# Feeding difficulties in infants with unrepaired cleft lip and palate and HIV-exposure

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**A dissertation submitted in fulfilment of the requirements for the degree**

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**In the Department of Speech-Language Pathology and Audiology, Faculty of Humanities, University of Pretoria**

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# Abstract


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| **Title** | **Feeding difficulties in infants with unrepaired cleft lip and palate and HIV-exposure** |



**Abstract:**

**Background:** There is limited description of the feeding characteristics of infants with unrepaired cleft lip and palate (CLP), exposed to HIV and antiretroviral treatment.

**Objective:** To determine whether the feeding characteristics of very young infants with unrepaired CLP and HIV-exposure (HIV-E) differ significantly to that of infants with unrepaired CLP only.

**Method:** A two-group comparative design with a validated measure, the Neonatal Feeding Assessment Scale (Viviers, 2016) was used. The effectiveness of oral feeding skills (OFS) between the two groups were measured based on the objective measure described by Lau and Smith (2011). Twelve participants with unrepaired CLP and HIV-E and 13 with unrepaired CLP were matched according to cleft type and use of feeding obturator. There were no significant differences between the groups for mean age, birth weight and gestation. Participants were between two and 89 days old, bottle fed, and had no syndrome/co-occurring disorder.

**Results:** Nine (75%) participants in the research group (RG) and only two (15.38%) in the control group (CG) presented with the likelihood of oropharyngeal dysphagia (OPD). Apart from feeding difficulties as a result of structural impairment of the cleft, the RG showed symptoms of neurological involvement, such as absent rooting. The RG consumed less milk in the same time than the CG. The RG experienced more problems since birth as they were in the neonatal intensive care unit for longer and took longer to achieve successful bottle feeding.

**Conclusion:** The RG presented with distinctive symptoms of OPD. More studies using different measuring tools, such as the Modified Barium Swallow Study are required to strengthen the evidence.



**Keywords: HIV-exposed (HIV-E) infants, unrepaired cleft lip and palate, feeding difficulties, oropharyngeal dysphagia (OPD), oral feeding skills, Neonatal Feeding Assessment Scale (NFAS).**

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*"Commit to the Lord whatever you do, and all your plans will succeed" (Proverbs 16:3).*

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# Abbreviations

| | |
|---|---|
| **ACPA** | American Cleft Palate-Craniofacial Association |
| **AIDS** | Acquired immune deficiency syndrome |
| **ART** | Antiretroviral treatment |
| **ARV** | Antiretroviral |
| **ASHA** | American Speech-Language-Hearing Association |
| **cART** | Combined antiretroviral therapy |
| **CLP** | Cleft lip and palate |
| **CNS** | Central nervous system |
| **EFV** | efavirenz |
| **FCDC** | Facial Cleft Deformities Clinic |
| **FTT** | Failure to thrive |
| **HAART** | Highly active antiretroviral therapy |
| **HFI** | Household food insecurity |
| **HIV** | Human immunodeficiency virus |
| **HIV-E** | HIV-exposed/exposure |
| **HPCSA** | Health Professions Council of South Africa |
| **LBW** | Low birth weight |
| **LBW/PTB** | Low birth weight and preterm birth |
| **LV** | Left ventricle |
| **MBSS** | Modified Barium Swallow Study |
| **MTCT** | Mother-to-child transmission |
| **NFAS** | Neonatal Feeding Assessment Scale |
| **NNS** | Non-nutritive sucking |
| **NS** | Nutritive sucking |
| **NVP** | Nevirapine |
| **OFS** | Oral feeding skills |
| **OPD** | Oropharyngeal dysphagia |
| **PCR** | Polymerase chain reaction |
| **PMTCT** | Prevention of mother-to-child-transmission |
| **PTB** | Preterm birth |
| **RTHB** | Road To Health Booklet |
| **SLT** | Speech-Language Therapist |
| **VSGA** | Very small for gestational age |
| **UNAIDS** | Joint United Nations Programme on HIV/AIDS |
| **UNICEF** | United Nations Children’s Fund |
| **WHO** | World Health Organization |
| **ZDV** | Zidovudine |

# List of Tables and Figure

# Chapter 1 Introduction

*The aim of the chapter is to provide a broad overview on the available research of the feeding characteristics of infants with HIV-infection and infants with unrepaired cleft lip and palate. An overview on the limited research regarding feeding difficulties of infants with HIV and ART exposure is given. The problem statement is that no available research on the feeding difficulties of infants with unrepaired CLP, HIV-exposure and ART-exposure could be found. The chapter concludes with the rationale and research question. Terminology as used in the dissertation and an outline of chapters are included.*

## 1.1 Introduction

South Africa remains the epicentre of the global human immunodeficiency virus (HIV) epidemic (Naidoo & McKerrow, 2015). An estimated 36.7 million people are living with HIV globally and 48.5% of these are women who may be in the reproductive age group (Joint United Nations Programme on HIV/AIDS [UNAIDS], 2017). Prior to the availability of antiretroviral treatment (ART), infants born to HIV positive women, were infected with HIV (Wudineh & Darntew, 2016). Since antiretrovirals (ARVs) became available and accessible, the medication was found to be critical in the care and management of HIV-infected individuals (Naidoo & McKerrow, 2015). Until now the benefits of ARVs have been found to outweigh the adverse risks thereof (Uthman et al., 2017).

Highly active antiretroviral therapy (HAART) is effective in delaying the progression of the HI-virus type 1 disease, preventing mother-to-child-transmission (MTCT), as well as reducing HIV-related infant death (Fasunla et al., 2014). With increased access to ARVs, the mortality of mothers and infants with HIV and/or acquired immunodeficiency syndrome (AIDS) has decreased (UNAIDS, 2017). Since the prevention of mother-to-child-transmission (PMTCT) programme has been implemented in South Africa, the percentage of HIV-positive pregnant women receiving ART has increased from 93% in 2010 to >95% in 2016 (UNAIDS, 2017). Furthermore, the number of new paediatric HIV infections in South-Africa have been reduced from 25 000 in 2010 to 12 000 in 2016 (UNAIDS, 2017). Therefore, many infants are now exposed to HIV, but not necessarily infected (Sugandhi et al., 2013). The new population of infants and

children with HIV-exposure (HIV-E) and ART exposure, should therefore be described. In order to include the new population of infants, different guidelines for feeding have been introduced.

The World Health Organization (WHO) recently established new guidelines for infant feeding practices and PMTCT in infants born to HIV-positive mothers (WHO, 2016; WHO & United Nations Children's Fund [UNICEF], 2016). Guidelines include reducing the availability of free infant formula, lifelong use of antiretrovirals (ARVs) for all pregnant or breastfeeding HIV-positive women regardless of the CD4+ cell count (WHO, 2016; WHO & UNICEF, 2016). The recommendations also include that HIV-E infants receive dual prophylaxis with Zidovudine [ZDV] (twice daily) and Nevirapine [NVP] (once daily) for the first six weeks of life, whether breastfed or formula fed and a 12 week extended use of NVP alone or dual post-exposure prophylaxis, to ensure the PMTCT during breastfeeding (WHO, 2016). Furthermore, guidelines state that mothers living with HIV and breastfeeding, should do so exclusively for the first six months, introduce appropriate complimentary feeds and may continue breastfeeding for up to 24 months or longer, while being on ART (WHO & UNICEF, 2016).

There have been concerns about the use of efavirenz (EFV), as it has been associated with heterogeneous central nervous system (CNS) defects in animal studies (Fasunla et al., 2014). EFV has also been reported to cause neural tube defects in human foetuses exposed to EFV during the first trimester of pregnancy (De Santis, Carducci, De Santis, Cavaliere & Straface, 2002; Saitoh, Hull, Franklin & Spector, 2005). However, a recent systematic review and meta-analysis reported only one neural tube defect in infants born to mothers who used EFV-based cART (combined antiretroviral therapy) compared to non-EFV based cART (Ford, Calmy & Mofenson, 2011). This is a lower rate than what is expected from the general population (Ford et al., 2011). Current evidence evaluating the outcomes in the new population of HIV-E infants indicates that no association has been found between in-utero exposure to any ART and neurodevelopmental outcomes, from nine months up to the age of two years, when using a standardized measure of infant development (Alimenti et al., 2006;

Chaudhury et al., 2017; Le Doaré, Bland & Newell, 2012; Lindsay, Malee, Brouwers & Hughes, 2007). However, subtle delays have been found in cognitive and motor functioning as well as language and behaviour in children aged between three to five years of age (Brackis-Cott, Kang, Dolezal, Abrams & Mellins, 2009). There appears to be no evidence of neurodevelopmental difficulties in neonates and very young HIV-E infants receiving ART. Although prenatal exposure to ART has not yet been linked to cleft lip and palate (CLP), some infants born with CLP may have been exposed to a double teratogenic effect, which includes the HI-virus and ARV medication (Bisto et al., 2015; Uthman et al., 2017).

CLP is the fourth most common birth defect and the most common form of craniofacial defect (De Vries et al., 2014; Kummer, 2014). Without taking race, sex, or cleft type into consideration, an overall rate of cleft occurrence of 1-in-500 to 1-in-1000 live births worldwide have been reported (Murray, 2002). Clefts are anomalies in the structure of the upper lip, alveolus, nose, hard palate and soft palate and can vary in severity (Perry & Zajac, 2017). The embryological development of the lip and the alveolus occurs around six to seven weeks of gestation and that of the palate at eight to nine weeks of gestation (Kummer, 2014). If these embryological processes are disrupted by the interaction of genetic and environmental factors, such as cigarette smoke, a cleft may occur (Kummer, 2014; Leslie & Marazita, 2013; Zajac & Vallino, 2017).

Infants with CLP may present with multiple problems and therefore effective management requires an interdisciplinary cleft team (American Cleft Palate-Craniofacial Association [ACPA], 2009). Treatment varies across centres. An example of an established treatment protocol at the largest treatment centre in South Africa is the Facial Cleft Deformities Clinic (FCDC) at the University of Pretoria. The cleft of the soft palate (including the cases of infants with unilateral or bilateral cleft lip, alveolus, and palate) are repaired at the age of five months and an isolated soft palate cleft or only a soft and hard palate cleft, is first operated on at seven months (Bütow, 1995). The first problem in this population is feeding. The first role of the speech-language therapist (SLT) in collaboration with the team's nursing professionals is therefore to assess the infant's feeding in the first few days of life and to ensure an

adequate feeding method to attain adequate nutrition (ACPA, 2009; American Speech-Language-Hearing Association [ASHA], 2017a).

Prior to surgery, the type of cleft an infant presents with determines the severity of the feeding difficulties (Kummer, 2014). Infants with an isolated cleft lip generally do not have significant feeding problems (Kummer, 2014; Zajac & Vallino, 2017). However, infants with an unrepaired complete cleft of the primary palate, including the lip and alveolus, may have some difficulty in feeding due to limitations in the ability to seal the lips and compress the nipple (Zajac & Vallino, 2017). Infants with unrepaired uni- or bilateral complete CLP or clefts of the hard and soft palate have significant feeding difficulties, due to the inability to generate sufficient negative intraoral pressure during sucking, which leads to nasal regurgitation as well as excessive air intake during feeding (Gupta, Luthra & Sharma, 2015). Due to the difficulties in oral feeding, infants use excessive amounts of energy, therefore resulting in a low calorie intake and a delay in their growth (Bessel et al., 2004; Kummer, 2014). Breastfeeding may not be possible in infants with unrepaired CLP and therefore modified nipples and feeding obturators may be necessary for successful feeding (Gupta et al., 2015; Zajac & Vallino, 2017). All of these difficulties may lead to the disruption in the efficiency of feeding and may result in poor weight gain and caregiver-infant frustration (Zajac & Vallino, 2017). Therefore, during the early stage of infancy, monitoring the nutrition and weight gain of infants with CLP is a priority (Duarte, Ramos & De Almeida Freitos Cardosa, 2016). As in the case of infants with unrepaired CLP, the feeding difficulties associated with HIV-positive infants are also well documented.

Feeding difficulties in infants with HIV infection may include problems with oral intake due to odynophagia, aspirating on liquids, lengthy feeding sessions, refusal to feed, failure to thrive (FTT) and poor weight gain, as well as weak and discoordinated tongue movements (Pressman, 2010; Pressman & Morrison, 1998). Although, infants with HIV-infection may present with oropharyngeal dysphagia (OPD) and/or oesophageal dysphagia, it appears that the oral phase is primarily affected (Lazarus, 2010; Pressman, 2010). Developmental delays, intermittent oral dysphagia related to thrush, as well as severe dysphagia due to progressive encephalopathy were also found in

infants with HIV infection (Lazarus, 2010). Infants with HIV and developmental delays are at a high risk for silent aspiration, while nasopharyngeal incoordination has also been noted in infants with HIV encephalopathy (Pressman, 2010). Furthermore, oesophageal mucosal pattern irregularity related to esophagitis, gastroesophageal reflux with oral regurgitation, as well as para-oesophageal fistulas, all contributing to problematic feeding, have been found in infants with HIV infection (Pressman & Morrison, 1998).

Although much research has been documented on the feeding characteristics of HIV-positive infants, the feeding characteristics of the HIV-E and ART-exposed infant population still require investigation. Although there appears to be no evidence of neurodevelopmental difficulties in neonates and very young HIV-E infants receiving ART, there are reports of feeding difficulties in the population. It appears that the feeding of the HIV-E infant population remains challenging due to the confounding effects of ART exposure and the effects that it may have on the infant (Evans, Humphrey, Ntozini & Prendergast, 2016). Infants receiving HAART may experience negative side effects related to feeding and swallowing, which includes nausea, vomiting, oral ulcers, gastrointestinal symptoms, diarrhoea, and fatigue (Lipman, Baker & Johnson, 2004). HIV is a state of chronic inflammation, and inflammation in the HIV-positive mother is a significant cause of preterm birth (PTB), intrauterine growth restriction, and pre-eclampsia (Mandelbrot & Sibiude, 2017). Infants exposed to HIV and ART during pregnancy are therefore at risk of low birth weight [LBW/PTB] (Mandelbrot & Sibiude, 2017). There is also an increase in PTB and concomitant LBW when mothers with a low CD4+ cell count started ART before conception in comparison to those who started ART after conception (Uthman et al., 2017; Mandelbrot & Sibiude, 2017). Maternal use of HAART is also associated with infants that are born very small for gestational age [VSGA] (Parekh et al., 2011). It therefore appears that the confounding effects of HAART and LBW/PTB can influence the feeding of infants with HIV-E.

PTB in itself is a risk factor for feeding difficulties, as preterm infants are at an increased risk for swallowing difficulties associated with immature suck-swallow and

respiration incoordination (Lefton-Greif & Arvedson, 2016). Preterm infants are also at risk for infections, growth failure, bronchopulmonary dysplasia, necrotizing enterocolitis, and neurologic sequelae in the neonatal intensive care unit (NICU), which are associated with neurodevelopmental and feeding difficulties later in life (Jadcherla et al., 2017). Infants with swallowing difficulties, regardless of the underlying etiology are at risk of aspiration pneumonia, malnutrition, developmental deficits and stressful infant-caregiver interactions (Lefton-Greif & Arvedson, 2016).

LBW shows an interactional effect with PTB, as the two conditions co-occur in most infants, but LBW in itself may show additional effects on feeding. LBW is associated with under-nutrition, a fluctuation in growth later in the infant's life, as well as growth stunting, which may have an effect on the infant's health and cognitive development (Sugandhi et al., 2013; Weaver, 2006). Infants born VSGA are at risk for developmental delays which can lead to secondary conditions that may affect their growth and nutritional well-being (Adams, Elias & Council on Children with Disabilities, 2014; Parekh et al., 2011).

HIV-E infants are also more prone to be infected with additional maternally transmitted infections, including pneumonia, pneumocystis jiroveci pneumonia and candidiasis with oesophageal and tracheobronchial disease (Evans, Jones & Prendergast, 2016; Mofenson, Oleske, Serchuck, Van Dyke & Wilfert, 2005). Respiratory difficulties in infants are a significant cause of paediatric dysphagia (Arvedson & Brodsky, 2002). Furthermore, HIV-E infants are at risk for cardiac defects, causing poor blood circulation in their bodies, which can lead to fatigue and could lead to difficulties in feeding (Arvedson & Brodsky, 2002; Lipschultz et al., 2011). It is clear that there are a number of risks for feeding in infants with HIV- and ART exposure.

Preterm infants, infants with upper-aerodigestive tract anomalies, CNS impairments, neurodevelopmental delays and craniofacial anomalies are known to be at risk for OPD (Lefton-Greif, Carroll & Loughlin, 2006). These conditions may all have an impact on the structural integrity of the oropharynx or the structural integrity of the

neuromuscular and respiratory process involved in swallowing (Lefton-Greif et al., 2006). Therefore, in addition to the risk of PTB and concomitant LBW in the population of infants with CLP and HIV-E, justifies the importance of investigating the feeding characteristics of infants with CLP who also have HIV- and ART exposure.

Available research suggests that infants with HIV-E do not experience the pervasive effects that HIV has on the CNS, compared to HIV-infected infants. However, infants with HIV-E may continue to experience the lasting effects of HIV beyond the transmission period, because of environmental factors, orphan hood, stigma, discrimination, and extreme poverty (Himmelgreen et al., 2009; Shapiro & Lockman, 2010; Sherr et al., 2014; Sugandhi et al., 2013; Swanepoel & Louw, 2010). Infants born to HIV-positive mothers are more prone to malnutrition as the caregiver's health status and caregiving ability may have adverse effects on the HIV-E infant's weight and growth (Muhangi et al., 2013; Trivedi, Anjali, Silky, Kosambiya & Shah, 2014).

Weight-for-age and length-for-age in HIV-E infants were found to be significantly lower when exposed to prolonged ART in utero compared to infants that were only exposed to a single drug prophylaxis before birth (Powis et al., 2016). However, the most significant differences in growth between HIV-E and HIV-unexposed infants were within the first month of life and minimal differences were noted later on in infancy (Isanaka, Duggan & Fawzi, 2009).

A global overlap has been found between household food insecurity (HFI) and HIV/AIDS (Kimani-Murage et al., 2011; UNAIDS, 2009). Households with a low-socioeconomic status are also more likely to have HFI and a lack of food with adequate nutritional value (Ivers & Cullen, 2011; Saaka & Shaibu, 2013). Therefore, the HIV-E infant population residing in poverty may also experience poorer health outcomes and poor nutrition related to food insecurity (Hendricks, Eley & Bourne, 2007; Sugandhi et al., 2013). Poverty also affects resources and the quality of care that the infant will receive, leading to difficulties in providing sensitive, responsive and stimulating care (Foster, 2005; UNICEF, 2006).

Mothers experience stress due to poverty, which may also be linked to instances of depression (Perez-Escamilla, 2012). It is also well documented that depression and emotional stress are highly prevalent in HIV-positive women (Bernatsky, Souza & De Jong, 2007; Lagomasino & Rodriguez, 2006; Ross, Sawatphanit & Zeller, 2009; Shannon & Lee, 2008; Sherr, Clucas, Harding, Sibley & Catalan, 2011). Perinatal- and postnatal depression as well as environmental and maternal stressors may lead to the risk of missing the infant's routine medical visits and immunizations as well as difficulties in caregiver-infant attachment, providing optimal care, multiple adverse developmental outcomes, risk of childhood behavioural outcomes, poor cognitive development, FTT and learning difficulties (Kapetonavic et al., 2009; Rochat, Mitchell & Richter, 2008). These challenges and associated factors may also have an effect on the nutrition and growth of infants with HIV-E.

From the review of literature presented, it is clear that infants with unrepaired CLP are likely to experience feeding problems, while infants who are HIV-positive also have difficulties with feeding. However, the feeding of infants with unrepaired CLP exposed to HIV, appears not to have been described in literature.

### 1.2. Problem statement and research question

The feeding difficulties of infants with unrepaired CLP are well documented (Kummer, 2014; Zajac & Vallino, 2017). There is also evidence regarding the feeding difficulties of infants with unrepaired CLP with syndromes or associated anomalies, such as Pierre-Robin sequence, Velocardiofacial syndrome, and Van der Woude syndrome (Cooper-Brown et al., 2008; Kummer, 2014; Reid, Kilpatrick & Reilly, 2006; Zajac & Vallino, 2017). There is available literature describing the impact of HIV on different aspects in the infant's life, such as development and socio-emotional challenges that may arise. There are no known studies describing the feeding characteristics of infants with unrepaired CLP and HIV-E. Therefore, the following research question is posed: Do the feeding characteristics of very young infants with unrepaired CLP and HIV-E differ significantly from the feeding characteristics of infants with unrepaired CLP only?

If differences in feeding can be found between the two groups, the results from this study may isolate the feeding difficulties of infants with HIV-E from the feeding difficulties that are expected to be found in infants with unrepaired CLP.

Feeding difficulties put infants at risk of inadequate nutrition, resulting in pervasive and far-reaching implications in the infant's life (Pressman, 2010). The activity of feeding is a crucial component in developing an optimal nutritional status, provides opportunities for mother-infant attachment and forms the basis for important developmental functions (Kummer, 2014). Therefore, early identification of feeding difficulties is essential in ensuring optimal growth and development in all infants (Arvedson & Brodsky, 2002). SLTs are specialists at screening and assessing infants for possible feeding and/or swallowing disorders (ASHA, 2016). Therefore, this research study may assist SLTs in anticipating the complex feeding difficulties that this unique population may present with, resulting in early identification of feeding disorders, and the ability to make informed decisions, appropriate referrals, and develop strategies in treating these infants timeously. The knowledge will also guide SLTs in creating awareness and educating caregivers about the feeding of the population of infants, in order to make informed decisions (ASHA, 2016). The data gained from this study may also support SLTs in the collaborative team care of the unique population of infants with unrepaired CLP and HIV-E.

## 1.3 Clarification of terminology as used in the dissertation

### Antiretroviral treatment (ART)

ART refers to the treatment of people that are infected with HIV (WHO, 2017). The standard ART consists of a combination of at least three ARV drugs, frequently called highly active ART (HAART), that are used to reduce and ultimately stop the progression of HIV and onward transmission, such as MTCT of the virus (WHO, 2017).

### Highly Active Antiretroviral therapy (HAART) or Combined antiretroviral therapy (cART)

Combined antiretroviral therapy (cART) which is now the preferred term can also be referred to as HAART (International Association of Providers of Aids Care, 2014).

cART includes a combination of different classes of ARV medication that is customized, based on factors such as the patient's viral load, the strain of the virus, the CD4+ cell count, and other considerations. HAART is able to control the viral load and can delay or prevent the onset of symptoms or progression to AIDS (National Institute of Drug Abuse, 2012). HIV-exposed (HIV-E) infants receive dual prophylaxis with ZDV (twice daily) and NVP (once daily) for the first six weeks of life, whether breastfed or formula fed, and a 12 week extended use of NVP alone or dual post-exposure prophylaxis, to ensure the PMTCT during breastfeeding (WHO, 2016).

**HIV-affected infants**

When the risk of HIV infection has passed and infants are HIV-E but uninfected, they will continue to be affected by the impact of HIV on their families and the associated psychosocial and economic difficulties (Evans et al., 2016; Sugandhi et al., 2013). Furthermore, infants with HIV-E may experience long-term adverse effects of ARV medication and are at a higher risk of acquiring infections related to HIV through communicable opportunistic infections of their parents (Sugandhi et al., 2013). In contrast to HIV-affected infants, the terms HIV-positive, HIV encephalopathy, HIV infection and HIV and AIDS were used in this dissertation to refer to infants with HIV infection.

**HIV-exposed (HIV-E) infants**

As a result of public health interventions and increased access to ART the mortality of mothers and infants with HIV/AIDS has decreased, the rates of MTCT has decreased recently and the number of new paediatric HIV infections have been reduced (Adam, 2015; Rosala-Hallas, Bartlett & Filteau, 2017; UNAIDS, 2016). This has resulted in infants that are exposed to HIV, but not necessarily infected (Sugandhi et al., 2013).

The WHO states that HIV-E infants should receive dual prophylaxis with ZDV (twice daily) and NVP (once daily) for the first six weeks of life, whether breastfed or formula fed and a 12 week extended use of NVP alone or dual post-exposure prophylaxis, for breastfed infants. The South African National Department of Health 2015 guidelines recommend that infants exposed to HIV in utero are tested at birth with the use of a

polymerase chain reaction (PCR) test, thereafter repeat HIV PCR testing should be conducted at 10 weeks, which is four weeks after completion of initial ZDV/NVP. Repeat PCR testing should be done at 18 weeks of age on all HIV-E infants without confirmed HIV infection and those that received a 12 week extended use of NVP, even if they were tested earlier (South-African National Department of Health, 2015). Infants that presented with two negative PCR test results (at birth and 10 weeks or any other time if indicated) are viewed as HIV-E uninfected (National Department of Health, 2015). If any of the two PCR tests were positive, a confirmatory PCR test should be done and ART should be initiated while waiting for confirmatory results (National Department of Health, 2015).The term HIV-E is therefore used in this dissertation as all participants were exposed to ART in utero, however, not all participants were old enough for the 10 week PCR test or 18 week confirmatory PCR test, to establish if all the participants were HIV-E but uninfected.

**Paediatric dysphagia**

Paediatric dysphagia, also referred to as a swallowing disorder, is impaired swallowing, secondary to dysfunction in the oral, pharyngeal and/or oesophageal phases of swallowing (Arvedson & Brodsky, 2002; ASHA, 2017b). The paediatric period or childhood is from birth to 18 years (Louw & Louw, 2007). In this dissertation the focus is on the early infancy stage of the paediatric period. Dysphagia can occur in any stage of the swallow, from the preparation of the liquid or solid in the oral cavity to form a bolus, to propelling the bolus posteriorly through the oral cavity, then initiating a swallow and moving the bolus through the pharynx, and lastly moving the bolus with peristaltic movements through the cervical and thoracic oesophagus, into the stomach (ASHA, 2017b). The oral phase of swallowing is primarily affected in infants with unrepaired CLP and infants that are HIV-positive (Kummer, 2014; Lazarus, 2010; Pressman, 2010). The preferred term used by SLTs is oropharyngeal dysphagia (OPD) and was introduced in the literature by Logemann in 1983 already. This term refers to difficulties in the oral and/or pharyngeal stages of swallowing (Logemann, 1983; Shaker, 2006). OPD may result from abnormalities impacting the upper oesophageal sphincter, pharynx, larynx, or tongue in isolation or in combination

(Shaker, 2006). The term is widely used in the field of Speech-Language Pathology as SLTs assess and treat patients with swallowing disorders primarily in these two stages of swallowing in contrast to oesophageal dysphagia which is treated by trained physicians (ASHA, 2004).

**Paediatric feeding difficulties**

The term overlaps with OPD but is a broader concept. According to ASHA (2017c) feeding difficulties refers to difficulty in gathering the bolus as well as preparing to suck, chew or swallow, and include difficulties in picking up the food and getting it to the mouth as well as exterior spillage of the bolus from the mouth due to the inability to keep the lips closed (ASHA, 2017c). This use of the term in the broad sense can also refer to the failure of the infant to physically feed or not attaining enough food to gain sufficient weight and grow optimally (Boon, 2014; Kedesdy & Budd, 1998). It appears that the term OPD is not used in the literature to describe the feeding difficulties of infants with unrepaired CLP. However, OPD also apply to infants with unrepaired CLP as they usually have difficulty with sucking, due to the inability to generate sufficient intra-oral pressure, which leads to nasal regurgitation when they swallow (Gupta et al., 2016). Furthermore, they also have difficulty in sealing and compressing the nipple, which might lead to exterior spillage (Zajac & Vallino, 2017). Feeding difficulties, excluding the OPD are not only managed by SLTs but can also be managed by nursing professionals, nutritionists and lactation specialists (ASHA, 2017a). In collaboration with the SLT, the nursing professionals, nutritionists and lactation specialists may ensure an adequate method for feeding and successful feeding, nutrition and weight gain (ASHA, 2017a).

## 1.4 Outline of chapters

**Chapter 1:** Introduction to the topic, problem statement, research question, rationale and terminology as used in the dissertation

**Chapter 2:** Methodology used in the research study

**Chapter 3:** Article submitted to African Health Sciences

**Chapter 4:** Summary of research results, contributions, implications and conclusion

# Chapter 2 Method

*The aim of this chapter is to provide a comprehensive description of the research methodology followed in the study in order to determine whether the feeding characteristics of very young infants with unrepaired cleft lip and palate and HIV-exposure differ significantly to that of infants with unrepaired cleft lip and palate only. The aim and objective of the study will be discussed as well as the research design, ethical considerations, participants, material and apparatus, and all the procedures throughout the study. The chapter concludes with a discussion of reliability and validity.*

## 2.1 Introduction

It is important for infants with unrepaired CLP and HIV-E to receive the needed services in order to achieve an optimal nutritional status and weight in preparation for surgery. Services should be based on the components of evidence-based practice that include the integration of the highest level of available evidence with clinical expertise and patient values (Meline, 2010). Therefore, it is important that the research design and method is planned in a functional and purposeful way in order to acquire data that will be relevant to the specific research problem of this study (Leedy & Ormrod, 2014). Furthermore, this chapter will provide a more comprehensive and extensive description of the selected procedures, than described in the article (Chapter 3).

## 2.2 Aim

The aim of this study was to determine whether the feeding characteristics of very young infants with unrepaired CLP and HIV-E differ significantly to that of infants with unrepaired CLP only.

## 2.3 Research design

A quantitative research approach was used as it objectively describes the characteristics of data in numerical terms (Maxwell & Satake, 2006). The numbers that were obtained from the data represent aspects of the observable and physical world

(Leedy & Ormrod, 2014). The Neonatal Feeding Assessment Scale [NFAS] (Viviers, 2016) and the objective measure of oral feeding skills (OFS) described by Lau and Smith (2011) are outcome measures providing quantitative data based on observation of feeding in natural circumstances.

The study was pre-experimental in nature using a static comparative group design (Leedy & Ormrod, 2014). According to Leedy and Ormrod (2014) pre-experimental research is conducted to form a tentative hypothesis that should be followed up with more controlled studies. No research that isolates the feeding difficulties of HIV-E infants with unrepaired CLP could be found during the planning, conducting and documenting of the study. A pre-experimental design is applicable to the study as the participants in the research group (RG) and control groups (CG) were not randomly selected individuals but were purposively selected (Leedy & Ormrod, 2014). The study therefore attempted to confirm an alternative hypothesis, which states that there is a statistically significant difference between the feeding of participants with unrepaired CLP and HIV-E, compared to participants with unrepaired CLP only. The design allowed for the comparison of the feeding characteristics of the RG (n=12), infants with unrepaired CLP and HIV-E, and the CG (n=13), infants with unrepaired CLP and HIV-unexposed.

### 2.4 Ethical considerations

Research ethics include encouraging honesty during the collection and reporting of the data, accurately describing the research procedures that were followed and treating all research participants equally without discrimination (Meline, 2010). Permission to conduct research and access client files at the FCDC was obtained from Prof. F.J. Jacobs, Head of the Department of Maxillo-Facial-Oral Surgery at the Faculty of Dentistry of the University of Pretoria (Appendix A). Ethical clearance was obtained from the Research Ethics Committee of the Faculty of Health Sciences (Appendix B) as well as the Research Ethics Committee of the Faculty of Humanities (Appendix C). The following research ethical principles were adhered to:

### *2.4.1 Autonomy*

When specific people are intentionally enlisted to participate in research they should be informed of the nature of the study and given an opportunity to decide whether they wish to participate (Leedy & Ormrod, 2014). All parents or caregivers provided consent on behalf of their infants to participate in the study. They had to be over the age of 18 years to provide informed consent. The parents or caregivers of the participants received sufficient information regarding the study and the usage of the data that were collected (Appendix D). They were provided with the opportunity to decide whether they wish to participate in this study, and were also informed that they could withdraw from the study at any time if they wished to do so. The parents or caregivers were then asked to provide written or verbal consent on behalf of their infant (Appendix D). If the participants' mother did not share the language the study was conducted in, which was English or Afrikaans, an interpreter (such as a nurse or staff member of the FCDC), fully comprehending the study would have been used to obtain written consent in English from the participant's mother. Written consent would then have been obtained from the interpreter as well. However, in the study all mothers were competent in the languages spoken by the researcher and was able to provide written consent before data were collected.

### *2.4.2 Beneficence*

Beneficence emphasizes the moral importance referring to what is best for the client and their well-being (Health Professions Council of South Africa [HPCSA], 2008). The avoidance of stigmatization in the case of HIV in the mother and the infant was achieved, as all infants with an unrepaired CLP under the age of three months were approached and voluntary informed consent was obtained from their primary caregivers. Participants' client files and Road to Health Booklets (RTHB) were perused in order to obtain the PCR test results to indicate the HIV-status of participants. The parents of participants were provided with verbal feedback and guidance on the feeding characteristics and possible feeding difficulties that were identified after the clinical assessment was conducted. If necessary, the appropriate referrals and

recommendations were made regarding the treatment of the feeding difficulties that were identified.

### *2.4.3 Confidentiality and anonymity*

Under no circumstances should a researcher disclaim information, either written or verbal in such a way that other people become aware of the particulars of the participants involved, unless written consent has been provided (Leedy & Ormrod, 2014). All possible participants whether HIV-E or unexposed were approached to participate in the research. The HIV-E participants were not isolated in the identification of the maternal HIV-status, as the clinic files and RTHB of all participants were perused in order to obtain information regarding their status. The names and identifying particulars of the participants were only available to the researcher, and the second rater, but were treated confidentially. Furthermore, the parents were informed that the data would be described anonymously in the research article and dissertation. To comply with the regulations of the University of Pretoria, the data are securely stored in hard copy as well as electronic format at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for 15 years.

### *2.4.4 Non-maleficence*

Researchers are expected to bring no harm to participants and the risks should not be significantly greater than the normal risks of daily living (Leedy & Ormrod, 2014; Meline, 2010). A feeding observation was completed, during the participants' scheduled visit to the clinic. The participants were therefore not inconvenienced in any way. A single typical feeding session was observed by the researcher in a private cubicle at the clinic, while the mother fed the infant. The infant's own bottle and milk was used, which prevented the risk of infection.

### *2.4.5 Honesty with professional colleagues*

The dissertation and article are presented honestly and unambiguously, without deceiving information about the nature of the results or misinterpreting any of the procedures that were followed to obtain the data.

### *2.4.6 Competence of the researcher*

The researcher is a registered SLT at the HPCSA. She is trained in conducting the data collection procedures that were followed.

## 2.5 Participants

### *2.5.1 Setting*

Since the aim of the study was to determine whether the feeding characteristics of very young infants with unrepaired CLP and HIV-E differ significantly to that of infants with unrepaired CLP only, data were collected at the FCDC at the University of Pretoria. This clinic has a patient flow of approximately 50 to 60 patients per month with an average of 750 patient consultations per annum and is the largest clinic of its kind in South- Africa (Bütow, Du Plessis, Honey & Van den Berg, 2009). The FCDC has a formal treatment protocol from birth to eighteen years of age, while patients are followed up and treated by a multidisciplinary team (Bütow, 1995; Bütow & Van Wyk, 2007). The researcher has no relationship with the clinic other than having been the principal investigator in the research project. Typical patients in this clinic present with craniofacial disorders and other difficulties. Effective management therefore involves a wide range of specialists on the cleft team.

### *2.5.2 Participant selection criteria*

Participants were selected using nonprobability purposive sampling. This sampling method, described by Leedy and Ormrod (2014) is relevant to the study as the researcher was not able to predict or guarantee that each element of the population could be represented in the sample. Purposive sampling were used as the researcher chose to use participants that represented a specific population of infants, namely infants with unrepaired CLP and HIV-E. As there are not large numbers of patients at the clinic with unrepaired CLP and HIV-E, randomised sampling was not possible. In order to ensure a reasonable sample size, and controlling for all variables, all participants willing to participate in the research was therefore selected. There were 12 participants with unrepaired CLP and HIV-E and 13 participants with unrepaired

CLP only. The total sample of participants in the study were therefore n=25. Table 1 depicts the inclusion and exclusion criteria of the two groups in the study.

**Table 1 Participant selection criteria**

| Participant selection criteria | | |
|---|---|---|
| **Groups** | **Control group (CG)** | **Research group (RG)** |
| **Inclusion criteria** | 1. Unrepaired CLP<br>2. Bottle fed<br>3. Aged 0-3 months<br>4. Mothers should be over the age of 18 years in order to provide informed consent. | 1. Unrepaired CLP and HIV-E<br>2. Bottle fed<br>3. Aged 0-3 months<br>4. Mothers should be over the age of 18 years to provide informed consent. |
| **Exclusion criteria** | 1. Infants with an isolated cleft lip<br>2. Infants with a syndrome or co-occurring disorder<br>3. Infants using tube, cup, or syringe feeding | |

Infants with syndromes, such as Pierre-Robin sequence, Velocardiofacial syndrome, and Van der Woude syndrome or any neurological disorders were excluded from the study to prevent any confounding factors that could have had an impact on feeding difficulties not associated with CLP. Close matching for cleft type and use of feeding obturators between study groups were achieved as indicated in Table 2 (on the next page).

**Table 2 Matching of study groups**

| RG<br>Infants with unrepaired CLP and HIV-E(n=12) | | | CG<br>Infants with unrepaired CLP (n=13) | | |
|---|---|---|---|---|---|
| **Participant number** | **Type of cleft** | **Use of feeding obturator** | **Participant number** | **Type of cleft** | **Use of feeding obturator** |
| **R9** | Unilateral cleft lip and alveolar ridge | No | C18 | Unilateral cleft lip and alveolar ridge | No |
| **R6** | Unilateral CLP | No | C5 | Unilateral CLP | Yes |
| **R8** | Unilateral CLP | Yes | C14 | Unilateral CLP | Yes |
| **R11** | Unilateral CLP | No | C15 | Unilateral CLP | No |
| | | | C24 | Unilateral CLP | No |
| **R1** | Bilateral CLP | Yes | C2 | Bilateral CLP | Yes |
| **R4** | Bilateral CLP | Yes | C3 | Bilateral CLP | No |
| **R12** | Bilateral CLP | No | C22 | Bilateral CLP | No |
| **R16** | Bilateral CLP | No | | | |
| **R10** | Soft palate cleft | No | C7 | Soft palate cleft | No |
| **R19** | Soft palate cleft | No | C17 | Soft palate cleft | No |
| | | | C21 | Soft palate cleft | No |
| | | | C23 | Soft palate cleft | No |
| **R20** | Cleft of the hard and soft palate | No | C18 | Cleft of the hard and soft palate | No |
| **R25** | Cleft of the hard and soft palate | No | | | |

According to Table 2, each group had three participants using a feeding obturator. Feeding obturators were only supplied at the first visit to the FCDC if a participant had a uni- or bilateral complete cleft, or a cleft of the soft palate and a 50% cleft of the hard palate. If a participant had a hard and soft palate cleft and fed well with a bottle or had a narrow cleft, no obturator was provided. Obturators are adjusted regularly to accommodate facial growth. Although a wide range of clefts were present in each group, the cleft types between the groups were closely matched.

### *2.5.3 Participant selection procedures*

After permission had been obtained from the head of the FCDC and ethical clearance was granted, the researcher was able to identify potential participants. The identification and selection of the participants were based on the inclusion criteria after the potential participants' parents or caregivers provided informed consent. Therefore, the participants were specifically selected according to the inclusion and exclusion criteria. However, this study had a small sample size due to the limited time frame that data could be collected and the limited number of infants in the population of infants with CLP and HIV-E that are available.

### *2.5.4 Participant description*

**Table 3 Participant description (n=25)**

| Characteristics | RG Infants with unrepaired CLP and HIV-E (n=12) | | | | CG Infants with an unrepaired CLP (n=13) | | | | p-values |
|---|---|---|---|---|---|---|---|---|---|
| | **Number** | **Percentage** | **-** | **-** | **Number** | **Percentage** | **-** | **-** | **-** |
| **Gender (Male)** | n= 4 | 33.30% | - | - | n= 7 | 53.80 % | - | - | 0.038* |
| | **Mean** | **Standard deviation** | **Mode** | **Range** | **Mean** | **Standard deviation** | **Mode** | **Range** | **-** |
| **Chronological age (days)** | 47. 92 | 29.42 | 31.00 | 8-89 | 37.00 | 27.91 | 33.00 | 2-89 | 0.235 |
| **Gestation age (weeks)** | 39.50 | 1.73 | 40.00 | 36-42 | 39.00 | 1.29 | 40.00 | 36-40 | 0.419 |
| **Birth weight (kg)** | 2.91 | 0.51 | 2.50 | 2.35-3.80 | 3.29 | 0.57 | 2.94 | 2.40-4.60 | 0.096 |
| **Duration of NICU stay (days)** | 11.00 | 9.88 | 14.00 | 1-39 | 6.4 | 4.94 | 2.00 | 1-14 | 0.178 |
| **Number of days before bottle fed since birth** | 9,17 | 10.38 | 1.00 | 1-39 | 2.85 | 2.03 | 1.00 | 1-8 | 0.042* |

According to Table 3 there were no significant differences between the two groups for chronological age, gestation age and birth weight, which indicates further equivalence between the two groups. Although not statistically significant, the mean birth weight of the RG was lower than that of the CG. The majority of participants in both groups were born full term, however, successful breastfeeding was not feasible from birth due to the presence of CLP. Therefore, all participants in both groups received tube feeding for at least one day. The participants in the RG experienced problems early on as they had a longer NICU hospitalisation (not statistically significant) and took on average seven days longer before they were able to wean off of tube feeding, and achieve successful bottle feeding (p=0.042). A more detailed description of the RG and CG participants can be found in Appendix E and F irrespectively. Table 4 (on the next page) describes the participants' mothers.

**Table 4 Description of participants' mothers (n=25)**

| | Mothers of RG | Mothers of CG |
|---|---|---|
| **Age of mothers** | - | - |
| **Mean** | 30.33 | 26.00 |
| **Mode** | 23.00 | 19.00 |
| **Standard deviation** | 5.40 | 5.79 |
| **Use of ARVs during pregnancy** | 100% | - |
| **Starting prior to pregnancy** | (n=11) 91.70% | - |
| **Starting in first trimester** | (n=1) 8.30% | - |

According to Table 4 all the mothers of participants in the RG were using ART during pregnancy. All participants in the RG were therefore exposed to HIV and ART during gestation. Six of the participants did not receive any ARVs as their HIV status was already confirmed negative, five participants received NVP and one received dual prophylaxis (NVP/ZDV). It is known that exposure to ART in utero could have had confounding effects on infants, such as oral thrush and increased exposure to coinfections, which could lead to additional difficulties with feeding (Evans et al., 2016). Receiving ARTs themselves may have also led to negative side effects related to feeding and swallowing (Lipman et al., 2004). None of the RG mothers reported that the participants presented with these side effects.

## 2.6 Material and apparatus

The NFAS (Viviers, 2016) (Appendix G) was used during the feeding observation of the participants. The aim of the NFAS is to identify and describe OPD in very young infants, especially when instrumental assessment procedures, such as the Modified Barium Swallow Study (MBSS) are not available or feasible. The NFAS is minimally invasive, was developed by using the Delphi method (Okoli & Pawlowski, 2004) and aims to provide a developmentally supportive approach to a feeding assessment of very young infants (Viviers et al., 2016). The NFAS is a validated outcome measure that relates to the local need of South Africa and was designed for infants from 32-39 weeks gestation as well as infants from 40 weeks to four months post-term (Viviers, 2016). A study by Viviers et al. (2017) to determine the psychometric performance of

the NFAS utilised infants with a mean corrected age of 36.89 weeks, with 32 weeks gestation to four months post term as inclusion criteria (Viviers et al., 2017). Therefore, the age range of the scale is applicable to this study. The NFAS can be used to observe breastfeeding or bottle feeding (Viviers, 2016). Furthermore, the validation study also included HIV-E infants in the sample (Viviers et al., 2017). Therefore the NFAS as outcomes measure was considered applicable to the current study. The content and items of the scale were selected based on theoretical constructs related to neonatal feeding and clinical assessments of feeding difficulties in early infancy (Viviers, 2016). Table 5 summarises the content of the NFAS and explains the rationale to use each section in the current study.

**Table 5 Content of the NFAS**

| Sections | Subsections | The importance for inclusion |
|---|---|---|
| **A. Functioning of physiological subsystems** | • Observation of heart rate (Not observed in this study as infants were not attached to a cardiac monitor.)<br>• Observation of respiratory function (Signs of abnormal respiratory functioning were identified ) | It is known that HIV-positive mothers are likely to be co-infected with opportunistic infections and that they are more likely to transmit these infections to their infants, whether the infants are infected or uninfected with HIV (Mofenson et al., 2005). These infections include bacterial infections (with pneumonia), pneumocystis jiroveci pneumonia and candidiasis (with oesophageal and tracheobronchial disease) (Mofenson et al., 2005). Respiratory difficulties in infants are a significant cause of paediatric dysphagia (Arvedson & Brodsky, 2002). Therefore, it was important to observe the participants respiratory function to compare the respiratory functioning of infants with unrepaired CLP and HIV-E to infants with unrepaired CLP only. |
| **B. State of alertness during feeding** | | It is known that HIV-E infants that were exposed to ART in utero, present with reduced left ventricle (LV) mass, LV dimension and septal wall thickness up to the age of two years (Lipschultz et al., 2011). This heart condition results in an overall loss of cardiac tissue and the inability of the septum to grow in response to the infant's increasing body surface (Lipschultz et al., 2011). Infants with heart defects may have poor blood circulation in their bodies, which can lead to fatigue (Arvedson & Brodsky, 2002). Infants with unrepaired CLP and HIV-E, that have heart defects, may cause the infant to fall asleep during feeding and result in difficulty to complete feeds and gain weight |

| Sections | Subsections | The importance for inclusion |
|---|---|---|
| | | optimally. Therefore, the state of alertness was observed in order to compare the state regulation of infants with unrepaired CLP and HIV-E to infants with unrepaired CLP only. |
| **C. Stress cues during feeding** | • State-related stress cues<br>• Motor-related stress cues<br>• Mild autonomic related stress cues<br>• Moderate autonomic-related stress cues<br>• Severe autonomic-related stress cues | The infant's ability to appropriately respond to sensory stimuli is crucial in the process of feeding readiness (Viviers et al., 2017). Therefore, by observing the state, motor, and autonomic related stress cues that the participant presented with during feeding, assisted the researcher in describing the stress cues that participants with unrepaired CLP and HIV-E may present with. |
| **D. General movement and muscle tone screening** | In this study only the sub-sections of 40 weeks term – four months post-term were used:<br>• General movement and muscle tone at rest<br>• General movement and muscle tone during feeding | The importance of good postural control for safe and efficient feeding is well documented in the research (Arvedson & Brodsky, 2002). Therefore, it was important for the researcher to observe the participant's muscle tone and postural control, to interpret the feeding characteristics (Arvedson & Brodsky, 2002). |
| **E. Oral peripheral examination** | • Oral reactions<br>• Oral structure and function<br>• Observation of cranial nerve (CN) functioning to indicate symptoms of dysfunction | Factors such as the presence of a rooting response and the quality of tongue movement can lead to an assumption on the infant's ability to suck (Arvedson & Brodsky, 2002). Infants with unrepaired CLP have structural deficits that have an effect on the infant's feeding ability (Kummer, 2014). Therefore, it was important to observe the oral reactions, structure and function as well the CN functioning to determine the feeding characteristics that infants with unrepaired CLP and HIV-E, may present with compared to infants with unrepaired CLP only. |
| **F. Clinical feeding and swallowing evaluation** | In this study only the sub- sections of 40 weeks term – four months post term were used:<br>• Non-nutritive sucking (NNS)<br>• Nutritive sucking (NS) | A normal infant will close their mouth and initiate a sucking pattern spontaneously and immediately (Arvedson & Brodsky, 2002). As mentioned it is known that infants with unrepaired CLP have difficulties with feeding (Kummer, 2014). Furthermore, it is also known that HIV-positive infants have difficulties with all phase of feeding (Pressman, 2010). Therefore, in order to determine the feeding characteristics of infants with unrepaired CLP and HIV-E, compared to infants with unrepaired CLP only, a clinical feeding and |

| Sections | Subsections | The importance for inclusion |
|---|---|---|
| | • Behavioural responses to feeding<br>• Symptoms of OPD | swallowing evaluation was conducted during the feeding observation of the participants. |

It is clear that the NFAS is a comprehensive assessment tool, and includes observation of all the necessary signs and symptoms associated with feeding. The NFAS, is scored using a binary system in order to navigate the clinician to identify and describe the presence or absence of OPD (Viviers et al., 2016). All sub-sections are scored on a YES/NO basis. YES is scored if the sign or symptom of OPD is present and NO is scored if the sign or symptom is not present. The overall outcome of each sub-section is scored YES if OPD is likely to be present and is scored NO if OPD is not likely to be present. The overall diagnostic outcome of the test is scored YES for OPD likely to be present if a score of three or more are obtained from the different sections. Appendix H shows the scoring criteria for the overall outcomes in each section of the NFAS.

The effectiveness of OFS between the two groups were measured based on the objective measure of OFS described by Lau and Smith (2011). The components included recording the volume of milk prior to the feeding session, the duration of the entire feeding session, the rate of milk transfer per minute and the total volume of milk over the entire feeding session. Any events during feeding, such as apnoea, coughing, choking, or nasal regurgitation were also noted. The aim of this measurement was to compare the effectiveness of OFS between the RG and CG.

Apparatus: An IOS stopwatch app was used to determine the duration of the oral feeding sessions in minutes.

The data-collection sheet (Appendix I) was compiled for the study from the Oral-Motor and Feeding Evaluation (Arvedson & Brodsky, 2002) as well as items from the Risk Assessment (Kritzinger, 2012). The aim was to obtain demographic and background information from the participants' parents prior to the feeding evaluation.

## 2.7 Research procedures

### *2.7.1 Pilot study*

Prior to the commencement of data collection, a pilot study was conducted. A pilot study is a preliminary version of the more in depth and extensive planned study (Maxwell & Satake, 2006). Therefore, the first two participants from the specific population of interest were included in the pilot study. According to Maxwell and Satake (2006) a pilot study serves to determine if the research procedures will be feasible to obtain data and to make adjustments where needed. Confounding variables were controlled to stay consistent across the procedures, thereby promoting the internal validity of the study. This included the researcher being the only person explaining the study to the parents of the possible participants in order to ensure understanding. The feeding was observed and questions were asked in a cubicle of the clinic. The setting was private, limiting the environmental noise. All participants were fed by their mothers using their own standardized CLP bottles and own milk during the feeding sessions. The researcher used a generalized IOS stopwatch app to determine the duration of the entire feeding session in minutes and utilised a second rater each time to ensure that the correct measurements of the volume of milk were taken.

The pilot study was conducted on the first day of data collection at the FCDC between 7:30 and 12:00 (clinic hours). The researcher included one infant in the RG and one infant in the CG to determine if the data collection procedures would be feasible in both of these groups. All of the necessary questions were obtained and the researcher did not experience any difficulties in the observation of the feeding of these two infants. Furthermore, the researcher found the NFAS to be user friendly and was able to thoroughly describe the feeding of these two infants by using this scale. The researcher made sure to obtain the volume of milk in the bottle prior to the start of feeding to ensure that the correct volume was obtained after completion of the feeding session. The researcher also set the IOS stopwatch app prior to feeding to ensure that the stopwatch was started at the correct time. The data collection procedures were conducted without any difficulties and no adjustments were needed prior to the commencement of data collection. Furthermore, as no adjustments were made, these

two participants were included in the study as the results that were obtained in the pilot study were viable.

### *2.7.2 Data collection*

Once potential participants with an unrepaired CLP between birth and three months were identified, the parents or caregivers were approached and voluntary informed consent was obtained. Questions were then asked to the parents and the client files were perused, in order to obtain the maternal HIV-status as well as the necessary pre, peri- and postnatal history. Prior to the observation of feeding, questions about the manner of feeding were asked in order to describe the type of bottle and milk that was used by the mother, the feeding intervals and positioning of the infant during feeding.

Thereafter, the researcher observed a single typical feeding session by the mother of the participant, by standing and watching in an unobtrusive way, during the participants' scheduled visit to FCDC in a private cubicle, limiting environmental noise. Participants using an obturator during feeding were observed with the obturator in place. During the feeding observation the researcher scored the two outcome measures namely the NFAS and measurement of OFS. A second rater also observed 12% of the sample with the researcher by using her own documents of the NFAS to score. Comparisons between the two sets of scores and deductions about the inter-rater reliability could be made. The second rater observed the participants on three different occasions and made sure to observe more than 10% of the sample. The second rater is a SLT, registered with the HPCSA that is trained in conducting the data collection procedures that were followed. After conclusion of the feeding observation, the results were discussed with the parents and the necessary recommendations and referrals were made. Data collection occurred for a period of 8 months.

### *2.7.3 Data analysis*

A 100% agreement between the researcher and second rater was found for the scoring of the overall outcome of the NFAS. Descriptive statistics and inferential statistics were used to analyse the data. The data were processed and analysed by using the Statistical Package for the Social Sciences as well as SAS release 9.4 (SAS Institute Inc.), which was run under Microsoft Windows for a personal computer. All

statistical tests were two sided and p-values ≤ 0.05 were considered significant. Nonparametric statistical measures were used due to the small sample size of the study and the distribution of the data. The Wilcoxon test and Fishers exact test were used to compare the participant characteristics, the results of the NFAS of the two groups, the effectiveness of OFS between the two groups, and the scores obtained from the raters to determine inter-rater reliability.

## 2.8 Reliability and validity

### *2.8.1 Reliability*

Reliability is the consistency with which a measuring tool yields a certain, consistent result when the specific concept being measured has not changed (Leedy & Ormrod, 2014). The reliability of the study was enhanced by using published outcome measures, namely the NFAS and the measurement of OFS (Lau & Smith, 2012; Viviers, 2016; Viviers et al., 2017).

The measurement of OFS has been used to assess feeding in preterm infants (Lau, Fucile & Gisel, 2012; Lau & Smith, 2011). The NFAS presents with acceptable inter-rater reliability, due to the significant agreement beyond chance achieved in the inter-rater reliability results (Viviers et al., 2017). It therefore means that more than one clinician is likely to achieve the same results when using the NFAS.

This study aimed to achieve high inter-rater reliability. This type of reliability is the extent to which two or more individuals evaluating the same performance renders identical results (Leedy & Ormrod, 2014). Another qualified SLT assessed 12% of the sample with the researcher, by using the same procedure as the researcher in order to increase the reliability of the study. The researcher also added a pilot study to test out the procedures of this study prior to commencing with data-collection, thereby further enhancing the reliability of the study.

### *2.8.2 Validity*

Validity of a measurement tool is the extent to which it measures what it is intended to measure and providing scores whose differences reflect the true differences of the

variable that is being measured, and no random or constant mistakes (Bless & Higson-Smith, 2004; Leedy & Ormrod, 2014).

The NFAS was validated against the gold standard, the MBSS, and the preliminary performance of the scale was described as promising (Viviers et al., 2017). Criterion validity refers to how well a test can predict a particular outcome (Maxwell & Satake, 2006). The high sensitivity and specificity of the NFAS shows its ability to accurately describe and identify OPD, as well as recognising the absence of OPD, therefore resulting in very few false positives (Viviers et al., 2017). The diagnostic accuracy (85 %) of the NFAS further strengthens the criterion validity (Viviers et al., 2017).

# Chapter 3 Research Article

*This article was submitted to the journal, African Health Sciences. The format of the article is that of the journal and differs from the rest of the dissertation.*

**Feeding difficulties in infants with unrepaired cleft lip and palate and HIV-exposure**

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**Abstract**

**Background:** There is limited description of the feeding characteristics of infants with unrepaired cleft lip and palate (CLP), exposed to HIV, but not necessarily infected.

**Objective:** To determine whether the feeding characteristics of very young infants with unrepaired CLP and HIV-exposure (HIV-E) differ significantly to that of infants with unrepaired CLP only

**Method:** A two-group comparative design with a validated measure, the Neonatal Feeding Assessment Scale was used. The effectiveness of oral feeding skills (OFS) between the two groups were measured based on the objective measure of OFS by Lau and Smith (2011). Twelve participants with unrepaired CLP and HIV-E and 13 with unrepaired CLP were matched according to cleft type and use of feeding obturator. There were no differences between the groups for mean age, birth weight and gestation. Participants were between two and 89 days old, bottle fed, and had no syndrome/co-occurring disorder.

**Results:** Nine (75%) participants in the research group (RG) and only two (15.38%) in the control group (CG) presented with the likelihood of oropharyngeal dysphagia (OPD). Apart from feeding difficulties as a result of structural impairment, the RG showed symptoms of neurological involvement.

**Conclusion:** The RG presented with distinctive symptoms of OPD. More studies using different measuring tools, such as the Modified Barium Swallow Study are required to strengthen the evidence.

**Keywords:** HIV-exposed (HIV-E) infants, unrepaired cleft lip and palate, feeding difficulties. (Only three allowed in the journal).

**Introduction**

Prior to the availability of antiretroviral treatment (ART), infants born from HIV-positive mothers were infected with HIV[1]. Since the prevention of mother-to-child-transmission

(PMTCT) programme has been gaining success in South Africa, the percentage of HIV-positive pregnant women receiving ART, has increased from 93% in 2010 to >95% in 2016[2]. Therefore, ARTs have become accessible to more pregnant women, and their use during pregnancy was found to be safe in trials to date[3]. In 2016 the World Health Organization (WHO) established new guidelines for infant feeding and PMTCT in infants born to HIV-positive mothers[4,5]. Guidelines include reducing the availability of free infant formula; lifelong use of ARTs for all pregnant or breastfeeding HIV-positive women, regardless of the CD4+ cell count[4,5]. HIV-exposed (HIV-E) infants should receive dual prophylaxis with daily Zidovudine (ZDV) and Nevirapine (NVP) for the first six weeks of life, whether breastfed or formula fed, and a 12-week extended use of NVP alone or dual treatment (ZDV/NVP), to ensure PMTCT during breastfeeding[5]. Guidelines state that mothers on ARTs may breastfeed exclusively for the first six months, introduce appropriate complimentary feeds and may continue breastfeeding for up to 24 months or longer[4].

With the new ART-era, increased numbers of women of childbearing age are accessing combined antiretroviral therapy (cART) and conceive on efavirenz-based cART[6], resulting in many infants being exposed to HIV, but not necessarily infected[7,8]. To date no association has been found between in-utero exposure to any ART and neurodevelopmental outcomes, in early infancy and up to the age of two years[9]. However, subtle delays have been found in cognitive and motor functioning as well as language and behaviour in children three to five years of age[10]. Although prenatal exposure to any form of ART has not yet been linked to cleft lip and palate (CLP), infants born with the condition may have been exposed to a double teratogenic effect, which includes the HI-virus and ART medication[11]. As two separate groups, feeding difficulties of infants with unrepaired CLP, and infants with HIV infection are described in

great detail in the literature. There appears to be no reports on feeding characteristics of infants with unrepaired CLP exposed to HIV, receiving ART.

The type of cleft determines the severity of feeding difficulties before repair[12]. Isolated cleft lip generally does not cause significant feeding difficulties[12,13]. Infants with clefts of the primary palate, including the lip and alveolus, might have difficulty to obtain a lip seal and nipple compression[13]. Infants with uni- or bilateral CLP or clefts of the hard and soft palate have significant feeding difficulties due to the inability to generate sufficient negative intraoral pressure during sucking, leading to nasal regurgitation and excessive air intake during feeding[14]. Breastfeeding in infants with unrepaired CLP may not be possible, and modified nipples and feeding obturators may be necessary for successful feeding[14].

Specific feeding difficulties associated with HIV-infected infants are also well-known, such as problems with oral intake due to odynophagia, aspiration, lengthy feeding sessions, refusal to feed, failure to thrive and weak/discoordinated tongue movements[15]. Although all swallowing phases might be affected in infants with HIV, the oral phase appears to be primarily affected in infants infected with HIV and infants with unrepaired CLP[12,15].

Feeding methods used with HIV-E infants remain challenging due to the confounding effects of ART exposure and the resulting effects on the fetus[7,16]. Infants exposed to HIV and ART are at risk of low birth weight and preterm birth (LBW/PTB)[17]. Breastfeeding readiness may be compromised at birth and later introduction of breastfeeding is often unsuccessful. HIV-E infants may continue to experience effects of HIV in their families, due to psychosocial and economical challenges[18]. Therefore, the aim of this study was to determine whether the feeding characteristics of very young infants with unrepaired CLP and HIV-E differ significantly to that of infants with unrepaired CLP only. Results from this study may isolate specific feeding

characteristics associated with HIV-E infants with CLP. The information may assist speech-language therapists and other healthcare professionals to anticipate feeding support for this unique population, resulting in early identification of feeding difficulties, and the development of strategies to assist parents effectively.

## Methods

### Setting and participants

The study was conducted at the Facial Cleft Deformities Clinic (FCDC) of an academic dental hospital in Pretoria, South Africa. The clinic has an established CLP treatment protocol from birth to eighteen years, during which patients are followed-up by a multidisciplinary team[19]. A unilateral or bilateral cleft lip, alveolus, and clefts of the soft palate are repaired at five months and an isolated soft palate cleft or only a soft palate and hard palate cleft, is first operated on at seven months[20]. Nonprobability purposive sampling was used to select (n=25) participants. The study was pre-experimental and exploratory in nature using a two-group design. Pre-experimental research is conducted to form a tentative hypothesis that should be followed up with more controlled studies[21]. The study therefore attempted to confirm an alternative hypothesis, which proposed that there was a statistically significant difference between the feeding of participants with unrepaired CLP and HIV-E, compared to participants with unrepaired CLP only. The design allowed for the comparison of the feeding characteristics of infants with unrepaired CLP and HIV-E (n=12) to infants with CLP only and HIV-unexposed (n=13). All parents of infants with unrepaired CLP, who were bottle fed and ≤3months old were asked to participate. Infants using tube, cup, or syringe feeding, and with syndromes or co-occurring disorders, were excluded. Close matching for cleft type and use of feeding obturators between study groups were achieved(Table 1).

**Table 1 Matching of study groups**

| Research Group (RG) Infants with unrepaired CLP and HIV-E (n=12) | | | Control Group (CG) Infants with unrepaired CLP (n=13) | | |
|---|---|---|---|---|---|
| **Participant number** | **Cleft type** | **Feeding obturator** | **Participant number** | **Cleft type** | **Feeding obturator** |
| **R9** | Unilateral cleft lip and alveolar ridge | x | C18 | Unilateral cleft lip and alveolar ridge | x |
| **R6** | Unilateral CLP | x | C5 | Unilateral CLP | √ |
| **R8** | Unilateral CLP | √ | C14 | Unilateral CLP | √ |
| **R11** | Unilateral CLP | x | C15 | Unilateral CLP | x |
| | | | C24 | Unilateral CLP | x |
| **R1** | Bilateral CLP | √ | C2 | Bilateral CLP | √ |
| **R4** | Bilateral CLP | √ | C3 | Bilateral CLP | x |
| **R12** | Bilateral CLP | x | C22 | Bilateral CLP | x |
| **R16** | Bilateral CLP | x | | | |
| **R10** | Soft palate cleft | x | C7 | Soft palate cleft | x |
| **R19** | Soft palate cleft | x | C17 | Soft palate cleft | x |
| | | | C21 | Soft palate cleft | x |
| | | | C23 | Soft palate cleft | x |
| **R20** | Cleft of the hard and soft palate | x | C18 | Cleft of the hard and soft palate | x |
| **R25** | Cleft of the hard and soft palate | x | | | |

CLP, Cleft lip and palate; HIV-E, HIV-exposure

Remove extra spacing between rows as in chapter 2

According to Table 1, each group had three participants using feeding obturators. Feeding obturators were supplied at their first visit to the FCDC if participants had uni- or bilateral complete clefts or soft palate and 50% hard palate clefts. If the participant had a soft and hard palate cleft and fed well with a bottle, or had a narrow cleft, no obturator was provided. Obturators are adjusted regularly to accommodate facial growth. Although a wide range of clefts were present in each group, the type of clefts between the groups were closely matched.

**Table 2 Participant description (n=25)**

| Characteristics | RG Infants with unrepaired CLP only and HIV-E (n=12) | | | | CG Infants with an unrepaired CLP (n=13) | | | | p-values |
|---|---|---|---|---|---|---|---|---|---|
| | **Number** | **Percentage** | **-** | **-** | **Number** | **Percentage** | **-** | **-** | **-** |
| **Gender (Male)** | n= 4 | 33.30% | - | - | n= 7 | 53.80 % | - | - | 0.038* |
| | **Mean** | **Standard deviation** | **Mode** | **Range** | **Mean** | **Standard deviation** | **Mode** | **Range** | **-** |
| **Chronological age (days)** | 47. 92 | 29.42 | 31.00 | 8-89 | 37.00 | 27.91 | 33.00 | 2-89 | 0.235 |
| **Gestation age (weeks)** | 39.50 | 1.73 | 40.00 | 36-42 | 39.00 | 1.29 | 40.00 | 36-40 | 0.419 |
| **Birth weight (kg)** | 2.91 | 0.51 | 2.50 | 2.35-3.80 | 3.29 | 0.57 | 2.94 | 2.40-4.60 | 0.096 |
| **NICU stay (days)** | 11.00 | 9.88 | 14.00 | 1-39 | 6.4 | 4.94 | 2.00 | 1-14 | 0.178 |
| **Number of days before bottle fed since birth** | 9,17 | 10.38 | 1.00 | 1-39 | 2.85 | 2.03 | 1.00 | 1-8 | 0.042* |

NICU, Neonatal intensive care unit

Table 2 shows no significant differences between the two groups for chronological age, gestation age and birth weight, which indicates further equivalence between the two groups. Although not statistically significant, the mean birth weight of the research group (RG) was slightly lower than that of the control group (CG). The majority of participants in both groups were born full term, but breastfeeding was not feasible due to the presence of CLP. All participants were tube fed for at least one day. The RG experienced more problems early on as they had a longer NICU hospitalisation (not statistically significant) and took on average seven days longer before being able to wean off of tube feeding, and achieve successful bottle feeding (p=0.042).

**Table 3 Description of participants' mothers (n=25)**

| | Mothers of RG | Mothers of CG |
|---|---|---|
| **Age** | - | - |
| **Mean** | 30.33 | 26.00 |
| **Mode** | 23.00 | 19.00 |
| **Standard deviation** | 5.40 | 5.79 |
| **Use of ARVs during pregnancy** | 100% | - |
| **Starting prior to pregnancy** | (n=11) 91.70% | - |
| **Starting in first trimester** | (n=1) 8.30% | - |

ARVs, Antiretrovirals

According to Table 3 all RG mothers were using ARVs during pregnancy. All RG participants were therefore exposed to HIV and ARVs during gestation. Six participants did not receive any ARVs after birth as their HIV status was already confirmed negative, five participants received NVP and one received (NVP/ZDV). It is known that exposure to ART in utero can have confounding effects on infants, such as oral thrush and increased exposure to coinfections, which could lead to additional feeding difficulties[16]. Receiving ARVs can also lead to negative side effects related to feeding and swallowing[22]. None of the RG mothers reported that the participants presented with these side effects.

**Material**

The Neonatal Feeding Assessment Scale (NFAS), a locally developed tool, was used to observe participants' feeding. The NFAS aims to identify and describe oropharyngeal dysphagia (OPD) in very young infants, and address needs in resource-constrained countries by reducing the need for Modified Barium Swallow Studies (MBSS)[23]. The NFAS consists of six sections including observing the infant's physiological status, state of alertness, stress cues, general movement and muscle tone during feeding, an oral peripheral evaluation and a clinical feeding and swallowing evaluation[23]. The oral peripheral evaluation entails observations of the infant's oral reactions, oral structure and function, and cranial nerve function to indicate possible symptoms of OPD[23]. The clinical feeding and swallowing evaluation includes observations of non-nutritive sucking (NNS), nutritive sucking (NS), and behavioural responses to feeding, and specific symptoms of OPD[23]. Symptoms of OPD may include uncoordinated tongue movements during NNS and NS, poor/weak sucking response, and coughing or gurgling during/after swallowing[23]. Criterion validity and inter-rater reliability of the NFAS was established with very young LBW/PTB infants[24]. The NFAS was supplemented with an objective measure. The effectiveness of oral feeding skills (OFS) between the two groups were

measured by using an objective measure of OFS and was determined by recording the volume of milk prior to feeding, the feeding session duration, the rate of milk transfer per minute, and the total milk volume consumed over the entire feed[25].

**Procedures**

Institutional ethical clearance (protocol #43/2017; GW20170310HS) was obtained. Potential participants were identified and voluntary informed consent was requested from mothers (≥18 years) on behalf of their infants. A pilot study was conducted on the first two participants. As no adjustments were made to the data collection instruments and procedures, the pilot participants were included in the main study. Data were collected prospectively by the first author. Clinic files were reviewed and parents briefly interviewed to obtain relevant demographic information and background history. Prior to the feeding evaluation mothers were guided by the team's nursing professionals on the most appropriate feeding method for their infants. The prosthodontist also evaluated the infant should a feeding plate be required. An oral peripheral evaluation was conducted by the researcher using gloves and an adjustable light. The purpose was to determine the presence or absence of specific oral reflexes and observing the oral structure and function. The observation of cranial nerve function to indicate possible symptoms of dysfunction such as a weak cry, weak lip seal, facial asymmetry and reduced tongue movements were conducted prior to and during the feeding session. A single bottle-feeding session by the mother during the participant's scheduled appointment at the FCDC was observed. The observation was conducted in a private cubicle, which limited environmental sound. Participants were fed using their own bottles and milk, either formula or expressed breast milk. The researcher used a generalised IOS stopwatch app to determine the duration of the feeding session. The researcher recorded the volume of milk in the bottle prior to the start of feeding to ensure that the correct volume was obtained after completion of the feeding

session. The volume of milk consumed, duration of the feeding session and the rate of milk transfer as described by Lau and Smith[26] were calculated separately to determine the effectiveness or oral feeding in the participants. Some participant's feeds were shorter than five minutes which meant that the combined proficiency could not be measured to determine the level of OFS as intended. The combined proficiency of feeding is the volume of milk taken during the first five minutes divided by the total volume of milk prescribed in millilitres and the rate of milk transfer per minute[25]. The aim of this measurement was therefore to compare the effectiveness of OFS between the RG and CG as described in the results. After completion of the feeding session the outcomes were discussed with parents and recommendations and referrals were made.

**Data analysis**

The NFAS is scored using a binary system (YES/NO) for each item in the six subsections to navigate clinicians to identify the presence/absence of OPD[23]. All the items of the different sub-sections were scored YES if the signs/symptoms were observed during feeding or NO if absent. The overall outcome of each sub-section was scored YES if OPD was likely to be present and NO if OPD was not likely to be present. The overall diagnostic outcome of the test is scored YES for OPD likely to be present if a score of three or more was obtained from the different sub-sections. A second rate observed three (12%) participants. The two sets of scores were compared to determine inter-rater reliability. A 100% agreement between the researcher and second rater was found for scoring of the overall outcome of the NFAS. Data were analysed by using the Statistical Package for the Social Sciences (SPSS) and SAS release 9.4 (SAS Institute Inc.). All statistical tests were two-sided and $p \leq 0.05$ was considered significant. Nonparametric statistical measures were used due to the small sample size and the distribution of data. The Wilcoxon test and Fishers exact test were used to compare participant

characteristics, results of the NFAS and OFS between the two groups, and the scores obtained from the two raters to determine inter-rater reliability.

**Results**

**Table 4 Overall outcome of the Neonatal Feeding Assessment Scale**

| Outcome | RG Infants with unrepaired CLP and HIV-E (n=12) | CG Infants with unrepaired CLP (n=13) | Total | p-value |
|---|---|---|---|---|
| **Dysphagia likely to be present** | 75.00 % (n=9) | 15.38% (n=2) | 11 | |
| **Dysphagia NOT likely to be present** | 25.00 % (n=3) | 84.62% (n=11) | 14 | 0.0048* |
| **Total** | 12 | 13 | 25 | |

According to Table 4 there was a statistically significant difference between the number of participants likely to present with OPD and the number not likely to present with OPD, irrespective of the RG or CG. Therefore, the results indicated that participants in the RG were more likely to present with OPD than their HIV-unexposed counterparts.

**Table 5 Outcomes of the sub-sections of the Neonatal Feeding Assessment Scale**

| Sub-sections | Outcome | Infants with unrepaired CLP and HIV-E (n=12) | Infants with unrepaired CLP only (n=13) | p-values |
|---|---|---|---|---|
| Section A: Functioning of physiological subsystems | Dysphagia likely to be present | 25.0% (n=3) | 23.1% (n=3) | 0.248 |
| | Dysphagia NOT likely to be present | 75.0% (n=9) | 76.9% (n=10) | |
| Section B: State of alertness | Optimal state of alertness | 41.7% (n=5) | 46.2% (n=6) | 0.4147 |
| | Non-optimal state of alertness | 58.3% (n=7) | 53.8% (n=7) | |
| Total outcome of section A & B | Dysphagia likely to be present | 16.7% (n=2) | 15.4% (n=2) | |
| | Dysphagia NOT likely to be present | 83.3% (n=10) | 84.6 (n=11) | 0.488 |
| Section C: Stress cues | Dysphagia likely to be present | 66.7% (n=8) | 30.8% (n=4) | |
| | Dysphagia NOT likely to be present | 33.3% (n=4) | 69.2% (n=9) | 0.115 |
| Section D: General movement and muscle tone at rest and | Dysphagia likely to be present | 16.7% (n=2) | 7.7% (n=1) | 0.564 |
| | Dysphagia NOT likely to be present | 83.3% (n=10) | 92.3% (n=12) | |
| Section E: Oral peripheral evaluation | Dysphagia likely to be present | 91.7% (n=11) | 46.2% (n=6) | 0.025* |
| | Dysphagia NOT likely to be present | 8.3% (n=1) | 53.8% (n=7) | |
| Section F: Clinical feeding and swallowing evaluation | Dysphagia likely to be present | 91.7% (n=11) | 30.8% (n=4) | 0.008* |
| | Dysphagia NOT likely to be present | 8.3% (n=1) | 69.2% (n=9) | |

A statistically significant difference between the likelihood of dysphagia was obtained in the overall outcome of the NFAS (Table 4), but Table 5 shows sub-sections A to D were not statistically significant different between the two groups. The two groups were therefore mostly similar regarding their physiological sub-systems during feeding. Although no statistically significant difference were found between the states of alertness of the two groups, most of the participants in the CG were in an optimal state of alertness during feeding whereas most of the RG were in a non-optimal state, such as deep- and light sleep, drowsy, alert, agitated or crying. No statistically significant difference was found between the stress cues of the two groups,

however, more participants in the RG showed stress cues. These included a panicked or worried look, straining or squirming, and skin colour changes. The majority of participants in both groups presented with normal general movement and muscle tone during feeding, but one participant in the CG and two (16.67%) in the RG presented with increased stiffness during feeding. Statistically significant differences between the groups were found for sub-sections E and F, emphasising unique feeding difficulties of the participants in the RG. Specific oral peripheral deviations in section E were as follows: The majority of participants in both groups did not have a sufficient lip seal or closure at rest or during feeding. All participants had structural deviations of the lip and palate or of the palate only. One RG participant presented with microglossia. Participants with OPD in both groups presented with a cycle of <10 sucks per burst for NNS and NS. The following deviations were observed in section F: The RG with OPD did not show transverse tongue reactions or a rooting response, showed delayed initiation of sucking, uncoordinated tongue movements, and gurgling during feeding, whereas the CG participants did not show any of these symptoms. Table 6 depicts a comparison of the effectiveness of the OFS calculated during the feeding session.

**Table 6 Comparison of the effectiveness of oral feeding skills between the two groups**

| | Infants with unrepaired CLP and HIV-E (n=12) | | | Infants with an unrepaired CLP (n=13) | | | p-values |
|---|---|---|---|---|---|---|---|
| **OFS** | **Mean** | **Standard deviation** | **Range** | **Mean** | **Standard deviation** | **Range** | **p-values** |
| **Volume of milk presented by the mother prior to the feeding session (ml)** | 165.42 | 74.15 | 50-260 | 95.54 | 50.58 | 30.00-200.00 | 0.022* |
| **Duration of feeding (minutes)** | 7.89 | 6.70 | 2.25-25.00 | 7.96 | 6.24 | 1.43-25.00 | 0.765 |
| **Rate of milk transfer/minute (ml)** | 4.80 | 7.05 | 1.42-26.67 | 7.97 | 8.50 | 2.00-34.96 | 0.0133* |
| **Total milk volume consumed during the entire feed (ml)** | 24.00 | 16.91 | 5.00-60.00 | 41.08 | 18.98 | 15.00-80.00 | 0.025* |

ml, millilitres

Table 6 shows that the RG mothers presented more milk to the infant prior to the feeding session. No clarification can be offered for the increased milk volume in the bottles, as the groups did not differ in age, and all mothers were provided with the same guidelines on the volume of milk according to the infant's age at the first visit to FCDC (personal communication with Sr Du Plessis and Sr van den Berg, community health nurses at the FCDC). In approximately the same time, participants in the RG had a smaller intake of milk compared to the CG. The RG were most likely to present with OPD and consumed the least amount of milk. Participants in the RG most likely to present with OPD as indicated by the NFAS, also consumed the least amount of milk as determined by the effectiveness of OFS, as compared to the CG. It therefore appears that participants identified with OPD on the NFAS were also the same participants with the lowest effectiveness of OFS. The results of the two measuring instruments therefore appear to supplement one another, thereby increasing the reliability of

the findings. It appears that the results of the two measuring instruments supplemented one another, thereby increasing the reliability of the findings.

**Discussion**

The purpose of this study was to investigate whether differences exist between the feeding characteristics of infants with unrepaired CLP and HIV-E, compared to infants with unrepaired CLP only. The type of cleft the participants presented with and the use of feeding obturators were matched. A different variety of clefts were present in each group. On average the groups were similar in age, gestation age and birth weight, which are factors known to influence feeding[26]. Confounding factors contributing to a biased distribution of feeding difficulties between the two groups were therefore limited.

A clear difference was found between the overall outcome of the presence of OPD in the RG and CG. OPD was expected in both groups as they all have an unrepaired CLP, however, more participants in the RG presented with OPD compared to the CG. Participants with OPD in both groups presented with inadequate or weak lip seal and <10 sucks per burst before pausing during the NNS and NS. This was expected as infants with unrepaired CLP are known to have difficulties with nipple compression and to generate sufficient negative intraoral pressure during sucking[12,13,14]. As expected and also described in the CLP literature, all participants in this study were bottle fed as breastfeeding was not possible[13,14]. Additional feeding difficulties, not associated with unrepaired CLP and not detected in the CG, were observed in RG participants with OPD. Participants with OPD in the RG did not display rooting responses, or transverse tongue reactions, and showed uncoordinated tongue movements and delayed sucking initiation. HIV-positive infants are known to present with weak or uncoordinated tongue movements[15]. Delayed initiation of sucking is associated with an absence of rooting and uncoordinated tongue movements[27]. The rooting response and transverse tongue reaction are

both reflexes important during the normal process of feeding and swallowing in very young infants[27]. The hypoglossal nerve, involved in the regulation of coordinated tongue movements, plays an integral part in oral feeding[27,28]. In addition, the length of NICU stay and subsequent increased non-oral feeding in some of the RG participants could also have contributed to the absence of a rooting response and uncoordinated tongue movements. The presence or absence of specific oral reflexes facilitated by the cranial nerves could be indicative of an infant's neurological stability[29]. Normal sucking, swallowing, and respiratory functions are controlled by the central pattern generators in the brain[30]. It is assumed that NS will be sufficient when the maturity levels of these central pattern generators are adequate[31]. It therefore appears that the feeding difficulties of the RG with OPD were not only as a result of structural abnormalities, but showed symptoms of possible neurological involvement.

Safe and successful bolus transportation relies on the timely synchronization of sucking[31]. Therefore, due to delayed initiation and poor synchronization of sucking, the rate of milk transfer per minute and the total volume of milk consumed by the RG with OPD were less. Agreement between the results of the two measuring tools were therefore found.

In contrast to other studies of young infants with exposed to HIV[7,32,33], no cases of pneumonia or pneumocystis jiroveci pneumonia (PJP) or any cardiac defects were found in the RG. The nature of the clinic could have had an impact on this, as the FCDC is an outpatient clinic and infants with pneumonia, PJP or cardiac defects would most likely have been inpatients.

The extended tube feeding duration and prolonged NICU-stay found in the RG were the first signs of differences between the study groups and may therefore be viewed as predictive risks in the early identification of OPD in HIV-E infants with CLP. Feeding is a complex process and the ability to feed successfully from birth has an effect on caregiver-infant attachment, which is essential to an infant's development[27]. Feeding and swallowing difficulties can have

serious impacts on weight gain, growth, and development[34]. Early identification and intervention of OPD in infants with CLP and HIV-E is essential.

## Conclusion

In comparison with the few CG participants identified with OPD, the RG presented with unique symptoms of OPD and difficulties with OFS. Participants in the RG were not infected with HIV at the time of data collection, but were exposed to HIV and ARTs in utero and some after birth as well. It appears that HIV-E participants with unrepaired CLP and OPD presented with a unique feeding profile, suggesting possible neurological involvement in the symptoms of their feeding difficulties. At this stage there is no known study isolating the feeding difficulties of HIV-E infants with unrepaired CLP. The sample size of the study was small, but is expected as this population may never be available in large numbers. Since larger sample sizes are unlikely to be found in the population of infants with unrepaired CLP and HIV-E, more studies using other measuring tools for feeding, such as the MBSS are required to confirm the results and increase the evidence of the present study. The results of this exploratory study confirm the tentative alternative hypothesis that there were significant differences between the feeding of the RG and CG.

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## Competing interests

The authors declare that they have no financial or personal competing interests that may have influenced them in writing this article.

**Authors' contributions**

E.V. wrote the manuscript and collected and analysed the data. E.K. and A. K. assisted with the design of the study and the writing of the manuscript.

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**Tables**

# Chapter 4 Contributions, Implications and Conclusion

*The aim of this chapter is to provide a summary of the results, discuss the contributions and implications of the study and end with a conclusion. A critical evaluation of the strengths and limitations of the study as well as recommendations for the direction of future research are discussed. The chapter concludes with an overall view of the topic that was studied.*

## 1.1 Summary of research results and contributions of the study

The purpose of this study was to determine whether the feeding characteristics of very young infants with unrepaired CLP and HIV-E differ significantly to that of infants with unrepaired CLP only. A wide variety of clefts were present in the sample. However, the type of cleft the participants presented with and the use of feeding obturators were closely matched. On average the groups were similar in age, gestation age, and birth weight. These are factors known to influence feeding (Jadcherla, 2016). Confounding factors contributing to a biased distribution of feeding difficulties between the two groups were therefore limited.

A clear difference was found between the overall outcome of the presence of OPD in the RG and CG. Nine (75%) participants in the RG and only two (15.38%) in the CG presented with the likelihood of OPD. Participants with OPD in both groups presented with inadequate or weak lip seal and <10 sucks per burst before pausing during the NNS and NS. Apart from feeding difficulties as a result of structural impairment, the RG showed symptoms of neurological involvement. The RG consumed less milk in the same time than the CG. The RG experienced more problems since birth as they were in the NICU for longer and took longer to achieve successful bottle feeding.

No statistically significant differences were found between the two groups for sub-sections A to D of the NFAS, which included, functioning of physiological subsystems, state of alertness, stress cues and general movement and muscle tone during feeding. However, statistically significant differences were found for sub-sections E and F, which included an oral peripheral evaluation and clinical feeding and swallowing evaluation, thereby indicating that participants in the RG had additional feeding

difficulties not found in the CG. A total of 75% (n=9) of participants in the RG presented with the likelihood of dysphagia, whereas only 15, 38% (n=2) of the CG participants were likely to present with dysphagia. Therefore, a clear difference was found between the overall outcome of the presence of OPD in the RG and CG. OPD was expected in both groups as they all had an unrepaired CLP, but far more participants in the RG presented with OPD compared to the CG. Additional feeding difficulties not associated with unrepaired CLP and not detected in the CG, were observed in the RG. Figure 1 (on next page) depicts the feeding difficulties that were observed in the participants with OPD in both groups.

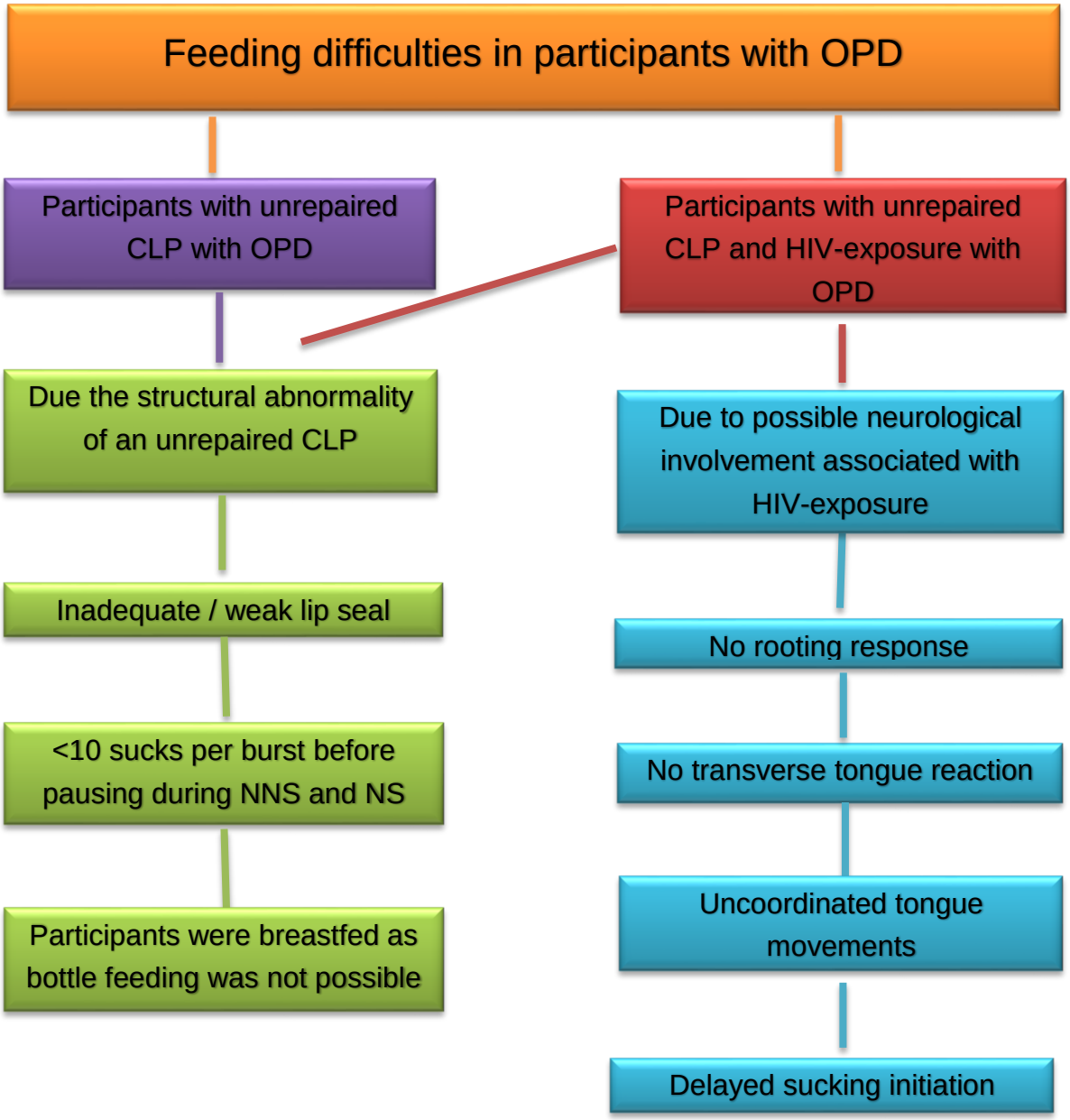


**Figure 1 Feeding difficulties in participants with OPD**

As depicted in Figure 1, the RG participants presented with additional feeding difficulties to the problems found in the study and also described in the literature for young infants with unrepaired CLP. The feeding difficulties associated with unrepaired CLP in both groups with OPD were expected, as infants with unrepaired CLP are known to have difficulties in compressing the nipple and generating sufficient negative intraoral pressure during sucking, which leads to nasal regurgitation (Kummer, 2014;

Gupta et al., 2015; Zajac & Vallino, 2017). HIV-positive infants are known to present with weak or uncoordinated tongue movements (Pressman, 2010). Delayed initiation of sucking is associated with an absence of rooting and uncoordinated tongue movements (Arvedson & Brodsky, 2002). The rooting response and transverse tongue reaction are both reflexes important during the normal process of feeding and swallowing in very young infants (Arvedson & Brodsky, 2002). The hypoglossal nerve, involved in the regulation of coordinated tongue movements, plays an integral part in oral feeding (Arvedson & Brodsky, 2002; Delaney & Arvedson, 2008). The tongue is required to move the bolus posteriorly into the pharynx with a propelling movement (Gingrich, Stierwalt, Hageman, LaPointe, 2012). Therefore, if the participants in the RG presented with uncoordinated tongue movements, the posterior movement of the bolus will not always be sufficient. The presence or absence of specific oral reflexes facilitated by the cranial nerves could be indicative of an infant's neurological stability (Hall, 2001). Normal sucking, swallowing, and respiratory functions are controlled by the central pattern generators in the brain (Amaizu, Shulman, Schanler & Lau, 2007). Swallowing and sucking also requires neuromuscular control in order to achieve successful bolus transport into the oesophagus (Matsuo & Palmer, 2009). It is assumed that NS will be sufficient when the maturity levels of these central pattern generators are adequate (Lau, 2016).

It therefore appears that the additional feeding difficulties of the RG with OPD were not only as a result of structural abnormalities, but showed possible neurological involvement. HIV-positive infants are at risk of developing encephalopathy as the HI-virus may enter the CNS early on during infection (Pressman, 2010). HIV-encephalopathy can be seen when a child fails to, or shows difficulty to attain specific developmental milestones, when there is loss of intellectual ability, impaired brain growth, acquired microcephaly, or an acquired symmetric motor deficit (Tardieu et al., 2000). Infants in the RG of this study were not necessarily infected with HIV, but were exposed to HIV and ART in utero and some infants after birth as well. According to the literature, no association has been found between in-utero ART exposure and neurodevelopmental outcomes from nine months up to the age of two years (Alimenti et al., 2006; Chaudhury et al., 2017; Le Doaré et al., 2012; Lindsay et al., 2007;

Williams et al., 2010). However, it appears that this study is one of the first known studies that shows developmental difficulties, in particular OPD, in the very young HIV-E infant population.

Safe and successful bolus transportation relies on the timely synchronization of sucking (Lau, 2016). Therefore, due to delayed initiation and poor synchronization of sucking, the rate of milk transfer per minute and the total volume of milk consumed by the RG with OPD were less compared to the CG. On average, the RG mothers also presented more milk to their infants prior to the feeding session. No clarification can be offered for the increased milk volume in the bottles, as the groups did not differ in age, and all mothers were provided with the same guidelines on the volume of milk according to the infant's age at the first visit to FCDC (personal communication with Sr Du Plessis and Sr van den Berg, community health nurses at the FCDC).

In contrast to other studies of young HIV-E infants (Evans et al., 2016; Lipschultz et al., 2011; Mofenson et al., 2005), no cases of pneumonia or pneumocystis jiroveci pneumonia or any cardiac defects were found in the RG. The absence of these health concerns in the participants may be unique to the current study as mothers had to travel to the clinic, often by public transport, and would not have travelled with infants who were ill.

The research question "Do the feeding characteristics of very young infants with unrepaired CLP and HIV-E differ significantly from the feeding characteristics of infants with unrepaired CLP?" could therefore be successfully answered. The alternative hypothesis is confirmed, i.e. there is a statistically significant difference between the feeding characteristics of participants with unrepaired CLP and HIV-E, compared to the feeding characteristics of participants with unrepaired CLP only.

### 1.2 Theoretical implications of the study

Since the PMTCT programme has been implemented in South Africa, the percentage of HIV-positive pregnant women, receiving ART has increased from 93% in 2010 to >95% in 2016 (UNAIDS, 2017). Furthermore, the number of new paediatric HIV infections in South-Africa have been reduced from 25 000 in 2010 to 12 000 in 2016

(UNAIDS, 2017). The majority of HIV-E infants born to HIV-positive mothers, receiving ART, will therefore now be uninfected due to the successful development and implementation of the PMTCT programmes (Filteau, 2009; Lé Doare et al., 2012; Sugandhi et al., 2013; WHO, UNICEF & UNAIDS, 2013). A new emerging group of infants at risk for OPD were therefore identified in this study. Practicing SLTs should be made aware of this new group of infants at risk of OPD and undergraduate SLT training should now include the assessment and management of this group of infants and their mothers, into the curriculum.

The birth of an infant with a cleft does not only affect the infant but also has an effect on the family (Stock, Stoneman, Cunniffe & Rumsey, 2016). Parents report challenges regarding the diagnosis, caring for the infant after birth, ongoing treatment and concerns about the infant's future (Nelson, Kirk, Caress & Glenny, 2012). Furthermore, having a sibling with CLP in the family are also known to have an impact on the unaffected sibling as they may be in competition with the sibling with a CLP who receive more attention from the parents (Stock et al., 2016). CLP with HIV-E or not has an impact on many aspects, therefore all factors should be considered holistically when studying the feeding of infants with CLP.

### 4.3 Clinical implications of the study

The additional feeding difficulties of participants with unrepaired CLP and HIV-E can be described as a cluster of complex problems. An interdisciplinary team approach is recommended by the ACPA (2009) to assess and treat infants with CLP in all areas of health, feeding and development. This new distinctive group of infants with unrepaired CLP and HIV-E, should not be overlooked and should be recognised among all the group of infants with unrepaired CLP. More attention may be given to infants with CLP and HIV, since feeding problems are expected. Not only should all SLTs be made aware and trained on how to assess and treat the HIV-E group with CLP, but the interdisciplinary team members, i.e. the maxillo-facial-oral surgeons, orthodontists, prosthodontists and community health nurses should also be made aware in order to provide the appropriate services. The participants in the RG

presented with problems from birth already, as the first differences between the RG and CG were extended tube feeding duration and prolonged NICU-stay directly after birth. These differences could be seen as the signs of risk for OPD. Literature indicates that the most significant differences in growth between HIV-E and HIV-unexposed infants are seen within the first month of life and minimal differences are noted later on in infancy (Isanaka, et al., 2009). Differences in birthweight is in agreement with the current study. Although not statistically significant, the mean birth weight in the RG was lower than that of the CG. Infants with unrepaired CLP have to weigh at least 5kg before surgery can commence according to the protocol at the FCDC (Bütow, 1995). Therefore, this group of infants with unrepaired CLP and HIV-E, with OPD, may have difficulty in attaining the required weight in time for surgery. The early signs of possible poor weight gain emphasises the importance of early identification of the group of HIV-E infants with CLP, in order to manage the OPD so that the infants will be able to feed sufficiently and effectively.

## 4.4 Strengths and limitations of the study

### 4.4.1 Strengths of the study

- The participants in both groups were closely matched according to the type of cleft and use of feeding obturators. Feeding obturators were supplied to the participants at their first visit to the FCDC when presenting with a uni- or bilateral complete cleft or a cleft of the soft palate and 50% hard palate. If the participant had a soft and hard palate cleft and fed well with a bottle, or had a narrow cleft, no obturator was provided.
- Infants with associated syndromes or conditions were excluded from the study. This further strengthened the results, as infants with CLP and associated syndromes or conditions are known to have neurological involvement (Kummer, 2014). Syndromic CLP would have been a confounding factor, preventing the isolation of the neurological feeding difficulties in the participants.
- On average the two groups were similar in age, gestation age and birth weight, which are factors known to influence feeding (Jadcherla, 2016). Therefore

confounding factors contributing to a biased distribution of feeding difficulties between the two groups were limited.

- According to the NFAS the RG was most likely to present with OPD and the results of the OFS showed that they also consumed the least amount of milk. Therefore, the results of the two measuring instruments supplemented and confirmed one another, thereby increasing the reliability of the findings.
- The reliability of the study was enhanced by using published outcome measures, namely the NFAS and the measurement of OFS (Lau & Smith, 2012; Viviers et al., 2016; Viviers et al., 2017). The measurement of OFS has been used to assess the OFS in preterm infants (Lau et al., 2012; Lau & Smith, 2012). The NFAS presents with acceptable inter-rater reliability, due to the significant agreement beyond chance achieved in the inter-rater reliability results (Viviers et al., 2017).
- The validity of the study was enhanced as the NFAS was validated against the gold standard, the MBSS, and the preliminary performance of the scale was described as promising (Viviers et al., 2017). The high sensitivity and specificity of the NFAS shows its ability to accurately describe and identify OPD, as well as recognising the absence of OPD, therefore resulting in very few false positives (Viviers et al., 2017). The diagnostic accuracy of the NFAS further strengthens the criterion validity of the scale (Viviers et al., 2017).
- A second rater was utilised to score 12% (n=3) of the participants of the sample with the researcher, by using her own record forms of the NFAS. A 100% agreement between the researcher and second-rater was found for the scoring of the NFAS, which further strengthens the results.

### 4.4.2 Limitations of the study

- The study had a small sample size, but it was expected as this population may never be available in large numbers.
- This study did not go into depth about the demographic information about the mother, which could have assisted in the identification of poverty and additional environmental factors possibly having an effect on the manner of feeding with the participants.

- The participants could have been weighed during data collection in order to determine weight gain since birth. During the first month of life the most significant differences in growth between HIV-E and HIV-unexposed infants are noted and minimal difference are noted later on in infancy (Isanaka et al., 2009).Therefore, it will be beneficial to compare not only the weight at birth but also during early infancy between the two groups.

### 4.5 Recommendations for future research

- Since larger sample sizes are unlikely to be found in the population of infants with unrepaired CLP and HIV-E, more studies using other measuring tools for feeding, such as the MBSS are required to confirm the results and increase the evidence of the present study.
- In order to further increase the evidence, a longitudinal study, which involves repeated observations over an extended period of time (Maxwell & Satake, 2006) is recommended. During a longitudinal study, research on the following three groups are recommended: Infants with unrepaired CLP never exposed to HIV, infants with unrepaired CLP and HIV-E and infants with unrepaired CLP who are HIV-positive. As heart problems are described in HIV-E infants, this should also be included in the data collection protocol of such a longitudinal study.
- The psychosocial effects and birth outcomes that HIV and ART exposure as on the infants who may be uninfected justifies the need for further research.

### 4.6 Conclusion

In comparison with the few participants with unrepaired CLP identified with OPD, the participants with unrepaired CLP and HIV-E presented with unique symptoms of OPD and difficulties with OFS. Participants with unrepaired CLP and HIV-E, were not infected with HIV at the time of data collection, but were exposed to HIV and ARTs in utero and some after birth as well. It appears that participants with unrepaired CLP and HIV-E, who presented with OPD showed a unique and complex feeding profile, suggesting possible neurological involvement in the symptoms of their feeding difficulties. At this stage there is no known study isolating the feeding difficulties of

infants with unrepaired CLP and HIV-E. Feeding is a complex process and the ability to feed successfully from birth has an effect on caregiver-infant attachment, which is essential to an infant's development. Early identification and treatment of the feeding difficulties in this new group of infants are therefore essential.

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# Appendices

**APPENDIX A:** Letter granting permission from Facial Cleft Deformities Clinic

**APPENDIX B:** Ethical clearance letter from Faculty of Health Sciences Research Ethics Committee

**APPENDIX C:** Ethical clearance letter from Faculty of Humanities Research Ethics Committee

**APPENDIX D:** Parent/ caregiver information leaflet & informed consent form

**APPENDIX E:** Detailed description of research group participants

**APPENDIX F:** Detailed description of control group participants

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**APPENDIX H:** Scoring criteria for the different sections of the Neonatal Feeding Assessment Scale (Viviers, 2016)

**APPENDIX I:** Data collection sheet

## Appendix A: Letter granting permission from Facial Cleft Deformities Clinic

UNIVERSITEIT VAN PRETORIA
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Faculty of Humanities
Department of Speech-Language Pathology and Audiology

**Permission to access the client files and do research at the Facial Cleft Deformities Clinic (FCDC).**

**To:** Head of Maxillo-Facial and Oral Surgery
Prof F. J. Jacobs

**Re: Permission to conduct research at the Facial Cleft Deformities Clinic (FCDC)**

I, Erantia Visser, a Masters student in Speech-Language Pathology at the University of Pretoria, would like to do research at the Facial Cleft Deformities Clinic (FCDC), University of Pretoria. I am requesting permission to conduct a study on FCDC grounds that involves access to patient records as well as patients during their typical monthly follow-up visits to the clinic.

The title of the study is: 'Feeding characteristics of infants with HIV exposure and cleft lip and palate (CLP): A comparative study'. All participants with a CLP, prior to receiving surgery that are bottle fed, and between the ages of birth to three months, will be included in the study. Infants with HIV exposure will also be included in the study. A short interview with the parent or caregiver will be conducted, and the clinical file perused, to acquire the relevant demographic and background history. The researcher will observe one typical feeding session during the participants' scheduled visit to FCDC, by using the level of OFS measure (Lau and Smith, 2011). Furthermore, relevant demographic information, pre-, peri- and postnatal history, feeding history, as well as an observation of the infants' feeding, will be obtained by using the Oral-Motor and Feeding Evaluation by Arvedson and Brodsky (2002). Any other additional conditions, characteristics or associated symptoms will be noted. The feeding assessments that will be conducted will not intrude on the regular routines at FCDC. I intend to publish the findings of the study in a scientific journal and intend to protect the personal identity of the patients by assigning each patient a random code number. I undertake not to proceed with the study until I have received approval from the Faculty of Health Sciences Research Ethics Committee, University of Pretoria.

Yours sincerely

Visser

Ms. Erantia Visser
Researcher
Contact details: 076 818 0315

Krüger

Mrs Esedra Krüger
Supervisor

G. M. Kritzinger

Prof. Alta Kritzinger
Supervisor

**Permission to do a research study at this clinic and to access the information as requested is hereby approved.**

Head of Maxillo-Facial and Oral Surgery
Prof. F. J. Jacobs

Date 11/01/2017

# Appendix B: Ethical clearance letter from Faculty of Health Sciences Research Ethics Committee

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 28 August 2018.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
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Faculty of Health Sciences Research Ethics Committee

**26/01/2017**

**Approval Certificate**
**New Application**

**Ethics Reference No.: 43/2017**

**Title:** Feeding characteristics of infants with HIV exposure and cleft lip and palate: A comparative study [MA Speech-Language Pathology]

Dear Erantia Visser

The **New Application** as supported by documents specified in your cover letter dated 23/01/2017 for your research received on the 23/01/2017, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 25/01/2017.

Please note the following about your ethics approval:
- Ethics Approval is valid for 1 year
- Please remember to use your protocol number **(43/2017)** on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

**Ethics approval is subject to the following:**
- The ethics approval is conditional on the receipt of **6 monthly written Progress Reports**, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further 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.

We wish you the best with your research.

**Yours sincerely**

**Dr R Sommers,** MBChB; MMed (Int); MPharMed,PhD
**Deputy Chairperson** of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

*The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health).*

☎ 012 356 3084 deepeka.behari@up.ac.za / fhsethics@up.ac.za http://www.up.ac.za/healthethics
✉ Private Bag X323, Arcadia, 0007 - Tswelopele Building, Level 4, Room 60, Gezina, Pretoria

## Appendix C: Ethical clearance letter from Faculty of Humanities Research Ethics Committee

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

31 March 2017

Dear Ms Visser

| | |
|---|---|
| **Project:** | **Feeding characteristics of infants with HIV exposure and cleft lip and palate: A comparative study** |
| **Researcher:** | **E Visser** |
| **Supervisor:** | **Ms E Krüger** |
| **Department:** | **Speech-Language Pathology and Audiology** |
| **Reference number:** | **13125282 (GW20170310HS)** |

Thank you for the application that was submitted for ethical consideration.

I am pleased to inform you that the above application was **approved** by the **Research Ethics Committee** on 30 March 2017. Data collection may therefore commence.

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 the actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

We wish you success with the project.

Sincerely

**Prof Maxi Schoeman**
**Deputy Dean: Postgraduate Studies and Ethics**
**Faculty of Humanities**
**UNIVERSITY OF PRETORIA**
**e-mail:tracey.andrew@up.ac.za**

CC:
Supervisor(s): Ms E Krüger and Prof A Kritzinger
HoD: Prof B Vinck

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Faculty of Humanities
Department of Speech-Language Pathology and Audiology

## PARENT/ CAREGIVER INFORMATION LEAFLET & INFORMED CONSENT FORM

Dear parent/ caregiver

**Title of the study: Feeding characteristics of infants with HIV exposure and cleft lip and palate: A comparative study**
**Name of researcher:** Erantia Visser
**Contact details:** 076 818 0315/ erantiav@gmail.com

### INTRODUCTION

You are invited to volunteer your baby for a research study. This information leaflet will help you to decide if you want your baby to participate. Before you agree to take part you should fully understand what is involved. If you have any questions that this leaflet does not fully explain, please do not hesitate to ask the researcher (Erantia Visser; 076 818 0315).

### WHAT IS THE NATURE AND PURPOSE OF THE STUDY

It is very important to find babies with feeding difficulties early so that they and their families can be provided with the necessary help. By assessing your baby's feeding I would like to find the feeding difficulties in babies with HIV exposure and cleft lip and palate, in order to help these babies as best as possible. Parents and caregivers with babies younger than three months with a cleft lip and palate with or without HIV exposure will be asked to participate in this study. I will be studying two groups of babies with cleft lip and palate. The one group has HIV exposure and the other group was not exposed to HIV.

### EXPLANATION OF PROCEDURES TO BE FOLLOWED

This research study includes answering questions about your baby's birth history and your health during pregnancy, as well as how your baby copes with feeding. The researcher will watch your baby's entire feeding and will give you information afterwards. If necessary, the right specialist at the clinic will be asked to help you and your baby with feeding.

### POTENTIAL RISK AND BENEFITS INVOLVED IN THIS RESEARCH STUDY

I will watch your baby's normal feeding and you will be the one feeding your baby with your baby's own bottle and own milk. There will be no discomfort or risks involved when participating in this research study. The benefit for participating in this study is that you will receive feedback on your baby's feeding and, if necessary, you will be referred for the right services with someone who can help your baby.

### WHAT ARE YOUR BABY'S RIGHTS AS A PARTICIPANT IN THIS RESEARCH STUDY?

Your participation in this study is entirely voluntary. You can refuse to let your baby participate or stop at any time during the assessment without giving any reason. Your withdrawal will not affect your baby, or his/her treatment at this clinic in any way.

**HAS THE STUDY RECEIVED ETHICAL APPROVAL?**

This study has received written approval from the Research Ethics Committee of the Faculty of Health Science, telephone numbers: (012) 356 3084/ 012 356 3085 and the Faculty of Humanities, telephone numbers: (012) 420 850, at the University of Pretoria.

**CONFIDENTIALITY**

All information that you provide regarding your baby will be kept strictly confidential. Once we have used the information no one will be able to identify your baby. The information that may be reported in research reports and articles in scientific journals will not include any information that may identify you or your baby. Your baby's name will not be used and all results will be kept private and confidential. The information will be securely stored, for a minimum of 15 years at the Communication Pathology Building, University of Pretoria.

If you are willing to let your baby participate in this research study, please sign the consent form that is attached. If you have any further questions, please feel free to ask me at (076) 818 0315 or my supervisors at (012) 420 4910.

Kind regards

Visser

Ms E Visser - Researcher

A. M. Kritzinger

Prof. A Kritzinger - Supervisor

Krüger

Mrs E Krüger - Supervisor

Prof. B Vinck

HEAD: Department of Speech-Language Pathology and Audiology

**INFORMED CONSENT FOR PARENTS/ CAREGIVERS (on behalf of minors under the age of 18 years)**

I hereby confirm that I have been informed by the researcher, Ms Erantia Visser, about the nature, process, risks, discomforts and benefits of the study, titled: 'Feeding characteristics of infants with HIV exposure and cleft lip and palate: A comparative study'. I have also received, read and understood the above written information (Information Leaflet and Informed Consent) regarding the study.

I know that the results of the study, and personal information of my baby, will not be available to anyone. I am participating willingly. I understand that if I wish to stop with the study, it will not influence my baby's treatment at this clinic in any way.

Please mark whether you give permission that the information may be used for further research. Herewith I give consent that the information that was gained in this study may be used for future research

Yes ☐ No ☐

Parent/ Caregivers Name:_____ (Please print)

Parent/ Caregivers Signature: _____Date:_____

Participant's Name:_____

Researcher's Name: Erantia Visser

Researcher's Signature:_____ Date: _____

Witness Name: _____Witness's Signature: _____Date:_____

**VERBAL PARTICIPANT INFORMED CONSENT**

I the undersigned, have read and have fully explained the participant information leaflet, which explains the nature, process, risks, discomforts and benefits of the study to the parent or caregiver, named_____ and/or his/her relative, which I have asked to participate in the study. The parent/ caregiver indicates that s/he understands that the results of the study, including if he/she wishes to discontinue with the study that his/her withdrawal will not affect his/her baby and treatment of his/her baby in any way.

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

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

Researcher's Name: Erantia Visser

Witness's Name: _____Witness's Signature: _____Date: _____

**Appendix E: Detailed description of research group participants**

| Infants with unrepaired CLP with HIV-E but no infection (n=12) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Participant nr | Type of cleft | HIV-E | Feeding obturator | Age in days | Gender | Gestation age | Birth weight (kg) | Duration of NICU stay in days | Number of days before bottle fed after birth |
| R9 | Unilateral CL and alveolar ridge | Yes | No | 47 | Female | 40 weeks | 2,5 | 10 | 8 |
| R6 | Unilateral CLP | Yes | No | 11 | Male | 40 weeks | 2,9 | 11 | 7 |
| R8 | Unilateral CLP | Yes | Yes | 35 | Male | 40 weeks | 2,5 | 14 | 14 |
| R11 | Unilateral CLP | Yes | No | 67 | Female | 36 weeks | 2,7 | 7 | 7 |
| R1 | Bilateral CLP | Yes | Yes | 65 | Female | 36 weeks | 2,5 | 14 | 6 |
| R4 | Bilateral CLP | Yes | Yes | 21 | Male | 40 weeks | 2,9 | 14 | 14 |
| R12 | Bilateral CLP | Yes | No | 31 | Female | 40 weeks | 2,4 | 9 | 1 |
| R16 | Bilateral CLP | Yes | No | 89 | Male | 42 weeks | 3,5 | 39 | 37 |
| R10 | Soft palate cleft | Yes | No | 31 | Female | 40 weeks | 2,5 | 5 | 1 |
| R19 | Soft palate cleft | Yes | No | 83 | Female | 40 weeks | 3,8 | 1 | 1 |
| R20 | Soft palate and hard palate cleft | Yes | No | 8 | Female | 40 weeks | 3,7 | 8 | 2 |
| R25 | Soft palate and hard palate cleft | Yes | No | 87 | Female | 40 weeks | 3,1 | 6 | 4 |

## Appendix F: Detailed description of control group participants

| Infants with unrepaired CLP (n=13) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Participant nr | Type of cleft | HIV-E | Feeding obturator | Age in days | Gender | Gestation age | Birth weight (kg) | Duration of NICU stay in days | Number of days before bottle fed after birth |
| C18 | Unilateral CL and alveolar ridge | No | No | 69 | Male | 40 weeks | 2,9 | 6 | 1 |
| C5 | Unilateral CLP | No | Yes | 33 | Male | 38 weeks | 3,7 | 14 | 4 |
| C14 | Unilateral CLP | No | Yes | 7 | Male | 39 weeks | 3,2 | 2 | 1 |
| C15 | Unilateral CLP | No | No | 6 | Male | 40 weeks | 3,4 | 6 | 2 |
| C24 | Unilateral CLP | No | No | 89 | Female | 38 weeks | 3,5 | 2 | 1 |
| C2 | Bilateral CLP | No | Yes | 67 | Female | 36 weeks | 2,4 | 14 | 5 |
| C3 | Bilateral CLP | No | No | 31 | Male | 40 weeks | 4,6 | 14 | 3 |
| C22 | Bilateral CLP | No | No | 2 | Female | 40 weeks | 2,7 | 2 | 2 |
| C7 | Soft palate cleft | No | No | 36 | Male | 40 weeks | 3,5 | 5 | 4 |
| C17 | Soft palate cleft | No | No | 47 | Female | 40 weeks | 2,9 | 1 | 1 |
| C21 | Soft palate cleft | No | No | 4 | Female | 38 weeks | 3,1 | 4 | 2 |
| C23 | Soft palate cleft | No | No | 20 | Male | 40 weeks | 3 | 3 | 2 |
| C13 | Soft palate and hard palate cleft | No | No | 14 | Female | 38 weeks | 4,05 | 10 | 8 |

## Appendix G: Neonatal Feeding Assessment Scale

NEONATAL FEEDING ASSESSMENT SCALE: 32 WEEKS – 4 MONTHS POST TERM (IFAS)

(Compiled by Mari Viviers, 2016)

| | |
|---|---|
| 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 (<20 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 – 55 breaths per minute) | YES | NO | |
| A.2.2.1 Tachyapnoea (>45 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, Jonhson & 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**<br>(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. {Rooting reaction starts to integrate (diminish) by 3 0 6 months of age.} | YES | NO |
| 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 | YES | NO |
| E.6.3 Maxillary hypoplasia | 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**<br>(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 | 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 H: Scoring criteria for the different sections of the Neonatal Feeding Assessment Scale (Viviers, 2016)

| Section | Scoring criteria |
|---|---|
| **Section A** | If one YES was obtained in a sub-section, YES was selected for the likelihood of dysphagia being present. |
| **Section B** | If a non-optimal state of alertness was present during feeding, then YES was selected for the likelihood of dysphagia being present. |
| **Section A & B** | If both sections obtained YES responses, a YES was indicated for the likelihood of dysphagia being present |
| **Section C** | If YES was selected for 3 or more items in this section, YES was indicated for the likelihood of dysphagia being present |
| **Section D** | If abnormal posture is present at rest and during feeding or only during feeding, then YES was indicated for the likelihood of dysphagia being present. |
| **Section E.1** | If the sucking reflex is absent, YES was selected for the likelihood of dysphagia being present. |
| **Section E.2 – E.5** | If YES was selected for any structural or physiological abnormality that is likely to impact on any of the stages of swallowing, then YES was selected for the likelihood of dysphagia being present. |
| **Section E.7** | If a score of 2 or more YES response were obtained, then YES was selected for the likelihood of dysphagia being present. |
| **Section F.1.1 – F.1.2** | If a score of 2 or more YES response were obtained, then YES was selected for the likelihood of dysphagia being present. |
| **Section F 1.3 – F.1.4** | If a score of 2 or more YES response were obtained, then YES was selected for the likelihood of dysphagia being present. |
| **Section F.2** | If a score of more than 0 YES response were obtained, then YES was selected for the likelihood of dysphagia being present. |
| **Section F.3 – F.4** | If a score of more than 0 YES response were obtained, then YES was selected for the likelihood of dysphagia being present. |
| | |

# Appendix I: Data collection sheet

| Case History: | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Family and Social History** | | | | | | | | | | | |
| ***Primary caregivers: (Indicate with an X)*** | | | | | | | | | | | |
| Parent | | Direct family member | | Foster parent | | Other: | | | | | |
| ***Family history:*** | | | | | | | | | | | |
| Level of Maternal education: | | | | | | | | | | | |
| ***(If yes, specify)*** | | | | | | | | | | | |
| Any neurological problems | | | | | | | | | | **Y** | **N** |
| Any history of cleft lip and palate or craniofacial anomalies | | | | | | | | | | **Y** | **N** |
| Any feeding problems in family | | | | | | | | | | **Y** | **N** |
| Family history of respiratory/ breathing problems (asthma/ allergies) *(If yes, specify)* | | | | | | | | | | **Y** | **N** |
| Environmental factors (smoking/pets) *(If yes, specify)* | | | | | | | | | | **Y** | **N** |
| Other: | | | | | | | | | | | |
| **Prenatal History** | | | | | | | | | | | |
| ***Maternal factors:*** | | | | | | | | | | | |
| Age of mother: | | | | | | | | | | | |
| Medication during pregnancy *(If yes, specify).* | | | | | | | | | | **Y** | **N** |
| ***Antiretroviral therapy:*** *( If yes, specify type)* | | | | | | | | | | **Y** | **N** |
| Prior to pregnancy | | | **Y** | **N** | During pregnancy | | | | | **Y** | **N** |
| ***Substance abuse:*** | | | | | | | | | | | |
| Smoking | **Y** | **N** | Alcohol | **Y** | **N** | Other drugs | | | | **Y** | **N** |
| ***Viral infections:*** | | | | | | | | | | | |
| HIV/AIDS | **Y** | **N** | Cytomegalovirus | **Y** | **N** | Rubella | | | | **Y** | **N** |
| Toxoplasmosis | **Y** | **N** | Herpes | **Y** | **N** | Tuberculosis | | | | **Y** | **N** |
| Colds | **Y** | **N** | Flu | **Y** | **N** | Other( If yes, specify) | | | | **Y** | **N** |
| ***Additional factors:*** | | | | | | | | | | | |
| Diabetes | | | **Y** | **N** | Radiation | | | | | **Y** | **N** |
| Blood group incompatibility | | | **Y** | **N** | Hospitalization during pregnancy | | | | | **Y** | **N** |
| Premature rupture of the membranes | | | **Y** | **N** | Placental problems: placenta abruptio/ previa | | | | | **Y** | **N** |
| Toxaemia, Pre-eclampsia/ HELLP syndrome | | | **Y** | **N** | Bleeding | | | | | **Y** | **N** |
| Thyroid diseases | | | **Y** | **N** | Polyhydramnios | | | | | **Y** | **N** |
| Other: | | | | | | | | | | | |
| ***Paternal factors*** | | | | | | | | | | | |
| ***Substance abuse:*** | | | | | | | | | | | |
| Smoking | **Y** | **N** | Alcohol | **Y** | **N** | Other drugs | | | | **Y** | **N** |
| **Birth History** | | | | | | | | | | | |
| ***Birth weight:*** | | | | | ***Gestational Age:*** | | | | | | |
| ***Apgar scores*:** | 1 min: | | | 5 min: | | | 10 min: | | | | |
| ***Birth:*** | | Normal | | | | C-section | | | | | |
| ***Assisted delivery:*** | | Vacuum | | | | Forceps | | | | | |
| ***Small for gestational age/ Intrauterine retardation*** *(If yes, specify)* | | | | | | | | | | **Y** | **N** |

| Neonatal period | | |
|---|---|---|
| Oxygen received after birth and duration: | **Y** | **N** |
| Ventilation: Type and duration: | **Y** | **N** |
| Bradycardia and apnoeic attacks | **Y** | **N** |
| Neonatal convulsions | **Y** | **N** |
| Infections (*If yes, specify)* | **Y** | **N** |
| Number of days before breast fed/ bottle fed: | | |
| Number of days in NICU: | | |
| Prolonged hypoxia or anoxia/ respiratory distress | **Y** | **N** |
| Surfactant therapy | **Y** | **N** |
| Cardiac problems | **Y** | **N** |
| Other complications *(If yes, specify)* | **Y** | **N** |
| ***Breathing rate and effort: (****Indicate with an X)* | | |
| Stridor | | Stertor | |
| ***Medication:*** *(If yes, specify)* | **Y** | **N** |
| ***Weak or dysrhythmic non-nutritive suck (pacifier or finger):*** *(If yes, specify)* | **Y** | **N** |

| Other factors | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| ***Past medical/ surgical history:*** | | | | | | | | |
| Upper GI or scintiscan | **Y** | **N** | Videoflouroscopic swallow study | **Y** | **N** | Surgical procedures (If yes, specify) | **Y** | **N** |

| Current feeding | | | | | |
|---|---|---|---|---|---|
| ***Position:*** | | | | | |
| Cradle held | **Y** | **N** | Upright held | **Y** | **N** |
| ***Duration: (If yes, tick with an X)*** | | | | | |
| 20 minutes | | 30- 40 minutes | | >than 45 minutes | |
| ***Intervals: ( If yes, tick with an X)*** | | | | | |
| 2 hours | | 3 hours | | 4 hours | | Other: | |
| ***Feeding methods:*** | | | | | |
| Bottle type: | | | | | |
| ***Feeding methods:*** | | | | | |
| ***Feeding obturator*** ***Vitamin/mineral supplement:*** (If yes, specify) | Expressed breast milk: | **Y** | **N** |
| | Formula: | **Y** | **N** |
| **Effectiveness of oral feeding skills:** | | **Y** | **N** |
| ***Volume of milk prior to feeding session:*** | | **Y** | **N** |

| Effectiveness of oral feeding skills: | | | | | | | |
|---|---|---|---|---|---|---|---|
| ***Volume of milk taken during the first 5 minutes:*** *(Indicate with an X)* 0-5 ml | | ***Duration of entire feeding session in minutes:*** | | ***The rate of milk transfer (RT) over the entire feeding session (millilitres per min):*** | | | |
| | | | | **ml** | | **min** | |

| ***Total volume of milk take during the entire feeding session****: (Indicate with an X)* | | | | | | | |
|---|---|---|---|---|---|---|---|
| 0-5 ml | | 5-10 ml | | 10-15 ml | | 15-20 ml | |
| 20-25 ml | | | | | | | |
| 40-45 ml | | 5-10 ml | | 10-15 ml | | 15-20 ml | |
| 60-65ml | | 25-30 ml | | 30-35 ml | | 35-40 ml | |
| 80-85ml | | 45-50 ml | | 50-55 ml | | 55-60 ml | |