

Research Protocol

Implementation and Evaluation of the Eat, Sleep, Console Model of Care for Babies Diagnosed with Neonatal Abstinence Syndrome: A Scoping Review Protocol

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Abstract

Introduction: Infants diagnosed with neonatal abstinence syndrome (NAS) or neonatal opioid withdrawal syndrome (NOWS) constitute a growing population in Canada. In most facilities, an outdated model of care is used to guide the care and assessment of babies diagnosed with NAS. Challenges with this outdated model have prompted the transition to a novel approach to care, the Eat, Sleep, Console model. Despite this promising intervention to improve patient and health system outcomes, little is known on how to effectively implement and evaluate the model in clinical practice. **Objectives:** We will conduct a scoping review to address the question, "How has the Eat, Sleep, Console model been implemented and evaluated in practice?". Methods: We will follow the JBI methodology for scoping reviews and Arksey and O'Malley's scoping review framework. Reporting will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR). Published and unpublished literature will be included in the review. The following databases and grey literature will be searched: MEDLINE, Embase, CINAHL, PsycInfo, Google Scholar, and websites identified in a Google website search. Two independent reviewers will screen literature and extract data based on predetermined eligibility criteria and data extraction tools. We will narratively describe quantitative data, along with completing an inductive thematic analysis of qualitative findings. Furthermore, we will conduct a directed content analysis of qualitative findings using the COM-B model of behaviour and RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework. We anticipate findings will be used to support future implementation of the Eat, Sleep, Console model into clinical practice, including subsequent evaluation of implementation.

Keywords: Nursing models; Neonatal nursing; Knowledge; Systematic Review; Evaluation; Implementation; Health research



Introduction

Rates of neonatal abstinence syndrome (NAS) or neonatal opioid withdrawal syndrome (NOWS) are growing in Canada (Lacaze-Masmonteil & O'Flaherty, 2018). The incidence of NAS in Canada has nearly tripled from 2003 to 2014, with incidence rates rising from 1.8 to 5.4 per 1000 live births (Filteau et al., 2018). NAS is an umbrella term encompassing all infants experiencing signs of withdrawal to noxious substances, such as illicit or prescription drugs exposed to them in utero. NOWS is a more specific and inclusive term for infants experiencing withdrawal specific to opioid exposure in utero (Jansson & Patrick, 2019). This syndrome is diagnosed through characterized signs of withdrawal experienced by infants following birth. These signs, including irritability, poor feeding, hypertonia, and tremors, are highly dependent on many interrelated factors such as maternal substance use, exposure length, and gestational age (Anbalagan & Mendez, 2021; Dodds et al., 2019; Lacaze-Masmonteil & O'Flaherty, 2018). The care for this population goes beyond caring for an individual patient, as mothers/pregnant persons with substance use disorder are an integral part of the infant's care. Mothers/pregnant persons with substance use disorder have complex health care needs, and continue to face stigma and discrimination in health care services (Stone. 2015). Mothers/pregnant persons with substance use disorder often avoid prenatal care for fear of punishment and discrimination (Stone, 2015), and therefore the exponential growth of the NAS population has a potential of being even greater than demonstrated in recent studies.

exponential growth The of this population in the last 10 years (Gomez-Pomar & Finnegan, 2018; Lacaze-Masmonteil & O'Flaherty, 2018) has contributed to increased challenges within the already taxed health care system. Challenges include increased lengths of hospital stay and increased use of pharmacological management in treatment for infants diagnosed with NAS (Anbalagan & Mendez, 2021; Filteau et al., 2018; Wachman et al., 2018). Canada has demonstrated a startling increase in health care costs for infants diagnosed with NAS, with numbers nearly doubling between 2010 and 2014; total health care associated costs rose from \$15.7 to \$26.9 million (Filteau et al., 2018). Increased length of hospital stay is a primary reason for high trends in health care associated costs, with an average hospital stay of 15 days for infants diagnosed with NAS (Filteau et al., 2018; Winkelman et al., 2018).

Current clinical practice guidelines demonstrate a clear knowledge gap in bestavailable evidence in the literature for the care of infants with NAS and their families (Anbalagan & Mendez, 2021; Curran et al., 2020; Grossman, Osborn, & Berkwitt, 2017; Holmes et al., 2016; Schiff & Grossman, 2019; Singh & Davis, 2021). In most facilities, an outdated model of care, the Finnegan Neonatal Abstinence Scoring Tool (FNAST), is used to guide the care and assessment of babies diagnosed with NAS. Challenges with the FNAST have been cited in the literature, such as the subjectiveness, invasiveness, and length of the proposed assessment (Anbalagan & Mendez, 2021). Additionally, the lack of collaboration with families contributes to the stigma and discrimination traditionallv felt bv mothers/pregnant persons with substance use disorder (Cleveland & Bonugli, 2014).

The FNAST has contributed to increased hospital costs related to extended lengths of hospital stays and pharmacological treatment, and this has ultimately encouraged the transition to an evidence-based model of care titled the Eat, Sleep, Console (ESC) model (Grossman, Berkwitt, et al., 2017; Grossman et al., 2018). The ESC model of care is a novel approach designed to address the challenges present with the FNAST (Grossman, Osborn, & Berkwitt, 2017). This model of care was systematically developed through quality improvement studies and emphasizes a function-based evaluation, which has been shown to decrease the length of hospital stay and improve care of infants diagnosed with NAS (Grossman, Berkwitt, et al., 2017; Grossman, Osborn, & Berkwitt, 2017; Holmes et al., 2016).

Despite the existence of a promising



evidence-based intervention to improve patient and health system outcomes, large changes in health systems—like implementing the ESC model—are often not sustained in practice due to poor implementation and evaluation planning (Nyström et al., 2014). Research shows that evidence-based interventions are more likely to succeed when a theory-informed, systematic approach is used in the implementation and evaluation of interventions (Craig & Petticrew, 2013).

As of yet, there has been no systematic exploration into the implementation and evaluation methods used in integrating the ESC model into clinical practice. The effectiveness of an intervention, such as the ESC model, is heavilv dependent on the success of implementation strategies employed (Proctor et al., 2011). Further, systematic evaluations of interventions are shown to improve intervention outcomes (Limbani et al., 2019). As such, efforts are needed to understand how to systematically implement and evaluate the ESC model in health care practice, in order to improve the success of implementation and sustainability of the model. The purpose of this scoping review is to map and characterize the

evidence related to the implementation and evaluation of the ESC model in health care practice. Additional objectives include the following: (a) Identify barriers and facilitators to the implementation of the ESC model into practice within the capability, opportunity, and motivation-behaviour (COM-B) model (Michie et al., 2011) and theoretical domains framework (TDF; Cane et al., 2012); (b) identify reported outcome measures in these studies; and (c) identify evaluation methods of the ESC model in practice within the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework (Glasgow et al., 2019). See Table 1 for a list of operationalized terms and definitions to be used.

This review is part of the foundation for a multi-phased project to systematically complete a process evaluation of the ESC model in clinical practice. Findings from this scoping review will be used to guide subsequent phases of the process evaluation. Furthermore, findings will contribute to development of implementation and evaluation methods to be used in future clinical settings.

Table 1

Operationalized Terms and Definitions

Term	Definition
Eat, Sleep, Console (ESC) model of care	A novel care approach for infants diagnosed with neonatal abstinence syndrome, created by Grossman and colleagues in 2017 (Grossman et al., 2018). Studies also containing the following basic foundations of the ESC model will also be considered, as often the ESC model has been implemented as part of a multi-modal approach (Schiff & Grossman, 2019): non-pharmacological interventions, collaboration among care members, and preservation of the mother/birth-parent-infant dyad.
Evaluation method	Methods or techniques "used to determine the success of the implementation and to guide efforts to maintain or sustain implementation success." (Harrison & Graham, 2021, p. 275)
Implementation strategy	"methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice." (Proctor et al., 2013, p.2)
Neonatal abstinence syndrome (NAS)	Diagnosis for all infants experiencing symptoms of withdrawal from any noxious substance exposed to them in utero.

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Neonatal opioid withdrawal syndrome (NOWS) Outcome

Diagnosis specific and inclusive of all infants experiencing withdrawal specific to opioid exposure in utero. "a planned, a priori assessment described in the study methods that is used to determine a change in status as a result of interventions, can be measured or assessed as a component of the study, and is not something of futuristic benefit." (University of Waterloo, n.d.)

Methods

We will conduct a scoping review guided by the IBI scoping review methodology (Peters et al., 2015) and the Arksey and O'Malley scoping review framework (Arksey & O'Malley, 2005). The two review methodologies have been used for their complementarity. Arksey and (2005) provide O'Malley foundational knowledge in conducting a scoping review in consultation with key knowledge users. The five-step process outlined by Arksey and O'Malley is further substantiated with the rigorous scoping review methodology developed by JBI (Peters et al., 2015). For our reporting, we will use the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR; Tricco et al., 2018).

Stage 1: Identifying the Research Question

The aim of the scoping review is to map out and characterize the evidence related to the implementation and evaluation of the ESC model in health care practice. To achieve the outlined research objectives discussed above, we will address the following research questions:

1. How has the ESC model been implemented and evaluated in practice?

1.1 What strategies have been used to implement the ESC model of care into practice?

1.2 What are the reported barriers and facilitators to the implementation of the ESC model of care?

1.3 How is the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) evaluated in the implementation of the ESC model of care?

1.4 What are the reported measures and outcomes?

Stage 2: Identifying Relevant Studies

To ensure identification of relevant studies, we have outlined key inclusion criteria based on the mnemonic recommended by JBI for scoping reviews, including the categories of participant, concept, and context (Peters et al., 2020).

Participants

This review will consider all literature that includes implementation of the ESC model of care for infants diagnosed with NAS and/or NOWS. Infants involved in the implementation/evaluation of the model must have a primary diagnosis of NAS and be considered a term gestation (>37 weeks), as having additional comorbid conditions could potentially impact the outcomes of the implementation. For example, infants born prematurely before 37 weeks gestation could have potential complications influencing the implementation and evaluation outcomes of the ESC model of care. Literature involving implementation by all clinicians (e.g., nurse practitioners, physicians, registered nurses) will be considered. There will be no exclusion criteria based on gender or years of experience of the clinicians.

Concept

This review will consider all literature that includes the ESC model of care, an assessment tool created by Grossman and colleagues in 2017 (Grossman et al., 2018). Literature containing all three of the basic foundations of the ESC model will also be



considered, as often the ESC model has been implemented as part of a multi-modal approach (Schiff & Grossman, 2019). Basic elements of the ESC model of care are non-pharmacological interventions, collaboration among care members, and preservation of the mother/birth-parent-infant dyad.

This review will consider all studies reporting on the implementation of the ESC model of care into practice. For the purpose of this review, implementation strategies are defined as "methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice" (Proctor et al., 2013, p. 2). This review will also consider studies that have evaluated the ESC model of care in practice. For the purpose of this review, evaluation methods are defined as any method or technique "used to determine the success of the implementation and to guide efforts to maintain or sustain implementation success" (Harrison & Graham, 2021, p. 275).

Context

This study will review all literature that includes implementation and evaluation of the ESC model of care in all clinical settings where the mother/birth-parent-infant dyad is preserved. This includes settings where the mother/birth parent is not separated from the infant, such as postpartum maternity settings or neonatal intensive care units with couplet care. There are no exclusion criteria on geographical location of the studies. See Table 2 for the summary of eligibility criteria.

Table 2

Eligibility Criteria

Inclusion		Exclusion	
Population	Infants with primary diagnosis of NAS and/or NOWS who are being cared for with the ESC model of care.	Infants born before 37 weeks gestation and/or with additional comorbidities (e.g., congenital anomalies).	
Topic	Eat, Sleep, Console (ESC) model of care, a novel care approach developed by Grossman and colleagues in 2017. Variations of this model will also be included if basic elements are included: non- pharmacological interventions, collaboration among care members, and preservation of the mother/birth-parent-infant dyad.	Other care models for NAS/NOWS (e.g., Finnegan Neonatal Abstinence Scoring Tool).	
Setting	All clinical/hospital settings where the mother/birth-parent-infant dyad is preserved (e.g., postpartum floors, neonatal intensive care units with couplet care).	Clinical settings where infants with NAS are separated from their mother/birth parent.	
Source	Primary research papers (including in press papers), theses, preprints, opinion pieces.	Books, abstracts, commentaries.	
Type of Study	All study designs.	N/A	
Language	English	Non-English language	

Search Strategy

We collaborated with a health science librarian to develop a comprehensive search strategy, locating relevant scholarly literature. The aim of the search strategy will be to identify peer-reviewed published and unpublished primary studies and reviews. We identified a gap in literature of completed systematic reviews on



this topic; however, we will mine literature reviews identified in this search, including only the articles encompassed in the literature review identified. We will include only studies reported in English. Furthermore, we will not have date limiters, allowing for the exploration of trends in strategies over time. We will employ JBI's three-step search strategy methodology to ensure systematic development of the proposed strategy (Peters et al., 2020). In Step 1, we will develop and conduct a preliminary search in MEDLINE. This will enable us to analyze the text words used in the title and abstracts to further develop and redefine our full search strategy. In Step 2, after completing revisions and finalizing the proposed search strategy, S. M. Gallant will adapt the strategy in consultation with a librarian, M. Rothfus, including modifications for database-specific headings, search fields, and operators. Once the strategy is modified, S. M. Gallant will run the search in the selected databases for the review. As this is a student-led scoping review, searches will be led by the student in consultation with a librarian. This search strategy has been peer-reviewed by a second librarian through engagement with the Peer Review of Electronic Search Strategy guidelines (PRESS; McGowan et al., 2016). An example of the proposed search strategy run through MEDLINE (Ovid) is included in Appendix A. Step 3 will include two parts. First, we will complete ancestry searching, exploring the reference list of included sources to identify additional relevant articles. Next, we will use forward citation tracing to search for additional relevant articles that have cited the original identified sources in the search.

Grey Literature

To broaden the depth of the scoping review, we will complete a systematic grey literature search that includes the grey literature databases ProQuest Dissertations and Theses and Open Access Theses and Dissertations. Additionally, we will search grey literature resources identified in the Canadian Agency for Drugs and Technologies in Health checklist *Grey Matters: A Practical Tool for Searching Health-Related Grey Literature* (Canadian Agency for Drugs and Technology in Health, 2019), along with websites of research, academic, and health system organizations. We will ensure reference chaining is conducted with all included articles. We will include the following types of grey literature: white papers, reports, and clinical practice guidelines.

Google Search. Finally, we will engage in Godin's targeted Google search methodology to search for grey literature (Godin et al., 2015). Godin's methodology involves engagement in two distinct steps. First, we will conduct 10 unique Google searches with designated keywords reflective of inclusion criteria. Following this, we will review the first 100 results of each search and identify any relevant websites. We will hand-search relevant websites to locate relevant literature meeting inclusion criteria.

We will document both searches using an Excel spreadsheet. We will include the following documentation: database searched, search words used, results received, and reference chaining and respective URLs.

Stage 3: Study Selection

Once the proposed searches have been completed, we will collate all identified citations into Covidence (https://www.covidence.org/), and duplicates will be automatically removed from the screening process. Two independent reviewers will screen each title and abstract against the outlined inclusion and exclusion criteria. Following this, full-text articles will be retrieved and uploaded to Covidence. Again, two independent reviewers will assess individual articles for eligibility criteria. Throughout this process, reasons for exclusion will be documented and included in the full review publication. Discussion or involvement of a third reviewer will be requested to resolve any discrepancies between reviewers. We will use the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR; Tricco et al., 2018) to report our process and findings.



Knowledge User Involvement

Co-authors C. Mann, A. Falconer, and R. McLeod are all key knowledge users in the health system setting. They were most recently involved as clinicians in the implementation of the ESC model of care at a local tertiary care facility for women and newborn health. Dr. C. Cassidy is an implementation scientist and will provide expert insight into review questions and data analysis. There will be no patient or public engagement in the review; however, findings will be shared with patients and health system leaders' part of the larger research team to further focus research questions and inform next steps.

Stage 4: Charting the Data

Two independent reviewers will extract and chart data into a piloted data extraction tool developed using Microsoft Excel. See Appendix B for draft extraction tool. The data extraction tool has been developed by the research team and will be piloted with five studies, ensuring consistency in reporting. Modifications will be made as needed and will be disclosed in full review. The following information will be captured in the tool: (a) general characteristics (title, authors, country of origin, research design), (b) descriptions of clinical setting (e.g., postpartum maternity floor, neonatal intensive care units with couplet care) and geographical location (i.e., rural and urban), (c) description and characteristics of implementation strategies for the ESC model of care, (d) clinician-reported and/or patient-reported barriers and facilitators for implementation, (e) description and characteristics of evaluation methods used, and (f) reported outcomes. Discussion and involvement of a third reviewer will address any identified discrepancies in reporting. Authors will be contacted in the case of missing information outlined in the data extraction tool.

This review will use frameworks and taxonomies to address the outlined research objectives and questions (as outlined in the bolded sections below). A coding strategy will be piloted and modified as needed to ensure consistency among reviewers. First, the primary reviewer will code the entire data extracted, followed by a second reviewer completing a verification of the coded data. As data coding is an iterative process, throughout the coding sessions there is potential for alterations to the coding strategy used; modifications will be outlined in the full scoping review (Pollock et al., 2023). Discussion or involvement of a third reviewer will resolve any discrepancies noted in the coding process.

Barriers and Facilitators in the Implementation of the ESC Model of Care into Clinical Practice (1.1)

We will use a directed content analysis (Hsieh & Shannon, 2005) guided by the COM-B model (Michie et al., 2011) and TDF (Cane et al., 2012) to explore clinician- and patient-reported barriers and facilitators in the implementation of the ESC model of care. Authors of this review have selected the COM-B model and TDF specifically due to their ability to provide a comprehensive overview of the internal and external influences on behaviour change at an individual level (clinician/patient; Cane et al., 2012; Michie et al., 2011). Furthermore, both frameworks have been cited in health care research as effective tools to inform the development of implementation strategies and challenges address within existing implementation (Glowacki et al., 2019; Jabbour et al., 2018; Surr et al., 2020). In our proposed scoping review, we will extract narrative descriptions of barriers and facilitators to implementation. Narrative descriptions will be further coded into the domains of the COM-B model and TDF. It is anticipated that coded barriers and facilitators will provide foundational knowledge to inform future efforts in both exploring the research implementation and actively integrating the ESC model of care into clinical practice.

Implementation Strategies (1.2)

We will explore and categorize implementation strategies using Waltz and colleagues' Expert Recommendations for Implementing Change (ERIC) taxonomy (Waltz et al., 2015). The ERIC taxonomy comprises 73



distinct knowledge translation methods with definitions. The taxonomy will allow reviewers to understand the operationalization of extracted implementation strategies. this review use Specifically, will the categorization and strategy ratings, noting importance and feasibility of the proposed strategies to extract data from included articles. We will use the nine broad categories of Waltz and colleagues' taxonomy to code the data extracted from this review: (a) use of evaluative and iterative strategies, (b) provide interactive assistance, (c) adapt and tailor to context, (d) develop stakeholder interrelationships, (e) train and educate stakeholders, (f) support clinicians, (g) engage consumers, (h) utilize financial strategies, and (i) change infrastructure (Waltz et al., 2015).

The RE-AIM of Evaluation Methods Used for the ESC Model of Care Into Clinical Practice (1.3)

This review will explore evaluation methods used for the implementation of the ESC model into clinical practice with the lens of the reach, effectiveness, adoption, implementation, maintenance (RE-AIM) framework (Glasgow et al., 2019). The RE-AIM framework allows for an analysis of interconnected factors on multiple levels, including the individual, organizational, and community levels (Glasgow et al., 2019). Narrative descriptions of data extracted from the studies on evaluation methods used will be coded into the five categories of the RE-AIM framework. Coded methods used to evaluate the implementation of the model from the lens of the RE-AIM framework will serve as a foundation for the process evaluation planning of the larger multi-phased proposed project. This review will examine the processes of implementation and evaluation. It is not an effectiveness or impact study.

Reported Outcomes (1.4)

This review will explore outcomes cited for the implementation of the ESC model of care into clinical practice. We will categorize evidence-based practice measures (Bick & Graham, 2010) into three categories: patient, health care provider, and health system outcomes. To further characterize patient-level outcomes, this review will consider the following: (a) patient-reported outcomes (e.g., signs of withdrawal; Kingsley & Patel, 2017), (b) patient experience (e.g., satisfaction; Kingsley & Patel, 2017), and (c) patient health outcomes (e.g., less pharmacological treatment needed due to a less severe withdrawal; Bick & Graham, 2010). Health care provider outcomes can be knowledge, defined as attitude (e.g., satisfaction), and behaviour changes (i.e., practice changes; Bick & Graham, 2010). Finally, health system-related outcomes could include changes in length of hospital stay or changes in hospital costs.

Stage 5: Collating, Summarizing, and Reporting the Results

We will present findings in comprehensive tables based on outlined research objectives. We will also create a diagram to showcase barriers and facilitators, along with а comprehensive diagram representing strategies used-reflective of the RE-AIM framework—to evaluate the ESC model of care (Aromataris & Munn, 2020). An inductive thematic analysis approach will be used to analyze and describe qualitative data (Braun & Clarke, 2006). Furthermore, we will provide numerical descriptive summaries where possible (e.g., frequency of cited barriers and facilitators and/or outcomes). Finally, we will provide a comprehensive narrative summary to accompany the above visual presentations and further support how research objectives were met.

Ethics and Dissemination

This scoping review aims to provide a synthesis of publicly available literature, and therefore will not require ethical approval. The main goal of this proposed scoping review is to map out and characterize the available evidence on implementation strategies and evaluation methods used in the integration of the ESC model into clinical practice. We anticipate



findings will be used to support future implementation and evaluation of the ESC model into clinical practice. As such, we will disseminate findings in an open access, peerreviewed journal publication, along with presenting findings at relevant conference presentations. This review is part of a multiphase project conducting a process evaluation of the implementation and evaluation of the ESC model of care into clinical practice. Findings from this scoping review will provide foundational knowledge to inform the planning and development of semi-structured interview questions to elicit qualitative data collection on local barriers and facilitators of the implementation of the ESC model into clinical practice. Furthermore, the analysis of evaluation methods to evaluate implementation of the model will be used to guide the comprehensive process evaluation founded on the RE-AIM framework.

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Appendix A

Example Search Strategy in MEDLINE (Ovid)

#	Query	Results from May 23, 2023
1	eat sleep console.ti,ab,kf.	32
2	("ESC" adj1 (model or method or approach or protocol)).ti,ab,kf.	69
3	1 or 2	90



Appendix B

Data Extraction Tool (draft)

General Paper Characteristics
Title:
Year:
Author:
Country of Origin:
Research Design:
Clinical Setting
Description of clinical setting:
Geography:
o Urban
o Rural
• Not Reported
Implementation Strategies
Description of Implementation Strategy:
Reported Barriers and Facilitators (Clinician and Patient)
Clinician-Reported Barriers:
Clinician-Reported Facilitators:
Patient-Reported Barriers:
Patient-Reported Facilitators:
Evaluation Methods
Description of evaluation method(s):
Outcomes
Patient-Level Outcome(s):
Health Provider–Level Outcome(s):
Health System-Level Outcome(s):