddles. Each participant was emailed a $20 electronic-gift-card in appreciation for participating.	Method – recruitment and participants
12.	Sample size	Thirteen.	Results
13.	Non-participation	Not applicable.	-
	Setting		
14.	Setting of data collection	Interviews were conducted by one researcher (NDG) either in person, by telephone or via a videoconferencing software, between May 2022 and January 2023.	Method – Data collection
15.	Presence of non-participants	None	-

No.	Item	Applicability to this study	Location in thesis
16.	Description of sample	77% were women. Six out of 13 responded to the participant information survey; ages ranged from less than 30 to over 50 years of age and practice experience ranged from 6 to over 20 years.	Results
	Data collection		
17.	Interview guide	The development of the interview guide for the nurse participants was informed by the theoretical domains framework (TDF) (Michie et al., 2005) which contains 14 theoretical domains grounded in psychological theory (Table 1). Interview guides are available upon request from the corresponding author.	Method – interview guide
18.	Repeat interviews	None	-
19.	Audio/visual recording	The interviews were digitally audio recorded, transcribed using an automated transcription software and manually de-identified prior to analysis.	Method – Data collection
20.	Field notes	Field notes were included in memos after, not during, conducting the interview.	Method – data collection
21.	Duration	The interviews ranged in duration from 13 minutes to 1-hour and 7-minutes, with a mean interview time of 23-minutes.	Results
22.	Data saturation	Theoretical saturation was sought and reached for the nursing sample when the participants revealed no new information, but not from the physician and allied health sample as they were not the primary target of the study.	Method – identifying relevant theoretical domains
23.	Transcripts returned	We decided not to conduct member checks out of respect for their expressed and implied lack of availability for the study, otherwise would have strengthened trustworthiness of the results.	Strengths and Limitations
	Domain 3: Analysis and findings		
	Data analysis		

No.	Item	Applicability to this study	Location in thesis
24.	Number of data coders	NDG and LNP coded all interviews.	Method - coding
25.	Description of the coding tree	Initially, two researchers (NDG, LNP) worked independently to create the codebook (comprised of codes (TDF domains) description of the code, and examples of the coded text that fall under each code) by deductively coding two transcripts into the TDF domains. Responses that were coded in different domains by the researchers were discussed to establish consensus. The two researchers then went on to code each transcript deductively using the codebook, where specific sections of text were categorized into one or more of the TDF domains. In instances where single domain allocation agreement could not be reached, the researchers agreed that the response could be placed in both domains. Consensus between the two researchers was reached for each segment of coded text after coding the remaining transcripts.	Method - coding
26.	Derivation of themes	Merged belief statements were created by clustering individual belief statements with a common meaning by examining all beliefs statements from the entire sample of participants. A frequency count of the number of participants who mentioned the belief was calculated for each merged statement from the nursing sample and separately for the physician and allied health sample; each participant was counted only once within a particular theme. Overarching themes were then generated by further synthesis of the merged belief statements by clustering statements with a similar underlying theme. The overarching themes' sub-themes represent the determinants (barriers and facilitators) which are perceived to influence performance of the target behaviour (Atkins et al., 2017). One researcher (NDG) generated the overarching themes, while the other researcher (LNP) interrogated and confirmed those.	Method - Generation of merged belief statements and overarching themes.
27.	Software	NVivo 12.	Method - analysis

No.	Item	Applicability to this study	Location in thesis
28.	Participant checking	We decided not to conduct member checks out of respect for their expressed and implied lack of availability for the study, otherwise would have strengthened trustworthiness of the results.	Strengths and Limitations
	Reporting		
29.	Quotations presented	Yes.	Results, Table 2, and Additional File
30.	Data and findings consistent	Yes	Results, Table 2, and Additional File
31.	Clarity of major themes	Six overarching themes included sub-themes of facilitators (n = 9) and, six overarching themes consist of barriers (n = 20) to SI use.	Results – relevant domains
32.	Clarity of minor themes	Table 2 displays the overarching themes and sub-themes of facilitators of SI use by nurses. The OMRU element with corresponding sub-themes and the number of factors identified were: 1) the innovation; perceptions of SI (n=1) and 2) the potential adopters; nurses' awareness of SI (n=1), nurses' knowledge and skill to perform SI (n=2), nurses' attitudes and intentions towards SI (n=2), nurses' role in SI (n=2), nurses' use of SI (n=1). Table 3 displays the overarching themes and sub-themes of barriers to SI use by nurses. Barriers were identified within two key elements from the OMRU: the potential adopters; nurses' awareness of SI (n=1), nurses' knowledge and skill to perform SI (n=6), nurses' attitudes and intentions towards SI (n=4), nurses' use of SI (n=1), concerns about performing SI (n=1) and, the practice environment; environment and contextual factors influencing use of SI by nurses (n=7).	Results, Facilitators to SI use by nurses, Barriers to SI use by nurses, Discussion – Future implications

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care. 2007. Volume 19, Number 6: pp. 349 – 357

Appendix P: Sample size for a descriptive study of a dichotomous variable.

This is the estimated sample size required for the retrospective chart audit in Study 2.

95% confidence interval

Width of Confidence Interval	**0.10**	**0.15**	**0.20**	**0.25**	**0.30**
Expected Proportion (P)					
0.10	139				
0.15	196	88			
0.20	246	110	62		
0.25	289	128	73	47	
0.30	323	144	81	52	36
0.40	369	164	93	60	41
0.50	384	171	96	62	43

Note. Table from Patient Safety-Quality Improvement. (2016). Determining a Statistically Valid Sample Size. Duke University, School of Medicine. The estimated proportion of patients not receiving sedation interruption is estimated = 27.8%. With a width of confidence interval set at 0.20 and a confidence level of 95%, the sample needed is 81 charts.

The benchmark for the estimated proportion of patients not receiving sedation interruption was from "Adherence with daily interruption was 72.2% of all eligible study days for an average patient and 85.6% for all eligible patient-days. Fifty-three percent of patients missed at least 1 daily interruption, and 6 patients missed every scheduled interruption" (Mehta et al., 2012, p.6).

Reference

Mehta S, Burry L, Cook D, et al. Daily Sedation Interruption in Mechanically Ventilated Critically Ill Patients Cared for With a Sedation Protocol: A Randomized Controlled Trial. JAMA. 2012;308(19):1985–1992. doi:10.1001/jama.2012.13872.