



Tube-to-oral transition pathway to guide feeding advancement in moderate-to-late preterm infants: A systematic review

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PREFACE

The foundation for this research originally stemmed from my passion and intrigue for premature neonates. As these small human beings are born into a world of uncertainty and great trauma, I remain in awe of their resilience and willingness to show so much fight, even when least expected.

It is my passion to not only know everything possible about premature neonates, but to contribute even the smallest piece to the existing body of knowledge we have about them.

In truth, I could not have achieved my current level of success without a strong support group. The saying that goes: “No man is an island” has always been something I strongly believe in. This saying has been evident more times than I can remember.

The fulfilment of this dissertation would not have been possible without the guidance of my exceptional supervisor, Prof Welma Lubbe, who encouraged me throughout this whole process and willingly shared her neonatal expertise. Her determination and will to overcome any challenge she is faced with, is a true inspiration. Thank you for your support, knowledge and guidance.

I would also like to thank Dr Suegnet Scholtz, my co-supervisor, for the many hours of editing and assistance that you contributed towards the completion of my dissertation.

I want to extend my greatest appreciation to Clarina Vorster for the technical and language editing; your input helped a great deal.

Thank you to Mrs G Beukman, who helped to retrieve journal articles during the study.

Thank you to work colleagues who encouraged me throughout the journey of completing this dissertation. Thank you for teaching me that people with great passion can make the impossible happen.

My parents, who have always believed in me, without any doubt, who stood by me, even when I did not realise I needed support - thank you for your unwavering support and for respecting me for the person I have become and all of the life lessons learned.

Last, but certainly not least, the person who played the biggest role in the completion of this dissertation is my loving fiancé, Andre Tonkin, who supported me with love and understanding and who was my personal cheerleader all the way – this dissertation is dedicated to you.

ABSTRACT

Background: Oral feeding for preterm infants are a complex process and a delay in attaining full oral feedings can detain hospital discharge, considerably increase the cost of care and lead to unnecessary hospital readmissions. Moderate-to-late preterm neonates are often regarded as 'small newborns', and their clinical needs and conditions receive little individualised attention.

Research aim/objectives: This study attempted to explore the best evidence to determine the factors to be considered when facilitating the transition process of tube-to-oral feeding in the moderate-to-late preterm neonate admitted to the neonatal ward.

Method: A six-step systematic review of literature was conducted to answer the review question. ScienceDirect, EBSCOhost, Elsevier, Scopus, AePublications electronic databases were scoped for relevant articles and then evaluated by using the PRISMA. Final articles were appraised using the John Hopkins and CASP tools.

Results: Factors that influence tube-to-oral transition include NNS (Non-nutritive Sucking), Provider education and caregiver skills, Cue-based-feeding, Kangaroo Mother Care (KMC), Neurological maturity and State of behavioural organisation.

Conclusion: Results lean towards cue-based feeding as the most effective approach for a successful transition from tube-to-oral feeding; however, there seems to be scarcity in the supporting evidence to design a pathway for the moderate-to-late preterm neonate.

Keywords: feeding assessment, feeding instrument, feeding scales, tube-to-oral transition, preterm feeding.

DECLARATION

I, S Nel (216 33 959), a Master of Nursing Science student, declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

Furthermore, I declare:

- Where I have consulted the published work of others, this is always clearly attributed;
- Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this dissertation is entirely my own work;
- I have acknowledged all main sources of help;
- None of this work has been published but will be submitted to peer-reviewed journals for review.

I conducted all research and compiled this dissertation under the supervision of Prof W Lubbe and Dr Suegnet Scholtz.

The article "Tube-to-oral transition pathway to guide feeding advancement in moderate-to-late preterm neonates: A systematic review." will be submitted to the *Journal of Perinatal and Neonatal Nursing*. The article was written according to the journal's author guidelines included in **Annexure D** of this dissertation. References for chapters one, two and four are presented according to the North-West University Harvard style at the end of chapter two. References in the article (Chapter 3) are presented at the end of chapter three according to the specific journal's author guidelines. No copyright permission has been obtained from the editor of the journal, as this will be acquired should the article be accepted for publication. Permission to publish this manuscript as part of the dissertation has been obtained from the study leaders as co-authors of the manuscript.

PRETERM NEONATE-RELATED LANGUAGE USED IN THIS RESEARCH REPORT

Prematurity According to the World Health Organization (WHO, 2018), prematurity is the condition when a neonate is born alive before 37 weeks of pregnancy has been completed.

Preterm/premature A Preterm or premature neonate refers to the 'person' being born before 37 weeks of pregnancy is completed (WHO, 2018). These two terms are used interchangeably; they both refer to the baby being born too early. There are sub-categories to preterm birth, based on gestational age:

- Extremely preterm (<28 weeks)
- Very preterm (28 to <32 weeks)
- Moderate-to-late preterm (32 to <37 weeks) (WHO, 2018)

For the purpose of this study, the moderate-to-late preterm category was the focus.

Tube feeding Tube feeding is defined as a method of delivering nutrients and other fluids through a gastro-intestinal tube that is inserted through the nose or mouth going into the stomach, when the individual is unable to feed orally (Holland, 2020).

Tube-to-oral feeding This term refers to the transition of feeding from a nasogastric (or orogastric) tube to consuming food (in this case, breastmilk) orally.

Clinical pathway Clinical pathways are standardised, evidence-based management blueprints, which identify the appropriate steps of a clinical intervention, timeframes, milestones and expected outcomes for a homogenous patient group (Lawal, *et al.*, 2016).

The purpose of using a clinical pathway in this study was to support the implementation of evidence-based practice and improve clinical processes by reducing risk, reduce duplication

through the use of a standardised tool and furthermore, reduce variation in health service process delivery (Toy *et al.*, 2018:901).

Neonatal ward

Neonatal ward refer to any setting where clinical healthcare professionals manage the care (especially feeding) of moderate-to-late preterm neonate. Neonatal wards include the Neonatal Intensive Care Unit (NICU), neonatal high care, growing preterm wards and Kangaroo Mother Care (KMC) rooms.

Oral feeding

Oral feeding includes the ingestion of fluids and food per mouth (Merriam-Webster Inc., 2021). In this dissertation context, it will refer specifically to the preterm neonate's ingestion of breastmilk or formula milk per mouth.

Health care professional

They are defined as people "providing health services in terms of any law", including the Allied Health Professions Act 63 of 1982, the Health Professions Act 56 of 1974, the Nursing Act 50 of 1978, the Pharmacy Act 53 of 1974, and the Dental Technicians Act 19 of 1979. This means doctors, nurses, dentists, pharmacists and medical specialists (South Africa, National Health Act, 61 of 2003). In this dissertation, the Nurse or Nursing staff in the neonatal ward constitute the Health Care Professional.

LIST OF ABBREVIATIONS

BP	Blood pressure
BPM	Beats per minute
CASP	Critical Appraisal Skill Programme
EBF	Exclusive breastfeeding
EBP	Evidence-based practice
HCP	Health Care Provider
HR	Heart rate
HREC	Health Research Ethics Committee
KMC	Kangaroo mother care
NNS	Non-nutritive Suckling
NuMIQ	Nursing and Midwifery Inquiry for Quality
NWU	North-West University
NNS	Non-nutritive sucking
PIOS	Population, Intervention, Outcome and Study Design
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
SR	Systematic Review
VLBW	Very low birth weight
WHO	World Health Organization

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CHAPTER 1: OVERVIEW OF THE STUDY

1.1 INTRODUCTION

Oral feeding for the preterm infant is a complex process, and a delay in attaining full oral feedings can delay hospital discharge, considerably increase the cost of care and lead to unnecessary hospital readmissions (Gennattasio *et al.*, 2015:97). The aim of this study was to synthesise current evidence regarding transition guidelines for preterm neonates from tube-to-oral feeds with a specific focus on the moderate-to-late preterm infant. In this chapter, the proposed research question, aim and objectives are presented together with the most suitable methodology to address this question.

1.2 BACKGROUND INFORMATION

In general, when a baby is born too early, their bodily systems are immature, and they are exposed to factors and experiences they will not necessarily have had in-utero, putting them at risk for a number of health issues and developmental delays (Gagne, 2017).

According to the Born Too Soon Global Action Report on Premature Birth (WHO, 2012), approximately 15 million babies are born prematurely worldwide. The moderate preterm neonates account for more than 80% of these preterm neonatal births.

Among the challenges the moderate-to-late preterm neonate might face, the biggest one is the establishment of successful oral feeding. The oral feeding for a preterm neonate is usually problematic, as they have less muscular strength, coordination challenges and experience more difficulty with latching, sucking and swallowing, compared to the term infant (Dosani *et al.*, 2017:2). With the moderate-to-late preterm neonates' large contribution to the premature population, it seems worthwhile that healthcare providers pay close attention to inexpensive interventions to improve and manage feeding problems that the moderate-to-late preterm neonate can experience (Corvaglia & Aceti, 2014: A37).

The process of transition from tube-to-oral feeding is one of the most complex challenges that the preterm neonate must overcome and difficulty in this transition process occurs in more than 30% of preterm neonates (Lima *et al.*, 2015:107; Morag *et al.*, 2019:1). Some of these difficulties include 1) physiological and neurological immaturity, 2) muscle hypotonia and 3) hypersensitivity to environmental stimuli (Lima *et al.*, 2015:106; Dodrill, 2011:324). Consequently, preterm neonates are traditionally tube-fed until they can successfully be fed orally.

Immaturity of the preterm neonate's oral-motor system, with specific reference to an inability to coordinate sucking, swallowing and breathing, has a negative impact on oral feeding skills. Physiological difficulties might include a decrease in oxygen saturation, an increase in heart rate, a patent ductus arteriosus and difficulty in thermoregulation. Neurological immaturity can suggest delayed cognitive skills, cerebral palsy and the risk of developing retinopathy due to prematurity (Beke, 2018:27; Romeo *et al.*, 2020:475).

Poor oral-motor developments in neonates are common, and the prevalence of feeding dysfunctions in former premature neonates (up to one year of age) is twice that of full-term neonates (Harding *et al.*, 2018:150). Furthermore, premature neonates may experience delayed transition to independent oral feeding, which exposes them to the possibility of long-term tube feeding (Viswanathan & Jadcherla, 2019:1258). It is clear from these above-mentioned immaturities and inability experienced by preterm neonates that they require some sort of support or assistance needed by their healthcare professional, within the first few weeks of life, to address their difficulty with feeding. Preterm neonates could benefit from interventions that promote transition to breastfeeding, which will be elaborated on later in chapter two. Preterm neonates could benefit from interventions that promote the transition to breastfeeding (Cartwright *et al.*, 2017:356; Maastrup *et al.*, 2021). Oral feeds include breastfeeding, but can include breastmilk in a feeding bottle or finger feeding on breastmilk with a tube.

Premature birth could lead to severe complications. As part of the premature neonate's essential medical management, they are exposed to a range of invasive procedures, such as tube-feeding, intubation and suctioning, influencing their breathing and swallowing mechanisms. These interventions might further impede feeding development in these high-risk neonates, as the intubation and continuous suctioning can also lead to oral sensitivity and refusal of oral feedings as the neonate has a negative association with oral stimulation (Geddes *et al.*, 2013:156; Bird, 2020). Furthermore, the preterm neonate also experiences problems with oxygen saturation regulation and heart rate fluctuations during feeding (Araújo *et al.*, 2016:212).

When compared to the full-term neonate (>37 weeks gestation), the late preterm neonate is at higher risk of developing medical complications, including thermal instability, respiratory problems, hypoglycaemia, jaundice and feeding problems (Corvaglia & Aceti, 2014: A37; Karnati *et al.*, 2020:37).

The successful transitioning from tube-to-oral feeding is associated with earlier hospital discharge and positive neurodevelopmental outcomes in premature neonates (Viswanathan & Jadcherla, 2019:1257). Yet, in contrast to the large number of neonatal nutrition literature focusing on the management of very low birth weight (VLBW) infants (neonates <33 weeks

gestation), relatively little attention has been paid to the moderate-to-late preterm neonate's (32 to <37 weeks gestation) feeding management (Crippa *et al.*, 2019:313).

While VLBW infants present a vulnerable clinical picture, the moderate-to-late preterm neonate's physical presentation can be deceiving. They often present similar to full-term babies, and their feeding is managed as such; however, they still have a degree of immaturity on all levels of functionality that places them at higher risk of many clinical problems (Alexander & Bloomfield, 2019:338). Compared to the VLBW infant, who receives feeding support in highly supervised, specialist clinical environments, the moderate-to-late preterm neonate is usually cared for in a less structured environment that may negatively influence best clinical practice and health outcomes (Gianni *et al.*, 2015:1).

Oral feeding for the preterm neonate is a complex physiological process that depends primarily on the coordination of sucking, swallowing and respiration (Lau, 2015:8). Attempting to determine the golden moment to initiate oral feeding in preterm neonates is a challenging task. Parameters such as gestational age, maturation and clinical conditions should also be considered in the decision-making (Brumbaugh *et al.*, 2018:47). Nevertheless, these parameters cannot be observed in isolation because they are not sufficient to initiate successful oral feedings safely.

Different interventions, like non-nutritive suckling (NNS) through the utilisation of a pacifier, early introduction to suck-feedings as well as pre-feeding oral and perioral stimulations (cheeks, lips, jaws, gums and tongue) have shown to be effective in accelerating the transition from tube-to-full oral feeding and reducing the duration of hospital stay in the moderate-to-late preterm neonate (Harding *et al.*, 2018:147; Neiva *et al.*, 2014:393).

Instruments and tools addressing feeding difficulties in preterm infants have a broad focus. Some instruments focus on feeding readiness, while others assess feeding quality. Some tools focus on oral feeding as a whole (as it is a comprehensive process), while there are feeding instruments that exclude preterm neonates and only focus on full-term neonates (such as the Early Feeding Skills Assessment and Neonatal Oral Motor Assessment Scale) (Azuma & Maron, 2020:25; Gennattasio *et al.*, 2015:100). A few studies provided information on the use of cue-based or neonate-driven feeding, comparing them to traditional volume-driven feeding regimes (Puckett *et al.*, 2008:623; Whetten, 2016:507). Some of these instruments isolate specific criteria, such as physical factors, gestational age and infant weight, to determine readiness. None of these instruments is a valid measure of the moderate-to-late preterm neonate's ability to successfully transition from tube-to-oral feeds (Fujinaga *et al.*, 2018:96).

None of these instruments, used on their own, contains comprehensive assessment criteria for the preterm infant's immature physiology and skillset.

Current feeding instruments and guidelines have various focuses and applications, although they all attempt to support preterm infant feeding. However, there is still a lack of a clinical decision pathway where all these feeding considerations are valued to guide the clinician in supporting the infant when moving from tube to oral feeding at the best time for the infant and with the least stress, therefore this became the aim of this study

However, as these instruments are often not focused on the moderate-to-late preterm infant, their neurologic immaturity and their display of disorganised behaviour at the beginning of oral feeds (Bingham *et al.*, 2012:30), oral feeding remains an ongoing challenge. The instruments referred to are discussed in more detail in the literature review. A negative outcome of implementing existing checklists for the transition from tube-to-oral feeding, for the infant includes repeated failure to feed properly (Prade *et al.*, 2016:2; Maastrup *et al.*, 2014:2).

Even though an abundance of research in this field is already available, the protocol of the most appropriate clinical pathway to follow for the advancement of the tube-to-oral feeding process for the moderate-to-late preterm infant is still not clear.

Such a detailed clinical pathway is especially important in the context where healthcare professionals, who work with preterm neonates, may not have extensive, specialised training on this topic, but must still provide safe care.

1.3 RESEARCH PROBLEM

Various tools to assess different aspects of feeding in infants and preterm neonates are available, but none guiding the healthcare professional through the decision-making process to determine the ideal time of transition from tube-to-oral in the preterm infant, with specific reference to the moderate-to-late preterm infant.

The moderate-to-late preterm neonate accounts for about 80% of the premature population worldwide, they face great challenges with the establishment of successful oral feeding and their feeding care is often overlooked or incorrectly compared to the full-term neonate. When there is focus on interventions to facilitate tube-to-oral feeding for these preterm neonates, their problematic, coordination challenges and difficulty with latching can be successfully addressed and the repeated admissions, delay in discharge and other medical conditions will improve.

An evidence-based clinical pathway is required to support clinicians, even in the absence of extensive training and/or experience, to support the preterm infant in the tube-to-oral feeding transition process. Therefore, this systematic review aimed to explore the literature to develop

a pathway that healthcare professionals can use to guide their clinical decision-making when supporting moderate-to-late preterm neonates with the transition from tube-to-oral feeding.

1.4 RESEARCH QUESTION

The following question guided this research:

What are the factors that a pathway should consider to support the successful tube-to-oral transition process for moderate-to-late preterm neonates?

1.5 RESEARCH AIM AND OBJECTIVES

1.5.1 Aim

The aim of this study was to explore the literature to develop a pathway that healthcare professionals can use to guide their clinical decision-making when supporting moderate-to-late preterm neonates with the transition from tube-to-oral feeding.

1.5.2 Objectives

The objectives of this study were to:

- Explore the best available evidence by means of a systematic review to determine the factors to be considered when facilitating the transition process of tube-to-oral feeding in a moderate-to-late preterm neonate who has been admitted to the neonatal ward.
- Draft a pathway for healthcare professionals that guides clinical decision-making during the tube-to-oral feeding transition process of the moderate-to-late preterm neonate, based on the findings of the systematic review.

1.6 SIGNIFICANCE OF THE RESEARCH

In the interest of improving the quality of the feeding advancement from tube-to-oral transition, the moderate-to-late preterm infant's health and wellbeing might be optimised by means of a comprehensive clinical pathway.

1.7 RESEARCH METHOD

In this section, the researcher defines and explains the study's context, population, inclusion and exclusion criteria, sampling, as well as the data collection and analysis processes.

The six-phase guide for preparing the systematic literature review was utilised as the guideline for this study (Souza *et al.*, 2010:102). This six-phase approach was chosen as the most suitable for this study, as this is the most used process for systematic reviews.

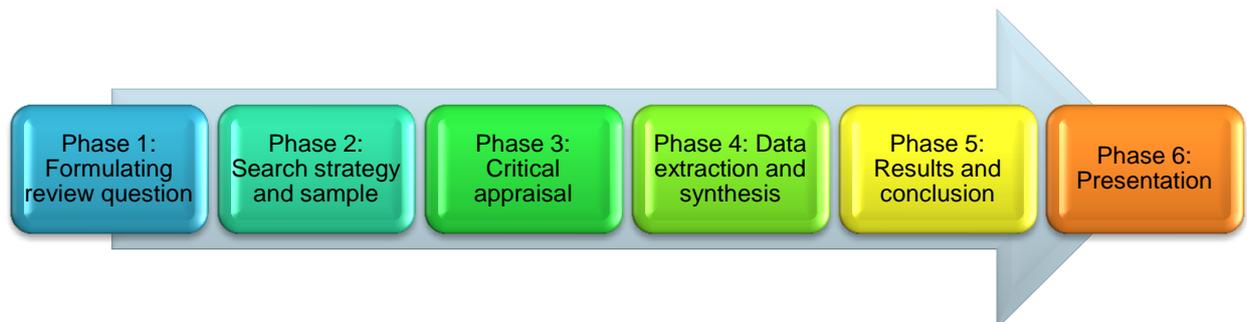


Figure 1-1: Phases of systematic review

(Souza *et al.*, 2010)

The researcher suggested that the systematic review was the best method for research on this topic, as there is a vast database of published literature, which makes keeping up with the best evidence a difficult task. Exploring the various internet articles can be very challenging and time-consuming, especially when the researcher is inexperienced and have limited research skills (Ten Ham-Baloyi & Jordan, 2016:120). There is a need for good quality information on the use-ability of a large number of tube-to-oral feeding interventions

The research methodology is discussed in detail as part of the manuscript in Chapter 3. In this section, only a brief overview of the process is provided.

1.8 RESEARCH DESIGN

The systematic process was followed in this research, which included the six phases of a systematic review. These are (i) Formulating a review question, (ii) Search Strategy and Sampling Literature, (iii) Critical appraisal, (iv) Data extraction and synthesis, (v) Results and conclusion and (vi) Presentation (Souza *et al.*, 2010).

A systemic review, which included the review of various research studies, provided evidence-based practice for health care professionals who care for the moderate-to-late preterm neonate and identified items to be included in an appropriate clinical pathway for feeding transition.

Data sources were identified with a PIOS (Population; Intervention explored; Outcome to be addressed and Study design) question and appraised using the CASP (Critical Appraisal Skills Programme) tool (**Annexure A**) as well as the Johns Hopkins Appraisal Instrument for Research (**Annexure B**) to screen and evaluate the relevance of the data related to the

research question and evaluate the rigour and methodology quality. There are a series of CASP tools available – for the dissertation, the researcher used the applicable ones to the research design i.e. for qualitative studies, the qualitative CASP tool, for quantitative research design, the quantitative CASP tool. To avoid making the dissertation lengthy, I only include the CASP tool for qualitative studies as **Annexure A**. The other CASP checklists can be accessed on the following link: <https://casp-uk.net/casp-tools-checklists/>

The six-phase approach to the Systematic Review will be briefly discussed, with elaboration in Chapter 3.

1.8.1 Phase one: Formulating a review question

The review question formulated in this phase was significant, as it served as a guideline that determined which studies to be included and excluded (Stern *et al.*, 2014:53). It was the benchmark measure for deciding how to identify studies for the review that had been assessed and the results that had been measured (Garg, 2016: 642; Gray *et al.*, 2017:144).

PIOS assisted to breaking down the question into discrete components that helped to formulate the review question and it helped to develop a search strategy. This structured format was a way to improve the scientific rigor (Munn *et al.*, 2018:2).

The PIOS format was utilised in this review to develop a clinical question to guide the research (Gray *et al.*, 2017:145). After PIOS was established, the review question was formulated; furthermore, synonyms of the identified elements were also identified to be included in the search. This format included the following necessary elements:

Table 1-1: PIOS question for this review

P	Population/participants	Premature neonates of gestation between 32-37 weeks
I	Intervention explored	Tube-to-oral feeding transition
O	Outcome to be addressed	Factors that influence the successful tube-to-oral transition of preterm neonates
S	Study design	All study designs

1.8.2 Phase two: Search strategy and sampling literature

The review question as formulated in phase one was used as a guideline to identify the keywords used for the search. Different keywords and their synonyms were used during the scoping review, which was done prior to the proposal to test the search strategy and exploring

the literature to determine the most applicable keywords. The keywords that guided the search for the correct research studies.

Keywords/phrases that was used in this study included: premature feeding, premature birth, neonatal development, neurological development, feeding assessment, premature newborn, neonatal examinations, tube feeding, enteral feeding of preterm neonates, premature feeding guidelines, motor development in preterm neonates, sucking ability in preterm neonates, feeding problems in preterm neonates, neonate-driven feeding, cue-based feeding, volume-driven feeding, preterm feeding: guide, protocol, pathway, algorithm, guideline, advancement, interventions, feeding instrument, feeding scales.

Electronic databases that were consulted included ScienceDirect, EBSCOhost, Elsevier, Scopus, AePublications, university catalogues (theses and dissertations), Google (academic and non-academic sources) and Cochrane library (systematic reviews) with a crosscheck using Google Scholar to ensure that no relevant documents were missed.

Literature screening was done by an independent reviewer and on various levels, starting with title and topic, followed by the abstract and finally, full-text reviews of selected documents. The inclusion criteria were formulated as:

Table 1-2: Inclusion criteria

INCLUSION CRITERIA	JUSTIFICATIONS
<ol style="list-style-type: none"> 1. All study designs to be included. 2. All types of publications in either Afrikaans or English were considered for inclusion. 3. Titles and summaries of relevant studies reported in other languages reviewed, to determine their relevance for inclusion in the study. 4. Theses and dissertations were included. 5. Studies addressing the review question in a comprehensive manner were included. 6. Only studies published between 2007 and 2020 were included. 	<ol style="list-style-type: none"> 1. To encompass comprehensive perspectives within the study. 2. The researcher and co-reviewer are competent in both languages – ensuring an accurate understanding of publications and improving the quality of the systematic review. 3. To decrease limitations of information bias. 4. To decrease limitations of information bias. 5. To ensure the validity of the study content. 6. To ensure relevance and accuracy of the most recent evidence: literature before this time could be outdated, and newer scientific evidence is available. Limited number of studies focusing on the moderate-to-late preterm neonate – expand search. The practice of moving

INCLUSION CRITERIA	JUSTIFICATIONS
	from volume-driven to infant-driven/ cue-based feeding was first reported in literature during 2007

Table 1-3: Exclusion criteria

EXCLUSION CRITERIA	JUSTIFICATIONS
1. Duplicated studies, only the most recent version of the study was included.	1. To ensure a valid and reliable pool of studies for inclusion in the systematic review.
2. Studies with little or no relevance pertaining to the moderate-to-late preterm neonate's feeding.	2. To ensure that the study remains focused on the research question.
3. Textbooks were excluded.	3. Since they contain secondary data and could contain outdated data.

The Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) flow chart (refer to **Table 3-1**) was used to capture the literature screening process (Moher *et al.*, 2009).

1.8.3 Phase three: Critical appraisal

Within this phase, an organised approach to weighing the rigour and characteristics of each study was followed. The validity of the methods and results were checked and the quality of each study was determined, as well as their usefulness in practice (Souza *et al.*, 2010:107).

Two critical appraisal instruments were used to appraise the studies, based on their designs, namely The various Critical Appraisal Skills Programme (CASP) instrument the specific research design (**Annexure A- only an example of the qualitative CASP tool**) and the Johns Hopkins nursing evidence-based practice appraisal tool for research evidence (**Annexure B**). The other CASP checklists can be accessed on the following link: <https://casp-uk.net/casp-tools-checklists/>

The CASP and Johns Hopkins appraisal tool generally have almost the same approach in three steps: 1) enquiring whether the study is valid, 2) deciding whether the study is unbiased by evaluating its methodological quality and 3) questioning the results of the article. If the study is valid, a score was allocated to indicate clinical significance. The last step involved deciding if the evidence applied to the research question. The findings were summarised through a data summary table (**Table 3-5**).

1.8.4 Phase four: Data extraction and synthesis

During data extraction and synthesis, a data extraction table (see **Table 3-6** and **Annexure C**) was constructed. The table consists of two parts and presents each article's author, country, study design, factors/items included in a pathway, as well as main conclusions. Synthesis was then done by clustering and interrelating ideas from several sources to form a new and more comprehensive picture of what information was available on a subject (Gray *et al.*, 2017:690).

Thematic analysis was used to identify the recurring elements or factors. The steps followed for this data syntheses was as follows: Step 1: becoming familiar with the data. This includes reading through all the articles. In this phase, notes are made on understanding and possible themes that stand out (Nowell *et al.*, 2017:4).

Step 2 includes generating/identifying initial codes. Data is organised in a meaningful and systematic way and each segment of data that was relevant to or captured something interesting about our research question (Nowell *et al.*, 2017:5).

In the next step, there is a clear search for themes. A theme is defined as a pattern that captures something significant or interesting about the data and/or research question. At the end of this step, the codes are organised into broader themes that seemed to say something specific about this research question (Nowell *et al.*, 2017:8).

Step 4 is reviewing the themes. During this phase, the preliminary themes that were identified in the previous phase are reviewed, modified and developed (Nowell *et al.*, 2017:9).

During step 5, the themes are defined: this is the final refinement of the themes, and the aim is to determine the core/essence of what each theme is about. The final phase writing-up refers to the discussion of the results (Nowell *et al.*, 2017:10).

1.8.5 Phase five: Results and conclusion

In this phase, the analysed data from the included studies were combined. An analysis was done to determine the elements needed in a clinical pathway to guide the decision-making process in tube-to-oral feeding transition for moderate-to-late preterm neonates. In addition to identifying eventual gaps in knowledge, it was possible to set priorities for future studies (Souza *et al.*, 2010:107). These priorities and gaps will be discussed in chapter four. The combination of identified elements provided the platform for the interpretation of the data and to answer the research question.

1.8.6 Phase six: Presentation

The results were formulated in an article (refer to Chapter 3) that will be submitted to the *Journal of Perinatal and Neonatal Nursing*. The results will be used for presentations at relevant academic conferences and inform clinical practice; therefore, inclusion in policy was envisioned (the latter being outside the scope of this study). Furthermore, if possible, a drafted pathway for healthcare professionals to guide clinical decision-making during tube-to-oral feeding transition, of the moderate-to-late preterm neonate will form part of the presentation.

1.9 RIGOUR

Rigour is the umbrella term used to describe all the strategies to ensure that the research encompasses trustworthiness, validity and reliability (Cypress, 2017:254). The systematic review ensured a rigorous and transparent manner to review the available evidence on the focused research question (Cypress, 2017:254).

The purpose of a systematic review and meta-analysis is to answer a formulated research question. This question should lead to a valid answer by means of a systematic, specific and consistent method of searching; identifying, and appraising appropriate evidence (Mittal *et al.*, 2017:318).

These systematic reviews are the core of evidence-based practice for various stake-holders, i.e., clinicians, researchers and policy-makers meaning that information has to go through the rigorous process (Mittal *et al.*, 2017:318).

Validity refers to the logical or factual basis of research. Validity is ensured by using certain mechanisms (Gray *et al.*, 2017:700). Each research approach is guided by these mechanisms, namely standards and rules that guide the researcher to generate valid scientific knowledge (Gray *et al.*, 2017:700; Mallett *et al.*, 2012:445).

The data extraction took place in an objective manner to ensure that the data and study have validity. Through a systematic review, various studies with different research methods were gathered during sampling and contributed to decreased bias and supported the truth of the findings.

The researcher was supported by supervisors in order to ensure validity. During the whole research process, two reviewers were involved to ensure validity and rigour. The reviewers had previous knowledge and experience in systematic reviews and were research experts in the field of neonatology.

Neutrality: An independent co-reviewer participated in the study selection as well as the critical appraisal phases of the systematic review. A consensus discussion was held to ensure that only relevant studies were included and bias was eliminated (Burr, 2014).

Consistency: This was ensured by gathering studies that addressed the research question (Walker & Hopp, 2017:132). A clear audit trail was kept of how the studies were obtained, what kinds of studies were obtained and what data extraction took (**Table 3-6**) place.

Consistency was achieved by means of the researcher, who identified that there was a knowledge gap after a thorough scoping of the available literature on the topic. Conceptual structuring of the identified topic took place early in the research process to ensure that structured research took place. The purpose of a systematic review is not to duplicate knowledge but to combine and reconstruct the information gathered during primary research, giving another perspective to the understanding of the topic (Booth *et al.*, 2012:11).

The following section will cover the ethical considerations for this study.

1.10 ETHICAL CONSIDERATIONS

Ethical principles for health research in South Africa are to identify and practice good, desirable and acceptable conduct, to protect the welfare and rights of research participants and to reflect the basic ethical values of beneficence, justice and respect for persons (Brink *et al.*, 2018:35; Wagner & Wiffen, 2011:130).

Respect for the person

This was a systematic review study; thus, acknowledgement of original authors of the included studies were of utmost importance in order to prevent plagiarism by perpetrating acts of intellectual theft. By referencing in the correct manner, namely the Harvard style of referencing and the AMA referencing style for the article as per the author's guidelines for the *Journal of Perinatal and Neonatal Nursing*, plagiarism was prevented (North-West University, 2020:5). The researcher was dedicated to ethical research, and this study aimed to comply with expected ethical standards.

Principle of beneficence

Beneficence refers to acting in such a way to benefit others while promoting their welfare and safety. The beneficence principle includes two specific research aspects: (1) participants' right to freedom from harm and discomfort and (2) participants' rights to protection from exploitation

(Barrow *et al.*, 2020). This research did not infringe on any person's right to freedom and did not harm anyone as the study did not include any human subjects.

Principle of justice

The purpose of this systematic review was to identify and process published material's information in a systematic and transparent manner. The ultimate goals were to ensure comprehensiveness and reduce systematic errors (bias) in the processing of relevant information; thus, contributing to good evidence-based decision-making (Crawford *et al.*, 2010:593; Mertz *et al.*, 2016:1).

Firstly, the research proposal was submitted to and approved by the NuMIQ scientific review committee, and secondly, ethical clearance was obtained by the Health Research Ethics Committee (HREC) of the North-West University, Faculty of Health Sciences (NWU-00138-17-S1) (**Annexure H**).

In order for information to be presented in an unambiguous, unbiased manner, correct records of all information were kept safe by the researcher. To prevent confusion and misunderstanding, the scientific quality of the study should be ensured (NWU, 2020).

1.11 DISSEMINATION OF THE RESULTS OF THE STUDY

The results were formulated in an article that will be submitted to the *Journal of Perinatal and Neonatal Nursing*. It was and will be used for presentations at relevant academic conferences, such as the Annual Perinatal Priorities conference.

1.12 DISSERTATION LAYOUT

This dissertation was prepared in article format as per the guidelines of the North-West University (NWU, 2018).

Table 1-4: Dissertation layout

Chapter 1:	Overview of the study.
Chapter 2:	Manuscript prepared for submission: Identifying interventions to support the moderate to late preterm infant's transition from tube-to-oral feeding (discussion paper).
Chapter 3:	Manuscript prepared for submission: Tube-to-oral transition pathway to guide feeding advancement in moderate to late preterm neonates: A systematic review: Original research paper. Article will be submitted to the <i>Journal of Perinatal and Neonatal Nursing</i> .

1.13 DATA MANAGEMENT PLAN

The articles and other evidence were securely stored on a dedicated Dropbox folder and a backup on an external hard drive. Only the researcher had access to the documentation, and the storage was password protected. The articles and study evidence were electronically mailed to the co-reviewer in a secure Microsoft Word and PDF format in order to assist with the systematic review process. Thereafter, the data was only accessed and managed by the researcher and supervisors.

1.14 ROLES AND QUALIFICATIONS OF THE RESEARCH TEAM MEMBERS

This section outlines the names, qualifications and roles of the research team.

Table 1-5: Roles and qualifications of the research team

	Names	Qualifications	Roles
1.	Prof Welma Lubbe	PhD; M Tech; BCur Honours: Midwifery and Neonatal Nursing Science, Nursing Education, FANSA	Supervisor
2.	Dr Suegnet Scholtz	DCur; MCur; Critical Care Nurse Specialist, Nursing Education, Nursing Management	Co-supervisor
3.	Miss Sonja Nel	Nursing Education, Nursing Management, B Cur	MCur (Candidate)
4.	Mrs MM Kohn	MCur; BCur	Co-reviewer

1.15 CONFLICTS OF INTEREST

There were no conflicts of interest as the researcher did not financially benefit from this study other than obtaining a master's degree.

1.16 SUMMARY

In this chapter, the literature background was discussed that led to the formulation of a problem statement and research question. The preliminary literature search led to the identification of the current evidence and the formulation of the aim and objectives. The research design and method were chosen as the most effective way of conducting the systemic review of literature available on the topic. This provided an outline for the research process. The next chapter presents the literature reviewed regarding interventions to support the moderate-to-late preterm infant's transition from tube-to-oral feeding.

CHAPTER 2: LITERATURE REVIEW

Identifying interventions to support the moderate to late preterm infant's transition from tube-to-oral feeding (discussion paper).

2.1 INTRODUCTION

The aim with this chapter was to provide a scientific background of literature substantiating the systematic review conducted during the study. A broader narrative literature review was performed to explore current literature on the moderate-to-late preterm neonate and their feeding struggles, to provide additional background literature for the systematic review and to guide the formulation of the research question.

The moderate-to-late preterm neonate is at higher risk of developing medical complications, including thermal instability, respiratory problems, hypoglycaemia, jaundice and feeding problems than the term neonate (Corvaglia & Aceti, 2014: A37; Crippa *et al.*, 2019:315). The establishment of successful feeding in moderate-to-late preterm neonates is usually problematic, as they have less muscular strength and more difficulty with latching, sucking and swallowing than term infants (Dosani *et al.*, 2017:8; Lapillonne *et al.*, 2019:262). For this reason, healthcare providers should pay more attention to manage feeding problems that the moderate-to-late preterm neonate might experience (Corvaglia & Aceti, 2014: A37; Lapillonne *et al.*, 2019:264).

This literature review aims to give a background regarding the moderate-to-late preterm infant, by focusing on feeding as their most evident challenge. The review includes the normal development of feeding; it explores the premature neonate's struggle with oral feeding, explains that the transition from tube-to-oral is not an automatic occurrence but requires fine-tuned support and provides an overview of the transition programmes reported in literature.

2.2 PRETERM DEVELOPMENT RELATED TO FEEDING

Feeding requires active effort by the infant; they must have exact timing and coordination for sucking, swallowing and breathing during a feed (Arvedson *et al.*, 2010:321; Dodrill, 2011: 325). Feeding, swallowing, and respiration are functions that are coordinated by the medulla in the lower part of the brain, as well as the cranial nerves (Seladi-Schulman, 2019). Oral feeding in premature infants should be efficient to preserve energy for growing, safe to avoid aspiration and should not endanger their respiratory status (Da Costa *et al.*, 2008:247).

Later in life, at around three years of age, the infant's successful communication skills will be directly related to successful feeding and swallowing (Vieira *et al.*, 2016:1360). Normal feeding patterns reflect the early developmental pathways that are the basis for adult communication skills (Adolph & Franchak, 2017:11; Vieira *et al.*, 2016:1361).

A significant correlation exists between the level of maturity of an infant's sucking, and their gestational age and feeding performance are correlated with the progression of oral feeding (Neto *et al.*, 2016: 95). Sucking and swallowing reflexes are developed *in utero* and only mature during the third trimester. The moderate-to-late preterm infant is deprived of this maturation time. They are in "an abnormal" situation. These preterm infants have to complete their development in the extrauterine environment (De Carolis *et al.*, 2016:87; Pineda *et al.*, 2020:646).

Sucking (during a feed) involves a rhythmic movement of the tongue and jaw that results in milk flowing out of the nipple due to changes in intra-oral pressure (Elad *et al.*, 2014:5231). This can be explained as an act of pulling and pushing - a negative pressure (suction) and a positive pressure (compression). The positive pressure creates a rhythmic compression of the nipple between the neonate's tongue and the palate, which pushes the milk out of the nipple into the oral cavity (Macías & Meneses, 2011:297).

The suckling, swallowing and breathing coordination is the most complex sensorimotor process the preterm newborn infant undertakes (Dodrill, 2011:325; McClure, 2013:14; Neto *et al.*, 2016:87). The premature infant's pattern differs from that of a full-term infant. Evidence suggests that there are five primary developmental stages of sucking that note the maturational process (as seen in **Figure 2-1**). These stages specifically highlight the relationship between the development of sucking and oral feeding performance in preterm infants (Arvedson *et al.*, 2010:323; Lau, 2014:27).

During stage 1, there is no suction and an arrhythmic expression only – this is the most immature stage. Stage one is divided into (1a) no suction and arrhythmic expression as well as (1b) arrhythmic alternation of suction and expression (Arvedson *et al.*, 2010:324). Stage 2 is characterised by (2a) no suction and rhythmic expression and (2b) arrhythmic alternations of suction and expression coupled with sucking bursts (Arvedson *et al.*, 2010:323). As they progress to stage 3, there is (3a) no suction but rhythmic expression. Stage 3b is identified with rhythmic suction and expression, as well as suction amplitude that increases a wide amplitude range and prolonged sucking bursts. Stage 4 shows rhythmic suction and expression, well-defined suction and a decrease in amplitude range. The final stage, stage 5, is the most mature with rhythmic alternation of suction/expression (Arvedson *et al.*, 2010:324).

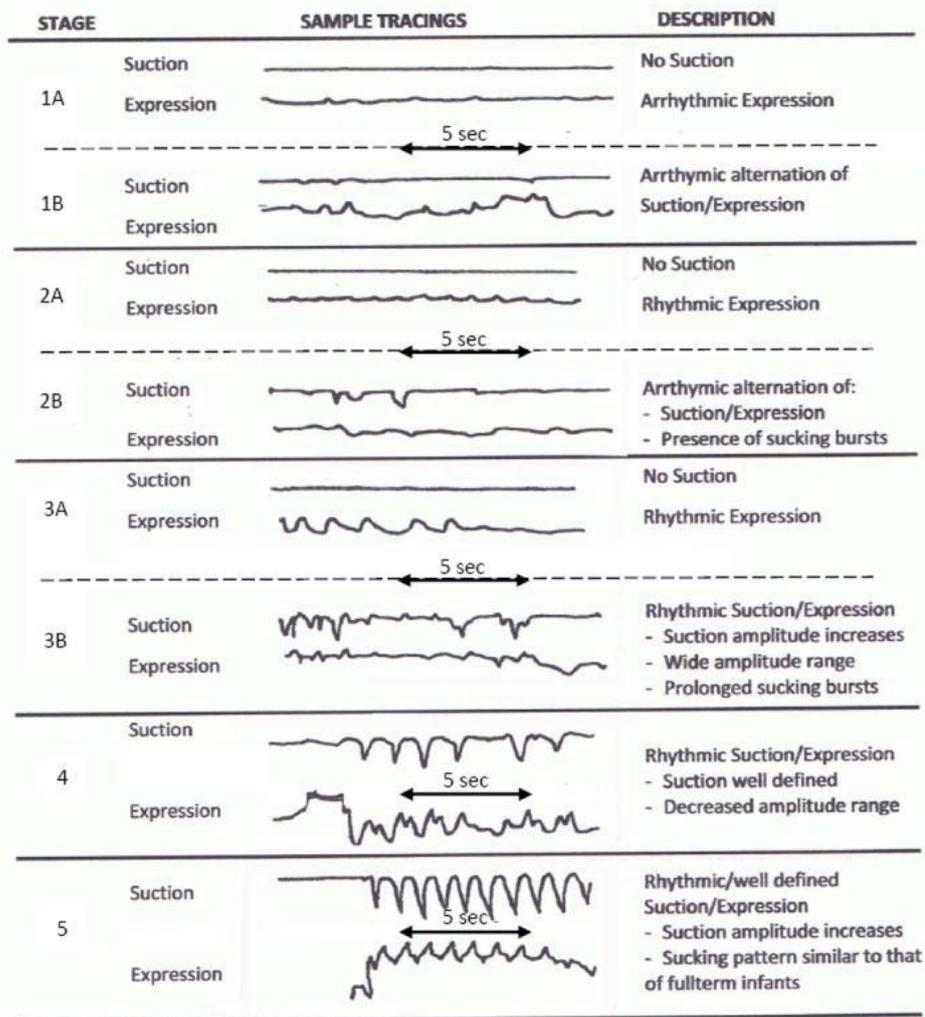


Figure 2-1: Five primary developmental stages of sucking that note the maturational process

(Arvedson et al., 2010:324)

The swallowing process includes the oral preparatory, pharyngeal and oesophageal phases. These are involved in the formation of the milk bolus and its transport to the stomach through the pharynx and oesophagus (Lau, 2016:620). The swallowing process is one which the late preterm infant has not yet mastered. Correct and safe swallowing requires the integration and proper timing of the oropharyngeal structures (the tongue, soft palate, pharynx, larynx and oesophagus).

Swallowing occurs during all phases of respiration, although most swallowing occurs during expiration (Lau, 2016:617). The coordination of respiration and swallowing is dependent on posture. Evidence has shown that infants swallow predominantly during late expiration when

feeding in the upright position. The late preterm infant has other health concerns that might influence this prerequisite for correct positioning, such as low tonus (Lau, 2016:617).

True suckling is observed from 18 to 24 weeks *in utero*. True suckling refers to the characteristic backward (more pronounced) and forward movement of the tongue as it fills the oral cavity. This is needed for taste and rolling of the milk into the oesophagus and taste buds are already observed at seven weeks' gestation (Delaney & Arvedson, 2008:106). It is believed that sucking motions increase in frequency in the later months of foetal life (Delaney & Arvedson, 2008:106).

Non-nutritive sucking (NNS) is suggested by various scholars to precede feeds, and according to Lubbe (2018:5), this type of NNS stimulation will provide sucking opportunities for the preterm infant. This is encouraged because NNS holds numerous benefits for the preterm infant, e.g. it contributes to their physiological stability, protects them against aspiration and contributes to faster transition from tube to oral feeds. NNS is seen as stimulation for the oral muscles and sucking reflexes, providing opportunity for the neonate to practice sucking, swallowing and breathing.

Non-nutritive sucking (NNS) is observed at around 26 weeks of gestation; however, the rhythmic, organised pattern of sucking is only well established between 32 and 34 weeks (Thoyre *et al.*, 2003). Even though the sucking reflex is well developed between 28 and 30 weeks, the infant will get tired easily, as they are still physiologically immature. This is observed as they have not had opportunity to practice the sucking, swallowing and breathing sequence. Non-nutritive sucking is necessary to facilitate the development of the sucking reflex (Pinelli & Symington, 2005). This contributes to the preterm infant's feeding ability, as NNS provides opportunity to practice the suck-swallow and breathe cycle, in a safe and controlled environment (Harding, 2018; Noori *et al.*, 2018: e59657).

Proper oxygenation is needed for safe oral feeding (Andresen & Saugstad, 2020:2). The respiratory rate in infants should be between 40 and 60 breaths per minute or 1.0 to 1.5 seconds per cycle of inspiration and expiration (Andresen & Saugstad, 2020:2; Lau, 2016:617). The interruption of airflow during a swallow is between 0.35 and 0.7 seconds. Impairment in feeding can be seen if the frequency of swallows increases or tachypnoea (>60 breaths per minute) occurs (Lau, 2016:617).

A late preterm neonate born with an immature respiratory system, predisposes them to experience an even more significant feeding challenge than usual (Lau, 2016:617). Apnoea of prematurity (when a preterm baby pauses breathing for more than 15 to 20 seconds or pauses

breathing for less than 15 seconds but has a slow heart rate or low oxygen level) is also fairly common in premature newborns (Pitone, 2018).

Apnoeic episodes are more frequent during feeds, due to immaturity of coordination between breathing, sucking, and swallowing, stimulation of the laryngeal reflex, and diaphragmatic fatigue. Reduced lung volumes due to abdominal distension and increased work of breathing are also associated with an increase in apnoeic spells after feeds (Picone *et al.*, 2014: 102). During an oral feed, the neonate's minute ventilation decreases, expirations are prolonged, and inspirations are shortened. If these occur simultaneously, the balance of oxygen-carbon dioxide exchanges is threatened (Andresen & Saugstad, 2020:2). Consequently, some preterm infants may have difficulty tolerating oral feeding for a prolonged time (Lau, 2016:620). Taking into consideration that the moderate-to-late newborn has to coordinate these functions in their premature state, they are likely to have a risk of having feeding problems.

2.3 PREMATURITY RATES AND CHALLENGES

Globally, every year approximately 15 million neonates are born as premature infants (before 37 weeks gestation) (WHO, 2018). An estimate of 1 million deaths in 2015 were children under five years of age as a result of preterm birth complications (WHO, 2018). Three-quarters of these deaths could have been prevented (WHO, 2018). Furthermore, the WHO reports that in low- and middle-income countries, half of the infants born at or below 32 weeks gestation still die due to the absence of cost-effective care and well-skilled health care professionals (Chawanpaiboon *et al.*, 2019:37; Frey & Klebanoff, 2016).

To clarify what is meant by preterm infant: it is any infant born before 37 weeks of gestation (WHO, 2018:1). The preterm infant can be categorised into preterm birth, based on gestational age:

- extremely preterm (less than 28 weeks)
- very preterm (28 to 32 weeks)
- moderate to late preterm (32 to 37 weeks)

Although prematurity is considered a global problem, more than 60% of premature births occur in Africa and South Asia. As South Africa experiences so many premature infant births, improving complications of these premature infants should be a priority (Chawanpaiboon *et al.*, 2018:37; Steyn *et al.*, 2017:2).

Evidence emphasises that oral feeding issues are the prominent reasons for delayed hospital discharge in late preterm infants but have not attracted as much attention as with early preterm

infants, due to their apparent greater maturity and healthy clinical condition (Lau *et al.*, 2015:2; Premji *et al.*, 2017). Nevertheless, when compared with term infants, the late preterm infant experiences greater morbidity and mortality, longer hospital stays and increased incidences of hospital readmission due to feeding problems (Lau, 2015:3; Harron *et al.*, 2017:230). Premature births are one of the most common reasons for prolonged hospital admission in South Africa, with higher prematurity birth rates occurring in public sector hospitals (Lau, 2015:1; Parag & McKerrow, 2014:48).

The moderate-to-late preterm infant may experience delayed or inadequate transition to the extrauterine environment (Gallacher *et al.*, 2016:31). Careful consideration of knowledgeable staffing during this transition (1–12 hours after birth) for this population of infants is needed, as they are at risk for uncoordinated suck-swallow-respiration, dehydration and severe hyperbilirubinemia (Karnati *et al.*, 2020:39; Phillips *et al.*, 2013:5). In addition, preterm infants encounter numerous barriers to breastfeeding due to their immature physiological and neurodevelopmental systems (O’Sullivan *et al.*, 2015:3).

2.4 PREMATURE NEONATE’S STRUGGLE WITH FEEDING

During the first weeks of extrauterine life, infants experience transitions and changes as part of the developmental process. This transition from being a foetus to a newborn is the most intricate adaptation that occurs in human experience; it poses an even greater challenge to the newborn is exposed to this transition prematurely (Hillman *et al.*, 2012:771; Morton & Brodsky, 2016:396).

Premature infants have anatomical and physiological immaturity and low energy levels with high nutrient requirements for development and growth (Juvé-Udina *et al.*, 2015:87). The risk of mortality and morbidity is significantly increased in premature infants as compared to full-term infants. There are numerous complications from prematurity due to physiologic systems that are structurally and functionally immature (Bensley *et al.*, 2016:654). Clinicians often make the mistake of assuming the late preterm is similar to a full-term infant. It is a great injustice to the optimal care of the late preterm infant to think that they can be viewed as full-term infants (Adamkin, 2006:832; Currie *et al.*, 2018:6). Compared to the full-term neonate, the late preterm infant will have more difficulty feeding because of their immaturity. They may be sleepier and have less stamina, and have more difficulty with latching, sucking and swallowing (Crippa *et al.*, 2019:313; Gianni, *et al.*, 2015:2). The late preterm infant has difficulty maintaining body temperature, increased vulnerability to infection, more significant delays in bilirubin excretion and more respiratory instability than the full-term infant (Adamkin, 2006:832; McClure, 2013:11).

Immaturity combined with a high nutrient requirement as well as with the factors mentioned means that feeding could be a significant obstacle in growth and development. Their sleepiness and inability to suck vigorously is often misinterpreted as sepsis, leading to unnecessary separation and treatment (Adamkin, 2006:832; Pineda *et al.*, 2019:269). Premature infants have unique physiology: their physiology is immature, and they have an inability to maintain thermoregulation, hypotonia, respiratory and circulatory alterations (Stavis, 2019). Furthermore, their behavioural characteristics - easily irritability, hyperactivity, inability to sustain a quiet alert state - prone them to have difficulties in oral feeding (Askin & Wilson, 2009:315; Osilla *et al.*, 2021).

Thoyre *et al.* (2003:11) highlight that the suck-swallow-breathe coordination, the infant's interest in sucking and their behavioural and organisational skills could be decisive factors that facilitate a safe transition from tube-to-oral feeding. There are so many factors to take into consideration when assessing the moderate-to-late preterm neonate's transition from tube-to-oral feeding (Degenaar & Kritzinger, 2015:2). These factors could include their neurobehavioral maturation, behavioural stability and their ability to deal with the surrounding environment, motor development, as well as oral-motor development (Thoyre *et al.*, 2003:11; Lessen, 2011: 130).

All the preterm neonate's organ systems are involved in the extrauterine adaption process - the primary and immediate transformations are the establishment of breathing concurrently with changes in pressures and flows within the cardiovascular system. The preterm neonate must also speedily control its energy metabolism and thermoregulation (Hillman *et al.*, 2012: 774; Muelbert *et al.*, 2019:48). The preterm human is at a significant disadvantage for thermoregulation as brown adipose tissue has not developed in quantity and is not available to respond to cold stress. If their relatively small body surface area is combined with their inability to produce enough heat, preterm infants are predisposed to hypothermia as well (Hillman *et al.*, 2012:774).

The significant increase in cardiac output that the neonate experiences is closely associated with increased oxygen consumption. When this is combined with immaturely developed organs and systems, they are (potentially) unable to meet these increased demands (Andresen & Saugstad, 2020:2; Hillman *et al.*, 2012:774).

The preterm cardiovascular system is less physiologically and metabolically mature, resulting in an increased predisposition toward dysregulation and hemodynamic instability (Hillman *et al.*, 2012:774). It is often seen that preterm neonates exhibit increased vagal tone and risk for bradycardia. This results in a tachypnoea, poor feeding and poor growth. Furthermore, they are at high risk for neurologic insult and dysregulation. Apnoea of prematurity is related to

neurologic immaturity due to a blunted response of preterm infants to hypoxia and hypercarbia (Cartwright *et al.*, 2017:350; Hillman *et al.*, 2012:774). When the infant experiences respiratory and cardiovascular instability, there is bound to be low energy levels, making an energy-consuming task, such as feeding, challenging (Hillman *et al.*, 2012:774; Tan *et al.*, 2018:2).

Further to the structural or physiological immaturity, the moderate-to-late preterm infant's high nutrient requirement to grow depletes their already low energy levels. Evidence suggests that the preterm neonate has a higher fluid, nutrient and energy intake need (per kg body weight) compared to other patients (Fusch & Samiee-Zafarghandy, 2014:712; Randis, 2008:647). Compared to the term neonate, the preterm infant has a greater need for a carefully tailor-made feeding plan to suit their specific requirements to prevent imbalances and dehydration (Azuma & Maron, 2020:24; Gianni *et al.*, 2015:4; Randis, 2008:647).

Premature neonates have immature lungs that have difficulty to adequately ventilate due to a lack of surfactant (to decrease surface tension) production. Consequently, Transient Tachypnoea of the Newborn (TTN) is frequently observed in the moderate-to-late preterm neonate (Crippa *et al.*, 2019:320; Hillman *et al.*, 2012:774). This is a consequence of ineffective clearance of foetal lung fluid because of the decreased surfactant production. To resolve these problems, medical interventions such as mechanical ventilation are often needed, and oral feeds are delayed (Hillman *et al.*, 2012:776; Pineda *et al.*, 2019:276).

Premature infants may be unable to receive adequate direct oral nutrition after birth due to gastrointestinal tract immaturity with the imminent threat of developing necrotising enterocolitis, as well as muscular and neurological immaturity and hence, they require tube feeding (Adamkin, 2006:833; Fanaro, 2013). There is also a risk of hypoglycaemia, and fluctuations in blood sugar levels are often observed in premature infants during their adaptation to extrauterine life, showing a connection to their high nutrient requirements (Adamkin, 2006:833; Barbosa *et al.*, 2018:70).

The potential maternal (Diabetes, Hypertension or surgical intervention) and infant problems contribute to and impact the success of the late preterm neonate's feeding success. These problems elevate the risk for hypothermia, hypoglycaemia, excessive weight loss, slow weight gain, failure to thrive, prolonged artificial milk supplementation, exaggerated jaundice, kernicterus, dehydration, fever secondary to dehydration, re-hospitalisation and breastfeeding failure (Adamkin, 2006:834; Lapillonne *et al.*, 2019:261-263).

All these complications stemming from immature systems contribute to the significant feeding obstacle that stands in the way of successful transitioning. It is evident that this transition from

tube-to-oral feeding is not a reflex but rather a process that requires knowledgeable and skilled support.

2.5 AVAILABLE TOOLS AND GUIDELINES

A brief description of the available tools and assessment guidelines for infant feeding includes the Early Feeding Skills assessment tool, the Neonatal Oral-Motor Assessment Scale and the Preterm Oral Feeding Readiness Scale. Furthermore, feeding approaches such as Infant driven and Cue-based Feeding are briefly discussed.

2.5.1 The Early Feeding Skills (EFS) assessment tool for preterm infants

Thoyre *et al.* introduced the EFS in 2005 (Thoyre *et al.*, 2005). The EFS assessment tool is a checklist for assessing infant readiness for and tolerance of feeding and profiling the infant's developmental stage regarding specific feeding skills (Gennattasio *et al.*, 2015:100). This 36-item observational measure of oral feeding skills tool specifically assess the abilities to 'remain engaged in feeding, organise oral-motor functioning, coordinate swallowing with breathing and maintain physiologic stability (Gennattasio *et al.*, 2015:100). This instrument guides the healthcare professionals to observe the preterm neonate's (aged between birth and 52 weeks) early feeding skills in three key dimensions: the ability to organise oral-motor functioning, the ability to coordinate swallowing and the ability to maintain physiological stability (Thoyre *et al.*, 2003:10). The EFS can be used from the time of initiation of oral feeding through the maturation of the oral feeding skill and assess an infant's feeding skills according to the highest skill level he is capable of demonstrating.

2.5.2 The NOMAS (Neonatal Oral-Motor Assessment Scale)

The NOMAS (Neonatal Oral-Motor Assessment Scale) was developed in 1983 by Marjorie Meyer Palmer (Zarem *et al.*, 2013:2). The NOMAS assessment scale is intended for the evaluation of neonatal sucking patterns in preterm and term infants. The NOMAS provides an encompassing description of the infant's feeding patterns and enables the user to identify normal oral-motor patterns and differentiate disorganised from dysfunctional patterns (Zarem *et al.*, 2013:2). The NOMAS is used for pre-and post-test measurements to identify treatment effectiveness, to record developmental and changing patterns and to confirm oral-motor dysfunction or disorganisation in the poor feeder. This instrument can predict the developmental outcome at 24 months of age (Zarem *et al.*, 2013:2).

2.5.3 The Preterm Oral Feeding Readiness Scale (POFRAS)

The Preterm Oral Feeding Readiness Scale (POFRAS) assesses aspects of physiology, behaviour and non-nutritive sucking to establish the preterm infant's readiness to feed orally (Bolzan *et al.*, 2016:285). POFRAS is an instrument of easy and quick employment in clinical practice that considers various aspects, including the level of maturity, state of consciousness and oral-motor skills and was introduced by Fujinaga *et al.* (2018:96).

This scale consists of 5 (five) categories, including corrected Gestational Age, Behavioural Organisation (3 items), Oral Posture (2 items), Oral Reflexes (4 items) and Non-nutritive Sucking (8 items) with a total of 18 items to evaluate. Each item is scored from 0~2; the higher the score, the better prepared the infant is for oral feeding (Fujinaga *et al.*, 2018:96).

Evaluation of the readiness to feed orally based on this scale may not be sufficient to determine the success of oral feeding because other elements of feeding are also relevant, such as the coordination between the functions of sucking, swallowing and breathing skills of the preterm neonate. Furthermore, this scale is only useful for the first few minutes of a feed (Fujinaga *et al.*, 2018:96). It requires intensive training, and it could be time-consuming to fully understand and use the instrument for its application.

2.5.4 Infant-Driven Feeding Scales

Infant-Driven Feeding Scales were fathered by Ludwig and Waitzman to integrate a cue-based approach into feeding practices of premature infants in the NICU (Gelfer *et al.*, 2015:65). It encompasses scales on feeding readiness, quality of nipple feeding and caregiver techniques. The scales are used in unison to capture the infant's readiness to nipple feed, the infant's feeding abilities as well as techniques used by the caregiver who is feeding the infant (Gelfer *et al.*, 2015:65).

2.5.5 Cue-based Feeding Approach

The cue-based feeding approach attempts to standardise the approach to feeding of the preterm infant based on the infant's own ability to feed. It individualises care to include the neonate's readiness cues, disengagement cues as well as developmentally supportive feeding techniques (Shaker, 2013:405). Feeding practices are based on infant behaviours and cues that indicate their readiness to feed. This approach to feeding considers the infant's alert state, rooting, interest and competence in non-nutritive sucking or muscle tone (McClure, 2013:11). Cue-based feeding has been proven to decrease the transition time from tube-to-oral feed, to lower resource utilisation and to minimise practice variability, and it provides more consistent objective care of the premature neonate (Shaker, 2013:405).

The need for an objective, easy-to-use clinician's guide requiring little specialised training that is not time-consuming and can be used by all healthcare workers in NICU, irrespective of their primary profession, is evident. **Table 3-1** provides a summary of these available tools and guidelines.

2.6 CONCLUSIONS AND RECOMMENDATIONS FOR FURTHER RESEARCH AND PRACTICE

Various approaches regarding tube-to-oral transition are available. To provide for the feeding needs of the moderate-to-late premature infants, health care providers should aim to deliver the best available care. This can be achieved most effectively through decisions that combine research findings and clinical expertise. The challenge that clinicians most commonly face is to integrate all these sources and ensure evidence-based care in practice. No systematic review on the topic to identify critical elements that should be considered when planning/designing a tube-to-oral intervention has been found in a scoping review.

In the literature, various tools for assessing feeding effectiveness and quality could be found. However, these tools require extensive training, knowledge and skills to use and are aimed at healthcare professionals only. Since parents are an integral part of preterm infant care and should be included as primary caregiver (also in feeding), there seems to be a paucity in evidence that health care professionals can use with parents to make critical decisions when timing and implementing the transition from tube-to-oral feeding. Parental interventions in this process are also not well described, and therefore, it became evident that the elements to be considered when planning tube-to-oral transition should be identified to direct health care professional's decision-making and to provide a guideline that can be used to potentially assess newly developed feeding tools.

The identification of the opportune moment to introduce oral feeds for the preterm infant is not easy and founded on various elements, including a holistic approach to a complex challenge. There should be an evaluation of the infant's maturity factors, weight, activity level, respiratory status as well as sucking abilities (Askin & Wilson, 2014:345).

A clinical pathway will assist in supporting the implementation of clinical guidelines and protocols (Lawal *et al.*, 2016; Rotter *et al.*, 2019). The clinical pathway is needed to support clinical management and provide detailed guidance, to improve continuity and coordination of care of the feeding approach of the moderate-to-late preterm infant, especially in South Africa. Furthermore, fine-tuned support is needed to provide in the feeding needs for this group of infants. It will offer a decision-making tree format of the decisions to be made and the care to be provided.

2.7 SUMMARY

The main focus of this chapter was to provide a literature background to understand the research question. Through a thorough review of available research and articles, relevant sources were identified that could provide insight into the transition of tube-to-oral feeding from moderate-to-late preterm neonates. Chapter 3 presents the study conducted to answer the research question using the systematic review method.

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CHAPTER 3: ARTICLE

Introduction

Chapter 3 presents the results obtained from conducting the systematic review in an article format. The article has been written according to the author guidelines of *The Journal of Perinatal & Neonatal Nursing* (presented in **Table 3-1**). According to the guidelines, references must adhere to the *American Medical Association Manual of Style (AMA)* format.

The journal instructs the limitation of abbreviations and acronyms and avoid general statements. Page numbers must be visible in the upper right-hand corner. Furthermore, the manuscript length (excluding all references, tables, figures) should not exceed 16 pages. Identifying information (authors' names) should not be included in the manuscript.

Because the article has not yet been submitted for publication, no permission was required from the journal for including the article in this thesis.

Annexures, are cross-referenced in a table and added to this dissertation for the purposes of examination; however, according to author guidelines (**Annexure D**), only the cross-reference table will be used when submitting to the journal.

The journal gave a specific abstract word count to which the researcher had to adhere:

Abstract: 200 words (200 according to guidelines)

Title Page**Tube-to-oral transition pathway to guide feeding advancement in moderate-to-late preterm neonates: A systematic review**

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Abstract

Background: Oral feeding for preterm infants are a complex process and a delay in attaining full oral feedings can delay hospital discharge, considerably increase the cost of care and lead to unnecessary hospital readmissions. Moderate-to-late preterm neonates are often regarded as 'small newborns', and their clinical needs and conditions receive little attention.

Research aim/objectives: This study aimed to explore the best evidence to determine the factors to be considered when facilitating the transition process of tube-to-oral feeding in the moderate-to-late preterm neonate admitted to the neonatal ward.

Method: A six-step systematic review of literature was conducted to answer the review question. ScienceDirect, EBSCOhost, Elsevier, Scopus, AePublications electronic databases were scoped for relevant articles and then evaluated by using the PRISMA. Final articles were appraised using the John Hopkins and CASP tools.

Results: Factors that influence tube-to-oral transition include NNS (non-nutritive sucking), provider education and caregiver skills, cue-based-feeding, Kangaroo Mother Care (KMC), neurological maturity and state of behavioural organisation.

Conclusion: Results lean towards cue-based feeding as the most effective approach for a successful transition from tube-to-oral feeding; however, there seems to be a scarcity in the supporting evidence to design a pathway for the moderate-to-late preterm neonate.

Keywords: feeding assessment, feeding instrument, feeding scales, tube-to-oral transition, preterm feeding

Manuscript

Background

Successful transitioning from tube-to-oral feeding is a significant indicator of the moderate-to-late preterm (32 to 37 weeks gestation)¹ neonate's maturation progress, and only once they have mastered this transition can they safely be discharged.² Their ability to successfully attain this transition is emphasised because it remains a necessary skill for the neonate to sustain growth and development.²

Successful transitioning from tube-to-oral feedings encompasses the assimilation of complex physiological functions and mature neurobehavioral development.³ Moderate-to-late preterm neonates, start their feeding journey with an immature and neurologically compromised system.⁴

Over the last several years, research has provided extensive reporting and investigation into the very preterm neonate's (>28 to 32 weeks)¹ feeding challenges and transition to oral feeding.⁵ This is unfortunately not the same for the moderate-to-late preterm infant, whose clinical needs and conditions have enjoyed less attention until recent years³. Great insights and improvements in research have allowed for the understanding and enhancement of the moderate-to-late preterm neonate's clinical feeding needs.⁴

The full-term infant (>37 weeks gestation)¹ is born with skills to coordinate their suck, swallow and respiration, ready to oral feed. As there are so many similarities between the full-term and moderate-to-preterm neonate, there is often the misconception that these two categories of neonates have the same skills and function exactly the same.⁶ The moderate-to-late preterm neonate, agreeably similar to the full-term infant in some respects, still lack their physiological stability and neurodevelopmental progress, meaning that they must still learn and develop these skills.⁶

However, despite the vast amount of research available aimed to assist in improving the moderate-to-late preterm infant's quality of life, they still face a huge feeding challenge.^{6;7} This is none other than the prominent clinical challenge of successfully transitioning from tube-to-oral feeding in order to advance their oral feedings to achieve the best feeding outcome.⁷

The already vulnerable and compromised preterm neonate's ability to participate and master oral feeding behaviour is dependent on various factors. The complexity of these factors has directed researchers to investigate individualised assessment of a neonate's abilities.⁸⁻¹⁰

Research has reported on various strategies, tools and instruments for helping neonates to successfully transition from tube-to-oral feeding, with most of them focusing solely on single factors to achieve success.¹¹ These do not take into consideration the holistic physiological system of the neonate and only a few of these instruments are suitable for the moderate-to-late preterm neonate (see **Table 3-1**).

Table 3-1: Descriptions of the Neonatal Feeding Assessment Tools

Tools	EFS	IBFAT	LATCH	MBA	NOMAS	POFRAS
Authors	Thoyre, Shaker, & Pridham (2005)	Matthews (1988)	Jensen, Wallace, & Kelsay (1994)	Mulford (1992)	Braun & Palmer (1986)	Cannot find Authors
Purpose	Provides a means of identifying infant readiness for and tolerance of feedings well as profiling the infant's developmental stage regarding specific feeding skills.	Attempts to measure the neonate's feeding behaviours.	Identify and direct appropriate interventions needed to assist the mother/neonate dyads, with breastfeeding and to facilitate charting	Assess both maternal and neonatal breastfeeding behaviours.	Identify and quantify neonatal oral-motor behaviours.	Evaluate the influence of behavioural states on the readiness of the premature infant to initiate breastfeeding

Tools	EFS	IBFAT	LATCH	MBA	NOMAS	POFRAS
Mode	Bottle-feeding or Breastfeeding	Breastfeeding	Breastfeeding	Breastfeeding	Bottle-feeding or Breastfeeding	Not specified
Age group	All Preterm neonates	Term neonates	None specified	Term neonates	All Preterm and term neonates	All Premature neonates
Components	Oral feeding, readiness, oral feeding skills, oral feeding recovery.	Infant's state, readiness to feed, rooting, sucking, fixing and mother's satisfaction	Latch; Audibility; Swallowing; Type of nipple; Comfort and Help/holding.	Signalling, positioning, fixing, milk transfer, ending.	Oral-motor components: jaw movements, tongue movements	Corrected age, state of behavioural organization, oral posture, oral reflexes, non-nutritive sucking
Number of items	36	6	5	10	28	18
Method of scoring	Checklist	Assigns a score of 0, 1, 2, or 3 to five factors.	Rating 0-2 for each item	Five for maternal behaviours, five for infant behaviours.	Checklist to classify neonate's oral-motor patterns as normal, disorganized, or dysfunctional.	0 to 2 score for each item of each category
Range of Scoring	None mentioned	Scores range from 0 to 12.	0-10	0-10	None mentioned	0-36
Validation of the instrument	Validated	Validated	Validated	Validated	Validated	Validated
Person scoring	Occupational therapist, speech therapist and Nurses	Mother or Any trained Healthcare Professionals	Mother or Postnatal caregiver	Any trained Healthcare Professionals	Any trained Healthcare Professionals	Any trained Healthcare Professionals
Limitation	Specialised 3 day online and practical training course. Participant to pass a reliability test and a non-exclusive copyright licence to use the material must be	Specialised training needed.	Specialised training needed.	Specialised training needed.	Specialised training needed.	Specialised training needed.

Tools	EFS	IBFAT	LATCH	MBA	NOMAS	POFRAS
	obtained following the course.					
*EFS = Early Feeding Skills Assessment Tool; IBAT= Infant Breastfeeding Assessment Tool; MBA = Mother-Baby Assessment; NOMAS = Neonatal Oral-Motor Assessment Scale; POFRAS = Preterm Oral Feeding Readiness Assessment Scale						

The NICU's approach toward feeding can also be a determinant that predicts the moderate-to-late preterm neonate's ability for tube-to-oral transition, as the healthcare professionals have the responsibility to support and guide this vital task. Moreover, if there is a lack of skilled, trained or dedicated health care professionals, none of the above-mentioned tools or instruments will be understood or correctly implemented.¹²

The traditional, transitional feeding approach (volume-driven feeding) is still commonly practised in many NICUs as it is convenient for the clinician, but it disregards the infant's behavioural and feeding cues^{12;13}. Furthermore, it does not take into consideration the physiological coordination and development of the preterm neonate.^{12;13}

Various tools to assess different aspects of feeding in infants and preterm neonates are available, but none is guiding the healthcare professional through the decision-making process to determine the ideal time to transition from tube-to-oral in the preterm infant, with specific reference to the moderate-to-late preterm infant.

An evidence-based clinical pathway is required to support clinicians, even in the absence of extensive training and/or experience, to support the preterm infant in the tube-to-oral feeding transition process. Therefore, this systematic review aimed to explore the literature to develop a pathway, which healthcare professionals can use to guide their clinical decision-making when supporting moderate to late preterm neonates to transition from tube-to-oral feeding.

Aims and Objective

The review aimed to explore the literature to develop a pathway, which healthcare professionals can use to guide their clinical decision-making when supporting moderate-to-late preterm neonates with the transition from tube-to-oral feeding.

The objective was to explore the best available evidence by means of a systematic review to determine the factors to be considered when facilitating the transition process of tube-to-oral feeding in a moderate-to-late preterm neonate that is admitted to the neonatal ward.

Method

A systematic review (SR) was conducted to gain understanding and to identify the best available evidence concerning the factors needed to be considered for the successful transition from tube-to-oral feeding for the moderate-to-preterm neonate.

The six-phase systematic approach was followed.¹⁴

1. Developing a review question
2. Search Strategy and Sampling literature
3. Critical appraisal
4. Data extraction and Synthesis
5. Results and Conclusions
6. Presentation

The researcher considered the systematic review to be the best approach to answering the question, as this study required a rigorous and well-defined process to explore and work through the overwhelming amount of preterm neonate information on the topic.¹⁵

Phase one: Preparing a review question.

The PIOS format was utilised in this review to develop a clinical question to guide the research.¹⁶ This format included the elements: population, intervention explored, outcome to be addressed and study design¹⁶.

Table 3-2: PIOS question for this review

P	Population/participants	Premature neonates of gestation between 32-37 weeks
I	Intervention explored	Tube-to-oral feeding transition
O	Outcome to be addressed	Factors that influence the successful tube-to-oral transition of preterm neonates to formulate a clinical pathway.
S	Study design	All study designs

By using the PIOS format, the following review question was formulated:

What factors should be included in a clinical pathway to support the successful tube-to-oral transition process in moderate-to-late preterm neonates?

Phase two: Searching and sampling literature.

A systematic search process was carried out with the aim to gather all the relevant literature pertaining to the moderate-to-late preterm neonate and their transitioning from tube-to-oral feeding. The review question formulated in this phase was significant, as it served as a guideline that determined which studies had been included and which had been excluded.

A scoping review was conducted to determine the best keywords for this review and the keywords that were included were: premature feeding, premature birth, neonatal development, neurological development, feeding assessment, premature newborn, neonatal examinations, tube feeding, enteral feeding of preterm neonates, premature feeding guidelines, motor development in preterm neonates, sucking ability in preterm neonates, feeding problems in preterm neonates, neonate-driven feeding, cue-based feeding, volume-

driven feeding, preterm feeding: guide, protocol, pathway, algorithm, guideline, advancement, interventions, feeding instrument, feeding scales.

Combining the below- mentioned criteria (from screening phase) and by using the keywords selected, specific electronic databases (ScienceDirect, EBSCOhost, Elsevier, Scopus, AePublications), University catalogues (theses and dissertations), Google (academic and non-academic sources) and Cochrane library (systematic reviews) were searched. The output was filtered in order to identify the most relevant articles related to the moderate-to-late preterm neonate and the transition from tube-to-oral feeding. A cross-check of data was done by using Google Scholar to ensure that no applicable documents were missed.

Literature screening was done by an independent reviewer and on various levels, starting with title and topic, followed by the abstract and then full-text reviews of selected documents.

Inclusion and Exclusion Criteria

During the search phase, both the inclusion as well as exclusion criteria were considered.

The inclusion criteria that were implemented identified the most suitable studies in a consistent, reliable, uniform and objective manner (**Table 3-3**)¹⁴. The exclusion criteria (**Table 3-4**) ensured that the irrelevant articles to this study, were excluded.

Table 3-3: Inclusion criteria

INCLUSION CRITERIA	JUSTIFICATIONS
<ol style="list-style-type: none"> 1. All study designs to be included. Studies, which used qualitative, quantitative or mixed methodologies. 2. All types of publications in either Afrikaans or English were considered for inclusion. 3. Titles and summaries of relevant studies reported in other languages were reviewed, to determine their relevance for inclusion in the study. 4. Theses and dissertations were included. 5. Studies addressing the review question in a comprehensive manner were included. 6. Only studies published between 2007 and 2020 were included. 	<ol style="list-style-type: none"> 1. To encompass comprehensive perspectives within the study. 2. The researcher and co-reviewer are competent in both languages – ensuring an accurate understanding of publications and improving the quality of the systematic review. 3. To decrease limitations of information bias. 4. To decrease limitations of information bias. 5. To ensure the validity of the study content. 6. To ensure relevance and accuracy of the most recent evidence: literature before this time could be outdated, and newer scientific evidence is available. The practice of moving from volume-driven to infant-driven/ cue-

INCLUSION CRITERIA	JUSTIFICATIONS
	based feeding was first reported in literature during 2007.

Table 3-4: Exclusion criteria

EXCLUSION CRITERIA	JUSTIFICATIONS
<ol style="list-style-type: none"> 1. Duplicated studies, only the most recent version of the study was included. 2. Studies with little or no relevance pertaining to the moderate-to-late preterm neonate's feeding. 3. Textbooks were excluded. 	<ol style="list-style-type: none"> 1. To ensure a valid and reliable pool of studies for inclusion in the systematic review. 2. To ensure that the study remains focused on the research question. 3. Since they contain secondary data and could contain outdated data.

Recording the Literature Search

In order to ensure that clear records of all the studies were kept, the articles were uploaded to a password protected Dropbox cloud-based storage system. This ensured secure and efficient remote accessibility.

The researcher (and an independent reviewer) then reviewed the document abstracts to ensure that the mentioned criteria were met and bias was eliminated (**Annexure E**). During the final stage of selecting the studies, both reviewers accepted the eligible studies based on the inclusion and exclusion criteria.^{17;18}

The Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) flow chart (refer to **Figure 3-1**) was used to capture the literature screening process.¹⁹

Initially, 158 articles were identified by using the key words in a search of the electronic databases. Duplicates were removed according to PRISMA on next page – 156 articles remained. Through the process of elimination (reading titles and abstracts), only of 20 articles met the inclusion criteria and were included in the critical appraisal. Both the researcher and independent reviewer agreed on the articles for inclusion.

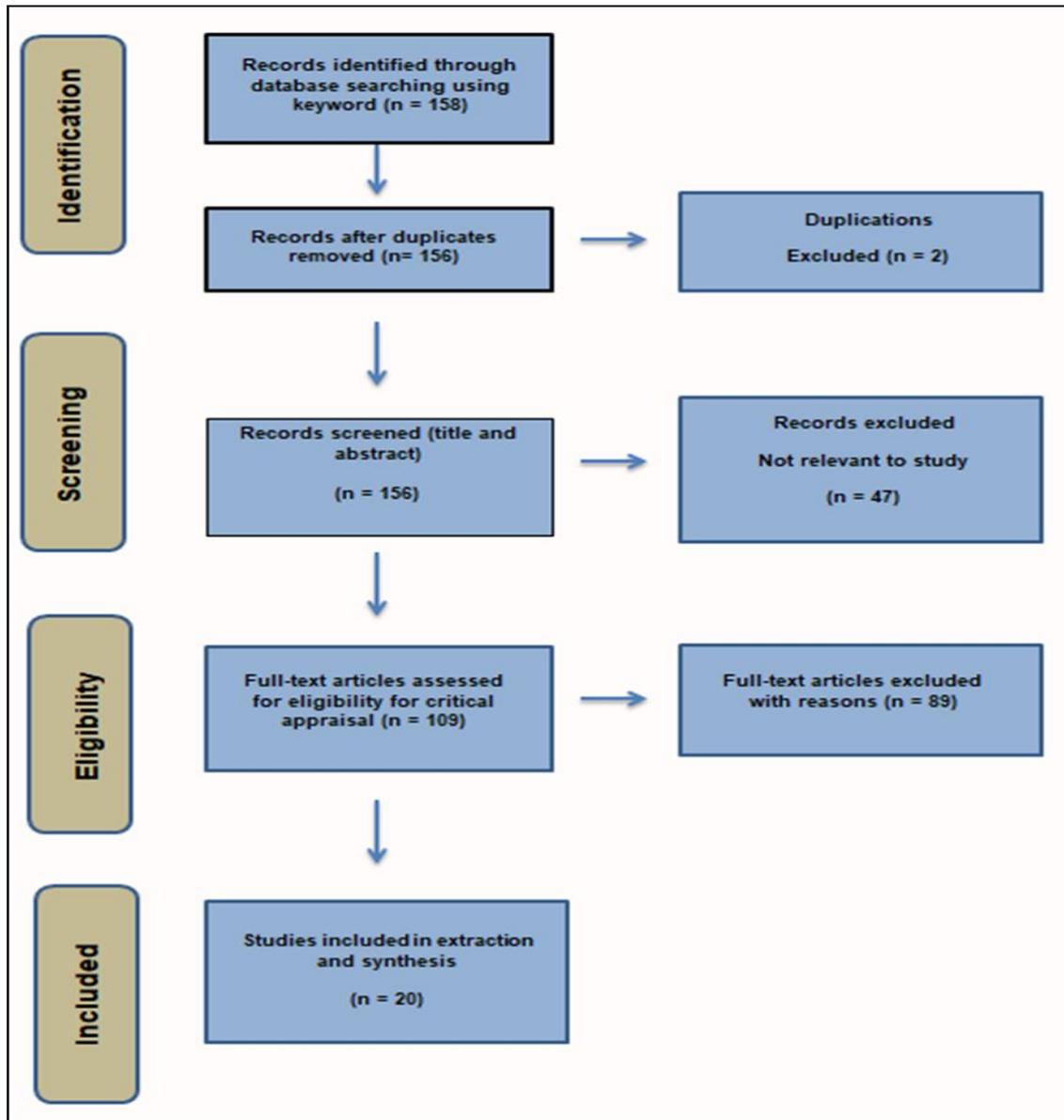


Figure 3-1: Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) flow chart for articles related to tube-to-oral transitioning of the moderate-to-late preterm neonate.¹⁹

Phase three: Critical appraisal

Within this phase, an organised approach to weighing rigour and characteristics of each study was followed. The validity of the methods and results were checked, the quality of each study, as well as their usefulness in practice, was determined.¹⁴

Two critical appraisal instruments were used to appraise the studies, based on their designs, namely The Critical Appraisal Skills Programme (CASP) instrument (**Annexure A**) and the Johns Hopkins nursing evidence-based practice appraisal tool (**Annexure B**). These instruments were selected based on their ability to provide a framework in which nursing-related data could be appraised and to ensure that each article addressed the research focus in an explicit and transparent way.

Critical appraisal instruments, the CASP instrument and John Hopkins appraisal tool, used in this study have almost the same approach in three steps: 1) enquiring whether the study is valid, 2) deciding whether the study is unbiased by evaluating its methodological quality and 3) questioning the results of the article. If it was found that the study is valid, a score was allocated to indicate clinical significance. The last step involved deciding if the evidence applied to the research question.

The CASP checklists consists of 10 (qualitative checklist & Systematic Reviews) or 11 questions (Randomised Control Trial Standard checklist) (example of qualitative checklist in **Annexure A**) to be answered to appraise an article based on the type of study. One point was awarded for a YES answer and zero for a NO answer. The total score was added at the end of the critical appraisal, meaning that the highest possible score was 10 or 11 respectively. The other CASP checklists can be accessed on the following link: <https://casp-uk.net/casp-tools-checklists/>

A higher score indicated that an article and its content was deemed as reliable, valuable and relevant to the study. From the articles that were critically appraised, there were 6 systematic reviews, 2 randomised control trials, 7 qualitative research design, 4 quantitative research design and 1 time Series study. It was found that 15 articles scored 8 points, while the remaining 5 scored 9 points. This indicated that these articles were of high methodological quality and could therefore be included in the next step – data synthesis.

The Johns Hopkins score allocation was done according to a predetermined scoring guideline as seen in **Annexure B**. A quality rating and level of evidence score was awarded to each article. A higher quality rating and level of evidence is needed for articles to be thought of as valuable and reliable research.

As seen in **Table 3-5**, the 20 articles scored as follows:

1. 10 articles scored a B quality rating on an evidence level of 3
2. 7 articles scored a B quality rating on an evidence level of 2
3. 1 article scored a B quality rating on an evidence level of 1
4. 1 article scored an A quality rating on an evidence level of 3
5. 1 article scored an A quality rating on an evidence level of 1

The findings were summarised by means of a data summary table (see **Table 3-5**).

Table 3-5: Critical Appraisal Outcome

	Article	Author	Year	CASP tool	Johns Hopkins Critical Appraisal instrument	
				Score	Quality Rating of Evidence	Level of evidence
1	Timing introduction and transition to oral feeding in preterm infants: current trends and practice.	Breton & Steinwender	2008	8	B	3
2	Establishing breastfeeding with the late preterm infant in NICU.	Briere <i>et al.</i>	2015	8	B	3
3	A continuous quality improvement project to implement infant-driven feeding as a standard of practice in the newborn/infant Intensive Care Unit.	Chrupcala <i>et al.</i>	2015	8	B	2
4	From tube to breast: the bridging role of semi-	Davanzo <i>et al.</i>	2014	9	B	3

	Article	Author	Year	CASP tool	Johns Hopkins Critical Appraisal instrument	
				Score	Quality Rating of Evidence	Level of evidence
	demand breastfeeding					
5	Readiness for oral feeding and oral motor function in preterm infants.	Yamamoto <i>et al.</i>	2017	N/A	B	2
6	Behavioral state and the premature's readiness performance to begin oral feeding	Fujinaga <i>et al.</i> ,	2018	8	B	2
7	Infant driven feeding for preterm infants: learning through experience.	Gelfer, McCarthy, & Spruill	2015	8	B	2
8	Preterm newborn readiness for oral feeding: systematic review and meta-analysis.	Lima <i>et al.</i> ,	2014	8	B	3
9	Clinicians guide for cue-based transition to oral feeding in preterm infants: an easy-to-use clinical guide.	Welma Lubbe	2018	8	A	3
10	The effects of an early oral stimulation program on oral feeding of preterm infants.	Lyu <i>et al.</i>	2014	8	A	1
11	Ad libitum or demand/semi-demand feeding versus scheduled interval feeding for preterm infant (review).	McCormick Tosh & McGuire	2010	8	B	3
12	Characteristics of the transition technique from enteral tube feeding to breastfeeding in preterm newborns.	Medeiros <i>et al.</i>	2011	N/A	B	3
13	Association between readiness for oral feeding and feeding performance in preterm neonates.	Prade, <i>et al.</i>	2016	9	B	3
14	Oral feeding performance in premature infants.	Otto & De Almeida	2017	N/A	B	2
15	Effect of four	Pickler <i>et al.</i>	2015	8	B	1

	Article	Author	Year	CASP tool	Johns Hopkins Critical Appraisal instrument	
				Score	Quality Rating of Evidence	Level of evidence
	approaches to oral feeding progression on clinical outcomes in preterm infants.					
16	Contributing to content validity of the infant-driven feeding scales through Delphi surveys	Waitzman, Ludwig & Nelson	2014	9	B	2
17	Evaluation of orofacial characteristics and breastfeeding in preterm newborns before hospital discharge.	Castelli & Almeida	2015	N/A	B	3
18	Premature: growth and its relation to oral skills.	Vargas <i>et al.</i>	2015	8	B	2
19	A critical review of interventions supporting transition from gavage to direct breastfeeding in hospitalised preterm infants.	Ziadi, Héon & Aita	2016	9	B	3
20	Transition from tube to full oral feeding (breast of bottle) – a cue-based developmental approach.	White & Parnell	2013	N/A	B	3

Phase four: Data extraction and synthesis.

During data extraction and synthesis, a data extraction table (**Table 3-6 and Annexure C**) was constructed. The table presents each article's author, country, study design, factors/items that were included in a pathway, as well as main conclusions. Synthesis was then done by clustering and interrelating ideas from several sources to form a new and more comprehensive picture of what information is available on a subject.¹⁶

Thematic analysis was used to identify the recurring elements or factors. The steps followed for this data syntheses was as follows: Step 1: becoming familiar with the data. This includes

reading through all the articles. In this phase, notes are made on understanding and possible themes that stand out.¹⁷

Step 2 includes generating/identifying initial codes. Data is organised in a meaningful and systematic way and each segment of data that was relevant to or captured something interesting about our research question. In the next step, there is a clear search for themes.¹⁷ A theme is defined as a pattern that captures something significant or interesting about the data and/or research question. At the end of this step, the codes are organised into broader themes that seemed to say something specific about this research question.¹⁷

StepPhase 4 is reviewing the themes. During this step, the preliminary themes that were identified in the previous phase are reviewed, modified and developed. During step 5, the themes are defined: this is the final refinement of the themes, and the aim is to determine the core/essence of what each theme is about. The final step, writing-up refers to the discussion of the results.¹⁷

Results

Phase five: Results and conclusions

An analysis of the critically appraised data was done to determine the factors needed in a clinical pathway to guide the decision-making process for the tube-to-oral feeding transition for the moderate-to-late preterm neonate. Consequently, the various gaps and limitations in the existing knowledge were identified, and recommendations for further studies could be made.

The consistent factors that were identified from the data evaluation:

1. Neurological maturity
2. State of behavioural organisation
3. Cue-based feeding
4. Provider education and skills

5. Non-nutritive Sucking (NNS)
6. Kangaroo Mother Care (KMC)

These factors are presented in **Table 3-6** and **Annexure C** and discussed in more depth in the section that follows.

Table 3-6: Data Extraction and Synthesis Table (Part 1)

Title and Author		Main findings	Factors identified from Synthesis					
			Neurological Maturity	State of behavioural organisation	Cue-based feeding	Provider education and skills	Non-nutritive Suckling (NNS)	Kangaroo Mother Care (KMC)
1	Timing introduction and transition to oral feeding in preterm infants: current trends and practice (Breton & Steinwender, 2008)	<ul style="list-style-type: none"> • Early introduction, rapid transition to oral feeds in healthy preterm infants. • Consider preterm characteristics. • Developmentally appropriate feeding techniques advised. • Early introduction of oral feeds- timed and responds to infant behaviour/state. • Infants unable to fully transition for medical reasons still benefit from systematic approach to the introduction and advancement of oral feeds. • Evidence for cue-based feeding advancement. • Evidence and clinical experience -less stable medically infants use developmentally and cue-based oral feeding. 	X	X	X	X	X	
2	Establishing breastfeeding with the late preterm infant in NICU (Briere <i>et al.</i> , 2015)	<ul style="list-style-type: none"> • Breastfeeding preterm neonates are challenging. • Preterm neonates developmentally disadvantaged compared to term infants. • HCP practice consistent care giving and maintain best evidence knowledge of challenges. • Formalised methods for preterm feeding. 	X		X	X		X

Title and Author		Main findings	Factors identified from Synthesis					
			Neurological Maturity	State of behavioural organisation	Cue-based feeding	Provider education and skills	Non-nutritive Suckling (NNS)	Kangaroo Mother Care (KMC)
		<ul style="list-style-type: none"> Physiological assessment is pertinent. Direct breastfeeding should be the first oral feeding offered. HCP to provide education and support. 						
3	A continuous quality improvement project to implement infant-driven feeding as a standard of practice in the newborn/infant Intensive Care Unit (Chrupcala <i>et al.</i> , 2015)	<ul style="list-style-type: none"> Nurses play vital role in the care of neonates. Infants on cue-based feeding become successful oral feeders and safely discharged home regardless of gestational age or diagnosis. HCP from all disciplines - education and empowerment families to provide competent, evidence-based care. Feeding plan should be evaluated on daily basis, changes to be made after assessment findings. Family members should take an active role in feeding. 	X		X	X	X	X
4	From tube to breast: the bridging role of semi-demand breastfeeding (Davanzo <i>et al.</i> , 2014).	<ul style="list-style-type: none"> Developmental stage Neurological maturity KMC Awake/sleep stage 	X	X				X
5	Readiness for oral feeding and oral motor function in preterm infants (Yamamoto <i>et al.</i> , 2017).	<ul style="list-style-type: none"> Preterm newborns with normal oral motor functioning – could feed orally. Oral motor dysfunction - not ready to initiate the first oral 	X	X	X	X	X	

Title and Author		Main findings	Factors identified from Synthesis					
			Neurological Maturity	State of behavioural organisation	Cue-based feeding	Provider education and skills	Non-nutritive Suckling (NNS)	Kangaroo Mother Care (KMC)
		feeding.						
6	Behavioral state and the premature's readiness performance to begin oral feeding (Fujinaga <i>et al.</i> , 2018)	<ul style="list-style-type: none"> Behavioral state influences the performance of the readiness of premature infants to start oral feeding. Behavioral state must be taken into account because in the alert state they will be able to feed themselves with greater effectiveness. 		X	X		X	
7	Infant driven feeding for preterm infants: learning through experience (Gelfer, McCarthy, & Spruill, 2015)	<ul style="list-style-type: none"> An interdisciplinary team approach is needed for different perspectives, knowledge and expertise. Involving parents early helped with the transition. Culture change is a process. By allowing time for staff to adjust, as well as continue educational programs, we are able to transition to a more developmentally appropriate model of care. Ownership of the feeding process using scales develops nurse autonomy and fosters assertiveness when advocating for infants. Cue based feeding empowers nurses to make decisions that will help infants achieve full oral feedings faster. 	X		X	X		
8	Preterm newborn readiness for oral feeding: systematic review and meta-analysis (Lima <i>et al.</i> , 2014)	<ul style="list-style-type: none"> Important to use standardised evaluations for the aid of health care teams in determining the appropriate and safe moment for neonate. Stimulation of the motor and oral sensorial system for the transition period to full oral feeding - decrease of the 	X			X	X	

Title and Author		Main findings	Factors identified from Synthesis					
			Neurological Maturity	State of behavioural organisation	Cue-based feeding	Provider education and skills	Non-nutritive Suckling (NNS)	Kangaroo Mother Care (KMC)
		<p>hospital time of permanence and costs.</p> <ul style="list-style-type: none"> Further and stronger research is needed. 						
9	Clinicians guide for cue-based transition to oral feeding in preterm infants: an easy-to-use clinical guide (Welma Lubbe, 2018)	<ul style="list-style-type: none"> Transition based on infant maturity - successful oral feeding with less energy expenditure, higher rates of success and even better parental functioning. Clear, evidence-based guidelines should be available for the healthcare professional/care giver to enable effective evaluation of maturity and readiness for oral feeding. Clear recommendations to HCP to support transition process for optimal feeding success. Cue-based feeding provides the best. outcome and supports transition to independent oral feeding in the preterm infant very well. 	X		X	X	X	X
10	The effects of an early oral stimulation program on oral feeding of preterm infants (Lyu <i>et al.</i> , 2014)	<ul style="list-style-type: none"> Oral stimulation can shorten the transition time from introduction of oral feeding to full oral feeding and improve oral feeding performance. Pre-feeding oral stimulation is safe, simple and beneficial to infants. 	X				X	
11	Ad libitum or demand/semi-demand feeding versus scheduled interval feeding for preterm infant (review) (McCormick, Tosh & McGuire, 2010)	<ul style="list-style-type: none"> Current data is not sufficient to determine whether feeding <i>ad libitum</i> or demand/semi demand versus feeding prescribed volumes at scheduled intervals improves outcomes for preterm infants. Limited evidence exists that feeding preterm infants with 	X		X		X	

Title and Author		Main findings	Factors identified from Synthesis					
			Neurological Maturity	State of behavioural organisation	Cue-based feeding	Provider education and skills	Non-nutritive Suckling (NNS)	Kangaroo Mother Care (KMC)
		<p><i>ad libitum</i> or demand/semi-demand regimens allows earlier attainment of full oral feeding and earlier hospital discharge.</p> <ul style="list-style-type: none"> There is a need for a large pragmatic RCT to assess whether an <i>ad libitum</i> or demand/semi-demand feeding regimen is beneficial. 						
12	Characteristics of the transition technique from enteral tube feeding to breastfeeding in preterm newborns (Medeiros <i>et al.</i> , 2011)	<ul style="list-style-type: none"> The preterm new-born's weaning from enteral feeding directly to breastfeeding is possible. Further research is needed – regarding weaning directly from enteral feeding to breastfeeding in newborns, with KMC. Breastfeeding is a practical and positive way for the mother to deal with premature birth, best and safest feeding method. 	X	X		X	X	X
13	Association between readiness for oral feeding and feeding performance in preterm neonates (Prade, <i>et al.</i> , 2016)	<ul style="list-style-type: none"> The PROFAS contributed to the prognosis of oral feeding outcomes in premature newborn younger than 34 weeks of gestational age. However, it does not replace the need for an assessment of swallowing mechanics prior to the onset of oral feeding. 	X	X	X		X	X
14	Oral feeding performance in premature infants (Otto & De Almeida, 2017)	<ul style="list-style-type: none"> Intervention with swallowing training allowed good performance in oral feeding skills and helps them to start oral feeding and obtaining exclusive oral feeding in a short period, with oral readiness. 	X				X	

Title and Author		Main findings	Factors identified from Synthesis					
			Neurological Maturity	State of behavioural organisation	Cue-based feeding	Provider education and skills	Non-nutritive Suckling (NNS)	Kangaroo Mother Care (KMC)
		<ul style="list-style-type: none"> Although swallowing exercises have shown good results, more research is still needed. 						
15	Effect of four approaches to oral feeding progression on clinical outcomes in preterm infants (Pickler <i>et al.</i> , 2015)	<ul style="list-style-type: none"> Recommendation that the start of oral feedings occurs when infants are showing signs of physiological and behavioural readiness, physiologic stability, wakefulness at feeding times and interest and ability to suck on a nipple. Once oral feedings are started, infants must be assessed for readiness at every scheduled feeding including observation of physiologic stability and wakefulness or ease with which the infant achieves a stable awake state when handled. If the infant is awake at a scheduled feeding time and is not physiologically distressed, the infant should be offered the opportunity to feed orally. Opportunity to feed orally, regardless of the volume taken orally, speeds the transition to full oral feeding and to hospital discharge. 	X	X	X		X	
16	Contributing to content validity of the infant-driven feeding scales through Delphi surveys (Waitzman, Ludwig & Nelson, 2014)	<ul style="list-style-type: none"> Recommendation that IDF be used in combination with the infant's cues- specialised comprehensive education and family inclusion is important to infant feeding success. 	X		X	X	X	
17	Evaluation of orofacial characteristics and breastfeeding in preterm newborns before hospital	<ul style="list-style-type: none"> Premature newborns with an alert state of consciousness showed better positioning during breastfeeding than preterm neonate in a mild somnolent 	X		X		X	

Title and Author		Main findings	Factors identified from Synthesis					
			Neurological Maturity	State of behavioural organisation	Cue-based feeding	Provider education and skills	Non-nutritive Suckling (NNS)	Kangaroo Mother Care (KMC)
	discharge (Castelli & Almeida, 2015)	<p>state.</p> <ul style="list-style-type: none"> • Tongue movement and suction force in non-nutritive sucking were appropriate to assist with oral feeding. • Limiting factors such as reduced sample size and possible selection bias, due to the convenience sample used. • Speech therapists must be part of the multiprofessional teams, due to their expertise in the evaluation of the orofacial sensori-motor system and breastfeeding. 						
18	Premature: growth and its relation to oral skills (Vargas <i>et al.</i> , 2015)	<ul style="list-style-type: none"> • Preterm infant oral skill significantly correlates with transition time from tube to oral feeding. • Preterm infants with higher levels of oral skill changed in less than half of the time if compared to the others. • Earlier discharge from hospital. • NNS improved oral skill and consequently had weight evolution in the feeding transition period. 	X		X		X	
19	A critical review of interventions supporting transition from gavage to direct breastfeeding in hospitalised preterm infants (Ziadi, Héon & Aita, 2016)	<ul style="list-style-type: none"> • Aim: identify and analyse interventions that promote the transition from gavage to direct breastfeeding in preterm infants hospitalised in the NICU. • Positive benefits for preterm infants during the transition from gavage to direct breastfeeding - higher breastfeeding rates, an acceleration of the transition to direct breastfeeding and earlier discharge. • NNS and oral stimulation and the promotion of direct 		X	X	X		X

Title and Author		Main findings	Factors identified from Synthesis					
			Neurological Maturity	State of behavioural organisation	Cue-based feeding	Provider education and skills	Non-nutritive Suckling (NNS)	Kangaroo Mother Care (KMC)
		breastfeeding and avoidance of bottles assist with the transition.						
20	Transition from tube to full oral feeding (breast of bottle) – a cue-based developmental approach (White & Parnell, 2013)	<ul style="list-style-type: none"> The aim of this project was to introduce an evidence-based approach to oral feeding development based on an infant's emerging behavioural cues. Evidence suggests that doing so benefits the infant from a neuro-developmental point of view over the long term. Reduces the risk of feeding difficulties and future feeding aversions caused by negative oral feeding experiences. Cue-based approach to oral feeding would be beneficial as the norm. It involves parents more actively in the recognition of their baby's emerging feeding skills and aims to move parents away from regarding feeding as a task with time and volume limits and instead to see feeding as occasions to nurture their baby. Despite the longer-term advantages of a cue-based approach, the most significant priority for senior medical and nursing staff remains in getting the infants home as soon as possible. This aim is riven by the need to reduce the duration of separation between mothers and their infants as well as the costs of hospital stay and the need to make room for new admissions. 		X	X	X		X

Discussion

Researchers agree that breastfeeding or oral feeding remains a challenge for the moderate-to-late preterm infant.²²⁻²⁴ When compared (as it often happens) to the full-term infant, these neonates can present as developmentally disadvantaged.²² It is therefore vital that methods to transition from tube-to-oral feeding are easily understandable for the staff within the NICU, formalised and practical.²²⁻²⁵ The conventional NICU setting and traditional transition feeding methods (such as volume driven feeding) currently implemented, poses various barriers to the preterm neonate to obtain successful transition and need to be re-evaluated and preferably changed.^{24;25}

Furthermore, research has shown that the moderate-to-late preterm neonate's feeding plans should be re-evaluated on a daily basis.²³ Continuous adjustment is necessary to suit the neonate's physiological status and align with their observed behavioural state and stress cues.^{23;25;26} Taking into consideration the holistic neonate, NICU culture should also adapt to the neonate's developmental needs; include the mother and father, or the primary external caregiver and empower them to take an active role in the neonate's feeding to ensure long term success.²² Empowering the NICU staff members with knowledge and skills, could help with empowering the family members to take ownership of the moderate-to-late preterm infant's feeding, and ultimately ensure successful transitioning from tube-to-oral feeding.

In line with the current research, this study proved that various factors must be taken into consideration when a moderate-to-late preterm neonate is transitioned from tube-to-oral feeds. There was found that factors such as neurological maturity, state of behavioural organisation, cue-based feeding, provider education and skills and NNS as well as Kangaroo Mother Care play a role in this aforementioned transitioning. These factors should be taken into consideration when this category preterm neonate is assessed and supported to full oral feeds.

When family members are empowered and included in decision making regarding the care and feeding of the preterm neonate, they become part of the interdisciplinary team within the NICU

setting.²⁴ Different perspectives, knowledge and expertise would assist in bringing about changes in the best interest of the preterm neonate. Subject matter experts and parents in the same team would create a task force to inspire clinical interventions explicitly for the vulnerable neonate.²⁵

Clinically, factors related to the successful tube-to-oral feeding transition (explained in the study) cannot be stagnant or based solely on traditional opinion, such as gestational age in isolation. The age of the premature neonate will merely guide the health care professional on the possible physiological capabilities of the neonate.^{24;27} Researchers recommend that neonates can start as early as 34 weeks with oral feeds, provided that they are neurologically mature, have mastered the suck-swallow-breathe (SSB) co-ordination and display behavioural cues for oral feeding readiness.^{26;27} While in clinical practice, the medical doctor or specialist base readiness on weight. According to the existing body of knowledge available on premature neonates, physiologically stable preterm infants generally transition from tube-to-oral feedings at 32–34 weeks gestational age.^{28;29}

The factors identified are discussed next.

Neurological maturity

Infants born preterm¹ have immature organ systems that often need additional support to survive.²⁸ Naturally, the moderate-to-late preterm neonate's neurological system will also be immature and not function optimally.²⁸

The intense skills and abilities needed, such as coordination of sucking, breathing and sucking, for the transitioning from tube-to-oral feeding in the preterm neonate should thus be depended on the infant's neurological maturity.^{28;29} When this factor is considered during their transition to oral feeding, it may result in more successful oral feeding, with less energy expenditure, higher rates of success and even better parental functioning.²⁹

Prior to any tube-to-oral feeding advancement, physiological and neurological maturity needs to be observed as these systems' maturity level will guide the neonate's ability to transition to oral feeding.²⁹ By performing this assessment and being guided by the results, the feeding transition would be safer and beneficial not only for the neonate's current condition, but also for long term development.^{21:29} Furthermore, once the oral feeding starts, the neonate has to be assessed for readiness at every scheduled feeding – this includes observation of physiologic stability and wakefulness or ease with which the infant achieves a stable awake state when handled.²⁶

Based on this observed and assessed neurological maturity, researchers recommends that the health care professional guide parents to start with the oral feeding once the preterm neonate is exhibiting signs of physiological and behavioural readiness.^{26;29} Clear, evidence-based guidelines are needed to guide preterm neonatal care. This will enable effective assessment of the neonate's maturity and readiness for oral feeding.²⁹ Literature draws more reference to the maturity development and assessment of the preterm infant in general and research could not be applied to the moderate-to-late neonate.

Even if the preterm infant is unable to fully transition for medical reasons, they can still benefit from a systematic approach to the early introduction and advancement of oral feeds, based on their neurological maturity.³⁰

State of behavioural organisation

If the moderate-to-late preterm neonate is not neurologically mature enough to manage the transitional task to oral feeds, they will not have a good behavioural organisation. There needs to be a holistic approach and careful consideration of a neonate's characteristics, when facilitating tube-to-oral feeding transitioning. Factors including neurological maturity (feeding readiness cues) and behaviour organisation is crucial to avoid adverse effects such as aspiration, airway obstruction and increased oxygen requirements.^{30;31}

The neonate's behavioural state influences their performance and readiness to initiate oral feeding. This becomes important at the time of oral feed introduction. The preterm neonate would be able to feed with greater effectiveness while they are in the alert state.³¹

This means that they must show clear signs of wakefulness at feeding times.²⁶ Once oral feeding sessions start, the neonate's readiness at every scheduled feeding must be assessed. This includes observing their wakefulness and ease with which the neonate achieves a stable awake state when handled.²⁶ Nurses are encouraged to not attempt a feeding with a preterm neonate when they show disinterest, or they do not have the necessary energy or ideal behavioural state required for feeding.^{25; 26}

A review included in the study, had fair evidence to suggest that strategies to improve the preterm neonate's state organisation and enhanced maturation of skills resulted in successful attainment of full oral feeding.^{21;30} The 2015 study by Chrupcala et al. provides support that the premature neonate should be in the alert, quiet state and consideration to their feeding readiness and feeding cues is of the utmost importance, as this will avoid adverse effects, such as aspiration, airway obstruction, increased oxygen requirements and weight loss. When preterm neonates are afforded the optimal opportunity to transition from tube-to-oral feed, based in their correct behavioural state and neurodevelopmental cues, they would achieve successful transitioning.^{21; 30}

Authors such as Breton & Steinwender's (2008) research evidence, combined with their and Davanzo et al. (2014) clinical experience, suggested that even less medically stable preterm neonates could likely benefit from developmental maturity and cue-based oral feed.^{22;30}

Furthermore, authors such as Lubbe, Breton et al., Yamamoto et al. and McCormick et al., all agree that a guideline for these less stable preterm neonates are required to assist clinicians in supporting their introduction and attainment of oral breast or bottle feeding.^{28;30;35;46}

Literature also recommend that these types of guidelines would be invaluable to facilitate inter-professional practice and decision making to provide a safe, tailor-made and successful oral

feeding experience for the preterm infant. As observed in the results, the behavioural state is capable of significantly influencing the transitioning and attaining oral feeding, corroborating data already found in the literature^{30;31;34}

The limitation to Breton & Steinwender's is that they did not focus on the moderate-to-late preterm infant, as they generalised for the complete preterm neonate population and they cautioned against applying the results to medically challenged preterm neonates. Their research lacked randomisation and power because of their small sample sizes.³⁰

Cue-based feeding

The moderate-to-late preterm neonate's advancement to oral feeding must be accomplished before discharge from the hospital. Traditionally, the preterm neonate learning to feed orally is given a predetermined volume of breast milk at a scheduled interval, regardless of their individual ability to coordinate the feeding.^{30;34} This approach appears to be based on the assumption that the experience of oral feeding is too stressful for a preterm neonate, which requires more energy consumption by the neonate resulting in poor weight gain and fatigue.^{20-22;24;28}

The suggestion of the cue-based feeding approach is based on allowing the neonate to dictate the timing, duration and volume of the oral feed.^{28;31;43;46} This would result in the neonate's improved state organisation and sleep-wake patterns, reduced energy expenditure and the ability to faster transition to full oral feeding. This feeding approach suggests that the transition to oral feeding occurs when the neonate present with signs of physiological and behavioural readiness, physiologic stability, wakefulness at expected feeding times and an interest and ability to suck.^{26;40;51}

A 2015 study, investigated infant-driven feeding as the standard of practice and found numerous benefits of infant-driven, cue-based and ad-lib feeding approaches for the preterm neonate.²¹ The length of feeding was determined by the neonate's behaviour and feeding was

discontinued if the infant stopped or fell asleep. The study only included 20 preterm neonates, between 32 to 34 weeks corrected gestational age that demonstrated feeding cues, and were admitted to a NICU with a wide variety of medical and surgical diagnoses (including but not limited to the following: gastroschisis, omphalocele, congenital diaphragmatic hernia, lung lesions, prematurity, cardiac anomalies, necrotising enterocolitis, myelomeningocele, hyperinsulinism, sacrococcygeal teratoma, intestinal atresias and sepsis).²¹

Even though the study included the moderate-to-late preterm neonate population, and the feeding approach focused on neonatal behaviour and infant responses to feeding readiness, the sample size was very small to allow drawing concrete conclusions.²¹

Furthermore, another study describes the outcome of their evidence-based protocol for semi-demand breastfeeding aimed to promote transition from tube to breast.²² This 2014 article explains that their protocol was developed and based on the premise that preterm neonates will exhibit breastfeeding competence and then only their transition from tube-to-oral feeding would be successful, rather than simply on practices and staff opinions. They suggest that breastfeeding can be implemented as early as 27 to 28 weeks, with full breastfeeding at 32/33 weeks gestation in a specific NICU setting.²²

Unfortunately, the article does not specify their sample size, however the authors stress the need for randomised controlled trials that are needed to further clarify and support the semi-demand feeding approach and clinically influence on outcomes such as growth and time to discharge from hospital, both in late preterm infants and in very low birth weight infants.²²

A 2008 systematic review that focused on the perfect timing of introduction and transition to oral feeding in the preterm neonate concluded that early introduction should be timed and respond to the neonate's behavioural cues.³⁰

According to the study, early introduction in tube-to-oral feeding could result in swift transitioning to oral feeds in healthy preterm neonates. They also found that there is adequate evidence to

support the creating of feeding practice or opportunity that leads to maturation of the preterm neonate's sucking pattern and earlier attainment of full oral feeding, if the preterm infant is healthy.³⁰

Evidence from Whetten (2016) and Prade et al. (2016) support this research article's finding that preterm neonates who are fed via cue-based feeding reaches full oral feeding status quicker than their volume-feeding counterparts and have shorter lengths of stay in the hospital.^{34;49} This feeding strategy has gained popularity as it has shown to have almost no adverse effects on the preterm neonate.^{30; 32}

Cue-based feeding has shown that neonates who are fed based on their displayed behavioural and developmental cues, can become successful oral feeders and could be safely discharged home sooner, regardless of their gestational age or diagnosis.^{24;28} Evidence and clinical experience are supporting that even less medically stable neonates are more likely to benefit from developmentally and cue-based oral feeding.³²

This feeding approach provides the best possible outcome and supports the transition to oral feeding in the preterm neonate. It also contributes to lower stress levels associated with feeding success in parents and health care professionals.^{31; 32}

Cue-based feeding has shown to not only support preterm neonates with successful transitioning from tube-to-oral feeding, but also empowers nurses to make decisions that will help infants achieve their full oral feedings faster.²⁷ Changing practice to cue-based feedings in the hospital setting and ensuring the transition is infant-driven would require staff education, adjustment of documentation and team-based communication.³⁴ Thus, such an approach should be implemented for preterm NICU infants instead of an approach focused solely on volume intake and weight gain.²⁸

Provider education and skills

A study published in 2015, found that adopting best feeding practices for moderate-to-late preterm neonates often requires a mind shift in how nurses and other care providers view their feeding approaches interventions in the hospital setting.²⁰ Briere et al. (2015) supports the view of preterm neonate feeding as requiring skilled care and that the introduction of oral feedings and transition from tube-to-oral feedings require continuous assessment and the application of evidence-based knowledge.²⁰

If not trained, on the other side of this transition from tube-to-oral feeding challenge, the NICU (Neonatal Intensive Care Unit) health care professional is also confronted with an inability to knowledgeably support the moderate-to-late preterm neonate.^{12;20}

Within the NICU or hospital environment, the health care professional who is responsible for the daily facilitation and support of the moderate-to-late preterm neonate, needs a certain set of skills and knowledge (understanding neonatal developmental milestones, feeding techniques) to be able to fulfil this critical role.^{23;25} Furthermore, the parents also play a vital role to nurture, support and identify cues in the care of these preterm neonates. They essentially form part of the neonate's caregiving team.^{23; 24}

The neonate's caregiving team must be equipped with the necessary skills and knowledge to provide the neonate and parents with the appropriate guidance to ensure that oral feeding is achieved.^{24; 27; 28} The neonate's care provider should be skilled with the ability to practice consistent care giving and maintain best evidence knowledge of tube-to-oral feeding guidance and its challenges within this population.^{21;25;28}

Health care professionals at times lack the knowledge and skill to determine the golden moment when this particular group of preterm neonates is ready to begin their transition to oral feeding process.³⁷ Before the ideal interventional approach for the moderate-to-late preterm neonate can be identified, the health care professional must determine when the neonate is holistically

equipped (all neurological and other systems are optimally functioning) to start transitioning to their oral feeding.¹¹

Keeping all of the above in mind, the feeding approach's clinical pathway should be easy enough to be understood and practical, for even the most basic level of care available in the hospital setting.³⁵ There are usually no expendable resources nor time available for elaborate training plans and workshops, as the nursing profession is experiencing a continuous shortage of staff.^{35; 36}

The caregiver should not only be knowledgeable about how to assist the neonate with tube-to-oral feeding transition, but also be able to help the neonate's parents with proper education and support.^{23;24;27} This is only possible when the transition pathway is simple, easy to understand and the minimum training is needed.²³ When there is an integrated approach, which includes the health care providers from multiple disciplines, to guide the transition from tube-to-oral feeding for the preterm neonate, the education and empowerment of families are enriched and competent, evidence-based care is supported.^{24;31}

Literature has shown that in instances where health care professionals, specifically Nurses, were motivated, willing and received proper, yet fundamental, training on the topic of general feeding clinical pathways, they are more inclined to take responsibility for the neonate's feeding approach.^{38;39} Furthermore, shifting the responsibility for the preterm neonate's feeding to the health care professional has shown to develop the nurse's autonomy and fosters assertiveness when advocating for neonates.^{27;38;39}

Neonatal caregivers have a responsibility to understand the challenges and barriers that have an impact on the initiation of oral feedings in preterm infants and to identify factors that influences their achievement of oral feeding.

Another 2015 study stated that nurses play a vital role in the care of preterm neonates and can have an immediate and lasting effect on their health outcomes.²¹ The study demonstrated that

infants who are fed according to cues can become successful oral feeders and can be safely discharged home regardless of gestational age or diagnosis.²¹ The same study attributed their success to a strong collaboration between health care providers of all disciplines and the education and empowerment of families to provide competent, evidence-based care. Indicating that collaboration of all health care providers involved in the care of the preterm neonate is essential to their oral feeding success.²¹ Their suggested empowerment of families to provide care, is best achieved through education is echoed by a few of the other researchers.²¹

In agreement with other research, the study suggests that support for the tube-to-oral feeding transitioning requires skilled health care providers, to practice consistent care giving and maintain current knowledge of breastfeeding challenges and appropriate feeding approaches for this vulnerable population.^{21;24;35;40} They suggest a clinical pathway or protocol to be comprehensively researched to provide consistent feeding related care giving for the late preterm neonate.²¹

Non-nutritive sucking (NNS)

In addition to implementing feeding assessment instruments, several other strategies have been associated with the efficient transition from tube-to-oral feeding in the moderate-to-late preterm neonate population.⁴⁰ One of these strategies include Non-nutritive sucking (NNS), where a pacifier or finger can be used to stimulate oral sucking reflexes that are integral to attaining a full oral feed.^{39;40}

Literature recommends that, if possible, the preterm neonate receive direct breastfeeding as their first oral feed.^{23;28;32} Not only will the breastmilk be beneficial for the nutrition of the neonate, but the non-nutritive sucking (NNS) experience will assist the preterm neonate in developing their ability to suck (and swallow) for feeding purposes.^{23;28;32} NNS is not only practised for comfort purposes, but the NNS intervention reduces the time to transition from tube-to-oral feeding, the time to transition from initiation of oral feeding to full oral feeding, as well as the length of hospital admission.^{32; 40; 41}

When a fully awake state is observed in preterm neonates and they do not exhibit any signs of physiological distress, they should be offered the opportunity to suck from the breast/bottle, for non-nutritional reasons.²⁸ If the health care professional is knowledgeable, they will use every opportunity possible to support the neonate with NNS.³² These opportunities should be timed and in-response to the neonate's behaviour and awake state, as this may lead to earlier attainment of their full oral feeding.^{28; 32}

Early sucking interventions, which include swallowing training, have a positive impact on the neonate's development of oral feeding skills, contributing to an earlier start of attaining a successful tube-to-oral feeding transition.^{32; 42; 43} Not only has early sucking been evident to assist the neonate with oral feeding, but it also shortens the transition time, from tube-to-oral feeding, with oral readiness at early gestational ages.^{31; 42; 46}

Even though the preterm neonate's early sucking and swallowing exercise exposure have shown good results, there are combined limitations and more research is needed, preferably with larger samples, in order for the research to be valid.^{32;47} Research does not appear to show any specific advantages of starting oral feedings earlier for the moderate-to-preterm infant.^{26; 35} However the opportunity for the neonate to practice their oral feeding skills, regardless of the amount of milk ingested, is valuable and can escalate their transition from tube-to-oral feeding, with subsequent earlier hospital discharge.^{28; 31; 37}

Furthermore, good evidence supports NNS stimulation (as part of the feeding opportunity) before starting the preterm neonate with oral feeding, as research found that it could potentially mean an increased feeding efficiency, earlier success of their oral feeds and enhancement of the preterm neonate's feeding skills.³⁰

A Brazilian (2017), cross-sectional and qualitative study, consisting of a sample of 45 healthy and clinically stable preterm neonates conducted in 2017, assessed the neonate's first oral feeding with two tools: the Schedule Oral Motor Assessment (SOMA) tool and the Preterm Oral Feeding Readiness Assessment Scale (POFRAS).³⁵

In the study, an oral simulation program was implemented in an NICU. It shortened the transition time from the introduction of oral feeding to full oral feeding and improved the preterm neonate's oral feeding performance.³⁵ The authors concluded that all preterm newborns with readiness to initiate oral feedings had to display normal oral motor functions.^{32; 36} Those in the group of preterm neonates, with oral motor dysfunction, cannot possibly be ready to initiate the first oral breastfeeding.^{32;37;40}

Feștilă, et al. (2014) and Ziadi et al. (2016) both demonstrated the positive impact of oral stimulation (NNS) prior to the introduction of oral feedings and have been strongly associated with reduced length of time in tube-to-oral transitioning in preterm neonates, increased overall intake and higher breastfeeding rates.^{39;40}

Preterm neonates who have been systematically exposed to opportunities of NNS before the initiation of oral feedings display a shorter interval for achievement of full oral feedings than neonates who have not been exposed to this strategy. Additionally, literature claims that prolonged hospitalisation and inefficient oral stimulation could contribute to the rising of feeding difficulties in the preterm neonates. Also found in other studies, it was mentioned that oral motor dysfunction is an indication that the preterm neonate cannot initiate oral feeding.^{30;35}

Kangaroo Mother Care (KMC)

A 2015 published review found that the late preterm neonate requires a unique set of interventions for oral feeding success even though this population is often perceived as small, full-term infants. This correlates with other research results, where it is highlighted that the late preterm infant's oral readiness to feed cannot be compared to the term infant, as they do not have the neurological maturity of the term neonate.^{20;40} This preterm neonate has weaker sucking ability, an uncoordinated suck-swallow-breathe reflex and lower milk intake. They recognise that maternal factors played a role in the oral feeding success of the late preterm neonate, as milk supply is established and maintained by skin-to-skin contact and maternal sensitivity to the neonate's feeding cues, sleep and alert states.²⁰

Barriers to the successful tube-to-oral feeding experienced by the moderate-to-late preterm neonate is a bit different from the other categories of preterm neonates. The moderate-to-late preterm neonate requires the support and environment where personal tactile touch by mainly their parents is needed.^{22;25;28} The inability for parents to room-in (neonate is allowed to sleep in the same room as the parents) with their neonate poses as one of these barriers for oral feedings, as this limits access to kangaroo mother care (KMC) for feeding at the times the neonate's behaviour shows oral feeding readiness. Another critical barrier for direct breastfeeding is the lack of competent and skilled health care professionals within the hospital setting, to provide support and care for personalised feeding.^{19;25}

Research studies where the preterm neonate was transitioned from tube to breastfeeding while practicing KMC in between, facilitated earlier transitioning.³³ KMC can benefit not only the neonate's physiological wellbeing and oral feeding ability, but also show benefits for maternal health.^{33;34-36} Oral feeding combined with KMC is a practical and positive way for the premature neonate's mother to deal with the premature birth of her baby and provide him with the best and safest way possible of tube-to-oral transitioning.^{20; 33} Oral feeding combined with KMC is a practical and positive way for the premature neonate's mother to deal with the premature birth of her baby and provide him with the best and safest way possible of tube-to-oral transitioning.^{20; 33}

Limitations

The field of data collection was limited as only a few studies focused on the moderate-to-late preterm neonate's feeding complexities and problems. The samples used in the articles were also small in size, making generalisation difficult. Randomised controlled trials are considered to be the stronger and most reliable method to measure the effectiveness of an intervention or treatment.^{45; 46}

Conclusion

In conclusion, this evidence does point out that the cue-based feeding approach takes into consideration almost all of the factors identified in this study: neurological maturity, state of behavioural organisation, Kangaroo Mother Care, Non-nutritive sucking, provider education and skills and cue-based feeding. The evidence suggests that the cue-based feeding model offers a more positive feeding experience and promotes neurodevelopmental maturity of the preterm neonate's ability to transition from tube-to-oral feeding.

It remains critical that focus is shifted to the moderate-to-late preterm neonate as they are compared to the full term neonate, and as they represent the largest number of preterm neonate population, it is pertinent to do more research into their feeding (and other) needs.

The evidence leans towards cue-based feeding as the most effective approach for successful transition from tube-to-oral feeding, there seems to be limited supporting evidence from this review to design a comprehensive pathway specifically for the moderate-to-late preterm neonate and consequently a solid recommendation cannot be made. The recommendation is that there is further research done to develop a clinical pathway, by using the factors explained in this review as a starting point.

The quantity of evidence is small; however, the quality is high and it provided six factors, which should be included in a care pathway to guide tube-to-oral transition in the moderate to late preterm infant. The quality of evidence includes empirical studies with (large/small) sample sizes. It would strengthen the evidence if Randomised Control Trials could be planned to support the current available evidence.

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CHAPTER 4: CONCLUSIONS, LIMITATIONS AND RECOMMENDATIONS

4.1 INTRODUCTION

In this final chapter, conclusions are presented based on the data gathered and analysed during the current systematic review. The research question, “What are the factors that a pathway should consider to support the successful tube-to-oral transition process for moderate to late preterm neonates?” provided the foundation and guidance for this study. Potential recommendations for further research as well as limitations encountered during the research process are described in this chapter.

4.2 PURPOSE AND OBJECTIVES OF THE STUDY

The aim of this research was to explore the factors that could be considered when facilitating the transition process of tube-to-oral feeding in a moderate-to-late preterm neonate. The objectives were to explore the best available evidence through a systematic review to determine the factors mentioned above. Evidence collected in this review supports the recommendation of the drafting of a clinical pathway for healthcare professionals to guide their clinical decision-making during the tube-to-oral feeding transitioning process. These factors identified for the pathway were: neurological maturity, the neonate’s state of behavioural organisation, cue-based feeding, provider education and skills, non-nutritive suckling, and kangaroo mother care.

This systematic review concluded that best available evidence indicates that a cue-based feeding approach, which includes all of the factors mentioned above, would be neurologically and developmentally appropriate for the moderate-to-late preterm neonate’s transitioning from tube-to-oral feeding.

4.3 LIMITATIONS OF THE STUDY

Scientific evidence on the factors to consider when facilitating the moderate-to-late preterm neonate, with their transition from tube-to-oral feeding and to draft the associated pathway was limited. Although, research had been done on various existing feeding instruments, it is not specific to the moderate-to-late preterm neonate. There was not enough concrete evidence to achieve the formulation of a pathway, as there is a lack of sufficient focus on the moderate-to-late preterm infant in the articles found.

4.4 RECOMMENDATIONS

4.4.1 Recommendations for Practice

Best available evidence revealed value for the preterm neonate to be facilitated through a cue-based or infant driven approach to feeding. Staff working in the NICU should be coached and implement these approaches as a strategy to ease the transition from tube-to-oral feeding for the moderate-to-late preterm infant. Workshops or webinars could be organised for the staff to attend. Manuals can be compiled and shared with hospitals or posters can be made available to the NICU for awareness and guidance. There should be more emphases placed on the feeding care of the moderate-to-late preterm neonate, as they are wrongfully compared to the full-term infant. The information should also be shared with women who have moderate-to-late preterm neonates – in NICU or otherwise, to improve preterm neonate health outcomes

4.4.2 Recommendations for Future Research

The specific clinical pathway for the transition from tube-to-oral feeding for the moderate-to-late preterm neonate appears to be inadequately researched and further research is required to study this topic. Future studies should investigate the factors found from the systematic review, specifically associated with the moderate-to-late preterm neonate. There is a need to develop and clinically test a clinical pathway comprising specific factors that influence the transitioning from tube-to-oral feeding for the moderate-to-late preterm neonate. Such a pathway could provide an evidence based transitioning strategy to enhance oral feeding while ensuring the neonate's mother is actively involved in their care.

Exploration of strategies with targeted interventions to support the moderate-to-late preterm neonate:

- Exploration of barriers to oral feeding in the NICU
- To investigate ways to include the mother in the feeding approach
- Development of a pathway for typical transition tube-to-oral feeding with better understanding and study of targeted interventions to support this transition in the NICU and beyond

4.4.3 Recommendations for education

Nursing and midwifery curricula should include more in-depth evidence-based transition from tube-to-oral advancement, i.e. move focus on the available comprehensive feeding tools/instruments. Such information would not only guide nursing students during clinical

practice in NICU but also within resource-limited environments. Additional training in the form of short courses specifically in cue-based feeding and other infant-driven feeding approaches.

4.4.4 Recommendations for policy

Policies and protocols within the NICU and KMC facilities should be amended to include a standard and comprehensive, tube-to-oral feeding pathway that is easy to understand, scientifically sound, and evidence-based for the moderate- to-late preterm neonate as well as cue-based feeding.

4.5 CLOSING STATEMENT

The evidence points out that the cue-based feeding approach considers the factors identified in this study, i.e. Neurological maturity, state of behavioural organisation. The evidence suggests that the cue-based feeding model offers a more positive feeding experience and promotes the neurodevelopmental maturity of the preterm neonate's ability to transition from tube-to-oral feeding.

The evidence leans towards cue-based feeding as the most effective approach for successful transition from tube-to-oral feeding, there seems to be limited supporting evidence from this study to design a comprehensive pathway specifically for the moderate-to-late preterm neonate. The recommendation is that the factors identified in the study, be considered for a clinical pathway.

ANNEXURE A: CASP APPRAISAL TOOL – QUALITATIVE EXAMPLE



CASP Checklist: 10 questions to help you make sense of a **Qualitative** research

How to use this appraisal tool: Three broad issues need to be considered when appraising a qualitative study:

- ▶ Are the results of the study valid? (Section A)
- ▶ What are the results? (Section B)
- ▶ Will the results help locally? (Section C)

The 10 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is “yes”, it is worth proceeding with the remaining questions. There is some degree of overlap between the questions, you are asked to record a “yes”, “no” or “can’t tell” to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

About: These checklists were designed to be used as educational pedagogic tools, as part of a workshop setting, therefore we do not suggest a scoring system. The core CASP checklists (randomised controlled trial & systematic review) were based on JAMA ‘Users’ guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL, and Cook DJ), and piloted with health care practitioners.

For each new checklist, a group of experts were assembled to develop and pilot the checklist and the workshop format with which it would be used. Over the years overall adjustments have been made to the format, but a recent survey of checklist users reiterated that the basic format continues to be useful and appropriate.

Referencing: we recommend using the Harvard style citation, i.e.: *Critical Appraisal Skills Programme (2018). CASP (insert name of checklist i.e. Qualitative) Checklist. [online] Available at: URL. Accessed: Date Accessed.*

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Paper for appraisal and reference:

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments:

4. Was the recruitment strategy appropriate to the aims of the research?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- If the researcher has explained how the participants were selected
- If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study
 - If there are any discussions around recruitment (e.g. why some people chose not to take part)

Comments:

5. Was the data collected in a way that addressed the research issue?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- If the setting for the data collection was justified
- If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)
- If the researcher has justified the methods chosen
 - If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)
 - If methods were modified during the study. If so, has the researcher explained how and why
 - If the form of data is clear (e.g. tape recordings, video material, notes etc.)
 - If the researcher has discussed saturation of data

Comments:

6. Has the relationship between researcher and participants been adequately considered?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location
- How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments:

Section B: What are the results?

7. Have ethical issues been taken into consideration?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained
- If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)
- If approval has been sought from the ethics committee

Comments:

8. Was the data analysis sufficiently rigorous?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
 - To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments:

9. Is there a clear statement of findings?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider whether

- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments:

Section C: Will the results help locally?

10. How valuable is the research?

HINT: Consider

- If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature)
- If they identify new areas where research is necessary
- If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used

Comments:

ANNEXURE B: JOHNS HOPKINS APPRAISAL TOOL

Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal Tool			
			Evidence Level and Quality: _____
Article Title:		Number:	
Author(s):		Publication Date:	
Journal:			
Setting:		Sample (Composition & size):	
Does this evidence address my EBP question?		<input type="checkbox"/> Yes	<input type="checkbox"/> No Do not proceed with appraisal of this evidence
Level of Evidence (Study Design)			
A. Is this a report of a single research study? <i>If No, go to B.</i>			
1. Was there manipulation of an independent variable? 2. Was there a control group? 3. Were study participants randomly assigned to the intervention and control groups?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
		<input type="checkbox"/> Yes	<input type="checkbox"/> No
		<input type="checkbox"/> Yes	<input type="checkbox"/> No
		<input type="checkbox"/> Yes	<input type="checkbox"/> No
If Yes to all three, this is a Randomized Controlled Trial (RCT) or Experimental Study →		<input type="checkbox"/> LEVEL I	
If Yes to #1 and #2 and No to #3, OR Yes to #1 and No to #2 and #3, this is Quasi Experimental (some degree of investigator control, some manipulation of an independent variable, lacks random assignment to groups, may have a control group) →		<input type="checkbox"/> LEVEL II	
If No to #1, #2, and #3, this is Non-Experimental (no manipulation of independent variable, can be descriptive, comparative, or correlational, often uses secondary data) or Qualitative (exploratory in nature such as interviews or focus groups, a starting point for studies for which little research currently exists, has small sample sizes, may use results to design empirical studies) →		<input type="checkbox"/> LEVEL III	
NEXT, COMPLETE THE BOTTOM SECTION ON THE FOLLOWING PAGE, "STUDY FINDINGS THAT HELP YOU ANSWER THE EBP QUESTION"			
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Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal Tool

B. Is this a summary of multiple research studies? *If No, go to Non-Research Evidence Appraisal Form.*

Yes No

1. Does it employ a comprehensive search strategy and rigorous appraisal method (Systematic Review)? *If No, use Non-Research Evidence Appraisal Tool; if Yes:*

Yes No

- a. Does it combine and analyze results from the studies to generate a new statistic (effect size)? (Systematic review with meta-analysis)
- b. Does it analyze and synthesize concepts from qualitative studies? (Systematic review with meta-synthesis)

Yes No

Yes No

If Yes to either a or b, go to #2B below.

2. For Systematic Reviews and Systematic Reviews with meta-analysis or meta-synthesis:

- a. Are all studies included RCTs? → LEVEL I
- b. Are the studies a combination of RCTs and quasi-experimental or quasi-experimental only? → LEVEL II
- c. Are the studies a combination of RCTs, quasi-experimental and non-experimental or non-experimental only? → LEVEL III
- d. Are any or all of the included studies qualitative? → LEVEL III

COMPLETE THE NEXT SECTION, "STUDY FINDINGS THAT HELP YOU ANSWER THE EBP QUESTION"

STUDY FINDINGS THAT HELP YOU ANSWER THE EBP QUESTION:

NOW COMPLETE THE FOLLOWING PAGE, "QUALITY APPRAISAL OF RESEARCH STUDIES", AND ASSIGN A QUALITY SCORE TO YOUR ARTICLE

Appendix D
Evidence Level and Quality Guide

Evidence Levels	Quality Ratings
<p>Level I</p> <p>Experimental study, randomized controlled trial (RCT)</p> <p>Explanatory mixed method design that includes only a level I quantitative study</p> <p>Systematic review of RCTs, with or without meta-analysis</p>	<p>Quantitative Studies</p> <p>A High quality: Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence.</p> <p>B Good quality: Reasonably consistent results; sufficient sample size for the study design; some control, fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence.</p> <p>C Low quality or major flaws: Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn.</p> <p>Qualitative Studies</p> <p>No commonly agreed-on principles exist for judging the quality of qualitative studies. It is a subjective process based on the extent to which study data contributes to synthesis and how much information is known about the researchers' efforts to meet the appraisal criteria.</p> <p><i>For meta-synthesis, there is preliminary agreement that quality assessments of individual studies should be made before synthesis to screen out poor-quality studies¹.</i></p> <p>A/B High/Good quality is used for single studies and meta-syntheses².</p> <p>The report discusses efforts to enhance or evaluate the quality of the data and the overall inquiry in sufficient detail; and it describes the specific techniques used to enhance the quality of the inquiry. Evidence of some or all of the following is found in the report:</p> <ul style="list-style-type: none"> • Transparency: Describes how information was documented to justify decisions, how data were reviewed by others, and how themes and categories were formulated. • Diligence: Reads and rereads data to check interpretations; seeks opportunity to find multiple sources to corroborate evidence. • Verification: The process of checking, confirming, and ensuring methodologic coherence. • Self-reflection and scrutiny: Being continuously aware of how a researcher's experiences, background, or prejudices might shape and bias analysis and interpretations. • Participant-driven inquiry: Participants shape the scope and breadth of questions; analysis and interpretation give voice to those who participated. • Insightful interpretation: Data and knowledge are linked in meaningful ways to relevant literature. <p>C Low quality studies contribute little to the overall review of findings and have few, if any, of the features listed for high/good quality.</p>
<p>Level II</p> <p>Quasi-experimental study</p> <p>Explanatory mixed method design that includes only a level II quantitative study</p> <p>Systematic review of a combination of RCTs and quasi-experimental studies, or quasi-experimental studies only, with or without meta-analysis</p>	
<p>Level III</p> <p>Nonexperimental study</p> <p>Systematic review of a combination of RCTs, quasi-experimental and nonexperimental studies, or nonexperimental studies only, with or without meta-analysis</p> <p>Exploratory, convergent, or multiphasic mixed methods studies</p> <p>Explanatory mixed method design that includes only a level III quantitative study</p> <p>Qualitative study Meta-synthesis</p>	

Appendix D
Evidence Level and Quality Guide

Evidence Levels	Quality Ratings
<p>Level IV</p> <p>Opinion of respected authorities and/or nationally recognized expert committees or consensus panels based on scientific evidence</p> <p>Includes:</p> <ul style="list-style-type: none"> • Clinical practice guidelines • Consensus panels/position statements 	<p>A High quality: Material officially sponsored by a professional, public, or private organization or a government agency; documentation of a systematic literature search strategy; consistent results with sufficient numbers of well-designed studies; criteria-based evaluation of overall scientific strength and quality of included studies and definitive conclusions; national expertise clearly evident; developed or revised within the past five years</p> <p>B Good quality: Material officially sponsored by a professional, public, or private organization or a government agency; reasonably thorough and appropriate systematic literature search strategy; reasonably consistent results, sufficient numbers of well-designed studies; evaluation of strengths and limitations of included studies with fairly definitive conclusions; national expertise clearly evident; developed or revised within the past five years</p> <p>C Low quality or major flaws: Material not sponsored by an official organization or agency; undefined, poorly defined, or limited literature search strategy; no evaluation of strengths and limitations of included studies, insufficient evidence with inconsistent results, conclusions cannot be drawn; not revised within the past five years</p> <p>Organizational Experience (quality improvement, program or financial evaluation)</p> <p>A High quality: Clear aims and objectives; consistent results across multiple settings; formal quality improvement, financial, or program evaluation methods used; definitive conclusions; consistent recommendations with thorough reference to scientific evidence</p> <p>B Good quality: Clear aims and objectives; consistent results in a single setting; formal quality improvement, financial, or program evaluation methods used; reasonably consistent recommendations with some reference to scientific evidence</p> <p>C Low quality or major flaws: Unclear or missing aims and objectives; inconsistent results; poorly defined quality improvement, financial, or program evaluation methods; recommendations cannot be made</p> <p>Integrative Review, Literature Review, Expert Opinion, Case Report, Community Standard, Clinician Experience, Consumer Preference</p> <p>A High quality: Expertise is clearly evident; draws definitive conclusions; provides scientific rationale; thought leader(s) in the field</p> <p>B Good quality: Expertise appears to be credible; draws fairly definitive conclusions; provides logical argument for opinions</p> <p>C Low quality or major flaws: Expertise is not discernable or is dubious; conclusions cannot be drawn</p>
<p>Level V</p> <p>Based on experiential and nonresearch evidence</p> <p>Includes:</p> <ul style="list-style-type: none"> • Integrative reviews • Literature reviews • Quality improvement, program, or financial evaluation • Case reports • Opinion of nationally recognized expert(s) based on experiential evidence 	

¹ https://www.york.ac.uk/crd/SysRev/ISSI/WebHelp/6_4_ASSESSMENT_OF_QUALITATIVE_RESEARCH.htm

² Adapted from Polit & Beck (2017).

ANNEXURE C: TABLE 3-6 DATA EXTRACTION TABLE (PART 2)

Research question: What (which items) should a transition of the moderate to late preterm neonate from tube-to-oral feeding clinical pathway include, to be used by healthcare professionals?						
	Study information	Author	Country	Study design	Factors/ Items included	Main conclusions
1.	Timing introduction and transition to oral feeding in preterm infants: current trends and practice	Breton & Steinwender (2008)	Canada	Systematic review	<ul style="list-style-type: none"> ▪ NNS (Non-nutritive Sucking) ▪ Sucking-Swallowing Breathing (SSB) co-ordination ▪ Provider education ▪ Cue-based feeding ▪ Awake-sleep state 	<ul style="list-style-type: none"> ▪ Early introduction, rapid transition to oral feeds in healthy preterm infants. ▪ Consider preterm characteristics. ▪ Developmentally appropriate feeding techniques advised. ▪ Early introduction of oral feeds- timed and responds to infant behaviour/state. ▪ Infants unable to fully transition for medical reasons-still benefit from systematic approach to the introduction and advancement of oral feeds. ▪ Evidence for cue-based feeding advancement. ▪ Evidence and clinical experience -less stable medically infants use developmentally and cue-based oral feeding.
2.	Establishing breastfeeding with the late preterm infant in NICU.	Briere <i>et al.</i> , (2015)	USA	Systematic review	<ul style="list-style-type: none"> ▪ Cue-based feeding ▪ Stress cues ▪ Sucking-swallow breathe co-ordination ▪ Provider education ▪ Skin-to-skin 	<ul style="list-style-type: none"> ▪ Breastfeeding preterm neonates are challenging. ▪ Preterm neonates developmentally disadvantaged compared to term infants. ▪ HCP practice consistent care giving and maintain best evidence knowledge of challenges.

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	Study information	Author	Country	Study design	Factors/ Items included	Main conclusions
						<ul style="list-style-type: none"> ▪ Formalised methods for preterm feeding. ▪ Physiological assessment is pertinent. ▪ Direct breastfeeding should be the first oral feeding offered. ▪ HCP to provide education and support.
3.	A continuous quality improvement project to implement infant-driven feeding as a standard of practice in the newborn/infant Intensive Care Unit.	Chrupcala <i>et al.</i> , (2015)	USA	Qualitative Research Design	<ul style="list-style-type: none"> ▪ Cue-based feeding ▪ Caregiver skills ▪ Suck-swallow-breathe co-ordination ▪ Opportunities NNS ▪ Skin-to-skin 	<ul style="list-style-type: none"> ▪ Nurses play vital role in the care of neonates. ▪ Infants on cue-based feeding become successful oral feeders and safely discharged home regardless of gestational age or diagnosis. ▪ HCP from all disciplines - education and empowerment families to provide competent, evidence-based care. ▪ Feeding plan should be evaluated on daily basis, changes to be made after assessment findings. ▪ Family members should take an active role in feeding.
4.	From tube to breast: the bridging role of semi-demand breastfeeding.	Davanzo <i>et al.</i> , (2014)	Italy	Qualitative Research Design	<ul style="list-style-type: none"> ▪ Developmental stage ▪ Neurological maturity ▪ KMC ▪ Awake/sleep stage 	<ul style="list-style-type: none"> ▪ NICUs are still conventionally organised and barriers to early establishment of breastfeeding needs to be addressed. ▪ Barriers: limited access to KMC, lack of lactation trained staff, and routine use of bottles. ▪ Tools have been developed based on evidence-based knowledge about

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	Study information	Author	Country	Study design	Factors/ Items included	Main conclusions
						breastfeeding competence in preterm infants rather than simply on practices and staff opinions. <ul style="list-style-type: none"> ▪ RCT are needed further clarify if cue-based feeding influences clinically important outcomes - growth and time to discharge, in late preterm infants.
5.	Readiness for oral feeding and oral motor function in preterm infants.	Yamamoto <i>et al.</i> , (2017)	Brazil	Cross sectional and quantitative design	<ul style="list-style-type: none"> ▪ Behavioral state ▪ Sucking, swallowing and breathing co-ordination ▪ Neurological maturity ▪ NNS ▪ Care giver skills ▪ Behavioral cues 	<ul style="list-style-type: none"> ▪ Preterm newborns with normal oral motor functioning – could feed orally. ▪ Oral motor dysfunction - not ready to initiate the first oral feeding.
6.	Behavioral state and the premature's readiness performance to begin oral feeding.	Fujinaga <i>et al.</i> , (2018)	Brazil	Qualitative Research Project	<ul style="list-style-type: none"> ▪ State of behavioral organization ▪ NNS ▪ Cue based feeding ▪ Suck-Swallow and breath Coordination(SSB) ▪ Caregiver education 	<ul style="list-style-type: none"> ▪ Behavioral state influences the performance of the readiness of premature infants to start oral feeding. ▪ Behavioral state must be taken into account because in the alert state they will be able to feed themselves with greater effectiveness.
7.	Infant driven feeding for preterm infants: learning through experience.	Gelfer, McCarthy, & Spruill (2015)	Texas	Qualitative Research Project	<ul style="list-style-type: none"> ▪ Caregiver education ▪ Readiness behavior ▪ Cue-based feeding ▪ Oral skills 	<ul style="list-style-type: none"> ▪ An interdisciplinary team approach is needed for different perspectives, knowledge, and expertise. ▪ Involving parents early helped with the transition. ▪ Culture change is a process. By

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	Study information	Author	Country	Study design	Factors/ Items included	Main conclusions
						<p>allowing time for staff to adjust, as well as continue educational programs, we are able to transition to a more developmentally appropriate model of care.</p> <ul style="list-style-type: none"> ▪ Ownership of the feeding process using scales develops nurse autonomy and fosters assertiveness when advocating for infants. ▪ Cue based feeding empowers nurses to make decisions that will help infants achieve full oral feedings faster.
8.	Preterm newborn readiness for oral feeding: systematic review and meta-analysis.	Lima <i>et al.</i> , (2014)	Brazil	Systematic review	<ul style="list-style-type: none"> ▪ NNS ▪ Oral stimulation ▪ Skilled caregivers ▪ Motor sensorial stimulation 	<ul style="list-style-type: none"> ▪ Important to use standardized evaluations for the aid of health care teams in determining the appropriate and safe moment for neonate. ▪ Stimulation of the motor and oral sensorial system for the transition period to full oral feeding - decrease of the hospital time of permanence and costs. ▪ More and stronger research is needed.
9.	Clinicians guide for cue-based transition to oral feeding in preterm infants: an easy-to-use clinical guide.	Welma Lubbe (2018)	South Africa	Systematic review	<ul style="list-style-type: none"> ▪ Cue-based feeding ▪ Skilled caregiver ▪ Neurological maturity ▪ NNS ▪ KMC ▪ Suck-swallow- 	<ul style="list-style-type: none"> ▪ Transition based on infant maturity - successful oral feeding with less energy expenditure, higher rates of success, and even better parental functioning. ▪ Clear, evidence-based guidelines should be available for the healthcare

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	Study information	Author	Country	Study design	Factors/ Items included	Main conclusions
					breathe co-ordination	<p>professional/care giver to enable effective evaluation of maturity and readiness for oral feeding.</p> <ul style="list-style-type: none"> ▪ Clear recommendations to HCP to support transition process for optimal feeding success. ▪ Cue-based feeding provides the best. outcome and supports transition to independent oral feeding in the preterm infant very well.
10.	The effects of an early oral stimulation program on oral feeding of preterm infants.	Lyu <i>et al.</i> , (2014)	China	Randomized controlled trial	<ul style="list-style-type: none"> ▪ NNS ▪ Suck-swallow breathing co-ordination 	<ul style="list-style-type: none"> ▪ Oral simulation can shorten the transition time from introduction of oral feeding to full oral feeding and improve oral feeding performance. ▪ Pre-feeding oral stimulation is safe, simple and beneficial to infants.
11.	Ad libitum or demand/semi-demand feeding versus scheduled interval feeding for preterm infant (review).	McCormick, Tosh & McGuire (2010)	United Kingdom	Systematic review	<ul style="list-style-type: none"> ▪ Cue-based feeding ▪ Neurological maturity ▪ NNS 	<ul style="list-style-type: none"> ▪ Current data is not sufficient to determine whether feeding <i>ad libitum</i> or demand/semi demand versus feeding prescribed volumes at scheduled intervals improves outcomes for preterm infants. ▪ Limited evidence exists that feeding preterm infants with <i>ad libitum</i> or demand/semi-demand regimens allows earlier attainment of full oral feeding and earlier hospital discharge. ▪ There is a need for a large pragmatic RCT to assess whether an <i>ad libitum</i> or demand/semi-demand feeding

Research question: What (which items) should a transition of the moderate to late preterm neonate from tube-to-oral feeding clinical pathway include, to be used by healthcare professionals?

	Study information	Author	Country	Study design	Factors/ Items included	Main conclusions
						regimen is beneficial.
12.	Characteristics of the transition technique from enteral tube feeding to breastfeeding in preterm newborns.	Medeiros <i>et al.</i> , (2011)	Brazil	Quantitative Research design	<ul style="list-style-type: none"> ▪ Behavioral state ▪ Neurological maturity ▪ Caregiver skill ▪ Suck-swallow-breathing co-ordination ▪ NNS ▪ KMC 	<ul style="list-style-type: none"> ▪ The preterm newborn's weaning from enteral feeding directly to breastfeeding is possible. ▪ Further research is needed – regarding weaning directly from enteral feeding to breastfeeding in newborns, with KMC. ▪ Breastfeeding is a practical and positive way for the mother to deal with premature birth, best and safest feeding method.
13.	Association between readiness for oral feeding and feeding performance in preterm neonates.	Prade, <i>et al.</i> ,(2016)	Brazil	Qualitative Research design	<ul style="list-style-type: none"> ▪ Neurological maturity ▪ Behavioral organization state ▪ NNS ▪ SSB co-ordination ▪ Feeding cues 	<ul style="list-style-type: none"> ▪ The PROFAS contributed to the prognosis of oral feeding outcomes in premature newborn younger than 34 weeks of gestational age. ▪ However, it does not replace the need for an assessment of swallowing mechanics prior to the onset of oral feeding.
14.	Oral feeding performance in premature infants.	Otto & De Almeida (2017)	Brazil	Time Series Quasi Experiment	<ul style="list-style-type: none"> ▪ NNS ▪ SSB coordination ▪ Feeding practice opportunities 	<ul style="list-style-type: none"> ▪ Intervention with swallowing training allowed good performance in oral feeding skills, and helps them to start oral feeding and obtaining exclusive oral feeding in a short period, with oral readiness. ▪ Although swallowing exercises have shown good results, more research is still needed.
15.	Effect of four	Pickler <i>et al.</i> ,	USA	Randomized	<ul style="list-style-type: none"> ▪ SSB co-ordination 	<ul style="list-style-type: none"> ▪ Recommendation that the start of oral

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	Study information	Author	Country	Study design	Factors/ Items included	Main conclusions
	approaches to oral feeding progression on clinical outcomes in preterm infants.	(2015)		experimental design	<ul style="list-style-type: none"> ▪ Neurological maturity ▪ Behavioral state ▪ NNS ▪ Cue-based 	<p>feedings occurs when infants are showing signs of physiological and behavioural readiness, physiologic stability, wakefulness at feeding times, and interest and ability to suck on a nipple.</p> <ul style="list-style-type: none"> ▪ Once oral feedings are started, infants have to be assessed for readiness at every scheduled feeding including observation of physiologic stability and wakefulness or ease with which the infant achieves a stable awake state when handled. ▪ If the infant is awake at a scheduled feeding time and is not physiologically distressed, the infant should be offered the opportunity to feed orally. ▪ Opportunity to feed orally, regardless of the volume taken orally, speeds the transition to full oral feeding and to hospital discharge.
16.	Contributing to content validity of the infant-driven feeding scales through Delphi surveys.	Waitzman, Ludwig & Nelson (2014)	USA	Qualitative Research Design	<ul style="list-style-type: none"> ▪ Neurological maturity ▪ Cue based ▪ NNS ▪ Caregiver education 	<ul style="list-style-type: none"> ▪ Recommendation that IDF be used in combination with the infant's cues-specialized comprehensive education and family inclusion is important to infant feeding success.
17.	Evaluation of orofacial characteristics and breastfeeding in preterm newborns	Castelli & Almeida (2015)	Brazil	Quantitative Research Design	<ul style="list-style-type: none"> ▪ NNS ▪ Neurological maturity ▪ Caregiver education 	<ul style="list-style-type: none"> ▪ Premature newborns with an alert state of consciousness showed better positioning during breastfeeding than preterm neonate in a mild somnolent

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	Study information	Author	Country	Study design	Factors/ Items included	Main conclusions
	before hospital discharge.				<ul style="list-style-type: none"> ▪ SSB coordination 	<p>state.</p> <ul style="list-style-type: none"> ▪ Tongue movement and suction force in non-nutritive sucking were appropriate to assist with oral feeding. ▪ Limiting factors such as reduced sample size and possible selection bias, due to the convenience sample used. ▪ Speech therapists must be part of the multiprofessional teams, due to their expertise in the evaluation of the orofacial sensori-motor system and breastfeeding.
18.	Premature: growth and its relation to oral skills.	Vargas <i>et al.</i> , (2015)	Brazil	Qualitative Research Design	<ul style="list-style-type: none"> ▪ NNS ▪ Neurological maturity ▪ Cue-based feeding 	<ul style="list-style-type: none"> ▪ Preterm infant oral skill significantly correlates with transition time from tube to oral feeding. ▪ Preterm infants with higher levels of oral skill changed in less than half of the time if compared to the others. ▪ Earlier discharge from hospital. ▪ NNS improved oral skill and consequently had weight evolution in the feeding transition period.
19.	A critical review of interventions supporting transition from gavage to direct breastfeeding in hospitalized preterm infants.	Ziadi, Héon & Aita (2016)	Canada	Systematic review	<ul style="list-style-type: none"> ▪ NNS ▪ Caregiver education ▪ KMC ▪ Cue based approach 	<ul style="list-style-type: none"> ▪ Aim: identify and analyse interventions that promote the transition from gavage to direct breastfeeding in preterm infants hospitalized in the NICU. ▪ Positive benefits for preterm infants during the transition from gavage to

Research question: What (which items) should a transition of the moderate to late preterm neonate from tube-to-oral feeding clinical pathway include, to be used by healthcare professionals?

	Study information	Author	Country	Study design	Factors/ Items included	Main conclusions
						<p>direct breastfeeding - higher breastfeeding rates, an acceleration of the transition to direct breastfeeding, and earlier discharge.</p> <ul style="list-style-type: none"> ▪ NNS and oral stimulation, and the promotion of direct breastfeeding and avoidance of bottles assist with the transition.
20.	Transition from tube to full oral feeding (breast of bottle) – a cue-based developmental approach.	White & Parnell (2013)	United Kingdom	Quantitative Research Design	<ul style="list-style-type: none"> ▪ Cue-based feeding ▪ Caregiver education ▪ KMC ▪ Behavioral state regulation 	<ul style="list-style-type: none"> ▪ The aim of this project was to introduce an evidence- based approach to oral feeding development based on an infant’s emerging behavioural cues. ▪ Evidence suggests that doing so benefits the infant from a neuro- developmental point of view over the long term. ▪ Reduces the risk of feeding difficulties and future feeding aversions caused by negative oral feeding experiences. ▪ Cue-based approach to oral feeding would be beneficial as the norm. ▪ It involves parents more actively in the recognition of their baby’s emerging feeding skills and aims to move parents away from regarding feeding as a task with time and volume limits and instead to see feeding as occasions to nurture their baby. ▪ Despite the longer-term advantages of

Research question: What (which items) should a transition of the moderate to late preterm neonate from tube-to-oral feeding clinical pathway include, to be used by healthcare professionals?

	Study information	Author	Country	Study design	Factors/ Items included	Main conclusions
						<p>a cue based approach, the most significant priority for senior medical and nursing staff remains in getting the infants home as soon as possible.</p> <ul style="list-style-type: none"> ▪ This aim is as much driven by the need to reduce the duration of separation between mothers and their infants as it is driven by the costs of hospital stay and the need to make room for new admissions.

ANNEXURE D: AUTHOR'S GUIDELINES FOR JOURNAL OF PERINATAL AND NEONATAL NURSING

Information for Authors

Scope

The purpose of The Journal of Perinatal & Neonatal Nursing (JPNN) is to provide nurses caring for perinatal and neonatal patients and their families with evidence-based information that is cutting-edge and relevant to clinical practice. We publish manuscripts that have strong clinical implications for perinatal and neonatal practice. These manuscripts are focused on a central theme for each issue, with one issue a year dedicated to various selected topics. The topics of the issues are determined by the editorial board members based on their collective assessment of the most important issues relevant to practice. These topics are posted on the JPNN website and can be found here.

We welcome authors to submit clinically focused, academically sound articles that (1) add new knowledge to the field of perinatal/neonatal nursing, (2) challenge and/or confirm existing knowledge or (3) provide information that ensures practice is evidence-based and uniformly excellent across the perinatal and neonatal care spectrum. Papers achieving these goals may be original research, systematic or scoping reviews, state of the science or practice reports, or quality improvement reports. All manuscripts are peer-reviewed. Acceptance or rejection of manuscripts is based on the peer-review process and how well matched the manuscript is with the scope of the journal as assessed by the editor.

Query letters including an outline of the proposed manuscript are encouraged and should be e-mailed directly to the appropriate editors. To ensure transparency in research reports where randomization of subjects was involved, authors must include a CONSORT diagram. Review manuscripts should follow established guidelines for systematic reviews and evidence-based interventions, such as the Cochrane Handbook of Systematic Reviews for Interventions. For Systematic Reviews and Meta-Analyses, the PRISMA statement (www.prisma-statement.org) is recommended for appropriate formatting and flow diagrams. For Scoping Reviews use of PRISMA guidelines is encouraged. Reports of quality improvement work should follow the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines, which are outlined here: <http://www.squire-statement.org>. It is expected that the Corresponding author will respond to all editorial questions and inquiries in a timely manner at the time the page proofs are forthcoming from the publisher to not delay publication of the issue.

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A submitted manuscript must be an original contribution not previously published (except as an abstract or a preliminary report), must not be under consideration for publication elsewhere, and, if accepted, must not be published elsewhere in similar form, in any language, without the consent of the publisher. Each person listed as an author is expected to have participated in the study and/or manuscript process to a significant extent. Please follow the International Committee of Medical Journal Editors (ICMJE) authorship criteria, which can be reviewed here: <http://www.icmje.org>. Although the editors and referees make every effort to ensure the validity of published manuscripts, the final responsibility rests with the authors, not with the Journal, its editors, or the publisher. JPNN is a member of the Committee of Publication Ethics (COPE): www.publicationethics.org

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Authors must state all possible conflicts of interest in the manuscript, including financial, consultant, institutional and other and other relationships that might lead to bias or a conflict of interest. If there is no conflict of interest, this should also be explicitly stated as none declared. All sources of funding should be acknowledged in the manuscript. All relevant conflicts of interest and sources of funding should be included on the title page of the manuscript with the heading “Conflicts of Interest and Source of Funding:” For example:

Conflicts of Interest and Source of Funding: Author 123 has received honoraria from Company XYZ/. Author B is currently supported by a grant (#12345) from Organization XYZ and is on the speaker’s bureau for Organization ABC. The remaining authors have no conflicts to declare at this time.

- **Patient Anonymity and Informed Consent**

It is the author's responsibility to ensure that a patient's anonymity be carefully protected and to verify that any experimental investigation with human subjects reported in the manuscript was performed with informed consent and following all the guidelines for experimental investigation with human subjects required by the institution(s) with which all the authors are affiliated. Authors should mask patients' eyes and remove patients' names from figures unless they obtain written consent from the patients and submit written consent with the manuscript.

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- All excerpts from a newspaper article or other short piece
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Manuscript Preparation

Manuscripts that do not adhere to the following instructions will be returned to the corresponding author for technical revision before undergoing peer review.

Each manuscript must include the following, each on its own page:

Title page including

(1) title of the article

(2) author names (with highest academic degrees) and affiliations (including titles, departments, and name and location of institutions of primary employment)

(3) corresponding author's name and complete address including email, and

(4) any acknowledgments credits, or disclaimers.

The title page must also include disclosure of funding received for this work from any of the following organizations: National Institutes of Health (NIH); Wellcome Trust; Howard Hughes Medical Institute (HHMI); and other(s). See the "Conflicts of Interest" section above for more information.

Abstract of 200 words or fewer describing the main points of the article. Limit the use of abbreviations and acronyms and avoid general statements (e.g. the significance of the results is discussed, etc.). If it is a research article, prepare a structured abstract describing

(1) what was observed or investigated,

(2) the subjects and methods, and

(3) the results and conclusions.

Key Words 3-5 key words that describe the contents of the article like those that appear in the Cumulative Index to Nursing and Allied Health Literature (CINAHL) or the National Library of Medicine's Medical Subject Headings (MeSH).

Abbreviations Write out the full term for each abbreviation at its first use unless it is a standard unit of measure. Avoid error prone abbreviations as identified by the Institute for Safe Medicine Practices, a complete list is available at: <http://www.ismp.org/Tools/errorproneabbreviations.pdf>

Precis – A synopsis of the manuscript of 25 words or fewer.

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The manuscript will be submitted as a separate file when you are instructed to attach files to your submission. Compose your manuscript using your computer and Microsoft Word software, then attach this file when you reach the "attach files" step in the submission process.

Please note the following guidelines for preparing your manuscript:

- Prepare the manuscript double spaced in Microsoft Word. Leave a one-inch margin on all sides. Do not right justify.
- Type all headings on a separate line.
- Number all manuscript pages consecutively in the upper right-hand corner (text and references, followed by illustrations on separate pages).
- All legends for Tables and Figures are to be included with the manuscript; include these at the end of manuscript after the list of references. Tables and Figures are attached as separate files when you reach "attach files" in the submission process. Prepare tables and figures in a format ready for reproduction. Further instructions for preparing figures are given below.
- Manuscript length (excluding all references, tables, figures) should be no more than 16 pages (standard 8.5 x 11 inch page size).
- Use the American Medical Association Manual of Style, 10 Edition, Copyright 2007 for citations and references. See examples for citations and references below.
- No identifying information (authors' names) should be included on the manuscript. If you cite your own works, list them as "Author, YYYY" in the citation and the reference list in order to maintain your anonymity for the review process.
- Every manuscript should contain a 'Discussion' section.

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The authors are responsible for the accuracy of the references. Include the references (double-spaced) at the end of the manuscript. Cite the references in text in the order of appearance. Cite unpublished data—such as papers submitted but not yet accepted for publication and personal communications, including e-mail communications—in parentheses in the text.

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Leidecker, K, Dorman, K. Pulmonary disorders complicating pregnancy: An overview. *J Perinat Neonat Nurs*. 2016; 30(1): 45-5318:41—58.

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Sumner J Yaffe MD, Jacob V Aranda MD, PhD, FRCP(C), Neonatal and Pediatric Pharmacology, Lippincott Williams & Wilkins, 4th ed. 2010

Simpson KR, Creehan PA. Strategies to develop an evidence-based approach to prenatal care and pregnancy and childbirth practices of selected cultures and religions. *AWHONN's Perinatal Nursing*. 4th ed. 2013.

For multiple authors in journals and books:

- If six or fewer, list all authors
- If more than six, list the first three followed by et al.

- **Figures**

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2. Create, Scan and Save your artwork and compare your final figure to the Digital Artwork Guideline Checklist (below).
3. Upload each figure to Editorial Manager in conjunction with your manuscript text and tables.

B) Digital Artwork Guideline Checklist

Here are the basics to have in place before submitting your digital artwork:

- Artwork should be saved as TIFF, EPS, or MS Office (DOC, PPT, XLS) files. High resolution PDF files are also acceptable.
- Crop out any white or black space surrounding the image.
- Diagrams, drawings, graphs, and other line art must be vector or saved at a resolution of at least 1200 dpi. If created in an MS Office program, send the native (DOC, PPT, XLS) file.
- Photographs, radiographs and other halftone images must be saved at a resolution of at least 300 dpi.
- Photographs and radiographs with text must be saved as postscript or at a resolution of at least 600 dpi.
- Each figure must be saved and submitted as a separate file. Figures should not be embedded in the manuscript text file.

Remember:

- Cite figures consecutively in your manuscript.
- Number figures in the figure legend in the order in which they are discussed.
- Upload figures consecutively to the Editorial Manager web site and enter figure numbers consecutively in the Description field when uploading the files.

If a figure has been previously published, in part or in total, acknowledge the original source and submit written permission from the copyright holder to reproduce or adapt the material. Include a source line. Type "Source: Author" on figures that you created. This will help Lippincott Williams & Wilkins identify the status of each figure.

Supply a caption for each figure, typed double spaced on a separate sheet from the artwork. Captions should include the figure title, explanatory statements, notes, or keys and source and permission lines.

- **Tables**

Tables will be submitted as a separate file when you are instructed to attach files to your submission. Create tables using the table creating and editing feature of your word processing software. Do not use Excel or comparable spreadsheet programs. Group all tables in a separate file. Cite tables consecutively in the text, and number them in that order. Each table should appear on a separate page and should include the table title, appropriate column heads, and

explanatory legends (including definitions of any abbreviations used). Do not embed tables within the body of the manuscript. They should be self-explanatory and should supplement, rather than duplicate, the material in the text.

Tables should be on a separate page at the end of the manuscript.

Number tables consecutively and supply a brief title for each.

Include explanatory footnotes for all nonstandard abbreviations. For footnotes, use the following symbols, in this sequence: *, †, ‡, §, ||, **, ††, etc.

Cite each table in the text in consecutive order.

If you use data from another published or unpublished source, obtain permission and acknowledge fully. Type "Source: Author" on tables that you created.

- **Supplemental Digital Content**

Supplemental Digital Content (SDC): Authors may submit SDC via Editorial Manager to LWW journals that enhance their article's text to be considered for online posting. SDC may include standard media such as text documents, graphs, audio, video, etc. On the Attach Files page of the submission process, please select Supplemental Audio, Video, or Data for your uploaded file as the Submission Item. If an article with SDC is accepted, our production staff will create a URL with the SDC file. The URL will be placed in the call-out within the article. SDC files are not copy-edited by LWW staff, they will be presented digitally as submitted. For a list of all available file types and detailed instructions, please visit <http://links.lww.com/A142>.

SDC Call-outs

Supplemental Digital Content must be cited consecutively in the text of the submitted manuscript. Citations should include the type of material submitted (Audio, Figure, Table, etc.), be clearly labelled as "Supplemental Digital Content," include the sequential list number, and provide a description of the supplemental content. All descriptive text should be included in the call-out as it will not appear elsewhere in the article.

Example:

We performed many tests on the degrees of flexibility in the elbow (see Video, Supplemental Digital Content 1, which demonstrates elbow flexibility) and found our results inconclusive.

List of Supplemental Digital Content

A listing of Supplemental Digital Content must be submitted at the end of the manuscript file. Include the SDC number and file type of the Supplemental Digital Content. This text will be removed by our production staff and not be published.

Example:

Supplemental Digital Content 1.wmv

SDC File Requirements

All acceptable file types are permissible up to 10 MBs. For audio or video files greater than 10 MBs, authors should first query the journal office for approval. For a list of all available file types and detailed instructions, please visit <http://links.lww.com/A142>.

Manuscript Submission

All manuscripts must be submitted on-line through the JPNN Editorial Manager Web site at <http://jpnn.edmgr.com/>.

First-time users: Click the Register button from the menu above and enter the requested information. On successful registration, you will be sent an E - mail indicating your username and password. Print a copy of this information for future reference.

Return users: If you have received an E-mail from us with an assigned user ID and password, or if you are a repeat user, do not register again. Just log in. Once you have an assigned ID and password, you do not have to re-register, even if your status changes (that is, author, reviewer, or editor).

Authors: Please click the log-in button from the menu at the top of the page and log in to the system as an Author. Submit your manuscript according to the author instructions. You will be able to track the progress of your manuscript through the system. If you have any inquiries regarding perinatal content, please contact Diane J. Angelini, EdD, CNM, NEA-BC, FACNM, FAAN, Senior Perinatal Editor at angelinidiane@yahoo.com. For neonatal content, please contact Katherine Gregory, PhD, RN, Neonatal Editor at katherine.gregory.234@gmail.com. Requests for help and other questions will be addressed in the order they are received.

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Manuscript Review Process

It is understood that articles are submitted solely to JPNN and have not been published previously. There are two stages of manuscript review prior to acceptance of the article.

First, the respective editor reviews manuscripts for relevance to the journal. Manuscripts that are considered appropriate and relevant by the editor are reviewed by at least two members and often three members of the Editorial Board. Members of the Board evaluate manuscripts based on the following criteria:

- concise, logical ordering of ideas
- sound argument and defence of original ideas
- accuracy of content
- adequacy of documentation
- consistency with the purpose of the journal.

Second, the Editor makes a decision regarding acceptance of the article for publication based on the comments and recommendations of the Editorial Board reviewers. At least two reviewers must recommend the article for publication for the article to be accepted by the Editor. A rejection by one reviewer may eliminate that manuscript from further review.

AFTER ACCEPTANCE

- **Page Proofs and Corrections**

Corresponding authors will receive electronic page proofs to check the copyedited and typeset article before publication. Portable document format (PDF) files of the typeset pages and support documents (e.g., reprint order form) will be sent to the corresponding author by E - mail. Complete instructions will be provided with the E - mail for downloading and printing the files and for faxing the corrected page proofs to the publisher. Those authors without an E - mail address will receive traditional page proofs. It is the author's responsibility to ensure that there

are no errors in the proofs. Changes that have been made to conform to journal style will stand if they do not alter the authors' meaning. Only the most critical changes to the accuracy of the content will be made. Changes that are stylistic or are a reworking of previously accepted material will be disallowed. The publisher reserves the right to deny any changes that do not affect the accuracy of the content. Authors may be charged for alterations to the proofs beyond those required to correct errors or to answer queries. Proofs must be checked carefully and corrections faxed within 24 to 48 hours of receipt, as requested in the cover letter accompanying the page proofs.

- **Video Abstract**

Consider preparing a video abstract to accompany your article if it is accepted for publication. A video abstract can draw attention to your article and enhance the range of audience that it reaches. For more information, see the “Journal Toolkit: How to Create a Video Abstract” (http://edmgr.ovid.com/ans/accounts/Journal_Toolkit_Video_Abstract.pdf)

- **Social Media and Press Release Instructions**

The journal encourages all authors to publicize their work once the article has published ahead of print online. Whether with a press release, blog post, or social media blast, we support your desire to drive awareness and interest to your research.

If you intend to promote your article, please review the Wolters Kluwer guidelines before doing so: [http://edmgr.ovid.com/anc/accounts/Press_Release_Guidelines_final\(1\).pdf](http://edmgr.ovid.com/anc/accounts/Press_Release_Guidelines_final(1).pdf). This document will help you tailor your communication strategies as well as informing you of helpful regulations, such as embargo dates.

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ANNEXURE E: CO-REVIEWER LETTER

LETTER OF AGREEMENT FROM CO-REVIEWER

I, MM KOHN, hereby declare that I agree with the studies selected by the researcher, Sonja Nel, (216 33 959) for the research project: "*Tube-to-oral transition pathway to guide feeding advancement in moderate to late preterm neonates: A systematic review*".

The research studies I did not agree with were discussed with the researcher and an agreement was reached regarding the inclusion of the study.

The researcher and I agreed that all the articles met the inclusion criteria.

The CASP and Johns Hopkins critical appraisal methods were used for all the studies, to determine the quality of each study.

The appraisal tools were provided by the researcher.

Signed on this 13th day of October 2020, at Potchefstroom.

A handwritten signature in black ink, appearing to read 'MM Kohn', is written on a light blue background.

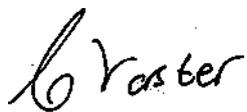
Co-reviewer Signature

ANNEXURE F: CERTIFICATE OF EDITING

CERTIFICATE OF EDITING

I, C Vorster (ID: 710924 0034 084), Language editor and Translator and member of the South African Translators' Institute (SATI member number 1003172), herewith declare that I did the language editing of a dissertation written by Ms S Nel from the North-West University (student number: 21633959).

Title of the dissertation: Tube-to-oral transition pathway to guide feeding advancement in moderate-to-late preterm neonates: A systematic review



19 March 2021

C Vorster

Date

ANNEXURE G: SIGNED DECLARATION

1. SECTION 8: DECLARATIONS

Applications and declaration are filled in and signed by:

- Sec 8a: Study Leader
- Sec 8b: Statistical Consultant
- Sec 8c: Research Director

The pages with declarations and signatures must be scanned with this form.

[SCAN ALL SIGNED DECLARATIONS]

Health Research Ethics Application

Study Leader (Title, Initials and Surname)	Study Title (see § 1.1)
Prof. W Lubbe	Tube-to-oral transition pathway to guide feeding advancement in moderate to late preterm neonates: A systematic review

NWU Ethics Number												
N	W	U	-									

1.1 Sec 8a: Study Leader

Application and Declarations by Study Leader

I, the undersigned, hereby apply for approval of the research study as described in the preceding proposal and declare that:

- 1.1.1 The information in this application is, to the best of my knowledge, correct and that no ethical codes will be violated with the study;
- 1.1.2 I will make sure that the study is managed ethically justifiably from start to finish;
- 1.1.3 In the case of human participants;
 - 1.1.3.1 I will put it clearly to all participants that participation (including assent) in any research study is absolutely voluntary and that no pressure, of whatever nature, will be placed on any potential participant to take part;
 - 1.1.3.2 I will put it clearly to all participants that any participant may withdraw from the study at any time and may ask that his/her data no longer be used in the study, without stating reasons and without fear of any form of prejudice;
 - 1.1.3.3 every participant who takes part in the study will receive the accompanying form for informed consent and it will be ensured that every participant understands the information (including the process and risks) fully;
 - 1.1.3.4 every participant will sign the informed consent in writing before the study commences, or a witness will stand in on behalf of the participant when the participant is illiterate;
 - 1.1.3.5 the written permission of the parent or legal guardians of all minor subjects will be obtained before the research commences;
 - 1.1.3.6 any foreseeable risk is restricted to the minimum, any permanent damage is avoided as far as possible and that appropriate precautions and safety measures are in place;
 - 1.1.3.7 confidentiality of all the information of all participants will be respected and ensured;

April 2016

1

Health Research Ethics Application

Study Leader (Title, Initials & Surname)	Study Title (see § 1.1)
Prof. W Lubbe	Tube-to-oral transition pathway to guide feeding advancement in moderate to late preterm neonates: A systematic review

NWU Ethics Number

N	W	U	-																
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1.2 Sec 8b: Statistical Consultant (If applicable)

CURRENTLY STATISTICAL SERVICES FROM THE INTERNATIONAL PRIMARY INVESTIGATOR WILL BE UTELISED AS PER THE INTERNATIONAL PROTOCOL.

The statistician of the Statistical Consultation Service of the North-West University completes this section (where applicable).

1.2.1 Have you ascertained that the statistical analyses to be used in this study is justifiable according to your judgement?

Please mark with X in the appropriate box and provide details.

Yes	No	Remarks
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Type here

Name (Title, Full Names & Surname)	Qualifications
Type here	Type here

Signature

Date

2	0			-			-		
c	c	y	y		m	m		d	d

Remember to save your document regularly as you complete it!

Health Research Ethics Application

Study Leader (Title, Initials & Surname)	Study Title (see § 1.1)
Prof. W Lubbe	Tube-to-oral transition pathway to guide feeding advancement in moderate to late preterm neonates: A systematic review

NWU Ethics Number

N	W	U	-																
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1.2 Sec 8b: Statistical Consultant (If applicable)

CURRENTLY STATISTICAL SERVICES FROM THE INTERNATIONAL PRIMARY INVESTIGATOR WILL BE UTELISED AS PER THE INTERNATIONAL PROTOCOL.

The statistician of the Statistical Consultation Service of the North-West University completes this section (where applicable).

1.2.1 Have you ascertained that the statistical analyses to be used in this study is justifiable according to your judgement?

Please mark with X in the appropriate box and provide details.

Yes	No	Remarks
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Type here

Name (Title, Full Names & Surname)	Qualifications
Type here	Type here

Signature

Date

2	0			-			-		
c	c	y	y		m	m		d	d

Remember to save your document regularly as you complete it!

ANNEXURE H: APPROVAL CERTIFICATE



Private Bag X8001, Potchefstroom,
South Africa, 2520

Tel: (018) 299-4900
Faks: (018) 299-4910
Web: <http://www.nwu.ac.za>

Research Ethics Regulatory Committee

Tel: +27 18 299 4849

Email: Ethics@nwu.ac.za

ETHICS APPROVAL CERTIFICATE OF STUDY

Based on approval by Health Research Ethics Committee (HREC) on 13/11/2017, the North-West University Research Ethics Regulatory Committee (NWU-RERC) hereby approves your study as indicated below. This implies that the NWU-RERC grants its permission that provided the special conditions specified below are met and pending any other authorisation that may be necessary, the study may be initiated, using the ethics number below.

Study title: Tube-to-oral transition pathway to guide feeding advancement in moderate to late preterm neonates: A systematic review														
Study Leader/Supervisor: Prof W Lubbe														
Student: Ms S Nel- 21633959														
Ethics number:														
N	W	U	-	0	0	1	3	8	-	1	7	-	A	1
Institution			Study Number					Year		Status				
Status: S = Submission; R = Re-Submission; P = Provisorial; Authorisatort; A = Authorisation														
Application Type: Systematic review														
Commencement date: 13/12/2017														
Risk: Minimal														
Approval of the study is initially provided for a year, after which continuation of the study is dependent on receipt of the annual (or as otherwise stipulated) monitoring report and the concomitant issuing of a letter of continuation.														

General conditions:

While this ethics approval is subject to all declarations, undertakings and agreements (incorporated and signed in the application form, please note the following:

- The study leader (principle investigator) must report in the prescribed format to the NWU-RERC via HREC:
 - annually (or as otherwise requested) on the monitoring of the study, and upon completion of the study
 - without any delay in case of any adverse event or incident (or any matter that interrupts sound ethical principles) during the course of the study.
- Annually a number of studies may be randomly selected for an external audit.
- The approval applies strictly to the proposal as stipulated in the application form. Should any changes to the proposal be deemed necessary during the course of the study, the study leader must apply for approval of these amendments at the HREC, prior to implementation. Should there be any deviations from the study proposal without the necessary approval of such amendments, the ethics approval is immediately and automatically forfeited.
- The date of approval indicates the first date that the study may be started.
- In the interest of ethical responsibility the NWU-RERC and HREC retains the right to:
 - request access to any information or data at any time during the course or after completion of the study;
 - to ask further questions, seek additional information, require further modification or monitor the conduct of your research or the informed consent process.
 - withdraw or postpone approval if:
 - any unethical principles or practices of the study are revealed or suspected,
 - it becomes apparent that any relevant information was withheld from the HREC or that information has been false or misrepresented,
 - the required amendments, annual (or otherwise stipulated) report and reporting of adverse events or incidents was not done in a timely manner and accurately,
 - new institutional rules, national legislation or international conventions deem it necessary.
- HREC can be contacted for further information or any report templates via Ethics-HRECApply@nwu.ac.za or 018 299 1206.

The RERC would like to remain at your service as scientist and researcher, and wishes you well with your study. Please do not hesitate to contact the RERC or HREC for any further enquiries or requests for assistance.

Yours sincerely

Prof. Refilwe Phaswana-Mafuya

Chair NWU Research Ethics Regulatory Committee (RERC)