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Acknowledgements

"It takes a village to raise a child" **-African proverb**

I would like to acknowledge my "village" that supported me to "raise" my thesis:

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Research outputs and awards

This thesis is based on the following articles that were accepted and submitted for publication by international and national peer reviewed journals:

1. Viviers, M., Kritzinger, A., & Vinck, B. (2016). Development of a clinical feeding assessment scale for high-risk neonates in South Africa. *South African Journal of Communication Disorders* (In press).
2. Viviers, M., Kritzinger, A., Vinck, B., & Graham, M. (2016). Preliminary psychometric performance of the Neonatal Feeding Assessment Scale. *South African Journal of Communication Disorders* (In press).
3. Viviers, M., Kritzinger, A., Vinck, B., & Graham, M. (2016). Validity and reliability of the Neonatal Feeding Assessment Scale (NFAS). *Journal of Public Health in Africa* (Submitted).

Parts of this thesis have been presented at an international conference on dysphagia:

1. Viviers, M., & Kritzinger, A. (2016). The development and preliminary performance of a newly developed Infant Feeding Assessment Scale (NFAS). Poster presented at *The Annual Dysphagia Research Society (DRS) Meeting, Tucson USA,* 26 February 2016.
2. Viviers, M., & Kritzinger, A. (2016). The reliability and validity of the NFAS. Paper presented at *The Annual Dysphagia Research Society Meeting, Tucson USA, 25 February 2016.*

Awards received for paper presented at the annual DRS 2016 conference:

1. First place – New Investigators forum – Best new investigator in the field of dysphagia
2. First place – Best oral paper presentation
3. Springer International Travel scholarship

Parts of this thesis have been accepted for an oral and poster presentation at the upcoming national conference for Speech-language therapists in South Africa hosted by the South African Speech-Language-Hearing Association (SASLHA) 2016:

1. Viviers, M., & Kritzinger, A. (2016). The development of the Neonatal Feeding Assessment Scale. Paper to be presented at *ENT/SASLHA/SAAA conference, Johannesburg, South Africa*, September 2016.
2. Viviers, M., & Kritzinger, A. (2016). The Neonatal Feeding Assessment Scale – a reliable and valid assessment tool for the South African context. Poster to be presented at *ENT/SASLHA/SAAA conference, Johannesburg, South Africa,* September 2016.

Abstract

There is a dearth of validated neonatal feeding assessment instruments available for use in clinical practice in resource-constrained developing contexts. The Neonatal Feeding Assessment Scale (NFAS) was developed to identify and diagnose oropharyngeal dysphagia (OPD) in neonates. The main aim of the study was to develop and test the psychometric performance of a clinical assessment scale for the early identification and diagnosis of OPD in the high-risk neonatal population in South Africa. To meet the main aim, the research project was divided into three separate studies.

The research design across the three studies was an exploratory sequential mixed-method design. The NFAS was developed using the Delphi method in the first study. Two international and three South African speech-language therapists (SLTs) formed the expert panel that participated in two rounds of electronic questioning to develop the instrument. For the second and third studies, a comparative cross-sectional within-subject design was used. In the second study the participants were 20 neonates with a median age of 35.0 weeks gestational age (GA) in a 29-bed neonatal intensive care unit (NICU). In the third study 48 participants with a median age of 35.5 weeks GA were included. During the second study the preliminary psychometric performance of the NFAS was determined and in the third study, the final psychometric properties of the NFAS were determined to describe the validity and reliability of the NFAS.

The NFAS was developed and approved, using expert collaboration through the Delphi method in the first study. All participants agreed on the need for the development of a valid clinical feeding assessment instrument to use with the high-risk neonatal population. The initial NFAS consisted of 240 items across 8 sections; after the Delphi process was implemented, the final format was reduced to 211 items across 6 sections. The final format of the NFAS is scored using a binary scoring system guiding the clinician to identify the presence or absence of OPD. All members agreed on the format, the scoring system and the feeding constructs addressed in the final format of the NFAS.

The second study showed that 9 out of 20 participants presented with OPD on the NFAS. Comparison of NFAS results with modified barium swallow studies (MBSS).

indicated that all participants with OPD were correctly identified (100% specificity). The sensitivity was 78.6%, indicating that three participants were falsely identified with OPD on the NFAS. The instrument took approximately 30 minutes to complete during observation of a habitual feeding session with the mother. Inter-rater reliability was determined on 50% (n=10) of the study sample. Substantial agreement (80%) was obtained between two raters in five of the six sections of the NFAS and on the diagnostic outcome of the scale. The preliminary performance of the NFAS appeared to be promising. The formal validation process of the NFAS then followed on a larger sample in the third study.

Results of the third study indicated that 15 of the 48 participants were identified with OPD on the NFAS, whereas 14 of these 15 infants were diagnosed on MBSS. A sensitivity score of 78.6% was obtained, with specificity determined to be 88.2% for the newly developed NFAS. The subsequent accuracy of the NFAS to identify OPD correctly was 85.4% when compared with the MBSS outcome. Inter-rater reliability was determined using 35% of the sample. The agreement on overall instrument outcome between the two raters was considered substantial beyond chance, with Cohen's Kappa at 0.598, with an asymptotic standard error of 0.211. The scale may be of use to SLTs working without MBSS equipment and to reach underserved preterm neonates. Inexperienced SLTs may benefit from observational prompts provided by the NFAS. The NFAS may be suitable for use in South Africa and similar developing contexts to identify and diagnose high-risk neonates with OPD.

Keywords

Clinical assessment

Delphi method

Diagnostic accuracy

Inter-rater reliability

Modified Barium Swallow study

Neonatal Feeding Assessment Scale

Oropharyngeal dysphagia Sensitivity

Specificity

Validity

List of abbreviations and acronyms

ARV	Antiretroviral
ASHA	American Speech-Language-Hearing Association
ASE	Asymptotic standard error
BPD	Bronchopulmonary dysplasia
CNS	Central nervous system
CPG	Central pattern generator
ED	Esophageal dysphagia
EFS	Early Feeding Skills
EI	Early intervention
FASD	Foetal Alcohol Spectrum Disorder
FEES	Fiberoptic Endoscopic Evaluation of Swallowing
FN	False negative
FTT	Failure-to-thrive
FP	False positive
GA	Gestational age
GER	Gastro-esophageal reflux
GERD	Gastro-esophageal reflux disease
HIE	Haemorrhagic ischemic encephalopathy
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HPCSA	Health Professions Council of South Africa
IUGR	Intra-uterine growth retardation
LBW	Low birth weight
MBSS	Modified Barium Swallow study
MTCT	Mother-to-child-transmission
NFAS	Neonatal Feeding Assessment Scale

NICU	Neonatal Intensive Care Unit
NNS	Non-nutritive sucking
NS	Nutritive sucking
NOMAS	Neonatal Oral-Motor Assessment Scale
NPV	Negative Predictive Value
OPD	Oropharyngeal dysphagia
PMTCT	Prevention of mother-to-child-transmission
PPV	Positive Predictive Value
RDS	Respiratory Distress Syndrome
SA	South Africa
SASLHA	South African Speech-Language-Hearing Association
SD	Standard deviation
SGA	Small for gestational age
SLP	Speech-language pathology
SLT	Speech-language therapist
SOFFI	Support of Oral Feeding for Fragile Infants
SOMA	Schedule for Oral-Motor Assessment
SSB	Suck-swallow-breathe
STARD	Standards for Reporting of Diagnostic Accuracy
TN	True negative
TP	True positive
US	United States
WHO	World Health Organization
WMA	World Medical Association

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(*Figure numbering in the following chapters 4 – 6 will not follow on from chapter 1-3, since publication guidelines were adhere to)

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Declaration

I, Maria Magdalena Viviers, hereby declare that the work on which this thesis is based is my original work – except where acknowledgements indicate otherwise – and I have used the American Psychological Association 6th edition (2010) system of referencing. I declare that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree at this or any other university.

Signature: _____

Date: 31 August 2016

Chapter I

Introduction

Aim of the chapter: To introduce the topic of neonatal dysphagia, pose the problem statement and state the rationale for the study and the research questions. Terminology as used in the thesis is explained.

1.1. Introduction

The early diagnosis of feeding and swallowing difficulties in neonates and infants is of vital importance to prevent and minimize associated medical and developmental complications (Prasse & Kikano, 2009). The goal of early identification and diagnosis of dysphagia in this vulnerable population is to describe the nature of the problem, and subsequently determine an appropriate treatment plan in support of health, development and adequate nutrition (Bruns & Thompson, 2012). Feeding and swallowing difficulties in infancy are considered to be multi-dimensional, due to the complex nature and variety of physiological systems involved in dysphagia (Arvedson, 2008; Jadcherla, 2016). Hence feeding and swallowing difficulties require a multi-factorial approach to clinical assessment and treatment (Arvedson, 2008). The majority of infants with feeding difficulties have at least one medical diagnosis as contributing factor, and 50% of infants and children with dysphagia have multiple causative factors contributing to dysphagia (Lefton-Greif, 2008). The diverse spectrum of dysphagia aetiologies in the early years necessitates a multi-dimensional and comprehensive assessment approach in clinical practice.

In the preterm population (infants born before 37 weeks gestation – World Health Organization [WHO], 2015) neonates under 28 weeks gestational age (GA) present with significant oral feeding delays associated with immaturity and increased time spent in the neonatal intensive care unit (NICU) compared with neonates older than 28 weeks GA (Jadcherla et al., 2009). It is not only delayed oral feeding that is associated with dysphagia in infants in the NICU. A prevalence range of 25–35% of oropharyngeal dysphagia (OPD) in preterm and low-birth-weight (LBW) neonates has been reported in studies (DeMauro, Patel, Medoff-Cooper, Posencheg, & Abbasi, 2011; Zehetgruber et al., 2014). The most recent prevalence estimate of 10.5% to 24.5% of feeding and swallowing disorders in premature infants may be

more realistic (Jadcherla, 2016). However, accurate prevalence figures of neonatal dysphagia are not available in the United States (US) (Jadcherla, 2016), nor in South Africa. The high prevalence of OPD in the NICU population, which includes preterm, LBW and sick term infants, is one of the reasons why the term 'neonatal dysphagia' is now used. The high prevalence of neonatal dysphagia further emphasizes the need for appropriate early clinical assessment of feeding disorders and OPD in high-risk neonates, in order to prevent feeding difficulties continuing into infancy and early childhood.

Neonatal dysphagia is thus a real concern for healthcare providers in the NICU and affects a neonate's discharge. A comprehensive definition of dysphagia by Dodrill and Gosa (2011:24) was adopted for this research study. The authors define dysphagia as "any disruption to the swallow sequence that results in a compromise of the safety, efficiency, or adequacy of nutritional intake". Neonatal dysphagia therefore refers to any feeding problem affecting the various stages of swallowing leading to nutritional compromise in some form or another in the high-risk neonate (Jadcherla, 2016). Two different types of dysphagia are mainly distinguished in literature. Typically there is OPD, representing a combination of difficulties experienced in the oral and pharyngeal stage of swallowing and oesophageal dysphagia (ED) linked to oesophageal stage difficulties (Jadcherla et al., 2009; Lefton-Greif, 2008; Rommel, De Meyer, Feenstra, & Veereman-Wauters, 2003). OPD together with ED represent the major types of dysphagia in neonates (Jadcherla et al., 2009).

As mentioned, the causes of neonatal dysphagia may be multi-factorial and complex. Usually the causes are a combination of various medical conditions, neurological and organ system immaturity and the neonate's limited ability to tolerate stress (Jadcherla, 2016; Jadcherla et al., 2009). Figure 1.1 shows the causes of neonatal dysphagia, with additional prevalent causes in South Africa.

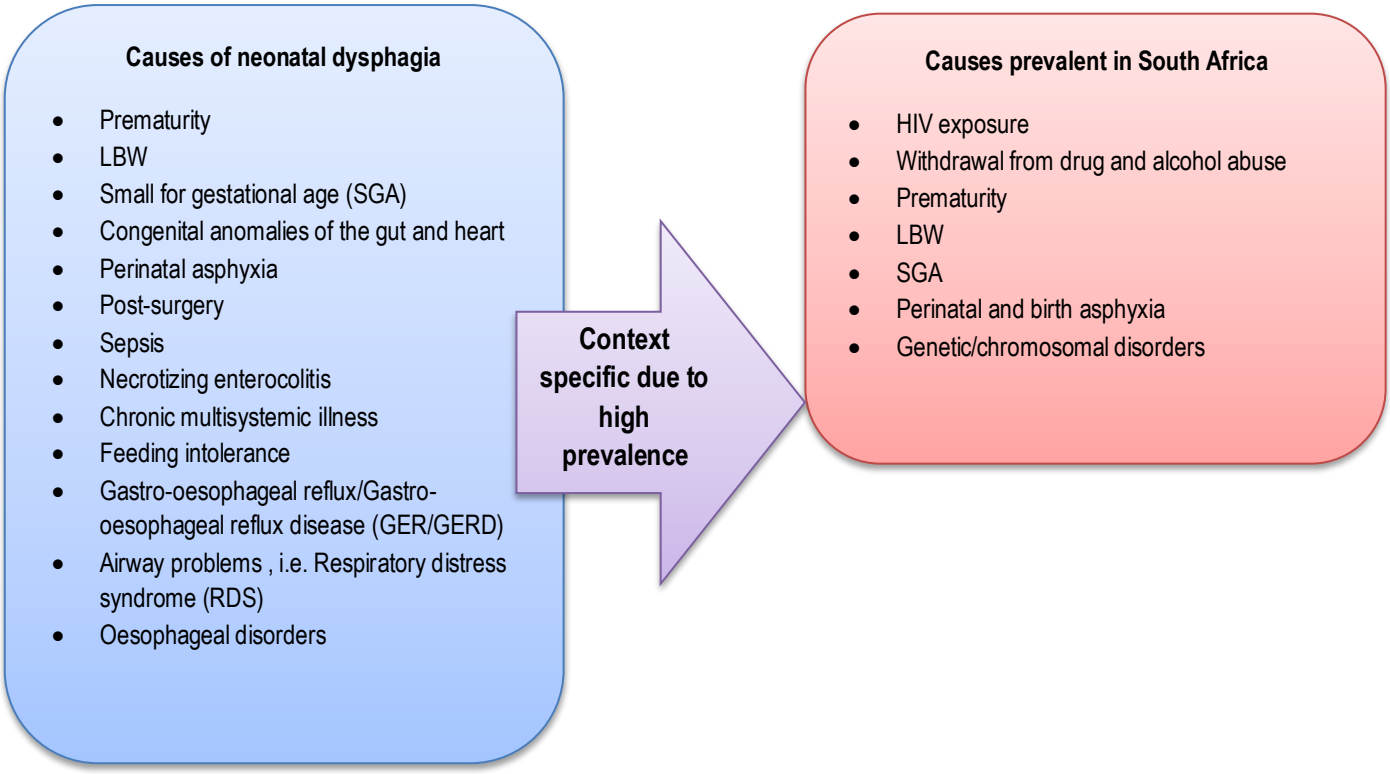

Figure 1.1 Causes of neonatal dysphagia with specific reference to the South African context (Compiled from: Arvedson, 2008; Jadcherla, 2016; Jadcherla et al., 2009; Pike, Pike, Kritzinger, Krüger & Viviers, 2016; Gordon, 2012; Hyams, 2013)

As shown in Figure 1.1, a variety of medical and developmental conditions, often in clusters, can contribute to the cause of neonatal dysphagia. In South Africa the high prevalence of some conditions, such as HIV exposure is highlighted. All neonates born to mothers who are HIV-positive may have feeding issues, since the neonate's feeding is dependent on the mother's HIV status and choice of feeding method after receiving HIV counselling (WHO, 2010). Infants with HIV exposure are thus at a higher risk of having dysphagia or other feeding difficulties than typically developing infants (Nel & Ellis, 2012). HIV crosses the blood-brain barrier, causing neurological complications in infants (Pressman, 2010). However, feeding and swallowing difficulties in neonates exposed to HIV may not be evident soon after birth and may evolve over time (Nel & Ellis, 2012), resulting in the use of the term 'emerging dysphagia'. Initially, HIV is more likely to affect the central rather than the peripheral nervous system (Pressman, 2010). The control centres for swallowing and sucking are situated in the brainstem (Barlow, 2009a) and therefore feeding may not be affected by HIV exposure in the neonatal stage. However, encephalopathy may

ensue, of a static or progressive nature, and because of disease progression dysphagia may develop during infancy (Pressman, 2010).

Alternatively, neonates exposed to HIV may be at risk of developing dysphagia due to an increased incidence of prematurity, LBW and SGA in this population (Coutsadis, Coovadia, & Wilfert, 2008; Doherty, Chopra, Nkonki, Jackson, & Greiner, 2006). The morbidity and mortality associated with HIV exposure in neonates remain a global health burden, not only affecting countries such as South Africa in the sub-Saharan Africa region (Barron et al., 2013).

In addition to the high prevalence of HIV exposure in neonates, perinatal asphyxia leading to hypoxic ischaemic encephalopathy (HIE) is a serious problem in developing countries such as South Africa (Padayachee & Ballot, 2013). In severe cases of HIE the brainstem may also be affected, due to the diffuse nature of injury from hypoxia. Since the central pattern generators (CPGs) for sucking, swallowing and respiration are located in the medulla, neonates may present with impaired sucking due to immature suck-swallow-breathe (SSB) synchrony (Lau, 2016). Asphyxia during difficult labour and birth is confirmed as a major cause of neonatal dysphagia (Jadcherla, 2016).

Prematurity, LBW and SGA are also globally recognised causes of neonatal dysphagia (Jadcherla, 2016), with a high prevalence of these conditions in South Africa (WHO, 2012). Dysphagia in the preterm population may be characterized by uncoordinated SSB interaction, desaturation events, decreased sustained sucking, GER, aspiration and high rates of silent aspiration (De Mauro et al., 2011; Pike et al., 2016; Uhm, Yi, Chang, Cheon, & Kwon, 2013). In neonates with LBW, oral feeding difficulties together with GER may affect their feeding ability (Sherrow et al., 2014). LBW and prematurity also place neonates at risk for posttraumatic feeding disorder (Wilken & Bartmann, 2014). Posttraumatic feeding disorder of infancy develops due to repeated medical interventions and negative experiences intra-orally and in the orofacial area during hospitalization in the NICU. These negative and at times painful experiences may lead to behavioural difficulties during oral feeding (Wilken & Bartmann, 2014). SGA was associated with OPD and ED in a small South African study (Pike et al., 2016). Neonates who are SGA are also at high risk of presenting

with RDS, which impacts on the SSB sequence and sustained nutritive sucking (NS) during oral feeding (Pike et al., 2016; Zehetgruber et al., 2014).

South Africa has the highest incidence of Foetal Alcohol Spectrum Disorder (FASD) in the world (May et al., 2007; Viljoen et al., 2006). Alcohol exposure in utero may contribute to withdrawal after birth, impeding feeding in the neonatal period and during early infancy. Neonates with alcohol exposure in utero may also present with intrauterine growth restriction (IUGR), postnatal growth restriction, central nervous system disorder, irritability and LBW, affecting feeding (De Beer, Kritzinger & Zsilavecz, 2010; Jones, 2011; Kvigne et al., 2004; O'Leary, 2004). The nature of the feeding difficulties in neonates and infants with FASD has not yet been well documented. The prevalence of genetic, chromosomal and neurodevelopmental disorders, such as cerebral palsy, is also high in South Africa (Barratt & Ogle, 2010; Department of Health, 2001). Prevalence data on dysphagia amongst neonates and infants with genetic and chromosomal disorders is unavailable for South Africa. The estimated incidence of feeding and swallowing difficulties in infants with neurodevelopmental disorders in South Africa is 29% (Barratt & Ogle, 2010). In chromosomal disorders, such as Down Syndrome, low muscle tone, congenital cardiac disorders and sensory integration impairment is associated with OPD in infancy (Barratt & Ogle, 2010). To address the needs of such high-risk neonates in South Africa, valid clinical assessment should form the foundation of evidence-based intervention for OPD.

Internationally and locally there are inconsistencies in clinical assessment practices used in paediatric and neonatal dysphagia (Arvedson, 2008; Botha & Schoeman, 2011; Vermeulen, 2015). Such inconsistencies are perhaps not expected in developed countries, since service delivery in the NICU by multiple professionals is guided by high standards of training, various healthcare regulations and evidence-based professional guidelines. In a developing country such as South Africa there is a dearth of research regarding the clinical assessment practices used by local speech-language therapists (SLTs) in this field of practice. Two local studies (Botha & Schoeman, 2011; Vermeulen, 2015) have indicated a need for evidence-based assessment instruments to reliably identify paediatric dysphagia relevant to the local context. Findings by Botha and Schoeman (2011) revealed inconsistency in assessment practices, similar to studies conducted in developed countries such as

Ireland, Australia and the US (Mather-Schmidt & Kurlinski, 2003; Pettigrew & O'Toole, 2007). Botha and Schoeman (2011) found a critical need for a clinical dysphagia assessment instrument for neonates and very young infants specific to the South African context.

The South African Speech Language and Hearing Association [SASLHA] (2011a) specifies that SLTs' scope of practice in paediatric dysphagia includes both clinical and instrumental evaluation of oral, pharyngeal and upper oesophageal function. In the same SASLHA (2011a) Guidelines for Paediatric Dysphagia there is no specific reference to neonates; this population appears to be included in the term 'infants'. In South Africa the term 'paediatric dysphagia' is thus used to refer to neonates, infants and children below 12 years of age who presents with dysphagia. The problem for SLTs in South Africa is the current lack of context-specific dysphagia assessment instruments for use with neonates and infants. The lack of assessment instruments appears to be widespread. Although recognition of the unique needs posed by neonatal dysphagia has increased (Jadcherla et al., 2009; Jadcherla, 2016), research into development of clinical assessment instruments and procedures for this population continues to remain limited (Heckathorn, Speyer, Taylor, & Cordier, 2015). However, there is a large body of literature on swallowing and feeding disorders from various perspectives such as medical, nursing, nutritional and oral-motor functioning in infants (Arvedson, 2008; Arvedson & Brodsky, 2002; Davis & Conti, 2003; De Matteo, Matovich, & Hjarterson, 2005; Dusick 2005; Wolthuis-Stigter et al., 2015; Zehetgruber et al., 2014). The studies confirm the lack of current research into the development of valid and reliable clinical assessment instruments in the area of neonatal dysphagia.

Research into paediatric dysphagia is still relatively young in South Africa. Investigators are exploring various topics in paediatric and neonatal dysphagia, thereby contributing to the body of evidence for practice in developing countries (Barratt & Ogle, 2010; Botha & Schoeman, 2011; Chadinha, 2015; Degenaar & Kritzinger, 2015; Dickinson, Malan, & Pike, 2012; Evens, 2002; Gordon, 2012; Hyams, 2013; Klimek & Merven, 2013; Norman, Louw, & Kritzinger, 2007; Oosthuizen, 2012; Pike et al., 2016; Sepeng & Ballot, 2015; Uys, 2000). It is important that SLTs in South Africa should be knowledgeable about the complex nature and causes of neonatal dysphagia, often specific to contexts such as HIV

exposure and associated medical conditions, to guide them in assessment and treatment practices. The SLT should also be aware of the wide-ranging impact of feeding and swallowing difficulties on neonatal development and parent-infant attachment. Clinical assessment should therefore encompass feeding and feeding-related behaviours, and also consider the impact of the transactional nature of the mother-infant relationship on the neonate during feeding (Davies et al., 2006). The feeding relationship emphasizes the dyadic nature of feeding problems that exist not only within the infant but possibly also within the mother-infant relationship (Chatoor, 2000; Davies et al., 2006).

In a recent review, Pados and colleagues found a lack of validated feeding assessment scales for infants younger than six months that are supported by high-level evidence (Pados, Park, Estrem, & Awotwi, 2016). They concluded that the *Early Feeding Skills Assessment* [EFS] checklist (Thoyre, Shaker & Pridham, 2005) was one of the instruments that had some supportive psychometric development and testing in the neonatal population. However, no supportive data on the content validity for the EFS has been published. Therefore the need for a validated context-specific feeding assessment instrument is clear, especially in view of the high prevalence of a number of medical conditions related to OPD in South Africa. SLTs practising in South Africa should be thoroughly prepared to evaluate these infants and make informed decisions on appropriate management of OPD in high-risk neonates. An instrument that could guide comprehensive clinical assessment and decision making might benefit SLTs in providing evidence-based services in South Africa.

1.2. Neonatal dysphagia assessment in the South African context – problem statement, rationale and research questions

In many developing countries such as South Africa, radiological equipment for performing a modified barium-swallow study (MBSS) is lacking at the different levels of public healthcare. For instance, MBSS equipment is only available at tertiary healthcare facilities in Gauteng province, where the study was conducted. Moreover, skilled and experienced SLTs are not always readily available to interpret MBSS assessment results accurately. MBSS assessment findings may therefore not always be used optimally for intervention decisions in the hospitals. SLTs practising in other

developing middle-income countries, such as Malaysia, with a similar multi-ethnic and multi-cultural client base as South Africa, also indicated a lack of confidence, knowledge and skills in managing paediatric dysphagia. SLTs in Malaysia also face infrastructural challenges (e.g. lack of MBSS availability) which constrain optimal service delivery and achievement of best-practice standards (Mustaffa Kamal, Ward, Cornwell, & Sharma, 2015). These challenges are comparable to those faced by SLTs in South Africa. So a number of factors, such as the lack of validated neonatal dysphagia assessment tools, adequately trained SLTs to identify and diagnose the presence of dysphagia, and a lack of healthcare equipment and resources (Mustaffa Kamal et al., 2015) have contributed to identifying the research problem in this study. A clear need for valid dysphagia assessment instruments to use in clinical practice with the neonatal population was identified.

Despite limited sensitivity and specificity data for various infant assessment instruments, there has been a surge in the popularity of clinical assessment scales to prevent unnecessary radiation exposure from over-referral for MBSS (De Matteo et al., 2005; Heckathorn et al., 2015). Clinical assessment scales are also used to compensate for the lack of MBSS equipment in resource-constrained hospitals in the public healthcare sector in developing countries such as South Africa. Due to a history of segregation in South Africa, equal access to healthcare has been a continuing challenge (McLaren, Ardington, & Leibbrandt, 2014). Since 1994, significant growth in access to public healthcare services has been noted, yet limited increases in funding and lack of adequate policy guidelines have hampered provision of quality health services equal to those received in the private system in South Africa (Ataguba & Alaba, 2012). At present, South Africa's compulsory community service year for newly qualified SLTs has resulted in increased access to SLTs in the public healthcare system. Despite increased access, the number of SLTs experienced in managing medically complex neonates with OPD in the NICU context may still be inadequate.

In the field of neonatal dysphagia, research should therefore develop evidence-based assessment practices to support SLTs in public and private healthcare in South Africa. A validated clinical feeding assessment instrument would not be designed to replace objective instrumental assessment (Arvedson, 2008; De Matteo

et al., 2005; Rommel, 2006), but is proposed to assist with accurate early identification and diagnosis of OPD in neonates.

The impetus for the development of a new clinical assessment instrument derives from the lack of validated neonatal assessment instruments to evaluate the presence or absence of OPD (Arvedson, 2008; Arvedson & Brodsky, 2002; Hall, 2001; Heckathorn et al., 2015; Palmer, Crawley, & Blanco, 1993; Reilly, Skuse, Mathisen & Wolke, 1995; Sheppard, 1987, Tuchman, 1989; Wolf & Glass, 1992). Research interest in neonatal and paediatric dysphagia resulted in a few relevant and reliable assessment instruments such as the *Neonatal Oral Motor Assessment Schema* [NOMAS] (Palmer et al., 1993) and the *Schedule for Oral Motor Assessment* [SOMA] (Reilly et al., 1995; Reilly, Skuse, & Wolke, 2000), but these instruments focus on specific functional skill units and do not provide a comprehensive overview of the total feeding process and stress experienced by the neonate during feeding (Rogers & Arvedson, 2005). Nor do these instruments provide a conclusive diagnosis of the presence or absence of OPD.

The research team led by Thoyre et al. (2005) contributed the EFS to this area of practice. The EFS investigates feeding in neonates and young infants in a comprehensive manner by means of a checklist format, but also does not reach a diagnosis of OPD. Arvedson (2008) has added weight to the rationale for the development of a new instrument by stating that there is no universally accepted neonatal feeding assessment instrument in widespread clinical use, and that most of the existing scales lack standardization and validation. Recently Heckathorn et al. (2015), together with Pados et al. (2016), reiterated the need for valid clinical assessment instruments to support evidence-based practice in assessing feeding and swallowing difficulties in the neonatal and infant populations. Clinical assessment, as compared with instrumental assessment, is considered to be minimally invasive and useful for investigating signs and symptoms of OPD or aspiration (Arvedson & Lefton-Greif, 1998; Heckathorn et al., 2015; Leder, 1997).

It is proposed that a newly developed, valid clinical assessment instrument to identify and diagnose OPD may have several benefits, such as

- Enabling clinical assessment without the need to wait for availability of other team members required for MBSS

- Reduced waiting periods for MBSS, since unnecessary referrals may decrease
- Reduced expenses incurred during MBSS procedures
- Decreased radiation exposure in high-risk neonates
- Saving of costs to the already overburdened public healthcare sector in South Africa from untreated neonatal dysphagia and related complications such as an increased length of stay in the NICU, and increased mortality and comorbidity.

Therefore, evidence-based clinical assessment procedures could contribute to improved service delivery to high-risk neonates, and reduce healthcare costs. Evidence-based practice requires that the validity and reliability of newly developed assessment instruments should be supported by appropriate research results (Heckathorn et al., 2015). Dysphagia in high-risk neonates can have long-term negative effects on development if not addressed optimally through early diagnosis (Jadcherla, 2016). A high-risk status implies that the neonate's interaction and participation during feeding has been disrupted by an NICU stay after birth and/or the presence of conditions such as LBW, prematurity, SGA, HIV exposure, withdrawal from drugs and alcohol, perinatal/birth asphyxia and genetic/chromosomal disorders in South Africa (Bradshaw et al., 2008).

Therefore a need was evident for the development of a valid and reliable clinical assessment instrument with high sensitivity and specificity for the early identification and diagnosis of OPD compared to objective MBSS results. The following research questions were posed:

Study 1: Three research questions were investigated in the first study.

- What is the opinion of a panel of experts regarding the need for a validated clinical feeding assessment scale?
- Which items are appropriate for inclusion in the Neonatal Feeding Assessment Scale (NFAS)?
- Does the NFAS present with face and content validity?

Study 2:

- What are the preliminary psychometric properties of the newly developed NFAS in a small sample of high-risk neonates?

Study 3:

Does the NFAS maintain valid and reliable psychometric properties when a larger sample is utilized?

1.3. Roadmap for the thesis

This section clarifies the relevant terminology as used in the thesis and provides an outline of the chapters.

1.3.1. Terminology as used in the thesis

Clinical assessment:

The term *assessment* has been used interchangeably with evaluation. Clinical assessment in this context refers to the direct evaluation of feeding, feeding-related behaviour and swallowing skills in an infant, without the use of instrumentation such as the MBSS. A clinical assessment is comprehensive and can provide diagnostic information regarding the nature of feeding and swallowing difficulties present in the neonate.

(Arvedson & Brodsky, 2002; Arvedson, 2008; Heckathorn et al., 2015)

Instrumental assessment:

In contrast with clinical assessment, instrumental assessment of swallowing refers to any assessment procedure in which visualization equipment, such as X-ray and fiberoptic nasal endoscopes, is used to view components of the swallowing process or the complete swallowing process directly in real time. Instrumental assessment allows the clinician to observe those components of the swallow not visible during a clinical assessment. Instrumental assessment includes MBSS or fiberoptic endoscopic evaluation of swallowing (FEES). The MBSS is considered the gold standard of instrumental assessment, since it allows the most accurate diagnosis of different types of dysphagia. MBSS provides dynamic views of the oral, pharyngeal

and oesophageal stages of swallowing directly, in real time, and can also be stored electronically for comparison studies.

(Arvedson & Brodsky, 2002; Arvedson & Lefton-Greif, 1998; Groher & Crary, 2010)

Gold standard:

The gold standard is a test/instrument that is widely recognized as the best test available to diagnose the condition – in this study OPD – under investigation. The gold standard is the accepted diagnostic test/instrument that is assumed to determine the true presence of the disorder under investigation, regardless of positive or negative test findings or sensitivities or specificities of other diagnostic tests used. In dysphagia the MBSS is considered the gold standard for diagnosis of OPD in all age groups.

(Arvedson, 2008; Arvedson & Brodsky, 2002; Arvedson & Lefton-Greif, 1998; Dawson & Trapp, 2004)

High-risk neonate:

High-risk status implies the existence of anything that interferes with the neonate's ability to interact with the environment or participate in an expected activity, such as feeding, in a normal manner. This term is thus used to refer to neonates experiencing difficulty in engaging and participating in oral feeding. High-risk neonates may be term infants requiring NICU services after birth, or neonates who present with conditions and diagnoses such as LBW, prematurity, SGA, HIV exposure, HIE, FASD, and RDS. The high-risk status is thus defined by anything that may interfere with the typical developmental trajectory of feeding development that can contribute to dysphagia in the neonatal population.

(Jadcherla, 2016; Philbin & Ross, 2011; Rossetti, 2001)

Swallowing:

Swallowing requires refined sensorimotor integration controlled by the cortex and brainstem to integrate deglutition with protection of the aerodigestive system. Swallowing is a complex process reliant on the coordination of several anatomical structures and cranial nerve involvement to move a bolus successfully from the oral cavity to the stomach. Swallowing consists of four stages: the oral preparatory stage, oral stage, pharyngeal stage and the oesophageal stage. In this thesis the comprehensive term is used to refer to all stages inclusively.

(Arvedson & Brodsky, 2002; Prasse & Kikano, 2009; Rogers & Arvedson, 2005)

Neonatal dysphagia:

The recent comprehensive definition of dysphagia by Dodrill and Gosa (2011:24) was adopted for this research study. Dysphagia is defined as “any disruption to the swallow sequence that results in a compromise of the safety, efficiency, or adequacy of nutritional intake”. Neonatal dysphagia refers to swallowing difficulties that may be experienced beyond the timeframe of the traditional 28-day neonatal period, and rather refers to the period that an infant stays in the NICU. An NICU stay may extend beyond 28 days, as with participants in this study. Therefore the NFAS can be used for very young infants who are in the NICU from birth, regardless of the duration of the stay.

(Dodrill & Gosa, 2011; Jadcherla, 2016)

Paediatric dysphagia:

Paediatric dysphagia was used in the past to refer to dysphagia from birth into childhood. In this study paediatric dysphagia is used to refer to swallowing difficulties in any of the four stages of swallowing experienced beyond the neonatal period and NICU stay. Paediatric dysphagia occurs because of complex health, medical and developmental conditions and does not only arise from hospitalization in the NICU.

(Arvedson & Brodsky, 2002; Hall, 2001; Lefton-Greif, 2008)

Oropharyngeal dysphagia:

This term refers to swallowing difficulties experienced during the oral and/or pharyngeal stage of the swallowing process. Currently a diagnosis of OPD in neonates and infants is common to describe problems in the two stages of swallowing in combination. The term OPD has been used in research in the medical profession since its use in 1975 by Hurwitz and colleagues. In the speech-language pathology research and literature the term OPD in the paediatric and adult populations has been used since 1983, when it was introduced by Logemann.

(Arvedson, 2008; Hurwitz, Nelson, & Haddad, 1975; Lefton-Greif, 2008; Logemann, 1983)

Feeding disorder:

A feeding disorder refers to difficulties experienced in a range of eating activities, and is not limited to the four stages of swallowing. It may include learned maladaptive behavioural responses to eating or may be caused by a disorder in the structures and mechanisms involved in ingesting food/drink. Feeding disorders may cause delays in the acquisition of age-appropriate feeding skills. All children with swallowing disorders have feeding disorders, but not all children with feeding disorders have swallowing disorders. Feeding disorders were not the focus of this study.

(Arvedson, 2008; Arvedson & Brodsky, 2002; Hall, 2001; Swigert, 2010)

Penetration:

Penetration occurs when bolus particles such as those from formula milk or breast milk penetrate the larynx above the level of the true vocal folds and do not pass below this level. Penetration can occur before, during, or after swallowing and can include any materials. When penetration occurs, chemoreceptors in the larynx may trigger a protective cough response to expel the foreign material and prevent entrance into the airway below the level of the true vocal folds. Penetration is reliably diagnosed in the neonatal population with FEES or MBSS.

(Arvedson, 2008; Arvedson & Brodsky, 2002; Arvedson & Lefton-Greif, 1998; Lefton-Greif, 2008)

Aspiration:

In contrast to penetration, aspiration occurs when foreign materials enter the larynx and subsequently the airway below the level of the true vocal folds. It may occur before, during or after swallowing (primary aspiration), or after the feed as a result of GER (secondary aspiration), and can include any materials. Aspiration may be silent, when the protective cough response is absent. There are a number of subjective signs of aspiration in addition to coughing, such as wet vocal quality and desaturation.

(Arvedson & Brodsky, 2002; Arvedson & Lefton-Greif, 1998)

Speech-language therapist:

According to the Health Professions Council of South Africa (HPCSA) clinicians in the field of speech-language pathology in South Africa is registered to practice as 'speech-language therapists' (SLTs). This title may be different than is used in the US, the United Kingdom and Australia.

(HPCSA, 2011)

1.3.2. Outline of the chapters for the thesis

The outline of the dissertation is provided below:

PART I: Introduction, theoretical perspectives and methodology

- Chapter 1: Introduction
- Chapter 2: Theoretical perspectives on neonatal dysphagia and clinical assessment of OPD
- Chapter 3: Methodology

PART II: Published and submitted papers

- Chapter 4: *Article 1*: Development of a clinical feeding assessment scale for high-risk neonates in South Africa
- Chapter 5: *Article 2*: Preliminary psychometric performance of the Neonatal Feeding Assessment Scale (NFAS)
- Chapter 6: *Article 3*: Validity and reliability of the Neonatal Feeding Assessment Scale (NFAS)

PART III: Conclusion and future perspectives

- Chapter 7 – General conclusions, implications and future perspectives

1.4. Chapter summary

This chapter provided an introduction to the three studies on the topic of assessment and diagnosis of OPD in neonates. A discussion of the aetiology, nature and contextual factors contributing to neonatal dysphagia in South Africa was presented. The dimensions of the research were discussed in terms of the rationale, problem statement and research questions. Lastly, the terminology as used in the thesis was clarified, followed by an outline of the chapters included in the thesis.

Chapter 2

Theoretical perspectives on neonatal dysphagia and clinical assessment of OPD

Aim of the chapter: The theoretical underpinnings for developing the Neonatal Feeding Assessment Scale (NFAS) are discussed and a framework for viewing neonatal feeding difficulties, in particular oropharyngeal dysphagia (OPD), from a speech-language pathology perspective is suggested.

2.1. Introduction

The importance of the relationship between dysphagia and the high-risk neonate's medical conditions (Prasse & Kikano, 2009) is emphasized when viewing OPD from a speech-language pathology perspective. The underlying condition may cause or exacerbate OPD or may be present as a result thereof (Groher & Crary, 2010; Prasse & Kikano, 2009). The impact of the NICU environment and the parent-infant relationship should also be considered when investigating the contributing factors and the effect of dysphagia and feeding difficulties on this vulnerable population. The SLT should possess integrated knowledge of the developmental trajectory of typical feeding and swallowing skills during gestation, the neonatal period and early infancy (Medoff-Cooper, Rankin, Zhuoying, Liu, & White-Traut, 2015; Wolthuis-Stigter et al., 2015). In addition an understanding of the nature of neonatal dysphagia, its various aetiologies and contributing factors should be an integral part of the SLT's knowledge base (Jadcherla, 2016). A solid knowledge base guides the SLT to assess oral feeding skills in a developmentally supportive manner.

2.2. Typical development of feeding skills

Knowledge of the typical development of oral feeding skills enables the SLT to differentiate between normal physiology and pathology during clinical and instrumental assessment. An understanding of the underlying neural control directing the development of the SSB sequence is relevant to assess the high-risk neonate's feeding skills in a developmentally appropriate manner. The neural control and development of the SSB sequence as three coordinated motor patterns is thus the key concept to understand. Sucking and swallowing begins in utero between 15 to

18 weeks gestation, but does not yet demonstrate a characteristic patterned rhythm (Barlow, Lund, Estep & Kolta, 2010). The beginnings of patterned and rhythmic oral sucking-swallowing behaviour, regulated by CPGs only emerge between 28 and 33 weeks GA (Barlow et al., 2010). Brainstem myelination as precursor to CPG function occurs between 18 to 24 weeks GA (Delaney & Arvedson, 2008). The sensorimotor control of oral feeding involves a variety of CPGs in the brainstem forming a bilateral network of interneurons to allow spatiotemporal integration during the post-natal SSB sequence (Barlow, 2009a). Breathing efforts appear to be the last function integrated into successful oral feeding (Porges & Furman, 2011).

The SSB pattern is not only reliant on brainstem control, adequate myelination and motor performance but also on sensory input regulated by the primary trigeminal afferents (Barlow, 2009b). Sensory input received by these afferents prepares the neural pathway of swallowing and also plays a role in gastric motility in the post-natal period (Barlow, 2009a). Neurological control of the SSB sequence thus develops from the CPGs in the brainstem reticular formation (Porges & Furman, 2011). The cortical regulatory contribution from the sensorimotor areas, motor cortex and cerebellum also plays a role in the SSB sequence to establish safe oral intake (Barlow, 2009a; Barlow, 2009b). The suck-swallow pattern develops during late gestation and then the SSB pattern refines throughout the first year of life (Delaney & Arvedson, 2008) to lay the foundation for safe and successful oral sensory experiences, such as non-nutritive sucking (NNS) on a pacifier and mouthing of objects, and safe oral feeding.

Acquisition of oral feeding skills in infancy is not only reliant on the SSB sequence, but also influenced by a variety of other factors during feeding, such as positional support, maternal-infant interaction, and the mother's ability to read the infant's hunger cues and reduce the infant's stress responses. A timeline illustration depicts the major developmental events of typical feeding development during the pre-, peri- and early post-natal period in neonates in Figure 2.1. The timeline reflects research on the typical developmental trajectory of feeding and swallowing during foetal life to early infancy (Arvedson & Brodsky, 2002; Browne & Ross, 2011; Darrow & Harley, 1998; Lau, 2016; Nugent, Keefer, Minear, Johnson, & Blanchard, 2007; Rudolph & Thompson Link, 2002; Uhm et al., 2013; Watson Genna, 2013) – see Figure 2.1.

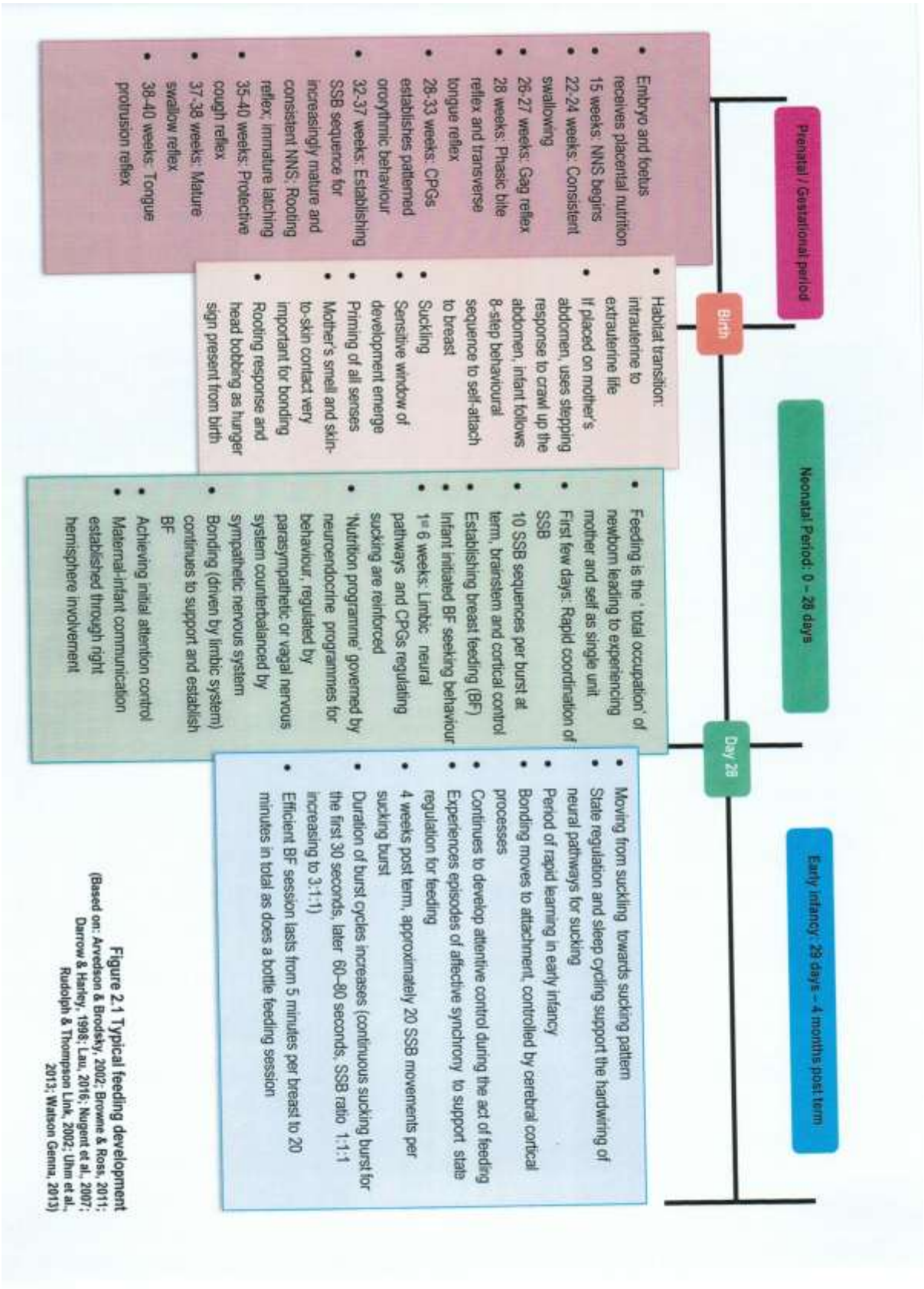

Figure 2.1 Typical feeding development
(Based on: Arvedson & Brodsky, 2002; Browne & Ross, 2011; Darrow & Harley, 1998; Lau, 2016; Nugent et al., 2007; Rudolph & Thompson Link, 2002; Uhm et al., 2013; Watson Genna, 2013)

The development and refinement of oral feeding further involves the integration of many patterns and behaviours which continue to develop during infancy, as represented in Figure 2.1. Preterm birth, however, disrupts the neurotypical developmental trajectory of feeding and swallowing during the last trimester of gestation. The consequences of preterm birth have a global impact on the neonate's oral feeding abilities, health, development, and maternal-infant attachment and interaction (Brittain et al., 2015; Bruns & Thompson, 2012; Crapnell et al., 2013). Understanding the impact of prematurity on the neonate's early period of development is relevant for the SLT to conduct a feeding assessment with the purpose of identifying and describing OPD.

Another purpose of developmentally appropriate clinical assessment is to accurately determine the timing of the disruption of typical feeding development and what went wrong due to the disruption (Crapnell, Woodward, Rogers, Inder, & Pineda, 2015). The SLT will then be able to support the attainment of oral feeding skills as part of the multidisciplinary team working in the NICU. Supporting attainment of safe oral feeding during this critical window of development in preterm neonates is important to allow adequate SSB integration to develop, to foster positive responsive maternal-infant interaction and to ensure adequate nutritional intake. This study focused on the development of a valid clinical assessment instrument to identify OPD in high-risk preterm neonates due to the lack of such instruments in neonatal dysphagia practice. The reciprocal relationship between neonatal OPD and the complex underlying medical conditions and contributing factors were taken into consideration for the development of the NFAS.

2.3. The complexity of neonatal dysphagia

The complex nature and diverse signs and symptoms of OPD, together with the negative or fatal sequelae in high-risk neonates, necessitate a comprehensive approach to clinical assessment. The SLT's perspective on neonatal dysphagia is guided in part by the profession's scope of practice (ASHA, 2005; SASLHA, 2011a) and hence mainly involves the assessment, diagnosis and management of OPD, the identification of ED, as well as parent training to support safe feeding. The SLT does,

however, not treat ED, since it reaches beyond the SLT's scope of practice. The SLT's training and scope of practice allows for a unique perspective on OPD.

It appears that the complex nature of OPD during infancy was first comprehensively described in the landmark text by Wolf and Glass (1992). The authors viewed feeding and swallowing as an integrated multi-system skill that requires a multidisciplinary team approach when the disorder is present. Wolf and Glass (1992) then introduced the Problem-driven model of assessment to support their view. The Problem-driven model's premise was to describe and define feeding and swallowing difficulties in the paediatric population. This model is directed by the identification of a problem that causes the infant's feeding difficulty. Wolf and Glass (1992) indicated that their rationale for implementing a Problem-driven model in assessment is that many infants with feeding disorders do not have an established medical diagnosis. However, when a medical diagnosis does exist it may or may not be related to the feeding problem. Wolf and Glass (1992) assisted the SLT to investigate feeding difficulties from a different perspective, than considering the medical diagnosis as the only cause of OPD, to describe the feeding problem.

Within the Problem-driven approach there are four different categories to determine the underlying constellation of the aetiology of the feeding problem. According to Wolf and Glass (1992) the common denominator amongst the categories is that each category is based on a presenting problem related to infant feeding. This model required an initial set of primary evaluations within a hierarchical approach to render more effective identification of simple and complex feeding problems.

The four categories in the Problem-driven model are the Feeding-related apnea model, the Feeding problem model, the Respiratory compromise model and the Poor weight gain model (Wolf & Glass, 1992). The Problem-driven model was proposed to support the clinician to determine the cause of feeding problems more accurately, and to support more effective treatment than when investigating OPD from the perspective of a traditional medical model alone. As Wolf and Glass' (1992) model was not diagnostically driven, it only proposed to describe feeding and swallowing difficulties in infants. Diagnostic advances in the field of neonatology have been numerous in the medically complex neonatal population since the introduction of the Problem-driven model. The profession of speech-language pathology (SLP) has also

improved in diagnostic skills relevant to the diagnosis of OPD in the neonatal and infant population. The aforementioned model is currently too simplistic in its view of OPD and does not adequately address the complex and interactional nature of the multiple causes and contributing factors of neonatal dysphagia. It is also difficult for the SLT to accurately diagnose and describe OPD without adequate consideration of the risk factors and complex medical conditions in neonates. A multidisciplinary team approach remains a requirement to comprehensively investigate OPD and its related diagnoses and pathophysiology (Jadcherla, 2016).

Shifting from a single focus, on either a medical diagnosis or a limited description of the feeding problem, to multiple perspectives may assist the SLT to perform a comprehensive clinical assessment. Using a multiple perspective may, in turn, contribute to earlier identification and accurate diagnosis of OPD. Such multiple perspectives include the consideration of the interaction between diagnosis, contributing factors and the transactional nature of the maternal-infant feeding dyad together with resulting symptoms of OPD. A neonate may present with various diagnoses such as bronchopulmonary dysplasia (BPD) and RDS, as well as contributing factors such as LBW and SGA which may impact on or cause OPD (Jadcherla, 2016). The advantage of using multiple perspectives during neonatal feeding assessment contributes to better insight regarding numerous underlying physiological and anatomical problems, together with maternal-infant attachment problems that may exacerbate OPD. Physiological problems in neonates may represent, for example, the immaturity of the neonate's various systems, the impact of illness on attainment of safe oral feeding and the pathophysiology of OPD in a specific neonate (Jadcherla, 2016; Pike et al., 2016; Zehetgruber et al., 2014). The observable signs and reported symptoms of OPD can be heterogeneous and non-specific in the neonatal population (Jadcherla, 2016; Uhm et al., 2013). Anatomical problems in the neonatal population may include, structural deficits, such as cleft lip and palate (Alperovich, Frey, Shetye, Grayson, & Vyas, 2016), and tongue and lip ties (Kotlow, 2013; Power & Murphy, 2014) that may all impact on oral feeding skills. Maternal-attachment problems may be caused by the mother's inexperience and anxiety to care for her preterm infant (Crapnell et al., 2013; Crapnell et al., 2015; Petzoldt, Wittchen, Einsle, & Martini, 2016; Woodward et al., 2014). Difficulties in the maternal-infant feeding dyad may be characterized by an inability to read the

neonate's hunger cues or not being appropriately responsive to adapting to the stress cues displayed by the neonate (Shaker, 2013). Attachment problems and feeding difficulties may also be exacerbated by interrupted maternal milk supply due to a period of parenteral feeding or delayed reunion with the mother in the NICU, especially in the case of extreme preterm infants (Alan et al., 2013; Lapillonne, O'Connor, Wang, & Rigo, 2013; Lau, Fucile, & Schanler, 2015). Using multiple perspectives during feeding assessment supports the SLT to provide individualized assessment and management of neonatal OPD.

2.4. The influence of OPD on neonatal physiology and development

Feeding and swallowing are intrinsically linked to every neonate's basic physiological needs. A limited view of this intrinsic relationship is stated by Newman and Petersen (2006:360) "Swallowing cannot be separated from feeding and feeding cannot be separated from development. Swallowing also has a direct impact on nutrition, and adequate nutrition is required for growth and development of every bodily system in a developing child". OPD thus has a far reaching impact on the holistic well-being, development and health status of every infant. To expand on Newman and Petersen's (2006) somewhat restricted view of the impact of dysphagia on an infant, Arvedson and Brodsky (2002) provided a more comprehensive perspective. Arvedson and Brodsky's (2002) perspective state that successful feeding forms the foundation for not only general development and somatic growth but also communication development and psycho-social well-being in the neonate's primary relationships. This more comprehensive perspective is echoed in the current research study.

As a result of OPD the potential severe consequences for the neonates' developmental progression, behavioural development, status of nutrition and stress levels can have a far reaching impact on the neonate's family patterns of interaction (Lau et al., 2015). Consequences such as maternal post-partum depression, post-intensive care syndrome-family, anxiety during caregiver activities once the neonate is discharged home, and changing family dynamics whilst the infant is in the NICU, and once again upon discharge, may be present (Davidson, Jones, & Bienvenu, 2012; Lai, Hung, Stocker, Chan, & Liu, 2015; Petzoldt et al., 2016). A family may

develop postintensive care syndrome-family when their response to their infant's critical illness leads to adverse psychological outcomes such as anxiety and post-traumatic stress disorder (Davidson et al., 2012). Acute stress levels are another consequence for the family of a preterm neonate with OPD (Davidson et al., 2012; Spinelli, Poehlmann, & Bolt, 2013; Woodward et al., 2014). Family stress may be exacerbated by the cost of an extended hospital stay and future services (Lasiuk, Comeau, & Newburn-Cook, 2013) to address developmental delays together with continued OPD and feeding difficulties. Dysphagia, in particular OPD, is associated with increased morbidity and mortality due to various complications such as RDS, apnoea, bradycardia, desaturation, cardio-respiratory events, laryngeal penetration and aspiration, airway/lung diseases, failure-to-thrive (FTT) and developmental delay (Jadcherla, 2016; Weir, McMahon, Taylor, Chang, & Barratt, 2010). It is thus evident that OPD may not only have far reaching consequences for the neonate and family, but also for the healthcare system (Johnson, Patel, Bigger, Engstrom, & Meier, 2014), necessitating implementation of effective assessment and management practices as early as possible in the neonate's life.

The Problem-driven model (Wolf & Glass, 1992) did not encourage the SLT to identify the neonate's inherent strengths during feeding and an asset-based approach was not focused on in the early 90s when the Problem-driven model was first introduced in to practice. An asset-based approach stands in opposition to a traditional medical model of care (Newland, L'Huillier, & Petrey, 2013), together with an ecologically valid systems approach (Bronfenbrenner, 1993; Bruns & Thompson, 2012), and are proposed to be used in developmentally appropriate assessment and management of neonatal dysphagia.

To develop a novel clinical feeding assessment instrument for neonates the researcher reviewed accepted theories used by researchers and SLTs about OPD and feeding difficulties in combination with early intervention (EI) theory. Four main theoretical perspectives (Als, 1982; Berlin, Davies, Lobato & Silverman, 2009; Bronfenbrenner, 1993; Thoyre et al., 2005) were used in the development of the NFAS. Figure 2.2 introduces the theories that were used as basis for developing the new instrument to identify OPD in high-risk neonates.

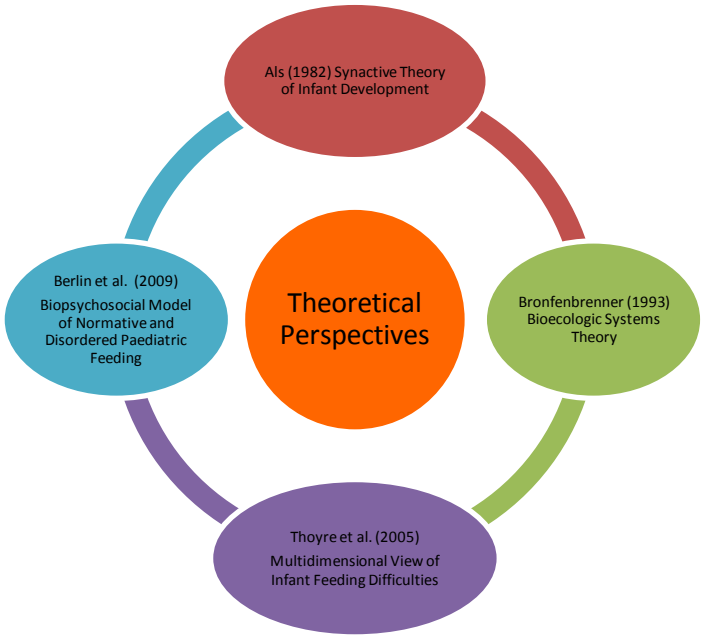

Figure 2.2 Theoretical perspectives contributing to the development of the NFAS

2.5. Theoretical framework underpinning the Neonatal Feeding Assessment Scale

From various models and theoretical approaches describing typical infant feeding development and studies on OPD in the neonatal period and early infancy, a theoretical framework considering the landscape of OPD in neonates and very young infants, is suggested. This framework attempts to address the complexity of OPD in the neonatal population. Four major theoretical contributions that were incorporated in the framework, namely Thoyre et al.'s Multidimensional View of Infant Feeding Difficulties (Thoyre et al., 2005; Thoyre, Park, Pados, & Hubbard, 2013), Berlin and colleagues' Biopsychosocial Model of Normative and Problematic Paediatric Feeding (Berlin et al., 2009), Bronfenbrenner's (1993) classic Bioecologic Systems Theory, and lastly Als' Synactive Theory of Infant Development (1982; Als et al., 1994). These theoretical contributions guided the researcher to view the landscape of OPD in the neonatal stage as ever evolving, considering several etiological pathways, together with internal and external factors and developmental attainment over time.

Thoyre and colleagues' Multidimentional View describes feeding difficulties in the NICU context as complex, with multiple causes and contributing factors (Thoyre et al., 2005; 2013). The Multidimensional View of Infant Feeding Difficulties (Thoyre et al., 2005; 2013) is the only theoretical view developed by SLTs amongst the four chosen theoretical perspectives. This view developed from the authors' clinical work with neonates and infants with feeding difficulties in the NICU. They emphasize that the purpose of assessment should not merely be to identify the neonate's feeding outcomes. Assessment should rather also describe the neonate's abilities and how the infant adapts to the challenge of oral feeding within an asset-based approach. Such a descriptive approach values the dynamic and variable nature of feeding, recognizes the role of maturation, the gaining of feeding experience and the inherent variability during the feeding session as changes occur.

The attainment and refinement of oral feeding skills takes place in an extrauterine environment after full term birth, or due to a disruption of intrauterine development by preterm birth. The neonate needs support to meet nutritional requirements and attainment of safe and adequate oral feeding skills in the extrauterine environment. The SLT should provide this necessary support with the selection of appropriate feeding strategies and methods. Clinical assessment of feeding and swallowing abilities should include the neonate's ability to engage with the mother, the organization of oral-motor movements for successful feeding, sustained attention and energy for the duration of the feed, adaptation to the challenges of feeding, coordination of the SSB sequence and maintaining physiological stability during the feeding process (Thoyre et al., 2005). The focus during clinical assessment is specifically on determining the readiness for oral feeding and not making a diagnosis of OPD in this model.

The advantages of the Multidimensional View of Infant Feeding Difficulties (Thoyre et al., 2005; 2013) are that this perspective may guide the SLT to be not only diagnostically driven, but to also investigate the complexity of feeding difficulties in infancy from various angles to comprehensively describe the problems and strengths displayed by the infant during feeding. One of the minor drawbacks of this view may be the lack of in-depth description of the interaction between the infant's various developmental systems as well as mother-infant interaction, and the role this dynamic may play in physiological stability during feeding.

The researcher selected certain components from Thoyre and colleagues' (Thoyre et al., 2005; 2013) view to include in the proposed theoretical framework for viewing neonatal OPD – see Table 2.1. From this theoretical view the researcher used the concept of physiological stability as precursor to successful and safe attainment of oral feeding skills, together with the inclusion of oral-motor skills and the SSB sequence during the clinical investigation of neonatal OPD. Finally, the researcher also retained the asset-based approach of describing an infant's feeding performance during assessment.

The Multidimensional View of Infant Feeding Difficulties (Thoyre et al., 2005; 2013) shares some commonalities with the Biopsychosocial Model of Normative and Problematic Paediatric Feeding (Berlin et al., 2009) chosen as second model to incorporate in the suggested framework of neonatal feeding skills and OPD. Commonalities, such as considering the systemic influence of risk factors on displayed feeding skills and the impact thereof on the infant's physiological functioning, were found. The Biopsychosocial Model of Normative and Problematic Paediatric Feeding (Berlin et al., 2009) offers a perspective on normal feeding that is not included in Thoyre and colleagues' view that mainly focuses on developmental readiness for oral feeding (Thoyre et al., 2005; 2013).

The Biopsychosocial Model (Berlin et al., 2009) was developed from a psychological perspective, providing a different angle from the SLP perspective offered by Thoyre and colleagues (Thoyre et al., 2005; 2013), since the authors were predominantly researchers in the field of clinical and family psychology. Psychosocial factors and the role it plays in the reciprocal maternal-infant relationship, the transactional nature of the relationship and how mismatch in this relationship may either hinder or promote feeding development, is uniquely emphasized in this model. The maternal-infant relationship may increase or decrease the feeding dyad's resilience or susceptibility to feeding problems across the course of infant development.

The impact of feeding difficulties on the maternal-infant feeding dyad is explained in-depth in the Biopsychosocial Model (Berlin et al., 2009). Paediatric feeding difficulties are described against the backdrop of known risk factors associated with feeding problems and relevant developmental theories of causation of paediatric feeding difficulties in this model (Kedesdy & Budd, 1995; Linscheid, Budd, &

Rasnake, 1995; Linscheid & Murphy, 1999). The Biopsychosocial Model (Berlin et al., 2009) was selected for this study since it offers a comprehensive perspective to synthesize information about the transactional nature of feeding in normal and disordered paediatric populations. A framework to support the prevention of associated behavioural difficulties that may arise along with feeding problems is provided, and the model encourages interdisciplinary management of feeding difficulties.

The Biopsychosocial Model (Berlin et al., 2009), similar to the Multidimensional View of Infant Feeding Difficulties (Thoyre et al., 2005; 2013), recognizes the complex nature of infant feeding and the influence of transactional factors, for example genetics, sociocultural factors and family interaction that may interfere with the development of typical feeding skills and behaviours over time. Berlin and colleagues (2009), however, emphasize the relational factors more than Thoyre's teams (Thoyre et al., 2005; 2013) by describing the impact of maternal responsiveness or lack thereof on the mother-infant dyad during feeding. The theoretical underpinnings of the Biopsychosocial Model (Berlin et al., 2009) include different causes and mechanisms of feeding problems in the paediatric population, considering the biomedical, behavioural and emotional factors that may cause and contribute to OPD in infants.

The clinical implications arising from this model are that a comprehensive multidisciplinary assessment, guided by a developmental perspective on OPD, is relevant to practice. Such a comprehensive assessment to investigate the extent, to which the various components contribute to OPD in neonates, should be used by the SLT. The researcher incorporated various aspects of the Biopsychosocial model in the proposed theoretical perspective on neonatal OPD – see Table 2.1. Although this model was not specifically developed for the NICU context it is considered useful since it is comprehensive in nature and based on a developmental perspective. The model considers the contribution of relational, biomedical, interpersonal and psychodynamic factors to feeding difficulties, to guide the SLT's clinical practice with high-risk neonates with OPD.

The Multidimensional View of Infant Feeding Difficulties (Thoyre et al., 2005; 2013) and the Biopsychosocial Model (Berlin et al., 2009) both support the SLT to view

OPD as complex with multiple contributing factors, but does not extend to formally describe the impact of the community and broader cultural context on the neonate's development. Therefore the Bioecologic Systems Theory (Bronfenbrenner, 1993) was selected for its unique contribution allowing the researcher to place OPD within a more dynamic systems perspective when compared to the previous two models. Berlin et al. (2009) refer to contextual factors in their model, but Bronfenbrenner's theory (1993) describes the concept of systems, which covers a much broader scope than contextual factors alone. The Bioecologic Systems Theory (Bronfenbrenner, 1993) was incorporated in the researcher's proposed theoretical view of neonatal OPD and infant feeding, since the impact of these broader systems on the acquisition of feeding skills and the development of OPD was not comprehensively addressed by Thoyre and colleagues or Berlin and colleagues (Berlin et al., 2009; Thoyre et al., 2005; 2013). The Bioecologic Systems Theory has specific relevance to high-risk neonates in NICUs in public hospitals in South Africa.

The Bioecologic Systems Theory (Bronfenbrenner, 1993) considers transactional factors, not only in relation to the maternal-infant relationship, but also by viewing the infant in a variety of larger inter-related nested contexts which may impact on the infant's development – see Figure 2.3. Five socially organized subsystems that support and guide human development, namely the microsystem, mesosystem, exosystem, macrosystem and chronosystem, was introduced in this theory (Bronfenbrenner, 1993).

The microsystem refers to the immediate settings (Garbarino & Ganzel, 2000) in which the neonate functions in the extrauterine environment. The NICU and the neonate's family constitute the immediate microsystems to support development after birth. Neonatal interactional relationships form the mesosystem representing bidirectional influences between microsystems. Mesosystems are representational of relationships between the microsystems (Garbarino & Ganzel, 2000) in the neonate's life. In the immediate environment of the NICU the interaction between the healthcare team and neonate reflects one mesosystem. A further mesosystem relevant to an infant with OPD is maternal-infant attachment and interaction in the unfamiliar and stressful NICU setting. Both these mesosystems may have a far-reaching impact on the development of feeding skills in the neonatal period. The mother's role in the family home may in turn impact on maternal-infant interaction.

The home life of the family represents additional relationships and interactions forming a further mesosystem which may add to or detract from the neonate's development. Positive links between the different mesosystems may strengthen the impact of these systems to support neonatal development in an integrated manner.

A further system proposed in the Bioecologic Systems Theory is the exosystem. The exosystem bears on neonatal development without the infant playing a direct role in this system (Garbarino & Ganzel, 2000). The exosystem offers both risk and opportunity to change interactions in the micro- and mesosystems. Healthcare policies, maternity leave provided by an employer, as well as environmental factors, are all examples of contributors to the exosystem. The neonate has no direct interaction with the exosystem. Despite no direct interaction with the infant, the exosystem still impacts on neonatal development. Healthcare practices and policies in South Africa significantly impact on the care provided in NICUs in public hospitals. Consistent implementation of evidence-based developmentally appropriate care practices proven to support neonatal development (Altimier & Philips, 2013; Coughlin, Gibbins & Hoath, 2009), is not yet implemented in all public or private healthcare facilities in South Africa. Service delivery in NICUs is further dependent on the hospital's policy, such as the implementation of the updated and expanded Baby-friendly Initiative (WHO, 2009) during pre- and post-delivery care promoting support of breastfeeding. The nursing staff's level of training when caring for ill neonates also impacts significantly on neonatal care in the NICU (Coughlin et al., 2009; Medoff-Cooper et al., 2015). Environmental factors, such as poverty, HIV/AIDS, illiteracy and low levels of parental education are risk factors specific to the South African context (Van der Linde, Swanepoel, Glascoe, Louw, & Vinck, 2015) that may negatively affect the family structure and maternal-infant interaction as part of the exosystem. The exosystem also represents the multi-cultural, multi-linguistic and multi-religious South African context, including parental beliefs and customs surrounding feeding practices. The mother's choice of feeding practice may also impact on neonatal health and development of feeding skills. Mothers in South Africa either implement mixed feeding (combination of breast milk and infant formula), exclusive breastfeeding or replacement feeding (infant formula) (Department of Health, 2007; Goga et al., 2012). Feeding practices are influenced by factors such as the mother's socio-economic status and health status (Goga et al.,

2012). In South Africa there is a high incidence of mother-to-child-transmission (MTCT) of HIV/AIDS (Coutsadis et al., 2009; Department of Health, 2015). HIV-positive mothers are counselled by the healthcare team on the benefits and disadvantages of different feeding practices for the neonate (Department of Health, 2007; 2015; Goga et al., 2012). The South African government recommends the practice of exclusive breastfeeding or exclusive appropriate replacement feeding (infant formula), for the first six months of the infant's life and not mixed feeding (Department of Health, 2015). Infants of HIV-positive mothers are supplied with anti-retroviral medication as first-line regimen treatment from birth (Department of Health, 2015).

The meso- and exosystems are situated in a broader context of cultural, ideological and institutional patterns. These patterns form the macrosystem to represent the ecology of human development (Garbarino & Ganzel, 2000). Policies developed by international agencies such as the WHO together with government policies impact on the services provided to the neonate and family in the NICU. Institutional policies and governmental guidelines are examples of the macrosystem that indirectly impact on the type of healthcare information and services provided to neonates and families in the NICU. The WHO Global Strategy for Infant and Young Child Feeding (2003) emphasizes that adequate support should be available to mothers and families to help them to provide optimal nutrition to infants and young children. Support should be provided on governmental and institutional level to support mothers to make informed choices about feeding options for infants. Exclusive breastfeeding should also be promoted for the first six months of an infant's life, if this is an option for the mother. The South African Department of Health's Infant and Young Child Feeding Policy (2007) also emphasizes the importance of adequate nutrition to support an infant's health and development. The policy provides guidelines to the healthcare teams in various settings, including the NICU, about feeding support services during the pre- and post-natal period and more specifically, on how to support mothers with feeding options during difficult circumstances. One of the key recommendations of this policy links to the aforementioned WHO Global Strategy for Infant and Young Child feeding (2003), by endorsing the promotion, protection and support of exclusive breastfeeding when possible. These policies and guidelines are examples of factors in the macrosystem that dictate the service delivery and care to high-risk

neonates in NICUs in the public hospital context in South Africa. The last system, the chronosystem adds a time continuum to the interrelated systems (Garbarino & Ganzel, 2000) linking the development of the attainment of feeding skills and societal changes about infant feeding practices over time. It is evident that the Bioecologic Systems Theory provides a layered view to add richness and depth to the SLP perspective of neonatal OPD and feeding difficulties.

Bronfenbrenner's (1993) theory was not intended for a specific context but can be applied to a medical context and to dysphagia in the neonatal stage and infancy. The researcher supports the transactional nature of systems impacting on feeding development and therefore adopted these concepts in the proposed theoretical view of infant feeding and neonatal OPD, including all five of the systems described by Bronfebrenner (1993) – see Figure 2.3.

The concept of the time continuum used in the chronosystem connects to the Synactive Theory of Infant Development of Als (1982), which contributed one of the first developmental perspectives on neonatal development from womb to NICU, and the transition to the family caregiving environment upon discharge. The Synactive Theory was the last theory explored to develop the researcher's view of neonatal feeding development and OPD. This is the only selected theory that originated from a medical developmental perspective, to contribute to the theoretical framework to develop the NFAS.

Als (1982) believed that environments should be "good enough" to support progress along the infant's developmental trajectory, in this case focusing on the neonate's feeding development in the NICU. The Synactive Theory of Infant Development (Als, 1982) aimed to assist medical professionals, neonatal nurses and allied health clinicians to understand and assess infant development and behaviour in the context of the NICU. The continuous interplay of subsystems within the infant and interaction with the environment, expresses a predetermined developmental agenda, and the resultant impact of interaction in the NICU on the infant's physiological stability, is described by the Synactive Theory of Infant Development (Als, 1982; Als et al., 1994).

Five subsystems inherent to early infant development are described by Als (1982). These include the autonomic, motor, and state-organizational systems, the

attentional-interactive system and the self-regulatory system. Using these subsystems to describe and understand infant behaviour is widely accepted in research and clinical practice of various medical, nursing and allied health professions (Als, Butler, Kosta & McAnulty, 2005; Coughlin et al., 2009; Kenner & McGrath, 2004; Pickler, 2004; Thoyre, 2007; Thoyre et al., 2005; 2013). Problems within the various subsystems reflect in poor modulation and integration of systemic functions – all of which may adversely impact on neonatal feeding and result in OPD. Clinicians use these subsystems to help with the categorization of feeding problems the infant may experience according to physiological processes. This theory may assist the SLT to evaluate subsystem functioning during feeding, to enable the identification of stress cues in the neonate and to determine the impact of neonatal state transitions on optimal alertness for successful oral feeding.

Since SLTs are tasked to support feeding as part of a broader developmental agenda of the neonate within the NICU, they play a role to determine readiness for safe oral feeding (Thoyre et al., 2013). The SLT also provides guidance on the type of nutritional intake, method of receiving nutrition and positive oral sensory experiences (Arvedson, Clark, Lazarus, Schooling, & Frymark, 2010; ASHA, 2005; Swigert, 2010). Guidance is provided to counteract invasive and negative oral sensory experiences that form part of some routine medical care in the NICU. The Synactive Theory of Infant Development (Als, 1982) may guide the SLT to provide parent training as well as assessment and intervention in a developmentally appropriate way to identify the neonate's abilities, challenges and accomplishments in terms of OPD and feeding development over time. Als' (1982) theory offered the researcher a foundation for viewing the interdependent development of neonatal feeding over time by incorporating a systemic physiological assessment when OPD is suspected in neonates.

Selected components of the four different theoretical perspectives were integrated to view neonatal feeding and OPD within a multidimensional systems perspective to support the development of the NFAS. The components of each theory or model relevant to the researcher's suggested framework is summarized in Table 2.1.

Table 2.1 Theoretical components integrated in the theoretical framework of neonatal feeding and OPD

Multidimensional view (Thoyre et al., 2005; 2013)	**Biopsychosocial view (Berlin et al., 2009)**	**Bioecologic Systems Theory (Bronfenbrenner, 1993)**	**Synactive Theory (Als, 1982)**
• Physiological stability • Oral-motor skills • SSB coordination • Asset-based focus	• Transactional relational nature of feeding • Biomedical factors • Interpersonal factors • Behavioural/ psycho-dynamic factors	• Transactional nature of systems impacting on development • Microsystems • Mesosystem • Exosystem • Macrosystem • Chronosystem	The five subsystems of infant development: • Autonomic subsystem • Motor development • State organization • Attention and interaction • Self-regulation And the: • Identification of strengths, challenges and accomplishments of the infant

The theoretical components in Table 2.1 were integrated to represent the proposed framework for SLTs to view neonatal feeding development and OPD. The integrated framework is illustrated in Figure 2.3.

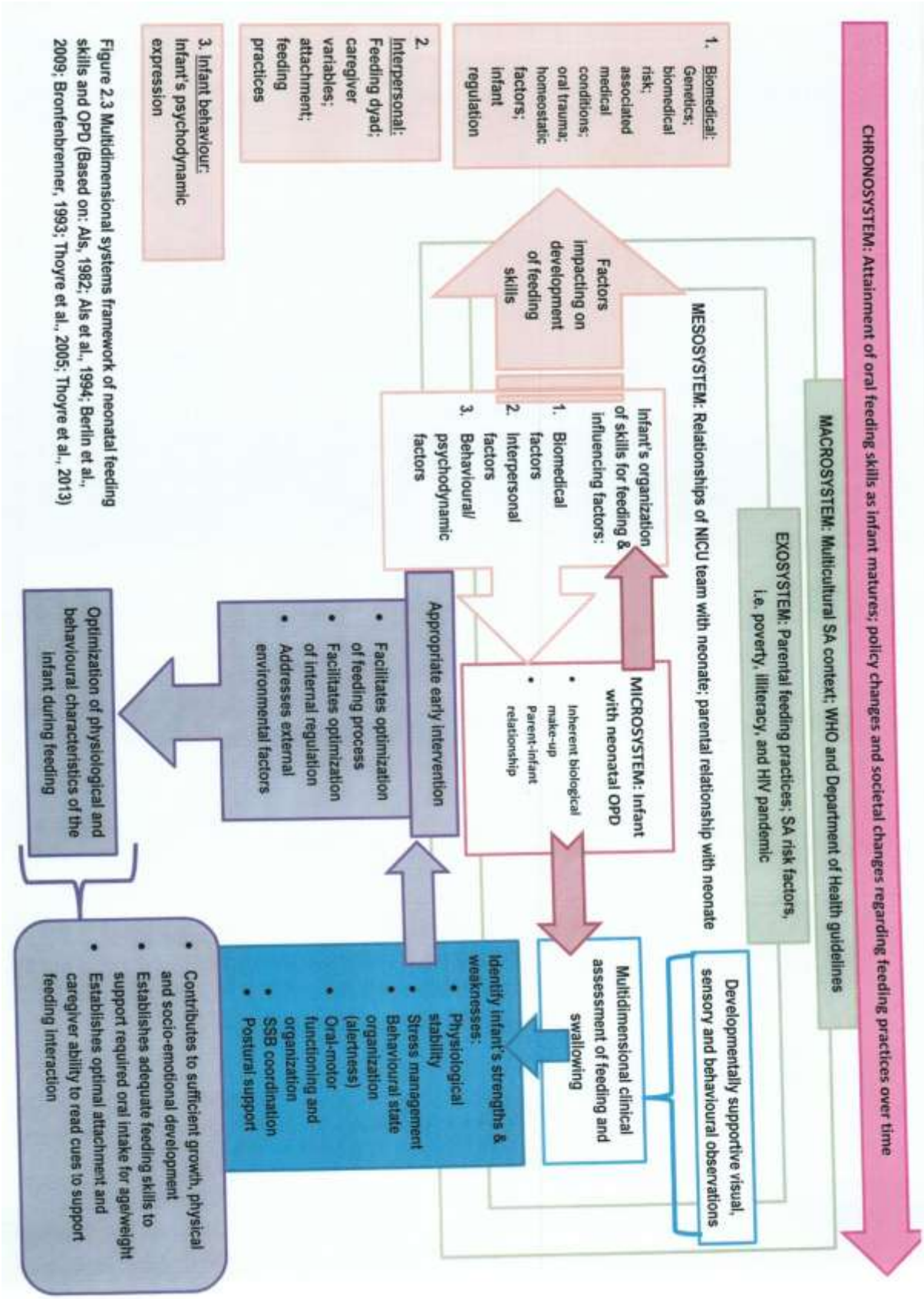

Figure 2.3 Multidimensional systems framework of neonatal feeding skills and OPD (Based on: Als, 1982; Als et al., 1994; Berlin et al., 2009; Bronfenbrenner, 1993; Thoyre et al., 2005; Thoyre et al., 2013)

2.6. A speech-language pathology perspective on the assessment of neonatal dysphagia in South Africa

The role of the SLT in assessment is described by the SASLHA (2011a) Guidelines for Paediatric Dysphagia as including comprehensive clinical assessment, instrumental assessment when and if available, and consulting with a multidisciplinary team to diagnose dysphagia in the paediatric population. However, no specific guidelines for the neonatal population are provided which may indicate a need for revision of the guidelines to include new evidence-based practice that has emerged since the guidelines were published in 2011. During assessment, additional factors such as the WHO Guidelines on Infant Feeding in the Context of HIV (2010), and the South African Consolidated Guidelines for the Prevention of Mother-to-Child Transmission of HIV (PMTCT) and the Management of HIV in Children, Adolescents and Adults (Department of Health, 2015), should be taken into consideration. Both these sets of guidelines recognize the important impact of antiretroviral medication (ARVs) during the breastfeeding period, and recommend that infant feeding practice, i.e. breastfeeding with ARV intervention for mother and infant, to reduce transmission, or avoidance of all breastfeeding, should be promoted and supported. The WHO (2010) Guidelines recommended an extension of the period of breastfeeding for mothers known to be HIV-infected from six months to at least 12 months of age. Infant formula as replacement feeding in South Africa is, however, only supplied for the first six months of the infant's life (Department of Health, 2015). The recommendation that replacement feeding should not be used unless it is acceptable, feasible, affordable, sustainable and safe (AFASS) are still adhered to in the Consolidated Guidelines (Department of Health, 2015) of the South African government. The encouragement of exclusive breastfeeding, together with the introduction of first foods from six months of age, until the infant reaches 12 months of age is also recommended in the 2015 South African Guidelines (Department of Health, 2015).

The impact of environmental systems, relational factors, and nutritional components together with all the stated guidelines and policies should be considered when assessing a neonate's feeding and swallowing abilities in the NICU setting in South Africa. These systems and factors will guide the NICU team with the creation and

implementation of feasible intervention for neonatal dysphagia, extending from the NICU to the home setting.

From Figure 2.3 it is clear that the SLP perspective should be broad but focused on OPD. The SLT should therefore consider the maturation of the neonate's systems and maternal interaction with the neonate, especially during feeding. Of further importance is supporting teamwork in the NICU and the implementation of developmentally appropriate care not only during assessment, but also when providing intervention for OPD in neonates.

2.7. Summary

This chapter provided the researcher's theoretical perspective on neonatal dysphagia based on a literature review of appropriate theories and models used by different disciplines involved in service provision to neonatal and infant populations.

Chapter 3

Methodology

Aim of the chapter: To describe the different methods used in the three studies that was conducted to develop and validate the Neonatal Feeding Assessment Scale (NFAS).

3.1. Introduction

The three studies comprising this research project reside in the domain of health research within the medical branch of SLP. Health research focuses on resources necessary to provide evidence-based health services (Shi, 2007). A novel clinical assessment instrument in neonatal dysphagia would be considered a resource that can potentially contribute to evidence-based services to neonates. The project also linked to applied research (Meline, 2010) conducted for the purpose of improved understanding of the clinical process of assessment and reliable diagnosis of neonatal dysphagia. Applied research may contribute more than basic research to the medical SLP community involved in evidence-based practice in neonatal health services (Meline, 2010).

3.2. Aims of the study

3.2.1. Main aim

The main aim of the study was to develop and test the psychometric performance of a clinical assessment scale for the identification and diagnosis of OPD in the high-risk neonatal population in South Africa.

3.2.2. Aims and objectives

To meet the main aim the research project was divided in three separate studies:

Study 1: The aim was to develop and validate the content of a novel clinical feeding assessment scale to identify and diagnose OPD in neonates. The objectives to support the aim were, a) to determine if the panel of experts agreed about the need for a validated clinical feeding assessment scale, to b) select appropriate items for

inclusion in the NFAS, and to lastly c) establish face and content validity of the NFAS based on expert input.

Study 2: The aim for the second study was to determine the preliminary psychometric performance of the NFAS to identify OPD in a small sample of neonates. The objectives were to determine the sensitivity, specificity, accuracy and predictive values of the NFAS, in comparison to the MBSS and to verify inter-rater reliability.

Study 3: Based on the promising performance of the NFAS on a small sample, the aim of the third study was to determine the validity and reliability of the NFAS in comparison to the MBSS in a larger sample. To achieve this aim, the objectives were to, a) describe the diagnostic outcomes of the participants on the MBSS and the NFAS, and b) to determine the specificity, sensitivity, accuracy and predictive values of the NFAS to establish criterion validity. The final objective was, c) to determine the inter-rater reliability of the NFAS.

3.3. Research design

The research design consolidating the three studies was an exploratory sequential mixed method design (Creswell, 2014). Although Creswell (2014) initially developed the exploratory sequential mixed method design as a two phase model from a social research perspective, it was considered useful for the purpose of combining a qualitative and quantitative phase of research in the domain of health research. Such cross-field application of a social research design used in health research can add value to a study (Shi, 2007).

An exploratory sequential approach starts with a qualitative phase followed by a quantitative phase and has also been referred to as an ‘instrument development design’ (Creswell, 2014; Creswell & Plano Clark, 2011). The instrument is mainly developed based on the results of the qualitative phase and then administered to a sample of participants to obtain quantitative data, as was done in this study. The main benefit of this design is that it is suitable for developing and testing a new instrument if no other instrument to investigate or measure phenomena is currently available.

3.3.1. Study 1: Delphi method design

In study 1 the Delphi method (Okoli & Pawlowski, 2004) represented the qualitative phase used to develop the NFAS. The Delphi review process considered systematically obtained expert judgements of whether the newly developed assessment instrument represented all facets of the concept under consideration, in this case neonatal feeding skills. The primary strength of the Delphi method was the independent exploration of the content and scoring of the instrument that required external judgment (Du Plessis & Human, 2007).

The Delphi method is a survey technique consisting of more than one stage to facilitate a group's communication about the review of a complex construct (De Villiers, De Villiers, & Kent, 2005; Du Plessis & Human, 2007; Hassan, Keeney, & McKenna, 2008; Okoli & Pawlowski, 2004). The Delphi method's scientific merit has also been established in the South African research context in the field of nursing practice (De Villiers et al., 2005) and in the international arena of health research (Hassan et al., 2008).

3.3.2. Study 2 and 3: Cross-sectional comparative within-subject design

Study 2 and 3 represented the quantitative phase utilizing a cross-sectional comparative within-subject design (Irwin, Pannbacker, & Lass, 2008) to determine the psychometric performance of the NFAS in comparison to the MBSS, and establish the reliability and validity of the NFAS. The NFAS and MBSS results were compared specifically regarding outcome for diagnosis of OPD. In a comparative within-subject design all participants undergo all research procedures and statistical analysis for determining reliability and validity can be used (Irwin et al., 2008).

3.4. Ethical considerations

The approval of the Research and Ethics Committee of the Faculty of Humanities, University of Pretoria and the approval of the Medical Research Ethics Committee of the Gauteng Department of Health, was obtained prior to the commencement of the study – see Appendix A. The chief executive officer of the academic hospital serving as research site in Gauteng granted permission to conduct the study.

In health research the Declaration of Helsinki (World Medical Association [WMA] Declaration of Helsinki Working Group, 2013) and ethical research guidelines (De Vos, Delport, Fouche & Strydom, 2011) provided principles for the researcher to conduct ethical research involving human participants. Neonates with OPD are considered a vulnerable population since the most severe consequence of OPD may be death, therefore ethical decision making and consideration in the research process should be strictly implemented.

The following ethical principles were adhered to:

Malfescence and beneficence (WMA Declaration of Helsinki Working Group, 2013):

This ethical principle ensured protection against harm for participants guiding the researcher to act in the best interest of the participants (De Vos et al., 2011). Due to the advancement of life-saving medical technology in the NICU context more high-risk neonates are surviving, but problems such as OPD are now emphasized. It is thus the researcher's responsibility to adhere to research ethics when developing new tools for practice to improve quality of life.

Study 1: Participation in this study was not harmful to the expert panel members. Their ideas were not judged by others, thereby lessening possible intimidation to participate.

Study 2 and 3: During the clinical assessment of the neonate due precautions for safety had been taken to prevent any harm to the participants. The participant's treating physician gave consent that the neonate was medically stable to undergo a clinical and instrumental feeding assessment. Participants were assessed in a developmentally supportive position in the cot/incubator and on the parent's lap to prevent undue discomfort and distress during clinical assessment. The risk of radiation exposure during instrumental assessment was explained to the parents together with the safety of the MBSS procedure (Brenner & Hall, 2007; Hiorns & Ryan, 2006). Relevant feeding treatment options were discussed with the parents after clinical and instrumental assessment was completed. The discussion was non-discriminatory to refer the neonate and family to appropriate professional services

such as speech-language therapy, occupational therapy and gastroenterology in the hospital.

Confidentiality (WMA Declaration of Helsinki Working Group, 2013):

The researcher had an obligation to the participants to maintain confidentiality to protect personal information (De Vos, et al., 2011). The identities of the participants were known to the researcher. The researcher respected the participants by also informing them of their right to withdraw from the study without any negative consequences.

Study 1: The panel members were blinded to each other's identities and their identities were only known to the researcher. Participants provided opinions to the researcher only, who integrated responses as that of the group and not of individual participants, to allow open participation.

Study 2 and 3: No personal information of the mothers or the neonates was disclosed. A number was allocated to each infant participant's documentation to allow anonymity throughout the research process. Information was kept confidential at all times during the research process. Data are securely stored in the Department of Speech-Language Pathology and Audiology at the University of Pretoria, where it will remain for 15 years.

Informed consent (WMA Declaration of Helsinki Working Group, 2013):

To enable participants to provide informed consent all relevant information regarding the aims and objectives of the research, the procedures that the participants would have undergone, the possible advantages and disadvantages and safety issues, as well as the credibility and competence of the persons performing the research were disclosed (De Vos et al., 2011).

Study 1: The expert panel member participants provided informed consent to form part of the panel – see Appendix B for Information leaflet.

Study 2 and 3: The mothers of the high-risk neonates were approached in the NICU to give informed consent to participate in the study. A Parent information leaflet – see Appendix C – was provided in English, Afrikaans and Setswana (the three major languages spoken in the city where the study was conducted) to explain the purpose

and nature of the study. An interpreter was used with four mothers who were illiterate and verbal consent was obtained from each.

Justice (WMA Declaration of Helsinki Working Group, 2013):

Just treatment of participants during the research process should be implemented at all times (WMA Declaration of Helsinki Working Group, 2013).

Study 1: The researcher only selected expert panel members who were recognized as experts in the field of paediatric dysphagia, as evidenced by peer-reviewed publications, post-graduate qualifications and a minimum of five years clinical experience.

Study 2 and 3: All parents of neonates in the NICU at the research site were approached to participate in the study if the treating physician declared their infant to be stable to undergo the research procedures. All neonates meeting the inclusion criteria were enrolled in the study. The clinical feeding assessment was within the scope of practice of the researcher and data collectors, who were all registered with the Health Professions Council of South Africa (HPCSA). The researcher ensured that the data collectors were skilled in clinical and instrumental assessment of high-risk neonates.

Truthful (WMA Declaration of Helsinki Working Group, 2013):

A researcher is expected to act truthfully in disclosing results and when acknowledging resources and persons who consulted and collaborated on the project (De Vos et al., 2011).

The research results were disclosed in the format of a dissertation and two published and one submitted articles in accredited, peer-reviewed scientific journals. All references and sources were acknowledged through the appropriate citation method required for the dissertation and the individual journals. Acknowledgement of contribution to the research study was done by granting co-author status and special acknowledgement in Article 3 for consultation (study 3). A plagiarism declaration was included in the dissertation stating that the study contained original work by the researcher to fulfil doctoral degree purposes at the University of Pretoria.

3.5. Participants

The participants in this research study consisted of two groups, the expert panel members in study 1 and the neonatal participants in study 2 and 3. The sampling method, sample size, participant selection criteria and participant description is now presented.

3.5.1. Sampling method

Study 1: A non-probability purposive sampling method (Leedy & Ormrod, 2014) was used to select the expert panel members. The use of this sampling method was corroborated by Nelson (2009) who stated that the goal for qualitative research, such as when utilizing the Delphi method, is to obtain expert opinion and to therefore recruit participants that the researcher considered to be the best sources of knowledge.

Study 2 and 3: Non-probability consecutive sampling (Maxwell & Satake, 2006) was used. This sampling method allowed the researcher to choose participants for the particular purpose of the study over a period of time (Maxwell & Satake, 2006). Successful implementation was achieved because clear participant selection criteria were followed. This allowed the researcher to sample participants who met the pre-established inclusion criteria. The research site had a 29 bed NICU which was on average 70% occupied during the 13 months of data collection. A sufficient number of participants were available at the single site to complete data collection within a reasonable time frame.

3.5.2. Sample size

Study 1: Five expert panel members acted as participants in this study. Three local and two international SLTs formed part of the panel. A sample of five participants was used since the Delphi group size does not depend on statistical power, but rather on group dynamics for arriving at consensus among experts (Okoli & Pawlowski, 2004). Furthermore, non-response is very low in Delphi studies (Okoli & Pawlowski, 2004), as was seen in this study where a 100% response rate was achieved.

Study 2: The sample size for a preliminary study of the NFAS consisted of 20 neonates. In consultation with a biostatistician it was determined that 20 participants is the minimum requirement for such a small scale preliminary study as advised by Dawson and Trapp (2004). This sample size will enable statistical report on psychometric performance (Dawson & Trapp, 2004) of the NFAS in comparison to the MBSS.

Study 3: In the final study a larger sample size may increase generalizability and usefulness of results (Meline, 2010). When studying vulnerable groups in prospective neonatal research Da Costa and Van der Schans (2008) suggest a sample size of at least 30 participants. A sample size of 48 participants was achieved in study 3, which was considered the main study to determine reliability and validity of the NFAS.

3.5.3. Participant selection criteria

Two different participant groups were selected for the three studies. Inclusion criteria were specified for each study.

Study 1:

1. The expert participant had to hold a minimum professional qualification of a Master's degree in Speech-Language Pathology or Speech-Language Pathology and Audiology from an accredited tertiary education facility locally or internationally.
2. The participant was required to have a minimum of five years clinical experience in the field of neonatal dysphagia.
3. The expert could reside in South Africa or internationally to ensure a broad demographic representation. As participation was via electronic mail there were no restrictions to the location of participants. A small group of SLTs in South Africa are considered experts in neonatal dysphagia. Therefore potential participants were known for their publications and conference presentations in the field. Potential international participants were identified by means of their publication records in neonatal and paediatric dysphagia.

Study 2 and 3:

1. Any neonate with a high-risk status such as prematurity, LBW or HIV exposure or another high-risk factor increasing the likelihood that the infant would present with neonatal dysphagia could participate.
2. The neonate should present with reported feeding difficulties.
3. The neonate should have been an in-patient in the NICU at the research site.
4. The neonate should have been declared medically stable for clinical and instrumental assessment by the treating physician.
5. The neonate should have been within the age range of 32 weeks GA to four months corrected age post term. This age range was deemed appropriate to cover the neonatal and early infancy period of development in feeding. Oral feeding is typically introduced from 32 weeks GA in many NICUs since a NS response is emerging to support oral intake (Browne & Ross, 2011). NS gradually integrates and strengthens until 37 weeks GA to be well established and coordinated (Lau & Smith, 2011; Rogers & Arvedson, 2005; Thoyre, 2007). High-risk infants presenting with LBW, SGA and prematurity are also more at risk of developing OPD or presenting with FTT than their counterparts with appropriate weight for age (Browne & Ross, 2011; Pike et al., 2016).

The exclusion criteria for study 2 and 3 were that neonates declared medically unstable were not included in the study.

3.5.4. Participant description

The sample size for study 1 was five (n=5) and the sample sizes for study 2 and 3 respectively were 20 and 48. In Table 3.1, 3.2 and 3.3 the participants of the three different studies are described.

Table 3.1 Participant description for study 1 (n=5)

Characteristics	Number of participants
Gender:	
Female	**5**
Male	**0**
Years of working experience:	
5-10 years	**1**
10-20 years	**1**
>20 years	**3**
Working context:	

Public healthcare	**1**
Private healthcare	**1**
Academic and public healthcare	**2**
Other: Non-governmental organization providing clinical services	**1**
Citizen country:	
South Africa	**3**
USA	**2**
Qualification:	
Master's degree	**2**
Doctoral degree	**3**

According to Table 3.1 the participant inclusion criteria were met. All participants had postgraduate qualifications in the field of Speech-Language Pathology. Both international experts had peer-reviewed research publications in the field of neonatal and paediatric dysphagia which demonstrated their advanced knowledge. In addition, the international experts had more than 20 years of clinical experience working in the field of paediatric dysphagia. This highlighted the long history of paediatric dysphagia intervention in America, as well as the experts' significant clinical experience. Only one of the South African participants had more than 20 years' clinical experience.

For study 2 and 3 neonates admitted to a 29 bed NICU at a tertiary academic hospital in Gauteng, South Africa was sampled. The participant sample of study 2 is presented in Table 3.2.

Table 3.2 Participant description of study 2 (n=20)

Participant characteristics	Mean	Median	Mode	Standard Deviation (SD)
Gestational age at birth or duration of pregnancy (weeks)	35.15	35.00	32	3.066
Birth weight (kilograms)	2.17	1.94	3.3	0.845
Corrected age at assessment (weeks)	36.89	36.5	35	2.850
Number of days in NICU	12.65	6.00	6	11.582

As evident in Table 3.2 the participants were born preterm at a mean GA of 35.15 weeks with a small SD of approximately 3 weeks (SD=3.066). The most commonly occurring (mode) GA was 32 weeks. The mean birth weight of the participants was low, 2.17 kg (SD=0.845) with a less than 1 kg variation in this sample of participants.

The mean length of stay in the NICU was 12.65 days (>10 days), which is considered a risk factor for presenting with developmental difficulties in various domains (Joint Committee on Infant Hearing, 2007). The average corrected age at assessment was 36.89 weeks which was an appropriate age to conduct clinical and instrumental feeding assessments since NS emerges from 32 weeks GA (Browne & Ross, 2011; Thoyre et al., 2005). Additionally the sample consisted of slightly more female participants (60%) than males. The main study sample is represented in Table 3.3.

Table 3.3 Participant description of study 3 (n=48)

Participant characteristics	Mean	Median	Mode	Standard Deviation (SD)
Gestational age at birth (weeks)	35.58	35.0	34	3.06
Birth weight (kilograms)	2.118	1.960	1.400	0.718
Corrected age at assessment (weeks)	36.96	36.85	35.00	2.92
Number of days in NICU	9.52	7.00	4	8.71

The sample consisted of 48 preterm high-risk neonates with a mean GA of 35.58 weeks (SD=3.06). The main and preliminary samples had a relatively similar standard deviation indicating acceptable levels of variance across these two samples (Dawson & Trapp, 2004). The average birth weight was slightly less than in the preliminary sample at 2.11kg indicating LBW. A comparable mean corrected age at assessment was present between the two samples. More females (57%) than males formed part of the sample, which was similar to the sample in study 2.

In comparison the samples from study 2 and 3 were relatively similar indicating homogenous characteristics regarding GA and birth weight, minor difference in the length of NICU stay with the main sample of participants falling just below the acknowledged developmental risk that more than 10 days NICU stay may represent. The sample characteristics in the two studies were relatively similar.

3.6. Material and apparatus

Since the current study developed a novel feeding assessment instrument for neonates and compared the psychometric performance of NFAS to the gold standard for assessment instruments in the paediatric population, the MBSS, various

materials and apparatus were required. An overview of required material and apparatus for each study is presented in Table 3.4.

Table 3.4 Overview of material and apparatus of the three studies

Study 1: Development of the NFAS	Study 2 and 3: Preliminary psychometric performance, reliability and validity of NFAS
• Participant information brochure – Appendix B • 2 x questionnaires for Delphi process – Appendix D	• Parent information leaflet (Setswana, English and Afrikaans) – Appendix c • Interview and case history form (including Risk Assessment Form [Kritzinger, 2005]) – Appendix E • Medical records of neonates • Neonatal Feeding Assessment Scale (NFAS) – Appendix F • MBSS Checklist and MBSS review guidelines(based on Arvedson & Brodsky, 2002; Hall, 2001; Swigert, 2010) – Appendix G • Barium sulphate solution (E-Z-HD™) • C-arm and videofluoroscopy unit (SYSCO 19" Multi DiagnostEleva FD – Philips (Netherlands) • NUK MedicPro First Choice™ 120 ml infant bottle with a MedicPro™ disposable TPE Teat size 1 • Tumble Forms 2 Feeder Seat™ • Mother's expressed breast milk/recommended infant formula for participant prescribed by dietician

Study 1: The Participant information brochure – see Appendix B - was attached in portable document format to the electronic mail distributed to all the panel members. The purpose of the brochure was to inform the participants of the nature and procedures of the study, what will be expected of them during participation, the time frame of the study and to obtain informed consent. The Delphi process consisted of two rounds. Two self-composed electronic questionnaires were used to assist the expert panel to evaluate the initial version of the NFAS. The two questionnaires contained questions on the relevance of separate sections and items relating to the different neonatal systems involved during feeding on the NFAS. Both questionnaires gave the participants the opportunity to offer recommendations on the addition or removal of sections and items, to comment on different scoring methods, to judge the comprehensiveness of the NFAS, and the relevance of the instrument for clinical use in hospitals.

Open-ended and some close-ended questions were also included addressing face validity, user friendliness, and the format of the instrument and technical editing. The first questionnaire focused on the content domains of skills related to neonatal

feeding and swallowing. The second questionnaire was developed based on the responses and feedback obtained in the first questionnaire. The NFAS was adapted according to the experts' feedback. The revised NFAS was then sent out with the second questionnaire. Information on the rationale of content selection for the questionnaires is discussed in the section, 'Material', in Chapter 4.

Study 2 and 3: The purpose of the Parent information leaflet was to inform the mothers of the nature and procedures of the study, the time frame of the study, the risk of radiation exposure during the MBSS procedure, information on withdrawal from participation without prejudice, and to obtain informed consent. In addition, a Parent interview and case history form included pre-, peri- and postnatal information, and a description of the feeding problem according to the parents (based on Arvedson & Brodsky, 2002; Hall, 2001; Henning, 2002; Kritzinger, 1994; Swigert, 2010). Medical records were used for obtaining additional information.

The development of the NFAS is comprehensively discussed in Study 1 (see Chapter 4). To develop a valid and reliable clinical feeding assessment instrument a clearly delineated theoretical framework was used as foundation. The NFAS was developed based on the principles of EI (ASHA, 2008; Rossetti, 2001) and developmentally appropriate care (Ensher & Clark, 2009) supported by the four theoretical perspectives introduced in Chapter 2. The NFAS incorporated an asset-based approach integrating various constructs of evidence-based practice in the field of neonatal and paediatric OPD. An EI principle such as focusing on parent-infant attachment is of great importance for optimal neonatal development and pleasurable oral feeding (Shaker, 2013). Teamwork is also considered an important EI principle in the NICU (ASHA, 2005). In the assessment process the importance of a multidisciplinary approach is acknowledged and the SLT as team member may use the NFAS to focus on the act of feeding. A developmental appropriate care approach is followed to reduce handling, sensory overload and physiological instability in the neonate (Ensher & Clark, 2009). To reduce physical handling the clinician only elicits oral primitive reflexes and feeding related behaviour (i.e. NNS) whereas the mother provides the feed via breast/bottle. The SLT observes the entire feeding session. The mother providing the habitual feeding links to the parent-centred principle of EI. The neonate's strengths during the feeding assessment with the NFAS are

considered within an asset-based approach to compensate for activity-participation limitations during feeding (Fraker & Walbert, 2003; Thoyre et al., 2013; WHO, 2001).

The content and item selection of the NFAS - see Appendix F - was based on theoretical constructs related to neonatal feeding and the clinical assessment of feeding difficulty in early infancy. The item selection in the sections of the NFAS was based on theoretical constructs related to neonatal and early infant feeding, and the clinical assessment of feeding skills. The NFAS relies on physiological observations of the neonate during feeding, how neonatal state is influenced by feeding and how feeding may subsequently disrupt a regulated state (Browne & Ross, 2011) in the neonate with feeding difficulties and an associated display of stress cues.

The MBSS Checklist developed for this study indicated the stages of swallowing - oral, pharyngeal and oesophageal stages according to Arvedson and Brodsky (2002) - the presence or absence of any form of dysphagia in each of the stages (Swigert, 2010), and penetration or aspiration in the pharyngeal stage (Hall, 2001; Swigert, 2010). A MBSS Review Guideline accompanied the MBSS Checklist (Arvedson & Brodsky, 2002; Gewolb & Vice, 2006; Hall, 2001; Jadcherla, 2016; Lau & Smith, 2011). During the MBSS instrumental assessment procedure, a solution of barium sulphate was reconstituted by mixing the powder (E-Z-HD™) with the mothers' expressed breast milk or recommended formula. During fluoroscopy (SYSCO 19" version Multi DiagnostEleva FD screening machine from Philips, Netherlands) the continuous mode with appropriate collimation was used to limit radiation exposure but still obtain the clearest view of the bolus procession (Hernanz-Schulman, Goske, Bercha, & Strauss, 2011; Scott, Fujii, Behrman, & Dillon, 2014). Additional information on MBSS analysis regarding frame rate and exposure time is provided in the data analysis section in Chapter 6. A NUK MedicPro First choice™ 120ml infant bottle with a MedicPro™ disposable TPE Teat size 1 was used (Moral et al., 2010). Participants were positioned with appropriate supported seating in a Tumble Forms 2 Feeder Seat™ and viewed in the lateral projection.

3.7. Procedures

3.7.1 Overview of the procedures followed in the development of the NFAS

The development of a new instrument should proceed according to a structured process and methodology (Cresswell & Plano Clark, 2011). According to Cresswell (2014) the first step in the process of instrument development after thorough review of appropriate theories and models of the construct under investigation (i.e. neonatal dysphagia), constitutes the review of relevant literature of other assessment instruments. In the literature there were a limited number of instruments available for use with neonates and infants, such as the NOMAS (Palmer et al., 1993), the SOMA (Skuse et al., 1995), the EFS (Thoyre et al., 2005), and the Support of Oral Feeding for Fragile Infants [SOFFI] (Ross & Philbin, 2011). Existing instruments, such as the NOMAS, SOMA, EFS, and SOFFI provided information on the assessment instruments' style and approach as the items generated for these instruments were designed to measure specific constructs related to neonatal and infant oral-motor, feeding- and swallowing skills and not OPD as a whole. The purpose and reason why these existing instruments may not be comprehensive enough for the assessment of neonatal dysphagia within a holistic framework in the developing context of South Africa, is presented in Table 3.5.

Table 3.5 Summary of existing infant feeding assessment instruments

Name of instrument	Purpose of instrument	Reason for being inappropriate for the purpose of comprehensive description and identification of OPD
NOMAS (Palmer et al., 1993)	To assess sucking patterns with specific focus on functional motor skills of the tongue and jaw. Describes neonatal sucking pattern according to organization of skills.	It does not focus on total description of the feeding process and interaction between infant systems to reflect stress experienced by the infant. Only reaches a diagnosis regarding sucking behaviour and not regarding the presence or absence of dysphagia. Expensive training and certification is required for SLTs to use the NOMAS in research or clinical practice, which limits the access for South African SLTs to use it.
SOMA (Skuse et al., 1995)	To assess the oral motor function involved in the oral phase of feeding in various age groups (validated for use with infants from 8-24 months). The outcome of assessment classifies the infant or young child's oral motor function during feeding as normal or abnormal.	This instrument is not user friendly for the neonatal population, and it is not validated for use with neonates or infants younger than eight months. It can also not be used for breast feeding infants and does not reach a diagnostic conclusion. Therefore this instrument is not suitable to assess neonatal feeding skills holistically.
EFS (Thoyre et	This instrument is used to assess	The EFS is perhaps closer to the

al., 2005)	three components of feeding skills in neonates, namely early feeding readiness, oral feeding skills and oral feeding recovery. It assesses an infant's readiness for and tolerance of feeding and can be used to profile the infant's developmental stage regarding these specific feeding skills.	researcher's view of feeding assessment in high-risk neonates and does not only focus on the oral motor skills as does the NOMAS and SOMA, but also includes other components of feeding ability. However, all relevant subsystems, reflexes, anatomy and physiology of all oral structures involved in feeding, together with NNS and NS and identification of signs and reported symptoms of OPD is not included. The focus of the EFS is more on determining readiness for oral intake on a daily basis.
SOFFI Bottle feeding algorithm (Philbin & Ross, 2011)	This instrument is used to assess and support bottle feeding in preterm and ill infants in the NICU. The authors state that the majority of infants in American NICU's are bottle fed (Ross & Philbin, 2011) therefore the focus on bottle feeding alone. The SOFFI requires the parents to look at the behavioural and biological communication channels of the infant to support focus on quality of feeding over quantity of feeding. It consists of multiple assessments and 'yes/no'-questions to guide the actions during the feeding session.	Bottle feeding are not encouraged in public hospital NICUs in South Africa, since the WHO Guidelines on Infant Feeding (2010) and the South African Department of Health's policy on Infant and Young Child Feeding (2007) which encourages breast feeding are adhered to. The SOFFI method is also based on Als' (1982) Synactive Theory of Infant Development which the researcher used in the development of the NFAS. With the SOFFI a specific sequence of assessments are followed and the assessment can be performed under guidance by an SLT or trained neonatal nurse. The SOFFI also does not reach a conclusive diagnosis of type of feeding difficulty that may be present.

After reviewing existing instruments, the second step consisted of the compilation of the items to be included in the NFAS. Thirdly, experts in the subject field were consulted to review the preliminary instrument where after expert feedback was used to determine face and content validity of the newly developed assessment instrument (Du Plessis & Human, 2007). A preliminary study then investigated the preliminary performance of the NFAS. In Table 3.6 a summary description of the processes is presented.

Table 3.6 Instrument development process

Processes	Description of processes
1. Determine the focus of the assessment instrument	• Researcher identifies the target population to be assessed, the purpose/s of the assessment instrument and the contexts in which the tool are likely to be used. • Access relevant literature and other assessment instruments for this target population and interpret the literature and instruments to establish evidence required to generate assessment items. • Identify, access and interpret organisational and ethical requirements relevant to the development of the assessment tool. • Identify other related documentation to inform assessment instrument development.
2. Design and	• Select assessment methods that support the collection of defined

	development of the assessment instrument	evidence, taking into account the context in which the assessment will take place and meeting the principles of assessment. • Consider how the assessment instrument will be administered. • Generate relevant items to be included in the instrument. • Develop specific assessment sections and subsections with relevant items that address the construct/s that will be assessed. • Define and document clear and specific procedures and scoring criteria for the assessor/researchers regarding the administration and use of the instrument.
3.	**Review and trial the assessment instrument**	• Check draft assessment instrument against relevant literature and other instruments in the field of study and amend the instrument as needed. • Delphi-study: Obtain expert opinion in the field of assessment of the construct under investigation. • Trial the assessment instrument in a pilot study to check content and applicability and preliminary performance. • Collect feedback from the assessors who participated in the trial of the instrument. • Make final amendments to instrument. • Appropriately format and file the finalized instrument for use in the main study to validate psychometric properties of the instrument.

(Department of Education, Australian Government, 2012; Howe, Lin, Fu, Su & Hsieh, 2008; Leedy & Ormrod, 2014)

3.7.2 Specified procedures followed in each study

Next the specific procedures followed during the implementation of each study are presented in Figure 3.1 where after each study's procedures are discussed individually.

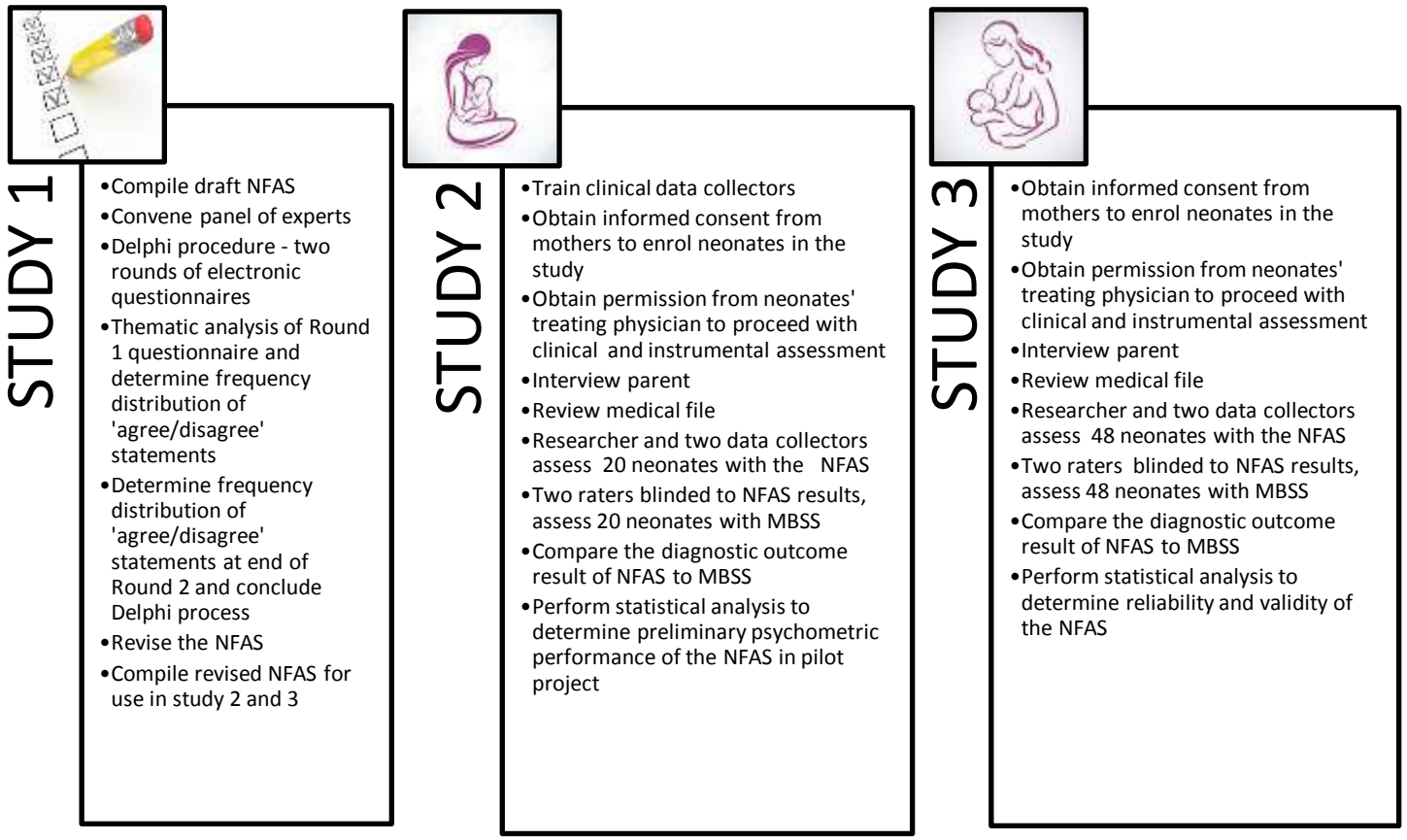

Figure 3.1 Overview of research procedures

Study 1: The researcher compiled the draft NFAS by performing an extensive literature review as recommended for instrument development by St Pierre et al. (2010) to build the theoretical foundation of the scale. For this purpose published oral feeding assessment instruments for neonates and infants such as the NOMAS (Palmer et al., 1993), the SOMA (Skuse et al., 1995), the EFS (Thoyre et al., 2005), and the SOFFI (Philbin & Ross, 2011) were critically evaluated. None of these instruments were considered applicable to use in the South African context - see Table 3.5 - since the instrument should provide for assessment of breastfeeding in addition to bottle feeding as an option. The WHO Guidelines for Infant Feeding (2010) promote exclusive breastfeeding for the first six months of an infant's life and are followed in public hospitals in South Africa. Infant and neonatal feeding options to prevent MTCT of HIV (Department of Health, 2015) should also be considered when selecting an assessment instrument. Furthermore, such an assessment instrument should offer the earliest possible valid identification of OPD in premature

neonates to translate to effective management. The researcher also drew from her own clinical experience working in NICUs in private and public hospitals in Gauteng, South Africa and in the United Kingdom.

Sonies et al. (2009) stated that convening an expert panel is the most common method for establishing content validity to evaluate a new instrument. After consent was obtained from the five SLT participants to serve as expert panel members, the researcher proceeded to develop the first questionnaire to use in the Delphi procedure - see Figure 3.1. Participation in Round 1 took three weeks and all the participants responded within the stipulated timeframe. The Delphi method was used to obtain the anonymous opinions of various experts on constructs of neonatal feeding assessment and neonatal feeding skills contained in the different sections and items of the NFAS. Collation and thematic analysis of Round 1 responses were performed. Drafting the second questionnaire and revising the NFAS took approximately four weeks. Round 2 was then initiated and completed in three weeks. After Round 2 was concluded and the researcher analysed the data with frequency distribution, a consensus had been reached and the Delphi process was terminated. The Delphi process resulted in the final format of the NFAS to be used in study 2 and 3.

Study 2: During instrument development a preliminary performance study is recommended (Sonies et al., 2009). Three final year graduate students in speech-language pathology and the main researcher collected data. The graduate student data collectors were trained. Training was provided in a six hour session on the content, administration and scoring of the NFAS. After the training session each trainee was expected to accumulate four practice assessments before data collection was initiated. Inter-rater reliability data were obtained for two of the four data collectors (excluding the researcher to limit bias) on 10 infants (50% of sample) – the inter-rater reliability data are presented in Chapter 5. The mothers' of the participants (n=20) were interviewed, medical files were reviewed and a clinical feeding assessment using the NFAS, and a MBSS were performed. The MBSS was conducted within seven days of the clinical assessment. The interviews, medical file review and clinical feeding assessments were conducted by the researcher, a qualified SLT and three graduate students in SLP.

Two senior SLTs working at the hospital conducted the MBSS while blinded to the participants' feeding history and diagnostic outcome on the NFAS. The MBSS and NFAS results were compared to attain the preliminary psychometric properties, to determine if the revised NFAS should be validated on a larger sample of neonates. The outcome of study 2 indicated that the NFAS was now ready to be used in a validation study.

Study 3: The main study now commenced. The mothers' of 48 neonates were interviewed, medical files were reviewed and a clinical feeding assessment using the NFAS, and a MBSS were performed. Similar to Study 1 a MBSS was conducted within seven days of the clinical assessment. The interviews, medical file review and clinical feeding assessments were conducted by the researcher, a qualified SLT and three graduate students in SLP. Inter-rater reliability data were obtained for two of the four data collectors (excluding the researcher to limit bias) on 17 infants (35% of sample) – the results are presented in Chapter 5. The same two senior SLTs acting as raters in study 2, conducted the MBSS while blinded to the participants' feeding history and diagnostic outcome on the NFAS. The MBSS and NFAS results were statistically compared to determine the reliability and validity of the NFAS for clinical use in developing contexts similar to South Africa.

With reporting of the results of the three studies in the peer-reviewed articles the researcher followed international recommended guidelines for reporting and disseminating diagnostic results of a new assessment instrument. The Standards for Reporting of Diagnostic Accuracy (STARD) checklist developed by the TDR Diagnostic Evaluation Expert Panel in 2010 was used as a form of self-evaluation of Study 2 and 3. The STARD (TDR Diagnostic Evaluation Expert Panel, 2010) guidelines were followed since Study 2 and 3 investigated the performance and accuracy of a new 'test' to determine validity and reliability of the NFAS. Researchers in resource constrained developing contexts deal with challenges to adequately evaluate a new diagnostic tool (Bossuyt, et al., 2003a). It is the instrument developers' responsibility to implement appropriate performance testing to ensure that the data adds new information to the existing knowledge pool that researchers and clinicians draw from (Bossuyt, et al., 2003a; Bossuyt, et al., 2003b).

It is recommended that instrument developers use the STARD checklist (TDR Diagnostic Evaluation Expert Panel, 2010) to indicate whether all components of test performance were investigated and reported. Table 3.7 demonstrates adherence to the international STARD guidelines provided by the TDR Diagnostic Expert Panel (2010).

Table 3.7 Adherence to STARD checklist: Study 2 and 3

STARD checklist and indicator of adherence (√ / × / n/a)	Item description	Inclusion of recommended information
Title/Abstract/ Keywords **1.**√	1. Identify the article as a study of diagnostic accuracy	The term *diagnostic accuracy* was used in the abstract of both studies
Introduction **2.**√	2. State the research questions or study aims, such as estimating the diagnostic accuracy or comparing accuracy between tests or across participant groups	The *research question* of both studies appears in the last paragraph of the introduction. The *study aims* were included in the methodology sections according to author guidelines for the specific journals. The *objectives* of both studies state that diagnostic accuracy was investigated by comparing the outcomes of two 'tests', the NFAS to the MBSS.
METHODS		
Participants **3-6.**√	3. The study population: the inclusion criteria and exclusion criteria, the setting and the locations where the data were collected. 4. Description of participant recruitment. 5. Description of participant sampling. 6. Description of data collection.	3. The *inclusion criteria* of both studies were presented in the procedure section of the published articles. The *setting/locations* of data collection were described under Participants in both studies. 4-6.In both studies there was a clear description of how participants was approached to participate in the study, on how the sampling occurred and how data collection took place.
Test Methods **7.**√ **8.**√ **9.**√ **10-11.**√	7. Description of the use of the reference (gold) standard and its rationale. 8. Description of the technical specification of the material and methods, including how and when measurements were taken. 9. Description of the scoring units and/or cited references for the index assessment (NFAS) and the gold standard (MBSS). 10. The number, training and expertise of the persons executing and reading the index assessment (NFAS) and the gold standard	7. The use of the MBSS as acknowledged gold standard in the field of dysphagia practice was motivated. 8. All materials and apparatus used in both studies were reported on. 9. The scoring method and scoring guidelines for the NFAS were explained to data collectors in training in study 2. The same data

	(MBSS). 11. Indicate whether the readers of the index tests and gold standard were blind to the results of the other test, and/or describe clinical information available to them.	collectors performed data collection in study 3 where the scoring was again summarized in the material description section of the articles. 10-11. These stated components were addressed in the participant and procedure sections in both articles.
Statistical Methods **12.**√ **13.**√	12. Methods for calculating or comparing measures of diagnostic accuracy and description of statistical methods. 13. Methods for calculating test reproducibility, if done.	12. The inferential statistical tests used to determine the psychometric performance of the NFAS against the MBSS are described in the data analysis section of both studies. 13. Inter-rater reliability testing was determined on a segment of the sample in both studies and are described in the data analysis section of both published papers.
RESULTS		
Participants **14.**√ **15.**√ **16.**√	14. Provided the time period of the study (including start and end dates). 15. Description of the clinical and demographic characteristics of the study population. 16. The number of participants meeting the inclusion criteria for the study.	14. These dates were indicated in the procedures sections of both studies. 15. The characteristics of both participant groups were described in the relevant section of both papers. 16. The sample size was described in both articles.
Test Results **17.**√ **18.**√ **19.**√ **20.**√	17. Time interval between index test (NFAS) and gold standard (MBSS). 18. Define criteria in participants with the target condition (OPD); other diagnoses in participants without the target condition (ED). 19. A cross tabulation of the results of the index tests (NFAS) by the results of the gold standard (MBSS). 20. Any adverse events from performing the index test (NFAS) or the reference standard (MBSS).	17. The time interval between the performance of the NFAS and the MBSS was indicated in the results section of both studies. 18. The results included a report on the number of participants identified with OPD on the NFAS and the MBSS. The comparison results were also provided. The number of participants who presented with ED was indicated in the results section of both studies. 19. A cross tabulation indicating specificity and sensitivity results together with predictive values and diagnostic outcome was provided in the results report in both published papers. 20. There were no adverse events to report on in either of the studies.
Estimates **21.**√ **22.n/a** **23.n/a** **24.n/a** **25.**√	21. Estimates of diagnostic accuracy and measures of statistical uncertainty. 22. How indeterminate results, missing responses, and outliers of the index tests were handled. 23. Estimates of variability of diagnostic accuracy between subgroups of participants, readers or centres, if done. 24. Estimates of test reproducibility, if done.	21. Diagnostic accuracy of the NFAS in comparison to the MBSS was reported on in the results section of both papers. 22. An unexpected result of no penetration or aspiration on MBSS was found in Study 2 and 3. 23. Not applicable to either study. 24. Not applicable to either study.

	25. Discussion of the clinical applicability of the study findings.	25. Further validation options and clinical use were discussed in the discussion and conclusion section of Study 2. The clinical use of the NFAS was discussed in Study 3. This discussion was presented in the discussion and conclusion section of the article.

The STARD checklist (TDR Diagnostic Evaluation Expert Panel, 2010) assisted the researcher to follow a valid procedure on reporting outcomes of a novel assessment instrument. Using this checklist increased the validity of the psychometric performance results reported, since all the requirements were adhered to (Hulley, Cummings, Browner, Grady, & Newman, 2013). Study 2 and 3 met 23 of the 25 stated criteria. Two criteria, namely 'Estimates of variability of diagnostic accuracy' and 'Test reproducibility' were not applicable to either of the studies.

3.8. Data analysis

Study 1: Round 1 of the Delphi procedure mainly rendered descriptive data which was analysed according to emerging themes linked to the various sections of the draft NFAS. Thematic analysis was used as a tool to enable the researcher to identify, analyse and report patterns of themes that was embedded in the data set and items (Braun & Clarke, 2006). The responses to questions in the questionnaire was coded and then grouped to actively comb through the data for themes. A theme was identified to capture data when it related to the overall research question (Braun & Clarke, 2006). Themes were identified using a realist semantic approach where the common threads from the questions and related participant responses were identified as themes (Braun & Clarke, 2006). Themes were prevalent across all five participants' responses and were strongly linked to the data itself. Once initial themes were identified, it was reviewed and a final name was allocated to the theme.

In Round 2 descriptive statistics to determine percentage of agreement (%) among expert panel members were used. Feedback from both rounds was interpreted and then the draft NFAS was revised according to the panel member recommendations.

Study 2 and 3: Data obtained from the Parent interview, case history form and medical file, as well as the NFAS were prepared for analysis by determining what type of variable/s the data represented. In this study continuous and categorical

variables were present. A continuous variable take on a range of values and exhibited the mathematical property known as order (Meline, 2010), such as the neonates' GA or birth weight. Identifying categorical variables enabled the researcher to assign the participant to a category based on whether they possess some characteristic or not (Meline, 2010), such as being male/female, or presenting with suspected OPD or not. The number of categories was dependent on the different items in the case history form and the assessment instrument.

To analyse clinical data appropriately Leedy and Ormrod (2014) recommends following specific steps. The steps and application was followed during study 2 and 3 - see Table 3.8.

Table 3.8 Application of data analysis steps for Study 2 and 3

Steps of sequential analysis (based on Leedy and Ormrod, 2014)	Application to Study 2 and 3
Step 1: Logical organization of details about the case	• Allocating participant numbers to all the cases. • Arranging parent interview, case history forms and NFAS according to the participant numbers. • Arranging MBSS Checklists according to the participant numbers.
Step 2: Categorization of data	• Tabulation of case history data obtained from the interview and hospital files in Microsoft Word™ (2010) and Microsoft Excel™ (2010) spread sheets. This data were used to describe the participants' characteristics. • Tabulation of clinical assessment data according to the outcomes of the different sections on the NFAS and the diagnostic outcome of the scale • Tabulation of MBSS data according to diagnostic outcome • Lastly tabulation of the comparative data between the diagnostic outcome of the NFAS and the MBSS was completed. • Inferential statistical analyses of data were executed with SAS™ version 9.3.
Step 3: Interpretation	• The results were interpreted according to the objectives of each study. • The results were compared to current literature in field of neonatal dysphagia.
Step 4: Synthesis of data and generalization	• A synopsis of the psychometric performance of the NFAS was discussed and conclusions were drawn. • Data were organized in tables and figures to meet the objectives of each study. • Generalization of the validity and reliability of the NFAS was approached with caution due to a relatively small sample size, and the specific middle-income, developing, public health care context in South Africa in which it was developed.

A biostatistician and a statistical consultant at the Department of Statistics, at the University of Pretoria provided statistical support to assist the researcher to analyse

the quantitative data. A summary of the statistical analysis performed for each of the studies is provided in Table 3.9.

Table 3.9 Summary of statistical analysis for Studies 2 and 3

Type of data	Statistical analysis procedure
STUDY 2: Quantitative data to determine *preliminary psychometric properties* of the NFAS	1. Participant description: Mean, median, mode, SD 2. Determine preliminary NFAS performance using inferential statistics: • Sensitivity (%) • Specificity (%) • Positive Predictive Value (PPV) (%) • Negative Predictive Value (NPV) (%) • Diagnostic accuracy (%) • Inter-rater reliability (Cohen's Kappa; P Bar; Asymptotic Standard Error [ASE])
STUDY 3: Quantitative data to determine *validity and reliability* of the NFAS	1.Participant description: Mean, median, mode, SD 2.NFAS instrument performance to determine reliability and reliability from the psychometric performance data using inferential statistics: • Sensitivity (%) • Specificity (%) • Positive predictive value (PPV) (%) • Negative predictive value (NPV) (%) • Diagnostic accuracy (%) • Inter-rater reliability (Cohen's Kappa; P Bar; ASE)

The interpretation of the statistical analysis of each study is presented and discussed separately in each of the chapters (5 and 6) containing accepted (local) and submitted (international) publications to peer-reviewed journals. Table 3.10 presents the Kappa value interpretation guidelines used in study 2 and 3.

Table 3.10 Inter-rater reliability: Interpretation guidelines for Kappa values

Kappa values	Interpretation of level of agreement (Dawson & Trapp, 2004)	Kappa values	Interpretation of level of agreement (Landis & Koch, 1977)
1.00	Perfect agreement	>0.75	Excellent agreement beyond chance
0.93-0.99	Excellent agreement		
0.81-0.92	Very good agreement	0.40-0.75	Good agreement beyond chance
0.61-0.80	Good agreement		
0.41-0.60	Fair/substantial agreement	<0.40	Poor agreement beyond chance
0.21-0.40	Slight agreement		
0.01-1.20	Poor/chance agreement		
<=0	No agreement		

3.9. Reliability and validity

A newly developed assessment instrument should possess adequate psychometric properties such as validity, reliability, predictive ability and diagnostic accuracy to be

gauged useful for clinical practice (Lambert, Gisel, & Wood-Dauphinee, 2001). The measures implemented to enhance reliability and validity of the study findings will be discussed for each individual study.

Study 1: This study pursued the establishment of content and face validity of the NFAS. The Delphi method contributed to content validation since experts were asked to judge the researcher's interpretation and categorization of variables included in the NFAS. The fact that the experts' responses are blinded to one another, but not to the researcher permitted this validation, unlike in group electronic mail communications (Okoli & Pawlowski, 2004). In addition the experts had to consider the content validity of the NFAS by judging if it provided a representative measure of neonatal feeding behaviour. The inherent richness of the data collected with the Delphi method in comparison to traditional surveys, also contributed to content validity. The two rounds provided the experts with opportunity to revise responses and feedback in the last round. The face validity of the NFAS was also established during the Delphi process. The experts had to judge face validity by determining the degree to which an assessment instrument (NFAS) subjectively appears to measure the construct (neonatal OPD) that it is supposed to measure (Lambert et al., 2001).

Study 2: In study 2 the researcher aimed to determine the preliminary sensitivity and specificity, together with inter-rater reliability of the NFAS to determine if a further validation study would be considered appropriate.

Study 3: The main study set out to investigate the psychometric properties of the NFAS to determine if it could be considered a reliable and valid clinical tool for use in the resource constrained developing context of South Africa to identify OPD in preterm high-risk neonates.

3.10. Summary

In this chapter the exploratory sequential mixed method design guided the research in all three studies. In study 1 the Delphi method was used to mainly obtain qualitative data and study 2 and 3 utilized a cross-sectional comparative within-subject design to obtain quantitative data. The research designs were explained by linking it to the rationale of each selected design. Then the selection of participants

was described by presenting the inclusion criteria. Thereafter the sample of five expert panel members and 68 neonate participants (Study 2 n=20; Study 3 n=48) were described. An overview of all the material used in the three consecutive studies was provided. The data collection procedures entailed the use of the Delphi method for study 1 and in study 2 and 3 it consisted of the parent interview, review of medical files, clinical assessment with the NFAS and instrumental assessment with the MBSS.

Independent raters blinded to the NFAS outcomes performed and analysed the MBSS to compare to the NFAS findings. Data analysis for Study 1 was descriptive in nature. Statistical analysis to determine the psychometric properties of the NFAS was performed in study 2 and 3. The validation procedures to strengthen the reliability and validity of the NFAS in study 2 and 3 adhered to the internationally recommended STARD guidelines (TDR Diagnostic Evaluation Expert Panel, 2010).

Chapter 4

This article was accepted by the peer-reviewed journal, the South African Journal of Communication disorders, where it is currently in press. The format of the article is that of the journal and differs from the rest of the thesis.

Development of a clinical feeding assessment scale for high-risk neonates in South Africa

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Abstract:

Background: There is a need for validated neonatal feeding assessment instruments in South Africa. A locally developed instrument may contribute to standardized evaluation procedures of high-risk neonates and address needs in resource constrained developing settings.

Objective: The aim of the study was to develop and validate the content of a clinical feeding assessment scale to diagnose oropharyngeal dysphagia (OPD) in neonates.

Method: The Neonatal Feeding Assessment Scale (NFAS) was developed using the Delphi-method. Five international and South African speech-language therapists (SLTs) formed the expert panel, participating in two rounds of electronic questionnaires to develop and validate the content of the NFAS.

Results: All participants agreed on the need for the development of a valid clinical feeding assessment instrument to use with the neonatal population. The initial NFAS consisted of 240 items across 8 sections and after the Delphi-process was implemented the final format was reduced to 211 items across 6 sections. The final format of the NFAS is scored using a binary scoring system guiding the clinician to identify the presence or absence of OPD. All members agreed on the format, the scoring system and the feeding constructs addressed in the revised final format of the NFAS.

Conclusion: The Delphi-method and the diverse clinical and research experience of participants could be integrated to develop the NFAS which may be used in clinical practice in South Africa or similar developing contexts. Due to demographically different work settings marked by developed versus developing contexts, participants did not have the same expectations of a clinical dysphagia assessment. The international participants contributed to evidence-based content development. Local participants considered the contextual challenges of South African SLTs entering the field with basic competencies in neonatal dysphagia management, thereby justifying a comprehensive clinical instrument. The NFAS is aimed at clinicians working in NICUs where they manage large caseloads of high-risk neonates. Further validation of the NFAS is recommended to determine its criterion validity in comparison to a widely accepted standard such as the modified barium swallow study.

Keywords

Clinical assessment, Neonatal Feeding Assessment Scale, oropharyngeal dysphagia, diagnosis, validation

Introduction

Clinical assessment is an important part of evidence-based management of neonatal dysphagia (Thoyre, Park, Pados, & Hubbard, 2013). The purpose of clinical assessment is to establish the possible nature of the feeding problem, explore the parent's perception of the problem, the neonate's readiness for oral feeding, to make a differential diagnosis and to determine the need for multi-disciplinary management (Arvedson, 2008; Rommel, 2006; Thoyre et al., 2013). The two main components of such an assessment include a parent interview and medical chart review - to obtain the feeding, medical and developmental history - as well as the clinical feeding assessment (Arvedson, 2008; Lau & Smith, 2011). With the development of a novel clinical assessment instrument the researchers acknowledge the importance of comprehensive clinical assessment, but concurs with studies (Arvedson, 2008; De Matteo, Matovich, & Hjartarson, 2005; Rommel, 2006) that clinical assessment is not designed to replace objective instrumental assessment such as the modified barium swallow study (MBSS). A clinical instrument should support an accurate diagnosis and description of the feeding profile related to oropharyngeal dysphagia (OPD) in high-risk neonates. The use of validated instruments should be encouraged in clinical practice since it provides a common language among clinicians, facilitate the production of diagnostic data and promotes the evaluation of techniques and approaches used during clinical assessment (Brandao, Dos Santos, & Lanzilotti, 2013).

There is a high prevalence of LBW and prematurity in South Africa (WHO, 2012) contributing to neonatal OPD. In the US the prevalence of feeding disorders in premature neonates is estimated between 10.5%-24.5% (Jadcherla, 2016). Currently no prevalence figures on feeding disorders associated with prematurity are available in South Africa. The high prevalence of feeding disorders amongst the neonatal population supports the need for appropriate early clinical assessment and management of OPD, providing an impetus for the development of a valid clinical instrument to contribute to differential diagnosis. In the South African public health care sector there are resource constraints such as limited or no speech-language therapists (SLTs) to provide feeding services in some NICUs (Strasheim, Kritzinger & Louw, 2011). Speech-language therapists working in hospitals are also required to manage large caseloads apart from neonatal dysphagia and then do not have the opportunity to specialize in the field. In addition, inexperienced community service therapists are frequently the only service providers in some settings (Singh et al., 2015).

Existing dysphagia assessment instruments may not meet the needs in South Africa. Philbin and Ross (2011) developed the 'Support of Oral Feeding for Fragile Infants' (SOFFI) which includes a systematic approach to assessment of bottle feeding and clinical decision making for intervention. The Department of Health in South Africa promotes the World Health Organization guidelines (WHO, 2010) for infant feeding which recommend exclusive breastfeeding for the first six months of life (Department of Health, 2015). The bottle-feeding approach of the SOFFI therefore has limited application in the health care sector in South Africa. Some reliable clinical instruments that are supported by high-level evidence do exist, but do not focus holistically on neonatal feeding. The Neonatal Oral Motor Assessment Schema [NOMAS] (Palmer, Crawley, & Blanco, 1992) and the Schedule for Oral Motor Assessment [SOMA] (Reilly, Skuse, & Wolke, 2000) both focus on oral motor skills only (Pressman, 2010; Rogers & Arvedson, 2005). These two scales do not address a feeding assessment from a bio-psychosocial perspective to diagnose OPD. Such a perspective acknowledges the impact of NICU environmental stressors on state regulation, internal physiological disruptions on the neonate's subsystems and the resulting effects on the feeding process, as well as mother-infant interaction during feeding. A clinical assessment instrument should assist the SLT to assess all neonatal systems that contribute to and interact with the feeding process. The instrument should consider the sequential development of the sensory systems emerging throughout gestation in a developmentally supportive approach (Browne & Ross, 2011; Thoyre, 2007). Such an instrument should also be comprehensive to facilitate the description of symptoms related to sensory and motor-based feeding difficulties (Lau & Smith, 2011) that may result in OPD from 32 weeks gestational age. Neonatal OPD is any interference with the acts of feeding and/or swallowing that interrupts the oral or pharyngeal stage of swallowing compromising the development of typical feeding and swallowing

skills and the neonate's nutritional and respiratory status (Arvedson, 2008; Browne & Ross, 2011; Rogers & Arvedson, 2005). The condition is typically only diagnosed from 32 weeks gestational age when nutritive sucking (NS) should emerge (Rogers & Arvedson, 2005; Thoyre, 2007). To facilitate the assessment process an instrument should provide prompts for observation of a variety of signs and symptoms related to neonatal OPD.

The purpose of neonatal feeding assessment is to accurately diagnose OPD prevent the effects of OPD such as inadequate weight gain, dehydration, and limited oral sensory experience, to continue to impact on infancy and early childhood. Obtaining expert opinions on such a new instrument would be invaluable for the development and validation process. This article will report on experts' opinion on the development of the content and face validity of a clinical feeding assessment instrument.

Method

Aims

The aim was to develop and validate the content of a novel clinical feeding assessment scale to diagnose OPD in neonates. The objectives to support the aim were, a) to determine if the panel of experts agreed about the need for a validated clinical feeding assessment scale, to b) select appropriate items for inclusion in the Neonatal Feeding Assessment Scale (NFAS), and lastly c) to establish face and content validity of the NFAS based on expert input.

Design

The Delphi-method (Hassan, Keeney, & McKenna, 2008) was used to gather quantitative and qualitative data from an expert panel during two rounds of consecutive questionnaires. Qualitative data were obtained from open questions and quantitative data from closed questions. The Delphi-method was used to guide improvement of content and face validity of the new instrument. This method allowed the researchers to investigate whether the NFAS represented all facets of neonatal feeding skills. The primary strength of the Delphi-method is the objective exploration of issues that require judgment, such as the content and measurement methods when developing a clinical assessment instrument. Since the Delphi-method is considered one of the most commonly used research procedures to establish content validity of an assessment instrument by an expert panel (Hassan, et al., 2008) this design was considered suitable for the purpose of this study.

Participants

Five expert panel members were included in the study. Informed consent was obtained from all participants. Participant selection criteria included a Masters' degree qualification in Speech-Language Pathology from an accredited tertiary institution to guarantee a high level of expertise and at least five years clinical experience in the field of paediatric dysphagia. Participants could reside in South Africa or internationally. In Table 1 a summary of participant characteristics is provided.

Table 1 Participant description (n=5)

Characteristics	Number of participants
Gender:	
*Female	5
*Male	0
Years of working experience:	
*5-10 years	1
*10-20 years	1
*>20 years	3
Working context:	
*Public healthcare	1
*Private healthcare	1
*Academic and public healthcare	2
*Other: Non-governmental organization providing clinical services	1
Citizen country:	

*South Africa *USA	3 2
Qualification: *Master's degree *Doctoral degree	 2 3

All participants had postgraduate qualifications in the field of Speech-Language Pathology. Both international experts had doctoral degrees in paediatric dysphagia which demonstrated their advanced knowledge. In addition, the international experts had more than 20 years of clinical experience working in paediatric dysphagia. This highlighted the long history of paediatric dysphagia intervention in America as well as the experts' significant clinical experience. Only one of the South African participants had more than 20 years' clinical experience.

Materials

The NFAS will not be described in detail in this section since the purpose of the study was to develop and validate the content of the instrument. The NFAS was based on other clinical assessment instruments, studies on neonatal feeding development, relevant literature on prematurity, LBW and paediatric HIV/AIDS in the South African context and recent studies on neonatal dysphagia. Additionally the first author's clinical experience of service delivery in the private and public health care sectors in the NICU provided insight into local needs and knowledge of specific local constraints.

Two self-composed electronic questionnaires were used to obtain feedback from the expert panel on the content of the NFAS. Round one required a comprehensive overview of the NFAS and round two required targeted responses in closed question format about the revised content, structure and format of the NFAS. The two questionnaires contained questions on the relevance of separate sections and items relating to the different neonatal systems involved in feeding in the NFAS. Both questionnaires gave the participants the opportunity to offer recommendations on the addition or removal of sections and items, to comment on different scoring methods, to judge the comprehensiveness of the scale and its relevance to clinical use in hospitals. Open-ended and some close-ended questions were also included addressing face validity, user friendliness, and the format of the instrument and technical editing (Dawson & Trapp, 2004). For close-ended questions, reasons for answers had to be given. The questionnaires facilitated a deductive reasoning sequence to compile an authentic profile of neonatal feeding skill assessment. The first questionnaire focused on the content domains of skills related to neonatal feeding and swallowing (Als, et al., 1994; Arvedson, 2008; Arvedson & Brodsky, 2002; Bahr, 2001; Brazelton, 1973; Browne & Ross, 2011; Clark, 2009; Da Costa & Van der Schans, 2008; Darrow & Harley, 1998; Dieckmann, Brownstein, & Gausche-Hill, 2006; Gewolb & Vice, 2006; Hall, 2001; Henning, 2002; Hodgman, Hoppenbrouwers, & Cabal, 1993; Jadcherla, 2016; Karl, 2004; Nugent, Keefer, Minear, Johnson, & Blanchard, 2007; Prechtl & Beintema, 1964; Qureshi, Vice, Taciak, Bosma, & Gewolb, 2002; Rudolph & Thompson Link, 2002; Swigert, 2010; Tsai, Chen, & Lin, 2010; Van Haastert, De Vries, Helders, & Jongmans, 2006; Wolf & Glass, 1992; Wolff, 1959) - see Table 2. A draft version of the NFAS accompanied the first questionnaire.

Table 2 Content and rationale for expert panel questionnaire 1

Questions	**Rationale for including item in questionnaire**
Question 1.1-1.9 Do you consider the following section included in the NFAS to be comprehensive enough to obtain adequate information during a clinical assessment of a high-risk neonate's feeding skills?	To determine if the main components related to the construct of neonatal feeding are included in the different sections of the draft of the NFAS.
Question 2.1-2.9 Do you consider the following item/s included in the NFAS to be comprehensive enough to obtain adequate information during a clinical assessment of a high-risk neonate's feeding skills?	To determine if the items in each proposed section addressed the main components related to the construct of neonatal feeding.
Question 2.1-2.2	Participants could comment and reason

If you selected "no" for any particular item/section, motivate your choice and indicate items/sections to be added or omitted.	about the relevance of components, sections and items that investigates neonatal feeding skills.
Question 3 Comment further on the sections and items in the NFAS if all your opinions/suggestions could not be expressed in the previous questions.	Additional information could be offered that may not have been included by the preceding closed questions.
Question 4 Is the development of a validated clinical assessment instrument a relevant area of study?	To obtain the participants' opinion on the need and relevance for developing a neonatal dysphagia assessment instrument
Question 5 Is there a need for the development of a validated clinical assessment instrument to use in clinical practice with neonatal dysphagia in the international arena?	To determine the international need for such a tool.
Question 6.1-6.5 Please provide your opinion and recommendations regarding the following components of the NFAS: 6.1Scoring method 6.2Face validity 6.3 Professional appearance 6.4User friendliness 6.5Language and technical editing	6.1 To receive feedback on the proposed scoring method of the NFAS. 6.2-6.5 All aspects of face validity were included

The second questionnaire was developed based on the responses and feedback obtained in the first questionnaire. The NFAS was adapted according to the experts' feedback. The revised NFAS was then sent to the expert panel along with the summary of changes recommended in the first round. The second questionnaire was used to further refine the content and face validity of the instrument.

Table 3 Content and rationale for expert panel questionnaire 2

Question	Rationale for inclusion
1.The revised instrument is user friendly	To allow the participants to judge relevant components (sections and items) of the revised NFAS that should be considered in the final format of the instrument.
2.The format and technical editing of the revised instrument is acceptable	
3.The face validity of the revised instrument is acceptable	
4.The proposed scoring system of the revised instrument is acceptable	
5.The revised feeding constructs for the identified target population is acceptable	
6.The content validity of the revised instrument is acceptable	
7.Provide additional comments on the revised instrument	To provide an opportunity to the participants to give additional comments if they were of the opinion that a component was not sufficiently addressed with the questions posed in both questionnaires.

Procedures

Clearance was obtained from the Research ethics committee at the university where the study was conducted. The process of validation of a new assessment instrument commences with the initial development phase providing a sound theoretical foundation to link to clinical practice (St Pierre et al., 2010). The initial phase of instrument development consisted of the review of available published scales, checklists and literature and the researchers' own clinical experience. The second phase employed the Delphi-method to request expert judgement on the new clinical instrument. The panel members' identity was blinded to one another to enhance open participation in the instrument development process. The procedures followed in the study are depicted in Figure 1.

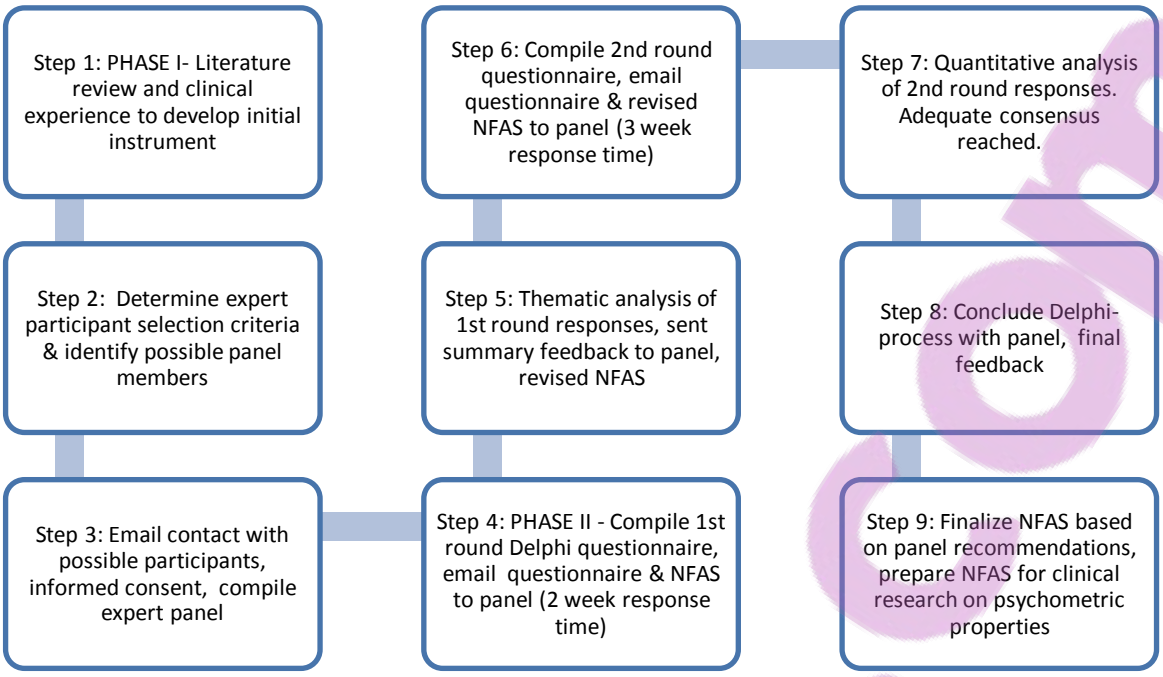

Figure 1 Flowchart of study procedures

The preliminary and revised instrument was sent to the expert panel to facilitate two rounds of questioning via email. The panel was blind to one another's responses. The aim of the first round was to allow the expert panel to judge the validity of the content domains in the instrument. Summarised feedback to the panel after round one served as the introduction of round two. The aim of the second round was to reach consensus on the recommendations of the first round, as well as on the content and the scoring system of the instrument. After the second round responses were received from the participants, the Delphi-process was concluded as majority agreement and no new additional content was suggested indicating that adequate consensus among panel members had been reached. The Delphi-method allowed rich data to be gathered since open- and closed questions could be used to probe the participants' views on the NFAS. Round one rendered descriptive data which was analysed according to emerging themes linked to the various content sections of the draft instrument.

Data analysis

According to Hassan and colleagues (2008) the Delphi-method is not intended to produce statistically significant results, but rather a synthesis of an expert group's opinion. Suggested changes according to the themes that emerged from the data will be discussed. Sections of the data of round one and all of the data from round two were analysed quantitatively using frequency counts.

Results

Results will be presented according to the three objectives of the study.

Objective A: Determining agreement on the need for a validated feeding assessment instrument

Three themes were identified linked to the content sections of the first questionnaire. The first content theme was the *Need for a valid assessment tool*. The second theme was *Content of the NFAS* and the last was *Scoring criteria.* Only the first theme's results are discussed with this objective. Question 4 and 5 in the first questionnaire investigated the rationale for the development of the NFAS. All participants (n=5; 100%) agreed that the development of a valid clinical assessment tool was a relevant area of study and confirmed the need for such a tool. Some participants also provided further comments to reflect their agreement.

Participant 4 stated "…there is definitely a need for a well-researched assessment tool for use with infants…" however, "internationally still a huge lack of normative data regarding sucking and swallowing along with more global developmental aspects of feeding in young infants….difficulty lies in subjectivity of observation of skills that are not measurable…"[Participant 2]. One of the South African panel members commented that "…in South African public healthcare an instrument would help with prioritization of a large case load on assessment outcomes that are valid…and prevent over referral to video swallows…."[Participant 5]. In addition one of the participants stated that a validated feeding assessment instrument might support clinicians in case management. The qualitative comments further supported the rationale for research to develop a validated feeding assessment instrument for use with the neonatal population.

Objective B: Content and item selection for the NFAS

The content and item selection of the preliminary NFAS was based on theoretical constructs related to neonatal feeding and the clinical assessment of feeding difficulty in early infancy. The instrument relies on physiological observations of the neonate during feeding and elicitation of oral responses. Neonatal states were included so that the influence on feeding and state disruption as a result of feeding difficulty may be observed. The structure of the initial draft of the NFAS included three different age categories - from 32 weeks gestational age to 4 months corrected age post term. These different age categories allowed for the inclusion of developmentally appropriate items. In Table 4 the content of the NFAS and the rationale for content selection is summarized.

Table 4 Preliminary NFAS content and rationale for item selection

Sections	Rationale	References
A: Physiological subsystem functioning	Since respiratory problems are one of the most common causes of paediatric dysphagia, assessment of respiratory patterns during feeding was included. Respiratory rate and heart rate may further reveal signs of dysphagia and possible chronic aspiration. Airway stability is a prerequisite for successful oral feeding.	Als, et al., 1994; Arvedson, 2008; Dieckmann, Brownstein, & Gausche-Hill, 2006; Hall, 2001; Hodgman, Hoppenbrouwers, & Cabal, 1993
B: State of alertness during feeding	As neonate's state typically varies during feeding, behaviour should be assessed to determine the optimal stage of alertness to proceed with oral feeding. The neonate should be in an optimal state of alertness for successful oral feeding. The different stages of alertness and subsequent impact on feeding ability were informed by the Synactive Theory of Development.	Als, 1982; Arvedson & Brodsky, 2002; Brazelton, 1973; Nugent, et al., 2007; Prechtl & Beintema, 1964; Wolff, 1959
C: Stress cues during feeding	A neonate's ability to respond to incoming sensory information plays a role in feeding readiness. Interaction between state regulation, the motor system and the autonomic nervous system should be observed to determine stress during feeding and to enable the clinician or parent to make adaptations.	Als, 1982; Brazelton, 1973; Hall, 2001; Karl, 2004; Tsai, Chen, & Lin, 2010
D: General movement and muscle tone screening	Adequate postural control is a prerequisite for safe and efficient feeding. Inadequate muscle tone, postural control or movement may impact negatively on oral feeding. If difficulties are observed, referral to an occupational therapist and/or a physiotherapist can be made.	Arvedson & Brodsky, 2002; Clark, 2009; Hall, 2001; Van Haastert, De Vries, Helders, & Jongmans, 2006
E: Oral peripheral evaluation	Successful swallowing requires the coordination of 31 muscles and five cranial nerves. Neonatal anatomy, physiology, primitive oral reflexes and underlying cranial nerve function should be assessed.	Arvedson & Brodsky, 2002; Bahr, 2001;Hall, 2001; Henning, 2002; Swigert, 2010; Wolf & Glass, 1992
F: Clinical feeding and swallowing evaluation	The purpose of clinical assessment is to observe the oral preparatory/oral stage of swallowing and make certain inferences about the pharyngeal stage, provide baseline feeding and swallowing data for further management and to determine progress.	Arvedson, 2008; Arvedson & Brodsky, 2002; Da Costa & Van der Schans, 2008; Darrow & Harley, 1998; Gewolb & Vice, 2006; Hall, 2011; Jadcherla, 2016; Qureshi, Vice, Taciak, Bosma, & Gewolb, 2002; Rudolph & Thompson Link, 2002; Swigert, 2010
G: Parent-Neonatal interaction during feeding	Success with infant feeding depends on the parent/caregiver's ability to monitor the neonate's stress cues and to make environmental adaptations in order to facilitate success. At-risk neonates' experience an increased potential for developing	Arvedson & Brodsky, 2002; Browne & Ross, 2011; Hall, 2001

	relational interaction difficulties. It is important to note that parent-infant interaction during feeding establishes a foundation for social communication interaction and the inherent reciprocity of the communication dyad.	
H: Use of compensatory strategies	As part of initial assessment the clinician should be able to recommend compensatory strategies to support successful feeding in the neonate. Strategies to consider may include modifying the positioning of the neonate during breast/bottle feeding, type of bottle/nipple used or external pacing during breast/bottle feeding. These strategies may empower the mother to feel in control of the feeding process and may build her confidence in meeting her infant's nutritional needs.	Arvedson & Brodsky, 2002; Hall, 2001; Swigert, 2010

All five participants contributed to both rounds of the Delphi process resulting in a 100% response rate. The results of rounds one and two are presented separately. The thematic analysis of the first theme of round one was discussed and examples of panel member responses to complement the data were provided in the first section of the results, however, in this section results related to the second and third themes are presented. The closed question responses of rounds one and two are combined and will be presented in table format.

Results of Round one

The second theme addressed the *Content of the NFAS*, Participant 1 stated "…it is a very comprehensive tool covering all necessary areas…". A similar comment was made by Participant 2. However, Participant 5 stated that "….section G [parent-neonate interaction] and H [use of compensatory strategies] are not that relevant to first-time assessment…I view it as part of treatment already….consider removing it from the current instrument". Three of the participants indicated that these two subsections were too subjective and not directly relevant to initial assessment and diagnosis of OPD. These subsections were then omitted from the final instrument. Four participants also suggested revision of some of the items related to feeding and swallowing ability in the content domains in sections C, E and F. Based on some participant's feedback (n=3) there was support for the notion of a comprehensive clinical assessment in the neonatal stage, despite indicating that the instrument was too lengthy.

The recommended *scoring system of the NFAS* (theme three) included allocation of marks if a skill/behaviour was present or absent. The clinician would then calculate a score for each section and a final score for feeding difficulties to conclude the assessment. The higher the score the more likely a neonate could be diagnosed with OPD. Theme three dealt with the *Scoring criteria*. Statements such as "…consider simplifying the scoring system for ease of use…might be confusing in current format" and "You need to score a concept to compare it to a gold standard to be able to validate it" [Participant 1] were made.

Another comment was "…the scoring system will be easier if binary scoring in a checklist format is used in the final version of the instrument….with a good explanation of administration guidelines…" [Participant 4]. One of the South African participants stated "the scoring system is a bit confusing in this format…instructions on how to assess the neonate should be expanded…since some speech therapists might lack experience….and need help…" [Participant 5]. Three participants suggested clearer administration guidelines and using a different approach to score the data. Results of round one led to the refinement of the initial scoring system. Binary choices were included for each item in all sections, with clear administration and scoring guidelines in the revised instrument. The scoring method was refined with assistance from a biostatistician to include a binary (yes/no) outcome for each section and a total score that will enable comparison to a widely accepted gold standard for swallowing assessment, in this case the MBSS.

In summary, all participants agreed on the need for more research to develop a validated assessment instrument. Three of the five participants agreed on the comprehensive nature of the

proposed content for the draft NFAS. Lastly, all the participants recommended refinement of the scoring system.

However, differences in opinion encountered in the feedback from participants in round one were analysed further to highlight how the South African panel members' responses differed from the international participants' contributions. These differences may be due to the disparity of resources between the developing and developed context of the participants, and challenges experienced in the local context that international participants may not be aware of. A difference in opinion was clearly evident between the two groups of panel members about the length of the instrument and item inclusion of which both components related to the comprehensive nature of the NFAS.

Results of Round two

Upon conclusion of round one the NFAS was revised according to recommended changes where the majority opinion (Dawson & Trapp, 2004) motivated the changes. To initiate round two a summary of the first round's recommendations and the revised instrument were sent to the participants.

Objective C: Face and content validity of the final version of the NFAS

The second questionnaire provided quantitative data that could be compared with some of the close-ended questions in round one. Round two offered an opportunity for additional comments by the panel members if they felt that the previous round did not address all their concerns. The comparative results of the two rounds are depicted in Table 5.

Table 5 Quantification of degree of agreement among participants (n=5)

Question topic	Round one		Round two	
	Agree (n=5)	Disagree (n=5)	Agree (n=5)	Disagree (n=5)
The instrument/revised instrument is user friendly	60%	40%	80%	20%
The format and technical editing of the instrument/revised instrument is acceptable	60%	40%	100%	0%
The face validity of the instrument/revised instrument is acceptable	60%	40%	80%	20%
The proposed scoring system of the instrument/revised instrument is acceptable	0%	100%	100%	0%
All the subsections and items in the draft should be included in the final instrument	60%	40%	n/a	n/a
The revised feeding constructs for the identified target population is acceptable	n/a	n/a	100%	0%
The content validity of the revised instrument is acceptable	n/a	n/a	80%	20%

According to Table 5 the majority of panel members' (n=4) opinions regarding some of the concepts probed in round one and again in round two (closed questions) reflected increased agreement on the probed components of the final version of the NFAS. One participant did not agree on the user friendliness, content and face validity in round one. To ensure scientific rigor the Delphi-process holds researchers accountable by providing a true account of the participation responses. As participants responded via email, data could be saved and verified. No qualitative comments were received in round two. According to Table 4, there were a number of disagreements in round one that was resolved in round two, which indicated high agreement among the panel. All members agreed on the format, the scoring system and the feeding constructs addressed in the revised final format of the NFAS.

The final content and checklist format of the NFAS, which resulted from the Delphi-process, consisted of six sections with different items. The NFAS is summarised in Table 6.

Table 6 Overview of the final NFAS

Sections and subsections included in the revised NFAS	Subsections removed from draft NFAS	Initial number of items	Revisions of the NFAS
A: Physiological functioning Subsections: -Heart rate -Respiratory function (According to three age categories)	Colour of neonate's skin	38 items	29 items (arranged according to gestational or corrected age ranges in both subsections). Nine items related to normal skin colour and skin discolouration were removed.
B: State of alertness during feeding	None	7 items	No changes
C: Stress cues during feeding Subsections: -State related stress cues -Motor related stress cues -Autonomic related stress cues (graded as mild, moderate or severe)	None	43 items	Reduced to 35 items, removing eight items related to various stress cues. -State related stress cues: removed four items such as 'discharge smiling', 'eye-floating', 'gaze aversion' and 'glassy-eyed'. -Motor related stress cues: removed one item namely, 'facial grimacing'. -Autonomic related stress cues: two moderate cues (bowel movement & multiple swallows) were removed together with one severe cue, namely 'reflux'.
D: General movement and muscle tone screening Subsections: -At rest -During feeding (According to three age categories)	None	17 items	Reduced to 12 items (arranged according to gestational or corrected age ranges in both subsections). Four items related to a conclusion about general muscle tone were removed and one item related to 'independent head support' that was not developmentally appropriate for the age ranges. Remaining items were reorganized related to observations at rest and during feeding in the various age categories.
E: Oral peripheral examination Subsections: -Oral reactions -Oral structure and function -Observation of cranial nerve function to indicate symptoms of possible dysfunction	Physical symptoms of illness	45 items	Increased to 72 items. A subsection's name was changed to 'Observation of cranial nerve function to indicate symptoms of possible dysfunction' was based on recommendations by the participants. Various symptoms in the subsection of cranial nerve function were separated for scoring generating an increase of 12 items. Two items related to symptoms of physical illness were removed. In the subsection of oral structure and function items in subcategories related to the lips, cheeks, palate, tongue and jaw at rest and during feeding were refined generating an increase of 18 items in this subsection.
F: Clinical feeding and swallowing evaluation Subsections: - NNS – according to two age categories - NS – according to two age categories -Behavioural response to feeding and non-nutritive sucking stimulation -Symptoms of OPD (NNS and NS are evaluated according to the different age categories)	-Saliva management -Feeding methods -Tactile response to NNS & NS -Positioning	90 items	Reduced to 56 items (items in the NNS and NS subsections are arranged according to gestational or corrected age ranges). Rephrasing of some items. Three items were removed in the saliva management subsection. The subsection on NNS was separated into two age categories and further refinement in the two categories generated 6 additional items. The NS subsection was also separated in to the same two age categories increasing items from eight to 32. An integrated subsection was created from two previous subsections, namely 'Avoidance behaviour during NS' and 'Infant's behavioural response to feeding method'. The new subsection was, 'Behavioural response to feeding method & NNS stimulation'. This integration reduced 26 items to 5 remaining items. The subsection of 'Positioning' was incorporated in subsection D. The subsection on 'Pharyngeal dysphagia' was changed to include 'Symptoms of oropharyngeal dysphagia' including two subcategories representing 14 items.

All the changes were made based on majority recommendations of the expert panel. According to Table 6 one subsection in Section A contained nine items relating to the discoloration of

the neonate's skin indicating lack of oxygen in the orofacial area. The majority of participants considered these items too subjective for accurate scoring therefore it was removed. Section B remained unchanged since participants suggested no changes. In Section C, 8 items relating to various stress cues were removed due to possible ambiguity, repetitiveness or vagueness indicated by three participants. Section D was reduced from 17 to 12 items to screen muscle tone and movement in a more concise manner since five of the items were considered redundant by four participants. In the last two sections (E and F) items suggested by all the participants were added to ensure comprehensive observations of oral structure as well as neonatal feeding and swallowing skills. However, the international panel members recommended that subsections (in Sections E and F) relating to physical symptoms of illness (e.g. oral thrush in neonates with HIV/AIDS), saliva management and feeding methods should rather be obtained from the neonate's medical record or during the parent interview and therefore it was removed. In some of the subgroupings in Sections E and F, where feeding skills relate to developmental level, two age categories were linked to assessment items and criteria leading to a reorganization of items. All the participants agreed on the use of these age categories. Age categories may enable serial assessment to build a feeding profile over time whilst the neonate is receiving hospital based care.

The components of comprehensive clinical feeding assessment that emerged were the observation of physiological status, state of alertness, stress cues, postural control and tone related to feeding position, oral-motor structure and function, NNS and NS, behavioural responses to feeding, and symptoms of OPD (Thoyre et al., 2013; Lau & Smith, 2011; Dodrill, Cleghorn, Donovan, & Davies, 2008). These components were all addressed in the revised NFAS. The length of the instrument relates to the local need and aim of a comprehensive assessment tool which should include signs and symptoms reflecting the presence of OPD in neonates.

Discussion

Need for the NFAS

The need for a clinical tool to assess OPD in high-risk neonates was established. In a review of oral feeding assessment instruments for infants younger than six months, the findings of Pados and colleagues (2016) support the identification of this need. They concluded that there is a need for the development and testing of feeding assessment tools for young infants to guide optimal clinical practice. It is also suggested that such assessment tools should allow use for breast and bottle feeding for consistent assessment across feeding methods. Meeting this need may facilitate more appropriate management of OPD in neonates, since intervention will be guided by reliable and comprehensive assessment findings with an accompanying diagnosis. Infants discharged with inadequate investigation into the feeding difficulties or unresolved feeding difficulties, LBW and prematurity are more at risk of developing failure-to-thrive than their term counterparts with appropriate weight for age (Browne & Ross, 2011). Valid and reliable assessment instruments will help clinicians to objectively evaluate feeding (Pados, Park, Esterem, & Awotwi, 2016).

Development, face- and content validity of the NFAS

The Delphi-method was used to develop the final format of the NFAS and to establish face and content validity. This was achieved by convening an expert panel to assist with the further development of a novel clinical feeding assessment instrument. The interaction process was collaborative and yielded constructive comments supporting the validation of the NFAS. The Delphi-process was helpful to consider appropriate feeding constructs for content selection, to develop a reliable scoring system and to enable transparency and replication of methodology. Differences in opinion between the local and international participants emerged and may likely be ascribed to the working context in developing versus developed countries, emphasizing the challenges present in the South African context. The participants' comments supported the rationale of the study regarding the development of a neonatal feeding assessment instrument supported by evidence, but also highlighted

the subjective nature of observation of skills related to neonatal feeding. This calls for more research on objective measurement of skills related to feeding difficulties in neonates.

The South African participants did not see a need to shorten the NFAS significantly since they felt that it ensures holistic and comprehensive clinical assessment that might be lacking in inexperienced clinicians. In contrast, the international participants were of the opinion that the instrument was too lengthy for clinical use in the initial version. This may be due to the international experts being more experienced than some of the South African participants in clinical practice, since both of the international experts had more than 20 years' experience working in the field of paediatric dysphagia. The participant responses assisted the researchers in refining the content and items of the NFAS.

South African participants considered comprehensiveness as important in clinical service delivery in resource constrained settings. Many inexperienced clinicians are conducting their community service year and require guidance. A comprehensive assessment instrument may prompt observations which may be missed when item descriptions are omitted. International participants focused on the subjectivity of some items which revealed that they were more experienced and therefore concerned with the levels of evidence to support the inclusion of sections and items, especially in a context where inexperienced SLTs may be using the NFAS. No difference in opinion regarding the scoring criteria and guidelines was noted. However, one international participant was the only expert who recommended consultation with a biostatistician, demonstrating knowledge of instrument development acquired during her research career.

Due to demographically different work settings marked by developed versus developing contexts impacting on healthcare service delivery, participants did not have the same expectations of a clinical assessment. The local participants were aware of inexperienced SLTs entering the public health system in their community service year and having to diagnose OPD without MBSS equipment. The NFAS was designed to prompt inexperienced SLTs to include appropriate content domains during clinical assessment and supports a comprehensive approach to assessment of neonatal feeding problems such as OPD. Paediatric and adult dysphagia were formally included as a module in undergraduate Speech-Language Pathology curricula in 2004 in South Africa (See Faculty of Humanities Undergraduate Syllabi and Regulations, 2004, University of Pretoria as an example). There is thus only an 11 year history of formal professional training at universities in South Africa. Although dysphagia is now an established component of local Speech-Language Pathology curricula, much research is still required. Dysphagia is a relatively new, yet growing field in the profession in South Africa with active pursuit of research (Blackwell & Littlejohns, 2010; Pike, Pike, Kritzinger, Krüger, & Viviers, 2016; Singh et al., 2015).

Outcome of the Delphi process

The participants had the opportunity to critically evaluate the revised NFAS as indicated by their change in responses in round two, leading to majority consensus (see Table 3). One of the members who did not agree on the user-friendliness of the draft instrument still indicated that the NFAS was too lengthy despite revision. This concern already emerged in round one and was addressed through implementing the recommended changes (see Table 7) and using a checklist format that improved effectiveness. The same participant indicated that the face and content validity were not completely adequate since many observations remained subjective in nature. The researchers attempted to include measurable items where possible to decrease subjectivity however this was not possible for all items. There remains a great need for further research on neonatal feeding skills and objective measurement technologies. The validity of content and items were supported by using current research on developmental skills and feeding abilities of neonates. The aforementioned concerns were addressed as far as possible in the final format of the NFAS. When interpreting results in a Delphi-process, the majority opinion motivated the changes, but if a valid contribution is offered by a single participant or a minority, the researchers may choose to use it (Okoli & Pawlowski, 2004). In the revised NFAS local needs were paramount and the South African participants preferred a comprehensive assessment instrument.

Similar to the NFAS, other researchers in health sciences also found the Delphi-method useful in contributing to the successful development of clinically relevant assessment instruments (Crist, Dobbelsteyn, Brousseau, & Napier-Phillips, 2004; Da Costa, Van den Engelhoek, & Bos, 2008; Schulz et al., 2009; Yousuf, 2007).The NFAS is aimed at clinicians working in NICUs, where they manage large caseloads of very young high-risk populations. An increased prevalence of high-risk neonates exists in developing countries such as South Africa (WHO, 2012). Early identification of OPD while these neonates are still accessible in the hospital is important to allow opportunity to train mothers to manage feeding difficulties before discharge. In addition, OPD appears to be more prevalent than growth problems in preterm neonates and are likely to continue into early childhood, thereby indicating the need for early intervention to address feeding difficulties and minimize caregiver stress (Crist et al., 2004).

The NFAS aims to provide a developmentally supportive approach to assessment as proposed by Thoyre and colleagues (2013). The NFAS is minimally invasive since assessment is mainly through observation of a broad scope of skills before and during feeding to prevent overloading neonatal sensory systems with physical handling. Studies by Philbin and Ross (2011) as well as Browne and Ross (2011) indicated that unnecessary physical handling may disrupt state regulation during this sensitive stage of neurological development. Another characteristic of the NFAS includes the parent/caregiver in family-centred service delivery. Mothers contribute greatly to feeding assessment by providing information about their infant, and their experience and feelings surrounding the feeding challenges. A family-centred developmentally supportive approach relates to current evidence in the field of neonatal dysphagia (Thoyre et al., 2013; Lau & Smith, 2011).

Conclusion

In South Africa the field of paediatric dysphagia was formally introduced to curricula at universities in 2004, but was practiced many years prior to this introduction. Issues such as resource constraints, inadequate infrastructure, new graduates required to manage large caseloads in the public health system, few expert clinicians in practice, and feeding difficulties related to HIV/AIDS are some of the challenges faced in practice (Blackwell & Littlejohns, 2010; Singh et al., 2015). Inexperienced clinicians may benefit from structured guidance provided by the NFAS in a resource restrained context where patient prioritization is key. The inherent limitations of the Delphi-method include judgements of a select panel which may not be representative of the opinions of all clinicians. The time consuming nature of participation which may impact on the thoroughness of the panel members' responses may also be a limitation. The final version of the NFAS reflects relevant areas of neonatal feeding prominently. The item selection clearly indicates the wide array of skills and components forming the foundation of neonatal feeding behaviour and responses that should be included in a comprehensive assessment instrument to be used by SLTs. The final content and checklist format of the NFAS was compiled as the first step in validating the NFAS and will be used in a future study to determine the preliminary psychometric properties of this instrument.

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Chapter 5

This article was accepted for publication in the peer-reviewed journal, the South African Journal of Communication Disorders where it is currently in press. The format of the article is that of the journal and differs from the rest of the thesis.

Preliminary psychometric performance of the Neonatal Feeding Assessment Scale

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OBJECTIVE: The objective was to determine the preliminary psychometric performance of a new clinical feeding scale to diagnose oropharyngeal dysphagia in neonates.
METHODS: Twenty neonates with a median age of 35.0 weeks gestational age were evaluated using the Neonatal Feeding Assessment Scale and modified barium swallow studies. The results were compared.
RESULTS: Nine of the 20 participants presented with oro-pharyngeal dysphagia on the Neonatal Feeding Assessment Scale. Comparison of the scale's results with instrumental modified barium swallow studies indicated all participants with oropharyngeal dysphagia were correctly identified (100% sensitivity). The specificity was 78.6%, indicating that three participants were falsely identified with oropharyngeal dysphagia on the scale. Inter-rater reliability was determined on 50% (n=10) of the sample. Substantial agreement (80%) was obtained between two raters in five of the six sections of the scale and on the diagnostic outcome.
CONCLUSION: The preliminary performance of the scale appears to be promising. A further validation study will take place.

Keywords

Modified barium swallow study, Neonatal Feeding Assessment Scale, oropharyngeal dysphagia, sensitivity, specificity, inter-rater reliability

Introduction

In a developing country such as South Africa there is a need for valid clinical assessment instruments for use by local speech-language therapists (SLTs) in neonatal dysphagia (Viviers, Kritzinger, & Vinck, In press) such a need was also identified by Botha and Schoeman and indirectly implied in the South African practice guidelines for paediatric dysphagia, as no standardised clinical assessment instrument is recommended to use with neonates (Botha & Schoeman, 2011; SASHLA, 2011a). Due to a lack of regulated service delivery and instrumental assessment equipment available for diagnosing dysphagia in the public healthcare sector, comprehensive clinical assessment may even be more important in developing countries such as South Africa than in developed countries. A limited number of SLTs experienced in the administration and interpretation of modified barium swallow studies (MBSS) or fiberoptic endoscopic evaluations of swallowing (FEES) are practicing in public and private healthcare sectors. Since objective assessment measures were encouraged there has been a rise in demand for MBSS in the paediatric population, but inadequate radiology infrastructure remains a concern (Hiorns & Ryan, 2006).

Pados and colleagues found a lack of validated feeding assessment scales for infants younger than six months that are supported by high level evidence in a recent review Pados, Park, Estrem, & Awotwi, 2016). They concluded that the Early Feeding Skills Assessment Instrument [EFS] (Thoyre, Shaker & Pridham, 2005) was one of the instruments that had some supportive psychometric development and testing in the neonatal population. However, no supportive data on the content validity offered by experts in the area of neonatal feeding for the EFS is published. Two additional instruments with the most extensive psychometric testing are the Neonatal Oral Motor Assessment Schema [NOMAS] (Palmer, Crawley, & Blanco, 1993) and the Schedule for Oral Motor Assessment [SOMA] (Reilly, Skuse, & Wolke, 2000) which focus on oral motor skills of the neonate and infant (Pressman, 2010; Rogers & Arvedson, 2005). These two scales do not consider the impact of environmental and internal disruptions on the infant's physiological subsystems and its resulting effects on the feeding process and mother-infant interaction. In comparison, the EFS aimed to assess oral feeding readiness in a more holistic manner. It is thus recommended that a wide range of infant systems and feeding skills should be evaluated in a comprehensive neonatal clinical assessment instrument than was included in the discussed instruments.

Since neonatal dysphagia services are an important component of early intervention, an assessment instrument should incorporate the principles of family-centred developmentally appropriate care, an asset-based approach, team collaboration and evidence based practice (ASHA, 2008; Ensher & Clark, 2009; Gooding, et al., 2011; SASLHA, 2011b; Thoyre, et al., 2005) . As the parent's first and enduring caregiving task after birth is to feed the infant, the primary caregiver should be central to the dysphagia assessment process. The value of parental description of the feeding difficulty and observation of a typical feeding routine between the mother and infant during clinical assessment may hold direct benefits for parental compliance during intervention. In contrast, during a MBSS the parent may not be as central to the assessment procedure.

To respond to the need for a valid neonatal dysphagia assessment instrument for use in resource constrained developing countries, the Neonatal Feeding Assessment Scale (NFAS) was developed and approved, using expert collaboration through the Delphi-method (Viviers, Kritzinger, & Vinck, In press). Panel members agreed on a need for a validated neonatal feeding assessment scale. South African panel members favoured a comprehensive instrument while international members contributed to evidence-based item inclusion and the

use of an objective scoring system (Viviers, Kritzinger, & Vinck, In press). Clinical assessment will never replace the gold standard of MBSS, but may contribute significantly to complex clinical decision-making in neonatal dysphagia. The research question posed for the current study was 'What are the preliminary psychometric properties of the newly developed Neonatal Feeding Assessment Scale?'

Methods

Aims and Objectives

The aim of the study was to determine the preliminary psychometric performance of the NFAS to diagnose OPD. The objectives were to determine the sensitivity, specificity and accuracy of the NFAS in comparison to the MBSS and to verify inter-rater reliability.

Design

A comparative within-subject design (Meline, 2010) was used to investigate the psychometric properties of the NFAS by comparing the NFAS and MBSS results.

Participants

Neonates admitted to a 29 bed neonatal intensive care unit (NICU) at a tertiary academic hospital in the Gauteng province of South Africa were purposively selected. Mothers were verbally informed of the study and through a brochure in English, Setswana or Afrikaans, the most prominent languages spoken in the city where the study was conducted. Written or verbal (in case of illiterate participants) informed consent was obtained from all mothers. Twenty neonates were selected. The participant inclusion criteria were that the neonate should have a high-risk status such as prematurity, low birth weight, exposure to HIV or another risk factor (e.g. craniofacial anomaly), predisposing the neonate to feeding and swallowing difficulties; be an in-patient in the NICU; be medically stable for assessment as determined by the treating physician; be within the age range of >32 weeks gestational age to four months corrected age post term at time of assessment. Neonates younger than 32 weeks gestational age are expected to display feeding and sucking difficulties as a result of immaturity and are typically not fed orally and were not included. Participant characteristics are presented in Table 1.

Table 1 Participant characteristics (n=20)

Neonate characteristics	Mean	Median	Mode	Standard Deviation (SD)
Gestational age at birth (duration of pregnancy)	35.15	35.00	32	3.066
Birth weight	2.17	1.94	3.3	0.845
Corrected age at assessment	36.89	36.5	35	2.850
Number of days in NICU	12.65	6.00	6	11.582

According to Table 1 the participants were born at a mean premature gestational age of 35.15 weeks (SD=3.066). The mean birth weight of the participants was low, 2.17 kg (SD=0.845) and the mean length of stay in the NICU was 6 days. Additionally, the sample consisted of slightly more female participants (60%). Other risk factors contributing to feeding difficulties were HIV exposure in utero or during delivery (30%, n=6), Respiratory distress syndrome (RDS) (55%, n=11) and hyperbillirubinemia (55%, n=11). Prematurity (80%, n=16) and low birth weight (LBW) (85%, n=17) were the most significant known risk factors for OPD (Pados, Park, Estrem, & Awotwi, 2016).

Materials

The newly developed feeding scale (NFAS) and a MBSS data collection form (based on Arvedson & Brodsky, 2002; Hall, 2001; Swigert, 2010) were used. The MBSS form indicated the stages of swallowing (oral, pharyngeal and oesophageal stages), the presence or absence of any form of dysphagia, and penetration or aspiration in the pharyngeal stage. In addition, a parent interview schedule included pre-, peri- and postnatal information, and a description of the feeding problem according to the parents (based on Arvedson & Brodsky, 2002; Hall, 2001; Swigert, 2010). Medical records were used for additional information.

The development and content of the NFAS was discussed in a previous study[1]. The item selection in the sections of the NFAS was based on theoretical constructs related to neonatal and early infant feeding, and the clinical assessment of feeding skills. The instrument relies on physiological observations of the infant during feeding, how infant state is influenced by feeding and how feeding may subsequently disrupt a regulated state in the infant with feeding difficulties and an associated display of stress cues.

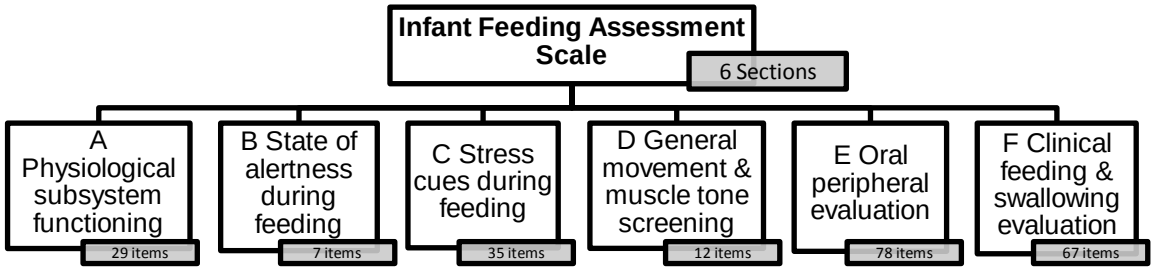

Figure 1 NFAS sections and items

Procedures

Clearance was obtained from the Research Ethics Committee at the university and the Medical Ethics Committee at the tertiary academic hospital where the study was conducted. The mothers' of the participants were interviewed, medical files were reviewed and a clinical feeding assessment using the NFAS, and a MBSS were performed. The MBSS was conducted within seven days of the clinical assessment. The interviews, medical file review and clinical feeding assessments were conducted by the first author, a qualified speech-language therapist and three graduate students in speech-language pathology. All data collectors were trained. Training was provided in a six hour session on the content, administration and scoring of the NFAS. After the training session each trainee was expected to accumulate four practice assessments before data collection was initiated. Inter-rater reliability data were obtained for two of the four data collectors (excluding the first author) on 10 infants (50% of sample). Two senior SLTs working at the hospital conducted the MBSS while blinded to the infants' feeding history and diagnostic outcome of the clinical assessments.

Since feeding is an integrated process, with infant responses in the different sections occurring simultaneously, the order in which sections of the NFAS are completed may vary. A breastfeeding session was observed or the mother was asked to prepare the bottle feed (expressed breast milk or formula) or supplemented breast feeding with tube feeding if the infant was not fully breast fed. The complete data collection procedures for the NFAS are presented in Appendix A. Scoring instructions for each section was indicated on the instrument. A binary Yes/No system were used. The outcome of each section is a Yes/No conclusion regarding the possible presence of OPD. Each section score is transferred to the

last page of the instrument where the overall diagnostic outcome of the assessment is calculated. When a score of three or more Yes-responses is obtained, the assessment outcome indicates that OPD is likely to be present. At least one of the three Yes-responses required for reaching the final diagnosis of OPD must either be obtained in Section E or F (Viviers, Kritzinger, & Vinck, 2016).

During the MBSS a solution of barium sulphate was reconstituted by mixing the powder with the mothers' expressed breast milk or recommended formula. During fluoroscopy the pulsed mode with appropriate collimation was used to limit radiation exposure (Hernanz-Schulman, Goske, Bercha, & Strauss, 2011; Scott, Fujii, Behrman, & Dillon, 2014). A NUK MedicPro First choice^{TM} 120ml infant bottle with a MedicPro^{TM} disposable TPE Teat size 1 was used. Participants were positioned with appropriate supported seating in a Tumble Forms 2 Feeder Seat^{TM}.

Data analysis

Frequency distributions were calculated for the NFAS data. Criterion validity was determined by calculating sensitivity (%) and specificity scores (%) based on the comparative data sets. Sensitivity determines the probability of the presence of OPD, whereas specificity reveals the probability that OPD will truly be absent, when using the NFAS (Dawson & Trapp, 2004). Positive predictive value (PPV) and negative predictive value (NPV) indicate whether the NFAS predicted the true positive and true negative diagnoses correctly (Dawson & Trapp, 2004). The higher the percentage score derived for PPV and NPV calculations, the better and more valid the predictive ability of the instrument (Dawson & Trapp, 2004). Cohen's Kappa with accompanying asymptotic standard error (ASE) was used to investigate the inter-rater reliability coefficient, together with P Bar calculations for the results obtained by two independent raters. The interpretation of the inter-rater reliability calculations (Kappa) according to Dawson and Trapp (2004) and Landis and Koch (1977) are provided in Table 2. A Kappa value of greater than 0.41 was considered a minimal reliability criterion (Dawson & Trapp, 2004). Accuracy of agreement between the NFAS and the MBSS diagnosis of OPD was also investigated.

Table 2 Interpretation guidelines for Kappa values for inter-rater reliability

Kappa values	Interpretation of level of agreement [21]	Kappa values	Interpretation of level of agreement[26]
1.00	Perfect agreement	**>0.75**	Excellent agreement beyond chance
0.93-0.99	Excellent agreement		
0.81-0.92	Very good agreement	**0.40-0.75**	Good agreement beyond chance
0.61-0.80	Good agreement		
0.41-0.60	Fair/substantial agreement	**<0.40**	Poor agreement beyond chance
0.21-0.40	Slight agreement		
0.01-1.20	Poor/chance agreement		
<=0	No agreement		

Results

NFAS results

The NFAS was administered on a sample of 20 participants to determine preliminary psychometric properties. The clinical assessment results were compared to the MBSS results to determine which participants presented with true OPD. In Table 3 the data obtained from the NFAS assessment is provided.

Table 3 NFAS results (n=20)

Section	Number of infants with indicators for OPD	Frequency distribution
A. Functioning of physiological subsystems*	2	10%
B. State of alertness during feeding*		
C. Stress cues during feeding	15	75%
D. Movement and muscle tone screening	4	20%
E. Oral peripheral examination	8	40%
F. Clinical feeding and swallowing evaluation	14	70%
Diagnosis of OPD	**9**	**45%**

*Scoring of Sections A and B are combined on the NFAS.

According to Table 3 nine infants (45%) presented with OPD on the NFAS. The positive identification of OPD could be explained by the participant characteristics -see Table 1- and the previously stated associated risk factors in the sample. As per scoring guidelines, the nine participants obtained a minimum score of three Yes-responses in the five sections, with one of the Yes-responses either in Section E or F of the NFAS. In Section C (Stress cues during feeding) and F (Clinical feeding and swallowing evaluation) the most indicators were observed in those neonates diagnosed with OPD. Some of the neonates were not attached to heart rate and respiratory monitors therefore certain items could not be scored in Section A and B (Physiological status and state of alertness) resulting in low scores in the combined section. As a result of the low scores in in the physiological status and state of alertness sections, the contributions of these sections to diagnose OPD should be investigated further in a larger sample. The NFAS results were then compared to the MBSS results to determine validity.

Criterion validity

Criterion validity determined the extent to which the NFAS agreed with the gold standard (MBSS) measuring the same variable. Measures to determine criterion validity included the predictive ability, sensitivity, specificity and accuracy of the instrument. The comparative results are presented in Table 4.

Table 4 Comparison between the MBSS and NFAS results (n=20)

		Outcome of MBSS (n=20)		**Total Participants (NFAS)**
		OPD present	**OPD absent**	
Outcome of NFAS (n=20)		**True Positive (TP)**	**False Positive (FP)**	
	OPD present	6	3	9
	% NFAS	66.7%	33.3%	100%
	% MBSS	100%	21.4%	
		False Negative (FN)	**True Negative (TN)**	
	OPD absent	0	11	11
	% NFAS	0%	100%	100%
	% MBSS	0%	78.6%	
Total participants (MBSS)	***Count***	6	14	20
	% NFAS	30%	70%	100%
	% MBSS	100%	100%	100%

Sensitivity and specificity

When comparing the MBSS and NFAS outcomes in Table 4, six of the neonates who presented with OPD were correctly identified with the NFAS however, three were incorrectly identified, resulting in a false positive rate of 21.4%. This comparison revealed the NFAS presented with a sensitivity of 100% when identifying OPD in neonates. The specificity of 78.6% reflects the probability of the NFAS to determine that a neonate does not present with dysphagia.

Predictive diagnostic ability of the NFAS

The PPV and NPV were calculated using the data in Table 4. The PPV was 100% (6/6x100) and the NPV was 78.6% (11/14x100). The higher the PPV and NPV (closer to 100%) the better the new assessment scale is doing to diagnose OPD when compared to the gold standard (Parikh, Mathai, Parikh, Chandra Sekhar, & Thomas, 2008). Based on the PPV and NPV scores the NFAS showed adequate predictive ability to determine when OPD would be present or absent. It was concluded that among those participants who had OPD the predictive ability of dysphagia being present was 100% and among those participants who did not have OPD the predictive ability of not having dysphagia was 78.6%.

Diagnostic accuracy of NFAS compared to MBSS

The overall accuracy was calculated using the specificity and sensitivity data. The accuracy of agreement on diagnosis of OPD between the NFAS and MBSS was 85% (11+6/20x100). The closer the accuracy score is to 100% the better agreement there is between the newly developed instrument and the gold standard (Dawson & Trapp, 2004).

The NFAS therefore presented with good preliminary sensitivity (100%) (Dawson & Trapp, 2004). Specificity was also considered to be good (Dawson & Trapp, 2004) at 78.6%. An assessment tool with a high specificity, sensitivity, PPV, NPV and accuracy is considered valuable in clinical practice (Lalkhen & McCluskey, 2008). The NFAS may possibly be a valid diagnostic instrument based on preliminary findings. The participants not diagnosed with OPD on MBSS, presented with oesophageal dysphagia or normal swallowing ability.

Different types of dysphagia exist in neonates, depending on the stage of swallowing that is affected (Pados, et al., 2016). Different types of dysphagia can also co-occur. Apart from the six participants diagnosed with OPD on the NFAS and the MBSS, the MBSS revealed additional results as expected. Based on MBSS results 40% (n=8) of the participants presented with oesophageal dysphagia, 10% (n=2) had OPD co-occurring with oesophageal dysphagia and four participants had normal swallowing. Two of the six neonates diagnosed with OPD on the NFAS presented with this co-occurrence. The prevalence of OPD (45%) found in this sample was higher than in some other studies (DeMauro, Patel, Medoff-Cooper, Posenscheg, & Abbasi, 2011). In 2014, Zehetgruber and colleagues reported a prevalence range of dysphagia in their sample of preterm and LBW infants, ranging from 25-35% (Zehetgruber, et al., 2014). The higher prevalence rate in this study may not be accurate since prevalence cannot be determined on such a small sample as utilised in this study.

Inter-rater reliability

Inter-rater reliability for all the sections and diagnostic outcome of the NFAS between two independent raters were determined using half of the sample (n=10). Cohen's Kappa with accompanying asymptotic standard error (ASE) was used to investigate the inter-rater reliability coefficient, together with P Bar calculations. A Kappa value of greater than 0.410 was considered a minimal reliability criterion and a P Bar value of 0.50 (Dawson & Trapp,

2004). The inter-rater reliability calculations of each section of the instrument are presented in Table 5.

Table 5 Inter-rater reliability of sub-sections and diagnostic outcome of the NFAS (n=10)

Section of NFAS	Kappa	Level of agreement	P Bar	Overall agreement between raters (%)	Asymptotic standard error (ASE)
A & B	1.000	Perfect agreement	0.90	90% Substantial beyond chance	N/A
C	0.286	Slight agreement – minimal acceptable level	0.60	60% Slight agreement	0.194
D	1.000	Perfect agreement	1.00	100% Perfect agreement	N/A
E	0.737	Substantial beyond chance	0.90	90% Substantial beyond chance	0.241
F	0.615	Substantial agreement	0.80	80% Substantial agreement	0.225
Agreement on NFAS outcome	***0.737***	***Substantial beyond chance***	***0.90***	***90% Substantial beyond chance***	***0.241***

The inter-rater reliability for two of the five sections of the instrument demonstrated substantial agreement beyond chance. In the combined section A and B as well as for section D, the assessment criteria were clear (0.90 -1.00 P Bar), therefore rendering the Kappa calculation obsolete for these sections. For Section C the results indicated only slight agreement, which may be due to the variability of infant state during the feeding process. Thus the variability inherent to infant state may have increased the difficulty to evaluate this section objectively. The two raters agreed on the instrument outcome in 90% (n=9) of the cases. The agreement on diagnostic outcome between the two raters was considered substantial beyond chance with an asymptotic standard error of 0.241(Dawson & Trapp, 2004). The preliminary results thus indicate good reliability (Dawson & Trapp, 2004) of the NFAS.

Discussion

The preliminary performance of the NFAS indicated that it is a valid method of assessing neonatal feeding skills, guiding clinicians to diagnose OPD, thereby potentially facilitating early detection and management of OPD. According to DeMauro and colleagues dysphagia is a significant disorder in preterm infants in developing countries and valid assessment instruments can compensate for the lack of population based studies (DeMauro, et al., 2011). The NFAS provides more descriptive information on feeding skills such as detailed information on stress cues and infant state, than the MBSS. Therefore it may also offer more intervention guidelines to inexperienced clinicians.

Criterion validity

The high sensitivity (100%) and specificity (78.6%) of the NFAS provide evidence of the ability of the scale to accurately diagnose the presence of OPD and in turn to also recognize the absence of OPD rendering very few false positives (21.4%). There appears to be limited information on the sensitivity and specificity properties of comparable assessments for oral motor difficulties in neonates and infants, such as the EFS, NOMAS and SOMA (Da Costa, Van Den Engel-Hoek, & Bos, 2008). The diagnostic accuracy (85%) of the NFAS and its good predictive ability (Dawson & Trapp, 2004) (PPV: 100%; NPV: 78.6%) in clinical use, showed that the scale is capable of measuring what it intends to measure.

As expected of a direct instrumental observational procedure, the MBSS gave additional diagnoses. The MBSS diagnosed oesophageal dysphagia and clearly showed the co-occurrence of the two types of dysphagia, OPD and oesophageal dysphagia. Since the focus of speech-language therapy is on assessment and intervention of OPD, preliminary results indicate that the NFAS could serve this purpose. All participants who truly presented with OPD were identified. When relying on clinical assessments only in contexts where MBSS is not available, the three false positive OPD results may not be viewed as disadvantageous. Further research is required to determine whether subsequent assessments on the same neonate using the NFAS may show different results.

Inter-rater reliability

The preliminary testing of the NFAS showed that acceptable inter-rater reliability was present. Due to the substantial agreement beyond chance achieved in the inter-rater reliability results (Kappa: 0.737; P Bar: 0.90) it appears that more than one clinician is likely to obtain the same results when using the NFAS. The pre-assessment training and test administration guidelines may be sufficient to support a clinician to obtain consistent results when administering the scale. The NFAS compares favourably with other widely used, instruments investigating components of feeding skills, such as the NOMAS (Palmer, et al., 1993) and the SOMA (Reilly, et al., 2000) that presented with good inter-rater reliability for clinical use in neonates and infants older than eight months respectively. A 2008 study by Da Costa and Van der Schans determined the inter-rater reliability of the NOMAS ranged from moderate to substantial agreement (Kappa: 0.40-0.65) (Da Costa & Van der Schans, 2008), although Palmer et al. (1993), the developers of the scale, did not test the final scale for reliability. The SOMA presented with a Kappa of <0.75 on a sample of 10 infants, indicating excellent agreement beyond chance (Reilly, Skuse, Mathisen, & Wolke, 1995). The authors of the EFS (Pados, et al., 2016) states that intra- and inter-rater reliability have been found to be stable and acceptable, but no data are provided to support this statement (Da Costa & Van der Schans, 2008).

Scoring criteria

The weighting of the different sections of the NFAS, in contributing to the diagnosis of OPD could not be determined adequately in this study due to the small sample size. It appears that state observation (Section B) may be difficult to score due to the fleeting nature of infant states and fluidity between some state changes during a feeding session. Simultaneous observation of different feeding skills in the infant is required when using the NFAS. While focusing on the oral area to observe aspects such as non-nutritive sucking (NNS) and the neonate's behavioural response to NNS during feeding, there may also be subtle stress cues and state changes taking place, with the result that some of the state changes and stress cues may be missed. In premature and LBW infants, state is influenced by a variety of factors, such as energy expenditure and endurance during feeding (Arvedson & Brodsky, 2002; Thoyre, Park, Pados, & Hubbard, 2013). Nugent and colleagues (2007) concurred that the accuracy of state observation requires that the clinician gains clinical experience and attend continued professional development training opportunities in the observation and interpretation of neonatal and infant behaviour. Since state regulation not only impacts on feeding but on the full spectrum of infant behaviour, it may not directly contribute to the diagnostic process during feeding assessment. Observation of state regulation is, however, recognized in the literature and other studies (Nugent, Keefer, Minear, Johnson, & Blanchard, 2007; Browne & Ross, 2011). Evaluation of state regulation may help the clinician to support the parent to identify infant states and understand that certain activities are more appropriate while the infant is one particular state than another. For

example, feeding is best supported when an infant is in one of the alert states (Stage 4, Quiet alert) without showing distress (Nugent, et al., 2007; Browne & Ross, 2011). Feeding in itself also acts as the initial primary regulator of physiological state since the very young infant uses primitive brainstem-visceral circuits during feeding as the underlying mechanism for state regulation (Browne & Ross, 2011).

Conclusion

In summary, neonatal dysphagia will remain a complex problem that requires multi-disciplinary, multidimensional assessment and treatment. In order to increase effective management of neonatal feeding and swallowing difficulties the standard of clinical assessment should improve in developing countries where services are not well regulated. The use of validated neonatal feeding assessment instruments should take priority to support evidence based practice (Miller, 2009; Pados, et al., 2016).

A comprehensive clinical assessment instrument addressing the overall feeding process in neonates which also provides systematic guidance in clinical decision-making for the diagnosis of OPD is recommended. The NFAS highlights the subtleties of the feeding process, and describe procedures of observation and elicitation that should not be overlooked during clinical assessment. Multidisciplinary team members and newly qualified or inexperienced clinicians should be able to use such an instrument if sufficiently prompted by the systematic procedures for administration outlined in the tool.

The different sections and items in the NFAS may assist to describe the feeding profile of high-risk neonates and consequently enable early and accurate clinical diagnosis of OPD in the absence of available instrumental assessments in resource constrained contexts. The validity of an assessment instrument is its real capacity to measure what it proposes to measure. This preliminary attempt at validation of the NFAS was performed by comparing it to the MBSS. A larger sample will be utilized to determine psychometric properties of the NFAS for clinical use in a follow-up study. In addition the contribution of the different sections of the NFAS to the eventual diagnosis of OPD in a neonate will also be investigated.

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Chapter 6

This article was submitted to the peer-reviewed journal, Journal of Public Health in Africa, where it is currently under review. The format of the article is that of the journal and differs from the rest of the thesis.

Validity and reliability of the Neonatal Feeding Assessment Scale (NFAS)

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Abstract:

A clinical instrument was developed to identify oropharyngeal dysphagia (OPD) in neonates. The main aim of the study was to determine the validity and reliability of the Neonatal Feeding Assessment Scale (NFAS) in comparison to the modified barium swallow study (MBSS) as gold standard. The sensitivity, specificity, accuracy and predictive value of the NFAS were investigated to determine criterion validity. Reliability of the NFAS was determined by inter-rater reliability scores. A within-subject design was implemented. A group of 48 premature neonates with a mean gestational age of 35.5 weeks were sampled in the neonatal intensive care unit. The NFAS consists of six subsections, including physiological stability, infant state, stress cues, screening of muscle tone and control, oral peripheral examination and feeding/swallowing assessment. The NFAS is administered by observing a typical feeding session together with elicitation of oral reflexes and sucking abilities. Administration takes approximately 30-45 minutes. Of those participants identified with OPD on the NFAS, 93% (14/15) received confirmatory diagnosis of OPD on MBSS. High sensitivity (78.6%) and specificity (88.2%) scores were obtained for the NFAS. The positive predictive value was 78.6%. Subsequently the accuracy of the NFAS to identify the

presence of OPD correctly was 85.4% when compared to the MBSS outcomes. Inter-rater reliability on the NFAS was determined using 35% of the sample. The agreement on overall instrument outcome between the two raters was considered substantial beyond chance, with Cohen's Kappa at 0.598, with an asymptotic standard error of 0.211. The NFAS may be of use to clinicians working without access to MBSS equipment and to reach underserved neonates. Inexperienced speech-language pathologists who may benefit from observational prompts to interpret neonatal feeding behaviour may also find the NFAS useful.

Keywords: Inter-rater reliability · modified barium swallow study · Neonatal Feeding Assessment Scale (NFAS) · oropharyngeal dysphagia diagnosis · validity

Introduction

Neonatal dysphagia is a complex condition and is caused by a variety of underlying etiologies.[1,2] The condition is associated with multiple medical problems such as bronchopulmonary dysplasia (BPD), congenital anomalies of the heart and gut, necrotizing enterocolitis, gastro-esophageal reflux disease (GERD), prematurity, low birth weight (LBW) and small-for-gestational age (SGA).[1] Clinicians should accordingly consider the complex interplay between various medical conditions along with associated risk factors and the evolving nature of dysphagia over time, in medically fragile neonates. An increase in the incidence of neonatal dysphagia could be attributed to a variety of factors such as improved survival rates of infants with medically complex conditions, improved identification of feeding and swallowing difficulties, expansion of the medical field of speech-language pathology within the neonatal intensive care unit (NICU), improved diagnostic ability with modified barium swallow studies (MBSS) and increase in skilled speech-language therapists (SLTs) managing feeding difficulties in high-risk neonates.[1-3] In the case of premature neonates, the immature digestive and respiratory systems of the neonate contribute to immature feeding skills, while essential medical management and comorbidities further

contribute to the interruption of feeding development.[1,4] Since it is possible to effectively bypass the oral feeding route in premature neonates by means of enteral and tube feeding, OPD may be a hidden problem and only receive attention once these neonates have difficulty transitioning to oral feeding when medically stable.

In 2015, Heckathorn and colleagues supported the need for the development of a validated non-instrumental assessment tool for feeding and swallowing function in infants.[3] The use of such non-instrumental tools may expedite evaluation and management of OPD in neonates and very young infants, to prevent long term sequelae that continue to negatively impact development.[1,5] Neonates with OPD are at risk of a compromised nutritional status, slow weight gain, regulatory problems, later behavioural difficulties and developmental delays.[6-9] Moreover, longstanding evidence indicates that persistent sucking or feeding difficulties in neonates are also a risk for increased healthcare costs and length of hospital stay.[1,10] When OPD is not managed early it may be difficult to utilize available resources optimally in the presence of constraints. Healthcare funding and physical as well as human resources should be utilized fully during assessment and treatment of neonatal dysphagia to ensure timely, cost-effective services. The best possible management of OPD is required since long term consequences can present if it is not managed timely and effectively. Hence early assessment of and intervention for OPD is advocated even when readiness for oral feeding may be delayed.

Oral dysphagia can be assessed clinically but if there is pharyngeal and/or oesophageal swallowing difficulties, MBSS will be required. The European Society for Swallowing Disorders (2013) confirmed the role of the MBSS as gold standard in the diagnosis of paediatric dysphagia in a position statement because it enables the dynamic viewing of the pathophysiology of the swallowing mechanism which cannot be investigated by clinical assessment alone.[3,11-12] The MBSS allows for accurate diagnosis of OPD and

oesophageal dysphagia (ED) in the neonatal and paediatric population.[12-13] In contrast to clinical assessment, the MBSS enables the detection of penetration and aspiration during feeding which may increase the neonate's risk of respiratory compromise.[13-15]

In cases where there may be limited access to MBSS or where a neonate is not medically stable to undergo instrumental assessment procedures, reliable clinical identification of OPD is required to provide effective and timely intervention. In turn, early identification and intervention may increase oral feeding opportunities, and decrease cost related to long-term medical and rehabilitation services. A valid instrument to address early identification of OPD remains unavailable for the neonatal population.[3] Development of the Neonatal Feeding Assessment Scale (NFAS) began in response to the need for an efficient, objective, and clinically valid means, to reliably identify OPD in high-risk neonates.

In a previous study of the NFAS preliminary psychometric properties indicated that the instrument presents with high sensitivity (100%), specificity (78.6%), accuracy (85%) and acceptable inter-rater reliability in comparison to the MBSS.[16] High psychometric scores may be expected when a small sample of participants is utilized such as in the preliminary study.[17] Research supporting the evaluation of the psychometric properties of clinical instruments is strongly recommended to determine the clinical validity and reliability for use in practice.[3] The need for further validation of the NFAS on a larger sample than used in the preliminary study was required. Consequently, the research question for the current study was: 'Does the NFAS maintain valid and reliable psychometric properties when a larger sample is utilized?'. The aim of the study was to determine the validity and reliability of the NFAS in comparison to the MBSS utilising a sample of 48 premature neonates.

Methods

Objectives

The objectives were a) to describe the diagnostic outcomes of the participants on the MBSS and the NFAS; b) to determine the specificity, sensitivity, accuracy and predictive values of the NFAS to establish criterion validity; and, c) to determine inter-rater reliability of the NFAS.

Design

A comparative within-subject design[18] was used to determine the psychometric properties of the NFAS on a group of high-risk neonates. The NFAS and MBSS results were then compared specifically regarding outcome for accurate identification of the presence of OPD.

Participants

Forty eight neonates admitted to a 29 bed NICU at a tertiary academic hospital in Gauteng, South Africa were purposely sampled. The inclusion criteria were: reported feeding difficulties, age range from 32 weeks gestational age (GA) to full term, medically stable for clinical and MBSS assessment as declared by the treating physician and present with at least one risk factor/medical condition associated with neonatal dysphagia. Verbal or written informed consent was obtained from all the mothers. The information brochure and informed consent were available in three official languages of South Africa (Afrikaans, English and Setswana).

Table 1 Participant description (n=48)

Participant characteristics	Mean	Median	Mode	Standard Deviation (SD)
Gestational age at birth (weeks)	35.58	35.0	34	3.06
Birth weight (grams)	2118	1960	1400	718.5
Corrected age at assessment (weeks)	26.96	36.85	35.00	2.92
Number of days in NICU	9.52	7.00	4	8.71

Table 1 indicated that the majority of participants presented with a >10 day duration of stay in the NICU (91.7%, n=44), LBW (85.4%, n=41) and late preterm birth (64.6%, n=31; mean GA of 35.58 weeks). Additional data from the case history and review of medical records highlighted numerous risk factors associated with neonatal feeding difficulties and dysphagia.[1,14] These risks were: hyperbillirubinemia (62.5%, n=30), delayed introduction of oral feeding (60.4%, n=29), respiratory distress syndrome (RDS) (47.9%, n=23) and exposure to HIV in utero or during birth (10.4%, n=5).

Material

A parent interview and case history form included pre-, peri- and postnatal information, and a description of the feeding problem according to the parents. Medical records were used for additional information. The NFAS and a MBSS checklist was developed for use in this study.[19] The philosophy underlying the NFAS is that neonatal feeding behaviour is complex and should be viewed in a holistic, integrated manner, acknowledging typical development in a broad range of developmental domains as the foundation for the evaluation of a neonate's feeding performance.[20-24] The NFAS does not exclusively focus on the domain of oral-motor skills and feeding method, but on the whole process of feeding in order to identify the presence or absence of OPD.

NFAS structure, rationale for inclusion of sections and scoring

The NFAS consists of six sections to support the clinical assessment of neonatal feeding skills to identify the presence or absence of OPD.[19] The six sections of the NFAS were scored using a binary system.[19] The different items are clear descriptions of observable behaviours, thereby prompting the SLT about behaviours to evaluate – see Appendix A for examples of items included in the NFAS. The scoring instructions were provided in each section to reach a composite score when the NFAS was completed.[19] The composite score

indicated if OPD was present or absent.[19] Clear administration guidelines are provided for all items.[19]

In Section A the assessment of the neonate's physiologic functioning, specifically respiratory and cardiac status, were included since respiratory problems are one of the most common causes of paediatric dysphagia.[10,14,25-28] Cardiac anomalies such as tachycardia or bradycardia may reveal signs of dysphagia in neonates before other behavioural indicators are present.[14,26] Section B focuses on the neonate's state as non-optimal alertness may negatively impact on feeding performance, thus demonstrating the synergistic influence of developmental skills on various activities.[20,26,30-33] A neonate's state is also influenced by the stress the neonate is experiencing while processing incoming sensory information during feeding. The synergistic interaction between the neonate's state regulation, motor system, and autonomic nervous system is assessed in Section C (Stress cues).

Motor performance (Section D) is screened to determine if inadequate muscle tone and/or motor control contribute to OPD. This domain is screened by SLTs to determine if an occupational or physical therapy referral may be beneficial for further assessment of motor performance.[26,30,34-35] Section E investigates the neonate's oral anatomy and primitive reflexes as well as the underlying cranial nerve function, all of which directly support feeding performance. Assessing these components enables the clinician to determine the impact of structural anomalies, functional problems and possible neurological compromise on the neonate's feeding skills.[26-27,30,36-37] The final section (Section F) helps the clinician to identify signs and reported symptoms of OPD. The clinician makes inferences based on these signs and symptoms representing oral and possible pharyngeal stage difficulties. Non-nutritive sucking (NNS) together with nutritive sucking (NS) is evaluated based on the neonate's strength, endurance, burst cycles and suck-swallow ratio. In addition the neonate's behavioural (i.e. turning the head away) and physiologic (i.e. becoming fatiqued) response to

NNS and NS are also documented.[26,30,37-42] Scoring guidelines allow the clinician to calculate a final composite score which indicates the likelihood of OPD being present or absent.

MBSS material and apparatus

The MBSS checklist developed for this study allowed the raters to indicate which stage of swallowing -oral, pharyngeal, and/or oesophageal- was affected based on the presence or absence of signs of dysphagia.[26,30,37] The rater also indicated whether penetration or aspiration was observed in the pharyngeal stage. In this study dysphagia was defined broader than only the presence of penetration or aspiration. A recent more comprehensive definition of dysphagia by Dodrill and Gosa[43] was adopted for diagnosis of OPD in this study. The aforementioned authors defined dysphagia as "any disruption to the swallow sequence that result in a compromise of the safety, efficiency, or adequacy of nutritional intake" (p.24).[43] The raters evaluated the MBSS for the presence of signs of dysphagia according to provided criteria. In the oral stage the following signs were indicative of oral dysphagia: excessive anterior milk loss, disorganized lingual stripping, weak sucking and incoordination of the suck-swallow-breathe (SSB) sequence.[26,20,37,40,42] During the pharyngeal stage the raters considered the presence of delayed elicitation of the pharyngeal swallow response, inadequate epiglottic inversion, laryngeal penetration, tracheal aspiration, cough in response to penetration/aspiration, resultant inadequate airway protection related to incoordinated suck-swallow-breathe (SSB) sequence, inadequate vocal fold adduction, pooling in the valleculae or/and pyriform sinuses, as well as nasopharyngeal reflux as signs of pharyngeal dysphagia.[23,26,30,37,40,42-43] In the esophageal stage the presence of GERD indicated ED.[1] The MBSS was performed using a fluoroscope (SYSCO 19" version Multi DiagnostEleva FD screening machine from Philips, Netherlands) with DVD recording capabilities.

Procedures

Before any research was conducted at the tertiary hospital, clearance was obtained from the Research Ethics Committees in the Faculties of Humanities and Medicine at the university and the tertiary academic hospital. Informed consent was given by all the mothers. Then an interview with the mother was completed, followed by a breast/bottle feeding assessment with the NFAS, and lastly a MBSS. During the MBSS procedure, a solution of barium sulphate was reconstituted by mixing the powder (E-Z-HDTM) with the 50 ml of the mothers' expressed breast milk or recommended infant formula. The participants were fed by one of the blind raters. Fluoroscopy ran during the initial five to 10 serial swallows and when dysfunction was observed. During fluoroscopy the continuous mode with appropriate collimation was used to limit radiation exposure but still obtain the clearest view of the bolus procession.[44-45] A frame capture rate of 30 frames per second was used.[44-45] The maximum duration of radiation exposure was 3 minutes.[44] A NUK MedicPro First choice^{TM} 120ml infant bottle with a MedicPro^{TM} disposable TPE Teat size 1 was used. Participants were positioned at a 45 degree upright angle with appropriate supported seating in a Tumble Forms 2 Feeder Seat^{TM} (Jackson, MI). The MBSS was viewed in the lateral projection. The neonate's feeding and swallowing abilities were assessed with MBSS within seven days (mean=2.25) of the clinical assessment. Recorded studies were viewed and interpreted by two senior hospital speech-language pathologists blinded to the clinical outcome of the NFAS. The first view was in real time. Then it was followed by slow motion and frame-by-frame analysis directly after the MBSS was concluded.

Data analysis

The NFAS results were analysed first where after comparison to diagnostic outcome on the MBSS were made by the main researcher. The inter-rater reliability on the NFAS was determined using Cohen's Kappa coefficients and P Bar calculations expressed as

percentages.[17] Statistically Kappa determines agreement beyond chance, whereas P Bar calculations could be seen as more significant since it ascribes an equal chance of the outcome of agreement or disagreement between raters.[17] The higher the percentage value (closer to 100%) reflected by the P Bar calculation the better the outcome of agreement.[17] A Kappa value of greater than 0.41 was considered a minimal reliability criterion and a P Bar value of 0.50.[17,46]

Criterion validity of the NFAS outcome in comparison to the diagnosis obtained on MBSS was determined by calculating sensitivity, specificity, positive and negative predictive value indicators and accuracy scores.[17] The higher the percentage score derived for sensitivity, specificity, accuracy and related indicators, the better and more valid the outcome of a newly developed instrument is considered to be.[17]

Results

NFAS results

OPD was identified in fifteen participants (31.3%) and 33 participants (68.7%) did not meet the criteria to be identified with OPD on the NFAS (Table 2). Signs and reported symptoms of oral and possible pharyngeal dysphagia could be documented on the NFAS, but pharyngeal and esophageal stage difficulties could not be confirmed without instrumental assessment.

MBSS results

The MBSS results and the NFAS results are presented together in Table 2 to enable comparison between the results.

Table 2 Comparative assessment results (n=48)

Assessment instruments	OPD present	OPD absent
1. NFAS	31.3% (n=15)	68.7% (n=33)
2. MBSS	29.2% (n=14)	70.8% (n=34)
Total agreement between assessment instruments	93.3%	97.1%

In the MBSS sample, 14 of the neonates presented with OPD (29.2%) and 25 presented with ED. Nine of the participants presented with no dysphagia. Co-occurrence of OPD and ED was present in 28.5% (n=4) of the participants. The total agreement between the NFAS and MBSS on accurate identification of OPD was 93.3%.

Comparative results of the NFAS and the MBSS

The clinical assessment results obtained on the NFAS were compared to the MBSS results to determine which participants (n=48) truly presented with OPD (29.2%) based on MBSS confirmation – see Table 2.

Validity

Criterion validity was determined by statistical comparison of the NFAS to the gold standard (MBSS). This was done since these assessments measured the same variable under investigation, i.e. the ability to identify the presence or absence of OPD. Table 3 provides the data related to the criterion validity of the NFAS.

Table 3 Comparison between the gold standard (MBSS) and the NFAS (n=48)

		Outcome of MBSS (n=48) OPD present	OPD absent	Total neonates in which OPD is present/ absent on NFAS
Outcome of NFAS (n=48)		**True Positive (TP)**	False Positive (FP)	
	OPD present	11	4	15
	% NFAS	73.3%	26.7%	100%
	% MBSS	**78.6%***	11.8%	31.3%
		False Negative (FN)	**True Negative (TN)**	
	OPD absent	3	30	33
	% NFAS	9.1%	90.9%	100%
	% MBSS	21.4%	**88.2%***	68.8%
Total neonates in which OPD is present/absent on MBSS	***Count***	14	34	48
	% NFAS	29.2%	70.8%	100%
	% MBSS	100%	100%	100%

*Sensitivity and specificity are indicated in bold.

As evident from Table 3, a sensitivity score of 78.6% was obtained with specificity determined to be 88.2% for the NFAS. The data demonstrated that one false positive (11.8%) was rendered by the NFAS, which could possibly be ascribed to the set inclusion criteria. The predictive ability of the instrument incidentally achieved exact agreement with the sensitivity

and specificity. The positive predictive value was 78.6% and the negative predictive value was 88.2%. The subsequent accuracy of the NFAS was 85.4% when compared to the MBSS outcome.

In those participants where OPD was identified on the NFAS (true positive) the probability of OPD being correctly identified was 78.6% and among those who had a negative outcome (true negative) the probability of not presenting with OPD was 88.2%. The NFAS therefore presents with high sensitivity, specificity, good predictive ability and good accuracy for identification of OPD during clinical assessment.

Reliability

Inter-rater reliability was determined for each section of the NFAS and for diagnosis for 35.0% of the sample, utilizing two raters. The results of each section and overall agreement on diagnostic outcome together with the asymptotic standard error (ASE) are depicted in Table 4.

Table 4 Inter-rater reliability for each section and overall diagnostic outcome of the NFAS (n=17)

NFAS section	Kappa	Level of agreement	P Bar	Overall agreement between raters (%)	ASE
A & B A Physiological subsystem functioning B State of alertness during feeding	0.062	Poor/chance agreement	0.764	76.4% agreement	0.044
C Stress cues during feeding	0.212	Slight agreement	0.176	17.6% agreement	0.141
D General movement & muscle tone screening	1.00	Perfect agreement	1.00	100% agreement	0.000
E Oral peripheral evaluation	0.628	Good agreement/Good agreement beyond chance	0.650	65% agreement	0.193
F Clinical feeding & swallowing evaluation	0.485	Fair agreement/Good agreement beyond chance	0.529	52.9% agreement	0.222
Total (Diagnostic outcome of NFAS)	***0.598***	***Substantial agreement***	***0.586***	***58.6% agreement***	***0.211***

According to Table 4 results of three of the five sections on the NFAS reached a minimally acceptable level of agreement between two independent raters. However, four of the five sections had an acceptable P Bar level of agreement. Substantial agreement beyond chance was achieved between the two raters on the identification of OPD with the NFAS resulting in an acceptable ASE of 0.211.[17]

Discussion

The purpose of the current study was to investigate the validity and reliability of the NFAS to determine if this instrument may be useful for the identification of OPD in high-risk neonates. The early identification of OPD in high-risk neonates leading to timely intervention, may decrease the economic and social burden in lower and middle income countries such as South Africa to support the overwhelmed public health care system.[54-55] Due to the possible life threatening nature of OPD in neonates, a valid clinical assessment instrument should be available to SLTs for use in the NICU.[10]

Validity and reliability of the NFAS in comparison to MBSS

The NFAS showed to be sensitive, specific, accurate and reliable to identify signs of OPD in the target population of this study. The diagnostic agreement between the NFAS and MBSS was very good[17] (85.4%), indicating that the presence of OPD can be identified with the NFAS. The accuracy of a screening or assessment instrument is better if the score is higher, thus a good instrument should be both high in sensitivity and specificity[17,47-49], as was demonstrated in the results obtained with the NFAS.

In the combined Sections A and B of the NFAS the Kappa value of 0.062 revealed that the two raters was not able to judge the physiological assessment criteria adequately, since some of the neonates were not attached to cardiac or respiratory monitors. Therefore,

the raters were unable to obtain monitor readings for some specific items in these sections at the time of assessment.

For Section C the results indicated only slight inter-rater agreement[17], which may be explained by the variability of neonatal state during feeding. The inherent variability of state may likely have negatively affected inter-rater reliability. In Section D perfect agreement (100%) was reached indicating that the screening criteria could be considered clear and objective.[17] When observing movement and posture, the whole body of the neonate can be evaluated. Movement and posture does not change as quickly as stress cues, which may involve only a fleetingly visible facial expression or autonomic response such as sighing. Neonatal behaviour is complex and some observed states and behaviours are more short-lived than others. Increased clinical experience in observation of complex behaviour, such as feeding, may improve the SLT's accuracy of observations. Increased understanding of neonatal states of alertness and stress cues can be achieved by training and may resolve scoring differences noted in Section A and B.

Section E and Section F both demonstrated good agreement beyond chance.[17] Of the five sections on the NFAS four of these sections had an acceptable P Bar level of agreement between raters.[17]

In this study, as in many research studies oral stage difficulties and pharyngeal stage difficulties were combined to indicate the presence of OPD.[50-51] Co-occurrence of OPD and ED is common in premature, high-risk neonates due to the immature respiratory system, uncoordinated SSB sequence, and the high prevalence of gastro-oesophageal reflux all of which impact the different stages of swallowing.[52]

An unexpected result was that none of the participants demonstrated penetration or aspiration during the MBSS. This surprising finding could not be explained in light of other studies' findings where different prevalence rates of penetration and/or aspiration in preterm

infants were reported. A wide range of penetration/aspiration prevalence rates are reported in various studies, ranging from 17.1% - 52.2%.[53-56] The absence of penetration/aspiration in this sample does not rule out the presence of a continued risk of aspiration in future since the MBSS is a limited view of feeding performance at one point in time. Resilience of the airway's protective mechanism may already be evident in these high-risk neonates. Furthermore, the MBSS procedure is shorter than a typical feeding session therefore the impact of fatigue on SSB during the instrumental assessment could be limited.

A prevalence range of 25-35% for OPD in preterm and LBW neonates has been reported in some studies.[50,57] The prevalence of OPD of 29.2% in this study concurs with previous research on this population. Premature neonates experience high rates of cerebral abnormalities and physiologic immaturity resulting in neurobehavioural dysfunction that may be expressed as difficulties with oral feeding.[1,58]

The NFAS may help SLTs to focus on the act and process of feeding to support valid and reliable identification of the presence of OPD during clinical assessment. The NFAS reduces the need for radiation exposure and is less invasive than the MBSS. The MBSS offers an observation of a discrete moment in time of the neonate's swallowing ability. Whereas the NFAS can be used more than once a day or in short succession to obtain a representative feeding profile of the neonate's feeding and swallowing abilities. The NFAS can be used when access to MBSS equipment is unavailable or while awaiting MBSS at another facility while the neonate is not medically stable to be transported.

Clinical use of the NFAS

The NFAS could be considered valid and reliable for clinical use in identifying the presence of OPD in high-risk late term neonates (mean GA=35.58 weeks) with risk factors such as prematurity, HIV exposure, RDS, LBW and increased length of NICU stay. In a

South African study by Pike et al., intrauterine growth restriction associated with SGA and an extended stay in the NICU was associated with OPD and ED in the same sample of participants.[59] Neonates with SGA were also at higher risk for presenting with RDS which is a known risk factor for dysphagia.[59] Jadcherla also noted that growth failure and respiratory illness are associated with neonatal dysphagia with difficulties specifically in the oral-pharyngeal stage of swallowing.[1] The results of the current study also found that physiologic immaturity is a contributing factor to neonatal dysphagia.

The NFAS may help SLTs to focus on the act and process of feeding to support valid and reliable identification of the presence of OPD during clinical assessment. The NFAS is less invasive than the MBSS and does not result in radiation exposure. The MBSS offers an observation of a discrete moment in time of the neonate's swallowing ability. Whereas the NFAS may be used more than once a day or in short succession to obtain a representative feeding profile of the neonate's feeding and swallowing abilities. One of the main advantages of the NFAS is that it can be used in developing countries where less or no access to MBSS is available or while awaiting MBSS at another facility while the neonate is not medically stable to be transported. Undergraduate and graduate students and inexperienced clinicians may be trained to identify OPD early, since the NFAS provides a valid and reliable means to assess neonatal OPD.

A notable feature of the NFAS is that assessment is guided by developmental supportive guidelines established for neonatal practice.[10] The observations made with the NFAS may be used to train parents to read their neonate's behavioural and stress signals during feeding (Section C) to facilitate optimal state organization for more successful participation in oral feeding and enhanced attachment. The neonate's strengths during the feeding process should be recognized and clearly communicated to the parents to compensate for activity-participation limitations such as a lack of endurance or disorganized sucking.[10,60]

The mother's interactional strengths should be highlighted to increase parental confidence during feeding to facilitate physiological stability for oral feeding readiness in the neonate. Involving the parents in their neonate's daily routines in the NICU may benefit attachment and reduce feelings of anxiety and helplessness in the midst of a stressful hospital experience.[29]

Conclusion

The early assessment and management of OPD in high-risk neonates is a priority since successful feeding with adequate weight gain is a discharge requirement from the NICU.[1] Although the NFAS cannot detect the presence of penetration and aspiration or show the possible etiology underlying physiological or anatomical impairment present during the oral and/or pharyngeal stages of swallowing, it may offer valid early identification together with descriptive information that can support intervention planning in resource constrained settings. The NFAS enables SLTs to categorize the different signs of OPD in five categories, namely those related to physiologic instability, stress, state, level of alertness and structural and functional limitations impacting on feeding. The NFAS is likely to provide a more in-depth description of the neonate's feeding abilities than can be achieved with instrumental assessment alone. Despite the subjective nature of the NFAS, it offers a description of the signs of OPD and oral feeding competencies displayed by the neonate. Further independent research of other psychometric characteristics of the NFAS should be explored to determine test-retest reliability and responsiveness related to effect-size. This type of clinical instrument holds potential for providing a means for the early identification and treatment of OPD in settings without access to instrumental assessment, and may positively impact on service delivery to underserved high-risk neonates with OPD.

Note: The NFAS is available on request from the corresponding author.

The authors declare that there is no conflict of interest.

Appendix A Examples of items from the NFAS

Example from Section A – Functioning of physiological subsystems

A.2c Signs of abnormal respiratory patterns during feeding		
A.2.4.1 Laboured/noisy breathing	YES	NO
A.2.4.2 Obligatory mouth breather	YES	NO
A.2.4.3 Non-obligatory mouth breather	YES	NO
A.2.4.4 Stridor	YES	NO
A.2.4.5 Rib cage flaring	YES	NO
A.2.4.6 Sternum depression/retraction	YES	NO
A.2.4.7 Irregular/shallow breathing	YES	NO
A.2.4.8 Intercostal retractions (related to Respiratory Distress Syndrome)	YES	NO

Example from Section C – Stress cues during feeding

Instructions: Observe the infant during feeding and note down the stress cues the infant displays. Circle either YES or NO for all items in Section C.		
State related stress cues		
C.1.1 Staring	YES	NO
C.1.2 Panicked, worried or dull look	YES	NO
C.1.3 Silent/weak cry	YES	NO
C.1.4 Dozing	YES	NO
C.1.5 Startle	YES	NO

Example from Section D – General movement & muscle tone screening

32 – 39 weeks AT REST		
D.1.1 Normal resting posture (full flexion of all limbs not yet present, relatively adequate muscle tone/flexion in lower limbs; partial flexion in upper limbs)	YES	NO
D.1.2 Extremely floppy/extended resting posture (all limbs)	YES	NO
D.1.3 Extremely stiff resting posture (arched head & neck/arched back)	YES	NO
32 – 39 weeks DURING FEEDING		
D.1.4 Normal resting posture (full flexion of all limbs not yet present, relatively adequate muscle tone/flexion in lower limbs; partial flexion in upper limbs)	YES	NO
D.1.5 Extremely floppy/extended resting posture (all limbs / froggy position)	YES	NO
D.1.6 Extremely stiff resting posture (arched head & neck/arched back)	YES	NO

Example from Section F – Clinical feeding & swallowing evaluation

Instructions: Only complete the sections relevant to the infant's current (adjusted) age for section F.1.1 – F.1.4.		
F.1.1 – F.1.2 Non-nutritive sucking (NNS) skills		
F.1.1 NNS characteristics of the preterm infant (32 – 39 weeks)		
Instructions: Use a pacifier/your little finger to stimulate a suckling response. For item F.1.1.1 the approximate number of suckles before a pause occurs, should be counted.		
F.1.1.1 Burst cycles of approximately < 10 sucks before pausing	YES(0)	NO (1)
F.1.1.2 Adequate endurance throughout the feeding session	YES(0)	NO (1)
F.1.1.3 Adequate lip closure around finger/pacifier	YES(0)	NO (1)
F.1.1.4 Attempted tongue cupping/grooving against finger/pacifier	YES(0)	NO (1)
F.1.1.5 Anterior-posterior tongue movement present during suckling	YES(0)	NO (1)
F.1.1.6 Adequate sucking strength	YES(0)	NO (1)
F.1.1.7 Coordinated suck-swallow-breathe rhythm	YES(0)	NO (1)
F.1.1.8 Normal breathing pattern with no catch-up breathing	YES(0)	NO (1)
SCORE OBTAINED SECTION F.1.1.: If a score of 2 or more is obtained, indicate YES for the likelihood of dysphagia being present.		
OUTCOME SECTION F.1.1: Dysphagia likely to be present	YES	NO

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Chapter 7

General conclusion, implications and future perspectives

Aim of the chapter: To discuss the implications of the three studies for assessment of neonatal dysphagia and to critically reflect on the limitations, challenges and strengths of the studies and make recommendations for future research and clinical practice.

7.1. Introduction

The purpose of this doctoral research project was to develop a valid neonatal feeding assessment scale (NFAS) to identify OPD. This was achieved through three studies: a) developing the content, structure and scoring of the NFAS; b) determining the preliminary psychometric properties of the NFAS; and finally, c) determining the validity and reliability of the NFAS. The implications of each study will be linked to current literature to reflect the consequences of this research and to describe the contribution of the research to the field of neonatal dysphagia in South Africa and possibly in a broader context.

7.2. Study 1: Development of a clinical feeding assessment scale for high-risk neonates in South Africa – implications for theory and practice

A need existed for a validated clinical feeding assessment instrument in the field of neonatal dysphagia. This need was evident in a survey among SLTs in South Africa (Botha & Schoeman, 2011) and also identified by different authors in the field of neonatal and paediatric dysphagia locally and abroad in the last six years (Dodrill & Gosa, 2015; Heckathorn et al., 2015; Lau & Smith, 2011; Pados et al., 2016; Pascoe, Norman & Rogers, 2013; Vermeulen, 2015).

Although the development of an assessment instrument and the validation thereof is time consuming and expensive, local SLTs and researchers are becoming more aware of the need for developing assessment instruments validated in the South African context (Pascoe et al., 2013). Locally developed instruments afford customization to the needs of vulnerable patient populations like high-risk neonates in a developing context, where the majority of patients are seen within the public healthcare system.

The cost of developing new clinical instruments to improve early identification and diagnosis of disorders may be prohibitive in view of economic constraints in research funding and healthcare sectors in South Africa. However, the Delphi method is feasible to use in its online format, as this does not incur a high cost, and therefore could be recommended for instrument development in South Africa. Currently and in the past the tendency in South Africa was to rather adapt and translate assessment instruments that are already available (Pascoe et al., 2013). It appears that the use of the Delphi method in medical SLT has not yet been established locally. However, it has been used successfully in numerous local educational, language and audiology research studies (Pascoe et al., 2013).

The successful development of the NFAS may encourage the use of the Delphi method for developing other contextually relevant clinical assessment instruments for use in future. Documenting the steps taken to develop the NFAS may also contribute to the development agenda of SLTs in South Africa as recommended by Pascoe et al. (2013). Publication of the current study may also enable replication of the Delphi method and procedures to allow other researchers in South Africa to develop evidence-based assessment instruments using expert collaboration.

7.3. Study 2: Preliminary psychometric performance of the Neonatal Feeding Assessment Scale – implications for theory and practice

Study 2 was a preliminary pilot study, successfully completed, with promising results of the performance of the NFAS to identify OPD (Viviers, Kritzinger, Vinck & Graham, In press). Despite the challenging goal to establish criterion validity of the NFAS against the MBSS as gold standard, the preliminary performance indicated adequate results to proceed to determine performance on a larger sample. The study demonstrated that the NFAS should be tested further in its current format. The promising results supported the relevance of conducting pilot studies to motivate further research in the field of instrument development. A pilot study is strongly recommended to determine if a newly developed instrument is viable and psychometrically sound enough to be investigated on a larger sample of participants, than included in a pilot study (Hulley et al., 2013). A pilot study also helps the researcher to determine cost predictors to determine economic feasibility of the instrument development process and how the instrument may contribute to

decreasing the economic healthcare burden of the population for which it is developed in future.

The value of this study for research in future may be that the methodology for pilot testing a newly developed instrument may be used in other research studies that could develop new instruments for use in various areas of SLT practice in the medical context in South Africa. Another positive outcome was that the psychometric data of the preliminary study indicated that the NFAS holds promise to be investigated further for use in the early identification of OPD in the NICU setting in public hospitals in South Africa.

7.4. Study 3: Validity and reliability of the Neonatal Feeding Assessment Scale – implications for theory and practice

Approved methods of instrument development (Cresswell, 2014; Creswell & Plano Clark, 2011; Dawson & Trapp, 2004; Leedy & Ormrod, 2014) were followed in developing the NFAS. The STARD checklist (TDR Diagnostic Expert Panel, 2010) requires researchers to review whether all components of test performance and the investigation thereof are reported (Bossuyt et al., 2003b). The use of this checklist enabled the researcher to comprehensively report on the outcomes regarding the diagnostic validity, reliability and accuracy of the NFAS.

The NFAS was shown to be sensitive (78.6%), specific (88.2%), reliable (Kappa 0.598; P Bar 0.586) and accurate (85.4%) to identify OPD in the target population (Viviers, Kritzinger, Vinck, & Graham, Submitted). The PPV was 78.6% and the NPV was 88.2% – both of which are above the suggested acceptable level of 60% for clinical assessment instruments (Dawson & Trapp, 2004). Psychometric data of other clinical feeding assessment instruments such as the NOMAS (Palmer et al., 1993), SOMA (Skuse et al., 1995; Reilly et al., 2000) and EFS (Thoyre et al., 2005) differs across these instruments. The final format of the NOMAS was not tested for reliability (Da Costa et al., 2008) and was not compared to MBSS outcomes for initial sensitivity and specificity results (Howe et al., 2008). Hence no direct comparison could be made with the psychometric data of the NFAS. The SOMA outcomes in comparison to MBSS results was studied and indicated a sensitivity of 87.5%, a specificity of 66.6% and 95.4% (PPV) with 40.0% (NPV) (Ko et al., 2011). In a review of the psychometric properties of various standardized diagnostic tools for assessing

oral readiness for feeding in infants by Da Costa et al. (2008) it was stated that the authors of the EFS (Thoyre et al., 2005) reported that content, intra- and inter-rater reliability was “stable and acceptable” without providing the necessary supportive data in the publication.

The psychometric data of the NFAS could therefore not be adequately compared to other infant feeding assessment instruments. Despite comparison not being available, the findings of the NFAS could be interpreted further to judge clinical usefulness and validity. The high NPV of 88.2% indicated that the NFAS yielded few false negatives (21.4%), signifying that there is a strong probability that a neonate with a negative result will not have OPD (Viviers et al., Submitted). A false negative result in an assessment may, however, lead to adverse health consequences (Norman & Streiner, 2008). The high PPV, rendering one false positive outcome (11.8%), increases the chances of achieving accurate identification of a disorder (Portney & Watkins, 2009). Early identification may lead to timely access to intervention to prevent the sequelae of OPD. Consistent inter-rater reliability results were achieved among the two raters with substantial agreement beyond chance. The NFAS can be reliably used in clinical practice to identify preterm neonates with OPD in the NICU setting in developing countries. Due to the high incidence of prematurity in South Africa, the NFAS can help SLTs in public and private hospitals in South Africa to advocate for early identification and establishment of developmentally supportive feeding programmes in NICUs.

The reliability and validity results of the NFAS met the STARD requirements for newly developed assessment instruments (TDR Diagnostic Expert Panel, 2010). The identification and diagnosis of a condition when using a new instrument in the healthcare context should be guided by data on sensitivity, specificity, accuracy and predictive values (Portney & Watkins, 2009). The use of the NFAS is not only diagnostic in nature, but also enables the description of a wide range of signs and symptoms of OPD. The NFAS provides the advantage of early identification of OPD with guided assessment to support the SLT to provide a rich description of these signs and symptoms of OPD. Validated assessment instruments such as the NFAS may also contribute to providing timely and effective intervention to high-risk neonates in the NICU. The NFAS may further support SLTs in their daily role in the NICU to increase the effectiveness of service delivery and promote teamwork as

evidence of accurate early identification of OPD can be provided. Timely evidence-based treatment may in turn decrease length of hospital stay and related healthcare costs (Jadcherla, 2016).

Theoretical implications may also be drawn from the content included in the NFAS. The different sections and items of the NFAS appeared to be essential components to identify and diagnose OPD, as an integrated composition of neonatal feeding and swallowing subsystems is represented (Arvedson & Brodsky, 2002; Jadcherla, 2016). The different sections complement one another to enable broader multidimensional systemic description of the neonate's feeding and swallowing skills in a manner concurrent with developmental supportive assessment practices promoted in NICUs.

The implications of the study for clinical practice in the field of neonatal dysphagia were also considered. The NFAS may assist the SLT to provide evidence-based feeding and swallowing assessment and diagnostic services in the NICU. The NFAS may also be used when access to MBSS equipment is unavailable, or while awaiting MBSS at another facility while the neonate is not medically stable to be transported. It may also be used for training and support to nursing staff in the NICU, to optimize human resources and the cost of service delivery. Training nurses to understand the descriptive information gained from the NFAS may enable them to view OPD from a different perspective. It may promote teamwork between SLTs and nurses to provide evidence-based support during feeding to high-risk neonates. The use of the NFAS in the NICU may provide inexperienced nurses with a clear understanding of SLT-recommended intervention options. The SLT should acknowledge the important role nursing staff plays in supporting oral feeding development in the NICU. Close collaboration between the nurses, SLTs and dieticians is required to support the health, nutrition and feeding development of neonates. Use of the NFAS in the NICU may integrate role expansion amongst SLTs and nurses.

Another aspect of importance in the NICU setting is for SLTs to involve parents in the daily care of the neonate during feeding times. Involving parents in the neonate's care in the NICU is important to promote attachment and interaction (Lubbe & Bornman, 2005; Lubbe, 2009). To improve parents' understanding of the team's approach to OPD (ASHA, 2005), certain sections (B – E) of the NFAS may be used

in an information-sharing discussion with parents. Such a discussion may also help the parents to feel more involved with their neonate's care (Lubbe & Bornman, 2005). The SLT may use the feeding profile from the NFAS together with information from specific sections (B and C) to train parents to read the neonate's state of alertness and stress cues. This may promote responsive maternal-infant interaction whilst supporting the engagement the neonate may be able to tolerate during feeding. Involving parents may benefit the development of attachment and reduce feelings of stress, anxiety and helplessness they may experience in the NICU setting (Lubbe & Bornman, 2005; Nugent et al., 2007). The SLT may provide comprehensive descriptive information about OPD to the neonatal team, including physicians, to facilitate improved team communication and interdisciplinary collaboration in the NICU. This study was an attempt to meet the local and international need for the development of valid clinical assessment instruments in the field of neonatal dysphagia (Botha & Schoeman, 2011; Heckathorn et al., 2015; Pados et al., 2016; Vermeulen, 2015).

To improve clinical training of SLTs at a tertiary level in South Africa, the NFAS may be considered for inclusion in clinical curricula at the five universities in South Africa that offer a degree in speech-language pathology. The NFAS may be used to train senior students in comprehensive clinical assessment of high-risk neonates to identify OPD and improve understanding of the complex nature of neonatal dysphagia.

Inexperienced clinicians completing their community-service year in South Africa, or independent SLTs early in their careers in private healthcare, could use the NFAS to guide them to assess neonatal feeding and swallowing skills, especially if they are working without senior SLT supervision. Based on the identification of OPD with the NFAS, it may support SLTs to refer only those neonates suspected of aspiration, silent aspiration and aspiration-related pneumonia for MBSS to plan optimal treatment.

In conclusion, the NFAS may support improved service delivery and reduce healthcare costs related to the assessment of OPD in high-risk preterm neonates in developing contexts, since the NFAS can be used in the absence of the MBSS to identify OPD accurately. However, the MBSS remains the standard for visualizing

the anatomy and pathophysiology of swallowing and identifying penetration and aspiration that cannot be determined clinically.

Valid early identification of OPD may contribute to improve the foundation of individualized treatment planning to optimize health, nutrition and development in high-risk preterm neonates.

7.5. Critical review of the study

The strengths, challenges and limitations of this research study were critically reviewed. This critical analysis has aided in considering future perspectives and research recommendations. The strengths, challenges and limitations are discussed below.

7.5.1. Strengths of the studies

Study 1: The prevailing strength of this study was that the researcher was able to develop and prepare the NFAS with expert collaboration. Electronic mail communication was efficient and overcame geographical distances. Local and international participants could be included in the panel.

Study 2: Psychometric outcomes of novel assessment instruments determine the validity of use in clinical practice (Crist et al., 2004; Da Costa et al., 2008; Portney & Watkins, 2009). Good preliminary psychometric performance on a small scale supported a study on a larger sample of neonates. This preliminary study confirmed the importance of pilot studies in instrument development, especially in resource-constrained contexts where limited research funding for new investigators at the beginning of their careers is available.

Study 3: Evidence-based practice dictates that early assessment and management of neonatal dysphagia is crucial (Heckathorn et al., 2015; Jadcherla, 2016; Jadcherla et al., 2009). It was determined that the NFAS accurately identifies and describes OPD in the preterm neonatal population. The NFAS may contribute to the limited pool of valid neonatal feeding assessment instruments available to SLTs practising in South Africa and other under-served countries. Development of the NFAS took place under conditions anticipated to be close to the real-world conditions under which the instrument may be used.

7.5.2. Contextual challenges faced during the research

Study 1: The research field in neonatal dysphagia is still relatively small in South Africa. There were a limited number of local experts in neonatal and paediatric dysphagia with both a publication record and clinical experience, to form part of the expert panel.

Study 2: Data collectors faced challenges to attain a minimum sample of neonates meeting the inclusion criteria for a pilot study. Physicians tended to discharge some participants before they could be assessed with MBSS. For this reason many data sets were incomplete and had to be discarded.

Study 3: Similar challenges were encountered than in Study 2. A total of 99 neonates were assessed with the NFAS, but after data collection was completed over a period of 10 months, only 48 participants had undergone all procedures. Other problems encountered during the course of the study were that the MBSS equipment was often fully booked due to large hospital caseloads and two hospital SLTs acting as raters, with a radiology technician, were not always readily available to perform the MBSS due to scheduling conflicts.

7.5.3. Limitations of the studies

Study 1: The size of the panel in this study was dependent on availability of expertise on the topic of neonatal dysphagia and instrument development. It might have strengthened the outcomes of the Delphi process if there was a more diverse multidisciplinary component. Multidisciplinary panel members including neonatal nurses, neonatologists and occupational therapists working in the field of neonatology and neonatal feeding could benefit the process of developing new instruments. Experts from different professions bring different views to the table, since neonatal dysphagia should be viewed from multiple perspectives. Such multiple perspectives are required to fully understand the complexity of OPD and the resulting consequences for the preterm neonatal population (Jadcherla, 2016).

Study 2: The use of an additional rater to determine inter-rater reliability of the MBSS diagnosis should have been considered. To circumvent this limitation, the researcher could have requested that a second SLT viewed recordings of the MBSS afterwards. Determining MBSS inter-rater reliability coefficients could have

strengthened the reliability results of the study. This same limitation would also apply to study 3.

Study 3: The outcomes of the main study should be interpreted with caution, since the sample size is still relatively small to allow for generalization of results across high-risk preterm neonatal populations. Moreover, since the NFAS is a comprehensive clinical assessment instrument, experienced clinicians may find the instrument too detailed and lengthy for their preference. Another limitation of the study was that the NFAS could not be validated on the full spectrum of high-risk infants, including a larger group of extremely preterm neonates, which might experience even greater swallowing and feeding difficulties than the current sample of late preterm neonates (average GA=35.5 weeks).

7.6. Recommendations for research

This is the time to use opportunities in the field of neonatal and paediatric dysphagia as there is an increase in the high-risk neonatal population in South Africa. Samuels, Slemming and Balton (2012) confirmed this increase and stated that an elevated incidence of early biological and psychosocial risks in countries such as South Africa is contributing to infant health and development outcomes. The impact of various risks, such as HIV exposure, on neonatal feeding and swallowing abilities could be explored further in research. Investigation of the prevalence of OPD in neonates with substance abuse withdrawal would be a relevant research project in the South African setting, considering the extremely high prevalence of FASD. A validated clinical instrument, such as the NFAS, may facilitate research into the prevalence, course, and observable pathophysiology and treatment of OPD in this high-risk population. The use of the NFAS may also circumvent practical problems such as unavailability of MBSS.

All five universities offering a degree in speech-language pathology in South Africa have offered formal theoretical and clinical training in dysphagia since 2003, as required by the HPCSA (2012). As a result interest and research in this field are growing. Experienced supervisors with publication records are emerging to guide research in this expanding field of practice.

There is scope for research regarding neonatal dysphagia in both the public and private sectors, since NICUs in each of these settings may be quite diverse in terms of availability of medical technology, variety of trained staff and specialized services from SLTs to assess and treat OPD in high-risk neonates.

Shrewd technological solutions are necessary for the best use of physical and human resources in healthcare in developing, as well as developed countries (Clark & Swanepoel, 2014). Therefore research evidence should support and come up with solutions to efficiently serve the neonatal population with OPD, without incurring unnecessary healthcare expenditure. The use of mobile health applications and the tele-health platform should also be considered in future research and practice with this population (Kumar et al., 2013).

Research in developed countries could also contribute to investigating the use of the NFAS across contexts. Independent research on the NFAS is required to investigate generalization of the results of this study. The following specific recommendations for future research in the field of neonatal dysphagia are made:

- To use the NFAS on a larger sample of preterm high-risk neonates presenting with similar characteristics to those in this study, to independently verify validity and reliability results.
- To make recommendations for further improvement or adaptations to the NFAS.
- To use the NFAS to study specific populations/medical conditions in the neonatal period in order to test the consistent performance to accurately identify OPD: late preterm infants, infants with HIE, infants with HIV exposure, infants with RDS, full-term infants with LBW and/or SGA, preterm neonates with intraventricular haemorrhage, preterm infants with congenital cardiac conditions such as patent ductus arteriosus, and preterm infants with BPD. Specific special populations with a high prevalence in South Africa such as Foetal Alcohol Spectrum Disorder, Down syndrome or craniofacial difficulties, could also be studied (Department of Health, 2001) .
- To develop a mobile application of the NFAS to facilitate access to clinicians in developing countries and remote rural areas in developed countries on m-health platforms.

- To investigate the transdisciplinary use of the NFAS in a tele-health context where SLTs can act as consultants in the absence of resident SLTs at healthcare facilities.
- Based on the recommendations of the expert panel in study 1, the component of mother-infant attachment and interaction was not included as a section in the NFAS. In future research, mother-infant attachment and how it may contribute to the mother's insight and management of the neonate with OPD may be explored. Such research on attachment and interaction may support the development of a valid instrument to assess feeding dyads where poor attachment and interaction is suspected in hospitalized high-risk neonates with OPD.
- To investigate the NFAS as a monitoring instrument to track progress of the development of oral feeding skills in high-risk neonates with OPD. Such tracking may reveal a feeding profile to emerge over time. This may guide SLTs to adjust intervention goals in a developmental supportive manner.

7.7. Future perspectives on neonatal dysphagia in South Africa

The professional body of SLTs in South Africa published paediatric dysphagia guidelines five years ago (SASLHA, 2011a). The guidelines were welcomed by clinicians since this provides a uniform guide for evidence-based clinical practice for SLTs working in the public and private healthcare sectors in South Africa. However, gaps in the guidelines (SASLHA, 2011a) are present. Firstly, the guidelines do not identify the neonatal population as a separate group from the paediatric population, requiring specialised attention. Secondly, no recommendations regarding the use of valid or standardized oral feeding and swallowing assessment instruments for neonates or infants are provided in the SASLHA (2011a) guidelines for paediatric dysphagia. Finally, the unique service delivery to the neonatal population is not addressed with adequate depth to guide inexperienced SLTs in assessment and intervention of high-risk infants in the NICU.

Currently there is a need for more SLTs to provide neonatal dysphagia services in both the public and private healthcare sectors in South Africa. Neonatal dysphagia services should be accessible to all high-risk neonates at risk of OPD who are born in hospitals. Due to limited expertise in neonatal dysphagia in South Africa, the use

of mobile and tele-health modalities may increase access and availability of SLT consultation services to high-risk neonates. Future development of mobile application of the NFAS may reduce cost of assessment of OPD in the NICU, but efficiency research on such an application is required. An application may facilitate easier access to the NFAS for SLTs using smart phones and tablets. Other benefits may be automated scoring of the NFAS, secure electronic storage of records, immediate availability of records when required, and easy sharing of data with a next clinician when neonates are discharged from the NICU to facilitate a smooth continuum of care. Such an application may offer one low-cost solution for early and reliable diagnosis of OPD and make assessment services in hospitals across South Africa available to underserved communities. The availability of the NFAS may facilitate remote research recruitment in a variety of hospitals across South Africa and abroad.

7.8. Conclusion

In summary, the three studies described the validation of a new clinical feeding assessment instrument to identify and diagnose OPD in high-risk neonates. These studies explored reliability and validity through determining sensitivity and specificity together with inter-rater reliability of the NFAS. Validity and reliability findings were considered adequate for clinical use.

The NFAS may support early identification of OPD and more appropriate clinical decision making in contexts such as South Africa, where service delivery of allied health professionals is not well regulated. It is hoped that the scope of the study may contribute to formalizing the concept of 'neonatal dysphagia' in South Africa. Neonatal dysphagia in a very young infant is distinct from paediatric dysphagia, as the disorder is emerging and may change over time due to maturation and cortical development during the early weeks of extrauterine life (Jadcherla, 2016). The present study contributed to evidence-based assessment practice in the field of neonatal dysphagia. The use of the NFAS may assist service delivery in the NICU by SLTs and may contribute to prioritizing neonates with OPD for intervention. The use of the NFAS is not limited to identification of OPD only, but also provides descriptive information to allow a rich description of a high-risk neonate's feeding profile. Neonates with confirmed OPD should receive daily intervention. These infants

should also be offered referral to appropriate medical and allied health team members to minimize functional and developmental limitations and in turn optimize safe participation in feeding. Daily intervention and appropriate referral may support neuro-protective development and improve quality of life in high-risk preterm neonates in the stressful environment of the NICU. The area of neonatal dysphagia is fertile ground for future research by independent researchers to strengthen and improve the validity of the NFAS.

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APPENDIX A ETHICAL CLEARANCE CERTIFICATE

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

* **FWA** 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
* **IRB** 0000 2235 IORG0001762 Approved dd 13/04/2011 and Expires 13/04/2014.

Universiteit van Pretoria
University of Pretoria

Faculty of Health Sciences Research Ethics Committee
Fakulteit Gesondheidswetenskappe Navorsingsetiekkomitee

DATE: 13/11/2012

NUMBER	**151/2012**
TITLE OF THE PROTOCOL	The development of a Diagnostically relevant clinical feeding instrument for High-Risk infants (>27 weeks gestational age to 4 months post term)
PRINCIPAL INVESTIGATOR	Mrs M M Viviers **Dept:**Communication Pathology;University of Pretoria. **Cell:** 0825051286 **E-Mail:** mari.debeer@up.ac.za / mmdebeer@hotmail.com
SUB INVESTIGATOR	None
STUDY COORDINATOR	None
SUPERVISOR	Prof A M Kritzinger **E-Mail:** alta.kritzinger@up.ac.za
STUDY DEGREE	D Phil in Communication Pathology
SPONSOR COMPANY	None
MEETING DATE	5/09/2012

The Protocol and Informed Consent Document were approved on 26/09/2012 by a properly constituted meeting of the Ethics Committee subject to the following conditions:

1. The approval is valid for 3 years period [till the end of December 2014], and
2. The approval is conditional on the receipt of 6 monthly written Progress Reports, and
3. The approval is conditional on the research being conducted as stipulated by the details of the documents submitted to and approved by the Committee. In the event that a need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

Members of the Research Ethics Committee:

Prof M J Bester	(female)BSc (Chemistry and Biochemistry), BSc (Hons)(Biochemistry), MSc(Biochemistry), PhD (Medical Biochemistry)
Prof R Delport	(female)BA et Scien, B Curationis (Hons) (Intensive care Nursing), M Sc (Physiology), PhD (Medicine), M Ed Computer Assisted Education
Dr NK Likibi	MBB HM – Representing Gauteng Department of Health) MPH
Dr MP Mathebula	(female)Deputy CEO: Steve Biko Academic Hospital; MBCHB, PDM, HM
Prof A Nienaber	(female) BA(Hons)(Wits); LLB; LLM; LLD(UP); PhD; Dipl.Datametrics(UNISA) – Legal advisor
Mrs MC Nzeku	(female) BSc(NUL); MSc(Biochem)(UCL, UK) – Community representative
Prof L M Ntlhe	MbChB (Natal) FCS (SA)
Snr Sr J Phatoli	(female) BCur(Eet.A); BTec(Oncology Nursing Science) – Nursing representative
Dr R Reynders	MBChB (Prtt), FCPaed (CMSA) MRCPCH (Lon) Cert Med. Onc (CMSA)
Dr T Rossouw	(female) MBChB (cum laude), M.Phil (Applied Ethics) (cum laude), MPH (Biostatistics and Epidemiology (cum laude), D.Phil
Dr L Schoeman	(female) B.Pharm, BA(Hons)(Psych), PhD – Chairperson: Subcommittee for students' research

2012/11/13MS: dd 2012/11/13: C:\Documents and Settings\user\My Documents\Protokolle\Grade briewe\Letters 2012\151.doc

DR R SOMMERS; MBChB; MMed(Int); MPharmMed
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

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UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

15 January 2013

Dear Prof Kritzinger

Project:	**The development of a diagnostically relevant clinical feeding assessment instrument for high risk infants (>27 weeks gestational age up to 4 months post term)**
Researcher:	**MM Viviers**
Supervisor:	**Prof A Kritzinger**
Department:	**Communication Pathology**
Reference number:	**20038021**

Thank you for your response to the Committee's letter of 6 December 2012.

I have pleasure in informing you that the Research Ethics Committee formally **approved** the above study at an *ad hoc* meeting held on 14 January 2013. Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should your actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

The Committee requests you to convey this approval to the researcher.

We wish you success with the project.

Sincerely

Prof. Sakhela Buhlungu
Chair: Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: sakhela.buhlungu@up.ac.za

APPENDIX B DELPHI STUDY: PARTICIPANT INFORMATION LEAFLET AND INFORMED CONSENT

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Faculty of Humanities
Department of Communication Pathology

Expert Panel Member Information Leaflet and Informed Consent

Study Title: The Development of a Diagnostically Relevant Clinical Feeding Instrument for High-Risk Infants

Researcher: Ms Mari Viviers

Degree: D.Phil in Communication Pathology

Dear Colleague

INTRODUCTION

As an expert in paediatric dysphagia, you are invited to participate in a research study. This information leaflet is to inform you regarding the nature, aims and methodology of the research study.

WHAT DOES YOUR PARTICIPATION ENTAIL?

As an expert panel member it will be required of you to review the Clinical Feeding Assessment Instrument compiled by the researcher.

RATIONALE OF THE RESEARCH STUDY

The focus of this study will be on clinical assessment and related diagnosis of paediatric dysphagia in high-risk infants 32 weeks gestational age up to four months chronological age. High-risk factors such as premature birth occur increasingly in South Africa compared to other developed countries;' partly due to the HIV/AIDS pandemic and poverty (Bradshaw et al., 2008). The study will be assessing high-risk infants with risk factors such as prematurity, low birth weight and exposure to HIV/AIDS. These infant populations present with risk indicators for the presence of paediatric dysphagia (Arvedson & Brodsky, 2004; Hall, 2001).

Currently a wide variability exists in clinical assessment practice supporting diagnostic conclusions in paediatric dysphagia internationally (Martino, Pron & Diamant, 2004; Mathers-Schmidt & Kurlinski, 2003; Pettigrew & O'Toole, 2007). One of the areas of need in clinical practice is a validated clinical assessment instrument to guide clinical practice and provide relevant diagnostic accuracy. A validated assessment instrument will contribute to the new era of evidence-based practice requirements (Johnson, 2006). In the research arena many studies have focused on refining instrumental assessment procedures for adults and using the data of

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these assessments to describe specific dysphagia characteristics related to disorders such as stroke and neurodegenerative diseases (Mann, 2001). The focus on instrumental assessment and rapid technological advances led to a neglect of the clinical foundation of dysphagia practice, yet the clinical assessment procedure continues to form the foundation of dysphagia practice.

It can be argued that validation of paediatric dysphagia instruments has been neglected. A shift has occured in the perception that an instrumental assessment is the only valid method to diagnose dysphagia. A clinical assessment instrument for the adult post-stroke population suffering from dysphagia was validated (Mann, 2001) heralding this shift. However, a clinical assessment instrument for the adult population with dysphagia cannot be adapted for the paediatric population due to differences with regard to the size of the anatomical structures, neurodevelopment and maturation that is still taking place in an infant, the lower prevalence of acquired disorders in infants, as well as the unique environmental and nutritional aspects that play a role during infancy.

Existing feeding observation instruments such as the *Schedule for Oral Motor Assessment (SOMA)* (Reilly, Skuse & Wolke, 2000), the *Neonatal Oral Motor Assessment Scale (NOMAS)* (Palmer, Crawley & Blanco, 1993) and the *Multidisciplinary Feeding Profile (MFP)* (Judd et al.,1988) do not focus on comprehensive descriptions of the total feeding process (Rogers & Arvedson, 2005). The instruments only focus on specific components involved in the acquisition of feeding and swallowing skills resulting in limitations regarding comprehensiveness (Rogers & Arvedson, 2005). Furthermore, the need for the currently proposed research project is highlighted by the concluding comments of Rogers and Arvedson (2005:81) that "*descriptive observations need objectivity with meaningful quantitative measures that can aid clinicians in decision making processes for management of infants and young children with feeding and swallowing disorders*". The authors also concur that a multitude of research opportunities abound in this area of practice. A research opportunity in the South African context exists since instrumental assessment equipment is not widely available in South Africa. Therefore a clinical dysphagia assessment instrument is of even greater importance for appropriate diagnosis and decision making when instrumental assessment equipment is not available.

NATURE OF THE RESEARCH STUDY

Phase I of the study will consist of the preliminary compilation of a Clinical Evaluation of Paediatric Dysphagia Assessment instrument (including review of the instrument by an expert panel), Phase II and III will consist of determining the validity of the assessment instrument through assessing high-risk infants with the assessment instrument to determine the following factors: specificity and sensitivity of the instrument in relation to a modified barium swallow study as well as inter-rater reliability and test-retest reliability.

A descriptive comparative cross-sectional research design will be used in Phase II and III. A structured case history interview with the parent/caregiver, obtaining background information from the infant's hospital file and a clinical feeding assessment session will be conducted. A blind rater will also conduct and rate the MBS during phase II when specificity and sensitivity of the clinical instrument will be determined.

WHAT IS THE PURPOSE OF THIS STUDY?

- The purpose of this study is firstly to develop a diagnostically relevant and validated clinical assessment instrument to assess feeding problems in high risk infants.
- The sub-aims are two pronged: To determine sensitivity and specificity of the clinical assessment instrument in relation to a modified barium swallow study, and secondly, to determine inter-rater reliability and test-retest reliability of the instrument.

WHAT IS THE PROCEDURE AND DURATION OF THIS STUDY?

To establish the content validity of a newly proposed assessment instrument, a rigorous procedure should be adhered to. Sonies et al. (2009) indicated that the most common method for establishing content validity is to convene an expert panel to evaluate a developing instrument. However, a specific method is required to obtain constructive feedback from a panel of experts in the field of paediatric dysphagia and high-risk infants.

For this study the Delphi method as a qualitative research approach will be used (Sumsion, 1998). It is a survey technique consisting of an iterative multistage process and commonly used in the health and social sciences research contexts (Hasson, Keeney & McKenna, 2008). In Figure 1 an outline of the Delphi review steps is depicted.

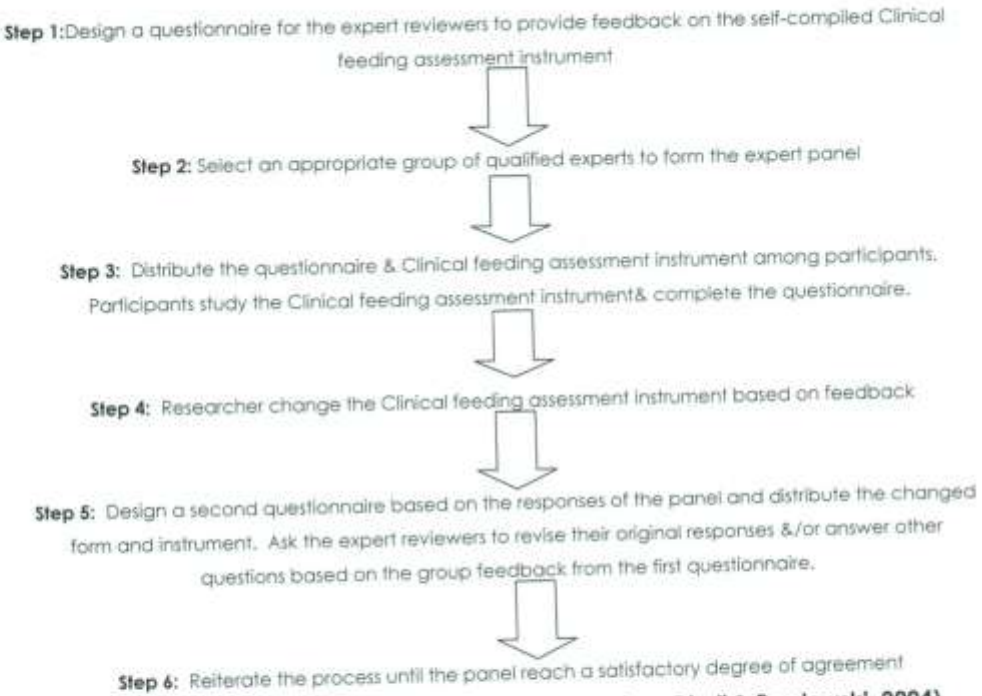

Figure1 Implementation of the Delphi method (Based on Okoli & Pawlowski, 2004)

As an expert panel member it will be required of you to review the clinical assessment instrument during a few rounds of judgment according to the Delphi-method of reaching a consensus. Your participation will take place via email. Upon receiving an email request from the researcher your will be granted one week (7 days) to provide your feedback. It will be required of you to make recommendations regarding the clinical assessment instrument. The

investigator will then review all the panel members' feedback and send out a subsequent questionnaire regarding the first round of results. Eight reviewers will be on the panel and the reviewers will not be known to one another. When satisfactory consensus according to the investigator has been reached, the process of being a panel member will come to conclusion. Upon completion of the study the results will be disseminated to you if you are interested.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

The study has received ethical approval by the Research and Ethics Committee of the Faculty of Humanities and the Faculty of Health Sciences at the University of Pretoria as well as the Gauteng Department of Health.

WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY?

Your participation in this study is entirely voluntary and you can refuse to participate or stop at any time without giving any reason.

MAY ANY OF THESE STUDY PROCEDURES RESULT IN DISCOMFORT OR INCONVENIENCE?

Participating in the study will not result in any discomfort to you.

WHAT ARE THE RISKS INVOLVED IN THIS STUDY?

There will be no harm to you if you decide to participate in this study. The results of the study will be disseminated to you if you want the information.

ARE THERE ANY WARNINGS OR RESTRICTIONS CONCERNING MY PARTICIPATION IN THIS STUDY?

There are no warnings or restrictions concerning your participation in this study.

FINANCIAL ARRANGEMENTS

You will not be paid to participate in this expert panel.

CONFIDENTIALITY

All information obtained during the course of this study is strictly confidential. The email communications will only be used for the purposes of the study and will be stored in hard and electronic copy for 15 years according to University regulations for data storage in a secure location at the Department of Communication Pathology.

Should you require any further information you are welcome to contact the investigator, Ms Mari Viviers on +27 082 505 1286 or [redacted] (w)/mmaepeen@hotmail.com (private).

Yours sincerely,

Ms Mari Viviers
Investigator

Prof. Alta Kritzinger
Promotor

Prof Bart Vinck

(Please complete below and scan and email it back to the researcher)

I hereby confirm that I have been informed by the investigator, Ms Mari Viviers, about the nature and purpose of this study. I have also received, read and understood the written information (Expert panel member Information Leaflet and Informed Consent) regarding the study.

I may, at any stage, withdraw my consent and participation in the study. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

Panel Member's Name: _____

Panel Member's e-mail signature: _____

Date: _____

I, Ms Mari Viviers herewith confirm that the above mentioned panel member has been informed fully about the nature and conduct of the above study.

5

APPENDIX C STUDY 2 AND 3: PARENT INFORMATION LEAFLETS AND INFORMED CONSENT

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Faculty of Humanities
Department of Communication Pathology

Ouer/Sorggewer Inligtings Brosjure en Ingeligte Toestemming

Titel van navorsingstudie: Die Ontwikkeling van 'n Diagnosties Relevante Kliniese Voedings Instrument vir Hoe Risiko Babas

Navorser: Me Mari Viviers

Graad: D Phil in Kommunikasiepatologie

Beste Ouer

INLEIDING

Jy en jou baba word uitgenooi om aan 'n navorsingstudie deel te neem. Hierdie inligtings brosjure word verskaf om jou te help om te besluit of jy wil deelneem. Voor jy instem om aan die studie deel te neem moet jy verstaan wat deelname sal behels. As jy enige vrae het wat nie ten volle deur die brosjure beantwoord word nie, moet asseblief nie huiwer om my te vra nie. Jy moet nie instem om deel te neem ten sy jy nie tevrede is met al die prosedures wat dit gaan behels nie.

AARD VAN DIE NAVORSINGSTUDIE

Vir hierdie studie benodig ek jou toestemming vir die volgende:

- om jou baba se geskiedenis in die hospitaal te beskryf asook jou baba se gesondheid en ontwikkeling sedert geboorte
- om jou baba se hospitaal rekord deur te gaan vir inligting
- om jou vrae oor jou swangerskap te vra asook jou baba se gesondheid en ontwikkeling sedert jy geboorte geskenk het, veral oor hoe jou baba suig en voed
- om jou baba na die x-straal afdeling te neem waar die hospitaal se spraak-taal terapeut 'n beeld (bewegende x-straal) van hoe jou baba sluk gaan neem. Die sluk toets sal met jou baba gedoen word binne 3 dae vandat ek jou baba in die saal gesien het.

Jou baba gaan blootgestel word aan bestraling vir 'n baie kort periode van tyd (nie langer as 10 minute nie). Jy sal by jou baba kan bly tydens die sluk toets en jy sal 'n beskermende jurkie dra tydens die procedure. Die x-straal toets word reeds vir 'n lang tyd met babas gebruik en word beskou as veilig

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As jou baba deel neem aan die toetse beteken dit nie dat daar iets fout is met jou baba se voeding nie. Nadat die toetse voltooi is sal ek die resultate met jou bespreek.

WAT IS DIE DOEL VAN DIE TOETSE?

Die doel van die studie is om 'n toets te ontwikkel vir babas wat suig, sluk of voedingsprobleme het.

HOE LANK SAL DIE TOETSE DUUR?

- Ek gaan vir jou vrae vra oor jou baba se gesondheid, ontwikkeling en ook oor jou gesondheid tydens jou swangerskap. Dit sal ongeveer 15 – 20 minute neem.
- Ek gaan jou baba se hospitaal rekord lees. Dit sal ongeveer 10 – 15 minute neem.
- Ek sal dan vir sekere dele van die ondersoek jou baba moet vashou en aan jou baba se arms, bene, gesiggie en die binnekant van jou baba se mond moet voel om die verhemelte en tong te ondersoek. Ek gaan daarna kyk hoe jy jou baba bors/bottle/buis voed. Ek sal my hande was voordat en nadat ek jou baba ondersoek het. Geen van die prosedures sal jou baba seer maak nie. Dit gaan ongeveer 20 – 30 minute neem.

As jou baba begin huil sal jy daar wees om jou baba te troos. Jy en jou baba sal nie geforseer word om enige iets te doen wat jy nie wil nie. Ek is opgelei om met babas en hulle ouers te werk in 'n neonatale/pediatriese intensiewe sorg of hoe sorg eenheid. Jy en jou baba sal nie geskei word tydens enige van die ondersoeke nie.

Ek benodig ook jou toestemming om:

- Notas te maak terwyl ek jou ondervra en terwyl ek jou baba se hospitaal rekord lees.
- 'n Video opname te maak van hoe ek jou baba ondersoek sodat twee ander terapeute kan sien hoe ek jou baba ondersoek het.
- Uitgepompte bors melk of water gemeng met 'n wit barium poeier vir jou baba te gee tydens die sluk toets. As jou baba tot dusver net deur 'n buisie voeding ontvang het sal die x-straal toets 'n veilige geleentheid bied om te sien hoe jou baba se suig en sluk vaardighede verbeter het.

HET DIE NAVORSINGSTUDIE ETIESE GOEDKEURING GEKRY?

Die Navorsing en Etiek Kommitee van die Fakulteit Geesteswetenskappe so wel as die Fakulteit van Gesondheidswetenskappe by die Universiteit van Pretoria het etiese goedkeuring vir die studie verskaf.

WAT IS JOU REGTE AS JY DEEL NEEM?

Jy gaan slegs aan die toetse en ondersoeke deel neem as jy wil. Jy besluit of jy en jou baba aan die studie wild eel neem. Jy kan enige tyd nee se of stop sonder om enige rede te gee. Ek kan jou en jou baba ook aan die studie onttrek as dit nie die regte tyd is om die toetse en ondersoek te doen nie, of as jou baba sou siek word.

GAAN ENIGE VAN DIE TOETSE PYNLIK OF ONGEMAKLIK WEES?

As jy en jou baba sou deelneem sal die geen ongemak of pyn veroorsaak nie. Die ondersoek waar ek aan die binne kant van jou baba se mond moet vat is nie seer nie, maar sommige babas hou nie daarvan nie. Die onderhoud en ondersoek tye sal met jou gereel word. Gedurende die onderhoud, ondersoek en toetse sal ek nie van jou verwag om enige iets te doen wat jy nie wil doen nie. Die sluk toets in die x-straal afdeling sal nie ongemaklik wees nie, maar jou baba sal in 'n stoeltjie met ondersteunende material geplaas word om die toets te doen. Die spraak-taal terapeut sal jou die heel tyd help.

WAT IS DIE RISIKOS VERBONDE AAN DIE STUDIE?

- Ek sal eers met jou baba se dokter praat om seker te maak dat ek jou baba kan ondersoek en toets en dat jou baba gesond genoeg is om vir die x-straal geneem te word vir 'n periode van ongeveer 45 minute.
- As jy sou besluit om deel te neem sal deelname nie skadelik wees vir jou of jou baba nie.
- Die ondersoek en toets resultate sal met jou bespreek word as jy die inligting wil he.
- Jy sal na toepaslike dokters en terapeute verwys word by die hospitaal as jou baba ekstra hulp met suig en voeding benodig.

IS DAAR ENIGE WAARSKUWINGS OF BEPERKINGS AANGAANDE MY DEELNAME AAN DIE STUDIE?

Daar is geen waarskuwings of beperkings aangaande jou en jou baba se deelname aan die studie nie. Om my te vertel dat jou baba aan MIV blootgestel is, is vrywillig en as jy die inligting met my deel sal dit vertroulik hanteer word. Slegs ek en my supervisor sal oor hierdie inligting beskik en jou baba se naam sal nooit aan sy/haar mediese toestand gekoppel word nie.

FINANSIELE VERGOEDING

Jy sal nie betaal word om aan die studie deel te neem nie.

VERTROULIKHEID

Alle inligting wat tydens die studie verkry word is streng vertroulik. Data wat in wetenskaplike joernale opgeteken kan word sal nie identifiserende inligting oor jou en jou baba se deelname aan die studie insluit nie.

Die video opname wat gemaak word tydens die ondersoek sal slegs vir die doel aangewend word wat ek in die brosjure aangedui het. Die opnames sal volgens universiteits regulasies vir 15 jaar in 'n veilige plek in die Departement Kommunikasiepatologie gestoor word.

Sou jy enige verdere navrae het, is jy welkom om my, Me Mari Viviers, te bel op 082 505 1286.

Vriendelike groete

Me Mari Viviers

Navorser

Prof Bart Vinck

Departementshoof en Mede-supervisor

Prof Alta Kritzinger

Supervisor

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VERBALE INGELIGTE TOESTEMMING

(van toepassing op ouer/sorggewer wat nie kan lees of skryf nie)

Ek, die ondergetekende, Me Mari Viviers, of die tolk, het die brosjure wat die aard en doel van die studie is, waaraan ek die ouer/sorggewer genooi het om deel te neem, vir die ouer/sorggewer, _____, voorgelees en ten volle verduidelik.

Die ouer/sorggewer het aangedui dat hy/sy verstaan en dat hy/sy enige tyd van die studie kan onttrek vir enige rede.

Ek sertifiseer hiermee dat die ouer/sorggewer ingestem het dat haar/sy baba aan die studie kan deel neem.

Ouer/Sorggewer se Naam: _____ (drukskrif asseblief)

Navorser se Naam: Mari Viviers

Navorser se Handtekening: _____

Datum: _____

Tolk se Naam: _____

Tolk se Handtekening: _____

Datum: _____

GESKREWE INGELIGTE TOESTEMMING

Ek bevestig hiermee dat ek deur Me Mari Viviers, of die tolk, ingelig is oor die studie en wat die toetse behels wat met my baba gedoen gaan word. Ek het ook die brosjure ontvang, gelees en verstaan aangaande die studie. Ek stem hiermee in dat my baba aan die studie mag deelneem en dat video opnames van myself en die baba gemaak kan word.

Ek is bewus daarvan dat al die inligting wat ek deel vertroulik gehou sal word. Ek mag, enige tyd, my toestemming en deelname aan die studie onttrek. Ek het genoeg geleenthede gehad om vrae te vrae en (vrywillig) verklaar hiermee dat ek en my baba gereed is om aan die studie deel te neem.

Ouer/Sorggewer se Naam: _____ (drukskrif asseblief)

Navorser se Naam: Mari Viviers

Navorser se Handtekening: _____

Datum: _____

Tolk se Naam: _____

Tolk se Handtekening: _____

Datum: _____

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Parent/Caregiver Information Leaflet and Informed Consent

Study Title: The Development of a Diagnostically Relevant Clinical Feeding Instrument for High-Risk Infants Investigator: Ms Mari Viviers

Degree: D.Phil in Communication Pathology

Dear Parent

INTRODUCTION

You and your baby are invited to participate in a research study. This information letter is to help you to decide if you would like to take part. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this letter, do not hesitate to ask me. You should not agree to take part unless you are completely happy about all the procedures involved.

NATURE OF THE RESEARCH STUDY

This is a study in which I need your permission to:

- describe your baby's history in the hospital and how your baby has been developing since birth
- look at your baby's hospital file for information
- ask you questions about your pregnancy and your baby's health and development since birth, especially about how your baby is sucking and drinking
- send your baby to the x-ray department where the hospital speech-therapist will take a picture (moving x-ray) of how your baby swallows. This swallowing test will be done within 3 days after I saw your baby in the ward.

Your baby will be exposed to radiation for a brief period of time (no longer than 10 minutes) when they take the x-ray. You will be able to stay with your baby for this test and will wear a gown to protect you. The x-ray test has been used for a long time on babies and is considered to be safe.

If you take part in these tests, it does not mean that there is something wrong with your baby's feeding. After the tests, I will discuss the results with you.

WHAT IS THE PURPOSE OF THE TESTS?

The purpose of this study is to make a test for babies that have problems to suck and drink.

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HOW LONG WILL THE TESTS TAKE?

- I ask you questions about your baby's health, development as well as about your health during the pregnancy. This will take about 15 - 20 minutes.
- I will read your baby's hospital file. This will take about 10 – 15 minutes.
- I will then need to hold your baby at times during the assessment, and touch your baby's arms, legs, face and inside your baby's mouth to feel the roof of the mouth and the tongue. I will then also watch how you breast/bottle/tube feed your baby. I will wash my hands before and after handling your baby. None of the things I do with your baby will hurt your baby. This will take about 20 – 30 minutes.

If your baby starts crying you will be right there to calm your baby and your baby will not be forced to do something. I am trained to work with babies and their parents in a neonatal/paediatric intensive or high care unit and hospital. You and your baby will not be separated at any time during the assessment.

I also need your permission to:

- Make notes during the time that I ask questions to you and when I read your baby's hospital file.
- Make a video recording for the research project for two other therapists to see how I tested your baby.
- Give your baby water/expressed breast milk mixed with a white barium powder. If your baby has been fed only through a tube thus far, the x-rays will provide a safe opportunity to see how sucking and swallowing has been getting better.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

The Research and Ethics Committee of the Faculty of Humanities as well as the Faculty of Health Sciences at the University of Pretoria have granted ethical approval for the study.

WHAT ARE YOUR RIGHTS IF YOU TAKE PART?

You only take part in these tests if you want to. You decide if you and your baby want to take part in the study or not. You can say no or stop at any time without giving any reason. I can also withdraw you from the tests if it is not the right time for you and your baby or if your baby gets sick.

IS ANY OF THESE TESTS GOING TO BE PAINFUL OR UNCOMFORTABLE?

If you and your baby take part it will not be uncomfortable for you or your baby. The test where I have to touch the inside of the baby's mouth is not painful, but some babies may not like this. The interview and assessment time will be arranged with you. During the interview and tests you will not be asked to do any tasks that you do not want to do. The swallowing test in the x-ray ward will not be uncomfortable, but your baby will need to be seated in a supported manner for this test. The speech-therapist will help you the whole time.

WHAT ARE THE RISKS INVOLVED IN THIS STUDY?

- I will first talk to your baby's doctor to make sure your baby can be tested by me and are healthy enough to go to the x-ray ward for a period of about 45 minutes.
- There will be no harm to you and your baby if you decide to participate in this study.

- The test results will be discussed with you if you want the information.
- You will be referred to appropriate doctors and therapists here in the hospital if your baby needs extra help with sucking and drinking.

ARE THERE ANY WARNINGS OR RESTRICTIONS CONCERNING MY PARTICIPATION IN THIS STUDY?

There are no warnings or restrictions concerning your participation in this study. Telling me whether your baby has been exposed to HIV/Aids is voluntary and if revealed will be treated with confidentiality. Only me and my supervisor will know this information and your baby's name will never be linked to his/her medical condition.

FINANCIAL ARRANGEMENTS

You will not be paid to participate in this research study.

CONFIDENTIALITY

All information obtained during the course of this study is strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you or your baby as participants in this study.

The video recording will only be used for the purposes stated in the letter and will be stored for 15 years according to University regulations in a secure location in the Department of Communication Pathology.

Should you have any more questions, you are welcome to phone me Ms Mari Viviers on 082 505 1286.

Yours sincerely,

Ms Mari Viviers

Investigator

Prof. Alta Kritzinger

Supervisor

Prof Bart Vinck

Department Head and Co-promotor

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VERBAL PATIENT INFORMED CONSENT *(applicable when parent/caregiver cannot read or write)*

I, the undersigned, Ms Mari Viviers, or the interpreter, have read and have explained fully to the parent/caregiver, named _____ , the parent/caregiver information leaflet, which has indicated the nature and purpose of the study in which I have asked the research participant to participate.The parent/caregiver indicated that he/she understands that he/she will be free to withdraw from the study at any time for any reason.

I hereby certify that the parent/caregiver has agreed to participate and let her baby participate in this study.

Parent/Caregiver's Name: _____ (please print)

Investigator's Name: Ms Mari Viviers

Investigator's Signature: _____

Date: _____

Interpreter's Name: _____

Interpreter's Signature: _____

Date: _____

WRITTEN INFORMED CONSENT

I hereby confirm that I have been informed by Ms Mari Viviers, or the interpreter about what the study is about and what tests they will do with my baby. I have also received, read and understood the letter (Parent/Caregiver Information Leaflet and Informed Consent) regarding the study. I hereby agree that my baby may take part in the study and that video recordings can be made of my self and my baby.

I am aware that all information will be kept confidential. I may, at any stage, withdraw my consent and participation in the study. I have had enough opportunity to ask questions and (of my own free will) declare myself and my baby ready to take part in the study.

Parent/Caregiver's Name: _____ (please print)

Parent/Caregiver's Signature: _____

Date: _____

Investigator's Name: Ms Mari Viviers

Investigator's Signature: _____

Date: _____

Interpreter's Name: _____ (please print)

Interpreter's Signature: _____

Date: _____

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Department of Communication Pathology

Setlankana sa Tshedimosetso ya Motsadi/Motlhokomedi le Tumalano ya Seemo

Setlhogo sa Thuto: Tlhagiso ya Didirisiwa Tse di Fitlheletsweng Tsa Kalafi Tse di Maleba Tsa go Fepa Masea A a Ka Tlhagelwang ke Kotsi Mmatlisisi: Ms Mari Viviers

Degree: DPhil Communication Pathology

Motsadi yo o Rategang

MATSENO

Wena le lesea la gago lo lalediwa go tsaya karolo mo thutopatlisisong. Lekwalo leno la tshedimosetso le kwaletswe go go thusa go bona gore a o ka kgona go tsaya karolo. Pele o ka dumela go tsaya karolo mo thutong eno o tshwanetse go tlhaloganya ka botlalo gore go akareleditswe eng. Fa o na le dipotso, tse di sa tlhalosiwang ka botlalo mo lekwalong leno, o se ka wa etsaetsega go botsa. O tshwanetse go dumela go tsaya karolo fa fela o kgotsofetse ka thulaganyo yotlhe e e akareleditsweng.

KAFA THUTOPATLISISO E LENG KA TENG

Eno ke thuto e ke tlhokang tetla ya gago ka go:

- tlhalosa hisitori ya lesea la gago kwa bookelong le kafa lesea la gago le gotseng ka teng fa e sale le tsholwa
- leba faele ya lesea la gago ya kwa bookelong go bona tshedimosetso
- go botsa dipotso ka boimana jwa gago le botsogo jwa lesea le kgolo ya lone fa e sale le tsholwa, segolobogolo ka ga go anya le go nwa mashi ga lesea la gago
- romela lesea la gago kwa lefapheng la x-ray kwa *speech-therapist* ya bookelo e tla tsayang setshwantsho (x-ray e e tsamayang) sa kafa lesea la gago le metsang ka teng. Teko eno ya go metsa e tla dirwa mo malatsing a le 3 morago ga gore ke bone lesea la gago mo phaposing ya bookelo.

Lesea la gago le tlile go nna mo teng ga marang ka nakwana (kwa tlase ga metsotso e le 10) fa re dira x-ray. O tla kgona go nna le lesea la gago fa go ntse go dirwa teko eno mme o tla apara *gown* go itshireletsa. Teko ya x-ray ke kgale e dirisiwa mo maseeng e bile e tsewa e sireletsegile.

Fa o tsaya karolo mo ditekong tseno, ga go reye gore go na le sengwe se se phoso ka go jesiwa ga lesea la gago. Morago ga diteko, ke tlile go tlotla ka dipholo le wena.

BOIKAELELO JWA DITEKO TSENO KE ENG?

Boikaelelo jwa thuto eno ke go dira teko mo maseeng a a nang le mathata a go anya le go nwa mashi.

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APPENDIX D DELPHI STUDY: QUESTIONNAIRES

Expert panel member questionnaire:

Review round 1

Please answer all the following questions as comprehensively as possible.

1. Do you consider the following subsections and included items of the clinical assessment instrument to be comprehensive enough to obtain adequate information during a clinical assessment of a high risk infant's feeding skills?

section	Yes	No	If "no", why not?
Section A: Physiological subsystems			
Section B: State Organization			
Section C: Self-regulatory ability in response to ss			
Section D: Motor organization			
Section E: Oral anatomy evaluation			
Section F: Clinical feeding & swallowing luation			
Section G: Parent-infant/ caregiver infant raction during feeding			
Section H: Classsification of possible feeding rswallowing disorder			
Section I: Suggested compensations & ommendations			

2. If you selected "no" for any particular subsection, please list suggested subsections to be added or even omitted/deleted and motivate suggestion or the lack of relevancy of the item in one sentence.

   _____

   _____

   _____

   _____

   _____

3. Do you consider the development of a validated clinical assessment instrument a relevant area of study? Yes___ No___
   If "no", why not?

   _____

4. Do you concur that there currently is an international need for the development of validated clinical assessment instruments in the area of paediatric dysphagia? Yes____ No _____

Expert Panel Member

Second Round

Dear Panel Member

Thank you for taking the time for this final participation round in this research project. Your contributions are very valuable to the research process.

Feedback Round 1:

- Some items were deleted due to measurability problems and other items were refined or added to the various sections.
- Sub-sections such as the Parent-Infant caregiver interaction during feeding will now be measured with a previously validated scale (either Thompson et al., 2009 or Barnard, 1978) and has been removed from the instrument.
- The relevance of the subsections and items regarding the final conclusion that this instrument should guide the clinician to, namely whether dysphagia is likely to be present or not (in essence a final yes/no diagnostic response), were further investigated and only the constructs which directly contributes towards identifying a feeding problem were retained.
- A scoring system has been added after consultation with two biostatisticians familiar with instrument development.

Instructions - Second round review:

The newly formatted and refined instrument is attached for your perusal. Please review the scoring system, face and content validity and whether all relevant constructs related to clinical assessment of feeding/sucking/swallowing in high risk infants are adequately covered in the proposed instrument.

The questionnaire guiding your review of the above mentioned topics is to follow. Please follow the instructions and **e-mail the questionnaire** back to me by **28 January 2012.**

Second round review questionnaire

SECTION 1: FACE VALIDITY

1. Could you please comment on the following aspects of face validity and user friendliness of the assessment instrument. Please indicate your response with a cross (x) in the appropriate column.

FACE VALIDITY	Agree	Disagree
Face validity is present.		
Appropriate professional appearance		
The assessment instrument is user friendly		
Language & technical editing are of an appropriately high standard.		

If disagree, WHY?

SECTION 2: CONTENT VALIDITY

2.1 Could you please comment on the following aspects of content validity of the assessment instrument. Please indicate your response with a cross (x) in the appropriate column

CONTENT VALIDITY	Agree	Disagree
Content validity is present.		
Appropriate constructs related to feeding and swallowing skills for premature infants >32 weeks are included		
Appropriate constructs related to feeding and swallowing skills for term to chronological age of 4 months are included		

If disagree, WHY?

2.2. Do you have any additional suggestions regarding the content validity of the instrument?

SECTION 3: SCORING SYSTEM

Aspects of the scoring system	Yes	Somewhat	No
3.1. Is the scoring system a **useful addition** to the instrument?			
3.2. Is the **instructions** on the use of the scoring system for each subsection **clear** enough?			
3.3. Is the **interpretation** of the scoring system for each subsection **easy to understand?**			

Additional comments regarding the scoring system:

SECTION 4: ADDITIONAL COMMENTS ON REVISED INSTRUMENT

Provide additional comments regarding any aspect of the revised instrument that you consider to be important in the further development or validation of the instrument.

THANK YOU FOR YOUR VALUABLE CONTRIBUTION BY COMPLETING THIS QUESTIONNAIRE

APPENDIX E STUDY 2 AND 3: INTERVIEW SCHEDULE AND RISK ASSESSMENT FORM

INTERVIEW SCHEDULE: CASE HISTORY OF HIGH RISK INFANTS >32 WEEKS TO 4 MONTHS CHRONOLOGICAL AGE

Personal information:

Name of child : _____
Date of birth : _____
Chronological age : _____
Gestational age at birth : _____
Birth weight : _____
Current weight : _____
Gender : _____

1.Current status:

1.1Diagnosis : _____
1.2Present concerns :

_____
_____
_____

1.3Has the problem changed (gotten better or worse)?:

_____
_____
_____

1.4Are there specific times when the problem is better or worse?:

_____
_____
_____

2.Medical history of mother and infant:

2.1List maternal illnesses or infections during pregnancy:

_____
_____

2.2List any other problems during pregnancy:

_____
_____

2.3List all medications taken during pregnancy:

_____
_____

2.4List all tests/x-rays done during pregnancy:

_____
_____

2.5Was alcohol/drugs/cigarettes used before/during the pregnancy by you/the mother?
Mother: Yes ☐ No ☐

2.6Length of pregnancy in weeks: ☐

2.7List any medications that the infant is currently taking:

_____

_____
_____

2.8List and describe any surgeries that the infant has had:

_____
_____
_____

2.9 List and describe any illnesses that the infant has experienced or are currently experiencing:

_____
_____
_____

2.10Has any genetic or neurologic testing been conducted? Yes No If yes, please describe.

_____
_____
_____

2.11 Is the infant currently receiving respiratory support? Yes No
If yes, select the appropriate option/s below

TRACHEOSTOMY	YES	NO
Tracheostomy in-situ		
Inflated cuff		
Partially inflated cuff		
Deflated cuff		
Suctioning of tracheostomy currently required		
Suctioning frequency (describe)		
Extubation in past week		

OTHER	YES	NO
Oxygen supplementation – nose cannula		
Continuous positive airway pressure (CPAP)		
Oxygen mask		
Oxygen head box		

3.Birthing history

3.1Duration of labour : _____ hours

3.2Type of delivery: Head first ☐ Feet first ☐ Caesarean section ☐ Breech ☐

3.3List any problems during labour and delivery:

_____
_____

3.4 Apgar scores – 1 min ☐ 5 min ☐ 10 min ☐

3.5 Did the infant receive ventilator support at birth? Yes ☐ No ☐

3.6 Did the infant experience prolonged hypoxia or anoxia/respiratory distress at birth/during labour? Yes ☐ No ☐

3.7Did the infant receive surfactant therapy? Yes ☐ No ☐
3.8 Did the infant experience cardiac problems at birth? Yes ☐ No ☐

3.9 Did the infant experience any other problems during labour or at birth? Please describe:
_____

4.Neonatal period (first 28 days):
4.1 Neonate state: Alert ☐ Lethargic (difficult to rouse) ☐

4.2 Reflexes: Rooting – Intact ☐ Absent ☐ Inconsistent ☐

4.3 Respiration:
4.3.1Support required: Yes ☐ No ☐
4.3.2Adequate independent respiration: Yes ☐ No ☐

4.4 Sucking:
4.4.1 Weak nutritive suck: Yes ☐ No ☐
4.4.2 Uncoordinated nutritive suck: Yes ☐ No ☐

4.4 Which medications did the infant receive in the neonatal period?
_____
_____
_____

5.Feeding and swallowing history:
5.1Was/is the infant breast fed? Yes ☐ No ☐

5.2 For how long was/is the infant breastfed? _____

5.3 Were/are there any problems with breastfeeding? Yes ☐ No ☐

5.4 Was/is the infant bottle fed? Yes ☐ No ☐

5.5 For how long was/is the infant bottle fed? _____

5.6 Were/are there any problems with bottle feeding? Yes ☐ No ☐

5.7 Was/ is the infant fed through a feeding tube? Yes ☐ No ☐

5.8 For how long was/ is the infant tube fed? _____

5.9 What is your infant's current feeding schedule? (i.e. every 2 hours)
_____
5.10List main nutritional source (i.e. breast milk, formula, pasteurized breast milk, intravenous feed) and approximate amounts:
_____
_____

5.11 Duration of average oral feeding: How long does it take the infant to complete a feed?

Less than 10 minutes ☐
10 – 20 minutes ☐
20 – 30 minutes ☐
Over 30 minutes ☐

5.12 Does/ have the infant receive/d any prescribed supplements? Yes ☐ No ☐
If yes, what?
_____

5.13 How would you describe your infant's appetite?

5.13.1Good ☐
5.13.2Inconsistent ☐
5.13.3Poor ☐

5.14 How is your infant usually positioned during feeding?

5.14.1Held on the lap ☐
5.14.2Lying down ☐
5.14.3Other ☐

5.15 How do you know when the infant is hungry? _____
5.16 How do you know when your infant is full? _____

5.17Please check all that apply to the infant:

5.17.1 Choking during a feed ☐
5.17.2 Liquid coming out the nose ☐
5.17.3 Drinks too little ☐
5.17.4 Drinks too much ☐
5.17.5 Perceived difficulty swallowing ☐
5.17.6 Trouble breathing during feeding ☐
5.17.7 Fussing during feeding ☐
5.17.8 Spitting milk out ☐
5.17.9 Gagging during a feed ☐
5.17.11 Reflux during/after feed ☐
5.17.12 Vomiting during/after feed ☐
5.17.13 Falling asleep during feeding ☐
5.17.14 Refuses oral feedings ☐
5.17.15 Stiffening during feeding ☐
5.17.16 Hyperextension during feeding ☐
5.17.17 Noisy breathing during/before/after feeding ☐
5.17.18 Gurgly voice quality during/before/after feeding ☐
5.17.19 Infant turning blue during / after feeding ☐

5.18 Is the infant having trouble gaining weight? Yes ☐ No ☐

5.19 Are feeding times pleasant for you? Yes ☐ No ☐

5.20 Does the child have behavioural problems during feeds? Yes ☐ No ☐

5.21 Does your infant use a pacifier? Yes ☐ No ☐

5.22 Does your infant dislike being touched around or in the mouth? Yes ☐ No ☐

5.23 How much does the infant drool?

5.23.1Never ☐
5.23.2Rarely ☐
5.23.3Occasionally ☐
5.23.4Frequently ☐
5.23.5Constantly ☐

5.24 What seems to help (or not help) your infant during feeding time?

_____
_____
_____

6. Social and family history:

6.1 Name of primary caregiver/s: _____
6.2 Relationship of primary caregiver to infant: _____
6.3 With whom is the infant living?: _____
6.4 How many siblings?:_____
6.5 Who usually feeds your infant?:_____
6.6 Provide short description of your infant's home/caregving environment:

_____
_____
_____

6.7 Are there any other feeding problems in the family?:

_____

References:

1. Arvedson, J.C. & Brodsky, L.2002. *Pediatric Swallowing and Feeding: Assessment and Management*. 2nd ed. Early Childhood Intervention Series. Thomson Delmar Learning.
2. Hall, K.D. 2001. *Pediatric Dysphagia: Resource Guide*. Singular Thomson Learning.
3. Swigert, N.B. 1998. *The Source for Pediatric Dysphagia*. LinguiSystems.

RISK ASSESSMENT

Alta Kritzinger, 1994 revised 2012

Name **Date**
Date of birth **Age**

Condition	Ideal	Risk
Prenatal History		
1. Age of mother	18-37 years	
2. Maternal education	Educated	
3. In vitro fertilization	Natural conception	
4. Repeated spontaneous abortions / still births	None	
5. Birth order of infant: Higher mortality for 1st and 3rd born children		
6. Smoking during pregnancy	No	
7. Alcohol / drug abuse	No	
8. Family history of hearing loss in children	None	
9. Multiple pregnancy	Single	
10. Antenatal care	-5 visits <35 w -8 visits >37 w	
11. Previous children: Mental disability, neurological disability, congenital disorders	None	
12. Viral infections: Cytomegalovirus, Rubella, Syphilis, Toxoplasmosis, Herpes, HIV/AIDS, TB, colds, flu	None	
13. Diabetes	No	
14. Threatened abortion	No	
15. Blood group incompatibility	No	
16. Medication during pregnancy	No	
17. Hospitalization during pregnancy	No	
18. Premature rupture of membranes	No	
19. Placental problems: placenta abruptio / previa	No	
20. Toxemia, Pre-eclampsia / HELLP syndrome	No	
21. *Duration of pregnancy	38-41 w	
22. Infant born at home / in hospital	In hospital	
22. Reason for premature birth		
Description of family circumstances: - Employment - Functional literacy - Means of transport - Involvement of both parents - Health - Living conditions		
Perinatal History	**Ideal**	**Risk**
23. Birth: Normal / Caesarian section	Normal	

24. Presentation at birth: Vertex / breech	Vertex	
25. Prolapse of cord around neck	None	
26. Instruments used	None	
27. Meconium aspiration	No	
28. Was the baby transported after birth? Reasons	No	
29. *Birth weight	3200g-3800g	
30. *Apgar score: 1 min & 5 min	7-10	
31. *Small for gestational age / Intrauterine growth retardation	Gestation age = birth weight	
32. Oxygen received and duration	< 10 days	
33. Ventilation: Type and duration	<10 days	
34. Respiratory distress syndrome: Grade I, II, III, IV	No	
35. Bronchopulmonary dysplasia	No	
36. Bradycardia and apnoeic attacks	No	
37. Retinopathy of prematurity	No	
38. Patent ductus arteriosus / Persistent fetal circulation	No	
39. Intra-ventricular haemorrhage: Grade I, II, III, IV	No	
40. Neonatal convulsions	No	
41. Hydrocephalus	No	
42. Necrotizing enterocolitis	No	
43. Meningitis	No	
44. Septicemia	No	
45. Other infections	No	
46. *Amino glycoside therapy (ototoxic) and duration	No	
47. *Hyperbilirubinemia: photo therapy and duration	No	
48. Blood transfusion / received plasma	No	
49. Number of days before bottle fed / breast fed	From birth	
50. Number of days on warm table and in incubator	None	
51. Received developmental appropriate care	From birth	
52. Number of days in NICU	None	
Established risk factors		
53. Cranio-facial abnormalities	None / <3 minor anomalies	
54. Other congenital disorders: Describe	None	

Key to risk assessment

***21 Duration of pregnancy / Duur van swangerskap (WHO, 2012)**

> 42 weeks	Post mature / Postmatuur
38 - 41 weeks	Full term / Voltermyn
32 - 37 weeks	Moderate to late preterm / Matige tot laat prematuriteit

28-32 weeks Extremely preterm / Ekstreme prematuriteit

***29 Birth weight / Geboortegewig (Southgate & Pittard, 2001)**

3 400g (3 200g - 3 800g)	Average birth weight / Gemiddelde geboorte gewig
1 500g - 2 500g	Low birth weight / Lae geboortegewig
< 1 500g	Very low birth weight / Baie lae geboortegewig
<1000g	Extremely low birth weight / Ekstreme lgg.

***30 Apgar score as indicator of neonatal asphyxia**
Apgartelling as aanduiding van neonatale asfiksie
(Rossetti, 2001)

1 / 5 Minute Apgar score

Serious asphyxia	0-3	Ernstige asfiksie
Moderate asphyxia	4-6	Matige asfiksie
Normal	7-10	Normaal

***31 Small-for-gestational age / Klein vir gestasie ouderdom**

Consult Table 1.10 for average fetal weight and size for gestational age in Rossetti, 2001:17.

***46 Amino glycosides / Aminoglukosides (ototoxic medication)**
(MIMS Medical Specialities, 1991)

Ototoxic drugs / Ototoksiese medikasie
Amicacin/Amiken, Fermentomycin, Garamycin, Gentomycin, Canamycin, Netromycin, Streptomycin, Tobromycin, Vancomycin.

***46 Hyperbilirubinemia / Hiperbilirubinemie**
(JCIH, 2007)

Bilirubin levels of more than 200 micro ml and a blood transfusion are high risk factors for sensorineural hearing loss and auditory neuropathy spectrum disorder

Bilirubinvlakke van meer as 200 micro ml en ‘n bloedtransfusie is hoërisikofaktore vir sensories-neurale gehoorverlies en ouditiew neuropatie spektrum afwyking

APPENDIX F STUDY 2 AND 3: NEONATAL FEEDING ASSESSMENT SCALE (NFAS)

NEONATAL FEEDING ASSESSMENT SCALE (NFAS)

Patient name:	Date of birth:
Gestational age at birth:	Current adjusted age:
Birth weight:	Current weight:
Diagnosis:	
Date of assessment:	
Examiner:	

SECTION A: FUNCTIONING OF PHYSIOLOGICAL SUBSYSTEMS

(Dieckman, Brownstein & Gausche-Hill, 2000; Henning, 2002; Hodgman, Hoppenbrouwers, & Cabal, 1993)

A.1. Observation of heart rate

Instructions: Observe the infant's heart rate if the infant is attached to a cardiac monitor during feeding, if not proceed to A.2. Complete the relevant items for the infant's current adjusted age.

A.1a Infant attached to cardiac monitor	YES	NO
32 – 39 weeks		
A.1.1 Normal heart rate (120 – 170 beats per minute)	YES	NO
A.1.1.1 Tachycardia (>170 beats per minute)	YES	NO
A.1.1.2 Bradycardia (<120 beats per minute)	YES	NO
40 weeks – 2 months 3 weeks post term		
A.1.2.1 Normal heart rate (100 – 150 beats per minute)	YES	NO
A.1.2.2 Tachycardia (>150 beats per minute)	YES	NO
A.1.2.3 Bradycardia (<100 beats per minute)	YES	NO
3 – 4 months post term		
A.1.3.1 Normal heart rate (90 – 120 beats per minute)	YES	NO
A.1.3.2 Tachycardia (>120 beats per minute)	YES	NO
A.1.3.3 Bradycardia (<90 beats per minute)	YES	NO
SCORE SECTION A.1: If bradycardia/tachycardia present indicate YES for the likelihood of dysphagia to be present		
OUTCOME SECTION A.1: Dysphagia likely to be present	YES	NO

A.2. Observation of Respiratory function			
Instructions: If the infant is attached to a respiratory monitor ***during feeding*** complete the items relevant to current (adjusted) age, as well as subsection A.2c. If the infant is *not attached to a monitor*, complete only subsection A.2c.			
A.2a Infant attached to respiratory monitor	YES	NO	
32 – 39 weeks			
A.2.1 Normal breathing rate (40 – 70 breaths per minute)	YES	NO	
A.2.1.1 Tachyapnoea (>70 breaths per minute)	YES	NO	
A.2.1.2 Apnoea (absent breathing efforts for > 15 seconds)	YES	NO	
40 weeks – 2 months 3 weeks post term			
A.2.2 Normal breathing rate (35 – 50 breaths per minute)	YES	NO	
A.2.2.1 Tachyapnoea (>50 breaths per minute)	YES	NO	
A.2.2.2 Apnoea (absent breathing efforts for > 15 seconds)	YES	NO	
3 – 4 months post term			
A.2.3 Normal breathing rate (35 – 45 breaths per minute)	YES	NO	
A.2.3.1 Tachyapnoea (>45 breaths per minute)	YES	NO	
A.2.3.2 Apnoea (absent breathing efforts for > 15 seconds)	YES	NO	
A.2c Signs of abnormal respiratory patterns during feeding			
A.2.4.1 Laboured/noisy breathing	YES	NO	
A.2.4.2 Obligatory mouth breather	YES	NO	
A.2.4.3 Non-obligatory mouth breather	YES	NO	
A.2.4.4 Stridor	YES	NO	
A.2.4.5 Rib cage flaring	YES	NO	
A.2.4.6 Sternum depression/retraction	YES	NO	
A.2.4.7 Irregular/shallow breathing	YES	NO	
A.2.4.8 Intercostal retractions (related to Respiratory Distress Syndrome)	YES	NO	
SCORE SECTION A.2: If tachyapnoea/apnoea present in items A.2.1-A.2.3.2, select YES for the likelihood of dysphagia being present. If items A.2.1-A.2.3.2 not scored, select NOT APPLICABLE (N/A). If YES was selected for any item/s in subsection A.2c, indicate YES for the likelihood of dysphagia being present.			
OUTCOME SECTION A.2.1-A.2.3.2: Dysphagia likely to be present	YES	NO	N/A
OUTCOME SECTION A.2c: Dysphagia likely to be present	YES	NO	
COMBINED OUTCOME SECTION A : If one YES obtained in a sub-section, select YES for likelihood of dysphagia being present.			
OUTCOME SECTION A: Dysphagia likely to be present	YES	NO	

SECTION B: STATE OF ALERTNESS DURING FEEDING
(Als, 1982; Brazelton, 1973; Nugent, Keefer, Minear, Johnson & Blanchard, 2007; Prechtl & Beintema, 1964; Wolff, 1959)

Instructions: Observe the infant's state of alertness during feeding. Select YES only once in this section, and score the remaining items NO.		
B.1.1 Stage 1 – Deep sleep	YES	NO
B.1.2 Stage 2 – Light sleep	YES	NO
B.1.3 Stage 3 – Drowsy	YES	NO
B.1.4. Stage 4 – Quiet alert	YES	NO
B.1.5 Stage 5 – Active alert	YES	NO
B.1.6 Stage 6 – Alert agitated	YES	NO
B.1.7 Stage 7 – Crying	YES	NO
SCORE SECTION B: Optimal state of alertness for feeding is indicated by a YES for either item B.1.4 or B.1.5. Items B.1.1-B.1.3 and B.1.6-B.1.7 reflects non-optimal states of alertness for feeding. A non-optimal state of alertness could likely contribute to a feeding problem.		
OUTCOME SECTION B: Non-optimal state of alertness during feeding	YES	NO
COMBINED SCORE FOR SECTION A & B:		
Section A	YES	NO
Section B	YES	NO
SCORE OBTAINED SECTION A & B OVERALL: If both sections obtained YES responses, indicate YES for the likelihood of dysphagia being present.		
OVERALL OUTCOME SECTION A & B: Dysphagia likely to be present	YES	NO

SECTION C: STRESS CUES DURING FEEDING (Als, 1982; Brazelton & Nugent, 1995; Hall, 2002; Karl, 2004)		
Instructions: Observe the infant during feeding and note down the stress cues the infant displays. Circle either YES or NO for all items in Section C.		
State related stress cues		
C.1.1 Staring	YES	NO
C.1.2 Panicked, worried or dull look	YES	NO
C.1.3 Silent/weak cry	YES	NO
C.1.4 Dozing	YES	NO
C.1.5 Startle	YES	NO
Motor related stress cues		
C.1.6 Twitching limbs	YES	NO
C.1.7 Hypextension of limbs	YES	NO
C.1.8 Fluctuating tone	YES	NO
C.1.9 Increased stiffness (arching/finger splays/fisting)	YES	NO
C.1.10 Excessive diffuse movements	YES	NO
Mild autonomic stress cues		
C.1.11 Gasping	YES	NO
C.1.12 Sighing	YES	NO

C.1.13 Sneeze	YES	NO
C.1.14 Sweating	YES	NO
C.1.15 Hiccup	YES	NO
C.1.16 Trembling jaw/limbs	YES	NO
Moderate autonomic stress cues		
C.1.17 Startling	YES	NO
C.1.18 Straining/Squirming	YES	NO
C.1.19 Averting gaze	YES	NO
C.1.20 Facial grimacing	YES	NO
C.1.21 Increased floppiness	YES	NO
C.1.22 Increased stiffness	YES	NO
C.1.23 Falling asleep during feeding	YES	NO
C.1.24 Crying during feeding	YES	NO
Severe autonomic stress cues		
C.1.25 Coughing	YES	NO
C.1.26 Gagging	YES	NO
C.1.27 Skin colour changes	YES	NO
C.1.28 Apnoea	YES	NO
C.1.29 Irregular respiration	YES	NO
C.1.30 Spitting up	YES	NO
C.1.31 Arching back	YES	NO
C.1.32 Breath holding	YES	NO
C.1.33 Bradycardia	YES	NO
C.1.34 Continued excessive crying	YES	NO
C.1.35 Choking	YES	NO
SCORE SECTION C: If YES selected for 3 or more items, then indicate YES for the likelihood of dysphagia being present.		
OUTCOME SECTION C: Dysphagia likely to be present	YES	NO

SECTION D: GENERAL MOVEMENT & MUSCLE TONE SCREENING (Clark, 2009; Van Haastert et al., 2006)		
Instructions: Observe the infant's muscle tone at rest and during handling for feeding. Complete all items in the section relevant to the infant's current (adjusted) age.		
32 – 39 weeks AT REST		
D.1.1 Normal resting posture (full flexion of all limbs not yet present, relatively adequate muscle tone/flexion in lower limbs; partial flexion in upper limbs)	YES	NO
D.1.2 Extremely floppy/extended resting posture (all limbs)	YES	NO
D.1.3 Extremely stiff resting posture (arched head & neck/arched back)	YES	NO

32 – 39 weeks DURING FEEDING		
D.1.4 Normal resting posture (full flexion of all limbs not yet present, relatively adequate muscle tone/flexion in lower limbs; partial flexion in upper limbs)	YES	NO
D.1.5 Extremely floppy/extended resting posture (all limbs / froggy position)	YES	NO
D.1.6 Extremely stiff resting posture (arched head & neck/arched back)	YES	NO
40 weeks term – 4 months post term AT REST		
D.2.1 Normal fully flexed resting posture of all limbs	YES	NO
D.2.2 Extended resting posture of all limbs (froggy position)	YES	NO
D.2.3 Stiff resting posture (arched head & neck/arched back)	YES	NO
40 weeks term – 4 months post term DURING FEEDING		
D.2.4 Normal fully flexed posture of all limbs maintained at midline	YES	NO
D.2.5 Floppy/extension of limbs/difficult to maintain midline flexion	YES	NO
D.2.6 Extremely stiff (arched head & neck – hyperextension pattern/arched back – shoulder retraction or elevation pattern)	YES	NO
SCORE SECTION D: If normal posture is indicated at rest and during feeding, then dysphagia is not likely to be present. Then select NO. If abnormal posture is noted at rest and during feeding or only during feeding, then dysphagia is likely to be present. Then select YES.		
OUTCOME SECTION D: Dysphagia likely to be present	YES	NO

SECTION E: ORAL PERIPHERAL EVALUATION

(Arvedson & Brodsky, 2002; Chapman Barr, 2001; Hall, 2001; Swigert, 2010)

E.1 Oral reactions

Instructions: The oral reactions should preferably be elicited BEFORE feeding if the infant presents with relatively adequate state regulation and appears alert.

Permanent reactions	**Stimulus & Appropriate expected response**	**Present**	**Absent**
E.1.1 Transverse tongue reaction	Stroke sides of tongue. Response: Tongue moves to the side that has been stimulated.	YES	NO
E.1.2.Sucking	Stroke tongue or touch hard palate. Response: Tongue should push little finger up against hard palate with good strength.	YES	NO
Temporary reactions	**Stimulus & Appropriate expected response**	**Present**	**Absent**
E.1.3 Phasic bite	Stimulate the gums by stroking the upper/lower gums. Response: Rapid rhythmical up and down movement of the jaw.	YES	NO
E.1.4 Tongue protrusion	Touch tongue tip. Response: Anterior tongue protrusion beyond the border of the lips.	YES	NO
E.1.5 Rooting reaction	Stroke cheek or corner of mouth. Response: Head move toward side of stimulus and mouth opens.	YES	NO

	{Rooting reaction starts to integrate (diminish) by 3 0 6 months of age.}		
E.1.6 Santmyer reflex	Administer a puff of air to the perioral area in the face of an alert non-crying infant. Response: Infant should swallow	YES	NO
E.1.7 Palmomental (Babkin) reflex	Bilateral pressure to the palms. Response: Mandibular depression & suckling movements of the tongue.	YES	NO
SCORES SECTION E.1: If the sucking reflex is absent dysphagia is likely to be present. Select YES.			
SECTION E.1: Dysphagia likely to be present		YES	NO

E.2 – E.5 Oral structure & function		
Instructions: Observe oral structure and function AT REST or where indicated DURING FEEDING.		
E.2 LIPS		
E.2.1 Symmetrical appearance	YES	NO
E.2.2 Lips touch when gums are together	YES	NO
E.2.3 Closure maintained *at rest*	YES	NO
E.2.4 Closure maintained around nipple *during feeding*	YES	NO
E.2.5 Upper lip tone at rest		
E.2.5.1 Normal appearance	YES	NO
E.2.5.2 Stiff / retracted	YES	NO
E.2.5.3 Floppy / inactive	YES	NO
E.2.6 Upper lip tone during feeding		
E.2.6.1 Normal appearance	YES	NO
E.2.6.2 Stiff / retracted	YES	NO
E.2.6.3 Floppy / inactive	YES	NO
E.2.7 Lower lip tone at rest		
E.2.7.1 Normal appearance	YES	NO
E.2.7.2 Stiff / curled in towards lower gum	YES	NO
E.2.7.3 Sagging	YES	NO
E.2.8 Lower lip tone during feeding		
E.2.8.1 Normal supportive appearance	YES	NO
E.2.8.2 Stiff / curled in towards lower gum	YES	NO
E.2.8.3 Sagging	YES	NO
E.2.9 Structural deviations of the lips		
E.2.9.1 Bilateral cleft lip	YES	NO
E.2.9.2 Unilateral cleft lip	YES	NO
E.2.9.3 Other (i.e lip pits etc.)	YES	NO

E.3 CHEEKS		
E.3.1 Age appropriately absent fat pads (32 – 39 weeks old infant) OR Fat pads present (40 weeks – 4 month old infant)	YES	NO
E.3.2 Stiffness during feeding	YES	NO
E.3.3 Inactivity / sagging during feeding	YES	NO
E.4 PALATE		
E.4.1 Intact hard palate	YES	NO
E.4.2 Cleft of the hard palate	YES	NO
E.4.3 Intact soft palate	YES	NO
E.4.4 Cleft of the soft palate (incl submucous cleft)	YES	NO
E.4.5 Intact uvula	YES	NO
E.4.6 Bifid uvula	YES	NO
E.5 TONGUE		
E.5.1 Normal size *at rest*	YES	NO
E.5.2 Macroglossia	YES	NO
E.5.3 Microglossia	YES	NO
E.5.4 Ankyloglossia	YES	NO
E.5.5 Normal muscle tone *at rest*	YES	NO
E.5.6. Protruded / thick appearance *at rest*	YES	NO
E.5.7 Retracted / bunched appearance *at rest*	YES	NO
E.5.8 Normal muscle tone / movement *during feeding*	YES	NO
E.5.9 Inactive / protruded tongue during feeding	YES	NO
E.5.10 Stiff / retracted tongue during feeding	YES	NO
E.5.11 Structural deviations of the tongue	YES	NO
E.5.12 Abnormal movement patterns		
E.5.12.1 Tongue thrust	YES	NO
E.5.12.2 Limited movement	YES	NO
E.6 JAW		
E.6.1 Normal appearance of the jaw	YES	NO
E.6.2 Micrognathia (small lower jaw)	YES	NO
E.6.3 Maxillary hypoplasia (midfacial retrusion)	YES	NO
E.6.4 Prognathism (protruded)	YES	NO
E.6.5 Retrognathism (retracted)	YES	NO
E.6.6 Abnormal movement patterns		
E.6.6.1 Jaw clenching	YES	NO
E.6.6.2 Jaw thrusting	YES	NO
SCORE SECTION E.2-E.6: If YES was selected to indicate any structural or physiological abnormality likely to impact on any of the stages of swallowing, select YES for the likelihood of		

dysphagia being present.		
OUTCOME SECTION E.2-E.6: Dysphagia likely to be present	YES	NO

E.7 Observation of cranial nerve function to indicate symptoms of possible dysfunction (Chapman Barr, 2001; Hall, 2001; Henning, 2002)		
Instructions: This section is to be completed based on the observation of oral structure and function "at rest" or "during feeding"(*). Item E.7.1.4 should be scored based on the elicitation of the rooting response in item E.1.5.		
E.7.1 CN V Trigeminal nerve dysfunction		
E.7.1.1 Reduced mandibular movements*	YES	NO
E.7.1.2 Failure to initiate sucking*	YES	NO
E.7.1.3 Weak lip seal*	YES	NO
E.7.1.4 Asymmetric reaction during rooting response	YES	NO
E.7.2 CN VII Facial nerve dysfunction		
E.7.2.1 Facial asymmetry	YES	NO
E.7.2.2 Reduced facial movements (at rest/when crying)	YES	NO
E.7.2.3 Weak lip seal*	YES	NO
E.7.3 CN IX Glossopharyngeal nerve dysfunction		
E.7.3.1 Failure to initiate sucking*	YES	NO
E.7.3.2 Suspected delayed swallow response*	YES	NO
E.7.3.3 Nasopharyngeal penetration (unrelated to structural deficit of hard/soft palate)*	YES	NO
E.7.4 CN X Vagus nerve dysfunction		
E.7.4.1 Absent voicing when crying (suspected vocal fold paralysis)	YES	NO
E.7.4.2 Weak cry (suspected vocal fold paresis)	YES	NO
E.7.4.3 Hypernasal cry	YES	NO
E.7.4.5 Suspected delayed swallow response*	YES	NO
E.7.4.6 Weak/poor sucking*	YES	NO
E.7.5 CN XII Hypoglossal nerve dysfunction		
E.7.5.1 Reduced tongue movements*	YES	NO
E.7.5.2 Weak/poor sucking*	YES	NO
SCORE SECTION E.7: If YES selected for any item in this section, indicate YES for the likelihood of dysphagia being present.		
OUTCOME SECTION E.7: Dysphagia likely to be present	YES	NO
OVERALL OUTCOME SECTION E:		
E.1	YES	NO
E.2 – E.6	YES	NO
E.7	YES	NO
SCORE OBTAINED SECTION E OVERALL: If a score of 2 OR more YES responses are obtained		

indicate YES for the likelihood of dysphagia being present.		
OUTCOME SECTION E OVERALL: Dysphagia likely to be present	YES	NO

SECTION F: CLINICAL FEEDING & SWALLOWING EVALUATION (Arvedson & Brodsky, 2002; Darrow & Harley, 1998; Rudolph & Thompson Link, 2002; Swigert, 2010)		
Instructions: Only complete the sections relevant to the infant's current (adjusted) age for section F.1.1 – F.1.4.		
F.1.1 – F.1.2 Non-nutritive sucking (NNS) skills		
F.1.1 NNS characteristics of the preterm infant (32 – 39 weeks)		
Instructions: Use a pacifier/your little finger to stimulate a suckling response. For item F.1.1.1 the approximate number of suckles before a pause occurs, should be counted.		
F.1.1.1 Burst cycles of approximately < 10 sucks before pausing	YES(0)	NO (1)
F.1.1.2 Adequate endurance throughout the feeding session	YES(0)	NO (1)
F.1.1.3 Adequate lip closure around finger/pacifier	YES(0)	NO (1)
F.1.1.4 Attempted tongue cupping/grooving against finger/pacifier	YES(0)	NO (1)
F.1.1.5 Anterior-posterior tongue movement present during suckling	YES(0)	NO (1)
F.1.1.6 Adequate sucking strength	YES(0)	NO (1)
F.1.1.7 Coordinated suck-swallow-breathe rhythm	YES(0)	NO (1)
F.1.1.8 Normal breathing pattern with no catch-up breathing	YES(0)	NO (1)
SCORE OBTAINED SECTION F.1.1.: If a score of 2 or more is obtained, indicate YES for the likelihood of dysphagia being present.		
OUTCOME SECTION F.1.1: Dysphagia likely to be present	YES	NO
F.1.2 NNS characteristic of the term (40 weeks) to four month post term infant		
Instructions: Use a pacifier/your little finger to stimulate a suckling response. For item F.1.2.1 the approximate number of sucks before a pause occurs, should be counted.		
F.1.2.1 Burst cycles of approximately 10 - 20 sucks before pausing	YES(0)	NO (1)
F.1.2.2 Adequate endurance throughout the feeding session	YES(0)	NO (1)
F.1.2.3 Adequate lip closure around finger/pacifier	YES(0)	NO (1)
F.1.2.4 Attempted tongue cupping/grooving against finger/pacifier	YES(0)	NO (1)
F.1.2.5 Anterior-posterior tongue movement present during suckling	YES(0)	NO (1)
F.1.2.6 Adequate sucking strength	YES(0)	NO (1)
F.1.2.7 Coordinate suck-swallow-breathe rhythm	YES(0)	NO (1)
F.1.2.8 Normal breathing pattern with no catch-up breathing	YES(0)	NO (1)
SCORE OBTAINED SECTION F.1.2: If a score of 2 or more is obtained, indicate YES for the likelihood of dysphagia being present.		
OUTCOME SECTION F.1.2: Dysphagia likely to be present	YES	NO
F.1.3 – F.1.4 Nutritive sucking (NS) skills		
F.1.3 NS characteristics of the preterm infant (32 – 39 weeks)		
Instructions: Ask the mother/caregiver/nurse to feed the infant. Observe the infant for the duration		

of the feeding session.		
F.1.3.1 Burst cycle of approximately < 10 sucks before pausing	YES(0)	NO (1)
F.1.3.2 Adequate endurance throughout the feeding session	YES(0)	NO (1)
F.1.3.3 Adequate lip closure/seal on nipple/bottle teat	YES(0)	NO (1)
F.1.3.4 Timely initiation of sucking	YES(0)	NO (1)
F.1.3.5 Adequate sucking strength	YES(0)	NO (1)
F.1.3.6 Coordinated suck-swallow-breathe rhythm	YES(0)	NO (1)
F.1.3.7 Clinical signs of possible aspiration during feeding:		
F.1.3.7.1 Gurgling	YES(1)	NO (0)
F.1.3.7.2 Coughing	YES(1)	NO (0)
F.1.3.7.3 Choking	YES(1)	NO (0)
F.1.3.7.4 Teary/watery eyes	YES(1)	NO (0)
F.1.3.8 Avoidance behaviour during feeding:		
F.1.3.8.1 Tongue thrust	YES(1)	NO (0)
F.1.3.8.2 Jaw clenching	YES(1)	NO (0)
F.1.3.8.3 Jaw thrusting	YES(1)	NO (0)
F.1.3.8.4 Lip retraction on presentation of nipple/bottle teat/small cup/syringe	YES(1)	NO (0)
F.1.3.8.5 Arching of the back & neck (extension pattern)	YES(1)	NO (0)
F.1.3.8.6 Turning the head away from the breast/bottle/cup/syringe	YES(1)	NO (0)
SCORE OBTAINED SECTION F.1.3: If a score of 2 or more is obtained, indicate YES for the likelihood of dysphagia being present.		
OUTCOME SECTION F.1.3: Dysphagia likely to be present	YES	NO
F.1.4 NS characteristics of the term (40 weeks) to 4 month post term infant		
Instructions: Ask the mother/caregiver/nurse to feed the infant. Observe the infant for the duration of the feeding session		
F.1.4.1 Burst cycle of approximately 10 - 20 sucks before pausing	YES(0)	NO (1)
F.1.4.2 Adequate endurance throughout the feeding session	YES(0)	NO (1)
F.1.4.3 Adequate lip closure/seal on nipple/bottle teat	YES(0)	NO (1)
F.1.4.4 Timely initiation of sucking	YES(0)	NO (1)
F.1.4.5 Adequate sucking strength	YES(0)	NO (1)
F.1.4.6 Coordinated suck-swallow-breathe rhythm	YES(0)	NO (1)
F.1.4.7 Clinical signs of possible aspiration during feeding:		
F.1.4.7.1 Gurgling	YES(1)	NO (0)
F.1.4.7.2 Coughing	YES(1)	NO (0)
F.1.4.7.3 Choking	YES(1)	NO (0)
F.1.4.7.4 Teary/watery eyes	YES(1)	NO (0)
F.1.4.8 Avoidance behaviour during feeding:		
F.1.4.8.1 Tongue thrust	YES(1)	NO (0)

F.1.4.8.2 Jaw clenching	YES(1)	NO (0)
F.1.4.8.3 Jaw thrusting	YES(1)	NO (0)
F.1.4.8.4 Lip retraction on presentation of nipple/bottle teat/small cup/syringe	YES(1)	NO (0)
F.1.4.8.5 Arching of the back & neck (extension pattern)	YES(1)	NO (0)
F.1.4.8.6 Turning the head away from the breast/bottle/cup/syringe	YES(1)	NO (0)
SCORE OBTAINED SECTION F.1.4: If a score of 2 or more is obtained, indicate YES for the likelihood of dysphagia being present.		
OUTCOME SECTION F.1.4: Dysphagia likely to be present	YES	NO
F.2 Behavioural response to feeding method & NNS stimulation		
Instructions: Observe the infant's acceptance of pacifier/little finger during NNS stimulation as well as during feeding.		
F.2.1 Infant accepts nipple/bottle teat/syringe/small medicine cup	YES(0)	NO (1)
F.2.2 Infant accepts pacifier/finger	YES(0)	NO (1)
F.2.3 Negative behavioural responses during feeding or NNS stimulation		
F.2.3.1Refusal by turning the head away from source of feeding or pacifier/finger	YES(1)	NO (0)
F.2.3.2 Arching or the back and neck (extension pattern) to avoid feeding	YES(1)	NO (0)
F.2.3.3 Emesis after feeding	YES(1)	NO (0)
SCORE OBTAINED SECTION F.2: If a score of more than 0 is obtained, indicate YES for the likelihood of dysphagia being present.		
OUTCOME SECTION F.2: Dysphagia likely to be present	YES	NO
F.3 – F.4 Symptoms of Oropharyngeal dysphagia		
Instructions: Completing this section is based on the clinician's interpretation of the observation of respiration during feeding, oral function, cranial nerve function, NNS stimulation and feeding.		
F.3 Oral symptoms		
F.3.1 Delayed initiation of sucking	YES(1)	NO (0)
F.3.2 Poor/weak sucking response	YES(1)	NO (0)
F.3.3 Absent sucking response	YES(1)	NO (0)
F.3.4 Uncoordinated tongue movement during NNS and NS	YES(1)	NO (0)
F.3.5 Inadequate lip closure with excessive anterior spillage during feeding	YES(1)	NO (0)
F.3.6 Multiple swallow attempts to initiate pharyngeal swallow response (feel for multiple tongue base retractions without appropriate hyolaryngeal elevation in an attempt to swallow)	YES(1)	NO (0)
F.4 Pharyngeal symptoms		
F.4.1 Gurgling during/after swallowing	YES(1)	NO (0)
F.4.2 Coughing during/after swallowing	YES(1)	NO (0)
F.4.3 Choking during/after swallowing	YES(1)	NO (0)
F.4.4 Teary eyes during/immediately after swallowing	YES(1)	NO (0)
F.4.5 "Wet" respiratory sounds	YES(1)	NO (0)

F.4.6 "Wet" vocal sounds	YES(1)	NO (0)
F.4.7 Suspected delayed pharyngeal swallowing response	YES(1)	NO (0)
F.4.8 Absent pharyngeal swallowing response	YES(1)	NO (0)
SCORE OBTAINED SECTION F.3-F.4: If a score of more than 0 is obtained, indicate YES for the likelihood of oropharyngeal dysphagia being present.		
OUTCOME SECTION F.3-F.4: Dysphagia likely to be present	YES	NO
OVERALL OUTCOME SECTION F:		
F.1.1 – F.1.2	YES	NO
F.1.3 – F.1.4	YES	NO
F.2	YES	NO
F.3 – F.4	YES	NO
SCORE OBTAINED SECTION F OVERALL: If a score of 2 OR more YES responses are obtained indicate YES for the likelihood of oropharyngeal dysphagia being present.		
OUTCOME SECTION F OVERALL: Dysphagia likely to be present	YES	NO

CALCULATING DIAGNOSTIC OUTCOME			
SECTION A & B	Dysphagia likely to be present	YES	NO
SECTION C	Dysphagia likely to be present	YES	NO
SECTION D	Dysphagia likely to be present	YES	NO
SECTION E	Dysphagia likely to be present	YES	NO
SECTION F	Dysphagia likely to be present	YES	NO
SCORING INSTRUCTION: If a score of 3 or more YES responses obtained in the section outcomes above, indicate YES for the final diagnosis of oropharyngeal dysphagia likely to be present. However, at least one of the 3 YES responses required for reaching the final diagnosis of oropharyngeal dysphagia being present, must either be obtained in SECTION E or F.			
Diagnostic outcome	Oropharyngeal dysphagia likely to be present	YES	NO

APPENDIX G STUDY 2 AND 3: MODIFIED BARIUM SWALLOW STUDY (MBSS) CHECKLIST AND GUIDELINES FOR REVIEW OF THE MBSS

Modified Barium Swallow Study Checklist

Client : _____-

Date of Birth: _____

Date of evaluation: _____

Instructions to blind rater:

Please tick off the appropriate results after completing the MBSS for the client. You can proceed as you normally would by providing feedback to the parent/caregiver and provide therapy or referrals if indicated. In the last column, circle the appropriate "yes" or "no" option.

Swallowing stage	Type of dysphagia	Yes	No	
Oral stage	Oral dysphagia			
Pharyngeal stage	Pharyngeal dysphagia			Penetration observed: Yes / No
				Aspiration observed: Yes / No
Oesophageal stage	Oesophageal dysphagia			

Signature of rater: _____

Guidelines for review of MBSS

Stage of swallowing	Signs of dysphagia
ORAL STAGE **(Arvedson & Brodsky, 2002; Gewolb & Vice, 2006; Hall, 2001; Lau & Smith, 2011; Qureshi et al., 2002; Swigert, 2010)**	• Excessive anterior loss of bolus • Incoordinated lingual stripping • Weak sucking • Incoordination of the suck-swallow-breathe (SSB) pattern • Spill over of bolus before initiation of swallow response
PHARYNGEAL STAGE **(Arvedson & Brodsky, 2002; Gewolb & Vice, 2006; Hall, 2001; Lau & Smith, 2011; Qureshi et al., 2002; Swigert, 2010; Dodrill & Gosa, 2015)**	• Delayed elicitation of the pharyngeal swallow response • Inadequate epiglottic inversion • Laryngeal penetration • Tracheal aspiration • Cough in response to penetration/aspiration • Inadequate airway protection related to incoordinated SSB • Inadequate vocal fold adduction (on posterior-anterior view) • Pooling in the valleculae during the swallow • Residue in the valleculae post-swallow • Pooling in the pyriform sinuses during the swallow • Residue in the pyriform sinuses post-swallow • Nasopharyngeal reflux
OESOPHAGEAL STAGE **(Jadcherla, 2016)**	• Gastroesophageal reflux (GER)

APPENDIX H PROOF OF ACCEPTANCE FOR PUBLICATION (STUDY 1 & 2) AND PROOF OF SUBMISSION FOR REVIEW (STUDY 3)

STUDY 1 E-MAIL CORRESPONDENCE

SAJCD Development of a clinical feeding assessment scale for very young infants in South Africa

Inbox X

AOSIS Publishing <submissions@sajcd.org.za> Aug 7

to me, Alta, Bart

You are receiving this email on behalf of the South African Journal of Communication Disorders. In the event of a requested response, you may respond directly to this email.

Dear Authors
Thank you for the revised manuscript and the list of changes made.
Congratulations your article has been accepted for publication in the SAJCD and the copyeditors will be in touch within the next few days to work with you to develop the article further for publication.
Kind regards
Dr Anita Edwards
SAJCD Editor in Chief
anitaedwards247@gmail.com

South African Journal of Communication Disorders
http://www.sajcd.org.za/index.php/sajcd

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STUDY 2 E-MAIL CORRESPONDENCE

SAJCD Editor Decision - 163: Revisions Required

9 messages

AOSIS Publishing <submissions@sajcd.org.za> Sun, Aug 28, 2016 at 5:50 PM
Reply-To: "Dr Anita L. Edwards" <anitaedwards247@gmail.com>
To: Mrs Mari M Viviers <marimviviers@gmail.com>

You are receiving this email on behalf of the South African Journal of Communication Disorders. In the event of a requested response, you may respond directly to this email.

Dear Authors

Ref. No.: 163
Title: Preliminary psychometric performance of the Neonatal Feeding Assessment Scale
Journal: South African Journal of Communication Disorders

We have reached a decision regarding your submission.

Our decision is that once you have taken the reviewer comments into account and made the required revisions the publication can be published.
Please provide a detailed list of the changes made in response to the reviewer comments listed below.

Kind regards
Dr Anita Edwards
SAJCD Editor in Chief

STUDY 3 E-MAIL CORRESPONDENCE

[JPHIA] Journal of Public Health in Africa [paper no. 600] - Submission Acknowledgement

Inbox x

Emanuela Fusinato <emanuela.fusinato@pagepress.org> 8:14 AM (3 hours ago)

to me, office

Dear Dr. Ms Mari M Viviers,

Thank you for submitting the manuscript "Validity and reliability of the Neonatal Feeding Assessment Scale (NFAS)" to Journal of Public Health in Africa. With the online journal management system that we are using, you will be able to track its progress through the editorial process by logging in to the journal web site:

Manuscript URL:
http://www.publichealthinafrica.org/index.php/jphia/author/submission/600
Username: mviviers0626

If you have any questions, please contact me. Thank you for considering this journal as a venue for your work.