The validation of a screening tool for the identification of feeding and swallowing difficulties in the paediatric population with HIV/AIDS

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Abstract

**Background:** The paediatric population with HIV is at higher risk for feeding and swallowing difficulties (FSD) than the general paediatric population, which may contribute to increased morbidity and mortality. Consequences of dysphagia may include insufficient nutritional intake leading to growth faltering, decreased quality of life, and risk of aspiration which may cause respiratory complications and permanent lung damage. Currently, no validated screening measures exist for the identification of FSD in infants and children with HIV/AIDS. Early identification and appropriate management of dysphagia is essential to prevent further complications and negative health outcomes.

**Research Aims:** To determine the validity and reliability of a caregiver questionnaire as a FSD screening tool in infants and children with HIV/AIDS. As a sub-aim, the nature of FSD and the relationship between FSD and other factors, such as age, lower respiratory tract infection, undernutrition and HIV-related factors were also described.

**Method:** A prospective, descriptive clinimetric research design was utilised. Three experts in the field of paediatric FSD were consulted to determine face and content validity of the tool. Key informant interviews were conducted with 15 caregivers of children with HIV, to determine the linguistic appropriates of the tool. Sixty-six participants with HIV/AIDS under the age of 13 years were recruited from the Infectious Diseases Clinic at Red Cross War Memorial Children’s Hospital. The screening tool and a comprehensive feeding and swallowing evaluation were conducted with all participants. Additional medical information, such as HIV data, anthropometry information and history of respiratory illness were recorded.

**Results:** The screening tool – the Feeding and Swallowing Questionnaire – was found to have face and content validity. Criterion validity was established with sensitivity of 92% and specificity of 59%. The tool has high internal consistency (Cronbach’s alpha = 0.78) and excellent inter-rater reliability (100% agreement). Twenty-five (38%; N=66) participants presented with FSD. Difficulties were noted in all phases of swallowing, as well as behavioural feeding difficulties and delays in reaching age-appropriate feeding and swallowing milestones. FSD were significantly inversely associated with age ($p=.008$) and length of time on antiretroviral therapy ($p=.014$) i.e. younger children and children on ART for a short period of time were most likely to have FSD.

**Conclusions:** The results confirm that the Feeding and Swallowing Questionnaire is a reliable and valid tool for the identification of FSD in infants and children with HIV. This tool identifies children likely to have FSD, thereby indicating referral for comprehensive assessment of feeding and swallowing, as well as the necessary management of any FSD. The results highlight the multifaceted nature of FSD in this population. Early identification of FSD may not only benefit the child, but may decrease the associated social and economic burden of frequent hospitalisation related to FSD.

**Keywords:** feeding and swallowing difficulty, paediatric, HIV/AIDS, sensitivity, specificity, validation, screening
Author’s Note

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*Referencing Style:*

The present dissertation has utilised the referencing style as per the American Psychological Association, 6th edition (2010).
**Glossary – Selected Terms**

**Aspiration:**
Aspiration occurs when foreign materials (e.g. saliva, food or liquid) penetrate the larynx and enter the airway below the level of the true vocal folds. Aspiration may occur either before, during or directly after the swallow (primary aspiration), or after the feed as a result of gastroesophageal reflux (secondary aspiration) (Arvedson & Brodsky, 2002).

**Assessment:**
In the context of feeding and swallowing difficulties, assessment refers to the clinical evaluation of feeding and swallowing, which is comprehensive and able to provide diagnostic information regarding the nature of feeding and swallowing difficulties. Feeding and swallowing assessment may include instrumental assessment such as videofluoroscopic swallowing assessment or Fiberoptic endoscopic evaluation of swallowing. The term assessment may be used interchangeably with evaluation (Arvedson & Brodsky, 2002; Groher & Crary, 2010).

**Bolus:**
A volume of liquid or food given orally or enterally (Arvedson & Brodsky, 2002).

**CD4:**
CD4 lymphocytes play an important role in immune function, and are destroyed by HIV. In the management of HIV/AIDS both absolute CD4 count and CD4 percentage are used to determine the level of immunosuppression – the lower the CD4 levels the more severe the degree of immunosuppression. In children, a CD4 percentage of below 15% indicates severe immunosuppression, between 15 and 24% indicates moderate suppression, and above 25% indicates minimal suppression (Department of Health, 2010; South to South, 2010).
**Dysphagia (swallowing difficulty):**

Dysphagia (i.e. difficulty in swallowing) can be defined as disorders in any of the phases of swallowing; namely, the oral preparatory, oral, pharyngeal and oesophageal phases (Arvedson & Brodsky, 2002).

**Feeding:**

Feeding is a broad term that includes the physiological process of eating and swallowing, as well as the child’s feeding and swallowing skill set, the external environment and interactions between the child and caregiver (Arvedson & Brodsky, 2002; Arvedson, 2008; Delaney & Arvedson, 2003).

**Feeding disorder:**

Arvedson (2008) describes feeding disorders as difficulties in a range of eating activities. Feeding disorders may be maladaptive learned behavioural responses to eating, or may be accompanied by a disorder in the mechanism of swallowing. Feeding difficulties include food refusal, disruptive behaviour during mealtimes and delays in acquiring age-appropriate feeding skills (Arvedson & Brodsky, 2002; Arvedson, 2008).

**Gastro-oesophageal reflux (GOR):**

Backflow of acidic contents from the stomach into the oesophagus (Arvedson & Brodsky, 2002).

**Gastro-oesophageal reflux disorder (GORD):**

Chronic backflow of stomach contents into the oesophagus resulting in damage to anatomical structures and possible inflammation of the oesophagus (Arvedson & Brodsky, 2002). GORD has been associated with feeding and swallowing difficulties (Field, Garland, & Williams, 2003).

**Growth faltering:**

Growth faltering is the preferred term to failure to thrive, and is also known as undernutrition. It refers to abnormal growth, whereby a child's weight falls below the 5th percentile (World Health Organization, 1995).
**HIV DNA PCR:**

HIV DNA PCR is a virologic test that detects HIV proviral DNA in the blood. This test is able to reliably detect HIV at any age – even in young infants (Department of Health, 2013; South to South, 2010).

**HIV ELISA and HIV Rapitest:**

HIV ELISA and HIV Rapitest are antibody tests used to detect antibodies made by the immune system in response to the HIV virus. As antibodies can be passed on from the mother to child and may remain detectable in the child until up to 18 months of age, a positive antibody test in a child under 18 months is not a reliable indication of HIV. A positive result does, however, indicate that the child has been exposed to the virus (Department of Health, 2013; South to South, 2010).

**Laryngeal penetration:**

Laryngeal penetration occurs when foreign materials (e.g. saliva, food or liquid) penetrate the larynx but do not pass below the level of the true vocal folds (Arvedson & Brodsky, 2002; Arvedson, 2008).

**Negative predictive value:**

Negative predictive value is the likelihood that an individual will not have the target condition when the test result is negative (Portney & Watkins, 2009).

**Odynophagia:**

Pain associated with swallowing (Arvedson & Brodsky, 2002).

**Pneumonia:**

Pneumonia is a type of pneumonitis, i.e. inflammation of the lungs due to infection (Zar, 2008).

**Positive predictive value:**

Positive predictive value is the likelihood that an individual will have the target condition when the test result is positive (Portney & Watkins, 2009).
**Screening:**

In the context of feeding and swallowing difficulties, screening refers to an initial, short examination of feeding and swallowing, which is not diagnostic in nature, but is able to identify the need for further assessment of feeding and swallowing difficulties (Arvedson & Brodsky, 2002; Groher & Crary, 2010).

**Sensitivity:**

Sensitivity is the ability of a test to yield a positive result when the target condition is present, therefore obtaining a true positive result (Hulley, Cummings, Browner, Grady, & Newman, 2013; Portney & Watkins, 2009).

**Specificity:**

Specificity is the ability of a test to yield a negative result when the target condition is absent, therefore obtaining a true negative result (Hulley et al., 2013; Portney & Watkins, 2009).

**Swallowing:**

Swallowing is a complex process which relies on the coordination of several anatomic structures (Arvedson & Brodsky, 2002; Groher & Crary, 2010; Prasse & Kikano, 2009; Rogers & Arvedson, 2005). Swallowing consists of four stages, namely:

1. **Oral Preparatory Phase:** The oral preparatory phase involves the introduction and the manipulation of the bolus into the oral cavity. The bolus may be chewed, or moved around the mouth during this phase. The oral preparatory phase is under voluntary control (Arvedson & Brodsky, 2002; Groher & Crary, 2010; Rogers & Arvedson, 2005).

2. **Oral Phase:** In the oral phase, the prepared bolus is moved posteriorly in the mouth by the tongue. This phases ends when the backwards movement of the bolus triggers the pharyngeal swallow. The oral phase is under voluntary control (Arvedson & Brodsky, 2002; Groher & Crary, 2010; Rogers & Arvedson, 2005).
3. **Pharyngeal Phase:** The pharyngeal phase is characterised by a series of steps initiated by the triggering of the pharyngeal swallow. The primary functions of these steps are to move the bolus through the pharynx while providing protective mechanisms for the closure of the airway and the prevention of material from entering the larynx. The pharyngeal phase is under involuntary neural control (Arvedson & Brodsky, 2002; Groher & Crary, 2010; Rogers & Arvedson, 2005).

4. **Oesophageal Phase:** The final phase, the oesophageal phase, is entirely involuntary, and involves the propulsion of the bolus through the gastrointestinal tract to the stomach, by peristaltic movements (Arvedson & Brodsky, 2002; Groher & Crary, 2010; Rogers & Arvedson, 2005).

**Viral load:**
Viral load refers to the concentration of human immunodeficiency virus in the blood. It is used to confirm the diagnosis of HIV infection in young children (less than 18 months of age) and to monitor the response to antiretroviral therapy. The goal of antiretroviral therapy is to decrease the viral load, with an undetectable viral load (less than 50 copies per mL of blood) being the ultimate goal (Department of Health, 2010; South to South, 2010).

**WHO clinical stages of HIV:**
The World Health Organization has developed a 4-stage system to classify HIV/AIDS. The WHO clinical stages may be used to determine ART eligibility, for monitoring clinical status over time, as well as determining success of ART. The four WHO stages indicate severity of symptoms as follows:

- **Stage I:** Asymptomatic.
- **Stage II:** Mild symptoms, such as chronic upper respiratory tract infections, recurrent oral ulcerations, or herpes zoster.
- **Stage III:** Moderate severity of symptoms, such as persistent oral candidiasis, pulmonary or lymph node tuberculosis, or chronic HIV-associated lung disease
- **Stage IV:** Severe symptoms, such as unexplained severe malnutrition, extrapulmonary tuberculosis, oesophageal candidiasis, HIV encephalopathy or cryptococcal meningitis (World Health Organization, 2010).
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<td>acquired immune deficiency syndrome</td>
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<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
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<td>AUC</td>
<td>area under the curve</td>
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<tr>
<td>CD4</td>
<td>cluster of differentiation 4</td>
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<tr>
<td>CFSE</td>
<td>Clinical Feeding and Swallowing Evaluation</td>
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<td>CLD</td>
<td>chronic lung disease</td>
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<tr>
<td>CNS</td>
<td>central nervous system</td>
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<td>DDS</td>
<td>Dysphagia Disorders Survey</td>
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<tr>
<td>ELISA</td>
<td>enzyme-linked immunosorbent assay</td>
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<tr>
<td>EOR/D</td>
<td>extra-oesophageal reflux/ disease</td>
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<tr>
<td>FEES</td>
<td>Fiberoptic Endoscopic Evaluation of Swallowing</td>
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<tr>
<td>FSD</td>
<td>feeding and/or swallowing difficulty or difficulties</td>
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<td>FSQ</td>
<td>Feeding and Swallowing Questionnaire</td>
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<tr>
<td>GIT</td>
<td>gastrointestinal tract</td>
</tr>
<tr>
<td>GOR/D</td>
<td>gastro-oesophageal reflux/ disease</td>
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<tr>
<td>HAZ</td>
<td>height-for-age z-score</td>
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<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
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<tr>
<td>HPCSA</td>
<td>Health Professions Council of South Africa</td>
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<tr>
<td>ICF</td>
<td>International Classification of Functioning, Disability and Health</td>
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<td>IDC</td>
<td>Infectious Diseases Clinic</td>
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<td>IRIS</td>
<td>immune reconstitution inflammatory syndrome</td>
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<td>LIP</td>
<td>lymphoid interstitial pneumonitis</td>
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<tr>
<td>LRTI</td>
<td>lower respiratory tract infection</td>
</tr>
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<td>MDG</td>
<td>Millennium Developmental Goal</td>
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<td>NRFIT</td>
<td>Nutrition and Feeding Risk Identification Tool</td>
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<td>NPV</td>
<td>negative predictive value</td>
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<tr>
<td>OPP</td>
<td>oral preparatory phase</td>
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<td>OP</td>
<td>oral phase</td>
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<td>PCP</td>
<td><em>Pneumocystis jiroveci</em> pneumonia</td>
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<td>PCR</td>
<td>polymerase chain reaction</td>
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<td>PHE</td>
<td>progressive HIV encephalopathy</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>PP</td>
<td>pharyngeal phase</td>
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<td>PPV</td>
<td>positive predictive value</td>
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<tr>
<td>RA</td>
<td>research assistant</td>
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<td>RCWMCH</td>
<td>Red Cross War Memorial Children’s Hospital</td>
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<td>ROC</td>
<td>receiver operator characteristic</td>
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<tr>
<td>SD</td>
<td>standard deviations</td>
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<tr>
<td>SLT</td>
<td>speech-language therapist</td>
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<tr>
<td>SOMA</td>
<td>Schedule for Oral Motor Assessment</td>
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<tr>
<td>STARD</td>
<td>Standards for Reporting of Diagnostic Accuracy</td>
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<tr>
<td>STEP-CHILD</td>
<td>Screening Tool of Feeding Problems Applied to Children</td>
</tr>
<tr>
<td>TB (MDR-, XDR-)</td>
<td>tuberculosis (multidrug-resistant, extensively drug-resistant)</td>
</tr>
<tr>
<td>VFSS</td>
<td>videofluoroscopic swallow study</td>
</tr>
<tr>
<td>WAZ</td>
<td>weight-for-age z-score</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WHZ</td>
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1. Introduction

Problem Statement

Morbidity and mortality related to HIV/AIDS in infants and children continue to be a health burden globally (Barron et al., 2013). The disease progresses much faster in the paediatric age-group than in adults, with infants and children who are HIV-infected at risk of developing HIV-related complications which may affect various systems in the body (Meyers et al., 2007). Many of these sequelae, whether infectious, such as opportunistic infections, or non-infectious, are preventable if optimal treatment is instituted (Abrams & Myer, 2013; Meyers et al., 2007).

One of these complications is dysphagia or feeding and swallowing difficulties (FSD), as infants and children who are HIV-infected are at a higher risk of having dysphagia or FSD than typically developing children (Melvin, Wright, & Goddard, 1997; Nel & Ellis, 2012; Pressman & Morrison, 1988; Pressman, 2010; Rabie et al., 2007). Although available literature reports a prevalence of FSD in 45%-80% of infants and children with HIV (Melvin et al., 1997; Nel & Ellis, 2012; Pressman & Morrison, 1988), an accurate report of the current prevalence of FSD in the paediatric population living with HIV/AIDS is not available. This apparent high reported prevalence is most likely due to inherent limitations in the research designs of previous studies, for example selection bias due to the inclusion of only children already referred for suspected FSD, or a small or limited sample size (Maxwell & Satake, 2006; Nel & Ellis, 2012). Most of the studies reporting prevalence of FSD in this population predate the introduction of antiretroviral therapy (ART) and may therefore not be an accurate reflection of current prevalence of FSD. Previous studies also differ in their operational definitions of dysphagia and feeding problems. Limited current research in this field further compounds the difficulty in reporting an accurate prevalence in this population. Furthermore, there are no incidence estimates available of FSD in the paediatric population with HIV/AIDS.

Feeding and swallowing difficulties in the general paediatric population are associated with increased morbidity and mortality due to complications such as respiratory illness (Prasse & Kikano, 2009; Weir, McMahon, Barry et al., 2007; Weir, McMahon, Taylor, Chang,
& Barratt, 2010) and growth faltering (Prasse & Kikano, 2009; Rogers & Arvedson, 2005), and may lead to decreased quality of life (Arvedson & Brodsky, 2002; Threats, 2007). Little research has been conducted regarding the impact of FSD in the paediatric population with HIV; however, it is possible that the consequences of dysphagia in this population may lead to negative health outcomes as severe as permanent lung damage or death (Nel & Ellis, 2012; Pressman, 2010).

Therefore early identification and management of feeding and swallowing difficulties is essential to prevent or reduce negative health consequences. The implementation of preventative strategies may further result in a decrease in the economic and social burden associated with HIV/AIDS (Kaul & Patel, 2001; Loveland, Mitchell, van Wyk, & Beale, 2010). Limited assessment material for FSD specific to the paediatric population with HIV in South Africa is available. A screening tool for the identification of FSD that is specific to the paediatric population with HIV/AIDS will be clinically useful, as the available literature shows a relatively high prevalence of FSD in this population.

The purpose of the study was therefore to validate a screening tool for the identification of FSD in the paediatric population with HIV/AIDS, to describe any associations between FSD and specific factors such as age, malnutrition, lower respiratory tract infections, and HIV-related factors, and to describe the nature of FSD in this population.

**Background**

In 2000, 189 countries endorsed the signing of the United Nations Millennium Declaration. This declaration was translated into eight Millennium Developmental Goals (MDGs) which outline key developmental areas requiring specific focus. The eight goals were measurable and were set within a timeline leading up to 2015 (Kirigia & Kirigia, 2007; UNAIDS, 2013a; United Nations, 2014). The Millennium Declaration recognized the burden of communicable diseases, in particular, that of the global HIV/AIDS epidemic. The sixth MDG aims to stop and reverse the global spread of HIV/AIDS by 2015 (Kirigia & Kirigia, 2007; UNAIDS, 2013a; United Nations, 2014).

Since the MDGs were first established, there has been significant improvement in approaches to the HIV/AIDS epidemic and in treatment guidelines (UNAIDS, 2013a).
Although this MDG is currently attainable for several countries, outcomes in low-income countries, such as South Africa, are significantly poorer than in the other income brackets (Kirigia & Kirigia, 2007; Travis et al., 2004; UNAIDS, 2013a; United Nations, 2014). This may be due to a number of reasons, such as limited access to primary health care, difficulties with early identification and referral of children infected vertically with HIV, financial constraints, and overwhelmed health systems unable to cope with the demand (G. S. Cooke, Little, Bland, Thulare, & Newell, 2009; M. L. Cooke, Goddard, & Brown, 2009; Kirigia & Kirigia, 2007; Silal, Penn-Kekana, Harris, Birch, & McIntyre, 2012; Travis et al., 2004).

In 2012, an estimated 35.3 million people were living with HIV worldwide, an increase from 33.4 million in 2008. This increase was likely due to the increasing number of people with access to ART, and improved survival rates. Of these 35.3 million people, 3.3 million were children under the age of 15 years – it is believed that the majority of these children were vertically infected through mother-to-child transmission, either prenatally, perinatally or due to breast-feeding (UNAIDS, 2013a; UNAIDS, 2013b). Sub-Saharan Africa remains the geographic region most affected by the HIV epidemic, accounting for approximately 71% of the world’s total HIV population, and 88% of the world’s total paediatric HIV population (UNAIDS, 2013b). An estimated 190 000 children in Sub-Saharan Africa died of AIDS-related deaths in 2012, accounting for more than 90% of the world’s paediatric AIDS-related deaths in that year (UNAIDS, 2013b).

The mid-year population estimates for South Africa in 2014 reported that approximately 10.2% of South Africa’s population was HIV positive – 5.51 million people (Statistics South Africa, 2014). These estimates do not include data regarding the paediatric population with HIV, however, UNAIDS (2013a) estimated that, in 2012, 410 000 children in South Africa were HIV positive.

An increasing number of children who are HIV-infected in South Africa are being provided with ART (Meyers et al., 2007). Prior to 2004, ART was not widely distributed. However, in April 2004, South Africa launched the National Antiretroviral Programme, which was in line with the World Health Organization (WHO) guidelines at the time (Boule et al., 2008; Johnson et al., 2012; Lowick, Sawry, & Meyers, 2012; Wilmshurst, Burgess, Hartley, & Eley, 2006). This programme improved previous guidelines for ART provision; however mortality and access to care continued to be a problem. In December 2009,
further changes were made to ART guidelines which targeted decreased mortality, as well as enhanced prevention efforts (Department of Health, 2010; South to South, 2010).

The latest guidelines regarding ART state that any child under the age of 5 years with confirmed HIV infection is eligible for ART, irrespective of their clinical stage or CD4 count. Eligibility for children between 5 and 15 years depends on the staging of the disease according to the WHO clinical staging of HIV/AIDS-related symptoms and their CD4 count (Department of Health, 2013). Certain conditions in children with confirmed HIV infection – such as age younger than 1 year, WHO stage 4 disease, or a CD4 count of <200 cells/μL or <15% – require initiation of an ART regime within seven days (Department of Health, 2013). In 2012, it was reported that 140,541 children in South Africa were receiving ART, which reflected 63% of the total children in need of ART at the time (UNICEF, 2013). However, despite improved treatment guidelines and regimes, access to care, especially in rural areas of South Africa, remains limited (Abrams & Myer, 2013).

The history of South Africa contributes to significant inequalities between races with regard to access to healthcare (McLaren, Ardington, & Leibbrandt, 2014). Historically, the segregation of health care services during Apartheid served to broaden the divide between races, as health services for non-white populations were neglected and received limited funding (Ataguba & Alaba, 2012). Post-Apartheid South Africa has seen noteworthy growth in the private health sector, which only provides health care services to 20% of the population. At the same time, use of public health care has increased, yet limited increases in funding and the development of useful policies have hampered efforts to provide quality health care equal to that provided in the private sector (Ataguba & Alaba, 2012; McLaren et al., 2014). In addition to these inequalities, individuals requiring public health care may fail to utilise such services, due to factors such as the high cost of transport or lack of local services (McLaren et al., 2014). Research has shown that lower socioeconomic status and levels of education are linked to poorer health outcomes (Ataguba & Alaba, 2012).

Although child mortality related to HIV/AIDS in South Africa remains high, especially when compared to developed countries; gains in decreasing child mortality due to HIV/AIDS have been made since the scaling up of ART services (Chopra et al., 2009). The relating improved access and availability of ART has resulted in a group of infants and children who are living longer than previously, yet still have a chronic illness (Johnson et al., 2012). The sequelae of HIV as a chronic illness are frequently documented in the literature.
(Baillieu & Potterton, 2008; De Baets, Bultery, Abrams, Kankassa, & Pazvakavambwa, 2007; Kaul & Patel, 2001; Lowick et al., 2012; Mody et al., 2014; Rabie et al., 2007; Rose, Hall, & Martinez-Alier, 2014; Theron et al., 2009; Van Rie, Harrington, Dow, & Robertson, 2007; Wilmshurst et al., 2006; Zar, 2008) and will be discussed.

General Medical Complications of HIV/AIDS in Infants and Children

Infants and children who are HIV-infected are at risk of developing HIV-related conditions, which may impact on the individual’s morbidity and mortality, as well as quality of life (Meyers et al., 2007; Rabie et al., 2007). Although several of these conditions may directly contribute to the development of FSD, they may also negatively impact the child’s general well-being and contribute towards the profile of a chronically ill child (Rabie et al., 2007; Schwartz & Rothlingova, 2011).

Conditions related to HIV may affect any of the body’s systems. Respiratory conditions present an important cause of morbidity and mortality in the paediatric population with HIV, with pneumonia remaining the most widespread reason for admission to hospital in African children with HIV (Theron et al., 2009; Zar, 2008). Theron et al. (2009) stated that respiratory complications may be the cause of death in as many as 50% of children with HIV/AIDS. Respiratory conditions include lower respiratory tract infections such as bacterial pneumonia, aspiration pneumonia, *pneumocystis jiroveci* pneumonia (PCP), and lymphoid interstitial pneumonia (LIP) (De Baets et al., 2007; Department of Health, 2010; Department of Health, 2013; South to South, 2010; Zar, 2008). Children with HIV are also at a higher risk of developing tuberculosis (TB) than the general paediatric population; especially in a country with a particularly high TB prevalence such as South Africa (Zar, 2008). TB may exacerbate HIV infection and lead to accelerated deterioration of immune function. TB also contributes to the development of Immune Reconstitution Inflammatory Syndrome (IRIS) in infants and children recently initiated on ART (South to South, 2010). The emergence of drug-resistant TB, such as multi-drug resistant (MDR) and extensively drug resistant (XDR) TB, has further complicated treatment of individuals with co-infection of HIV and TB (Chopra et al., 2009; De Baets et al., 2007). The progression of the TB infection to extrapulmonary is inextricably linked to immunosuppression. Tuberculosis infection may spread throughout the body, resulting in additional symptoms and negative health outcomes (South to South, 2010; Zar, 2008).
Children with HIV infection often present with gastrointestinal problems (M. L. Cooke et al., 2009). The most common aetiology of GIT symptoms is candidiasis infection, but symptoms may also be caused by factors such as cytomegalovirus, herpes simplex virus and idiopathic ulceration (M. L. Cooke et al., 2009; Rabie et al., 2007). M. L. Cooke et al. (2009) utilised endoscopy to investigate upper GIT disorders in children with HIV. They reported that the primary presenting GIT symptom was recurrent vomiting. A high correlation was found between oesophageal complaints and the presence of oesophageal candidiasis or cytomegalovirus, indicating the role of these conditions in the development of oesophagitis, odynophagia and related dysphagia (M. L. Cooke et al., 2009; Pressman, 2010). Candidiasis may manifest as oropharyngeal, laryngeal or oesophageal candida infection, however, the absence of oropharyngeal candida does not exclude the presence of oesophageal candida (M. L. Cooke et al., 2009). Chronic candidiasis is frequent in children with HIV; oesophageal candidiasis is a WHO stage 4 symptom of AIDS, indicating advanced disease progression (Loveland et al., 2010). Candidiasis also plays a role in causing or exacerbating gastro-oesophageal reflux disorder (GORD), a condition which may also result in oesophagitis, odynophagia and dysphagia (Mathisen, Worrall, Masel, Wall, & Shepherd, 1999; Pressman, 2010; Rommel, De Meyer, Feenstra, & Veereman-Wauters, 2003; Strudwick, 2003).

Gastrointestinal tract infections may have consequences such as dysphagia, malnutrition or decreased absorption of vital nutrients (Palmer, 2003; Rabie et al., 2007; Rose et al., 2014). As such, gastrointestinal disorders in the paediatric population with HIV may play a significant role in the development of undernutrition and growth faltering (Kaul & Patel, 2001). The nature and aetiology of malnutrition in the paediatric population with HIV is, however, complex, and gastrointestinal disorders may be only one factor contributing to the development of malnutrition (Mody et al., 2014; Palmer, 2003; Rose et al., 2014).

Rose et al. (2014) outline possible aetiologies of malnutrition in children with HIV in terms of medical and social factors. Medical factors contributing towards malnutrition in this population include increased nutritional requirements, chronic diarrhoea, infectious co-morbidities, and HIV enteropathy. Children with asymptomatic HIV may require an increased caloric intake of 10%, while children with HIV and co-existing infections may require up to 20-30% increased caloric intake. Diarrhoea is frequently documented in
children with HIV, and malnutrition may result from acute, recurrent or chronic diarrhoea (Rose et al., 2014). Malnutrition may further result in GIT mucosal dysfunction which impairs absorption of nutrients and establishes a cycle between infectious co-morbidities affecting the GIT and malnutrition. HIV enteropathy may also result in impaired malabsorption; however, this condition is caused directly by the HIV virus in the absence of any pathogens (Rose et al., 2014). In addition to these factors, ART may be associated with nausea, vomiting, a decreased appetite and abdominal pain, which have been linked with decreased oral intake (Pressman, 2010).

Social factors influencing malnutrition occur mainly in developing countries such as South Africa. These may include factors such as limited access to nutritious food due to socioeconomic reasons resulting in food insecurity, as well as barriers to timeous access of healthcare, either in the treatment of HIV, or of the related malnutrition (Palmer, 2003; Rose et al., 2014). Below average growth has been documented in between 50 and 80% of children with HIV (Palmer, 2003). Severe acute malnutrition (based on a weight-for-height z-score of less than -3) in children with HIV has a reported prevalence of up to 71% (Rose et al., 2014), and mortality from severe malnutrition in children with HIV is three times higher than in children without HIV (Mody et al., 2014; Rose et al., 2014). Children with concurrent HIV and severe malnutrition are at a higher risk of infections such as TB and candidiasis, as well as complications such as diarrhoea (Rose et al., 2014).

Infants and children with HIV/AIDS infection may present with neurological symptoms. HIV may invade the central nervous system (CNS) resulting in progressive or static HIV encephalopathy, a WHO stage 4 symptom of AIDS (Rabie et al., 2007). HIV encephalopathy may cause microcephaly, loss of previously acquired developmental milestones, motor deficits (e.g. cerebral palsy), neurodevelopmental delay or cognitive impairments (Kaul & Patel, 2001; Lowick et al., 2012; Van Rie et al., 2007; Wilmshurst et al., 2006). Progressive HIV encephalopathy (PHE) accounts for the majority of CNS symptoms in children with HIV infection (Van Rie et al., 2007).

Further complications of HIV/AIDS may include skin conditions (e.g. popular urticaria, molluscum contaigiosum, herpes simplex virus, herpes zoster, or warts) (Department of Health, 2013), anaemia, malignancies (Department of Health, 2013; South to South, 2010), renal disease or cardiac-related conditions such as HIV-related cardiomyopathy (G. S.
Cooke et al., 2009; Kaul & Patel, 2001; Nkuize, De Wit, Muls, Arvanitakis, & Buset, 2010; Rabie et al., 2007).

The health conditions associated with HIV may not only impact the overall health of a child, but may also contribute to the development or maintenance of FSD. Co-morbidities may thereby increase morbidity and mortality, while resulting in a decreased quality of life (Rabie et al., 2007; Schwartz & Rothlingova, 2011).
2. Literature Review

The Nature of FSD

Infants and children with HIV infection are at risk for feeding disorders, as well as difficulties in any of the four phases of swallowing (Melvin et al., 1997; Nel & Ellis, 2012; Pressman & Morrison, 1988; Pressman, 2010). Feeding and swallowing difficulties experienced by children with HIV infection may occur as consequences of other HIV-related conditions. Several HIV-related conditions such as neurologic disease, infectious co-morbidities and GIT disorders have been associated with FSD (Mathisen et al., 1999; Nel & Ellis, 2012; Reilly, Morgan, & Wisbeach, 2011; Strudwick, 2003; Theron et al., 2009). Due to a dearth of research specific to the field of FSD in the paediatric population with HIV/AIDS, research conducted in the general paediatric population will be used as a framework to discuss the nature of FSD in infants and children with HIV.

Feeding and swallowing difficulties may be caused by a single factor, or through a complex interaction of factors (Prasse & Kikano, 2009; Weir, McMahon, Barry, Masters, & Chang, 2009). Field, Garland and Williams (2003) found that the majority of FSD in the general paediatric population could be attributed to an interaction between biology and environment, and were frequently the result of an interaction of two or more factors. They suggested that FSD may be classified as either motivationally-based or skills-based (Field et al., 2003). Motivationally-based FSD are maintained due to the child’s environment, for example, caregivers facilitating the continuation of inappropriate mealtime behaviours such as the child’s refusal of certain types or textures of food, or mealtime avoidance behaviour. Skills-based FSD arise when children do not have specific physiologic skills in their feeding and swallowing repertoire, such as oral sensorimotor deficits (Field et al., 2003). This classification of FSD may, however, be problematic, as a clear distinction between motivationally- and skills-based problems is not always possible, and may neglect other aspects of FSD. Feeding and swallowing difficulties may be due to interplay of various factors; and it is possible for the nature of FSD to change over time due to factors such as the maturation of the child or improvement in health condition (Arvedson & Brodsky, 2002). In the general FSD literature, it is accepted that factors contributing to the development and maintenance of FSD can be grouped into four main areas, namely oral
sensorimotor, medical, physiological and behavioural (Berlin, Davies, Lobato, & Silverman, 2009; Prasse & Kikano, 2009; Rommel et al., 2003). As FSD are multifactoral, dysfunction in more than one of these areas simultaneously is possible (Rommel et al., 2003).

The movements of the lips, tongue and jaw play a crucial role in safe oral feeding (Arvedson, 2008). Any oral motor or oral sensory disorder may impact negatively upon feeding and contribute to FSD. It is possible to present with both oral motor and sensory disorders simultaneously (Arvedson, 2008; Rogers & Arvedson, 2005). Oral motor disorders have been significantly associated with anatomical anomalies, such as cleft lip or palate, and neurological conditions (Field et al., 2003), and may affect feeding functions such as sucking and chewing, lingual movement and oral control (Groher & Crary, 2010; Reilly et al., 2011).

Most oral sensory disorders can be classified as either hypersensitive or hyposensitive. A child with oral hypersensitivity, also known as oral defensiveness, may exhibit reluctance to eat certain flavours or textures of food, or may gag when these foods are introduced. Food avoidance or refusal may occur, resulting in the child being termed as a “picky” or “fussy” eater (Arvedson & Brodsky, 2002; Groher & Crary, 2010). A child with oral hyposensitivity will exhibit decreased awareness of where the bolus is in the oral cavity. Food may fall out of the mouth without the child realising, resulting in the child being termed as a “messy” eater. Children with hyposensitivity may also experience difficulty with controlling their secretions and drooling (Groher & Crary, 2010; Reilly et al., 2011). A significant association has been found between FSD due to oral sensory disorders and a history of aspiration and/or ventilation in the first 6 months of life (Rommel et al., 2003).

Infants and children with HIV may present with oral sensorimotor difficulties due to HIV-related conditions such as neurological impairment or neurodevelopmental delay, as well as conditions such as oropharyngeal candidiasis, which may increase oral sensitivity due to pain (Field et al., 2003; Pressman & Morrison, 1988; Pressman, 2010). Oral sensorimotor difficulties primarily affect the oral preparatory and oral phases of swallowing, which may result in slow or inefficient feeding, food refusal, or limited variety of food tastes and textures – all of which contribute to reduced oral intake. In addition, difficulties in the oral preparatory and oral phases may decrease the safety of swallowing and possibly lead to aspiration (Arvedson, 2008; Rogers & Arvedson, 2005).
Medically-based conditions are frequently identified as contributing toward FSD; therefore it is important to recognise the association between FSD and these specific health conditions (Field et al., 2003; Groher & Crary, 2010; Rommel et al., 2003). Feeding and swallowing difficulties have been closely linked to several health conditions such as respiratory illness, neurological deficits, GIT problems, undernutrition and growth faltering, and chronic illness (Field et al., 2003; Lefton-Greif & Arvedson, 2008; Prasse & Kikano, 2009; Reilly et al., 2011; Rommel et al., 2003; Weir et al., 2009; Weir et al., 2010). The relationship between FSD and these health conditions may be reciprocal – such conditions may lead to or exacerbate FSD; or may be sequelae of FSD (Prasse & Kikano, 2009).

The relationship between respiratory illness and FSD has been well-explored in the literature. Integrity of the airway is essential for successful and safe oral feeding (Arvedson, 2008). Respiratory illness may impair feeding, and children with respiratory conditions are at risk of developing FSD, specifically dysphagia (Arvedson, 2000; Field et al., 2003; Lefton-Greif & Arvedson, 2008). Children with chronic lung disease (CLD) tend to exhibit shortness of breath, increased respiratory rate and fatigue during feeding (Arvedson, 2000). This may negatively affect the temporal coordination of breathing and swallowing, thereby significantly increasing the risk of aspiration – an adverse outcome which may have particularly serious consequences in children with decreased respiratory resilience (Field et al., 2003; Lefton-Greif & McGrath-Morrow, 2007; Lefton-Greif & Arvedson, 2008). Respiratory illness may further exacerbate the effects of FSD by increasing energy requirements through increased metabolic rate (Field et al., 2003). As children with FSD are at risk of decreased oral intake, escalated energy requirements may increase the severity of malnutrition (Arvedson, 2000).

Respiratory illness may not only act as a causal factor in the development of FSD, it may also arise as a negative sequela of FSD. Infants and children presenting with dysphagia are at risk for aspiration (Lefton-Greif & Arvedson, 2008; Prasse & Kikano, 2009), which may be due to impaired swallowing, GORD, or poor management of oral secretions (Tutor & Gosa, 2012). Repeated aspiration is strongly associated with recurrent lower respiratory tract infections (LRTI) and CLD (Tutor & Gosa, 2012; Weir et al., 2009), particularly in children with neurological impairment (Benfer et al., 2014; Reilly & Skuse, 1992; Reilly et al., 2011). It is difficult to predict how severely aspiration may affect respiratory function in individual children. Several factors may affect a child’s respiratory resilience such as the presence of a
productive cough, the severity of dysphagia, nutrition status, and the presence of pre-existing respiratory illness (Lefton-Greif & McGrath-Morrow, 2007; Lefton-Greif & Arvedson, 2008; Weir, McMahon, Barry et al., 2007).

Respiratory conditions represent an important co-morbidity and cause of mortality in the paediatric population with HIV. Infants and children with HIV may be hospitalised several times throughout their lives for LRTI, with some children experiencing severe recurrent bouts of respiratory illness (Theron et al., 2009; Zar, 2008). The respiratory resilience of infants and children with HIV may be impaired due to a compromised immune system (Zar, 2008). Furthermore, as children with HIV are at risk of neurological complications, the risk of developing LRTI as a result of aspiration is further increased (Benfer et al., 2014; Reilly et al., 2011). The respiratory resilience of children with HIV in response to aspiration may be poor, as this population is at risk of pre-existing respiratory complications and malnutrition – factors which may decrease respiratory resilience (Lefton-Greif & McGrath-Morrow, 2007; Lefton-Greif & Arvedson, 2008; Weir, McMahon, Barry et al., 2007). The susceptibility to contracting TB, together with recurrent LRTI, increases the risk of permanent lung damage in this population. In addition to this, the increased risk of developing FSD further increases the risk of negative respiratory consequences due to aspiration (Theron et al., 2009).

Infants and children with HIV/AIDS infection may present with neurological deficits (Rabie et al., 2007) which may exacerbate pre-existing FSD in the paediatric population with HIV, or may, in fact, act as a causal factor in the development of FSD (Nel & Ellis, 2012). Progressive HIV encephalopathy (PHE) is a major cause of neurological impairment in infants and children with HIV – such an impairment may result in a deterioration in health and the loss of previously acquired feeding and swallowing skills, thereby increasing the risk of aspiration and negative respiratory consequences (Pressman, 2010; Van Rie et al., 2007). Children with HIV may also have a co-existing neurological diagnosis such as cerebral palsy (Rabie et al., 2007).

The relationship between neurology and FSD has been documented in the general paediatric population; infants and children with neurological deficits or neurodevelopmental delay are at an increased risk of FSD (Andrew, Parr, & Sullivan, 2012; Arvedson, 2000; Barratt & Ogle, 2010; Field et al., 2003; Lefton-Greif & Arvedson, 2008;
Reilly et al., 2011; Sullivan et al., 2000). Feeding and swallowing difficulties are frequently reported in children with neurological impairment (Reilly et al., 2011), with some reports of up to 80% prevalence (Barratt & Ogle, 2010; Calis et al., 2008; Reilly et al., 2011). In children with severe cerebral palsy, the prevalence of FSD may be over 90% (Andrew et al., 2012; Calis et al., 2008; Reilly & Skuse, 1992; Reilly, Skuse, & Poblete, 1996). Typical FSD in children with neurological impairment include difficulties in one or more phases of swallowing. Aspiration may occur in up to 70% of children with severe motor impairment (Andrew & Sullivan, 2010; Andrew et al., 2012; Reilly & Skuse, 1992; Reilly et al., 2011). Gastrointestinal tract difficulties are also frequently reported in children with neurological impairment, which may negatively affect feeding and swallowing (Andrew & Sullivan, 2010; Andrew et al., 2012; Reilly et al., 2011).

Difficulties in the oral preparatory and oral phases of swallowing may be characterised by oral sensorimotor difficulties. Reilly et al. (1996) reported that over 90% of their sample of preschool-age children with cerebral palsy had significant oral motor dysfunction, with over a third of this group presenting with severe oral motor dysfunction. The severity of oral motor dysfunction and FSD is influenced by the degree of motor involvement, thus children with motor impairment involving all four limbs may present with more severe oral motor dysfunction than children with unilateral motor impairment (Reilly et al., 1996; Reilly et al., 2011; Sullivan et al., 2000). Abnormal muscle tone and movement patterns in the body may also affect posture; there is a direct correlation between postural stability and oral motor function (Andrew & Sullivan, 2010; Andrew et al., 2012; Redstone & West, 2004). Without postural stability and trunk alignment, the head cannot be stable, thereby negatively influencing the fine movements of oral structures for feeding. Poor posture and alignment may also decrease optimal airway protection during swallowing. Head control is important for maintaining a safe airway, thus poor head control and posture may inhibit the protection of the airway during swallowing, resulting in penetration or aspiration (Andrew & Sullivan, 2010; Andrew et al., 2012; Redstone & West, 2004). Therefore poor posture may negatively impact oral movements, and may contribute towards decreased safety of swallowing (Redstone & West, 2004; Reilly et al., 2011).

Aspiration in children with neurological impairments is associated with an increased likelihood of recurrent LRTI and respiratory consequences, particularly in children who are immobile due to severe motor impairments (Reilly et al., 2011; Sullivan et al., 2000; Weir,
McMahon, Barry et al., 2007). In a study investigating FSD in children with neurological impairment, Sullivan et al. (2000) reported that recurrent LRTI were more common in children who choked on food and those who had difficulty swallowing lumpy consistency food. This indicates possible aspiration events leading to recurrent LRTI. Further risk factors for aspiration within this group include a weak gag or cough reflex (Tutor & Gosa, 2012); children with communication delays who are not able to effectively communicate their feeding difficulties to their caregivers (Barratt & Ogle, 2010); and difficulties with temporal coordination of breathing and swallowing (Tutor & Gosa, 2012). Although FSD in the paediatric population with neurological impairment are predominantly due to oral sensorimotor deficits and physiological causes, a strong behavioural component may also exist or develop over time (Arvedson, 2000; Groher & Crary, 2010; Lefton-Greif & Arvedson, 2008; Reilly et al., 2011). Infants and children with HIV may present with neurological impairment which may negatively influence feeding and swallowing (Nel & Ellis, 2012; Pressman, 2010; Rabie et al., 2007).

Gastrointestinal tract disorders have been associated with FSD in the general paediatric population (Arvedson & Brodsky, 2002; Mathisen et al., 1999; Rommel et al., 2003). Gastrointestinal tract disorders that may have adverse effects on feeding and swallowing include GORD, extra-oesophageal reflux disease (EORD), and gastrointestinal dysmotility (Arvedson, 2000; Arvedson & Brodsky, 2002; Mathisen et al., 1999; Oosthuizen, 2012; Prasse & Kikano, 2009; Rommel et al., 2003; Strudwick, 2003). Gastro-oesophageal reflux may be the most common GIT disorder contributing to FSD. In a study investigating the nature of FSD in 700 children, Rommel et al. (2003) found that GIT disorders were the most common medical diagnosis among children with FSD; with GORD being the most commonly identified medical condition underlying FSD. An unpublished study in South Africa reported similar findings, with more than half of the 446 participants with FSD presenting with GIT conditions (Oosthuizen, 2012). This highlights the significance of GORD in the development of FSD.

Gastro-oesophageal reflux has been identified as a cause of oesophagitis, a condition which may lead to odynophagia and dysphagia (Arvedson & Brodsky, 2002; Mathisen et al., 1999). As a result, GORD frequently results in negative experiences with feeding – such as vomiting, pain, coughing and gagging – leading to oral hypersensitivity, learned aversions and refusal of food, as well as behavioural difficulties related to feeding (Mathisen et al.,
Experiences with pain and discomfort related to feeding represent important causal factors in the development of food aversion or behavioural feeding difficulties (Arvedson & Brodsky, 2002; Groher & Crary, 2010). Field et al. (2003) found that the presence of food refusal was significantly higher in children with GORD, than those without. Mathisen et al. (1999) compared infants with and without GORD and found that the majority of infants with GORD displayed oral motor dysfunction and dysphagia, as well as exhibiting significantly more food refusal, more oral hypersensitivity, more episodes of choking, and decreased readiness for transition to solid foods. With GORD and EORD, it is possible for refluxed material from the stomach or oesophagus to enter the larynx and be aspirated. Such aspirate may be particularly harmful to the respiratory system due to the increased acidity of stomach refluxate (Arvedson & Brodsky, 2002; Strudwick, 2003).

Gastrointestinal tract conditions may be more prevalent in the paediatric population with HIV than in the general paediatric population (M. L. Cooke et al., 2009; Pressman, 2010), which may in turn increase the occurrence of FSD (Mathisen et al., 1999; Strudwick, 2003).

Gastrointestinal tract disorders are linked to undernutrition and growth faltering (Field et al., 2003). This may be due to factors such as food refusal and decreased oral intake due to feeding or swallowing dysfunction, as well as impairments in the absorption of nutrients from the GIT. Undernutrition further negatively affects the GIT by causing physiological changes such as atrophy of the GIT mucousal lining, decreased motility, reduced bile acid absorption and overgrowth of bacteria. Therefore undernutrition can exacerbate GIT dysfunction, and vice versa – causing a cycle of undernutrition and poor absorption of essential nutrients (Arvedson & Brodsky, 2002; Kirby & Noel, 2007; Strudwick, 2003).

Gastrointestinal tract disorders are frequent in infants and children with HIV (M. L. Cooke et al., 2009; Pressman, 2010). Certain opportunistic infections which this population are susceptible to, such as candidiasis and cytomegalovirus, may exacerbate GORD (M. L. Cooke et al., 2009; Kaul & Patel, 2001). Gastrointestinal tract infections in this population have been linked to difficulty gaining weight and poor absorption of nutrients. This places infants and children with HIV not only at risk of GIT-associated FSD, but also at risk of developing acute or chronic undernutrition and growth faltering (Kaul & Patel, 2001; Nel & Ellis, 2012; Rabie et al., 2007).
In the general paediatric population with FSD, nutrition status is an important factor in determining the severity of impairment (Prasse & Kikano, 2009). Adequate nutrition is particularly important in the first 2 years of life. Physical growth and central nervous system (CNS) development are rapid during this critical period, and undernutrition may inhibit such growth. Even with adequate nutrition at a later stage, infants may never recover from such impairments to the CNS (Arvedson & Brodsky, 2002). All types of FSD place a child at risk of developing undernutrition and growth faltering, especially when the FSD is associated with GIT dysfunction or neurological involvement (Reilly et al., 2011; Rommel et al., 2003). Undernutrition may also result in muscle wasting (Arvedson & Brodsky, 2002; Kirby & Noel, 2007). Feeding and swallowing difficulties may lead to malnutrition, which in turn affects oral sensorimotor function, possibly worsening the severity of the FSD (Arvedson & Brodsky, 2002; Groher & Crary, 2010). Growth faltering has been associated with developmental delays, cognitive impairments and behavioural difficulties (Arvedson & Brodsky, 2002).

Growth faltering has the potential to cause severe deterioration in chronic illnesses such as HIV/AIDS; and children with chronic illness may frequently experience periods of loss of weight, limited or no weight gain, due to co-existing medical complications or extended periods of hospitalisation (Arvedson & Brodsky, 2002; Pressman, 2010). Undernutrition and growth faltering are well-documented in the paediatric population with HIV (Palmer, 2003; Pressman, 2010; Rabie et al., 2007; Rose et al., 2014). As this population is already at risk of growth faltering, the effects of FSD as co-morbidity may significantly increase the risk of severe growth faltering, which may in turn increase the risk of mortality (Rose et al., 2014).

The correlation between FSD and chronic illness is multifactoral, with physiological and psychosocial factors playing a role (Schwartz & Rothlingova, 2011). Children with chronic medical problems, such as HIV/AIDS, exhibit FSD more frequently than healthy children (Field et al., 2003). Feeding and swallowing difficulties in children with chronic illness may be primarily due to physiological deficits, however, over time, a strong behavioural component may develop. Maladaptive behaviour could be related to the child’s behaviour during mealtimes (e.g. food refusal), to maladaptive interactions between caregivers and children, or to increased anxiety in the caregivers, children, or both (Arvedson & Brodsky, 2002; Schwartz & Rothlingova, 2011).
Children with HIV may encounter negative experiences related to chronic illness such as side-effects of medication, frequent hospitalisation or experiences with non-oral feeding (e.g. nasogastric tube feeding) (Schwartz & Rothlingova, 2011). These children may also encounter negative experiences directly related to feeding, such as pain when feeding or swallowing, vomiting during or after the feed, or long periods of non-oral feeding which may increase oral sensitivity and result in oral sensorimotor disorders when oral feeding is reintroduced (Arvedson & Brodsky, 2002; Pressman, 2010; Schwartz & Rothlingova, 2011).

The first two years of life are vital in developing feeding behaviours and sensory tolerance for a wide variety of food types and textures (Arvedson & Brodsky, 2002; Rogers & Arvedson, 2005). Children with chronic illness may not have so-called “normal” experiences with food during this period due to the afore-mentioned factors. When children have limited experiences with a variety of food and textures during this critical period, they may develop hypersensitivity and may not tolerate many types of food tastes and textures (Groher & Crary, 2010; Lefton-Greif & Arvedson, 2008; Schwartz & Rothlingova, 2011).

Caregivers experience significant stress and anxiety when managing a child with a chronic illness. These feelings may extend to mealtimes and impact upon the interaction between the caregiver and child. Such children frequently exhibit general fussiness, irritability or crying, which may further increase the caregiver’s anxiety. This may cause a cycle where the caregiver feels pressured to meet the child’s nutritional requirements through oral feeding, but encounters difficulties during the mealtime. The caregiver may thus resort to maladaptive responses such as cajoling and force-feeding. Maladaptive behaviours by caregivers such as these may increase the child’s anxiety, thereby exacerbating the original FSD (Arvedson & Brodsky, 2002; Schwartz & Rothlingova, 2011). Caregivers of infants and children with HIV may have HIV/AIDS themselves, thus the increased burden associated with feeding the child may further increase levels of stress and anxiety for the entire family unit (Schwartz & Rothlingova, 2011).

Physiological factors contributing to FSD can be defined as disorders in the physiology of feeding or swallowing (Groher & Crary, 2010). This can include any difficulties in the pharyngeal phase of swallowing, such as a delayed or absent swallow reflex, decreased pharyngeal contractions, in-coordination between swallowing and respiration, or
difficulties in the oesophageal phase of swallowing, such as disorders of the upper or lower oesophageal sphincter or disordered peristalsis (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010). Physiological factors may also be factors that affect feeding on a physiological level, such as decreased appetite and hunger (Arvedson & Brodsky, 2002; Berlin et al., 2009; Lefton-Greif & Arvedson, 2008). Physiological disorders may occur independently, or may be as a result of internal or external factors. For example, difficulties in the pharyngeal or oesophageal phase of swallowing may be due to neurological impairment. Decreased appetite could result from chronic illness or infection, as well as from medication, such as ART (Groher & Crary, 2010; Prasse & Kikano, 2009). As a result, physiological factors may contribute to FSD by causing or exacerbating dysphagia, as well as by altering feeding patterns, thereby leading to decreased oral intake (Prasse & Kikano, 2009; Schwartz & Rothlingova, 2011).

Finally, behavioural factors must be considered in the development and maintenance of FSD (Arvedson & Brodsky, 2002; Kerwin, 2003; Martin, Dovey, Coulthard, & Southall, 2013). Moderate to severe behavioural feeding difficulties are more frequent in children with physical impairments and medical illness (Kerwin, 2003). Caregivers of children with behavioural feeding difficulties often report concerns regarding poor appetite, fussiness with food and food refusal (Martin et al., 2013). According to Arvedson & Brodsky (2002), behavioural feeding problems may initially arise from medical conditions involving oral sensorimotor, neurologic, gastrointestinal or respiratory difficulties. However, feeding problems may persist once the medical condition has been resolved.

The persistence of the feeding problems may be due to several factors, such as limited exposure to “normal” eating practices during the course of the medical condition, negative experiences as a direct result of eating (e.g. pain due to gastroesophageal reflux or diarrhoea), negative experiences such as being forced to eat, or a combination of these factors (Arvedson & Brodsky, 2002; Groher & Crary, 2010; Kerwin, 2003; Lefton-Greif & Arvedson, 2008; Martin et al., 2013; Schwartz & Rothlingova, 2011). The interaction between behavioural feeding difficulties and medical conditions may also be reciprocal. Infants and children with medical conditions frequently develop behavioural problems after negative experiences with feeding, yet children with behavioural problems may develop medical conditions after continued problems with feeding and decreased oral intake lead to malnutrition (Groher & Crary, 2010).
Food refusal may develop due to classical conditioning or negative reinforcement (Kerwin, 2003; Martin et al., 2013). Classical conditioning of food refusal arises when ingestion of food is paired with negative experiences such as nausea, vomiting or discomfort, which results in an aversion to that food. Nausea, in particular, has been linked to the development of taste aversion (Kerwin, 2003). Food refusal of specific tastes and textures may also arise due to negative reinforcement. Negative reinforcement occurs when caregivers remove a specific food taste or texture from the meal after the child refuses it but fail to re-introduce the food at a later stage. This increases the likelihood of food refusal in the future (Kerwin, 2003). Caregivers of children with behavioural feeding difficulties tend to exhibit increased maladaptive mealtime behaviours such as coaxing, which may add to caregiver and child stress, and serve to reinforce behavioural feeding difficulties (Martin et al., 2013).

Whether FSD are based in oral sensorimotor, medical, physiological or behavioural roots, certain signs and symptoms may be observed which indicate the presence of FSD. In the general paediatric population, the signs and symptoms of FSD are used by health professionals to identify possible FSD and to indicate when a referral for a feeding and swallowing evaluation by a speech-language therapist (SLT) is necessary (Arvedson, 2008). These signs and symptoms may also be used by SLTs for the diagnosis of FSD and as an indication for further instrumental assessment (Weir et al., 2009). The signs and symptoms may indicate problems with swallowing or feeding, as well as identifying risks for aspiration (Arvedson, 2008; Weir et al., 2009).

Signs regarding the nature of the mealtime have been discussed in literature. These signs may include taking longer than 30 minutes to finish feeding (Arvedson, 2000; Arvedson & Brodsky, 2002; Arvedson, 2008) and stressful mealtimes for children and caregivers (Arvedson, 2008). Extended time to finish feeding may indicate difficulties with oral motor aspects of feeding, fatigue, food refusal or fussiness. Longer feeding times have been linked to an increased risk for malnutrition (Arvedson & Brodsky, 2002; Arvedson, 2008). Prolonged mealtimes may increase energy expenditure to a stage where the child is expending more energy than is consumed in calories, and may detract from time for opportunities for socialisation and development (Arvedson, 2000; Arvedson, 2008). Longer mealtimes have been associated with increased stress of the child and caregiver (Arvedson, 2008).
Signs of FSD may include the child’s general behaviour during mealtimes, such as crying or fussiness (Groher & Crary, 2010), irritability or lethargy (Arvedson, 2000; Arvedson & Brodsky, 2002; Arvedson, 2008), or refusal of food (Arvedson, 2000; Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010). Factors such as irritability or lethargy may be linked to underlying medical conditions. Children displaying irritability during mealtimes may be experiencing discomfort or pain due to possible GIT disorder and airway difficulties, while lethargy may be due to fatigue or medication (e.g. anticonvulsants) (Arvedson, 2008). As discussed previously, food refusal can indicate a range of FSD, such as oral sensorimotor difficulties, GIT disorders or behavioural issues (Arvedson, 2000; Arvedson, 2008). Signs such as regular vomiting and gagging may reflect oral hypersensitivity, discomfort or GORD (Arvedson, 2008; Groher & Crary, 2010; Weir et al., 2009).

Signs of FSD may be associated with oral motor dysfunction in the oral preparatory and oral phases of swallowing (Arvedson, 2008). Signs of oral preparatory phase disorder include symptoms related to impaired movement of the tongue, lips and jaw due to decreased strength, coordination, control or range of movement (Arvedson & Brodsky, 2002; Arvedson, 2008; Rogers & Arvedson, 2005). Anterior spillage of food during feeding may indicate poor lip closure, or the presence of tongue thrust – a reflexive action which may be considered pathological when it persists past the infant years (Arvedson & Brodsky, 2002). Signs of oral preparatory phase disorder in infants may include weak or in-coordinated sucking. This may be due to decreased strength and coordination of the lingual muscles and may result in fatigue and increased length of mealtimes (Arvedson & Brodsky, 2002; Rogers & Arvedson, 2005). Difficulty chewing solid foods may be due to decreased jaw strength and control, or inability of the tongue to manipulate the bolus in the mouth (Arvedson, 2008).

Signs of oral phase disorder relate to the propulsion of the bolus backwards in the mouth (Arvedson, 2008). The presence of residue on the tongue, hard palate or in the pockets of the mouth after the swallow indicates decreased tongue range of motion, strength and coordination. An increased oral transit time (the time it takes for the bolus to move posteriorly in the mouth) may also indicate decreased tongue strength and coordination (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010).
Other signs and symptoms of FSD may be related to malnutrition, such as a period of slowed weight gain or weight loss (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010), or to delayed development, such as continued drooling after 5 years (Arvedson & Brodsky, 2002; Arvedson, 2008), delayed feeding milestones (e.g. limited progression onto different food consistencies) (Groher & Crary, 2010), or dependence for feeding (Arvedson, 2008). Factors such as delayed feeding milestones and dependence for feeding may be indicative of neurodevelopmental delay or neurological impairment, but may also involve a behavioural element (Arvedson, 2008).

Signs of penetration or aspiration generally involve descriptions of respiratory distress or respiratory complications (Arvedson, 2008; Weir et al., 2009). Descriptions of voice quality have been used to indicate possible aspiration. These include a gurgly or wet voice (Arvedson & Brodsky, 2002; Arvedson, 2008; Weir et al., 2009) or changes in voice quality or hoarseness (Arvedson, 2000; Weir et al., 2009). A gurgly or wet voice indicates the presence of foreign material such as food, liquid or secretions in the airway, and can be noted when the infant or child phonates after swallowing. Changes in voice quality or hoarseness may indicate damage due to GORD (Arvedson, 2000). Respiratory distress signs involve changes to the child’s normal respiratory patterns during mealtimes, such as increased respiratory rate (Arvedson, 2000; Arvedson, 2008; Weir et al., 2009), coughing (Arvedson & Brodsky, 2002; DeMatteo, Matovich, & Hjartarson, 2005; Groher & Crary, 2010; Weir et al., 2009), choking (Groher & Crary, 2010; Weir et al., 2009), wheezing (Weir et al., 2009) or stridor (Arvedson, 2000). These respiratory signs indicate possible penetration and aspiration. The physiological responses to the introduction of foreign material into the airway can also be identified by other signs such as oxygen desaturation or bradycardia (Weir et al., 2009). Recurrent pneumonia must be treated as a sign of FSD and possible aspiration, warranting further investigation of feeding and swallowing abilities (Arvedson, 2000; Arvedson & Brodsky, 2002; Weir et al., 2009).

Studies by Weir et al. (2009) and DeMatteo et al. (2005) investigated which signs of penetration and aspiration have the best clinical accuracy in the general paediatric population. These signs were included as part of a clinical evaluation, and then compared to the results from an instrumental swallowing assessment – a videofluoroscopic swallow study (VFSS). Both studies found that aspiration and penetration occurred significantly more frequently with liquids than with puree consistency and solids. Weir et al. (2009)
found that coughing, wet voice and wet breathing were significantly associated with aspiration with thin fluids as identified by VFSS. Thus cough, wet voice and wet breathing can be considered good clinical markers of aspiration with liquids. DeMatteo et al. (2005) also reported that coughing was significantly associated with aspiration on thin liquids. It was further found that the best prediction model for aspiration on thin liquids included coughing, together with voice changes and gagging. Both these studies therefore show that clinically, coughing and wet voice during or after the ingestion of thin liquids are good indicators of aspiration.

DeMatteo et al. (2005) also investigated the efficacy of clinical evaluations by SLTs in identifying aspiration and penetration compared to VFSS. Using a clinical evaluation, SLTs were able to correctly identify 92% of the participants who aspirated on fluids, as identified by VFSS. This indicates that experienced SLTs can accurately identify possible aspiration and refer for instrumental assessment. Although the SLTs in the study by DeMatteo et al. (2005) were less confident in identifying aspiration with semi-solids and solids as the signs of solid aspiration were less overt than liquid aspiration, they tended to be over-cautious and referred for instrumental assessment more frequently when solid aspiration was suspected. This resulted in a low false negative rate, which indicated that the SLTs were able to correctly identify the majority of participants with aspiration. The presence of the signs and symptoms of FSD indicates the need for further clinical assessment of feeding and swallowing by a SLT.

Analysis of the Available Literature on FSD in the Paediatric Population with HIV

A search of several databases (MEDLINE, CINAHL, Cochrane Library, Africa-Wide Information and Academic Search Premier) was conducted in October 2014 for previous studies related to FSD in the paediatric population with HIV. The following terms were included in the search in various combinations: dysphagia, feeding, feeding disorder, swallowing disorder, deglutition, deglutition disorder, paediatric, HIV, and AIDS. The search yielded three studies published regarding FSD in the paediatric population with HIV/AIDS. These studies are summarised in Table 1.
Table 1

Summary of Previous Studies in the Field of FSD in the Paediatric Population with HIV

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Period</th>
<th>Areas of Feeding and Swallowing Assessed</th>
<th>Method of Assessment</th>
<th>Signs and Symptoms of FSD Identified</th>
<th>Geographic Location</th>
<th>N</th>
<th>Age Range</th>
<th>Study Design</th>
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<tr>
<td></td>
<td></td>
<td>Oral sensorimotor examination</td>
<td>Clinical evaluation</td>
<td>Coughing or choking during feeding</td>
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<td>VFSS when pharyngeal phase difficulty or aspiration was suspected</td>
<td>Refusal during feeding</td>
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<td>Aspiration</td>
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<td></td>
<td></td>
<td>Odynophagia</td>
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<td>Melvin et al. (1997)</td>
<td>A 9 month period between 1993 - 1994</td>
<td>Behavioural problems related to feeding</td>
<td>Caregiver interview</td>
<td>Poor appetite</td>
<td>UK</td>
<td>42 (26 HIV-positive; 16 HIV-negative)</td>
<td>&lt; 5 yrs</td>
<td>Prospective, correlational</td>
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<td>Refusal during feeding</td>
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<td>“Fussiness” with food</td>
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<td>Extended time to finish feeds</td>
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<td>Eating a limited range of food</td>
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<tr>
<td>Nel &amp; Ellis (2012)</td>
<td>June 2006 – March 2009</td>
<td>Dysphagia</td>
<td>Clinical evaluation</td>
<td>Poor feeding</td>
<td>South Africa</td>
<td>25 children with HIV</td>
<td>2 m to 7 yrs 8 m</td>
<td>Prospective, descriptive</td>
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<tr>
<td></td>
<td></td>
<td>Oral sensorimotor examination</td>
<td>VFSS when pharyngeal phase difficulty or aspiration was suspected</td>
<td>Respiratory complications</td>
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<td>Poor growth</td>
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The prevalence of FSD reported in these three studies was 45% (Pressman & Morrison, 1988), 50% (Melvin et al., 1997) and 80% (Nel & Ellis, 2012). This seemingly high prevalence of FSD may not be a true reflection of FSD in the paediatric population with HIV for a number of reasons. The study by Pressman and Morrison (1988) was conducted prior to the introduction of antiretroviral drugs in the treatment of HIV/AIDS, as the first antiretroviral drug, Zidovudine, only became available in 1987 (Warnke, Barreto, & Temesgen, 2007). Although there is no available research regarding the effects of ART on FSD in the paediatric population, it is possible that the current prevalence of FSD in this population is lower than reported by Pressman and Morrison (1988), due to increased availability and access to ART, which may result in improved outcomes (Department of Health, 2013; Johnson et al., 2012) including feeding. The high prevalence reported by Nel and Ellis (2012) may be an overestimate as participants in the study were already identified as having a suspected FSD and referred for an assessment, thus the sample of participants was not a true representation of the general paediatric population with HIV as the study exhibited selection bias.

A further limitation of the above studies is small sample sizes. Although many large-scale studies have been conducted in the field of paediatric HIV, none of these have addressed FSD. A small sample size can negatively impact the validity of the study’s results, as the sample may not be representative of the study population, or appropriate statistical analysis methods may not be available (Maxwell & Satake, 2006).

Another difficulty in quantifying prevalence of FSD in this population is the lack of standardisation of definitions for FSD and methodologies used in the aforementioned studies. While Nel and Ellis (2012) and Pressman and Morrison (1988) both investigated dysphagia, the assessment tool used by Melvin et al. (1997) primarily focused on feeding behaviours, such as food refusal or lack of appetite; thus providing limited information regarding swallowing difficulties or dysphagia. Likewise, as Nel and Ellis (2012) and Pressman and Morrison (1998) focused mainly on dysphagia, limited information regarding behavioural aspects of FSD was provided in the studies. As both feeding and swallowing components may be affected in infants and children with HIV, it is important to consider the interplay of all FSD elements. No studies investigating all facets of feeding and swallowing in the paediatric population with HIV have been conducted, thus no true reflections of prevalence in this population are available.
The participants recruited by Melvin et al. (1997) included children under the age of 5 years who had been exposed to HIV, with division of the participants into two groups – with HIV and without HIV – occurring retrospectively after the participants’ HIV status had been confirmed. This resulted in a comparison group of children who were exposed to HIV, but HIV-negative. This comparison group was, however, much smaller than the group of children with HIV, which may influence the accuracy of results. Melvin et al. (1997) found a higher prevalence of feeding difficulties among the children with HIV (50%), compared to the children without HIV (12%). This supports literature stating prevalence is higher in the paediatric population with HIV than in the general paediatric population (Nel & Ellis, 2012; Pressman & Morrison, 1988; Pressman, 2010).

As the available information on FSD in the paediatric population with HIV is limited, the above studies are able to provide insight into the nature of FSD in this population. The FSD reported in these studies were related to oral sensorimotor, physiological, HIV-associated medical conditions and behavioural factors. The nature of FSD reported in the paediatric population with HIV included poor appetite, food refusal and fussy eating (Melvin et al., 1997), dysphagia (Nel & Ellis, 2012; Pressman & Morrison, 1988) and aspiration (Nel & Ellis, 2012; Pressman & Morrison, 1988). Neither the study by Nel and Ellis (2012) nor the study by Pressman and Morrison (1988) clearly defined dysphagia in terms of the different phases of swallowing. Nel and Ellis (2012) reported on difficulties in the oral and pharyngeal phases of swallowing, while Pressman and Morrison (1988) do not provide any information regarding the various phases of swallowing.

Nel and Ellis (2012) reported oral phase difficulties most frequently, with 44% of the participants with dysphagia experiencing difficulties in this phase. As Nel and Ellis (2012) do not describe specific oral difficulties, it is not clear whether this figure includes oral preparatory phase difficulties. Pharyngeal phase difficulties were reported in 41% of the participants with dysphagia, while 25% of the participants presented with oral and pharyngeal phase difficulties simultaneously. Following VFSS, Nel and Ellis (2012) identified aspiration in 30% of the participants with dysphagia. All participants with abnormal VFSS results had evidence of respiratory involvement (Nel & Ellis, 2012).

Nel and Ellis (2012) identified recurrent respiratory infections, poor feeding and growth failure as indicators for a FSD assessment. Both Pressman and Morrison (1988) and Nel and
Ellis (2012) identified coughing as a sign of aspiration and dysphagia. Odynophagia was also identified in the studies by Nel and Ellis (2012) and Pressman and Morrison (1988) as contributing to FSD. In this population, odynophagia may be secondary to infection such as oral or esophageal candidiasis, or GORD (Blignaut, 2007; Pressman, 2010). Pressman and Morrison (1988) further identified food refusal with specific food consistencies, such as liquid, semi-solid or solid. The majority of swallowing difficulties identified in the study by Nel and Ellis (2012) were not due to structural abnormalities or pathologies. This may indicate a neurological deficit influencing oral sensorimotor abilities and the temporal coordination of swallowing and breathing (Arvedson & Brodsky, 2002; Reilly et al., 2011).

Melvin et al. (1997) identified feeding difficulties in the group of children with HIV. The majority of these difficulties were poor appetite, food refusal and fussiness with food. The “fussy eaters” were described as taking longer to finish their meal, and only eating a small amount or a limited range of food. These types of FSD may be linked to aversive and maladaptive learned behaviours related to chronic illness (Schwartz & Rothlingova, 2011). As Melvin et al. (1997) did not report on possible co-morbidities in the participants, it is not possible to comment on a possible associations between medical conditions and the development of behavioural feeding difficulties, which have been documented in the general paediatric population (Groher & Crary, 2010; Lefton-Greif & Arvedson, 2008; Schwartz & Rothlingova, 2011).

The above studies identified possible aetiologies for FSD in children with HIV. Nel and Ellis (2012) reported central nervous system involvement in 52% of their participants, which included HIV encephalopathy, cerebral palsy, seizures and neurodevelopmental delay. This highlighted the association between neurological impairment and swallowing disorders, which is supported by FSD literature in the general paediatric population (Calis et al., 2008; Reilly & Skuse, 1992; Reilly et al., 1996; Reilly et al., 2011; Sullivan et al., 2000). Pressman and Morrison (1988) identified specific aetiologies for dysphagia such as generalised developmental delay, dysphagia due to neurological involvement such as HIV progressive encephalopathy or brain tumour, or dysphagia due to fungal infection such as oropharyngeal candidiasis. The findings by Pressman and Morrison (1988) draw further attention to the association between neurological impairment (such as encephalopathy and brain tumour) and FSD.
It was noted that dysphagic symptoms were highly variable based on the current condition of the child (Pressman and Morrison, 1988). Pressman and Morrison (1988) reported that difficulties with feeding were compounded by respiratory difficulties, infections, fever and abdominal pain. It was further noted that respiratory difficulties, such as LRTI, increased the required caloric intake of the child. Thus, a LRTI could simultaneously exacerbate dysphagia while increasing caloric demand.

The types of FSD and related aetiologies reported in the afore-mentioned studies, such as neurological impairment, GIT dysfunction, chronic illness and behavioural factors, appear to reflect those noted in the general paediatric population (Arvedson & Brodsky, 2002; Groher & Crary, 2010; Lefton-Greif & Arvedson, 2008; Mathisen et al., 1999; Reilly et al., 1996; Reilly et al., 2011; Schwartz & Rothlingova, 2011; Strudwick, 2003; Sullivan et al., 2000). It is possible; however, that infants and children with HIV may experience co-morbidities such as these more frequently than the general paediatric population, with the possibility of such co-morbidities occurring simultaneously. These co-morbidities may contribute to the development, maintenance, or exacerbation of FSD with far-reaching consequences (Nel & Ellis, 2012; Pressman, 2010; Rabie et al., 2007).

Consequences of FSD

Limited research has been conducted specifically on the consequences of FSD in the paediatric population with HIV and FSD, thus research conducted on the consequences of FSD in the general paediatric population was consulted. The most common consequences of FSD in the general paediatric population are respiratory illness (Prasse & Kikano, 2009; Weir, McMahon, Barry et al., 2007; Weir et al., 2009), growth faltering (Palmer, 2003; Rose et al., 2014) and issues related to quality of life (Arvedson & Brodsky, 2002; Threats, 2007). FSD may also have an impact on development (Rossetti, 2001; So et al., 2014). Respiratory complications such as LRTI are frequently reported in children with dysphagia and are usually related to aspiration (Prasse & Kikano, 2009; Tutor & Gosa, 2012; Weir, McMahon, Barry et al., 2007; Weir et al., 2009; Weir et al., 2010). Aspiration of foreign materials may obstruct the airway or may result in bacterial pneumonia or pneumonitis. Recurrent and untreated lower respiratory tract infections may result in permanent lung damage, cor pulmonale and even death (Tutor & Gosa, 2012; Weir, McMahon, Barry et al., 2007; Weir et al., 2010).
Respiratory illness is relatively common in children with HIV (Zar, 2008), thus the presence of FSD characterised by aspiration may contribute to further and more severe deterioration of respiratory health. The development of LRTI and lung damage may present with a higher mortality rate in individuals with HIV/AIDS, particularly due to their already compromised immunological status and impaired respiratory resilience (Mofenson et al., 2009). Aspiration pneumonia should be considered as a possible aetiology of CLD in children with HIV and should be investigated further (Rabie et al., 2007; Weber, Gie, & Cotton, 2013).

The relationship between FSD, growth faltering and chronic illness has been previously discussed. HIV infection increases a child’s energy requirements by up to 10%, which may increase even further when the child is experiencing co-morbid conditions such as opportunistic infections (Palmer, 2003; Rose et al., 2014). When nutritional intake and nutrient absorption is compromised due to FSD, the ensuing growth faltering can significantly worsen the medical condition of a child with HIV/AIDS (Palmer, 2003). Growth faltering decreases a child’s general health resilience and ability to recover from HIV-related conditions (Nel & Ellis, 2012; Pressman & Morrison, 1988; Pressman, 2010). Growth faltering remains a noteworthy cause of extended hospitalisation in children with HIV (Melvin et al., 1997). Therefore the addition of FSD as a co-morbidity may exacerbate growth faltering (Arvedson, 2008; Tutor & Gosa, 2012) leading to more severe health consequences.

According to Threats (2007), the International Classification of Functioning, Disability and Health (ICF) is a useful tool in delineating the various factors contributing towards dysphagia and feeding disorders. The ICF Child and Youth Version (ICF-CY) is particularly useful, as it has been designed to provide a standardised framework and terminology when discussing the impact of health impairments on the activity and functioning of children (World Health Organization, 2007). In most societies, much value is placed on food and activities relating to eating; and eating can be considered a social event in the majority of cultures (Arvedson & Brodsky, 2002; Threats, 2007). Specific customs involving eating and drinking may have less to do with the physical act of consuming food, and more to do with celebration and human interaction (Threats, 2007). Feeding and swallowing difficulties have the potential to limit participation in everyday eating-related activities, resulting in negative psychosocial consequences. Children with FSD may develop depression and
anxiety surrounding their difficulties, with such emotions also possibly being experienced by caregivers (Arvedson & Brodsky, 2002). Certain caregivers may be more accustomed to assisting a child with a FSD, thereby limiting the impact of the FSD on participation; however, caregivers with HIV themselves may experience deteriorating health, or may even pass away. Thus, a child with HIV may have several different caregivers rotating at any time. This may further increase stress and anxiety of a child with FSD and their caregivers with regard to the feeding activity (Pressman, 2010; Threats, 2007).

Feeding and swallowing difficulties related to neurodevelopmental delay or neurological impairment, such as delays in reaching age appropriate feeding milestones and acquiring self-feeding skills, may negatively impact upon the child’s independence. Inability to self-feed may decrease enjoyment of meals and limit participation in mealtimes (Schwartz & Rothlingova, 2011; Threats, 2007). The culmination of these adverse consequences of FSD is a decrease in the quality of life of both the child and family members (Arvedson & Brodsky, 2002; Pressman, 2010).

Lefton-Greif and Arvedson (2007) further emphasised the use of the ICF in the field of paediatric FSD. The lack of standard definitions regarding FSD may hinder the description of difficulties in the paediatric population. The ICF therefore provides a standardised framework which may be used to describe the effects of FSD on a child’s activity and participation, as well as guiding treatment goals (Lefton-Greif & Arvedson, 2007).

A further possible consequence of FSD is prolonged hospitalisation due to sequelae such as respiratory illness or malnutrition. Thus the effects of prolonged hospitalisation and chronic illness on early childhood development must also be considered. When hospitalised for extended periods of time – for example, frequent hospitalisation due to recurrent LRTI – a child’s experiences with normal daily interactions, as well as opportunities to learn through interaction with the environment, are significantly reduced (Rossetti, 2001; Schwartz & Rothlingova, 2011). Hospital environments are not conducive to child development as caregivers are continuously changing, and the environment may be either over- or under-stimulating. Children may also have their sleeping patterns disrupted (So et al., 2014). The interaction between caregiver and child may be affected, with the caregiver experiencing feelings of anxiety or stress, which may negatively impact the attachment between the infant and caregiver (Rossetti, 2001). According to Rossetti (2001), the
interaction between the infant and caregiver plays a crucial role in development, especially that of communication. Infants who are ill tend to interact differently with their caregivers when compared to healthy infants. Even once the medical condition of the ill infant has improved, disordered patterns of interaction may persist due to learned behaviours. When considering these factors, it is clear that prolonged hospitalisation coupled with chronic illness may hinder appropriate early childhood development. This in turn may negatively impact feeding development (Arvedson & Brodsky, 2002). In the paediatric population with HIV, where delay in development may be secondary to HIV-related conditions such as encephalopathy, additional limitation of age-appropriate interactions with the environment may result in a child falling even further behind (So et al., 2014).

The numerous possible consequences of FSD may have a greater negative impact on health in the paediatric population with HIV/AIDS than in the general paediatric population, due to a compromised immunological status and the presence of co-morbid conditions related to HIV/AIDS. Thus, early identification and appropriate management of feeding and swallowing difficulties is essential to prevent further complications and negative health outcomes and to improve quality of life (Melvin et al., 1997; Nel & Ellis, 2012; Prasse & Kikano, 2009; Pressman & Morrison, 1988; Pressman, 2010).

**Screening Questionnaires and Checklists for Paediatric FSD**

According to the South African Speech Language and Hearing Association Ethics and Standards Committee (2011), screening for FSD is usually performed by health professionals other than SLTs. The role of SLTs in FSD screening is education of these health professionals regarding the risk factors for FSD, as well as the clinical signs of FSD (Arvedson & Brodsky, 2002; South African Speech Language and Hearing Association Ethics and Standards Committee, 2011). Early detection of FSD is therefore dependent on the identification of the signs of FSD by a wide array of health professionals (e.g. doctors, nurses, allied health professionals); followed by a referral to a SLT for a comprehensive feeding and swallowing assessment (Arvedson & Brodsky, 2002; Groher & Crary, 2010; Lefton-Greif & Arvedson, 2008).

As the paediatric population with HIV/AIDS is at an increased risk of FSD, a screening tool for FSD that can be used by any member of the multidisciplinary medical team would
be clinically useful. It is of particular importance to have such a screening tool in South Africa, where there is a lack of SLTs in the public health sector and the number of doctors and nurses working within South Africa’s Department of Health far outweigh the number of SLTs. The most of the children with HIV in South Africa attend follow-up appointments at primary health care institutions, the majority of which do not have a resident SLT, thus requiring patients with possible FSD to be referred to secondary or tertiary institutions (Department of Health, 2010; Department of Health, 2013; South to South, 2010). The lack of SLTs working within the government sector highlights the necessity for other health professionals to be able to understand and use a screening tool for FSD, in order to identify potential difficulties timeously in children with HIV and to refer them appropriately.

The available literature was searched to identify validated screening tools for FSD in the paediatric population with HIV/AIDS. A search of several databases (MEDLINE, CINAHL, Cochrane Library, Africa-Wide Information and Academic Search Premier) was conducted in October 2014 for validated screening tools specific to this population using the following key words in various combinations: pediatric, paediatric, screening, checklist, questionnaire, dysphagia, feeding and swallowing, deglutition, deglutition disorder, HIV, AIDS. At the time of the search, no published and validated screening tool for FSD in the paediatric population with HIV was found internationally or within the South African context.

The search did identify a screening tool for dysphagia in the general paediatric population. The 3-ounce water test is a screening test for aspiration due to oropharyngeal dysphagia (Suiter, Leder, & Karas, 2009). The age of participants in the study ranged from 2 to 18 years of age (mean 13.4 years), with the majority of the participants older than 10 years (Suiter et al., 2009). The 3-ounce water test requires participants to follow instructions, therefore use in infants, young children and children with neurological impairments would not be appropriate. According to the literature, the majority of children with FSD are under the age of 2 years and many have neurological impairment (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010; Reilly et al., 2011; Rommel et al., 2003), therefore the 3-ounce water test would not be appropriate for use with a large majority of the children with FSD. Furthermore, the 3-ounce water test only assesses for signs of aspiration, thereby neglecting other aspects of FSD, such as oral sensorimotor difficulties, behavioural feeding difficulties, or delays in reaching age-appropriate feeding
milestones – aspects which would be important to identify because of long term consequences and implications for further assessment. The use of the 3-ounce water test in the paediatric population with HIV/AIDS is thus not appropriate, especially when considering the multifaceted nature of FSD in this population. The sample population in the 3-ounce water test study is neither representative of the paediatric population with HIV/AIDS in either age distribution nor in health status. It has also been shown that infants and children with HIV/AIDS frequently exhibit FSD involving oral sensorimotor difficulties, behavioural difficulties and delays in feeding milestones; factors which would not be noted by the 3-ounce water test (Melvin et al., 1997; Pressman & Morrison, 1988; Pressman, 2010).

Other assessments of FSD identified in the literature included the Dysphagia Disorders Survey (DDS) (Sheppard, Hochman, & Baer, 2014), the Nutrition and Feeding Risk Identification Tool (NFRIT) (Sondel & Baroni, 1993), the Screening Tool of Feeding Problems Applied to Children (STEP-CHILD) (Seiverling, Hendy, & Williams, 2011), and the Schedule for Oral Motor Assessment (SOMA) (Skuse, Stevenson, Reilly, & Mathisen, 1995). The DDS was reported to be a valid and reliable tool for the identification of FSD in older children (above 8 years) with developmental disability, but is not appropriate for use with younger children (Sheppard et al., 2014). The NFRIT focuses primarily on nutritional intake, rather than specific feeding and swallowing difficulties, and has not been validated (Sondel & Baroni, 1993). The STEP-CHILD has been validated with the general paediatric population, however, this tool is limited to the identification of feeding difficulties, and is not able to identify dysphagia (Seiverling et al., 2011). The SOMA has been validated with young children with cerebral palsy and growth faltering, however, this tool is focuses on oral motor aspects and not swallowing. It is also not able to provide information regarding feeding difficulties (Skuse et al., 1995). These four instruments are therefore not appropriate tools to screen for feeding and swallowing difficulties in the paediatric population with HIV, as they do not encompass all the areas of feeding and swallowing, and have not been validated with this population.

A screening tool that is specific to, and has been validated with the paediatric population with HIV would be valuable, as it could be used by a range of health professionals (e.g. doctors, nurses, or allied health professionals) in frequent contact with the infant or child and would facilitate the early identification of FSD. As FSD in this
population may have poor health outcomes, early identification and management of FSD may significantly reduce negative consequences, thereby reducing morbidity and mortality, as well as the social and economic burden associated which such conditions.

Validating a Screening Tool

Screening can form a valuable part of secondary prevention in health care – health conditions may be detected earlier, at a time when treatment will cure the condition, or slow its progression – thereby resulting in improved health outcomes (Andermann, Blanquart, Beauchamp, & Déry, 2008; Elliman, Dezateux, & Bedford, 2002; Mant & Fowler, 1990). There are, however, certain conditions that must be met in order for screening to be feasible. Andermann et al. (2008) describe these conditions as follows: In order for screening to be of value, the condition being screened for should have serious potential implications for morbidity and mortality. The condition should be relatively prevalent, and accepted criteria for diagnosis must exist. As the goal of screening is early identification of health conditions, the condition must be treatable. There should also be a benefit to the early treatment and management of the condition. Plans should be in place for the full diagnostic assessment and treatment for individuals with positive screening results. Finally, the cost of the screening programme must be estimated – the cost of the screening, diagnostic and treatment procedures should be offset by savings in morbidity and mortality, as well as social and economic burden (Andermann et al., 2008).

A screening tool for the identification of FSD in the paediatric population with HIV fulfils all the aforementioned conditions. As previously discussed, FSD can result in a range of negative health consequences, thereby significantly increasing morbidity and mortality. Although an accurate estimate of the prevalence of FSD in this population is not available, available literature estimates prevalence rates of between 45% and 80% (Melvin et al., 1997; Nel & Ellis, 2012; Pressman & Morrison, 1988). This prevalence is high enough to warrant screening (Andermann et al., 2008; Elliman et al., 2002; South African Speech Language and Hearing Association Ethics and Standards Committee, 2011). The nature and types of FSD are quantified in the general paediatric literature, which provides adequate criteria for diagnosis of FSD. Feeding and swallowing difficulties are treatable, and it has been shown that early diagnosis and management may reduce the associated morbidity and mortality (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010). Speech-
language therapists are able provide comprehensive feeding and swallowing assessments and necessary treatment to individuals with positive screening results (Arvedson & Brodsky, 2002). The cost of screening for FSD in this population is thus justified, as early detection will reduce negative health consequences, including the associated costs for treatment of negative sequelae such as LRTI (Pressman, 2010).

Another important consideration for a screening tool is that it should be appropriate for the specific population. In South Africa, the majority of health professionals are mono- or bilingual – predominantly speaking English and Afrikaans. A small minority of health professionals, mainly nurses, speak an African language such as isiXhosa or Zulu (Deumert, 2010; Levin, 2006a; Levin, 2006b). Most of the patients utilising public health services, however, do not speak English as a first language, and it has been shown that many common English words used by health professionals are not in the patients’ vocabulary (Levin, 2006a; Levin, 2006b; Levin, 2006c). This emphasises the need for a screening tool that is linguistically appropriate.

Validity and reliability of new screening tools need to be determined before implementation in clinical settings. This ensures that the instrument being used has high quality and is appropriate for use in specific clinical settings (Scholtes, Terwee, & Poolman, 2011). Criterion validity is particularly important in screening – it is the degree to which the scores of a screening instrument reflect those of a “gold standard” or the accepted standard measurement in the field, and is generally determined by sensitivity, specificity and predictive value (Brink, Van der Walt, & Van Rensburg, 2012; Maxwell & Satake, 2006). According to Glascoe (1997), a screening instrument should have sensitivity levels of 70-80%, whereas Meisels (1989) suggested that sensitivity levels should be above 80%. Generally high levels of sensitivity are expected for screening tools as it is important that the highest amount of people be correctly identified with the disorder (Maxwell & Satake, 2006; Meisels, 1989). The trade-off of high levels of sensitivity may be lower specificity, resulting in false positives and over-referrals (Mant & Fowler, 1990). Glascoe (1997) stated that specificity levels of 70-80% are acceptable. A predictive value of above 50% is acceptable for a screening test (Glascoe, 1997). Predictive value is influenced by the prevalence of a condition; therefore, the likelihood of a screening tool yielding a true positive result is higher when testing for a condition with a high prevalence (Hulley et al., 2013; Maxwell & Satake, 2006).
Studies that aim to determine the diagnostic accuracy of a specific measure are important in the evaluation of new instruments such as screening tools. The validity of such studies may, however, be negatively affected by factors such as poor methodology, inaccurate selection of participants, incorrect analysis of data or improper reporting of results. The Standards for Reporting of Diagnostic Accuracy (STARD) statement was developed in order to improve the reporting of studies of diagnostic accuracy. Comprehensive reporting of studies of diagnostic accuracy allows readers to identify possible errors in methodology, as well as to judge the applicability of the results to specific populations. The STARD statement includes a checklist of 25 items relating to the reporting of a research study. The items in the checklist have been included to decrease potential bias, to identify limitations in the study, and to clearly outline the study population and methods in order to judge the applicability of the results in other populations or settings (Bossuyt et al., 2003).

The lack of an existing paediatric dysphagia screening tool and the need for early identification of feeding and swallowing difficulties supports the development and validation of such a tool. It is essential that a screening tool is both valid and reliable so that it can correctly identify infants and children at risk for feeding and swallowing difficulties (Groher & Crary, 2010). Difficulties with screening may include outcomes of false positives and false negatives which in this instance could lead to either referrals of children who do not actually present with dysphagia or a lack of referral for children who do present with dysphagia (Maxwell & Satake, 2006).

This study aims to address this research gap by validating a caregiver screening questionnaire for the identification of infants and children presenting with signs of FSD in the paediatric population who are HIV-infected. As discussed, FSD in this population may vary in nature; arising from complex interactions between oral sensorimotor difficulties, medical conditions, physiological disorders and behavioural difficulties. Signs and symptoms of FSD may be observed, which may indicate the need for further assessment of feeding and swallowing. Consequences of FSD, such as respiratory illness and growth faltering, may be severe, which emphasises the need for early identification of difficulties in feeding and swallowing.
Early referral for comprehensive assessment of feeding and swallowing by an SLT will facilitate early identification and management of FSD leading to improved health outcomes (Arvedson, 2000; Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010), decreased morbidity and mortality (Andermann et al., 2008; Arvedson & Brodsky, 2002), and an increased quality of life (Threats, 2007).
3. Methodology

3.1. Aims and Objectives:

Primary aim

The primary aim of this study was to determine the validity and the reliability of a caregiver questionnaire as a screening tool for feeding and swallowing difficulties in infants and children with HIV/AIDS.

Objectives

The following objectives were identified in order to achieve the primary aim:

1. To determine the face and content validity of the *Feeding and Swallowing Questionnaire*
2. To determine the linguistic appropriateness of the items included in the *Feeding and Swallowing Questionnaire*
3. To determine criterion validity of the *Feeding and Swallowing Questionnaire*
   3.1 To determine the sensitivity of the *Feeding and Swallowing Questionnaire* in correctly identifying participants with feeding and swallowing difficulties
   3.2 To determine the specificity of the *Feeding and Swallowing Questionnaire* in correctly identifying participants without feeding and swallowing difficulties
4. To determine the internal consistency reliability of the *Feeding and Swallowing Questionnaire*
5. To determine the inter-rater reliability of the *Feeding and Swallowing Questionnaire*

Sub-aim

The sub-aim of the study was to describe a profile of infants and children with HIV/AIDS and the presenting feeding and swallowing difficulties, as well as any associations with specific factors.
Objectives

The following objectives were identified to achieve the sub-aim:

1. To describe the child participants in terms of age and HIV-related factors
2. To compare participants with and without FSD to determine whether any relationship exists between feeding and swallowing difficulties and:
   - Age
   - HIV-related factors
   - Lower respiratory tract infection
   - Malnutrition and growth faltering
3. To describe the nature of feeding and swallowing difficulties presenting in infants and children with HIV/AIDS

3.2. Research Design

This research project utilised a descriptive, prospective clinimetric research design (Brink et al., 2012; Dekker, Dallmeijer, & Lankhorst, 2005; Maxwell & Satake, 2006). A descriptive research design allows the systematic description of phenomena through the observation and recording of variables (Brink et al., 2012; Du Plooy, 2009; Terre-Blanche, Durrheim, & Painter, 2006). This design allowed the researcher to describe the type and nature of FSD thoroughly, as well as to draw attention to possible associations between variables, such as FSD and medical conditions (e.g. HIV, lower respiratory tract infections, and malnutrition). A limitation of a descriptive research design is that it does not allow identification of causal relationships (Brink et al., 2012; Du Plooy, 2009; Hulley et al., 2013; Maxwell & Satake, 2006). This limitation did not affect this research project, however, as determining causal relationships was not included as an aim.

A prospective research design collects new data in the present (Maxwell & Satake, 2006; Portney & Watkins, 2009). The strength of using a prospective research design is that the data can be recorded systematically on a datasheet as it is collected, thus lowering the risk of missing data. The researcher is also able to clearly define what data is to be collected and the specific terminology to be used. The data can therefore be collected in a standardised manner, increasing the reliability of the data. In comparison, retrospective studies often present challenges such as inaccurately recorded or incomplete data, or a lack of standardised terminology and methods in obtaining the data (Brink et al., 2012; Maxwell
& Satake, 2006). Therefore, prospective research tends to be more reliable than retrospective research (Portney & Watkins, 2009). A limitation of prospective studies is that it may be difficult reaching the desired sample size (Brink et al., 2012; Maxwell & Satake, 2006). This limitation was addressed in this study by utilising a research site that has a large out-patient HIV clinic, as well as including in-patients.

A clinimetric research design aims to design and evaluate an instrument for use in clinical practice through the testing of its validity and reliability (Dekker et al., 2005; Scholtes et al., 2011). To determine the accuracy of an instrument, it is compared to a comprehensive clinical evaluation protocol. Test accuracy can be determined through the calculation of sensitivity, specificity and predictive value. Test sensitivity refers to the probability of the instrument correctly identifying an individual with a problem (true positive), whereas test specificity refers to the probability of the instrument correctly not identifying individuals who do not have the disorder (true negative). Predictive value includes positive predictive value (the probability of an individual having the disorder when the instrument’s results are positive) and negative predictive value (the probability of an individual not having the disorder when the instrument’s results are negative) (Maxwell & Satake, 2006; Scholtes et al., 2011). A clinimetric design allowed the screening tool in the current study to be assessed for validity and reliability, thereby determining the accuracy of the screening tool and addressing the primary aim of the study.

Key informant and expert opinion were used in the refinement of the screening instrument. A key informant interview is a type of structured interview which is conducted in order to obtain knowledge and insight from the participant (Kumar, 1989). In this study, caregivers provided information regarding the linguistic appropriateness of the English, Afrikaans and isiXhosa versions of the Feeding and Swallowing Questionnaire (FSQ).

Experts in the field of paediatric feeding and swallowing difficulties were also consulted to provide their opinion regarding the face and content validity of the FSQ (Portney & Watkins, 2009). Face and content validity of a health scale is typically determined by experts’ judgements on whether the tool appears to be appropriate for the desired purpose (Streiner & Norman, 2008). Expert opinion is frequently used in validation studies to establish face and content validity (Gosselin, Bourgault, Lavoie, Coleman, & Méziat-Burdin, 2014; McIntosh et al., 2010; Thoyre et al., 2014). The Questionnaire for Experts
(Appendix A) was developed to determine the experts’ opinions regarding the FSQ. The Questionnaire for Experts was kept as brief as possible, including only 5 questions, to limit the amount of time necessary to complete it and to promote participation of the experts. The potential for group bias in the expert opinion feedback was limited, as the experts remained anonymous to each other and completed the Questionnaire for Experts independently (Portney & Watkins, 2009).

The descriptive, prospective clinimetric research design that was used in this study was best suited for the validation of the FSQ, as well as for meeting the sub-aim of describing the profile of the participants and the presenting FSD, and any associations between FSD and specific factors.
Figure 1. Procedure Algorithm
3.3. Study Location

The research site was Red Cross War Memorial Children’s Hospital (RCWMCH), a tertiary hospital affiliated with the University of Cape Town. Enrolment took place in the paediatric infectious diseases unit, which cares for children with advanced HIV infection of 13 years of age and younger. Infants and children attending the infectious diseases unit generally attend a follow-up appointment at the clinic every one to three months, during which their progress on the ART programme is evaluated in terms of HIV/AIDS-related signs and symptoms, growth and nutritional status, neurodevelopmental progress and serial viral load and CD4 count measurements. This site was selected as it services a large catchment area, thereby ensuring optimal chances of recruitment.

3.4. Participants

3.4.1. Selection Criteria

Three groups of participants were included in this study, namely the experts, caregivers, and children attending the Infectious Diseases Clinic (IDC) at RCWMCH.

The experts were required to be SLTs working in South Africa, who had a minimum of 5 years clinical experience in the field of paediatric dysphagia. The experts identified to participate were asked if they had 5 or more years experience in paediatric dysphagia. This declaration was then verified by an independent third party, thus establishing their expertise in the field of paediatric dysphagia. No exclusion criteria were identified for the experts.

Caregiver participants were included on the basis that they were attending the IDC with their infant or child. It was necessary that the caregiver participants include five isiXhosa-speaking, five Afrikaans-speaking and five English-speaking caregivers. Caregivers identified for the isiXhosa and Afrikaans interviews were required to be primary language speakers of each language respectively. Caregivers identified for the English interviews could be primary- or secondary-speakers of English. Individuals accompanying infants or children to the clinic who were not primary caregivers were excluded as they may not have been able to answer the questionnaire accurately.
In order for a child participant to be included in the study, the following criteria had to be met:

- **Age:** Participants had to be under the age of 13 years. This is the age of children attending the paediatric infectious diseases clinic at RCWMCH, where the study was conducted.

- **Child participants had to have a confirmed diagnosis of HIV infection:**
  - If less than 18 months of age, a positive HIV DNA PCR confirmed by the pre-ART baseline viral load result.
  - If older than 18 months of age, 2 positive HIV serological test results (HIV ELISA or HIV Rapitest) or a positive HIV DNA PCR confirmed by the pre-ART baseline viral load result.

Child participants were excluded if they had severe respiratory distress characterised by laboured breathing or assistance with breathing (e.g. provision of supplemental oxygen), however patients could be included once the respiratory distress had resolved, as reported in the medical notes. Acute severe respiratory distress may affect the infant or child’s feeding and swallowing ability, thus affecting the reliability of the results of the assessment. Child participants were also excluded if their caregivers had participated in the caregiver interviews, as the re-use of the screening questionnaire with the same caregivers could affect the results due their familiarity with the tool. The child participants have been described in detail in the Results section, in order to facilitate the comparison of the child participants with and without FSD.

### 3.4.2. Recruitment Strategy

Ethics approval to conduct the study was obtained from the University of Cape Town’s Faculty of Health Sciences Human Research Ethics Committee (FHS HREC 374/2013) (Appendix B). Permission to conduct the study at RCWMCH was then obtained from the senior medical superintendent (Appendix C).

Caregiver and child participants were recruited at the out-patient paediatric Infectious Diseases Clinic (IDC), where they attended their routine follow-up sessions. Further child
participants were recruited from the in-patient medical wards at RCWMCH, where they were identified by the respective registrars of the wards. Informed consent was obtained from the caregiver participants (Appendix D, E & F) and legal guardians (Appendix G, H & I), and assent (Appendix J) was obtained from children older than 6 years. The recruitment of participants occurred between January and May 2014.

The experts were identified by the researcher’s supervisor as experts in the field of paediatric dysphagia in South Africa. They were invited to participate via e-mail, and were later contacted telephonically. They provided informed consent by replying to the e-mail.

3.4.3. Sampling

Non-probability, purposive sampling was used to select the experts (Portney & Watkins, 2009). This is a type of non-random sampling, in which the researcher specifically selects participants based on predefined criteria (Nelson, 2009; Portney & Watkins, 2009). Purposive sampling is useful when the researcher requires participants who will be a high-quality source of information, such as with experts in a given field (Nelson, 2009).

Non-probability, consecutive sampling was used to select caregiver and child participants (Brink et al., 2012; Maxwell & Satake, 2006). This is a type of non-random sampling, in which all members of the target population that fulfil the selection criteria will be asked to participate in the study, until the sample size is reached (Brink et al., 2012; Maxwell & Satake, 2006). All eligible individuals were invited to participate in the study.

3.4.4. Sample Size

Experts

Five speech-language therapists (SLTs) with experience in the field of paediatric FSD were invited to participate in an expert review of the FSQ. Three of these SLTs responded and participated in the review. According to Streiner and Norman (2008), between three and ten experts in a respective field are adequate for providing feedback on the screening tool through expert opinion.

The three expert participants were all female SLTs registered with the Health Professions Council of South Africa (HPCSA). They had work experience in both the public
and private health sector, and in academic settings. The expert participants’ experience in pediatric dysphagia ranged from 5½ years to 25 years.

**Caregiver Participants**

Fifteen participants took part in the key informant interviews to determine the linguistic appropriateness of the screening tool. Relatively few participants are usually selected for key informant interviews when compared to formal surveys. Most studies that utilise key informant interviews conduct between 15 and 35 interviews (Kumar, 1989; Marshall, 1996).

All fifteen participants were primary caregivers of children attending the IDC. Of these fifteen caregivers, 9 (60%; n=15) were mothers, 4 (26.7%; n=15) were grandmothers, and 2 (13.3%; n=15) were fathers. All five of the caregivers who were interviewed in English spoke isiXhosa as a primary language, but identified themselves as being proficient in conversational English. The FSQ has been previously trialled with first language speakers of English as part of the larger study. It is important, however, to determine the linguistic appropriateness of the English version of the FSQ with second-language speakers of English, as many of the patients or caregivers utilising public healthcare in South Africa do not speak English as a primary language. It is thus important to ensure that the terminology and language use of the English version of the FSQ is appropriate for second-language speakers of English.

The interviews conducted in isiXhosa and Afrikaans were conducted with primary language speakers in each of the languages respectively.

**Child Participants**

A total of 66 (N=66) child participants were included in the study. This sample size was calculated by a one-sample sensitivity and specificity power analysis using Epicalc 2000. Sensitivity and specificity were set at 90%, with a confidence interval of 95%. A total sample size of 63 (N=63) achieves 94% power to detect a change in sensitivity from 0.5 to 0.9 using a two-sided binomial test and 100% power to detect a change in specificity from 0.5 to 0.9 using a two-sided binomial test. The prevalence of dysphagia in the pediatric population with HIV was set at 25% for the power analysis. Although literature reported a prevalence of between 45% and 80%, these were likely to be over-estimates due to
limitations in the studies’ methodologies. Therefore prevalence was set at 25%, which correlates with the prevalence of FSD in the general paediatric population (Arvedson & Brodsky, 2002; Groher & Crary, 2010).

### 3.5. Research Personnel

*Feeding and Swallowing Questionnaire*

A research assistant (RA) administered the FSQ. The two RAs involved in this study were qualified SLTs, registered with the HPCSA. The RAs were trained in the administration of the FSQ, and were able to speak English and Afrikaans. An interpreter was used for isiXhosa when necessary. The RAs and the interpreter were required to sign confidentiality agreements.

*Clinical Feeding and Swallowing Evaluation*

The CFSE was administered by the researcher, who was trained in the administration of the evaluation. The researcher is a qualified SLT, registered with the HPCSA. The researcher is able to speak English and Afrikaans, and an interpreter was provided for isiXhosa-speaking participants. The CFSE was also administered by a RA for inter-rater reliability checks. The RA that performed these checks was blind to the results of the FSQ.

### 3.6. Materials and Instrumentation

#### 3.6.1. Feeding and Swallowing Questionnaire (FSQ)

The original screening instrument, the FSQ (Appendix K), as developed for the larger study conducted by Nel, Ellis, Norman and Rabie, was designed to identify feeding and swallowing difficulties in the paediatric population with HIV/AIDS. It was developed by two SLTs experienced in paediatric dysphagia together with a paediatric gastroenterologist as part of a larger ongoing study which is investigating feeding and swallowing difficulties in the paediatric population with HIV. During development of the questionnaire, experts in the field were consulted, as well as the available paediatric dysphagia literature. The revised versions of the FSQ, which include changes made after the current study’s expert
review and caregiver interviews, have been included as Appendix L (English), M (Afrikaans) and N (isiXhosa).

The FSQ takes less than 20 minutes to complete. The questionnaire includes the following areas: types of feeds the child is currently receiving, characteristics of the feeding session (e.g. length and difficulty), distress signals exhibited by the child during feeds (e.g. difficulty breathing, vomiting), difficulty eating different consistencies of food, weight of the child, and the presence of gagging, refusal of food, coughing or choking. The items in the FSQ are colour-coded blue or red according to the severity of the sign or symptom of FSD the item assesses. Blue items indicate less severe signs or symptoms, such as fussiness while feeding, not finishing a meal or gagging with food or liquids. Red items indicate more severe signs or symptoms, such as difficulty breathing while feeding, a wet voice after feeding, nasal regurgitation, or coughing or choking while feeding. The items were rated as blue or red depending on the potential negative health consequences related to the difficulty in feeding or swallowing. Red items were identified due to potential aspiration associated with the difficulty.

As such, the FSQ has specific pass/fail criteria. An individual is considered to have failed the FSQ when two or more blue items are marked, or when one or more red items are marked. Further assessment of feeding and swallowing abilities by a SLT is indicated when the FSQ yields a fail result.

The FSQ was translated into Afrikaans (Appendix M) and isiXhosa (Appendix N) by the Language Centre of Stellenbosch University. The translated versions were then translated back into English by first language speakers of Afrikaans and isiXhosa respectively, and then compared to the original English version of the FSQ for accuracy. As the FSQ is available in English, Afrikaans and isiXhosa, the three predominant languages in the Western Cape in South Africa are represented. The final versions of the Afrikaans and isiXhosa versions of the FSQ containing revisions made following the expert feedback and caregiver interviews are included as appendices. The FSQ has been previously piloted with first language English speakers, therefore this study focused on the linguistic appropriateness of the English FSQ with second language English speakers. As the majority of patients and caregivers attending government health institutions in South Africa do not speak English as a primary language,
the linguistic appropriateness of the FSQ with second language English speakers is an important consideration.

The reliability and validity of this instrument was the primary aim of this study and will therefore be addressed in the Results chapter.

3.6.2. Clinical Feeding and Swallowing Evaluation (CFSE)

A standard Clinical Feeding and Swallowing Evaluation (CFSE) (Appendix O) was used to assess participants’ feeding more comprehensively. No standardized, validated published measure for the comprehensive clinical evaluation of paediatric dysphagia is available. The current literature in this field includes guidelines and suggested protocols for the assessment of FSD. The CFSE was designed and developed by two speech-language therapists experienced in paediatric dysphagia and through review of the clinical assessment guidelines available in literature on paediatric dysphagia (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010; Hall, 2001; Lowick et al., 2012; Rabie et al., 2007; Reilly et al., 2011; Swigert, 2010). The CFSE was the gold standard method used for evaluating the FSQ.

Table 2 presents the areas included in the CFSE, as well as a rationale for the inclusion of each area, which provides face and content validity. The assessment consists of several components. Firstly, an interview with the caregiver regarding the child’s developmental and feeding history was conducted. Secondly, the child’s behaviour prior to feeding was observed and an oral motor structure examination was performed. Finally, an assessment of feeding was performed by evaluating the child’s ability to swallow different consistencies, namely liquids, semi-solids/puree and solids, depending on the child’s age and the developmental appropriateness of the consistencies. The liquid used for infants was breast milk or formula (as per the infant’s current feeding regime), and water for older children. The semi-solid used was yoghurt or porridge, and the solid used was a biscuit.
Table 2  
**Rationale for the Inclusion of the Areas and Items in the CFSE**

<table>
<thead>
<tr>
<th>Information</th>
<th>Items in the evaluation form</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>HISTORY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent/ caregiver concerns</td>
<td></td>
<td>The parent or caregiver will be able to provide information representative of an everyday feeding session, as well as identifying specific areas of difficulties in feeding sessions (Arvedson &amp; Brodsky, 2002; Arvedson, 2008)</td>
</tr>
<tr>
<td>Primary caregiver and who feeds the child</td>
<td>Items 1 &amp; 2</td>
<td>It is important to note if the caregiver being interviewed is the same person who feeds the child or spends the majority of time with the child. Caregivers who feed the child will be able to provide the most representative information regarding feeding sessions. Children may also exhibit different feeding behaviours when being fed by different individuals (Arvedson &amp; Brodsky, 2002)</td>
</tr>
<tr>
<td>Medical history – illnesses related to feeding or swallowing problems and previous dysphagia-related investigations</td>
<td>Items 3 &amp; 4</td>
<td>The illnesses named in Item 3, e.g. candida, middle ear infections, seizures, may cause, or be indicative of feeding and swallowing difficulties. Many of these illnesses are also related to HIV/AIDS (Arvedson &amp; Brodsky, 2002; Rabie et al., 2007). A history of a barium swallow, GI scope, or milk scan may be indicative of previous dysphagia or gastrointestinal problems (Arvedson, 2008; Groher &amp; Crary, 2010)</td>
</tr>
<tr>
<td>Developmental history</td>
<td>Item 5</td>
<td>Developmental delay has been associated with feeding and swallowing problems (Arvedson &amp; Brodsky, 2002). HIV/AIDS may result in developmental delays in children (Lowick et al., 2012; Rabie et al., 2007). A developmental history may provide information on whether a developmental delay may be influencing feeding and swallowing</td>
</tr>
<tr>
<td>Feeding history</td>
<td>Items 6-14</td>
<td>A detailed feeding history may highlight feeding difficulties, delays or problems associated with dysphagia. Information on the caregiver’s perception of feeding sessions can be obtained, which may provide insight into the FSD (Arvedson &amp; Brodsky, 2002; Arvedson, 2008; Prasse &amp; Kikano, 2009; Reilly et al., 2011)</td>
</tr>
<tr>
<td>Textures in diet</td>
<td>Item 15</td>
<td>Feeding development involves the introduction of different food textures and consistencies. If a child is not eating age-appropriate textures of food, it may indicate a difficulty with feeding or swallowing (Arvedson &amp; Brodsky, 2002; Groher &amp; Crary, 2010)</td>
</tr>
<tr>
<td>Utensils used for feeding</td>
<td>Item 16</td>
<td>The types of utensils used during feeding depend on the age and development of the child. Failure to use age-appropriate utensils during feeding may indicate a feeding or swallowing problem. Item 15 and 16 are therefore both indicative of delays in feeding milestones which may indicate a feeding or swallowing difficulty (Arvedson &amp; Brodsky, 2002)</td>
</tr>
<tr>
<td>Consistency-specific information</td>
<td>Item 17</td>
<td>Children with dysphagia often have more difficulty in managing certain consistencies than others. In general, they present with more difficulty with liquids than with semi-solids or solids. Changing of food consistencies may also form part of</td>
</tr>
</tbody>
</table>
### Clinical Assessment of Feeding and Swallowing

<table>
<thead>
<tr>
<th>Management of Dysphagia (Arvedson &amp; Brodsky, 2002)</th>
</tr>
</thead>
</table>

#### Signs of Dysphagia

| Items 18-27 | In a clinical assessment of feeding and swallowing, signs of dysphagia are useful in identifying possible problems, such as aspiration and the need for further instrumental assessment (Arvedson & Brodsky, 2002) |

#### PRE-Feeding Assessment

<table>
<thead>
<tr>
<th>Current Alertness of Child</th>
<th>Item 28</th>
<th>Infants exhibit different states (e.g. awake, drowsy, asleep), and develop the ability to transition between these states. Disorganisation in the state system of an infant may result in aversive reactions to sensory stimuli, which may negatively influence feeding (Arvedson &amp; Brodsky, 2002; Groher &amp; Crary, 2010)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiological Status of Child during Assessment</td>
<td>Item 29</td>
<td>Changes in respiratory rate, heart rate and oxygen saturation during feeds may indicate difficulties coordinating breathing and swallowing or some form of distress (Groher &amp; Crary, 2010)</td>
</tr>
<tr>
<td>Posture and Tone of Child</td>
<td>Item 30</td>
<td>Children with abnormal tone, such as hypertonia or hypotonia, may develop maladaptive postures that negatively affect feeding. Children with abnormal muscle tone may be at risk for oral sensorimotor difficulties (Arvedson &amp; Brodsky, 2002; Arvedson, 2008; Groher &amp; Crary, 2010)</td>
</tr>
</tbody>
</table>

#### Signs of Dysphagia

| Items 31-36 | In a clinical assessment of feeding and swallowing, signs of dysphagia are useful in identifying possible problems, such as aspiration (Arvedson & Brodsky, 2002). Decreased control of secretions may be a symptom of dysphagia. A wet voice may indicate penetration of secretions into the airway (Groher & Crary, 2010) |

#### Oral Motor Structure Examination

| Items 37-44 | An oral motor structure examination aims to identify any abnormal oral structures or movements that may negatively affect the child’s ability to feed, chew or swallow (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010) |

#### Feeding and Swallowing Assessment

<table>
<thead>
<tr>
<th>Non-nutritive Sucking (NNS)</th>
<th>Items 45-52</th>
<th>Non-nutritive sucking in infants is an indicator of nutritive sucking. An infant experiencing difficulty with NNS (e.g. strength or coordination) may experience similar problems with nutritive sucking (Arvedson &amp; Brodsky, 2002; Groher &amp; Crary, 2010)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion of Different Consistencies in the Assessment, Liquids, Semi-Solids and Solids</td>
<td>Assessment of Liquids – Items 54-75</td>
<td>Feeding development involves the introduction of different food textures and consistencies. If a child is not eating age-appropriate textures of food, it may indicate a difficulty with feeding or swallowing. Therefore, depending on the age of the child, different food consistencies should be assessed. Children with dysphagia often have more difficulty in managing certain consistencies than others. In general, they present with more difficulty with liquids than with semi-solids or solids. Changing of food consistencies may also form part of management of dysphagia (Arvedson &amp; Brodsky, 2002; Groher &amp; Crary, 2010)</td>
</tr>
</tbody>
</table>

#### Position during Feeding

| Item 53 | The position during feeding may impact on the ability to swallow. Maladaptive postures and positions due to abnormal movement or muscle impairments may affect feeding and swallowing. The position during feeding is also important in the assessment of oral motor structures. |
tone may negatively influence oral-motor control, resulting in feeding and swallowing difficulties (Arvedson & Brodsky, 2002; Groher & Crary, 2010)

| Item 58-59 | Infants who experience difficulties with nutritive sucking may not receive sufficient nutritional intake, may take longer to feed and may become fatigued during feeding sessions (Arvedson & Brodsky, 2002) |

The following items are included in the assessment of all consistencies (liquid, semi-solid and solid)

| Item 56, 79, 80, 94, 95 | Decreased lip closure may result in anterior spillage. Reduced tone in the lips may result in residue material remaining in the anterior sulcus after the swallow (Arvedson & Brodsky, 2002; Arvedson, 2008) |
| Item 57, 81, 96 | Significant anterior spillage may indicate difficulty with lip closure and/or tongue thrust (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010) |
| Item 61, 77, 97 | Decreased tongue movement may result in difficulty in forming the bolus and propelling it backwards in the mouth, as well as the presence of residue in the lateral sulcus, and on the tongue and hard palate after the swallow. Abnormal, reflexive tongue movements such as tongue thrust may result in anterior spillage and/or interfere with oral feeding (Arvedson & Brodsky, 2002; Arvedson, 2008) |
| Item 62, 76, 93 | Infants will open their mouths in response to a nipple or teat. Older children will open their mouths when presented with food. Failure to do so may be due to maladaptive behaviours related to feeding (Groher & Crary, 2010) |
| Item 63, 78, 98 | Decreased jaw movement may result in difficulty chewing food. Abnormal, reflexive jaw movements such as tonic bite may result in difficulty in feeding the child with certain utensils (Arvedson, 2008) |
| Item 64, 82, 99 | A delay or absence in the triggering of the swallow may result in penetration of material into the airway, and increases the risk for aspiration. The risk of aspiration is further increased with an absent swallow as the airway is not adequately protected when material moves into the pharynx (Arvedson, 2008) |
| Item 65, 83, 100 | Requiring multiple swallows to clear residue from the mouth and pharynx may indicate decreased oral motor control (Arvedson, 2008) |
| Item 66, 85, 102 | The presence of oral residue after swallowing may indicate decreased strength, control and coordination of the lips and tongue (Arvedson, 2008) |
| Item 67, 84, 101 | The presence of nasal regurgitation may indicate abnormal velopharyngeal function or a cleft palate (Arvedson & Brodsky, 2002) |
| Item 68, 86, 103 | Signs of aspiration are important to identify during a clinical feeding and swallowing assessment, as this indicates a feeding and swallowing difficulty. Signs of aspiration would suggest the need for additional assessment and instrumental assessment for further management (Arvedson & Brodsky, 2002; Arvedson, 2008) |
Clinical assessment of feeding and swallowing, such as the CFSE, is only able to infer difficulties in the pharyngeal phase of swallowing. Pharyngeal phase disorders can only be confirmed using instrumental assessment of swallowing such as VFSS. It would, however, be unethical to expose infants and children without suspected pharyngeal phase disorder to the radiation-risks associated with VFSS (Weir, McMahon, Long et al., 2007). In clinical practice, it is appropriate for an SLT to make a decision regarding the need for instrumental assessment based on the results of the clinical assessment (South African Speech Language and Hearing Association Ethics and Standards Committee, 2011). The purpose of the study is to determine the validity of a screening tool in comparison to a clinical assessment of feeding and swallowing, therefore the procedures of the study follow that which would occur in clinical practice, whereby only participants with suspected pharyngeal phase disorder are referred for instrumental assessment. The results of the instrumental assessments were not available after completion of the current study’s data collection. As a result, the pharyngeal phase difficulties reported in this study are based on observed signs and symptoms, and not on confirmed aspiration.

The inter-rater reliability of the CFSE was determined during the study. Inter-rater reliability refers to the accuracy of judgement of the assessment tool between different people (Maxwell & Satake, 2006). The researcher conducted the CFSE while a research assistant observed. Both completed an evaluation form independently. Once the evaluation was completed, the researcher and the research assistant compared their results. When they differed on any items, the items were discussed and an agreement was reached. Seven (10.61%; N=66) of the CFSE conducted were tested for inter-rater reliability. A kappa statistic of 0.88 was obtained. A kappa of above 0.8 indicates very good agreement between raters, while a kappa of between 0.6 and 0.8 indicates good agreement (Hulley et al., 2013).

| Signs of discomfort/aversion e.g. gags, cries, vomits | Items 69-74, 87-91, 104-108 | Children with feeding and swallowing difficulties may develop negative behaviours in response to food, due to discomfort or pain. The presence of these behaviours or signs of distress may indicate a feeding or swallowing problem (Arvedson & Brodsky, 2002; Groher & Crary, 2010) |

**RECOMMENDATIONS**

The recommendations provide information on the course of management to be followed, depending on the results of the Clinical Feeding and Swallowing Evaluation.
3.6.3. Questionnaire for Experts

The Questionnaire for Experts (Appendix A) was used to determine the face and content validity of the FSQ. Three of five SLTs agreed to participate and were required to review the FSQ and then to complete the Questionnaire for Experts. The Questionnaire for Experts consisted of 5 closed-ended questions related to the FSQ, These questions were selected to determine whether the FSQ fulfilled the requirements of a screening tool related to the representativeness of the content (i.e. will the FSQ be able to identify children of different ages with different feeding and swallowing difficulties?), time efficiency, the inclusion or exclusion of items, and the use of the FSQ by other types of health professionals. The experts were also able to provide additional comments or recommendations (Streiner & Norman, 2008).

3.6.4. Feedback from Caregivers

The Feedback from Caregivers form (Appendix P) was used to determine caregivers’ understanding of the items in the FSQ. The form was used to guide a key informant interview. Once the FSQ was administered, the caregivers were asked if the questionnaire contained any words, phrases or questions that they didn’t understand. Thereafter, the researcher went through the FSQ with the caregiver, asking the caregiver to explain certain key terms in the questionnaire, e.g. vomit, hoarse voice, gag, choke, to assess their understanding of these terms. When the caregivers misunderstood a term or provided a different explanation, the researcher explained the term and asked if the caregiver had any suggestions for additional explanations or different vocabulary that would clarify the term in the FSQ, which could be added to the questionnaire for clarity.

3.7. Procedures

3.7.1. Data Collection

Figure 1 depicts the procedures followed in the study, which are discussed below in more detail. After ethics approval was obtained from the University of Cape Town’s Faculty of Health Sciences’ Human Research Ethics Committee (Appendix B), permission to conduct the study was obtained from the medical superintendent at RCWMCH (Appendix C). The researcher met with the staff at the IDC, including the head nurse and doctors. The
researcher also met with the medical registrars working in the wards at RCWMCH, as well as with the head of the SLT department at RCWMCH, to explain the aims and procedures of the study.

Potential experts were identified by the researcher’s supervisor, and were invited to participate in providing their expert opinion (Appendix Q). The experts who responded were emailed the FSQ and the Questionnaire for Experts. The completed Questionnaire for Experts was sent back to the researcher who addressed the experts’ suggestions and subsequently implemented changes to the FSQ.

The key informant interviews were conducted with the caregiver participants. The interviews were conducted to determine caregivers’ understanding of the items in the FSQ and were guided by the Feedback from Caregivers form. The interviews were conducted verbally with the caregivers, in order to eliminate literacy issues. When the caregivers experienced difficulty in understanding the terminology in the questionnaire, they were asked to provide suggestions for clarification. The modifications suggested by the caregivers were considered and appropriate adaptations were made to the FSQ.

The adapted FSQ was administered by the research assistant with the child participants. Following the completion of the FSQ, all child participants underwent a comprehensive CFSE, which was conducted by the researcher. The researcher was thus blind to the results of the FSQ, to prevent bias. The CFSE was completed within 24 hours of the completion of the FSQ. Throughout the study, approximately 10% of the FSQs and CFSEs conducted were used for inter-rater reliability checks.

The folders of the child participants were reviewed for a history of LRTI. Lower respiratory tract infections may be considered a symptom of dysphagia; when aspiration leads to respiratory complications. Folders were further reviewed for a history of undernutrition or growth faltering, and height and weight measurements taken within one week of the assessment were recorded to determine current nutritional status. Information regarding motor and communication developmental milestones was obtained from the caregivers via a section in the CFSE.
The RCWMCH infectious diseases clinic database was accessed to obtain the results of the child participants’ virological testing closest to the assessment date. The latest CD4 percentages and viral load measurements were recorded, as well as the WHO stage of HIV prior to ART initiation. This information was available for all child participants except one, who had recently started attending RCWMCH infectious diseases clinic after being initiated on ART at Groote Schuur Hospital.

A standard data collection form was used to capture the data from the folders of the child participants – namely, a recorded history of LRTI and undernutrition, and height and weight measurements from the latest IDC visit. A standard data collection form was also used to capture the data obtained from the IDC database.

### 3.7.2. Data Analysis

The results of the FSQ were compared to the results of the comprehensive clinical evaluation protocol, the CFSE, to determine the accuracy of the FSQ in correctly yielding a true positive or true negative. The measures of test accuracy that were calculated include test sensitivity, test specificity, positive predictive value and negative predictive value. Sensitivity of the FSQ was calculated by dividing the number of true positives by the number of true positives plus the number of false negatives. Specificity of the FSQ was calculated by dividing the number of true negatives by the number of true negatives plus the number of false positives (Maxwell & Satake, 2006). The results of the test sensitivity and specificity calculations were presented in tabular form (two-by-two confusion matrix).

Positive predictive value refers to the probability that the participant has a FSD when the result of the FSQ is positive. It was calculated by dividing the number of true positives by the number of FSQ that yielded a positive result. Negative predictive value refers to the probability that the participant does not have a FSD when the result of the FSQ is negative. It was calculated by dividing the number of true negatives by the number of FSQ that yielded a negative result (Maxwell & Satake, 2006).

Although the FSQ does not use formal scoring, the items were weighted depending on their classification as blue or red. As the referral criteria for the FSQ were two blue items, or one red item, the blue items were scored as 0.5 and red items were scored as 1. Therefore a score of 1 or more would constitute a failed FSQ. This scoring was used to
present the data in a Receiver Operating Characteristics (ROC) graph. A ROC graph presents
the sensitivity plotted against one minus specificity, thus showing the trade-off between
true positives and false positives. The ROC graph was able to identify a cut-off test score
that ensures the highest possible sensitivity and specificity (Fawcett, 2006). The area
underneath the ROC curve was used as a further indication of test accuracy. The area under
the curve can range from 0.5 (for a poor test) to 1.0 (for a perfect test) (Hulley et al., 2013).

Inter-rater reliability of the FSQ and CFSE was calculated using kappa’s statistic. A kappa
statistic of above 0.6 is an indication of adequate inter-rater agreement (Hulley et al.,
2013). The internal consistency of the FSQ was determined by analysing the items using
Cronbach’s alpha (Fawcett, 2006; Maxwell & Satake, 2006). Cronbach’s alpha indicates
whether items in a test measure the same construct or characteristic (Maxwell & Satake,
2006). A Cronbach’s alpha of below 0.50 is unaccept able and indicates that several items in
a test may be measuring different constructs, while a value of above 0.80 is considered
excellent (Hulley et al., 2013).

Descriptive statistics (i.e. measures of central tendency, and frequency distributions)
were used to describe the nominal data obtained regarding the profiles of participants with
and without feeding and swallowing difficulties (Maxwell & Satake, 2006). This data
included gender, age range, type and nature of FSD, and HIV-related information. Weight
and height measurements taken within a week of the FSD assessment were available for
the child participants. These measurements were converted into z-scores using software
from WHO Anthro (2003) software and evaluated according to weight-for-height, height-
for-age and weight-for-age.

A low weight-for-height score (WHZ) was classified as a z-score below -2 standard
deviations (SD), which indicates acute malnutrition possibly due to significant recent weight
loss. A low height-for-age (HAZ) was also reflected by a z-score below -2 SD – this may
reflect a more on-going form of chronic malnutrition resulting in stunting and growth faltering. Low weight-for-age (WAZ) reflects both a low weight-for-height, and a low
height-for-age, thus possibly indicating both acute and chronic malnutrition. A weight-for-
age z-score of between -1 and -2 SD indicated mild growth faltering, between -2 and -3 SD
indicated moderate growth faltering, and a z-score of less than -3 SD indicated severe
growth faltering (World Health Organization, 1995).
Inferential statistics were used to determine the statistical significance of the relationship between FSD and factors, namely age, length of time on ART, HAZ, WAZ, WHZ, and a history of LRTI or malnutrition (Brink et al., 2012; Maxwell & Satake, 2006). Both parametric and non-parametric statistics were used due to the nature of the data (Brink et al., 2012). The distribution of age, length of time on ART, HAZ, WAZ and WHZ were determined by using the Shapiro-Wilk test. It was found that age and length of time on ART were non-normally distributed, thus distribution was described using median values and interquartile ranges. HAZ, WAZ and WHZ were normally distributed; therefore distribution was described using means and standard deviation (Brink et al., 2012; Maxwell & Satake, 2006).

The correlation between FSD and age and between FSD and length of time on ART were both determined by a Wilcoxon Rank sum test. This test was appropriate as it does not make assumptions regarding the distribution of scores, thus making it more powerful than the $t$-test when analysing data that is not normally distributed, such as age and length of time on ART (Maxwell & Satake, 2006). The correlation between HAZ, WAZ and WHZ and FSD respectively, was determined by using the $t$-test for independent samples, which is appropriate when comparing data from two independent groups, such as the group with FSD and the group without FSD (Maxwell & Satake, 2006). The correlation between a history of LRTI and FSD was determined by the Chi-square test, which is useful in evaluating hypotheses regarding nominal data, such as the presence or absence of a health condition (Maxwell & Satake, 2006). Finally, the correlation between a history of malnutrition and FSD was determined by the Fisher’s Exact test. Fisher’s Exact test is useful for the analysis of contingency tables (Maxwell & Satake, 2006).

3.7.3. STARD Checklist

A Standards for Reporting of Diagnostic Accuracy (STARD) checklist was completed for this study (Appendix R) after data analysis was completed. The STARD statement was developed to guide studies of diagnostic accuracy and to ensure that reporting of such studies encompasses all necessary aspects. The study meets all the criteria, which increases the validity of the study itself (Bossuyt et al., 2003).
4. Ethical Considerations

Ethics approval was obtained from the UCT Faculty of Health Sciences Human Research Ethics Committee (FHS HREC REF 374/2013; Appendix B), and permission to conduct the study at RCWMCH was obtained from the medical superintendent (Appendix C). The following ethical principles were adhered to in accordance with the Declaration of Helsinki for Medical Research Involving Human Subjects (World Medical Association, 2013). Each participant received an identifying code for anonymity. Only these identifying codes were used on assessment forms. All identifying information was removed from documents and there were no associations between the participants and the data. A master copy of the participants’ names and reference codes was kept, should it be necessary to refer back to the data. This master copy was kept separate from the rest of the data. The data was stored in a locked, access-controlled room and any electronic data was password-protected. All information obtained was kept strictly confidential, and was only accessed by the researchers involved in this study (Brink et al., 2012).

Respect for Autonomy

The experts provided informed consent by agreeing to participate in the expert review. Informed consent was obtained from all caregiver participants. Regarding the child participants, informed consent was obtained from the legal guardians and assent was obtained from all children older than 6 years. All participants had the right to withdraw from the study at any stage without any negative consequences. The informed consent and assent forms were translated into Afrikaans and isiXhosa, and informed consent procedures were conducted in the language in which the caregiver was most comfortable (Brink et al., 2012; Maxwell & Satake, 2006).

Beneficence

The participants did not receive any immediate benefits. Child participants with unidentified swallowing or feeding difficulties were identified and referred for further management, which may have had potential health benefits (Brink et al., 2012).
Non-Maleficence

The participants did not incur any harm. The screening questionnaire presented no risk. An assessment of feeding or swallowing difficulties presented no risk for a child without dysphagia. An assessment for a child with dysphagia presented minimal risk of aspiration. The risk was minimal due to the small volumes of food consistencies used in the assessment. When any suspected aspiration occurred, the assessment was stopped immediately, and participants were referred for further assessment and management. This thereby reduced further risk. Participants who presented with clinical signs of aspiration were referred back to the treating physician for further management as per hospital protocol (Maxwell & Satake, 2006). Routine clinical care continued as usual. Participation in the study only added an additional 30-45 minutes to their time at the clinic. Refusal to participate in the study did not affect clinical care or future health care services available to the individuals.

Justice

All individuals that fulfilled the selection criteria were included in the study. The results of the study will be available to the institution and clinic that participated, as well as through publication (Brink et al., 2012).
5. Results

The results are reported according to the aims and objectives of the study.

5.1. Face and Content Validity of the Feeding and Swallowing Questionnaire

The *Feeding and Swallowing Questionnaire* was reviewed by experts who agreed that the FSQ demonstrated face and content validity. The feedback obtained from the experts, as well as subsequent modifications made to the FSQ are summarised in Table 3. Modifications to the FSQ were implemented before the key informant interviews took place.
Table 3

**Expert Feedback**

<table>
<thead>
<tr>
<th>Question</th>
<th>Feedback from experts</th>
<th>Recommendation</th>
<th>Modification</th>
</tr>
</thead>
</table>
| 1. Would this screening questionnaire be able to identify that the following difficulties related to feeding and swallowing problems need further assessment:  
  - Oral-motor difficulties  
  - Oral-sensory difficulties  
  - Delay in feeding milestones  
  - Problems related to phases of swallowing (dysphagia)  
  - Consistency-specific difficulties | 100% agreed that the FSQ will be able to identify difficulties in all of the mentioned areas. This indicates that the FSQ has face validity. | None. | No modifications suggested. |
| 2. Can any of the items in the *Feeding and Swallowing Questionnaire* be omitted? | 100% did not identify any items that could be omitted. | None. | No modifications suggested. |
| 3. Do you think the age groups in items 14 to 30 are appropriate, i.e. that certain blocks are shaded; indicating that the skill described is not expected for a certain age group? | 100% agreed. | One (33.3%) expert suggested including a space to comment on feeding skills acquired earlier than the norm. | This suggestion has not been included. As the FSQ is a screening tool, it will not be necessary to include whether skills were acquired earlier. A space has been included, however, for additional comments at the end of the questionnaire. |
| 4. Do you think the options for frequency of problems in items 13 and 23-26 are appropriate? | 100% agreed. One (33.3%) expert suggested that an item needed clarification. Another expert suggested modifications to the layout of the questionnaire. | Question 13: It was unclear whether the fourth column required a tick or a comment. | This question has been modified to a yes/no question:  
  “Observe during session: if child older than 3 years and wearing a bib or has noticeable drooling:  
  **Yes** __  
  **No** __”  

Inclusion of subheadings  
This recommendation has not been included. As the FSQ covers a broad range of behaviours, grouping of the items into specific subheadings would necessitate the use of excessive subheadings. This would increase the length of the
5. Do you think the Feeding and Swallowing Questionnaire can be used by the following health professionals:
   - Speech-language pathologists
   - Allied health professionals
   - Nurse
   - Doctors

   100% agreed that the FSQ could be used by any of these health professionals.

   None. No modifications suggested.

6. General comments

   One (33.3%) expert suggested the addition of biographical information.

   Addition of a place for the child’s name, date of birth, and date of assessment.

   The FSQ was initially developed as a section of a broader health screening tool, in which biographical information and participant code were captured on a cover page. This has been corrected on the FSQ used for the current study. As this tool was being used for research purposes, a space for participant code, instead of the child’s name, was added, as well as a space for date of birth and date of assessment.

   One (33.3%) expert commented that the questionnaire can be used to track changes in feeding behaviour over time.

   None. No modifications suggested.

5.2. Linguistic Appropriateness of the Items in the Feeding and Swallowing Questionnaire

5.2.1. Key Informant Interviews – English

Table 4 summarises the feedback obtained from the caregiver participants from the interviews conducted regarding the linguistic appropriateness of the English version of the FSQ. All five (100%) of the caregivers interviewed in English identified terminology used in the FSQ that they were not familiar with. The caregivers’ suggestions for unfamiliar terminology were considered in order to maximise the linguistic appropriateness of the
FSQ when used with caregivers of infants and children with HIV attending a typical hospital in South Africa, when English may not be their primary language.

Table 4
Caregiver Interview Feedback for the English Version of the FSQ (n=5)

<table>
<thead>
<tr>
<th>Terminology not understood by the caregivers</th>
<th>Original item relating to caregivers’ comments</th>
<th>Recommendation</th>
<th>Modification to original item</th>
</tr>
</thead>
</table>
| Question 9: Wriggle – three of the caregivers (60%) reported that they did not understand this term. | Question 9. Does XXX become upset or fussy e.g. cry, 
_wriggle_, turn face away, with feeding? | One caregiver suggested the addition of a physical cue to demonstrate wriggle. The other two caregivers stated that although they did not understand the word, they were able to understand the question due to the use of other examples such as “turn face away” and “fussy.” | An instruction for a physical cue and demonstration was added to the question. |
| Question 11: Hoarse – two of the caregivers (40%) reported that they did not understand this term. | Question 11. Is XXX’s voice _hoarse_ or has it changed? | One caregiver suggested that a hoarse voice be described as a “scratchy voice” or “how your voice sounds when you are sick.” | The term “hoarse” has been retained in this question; however, the term “scratchy” has been added when describing voice quality. |
| Question 12: Gurgly – two of the caregivers (40%) reported that they did not understand this term. | Question 12. Does XXX’s voice sound _gurgly_ (wet) after drinking? | Both of caregivers stated that although they did not understand the term “gurgly,” they understood the alternative word provided (“wet”). | No modifications suggested, as the caregivers understood the question. |
| Question 13: Drool – four of the caregivers (80%) reported that they did not understand this term. | Question 13. Does XXX _drool_? | All four caregivers required further explanation when describing “drool.” Two of the caregivers recommended that a hand gesture would aid understanding. | The question has been modified to describe “drool” as when “spit runs out the mouth.” An instruction for a physical cue has also been added. |
| Question 21: Gag – four of the caregivers (80%) reported that they did not understand this term. | Question 21. Does XXX _gag_ (want to vomit – demonstrate) with liquids? | Although all four caregivers were not familiar with the term “gag”, they were able to understand the meaning once it had been described as “want to vomit” and the action of “gag” was demonstrated to them. | No modifications suggested, as the caregivers understood the question. |
| Question 29 and 30: Choke – one caregiver (20%) reported that they did not understand this term. | Question 29. Does XXX _choke_ with drinking? Question 30. Does XXX _choke_ with eating? | The caregiver suggested that “choke” be described as “when food/liquid goes down the wrong pipe.” | The respective questions have been modified to include a description of choking as “when food/liquid goes down the wrong pipe.” |
5.2.2. Key Informant Interviews – Afrikaans

Table 5 summarises the feedback obtained from the caregiver participants from the interviews conducted regarding the linguistic appropriateness of the Afrikaans version of the FSQ. None of the caregivers had difficulty understanding the Afrikaans terminology; however, inaccuracies in the translation of the FSQ from English to Afrikaans were identified. The caregivers’ suggestions for translations were considered in order to maximise the linguistic appropriateness of the Afrikaans version of the FSQ.

Table 5
Caregiver Interview Feedback for the Afrikaans Version of the FSQ (n=5)

<table>
<thead>
<tr>
<th>Item in the FSQ that was inaccurately translated</th>
<th>Original item relating to caregivers’ comments</th>
<th>Recommendation</th>
<th>Modification to original item</th>
</tr>
</thead>
</table>
| **Question 6:** Three caregivers (60%) identified that a section of this question had not been translated into Afrikaans. | Question 6. Tel XXX gewig op?  
- Well  
- Slowly  
- Not at all  
- Losing weight | The question requires caregivers to describe the child’s weight gain. The options provided were in English. Three caregivers (60%) suggested the following translations:  
- Well – **Goed**  
- Slowly – **Stadig**  
- Not at all – **Glad Nie**  
- Losing weight – **Verloor gewig** | The question was modified to include the caregivers’ suggestions for translation. |
| **Question 15:** Four caregivers (80%) reported that “graan” is not an appropriate translation of “cereal.” The Afrikaans term “graan” refers to grain, rather than to porridge. | Question 15. Eet XXX semi-vaste kos soos graan? | All four caregivers suggested that the term “graan” be replaced with “pap.” | The question was modified to include the caregivers’ suggestions for translation. |
| **Question 19:** Two caregivers (40%) identified that the Afrikaans translation of this question only asks whether the child messes food from his/her mouth while feeding. The original question asks whether the child messes liquids or food from his/her mouth while feeding. | Question 19. Mors XXX baie kos uit sy/haar mond uit tydens voeding? | The caregivers suggested that the question be modified to include liquids: “Mors XXX baie vloeistowwe of kos uit sy/haar mond uit tydens voiding?” | The question was modified to include the caregivers’ suggestions for translation. |
| **Question 20:** Four caregivers (80%) identified that the Afrikaans translation of this question only asks whether liquids or food come out of the child’s nose when they drink. It does not ask whether this happens when the child eats. | Question 20. Kom vloeistowwe of kos ooit uit XXX se neus uit terwyl hy/sy drink? | The caregivers suggested that the question be modified to include eating: “Kom vloeistowwe of kos uit XXX se neus uit terwyl hy/sy eet of drink?” | The question was modified to include the caregivers’ suggestions for translation. |
5.2.3. Key Informant Interviews – isiXhosa

Table 6 summarises the feedback obtained from the caregiver participants from the interviews conducted regarding the linguistic appropriateness of the isiXhosa version of the FSQ. None of the caregivers had difficulty understanding the isiXhosa terminology; however, inaccuracies in the translation of the FSQ from English to isiXhosa were identified. The caregivers’ suggestions for translations were considered in order to maximise the linguistic appropriateness of the isiXhosa version of the FSQ.

Table 6
Caregiver Interview Feedback for the isiXhosa Version of the FSQ (n=5)

<table>
<thead>
<tr>
<th>Item in the FSQ that was inaccurately translated</th>
<th>Original item relating to caregivers’ comments</th>
<th>Recommendation</th>
<th>Modification to original item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question 20:</strong> All five of the caregivers (100%) reported that this question was not translated correctly. This question should ask whether liquid or food ever comes out of the child’s nose while drinking or eating, however, the isiXhosa translation only asks if liquid or food falls out when drinking or eating. It fails to mention the nose.</td>
<td>Question 20. Ingaba ukutya okungamanzi okanye kutya kukhe kuphume ngenxa yengxolo ayenzayo uXXX xa esela okanye esitya?</td>
<td>All five caregivers agreed that the following isiXhosa version of the question is the correct translation: “Ingaba kukhe kuphume amanzi okanye ukutya ngempumlo xa uXXX esela okanye xa esitya?”</td>
<td>The question has been changed to the version suggested by the caregivers.</td>
</tr>
<tr>
<td><strong>Question 21:</strong> All five of the caregivers (100%) reported that this question was not translated correctly. This question should ask whether the child gags with liquids. All caregivers reported that the translated isiXhosa question asks whether you close the child’s mouth when they swallow liquids.</td>
<td>Question 21. Ingaba uXXX uye avalwe umlomo (xa efuna ukugabha – bonisa oko) xa esela?</td>
<td>All five caregivers agreed that the following isiXhosa version of the question is the correct translation: “Ingaba uXXX uya Khonyuluka xa esela?” Two caregivers stated that a demonstration of gag would also be useful.</td>
<td>The question has been changed to the version suggested by the caregivers. An instruction for a physical cue has been added.</td>
</tr>
<tr>
<td><strong>Question 22:</strong> All five of the caregivers (100%) reported that this question was not translated correctly. This question should ask whether the child gags with solids. All caregivers reported that the translated isiXhosa question asks whether you close the child’s mouth when they swallow solids.</td>
<td>Question 22. Ingaba uXXX uye avalwe umlomo (xa efuna ukugabha – bonisa oko) xa esitya?</td>
<td>All five caregivers agreed that the following isiXhosa version of the question is the correct translation: “Ingaba uXXX uya Khonyuluka xa esitya?” Two caregivers stated that a demonstration of gag would also be useful.</td>
<td>The question has been changed to the version suggested by the caregivers. An instruction for a physical cue has been added.</td>
</tr>
</tbody>
</table>
5.3. Criterion Validity of the Feeding and Swallowing Questionnaire

5.3.1. Sensitivity and Specificity of the Feeding and Swallowing Questionnaire

The FSQ and CFSE were conducted with 66 child participants. Table 7 shows the results of the FSQ compared to those of the CFSE, indicating test accuracy outcomes. The FSQ was conducted on the same day as the CFSE with all child participants. Twenty-three (34.8%; N=66) participants were correctly identified as having a FSD (true positives), while 24 (36.4%; N=66) participants were correctly identified without a FSD (true negatives). Two (3.0%; N=66) participants were incorrectly identified as not having a FSD, when they did in fact have a FSD (false negatives), and 24 (25.8%; N=66) participants were incorrectly identified as having a FSD, when they did not have any feeding and swallowing difficulties (false positives). The total of accurate test outcomes (true positive plus true negative) account for 71.2% of the total evaluations conducted.

Test sensitivity of the FSQ was calculated as 92% while test specificity of the FSQ was calculated as 59%.

Table 7

<table>
<thead>
<tr>
<th>Feeding and Swallowing Questionnaire</th>
<th>Comprehensive Feeding and Swallowing Evaluation</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition Positive (n)</td>
<td>Condition Negative (n)</td>
<td></td>
</tr>
<tr>
<td>Test Result Positive (n)</td>
<td>23</td>
<td>40</td>
</tr>
<tr>
<td>Test Result Negative (n)</td>
<td>2</td>
<td>26</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>66</td>
</tr>
</tbody>
</table>

5.3.2. Predictive Values of the Feeding and Swallowing Questionnaire

The positive predictive value (PPV) of the FSQ was calculated as 58%, while the negative predictive value (NPV) of the FSQ was calculated as 92%.

5.3.3. ROC Analysis

Figure 2 shows the ROC graph representing the true positive rate against the false positive rate of the FSQ. The area under the curve was 0.87 with a 95% confidence interval and a standard error of ±0.0465. The area under the curve is close to 1.0, thereby indicating that the test accuracy of the FSQ is high.
Table 8 shows the sensitivity, specificity, and percentage of participants correctly classified with or without FSD for various FSQ cut-off scores. A cut-off score of 1.5 allowed the most favourable trade-off between sensitivity and specificity, thereby maintaining the highest sensitivity and specificity, as well as correctly classifying 80.3% of the participants with or without FSD. This suggests that the referral criteria of the FSQ be changed to a cut-off score of 1.5, rather than 1, as this increases the specificity of the FSQ.

Table 8

<table>
<thead>
<tr>
<th>FSQ Cut-off Score</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Correctly Classified</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>92.0%</td>
<td>58.5%</td>
<td>71.2%</td>
</tr>
<tr>
<td>1.5</td>
<td>80.0%</td>
<td>80.5%</td>
<td>80.3%</td>
</tr>
<tr>
<td>2</td>
<td>72.0%</td>
<td>85.4%</td>
<td>80.3%</td>
</tr>
<tr>
<td>2.5</td>
<td>64.0%</td>
<td>92.7%</td>
<td>81.8%</td>
</tr>
<tr>
<td>3</td>
<td>48.0%</td>
<td>95.1%</td>
<td>77.3%</td>
</tr>
<tr>
<td>3.5</td>
<td>44.0%</td>
<td>97.6%</td>
<td>77.3%</td>
</tr>
<tr>
<td>4.5</td>
<td>32.0%</td>
<td>97.6%</td>
<td>72.7%</td>
</tr>
<tr>
<td>5</td>
<td>28.0%</td>
<td>97.6%</td>
<td>71.2%</td>
</tr>
<tr>
<td>5.5</td>
<td>24.0%</td>
<td>97.6%</td>
<td>69.7%</td>
</tr>
</tbody>
</table>
5.4. Inter-item Consistency of the Feeding and Swallowing Questionnaire

Cronbach’s alpha of 0.78 was obtained for the item-total correlation. This indicates an acceptable level of inter-item consistency. Cronbach’s alpha of individual items ranged from 0.7519 to 0.7949, therefore the individual items also had acceptable levels of inter-item consistency.

5.5. Inter-rater Reliability of the Feeding and Swallowing Questionnaire

Seven (10.61%; N=66) of the FSQ conducted were tested for inter-rater reliability. A kappa statistic of 1 was obtained, indicating a 100% agreement between the two raters. This shows that the FSQ has high usability among different raters, and will produce similar results among different raters.

5.6. Description of Child Participants

The 66 child participants included 38 (57.6%; N=66) males and 28 (42.4%; N=66) females. The participants’ age at the time of assessment ranged from 3 months to 10 years 6 months, with a mean of 32.7 months (SD ±29.7). The majority of the participants (57.6%; N=66) were below 24 months of age, with fifty-five (83.3%; N=66) of the participants under the age of 5 years. The age ranges typically used in feeding and swallowing development are used to describe the participants’ ages in Figure 3 below. More participants were assessed during out-patient visits than during hospitalisation, 90.9% versus 9.1% (N=66). Caregivers reported delayed motor or communication developmental milestones for 40 participants (60.6%; N=66).
The WHO clinical staging of HIV prior to commencement of ART is represented in Figure 4. This information was not available for one of the participants who had been initiated on ART at another tertiary hospital. The majority of the participants (87.9%; N=66) presented with symptomatic HIV infection as characterised by a WHO stage of 2 or higher.

Figure 4. WHO Clinical Staging of HIV/AIDS of Child Participants (N=66)
The results of the latest virological and immunological tests were available for all participants except for the participant mentioned above. In terms of virological and immunological testing, the participants can be divided into two groups: those on ART at the time of testing and those not. It is important to present the virological and immunological results of these two groups separately due to the direct effect of ART on CD4 percentage and viral load. The virological and immunological results are represented in Table 9. The mean CD4 percentage (CD4%) in both the groups was similar, however, the percentage of participants with a CD4% above 25% was higher in the group that was on ART at the time of testing than the group that had not yet been initiated on ART; 65.4% (n=52) compared to 53.8% (n=13). The differences with regard to viral load in the two groups are clear. The majority of participants in the group on ART had a viral load of less than 1000 (73.1%; n=52), while only 15.4% of the participants who were not on ART had a viral load less than 1000. Twenty-five percent of participants on ART had undetectable viral load levels, while no participants in the other group had undetectable levels. These results draw attention to the effect that ART has on increasing CD4 percentage, and decreasing viral load.

Table 9  
Virological and Immunological Status of Child Participants (N=66)

<table>
<thead>
<tr>
<th>Components of virological testing</th>
<th>On ART at the time of virological testing (n=52)</th>
<th>Not on ART at the time of virological testing (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 percentage (percentage of participants):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 15%</td>
<td>7.7</td>
<td>15.4</td>
</tr>
<tr>
<td>15 – 24.9%</td>
<td>26.9</td>
<td>30.8</td>
</tr>
<tr>
<td>≥ 25%</td>
<td>65.4</td>
<td>53.8</td>
</tr>
<tr>
<td>Mean CD4 percentage</td>
<td>27.7% (SD ±8.1)</td>
<td>26.3% (SD ±11.9)</td>
</tr>
<tr>
<td>Viral load (percentage of participants):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undetectable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1000</td>
<td>25</td>
<td>0</td>
</tr>
<tr>
<td>1000 – 10,000</td>
<td>48</td>
<td>15.4</td>
</tr>
<tr>
<td>10,000 – 10,000,000</td>
<td>13.5</td>
<td>0</td>
</tr>
<tr>
<td>&gt; 10,000,000</td>
<td>0</td>
<td>61.5</td>
</tr>
</tbody>
</table>

5.7. Comparison of the Participants with and without FSD

Twenty-five (37.88%; N=66) of the child participants presented with a FSD. The comparison between the groups with FSD and without FSD covered age, HIV-related factors, history of LRTI and undernutrition, and nutritional status at the time of assessment.
**Age**

Figure 5 shows the percentage of participants with and without FSD in each age range. It appears more of the participants with FSD fell in the age ranges below 24 months than the participants without FSD, 80% (n=25) compared to 43.9% (n=41). The median age in the group without FSD was 29 months (interquartile range 15 – 56 months), while the median age in the group with FSD was lower; 14 months (interquartile range 10 – 21 months). A statistically significant relationship was found between age and the presence of FSD ($p=0.008; p<0.01$), i.e. younger participants were more likely to have FSD.

![Figure 5. Comparison of Age Ranges in Participants with and without FSD](image)

**HIV-related factors**

Figure 6 compares the percentage of participants from each group (with and without FSD) in terms of the WHO staging of HIV. A higher percentage of participants (60%; n=25) with FSD had WHO stage 4 illness than those without FSD (41.5%; n=41). However, the total percentage of participants with severe HIV illness characterised by stage 3 or 4 was similar in both groups; 80% (n=25) in the group with FSD, and 87.9% (n=41) in the group without FSD. As WHO staging of HIV occurred prior to initiation on ART, it does not necessarily represent the health condition of the child at the time of the feeding and swallowing assessment, as some participants had already been receiving ART for years. It
does, however, show that the majority of the participants – with and without FSD – had severe, symptomatic HIV illness prior to ART initiation.

Table 10 shows the virological and immunological status of the group with FSD compared to the group without FSD. As before, the test results have been split into two groups: those on ART and those not on ART at the time of testing. The nature of the virological and immunological results and the division of participants into four groups makes direct comparison between the group with FSD and the group without FSD difficult. The mean CD4 percentage in all four groups was similar, ranging from 25.8 – 28.2%, indicating that, immunologically, there was little difference between the two groups. A higher percentage of participants with FSD on ART (82.3%; n=17) had viral load levels below 1000 copies/mL, compared to participants without FSD on ART (68.6%; n=35). This is contrary to what was expected, as it is expected that participants with FSD would be more likely to have a higher viral load. Due to the distinction between these four groups of participants, it was not possible to establish a relationship between virological and immunological status and FSD.

Figure 6. Comparison of WHO Stage of HIV/AIDS in Participants with and without FSD
Table 10
Comparison of Virological and Immunological Status of Participants with and without FSD

<table>
<thead>
<tr>
<th>Components of virological testing</th>
<th>On ART at the time of virological testing (n=52)</th>
<th>Not on ART at the time of virological testing (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FSD (n=17)</td>
<td>No FSD (n=35)</td>
</tr>
<tr>
<td>CD4 percentage (percentage of participants):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 15%</td>
<td>11.8</td>
<td>2.8</td>
</tr>
<tr>
<td>15 – 24.9%</td>
<td>17.6</td>
<td>34.3</td>
</tr>
<tr>
<td>≥ 25%</td>
<td>70.6</td>
<td>62.9</td>
</tr>
<tr>
<td>Mean CD4 percentage</td>
<td>(SD ±9)</td>
<td>(SD ±7.8)</td>
</tr>
<tr>
<td>Viral load (percentage of participants):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undetectable</td>
<td>17.6</td>
<td>28.6</td>
</tr>
<tr>
<td>&lt; 1000</td>
<td>64.7</td>
<td>40</td>
</tr>
<tr>
<td>1000 – 10,000</td>
<td>11.8</td>
<td>14.3</td>
</tr>
<tr>
<td>10,000 – 10,000,000</td>
<td>5.9</td>
<td>17.1</td>
</tr>
<tr>
<td>&gt; 10,000,000</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 7 shows the distribution of length of time on ART prior to assessment for feeding and swallowing. The group of participants with FSD had a median length of time on ART of 10 months (interquartile range 6 – 15 months), while the group of participants without FSD had a higher median of 19 months (interquartile range 9 – 46.5 months). A statistically significant relationship was found between FSD and the length of time on ART (p=.014). This indicates that the longer the participants were on ART, the less probability there was of having a FSD. Of the participants without FSD, 41.5% (n=41) had been on ART for longer than two years at the time of the feeding and swallowing assessment, whereas only 16% of the participants with FSD had been on ART for over two years.

![Figure 7. Comparison of Time between ART Initiation and FSQ in Participants with and without FSD](image-url)
**Reported History of Lower Respiratory Tract Infection**

A history of LRTI was documented in the medical folders of 68% (n=25) of participants with FSD, and 82.9% (n=41) of participants without FSD. Of the total participants, 77.3% (N=66) presented with a history of LRTI requiring hospitalisation at some stage during their lives, drawing attention to the high prevalence of respiratory illness in the paediatric population with HIV. No significant relationship was found between a history of LRTI and FSD ($p=.16$).

**Reported History of Undernutrition and Nutrition Status at the Time of Assessment**

A history of undernutrition was documented in the medical folders of 84% (n=25) of participants with FSD, and 65.9% (n=41) of participants without FSD. No significant relationship was found between a history of undernutrition and FSD ($p=.15$).

Table 11 shows the z-scores calculated for weight-for-height, height-for-age and weight-for-age in the groups of participants with and without FSD. In the group with FSD, 52% of participants (n=25) presented with a degree of growth faltering, while 12% presented with severe malnutrition characterised by a weight-for-age z-score of less than -3. Of participants without FSD, 48.8% (n=41) presented with a degree of growth faltering, while 12.2% participants presented with severe malnutrition. Anthropometrical measures are similar in both the group with FSD and without FSD – indicating that adequate growth and nutrition is a challenge for many infants and children with HIV. No significant relationship was found between FSD and growth faltering or undernutrition ($p>.05$).
Table 11
*Comparison of Anthropometry between Participants with and without FSD*

<table>
<thead>
<tr>
<th>Anthropometry data</th>
<th>FSD (n=25)</th>
<th>No FSD (n=41)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHZ (% of participants)</td>
<td>≥-2 92 8 0.24 (SD ±1.7)</td>
<td>≥-2 90.3 9.7 0.25 (SD ±1.65)</td>
<td>0.14</td>
</tr>
<tr>
<td>HAZ (% of participants)</td>
<td>≥-2 48 52 2.0 (SD ±1.5)</td>
<td>≥-2 51.2 48.8 1.81 (SD ±1.66)</td>
<td>0.32</td>
</tr>
<tr>
<td>WAZ (% of participants)</td>
<td>≥-1 48 20 12 -1.22 (SD ±1.8)</td>
<td>≥-1 48.8 26.8 12.2 12.2 -2.4 (SD ±1.60)</td>
<td>0.52</td>
</tr>
</tbody>
</table>

1Weight-for-height z-scores could not be calculated for 10 participants in the group without FSD, as they were older than 60 months. Normative data for WHZ is only available for less than 60 months of age; therefore the mean and SD values for this measure in the group without FSD were based on the results of 31 participants.

5.8. Description of the Nature of Feeding and Swallowing Difficulties Presenting in Infants and Children with HIV/AIDS (n=25)

The participants identified with FSD included 13 females and 12 males. The age of these participants ranged from 4 months to 6 years 8 months, with a mean of 20.64 months (SD ±17.26), and 80% under 24 months. The participants identified with FSD included 4 inpatients and 21 out-patients. Delayed motor or communication developmental milestones were reported by caregivers in 14 of the participants with FSD (56%; n=25).

The nature and type of FSD was determined by the CFSE. Feeding and swallowing difficulties were classified as swallowing difficulties (dysphagia), behavioural issues related to feeding, a delay in reaching feeding milestones or a combination of the above difficulties. The percentage of participants presenting with each type of FSD is represented in Figure 8. As it is possible to have difficulties in more than one area of feeding and swallowing simultaneously, the types of FSD are not mutually exclusive. Thirteen (52%; n=25) of the participants presented with a combination of FSD, suggesting that FSD in this population may be complex and multifaceted.
5.8.1. The Nature of Dysphagia (n=23)

Dysphagia was the most frequently reported FSD (92%; n=25). Participants presenting with dysphagia exhibited difficulties in all phases of swallowing, with oral preparatory phase difficulties occurring most frequently. The majority of participants with dysphagia presented with difficulties in more than one phase of swallowing (70%; n=23). Figure 9 shows the frequency of the swallowing difficulties in the various phases.
**Oral Preparatory Phase (OPP)**

The majority of the participants with dysphagia exhibited signs of oral preparatory phase disorder (91.3%, n=23). The signs of OPP disorder are summarised in Table 12, as well as the frequency with which the signs occurred. These signs can be separated into oral motor and oral sensory difficulties; however, due to the nature of FSD, these two types of difficulties may occur simultaneously. The most common difficulty among the participants with OPP disorder was food aversion or refusal, which may be due to oral motor or sensory difficulties. Other OPP difficulties found were mostly oral motor difficulties, such as poor lip closure and lingual control.

### Table 12

**Signs of Oral Preparatory Phase Disorder (n=21)**

<table>
<thead>
<tr>
<th>SIGNS OF ORAL PREPARATORY PHASE DISORDER</th>
<th>n</th>
<th>% within OPP (n=21)</th>
<th>% within FSD (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aversion or refusal of feeds</td>
<td>11</td>
<td>52.4</td>
<td>44</td>
</tr>
<tr>
<td>Poor lip closure/anterior spillage</td>
<td>9</td>
<td>42.9</td>
<td>36</td>
</tr>
<tr>
<td>Uncoordinated or reduced lingual control/ poor bolus formation</td>
<td>5</td>
<td>23.8</td>
<td>20</td>
</tr>
<tr>
<td>Pooling of bolus</td>
<td>5</td>
<td>23.8</td>
<td>20</td>
</tr>
<tr>
<td>Hyperactive gag response</td>
<td>5</td>
<td>23.8</td>
<td>20</td>
</tr>
<tr>
<td>Tongue thrust/ immature posterior-anterior movement</td>
<td>4</td>
<td>19</td>
<td>16</td>
</tr>
<tr>
<td>Weak, uncoordinated or absent suck</td>
<td>4</td>
<td>19</td>
<td>16</td>
</tr>
<tr>
<td>Reduced mandibular movement/ ineffective chewing</td>
<td>3</td>
<td>14.3</td>
<td>12</td>
</tr>
<tr>
<td>Drooling/ poor saliva control</td>
<td>2</td>
<td>9.5</td>
<td>8</td>
</tr>
<tr>
<td>Increased oral sensitivity</td>
<td>1</td>
<td>4.8</td>
<td>4</td>
</tr>
</tbody>
</table>

**Oral Phase (OP)**

Eight of the participants with dysphagia (34.8%; n=23) demonstrated signs of oral phase difficulties. These difficulties were oral motor in nature and reflected poor lingual control. The signs and frequency of the OP are summarised in Table 13.

### Table 13

**Signs of Oral Phase Disorder (n=8)**

<table>
<thead>
<tr>
<th>SIGNS OF ORAL PHASE DISORDER</th>
<th>n</th>
<th>% within OP (n=8)</th>
<th>% within FSD (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced anterior-posterior lingual movement/ poor bolus propulsion</td>
<td>7</td>
<td>87.5</td>
<td>28</td>
</tr>
<tr>
<td>Reduced lingual elevation/ residue on hard palate</td>
<td>4</td>
<td>50</td>
<td>16</td>
</tr>
</tbody>
</table>
**Pharyngeal Phase (PP)**

Signs of pharyngeal phase disorder were documented in 60.9% of participants with dysphagia. The frequency of these signs is summarised in Table 14. The majority of these signs indicated possible aspiration, e.g. coughing during or after swallowing liquids (DeMatteo et al., 2005; Weir et al., 2009), and a gurgly or wet voice after swallowing (Arvedson, 2008; DeMatteo et al., 2005; Weir et al., 2009).

Table 14

*Signs of Pharyngeal Phase Disorder (n=14)*

<table>
<thead>
<tr>
<th>SIGNS OF PHARYNGEAL PHASE DISORDER AND POSSIBLE PENETRATION AND ASPIRATION</th>
<th>N</th>
<th>% within PP (n=14)</th>
<th>% within FSD (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coughing during or after swallow of liquid</td>
<td>13</td>
<td>92.9</td>
<td>52</td>
</tr>
<tr>
<td>Gurgly/ wet voice during or after swallow</td>
<td>10</td>
<td>71.4</td>
<td>40</td>
</tr>
<tr>
<td>Coughing during or after swallow of semi-solid</td>
<td>6</td>
<td>42.9</td>
<td>24</td>
</tr>
<tr>
<td>Delayed trigger of swallow</td>
<td>3</td>
<td>21.4</td>
<td>12</td>
</tr>
<tr>
<td>Eye-tearing during or after swallow</td>
<td>3</td>
<td>21.4</td>
<td>12</td>
</tr>
<tr>
<td>Coughing during or after swallow of solid</td>
<td>2</td>
<td>14.3</td>
<td>8</td>
</tr>
<tr>
<td>Audible pooling of secretions</td>
<td>2</td>
<td>14.3</td>
<td>8</td>
</tr>
<tr>
<td>In-coordination of breath, suck &amp; swallow</td>
<td>1</td>
<td>7.1</td>
<td>4</td>
</tr>
<tr>
<td>In-coordination of breath and swallow</td>
<td>1</td>
<td>7.1</td>
<td>4</td>
</tr>
</tbody>
</table>

**5.8.2. The Nature of Behavioural Feeding Difficulties**

Eleven participants (44%; n=25) presented with behavioural difficulties associated with feeding and swallowing. It is likely that these behavioural difficulties were due to an interaction of several factors, including co-existing swallowing difficulties. Only one participant (4%; n=25) presented with a behavioural feeding disorder in the absence of any co-existing swallowing disorder. This participant exhibited signs of distractibility and decreased attention during mealtimes resulting in mealtimes taking an excessively long time to complete and frequent abandoning of eating in favour of other activities such as playing. The caregiver of this participant reported that she experienced stress and anxiety during mealtimes, particularly with regard to discipline.

The most common complaint made by caregivers regarding the child’s mealtime behaviours was that the child was a “fussy” eater. Of the participants with FSD, the caregivers of eleven (44%; n=25) labelled their child as a “fussy” or “picky” eater. This was particularly characterised by participants eating a very limited range of consistencies or flavours of food. Other behavioural difficulties included taking an excessive amount of time...
to finish a meal (20%; n=25), frequent spitting out of food (12%; n=25), and reluctance to self-feed even when possessing the necessary skills (4%; n=25).

5.8.3. The Nature of Delay in Acquiring Feeding Skills

Eight participants (32%; n=25) presented with a delay in acquiring age-appropriate feeding and swallowing abilities. Four participants (16%; n=25) exhibited a delay in transitioning from semi-solid foods to solid foods requiring mastication. All four of these participants also presented with oral motor difficulties, indicating that adequate oral motor function is necessary to transition to other consistencies of food. A delay in self-feeding was observed in six participants (24%; n=25), one of whom had difficulty using utensils such as a spoon, and five of whom had difficulty with both using utensils, and with eating finger foods. Two participants (8%; n=25) also exhibited an inability to drink from a cup, even when the cup was held by caregivers to control the rate of drinking. Of the eight participants presenting with a delay in feeding and swallowing abilities, seven presented with some form of developmental delay, ranging from motor delay to a global neurodevelopmental delay. This highlights the association between the development of feeding and swallowing abilities and general developmental milestones.

5.9. Summary

The criterion validity of the FSQ was established, as well as the cut-off score which results in the most favourable trade-off between sensitivity and specificity. The FSQ was also determined to have appropriate inter-rater reliability. No significant relationships were identified between the presence of FSD and reported history of LRTI, reported history of undernutrition or undernutrition at the time of the feeding and swallowing assessment. A significant relationship was however documented between FSD and age, as well as between FSD and the length of time on ART. The types of feeding and swallowing difficulties identified included oropharyngeal dysphagia, behavioural feeding difficulties and delays in acquiring feeding skills. Dysphagia was the most frequently reported FSD.
6. Discussion

The discussion is organised according to the aims and objectives of the study. The primary findings from the study will be discussed in terms of current literature. The limitations of the study will be discussed, as well as the clinical and research implications of the results.

Validation of the Feeding and Swallowing Questionnaire

The Feeding and Swallowing Questionnaire (Appendix L) is a caregiver-administered questionnaire designed to identify feeding and swallowing difficulties in the paediatric population with HIV/AIDS. The validity and reliability of the FSQ was determined through several measures.

The face and content validity of the FSQ was determined by experts in the field of paediatric FSD in the South African context. The process of determining content validity is different to other forms of validity, as there is no statistic measure or standard which describes an acceptable content validity (Keszei, Novak, & Streiner, 2010). The expert SLTs were able to assess whether the FSQ included all relevant areas, and whether there were any redundancies. The expert participants agreed that the FSQ had both face and content validity and did not identify any omissions or redundancies in the FSQ. Several of their comments, however, assisted in making the FSQ more functional in its usability. These comments included the addition of a space to record the child’s biographical information, which was later added.

A review of several available validation studies indicated that experts in a given field are frequently involved in the face and content validation of a measure (Gosselin et al., 2014; McIntosh et al., 2010; Thoyre et al., 2014). These studies involved the experts either rating the items in the measure using content validity indices (Thoyre et al., 2014), or providing feedback on the items (expert opinion feedback) (Gosselin et al., 2014; McIntosh et al., 2010). Expert opinion, such as used in the current study, is an appropriate method for determining face and content validity of a measure.
The key informant interviews with the caregivers served to validate the terminology used in the English, Afrikaans and isiXhosa versions of the FSQ; and to determine the linguistic appropriateness of the language use in the FSQ amongst the caregivers attending a public hospital in South Africa. As the majority of patients and caregivers attending public health services in South Africa do not speak English as a first language, it is important to either provide a tool that is in their primary language, or to ensure that the English version contains vocabulary familiar to them (Deumert, 2010; Levin, 2006a; Levin, 2006b). The majority of healthcare professionals, however, only speak English or Afrikaans, therefore an English tool with linguistic appropriateness aimed at the patients and caregivers may prove to be more usable by healthcare professionals (Deumert, 2010). This emphasised the need for an English version of the FSQ that utilises terminology easily understood by second-language English speakers.

During the key informant interviews with caregivers, several words in the English version of the FSQ were identified which were not in the caregivers’ vocabulary. In the case of two of the terms identified as problematic, the caregivers were still able to understand the meaning of the questions due to the use of further explanation or a physical demonstration of the action included in the item. The other four terms identified as problematic did not contain any qualifiers, which resulted in the caregivers not understanding the questions containing these terms. Once the meaning of these terms was clearly explained to the caregivers, they could provide alternative explanations from their own lexicon, as well as identifying possible physical demonstrations. These suggestions were added to the FSQ, thereby clarifying the meaning of problematic items and enhancing the linguistic appropriateness of the FSQ; specifically for second language speakers of English.

The key informant interviews regarding the Afrikaans and isiXhosa versions of the FSD did not identify any unfamiliar terminology; however, errors in the translation of the FSQ from English to the respective languages were identified. The errors in the Afrikaans version were relatively minor, and still largely maintained the general integrity of the question. The isiXhosa translation, however, contained major errors, where the translated items did not resemble the original English text. Levin (2006a) stated that translation of medically-based questionnaires from English to isiXhosa often proves difficult, as the isiXhosa lexicon may not contain accurate translations of English medical terminology. This
serves as a rationale to trial translated versions of questionnaires with its intended population. The errors in translation in the Afrikaans and isiXhosa versions were addressed by allowing the caregivers to provide an accurate translation, thereby increasing the reliability of the Afrikaans and isiXhosa translations of the FSQ, as well as enhancing the linguistic appropriateness of the language for first language speakers of each language group. In a validation study by Thoyre et al. (2014), parents of children with the target condition were interviewed in order to establish further content validation, and to receive feedback on the interpretation of the items in the measure. Although content validation was not a direct goal of the key informant interviews in the current study, the improved linguistic appropriateness and accuracy of translations adds to the overall content validity of the FSQ.

The criterion validity of the FSQ was determined by comparing the results of the FSQ to the CFSE. The sensitivity (92%) of the FSQ is higher than suggested levels, indicating that the FSQ is able to accurately identify children who have FSD, resulting in few under-referrals. The specificity (59%) of the FSQ was lower than the suggested levels. The low specificity indicates the FSQ is less precise in correctly identifying children who do not have FSD, thereby resulting in over-referrals. Generally, the sensitivity of screening instruments tends to be greater than the specificity (Glascoe, 1997), to avoid missing individuals with the target condition. With regard to FSD, where possible negative consequences may be severe, it is more important to accurately identify children with FSD, than to determine the absence of a FSD. Therefore it may be acceptable for a FSD screening tool to have a lower specificity in favour of a high sensitivity, where more children with FSD are likely to be correctly identified.

The positive predictive value (PPV) of the FSQ was 58%, while the negative predictive value (NPV) was 92% – both of which are above the suggested level. The high NPV indicates that the FSQ yielded few false negatives, and that there is a strong probability that an individual with a negative test result will not have a FSD (Maxwell & Satake, 2006; Portney & Watkins, 2009). The PPV was lower than the NPV. This indicates that there is less of a probability that an individual with a positive test result will in fact have a FSD. The lower PPV is also associated with increased false positives (Portney & Watkins, 2009). Although the PPV is lower than the NPV, it still falls within an acceptable range. As no other similar screening tests for FSD in the general paediatric population or in the paediatric
population with HIV exist, it is not possible to compare these measures of test accuracy. These results do, however, meet the requirements of screening tools in general medical practice, and may be refined in further research.

The area under the ROC curve (AUC) was 0.87, indicating high test accuracy (Hulley et al., 2013). The AUC may be a more useful and accurate indication of test accuracy than overall test accuracy, as the AUC is purely dependent on sensitivity and specificity, and is not dependent on prevalence of the disorder in the study population (Alberg, Park, Hager, Brock, & Diener-West, 2004). According to Alberg et al. (2004), overall test accuracy is strongly influenced by the prevalence in the test population, and may give a distorted indication of test accuracy in cases where differences in the level of sensitivity and specificity exist, such as with the FSQ. The AUC is thus the superior descriptor of test accuracy.

The ROC graph also provided information regarding the referral criteria of the FSQ. The ROC analysis allowed the identification of a cut-off score of the FSQ at which the most favourable trade-off between sensitivity and specificity is possible. The original cut-off score of 1 point for the FSQ resulted in a sensitivity of 92% and a specificity of 58.5%. With 1 as a cut-off score, 71.2% of participants were correctly classified as having a FSD, or not having a FSD. Although this sensitivity is appropriate and well within the accepted standards for a screening test, the low specificity resulted in many false positives, which would translate clinically to an SLT performing many additional comprehensive feeding and swallowing assessments with infants and children who did not have a FSD, thereby expending resources such as time unnecessarily.

It may be argued that a cut-off score of 1.5 points may be more appropriate, as it results in more participants (80.3%) being correctly classified as having a FSD, or not having a FSD; and provides a much more favourable trade-off between sensitivity and specificity. With a cut-off score of 1.5 points, sensitivity of 80% is achieved, and specificity of 80.5% is achieved – thus both sensitivity and specificity fall in the upper ranges of the suggested levels. The change in the cut-off point would translate to a change in the pass/fail criteria for the FSQ. Thus, instead of having fail criteria as either two blue items or one red item, it would be changed to be either three blue items; or one red and one blue item. This adjusted pass/fail criteria for the FSQ provides more favourable sensitivity and specificity.
According to Andermann et al. (2008), the total and relative costs of false negatives and false positives will guide decisions on which cut-off points will yield the most favourable sensitivity and specificity. As previously stated, false positives involve the cost of a follow-up session with an SLT, and may also involve costs to the caregivers, such as transportation costs to the follow-up session or the burden of being unnecessarily told that their child has FSD (Andermann et al., 2008; Elliman et al., 2002). False negatives, however, involve the cost of FSD being undetected and resulting in more severe health outcomes while the FSD goes untreated (Frankenburg, 1974).

In this case, the moving of the cut-off score to 1.5 points not only increases the number of participants accurately classified with or without FSD, but also increases the specificity, allowing both the sensitivity and specificity to fall well within the upper ranges of acceptability. Thus the cost of false positives is reduced, while still maintaining an appropriately high sensitivity. In South Africa, resources in clinical settings may be constrained; therefore a decreased false positive rate will result in less unnecessary expenditure. The relatively low risk of false negatives may be reduced by training members of staff at the Infectious Disease Clinic (IDC), such as nurses, to monitor for signs and symptoms of FSD closely and regularly. This may be beneficial, as infants and children with HIV are likely to attend regular follow-up sessions at IDC clinics.

Internal consistency of the FSQ was determined by using Cronbach’s alpha. A Cronbach’s alpha of 0.78 was obtained. According to Streiner (2003), a Cronbach’s alpha of 0.70 and higher is appropriate for assessment tools in the initial stages of research. Hulley et al. (2013) stated that a value of 0.80 and higher for Cronbach’s alpha is excellent. The value obtained for the FSQ is within the acceptable range, thereby indicating that the items in the FSQ are related to each other and have internal consistency (Maxwell & Satake, 2006; Streiner, 2003). In the area of FSD, it may be difficult to obtain a Cronbach’s alpha of higher than 0.80, due to the multifaceted nature of FSD (Streiner, 2003). The various items on the FSQ may, therefore, assess different aspects of FSD which may not necessarily be related to each other (Keszei et al., 2010; Streiner, 2003). For example, the FSQ may identify oral phase difficulties such as anterior spillage in one participant, while it may identify pharyngeal phase difficulties such as aspiration in another participant. Oral and pharyngeal phase difficulties are different aspects of FSD, and a participant who presents with oral phase difficulties may not necessarily present with pharyngeal phase difficulties,
and vice versa. Thus these two aspects may not be associated with each other, but both are signs of dysphagia. It is therefore not necessary for a participant to present with all the signs and symptoms of FSD, to receive a diagnosis of FSD. As a result, Cronbach’s alpha may not exceed 0.80 for a health measurement scale such as the FSQ, as then certain signs and symptoms of FSD would be excluded.

Inter-rater reliability for the FSQ was determined by kappa, and was calculated as 1, which indicates 100% agreement between raters. This shows that the FSQ has excellent inter-rater reliability; therefore the FSQ will provide consistent results amongst different raters (Streiner, 2003; Streiner & Norman, 2008). Inter-rater reliability of the FSQ was determined by SLTs. The FSQ was developed for use by a number of different health care professionals, such as nurses, doctors and allied health professionals, in addition to SLTs. The current inter-rater reliability, however, cannot be extended to include these professionals, especially when considering that these health care professionals may be less familiar with FSD than SLTs. Further research is required to determine inter-rater reliability of the FSQ when administered by health care professionals other than SLTs.

The Standards for Reporting of Diagnostic Accuracy (STARD) were followed for the reporting of the current study. The checklist developed as part of the STARD statement has been completed (Appendix R). This checklist ensures that all aspects of the study are reported accurately and reliably, which will allow readers to identify specific aspects of the validation of the FSQ, such as the participants, the measures used, the procedures followed, and the validation results (Bossuyt et al., 2003). As this study fulfils all the requirements of the STARD checklist, the validity of the study is strengthened, which in turn strengthens the validity of the study’s results (Hulley et al., 2013; Maxwell & Satake, 2006).

As a result of the validation process, the FSQ has evidence of being a reliable and valid test for the identification of FSD in the paediatric population with HIV/AIDS.

Comparison of the Participants with and without FSD

Various factors in the group with FSD and the group without FSD were compared, namely, history of LRTI, history of undernutrition or growth faltering, current nutrition
status, age, and HIV-related factors. Respiratory illness, such as LRTI, and undernutrition are commonly associated with both HIV and FSD. Neither LRTI, nor past or current undernutrition/growth faltering were determined to have a significant relationship with FSD. The high frequency of previous LRTI in the total sample (77.3%; N=66) is supported by the literature documenting respiratory illness in the paediatric population with HIV/AIDS (De Baets et al., 2007; Department of Health, 2013; Rabie et al., 2007; South to South, 2010; Theron et al., 2009; Zar, 2008). Lower respiratory tract infection appears to be a common co-morbidity of HIV, which may be responsible for frequent hospitalisation (Theron et al., 2009). The aetiology of respiratory illness in this population may be complex; however, the role of FSD in the development of LRTI cannot be overlooked. The high frequency of reported LRTI must also be considered as a possible causal factor for FSD, or for the exacerbation of an existing FSD.

A relatively high percentage (72.7%; N=66) of the total participants had a reported history of undernutrition or growth faltering, while 50% (N=66) presented with a degree of growth faltering; and nearly a quarter of the participants presented with moderate-severe growth faltering. As with LRTI, the aetiology of growth faltering and undernutrition in this population may be complex, with interaction between co-morbidities associated with HIV, including GIT difficulties (Zar, 2008), neurological impairment (Kaul & Patel, 2001; Lowick et al., 2012), increased metabolic rate due to infection (Rabie et al., 2007; Rose et al., 2014), and FSD (Arvedson & Brodsky, 2002; Prasse & Kikano, 2009; Pressman & Morrison, 1988; Pressman, 2010). Adequate nutrition and intact respiratory function therefore appear to be adversely affected in many infants and children with HIV/AIDS, regardless of the presence of FSD.

Feeding and swallowing difficulties may act as a causal factor in the development of respiratory illness due to aspiration, as well as growth faltering due to inadequate nutritional intake (Nel & Ellis, 2012; Pressman & Morrison, 1988; Pressman, 2010). It could therefore be expected that FSD may be associated with increased risk of respiratory illness and growth faltering. No statistically significant relationship, however, was found between FSD and a history of respiratory illness, a history of growth faltering, or current growth faltering. This may be due to the small sample size of the study, as well as due to a population that can be considered to be medically fragile, with complex medical issues. The interaction between FSD, respiratory illness and growth faltering in this population is
complex – FSD may lead to respiratory illness or growth faltering; or respiratory illness and growth faltering may lead to FSD (Nel & Ellis, 2012; Pressman, 2010). The high prevalence of respiratory illness and growth faltering in this population may also mask FSD. In the general paediatric population, respiratory illness and growth faltering may be considered significant “warning signs” of FSD, as these complications may not occur as frequently as in children with HIV (Altaf & Sood, 2008; Groher & Crary, 2010; Weir et al., 2009; Weir et al., 2010). In the paediatric population with HIV, however, these complications occur with increasing prevalence, and FSD may be overlooked as a potential causal factor.

A statistically significant relationship was documented between FSD and age in this population. No previous studies have investigated this relationship in the paediatric population with HIV. The probability of FSD significantly decreased as the child became older, with young children being most likely to have FSD. This may be due to a number of reasons. Infants born to mothers who are HIV-infected and did not receive PMTCT generally experience a period of severe illness immediately after birth (Abrams & Myer, 2013; G. S. Cooke et al., 2009; Meyers et al., 2007). ART may not be immediately effective, or may not have had a chance to stabilise the child’s condition at the time of feeding and swallowing assessment (Pressman, 2010; World Health Organization, 2010). Other children may only receive the diagnosis of HIV at a later age, resulting in delayed initiation of ART (G. S. Cooke et al., 2009; Meyers et al., 2007). Early childhood is also a critical period for growth and development. Difficulties in feeding and swallowing may be more apparent in this age group, as children encounter increased developmental demands relating to feeding and swallowing, such as transitioning to different food consistencies (Arvedson & Brodsky, 2002; Rossetti, 2001; Schwartz & Rothlingova, 2011). In contrast, older children may have experienced an extended period of disease stabilisation, thereby offering them increased “normal” developmental opportunities, and allowing them to exhibit gains in development and feeding skills (Pressman, 2010; Schwartz & Rothlingova, 2011).

A significant relationship between age and FSD is supported by general paediatric FSD literature. In the general paediatric population, the majority of infants and children presenting with FSD are less than 2 years of age (Arvedson & Brodsky, 2002; Oosthuizen, 2012; Rommel et al., 2003). Rommel et al. (2003) found a statistically significant relationship between age and FSD, and that medical and oral sensorimotor problems relating to FSD occurred significantly more frequently in children younger than 2 years.
Rommel et al. (2003) explained that this may be due to the importance of early neurological development on feeding. When early feeding milestones are delayed, a knock-on effect may result in later feeding milestones being delayed.

A statistically significant relationship was also reported between FSD and duration of ART. The probability of FSD significantly decreased the longer the child was on ART, with children that were newly or recently initiated on ART most likely to have FSD. Although no previous studies have examined the effect of ART on FSD, ART has been shown to improve the overall health condition of children in terms of immunological status and weight gain. ART has also been shown to improve neurological condition and GIT disorders, albeit at a slower rate than immunological status and weight gain (Nel & Ellis, 2012). As growth faltering, neurological deficits and GIT disorders may negatively impact FSD, it is likely that improvement in these areas due to ART may result in an improvement in FSD, or a reduction in risk of FSD.

Immunological status and WHO clinical staging of participants in the group with FSD and without FSD appeared to be similar. The comparison between the two groups of participants in terms of virological and immunological status was hampered by the fact that not all participants were on ART at the time of virological testing, thereby resulting in four distinct groups, and limiting the possibility of directly comparing the group with FSD to the group without FSD.

The Nature of Feeding and Swallowing Difficulties

Findings from the present study show that infants and children with HIV/AIDS may present with dysphagia in any of the phases of swallowing, as well as behavioural feeding difficulties and delays in achieving age-appropriate feeding and swallowing developmental milestones. This emphasises the need for assessment specific to this population that covers the entire range of FSD, not limited only to dysphagia.

Dysphagia was the most frequently reported FSD. The majority of the participants (70%; n=23) presenting with dysphagia had difficulties in more than one phase of swallowing. This indicates that the nature of dysphagia in this population may be multifaceted, and a wide range of signs and symptoms may be observed. This is supported by literature in the
paediatric population with chronic illness, where difficulties in multiple phases of swallowing are frequently reported (Arvedson & Brodsky, 2002; Schwartz & Rothlingova, 2011). The results of the current study also indicate that dysphagia in the paediatric population with HIV may not be based in only one cause, but may be due to an interaction of various causal factors influencing any of the phases of swallowing. For example, a child with disorders in the oral preparatory, oral and pharyngeal phases of swallowing may simultaneously experience difficulties with oral sensorimotor dysfunction, delayed triggering of the swallow reflex, in-coordination of swallowing and breathing, and aspiration. This highlights the importance of a comprehensive feeding and swallowing assessment to identify specific difficulties contributing to dysphagia (Arvedson & Brodsky, 2002; Arvedson, 2008; Lefton-Greif & Arvedson, 2008).

The presence of difficulties in multiple phases of swallowing in the paediatric population with HIV is supported by literature (Nel & Ellis, 2012; Pressman & Morrison, 1988; Pressman, 2010). Nel and Ellis (2012) reported that 25% of participants with dysphagia had difficulties in more than one phase of swallowing. This is further supported by research in the adult population with HIV/AIDS, as Halvorsen et al. (2003) found that 59% of participants with dysphagia had difficulties in both the oral and pharyngeal phases. Evidence from studies regarding the adult population, although useful to consider, cannot be generalised to the paediatric population. The presence of difficulties in more than one phase of swallowing is also supported by literature in the general paediatric population with FSD (Field et al., 2003; Oosthuizen, 2012; Rommel et al., 2003).

Comparison of the specific types of difficulties with swallowing is hampered due to lack of previous research specific to the paediatric population with HIV/AIDS, the limited description of dysphagia in previous studies, as well as differences in assessment methods used in previous studies. Although difficulties were encountered in all phases of swallowing in the current study, oral preparatory phase difficulties were documented the most frequently – 91.3% (n=23). Fewer participants experienced oral phase difficulties (34.8%). Past studies do not, however, differentiate between the oral preparatory and oral phases, thus providing limited information regarding specific difficulties in each of these phases. Similar to the current study, Nel and Ellis (2012) most frequently encountered oral phase difficulties. As Nel and Ellis (2012) do not differentiate between oral preparatory and oral phase difficulties, it is unclear whether these phases were collectively reported, or if no oral
preparatory phase difficulties were encountered. The lack of description regarding the oral preparatory and oral phases in the above studies thus makes comparison difficult. Previous research in the general paediatric population reported that oral preparatory phase difficulties occur the most frequently (Oosthuizen, 2012).

The majority of oral preparatory and oral phase difficulties encountered in the current study were due to oral sensorimotor dysfunction. The results thus indicate that infants and children with HIV/AIDS and FSD frequently present with poor oral skills. This may due to a number of factors, including those related to HIV, such as neurological complications (Nel & Ellis, 2012; Rabie et al., 2007), developmental delay (Arvedson & Brodsky, 2002) or opportunistic infections such as oropharyngeal and oesophageal candidiasis, which may increase oral sensitivity due to pain, thereby leading to oral sensorimotor dysfunction (Pressman & Morrison, 1988; Pressman, 2010).

Poor oral skills indicate possible difficulty with the manipulation and transit of a bolus (Arvedson & Brodsky, 2002; Rogers & Arvedson, 2005). Several participants had difficulty with adequate lip closure during feeding, which resulted in anterior spillage of food. Continuous anterior spillage may reduce the child’s oral intake, even to the point where the child is unable to maintain adequate nutrition or hydration. In the paediatric population with HIV who are already at a risk of growth faltering (Pressman, 2010; Rabie et al., 2007), the reduction in oral intake may lead to further deterioration of health (Arvedson & Brodsky, 2002; Rabie et al., 2007). Limited oral intake in this population may also negatively impact the ability to ingest medication such as ART (Nel & Ellis, 2012; Rabie et al., 2007). Poor oral skills may increase the risk of premature spillage of the bolus into the pharynx, thereby compromising the safety of the swallow and resulting in possible respiratory consequences (Arvedson & Brodsky, 2002).

As the current study only used clinical assessment of feeding and swallowing, only the clinical signs of pharyngeal phase difficulties could be reported, such as signs of possible penetration and aspiration (e.g. coughing and wet voice). This may result in an over- or under-estimation of the reported number of participants with pharyngeal phase difficulties. Signs of pharyngeal phase difficulties were documented in 60.9% (n=23) of the participants with dysphagia. The most common signs were coughing and wet voice, suggesting possible aspiration and the need for instrumental assessment to confirm pharyngeal phase
difficulties. Weir et al. (2009) and DeMatteo et al. (2005) reported that these signs are good clinical indicators of aspiration of liquids. A higher frequency of participants coughed during or after a swallow of liquids (n=13), than those who coughed during or after a swallow of solids (n=2). Weir et al. (2009) and DeMatteo et al. (2005) both found that, in children, penetration and aspiration were significantly more likely with liquids than with semi-solids or solids. The difference between prevalence of coughing with liquids and solids in the current study may also be due to the age of participants with FSD, as 36% of participants with dysphagia were under 1 year of age, and may not have been introduced to solid foods yet; thus this consistency was not assessed during the CFSE.

Nel and Ellis (2012) reported pharyngeal phase difficulties in 41% of participants with dysphagia; 75% of which aspirated at some stage during the assessment. Of the participants with aspiration, 83% had been referred for a feeding and swallowing assessment due to recurrent respiratory infections (Nel & Ellis, 2012). This supports literature in the general paediatric population linking FSD and respiratory illness (Arvedson, 2008; Rommel et al., 2003; Weir et al., 2009). Although Pressman and Morrison (1988) do not report on specific phases of swallowing, 24% of the participants with dysphagia were referred for VFSS, indicating that signs of pharyngeal phase difficulties were noted. No aspiration, however, was reported in these participants (Pressman & Morrison, 1988).

The study by Nel and Ellis (2012) used both clinical assessment of swallowing and instrumental assessment (VFSS) when indicated. Instrumental assessment is able to provide direct visualisation of the pharyngeal and oesophageal phases of swallowing, thus accurately identifying penetration and aspiration (DeMatteo et al., 2005). As the current study only made use of clinical assessment of swallowing, possible penetration and aspiration could not be confirmed. DeMatteo et al. (2005), however, reported that experienced SLTs are accurate in identifying aspiration of liquids through a clinical assessment of feeding and swallowing, and tend to over-estimate the risk with semi-solids and solids due to the lack of clinical signs, and therefore refer for instrumental assessment. In terms of penetration and aspiration, where health consequences may be serious, it is more valuable to refer patients for VFSS and identify participants with penetration and aspiration, than those without (Arvedson, 2008; DeMatteo et al., 2005).
The number of participants identified with signs of pharyngeal phase disorder indicates that the safety of swallowing in infants and children with HIV/AIDS and FSD may be compromised, leading to negative respiratory sequelae. As infants and children in this population are already at risk of respiratory illness, further risk due to FSD may result in severe deterioration in respiratory health. A cycle of FSD exacerbating respiratory illness, and respiratory illness in turn worsening FSD is thus established. These results shows that any assessment of FSD should cover all phases of swallowing, and may also indicate that instrumental assessment of swallowing (e.g. VFSS) may be necessary in addition to clinical evaluation of feeding and swallowing.

Nearly half of the participants with FSD had behavioural feeding difficulties. This is similar to the prevalence of behaviourally-based feeding problems reported by Melvin et al. (1997). The most common difficulty was participants eating a limited range of consistencies or flavours of food, followed by increased length of mealtimes. This is supported by findings by Melvin et al. (1997), where participants exhibited fussiness with food, took longer to finish feeds and ate a limited range of food. Almost half of the participants with FSD in the current study exhibited food refusal. Melvin et al. (1997) also reported food refusal as being a difficulty encountered in infants and children with HIV. This specific difficulty may be due to oral-sensory problems, or related conditions such as GORD. Learned aversions and food refusal may continue after the underlying conditions have resolved. These types of behavioural patterns are common in children with chronic illness (Berlin et al., 2009; Manikam & Perman, 2000). The majority of participants with behavioural feeding difficulties also had dysphagia, which draws attention to the role the dysphagia can play in the development of behavioural feeding difficulties.

Infants and children with HIV/AIDS are at risk of developmental delays. Caregiver-reported delayed milestones in motor or speech development were recorded in 60.6% of the total child participants (N=66), while delays were reported in 56% of the participants with FSD (n=25). This shows that the paediatric population with HIV are at risk for developmental delays, a finding which is supported in the literature (Baillieu & Potterton, 2008; Hilburn, Potterton, Stewart, & Becker, 2011; Lowick et al., 2012). These delays can be due to a number of factors, such as neurodevelopmental delay, HIV encephalopathy, prolonged periods of illness and hospitalisation, decreased opportunities for participation
and development, and disordered caregiver-child interaction patterns (Baillieu & Potterton, 2008; Lowick et al., 2012).

This can include delays in development of feeding skills, as the complex process of feeding is reliant on a number of developmental domains such as neurological, cognitive, sensory, motor, communication and even social (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010; Lefton-Greif & Arvedson, 2008). Of the participants with FSD, 8 (32%; n=25) presented with a delay regarding feeding and swallowing, 7 of which had reported delayed developmental milestones ranging from motor delay to global developmental delay. It is possible that these delays are related to impairments in other body functions, such as delayed general motor milestones, impaired cognition or oral motor deficits. It is unlikely that a delay in acquiring feeding and swallowing skills will occur in isolation.

Of the participants with a delay in transitioning to solid foods, all presented with oral sensorimotor dysfunction, reflected by dysphagia in the oral preparatory and oral phases of swallowing. Adequate oral motor control is required in the transition to solid foods. Poor oral motor skills may result in failed attempts with solid foods involving negative experiences such as coughing, gagging or choking. Negative experiences such as these may further exacerbate aversions to certain foods (Berlin et al., 2009). Similarly, a delay in self-feeding can also be related to general motor difficulties. None of the previous studies in this field have investigated the nature of delays related to feeding and swallowing.

This profile provided a limited overview of the types of feeding and swallowing difficulties in the paediatric population with HIV/AIDS. The nature of FSD in this population is complex and multifactorial, with interplay between HIV as a chronic illness, co-morbidities of HIV, and interactions between children and their immediate environment. Many of the health conditions associated with HIV, such as respiratory illness, neurological impairment, and GIT disorders have been shown to negatively impact on feeding and swallowing, thereby further increasing the morbidity and risk of mortality in this population.
Limitations, Clinical Implications and Future Research

A limitation of this study is the lack of a formal gold standard for the clinical assessment of feeding and swallowing. No standardised assessment tool exists for the comprehensive assessment of feeding and swallowing both locally and internationally. The complex nature of FSD in the paediatric population with HIV further complicates feeding and swallowing assessment, as a wide range of behaviours must be evaluated. This limitation has been addressed by using the CFSE, a tool which has been strictly based on literature in the field of paediatric FSD. In the development of the CFSE, the protocols for assessment in literature were thoroughly prescribed to, as well as the provision of literature-based rationales for the inclusion of each area and item in the CFSE (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010; Hall, 2001; Lowick et al., 2012; Rabie et al., 2007; Reilly et al., 2011; Swigert, 2010). This provides the CFSE with a strong face and content validity. The CFSE also includes items relating to dysphagia, behavioural feeding difficulties, and developmental delays (general and feeding-related); thus covering the entire scope of possible FSD (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010). The CFSE was, however, developed by a small group of South African SLTs, and may have less usability internationally.

A further limitation of this study may be the lack of instrumental assessment of swallowing, such as VFSS. This limitation makes it difficult to accurately comment on disorders in the pharyngeal and oesophageal phases of swallowing. As the VFSS involves doses of radiation, the use of VFSS with all participants, regardless of necessity, would be unethical (Weir, McMahon, Long et al., 2007). Children may be more susceptible to the negative side effects of radiation than adults, such as radiation-associated cancer and effects on development (Weir, McMahon, Long et al., 2007). Another instrumental assessment of swallowing, Fiberoptic Endoscopic Evaluation of Swallowing (FEES) may allow visualisation of the events directly before and after the pharyngeal swallow, as well as visualisation of penetration and aspiration (Arvedson, 2008). Although this method of instrumental assessment does not involve radiation, it is an invasive procedure that involves the insertion of a flexible endoscopic tube through the nose. This procedure is not routinely used or available as part of a clinical swallowing evaluation at the research site, and the procedure may be difficult in children under the age of 5 years (Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010). The invasiveness of the procedure
may prove traumatic from some children, and the use of FEES with all participants, regardless of necessity, would also be unethical (Arvedson, 2008).

The screening tool used in the study, the FSQ, was compared to a clinical assessment of feeding and swallowing, as the purpose of screening is to identify, rather than diagnose, individuals requiring further assessment. As such, the procedures in this study follow standard clinical practice, in which an SLT conducts a clinical assessment of feeding and swallowing, and decides whether further instrumental investigation is necessary based on the results of the clinical assessment (Arvedson, 2000; Arvedson & Brodsky, 2002; Arvedson, 2008; Groher & Crary, 2010; Prasse & Kikano, 2009; Swigert, 2010). Thus it is within the SLT’s scope of practice to determine the need for further instrumental assessment (Arvedson & Brodsky, 2002; Arvedson, 2008). The lack of instrumental assessment can therefore only be considered a limitation in terms of the description of the nature of FSD, not in the validation of the FSQ, as standard clinical practice was followed.

The results of this study show that the FSQ is a valid and reliable tool for the identification of signs of FSD and children at risk of FSD in the paediatric population with HIV, thereby indicating the need for further assessment and management. The FSQ is therefore appropriate for use in a clinical setting. The FSQ can be conducted in less than 20 minutes; and can thus be easily administered during a routine follow-up session at an infectious diseases clinic.

The results of this study also serve to highlight the nature of FSD in the paediatric population with HIV. The results indicate that many infants and children with HIV may experience FSD, which may in turn lead to negative health outcomes. This study may therefore have clinical implications for the routine screening of infants and children with HIV for FSD, and may serve to increase awareness of FSD in this population.

Due to the limited research conducted in this field, future research could focus on a number of areas. Firstly, research could be conducted to determine the incidence and prevalence of FSD in the paediatric population with HIV, as currently no such data exists in South Africa or internationally. Secondly, as the FSQ was designed for use by several different health professionals, such as nurses, doctors and allied health professionals, research could be conducted to determine its validity and reliability by these various health
professionals. In addition, as the FSQ has only been translated into Afrikaans and isiXhosa, translations of the FSQ in languages represented in other South African provinces, such as Zulu, can be developed and validated.

Lastly, future research can be conducted with a larger sample size to investigate the nature of FSD in this population. It is recommended that such research include both clinical assessments of feeding and swallowing, and instrumental assessments. Instrumental assessments will allow more accurate description of disorders in the pharyngeal and oesophageal phases of swallowing, with specific reference to penetration and aspiration. It may be beneficial to include older children with HIV, as the majority of the sample population in the current study were younger than 2 years of age. Possible aetiologies of FSD in the paediatric population with HIV must also be explored further, particularly the associations between FSD, neurological impairment and developmental delay in this population.
7. Conclusion

In conclusion, this study has shown that the FSQ is a valid and reliable screening tool for the identification of infants and children with possible FSD requiring further assessment in the paediatric population with HIV. Face and content validity were determined by the expert participants, while the linguistic appropriateness of language use in all three versions of the FSQ (English, Afrikaans and isiXhosa) was refined through interviews with caregivers. It was shown that the FSQ has criterion validity; however, adjustment of the pass/fail criteria may be necessary to maximise the sensitivity and specificity.

The profile of the participants with FSD has provided initial insight into the nature of FSD in this population. It has been found that age and length of time on ART are significantly associated with FSD. Infants and children with HIV may have difficulties with swallowing in any of the phases of swallowing, behavioural feeding difficulties or delays in achieving age-appropriate feeding and swallowing milestones. Difficulties in these areas may occur simultaneously. Consequences of FSD in this population may be particularly severe, due to already-compromised immune function, and decreased health resilience. Consequences such as LRTI and growth faltering may serve to worsen the medical condition, thereby increasing morbidity and mortality in infants and children with HIV. This emphasises the need for early identification of FSD in order to prevent the development of serious negative sequelae. Early identification may not only benefit the child, but may decrease the associated social and economic burden of frequent hospitalisation.
8. References


Deumert, A. (2010). 'It would be nice if they could give us more language': Serving South Africa’s multilingual patient base. Social Science & Medicine, 71(1), 53-61.


9. Appendices
Appendix A: Questionnaire for Experts

Instructions: Please review the attached Feeding and Swallowing Questionnaire, and complete the following questions. Please keep in mind that the Feeding and Swallowing Questionnaire is a screening instrument. When finished, return the completed Questionnaire for Experts to suzannevermeulensa@gmail.com. Once your questionnaire has been received, your comments and suggestions will be reviewed, together with those of the other of the experts. If indicated, changes will be implemented in the Feeding and Swallowing Questionnaire, and the revised version of the Feeding and Swallowing Questionnaire will be returned to you for further comments or suggestions. This process will continue until the expert panel reaches a satisfactory group consensus. The experts will remain anonymous to each other. Thank-you for your participation!

1. Would this screening questionnaire be able to identify that the following difficulties related to feeding and swallowing problems need further assessment (tick appropriate boxes)
   - [ ] Oral-motor difficulties
   - [ ] Oral-sensory difficulties
   - [ ] Delay in feeding milestones
   - [ ] Problems related to phases of swallowing (dysphagia)
   - [ ] Consistency-specific difficulties

   Comments:
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   ...................................................................................................................................................
   ...................................................................................................................................................

2. Can any of the items in the Feeding and Swallowing Questionnaire be omitted?
   - [ ] Yes
   - [ ] No

   If yes, state which items, and why they could be omitted:
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   ...................................................................................................................................................
   ...................................................................................................................................................
3. Do you think the age groups in items 14 to 30 are appropriate, i.e. that certain blocks are shaded; indicating that the skill described is not expected for a certain age group?
   - Yes
   - No
   If no, please explain why and suggest alternatives for these items:
   ...................................................................................................................................................
   ...................................................................................................................................................
   ...................................................................................................................................................

4. Do you think the options for frequency of problems in items 13 and 23-26 are appropriate?
   - Yes
   - No
   If no, please explain why and suggest alternatives for these items:
   ...................................................................................................................................................
   ...................................................................................................................................................
   ...................................................................................................................................................

5. Do you think the *Feeding and Swallowing Questionnaire* can be used by the following health professionals (tick appropriate boxes)
   - [ ] Speech-language pathologists
   - [ ] Allied health professionals (Physiotherapists, occupational therapists, dieticians)
   - [ ] Nurses
   - [ ] Doctors

Additional comments:
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Appendix B: Ethics Approval Letter

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7928
Telephone [021] 406 6338 • Facsimile [021] 406 6411
E-mail: sharece@health.uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

28 June 2013

HREC REF: 374/2013

Ms V Norman
Communication Science & Disorders
Health & Rehab
F45, OMB

Dear Ms Norman,

PROJECT TITLE: THE VALIDATION OF A SCREENING TOOL FOR THE IDENTIFICATION OF DYSPHAGIA IN THE PEDIATRIC POPULATION WITH HIV/AIDS

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has formally approved the above-mentioned study.

Approval is granted for one year till the 30th June 2014

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure Form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC. REF in all your correspondence.

Yours sincerely,

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS
Institutional Review Board (IRB) number: IRB00001938
This letter serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH-GCP) and Declaration of Helsinki guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.
Appendix C: Permission Letter to Medical Superintendent

3 June 2013

Dear Medical Superintendent

Re: Request to conduct a research project at the Hospital

I hereby request permission to conduct a research project at your hospital. I am an MSc Speech Pathology student at the University of Cape Town, being supervised by Vivienne Norman and Prof. Brian Eley. The title of my research project is “The validation of a screening tool for the identification of dysphagia in the paediatric population with HIV/AIDS.” The proposed research project has been approved by the UCT Faculty of Health Sciences’ Human Research Ethics Committee (HREC reference number: 374/2013).

The primary aim of this study is to determine the validity and the reliability of a caregiver questionnaire as a dysphagia screening tool in infants and children with HIV/AIDS. The objectives include:

1. To determine the face validity of the Feeding and Swallowing Questionnaire.
2. To determine the content validity of the Feeding and Swallowing Questionnaire.
3. To determine the linguistic appropriateness of the items included in the Feeding and Swallowing Questionnaire.
4. To determine criterion validity of the Feeding and Swallowing Questionnaire.
   4.1 To determine the sensitivity of the Feeding and Swallowing Questionnaire in correctly identifying participants with feeding and swallowing difficulties.
   4.2 To determine the specificity of the Feeding and Swallowing Questionnaire in correctly identifying participants without feeding and swallowing difficulties.
5. To determine the reliability of the Feeding and Swallowing Questionnaire.
6. To determine which items in the Feeding and Swallowing Questionnaire accurately identify feeding and swallowing difficulties.
7. To describe the profile of participants who have feeding or swallowing difficulties.

Participants will be recruited from the Infectious Diseases Clinic. The screening instrument, the Feeding and Swallowing Questionnaire, as well as a comprehensive swallowing and
feeding evaluation will be performed with all participants. Selected caregivers will also participate in a feedback session after the Feeding and Swallowing Questionnaire has been administered, in which their understanding of the terminology in the screening instrument will be assessed.

The participants will not incur any harm. The screening questionnaire presents no risk. The clinical assessment of feeding or swallowing difficulties presents no risk for a child without dysphagia. An assessment for a child with dysphagia presents minimal risk of aspiration. The risk is minimal due to the small volumes of food consistencies used in the assessment. Should any aspiration occur, the assessment will be stopped immediately, and participants will be referred for further assessment and management, thereby reducing further risk. Participants who present with clinical signs of aspiration will be referred back to the treating physician for further management as per hospital protocols.

The researcher will ensure that the participants’ anonymity and confidentiality is maintained at all times. The results of the study will be made available to the institution once the project is complete.

Please do not hesitate to contact me if any additional information is required.

Thank you for your consideration.

Kind regards,

Suzanne Vermeulen
Msc Speech Pathology student (VRMSUZ001)
suzannevermeulensa@gmail.com
Cellphone number: 084 626 7008

Mrs Vivienne Norman
MSc Supervisor
Lecturer Division of Communication Sciences and Disorders
Faculty Health Sciences, University of Cape Town
E-mail: vivienne.norman@uct.ac.za
Cellphone number: 083 414 7928

Professor Brian Eley
MSc Co-supervisor
Head of the Paediatric Infectious Diseases Unit, Red Cross Children’s Hospital

Professor Marc Blockman
Chair of Human Research Ethics Committee
021 406 6492
marc.blockman@uct.ac.za
Appendix D: Participation Information Leaflet and Consent Form for use by Caregiver Participants

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM FOR USE BY PARENTS AND LEGAL GUARDIANS (Caregiver Interview Sessions)

TITLE OF THE RESEARCH PROJECT: The validation of a screening tool for the identification of dysphagia in the paediatric population with HIV/AIDS

I am Suzanne Vermeulen, a student from the University of Cape Town, and this study will contribute towards my Master of Science Degree in Speech-Language Therapy. You and your child are being invited to take part in this research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is important that you understand what the project is about and how you and your child will be involved.

Your participation is entirely voluntary and you are free to say that you do not want to participate. If you say no, this will not affect you negatively in any way, and it will not affect the standard of your child’s health care. You are also free to stop your participation in the study at any point with no negative consequences, even if you do initially agree to take part.

This study has been approved by the Human Research Ethics Committee at University of Cape Town and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?
We are doing this study at Red Cross Children’s Hospital to find out about children with HIV infection and problems with eating and drinking. We want to see if we can find out about problems with eating and drinking just by asking the parent/legal guardian questions or if we need to look at the child and watch them eat and drink. We also want to see how two different tests for eating and drinking problems compare to each other. We want to find out more about eating and drinking in children who have HIV because we know that adults often have problems swallowing food and this causes them to lose weight or struggle to take their medication. Sometimes, when children have a problem swallowing, it makes eating and drinking difficult, and this can cause them to get sick with chest infections, or to lose weight. We would like to see if we can find these problems early and help them to eat or drink better.

If you agree to participate, we will ask you some questions about your child’s eating and drinking. This will take about 20 minutes. The results will be kept in a safe place and only the researcher will see them. After this, we will ask you a few questions about how you understood the words we used in the first set of questions. We want to find out if there are any words or terms that are difficult for you to understand. We will then discuss the difficult words and see if we can find any easier explanations.
This will all happen on the same day that you have your appointment at the clinic. If it seems that your child does have a problem swallowing, we will tell your doctor so that he or she can make an appointment with other health professionals to help your child further and your child will be seen by the speech therapist at the hospital for further management.

**Why has your child been invited to participate?**
Your child has been asked to participate in this study because he/she has HIV infection and may have problems eating or drinking.

**What will your responsibilities be?**
We will expect you to answer two questionnaires when you come to the clinic (you do not need to come in especially for the questionnaire). This will take about 45 minutes altogether. If we think your child does have a problem swallowing, he/she will be referred to the speech therapist at the hospital for further management and your doctor will be informed immediately.

**Will your child benefit from taking part in this research?**
Your child will be examined for swallowing disorders and if we think he/she has problems, we will refer your child for further assessment and management.

**Are there in risks involved in your child taking part in this research?**
There are no risks to participating in this part of the study, as you will only be asked questions.

**If you do not agree to allow your child to take part, what alternatives does your child have?**
If you do not want to participate in this study, your child’s normal medical treatment will not be influenced. The doctors who normally treat your child will still treat him/her. No treatment for your child will be stopped if you do not want to participate in the study. If you want to participate in this study and you become unhappy with any aspect of your child’s treatment or with the investigations done, you may stop your participation without any negative consequences for you or your child.

**Who will have access to your child’s medical records?**
Your child’s normal medical records will be stored by the hospital. Research records will be kept in a computer database and have a secret code to open the file. In addition, the information will not have your child’s name on it but will be identified by a secret number. Only the main researchers will know what that number is.

**Will you or your child be paid to take part in this study and are there any costs involved?**
No, you will not be paid to take part in the study. There will be no additional costs involved for you if you do take part, as the assessment will take place on the same day as your normal clinic appointment.

**Is there anything else that you should know or do?**
You should inform your usual doctor that your child is taking part in a research study. The results of the study will be presented at medical congresses and published in medical journals so that other doctors and speech therapists will know what we found in the study. At no time will your child’s identity be made known.
If new information becomes available during the course of study that changes the way we need to treat or test your child, we will tell you and change the treatment and tests that we use.

If you have any further queries or encounter any problems, you can contact Suzanne Vermeulen at Tel 084 626 7008 or her supervisor, Vivienne Norman at Tel 083 414 7928.

You can also contact Professor Marc Blockman, the chairperson of the University of Cape Town Human Research Ethics Committee, at 021 406 6492 if you have any questions or concerns regarding your rights as research participants.

If you wish, you may receive a copy of this information and consent form for your own records.

Suzanne Vermeulen  
MSc CSD student  
Cellphone number: 084 626 7008

Vivienne Norman  
MSc Supervisor  
Department of CSD  
Cellphone number: 083 414 7928

Professor Marc Blockman  
Chair of Human Research Ethics Committee  
021 406 6492
Please indicate:

☐ Participant took information leaflet
☐ Participant declined information leaflet

By signing below, I (name of parent/legal guardian)……………………........................ agree to allow my child (Name of Child) …………………………………… who is …… years old, to take part in a research study entitled The validation of a screening tool for the identification of dysphagia in the paediatric population with HIV/AIDS

I declare that:

• I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
• I/We have had a chance to ask questions and all our questions have been adequately answered.
• I/We understand that taking part in this study is voluntary and we have not been pressurised to take part.
• I/We may choose to leave the study at any time and not have any negative consequences.
• Routine clinical care will not be affected by participation in this study
• My child may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my child’s best interests, or if I do not follow the study plan, as agreed to.
• If my child is older than 6 years, he/she must agree to take part in the study and his/her ASSENT must be recorded on this form.

Signed at (place) ………………………………… on (date) …………………………………………

                                                      ......................................................................................................................................................
Signature of Parent/Legal Guardian                      Signature of Witness
Declaration By Investigator

I (name ) ................................................................. declare that:

- I explained the information in this document to ..............................................
- I encouraged him/her/them to ask questions and took adequate time to answer them.
- I am satisfied that he/she/they adequately understand all aspects of the research, as discussed above
- I did/did not use a translator. (If a translator is used then the translator must sign the declaration below.)

Signed at (place) ........................................ on (date) .................................

.......................................................... ..........................................................
Signature of Investigator Signature of Witness

Declaration By Translator

I (name ) ................................................................. declare that:

- I assisted the investigator (name) ........................................ to explain the information in this document to (name of parent/legal guardian) ................................ using the language medium of Afrikaans/Xhosa.
- We encouraged him/her/them to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the legal guardian fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (place) ........................................ on (date) .................................

.......................................................... ..........................................................
Signature of Translator Signature of Witness
Appendix E: Afrikaans Participation Information Leaflet and Consent Form for use by Caregiver Participants

DEELNEMER INLIGTINGSBROSJURE EN MAGTIGINGSVORM VIR DIE OUERS OF WETTIGE VOOGDE (ONDERHOUDSESSIES MET OUERS/VOOGDE)

TITEL VAN DIE NAVORSINGSPROJEK: Die bepaling van die geldigheid van ‘n siftingsinstrument vir die identifikasie van voedingsprobleme in die pediatriese groep met MIV/VIGS.

Ek is Suzanne Vermeulen, ‘n student aan die Universiteit van Kaapstad, en hierdie studie sal bydra tot my Meestersgraad in Spraak en Taal Patologie. U en u kind word uitgenooi om deel te neem aan hierdie navoringsprojek. Neem asseblief ‘n tydjie om al die inligting hier te lees – dit sal al die besonderhede van die projek verduidelik. Vra asseblief die navorser of dokter vrae omtrent enige deel van die projek wat u nie ten volle verstaan nie. Dit is belangrik dat u verstaan waaroor die projek gaan en hoe u daarby betrokke is.

U deelname is totaal vrywillig en u is vry om te sê dat u nie wil deelneem nie. Indien u nee sê, sal dit u nie negatief beïnvloed nie, en dit sal ook nie die standaard van u kind se gesondheidsorg beïnvloed nie. U mag ook u deelname by enige stadium van in die studie staak met geen negatiewe gevolge nie, al het u ook aanvanklik ingestem om deel te neem.

Hierdie studie is goedgekeur deur die Fakulteit van Gesondheidswetenskappe se Menslike Navorsings Etiese Komitee van die Universiteit van Kaapstad en sal uitgevoer word volgens die etiese riglyne en beginsels van die Internasionale Verklaring van Helsinki, Suid-Afrikaanse Riglyne vir Goeie Kliniese Praktyk en die Mediese Navoring Raad se Etiese Riglyne vir Navoring.

Waaraan handel hierdie navoringsstudie?
Ons doen hierdie studie by Rooikruis Kinderhospitaal om inligting in te win oor kinders met MIV-infeksie se probleme met eet en drink. Ons wil kyk of ons kan uitvind of kinders se eet-en drinkprobleme geïdentifiseer kan word deur net vrae aan die ouers te vra, of moet ons die kind waarnem met geen negatiewe gevolge nie, al het u ook daarvan nie.

Ons wil ook sien hoe twee verskillende toetses vir eet- en drinkprobleme met mekaar vergelyk. Ons wil meer uitvind oor eet en drink in kinders wat MIV het omdat ons weet dat volwassenes probleme met kos sluk kan hê. Dit veroorsaak dat hulle gewig verloor of sukkel om hulle medikasie te drink. Soms kan kinders ‘n probleem met sluk hê, wat eet en drink moeilik maak en wat dan veroorsaak dat hulle siek word met ‘n borsinfeksie of te veel gewig verloor. Ons wil sien of ons hierdie probleme vroeër kan identifiseer en u kind help om beter te eet en drink.

Indien u instem om deel te neem, sal ons u vrae vra omtrent u kind se eet en drink. Dit sal ongeveer 2 minute neem. Die resultate sal in ‘n veilige plek gehou word, en net die navorser sal dit kan sien. Daarna, sal ons u ‘n paar vrae vra oor hoe u die woorde in die eerste stel vrae verstaan het. Ons wil sien of daar enige woorde of terme is wat moeilik vir
u is om te verstaan. Ons sal dan hierdie moeilike woorde bespreek en kyk of ons nie makliker verduidelikings kan kry nie.

Hierdie proses sal alles op dieselfde dag as u kind se afspraak by die kliniek gebeur. As dit lyk asof u kind ’n probleem met sluk het, sal ons die dokter sê, sodat hy/sy ’n afspraak kan maak met ander verwante professionele gesondheidswerkersons om u kind te help. Dan sal u kind deur die spraakterapeut by die hospitaal gesien word om verdere behandeling.

_Hoekom is u kind genooi om deel te neem?_  
U kind is gevra om deel te neem omdat hy/sy MIV infeksie het, en daar probleme met eet of drink kan hê.

_Wat sal u verantwoordelikhede wees?_  
Ons verwag dat u twee vraelyste beantwoord wanneer u na die kliniek toe kom (u hoef nie spesiaal vir die vrae in te kom nie). Hierdie hele proses sal omtrent 45 minute neem. As ons dink dat u kind ’n probleem met sluk het, sal ons hom/haar na die spraakterapeut by die hospitaal verwys vir verdere behandelings. Ons sal ook dadelik die dokter laat weet.

_Sal u kind voordeel daaruit trek om aan hierdie navorsing deel te neem?_  
Ons sal na u kind se slukproses kyk en as ons probleme vermoed, sal ons u kind vir verdere assessering en behandeling verwys.

_Loop u kind enige risiko’s as u aan hierdie studie deelneem?_  
U kind loop geen risiko’s nie, omdat daar slegs vrae aan u gestel gaan word.

_Indien u nie instem om deel te neem nie, watter alternatiewe het u kind?_  
As u nie aan hierdie studie wil deelneem nie, sal u kind se mediese behandeling normaalweg voortgaan. Die dokters wat normaalweg u kind behandel sal hom/haar steeds behandel. Geen behandeling van u kind sal gestop word as u nie wil deelneem aan die studie nie. Indien u aan die studie deelneem en op enige stadium ongelukkig voel gedurende die ondervraging, mag u u deelname met geen negatiewe gevolge vir u of u kind stop.

_Wie sal toegang tot u kind se mediese inligting hê?_  
U kind se normale mediese rekords sal by die hospital gehou word. Navorsingsrekords sal op ’n rekenaar databasis bewaar word en daar sal ’n geheime kody wees om die lêer te open. Die inligting sal ook nie u kind se naam daarop hê nie, maar sal deur ’n geheime nommer geïdentificeer kan word. Slegs die hoofnavorsers sal weet wat u kind se nommer is.

_Sal u vir u deelname aan die studie betaal word en is daar enige kostes aan verbonden?_  
Nee, u sal nie betaal word om aan die studie deel te neem nie. Daar is vir u geen addisionele kostes betrokke indien u deelneem nie, omdat die onderhoud op dieselfde dag as u normale kliniekafspraak plaasvind.

_Is daar enigiets anders wat u behoort te weet of te doen?_  
U kan u dokter laat weet dat u deelneem aan ’n navorsingsprojek. Die uitslae van die studie sal by mediese kongresse voorgelê word en in mediese joernale gepubliseer word, sodat ander dokters en spraakterapeutê kennis kan neem van die bevindings van hierdie studie. U kind se identiteit sal op geen stadium openbaar gemaak word nie.
As enige nuwe inligting omtrent die assessering en behandeling van u kind beskikbaar word gedurende die verloop van die studie, sal ons u laat weet en die behandeling en toetse wat ons gebruik, verander.

Indien u enige verdere navrae het, of enige probleme teëkom, kan u vir Suzanne Vermeulen (084 626 7008), of haar toesighouer, Vivienne Norman (083 414 7928), kontak.

U kan ook vir Professor Marc Blockman, die voorsitter van die Universiteit van Kaapstad se Menslike Navorsings Etiese Komitee, (021 406 6492) kontak, indien u enige vrae of besorgdhede het oor u regte as navorsingsdeelnemers.

Indien u verkies, kan u ’n afskrif van hierdie inligtings- en magtigingsvorm ontvang.

Suzanne Vermeulen  
MSc CSD student  
Cellphone number: 084 626 7008

Vivienne Norman  
MSc Supervisor  
Department of CSD  
Cellphone number: 083 414 7928

Professor Marc Blockman  
Chair of Human Research Ethics Committee  
021 406 6492
Dui asseblief aan:
- Deelnemer het inligtingsbrosjure geneem
- Deelnemer het nie inligtingsbrosjure geneem nie

Deur hieronder te teken, stem ek (naam van ouer/wettige voog)……………………........................ in om deel te neem aan ’n navorsingstudie getiteld: Die bepaling van die geldigheid van ’n siftingsinstrument vir die identifikasie van voedingsprobleme in die pediatriese groep met MIV/VIGS.

Ek verklaar as volg:

- Ek het gelees of hierdie inligtings- en magtigingsvorm is vir my voorgelees en dit is in ’n taal geskryf waarin ek vlot en gemaklik is.
- Ek het geleentheid gehad om vrae te vra en al ons vrae is bevredigend beantwoord.
- Ek verstaan dat my deelname aan hierdie studie vrywillig is en daar is geen druk op my geplaas om deel te neem nie.
- Indien ek ter enige tyd sou verkies om nie met die studie voort te gaan nie, sal daar geen negatiewe nagevolge wees nie.
- Roetine kliniese sorg sal nie geaffekteer word deur deelname aan die studie nie.
- My kind mag gevra word om die studie te verlaat voordat dit klaar is, as die studiedokter en navorser voel dat dit in my kind se beste belang is, of as ek nie die studie se plan volg nie.
- As my kind ouer as 6 jaar oud is, moet hy/sy saamstem om in die studie deel te neem en sy INSTEMMING moet op hierdie vorm aangeteken word.

Geteken te (plek) ........................................ op (datum) ........................................

................................................................. .................................................................
Handtekening van Ouer/ Wettige Voog Handtekening van Getuie
Declaration By Investigator

I (name) .................................................................................................. declare that:

- I explained the information in this document to ................................................
- I encouraged him/her/them to ask questions and took adequate time to answer them.
- I am satisfied that he/she/they adequately understand all aspects of the research, as discussed above
- I did/did not use a translator. (If a translator is used then the translator must sign the declaration below.)

Signed at (place) .............................................................. on (date) ................................................

............................................................... .................................................................
Signature of Investigator                                                     Signature of Witness

Declaration By Translator

I (name) .................................................................................................. declare that:

- I assisted the investigator (name) .............................................. to explain the information in this document to (name of parent/legal guardian) ......................... using the language medium of Afrikaans/Xhosa.
- We encouraged him/her/them to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the legal guardian fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (place) .............................................................. on (date) ................................................

............................................................... .................................................................
Signature of Translator                                                     Signature of Witness
Appendix F: isiXhosa Participation Information Leaflet and Consent Form for use by Caregiver Participants

ISIHLOKO SOPHANDO: Ukubheka kuqinisekiso ngesixhobo sokuhlola ingxaki yokuginya ebantwane.


Inxaxheba yakho koluphando aıyısıso isinyanzelo, kwaye zive ukhulekile ukulandula ukuba ngaba unqwenela ukwenza njalo. Ukuba uye walandula, lo nto ayisose ikuchaphapazela ngendlela embi, kwaye ayisose ichaphazele umgangatho woncedo umntwana wakho alufanyayo ngempilo yakhe. Unalo ilungelo lokurhoxa ekuthatheni inxaxheba koluphando nanini na, kwaye akuzubakho ziphuma zimi ngokwenza lo nto, nokuba ubusewuvumile ukuthatha inxaxheba ekuqaleni.

Oluphando luphunyeziwe yiFaculty of Health Sciences’ Human Research Ethics Committee eYunivesithi yaseKapa, kwaye luyakuphathwa ngokwemigaqo nemithetho-siseko ye- International Declaration of Helsinki.

Lungtoni oluphando?

Senza uphando eRed Cross Children’s Hospital ukuze zifuSanjumwe ulwazi ngeengxaki zakunya nezokusela abathi abanye abantwana babenazo. Sifuna ukubona ukuba singafumisanisa ukuba iintsana nabantwana banengxaki ngokutya okanye ngokusela, ngokubuza nje umzali/umgcini osemthethweni imibuzo. Le mimbuza inganceda oomongikazi kunye noogqirha bafumane ezingxaki ngokusela nokutya kwangoko, kwaye bathumele iintsana/abantwana kwisigulo sosuleleko lwesifuba okanye ekuhle. Le nto ukuba iintsana nabantwana abanengxaki ngokusela nokutya bangafumane uncedo kwangoko, bangaphepha kwisigulo sosuleleko lwesifuba okanye ekuhle. Le nto ukuba u yayenayo phambi kokuba uye kwisigulo sosuleleko lwesifuba okanye ekuhle. Le nto ukuba u yayenayo phambi kokuba uye kwisigulo sosuleleko lwesifuba okanye ekuhle.

luzakwenzeka kwa ngemini enye nedinga onalo eSpeech therapy clinic.

**Kutheni umenyiwe ukuze uthathe inxaxheba?**
Umenyiwe ukuzeuthathe inxaxheba koluphando, kuba umntwana wakho unengxaki okanye wayenengxaki ngokutywa okanye ngokusela kakhule.

**Zithini iingxanduva zakho?**
Xa usiza ekinikhi, sizakubuza imibuzo emalunga nendlela umntwana wakho atya ngayo nangendlela asela ngayo. Le nto ingathatha imizuzu elishumi ukuya kwelishumi elinesihlanu, kwaye oludliwano-ndlebe luzakuqhutywa lo mzuzu usalinde ukubona i-speech therapist.

**Ingaba ikhona na inzuzo ngokuthatha inxaxheba koluphando?**
Awuzufumana inzuzo eqonde kuwe nqo koluphando, kwaye akukho ntlawulo ozakuyifumana ngokuthatha inxaxheba. Ezinye iintsana nabantwana abaneengxaki ngokutywa nokusela exesheni elizayo bangafumana inzuzo ngenkcazelo osinika yona.

**Ingaba bukhona na ubungozi obunoza ngokuthatha inxaxheba koluphando?**
Abukho ubungozi ngokuthatha unxaxheba koluphando, njengokuba uzakubuzwa imibuzo kuphela.

**Ukuba uyalandula ukuthatha inxaxheba,zeziphi ezinye iindlela onazo?**

**Ngubani ozakufikelela kwiliqwelwini zokuphendula xekhetha yomntwana wakho?**
lukufikelela kwiliqwelwini zokuphendula xekhetha yomntwana wakho, akukho iyikweyo, iziwelela iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhathi, iziwelela izikhath
nangokuginya. Iziphumo zoluphando zingafundisa oogqirha noomongikazi, okanye kwinqaku le jenali yobugqirha. Igama lomntwana wakho lizakusoloko ligcinwe liyimfielo.

Ukuba uneminye imibuzo okanye udibene nezinye iingxaki, ungaqhagamshelana uSuzanne Vermeulen (0846267008) okanye nomphathi wabo uVivienne Norman (083 414 7928). Bona ngezantsi iinkcukacha zoqhagamshelwano.

Ungaqhagamshelana noProfesa Marc Blockman, ongusihlalo we-University of Cape Town Human Research Ethics Committee, ku-021 406 6492 ukuba unemibuzo emalunga namalungelo akho njengomthathi-nxaxheba kuphando.

Ukuba uyanqwena, ungafumana ikopi yale nkcazelo kunye nefom yemvume xa ufuna ukuzigcina kwezakho iingxelo.

Sicela uphawule:
Umthathi-nxaxheba ulithathile iphetshana lenkcazelo
Umthathi-nxaxheba ulandule iphetshana lenkcazelo

Suzanne Vermeulen
MSc CSD student
Cellphone number: 084 626 7008

Vivienne Norman
MSc Supervisor
Department of CSD
Cellphone number: 083 414 7928

Professor Marc Blockman
Chair of Human Research Ethics Committee
021 406 6492
Ngokutyikitya igama lakho ngezantsi, mna (igama lo mzali/ lomgcini osemthethweni)........................................ndiyavuma ukuthatha inxaxheba inxaxheba kuphando olunesihloko, Ukubheka kuqinisekiso ngesixhobo sokuhlola ingxaki yokuginyo ebantwaneni.

Ndiyabhengeza ukuba:

- Ndiyendafunda okanye ndafundelwa le nkcazelo kunye nefom yemvume kwaye ibhalwe ngolwimi endiluvayo kwaye endikhululekileyo ngalo.
- Ndlilifumene ithuba lokucchini kwaye yonke imibuzo yethu yiphendulwe ngokucacileyo.
- Ndiyaqonda ukuba ukuthatha inxaxheba koluphando ayisiso isinyanzelo kwaye andinyanzelwanga ngumntu ukuba nithathe inxaxheba.
- Ndingakhetha kululunkathi olyufuna yonke nanini na, kungabikho ziphumo zibi endinonzima ngokwenza njalo.
- Ukuthalelo lwempilo lwesiqhelo ulaziphazela ukuthatha inxaxheba koluphando.

Isayinelwe e(indawo)...............................................ngomhla.............................................
....................................................................................
Utyikityo lomzali/ womgcini osemthethweni Utyikityo lwengqina

Isibhengezo somphandi

Mna(igama)..................................................ndibhengeza ukuba:

- Ndiye ndacisa le nkcazelo ekwelihwbuyo ku.........................................................
- Ndiye ndamkhathza ukuba abuze imibuzo, kwaye ndathatha ixesha elaneleyo ukuyiphendulu.
- Ndiyakhuluwa ukuba uyiqonde kakuhle yonke imiba yoluphando
- Ndiye ndasebenzisa/andisebenzisanga umguquli-zilwimi.

Isayinelwe e(indawo)...............................................ngomhla.............................................
....................................................................................
Utyikityo lomphandi Utyikityo lwengqina
Isibhengezo somguquli-zilwimi
Mna(igama)…………………………………………ndibhegeza ukuba:
- Ndincedise umphandi (igama)……………………..ukuba acacise le nkcazeloko ekwelihwebhu
  ku(igama lo mzali/umgcini osemthethweni)…………………….ndisebenzisa ulwimi
  lwesiXhosa/lwesiBhulu.
- Siye samkhuthaza ukuba abuze imibuza, sathatha nexhesha elanaleyel
  ukuyiphendula.
- Ndiye ndadlulisa inguqulelo eyiyo yentetho ebendiyibaliselwe
- Ndiyakholwa ukuba umzali/umgcini osemthethweni usiqonde sonke isiqulatho
  selixwebhu lemvume, kwaye yonke imibuza yakhe iphendulwe ngokwanele.

Isayinelwe e(indawo)……………………………ngomhla……………………………………..  
………………………………………………………….……………………………………………………………..
Utyikityo lomguquli-zilwimi  Utyikityo lwengqina
APPENDIX G: PARTICIPATION INFORMATION LEAFLET AND CONSENT FORM FOR USE BY PARENTS AND LEGAL GUARDIANS REGARDING THEIR OWN INVOLVEMENT

TITLE OF THE RESEARCH PROJECT: The validation of a screening tool for the identification of dysphagia in the paediatric population with HIV/AIDS

I am Suzanne Vermeulen, a student from the University of Cape Town, and this study will contribute towards my Master of Science Degree in Speech-Language Therapy. You and your child are being invited to take part in this research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is important that you understand what the project is about and how you and your child will be involved.

You and your child’s participation is **entirely voluntary** and you are free to say that you do not want to participate. If you say no, this will not affect you negatively in any way, and it will not affect the standard of your child’s health care. You are also free to stop your participation in the study at any point with no negative consequences, even if you do initially agree to take part.

This study has been approved by the Human Research Ethics Committee at University of Cape Town and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

**What is this research study all about?**

We are doing this study at Red Cross Children’s Hospital to find out about children with HIV infection and problems with eating and drinking. We want to see if we can find out about problems with eating and drinking just by asking the parent/legal guardian questions or if we need to look at the child and watch them eat and drink. We also want to see how two different tests for eating and drinking problems compare to each other. We want to find out more about eating and drinking in children who have HIV because we know that adults often have problems swallowing food and this causes them to lose weight or struggle to take their medication. Sometimes, when children have a problem swallowing, it makes eating and drinking difficult, and this can cause them to get sick with chest infections, or to lose weight. We would like to see if we can find these problems early and help them to eat or drink better.

If you agree to take part in this study, we will ask you questions about your child’s feeding and eating, and we will get some information about his/her health from his/her folder, e.g.
chest infections, medications. This will take about 20 minutes. The results will be kept in a safe place and only the researcher will see them. Later we will ask you questions from another questionnaire, which will also be about your child’s eating and drinking. The second questionnaire will take about 40 minutes.

What will your responsibilities be?
We will expect you to answer two questionnaires when you come to the clinic (you do not need to come in especially for the questionnaire). This will take about an hour altogether. If your child does have a problem swallowing, he/she will be referred to the speech therapist at the hospital for further management and your doctor will be informed immediately.

Will you or your child benefit from taking part in this research?
Your child will be examined for swallowing disorders and if he/she has problems, we will refer your child for the right treatment.

Are there in risks involved in you or your child taking part in this research?
There are no risks for you if you participate in this study. If your child does have a swallowing problem, there may be a small risk that he/she might choke on some of the food or liquid given to swallow. If we think that the food or liquid is going down the wrong way, we will immediately stop the assessment.

If you do not agree to take part, what alternatives do you and your child have?
If you do not want to participate in this study, your child’s normal medical treatment will not be influenced. The doctors who normally treat your child will still treat him/her. No treatment for your child will be stopped if you do not want to participate in the study.

If you want to participate in this study and you become unhappy with any aspect of your child’s treatment or with the investigations done, you may stop your participation without any negative consequences for you or your child.

Who will have access to your child’s medical records?
Your child’s normal medical records will be stored by the hospital. Research records will be kept in a computer database and have a secret code to open the file. In addition, the information will not have your child’s name on it but will be identified by a secret number. Only the main researchers will know what that number is.

Will you or your child be paid to take part in this study and are there any costs involved?
No, you will not be paid to take part in the study. There will be no additional costs involved for you if you do take part, as the assessment will take place on the same day as your normal clinic appointment.

Is there anything else that you should know or do?
You should inform your usual doctor that your child is taking part in a research study. The results of the study will be presented at medical congresses and published in medical
journals so that other doctors and speech therapists will know what we found in the study. At no time will your child's identity be made known.

If new information becomes available during the course of study that changes the way we need to treat or test your child, we will tell you and change the treatment and tests that we use.

If you have any further queries or encounter any problems, you can contact Suzanne Vermeulen at Tel 084 626 7008 or her supervisor, Vivienne Norman at Tel 083 414 7928.

You can also contact Professor Marc Blockman, the chairperson of the University of Cape Town Human Research Ethics Committee, at 021 406 6492 if you have any questions or concerns regarding your rights as research participants.

If you wish, you may receive a copy of this information and consent form for your own records.

Suzanne Vermeulen
MSc CSD student
Cellphone number: 084 626 7008

Vivienne Norman
MSc Supervisor
Department of CSD
Cellphone number: 083 414 7928

Professor Marc Blockman
Chair of Human Research Ethics Committee
021 406 6492
Please indicate:
☐ Participant took information leaflet
☐ Participant declined information leaflet

By signing below, I (name of parent/legal guardian)………………………………………… agree to take part in a research study entitled The validation of a screening tool for the identification of dysphagia in the paediatric population with HIV/AIDS

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I/We have had a chance to ask questions and all our questions have been adequately answered.
- I/We understand that taking part in this study is voluntary and we have not been pressurised to take part.
- I/We may choose to leave the study at any time and not have any negative consequences.
- Routine clinical care will not be affected by participation in this study.
- My child may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my child’s best interests, or if I do not follow the study plan, as agreed to.
- If my child is older than 6 years, he/she must agree to take part in the study and his/her ASSENT must be recorded on this form.

Signed at (place) ........................................ on (date) ........................................

.............................................................. ..............................................................
Signature of Parent/Legal Guardian Signature of Witness
Declaration By Investigator

I (name ) .................................................................. declare that:

- I explained the information in this document to ...........................................
- I encouraged him/her/them to ask questions and took adequate time to answer them.
- I am satisfied that he/she/they adequately understand all aspects of the research, as discussed above.
- I did/did not use a translator. (If a translator is used then the translator must sign the declaration below.)

Signed at (place) ........................................... on (date) ..........................

.......................................................... ..............................
Signature of Investigator  Signature of Witness

Declaration By Translator

I (name ) .......................................................... declare that:

- I assisted the investigator (name) ............................... to explain the information in this document to (name of parent/legal guardian) ........................... using the language medium of Afrikaans/Xhosa.
- We encouraged him/her/them to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the legal guardian fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (place) ........................................... on (date) ..........................

.......................................................... ..............................
Signature of Translator  Signature of Witness
PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM FOR USE BY PARENTS AND LEGAL GUARDIANS REGARDING THEIR CHILD’S INVOLVEMENT

TITLE OF THE RESEARCH PROJECT: The validation of a screening tool for the identification of dysphagia in the paediatric population with HIV/AIDS

I am Suzanne Vermeulen, a student from the University of Cape Town, and this study will contribute towards my Master of Science Degree in Speech-Language Therapy. You and your child are being invited to take part in this research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is important that you understand what the project is about and how you and your child will be involved.

You and your child’s participation is entirely voluntary and you are free to say that you do not want to participate. If you say no, this will not affect you negatively in any way, and it will not affect the standard of your child’s health care. You are also free to stop your participation in the study at any point with no negative consequences, even if you do initially agree to take part.

This study has been approved by the Human Research Ethics Committee at University of Cape Town and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?
We are doing this study at Red Cross Children’s Hospital to find out about children with HIV infection and problems with eating and drinking. We want to see if we can find out about problems with eating and drinking just by asking the parent/legal guardian questions or if we need to look at the child and watch them eat and drink. We also want to see how two different tests for eating and drinking problems compare to each other. We want to find out more about eating and drinking in children who have HIV because we know that adults often have problems swallowing food and this causes them to lose weight or struggle to take their medication. Sometimes, when children have a problem swallowing, it makes eating and drinking difficult, and this can cause them to get sick with chest infections, or to lose weight. We would like to see if we can find these problems early and help them to eat or drink better.

If you agree to let your child take part in this study, we will give your child something to eat and drink, to see how he eats and swallows.

Why has your child been invited to participate?
Your child has been asked to participate in this study because he/she has HIV infection and may have problems eating or drinking.
What will your responsibilities be?
If you give permission for your child to take part in this study, we will ask you and your child to do the following:

1. We will give your child some (tick age-appropriate food consistencies):
   - Milk/ water
   - Cereal (6 months old – 4 months if already introduced)
   - Yoghurt (from 12 months old)
   - Biscuit (from 10-12+ months)
   to see how he/she swallows. This will not take long, and will happen after we have asked you questions about your child’s eating and swallowing.

2. If it seems that your child does have a problem swallowing, we will tell your doctor so that he or she can make an appointment with other health professionals to help your child further and your child will be seen by the speech therapist at the hospital for further management.

Will you or your child benefit from taking part in this research?
Your child will be examined for swallowing disorders and if he/she has problems, we will refer your child for the right treatment.

Are there risks involved in you or your child taking part in this research?
If your child does have a swallowing problem, there may be a small risk that he/she might choke on some of the food or liquid given to swallow. If we think that the food or liquid is going down the wrong way, we will immediately stop the assessment.

If you do not agree to allow your child to take part, what alternatives does your child have?
If you do not want to participate in this study, your child’s normal medical treatment will not be influenced. The doctors who normally treat your child will still treat him/her. No treatment for your child will be stopped if you do not want to participate in the study.

If you want to participate in this study and you become unhappy with any aspect of your child’s treatment or with the investigations done, you may stop your participation without any negative consequences for you or your child.

Who will have access to your child’s medical records?
Your child’s normal medical records will be stored by the hospital. Research records will be kept in a computer database and have a secret code to open the file. In addition, the information will not have your child’s name on it but will be identified by a secret number. Only the main researchers will know what that number is.

Will you or your child be paid to take part in this study and are there any costs involved?
No, you will not be paid to take part in the study. There will be no additional costs involved for you if you do take part, as the assessment will take place on the same day as your normal clinic appointment.
Is there anything else that you should know or do?

You should inform your usual doctor that your child is taking part in a research study. The results of the study will be presented at medical congresses and published in medical journals so that other doctors and speech therapists will know what we found in the study. At no time will your child’s identity be made known.

If new information becomes available during the course of study that changes the way we need to treat or test your child, we will tell you and change the treatment and tests that we use.

If you have any further queries or encounter any problems, you can contact Suzanne Vermeulen at Tel 084 626 7008 or her supervisor, Vivienne Norman at Tel 083 414 7928.

You can also contact Professor Marc Blockman, the chairperson of the University of Cape Town Human Research Ethics Committee, at 021 406 6492 if you have any questions or concerns regarding your rights as research participants.

Suzanne Vermeulen  
MSc CSD student  
Cellphone number: 084 626 7008

Vivienne Norman  
MSc Supervisor  
Department of CSD  
Cellphone number: 083 414 7928

Professor Marc Blockman  
Chair of Human Research Ethics Committee  
021 406 6492
If you wish, you may receive a copy of this information and consent form for your own records.

Please indicate:

[ ] Participant took information leaflet
[ ] Participant declined information leaflet

By signing below, I (name of parent/legal guardian)……………………........................ agree to allow my child (Name of Child) ………………………………………… who is …… years old, to take part in a research study entitled The validation of a screening tool for the identification of dysphagia in the paediatric population with HIV/AIDS

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I/We have had a chance to ask questions and all our questions have been adequately answered.
- I/We understand that taking part in this study is voluntary and we have not been pressurised to take part.
- I/We may choose to leave the study at any time and not have any negative consequences.
- Routine clinical care will not be affected by participation in this study.
- My child may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my child’s best interests, or if I do not follow the study plan, as agreed to.
- If my child is older than 6 years, he/she must agree to take part in the study and his/her ASSENT must be recorded on this form.

Signed at (place) ………………………………… on (date) …………………………………

……………………………………………..                            ……………………………………………..
Signature of Parent/Legal Guardian                     Signature of Witness
Declaration By Investigator

I (name) ……………………………………………… declare that:
• I explained the information in this document to ……………………………………
• I encouraged him/her/them to ask questions and took adequate time to answer them.
• I am satisfied that he/she/they adequately understand all aspects of the research, as discussed above
• I did/did not use a translator. (If a translator is used then the translator must sign the declaration below.)

Signed at (place) …………………………….. on (date) ………………………………..

……………………………………………..                     ……………………………………………..
Signature of Investigator                                  Signature of Witness

Declaration By Translator

I (name) ………………………………………………declare that:
• I assisted the investigator (name) ……………………… to explain the information in this document to (name of parent/legal guardian) ……………………… using the language medium of Afrikaans/Xhosa.
• We encouraged him/her/them to ask questions and took adequate time to answer them.
• I conveyed a factually correct version of what was related to me.
• I am satisfied that the legal guardian fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (place) …………………………….. on (date) ………………………………..

……………………………………………..                     ……………………………………………..
Signature of Translator                                     Signature of Witness
Appendix H: Afrikaans Participation Information Leaflet and Consent Form for use by Parents and Legal Guardians

DEELNEMER INLIGTINGSBROSIJURE EN MAGTIGINGSVORM VIR DIE OUERS EN WETTIGE VOOGDE WAT HULLE EIE BETROKKENHEID AANDUI

TITEL VAN DIE NAVORSINGSPROJEK: Die bepaling van die geldigheid van ‘n siftingsinstrument vir die identifikasie van voedingsprobleme in die pediatriese groep met MIV/VIGS.

Ek is Suzanne Vermeulen, ‘n student aan die Universiteit van Kaapstad, en hierdie studie sal bydra tot my Meestersgraad in Spraak en Taal Patologie. U en u kind word uitgenooi om deel te neem aan hierdie navorsingsprojek. Neem asseblief ‘n tydjie om al die inligting hier te lees – dit sal al die besonderhede van die projek verduidelik. Vra asseblief die navorsers of dokter vrae omtrent enige deel van die projek wat u nie ten volle verstaan nie. Dit is belangrik dat u verstaan waaroor die projek gaan en hoe u daarby betrokke is.

U deelname is totaal vrywillig en u is vry om te sê dat u nie wil deelneem nie. Indien u nee sê, sal dit u nie negatief beïnvloed nie, en dit sal ook nie die standaard van u kind se gesondheidsorg beïnvloed nie. U mag ook u deelname by enige stadium van in die studie staak met geen negatiewe gevolge nie, al het u ook aanvanklik ingestem om deel te neem.

Hierdie studie is goedgekeur deur die Fakulteit van Gesondheidswetenskappe se Menslike Navorsings Etiese Komitee van die Universiteit van Kaapstad en sal uitgevoer word volgens die etiese riglyne en beginsels van die Internasionale Verklaring van Helsinki, Suid-Afrikaanse Riglyne vir Goeie Kliniese Praktyk en die Mediese Navorsing Raad se Etiese Riglyne vir Navorsing.

Waaroor handel hierdie navorsingstudie?
Ons doen hierdie studie by Rooikruis Kinderhospital om inligting in te win oor kinders met MIV-infeksie se probleme met eet en drink. Ons wil kyk of ons kan uitvind of kinders se eet- en drinkprobleme geïdentificeer kan word deur net vrae aan die ouers te vra, of moet ons die kind waarnem om die verschil tussen eet en drink.

Ons wil ook sien hoe twee verschillende toetses vir eet- en drinkprobleme met mekaar vergelyk. Ons wil meer uitvind oor eet en drink in kinders wat MIV het omdat ons weet dat volwassenes probleme met kos sluk kan hê. Dit veroorsaak dat hulle gewig verloor of sukkel om hulle medikasie te drink. Soms kan kinders ‘n probleem met sukkel hê, wat eet en drink moeilik maak en wat dan veroorsaak dat hulle seik word met ‘n borsinfeksie of te veel gewig verloor. Ons wil sien of ons hierdie probleme vroeër kan identifiseer en u kind help om beter te eet en drink.

Indien u instem om deel te neem, sal ons u vrae vra omtrent u kind se eet en drink, en ons sal inligting oor u kind se gesondheid uit sy lêer kry, b.v. borsinfeksesies, medikasies. Dit sal omtrent 20 minute neem. Die resultate sal in ‘n veilige plek gehou word, en net die navorsers sal dit kan sien. Na hierdie proses, sal ons u ‘n paar ander vrae vra. Dit sal ook omtrent u kind se eet en drink wees. Die tweede vraelys sal omtrent 40 minute neem.
**Wat sal u verantwoordelikhede wees?**
Ons verwag dat u twee vraelyste beantwoord wanneer u na die kliniek toe kom (u hoef nie spesiaal vir die vraelys in te kom nie). Hierdie hele proses sal omtrent ‘n uur neem. As ons dink dat u kind ‘n probleem met sluk het, sal ons hom/haar na die spraakterapeut by die hospitaal verwys vir verdere behandeling. Ons sal ook dadelik die dokter laat weet.

**Sal u kind voordeel daaruit trek om aan hierdie navorsing deel te neem?**
Ons sal na u kind se slukproses kyk en as ons probleme vermoed, sal ons u kind vir verdere assessering en behandeling verwys.

**Loop u of u kind enige risiko’s as u aan hierdie studie deelneem?**
U loop geen risiko’s nie. As u kind ‘n slukprobleem het, is daar ‘n klein risiko dat hy/sy aan die kos of vloeistof kan verstik. As ons vermoed dat die kos of vloeistof by die verkeerde pyp afgaan, sal ons onmiddellik die assessering stop.

**Indien u nie instem om deel te neem nie, watter alternatiewe het u kind?**
As u nie aan hierdie studie wil deelneem nie, sal u kind se mediese behandeling normaalweg voortgaan. Die dokters wat normaalweg u kind behandel sal hom/haar steeds behandel. Geen behandeling van u kind sal gestop word as u nie wil deelneem aan die studie nie. Indien u aan die studie deelneem en op enige stadium ongelukkig voel gedurende die ondervraging, mag u u deelname met geen negatiewe gevolge vir u of u kind stop.

**Wie sal toegang tot u kind se mediese inligting hê?**
U kind se normale mediese rekords sal by die hospital gehou word. Navorsingsrekords sal op ‘n rekenaar databasis bewaar word en daar sal ‘n geheime kode wees om die lêer te open. Die inligting sal ook nie u kind se naam daarop hê nie, maar sal deur ‘n geheime nommer geïdentiseer kan word. Slegs die hoofnavorsers sal weet wat u kind se nommer is.

**Sal u vir u deelname aan die studie betaal word en is daar enige kostes aan verbonde?**
Nee, u sal nie betaal word om aan die studie deel te neem nie. Daar is vir u geen addisionele kostes betrokke indien u deelneem nie, omdat die onderhoud op dieselfde dag as u normale kliniekafspraak plaasvind.

**Is daar enigiets anders wat u behoort te weet of te doen?**
U kan u dokter laat weet dat u deelneem aan ‘n navorsingsprojek. Die uitslae van die studie sal by mediese kongresse voorgelê word en in mediese joernale gepubliseer word, sodat ander dokters en spraakterapeute kennis kan neem van die bevindinge van hierdie studie. U kind se identiteit sal op geen stadium openbaar gemaak word nie.

As enige nuwe inligting omtrent die assessering en behandeling van u kind beskikbaar word gedurende die loop van die studie, sal ons u laat weet en die behandeling en toetse wat ons gebruik, verander.

Indien u enige verdere navrae het, of enige probleme teëkom, kan u vir Suzanne Vermeulen (084 626 7008), of haar toesighouer, Vivienne Norman (083 414 7928), kontak.
U can ook vir Professor Marc Blockman, die voorsitter van die Universiteit van Kaapstad se Menslike Navorsings Etiese Komitee, (021 406 6492) kontak, indien u enige vrae of besorgdhede het oor u regte as navorsingsdeelnemers.

Indien u verkies, kan u ’n afskrif van hierdie inligting en magtigingsvorm ontvang.

Suzanne Vermeulen  
MSc CSD student  
Cellphone number: 084 626 7008

Vivienne Norman  
MSc Supervisor  
Department of CSD  
Cellphone number: 083 414 7928

Professor Marc Blockman  
Chair of Human Research Ethics Committee  
021 406 6492
Dui asseblief aan:

☐ Deelnemer het inligtingsbrosjure geneem
☐ Deelnemer het nie inligtingsbrosjure geneem nie

Deur hieronder te teken, stem ek (naam van ouer/wettige voog)……………………........................ in om deel te neem aan ’n navorsingstudie getiteld: Die bepaling van die geldigheid van ’n siftingsinstrument vir die identifikasie van voedingsprobleme in die pediatriese groep met MIV/VIGS.

Ek verklaar as volg:

- Ek het gelees of hierdie inligtings- en magtigingsvorm is vir my voorgelees en dit is in ’n taal geskryf waarin ek vlot en gemaklik is.
- Ek het geleentheid gehad om vrae te vra en al ons vrae is bevredigend beantwoord.
- Ek verstaan dat my deelname aan hierdie studie vrywillig is en daar is geen druk op my geplaas om deel te neem nie.
- Indien ek ter enige tyd sou verkies om nie met die studie voort te gaan nie, sal daar geen negatiewe nagevolge wees nie.
- Roetine kliniese sorg sal nie geaffekteer word deur deelname aan die studie nie.
- My kind mag gevra word om die studie te verlaat voordat dit klaar is, as die studiedokter en navorser voel dat dit in my kind se beste belang is, of as ek nie die studie se plan volg nie.
- As my kind ouer as 6 jaar oud is, moet hy/sy saamstem om in die studie deel te neem en sy INSTEMMING moet op hierdie vorm aangeteken word.

Geteken te (plek) ............................................. op (datum) ..........................................

...................................................... .............................................................
Handtekening van Ouer/ Wettige Voog Handtekening van Getuie
Declaration By Investigator

I (name ) .................................................. declare that:

- I explained the information in this document to ........................................
- I encouraged him/her/them to ask questions and took adequate time to answer them.
- I am satisfied that he/she/they adequately understand all aspects of the research, as discussed above
- I did/did not use a translator. (If a translator is used then the translator must sign the declaration below.)

Signed at (place) ................................. on (date) .................................

........................................................................................................
........................................................................................................
Signature of Investigator                                             Signature of Witness

Declaration By Translator

I (name ) .................................................. declare that:

- I assisted the investigator (name) ........................................ to explain the information in this document to (name of parent/legal guardian) ................................ using the language medium of Afrikaans/Xhosa.
- We encouraged him/her/them to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the legal guardian fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (place) ................................. on (date) .................................

........................................................................................................
........................................................................................................
Signature of Translator                                             Signature of Witness
DEELNEMER INLIGTINGSBROSJURE EN MAGTIGINGVORM VIR DEUR OUERS EN WETTIGE VOOGDE OMTRENT HULLE KIND SE BETROKKENHEID

TITEL VAN DIE NAVORSINGSprojek: Die bepaling van die geldigheid van ‘n siftingsinstrument vir die identifikasie van voedingsprobleme in die pediatriese groep met MIV/VIGS.

Ek is Suzanne Vermeulen, ‘n student aan die Universiteit van Kaapstad, en hierdie studie sal bydra tot my Meestersgraad in Spraak en Taal Patologie. U en u kind word uitgenooi om deel te neem aan hierdie navorsingsprojek. Neem asseblief ‘n tydje om al die inligting hier te lees – dit sal al die besonderhede van die projek verduidelik. Vra asseblief die navorsers of dokter vrae omtrent enige deel van die projek wat u nie ten volle verstaan nie. Dit is belangrik dat u verstaan waaroor die projek gaan en hoe u daarby betrokke is.

U deelname is **totaal vrywillig** en u is vry om te sê dat u nie wil deelneem nie. Indien u nee sê, sal dit u nie negatief beïnvloed nie, en dit sal ook nie die standaard van u kind se gesondheidsorg beïnvloed nie. U mag ook u deelname by enige stadium van in die studie staak met geen negatiewe gevolge nie, al het u ook aanvanklik ingestem om deel te neem.

Hierdie studie is goedgekeur deur die Fakulteit van Gesondheidswetenskappe se Menslike Navorsings Etiese Komitee van die Universiteit van Kaapstad en sal uitgevoer word volgens die etiese riglyne en beginsels van die Internasionale Verklaring van Helsinki, Suid-Afrikaanse Riglyne vir Goeie Kliniese Praktyk en die Mediese Navorsing Raad se Etiese Riglyne vir Navorsing.

**Waarom handel hierdie navorsingstudie?**
Ons doen hierdie studie by Rooikruis Kinderhospitaal om inligting in te win oor kinders met MIV-infeksie se probleme met eet en drink. Ons wil kyk of ons kan uitvind of kinders se eet- en drinkprobleme geïdentifiseer kan word deur net vrae aan die ouers te vra, of moet ons die kind waarneem terwyl hy/sy eet en drink.

Ons wil ook sien hoe twee verschillende toets vir eet- en drinkprobleme met mekaar vergelyk. Ons wil meer uitvind oor eet en drink in kinders wat MIV het omdat ons weet dat volwassenes probleme met kos sluk kan hê. Dit veroorsaak dat hulle gewig verloor of sukkel om hulle medikasie te drink. Soms kan kinders ‘n probleem met sluk hê, wat eet en drink moeilik maak en wat dan veroorsaak dat hulle siek word met ‘n borsinfeksie of te veel gewig verloor. Ons wil sien of ons hierdie probleme vroeër kan identifiseer en u kind help om beter te eet en drink. Indien u instem om u kind deel te laat neem, sal ons u kind iets gee om te eet en te drink, om te sien hoe hy eet en drink.

**Hoekom is u kind genooi om deel te neem?**
U kind is gevra om deel te neem omdat hy/sy MIV infeksie het, en dalk probleme met eet of drink kan hê.
**Wat sal u verantwoordelikhede wees?**

Indien u instem om u kind deel te laat neem, sal ons vra dat u en u kind die volgende doen:

1. Ons sal u kind (merk vir die ouderdomstoepaslike kos)
   - [ ] Melk/water
   - [ ] Pap (6 maande oud – 4 maande as vroeër met vaste kos begin is)
   - [ ] Jogurt (vanaf 12 maande oud)
   - [ ] Koekie (vanaf 10-12+ maande)
   
   gee om te sien hoe hy/sy sluk. Hierdie taak sal nie lank neem nie, en dit sal gebeur nadat ons u vrae gevra het oor u kind se eet en drink.

2. Indien ons dink dat u kind ’n slugprobleem het, sal ons die dokter sê, , sodat hy/sy ’n afspraak kan maak met ander verwante professionele gesondheidswerkers om u kind te help. Dan sal u kind deur die spraakterapeut by die hospitaal gesien word vir verdere behandeling.

**Sal u kind voordeel daaruit trek om aan hierdie navorsing deel te neem?**

Ons sal na u kind se slukproses kyk en as ons probleme vermoed, sal ons u kind vir verdere assessering en behandeling verwys.

**Loop u of u kind enige risiko’s as u aan hierdie studie deelneem?**

U loop geen risiko’s nie. As u kind ’n slukprobleem het, is daar ’n klein risiko dat hy/sy aan die kos of vloeistof kan verstik. As ons vermoed dat die kos of vloeistof by die verkeerde pyp afgaan, sal ons onmiddellik die assessering stop.

**Indien u nie instem om deel te neem nie, watter alternatiewe het u kind?**

As u nie aan hierdie studie wil deelneem nie, sal u kind se mediese behandeling normaalweg voortgaan. Die dokters wat normaalweg u kind behandel sal hom/haar steeds behandel. Geen behandeling van u kind sal gestop word as u nie wil deelneem aan die studie nie. Indien u aan die studie deelneem en op enige stadium ongelukkig voel gedurende die ondervraging, mag u u deelname met geen negatiewe gevolge vir u of u kind stop.

**Wie sal toegang tot u kind se mediese inligting hê?**

U kind se normale mediese rekords sal by die hospital gehou word. Navorsingsrekords sal op ’n rekenaar databases bewaar word en daar sal ’n geheime kode wees om die lêer te open. Die inligting sal ook nie u kind se naam daarop hê nie, maar sal deur ’n geheime nommer geïdentifiseer kan word. Slegs die hoofnavorsers sal weet wat u kind se nommer is.

**Sal u vir u deelname aan die studie betaal word en is daar enige kostes aan verbonde?**

Nee, u sal nie betaal word om aan die studie deel te neem nie. Daar is vir u geen addisionele kostes betrokke indien u deelneem nie, omdat die onderhoud op dieselfde dag as u normale kliniekafsprak plaasvind.

**Is daar enigiets anders wat u behoort te weet of te doen?**

U kan u dokter laat weet dat u deelneem aan ’n navorsingsprojek. Die uitslae van die studie sal by mediese kongresse voorgelê word en in mediese joernale gepubliseer word, sodat
ander dokters en spraakterapeute kennis kan neem van die bevindinge van hierdie studie. U kind se identiteit sal op geen stadium openbaar gemaak word nie.

As enige nuwe inligting omtrent die assessorering en behandeling van u kind beskikbaar word gedurende die verloop van die studie, sal ons u laat weet en die behandeling en toetse wat ons gebruik, verander.

Indien u enige verdere navrae het, of enige probleme teëkom, kan u vir Suzanne Vermeulen (084 626 7008), of haar toesighouer, Vivienne Norman (083 414 7928), kontak.

U kan ook vir Professor Marc Blockman, die voorsitter van die Universiteit van Kaapstad se Menslike Navorsings Etiese Komitee, (021 406 6492) kontak, indien u enige vrae of besorgdhede het oor u regte as navorsingsdeelnemers.

Indien u verkies, kan u ‘n afskrif van hierdie inligtings- en magtigingsvorm ontvang.

Suzanne Vermeulen  
MSc CSD student  
Cellphone number: 084 626 7008

Vivienne Norman  
MSc Supervisor  
Department of CSD  
Cellphone number: 083 414 7928

Professor Marc Blockman  
Chair of Human Research Ethics Committee  
021 406 6492
Dui asseblief aan:

☐ Deelnemer het inligtingsbrosjure geneem
☐ Deelnemer het nie inligtingsbrosjure geneem nie

Deur hieronder te teken, stem ek (naam van ouer/wettige voog) ................................. in om my kind (naam van kind) ................................. wie ...... jaar oud is, deel te laat neem aan ’n navorsingstudie getiteld: Die bepaling van die geldigheid van ’n siftingsinstrument vir die identifikasie van voedingsprobleme in die pediatriese groep met MIV/VIGS.

Ek verklaar as volg:

- Ek het gelees of hierdie inligtings- en magtigingsvorm is vir my voorgelees en dit is in ’n taal geskryf waarin ek vlot en gemaklik is.
- Ek het geleentheid gehad om vrae te vra en al ons vrae is bevredigend beantwoord.
- Ek verstaan dat my deelname aan hierdie studie vrywillig is en daar is geen druk op my geplaas om deel te neem nie.
- Indien ek ter enige tyd sou verkies om nie met die studie voort te gaan nie, sal daar geen negatiewe nagevolge wees nie.
- Roetine kliniese sorg sal nie geaffekteer word deur deelname aan die studie nie.
- My kind mag gevra word om die studie te verlaat voordat dit klaar is, as die studiedokter en navorser voel dat dit in my kind se beste belang is, of as ek nie die studie se plan volg nie.
- As my kind ouer as 6 jaar oud is, moet hy/sy saamstem om in die studie deel te neem en sy INSTEMMING moet op hierdie vorm aangeteken word.

Geteken te (plek) ........................................ op (datum) ........................................

........................................
Handtekening van Ouer/ Wettige Voog

........................................
Handtekening van Getuie
Declaration By Investigator

I (name) …………………………………………… declare that:

• I explained the information in this document to ………………………………
• I encouraged him/her/them to ask questions and took adequate time to answer them.
• I am satisfied that he/she/they adequately understand all aspects of the research, as discussed above
• I did/did not use a translator. (If a translator is used then the translator must sign the declaration below.)

Signed at (place) …………………………… on (date) ……………………………

……………………………………………..                     ……………………………………………..
Signature of Investigator                                  Signature of Witness

Declaration By Translator

I (name) …………………………………………… declare that:

• I assisted the investigator (name) ………………… to explain the information in this document to (name of parent/legal guardian) ………………… using the language medium of Afrikaans/Xhosa.
• We encouraged him/her/them to ask questions and took adequate time to answer them.
• I conveyed a factually correct version of what was related to me.
• I am satisfied that the legal guardian fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (place) …………………………… on (date) ……………………………

……………………………………………..                     ……………………………………………..
Signature of Translator                                     Signature of Witness
Appendix I: isiXhosa Participation Information Leaflet and Consent Form for use by Parents and Legal Guardians

**ISIHLOKO SOPHANDO:** Ukubheka kuqinisekiso ngesixhobo sokuhlola ingxaki yokuginya ebantwaneni.


**Oluphando luphunyeziwe yiFaculty of Health Sciences’ Human Research Ethics Committee eYunivesithi yaseKapa, kwaye luyakuphathwa ngokwemigaqo nemithethosiseko ye- International Declaration of Helsinki.**

**Lungantoni oluphando?**

Senza uphando eRed Cross Children’s Hospital ukuze zifumane ulwazi ngeengxaki zokutya nezokusela abathi abanye abantwana babenazo. Sifuna ukubona ukuba singafumanisa ukuba iintsana nabantwana banengxaki ngokutya okanye ngokusela, ngokubuza nje umzali/umgcinini osemtethweni imibuzo. Le mibuzo inganceda oomongikazi kunye noogqirha bafumane ezingxaki ngokusela nokutya kwangoko, kwaye bathumele iintsana/abantwana kwi-speech therapist kwangoko. Ukuba iintsana nabantwana abanengxaki ngokusela nokutya bangafumana uncedo kwangoko, bangaphepha kwisigulo sosuleleko lwesifuba okanye ekubhityeni.

Ukuba uyavuma ukuthatha inxaxheba, sizakubuza imibuzo emalunga nengxaki yokutya nokusela umntwana wakho owayenayo phambi kokuba uye kwi-speech therapy, kwaye sijonge nefolda yakhe ukuze sifumane inkcazelombe ngempilo nangobunzima bakhe. Le nto ingathatha imizuzu elishumi ukuya kwelishumi elinesihlanu. Soze silifake igama lakho okanye elomntwana wakho kwinkcazelombe esiyifumanayo. Yonke inkcazelombe izakucinwawo ekhuselekileyo, kwaye ngabaphandi bodwa abazakuyijonga. Oludliwano-ndleba
luzakwenzeka kwa ngemini enye nedinga onalo eSpeech therapy clinic.

*Kutheni umenyiwe ukuze uthathe inxaxheba?*
Uményiwe ukuzeuthathe inxaxheba kolumphando, kuba umntwana wakho unengxaki okanye wayenengxaki ngokutya okanye ngokusela kakhule.

*Zithini iiingxanduva zakho?*
Xa usiza ekinikh, sizakubuza imibuzo emalunga nendlela umntwana wakho atya ngayo nangendlela asela ngayo. Le nto ingathatha imizuzo elishumi ukuya kwelishumi elinesihlanu, kwaye oludliwano-ndlebe luzakuqhutywa lo mzuzu usalinde ukubona i-speech therapist.

*Ingaba ikhona na inzuzo ngokuthatha inxaxheba koluphando?*
Awuzufumana inzuzo eqonde kuwe nqo koluphando, kwaye akukho ntlawulo ozakuyifumana ngokuthatha inxaxheba. Ezinye iintsana nabantwana abaneengxaki ngokutya nokusela exesheni elizayo bangafumana inzuzo ngenkcazelo osinika yona.

*Ingaba bukhona na ubungozi obunoza ngokuthatha inxaxheba koluphando?*
Abukho ubungozi ngokuthatha inxaxheba koluphando, njengokuba uzakubuzwa imibuzo kuphela.

*Ukuba uyalandula ukuthatha inxaxheba, zesiphi ezinye iindlela onazo?*

*Ngubani ozakufikelela kwixingxelo zobuggqirha zomntwana wakho?*

*Ingaba uzakubhatalwa ngokuthatha inxaxheba koluphando, kwaye ingaba akhona amaxabiso aqukiweyo koluphando?*
Hayi, awuzubhatalwa ngokuthatha inxaxheba koluphando. Akekho amaxabiso ongezelelikileyo kuwe xa uthatha inxaxheba koluphando, njengokuba oludliwano-ndlebe luza kwenziwa kwangemini enye nemini yedinga lakho laseklinikhi.

*Ingaba ikhona na enye into ekumele uyazi okanye uyenze?*
Iziphumo zolumphando zizakubikwa e-University of Cape Town, ukuze zonke iSpeech-Language Therapists zazi ukuba oluphando lubuye neziphumo ezithini. Le nkcazelo inganceda ekunyangeni ngcono iintsana nabantwana abaneengxaki ngendlela yokutya.
nangokuginya. Iziphumo zoluphando zingafundisa oogqirha noomongikazi, okanye kwinqaku le jenali yobugqirha. Igama lomntwana wakho lizakusoloko ligcinwe liyimfihlo.


Ukuba uyanqwena, ungafumana ikopi yale nkcazelo kunye nefom yemvume xa ufuna ukuzigcina kwezakho iingxelo.

Sicela uphawule:
Umthathi-ngxheba ulithathile iphetshana lenkcazelo
Umthathi-ngxheba ulandule iphetshana lenkcazelo

Suzanne Vermeulen
MSc CSD student
Cellphone number: 084 626 7008

Vivienne Norman
MSc Supervisor
Department of CSD
Cellphone number: 083 414 7928

Professor Marc Blockman
Chair of Human Research Ethics Committee
021 406 6492
Ngokutyikitya igama lakho ngezantsi, mna (igama lo mzali/ lomgcini osemthethweni)………………………..ndiyavuma ukuthatha inxaxheba kuphando olunesihloko, Ukubheka kuqinisekiso ngesixhobo sokuhlola ingxaki yokuginya ebantwaneni.

Ndiyabhengeza ukuba:

- Ndiyendafunda okanye ndafundelwa le nkcazelo kunye nefom yemvume kwaye ibhalwe ngolwimi endiluvayo kwaye endikhululekileyo ngalo.
- Ndilifumene ithuba lokubuza imibuzo kwaye yonke imibuzo yethu yiphendulwe ngokucacileyo.
- Ndiyaqonda ukuba ukuthatha inxaxheba koluphando ayisiso isinyanzelo kwaye andinyanzelwanga ngumntu ukuba nithathe inxaxheba.
- Ndingakhetha kululishiya oluphando nanini na, kungabikho ziphumo zibi endinozufama ngokwenza njalo.
- Ukathalelo lwempilo lwesiqheko aluzuchaphazeleka ngokuthatha inxaxheba koluphando.

Isayinelwe e(indawo)………………………..ngomhla…………………………………..
………………………………………………
…………………………………………………..
Utyikityo lomzali/ womgcini osemthethweni Utyikityo lwengqina

Isibhengezo somphandi

Mna(igama)………………………………ndibhegeza ukuba:
- Ndiye ndacacisa le nkcazelo ekwelixwebhu ku………………………………………
- Ndiye ndamkhuthaza ukuba abuze imibuzo, kwaye ndathatha ixesha elaneleyo ukuyiphendula.
- Ndiyakholwa ukuba uyiqonde kakuhle yonke imiba yoluphando
- Ndiye ndasebenzise/andisebenzisanga umguquli-zilwimi.

Isayinelwe e(indawo)………………………..ngomhla…………………………………..
………………………………………………
…………………………………………………..
Utyikityo lomphandi Utyikityo lwengqina
Isibhengezo somguquli-zilwimi

Mna(igama).........................................ndibhegeza ukuba:

- Ndincedise umphandi (igama)...........................ukuba acacise le nkcazelo ekwelixwebhu ku(igama lo mzali/umgcini osemthethweni)...............................ndisebenzisa ulwimi lwesiXhosa/lwesiBhulu.
- Siye samkhuthaza ukuba abuze imibuzo, sathatha nexesha elanaleyekuyiphendula.
- Ndiye ndadlulisa inguqulelo eyiyo yentetho ebendiyibaliselwe
- Ndiyakholwa ukuba umzali/umgcini osemthethweni usiqonde sonke isiqulatho selixwebhu lemvume, kwaye yonke imibuzo yakhe iphendulwe ngokwanele yo.

Isayinelwe e(indawa)..................................ngomhla..............................................
..........................................................................................................................
..........................................................................................................................

Utyikityo lomguquli-zilwimi

Utyikityo lwengqina
ISIHLOKO SOPHANDO: Ukubheka kuqinisekiso ngesihobo sokuhlola ingxaki yokuginya ebantwane.


Inxaxheba yakho koluphando ayisiso isinyanzelo, kwaye zive ukhulekile ukulandula ukuba ngaba unqwena ukwenza njalo. Ukuba uye walandula, lo nto ayisoze ikuchaphazela ngendlela embi, kwaye ayisoze ichaphazele umgangatho woncedo umntwana wakho alufanayo ngempilo yakhe. Unalo ilungelo lokurhoxa ekuthatheni inxaxheba koluphando nanini na, kwaye akuzubakho ziphuma zimbi ngokwenza lo nto, nokuba ubusewuvumile ukuthatha inxaxheba ekuqaleni.

Oluphando luphunyeziwe yiFaculty of Health Sciences’ Human Research Ethics Committee eYunivesithi yaseKapa, kwaye luyakuphathwa ngokwemigaqo nemithetho-siseko ye- International Declaration of Helsinki.

Lungantoni oluphando?

Senza uphando eRed Cross Children’s Hospital ukuze zifumane ulwazi ngeengxaki yokutya nezokusela abathile abanye abantwana babenazo. Sifuna ukubona ukuba singafumanisa ukuba iintsana nabantwana banengxaki ngokutya okanye ngokusela, ngokubuza nje umzali/umgcini osemthethweni imibuzo. Le nibuzo inganceda oomongikazi kunye noogqirha bafumane ezingxaki ngokusela nokutya kwangoko, kwaye bathumele iintsana/abantwana kwi-speech therapist kwangoko. Ukuba iintsana nabantwana abanengxaki ngokusela nokutya bangafumana uncedo kwangoko, bangaphepha kwisigulo sosuleleko lwesifuba okanye ekubhityeni.


Kutheni umenyiwe ukuze uthathe inxaxheba?

Umenyiwe ukuzeuthathe inxaxheba koluphando, kuba umntwana wakho unengxaki okanye wayenengxaki ngokutya okanye ngokusela kakuhle.
Zithini iingxanduva zakho?
Xa usiza eklinikh, sizakubuza imibuzo emalunga nendlela umntwana wakho atya ngayo nangendlela asela ngayo. Le nto ingathatha imizuzu elishumi ukuya kwelishumi elinesihlanu, kwaye oludliwano-ndlebe luzakuqhutywa lo mzuzu usalinde ukubona i-speech therapist.

Ingaba ikhona na inzuzo ngokuthatha inxaxheba koluphando?
Awuzufumana inzuzo eqonde kuwe nqo koluphando, kwaye akukho ntlawulo ozakuyifumana ngokuthatha inxaxheba. Ezinye iintsana nabantwana abaneengxaki ngokutya nokusela exesheni elizayo bangafumana inzuzo ngenkcazelosinika yona.

Ingaba bukhona na ubungozi obunoza ngokuthatha inxaxheba koluphando?
Abukho ubungozi ngokuthatha unxaxheba koluphando, njengokuba uzakubuzwa imibuzo kuhela.

Ukuba uyalandula ukuthatha inxaxheba,zeziphi ezinye iindlela onazo?

Ngubani ozakufikelela kwiingxelo zobugqirha zomntwana wakho?
Ingxelo zobugqirha zomntwana wakho zizakugcinwa esibhedlele njengesiqhelo. lngxelo zophando (inkcazelosikubuza ngayo) zizakucinwa kucinco-nkombolo yekhompyutha, kwaye ibenekekhowudi eyimfihlo ukuze ukwazi ukuyivula ifayili. Futhi, inkcazeloyizabhalwa igama lomntwana wakho kuyo, kodwa izakuchongwa ngenombolo eyimfihlo. Ngabaphandibodwa abaza kubanolwazi ngale nombolo.

Ingaba uzakubhatalwa ngokuthatha inxaxheba koluphando, kwaye ingaba akhona amaxabiso aqukiweyo koluphando?
Hayi, awuzubhatalwa ngokuthatha inxaxheba koluphando. Akekho amaxabiso ongezelekileyo kuwe xa uthatha inxaxheba koluphando, njengokuba udliwano-ndlebe luza kwenziwa kwangemini enye nemini yedinga laxho laseklinikh.

Ingaba ikhona na enye into ekumele uyazi okanye uyenze?
Iziphumo zoluphando zizakubikwa e-University of Cape Town, ukuze zonke iispeech-Language Therapists zazi ukuba oluphando lubuye neziphumo ezithimi. Le nkcazelolengangeda ekunyangeni ngcono iintsana nabantwana abaneengxaki ngendlela yokutya nangokuginya. Iziphumo zoluphando zingafundisa oogqirha noomongikazi, okanye kwingaku lejenali yobugqirha. Igama lomntwana wakho lizakusoloko ligcinwe liyimfihlo.

Ukuba uneminye imibuzo okanye udidene nezinye iingxaki, ungaqhagamshelana uSuzanne Vermeulen (0846267008) okanye nomphathi wabo uVivienne Norman (083 414 7928).
Bona ngezantsi iinkukacha zoqhagamshelwano.
Ungaqhagamshelana noProfesa Marc Blockman, ongusihlalo we-University of Cape Town Human Research Ethics Committee, ku-021 406 6492 ukuba unemibuzo emalunga namalungelo akho njengomthathi-nxaxheba kuphando.

Ukuba uyanqwena, ungafumana ikopi yale nkcazelo kunye nefom yemvume xa ufuna ukuzigcina kwezakho iingxelo.

Sicela uphawule:
Umthathi-nxaxheba ulithathile iphetshana lenkcazelo
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Ngokutyikitya igama lakho ngezantsi, mna (igama lo mzali/ lomgcini osemthethweni)………………………..ndiyavuma ukuthatha inxaxheba kuphando olunesihloko, Ukubheka kuqinisekiso ngesixhobo sokuhloka ingxaki yokuginya ebantwenedi.

Ndiyabhengeza ukuba:

- Ndiyendafunda okanye ndafundelwa le nkcazelo kunye nefom yemvume kwaye ibhalwe ngolwimi endiluvayo kwaye endikhululekileyo ngalo.
- Ndilifumene ithuba lokubuza imibuzo kwaye yonke imibuzo yethu yiphendulwe ngokucacileyo.
- Ndiyaqonda ukuba ukuthatha inxaxheba koluphando ayisiso isinyanzelo kwaye andinyanzelwanga ngumntu ukuba nithathe inxaxheba.
- Ndingakhetha kululweyini oluphando nanini na, kungabikho ziphumo zibi endinozufama ngokwenza njalo.
- Ukathalelo lwempilo lwesiqhelo aluzuchaphazeleka ngokuthatha inxaxheba koluphando.

Isayinelwe e(indawo)………………………..ngomhla…………………………………
……………………………………………… .................................................................
……………………………………………… …………………………………………………
Utyikityo lomzali/ womgcini osemthethweni Utyikityo lwengqina

Isibhengezo somphandi

Mna(igama)………………………..ndibhegeza ukuba:

- Ndiye ndacacisa le nkcazelo ekwelixwebhu ku………………………………………
- Ndiye ndamkhuthaza ukuba abuze imibuzo, kwaye ndathatha ixesha elaneleyo ukuyiphendula.
- Ndiyakholwa ukuba uyiqonde kakuhle yonke imiba yoluphando
- Ndiye ndasebenzisa/andisebenzisanga umguquli-zilwimi.

Isayinelwe e(indawo)………………………..ngomhla…………………………………
……………………………………………… .................................................................
……………………………………………… .................................................................
Utyikityo lomphandi Utyikityo lwengqina
Isibhengezo somguquli-zilwimi
Mna(igama)........................................ndibhegeza ukuba:
- Ndincedise umphandi (igama)............................ukuba acacise le nkazelo ekwelixwehhu
  ku(igama lo mzali/umgcini osemthethweni)................ndisebenzisa ulwimi
  lwesiXhosa/lwesiBhulu.
- Siye samkhuthaza ukuba abuze imibuzo, sathatha nexesha elanaleyi
  ukuyiphendula.
- Ndiye ndadlulisa inguqulelo eiyiyo yentetho ebendiyibaliselwe
- Ndiyakholwa ukuba umzali/umgcini osemthethweni usiqonde sonke
  isiqulatho selixwebhu lemvume, kwaye yonke imibuzo yakhe
  iphendulwe ngokwaneleyo.

Isayinelwe e(indawo)....................................ngomhla...........................................
..............................................................................
Utyikityo lomguquli-zilwimi                       Utyikityo lwengqina
Appendix J: Participation Information Leaflet and Assent Form

PARTICIPANT INFORMATION LEAFLET AND ASSENT FORM

TITLE OF THE RESEARCH PROJECT: A study to see if children in the Infectious Diseases Clinic have problems swallowing food.

I am Suzanne Vermeulen and I study Speech Therapy at the University of Cape Town.

What is RESEARCH?
Research is something we do to find new knowledge about the way things (and people) work. We use research projects or studies to help us find out more about disease or illness. Research also helps us to find better ways of helping, or treating children who are sick.

What is this research project all about?
Children who are sick for a long time or need to take medicine to keep them healthy, sometimes have problems eating or drinking. We do not know if this is a problem for children in our clinic. We want to ask you and your mother/father/caregiver questions that will help us find out if you have a problem swallowing.

Why have I been invited to take part in this research project?
You come to this clinic because you need to take medicine every day to keep you healthy. We want to know if children who come to this clinic have problem eating or drinking.

Who is doing the research?
I help the speech therapist who is doing this study. I will ask some questions and she will look at how you eat and drink.

What will happen to me in this study?
First, I am going to ask you and your mother/father/ caregiver some questions that will help me decide if you have problems eating or drinking. Later, another lady will watch you while you eat and drink something. If she thinks that there is a problem
with your swallowing we will speak to your doctor about what we should do next to help you swallow better.

**Can anything bad happen to me?**
If you find eating and drinking difficult, it might be a bit uncomfortable. If it is very difficult for you to eat and drink, we will stop.

**Can anything good happen to me?**
If we find that you have a problem with swallowing, we can help you eat and drink better.

**Will anyone know I am in the study?**
Only your mother/father/caregiver will know that are in the study. We will not tell anybody else. The forms we fill in are kept in a secret place where no one else can see them.

**Who can I talk about the study?**
You can talk to me or any of the other people in the study.

**What if I do not want to do this?**
You do not have to take part in this study. If you do take part but want to stop after a while you can say so. We will still treat you like any of the other children in the clinic.

**RESEARCHERS NAME(S):** Ms. Vivienne Norman

**ADDRESS:** Division of Communication Sciences and Disorders, Department of Health and Rehabilitation Sciences, F45 Old Main Building, Groote Schuur Hospital, Observatory, 7925

**CONTACT NUMBER:** 083 414 7928 / 084 626 7008
Do you understand this research study and are you willing to take part in it?

[ ] YES  [ ] NO

Has the researcher answered all your questions?

[ ] YES  [ ] NO

Do you understand that you can pull out of the study at any time?

[ ] YES  [ ] NO

_________________________ ____________________
Signature of Child          Date
Appendix K: Original Feeding and Swallowing Questionnaire

Feeding and Swallowing Questionnaire

I am going to ask you some questions about your baby / child’s drinking and eating. If there are problems I will refer him / her for a thorough assessment with the speech therapist.

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Please indicate which type of feeds XXX has everyday:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast feeding only ___   Bottle feeding only ____   Breast feeding &amp; Bottle feeding ______</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast feeding &amp; solids ___   Breast feeding, bottle feeding &amp; solids ___</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bottle feeding &amp; solids ______</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liquids &amp; solids _____</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:_____________________</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Does XXX have any problems with eating or drinking</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>3. Is it difficult for you, or anyone else, to feed XXX?</td>
<td>YES</td>
<td>NO</td>
<td>Over 2 years: N/A</td>
</tr>
<tr>
<td>4. Does it take longer than 30 minutes for XXX to finish Feeding / eating a meal?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>5. Does XXX get tired when s/he is drinking or eating?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>6. Is XXX picking up weight?</td>
<td>Well</td>
<td>Slowly</td>
<td>Not at all</td>
</tr>
<tr>
<td>7. Does XXX have problems breathing during feeding or after feeding? For example does breathing become faster, noisy, difficult?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>8. Does XXX finish his / her feeds / meals most of the time?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>9. Does XXX become upset or fussy e.g. cry, wriggle, turn face away, with feeding?</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
</tr>
</tbody>
</table>
10. Does XXX vomit with feeds?  
   | YES | NO | During feed:  | After feed:  
   |     |    |              |              
   |     |    | After medication | Anytime |

11. Is XXX’s voice hoarse or has it changed?  
   | YES | NO | >2 weeks | Refer ENT |

12. Does XXX’s voice sound gurgly (wet) after drinking?  
   | YES | NO |

13. Does XXX drool?  
   | YES | All the time | No | Observe during session: if child older than 3 years and wearing a bib or has noticeable drooling |
   |     | More during eating / drinking |
   |     | Only when teething |

<table>
<thead>
<tr>
<th>0 – 6 months</th>
<th>6 – 12 months</th>
<th>12 + months</th>
</tr>
</thead>
</table>
14. Does XXX drink liquids such as milk and water?  
   | YES | NO | YES | NO | YES | NO |

15. Does XXX eat semi-solids such as cereal?  
   | YES | NO | YES | NO | YES | NO |

16. Does XXX eat solids such as bread or biscuits?  
   | YES | NO | YES | NO |

17. Does XXX drink well from a bottle / breast?  
   | YES | NO | YES | NO |

18. Can XXX drink from a cup?  
   | YES | NO | YES | NO |

19. Does XXX mess / spill a lot from the mouth during feeding?  
   | YES | NO | YES | NO | YES | NO |

20. Does liquid or food ever come out of XXX’s nose while drinking or eating?  
   | YES | NO | YES | NO | YES | NO |

21. Does XXX gag (want to vomit – demonstrate) with liquids?  
   | YES | NO | YES | NO | YES | NO |

22. Does XXX gag (want to vomit – demonstrate) with food?  
<p>| N/A | YES | NO | YES | NO |</p>
<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
<th>YES</th>
<th>NO</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>23. Does XXX refuse to drink liquids such as milk or water?</td>
<td></td>
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<td></td>
<td></td>
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<td>Always</td>
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<td>24. Does XXX refuse to eat food?</td>
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<td>Once or twice</td>
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<tr>
<td>25. Does XXX spit out liquids such as milk?</td>
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<td>Always</td>
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<td>26. Does XXX spit out food?</td>
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<td>Once or twice</td>
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<tr>
<td>27. Does XXX cough with drinking?</td>
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<tr>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
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<td>28. Does XXX cough with eating?</td>
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<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
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<tr>
<td>29. Does XXX choke with drinking?</td>
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<tr>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
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<tr>
<td>30. Does XXX choke with eating?</td>
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<td></td>
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<tr>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
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</tr>
</tbody>
</table>

Referral criteria to SLT for clinical feeding and swallowing assessment:

- Any response shaded
- More than one response shaded
Appendix L: Revised Feeding and Swallowing Questionnaire

Feeding and Swallowing Questionnaire

Participant number:_________________ Date of birth: _____________________________

Date of assessment: ______________ Primary language of caregiver:_________________

I am going to ask you some questions about how your baby / child drinks and eats.

*Complete all sections and indicate responses clearly with comments if necessary*

<table>
<thead>
<tr>
<th>1. Please indicate which type of feeds XXX has everyday:</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast feeding only ____ Bottle feeding only ____ Breast feeding &amp; Bottle feeding ____</td>
<td></td>
</tr>
<tr>
<td>Breast feeding &amp; solids ____ Breast feeding, bottle feeding &amp; solids ____</td>
<td></td>
</tr>
<tr>
<td>Bottle feeding &amp; solids ____ Liquids &amp; solids ____ Other: ___________________________</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2 Does XXX have any problems with eating or drinking?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>3. Is it difficult for you, or anyone else, to feed XXX?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 2 years: N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Does it take longer than 30 minutes for XXX to finish feeding / eating a meal?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>5. Does XXX get tired when s/he is drinking or eating?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>6. Is XXX picking up weight?</th>
<th>Well</th>
<th>Slowly</th>
<th>Not at all</th>
<th>Losing weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>If objective evidence for weight loss or crossing centiles (RTHC)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>7. Does XXX have problems breathing during feeding or after feeding? For example does breathing become faster, noisy, difficult?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>8. Does XXX finish his / her feeds / meals most of the time?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>
9. Does XXX become upset or fussy e.g. cry, wriggle, turn face away, with feeding? *(demonstrate these behaviours with physical cue)*

| YES | NO | N/A |

10. Does XXX vomit with feeds?

| YES | NO | During feed | After feed | After medication | Anytime |

11. Is XXX’s voice hoarse, scratchy or has it changed?

| YES | NO | >2 weeks | Refer ENT |

12. Does XXX’s voice sound gurgly (wet) after drinking?

| YES | NO |

13. Does XXX drool (does spit run out of XXX’s mouth)? *(demonstrate with hand gesture)*

| YES | NO |

0 – 6 months | 6 – 12 months | 12 + months

14. Does XXX drink liquids such as milk and water?

| YES | NO | YES | NO | YES | NO |

15. Does XXX eat semi-solids such as cereal?

| YES | NO | YES | NO |

16. Does XXX eat solids such as bread or biscuits?

| YES | NO |

17. Does XXX drink well from a bottle / breast?

| YES | NO | YES | NO |

18. Can XXX drink from a cup?

| YES | NO | YES | NO |

19. Does XXX mess / spill a lot from the mouth during feeding?

| YES | NO | YES | NO | YES | NO |

20. Does liquid or food ever come out of XXX’s nose while drinking or eating?

<p>| YES | NO | YES | NO | YES | NO |</p>
<table>
<thead>
<tr>
<th></th>
<th>21. Does XXX gag (want to vomit – demonstrate) with liquids?</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
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<td>YES</td>
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<td></td>
<td>22. Does XXX gag (want to vomit – demonstrate) with food?</td>
<td>N/A</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
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<td>23. Does XXX refuse to drink liquids such as milk or water?</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
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<td></td>
<td>Always</td>
<td>Daily</td>
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<td>Once or twice</td>
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<td>24. Does XXX refuse to eat food?</td>
<td>YES</td>
<td>NO</td>
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<td>25. Does XXX spit out liquids such as milk?</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
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<td>Always</td>
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<td>26. Does XXX spit out food?</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
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<td></td>
<td>Always</td>
<td>Daily</td>
<td>Weekly</td>
<td>Once or twice</td>
<td>Always</td>
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<tr>
<td>Question</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
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<tr>
<td>27. Does XXX cough with drinking?</td>
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<tr>
<td>28. Does XXX cough with eating?</td>
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<tr>
<td>29. Does XXX choke with drinking (does liquid go down the wrong pipe)?</td>
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<tr>
<td>30. Does XXX choke with eating (does food go down the wrong pipe)?</td>
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</tbody>
</table>

**Referral criteria to SLT for clinical feeding and swallowing assessment:**

- Any response shaded
- More than one response shaded

**INDICATE (Please tick):**

- PASS
- FAIL

**Additional comments:**

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
Appendix M: Revised Afrikaans Feeding and Swallowing Questionnaire

Feeding and Swallowing Questionnaire (Voeding en Sluk Vraelys)

Participant number:_______________ Date of birth: _____________________________
Date of assessment: ______________ Primary language of caregiver:_______________

I am going to ask you some questions about your baby / child’s drinking and eating. If there are problems I will refer him / her for a thorough assessment with the speech therapist. (Ek gaan vir U vrae oor hoe u baba/kind drink en eet vra. Indien dit lyk asof daar probleme is, sal ek hom/haar na 'n spraakterapeut vir 'n deeglike evaluasie stuur.)

Complete all sections and indicate responses clearly with comments if necessary

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Dui asseblief aan watter tiepe voedings XXX elke dag eet:</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Slegs borsvoeding____ Slegs bottelvoeding ____ Borsvoeding and bottelvoeding ____</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Borsvoeding en vastekos ____ Borsvoeding, bottelvoeding en vastekos ____</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Borsvoeding en vastekos ____ Vloeistowwe en vastekos ____ Ander:________</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Het XXX enige problem met eet of drink?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>3. Is dit moeilik vir jou of enigiemand anders om XXX te voed?</td>
<td>YES</td>
<td>NO</td>
<td>Over 2 years: N/A</td>
</tr>
<tr>
<td>4. Neem dit langer as 30 minute vir XXX om klaar te eet of voed?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>5. Word XXX moeg as hy/sy drink of eet?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>6. Tel XXX gewig op?</td>
<td></td>
<td></td>
<td>Glad nie Verloor gewig If objective evidence for weight loss or crossing centiles (RTHC)</td>
</tr>
<tr>
<td>7. Het XXX probleme met asemhaling tydens of na voedings?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Byvoorbeeld, word die asemhaling vinniger, raserig, of moeilik?</td>
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<tr>
<td>Question</td>
<td>Options</td>
<td></td>
<td></td>
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<td>------------------------------------------------------------------------</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>8. Maak XXX sy/haar voedings meeste van die tyd klaar?</td>
<td>YES  NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Word XXX onsteld of knieserig (by huil, draai gesig weg) tydens voeding?</td>
<td>YES  NO  N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Gooi XXX op met voedings?</td>
<td>YES  NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Is XXX se stem hees of het dit verander?</td>
<td>YES  NO  &gt;2 weeks  Refer ENT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Klink XXX se stem nat nadat hy/sy gedrink het?</td>
<td>YES  NO</td>
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<tr>
<td>13. Kwyl XXX?</td>
<td>YES  All the time  More</td>
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<td></td>
<td>during eating / drinking</td>
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<td></td>
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<tr>
<td></td>
<td>Only when teething</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Drink XXX vloeistowwe soos melk en water?</td>
<td>YES  NO  YES  NO  YES  NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Eet XXX semi-vaste kos soos graan?</td>
<td>YES  NO  YES  NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Eet XXX vastekos soos brood of beskuitjies?</td>
<td>YES  NO  YES  NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Drink XXX goed aan die bors of uit ‘n bottel uit?</td>
<td>YES  NO  YES  NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Kan XXX uit ‘n koppie uit drink?</td>
<td>YES  NO  YES  NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. Mors XXX baie kos uit sy/haar mond uit tydens voeding?</td>
<td>YES  NO  YES  NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
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<td>--------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>20. Kom vloeistowwe of kos ooit uit XXX se neus uit terwyl hy/sy drink?</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>21. Word XXX ooit naar (wil hy braak – demonstreer) met vloeistowwe?</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>22. Word XXX ooit naar (wil hy braak – demonstreer) met vastekos?</td>
<td>N/A</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>23. Weier XXX om vloeistowwe soos melk en water te drink?</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Always</td>
<td>Daily</td>
<td>Weekly</td>
<td>Once or twice</td>
</tr>
<tr>
<td>24. Weier XXX om vastekos te eet?</td>
<td>N/A</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Always</td>
<td>Daily</td>
<td>Weekly</td>
<td>Once or twice</td>
</tr>
<tr>
<td>25. Spoeg XXX vloeistowwe soos melk uit?</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Always</td>
<td>Daily</td>
<td>Weekly</td>
<td>Once or twice</td>
</tr>
</tbody>
</table>
### Referral criteria to SLT for clinical feeding and swallowing assessment:

Any response shaded

More than one response shaded

**INDICATE (Please tick):**

PASS

FAIL

**Additional comments:**

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________
Appendix N: Revised isiXhosa Feeding and Swallowing Questionnaire

Feeding and Swallowing Questionnaire – isiXhosa version

Participant number:_______________ Date of birth: _____________________________

Date of assessment: ______________ Primary language of caregiver:_________________

Ndiza kukubuza eminye imibuzo ngokusela nangokutya kosana / komtwana wakho. Ukuba kukho iingxaki ndiza kumthumela apho aza kuhlolisiswa khona malunga nendlela athetha ngayo.

*Complete all sections and indicate responses clearly with comments if necessary*

<table>
<thead>
<tr>
<th>Section</th>
<th>Response</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nceda ubonakalise ukuba loluphi na uhlobo otyisa ngalo uXXX yonke imihla:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast feeding only ____</td>
<td>Bottle feeding only ____</td>
<td>Breast feeding &amp; Bottle feeding ____</td>
</tr>
<tr>
<td>Breast feeding &amp; solids ____</td>
<td>Breast feeding, bottle feeding &amp; solids ____</td>
<td></td>
</tr>
<tr>
<td>Bottle feeding &amp; solids ____</td>
<td>Liquids &amp; solids ____</td>
<td>Other: ___________________________</td>
</tr>
<tr>
<td>2. Ingaba uXXX unazo na ingxaki ngokutya okanye ngokusela</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>3. Ingaba kunzima kuwe okanye komnye umntu ukutyisa uXXX?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>4. Ingaba kuthatha ngaphezu kwemizuzu engama-30 ukuze uXXX akwazi ukugqiba ukutyiswa / ukutya ukutyisa?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>5. Ingaba uXXX uyunwana xa esele okanye esitya?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>6. Ingaba uXXX uye esenyuka esiqwini sakhe ngokobukhulu bomzimba?</td>
<td>Well</td>
<td>Slowly</td>
</tr>
<tr>
<td>7. Ingaba uXXX uneengxaki zokuphefumla xa esitya okanye emva kokuba etyile? Umzekelo, ingaba uphefumlela phezulu, ngokungxolayo, nzima?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Question</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-----</td>
<td>----</td>
</tr>
<tr>
<td>8. Ingaba uXXX uyakugqiba ukutya / izidlo zakhe amaxesha amaninzi?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>9. Ingaba uXXX uyacapuka okanye abe nochuku umz. alile, ajubalaze, ajike ubuso ajonge ecaleni, xa etyiswa?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>10. Ingaba uXXX uyagabha xa etyiswa?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>11. Ingaba ilizwi likaXXX lirhabaxa okanye litshintshile?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>12. Ingaba ilizwi likaXXX livakala lirhotyoza (emanzi) emva kokusela?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>13. Ingaba uXXX uvuz’izinkcwe?</td>
<td>YES</td>
<td>No</td>
</tr>
<tr>
<td>14. Ingaba uXXX uyazisela izinto ezifana nobisi namanzi?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>15. Ingaba uXXX utya izinto ezingaqinanga kuyaphi ezifana neepapa?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>16. Ingaba uXXX utya izinto eziqinileyo ezifana nesonka neebhiskithi?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>17. Ingaba uXXX usela kakhule ebhotileni / ebeleni uncanca kakhule?</td>
<td>YES</td>
<td>NO</td>
</tr>
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</table>

<table>
<thead>
<tr>
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<th>0 – 6 months</th>
<th>6 – 12 months</th>
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<td>14. Ingaba uXXX uyazisela izinto ezifana nobisi namanzi?</td>
<td>YES</td>
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<td>YES</td>
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<tr>
<td>15. Ingaba uXXX utya izinto ezingaqinanga kuyaphi ezifana neepapa?</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
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<tr>
<td>16. Ingaba uXXX utya izinto eziqinileyo ezifana nesonka neebhiskithi?</td>
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<td>YES</td>
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<td>17. Ingaba uXXX usela kakhule ebhotileni / ebeleni uncanca kakhule?</td>
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<td>NO</td>
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<td>18. Ingaba uyakwazi uXXX ukusela epayintini?</td>
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<td>YES</td>
<td>NO</td>
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<tr>
<td></td>
<td></td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>19. Ingaba uXXX uyingcolisa / uyangichithela ngokutya okuphuma emlonyenzi xa esitya?</td>
<td></td>
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<td></td>
<td>20. Ingaba kukhe kaphume amanzi okanye ukunya ngempumilo xa uXXX esela okanye xa esitya?</td>
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<tr>
<td></td>
<td>21. Ingaba uXXX uya Khonyuluka xa esela? (demonstrate with physical cue)</td>
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<tr>
<td></td>
<td>22. Ingaba uXXX uya Khonyuluka xa esitya? (demonstrate with physical cue)</td>
<td>N/A</td>
<td>YES</td>
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<td>23. Ingaba uXXX uyala ukusela izinto ezifana nobisi okanye amanzi?</td>
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<td>24. Ingaba uXXX uyala ukutya ukutya?</td>
<td>N/A</td>
<td>YES</td>
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**25. Ingaba uXXX uyanisitsa izinto ezingamanzi ezifana nobisi?**

<table>
<thead>
<tr>
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<tr>
<td><strong>Once or twice</strong></td>
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**26. Ingaba uXXX uyanakutsica ukutya?**

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</tr>
<tr>
<td><strong>Once or twice</strong></td>
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</tbody>
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**27. Ingaba uXXX uyanakhuholo xa esela?**

<table>
<thead>
<tr>
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<th>NO</th>
<th>YES</th>
<th>NO</th>
<th>YES</th>
<th>NO</th>
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</table>

**28. Ingaba uXXX uyanakhuholo xa esitya?**

<table>
<thead>
<tr>
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<th>YES</th>
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</thead>
<tbody>
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<td></td>
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<td></td>
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</tbody>
</table>

**29. Ingaba uXXX uyonini xa esela?**

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
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<th>YES</th>
<th>NO</th>
<th>YES</th>
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</thead>
<tbody>
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<td></td>
</tr>
</tbody>
</table>

**30. Ingaba uXXX uyonini xa esitya?**

<table>
<thead>
<tr>
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<th>YES</th>
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<th>YES</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Referral criteria to SLT for clinical feeding and swallowing assessment:**

Any response shaded

More than one response shaded

**INDICATE (Please tick):**

PASS  FAIL

**Additional comments:**

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
Appendix O: Clinical Feeding and Swallowing Evaluation

Clinical Feeding and Swallowing Evaluation

Participant number: ………………  Date of birth:………………………………………

Complete all areas or indicate Yes (✓), No (✗) or Not Applicable (NA)

Parent / caregiver concerns:

…………………………………………………………………………………………………
…………………………………………………………………………………………………
…………………………………………………………………………………………………
…………………………………………………………………………………………………
………………………………………………………………………………………………

History:

Family
1. Primary caregivers: …………………………………………………………………
2. Who feeds participant: …………………………………………………………………
3. History of any of the following:

<table>
<thead>
<tr>
<th></th>
<th>Yes / No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Candida</td>
<td></td>
</tr>
<tr>
<td>Pharyngeal Candida</td>
<td></td>
</tr>
<tr>
<td>Oesophageal Candida</td>
<td></td>
</tr>
<tr>
<td>Middle ear infections</td>
<td></td>
</tr>
<tr>
<td>Allergies</td>
<td></td>
</tr>
<tr>
<td>Mouth Breathing</td>
<td></td>
</tr>
<tr>
<td>Seizures</td>
<td></td>
</tr>
<tr>
<td>CMV</td>
<td></td>
</tr>
<tr>
<td>Snoring</td>
<td></td>
</tr>
<tr>
<td>Upper Respiratory Tract Infections</td>
<td></td>
</tr>
<tr>
<td>Other illnesses</td>
<td></td>
</tr>
</tbody>
</table>

4. Previous medical investigations and results:
   Barium swallow:……………………………………………………………………
   Milk Scan: ………………………………………………………………………
   GI Scope: ………………………………………………………………………
   Other:……………………………………………………………………
5. Developmental history:

<table>
<thead>
<tr>
<th></th>
<th>Age (where applicable)</th>
<th>Normal</th>
<th>Delayed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smiled</td>
<td></td>
<td>2-4 months</td>
<td></td>
</tr>
<tr>
<td>Sat unsupported</td>
<td></td>
<td>4-9 months</td>
<td></td>
</tr>
<tr>
<td>Crawled</td>
<td></td>
<td>5-14 months</td>
<td></td>
</tr>
<tr>
<td>Cruised along furniture</td>
<td></td>
<td>6-14 months</td>
<td></td>
</tr>
<tr>
<td>Walked</td>
<td></td>
<td>8-18 months</td>
<td></td>
</tr>
<tr>
<td>Said first words</td>
<td></td>
<td>12-18 months</td>
<td></td>
</tr>
<tr>
<td>2 words together</td>
<td></td>
<td>13-24 months</td>
<td></td>
</tr>
<tr>
<td>Grade in School</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learning Difficulties</td>
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Feeding history:

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Duration:</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Tube feeding</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Breastfed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Bottle fed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Cup fed</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

10. Position during feeding

<table>
<thead>
<tr>
<th></th>
<th>Held in arms</th>
<th>Held on lap</th>
<th>Infant seat/car seat</th>
<th>High chair</th>
<th>Chair at table</th>
<th>Wheelchair</th>
<th>Lying down</th>
<th>Other:</th>
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</thead>
</table>

11. Duration of meal times:

<table>
<thead>
<tr>
<th></th>
<th>&lt;20 minutes</th>
<th>20-40 minutes</th>
<th>40+ minutes</th>
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</thead>
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12. Completion of feeds

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Seldom</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
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</table>

13. Feeding Routine

<table>
<thead>
<tr>
<th></th>
<th>2 hours</th>
<th>3 hours</th>
<th>4 hours</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Regular mealtimes e.g. breakfast, lunch &amp; supper with snacks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

14. Describe a typical daily diet (24 hours):

…………………………………………………………………………………………………
…………………………………………………………………………………………………
…………………………………………………………………………………………………
…………………………………………………………………………………………………
…………………………………………………………………………………………………
…………………………………………………………………………………………………
…………………………………………………………………………………………………
15. Textures in diet

<table>
<thead>
<tr>
<th>Texture</th>
<th>Examples</th>
<th>Age introduced</th>
<th>Difficult for participant</th>
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<tbody>
<tr>
<td>Liquid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Puree</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lumpy puree</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solid</td>
<td></td>
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16. Utensils used

<table>
<thead>
<tr>
<th>Utensil</th>
<th>Age introduced</th>
<th>Caregiver/ Self</th>
<th>Utensil</th>
<th>Age introduced</th>
<th>Caregiver/ Self</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bottle</td>
<td>Spon</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sippy Cup</td>
<td></td>
<td>Fork</td>
<td></td>
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</tr>
<tr>
<td>Open Cup</td>
<td>Straw</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fingers</td>
<td>Sports bottle</td>
<td></td>
<td></td>
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<tr>
<td>Other</td>
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**Signs & Symptoms reported by caregiver**

17. Consistency-specific information

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<tbody>
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<td>Daily</td>
<td>Weekly</td>
<td>Once or Twice</td>
</tr>
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<td>Daily</td>
<td>Weekly</td>
<td>Once or Twice</td>
<td>Never</td>
</tr>
<tr>
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<td>Weekly</td>
<td>One or Twice</td>
<td>Never</td>
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<td>One or Twice</td>
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</tbody>
</table>
18. Fussy/cries during feeding: Yes........... No...........
19. Reports pain with swallowing: Yes (caregiver reported).......... Yes (self reported) ..........   No..........
20. Keeps food in mouth for a long time before swallowing: Yes........... No...........
21. Gurgly voice: No ............ Always ............ During feeding ............ After feeding ............
22. Noisy breathing: No ............ Always ............ During feeding ............
23. Postural changes during feeding (e.g. hyperextension): Yes........... No...........
   e.g. ........................................................................................ 
24. Falls asleep during feeding: Yes........... No...........
25. Colour changes with feeding: Yes........... No...........
26. Sensitive to touch around mouth: Yes........... No...........
27. Drools: All the time....... More during eating/drinking .......
   Only when teething ....... Does not drool .......

Pre-feeding assessment

28. State: Drowsy ............ Awake ............ Agitated ............ Crying ............
29. Physiological status

<table>
<thead>
<tr>
<th></th>
<th>Heart rate</th>
<th>Respiratory rate</th>
<th>Oxygen saturation level (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before feeding</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>During feeding</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After feeding</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

30. General posture and tone: Normal ............ Hypotonic ............
   Hypertonic ............ Fluctuating ............
31. Airway: Normal ............ Stridor ............ Stertor ............
   Tracheostomy ............ Ventilated ............ Oxygen dependent ......
32. Wet voice: Yes........... No...........
33. Audible pooling of secretions in pharynx: Yes........ No........
34. Bubbling of secretions at mouth: Yes........ No........
35. Pooling of secretions in mouth: Yes........ No........
36. Drools: No ...... Mild (around lips) ........... Moderate (on chin) ............

Severe (onto clothes) ...... Profound (onto table / objects) ............

Oral motor structure examination

37. Face: normal ............ symmetrical ............ asymmetrical........
38. Cheeks: normal ............ reduced tone ............
39. Lips: symmetrical ............ weakness L / R ............

closure maintained ......................no closure............ normal ............ retracted ............reduced tone ............
40. Tongue: symmetrical ............ asymmetrical ....................

protrusion in midline ............deviates L / R ............

hypotonic ................................hypertonic ....................

at rest: retracted ............ protrudes ....................

short frenulum ....................
41. Hard palate: normal ............ high arched ............ narrow ............

cleft ............
42. Soft palate: normal ............ cleft ....................
43. Jaw: normal ............ small ............ retracted ............

protruded ............

clenched ....................

stable ............ uncontrolled movement ....................

occlusion ....................
44. Dentition: ..........................................................

Feeding & Swallowing Assessment

Non-nutritive sucking (up to 9 months) – Exclude if N/A

45. Present ............ Absent ............
46. Rate: normal (2/sec) ............ slow ............ fast ............
47. Strength: normal ............ weak ............
48. Rhythm: normal ............ no rhythm ............ disorganized ....
49. Tongue cupping: present ............ absent ............ weak ............
50. Sucking bursts and pauses: ..........................................................

51. Suck : swallow ratio: ..........................................................

52. Abnormal responses: gag ............ tonic bite ............

Feeding and swallowing

53. Position during feeding assessment:..........................................................
Liquids:

54. Mode: Breast ............ Bottle ............ Spout cup ............ Cup ............
    Sports bottle ............ Straw ............ Other ............

55. Breast feeding: latch normal ............ poor latch ............

56. Lip closure: normal ............ poor seal ............

57. Anterior spillage: none ............ minimal ............
    moderate ............ significant ............

58. Sucking:

    Rate ............
    Strength (flow rate) ............
    Rhythm ............
    Bursts: normal .......... short sucking burst and long pause ............
    long sucking burst and short / no pause ............
    Suck: swallow ratio ............
    Suck, swallow and breathing co-ordination: normal ............
    inco-ordinated ............

59. Swallow and breathe co-ordination: normal ............
    inco-ordinated ............

60. Pooling of liquid in mouth: none ............ anterior ............
    lateral ............

61. Tongue movement: normal ............ reduced ............ thrusting ............
    poor bolus control ............

62. Anticipatory mouth opening: yes ............ no ............

63. Jaw movement: normal ............ thrust ............ tonic bite ............
    bites utensil ............

64. Trigger of swallow: normal ............ delayed ............ absent ............
    inconsistent ............

65. Swallows per bolus: ............

66. Oral residue after swallowing: none ............ anterior sulcus ............
    lateral sulci ............ tongue ............
    floor of mouth ............

67. Nasal regurgitation: yes ............ no ............

68. Signs of aspiration

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>Before Swallow</th>
<th>During Swallow</th>
<th>After Swallow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coughing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye Tearing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gurggle voice quality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased RR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colour</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Changes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Signs of discomfort / aversion

69. Gags with liquids: Yes........  No........
70. Averts face / refuses: Yes........ No........
71. Cries: Yes........  No........
72. Complains of painful swallowing: Yes........ No........
73. Does not complete feed: Yes........  No........
74. Vomits: none ………… during feed …………… after feed………………
75. Other comments / observations during liquid feed:

...........................................................................................................
...........................................................................................................
...........................................................................................................

Semi-solids / puree (cereal) – spoon feeding (from 6 months old – 4 months if introduced already)

76. Anticipatory mouth opening  yes ………… no ……………
77. Tongue movement: normal ……… reduced ……… thrusting ………

    poor bolus control………..
    poor bolus formation ……… cleans lips ………
78. Jaw movement: normal ……… thrust ………….. tonic bite ………

    bites utensil …………………
79. Lip closure:  normal ……… poor seal ………
80. Lip movement: none ………actively removes food from spoon ………

    sucks off spoon …………
81. Anterior spillage: none ……… minimal ……… moderate ………

    significant …………
82. Trigger of swallow: normal ……… delayed ……… absent ………

    inconsistent …………
83. Swallows per bolus: ……………………………………………………
84. Nasal regurgitation:  yes ………  no ……………
85. Residue of semi-solid: none ……… anterior sulcus ………

    lateral sulci ………….  tongue …………..

    floor of mouth ……… palate………………

86. Signs of aspiration

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>Before Swallow</th>
<th>During Swallow</th>
<th>After Swallow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coughing</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Eye Tearing</td>
<td></td>
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</tr>
<tr>
<td>Gurgle voice quality</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Increased RR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colour Changes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Signs of discomfort / aversion
87. Gags with semi-solid: Yes........ No........
88. Averts face / refuses: Yes........ No........
89. Cries: Yes........ No........
90. Does not complete feed: Yes........ No........
91. Vomits: none ............... during feed ............. after feed .............
92. Other comments / observations during semi-solid feed:

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Solids - biscuit (from 10 – 12 months depending on introduction)
93. Anticipatory mouth opening: yes ........... no ...........
94. Lip closure: normal ............. poor seal .................
95. Lip movement: none .............. active movement ........
               retracted .......... pursed............
96. Anterior spillage: none ............. minimal .................
               moderate ............. significant........
97. Tongue movement: normal ............. reduced .............
               thrusting ............. poor bolus control .............
               poor bolus formation ............. cleans lips .............
               lateralization .................
98. Jaw movement: normal / graded bite ..................thrust .............
               tonic bite .............
99. Trigger of swallow: normal ................. delayed .............
               absent ............. inconsistent.....
100. Swallows per bolus: .................................................................
101. Nasal regurgitation: yes .............. no .............
102. Residue after swallow: none ............. anterior sulcus .............
               lateral sulci .............tongue .............
               floor of mouth ............. palate .............
### 103. Signs of aspiration

<table>
<thead>
<tr>
<th>None</th>
<th>Before Swallow</th>
<th>During Swallow</th>
<th>After Swallow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coughing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye Tearing</td>
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<td></td>
</tr>
<tr>
<td>Gurgling voice quality</td>
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<td></td>
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<tr>
<td>Increased RR</td>
<td></td>
<td></td>
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<tr>
<td>Colour Changes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Signs of discomfort / aversion

104. Gags with solids: Yes........ No........
105. Averts face / refuses: Yes........ No........
106. Cries: Yes........ No........
107. Does not complete feed: Yes........ No........
108. Vomits: none ........... during feed ........... after feed .............
109. Other comments / observations during solid feed:

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### Recommendations

110. No intervention required...........................
111. Caregiver training specify).........................
112. No oral feeds........................................
113. Normal age appropriate diet..........................
114. Combined tube and oral feeds........................
115. Consistency modification: thickened liquids................
custard / nectar ................................
yoghurt / pudding ..............................
cereal / porridge ..............................
purees only........
soft diet, no pieces........
purees and solids ........

116. Utensils: spoon .................. spoon bottle .......... squeeze bottle ........
Other ........................................

117. Develop sucking: NNS .....................NS ..........................
118. Provide oral control for lip closure ..............................................................
119. Positioning: .................................................................................................
120. Graded sensory programme: .................................................................
121. Dry swallows to clear residue: .............................................................
122. Smaller meals ............................................................................................
123. Keep upright after feeds: ..........................................................
124. Other
..........................................................................................................................
..........................................................................................................................
..........................................................................................................................
..........................................................................................................................
125. Further investigations:  barium swallow ....... modified barium swallow ....
               pH study ................
126. Referrals:     ENT ...............  GIT ............... Dietician........
                   Physiotherapist .........  OT ................
                   Other ..............................

Other comments / observations :
..........................................................................................................................
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FINAL RESULT:

Feeding or swallowing difficulty:

YES  [ ]  NO  [ ]

If yes, describe the type and area of feeding or swallowing difficulty:
..........................................................................................................................
..........................................................................................................................
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Appendix P: Feedback from Caregivers form

Feedback from Caregivers Form

Date:................................................... Participant number:.........................

1. Are there any words, phrases or questions that you don’t understand?

☐ Yes

☐ No

If yes, state which words, phrases or questions you did not understand. What would you replace these words, phrases or questions with, to clarify the meaning.

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The researcher will go through the Feeding and Swallowing Questionnaire with the caregiver, asking the caregiver to explain certain key terms in the questionnaire, e.g. vomit, hoarse voice, gag, choke. The researcher will note the caregiver’s responses. Should the caregiver misunderstand the term, the researcher will explain the term and ask if the caregiver has any suggestions for additional explanations that would clarify the term in the Feeding and Swallowing Questionnaire.
Appendix Q: Invitation to Participate and Information for Expert Panel

The validation of a screening tool for the identification of dysphagia in the paediatric population with HIV/AIDS

Suzanne Vermeulen
Department of Communication Sciences and Disorders, UCT
Cellphone: 084 626 7008
E-mail: suzannevermeulensa@gmail.com

Invitation to participate in expert panel

Dear Speech-Language Therapist

You have been invited to participate in the following MSc Communication Sciences and Disorders study:

The validation of a screening tool for the identification of dysphagia in the paediatric population with HIV/AIDS.

The aim of this study is to determine the validity and reliability of the Feeding and Swallowing Questionnaire, a dysphagia screening tool for infants and children with HIV/AIDS.

Available literature reports a prevalence of dysphagia of 25% – 45% in the paediatric population with HIV/AIDS. The prevalence of dysphagia in this population is higher than in the general paediatric population. The consequences of dysphagia in the paediatric population with HIV/AIDS may also have a greater negative impact on health than in the general paediatric population, due to a compromised immunological status and the co-morbid conditions of HIV/AIDS. Previous research shows that children with HIV/AIDS who have dysphagia may not only exhibit difficulty with swallowing and aspiration, but may also experience difficulty in other areas of feeding, such as a delay in reaching feeding milestones and maladaptive behaviours during mealtimes. The available measures for paediatric dysphagia are not specific to the paediatric HIV/AIDS population, and none have been validated.

The screening tool in this study was designed and developed by two speech-language therapists experienced in paediatric dysphagia and a paediatric gastroenterologist, as part of a larger study investigating the prevalence and nature of dysphagia in children and infants with HIV. Experts in the field were consulted, as well as the available paediatric dysphagia literature, when the questionnaire was developed. The 30-question screening tool includes the following areas: types of feeds the child is currently eating, characteristics of the feeding session (e.g. length and difficulty), distress signals exhibited by the child during feeds (e.g. difficulty breathing, vomiting), difficulty eating different consistencies of
food, weight of the child, and the presence of gagging, refusal of food, coughing or choking. Certain items of the questionnaire carry more weight than others, with a pass/fail criteria indicating referral for further assessment of feeding and swallowing.

**What is your role?**

In order to determine the content validity of the items in the *Feeding and Swallowing Questionnaire*, the questionnaire must be reviewed by an expert panel. You have been invited to participate due to your experience in paediatric dysphagia. Should you agree to participate, you will be required to review the *Feeding and Swallowing Questionnaire*, and thereafter answer a short questionnaire consisting of 5 questions concerning the items in the *Feeding and Swallowing Questionnaire*. This should take approximately 20 minutes of your time. Your responses will be kept confidential and the members of the expert panel will remain anonymous to each other.

Once your completed questionnaire has been received, your comments and suggestions will be reviewed, together with those of the other members of the expert panel. If indicated, changes will be implemented in the *Feeding and Swallowing Questionnaire*, and the revised version of the *Feeding and Swallowing Questionnaire* will be returned to you for further comments or suggestions. This process will continue until the expert panel reaches a satisfactory group consensus. The members of the expert panel will remain anonymous to each other. You will not receive remuneration for participation in the study.

Once this study has been completed, you will be provided with a summary of the results, as well as a finalised copy of the *Feeding and Swallowing Questionnaire*.

Should you wish to participate, please respond to this E-mail by 4 September 2013, and you will be contacted with more information.

Your participation will be highly valued!

Regards,
Suzanne Vermeulen
MSc CSD student
E-mail: suzannevermeulensa@gmail.com
Cellphone number: 084 626 7008

Vivienne Norman
MSc Supervisor
Department of CSD
E-mail: vivienne.norman@uct.ac.za
Cellphone number: 083 414 7928

Professor Marc Blockman
Chair of Human Research Ethics Committee
021 406 6492
E-mail: marc.blockman@uct.ac.za
Cellphone number: 083 414 7928
By signing below, I (name of SLT).......................... agree to participate in the research study entitled **The validation of a screening tool for the identification of dysphagia in the paediatric population with HIV/AIDS**

I declare that:

- I have read and understand the information in the “Invitation to Participate” letter.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is voluntary and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- Any information I give will remain anonymous and the members of the expert panel will remain anonymous to each other

Signed at (place) ........................................ on (date) ........................................

.........................................................  .........................................................
Signature of SLT  Signature of Witness
# Appendix R: Completed STARD Checklist

**STARD checklist for reporting of studies of diagnostic accuracy**  
*(Version January 2003)*

<table>
<thead>
<tr>
<th>Section and Topic</th>
<th>Item #</th>
<th>Item</th>
<th>On page #</th>
</tr>
</thead>
<tbody>
<tr>
<td>TITLE/ABSTRACT/KEYWORDS</td>
<td>1</td>
<td>Identify the article as a study of diagnostic accuracy (recommend MeSH heading ‘sensitivity and specificity’).</td>
<td>In abstract</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>2</td>
<td>State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups.</td>
<td>37-38</td>
</tr>
<tr>
<td>METHODS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>3</td>
<td>The study population: The inclusion and exclusion criteria, setting and locations where data were collected.</td>
<td>42-43</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?</td>
<td>43-44</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in item 3 and 4? If not, specify how participants were further selected.</td>
<td>44</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?</td>
<td>53-55</td>
</tr>
<tr>
<td>Test methods</td>
<td>7</td>
<td>The reference standard and its rationale.</td>
<td>48-52</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.</td>
<td>46-55</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Definition of and rationale for the units, cut-offs and/or categories of the results of the index tests and the reference standard.</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>The number, training and expertise of the persons executing and reading the index tests and the reference standard.</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.</td>
<td>54</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>12</td>
<td>Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).</td>
<td>55-56</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>Methods for calculating test reproducibility, if done.</td>
<td>N/A</td>
</tr>
<tr>
<td>RESULTS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>14</td>
<td>When study was performed, including beginning and end dates of recruitment.</td>
<td>44</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>Clinical and demographic characteristics of the study population (at least information on age, gender, spectrum of presenting symptoms).</td>
<td>68-70</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<td></td>
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<tr>
<td>16</td>
<td>The number of participants satisfying the criteria for inclusion who did or did not undergo the index tests and/or the reference standard; describe why participants failed to undergo either test (a flow diagram is strongly recommended).</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Time-interval between the index tests and the reference standard, and any treatment administered in between.</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.</td>
<td>75-79</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>A cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.</td>
<td>66</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Any adverse events from performing the index tests or the reference standard.</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).</td>
<td>66</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>How indeterminate results, missing data and outliers of the index tests were handled.</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>Estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>Estimates of test reproducibility, if done.</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>DISCUSSION 25</td>
<td>Discuss the clinical applicability of the study findings.</td>
<td>94-96</td>
<td></td>
</tr>
</tbody>
</table>