

**GROWTH AND NUTRITIONAL STATUS OF FORMULA-FED INFANTS
AGED 2-10 WEEKS IN THE PREVENTION OF MOTHER-TO-CHILD
TRANSMISSION (PMTCT) PROGRAMME AT THE DR GEORGE
MUKHARI HOSPITAL, GAUTENG, SOUTH AFRICA.**

by

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of



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Declaration

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Date: 22 December 2008

ABSTRACT

INTRODUCTION: Since the start of the Prevention of Mother-to-Child Transmission (PMTCT) Programme at Dr George Mukhari Hospital in 2001, there has been no evaluation of the effect of formula feeding on the growth and dietary intakes of enrolled infants.

AIM: The aim of this study was to determine the short-term growth, anthropometry and dietary intake of infants from two to ten weeks of age who were entered into the PMTCT Programme at the Department of Human Nutrition at Dr George Mukhari Hospital from two to ten weeks of age.

METHODS: This was a descriptive, longitudinal (eight weeks duration) study. Anthropometric assessment including length and head circumference was performed at two weeks of age and thereafter at ten weeks of age. Weight measurement was performed at age two weeks (visit 1), six weeks (visit 2) and ten weeks (visit 3). Anthropometric measurements were compared with CDC 2000³ growth charts. Feeding practices and dietary intake (24 hour diet recall interview) were assessed at each of the four week interval visits and evaluated according to the DRIs⁵⁹. At the third visit, a socio-demographic interview and a usual food intake interview were performed.

RESULTS: A total of 151 [male ($N = 75$) and female ($N = 76$)] infants completed the study. A total of 110 (72%) mothers resided in the Soshanguve area and 138 (91%) of the mothers had attended high school. The majority (75%) of mothers was not generating an income from employment. Generally, mothers had access to safe drinking water and all (99%) but two mothers used pre-boiled water before preparing infant formula. The accuracy and correctness of reconstituting infant formula decreased with each visit as feeds were increasingly made too dilute. A total of 124 (82%) infants were exclusively formula fed. The remainder received water, water with sugar and/or complementary feeds. Mean energy and macronutrient intakes of both males ($N = 65$, 87%) and

females ($N = 61$, 80%) were below recommendations at age two weeks. Of all the macronutrients, fats were consumed the least by both males ($N = 67$, 89%) and females ($N = 66$, 87%) at visit 1. Catch up growth was evident and nutrient intakes improved as the study progressed. The mean weight gain of all infants from visit 1 to 2 was 1.2 (SD 0.3) kg and 0.9 (SD 0.3) kg from visit 2 to 3 (exceeding the CDC 2000³ recommendation for both male and female infants). The incidence of underweight, wasting and head circumference-for-age below the third percentile decreased from visit 1 to 3, but the number of stunted infants increased towards visit 3. The majority of infants in this study grew well in their first ten weeks of life. Growth accelerated as infants became older and growth faltering improved by ten weeks of age.

CONCLUSION: Overall, the growth of the infants referred to the PMTCT Programme at the Department of Human Nutrition at Dr George Mukhari Hospital would appear to be adequate but mothers' approach to formula feeding practices needs to be improved in some aspects of feeding their infants.

OPSOMMING

INLEIDING: Sedert die aanvang van die Prevention of Mother-to-Child Transmission (PMTCT) Program by Dr George Mukhari Hospitaal in 2001, was daar geen evaluasie van die effek van formula voeding op die groei en dieetinname van ingeskrewe babas nie.

DOEL: Die doel van hierdie studie was om die korttermyn groei, antropometrie en dieetinname van babas wat ingeskryf is by die PMTCT Program by die Departement van Mensvoeding te Dr George Mukhari Hospitaal vanaf ouderdom twee weke tot tien weke te bepaal.

METODE: Dit was 'n beskrywende, longitudinale (agttwee weke tydsduur) studie. Antropometriese bepaling naamlik lengte en kopomtrek is op twee weke en daarna op tien weke ouderdom gedoen. Massa is op twee weke (besoek 1), ses weke (besoek 2) en tien weke (besoek 3) gemeet. Antropometriese bepaling is met CDC 2000³ groeikaarte vergelyk. Voedingspraktyke en dieetinname (24 uur dieetherroep onderhoud) is tydens elk van die vier weeklikse besoeke bepaal en geëvalueer aan die hand van die DRI⁵⁹. 'n Sosiodemografiese onderhoud en gewoontelike voedselinname onderhoud is tydens besoek 3 gehou.

RESULTATE: 'n Totaal van 151 [manlik ($N = 75$) en vroulik ($N = 76$)] babas het die studie voltooi. Altesaam 110 (72%) moeders woon in die Soshanguve omgewing en 138 (91%) moeders het hoërskoolopleiding gehad. Die meerderheid moeders (75%) was werkloos. Moeders het oor die algemeen toegang tot veilige drinkwater gehad en almal (99%) behalwe twee het gekookte water gebruik om formule melk aan te maak. Die akkuraatheid en korrektheid van formule bereiding het afgeneem en is met elke besoek flouër aangemaak. Altesaam 124 (82%) babas

[onderskeidelik 57 (76%) manlike en 67 (88%) vroulike babas] het alleenlik formule melk ontvang. Die res het water, water met suiker en/of komplementêre voedsel ontvang. Die gemiddelde energie en makronutriënt inname van manlike ($N = 65$, 87%) sowel as vroulike ($N = 61$, 80%) babas was minder as die aanbeveling tydens die eerste twee lewensweke. Vet was die makronutriënt wat die minste deur beide manlike ($N = 67$, 89%) en vroulike babas ($N = 66$, 87%) ingeneem is tydens besoek 1. Groei het versnel en die inname van makronutriënte het toegeneem met die vordering van die studie. Die gemiddelde gewigstoename van alle babas vanaf besoek 1 tot 2 was 1.2 (SD 0.3) kg en 0.9 (SD 0.3) kg vanaf besoek 2 tot 3 ('n oorskryding van die CDC 2000³ aanbeveling vir die totale populasie en vir beide manlike en vroulike babas). Die insidensie van ondermassa, lae massa-vir-lengte en kopotrek-vir-ouderdom onder die derde persentiel het afgeneem vanaf besoek 1 tot 3, maar die getal babas met lae lengte-vir-ouderdom het toegeneem teen besoek 3. Die meerderheid babas het goeie groei getoon in die eerste tien lewensweke. Groei het toegeneem soos wat die babas ouer geword het en groeivertraging het verbeter teen die ouderdom van tien weke.

GEVOLGTREKKING: Die algehele groei van babas wat na die PMTCT Program by die Departement van Mensvoeding te Dr George Mukhari Hospitaal verwys is blyk voldoende te wees, maar moeders se benadering tot formule voedingspraktyke (in sommige aspekte van babavoeding) moet verbeter word.

DEDICATION

For Mack

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LIST OF ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
CDC	Centre for Disease Control
d	day
DNA	deoxyribonucleic acid
DRI	dietary reference intake
g	gram
HAART	highly active antiretroviral therapy
HIV	human immunodeficiency virus
HIV/AIDS	pertaining to HIV infection at any stage of the disease, including AIDS
IMR	Infant mortality rate
kCal	kilo calorie
kg	kilogram
kJ	kilo Joule
ml	millilitre
MEDUNSA	Medical University of Southern Africa
MRC	Medical Research Council
n	number, refers to sub-sample size
<i>N</i>	number, refers to total sample size
NCHS	National Centre for Health Statistics
PCR	polymerase chain reaction
PMTCT	prevention of mother-to-child transmission
RDA	recommended dietary allowance
RtHC	Road to Health Chart
STI	sexually transmitted infection
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
VCT	voluntary counselling and testing
WHO	World Health Organisation

LIST OF DEFINITIONS

Complementary feeds	any food or fluids, whether manufactured or locally prepared, given to an infant in addition to breast milk or infant formula
Dietary intake	refers to the intake of energy and macronutrients (protein, carbohydrates, fat)
Exclusive breastfeeding	WHO definition: “no other liquids or solids than breast milk, not even water given to an infant”
Exclusive formula feeding	giving formula milk to an infant as a breast milk substitute without complementary feeds, totally excluding breast milk
Feeding practices	in this study feeding practices refer to the volume, frequency (times per day), reconstitution of formula milk and/or any other solution or food items given to an infant.
Formula milk	breast milk substitute; any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose
Frankfort plane	a line between the lowest point on the margin of orbit (the bony socket of the eye) and the tragion (the notch above the tragus, the cartilaginous projection just anterior to the external opening of the ear), with the anatomical placement of the head in line with the spine ¹

HIV-exposed	children born or breastfed by women living with HIV
HIV-infected	laboratory tests for HIV antigens are positive
HIV-positive	laboratory tests for HIV antibodies and/or HIV antigens are positive ² . Infants positive for HIV antibodies and negative for HIV antigens may not be HIV infected.
24-hour diet recall	In this study 24-hour recall specifically refers to the number of bottle feeds given to the infant during the preceding 24 hours and including the preparation of bottle feeds.
Infant mortality rate (IMR)	the probability that a newborn dies before reaching age 1 year; ² a measure of the number of deaths in children under the age of one year per 1000 live births.
Mother-to-child transmission (MTCT)	also termed vertical transmission – transmission of HIV from a HIV-infected mother to a child during pregnancy, child birth, or breastfeeding.
Usual food intake	The usual food intake interview schedule refers to the infant's intake of formula milk (volume and frequency) and complementary feeds (time of day, type of food and drink and quantity) during the preceding 24 hours.

Weight gain

in this study weight gain refers to the nominal differences of values between ages two weeks, six weeks and 10 weeks at the 50th percentile for weight-for-age according to the CDC 2000 growth charts.³

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**CHAPTER 1: INTRODUCTION AND STATEMENT OF THE RESEARCH
QUESTION**

1.1 INTRODUCTION

According to the UNAIDS/WHO update of the acquired immunodeficiency syndrome (AIDS) epidemic in December 2005, human immunodeficiency virus (HIV) prevalence among South African pregnant women had reached its highest level to date at 29.5%.⁴ In 2006, it was estimated that of the 39.5 million HIV-infected people in the world, more than 63% were from sub-Saharan Africa. About 5.54 million people were living with HIV in South Africa, with 18.8% of the adult population aged 15 to 49 years, affected⁴. The HIV epidemic in South Africa is continuing relentlessly. According to epidemiologists from the Human Sciences Research Council, over 500 000 new infections occurred in 2005 as well as 2006, with the highest incidence in young women aged 15-24 years, at 4.6%.² The prevalence of HIV in the country varies geographically by province (Table 1.1) and reflects background socioeconomic conditions in terms of the HIV prevalence indicators for 2006²:

Table 1.1: Geographical HIV prevalence (%) in South Africa, 2006²

Geographical area	Total population prevalence rate (%)^a	Antenatal prevalence (%)^b
KwaZulu-Natal	15.7	40.2
Gauteng	14.5	35.8
Free State	13.9	33.7
Mpumalanga	13.4	32.5
North West	12.7	29.2
South Africa	11.2	28.3
Eastern Cape	10.0	27.7
Northern Cape	6.9	19.9
Limpopo	6.9	19.6
Western Cape	5.4	15.5

^a Total population prevalence rate include the percentage of the population including children, youth and adults who were infected in 2006

^b Prevalence rate (%) among pregnant women attending antenatal clinics in 2006

KwaZulu-Natal appeared to be the province worst affected by HIV/AIDS, whilst the Western Cape population had the lowest HIV prevalence rate of 5.4%. The

demographic impact of HIV/AIDS on the South African population was reflected by the decrease in life expectancy from 63 years in 1990 to 51 years in 2006, and the increase in the under-5 mortality rate from 65 deaths per 1000 live births in 1990 to 75 deaths per 1000 live births in 2006. People who lived in rural and urban informal settlements remained at highest risk for HIV infection.^{2, 4, 5} HIV prevalence continued to increase and infection and mortality remained a problem. Available information^{2,5} indicates that children are a particularly vulnerable group (Table 1.2) especially regarding high rates of mother-to-child transmission (MTCT) and the impacts of ill health and death of parents.

Table 1.2: HIV and AIDS indicators of South African children aged 0 – 14 years, 2006²

Births	Uninfected births (over calendar year)	1 057 000
	HIV positive births (over calendar year)	38000
	Infected through breastfeeding	26000
Living with HIV/AIDS	Children (0 – 14 years) living with HIV/AIDS	294 000
Prevalence of HIV in children by age	0 – 14 years	1.9%
	0 – 4 years	3.7%
	5 – 9 years	1.9%
	10 – 14 years	0.1%
Incidence	At or before birth (of births)	3.5%
	Breastfeeding ^a	2.4%
Number of children (<14 years) infected, by stage	Pre-AIDS	240 000
	Stage 4 (not on treatment)	27 000
	Receiving antiretroviral treatment	25 300
	Discontinued antiretroviral treatment	1 500

^a Number of infants infected through breastfeeding in calendar year divided by uninfected births in the same period

Note: numbers rounded to nearest thousand

The WHO/UNICEF/UNAIDS guidelines for reducing Mother-to-Child Transmission (MTCT) of HIV are directed at women in developing countries. It is stated that “when replacement feeding is acceptable, feasible, affordable, sustainable and safe,

avoidance of all breastfeeding by HIV-infected mothers is recommended; otherwise exclusive breastfeeding (no other liquids or solids than breast milk, not even water given to an infant) is recommended during the first six months of life.”⁶

The World Health Organisation (WHO) revised its earlier recommendation (pertaining to all infants, born either to HIV-infected or uninfected mothers) of exclusive breastfeeding of infants for 4-6 months of age to exclusive breastfeeding until “6 months” of age⁷ with the introduction of complementary feeds thereafter. Despite the recommendation that complementary feeding should only commence at six months of age, whether an infant was breastfed or formula fed, early (within the first two months of life) complementary feeding is a common practice in South Africa.⁸

1.2 INFANT MORTALITY IN SOUTH AFRICA

UNICEF estimates that not breastfeeding is responsible for 1.5 million child deaths per year worldwide.⁹ In South Africa, the major contributing factors to the infant mortality rate in lower socioeconomic areas are diarrhoeal disease, respiratory tract infection and malnutrition.¹⁰ It is thought that HIV have contributed to an increase of 42% in under-five mortality in South Africa in 2004 and 60% of hospital deaths were HIV-related in 2005. The under-five mortality rate has increased from 65 deaths per 1000 births in 1990 to 75 deaths per 1000 births in 2006.⁵ Transmission of HIV through breastfeeding is a public health problem in resource-limited settings. Of the estimated 630 000–820 000 newly HIV-1 infected infants in South Africa in 2005, breastfeeding could have contributed around 280 000-360 000 infant infections.¹¹ According to the National Indicators regarding the state of the South African HIV/AIDS epidemic, around 38 000 HIV-positive births occurred by mid-2006 (over one calendar year) of which 26 000 were reportedly infected through breastfeeding, resulting in a 2.4% incidence.² The infant mortality rate dropped from 51 deaths per 1000 live births in 2005 to 48 deaths per 1000 live births in 2006 in South Africa, with lower infant mortality rates in the two provinces providing most of the participants for the present study: North West Province (44 deaths per 1000 live births) and Gauteng (38 deaths per 1000 live births).² Apart from the association of HIV transmission with infant mortality, replacement feeding contributes to an increased infant mortality rate resulting from infectious illness caused by suboptimal sanitation, nutrition, housing

and socioeconomic factors.^{10, 12} It is often the pathogens in contaminated infant formula due to poor preparation and the lack of protective benefits of breast milk that puts an infant in a developing region at higher risk of disease.¹²

When faced with the risks of different feeding options in different socioeconomic contexts, policy makers and counsellors need guidance. Investigators could develop and use a mathematical model in an attempt to balance the relative risks and benefits of breastfeeding with other feeding options. However, such a model is limited by the lack of available data on the risks associated with various feeding options, as well as the assumption that all infants in a particular province or clinic have the same mortality risk.¹³

It is suggested that exclusive breastfeeding for six months should be encouraged where the infant mortality rate (IMR) is more than 25 per 1000 live births. Where the IMR is below 25 per 1000 live births, it is postulated that replacement feeding results in the greatest HIV free survival when it is the preferred method of feeding.¹³ In South Africa, no province has an IMR of less than 25 per 1000 live births². According to the proposed model, one would expect exclusive breastfeeding to be the preferred method of feeding, yet free formula is made available for all HIV-exposed infants by the Department of Health.^{10, 14, 15}

1.3 TRANSMISSION OF PAEDIATRIC HIV

1.3.1 Intrauterine/Intrapartum

Mother-to-child transmission of HIV is a well-established mode of HIV transmission. It is recognised that infection may occur *in utero*, during labour and through breastfeeding in the postnatal period.^{16, 17} It has been postulated that about 50% of the transmission of HIV occurs days before delivery as the placenta begins to separate from the uterine wall; another third occur during active labor and delivery, presumably through exposure of the infant to maternal blood and genital tract secretions. The remaining transmissions occur during early pregnancy or as a result of breastfeeding after delivery.¹⁸ It is estimated that 25-30% of HIV-infected mothers in South Africa will transmit the HI virus to their infant, a figure that rises to 40% in

developing countries.¹⁰ In the absence of intervention, the risk of transmission of HIV during the intrauterine period, intrapartum period and via breastfeeding, is about 7%, 13% and 15% respectively.¹⁹ Maternal factors that are known to increase the risk of HIV transmission through breast milk include advanced HIV disease, low CD4 count (<200 cells/ml or less), high viral load (e.g. >50 000 HIV viral particles or more/ml), acute maternal infection during pregnancy and low haemoglobin levels (< 10 g/dl).¹¹ Sexually transmitted disease coinciding with pregnancy and the use of illicit drugs during pregnancy may also facilitate the transmission of the virus.¹⁸ Preterm births, the duration of labour, the duration of ruptured membranes, the type of delivery (vaginal, instrumental, caesarean section), and births where the foetal skin is traumatised from obstetrical procedures, may influence HIV MTCT.^{10, 13, 20, 21}

Although intrauterine and intrapartum transmission can be substantially reduced through use of antiretroviral therapy, modifying infant feeding practices to reduce postnatal transmission is also complex. In industrialised countries like the United Kingdom (UK), where safe alternatives to breastfeeding are available, antiretroviral prophylaxis and elective caesarean section are applied and refraining from breastfeeding can reduce this risk to less than 2%.^{13, 16, 22, 23}

1.3.2 Breastfeeding

1.3.2.1 Mechanism of transmission

It is important to understand the viral dynamics of HIV in breast milk and the associated risk factors of MTCT of HIV. HIV can be transmitted through breast milk at any time during lactation. Breast pathology including mastitis and breast abscesses is a contributor to mother-to-child transmission (MTCT) due to its association with increased breast milk viral load.¹¹ Recent HIV infection and its associated high viral load doubles the risk of HIV transmission through breast milk as opposed to an established infection.⁹ Results from an intervention cohort study in KwaZulu-Natal (sample comprised HIV-infected and uninfected women who attended rural, semiurban and urban antenatal clinics) showed that the estimated risk of postnatal transmission of HIV was 4.04% in 20-26 week old infants who were exclusively breastfed, and who were HIV-negative at six weeks of age.¹¹ A similar

result of a 4.4% cumulative probability of infection between six weeks and six months in 118 exclusively breastfed infants (infants were breastfed for at least three months) was reported from a study in Durban, South Africa.¹¹ The rate of HIV infection in infants is cumulative as it increases with duration of breastfeeding.¹³

Infant related factors known to increase the risk of HIV transmission through breastfeeding include damage to mucous membranes (e.g. oral thrush) and damage to the lining of the intestinal mucosa caused by cow's milk or allergic reactions to complementary feeds. Mixed feeding (feeding both breast milk and other foods or liquids) may in turn affect intestinal permeability. This particular mucosal layer is less permeable in exclusively breast fed infants.^{13, 24}

Maternal risk factors with limited evidence for breast milk transmission of HIV include non-exclusive breastfeeding in the first six months of life, high breast milk viral load, subclinical mastitis (as evidenced by increased breast milk sodium levels) and low maternal serum levels of vitamins B, C, E²⁴ and retinol (used as an indicator of vitamin A status; low serum retinol is associated with shedding of HIV in genital tract secretions and breast milk).²⁵

Several studies pertaining to continued breastfeeding have indicated a reduced HIV prevention benefit. A randomised controlled trial conducted in Nairobi, Kenya aimed to determine the risk of breastfeeding transmission by assigning mothers in groups according to feeding mode i.e. breastfeeding vs. formula feeding. Cumulative probability of HIV-1 infection at 24 months was significantly higher for infants randomized to breastfeeding (36.7%) as opposed to those randomized to formula feeding (20.5%) ($p < 0.001$). The estimated risk of breast milk transmission was 16.2%. Most breast milk HIV-1 transmission occurred during early breastfeeding. Although the two-year mortality rates in both groups were similar (24.4% in the breastfeeding group vs. 20.0% in the formula feeding group), the rate of HIV-1-free survival at two years was significantly lower in the breastfeeding group (58%) than in the formula feeding group (70.0%) ($p = 0.02$).²⁶ According to an individual patient data meta-analysis of 4085 predominantly breastfed children by the Breastfeeding and HIV International Transmission Study (BHITS) Group, it was clear that the overall

risk of transmission via breastfeeding was cumulative throughout the breastfeeding period with a 4% risk for every six months of breastfeeding.^{9, 24}

The reduction and/or prevention of the risk of postnatal transmission through breastfeeding include the following approaches: avoidance of all breastfeeding and using replacement feeding instead, or exclusive breastfeeding for a limited duration with early and rapid cessation of breastfeeding around 4-6 months of age. The most popular and frequently recommended feeding option recommended for HIV-infected mothers in South Africa is replacement feeding with commercial infant formula provided freely through the PMTCT programme implemented at public health services.¹³

1.4 PREVENTION OF HIV TRANSMISSION

In the light of an overall estimated 15% of infants contracting HIV-infection from their HIV-infected mothers through breastfeeding¹⁹, these mothers face the dilemma of choosing a safe and suitable feeding option in an attempt to prevent and/or reduce HIV transmission to their infants. There are significant challenges in mobilising women to choose an ideal feeding option in settings where either formula feeding or exclusive breastfeeding with early weaning practices are uncommon. Furthermore, the particular choice could stigmatise the woman and her infant and subsequently compromise her adherence to a particular choice of feeding.²⁷

1.4.1 Exclusive Breastfeeding

According to the National Department of Health's Policy guideline for the implementation of PMTCT, exclusive breastfeeding refers to the practice of breastfeeding the newborn infant for a limited period of time (i.e. six months) without any supplementary feeding.⁵ It includes stopping breastfeeding completely at six months and an immediate introduction of solids. Weaning over a period of time should be avoided.^{15, 17} Early cessation of breastfeeding (before six months of age) amongst women with CD4 counts >350 is not recommended as it has been shown that early breastfeeding cessation in these women bear no additional benefits from HIV-free survival, and may even be detrimental to child health.⁵ This is in line with

the WHO definition of exclusive breastfeeding as the provision of breast milk only and no additional food, water, or other fluids with the exception of medicines and vitamin or mineral drops. Currently the WHO guidelines has no clear recommendation regarding weaning.⁷

There are many well-established clinical and psychological benefits of breastfeeding to both the mother and infant.¹⁰ Maternal health benefits include decreased resumption of ovulation leading to increased child-spacing, decreased postpartum bleeding, uterine involution and reduced risk of ovarian and breast cancer.^{24, 28} Breastfeeding increases family resources, it is a secure and safe way of feeding, it also plays an important role in strengthening the mother-infant bond and may promote sensory and cognitive development of the infant. The unique immunological properties of breast milk reduce the risk of infection, especially diarrhoea and respiratory infections (e.g. pneumonia).^{19, 24, 28} Breast milk is the ideal and natural first food for infants, meeting the infant's total nutritional requirements for the first six months of life since its composition changes during lactation and during a single feed. It continues to remain a valuable source of nutrition up to a child's second year of life.^{24, 28}

Further evidence to support a recommendation for exclusive breastfeeding by HIV-infected mothers in resource-limited settings follows from the intervention cohort study performed in KwaZulu Natal in 2001-2003. The study recruited 1372 HIV-infected pregnant women and 1345 HIV-negative pregnant women. Feeding practices and HIV status of their infants during a period of six months after delivery were assessed. Exclusive breastfeeding (i.e. breastfeeding only, with mixed feeding with liquids for a total of less than four separate or continuous days during the study) was practiced by 1132 (83%) of the HIV-infected mothers, while 109 (8%) mothers opted for replacement feeding (i.e. exclusion of breast milk, but possible inclusion of mixed feeding) and 35 (3%) started mixed feeding (including breastfeeding and other fluids or solid foods). When the transmission rate according to the mode of feeding was analysed, the risk of HIV transmission to infants who were initially breastfed and progressed to have received solids in addition to breast milk, was almost 11 times higher than among infants who were exclusively breastfed. A total of 203 mothers initially exclusively breastfed their infants and solids were introduced at a median age

of 147 days. Infants who were both breast and formula fed at 14 weeks of age were twice as likely to become infected as opposed to infants who were exclusively breastfed. By 6 months, infants who were exclusively breastfed were less likely to die than those that received replacement feeding ($p = 0.051$).¹¹

Breastfeeding may pose a risk for HIV-seropositive mothers. A randomised trial conducted in Kenya, revealed that 24-month maternal mortality among breastfeeding HIV-seropositive mothers was significantly higher than among the formula feeding mothers.²⁹ Further research however has indicated that breastfeeding does not increase the risk of mortality or any other health risk to the HIV-infected breastfeeding mother.²⁴

Mothers who have opted for exclusive breastfeeding are encouraged to wean as early as possible, i.e. within four to six months of birth and as abruptly as possible since research has shown that prolonged periods of mixed feeding pose a greater risk of HIV transmission to the infant.²⁷ Safer infant feeding (defined as exclusive breastfeeding followed by rapid cessation)¹³ is a growing dilemma surrounded by misconceptions and frustration of how best to counsel HIV-infected mothers.

Although breastfeeding is a natural act, mothers need active support to establish and sustain it. The baby-friendly hospital initiative (BFHI) has been instigated by the WHO and UNICEF. The foundation of the BFHI is the 10 steps to successful breastfeeding, increasing the prevalence of breastfeeding in centres where it was previously low.²⁸ South Africa had 178 (37%) hospitals with BFHI accreditation towards the end of 2005.¹³ The enormous value of breastfeeding should be acknowledged and serious consideration should be given when any other method of feeding is advised.

1.4.2 Exclusive Replacement Feeding

This involves the process of feeding a child of an HIV-infected mother who is not receiving any breast milk, with an alternative to breast milk, such as commercial infant formula, home prepared formula (prepared from fresh cow's, goat's or sheep's milk), or powdered full cream milk and evaporated milks modified by adding water

and sugar in measured amounts, aiming to provide the nutrients the child needs.^{10, 15, 30} Replacement feeding requires safe water supply, sterile feeding equipment, correct mixing techniques and methods of refrigeration of which there is often a lack of in many communities.¹⁵ The replacement feeding choice is of crucial importance to an HIV-infected woman as it has a major impact on the child's life: it can either potentially save the infant's life or expose the young infant to a high risk of diarrhoea and malnutrition.^{31, 32, 33} It is imperative that all women who choose to formula feed have an uninterrupted supply of clean and safe water, fuel and sufficient support (i.e. training for mothers and healthcare personnel in nutrition, hygiene, management of diarrhoea, status disclosure).¹² Guidelines from the Department of Health on "Feeding of infants of HIV positive women and the South African Breastfeeding Guidelines for Health Workers" provide recommendations for the establishment of safe infant feeding practices in case the mother is HIV-infected.¹⁵ The South African discussion paper on the Code of Marketing of Breast Milk Substitutes³⁴ is in line with the current policy on infant feeding in that it acknowledges certain circumstances where infant formula needs to be used. It advocates strict adherence to certain recommendations to avoid spill over to non-infected mothers and those who prefer breastfeeding.¹⁵ The recommendations include:

- Mothers should be provided with information and educational material to ensure proper use of infant formula.
- Mothers should receive information and be made aware of the social and financial implications of the use of infant formula. They should be informed about the health hazards of unnecessary or improper use of infant formula or other breast milk substitutes.
- Only health workers or other community workers should demonstrate feeding with infant formula if necessary and only to childminders who require such demonstrations.
- Counselling must consider the following factors when infant feeding practices are established: acceptability, feasibility, affordability, sustainability and safety.¹⁵

Currently, infant formula is supplied for a period of six months to mothers who choose to practise replacement feeding.^{10, 14, 15, 17}

However, there are risk factors associated with formula feeding, or the lack of breastfeeding, that may increase the risk of morbidity and mortality. A non-breastfed infant up to six months of age in a less-developed country has a six-fold risk of death caused by diarrhoea as opposed to a breast fed infant. For a six to 11 month old non-breastfed infant the risk of death due to diarrhoea drops to two-fold that of a breast fed infant.¹² Lack of breastfeeding is associated with increased intestinal permeability in young infants (aged 0-6 months) leading to a further association with enteric infections.¹² Upper respiratory tract infections, allergy and gastro-intestinal disorders are additional risks of formula feeding compared to breastfeeding in higher income families.¹⁰ Further biological disadvantages of not breastfeeding include the absence of protective immunologic and resistance factors such as immunoglobulins, phagocytes, T lymphocytes, lactoferrin and lysozymes. The intestinal flora of formula-fed infants contains enterobacterial and Gram-negative organisms that may become pathogenic due to inadequate amount of lactobacillus that is typically present in breast fed infants.¹²

Other factors that may increase the risk of morbidity and mortality in formula-fed infants include the following:

- Poor existing or unstable maternal socioeconomic situation^{10, 11, 12, 33}
- Low maternal educational level^{10, 11, 12, 23, 31}
- Young maternal age^{10, 31, 33}
- Inadequate and irregular supply of infant formula powder caused by either insufficient financial resources of the mother or poor service delivery from the supplier of infant formula to the government's PMTCT Programme^{10, 12, 33}
- Inadequate means of transport to access the formula supply¹⁰
- Inadequate supply of good quality and safe water^{10, 12, 31}
- Inadequate sanitation in the surrounding community^{10, 12, 33, 35}
- Lack of facilities to sterilise bottles/teats/cups/utensils^{10, 12}
- Inadequate supply of fuel for sterilisation (boiling water) or other sterilising solutions^{10, 12}
- Poor understanding and/or lack of skills regarding the methods of formula mixing and preparation, and inadequate knowledge to appreciate energy and nutrient needs of infants^{10, 12}

- Limited or lack of access to infant growth monitoring and health care services, and/or poor utilisation of such services¹⁰
- Stigmatisation of mothers using formula feeds^{10, 23, 27, 33}
- Superficial training on HIV and infant feeding leads to counsellors being unable to provide adequate support to HIV-infected mothers to successfully and safely carry out their feeding choice³¹
- Bacterial contamination at the point of manufacture – *Enterobacter sakazakii* has been found to be a frequent contaminant of powdered milk formulas. Milk formula can serve as an ideal substrate for bacterial growth, but also as a source of possible pathogens, especially when contaminated mixing utensils are used and/or if the prepared milk formula is kept at 35°C to 37°C for extended periods.³⁶

1.4.3 Other Feeding Options

1.4.3.1 Expressed and heat-treated breast milk

Since the HI virus is heat sensitive, heat treatment of expressed breast milk from an HIV-infected woman is a way of making breast milk safer for the infant. To pasteurise the milk, it should be heated to 62.5°C for 30 minutes, and cooled immediately.^{15, 37} To minimise contamination, heat treated breast milk should be stored in a sterilised container and kept in a refrigerator or cool place before and after heat treatment.^{12, 15, 37} However, the introduction of the Safer Breastfeeding Programme to HIV-infected women in Cato Manor, South Africa, during the period January 2000 to December 2003, showed a low uptake of the use of heat-treated expressed breast milk. The reasons that explained the reluctance of mothers to practice this particular feeding method included the following:

- Lack of information (posters and/or media coverage) since it is not officially endorsed by the Department of Health.
- Mothers felt that infants were not satisfied as a small amount of milk was expressed.
- The infant continued to demand the breast after a feed (probably the infant required comfort or contact with the mother).
- Lack of confidence in performing the procedure correctly.

- Mothers felt the procedure was stigmatizing.
- The procedure was time consuming.
- An alternative in the form of formula milk was readily available.

Mothers felt that the use of heat-treated expressed breast milk was a feasible feeding option only from six months of age.³⁸

1.4.3.2 Wet nursing

Wet nursing is considered to be an acceptable traditional feeding practice in some cultures,³⁷ but it remains a less common feeding method that has to be introduced and sustained on a daily basis.³⁹ In a interview survey complemented with focus group discussions among pregnant women attending antenatal clinics in Tanzania, wet nursing as a feeding method was regarded as neither feasible nor acceptable.³⁹ In addition, there is a risk of HIV transmission to the infant through this way of breastfeeding if the wet nurse is HIV-infected. The wet nurse could also become infected from an HIV-infected infant if she has some form of breast pathology.³⁷

1.4.4 WHO/UNICEF Policies and Guidelines

South Africa is classified as a middle-income country²² and has a prominent contrasting set of economic resources ranging from very poorly resourced deep rural areas to very sophisticated, developed city areas.¹⁰ Within the most appropriate general recommendations, it is of utmost importance to assess specific and individual situations. Within the framework of South Africa's national infant feeding policy and the Code of Marketing of Breast Milk Substitutes,^{13, 34} any special provisions for feeding infants of HIV-positive mothers must be acknowledged.

Among most mothers in Sub-Saharan Africa, breastfeeding is the norm and the most commonly practised and accepted method of feeding their infants, but the rates of exclusive breastfeeding are low as early introduction of liquids and complementary foods is common.^{8, 13, 40} On the basis of breastfeeding for the first six months of life being one of the best preventive public health measures for reducing child mortality, the WHO and UNICEF developed a Global Strategy for Infant and Young Child Feeding.⁴¹ It recommended exclusive breastfeeding for the first six months and

continued breastfeeding up to two years and beyond, with nutritionally adequate and safe supplemental foods from six months of age, along with appropriate and individualised support for the mother.⁶

As a result, WHO and UNICEF amended the guidance in the Global Strategy for Infant and Young Child Feeding.⁴¹ It was then recommended that women with HIV should completely avoid breastfeeding when replacement feeding was “acceptable, feasible, affordable, sustainable and safe (AFASS).” Women who had no reliable access to formula feeding were to continue breastfeeding until a suitable replacement was available.⁶ It is essential that women diagnosed with HIV during pregnancy are referred for assessment for antiretroviral treatment, since maternal viral load is an important factor in increasing the risk of HIV transmission through breast milk.¹³ Use of antiretroviral treatment to provide infant prophylaxis during breastfeeding, has shown to be effective in resource-limited settings.^{9, 13}

This guidance and the studies emphasizing the dangers of breastfeeding led some governments and programmes to acknowledge a moral obligation to provide infant formula to mothers with HIV. Botswana has one of the most stable, efficient and best-resourced democracies in Africa and executes one of the most aggressive and dynamic PMTCT programmes in the world.²³ Before Botswana’s PMTCT programme was initiated in 1998, mother-to-child transmission of HIV among HIV infected pregnant women was estimated at 30 to 40%. HIV transmission rates fell to less than 6% with rates as low as 3% recorded recently, with the implementation of the PMTCT programme. Botswana’s PMTCT programme therefore achieved more than a 90% reduction in transmission rates.⁴² According to reports at the Botswana International HIV Conference held in September 2006 in Gaborone, PMTCT was integrated into all of Botswana’s public health facilities (634 countrywide), testing a very high percentage of pregnant women for HIV and enrolling over 90% of those who test positive into the programme.⁴³ Despite keeping mothers countrywide well-stocked with one year’s free supply of infant formula, the programme bears challenges and the national infant mortality rate remains high.²³ Botswana’s PMTCT programme has focused much attention on safer infant feeding, especially after the diarrhoeal epidemic following unusually heavy rains and floods that occurred in late 2005/early 2006. Although Botswana’s piped water is usually safe, the increased risk

of contamination of the water supply was likely brought upon by the floods.³⁵ A Centre for Disease Control (CDC) analysis revealed that the water was contaminated; and caused a high risk of diarrhoea and death among infants who were not breastfed. According to newspaper reports, the Director of Public Health, explained that the gastroenteritis virus lead to rising numbers of infections and death affecting mainly children under five years of age, attributable to insufficient information among parents who quite often delayed seeking medical attention for their children.⁴⁴ Separate research conducted in Botswana, the Mashi study, had already shown that during the first year of life, all-cause mortality among HIV-exposed infants who were formula fed was higher than in those who were breastfed.^{11, 23} By 18 months of follow-up, HIV-free survival was almost similar between the two groups.²³

Over the last few years, studies^{11, 13} continuously demonstrated that mixed feeding (giving water or solid foods in addition to breast milk) resulted in much higher rates of transmission as opposed to exclusive breastfeeding. Subsequently, the WHO and UNICEF amended the guidance regarding advising mothers on infant feeding once again: when replacement feeding was not AFASS, HIV-infected mothers should exclusively breastfeed for the first months of life. As soon as replacement feeding could be obtained, the infant was to be weaned abruptly, so as to avoid a prolonged period of mixed feeding and minimise the heightened risk of HIV transmission. There was however, limited data to indicate the optimal time and manner to wean the infant.⁶

Studies from Malawi, Kenya, Uganda and Zambia showed an increased risk of infant morbidity (especially diarrhoea) upon abrupt cessation of breastfeeding before six months.⁷ This new evidence gave rise to a new consensus statement. The consensus statement on HIV and infant feeding was recently adopted by all relevant UN departments and agencies, following a technical consultation in Geneva, Switzerland, in October 2006, organized by WHO department of Child and Adolescent Health and development (CAH) on behalf of Interagency Task Team (IATT) on prevention of HIV infections in pregnant women, mothers and their infants. The consensus statement brings clarification of the revised WHO/UNICEF guidance and includes three recommendations:⁷

- “The most appropriate infant feeding option for an HIV-infected mother should continue to depend on her individual circumstances, including her health status and the local situation, but should take greater consideration of the health services available and the counselling and support she is likely to receive.
- Exclusive breastfeeding is recommended for HIV-infected women for the first six months of life unless replacement feeding is acceptable, feasible, affordable, sustainable and safe for them and their infants before that time
- When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected women is recommended
- Breastfeeding mothers of infants and young children who are known to be HIV-infected should be strongly encouraged to continue breastfeeding”

The recommendations were agreed on the basis of the latest evidence on HIV and infant feeding including the following:⁷

- “Exclusive breastfeeding for up to six months was associated with three to four fold decreased risk of transmission of HIV compared to non-exclusive breastfeeding...
- There are indications that highly active antiretroviral treatment (HAART) for treatment of eligible woman may reduce postnatal HIV transmission...
- In settings where antiretroviral prophylaxis and free infant formula were provided, the combined risk of HIV infection and death by 18 months of age was similar in infants who were replacement fed from birth and infants breastfed for three to six months
- Breastfeeding of HIV infected infants beyond six months was associated with improved survival compared to stopping breastfeeding...”⁷

From the above discussion, the following can be concluded: when an HIV-infected mother chooses breastfeeding, exclusive breastfeeding for the first six months can be recommended. This recommendation applies to HIV negative women and women who do not know their HIV status. However, breastfeeding by HIV infected mothers is not without risk for the infant. The risk of HIV transmission must be balanced with

risks associated with artificial feeding and this must be done for each HIV infected women on an individual basis.⁷

1.5 PREVENTION OF MOTHER-TO-CHILD TRANSMISSION IN SOUTH AFRICA

A national survey of HIV prevalence among women attending public antenatal clinics is conducted by the Department of Health on a yearly basis, providing the platform for making projections on HIV/AIDS trends. The antenatal HIV prevalence trend in the country is increasing (Table 1.3).

Table 1.3: Antenatal HIV prevalence (%) according to all provinces in South Africa, 1999-2005⁴⁵⁻⁵¹

Province	1999	2000	2001	2002	2003	2004	2005
Eastern Cape	18	20.2	21.7	23.6	27.1	28.0	29.5
Free State	27.9	27.9	30.1	28.8	30.1	29.5	30.3
Gauteng	23.9	29.4	29.8	31.6	29.6	33.1	32.4
KwaZulu-Natal	32.5	36.2	33.5	36.5	37.5	40.7	39.1
Limpopo	11.4	13.2	14.5	15.6	17.5	19.3	21.5
Mpumalanga	27.3	29.7	29.2	28.6	32.6	30.8	34.8
Northern Cape	10.1	11.2	15.9	15.1	16.7	17.6	18.5
North West	23	22.9	25.2	26.2	29.9	26.7	31.8
Western Cape	7.1	8.7	8.6	12.4	13.1	15.4	15.7
South Africa	22.4 ⁴⁵	24.5 ⁴⁶	24.8 ⁴⁷	26.5 ⁴⁸	27.9 ⁴⁹	29.5 ⁵⁰	30.2 ⁵¹

Aligned with the International standards for a comprehensive strategy, the PMTCT policy recognises the four integral elements of PMTCT to prevent HIV among women and children:

- Primary prevention of HIV especially among women of childbearing age;
- Preventing unintended pregnancies among women living with HIV
- Preventing HIV transmission from a woman living with HIV to her infant
- Providing appropriate treatment, care and support to women living with HIV and their children and families.¹⁷

The overall aim of the PMTCT programme is to prevent or reduce the rate of vertical transmission of HIV, improve health services and support for mothers and infants by means of integrating PMTCT interventions, including provision of voluntary counselling and testing (VCT) and where appropriate, nevirapine and formula milk for HIV-infected mothers in public sector health facilities throughout the country.^{17, 52} In its attempt to establish safe infant feeding practices the protocol states: “In an ideal world where safe and adequate formula feeding is possible and where ongoing support for the mother and monitoring of an infant is available....formula feeding is the principal recommended method of feeding. The risk of feeding the infant with breast milk substitutes (mainly infant formula) must be balanced against the risk of HIV transmission through breastfeeding. It is important to avoid being dogmatic but to assess every risk factor carefully and explore the extent and severity of any specific factor if present.”^{14, 15} The aim is that a mother should be able to make an informed choice about the way in which she wants to feed her child. HIV-infected women are counselled in the antenatal clinics regarding feeding options (the effect of breastfeeding and formula feeding on transmission of HIV). It is only after their informed choice to formula feed (vs. exclusive breastfeeding) their infants, that HIV-infected mothers are provided with formula milk (NAN Pelargon®) on a monthly basis for the first 6 months of the infant’s life. Education is given concerning how to make the feeding as safe as possible.^{10, 14, 15, 17, 53, 54} Mothers with unknown HIV status or who have tested negative for HIV-infection are advised to breastfeed. Ongoing counselling regarding nutrition and feeding options throughout the antenatal period is encouraged, as well as discussions with family members to ensure that the chosen option is sustained and that family members are supportive of these feeding behaviours.^{14, 15, 17}

For women who have chosen to breastfeed exclusively, special attention is paid to attachment and positioning of the infant at birth, and on demand feeding. She is currently advised by the National Department of Health’s Policy guideline for the implementation of PMTCT, to wean the baby from the breast abruptly at six months as part of the overall strategy to avoid HIV transmission while still gaining the maximum benefit of breastfeeding.⁵

Women who have chosen to formula feed are reminded of the correct and safe preparation of the feeding solution and the benefits of cup feeding. They receive at least two weeks' supply of infant formula and thereafter formula milk is dispensed at the local clinic or health care institution monthly for the period of six months.^{14, 15, 17}

1.5.1 Background of the Prevention of Mother-to-Child Transmission Programme

The PMTCT programme was conceptualised as early as 1999 at primary care level in South Africa.⁵⁵ It was decided to implement the programme in September 2001 in all nine provinces, with two pilot sites in each province. The pilot sites set out to identify operational limitations inherent to the introduction of such an intervention.¹⁷ In April 2002, the South African government recommitted itself to the 'HIV/AIDS and STI Strategic Plan for South Africa, 2000-2005', by instigating continued research with regard to the use of the antiretroviral drug, nevirapine, in the prevention of MTCT and development of a national roll-out plan for PMTCT.⁵⁶ In July 2002, the constitutional court issued a court order, requiring the government to expand PMTCT services broadly.^{15, 17} A total of 3064 facilities (hospitals, midwife obstetric units, community health centres and clinics) offered PMTCT services during 2005.⁵² The National Department of Health's report to the United Nations General Assembly Special Session on HIV and AIDS (UNGASS) contentiously states three widely different figures for nevirapine coverage, i.e. 15%, 55% and 78% in public sector facilities in 2004. An article by Meyers⁵⁷ quoted nevirapine coverage for HIV-infected pregnant women in South Africa to be about 30%, based on PMTCT task team reports. During the 2005/06 financial year 70% of Antenatal clinic attendees were counselled and tested for HIV of whom 26% tested positive. About 60% of pregnant women who tested positive for HIV had received Nevirapine.¹⁷

Progress has been made with regard to the expansion of VCT and PMTCT services, and the deployment of large numbers of health workers explicitly trained in current treatment guidelines.⁵⁶ In March 2007 a new draft HIV and AIDS and STI Strategic Plan for South Africa, 2007-2011 flowed from the National Strategic Plan of 2000-2005. This plan aims to:

- Reduce the rate of new HIV infections by 50%.

- Expand access to treatment, care and support to 80% of all people with a positive HIV diagnosis.
- Increase the number of people who have been tested for HIV to 70% of the population.
- Reduce MTCT to less than 5%.

The PMTCT Programme includes the following services: administration of a single dose of nevirapine to pregnant women at the time of labour and to newborn infants immediately after birth; free formula milk for six months after birth and continued counselling, education and support for mothers for 18-24 months.

Despite a universal PMTCT intervention programme coverage in the Western Cape region in 2003, an estimated 1400-1650 infected infants were born in the province that year with an average HIV prevalence rate of 13.1% (compared to a national prevalence of 27.9% and 37.5% in KwaZulu-Natal). The Western Cape Department of Health started to implement an intensified programme in 2004 aiming to reduce MTCT to less than 6%: women with CD4 count ≤ 200 cells/ μ l were to be treated with HAART while mother-infant pairs with a maternal CD4 count > 200 cells/ μ l were to be given a combination of zidovudine and single-dose nevirapine.⁵⁸

1.5.2 Infant Formula – NAN Pelargon®

NAN Pelargon® is the infant formula that is currently supplied by Nestlé, the sole company holding a government tender to supply the PMTCT programme countrywide. The product has various nutritional claims, including a low pH which protects against bacterial growth, facilitated protein digestion and improved mineral (calcium and iron) absorption.⁶⁰ The amounts of energy and nutrients provided by the recommended intake of NAN Pelargon®, however, deviate from the Dietary Reference Intakes (DRIs) for both male and female infants (Table 1.4).⁵⁹

Table 1.4: Comparison of recommended nutrient intake of NAN Pelargon® with the Dietary Reference Intakes⁵⁹

Comparison of recommended energy and macronutrient intake of NAN Pelargon® with the DRIs ⁵⁹					
DRI ² of energy and AI of macronutrients			Recommended intake of NAN Pelargon® and deviation (↑ or ↓) from the recommendation		
			Age		
			2 weeks (Visit 1) ^b	6 weeks (Visit 2) ^b	10 weeks (Visit 3) ^b
Energy in kJ (kCal)	Male	2394 (570)	1841.7 (440.6) (↓)	2302.3 (550.8) (↓)	2686.4 (642.6) (↑)
	Female	2184 (520)	1841.7 (440.6) (↓)	2302.3 (550.8) (↑)	2686.4 (642.6) (↑)
Protein (g/day)		9.1	9.8 (↑)	12.3 (↑)	14.4 (↑)
CHO (g/day)		60 ^a	49.9 (↓)	62.4 (↑)	72.8 (↑)
Fat (g/day)		31	22.4 (↓)	28 (↓)	32.6 (↑)

DRI = Dietary Reference Intakes⁵⁹

AI = Adequate Intake

CHO = Carbohydrates

↑ = Exceeds DRI

↓ = Below DRI

^a Average content of human milk

^b At visit 1 the infants were two weeks old; six weeks old at visit 2 and ten weeks old at visit 3

The DRIs⁵⁹ for infants aged zero to six months were used to evaluate the intake of energy and macronutrients of infants. The DRIs⁵⁹ differentiate between genders for energy, but the recommendation for the macronutrients (protein, carbohydrates and total fat) are similar for males and females. The DRI² for protein allows for comparison with two reference values: the Recommended Dietary Allowance (RDA) of 9.1g/day and an Adequate Intake (AI) of 1.52 g/kg/day which should be regarded as the mean intake for healthy infants receiving human milk. For the purpose of comparison to NAN Pelargon®, both the Recommended Dietary Allowance (RDA) of

9.1g/day and the Adequate Intake (AI) of 1.52g/kg/day was used to evaluate protein intake. Energy, carbohydrate and fat intake was evaluated by using the AI for infants up to six months.

When the energy obtained from the recommended daily intake of NAN Pelargon® (assuming that the correct mixing instructions and recommended volumes are adhered to) is compared to the DRI⁵⁹ (Table 1.4), two week old infants would consume too little energy. At two weeks of age, male infants would consume only 77% of the DRI for energy and female infants would consume 84% of the DRI for energy respectively. At six weeks of age, the daily energy intake of female infants would meet the requirements, but male infants would consume slightly less than the recommendation. At 10 weeks of age NAN Pelargon® would exceed the required daily energy intake.

With regards to the macronutrients, NAN Pelargon® exceeds the daily protein recommendation in all instances. Infants aged two weeks will have a carbohydrate deficit, but at ages six and 10 weeks, the infant formula will exceed the daily recommendation. The infant formula provides too little fat for two and six week old infants, but infants aged 10 weeks will consume more fat than the DRI.⁵⁹ By age 10 weeks the infant formula provides 112.7% more energy for males, 123.6% more energy for females, 158.2% more protein, 121.3% more carbohydrate and 105.2% more total fat than the recommendation.

Regarding regulatory issues, Codex Alimentarius (Standard for foods for infants and children)⁶¹ specifically require specific levels of the following nutrients in infant formulas: protein, linoleic acid, choline and 13 vitamins and 12 minerals. All these specifications are based on the amount per 100 kJ or per 100 kCal. Codex has upper limits for protein, fat, vitamins A and D, and sodium, potassium and chloride. Current regulations require a minimum protein content of 0.43g/100 kJ (1.8g/100 kCal) and allow a maximum of 0.96g protein/100 kJ (4.0g/100 kCal). Protein levels in current infant formulas are closer to 0.48-0.72g/100 kJ (2-3g/100 kCal).⁶² The protein content of NAN Pelargon® is 0.53g/100 kJ (2.2g/100 kCal) and well within the specified requirement. Although specific energy contents or concentrations of infant formulas are not required by regulation, manufacturers tend to provide instructions for

reconstitution of most standard formulas at about 2.83 kJ/ml (0.68 kCal/ml).⁶² The energy density of NAN Pelargon® is 2.79 kJ/ml (0.67 kCal/ml) when reconstituted correctly according to the recommended reconstruction guidelines. Infants will benefit from adequate and recommended energy consumption with such energy density form NAN Pelargon®.

The under consumption of energy during the first two weeks of life and the over consumption of energy and macronutrients at 10 weeks of age highlights the importance of human physiology of programming during relatively short early-life periods on the development of chronic disease later in life. Research has shown an association between rapid infancy weight gain and childhood obesity, whereas low infancy weight is associated with coronary heart disease.^{28, 63} A cohort study of European American subjects fed infant formula indicated that weight gain during the first week of life was associated with overweight status in adulthood.⁶³ There is an increased vulnerability to develop overweight and obesity and other chronic diseases of lifestyle in adults who had low birth weights, were undernourished and had stunted growth during infancy and childhood.¹⁶ Compared with breastfeeding, formula feeding has been associated with a more rapid weight gain in early infancy and with an increased risk for obesity in childhood and adolescence.⁶³

1.5.3 Limitations of the Programme

Poor longitudinal follow-up³¹ rates resulted from a prolonged follow-up of predominantly HIV-uninfected children, leading to a lack of data on HIV transmission rates.⁶⁴ This questions the government's ability to assess the efficacy of local PMTCT programmes since the implementation of PMTCT programmes at government-designated sites and nationally in July 2002.^{64, 65} PMTCT record-keeping was not standardised and records were in a fragmented format with no central coordination. This poor accessibility of data inhibits surveillance.⁶⁴

Weaknesses of the infrastructure and problems affecting the sound and effective management of the PMTCT Programme were not necessarily part of the programme and could not easily be controlled, but remain a direct consequence of the programme. Active interest and support of senior managers in the PMTCT

programme has led to faster and more effective implementation at some sites, however, the level and standard of leadership was not congruent in all provinces.⁶⁵ The available facilities have limited capacity to accommodate the increased utilisation of PMTCT services. Inadequate physical space and privacy restricted the provision of adequate counselling. Storage space continues to be a problem.⁶⁵

The terms “acceptable, feasible, affordable, sustainable, and safe” have not yet been properly defined in clinical studies. Assessment of “safe” and “feasible” feeding conditions is a challenge for counsellors and health workers.⁹ Furthermore, no studies have assessed the implementation or evaluation of guidelines based on AFASS.

1.5.3.1 Influence of health workers on infant feeding

The current WHO guidance states that HIV-infected mothers should be given information about the risks and benefits of various infant feeding options based upon their local and individual circumstances.⁷ They should be able to select the most appropriate feeding option for their situation. It is speculated that counsellors may encourage mothers to formula feed based on an optimistic assessment and finding that AFASS criteria are met. Not only are counsellors supposed to have the ability to explain complex scientific concepts on risk factors associated with breastfeeding and replacement feeding to a mother who is sometimes unaware of these dilemmas, they also have to grasp the dynamics of the social and household situation compassionately.^{9, 27, 33, 38}

The hierarchical relationship between women and health workers coupled with the inconsistent supply of free infant formula often causes women to choose the option they were told would best protect their infant.²⁷ A qualitative interview study conducted by Doherty *et al*²⁷ showed that of the 15 mothers who chose to formula feed, 12 had run out of formula milk at least once. Mothers without financial resources to sustain formula feeding had nothing to feed their infants when home and/or clinic stock was finished. Poor quality counselling, i.e. unclear and partial

messages can however have harmful effects on both HIV-infected mothers and those who are not HIV-positive leading to suboptimal infant feeding practices.^{27, 31} Staff training, availability of lay counsellors (or the lack thereof) and individual facility preferences strongly influence the quality and intensity of infant feeding counselling. Despite the national PMTCT protocol recommendation that mothers should be encouraged to practice their chosen feeding option exclusively, there is currently no formal infant feeding counselling given to women postnatally.²⁷

It should be acknowledged that the fear of HIV transmission is not unreasonable. It is the responsibility of programme managers, investigators, and policy makers to conduct local area-based assessments to concretely establish the feeding options and develop policies and evidence-based guidelines for health workers, nutrition education and behavioural change communication strategies to optimise safer infant feeding practices.

1.5.3.2 Stigmatisation

Mothers using free infant formula are often ridiculed and disrespected, coupled with high levels of stigma associated with HIV-infection.²⁷ An ethnographic study performed by Thairu *et al*³³ to identify socio-cultural influences on infant feeding decisions, found that in a community where breastfeeding is the norm, choosing to use replacement feeding was regarded almost as a confession of HIV infection. The social stigma of HIV infection coupled with beliefs about HIV transmission through breast milk and the quality of breast milk compared to infant formula, among other factors, have a strong influence on infant feeding practice.³³ The stigma associated with replacement feeding makes appropriate and effective infant feeding counselling difficult.²³

The Mashai study²³ conducted in Botswana speculated that social stigma was one of the most important factors preventing women from joining the PMTCT programme. It was found that women chose not to disclose their HIV status – probably in fear of stigma, and their failure to disclose relieved them from negative criticism from the surrounding society.

1.5.4 Strengths of the Programme

Botswana was the first country to successfully implement and execute its PMTCT programme since 1998. This middle-income country boasts good governance, political stability and commitment to reversing the HIV/AIDS epidemic²², and has the best primary health care and provision of water and sanitation in Southern Africa.³⁵ The highest percentage of HIV-infected pregnant women (approximately 85%) was identified in early 2006 and has received PMTCT services since then. A year's supply of free formula milk has been provided to over one third of all HIV-infected mothers, with an almost universal formula feeding practiced among HIV-positive women. Formula feeding was so strongly promoted in Botswana that many HIV-negative women are now avoiding breastfeeding. The rate of MTCT in Botswana has been found to lie between 15 and 40% with the highest adult HIV prevalence worldwide at 40%.²³

The Western Cape Provincial Health Department implemented a pilot PMTCT programme in January 1999 in the Khayalitsha health district. It was based on the original Thailand short-course zidovudine regimen and proved to be acceptable and effective in reducing MTCT. Subsequently, a provincial PMTCT programme, based on the HIVNET 012 nevirapine regimen was implemented in 2001 and achieved universal coverage in 2003. At that point in time, the PMTCT programme was between 40% and 50% effective.⁵⁸

A descriptive study done in Gauteng at the Coronation Women and Children's Hospital (CWCH) in 2001/2002 evaluated the nevirapine regimen and provision of formula milk for the first six months of life. It reported an HIV MTCT rate of 8.9% at three months of age as opposed to an estimated MTCT rate of 13.1% if most women in the CWCH PMTCT programme were breastfeeding.⁶⁴ The study therefore demonstrated that nevirapine-based interventions can be effectively implemented in South Africa.

Currently South Africa has the largest PMTCT programme in Africa.¹⁷

1.6 STATEMENT OF THE RESEARCH QUESTION

Between the start of the PMTCT Programme at Dr George Mukhari Hospital (previously known as the Ga-Rankuwa Hospital) in March 2002 and October 2006, an estimated 1256 infants born to HIV-infected mothers were referred to and have been seen by the Department of Human Nutrition at Dr George Mukhari Hospital. Within the scope of PMTCT services i.e. education, counseling and support for mothers up to 18-24 months, the role of the Department of Human Nutrition at Dr George Mukhari Hospital during the first 22 weeks of an infant born to a HIV-exposed mother who chose to formula feed her child was the following:

- a. Educating mothers concerning various aspects including basic hygiene principles, reconstitution of formula milk, growth of infants, healthy eating habits for mothers and introduction of solids to infants on an *ad hoc* basis. The HIV-positive status of the mother and subsequent HIV-exposed status of the infant was accepted in good faith based upon clinical judgment as presented in clinical records.
- b. Weighing of infants at each visit and advising and educating mothers if their infants demonstrated poor weight gain.
- c. Issuing of formula milk according to the national protocol
- d. “Discharging” of infants from the Department of Human Nutrition once infants reached 22 weeks of age. Therefore time was the only criterion for discharge. Infants with poor weight gain were referred to the Special Infant Scheme (initiated by the Gauteng Department of Health). HIV-infected infants requiring treatment (following HIV DNA PCR test performed at six weeks of age – however, at the time of compiling and final submission of the research protocol during mid-2006, PCR testing was routinely done at 12 months of age at Dr George Mukhari Hospital) were transferred to and supported by the Paediatric Antiretroviral Clinic where infants would be monitored comprehensively in terms of thorough overall nutritional assessment and regular updates of growth charts and supplemented as necessary with suitable nutritional products.

All other VCT, antenatal counseling, education, PCR testing, pre- and post test counseling, follow-up visits to the Paediatric Outpatients Department were dealt with by other departments in the hospital at the time of the study.

Between March 2002 and October 2006, infants entered into the PMTCT Programme were monitored at each visit by weight gain only. As a result, no sound nutritional status evaluation was performed during the 22 weeks of participation in the programme (as per the national protocol's recommended period to supply formula milk) or after discharge from the PMTCT Programme.

1.7 PURPOSE OF THE STUDY

The purpose of this research was to investigate the anthropometric measurements (weight, length and head circumference) of infants on the PMTCT programme from two to 10 weeks of age. Ten weeks of age is the midpoint of the full series of follow-up visits for formula fed infants (that is the 22 week or six month period during which free formula milk is provided). Furthermore, growth was monitored, usual dietary intake were determined and socio-demographic circumstances described.

CHAPTER 2: METHODOLOGY

2.1 STUDY AIM

The primary aim of the research was to determine the short-term growth, anthropometric variables, dietary intake of infants and socio-demographic background of formula fed infants entered into the PMTCT Programme for eight weeks from the age of two weeks.

2.2 STUDY OBJECTIVES

The following objectives were addressed:

- 1 To determine weight gain (the changes in weight between ages two, six and 10 weeks) of infants enrolled in the PMTCT Programme by comparing weight at two, six and 10 weeks of age.
- 2 To describe the growth of infants between two and 10 weeks of age, based on the comparison of the following anthropometric measurements with the reference values from the CDC 2000 growth charts³:
 - a. Weight-for-age
 - b. Weight-for-length
 - c. Length-for-age
 - d. Head circumference-for-age
- 3 To describe the feeding patterns (number of feeds per day) and energy and macronutrient intake of infants between two and 10 weeks of age, and the infants' usual dietary intake at 10 weeks of age.

2.3 STUDY DESIGN

The study was a descriptive, longitudinal study involving enrolment and monitoring changes in weight, length and head circumference and dietary intake of infants of HIV-infected mothers, who had been entered into the PMTCT Programme at the Department of Human Nutrition of Dr George Mukhari Hospital to receive formula milk.

2.4 SAMPLING

2.4.1 Study Population

The main area served by Dr George Mukhari Hospital, a tertiary government institution in Gauteng Province, is Soshanguve, which is an urban community situated 30km north west of Pretoria, and 10 km north east of the University of Limpopo (Medunsa Campus). It has a mixed population comprising of various African groups. The word Soshanguve is an acronym for 'SO' – *Sotho*, 'SHA' - *Shangaan*, 'NGU' – *Nguni*, 'VE' – *Venda*. The community has access to four formal structured clinics, one of which was in the process of starting a PMTCT service at the time of the study. The hospital's antenatal clinic and paediatric outpatient department served the immediate area and other areas such as Limpopo and North West Provinces. Although most Soshanguve women with uncomplicated pregnancies were advised to deliver at the clinic with a maternity section, pregnant women receiving antiretroviral therapy were obliged to attend the HIV, AIDS and sexually transmitted infection (STI) [HAST] programme at the hospital.

All HIV-infected mothers who had just given birth in the period 15th November 2006 to 2nd March 2007 or had been discharged from the labour ward at Dr George Mukhari Hospital and referred to the Department of Human Nutrition for entry into the PMTCT Programme were requested to participate in the study and complete the consent form(s) (Appendices 1 and 2), provided they met the inclusion criteria for the study. Upon their scheduled return for their first clinic visit i.e. two weeks after discharge, the written informed consent was confirmed and data collection commenced (Figure 2.1).

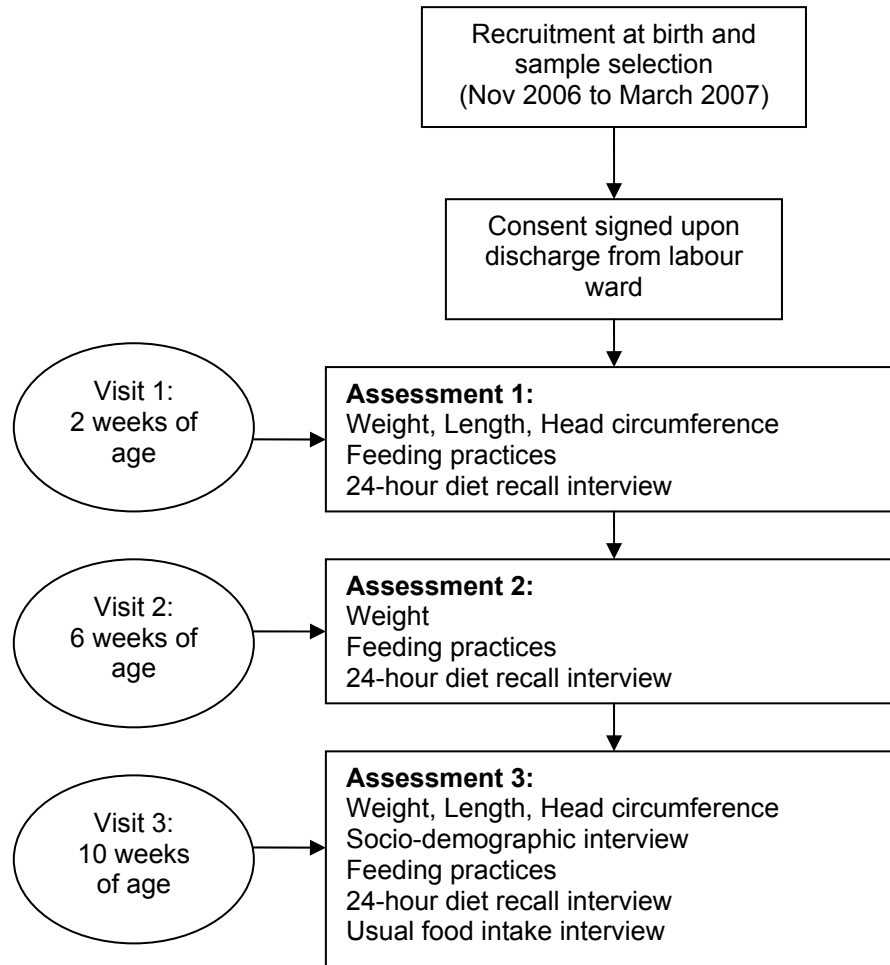


Figure 2.1: Time frame and flow diagram of the research plan

2.4.1.1 Selection criteria

Inclusion criteria

Two week old infants born to HIV-infected mothers at Dr George Mukhari Hospital together with their consenting mothers, both of whom received nevirapine according to the protocol of the PMTCT Programme and who had been formula fed since birth, were included in the study.

Exclusion criteria

- Infants born at any other hospital in the area.
- Infants born to HIV-infected mothers and who were older than two weeks at the time of the first visit.

- Infants born to HIV-infected mothers and who had received any breast milk either exclusively or combined with formula feeding for any period of time since birth.
- Infants brought by a person who was not the biological mother of the infant.
- Infants who were hospitalised or transferred to the neonatal unit immediately after birth
- Infants admitted to hospital for any reason during the course of the study.
- Infants with spinal curvature, contractures or muscular-skeletal deformities or any other birth defect which might have rendered the anthropometric measurements invalid.

2.4.2 Sample Size

A retrospective investigation, of all the fully completed records ($N = 53$) pertaining to the Department of Human Nutrition at Dr George Mukhari Hospital of infants born to HIV-infected mothers who had been entered into the PMTCT Programme from 1st March 2005 to 1st March 2006, was used to obtain data for a power analysis to determine the required sample size. From the existing PMTCT clinic data, the mean weight gain of infants from week 2 to week 10 was 2.8kg [Standard Deviation (SD) 1.2kg]. Based on these figures and a study population of 1256 mother-infant pairs (who had entered the PMTCT programme over the 12 months preceding this study), the required sample size at a 5% level of significance and a power of 0.8 to detect a treatment effect of 0.7 was calculated as 122 mother-infant pairs using the Power analysis module of Statistica version 7.⁶⁶ To account for dropouts, the calculated sample size was increased by 20% to reach 150 mother-infant pairs. The sample of mother-infant pairs was recruited from 15th November 2006 to 2nd of March 2007.

2.4.2.1 Interview schedule development

The questions for all the interview schedules (Appendices 3-7) were developed by the investigator in English. Translation to seTswana was done by an independent person proficient in both English and seTswana. Interview schedules were designed for use by the investigator, trained Dietitians and Diet Assistants. The investigator

conducted most of the interviews, but the trained Dietitians assisted with the interviews when the clinic became very busy. Diet Assistants performed translations whenever the interviews had to be conducted in seTswana. Questions were asked by the interviewer and the response of the participant was documented by the interviewer on the interview schedule itself.

Questions were asked around the preparation, frequency and volume of feeds of the previous day (24-hour diet recall) for each of the three visits. At each visit, questions were formulated to determine the mother's technique for reconstituting the formula milk (question 11 in Appendix 3, question 4 in Appendix 4, question 6 in Appendix 5), and the infant's formula milk consumption in terms of number of bottles and volume of each bottle drunk the previous day (question 12 in Appendix 3, question 5 in Appendix 4, question 7 in Appendix 5).

The infant's usual food intake interview schedule (Appendix 6) was designed as a modified 24-hour recall (see List of Definitions). This modified 24-hour recall was based on the 24-hour recall normally used by the Dietetic Unit and focused on the number and quantities of feeds. Questions 1, 3, 4 and 5 aimed to determine the infant's intake of formula milk (volume and frequency) and complementary feeds (time of day, type of food and drink and quantity) during the preceding 24 hours. Question 6 asked about any medication given to the infant since birth and question 7 aimed to establish whether other relatives or caregivers gave any complementary feeds to the infant since birth. In terms of ensuring reliable quantification of the dietary intake data, the investigator used an empty feeding bottle to help mothers indicate the quantities used.

The socio-demographic interview schedule (Appendix 7) included information on the following:

- Infant's gender and date of birth (questions 1 – 3).
- Mother's information (i.e. physical address, age, occupation/employment status, highest qualification) (questions 4 – 7).
- Hygiene information including source of drinking water, boiling of water used for formula milk preparation and cleaning of feeding bottles. Mothers were advised by either the investigator or the trained Dietitians or Diet assistants on

basic hygiene practices during the first visit and questions from the socio-demographic interview schedule (questions 8 – 11) aimed to determine the extent of adherence to hygiene principles.

- General information focusing on the medical history (questions 12 – 16) of the infant. Questions 12 and 13 aimed to determine whether the infant was taken to a medical institution or health professional since birth for vomiting, diarrhoea, constipation or any other ailments. Question 14 aimed to relate ailments with feeding practices - whether the administration of medicine influenced the intake of formula milk. Question 15 related to the time frame of treatment and question 16 aimed to establish whether there were periods when the infant had not received formula milk at all and for how long.

2.4.2.2 Pre-testing the interview schedules

The usual food intake interview schedule and socio-demographic interview schedule were pre-tested on 10 mothers with 10 week old infants attending the PMTCT Programme at Dr George Mukhari Hospital. These mothers were excluded from the study since their infants were not followed by the investigator since birth. The interview schedules were pre-tested to identify potential problems in the study for instance limited space for completing answers and indicating comments, and unclear order of questions. The reason for choosing 10 week old infants was that all the relevant interview schedules would be performed at age 10 weeks as opposed to either two or six weeks at which time the socio-demographic interview schedule would not have been used.

During the pre-test the format and presentation of the socio-demographic interview schedule was face validated by the investigator. It was assessed and found to be suitable with regards to logical sequence of questions, clear wording of questions, accurate translation, sufficient space for answers and appropriate use of open-ended and close-ended questions.

2.4.2.3 Training of research assistants

Three Diet Assistants (unqualified, in-house trained employees assisting with nutritional screening and foodservice) and two Registered Dietitians, employed by Dr George Mukhari Hospital, were trained for the study by the investigator directly prior to commencement of the study. The Dietitians and Diet Assistants were trained on the theoretical background of the study including the reason for and the importance of the research project. They were trained in basic interview techniques required for the study, such as asking questions in a neutral manner, not showing by words or facial expression to lead an answer, to avoid agreement, disagreement and/or surprise in response to answers, and to record answers to open questions accurately as they were provided. The Dietitians were specifically trained to perform the correct anthropometric measurement techniques especially with regards to assistance with the length measurement and in order to perform quality control measurements (see section 2.6.1.2). The investigator performed the reading and all the measurements were taken by the investigator, with assistance from the trained Dietitians. The Diet Assistants only acted as interpreters in the study when necessary. They only administered the questionnaires when a participant preferred to be interviewed in seTswana.

2.5 PILOT STUDY

A pilot study was performed at Dr George Mukhari Hospital after ethics approval from the relevant institutions had been obtained. The pilot study required a sample of 10 participants. The pilot study served as a trial run to revise the logistics of data collection before starting the actual field work. Since no problems were identified, the 10 participants were included in the final sample.

2.6 DATA COLLECTION

After training the research assistants and completing the pre-test and pilot study, the data collection commenced. Birth data were collected from the mother's medical file upon her discharge from the labour ward at which time consent was also obtained. All other required data were collected upon the infant's first follow-up visit at two

weeks of age. The 24-hour diet recall interview (part of the data entry form) was conducted and weight measured at all three visits. The 24-hour diet recall interview aimed to determine the consumption of formula milk and to assess the mother's methods of feed preparation. Feeding bottles, bowls and spoons were available to assist the estimation of volumes and amounts of feeds given. Length and head circumference were measured at visits 1 and 3, while the socio-demographic interview was conducted at visit 3 only (Figure 2.1). Anthropometric measurements were taken in the clinic area; the 24-hour diet recall interview was conducted in the clinic area and the administration of the socio-demographic interview schedule took place in a separate office to ensure privacy.

The investigator collected data during all follow-up visits except in the event of a mother not being familiar with English when a trained Diet Assistant used the seTswana interview schedule (Appendices 8 and 9). Interview schedules and record forms were checked after completion to identify missing data or aberrant responses. The investigator checked the records for completeness, legibility and clarity before leaving the respondent.

2.6.1 Anthropometry

The following anthropometric measurements were performed using standardised techniques as described in the literature.^{67, 68}

2.6.1.1 Weight

Weight was determined by using a Medway 3[®] standardised electronic scale (Masskot, Germiston, South Africa), which was certified by the supplier as calibrated. The scale was levelled on a table and the investigator ensured that it was zeroed before each measurement. Infants were weighed without any clothing and diapers to the nearest 0.01 kg. Mothers were requested to attend the Department of Human Nutrition at indicated times in order to ensure that weight measurements were taken

at the same time of the day (to control for circadian variation), but this was not always possible.

Variation in accuracy of measurements was reduced by weighing infants on one scale, at the same time as far as it was possible, by the same research team. An additional measure of quality control was incorporated by means of an independent Dietitian (no involvement in the study) repeating every 10th weight measurement. Instrument bias was minimised since the scale was calibrated by the manufacturing company prior to the pre-test and after one month of data collection. All equipment used was in good working order at the start of the study.

2.6.1.2 Length

The supine length measurement was measured on an inflexible length board (118 cm in length) with a fixed head board and adjustable footboard. Two people (Investigator and Dietitian) were required to position and hold the infant to accurately complete the measurement to the nearest 0.1 cm. The head was held at the top of the board with the Frankfort plane¹ perpendicular to the floor. The torso was positioned and straightened. The knees were flattened to fully extend the legs. The feet were placed together and flexed at 90°.

To improve the reliability of the measurements, length was measured twice and an average measurement was calculated. An additional measure of quality control of data entry was incorporated by means of an independent Dietitian (no involvement in the study) repeating every 10th length measurement.

2.6.1.3 Head circumference

Head circumference was measured by using a non-stretchable plastic coated tape scaled to 0.1 cm. The tape was placed superior to the supraorbital ridge and adjusted around the occiput to obtain maximum circumference. The plane of the tape was similar on both sides of the head. The tape was placed evenly against the skull. The measurement was performed whilst the infant was held on the mother's lap or when lying down on the changing mat.

Head circumference was measured twice and an average measurement was calculated. This step was performed to improve the reliability of the measurement. Similar to the measurement of weight and length, an additional measure of quality control of data entry was incorporated by means of an independent Dietitian (no involvement in the study) repeating every 10th measurement of head circumference.

2.7 DATA ANALYSIS

Data was captured and processed by the investigator with Microsoft Excel[®]. A consultant statistician was appointed by the Faculty of Health Science, University of Stellenbosch to assist with data analysis and additional statistical procedures. The EpiInfo 2000 programme⁶⁹ was used to do a comparison between the original datasheet and a duplicate datasheet to identify and eliminate any computer data entry errors.

2.7.1 Anthropometry

The variables reflecting nutritional status including percentiles for weight-for-age, weight-for-length, length-for-age and head circumference-for-age were quantitatively analysed using the EpiInfo2000 programme⁶⁹ and CDC 2000 growth charts.³ Although the WHO released new standards (based on a sample of healthy breastfed infants with high-quality complementary diets) for assessing the growth and development of children from birth to five years of age in April 2006⁷⁰, it was decided to use the CDC 2000 growth charts³ instead. The CDC growth charts³ were based on relatively few infants who were breastfed for more than a few months. It was therefore decided to use a reference against which a formula-fed infant population could be evaluated. Descriptive statistics (means, standard deviations and frequency distributions) were used to describe the demographic characteristics of the study sample. Infant ages were calculated in days from the date of birth to the first, second and third visits to the Department of Human Nutrition to collect formula milk. To identify the outliers with regards to age, three standard deviations (SD) above and below the mean of the age of infants at each visit was calculated. The mean and weight gains of infants from visit 1 to 2 and from visit 2 to 3 were calculated and compared with CDC growth charts.³ The growth was determined by calculating the

differences between weights of infants at ages two weeks, six weeks and 10 weeks and the CDC 2000³ recommended weight at the 50th percentile for ages two weeks, six weeks and 10 weeks. Growth was described in terms of the change in weight-for-age, weight-for-length, length-for-age and head circumference-for-age from visit 1 to 3 according to the following percentiles of the CDC 2000 growth charts:³ 3rd, 25th, 50th and 97th. The 3rd, 50th and 97th percentiles were chosen as they mimic the Road to Health Chart (RtHC)⁷¹ used by the Department of Health. The 25th percentile was included to have an extra point of reference to describe growth. Infants with weight-for-age, weight-for-length and length-for-age below the 3rd percentile were classified as underweight, wasted and stunted respectively. Infants with weight-for-length above the 97th percentile were classified as overweight. Differences between means of weight-for-age, length-for-age and weight-for-length were tested using the non-parametric bootstrap⁷² method.

2.7.2 Dietary Intake

Energy and macronutrients were derived from the number of scoops of NAN Pelargon® and the number of bottle feeds taken per day as reported on the 24-hour recall interview schedules (Appendices 3, 4 and 5). The usual food intake interview schedule (Appendix 6) was used to determine the contribution of complementary feeds to energy intake at 10 weeks of age. Nutrient analyses were done using the FoodFinder3 dietary analysis software⁷³ and compared with the Dietary Reference Intakes (DRIs)⁵⁹ and the recommendations from the World Health Organisation (WHO). Furthermore, intakes were presented as percentages of the required intake of energy (kJ/kg/day) and protein (g/kg/day) for infants aged 0-6 months.

The Chi-square test⁶⁶ and Fisher exact, one-tailed test⁶⁶ were used respectively to determine the difference between the following categorical variables: different methods of reconstitution of infant formula according to powder to water ratio; and changes in energy-, protein-, carbohydrate- and fat intake of infants over the three visits. The Analysis of Variance (ANOVA)⁶⁶ was used to determine differences in the continuous variables (weight changes of infants over the three visits).

2.7.3 Socio-Demographic Information

Gender of infants was used to differentiate between all the measured variables in terms of growth and dietary intake. Information gathered from the mother formed part of the background description of the sample of mother-infant pairs that were investigated in the study. Ailments that the infant had suffered since birth were investigated in relation to the impact on growth and feeding practices. The use of medication in relation to the exclusion of infant formula during periods of illness was investigated.

2.7.4 Safety of Formula Milk Preparation

Some of the basic hygiene principles in preparing infant formula were covered in the socio-demographic interview schedule such as the use of boiled water and proper reconstitution of the solution. Aspects such as using clean equipment and using cooled, preboiled water for preparation of formula milk, mixing of water and powder were evaluated according to the WHO guidelines on preparation of formula for bottle-feeding at home.⁷⁴ Differences in proportions of mothers following the correct procedures for preparing formula feeds were compared using the McNemar Bowker test.⁷⁵

2.8 ETHICS

The study was submitted for approval to the Committee for Human Research, Faculty of Health Science, University of Stellenbosch (Appendix 10), and the Research, Ethics and Publications Committee of the Faculty of Medicine of the University of Limpopo (MEDUNSA campus) (Appendix 11). Thereafter, permission to conduct the study was requested and received from the Chief Executive Officer of Dr George Mukhari Hospital.

The nature of the study was explained to all HIV-infected mothers who had just given birth and was referred to the Department of Human Nutrition to collect formula milk. Written informed consent was obtained. The standard informed consent form used by the Faculty of Health Sciences of the University of Stellenbosch was adapted for

this particular research study (Appendix 1). The standard informed consent form used by the Research, Ethics and Publications Committee of the Faculty of Medicine of the University of Limpopo (Medunsa) was also adapted and modified for this research study (Appendix 2). A summary of the study and the informed consent forms from both institutions were available in seTswana (Appendix 8, Appendix 9). Informed consent was confirmed once they returned with their infants after two weeks and participation in the study was commenced. English interview schedules were translated and seTswana speaking participants were interviewed in their own language.

Data were handled confidentially. A study number was consecutively allocated to participants upon entry to the study. Each participant received an identification card (Appendix 12) containing the participant's study number and appointments for follow-up visits. Participant identification information were omitted from study related material and documentation to ensure confidentiality of study participants. A separate list of the mother's name, hospital number and the corresponding infant's study number were kept by the investigator (Appendix 13). Participation in the study was voluntary and participants could withdraw at any time without penalty. Withdrawal at any time was also voluntary. All usual clinic practices were carried out during the study. No advice or care was withheld at any stage.

CHAPTER 3: RESULTS

3.1 SAMPLE DESCRIPTION

The final sample comprised of 151 mother-infant pairs after the exclusion of 95 infants for a number of reasons (Figure 3.1). After two months of data collection and due to the actual drop-out rate (45%) being higher than the one estimated (20%), it was decided to extend the recruitment period for another two weeks until 246 mother-infant pairs had been recruited.

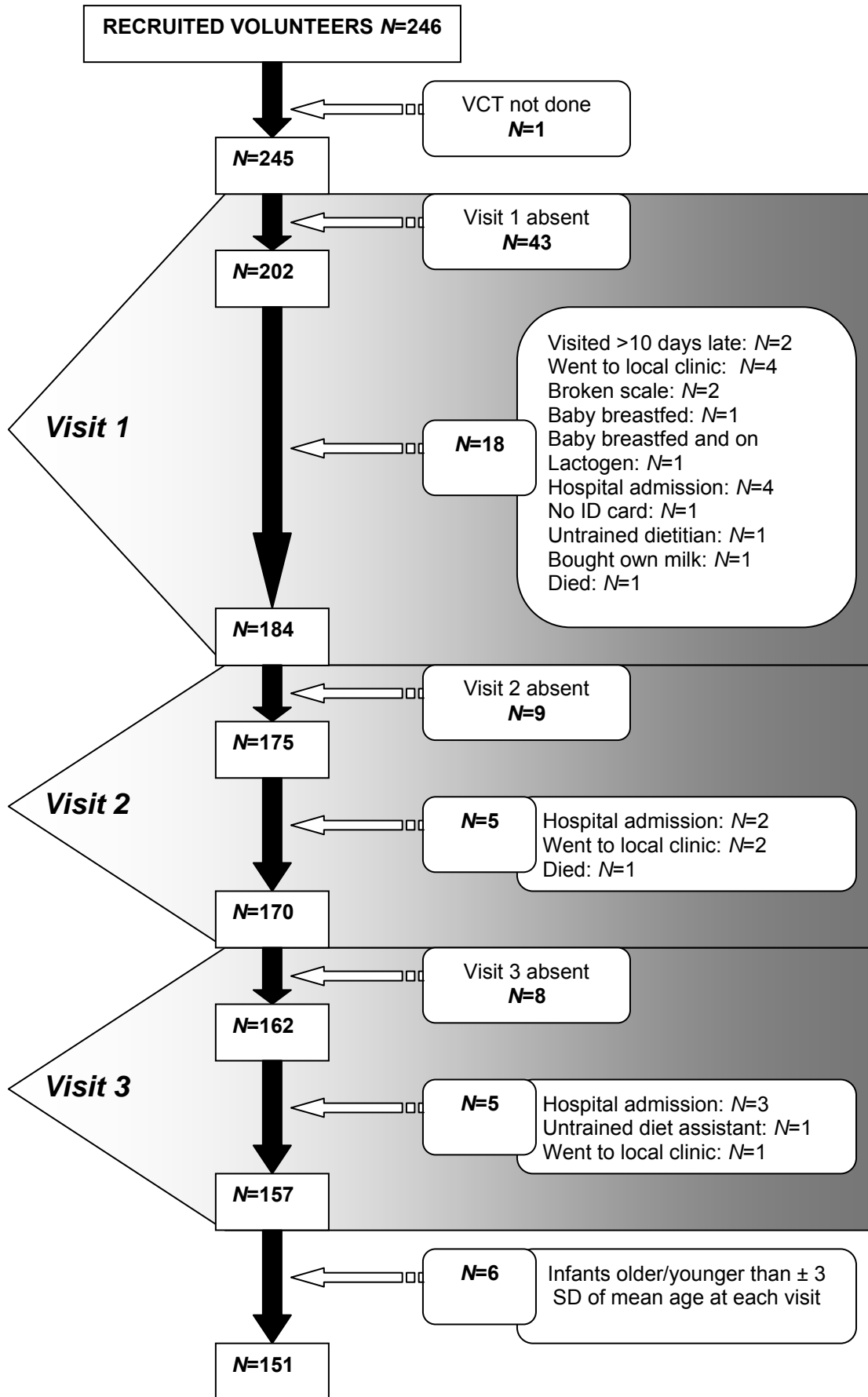


Figure 3.1: Flow diagram of the determination of the final sample

A total number of 3106 births were documented at Dr George Mukhari Hospital from November 2006 up to February 2007 (Table 3.1).

Table 3.1: Total births at Dr George Mukhari Hospital, from November 2006 to February 2007

Month	Number of births
1st - 30th November 2006	808
1st - 31st December 2006	770
1st - 31st January 2007	852
1st - 28th February 2007	676
Total	3106

Statistics from the antenatal clinic at Dr George Mukhari Hospital for the period 12th November 2006 to 3rd March 2007 (three days prior to the start of the study and one day after the completion of recruitment of participants; data collected from the weekly statistics kept by the antenatal clinic) revealed that more than 50% of the HIV-infected mothers chose exclusive formula feeding as opposed to exclusive breastfeeding (Table 3.2).

Table 3.2: Prevention of Mother-to-Child Transmission Programme statistics from the antenatal clinic at Dr George Mukhari Hospital (November 2006 – March 2007)

Month	Voluntary tested	HIV infected, after testing		Uninfected after testing		Births ^a	EFF ^b		EBF ^c	
		N	%	N	%		N	%	N	%
12 th – 30 th Nov 2006	40	12	30	28	70	98 ^d	62	63	37	37
1 st – 31 st Dec 2006	44	15	34	29	66	160 ^e	112	70	49	30
1 st – 31 st Jan 2007	54	17	31	37	69	165 ^f	113	69	51	31
1 st – 28 th Feb 2007	56	18	32	38	68	156	111	71	45	29
1 st – 3 rd March 2007	0	0	0	0	0	19 ^g	16	89	2	11
Total	194	62	32	132	68	597	420	70	184	30

^a Number of births (live or still birth) to HIV-infected women (including those who received VCT at antenatal clinic and those who knew their HIV-status prior to attendance at the antenatal clinic), including abortions and multiple births (twins, triplets, etc.)

^b Exclusive formula feeding

^c Exclusive breastfeeding

^d Includes 1 set of twins

^e Includes 2 sets of twins and 1 still birth

^f Includes 1 abortion, 1 still birth and 1 set of twins

^g Includes 1 still birth

Although a total of 420 HIV-infected mothers chose exclusive formula feeding as the feeding option (for the period 12th November 2006 to 3rd March 2007 – statistics from the antenatal clinic were maintained weekly, from Sundays up to Saturdays), only 311 mothers (74%) received free infant formula milk from the Department of Human Nutrition for the exact period of the study: Wednesday 15th November 2006 to Friday

2nd March 2007 at Dr George Mukhari Hospital (Table 3.3). The remaining 109 mothers (26%) could have collected infant formula from their nearest or local clinic.

Table 3.3: Attendance of the Prevention of Mother-to-Child Programme at the Department of Human Nutrition at Dr George Mukhari Hospital (November 2006 – March 2007)

Month	Number of attendees
15 th – 30 th November 2006	46
1 st – 31 st December 2006	88
1 st – 31 st January 2007	102
1 st – 28 th February 2007	67
1 st – 2 nd March 2007	8
Total	311

The reason for the discrepancy of the dates from the statistics kept by the antenatal clinic and the starting dates of the study was that the study commenced on a Wednesday, while the antenatal clinic always started keeping record of attendances on Sundays (i.e. statistics were commenced on the Sunday prior to the start of the study on the Wednesday). The same principle applied for the discrepancy of the last date of the recruitment of volunteers for participation in the study (i.e. Friday, 2nd March 2007) vs. the last date for maintaining statistics for antenatal clinic attendances (i.e. Saturday, 3rd March 2007).

The study sample included approximately 5% (151/3106) of the total number of deliveries at Dr George Mukhari Hospital during the study period (Table 3.1). Of the total attendees of the antenatal clinic ($N = 420$) at Dr George Mukhari Hospital during the study period, 311 HIV-infected mothers were referred to the Department of Human Nutrition. From the group of 311, 246 mother-infant pairs were enrolled and 157 (64%) completed the study. After calculating ± 3 standard deviation (SD) above and below the mean of the age of infants at each visit [mean age at visit 1 = 15 (SD 5) days; mean age at visit 2 = 43 (SD 8) days; mean age at visit 3 = 71 (SD 10) days] to accommodate for age variation at each visit (Table 3.4), a further 6 mother-infant pairs were excluded, bringing the total number of excluded participants to 95 (39% of

initial recruited 246 participants) and reaching a final sample of 151 (61%) (Figure 3.1).

Table 3.4: Mean ages (in days) of infants per visit of the final sample (N = 151)

	Visit 1		Visit 2		Visit 3	
	Mean	SD ^a	Mean	SD ^a	Mean	SD ^a
Male infants (N = 75)	15.6	1.3	43.2	2.2	71.2	2.5
Female infants (N = 76)	15.4	1.4	43.2	1.9	71.3	2.6
Total sample (N = 151)	15.5	1.4	43.2	2.0	71.3	2.5

^a Standard deviation

During the recruitment of participants, it was discovered that one mother did not receive counselling and testing and was referred back to the antenatal clinic. The majority (45%) of mother-infant pairs who were excluded failed to attend the first follow-up visit. Altogether 60 participants did not return for one of the three scheduled visits during the course of the study, for reasons unknown to the investigator. The exclusion criteria of hospital admission and breastfeeding applied to 9 (10%) and 2 (2%) mother-infant pairs respectively. Conditions, as reported by mothers, requiring hospital admission included vomiting ($N = 1$), vomiting and diarrhoea ($N = 2$), diarrhoea ($N = 1$), jaundice ($N = 2$), "brain infection" ($N = 1$), chicken-pox ($N = 1$), gastroenteritis/ HIV infection/ hypokalaemia ($N = 1$).

3.2 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF INFANTS

The gender distribution of the infants was 76 females and 75 males. The overall mean birth weight of infants who completed the study was 3.1 kg [Standard Deviation (SD) 0.4 kg]. Birth weight was normally distributed (Figure 3.2) with the mean birth weight of male and female infants being 2.98 (SD 0.4) kg and 3.2 (SD 0.5) kg respectively. The mean birth weights of male and female infants were significantly different (t-test, $p = 0.001$). Although 18 infants had a low birth weight (< 2500g), no

further meaningful statistical comparison of growth could be made between infants who had low and normal birth weight.

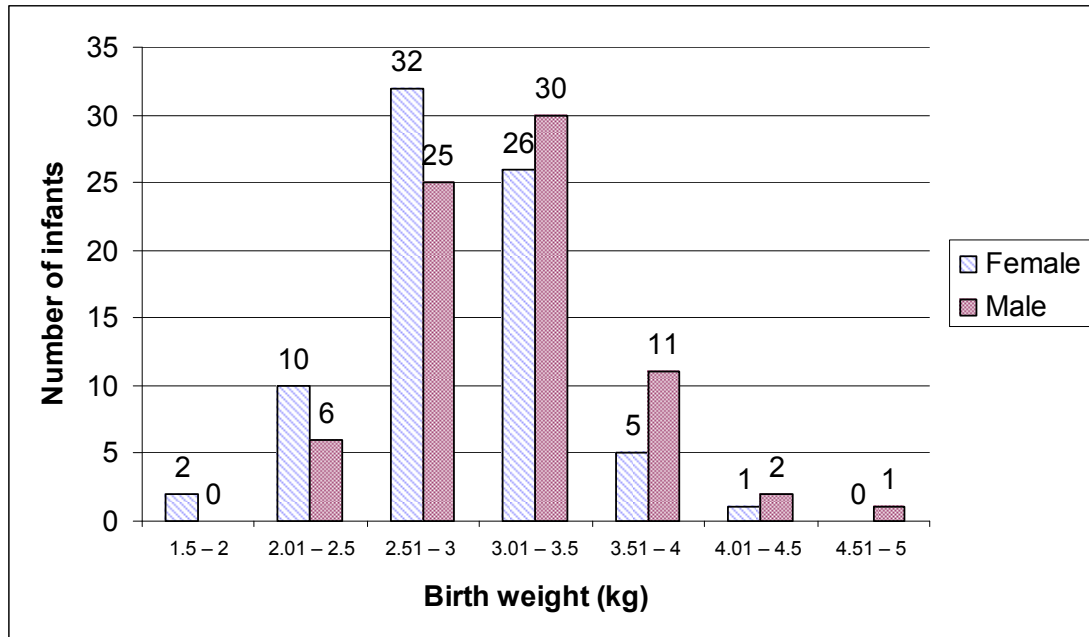


Figure 3.2: Birth weight distribution of infants included in the study by gender

3.2.1 Health of Infants and Use of Medication

The most common ailments infants in this study suffered from during their first 10 weeks of life as reported by mothers, included influenza-like symptoms ($N = 15$, 10%) and diarrhoea ($N = 9$, 6%), for which either the local clinic or a doctor was consulted (Table 3.5). “Other” illnesses included oral thrush, skin rash, ear infections, colic and genital sores. There were two (1%) infants who suffered from diarrhoea who received only oral rehydration treatment (ORT) without infant formula for a period of one and three days respectively. A total of 44% ($N = 66$) of the infants received medication (either prescribed by the doctor or given to the infant by the mother at her own discretion) (Table 3.5), which was mostly ($N = 41$; 62% of the 66 infants) taken at the time of the 6-week routine immunization consultation. Only six (4%) infants received both Panado and Bactrim.

Table 3.5: Common ailments among and medications received by the infants included in the study

Common ailments/medications		Number (N)	Percentage (%)
Ailment	Influenza/"cold", coughing, blocked nose	15	10.0
	Diarrhoea	9	6.0
	Constipation	7	4.6
	Vomiting	2	1.3
	Vomiting and diarrhoea	1	0.7
	Other	14	9.3
Medication (prescribed and self medication)^a	Sulphamethoxazole trimethoprim (Bactrim)	50	33.1
	Panado	16	10.6
Traditional medication	Gripewater	12	7.9
	Motswako (ORT) ^b	4	2.6
	Muthi we Nyoni ^c	2	1.3
Other solutions	Multivitamin syrup	21	13.9

^a Medications were prescribed by a doctor; other medication was given to the infant by the mother without a prescription

^b ORT = Oral rehydration treatment

^c Muthi we Nyoni is an antacid mixture

3.3 DEMOGRAPHIC CHARACTERISTICS OF MOTHERS

The sample was predominantly (81%) made up of women between 21 to 35 years of age (Table 3.6). The mean age of mothers was 28 (SD 5.9) years, with an age range of 17 to 43 years.

Of the total sample ($N = 151$), 130 (86%) of the mothers could be contacted or had telephone numbers. From the initial 246 recruited participants, 203 (83%) had contact numbers. Of the remaining 43 mothers with no contact numbers, 24 (56%) were part of the group that was excluded before reaching the final visit of the study. The majority (75%) of the mothers were not generating an income from employment at the time of the study. A total of 138 (91%) women had attended high school. Of the total sample, 110 (73%) mothers resided in Soshanguve, which is the main area served by the Hospital.

Table 3.6: Socio-demographic characteristics of mothers of infants included in the study

Characteristics		Number (N)	Percentage (%)
Age (years)	≤ 20	9	6.0
	21 – 25	48	31.8
	26 – 30	37	24.5
	31 – 35	37	24.5
	36 – 40	16	10.6
	41 – 45	4	2.6
Contact number	Contact number	130	86.1
	No contact number	21	13.9
Employment status	Unemployed	113	74.8
	Employed	32	21.2
	Scholar/student	6	4.4
Educational level	No education/up to grade 7 ^a	12	7.9
	Grade 8 - 9	13	8.6
	Grade 10 - 12	108	71.5
	Post matric	17	11.3
Area of residence	Soshanguve	110	72.8
	Ga-Rankuwa	10	6.6
	Pretoria	6	4.0
	Mabopane	6	4.0
	Brits	6	4.0
	Hammanskraal	4	2.6
	Other	7	4.6

^a One mother attended farm school, but could not specify which grade she completed

3.4 FEEDING PRACTICES

3.4.1 Safety of Formula Milk Preparation

Aspects such as using cleaned, sterilised feeding and preparation equipment and using cooled, preboiled water for preparation of formula milk, mixing of water and powder were evaluated according to the WHO guidelines on preparation of formula for bottle-feeding at home.⁷⁴

3.4.1.1 Feed preparers

The mother was the main person responsible for the preparation of infant formula at all visits [alone: visit 1: $N = 103$ (68%), visit 2: $N = 114$ (76%), visit 3: $N = 104$ (69%), or in conjunction with a caregiver: visit 1: $N = 47$ (31%), visit 2: $N = 35$ (23%), visit 3: $N = 44$ (29%)] (Figure 3.3). In the context of the study a caregiver refers to someone who helped look after the baby, including husbands, partners, older children, parents of the mother or father, relatives of the mother or father and formal childminders.

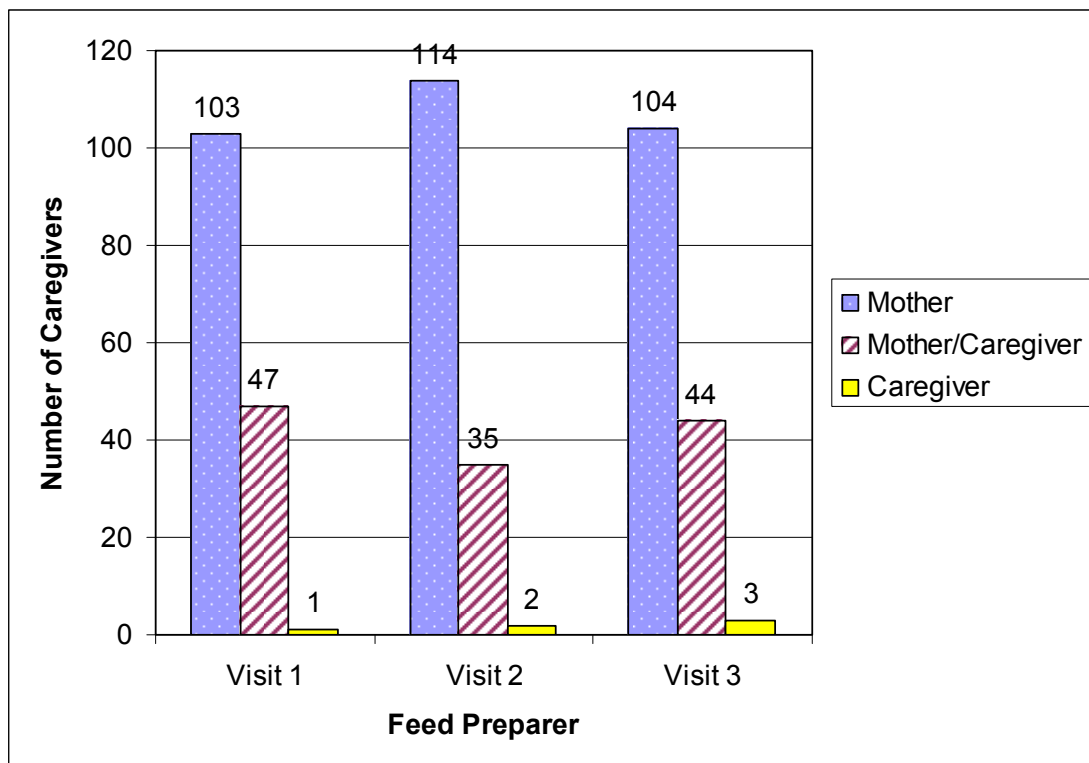


Figure 3.3: Distribution of feed preparers at each visit

3.4.1.2 Source of drinking water

A total of 122 (81%) mothers had access to safe drinking water from a tap inside their own house or yard, or from a neighbour (Table 3.7). All (99%) but two mothers boiled the water before they used it to prepare infant formula (Table 3.7).

3.4.1.3 Cleaning of bottles

Altogether 114 (74%) mothers used some form of detergent (e.g. Sunlight dishwashing liquid, Sunlight/OMO/Maq/Surf washing powder, Jik, Handy Andy) to wash bottles and teats (Table 3.7). Of the 37 mothers who refrained from using soap, 27 (73%) boiled bottles before or after use. Of the 89 mothers who boiled bottles before use, 62 (70%) also used detergents.

Table 3.7: Hygiene practices of mothers/caregivers included in the study

Hygiene information		Number (N)	Percentage (%)
Source of drinking water	Tap in house or yard or neighbour's tap	122	80.8
	Public tap	26	17.2
	Borehole or rainwater tank or well	2	1.3
	"Water from lorry" ^a	1	0.7
Use of boiled water	Used pre-boiled water for preparation of infant formula	149	98.7
	Did not use boiled water	2	1.3
Cleaning of bottles	Boiled bottle and/or teat	89	58.9
	Commercial soap	86	57.0
	No soap	37	24.5
	Soap and sterilising liquid	12	7.9
	Bleach or ammonia based detergents	10	6.6
	Sterilising liquid only	4	2.6
	Soap and bleach or ammonia based detergents	2	1.3

^a Water from water tank

3.4.2 Reconstitution of infant formula

When asked how they reconstituted the infant formula, most mothers adhered to the correct mixing guidelines of one level scoop of powder to 25 ml water (Table 3.8). The accuracy and correctness of mixing the infant formula, however, decreased with each visit (89% at visit 1, 89% at visit 2 and 85% at visit 3). The percentage of mothers who made feeds too dilute increased from 7% at visit 1 to 9% at visit 3. Adherence to the correct mixing of infant formula deteriorated towards the end of the study despite continuous corrective advice at each visit. The McNemar-Bowker test⁷⁵ for related variables, however, was not significant ($p = 0.39$) that is there was

not a statistically significant association between number of mothers correctly preparing feeds and the visit number.

Table 3.8: Reconstitution of infant formula according to the powder to water ratio

Ratio of scoops of powder: ml water	Visit 1		Visit 2		Visit 3	
	Number	%	Number	%	Number	%
1:25 (correct)^a	135	89.4	134	88.7	128	84.8
> 1:25 (too concentrated)^b	6	4.0	5	3.3	9	6.0
< 1:25 (too dilute)^c	10	6.6	12	7.9	14	9.3

^a One level scoop of powder to 25 ml of water

^b More than one level scoop of powder to 25 ml of water

^c Less than one level scoop of powder to 25 ml of water

The number of mothers who incorrectly added the measured volume of water to the required number of scoops of formula powder, decreased towards the third visit (13% at visit 1, 7% at visit 2 and 1% at visit 3) (Table 3.9). Of the 31 mothers who used the abovementioned technique, 24 (77%) adhered to the recommended ratio of 1: 25 for powder (1 scoop) to water (25ml). There was no significant difference (Chi-square test) in the reconstitution of infant formula between visit 1 and visit 2 ($p = 0.30$), however, there was a significant difference between visit 2 and visit 3 ($p = 0.05$) and between visit 1 and visit 3 ($p = 0.0003$).⁶⁶

Table 3.9: Reconstitution of infant formula according to powder to water ratio and by adding water to powder

Reconstituted infant formula	Visit 1		Visit 2		Visit 3	
	Number	%	Number	%	Number	%
Powder 1st ^a	20	13.2	10	6.6	1	0.7
1:25 (correct)^b	17	11.3	7	4.6		
> 1:25 (too concentrated)^c	2	1.3			1	0.7
< 1:25 (too dilute)^d	1	0.7	3	2.0		

^a Adding infant formula milk powder into the feeding bottle first, followed by water. Since the powder itself constitutes volume, less water will be used which leads to a concentrated solution

^b Correct ratio of one level scoop of powder to 25 ml of water, but water added to powder in stead of powder added to water

^c More than one level scoop of powder to 25 ml of water, and water added to powder in stead of powder added to water

^d Less than one level scoop of powder to 25 ml of water, and water added to powder in stead of powder added to water

Of the three mothers whose feeds were mixed too concentrated, one mother filled the bottle with powder up to the 100ml mark and filled the bottle up to 250 ml mark with water. Another mother measured the required 100 ml of water and then she boiled the water. This reconstituted milk was then too concentrated due to the evaporation of water during the boiling process. Both these instances occurred at the first follow-up visit and both mothers were made aware of the incorrect reconstitution of the solution and subsequent corrective measures were taken by means of repeat of correct mixing instructions. The third mother used about one and a half scoops per 25 ml of water and added water to the powder.

Only three (2%) mothers used infant formula brands that differed from the NAN Pelargon® that was supplied as per PMTCT protocol. One mother fell short of supply and failed to obtain NAN Pelargon® from the retail sector – she bought NAN 1® and gave it to the infant for two days prior to her second follow-up visit. The second mother was advised by her paediatrician to try different infant formulae (Isomil, Novolac) for one week (during the period between visit 2 and visit 3) to attempt to alleviate the infant's constipation. The third mother mixed (at visit 3) the

powdered infant cereal with reconstituted NAN 1®, but continued to give NAN Pelargon® per feeding bottle.

3.4.3 Introduction of Water and Complementary Feeds

Mothers were asked about their infants' intake of complementary foods during the preceding 24 hours to visit 3. A total of 124 (82%) infants [57 (76%) male infants and 67 (88%) female infants respectively] were exclusively formula fed. There was a significant difference (Fisher exact, one-tailed test) between the proportion male and female infants ($p = 0.04$) who were exclusively formula fed.⁶⁶ The remainder ($N = 27$, 18%) was given water, water with sugar and/or complementary feeds (Table 3.10). For the purpose of the study rooibos tea was regarded as water since the one infant who received rooibos tea, had no sugar or milk added to it.

Various additional fluids and complementary feeds ranging from water, water with added sugar, rooibos tea and a variety of commercial infant and home made cereals were introduced to 27 (18%) predominantly male ($N = 18$) infants. Altogether 21 (14%) infants received water, 14 of whom received only water in addition to formula milk. Complementary feeds were given to 12 (8%) infants (Table 3.10).

A small number of mothers ($N = 5$, 3%) gave their infants commercial infant cereal ($N = 3$, 2%) or water ($N = 2$, 1%) once before visit 3 but had stopped and they gave only infant formula at the time of the third visit. Only four (3%) mothers explained that a relative gave their infants fluids ($N = 2$) or complementary feeds ($N = 2$) in the past. The mother of one of the infants, who received water from a relative, said that she gave water to the infant at the time of visit 3. The addition of fluids or complementary feeds to the other three infants' intake had stopped and they were reportedly exclusively formula fed at the time of the 24 hour recall (Table 3.10).

Table 3.10: Frequency of infant formula, other fluids and complementary feeds given to infants by gender at 10 weeks of age

Type of feed	Total		Male (N = 75)		Female (N = 76)	
	Number	%	Number	%	Number	%
Formula only	124	82.1	57	76.0	67	88.2
Formula and other liquids/Complementary Feeds						
Formula, water	14	9.3	9	12.0	5	6.6
Formula, water, sugar	1	0.7	1	1.3		
Formula, water, sugar, CF ^a	2	1.3	1	1.3	1	1.3
Formula, water, CF ^a	4	2.6	4	5.3		
Formula, CF ^a	6	4.0	3	4.0	3	4.0
Total	151	100	75	100	76	100
Summary of Complementary Feeds						
Commercial cereal (e.g. Cream of maize, Cerelac)	8	5.3	6	8	2	2.6
Maize meal porridge	2	1.3			2	2.6
Purity	1	0.7	1	1.3		
Others (e.g. fruits, yogurt)	1	0.7	1	1.3		
Subtotal	12		8		4	

^aCF = complementary feeds

Altogether 21 (14%) infants received water, three of whom had sugar added to the water. Predominantly male infants (eight of the 12) received complementary feeds (Table 3.10 and Figure 3.4).

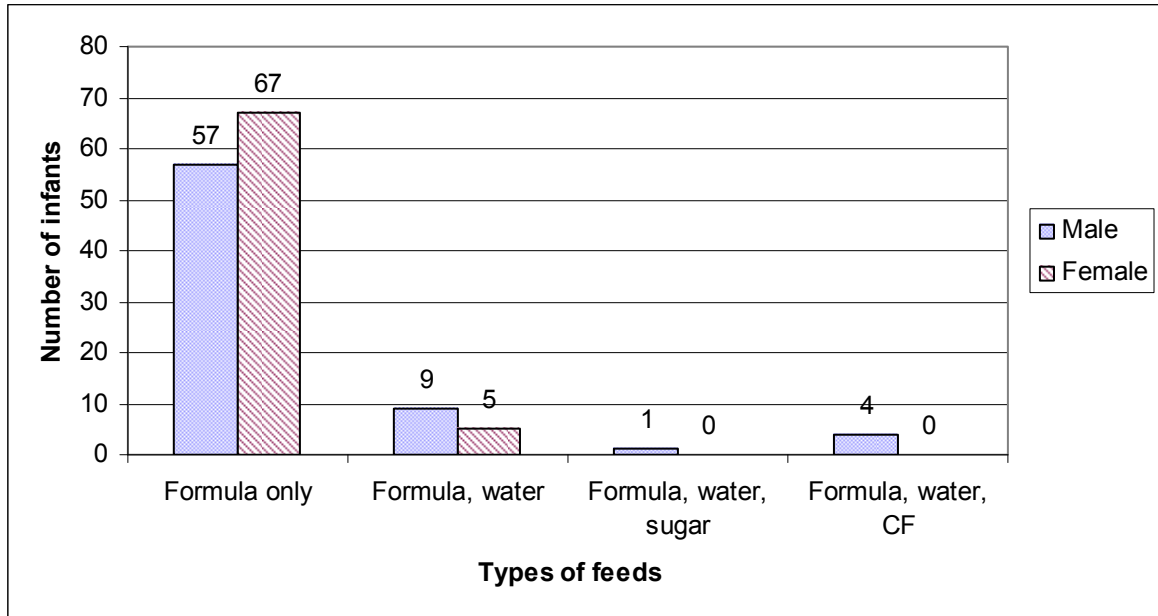


Figure 3.4: Summary of types of feeds given to infants

CF = complementary feeds (any food or fluids, whether manufactured or locally prepared, given to an infant in addition to infant formula)

3.5 DIETARY INTAKE

3.5.1 Exclusively Formula-Fed Infants

According to the feeding table on the label of the commercial infant formula, NAN Pelargon®, issued to the mothers, the following number of scoops and grammes of powder and energy intake per day is recommended (Table 3.11).

Table 3.11: Recommended amount of powder and daily energy intake according to NAN Pelargon® feeding table

Age of infant	Recommended number of measuring scoops to be used daily	Powder per day (gram)	Energy value kJ (kCal)	DRI ^a kJ (kCal)	
				Male	Female
1- 2 weeks	24	86.4	1841.7 (440.6)	2394 (570)	2184 (520)
3 – 4 weeks	25	90	1918.6 (459.0)	2394 (570)	2184 (520)
1 month	30	108	2302.3 (550.8)	2394 (570)	2184 (520)
2 - 3 months	35	126	2686.1 (642.6)	2394 (570)	2184 (520)

^a Dietary reference intake

Table 1.4 (Chapter 1, section 1.5.2) has provided an illustration of how the recommended intake of NAN Pelargon® formula of male and female infants deviated from that of the Dietary Reference Intakes (DRIs) [using the Adequate Intake (AI) component for energy and all the macronutrients and including comparison with the RDA for protein].⁵⁹ Since the age of the infants at visit 1 was 15 (SD 5) days (\pm two weeks) (Table 3.4), the recommendation of 1841.7 kJ (440.6 kcal) was used to compare the adequacy or lack thereof in relation to the AI.⁵⁹ At visit 2, the mean age of infants was 43 (SD 8) days (\pm six weeks or one and a half months), therefore the recommendation for a one month old infant, i.e. 2302.3 kJ (550.8 kcal) was used. At visit 3, the mean age of infants was 71 (SD 10) days (\pm 10 weeks or two and a half months), allowing for use of the recommendation of 2686.1 kJ (642.6 kcal).

Dietary intakes ($N = 138$) of exclusively formula fed infants were compared to the AI⁵⁹ of 1.52 g/kg/day as the minimum daily protein intake (Figure 3.5 and Figure 3.6). The remainder of the 151 infants (i.e. nine male and four female infants) were not included in this summary since they were not exclusively formula fed. Only a few infants (one male and four female infants at visit 1, one male and one female infant at

visit 2 and five male infants and one female infant at visit 3) consumed less protein than the AI⁵⁹ of 1.52 g/kg/day for infants up to six months of age (Figures 3.5 and 3.6). The majority of infants consumed more than 2 g of protein per kg per day throughout the course of the study. The number of infants with protein intakes in excess of 3.5 g/kg/day was notable: 29 (21%) at visit 1, 48 (35%) at visit 2 and 37 (27%) at visit 3.

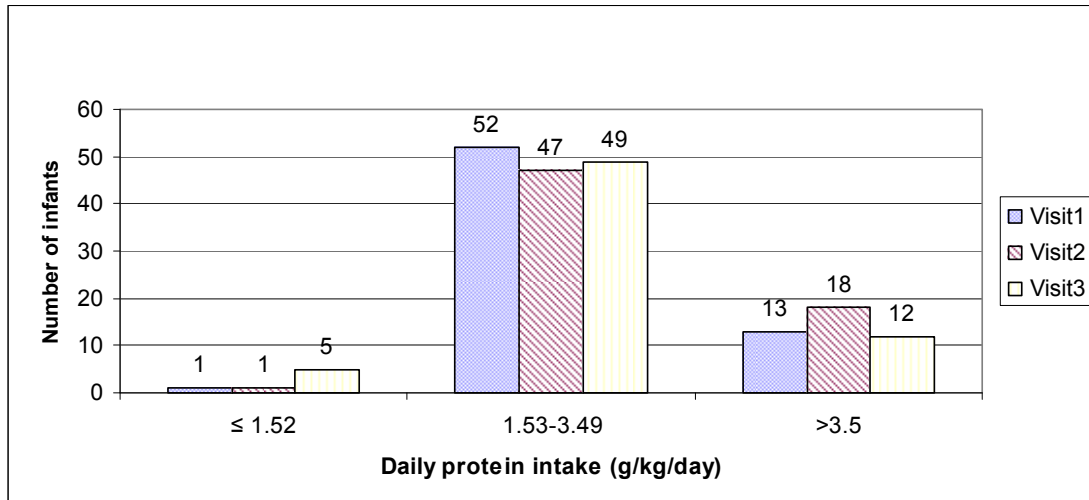


Figure 3.5: Protein intake of exclusively formula fed male infants (N = 66)^a

^a Only 66 male infants were exclusively formula fed, 1 male infant received sugar in addition to water and formula milk and 8 male infants received complementary feeds in addition to formula milk

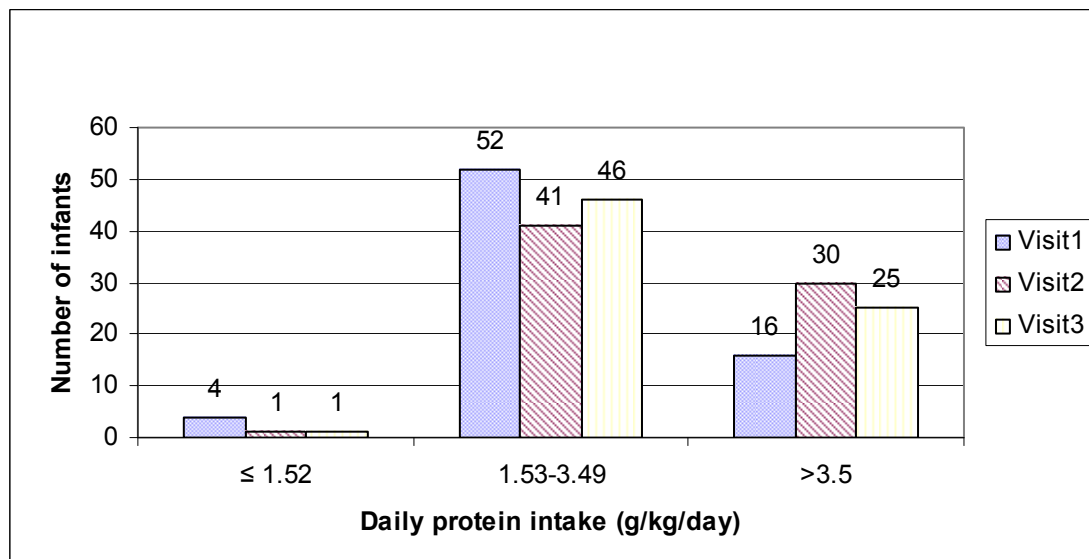


Figure 3.6: Protein intake of exclusively formula fed female infants (N = 72)^a

^a Only 72 female infants were exclusively formula fed, the remaining 4 received complementary feeds in addition to formula milk

3.5.2 Dietary Intake of All Infants

The dietary intake of all infants included in the study (including both exclusively formula fed infants and infants who received complementary feeds) indicated that the majority of males ($N = 65$, 87%) and females ($N = 61$, 80%) had a lower energy intake than the recommended during their first two weeks of life, at visit 1. The number of infants who consumed less energy than the AI, decreased at visit 2 (34 male infants and 22 female infants) and at visit 3 (19 male infants and 13 female infants) (Figure 3.7). More than half of the male and female infants consumed more than the AI for energy at both visit 2 and visit 3. There was no significant difference (Fisher exact, one-tailed test) between males and females' energy intake at visit 1 ($p = 0.20$) and visit 3 ($p = 0.15$), however there was a significant difference ($p = 0.03$) between males and females' energy intake at visit 2.⁶⁶

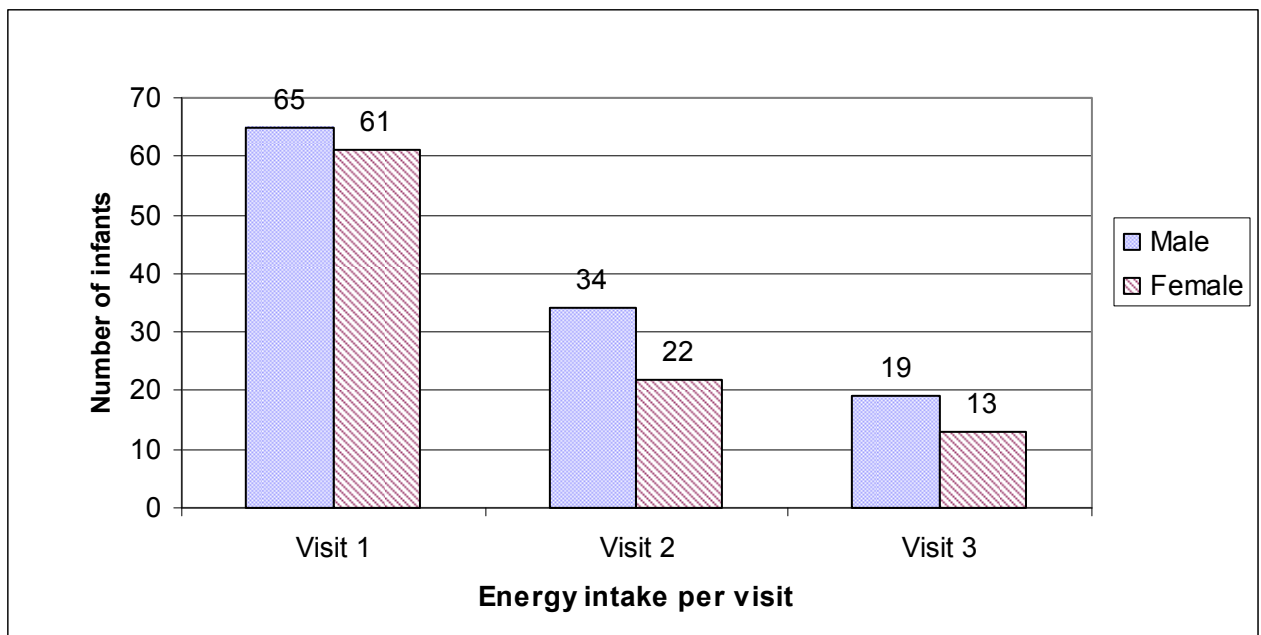


Figure 3.7: Number of infants with energy intakes below the AI⁵⁹ according to visit ($N = 151$)

A total of 33 (44%) male and 41 (54%) females had a protein intake below the recommendation at visit 1 but the protein consumption improved at visit 2 and 3; only 7 (9%) males and 5 (67%) females consumed too little protein at both visits 1 and 2 (Figure 3.8). There was no significant difference (Fisher exact, one-tailed test) between males and females' protein intake at visit 1 ($p = 0.15$), visit 2 ($p = 0.37$) and visit 3 ($p = 0.37$).⁶⁶

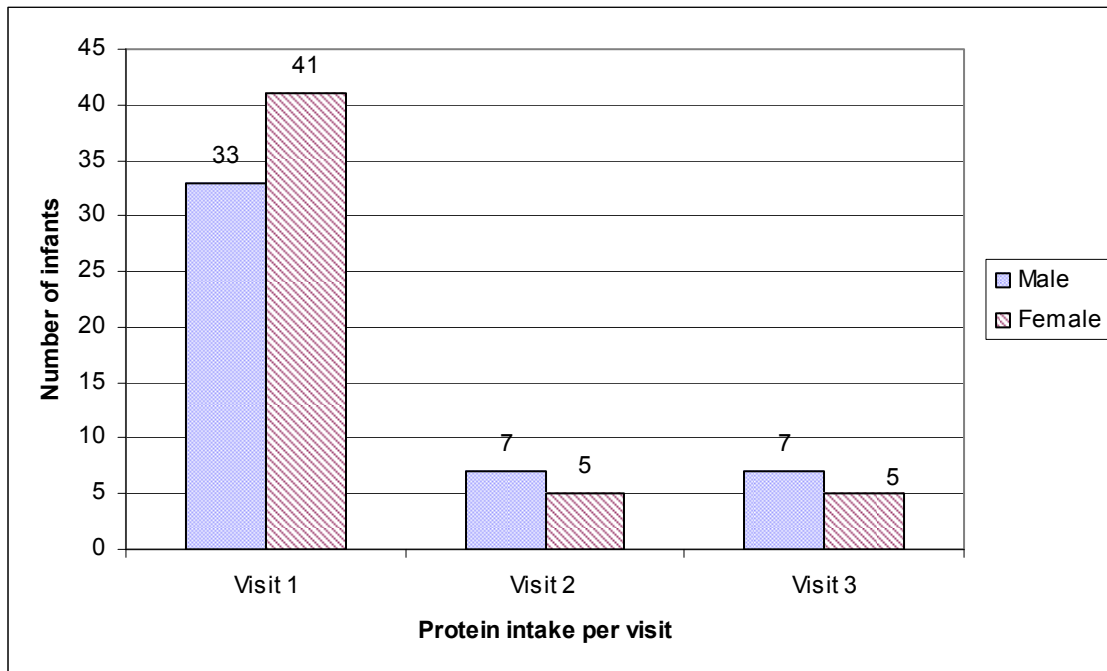


Figure 3.8: Number of infants with protein intakes below RDA (9.1 g/d)⁵⁹ at each visit (N = 151)^a

^a At visit 1 a total of 33 male infants and 41 female infants had a protein intake below the RDA of 9.1g/d. The number of infants with protein intakes below the RDA dropped to 7 male infants and 5 female infants at both visits 2 and 3.

More than 80% of both males ($N = 63$) and females ($N = 61$) consumed less than the AI for carbohydrate at visit 1. On average 31% of both male ($N = 24$) and female ($N = 23$) infants consumed too little carbohydrates at visit 2 and only 18% of both male ($N = 14$) and female ($N = 13$) infants consumed less carbohydrate than the recommended at visit 3. The carbohydrate consumption improved to such an extent so that male and female infants consumed on average 69% (at visit 2) and 82% (at visit 3) more carbohydrates than required (Figure 3.9). There was no significant

difference (Fisher exact, one-tailed test) between males and females' carbohydrate intake at visit 1 ($p = 0.35$), visit 2 ($p = 0.49$) and visit 3 ($p = 0.48$).⁶⁶

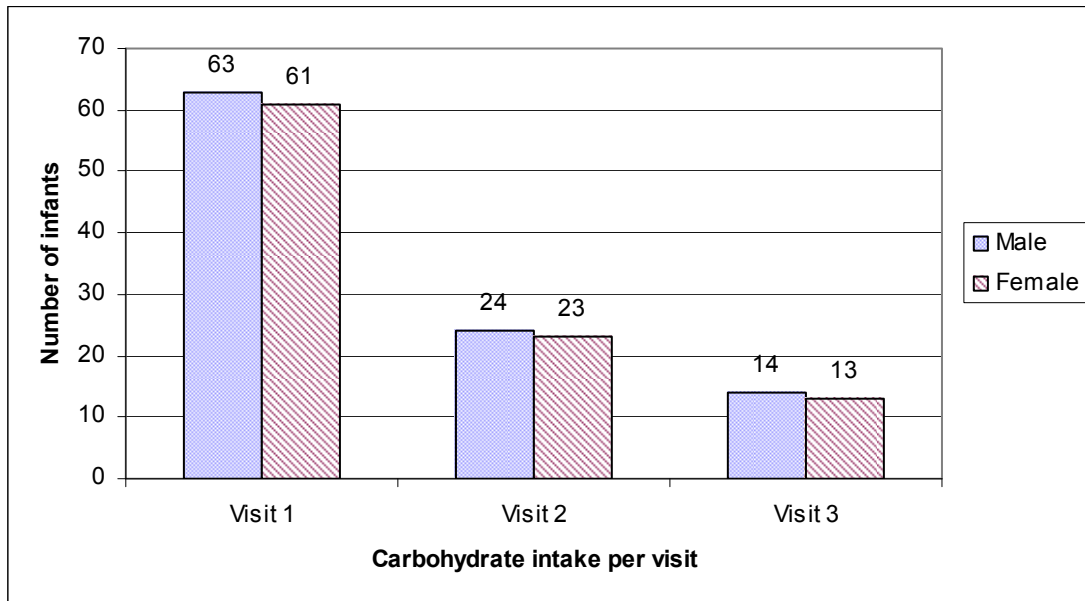


Figure 3.9: Number of infants with carbohydrate intakes below AI (60 g/d)⁵⁹ at each visit (N = 151)^a

^a At visit 1 a total of 63 male and 61 female infants had a carbohydrate intake below the AI of 60 g/d. The number of infants with protein intakes below the AI dropped to 24 male infants and 23 female infants at visit 2 and 14 male infants and 13 female infants at visit 3.

Of all the macronutrients, fats were consumed the least by both males ($N = 67$, 89%) and females ($N = 66$, 87%) at visit 1. At visit 2 the number of infants who had a fat intake above and below the recommendation were similar, but at visit 3 the number of infants with a fat intake below the recommendation, decreased to 22 (29%) and 26 (35%) for male and female infants respectively (Figure 3.10). There was no significant difference (Fisher exact, one-tailed test) between males and females' fat intake at visit 1 ($p = 0.41$), visit 2 ($p = 0.53$) and visit 3 ($p = 0.32$).⁶⁶

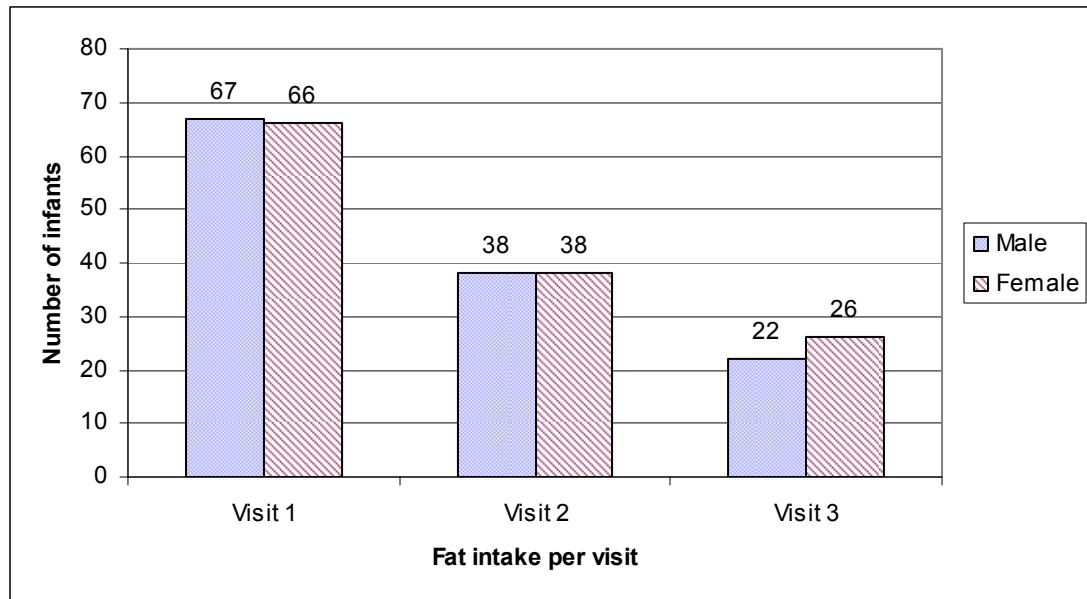


Figure 3.10: Number of infants with fat intakes below AI (31 g/d)⁵⁹ at each visit ($N = 151$)

3.6 ANTHROPOMETRY

3.6.1 Reproducibility of Anthropometrical Data

The reproducibility data (i.e. duplicate data gathered from every 10th measurement of weight, length and head circumference by the investigator and a registered dietitian with no involvement in the study) revealed no significant differences (t-test for paired samples) between the measurements for weight ($p = 1.00$), length ($p = 0.97$) and head circumference ($p = 0.89$).⁶⁹

3.6.2 Changes in Weight of Infants

For the purpose of the study the baseline weight was considered as the weight at visit 1, not birth weight, due to the fact that anthropometric measurements at birth were not taken by the investigator. The investigator started data collection from visit 1 onwards when the mean age of infants was 15 (SD 5) days. The mean weight gain of all ($N = 151$) infants from visit 1 (aged two weeks) to visit 2 (aged six weeks) was 1.22 (SD 0.3) kg. From visit 2 to visit 3 (aged 10 weeks) the mean weight gain of infants was 0.91 (SD 0.3) kg. The changes in weight between the ages two and 10

weeks on the 50th percentile points of the CDC 2000³ standards were taken as the reference value for comparison. The weight change of the sample was greater than the differences between weights at age 10 weeks and age two weeks of the 50th CDC 2000³ growth curve (Table 3.12). There was a significant difference (repeated measures ANOVA) in weight gain between males and females at age two to six weeks ($p = 0.005$) and at age six to ten weeks ($p = 0.002$).⁶⁶

Table 3.12: Mean weight gain of infants from 1st to 2nd visit and 2nd to 3rd visit in comparison to CDC 2000 growth charts³

Age range (weeks)	Weight gain (kg)						p – value ^d
	CDC 2000 ³	Male		CDC 2000 ³	Female		
		Mean	SD ^a		Mean	SD ^a	
Two to six	0.88 ^b	1.3	0.31	0.74 ^b	1.2	0.3	0.005
Six to ten	0.79 ^b	0.98	0.30	0.69 ^b	0.8	0.3	0.002
p – value ^c		< 0.0001			< 0.0001		

^a Standard deviation

^b The difference between the weights of males and females at ages two to six weeks and six weeks to 10 weeks and the 50th percentile on the CDC 2000 growth charts³

^c T-test⁶⁹ for dependent samples within the age range

^d Analysis of variance (ANOVA)⁶⁶ within the gender class

In contrast to the mean weight gain, the distribution of weight gain of infants revealed poorer results for a minority of infants. During the period between the first and second visit, five male infants and four female infants (6% combined) gained less weight than the CDC 2000³ reference weight gain of 0.88 kg for male infants and 0.74 kg for female infants respectively. The prevalence of poor weight gain increased during the period between the second and third visit, where 18 male infants and 22 female infants (26% combined) gained less weight than the reference 0.79 kg for male infants and 0.69 kg for female infants respectively (Table 3.13).

Table 3.13: Frequency of infants who failed to achieve recommended weight gain from Visit 1 to Visit 3 (in comparison to CDC 2000 growth charts³)

Variable	Period							
	From two weeks (Visit 1) to six weeks (Visit 2)				From six weeks (Visit 2) to ten weeks (Visit 3)			
Gender	Male		Female		Male		Female	
CDC reference ³ weight gain (kg)	0.88		0.74		0.79		0.69	
Infants (<i>N</i> , %)	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%
with poor weight gain	5	6.7	4	5.3	18	24.0	22	28.9
% of total sample	6.0				26.5			

More female infants ($N = 22$, 29%) than male infants ($N = 18$, 24%, Repeated measures analysis of variance, $p = 0.998$) had a poor weight gain in the period between the second (aged six weeks) and third visits (aged 10 weeks), with a range of 0.2 to 1.7 kg for females and 0.3 to 1.6 kg for males. The difference between weight gain among the genders is significant with $p = 0.002$ and the difference between weight gain over the two periods are also significant with $p < 0.0001$. Of the four female infants who gained weight poorly from age two to six weeks, three continued to gain insufficient weight up to age 10 weeks, as compared to only one of the five male infants.

3.7 GROWTH OF INFANTS

3.7.1 Weight-for-age of Infants

At visit 1, most ($N = 82$, 54%) infants' weights were between the third and 25th percentiles of the CDC 2000 growth charts³, as opposed to 23% ($N = 34$) of infants at visit 2 and 15% ($N = 23$) at visit 3 respectively (Figure 3.11). The different shaded

areas of the graph represent the percentile categories. The numbers within the shaded areas represent the number of infants within that specific percentile category (Figures 3.11, 3.15 and 3.19). The numbers of infants were distributed fairly equally between the 25th and 50th percentiles: 41 (27%) infants at visit 1, 46 (31%) infants at visit 2 and 41 (27%) infants at visit 3. The distribution of the weights of infants between the 50th and 97th percentiles were characterised by large differences at visit 1 ($N = 10$, 7%), visit 2 ($N = 64$, 42%) and visit 3 ($N = 79$, 52%) respectively.

Regarding the extreme distributions, the weights of a total of 18 (12%) infants fell below the third percentile for weight-for-age at visit 1, as compared to six (4%) at visit 2 and four (3%) at visit 3. The number of infants with weights above the 97th percentile increased progressively from zero at visit 1, to one infant at visit 2 and to four (3%) infants at visit 3 (Figure 3.11 - 3.13). Altogether weights of 93% of infants were below the 50th percentile for weight-for-age at visit 1.

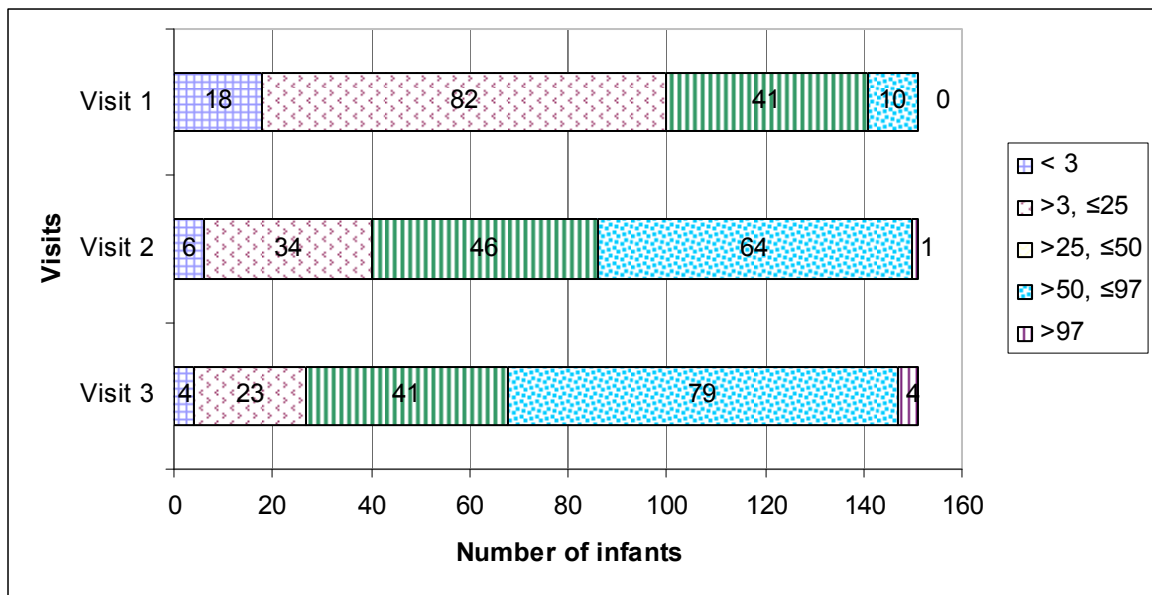


Figure 3.11: Distribution of infants according to weight-for-age percentiles of the CDC 2000 growth charts³ ($N = 151$)

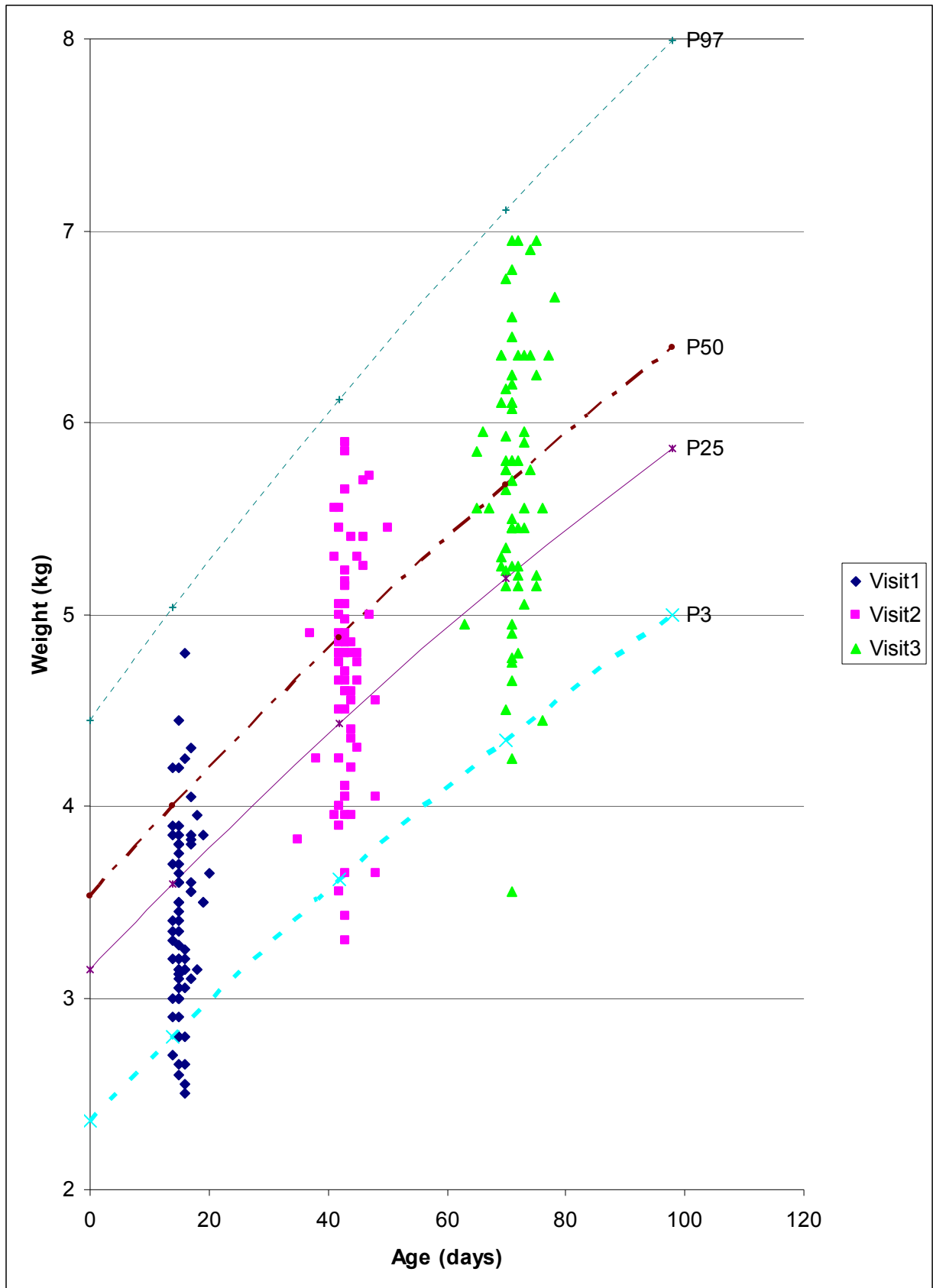


Figure 3.12: Weight-for-age distribution of male infants according to the CDC 2000 growth charts³ ($N = 75$)

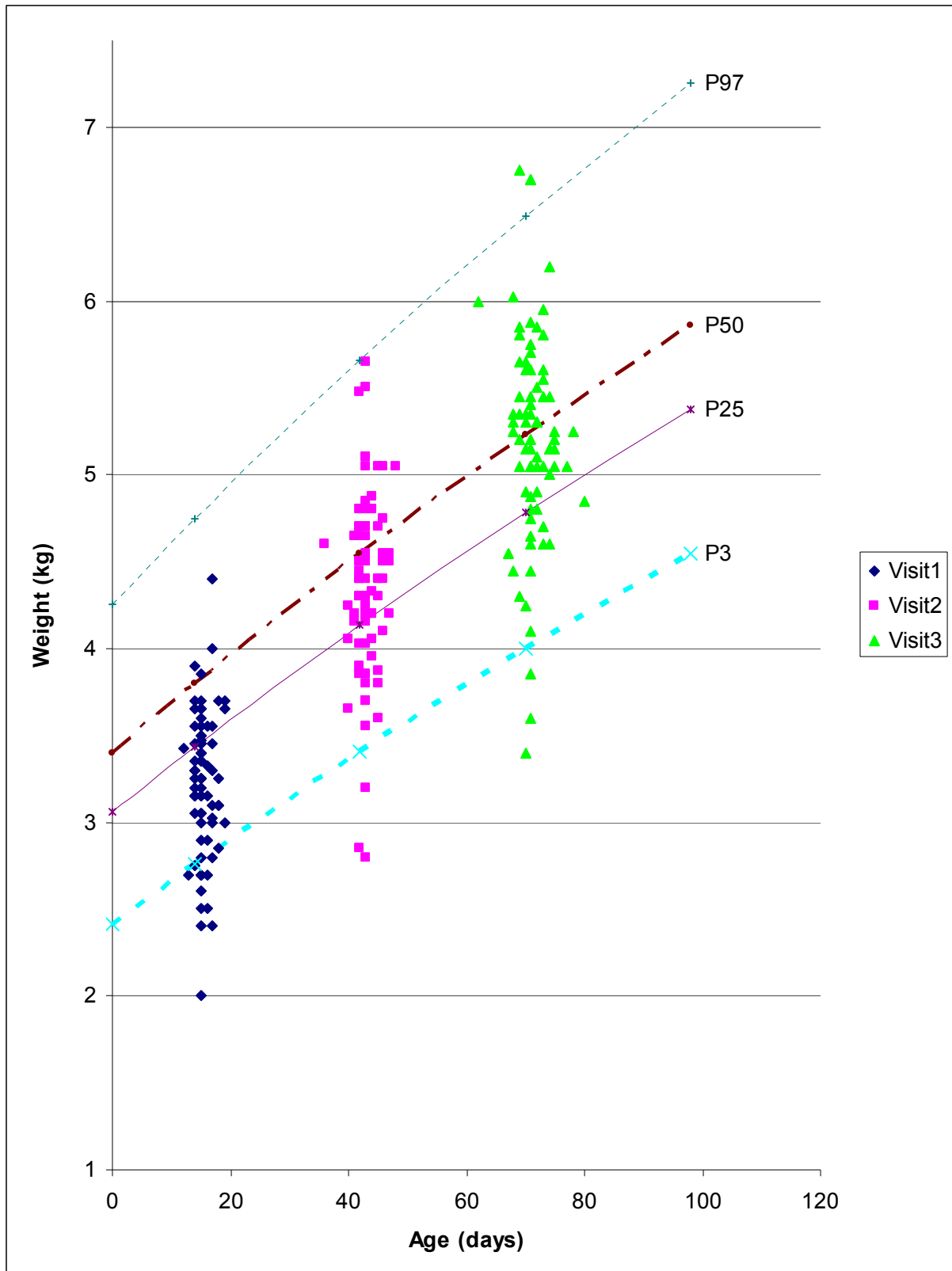


Figure 3.13: Weight-for-age distribution of female infants according to the CDC 2000 growth charts³ ($N = 76$)

From visit 1 to visit 2, 27% ($N = 40$) of infants followed the growth curve and gained weight steadily as opposed to 56% ($N = 84$) of infants who followed the growth curve from visit 2 to visit 3 (Table 3.14). From visit 1 to visit 2, 85 (56%) infants gained weight to such an extent that a major (either the 3rd, 25th, 50th or 97th) percentile was crossed (moved up), as opposed to 37 (25%) infants who gained weight and crossed a percentile from visit 2 to visit 3. Few infants lost weight and crossed a percentile (moved down) [one (1%) infant lost weight from visit 1 to visit 2 and three (2%) infants lost weight from visit 2 to visit 3]. From visit 1 to visit 2 four (3%) infants lost weight but no percentile was crossed, as opposed to 26 (17%) infants who lost weight from visit 2 to visit 3 without crossing a percentile.

Only 23 (15%) infants followed their growth curve for weight-for-age from visit 1 up to visit 3.

Table 3.14: Adherence and shifts in percentiles: Weight-for-age from Visit 1 to Visit 2, and Visit 2 to Visit 3 ($N = 151$)

Weight-for-age	Visit 1 to Visit 2		Visit 2 to Visit 3	
	<i>N</i>	%	<i>N</i>	%
Followed growth curve	40	26.5	83	55.0
Moved up 1 percentile	85	56.3	37	24.5
Moved up 2 percentiles	21	13.9	1	0.7
Moved down 1 percentile	1	0.7	4	2.6
Moved down 2 percentiles	0	0	0	0
Weight loss, no crossing of percentile	4	2.6	26	17.2
Total	151		151	

Relatively few infants remained on their growth curve from age two weeks (visit 1) to age six weeks (visit 2) with regards to their weight-for-age measurement: 5 (3%) infants remained below the 3rd percentile, 23 (15%) infants remained between the 3rd and 25th percentiles, 5 (3%) infants remained between the 25th and 50th percentiles and 10 (7%) infants remained between the 50th and 97th percentiles.

The number of infants who remained on their growth curve from age six weeks (visit 2) to age ten weeks (visit 3) with regards to their weight-for-age measurement, was more than double ($N = 92, 61\%$) the number of infants who remained on their growth curve for the corresponding visits ($N = 43, 29\%$).

The mean percentile for weight-for-age at visit 1 was the 29th percentile with a fairly narrow confidence interval (CI, 17.8-23.7) and increased to around the 45th percentile at visit 2 with a wider confidence interval (CI, 41.1-49.6). The mean percentile at visit 3 ended at the 55th percentile (CI, 50.7-59.4). There was a steeper increase in mean weight-for-age percentile distribution from visit 1 to visit 2 than from visit 2 to visit 3. The wider confidence interval at visit 2 and visit 3, as compared to the narrower confidence interval at visit 1, indicated a greater variation in the sample as time went by (Figure 3.14).

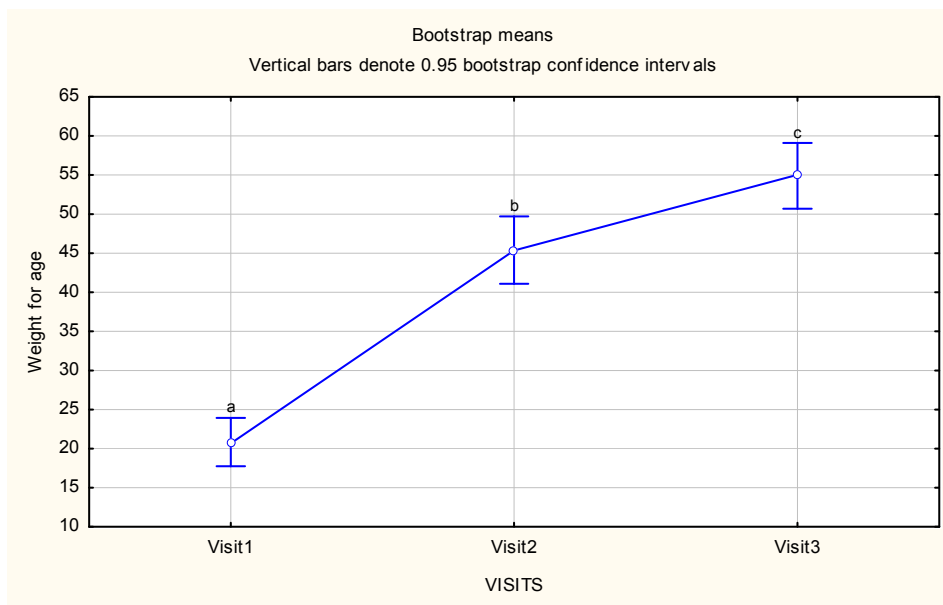


Figure 3.14: Mean percentile distribution for weight-for-age of all infants at each visit ($N = 151$)

Non-parametric bootstrap⁷² method used to calculate significant differences between visits; $p = 0.00$

a, b, c Vertical bars denote 0.95 bootstrap⁷² confidence intervals

3.7.2 Length-for-age of Infants

The comparison of length-for-age included the measurements taken at visit 1 and visit 3, since as per protocol length was not measured at visit 2. Most ($N = 53, 35\%$) infants' lengths-for-age were between the third and 25th percentiles. The lengths-for-

age of the majority of infants were between the third and 97th percentiles at visit 1 ($N = 144$, 95%) as well as at visit 3 ($N = 143$, 95%) (Figure 3.15 - 3.17).

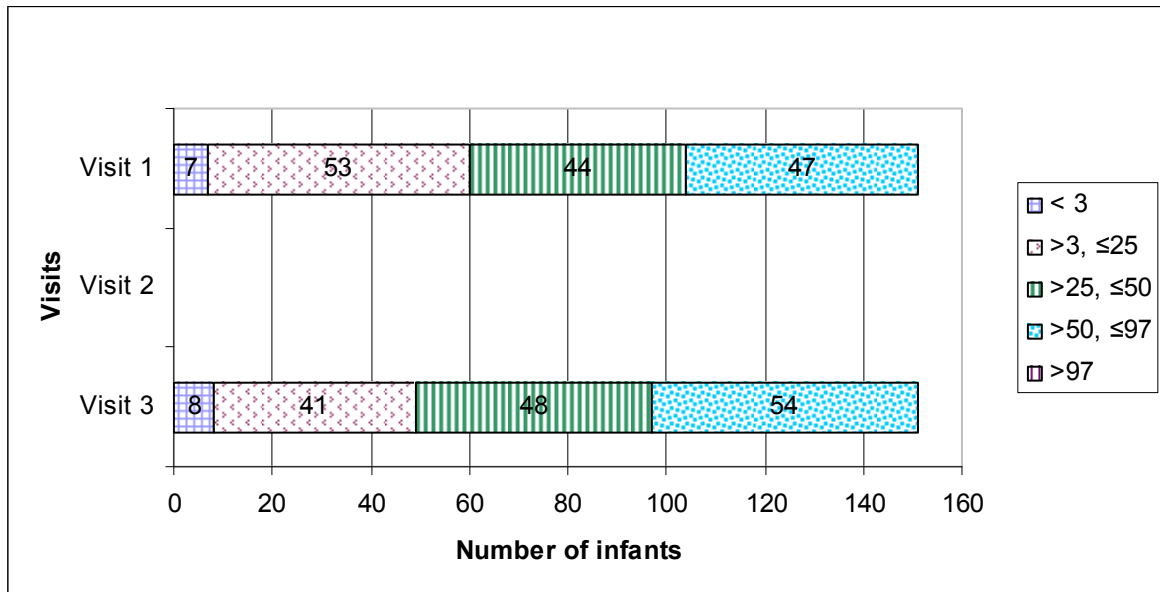


Figure 3.15: Distribution of the infants according to the length-for-age percentiles of the CDC 2000 growth charts³ ($N = 151$)

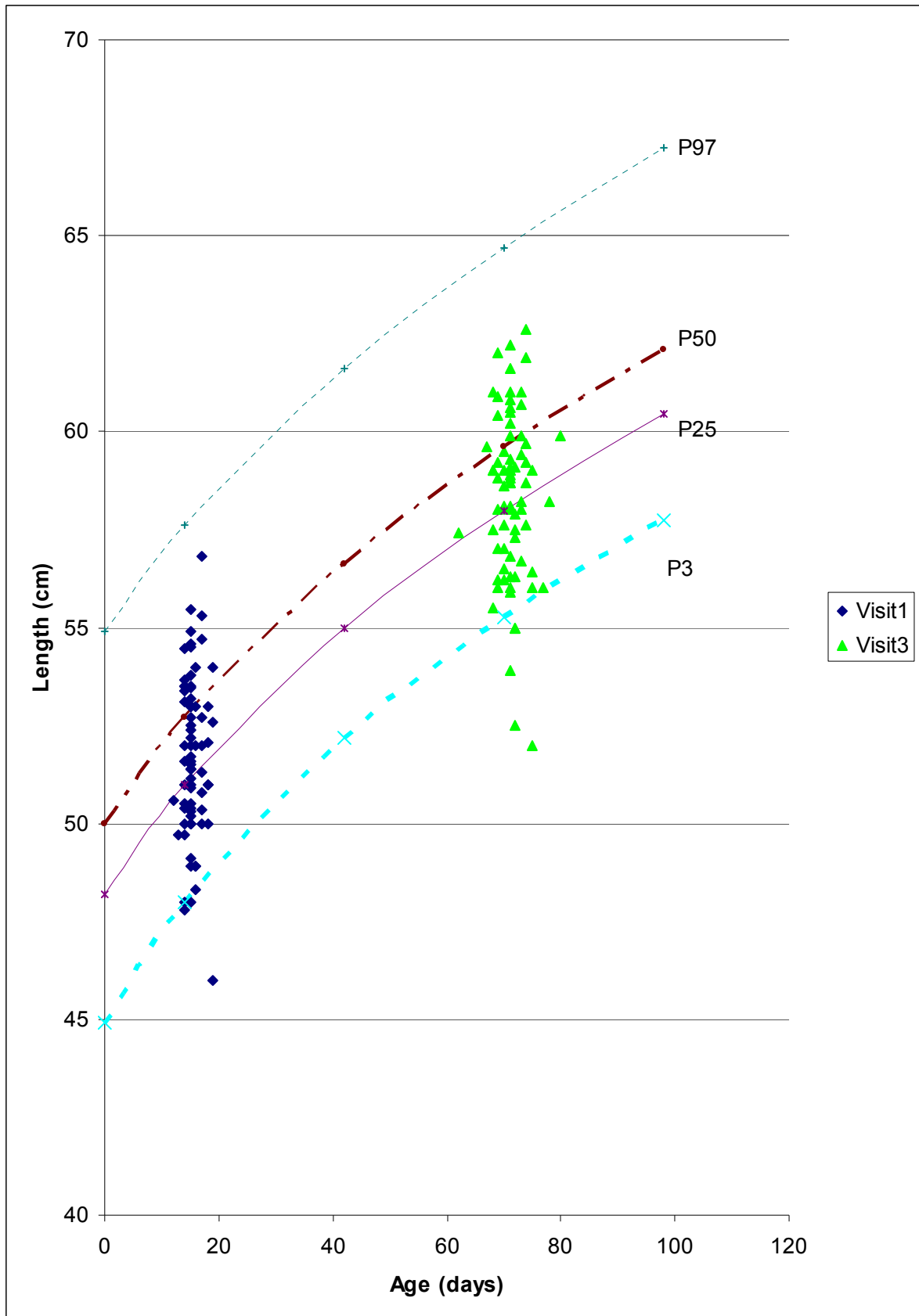


Figure 3.16: Length-for-age distribution of male infants according to the CDC 2000 growth charts³ ($N = 75$)

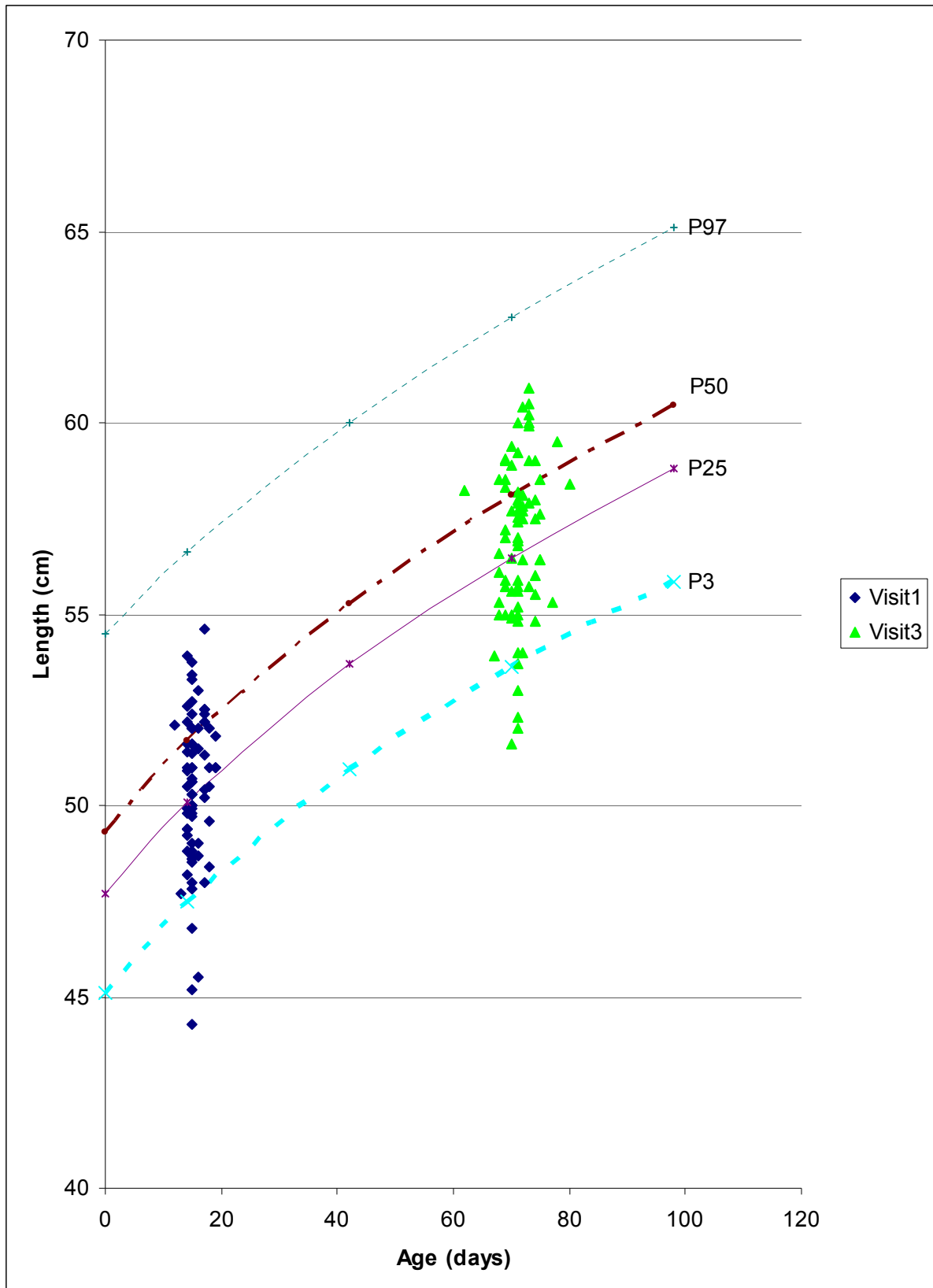


Figure 3.17: Length-for-age distribution of female infants according to the CDC 2000 growth charts³ ($N = 76$)

Although 57 (38%) infants followed the growth curve for length-for-age from visit 1 to visit 3, 20 (13%) infants' length deviated negatively from the growth curve for length-for-age (Table 3.15). A total of 18 (12%) infants moved down one percentile and two (1%) infants moved down two percentiles from visit 1 to visit 3. A total of 40 (27%) infants showed growth faltering with regards to length from visit 1 to visit 3 without crossing a percentile.

Table 3.15: Adherence and shifts in percentiles: Length-for-age from Visit 1 to Visit 3 (N = 151)

Length-for-age: two weeks (Visit 1) to ten weeks (Visit 3)	Number of infants (N)	Percentage (%)
Followed growth curve	57	37.7
Moved up 1 percentile	31	20.5
Moved up 2 percentiles	3	2.0
Moved down 1 percentile	18	11.9
Moved down 2 percentiles	2	1.3
No increase in length, no crossing of percentile	40	26.5
Total	151	

Only 4 (3%) infants' length-for-age measurements remained in the same percentile category from visit 1 up to visit 3 (i.e. percentile category below 3rd percentile), but more infants retained their percentile category in the following categories 3rd and 25th percentiles [31 (21%) infants], 25th and 50th percentiles [24 (16%) infants] and 50th and 97th percentiles [38 (25%) infants].

The mean percentile for length-for-age started at visit 1 on the 36th percentile with a fairly wide confidence interval (CI, 32.2-39.7) and increased to around the 41st percentile at visit 3 (CI, 36.8-44.9). The steep increase of the mean percentile length-for-age from visit 1 to visit 3 illustrated the significant difference between the mean percentile changes (non-parametric bootstrap method⁷², $p = 0.00013$) (Figure 3.18).

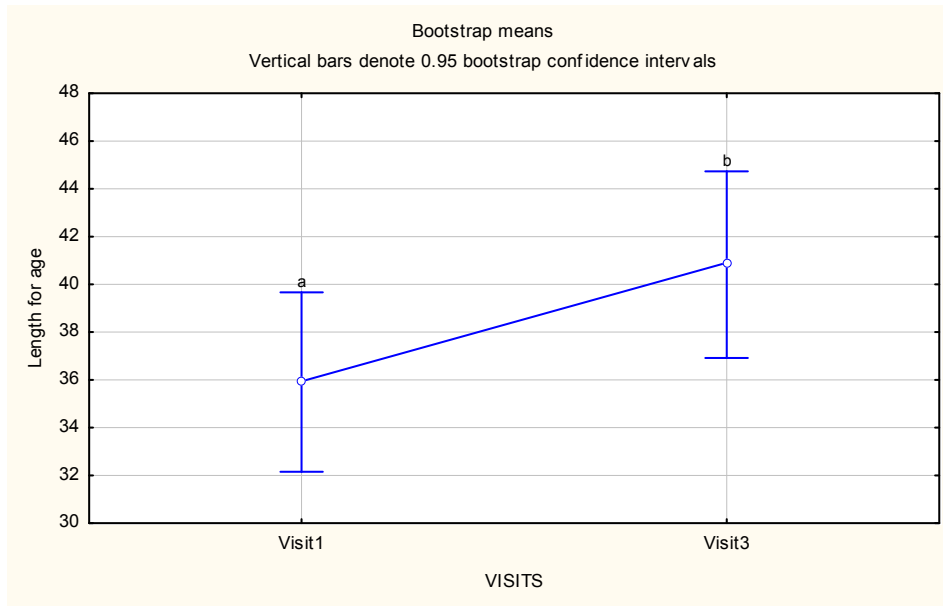


Figure 3.18: Mean percentile distribution for length-for-age of all infants at visit 1 and visit 3 ($N = 151$)

Non-parametric bootstrap⁷² method used to calculate significant differences between visits;

$p = 0.00013$

a, b, c Vertical bars denote 0.95 bootstrap⁷² confidence intervals

3.7.3 Weight-for-length of Infants

At visit 1, 18 (12% of total sample, 10 males and eight females) infants were wasted (weight-for-length below 3rd percentile) as opposed to only three stunted female infants at visit 3. Most infants ($N = 71$) had a weight-for-length between the third and 25 percentiles at visit 1, but at visit 3, the largest group of infants ($N = 91$) were categorised between the 50th and 97th percentiles, with 9 infants (6%) regarded as overweight (weight-for-length above 97th percentile) (Figure 3.19 – 3.21).

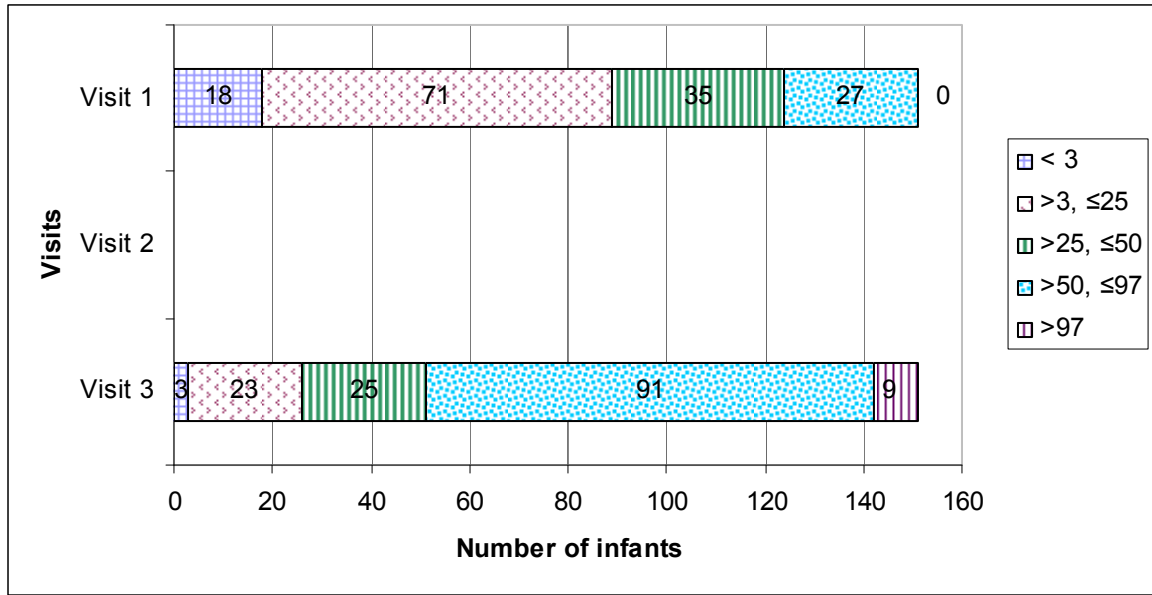


Figure 3.19: Distribution of infants according to the weight-for-length percentiles of the CDC 2000 growth charts³ (N = 151)

The weight-for-length distribution for male infants was predominantly concentrated under the 50th percentile at visit 1, whereas the weight-for-length distribution at visit 3 was concentrated on and around the 50th percentile. The distribution at visit 3 was more scattered so that it appeared as if there were male infants who were wasted at visit 3. The weight-for-length distribution for female infants appeared to overlap initially but separated according to visit 1 and visit 3. The distribution seemed to have been influenced by the length of infants, since the length-for-age distribution of infants was more discreet (Figure 3.16 and Figure 3.17).

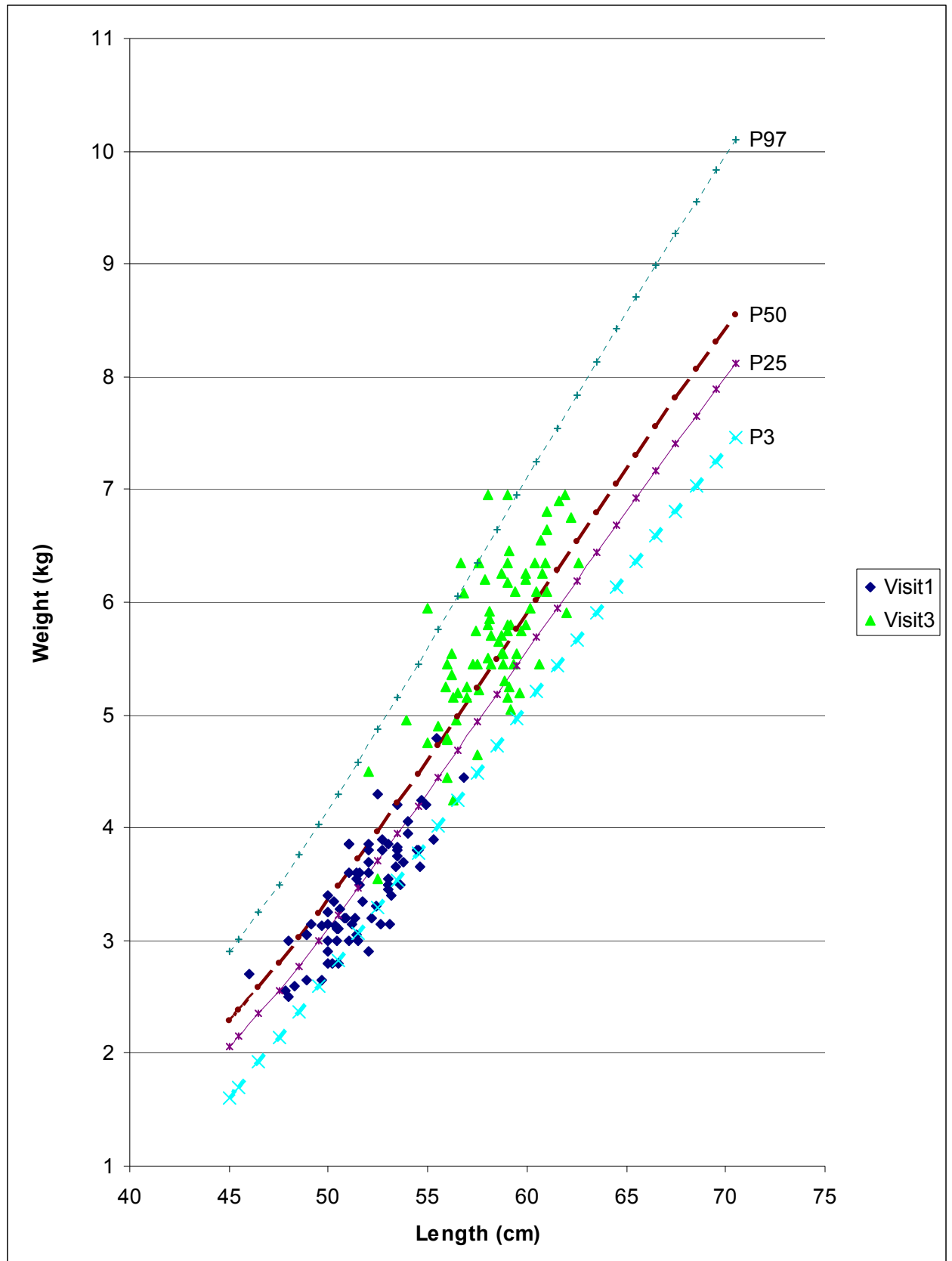


Figure 3.20: Weight-for-length distribution of male infants according to the CDC 2000 growth charts³ ($N = 75$)

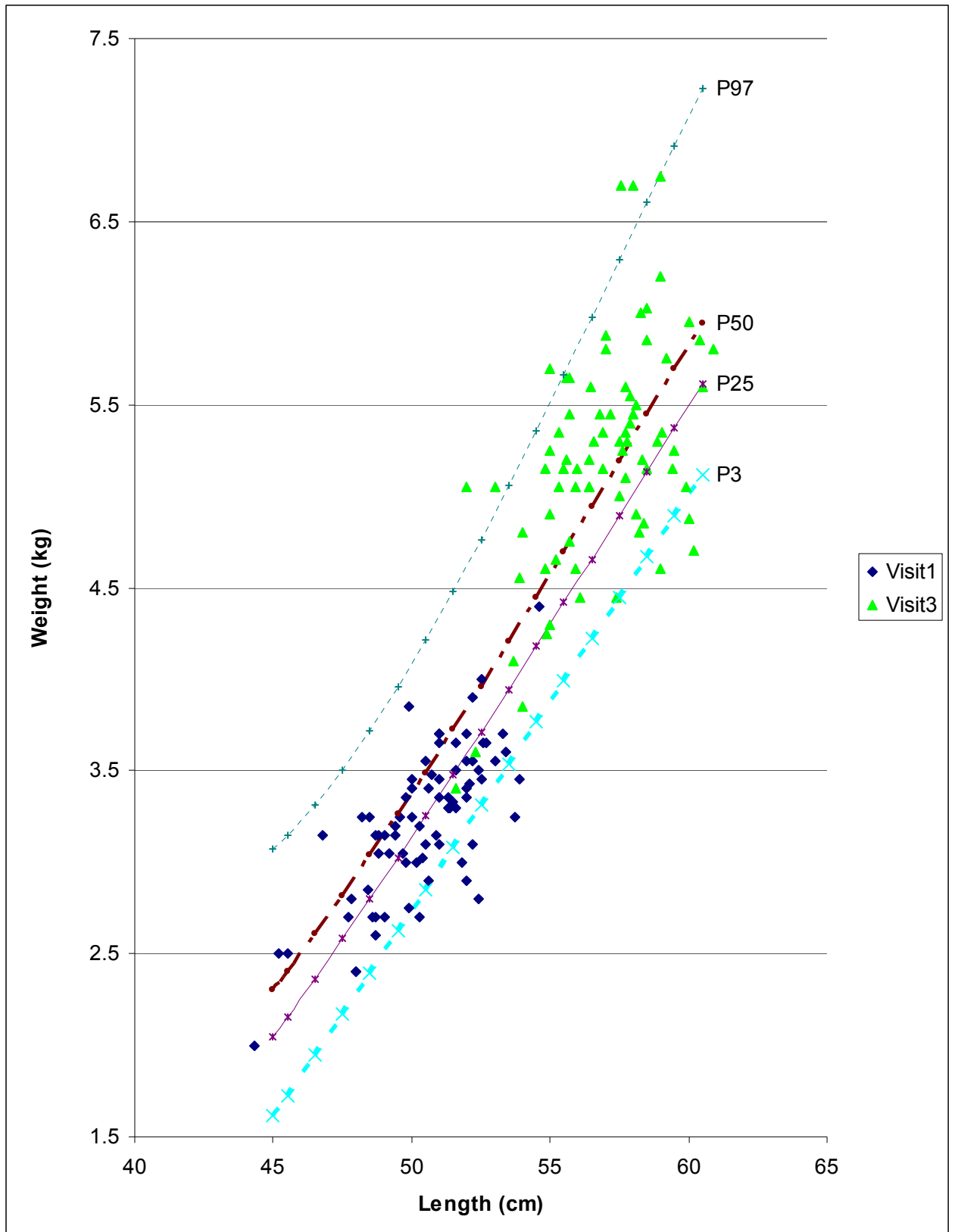


Figure 3.21: Weight-for-length distribution of female infants according to the CDC 2000 growth charts³ ($N = 76$)

With regards to the weight-for-length measurements, 14 (10%) and 17 (11%) infants remained in their respective initial percentile category namely between 3rd and 25th percentiles and between 50th and 97th percentiles from age two weeks to age ten weeks

The mean percentile for weight-for-length started at visit 1 from just above the 25th percentile with a fairly narrow confidence interval (CI, 22.0-29.2) and increased to around the 59th percentile at visit 3 with a wider confidence interval (CI, 54.8-64.1). The steep increase of weight-for-length mean percentile distribution from visit 1 to visit 3 depicts the significant difference between the mean percentile changes (non-parametric bootstrap method,⁷² $p = 0.00$) (Figure 3.22).

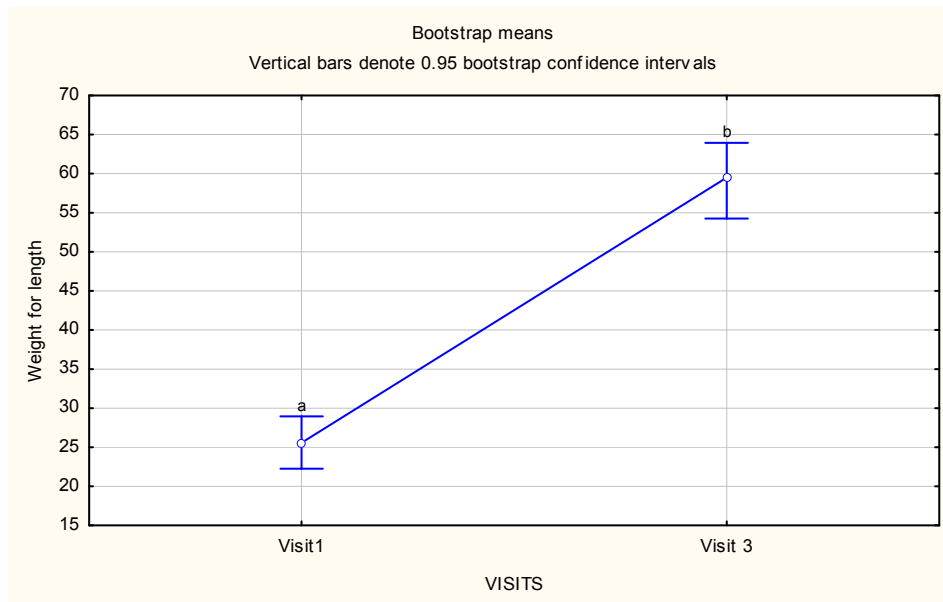


Figure 3.22: Mean percentile distribution weight-for-length of all infants at Visit 1 and Visit 3 (N = 151)

Non-parametric bootstrap⁷² method used to calculate significant differences between visits; $p = 0.00$

a, b, c Vertical bars denote 0.95 bootstrap⁷² confidence intervals

3.7.4 Head Circumference-for-age of Infants

The measurement of head circumference was taken only at visit 1 and visit 3 as per protocol. At visit 1, 50 (33%) infants had a head circumference above the 3rd percentile and below the 25th percentile. The head circumference of the majority (N = 146) of infants was between the third and 97th percentiles at visit 1 (N = 146) and at

visit 3 ($N = 149$). At visit 3, the largest group of infants ($N = 87$, 58%) was categorised between the 50th and 97th percentiles. The groups of infants that were categorised below the third percentile decreased from the first visit ($N = 5$) to the last visit ($N = 2$) (Figure 3.23 - 3.25).

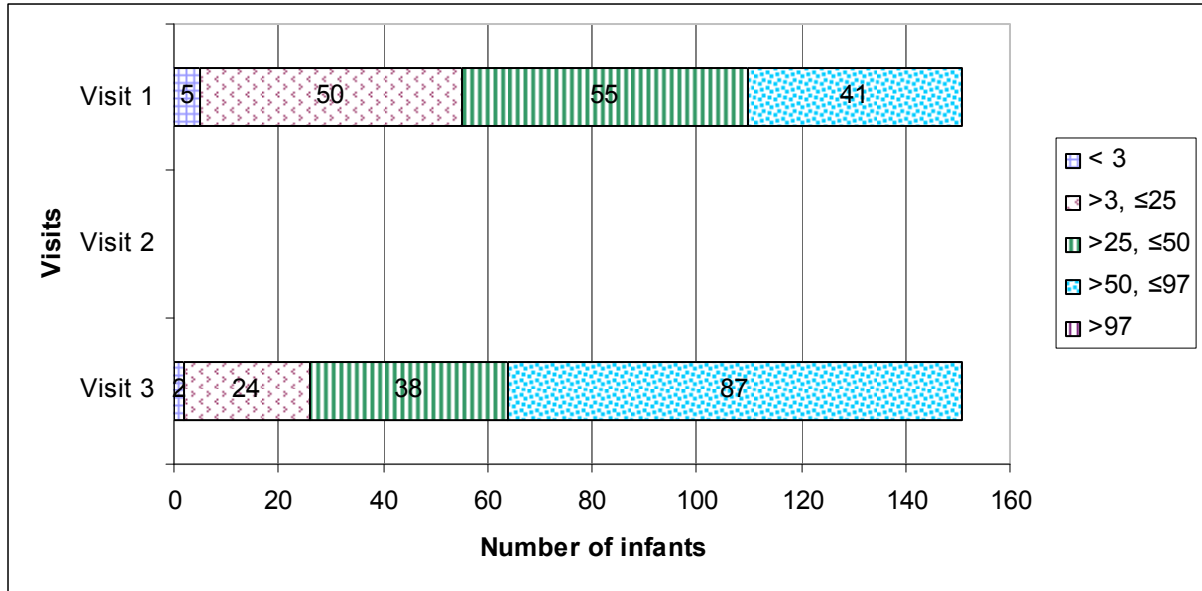


Figure 3.23: Distribution of infants according to the head circumference-for-age percentiles of the CDC 2000 growth charts³ ($N = 151$)

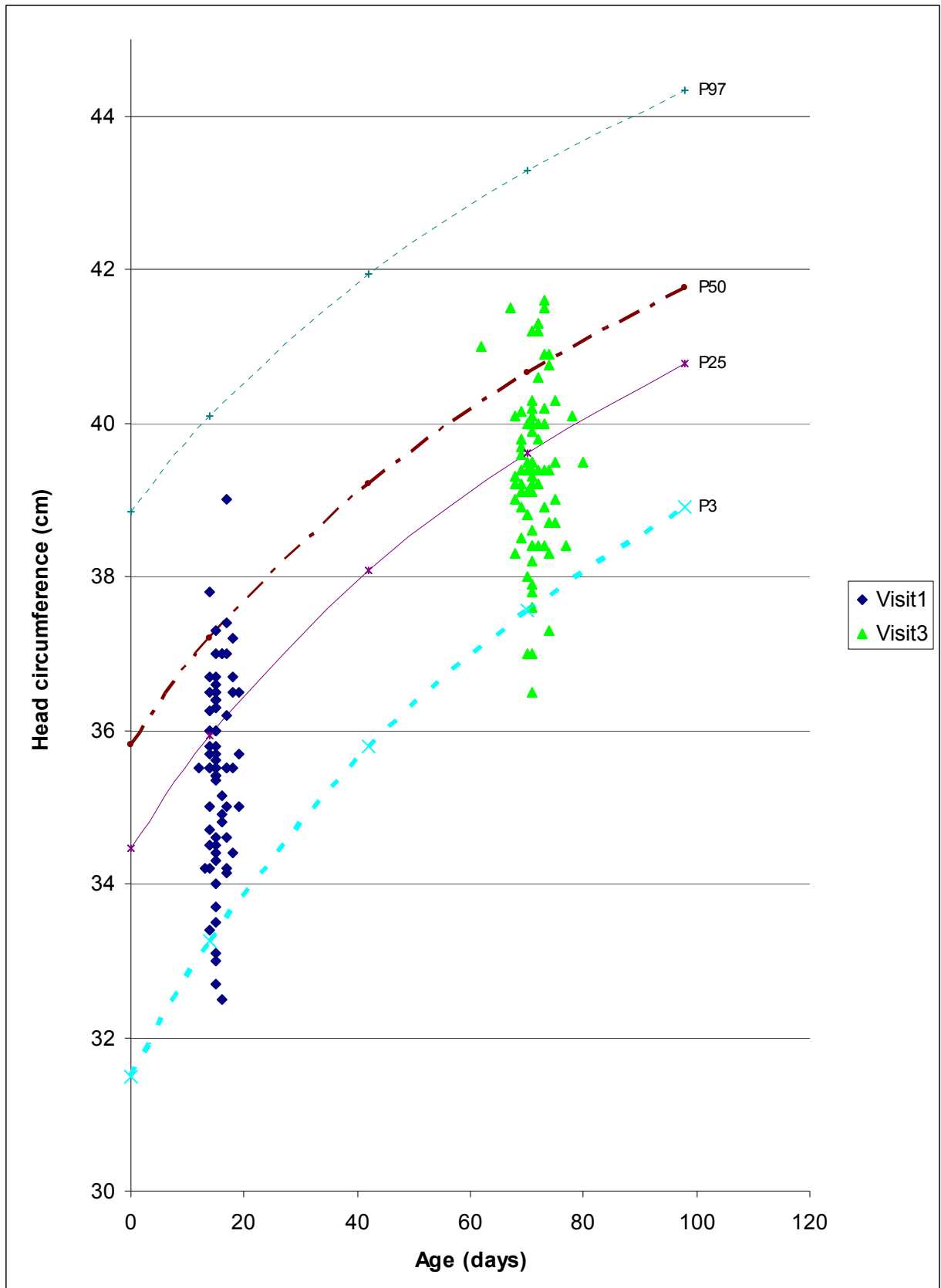


Figure 3.24: Head circumference-for-age distribution of male infants according to the CDC 2000 growth charts³ ($N = 75$)

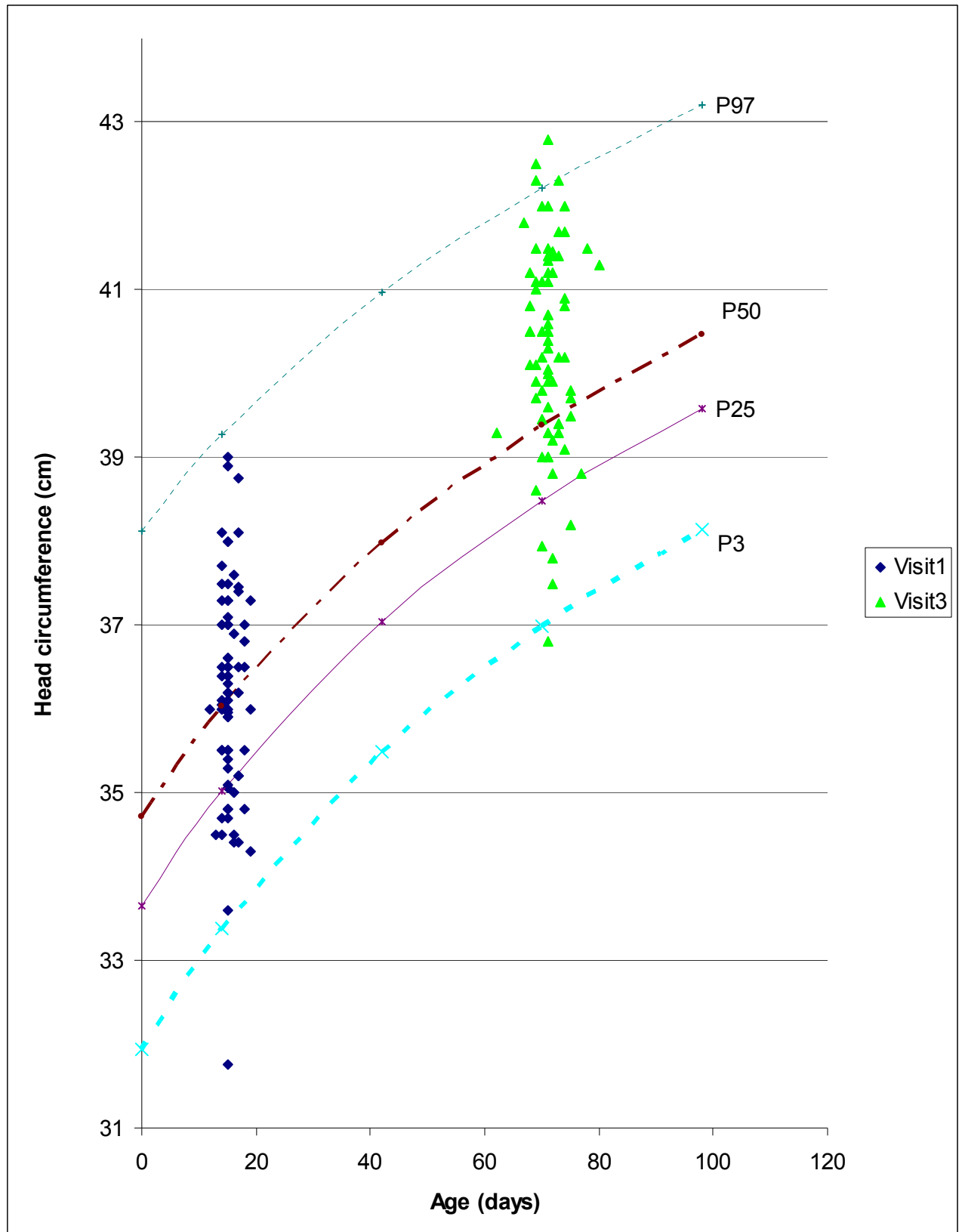


Figure 3.25: Head circumference-for-age distribution of female infants according to the CDC 2000 growth charts³ ($N = 76$)

A total of 58 (38%) infants followed the growth curve for head circumference-for-age from visit 1 up to visit 3 (Table 3.16). A greater number of infants' ($N = 73$, 48%) head circumference measurements increased from visit 1 to visit 3 so that up to two percentiles were moved up. Only five (3%) infants' head circumference measurements decreased and subsequently moved down a percentile, but 15 (10%) infants' head circumference measurements decreased from visit 1 to visit 3 without the crossing of a percentile.

Table 3.16: Adherence and shifts in percentiles: Head circumference-for-age from Visit 1 to Visit 3 ($N = 151$)

Head circumference-for-age: two weeks (Visit 1) to ten weeks (Visit 3)	Number of infants (N)	Percentage (%)
Followed growth curve	58	38.4
Moved up 1 percentile	64	42.4
Moved up 2 percentiles	9	6.0
Moved down 1 percentile	5	3.3
Moved down 2 percentiles	0	0
No increase in head circumference, no crossing of percentile	15	9.9
Total	151	

The head circumference of 73 (48%) remained in the same category; of which the majority of infants' (38, 25%) head circumference-for-age measurement was categorised between the 50th and 97th percentiles from visit 1 to visit 3.

The mean percentile for head circumference-for-age started at visit 1 on the 36th percentile with a fairly wide confidence interval (CI, 32.5-39.7) and increased to around the 52nd percentile at visit 3 (CI, 47.9-55.9). Once again the mean head circumference-for-age percentile showed a steep significant increase from visit 1 to visit 3 (non-parametric bootstrap method,⁷² $p = 0.00$) (Figure 3.26).

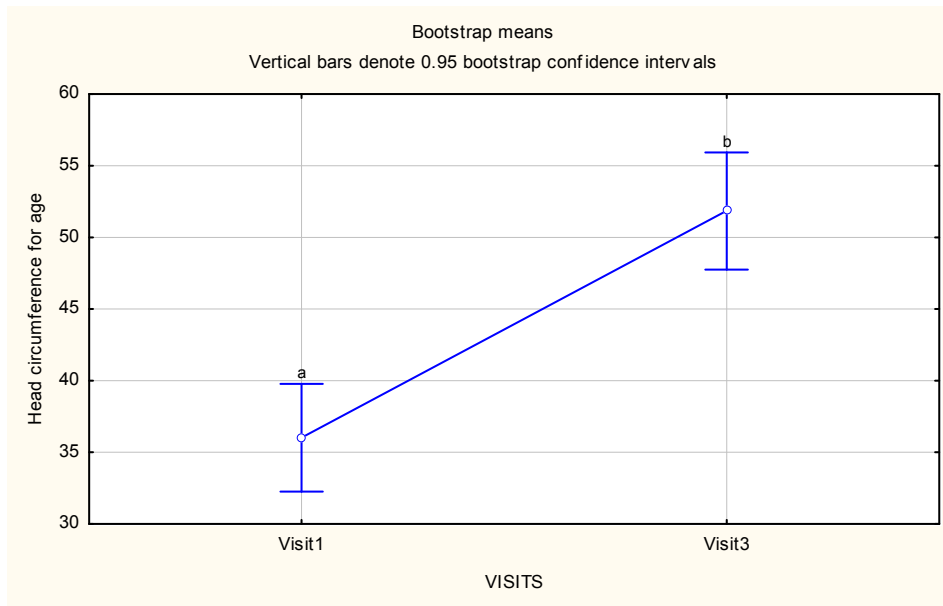


Figure 3.26: Mean percentile distribution for head circumference-for-age of all infants at Visit 1 and Visit 3 (N = 151)

Non-parametric bootstrap⁷² method used to calculate significant differences between visits; $p = 0.00$

a, b, c Vertical bars denote 0.95 bootstrap⁷² confidence intervals

3.7.4.1 Summary

Infants with weight-for-age, length-for-age and weight-for-length below the third percentile were classified as underweight, stunted and wasted respectively.

The percentage of underweight infants decreased from visit 1 (12%) to visit 2 (4%) to reach 2% at visit 3 (Table 3.15). During the 10 weeks of follow-up of infants, four infants (three females and one male) continued to be underweight (weight-for-age below the third percentile). Of the females only one infant consumed less energy (1752.3 kJ/d) than the recommended 2173.6 kJ/d (520 kCal/d). The infant formula was reconstituted correctly in all four instances. However, the male infant was reportedly given commercial infant cereal in addition to formula milk by the third visit, at which point total energy consumption had decreased from visit 2. The energy intake of the other two females was sufficient. The one male infant also consumed less energy (1726.8 kJ/d) than the recommended 2382.6 kJ/d (570 kCal/d).

The number of wasted infants (weight-for-length below third percentile) decreased from 12% at visit 1 to 2% at visit 3 (Table 3.17). Two female infants (other than those

found to be underweight) remained wasted (weight-for-length below the third percentile) throughout the follow-up period. Both infants consumed less than the recommended daily energy intake during the first two visits, but energy intake increased by visit 3. One of the infants' bottle feeds was reconstituted too concentrated.

The number of stunted infants (length-for-age below the third percentile) increased from seven (5% at visit 1) to eight (5% at visit 3) (Table 3.17). Only four infants (three females and one male) continued to have length-for-age below the third percentile throughout the study period. Most of the infants consumed too little energy initially, but energy intake increased as time went by. Infant formula was made too concentrated and diluted, respectively in two instances. The head circumference measurement of only five infants (3%) was below the third percentile as opposed to 2 (1%) infants at visit 3.

All of the above mentioned infants with growth faltering were reportedly exclusively formula fed, except one male infant.

A total of nine (6%) infants were overweight-for-length (weight-for-length above 97th percentile) at the third visit only.

Table 3.17: Distribution of anthropometric measurements of infants (N = 151) according to percentile categories

Visit	Measurement	Percentage	Percentiles				
			<3	3-25	25-50	50-97	>97
1	Weight-for-age	RF ^a	11.9	54.3	27.2	6.6	0
		CRF ^b	11.9	66.2	93.4	100	
	Length-for-age	RF	4.6	35.1	29.2	31.1	0
		CRF	4.6	39.7	68.9	100	
	Weight-for-length	RF	11.9	47.0	23.2	17.9	0
		CRF	11.9	58.7	82	100	
	HC ^c -for-age	RF	3.3	33.1	36.4	27.2	0
		CRF	3.3	36.4	72.8	100	
2	Weight-for-age	RF	4	22.5	30.5	42.3	0.7
		CRF	4	26.5	57	99.3	100
3	Weight-for-age	RF	2.6	15.3	27.1	52.4	2.6
		CRF	2.6	17.9	45	97.4	100
	Length-for-age	RF	5.3	27.2	31.7	35.8	0
		CRF	5.3	32.5	64.2	100	
	Weight-for-length	RF	2.0	15.2	16.6	60.2	6
		CRF	2.0	17.2	33.8	94	100
	HC ^c -for-age	RF	1.3	15.9	25.2	57.6	0
		CRF	1.3	17.2	42.4	100	

^a RF = Relative frequency

^b CRF = Cumulative relative frequency

^c HC = Head circumference

There was a similar distribution of all infants' anthropometric measurements between the third and 97th percentile categories at all visits. A larger number of infants (N = 18, 12%) was categorised below the third percentile for weight-for-age and weight-for-length at visit 1.

There was a distinct shift of distributions of all anthropometric measurements upon reaching ages six and 10 weeks: at visit 1 the majority of infants' weight-for-age (54%), weight-for-length (47%) and length-for-age (35%) were categorised between

the third and 25th percentiles; although 36% of infants' head circumference-for-age was between the 25-50th percentiles. Upon reaching six weeks of age at visit 2, the majority of infants (42%) had weight-for-age between the 50th and 97th percentiles. At visit 3, the majority of measurements (i.e. weight-for-age, weight-for-length, length-for-age and head circumference-for-age) were between 50th and 97th percentiles. It is noteworthy that no infants had weight-, length- or head circumference-for-age measurements above the 97th percentile at the first visit. It was only from visit 2 onwards that some infants were categorised above the 97th percentile, especially regarding weight-for-age (1% at visit 2 and 3% at visit 3) and weight-for-length (6% at visit 3).

For all anthropometric variables there was a significant difference between the means of percentiles at all visits ($p < 0.05$). The confidence interval became wider as the visits progressed and indicated a greater variation in the sample (Table 3.18).

Table 3.18: Statistical analyses for all anthropometric measurements of all infants at all visits (N = 151)

Anthropometric measurement	Visit	Mean of the percentile distribution	Standard error	LCL^a	UPL^b	p-value
Weight-for-age	1	20.7	1.5	17.8	23.7	0.0000
	2	45.3	2.1	41.1	49.6	
	3	55.0	2.2	50.7	59.4	
Length-for-age	1	37.0	1.9	32.2	39.7	0.00013
	3	40.9	2.1	36.8	44.9	
Weight-for-length	1	25.6	1.8	22.0	29.2	0.0000
	3	59.4	2.4	54.8	64.1	
Head circumference-for-age	1	36.1	1.8	32.5	39.7	0.0000
	3	51.9	2.0	47.9	55.9	

LCL = Lower confidence limit

UCL = Upper confidence limit

A 95% confidence interval (LCL, UCL) for proportions will contain all proportions between the lower limit (LCL) and the upper limit (UCL) with 95% confidence

CHAPTER 4: DISCUSSION

This descriptive, longitudinal study set out to determine the short-term growth, anthropometric variables and dietary intake of male ($N = 75$) and female ($N = 76$) infants entered into the PMTCT Programme at the Department of Human Nutrition at Dr George Mukhari Hospital for eight weeks up to the age of ten weeks. The research study also aimed to determine the feeding practices of formula fed infants and describe the socio-demographic characteristics of the HIV-infected mothers of the enrolled infants.

Key findings of the study were that the majority of male infants ($N = 65$, 87%) and female infants ($N = 61$, 80%) consumed too little energy as per recommendation during their first two weeks of life; a total of 33 (44%) male infants and 41 (54%) female infants had a protein intake below the recommendation; more than 80% of both males ($N = 63$) and females ($N = 61$) consumed less carbohydrate than required and of all the macronutrients, fats were consumed the least by both males ($N = 67$, 89%) and females ($N = 66$, 87%) at visit 1. Catch up growth was evident since intake of all the macronutrients improved as the study progressed and infants generally consumed more than 2g of protein per kg bodyweight by visits 2 and 3. The mean weight gain of all infants from visit 1 to 2 was 1.2 (SD 0.3) kg and 0.9 (SD 0.3) kg from visit 2 to 3 (exceeding the CDC 2000³ recommendation for the total infant population and for both male and female infants).

The incidence of underweight, wasting and head circumference-for-age below the third percentile decreased from visit 1 to 3, but the number of stunted infants increased towards visit 3.

4.1 SAMPLE DESCRIPTION

Mothers were counselled and tested for HIV-infection at the antenatal clinic and had decided to exclusively formula feed their infants before registering at the Department of Human Nutrition at the Dr George Mukhari Hospital for collection of formula milk.

Although the sample size was the required size as originally intended, recruitment had to be extended due to the high loss ($N = 60$, 40%) to follow-up. The majority of mothers ($N = 43$, 29%) failed to return for the first follow-up visit. Unfortunately there

were no clear explanations for the high drop-out rate. A possible reason for the high rate of absenteeism of 43 mother-infant pairs at visit 1, nine at visit 2 and eight at visit 3 could be that 18 (42%) of the 43 mothers who failed to attend visit 1 had no telephone number at which the investigator could contact them and investigate their failure to return.

Although all the mothers gave birth at Dr George Mukhari Hospital, they were advised to attend their local clinic for the routine 6-week check-up. This could explain why 7 (8%) of the mothers decided to continue visiting their local clinic for the collection of formula milk. One mother decided to buy the infant formula herself and was not willing to participate in the study any longer.

Some participants might have been lost due to hospitalisation or death. This study did not assess the progress of the mother's disease or her treatment. Some mothers might have become too ill to be able to return to the hospital for collection of infant formula. At the time of documenting the results of the study, two mothers contacted the investigator to report the death of their infants. The high rate of unemployment (75%) was not conducive to an optimal socioeconomic status. Perhaps the most sensitive and illusive factor is the fear of stigmatization upon feeding a new baby infant formula, especially where breastfeeding is the culturally preferred method of infant feeding. This exposes a mother who has also not yet disclosed her HIV-status to family members, to vulnerability and uncertainty regarding infant feeding. Doherty²⁷ found during in-depth interviews with a sub-sample of 40 women from a cohort of 650 HIV-infected mothers that such mothers struggled with recent HIV diagnosis. They were uncertain about how to care for their child and they often received suggestions from health care workers about ways to explain their chosen feeding method in an attempt to avoid the risk of stigma associated with HIV. Thairu's³³ ethnographic study in KwaZulu-Natal also showed that stigma and negative community attitudes compromised ease of disclosure of their HIV status and their choice of feeding method.

4.2 DEMOGRAPHIC DESCRIPTION OF MOTHERS AND INFANTS

The majority of mother-infant pairs ($N = 110$, 73%) resided in Soshanguve, which is one of the referral districts of Dr George Mukhari Hospital. The mean age of mothers in the study sample was 28 (SD 5.9) years, about four years older than the mean age [24 (SD 4.75)] of the mothers from the qualitative interview study done in three PMTCT pilot sites (Rietvlei, Umlazi and Paarl).²⁷ The age of all the mothers in this study fell within the age range of adult women with the highest HIV prevalence, i.e. 15 – 49 years.² This age distribution was similar to a descriptive pilot study conducted in the Western Cape that determined the knowledge, attitudes and practices of women regarding the PMTCT programme.⁷⁶

The group of infants included in the study were almost equally distributed with regards to gender (75 male infants and 76 female infants). A ± 3 SD above and below the mean of the age of infants at each visit was calculated to accommodate for age variation at each visit and to ensure a significantly large enough sample size. The type of delivery could have possibly influenced the age variation at visit 1 (with an affect of the following visits): mothers who had normal vaginal deliveries were usually discharged within 24 hours in the absence of complications, as opposed to the three to four day (or longer in the case of maternal complications) hospital stay of mothers who had undergone elective or emergency caesarean sections. No delivery data were collected. Mothers would only attend the Department of Human Nutrition for collection of infant formula upon discharge from the ward. The age variations at the other visits could have been caused by other clinic appointment dates (for example another date given by the antiretroviral clinic for treatment of the mother), insufficient means for transport, illness of either the mother or the infant or other family members.

4.2.1 Health of Infants

The majority of infants ($N = 103$, 68%) were healthy. Some infants were ill and the most common illnesses infants in this study suffered from during their first 10 weeks of life included influenza-like symptoms and diarrhoea. “Other” ailments (Table 3.5) included oral thrush, skin rash, ear infections, colic and genital sores. Ailments that

the infants had suffered and the use of medication were investigated in relation to feeding practices and the impact on growth. There were two infants who reportedly had diarrhoea. Both infants' mothers indicated that they had completely stopped formula milk for one and three days respectively while ORT was administered. Both infants' episodes of illness could have negatively influenced their growth, since both their length-for-age and head circumference-for-age growth curves deviated downwards. In fact, the one infant moved down one major percentile (the 25th percentile).

Historical natural-history studies conducted in the United States of America and Europe indicated that, in the absence of antiretroviral therapy and cotrimoxazole prophylaxis, around 20% of infants with vertical HIV-infection, was rapid progressors and developed AIDS or died within the first year of life. These infants were likely to present with conditions such as failure to thrive, chronic diarrhoea, oral thrush, hepatosplenomegaly, lymphadenopathy, and encephalopathy in the first months of life.⁷⁷ The majority of these symptoms were in line with what has been reported for HIV-infected infants not receiving antiretroviral treatment. Severe respiratory disease, caused by *Pneumocystis jirovecii* (formerly *carinii*) pneumonia or cytomegalovirus (or both) is a classic presentation in infants around 10-14 weeks of age.⁷⁷ Symptoms like diarrhoea and oral thrush might have therefore just occurred because they are common in infants of this age. The HIV status of infants in this study was not known, therefore no conclusions could be made as to whether the illnesses they suffered from were due to immunosuppression or not.

4.3 FEEDING PRACTICES

Although nutrition education is done on a continuous basis as part of the PMTCT service at the Department of Human Nutrition at Dr George Mukhari Hospital, various inappropriate infant feeding practices were identified, namely incorrect reconstitution of infant formula and early introduction of complementary feeds. Mothers were advised (at the first visit and at each visit thereafter once growth faltering or incorrect mixing procedures were identified) on the correct steps in preparing the infant formula, i.e. use cooled boiled water, measure required amount of water, add required amount of levelled scoops of formula powder to the water, washing and

sterilising of feeding equipment and handling of leftover reconstituted infant formula. The investigator assumed that the information gathered from mothers was true and accurate. It was also assumed that the interview schedules were accurate measures for collecting the required data. However, the practice effect could have contributed to mothers reporting information they knew would have been requested of them, since the same questions with regards to reconstitution of infant formula was asked at visit 1, 2 and 3.

4.3.1 Hygiene and Cleaning of Bottles

Despite the finding that all but two (1%) mothers used pre-boiled water for preparation of infant formula, the risk of contamination of the reconstituted formula could not be overlooked. This study, however, showed that 81% of mothers had access to safe water. This percentage is higher than has been documented in other studies: for example the study conducted in KwaZulu-Natal among women who attended seven rural clinics, one semi-urban and one urban clinic showed that 32.1% of all women had access to resources such as clean water, fuel for boiling water (electricity, gas or paraffin) and refrigeration.²⁹ Furthermore, all ($N = 149$, 99%) but two mothers ensured that the water used for reconstitution of infant formula was made safe by pre-boiling it. This practice correlated well with an exploratory study conducted by Dorosko¹² in a rural district of KwaZulu-Natal Province where the preparation of safe and hygienic commercial infant formula of 18 mothers was investigated. All of the studied mothers heated the water up to boiling point. Similar practices of cleaning of bottles and teats before use and the hygienic preparation of formula milk were reported by the pilot study performed on 36 women attending the antenatal clinic at the Vanguard Community Health Centre in the Western Cape.⁷⁶ A study conducted among HIV-infected mothers and their infants attending the paediatric antiretroviral treatment (ART) clinic at Dr George Mukhari Hospital in 2007, found that 76% of the home-prepared infant formula samples were contaminated, despite the mothers claiming to have used safe pre-boiled water when reconstituting the infant formula.⁷⁸ A cross-sectional study of mother-infant pairs attending a urban/peri-urban PMTCT clinic in KwaZulu-Natal in 2002 gathered data from structured interviews and home visits to observe reconstitution of infant formula. A

total of 67% of milk feeds contained at least one of the two major contaminants found, namely *Escherichia coli* or *Enterococci*.⁷⁹

4.3.2 Infant Formula Use

Even though mothers were instructed on the proper and correct volume of infant formula, number of feeds per 24 hours and reconstitution of infant formula at the first visit and at each visit thereafter when necessary, some mothers continued to prepare feeds either too dilute or concentrated. Although an empty feeding bottle was used to help mothers indicate the quantities of water and/or reconstituted infant formula, mothers might have used bottles with different volume indications i.e. fluid ounces instead of metric volumes. This could have led to misunderstandings between the investigator and the mother or over- and/or underreporting of volumes used. Adherence to the correct mixing of infant formula deteriorated towards the end of the study: 89% of mothers mixed infant formula correctly at visit 1; 89% at visit 2 and 85% at visit 3. Despite the decreased adherence, the average of 88% in this study is relatively in line with the 82% correct reconstitution reported by MacIntyre et al.⁸ One would anticipate mothers to give the correct answer upon requesting information about mixing of infant formula. It was expected that the practice effect could have contributed to a learned response and an improvement in the mixing of infant formula, not a worsening. Mothers were sometimes referred to the feeding table on the label of the infant formula (NAN Pelargon®) when incorrect reconstitution methods were identified – therefore they were exposed to the required volumes and scoops of infants at certain ages. A possible explanation for the decreased adherence to correct mixing of infant formula is that mothers might have become complacent once the infant became older.

4.3.3 Introduction of Water and Complementary Feeds

The finding that complementary feeds had been introduced to 12 (8%) of the infants at 10 weeks of age is much less than the reported 56 (37%) infants aged 40.6 (SD 8.7) days from a cross-sectional study performed by MacIntyre *et al*⁸ at the postnatal clinic at the Dr George Mukhari Hospital. Moeng⁴⁰ reported from a longitudinal lactation practice study in Soshanguve, that 56% of 307 infants were given soft

porridge while commercial cereals were used by only 24% of infants aged between one and two months; as opposed to report from MacIntyre that 23% and 12% of infants received thin maize meal porridge and commercial infant cereal respectively. A study by Mutanda,⁸⁰ conducted in the paediatric wards of Dr George Mukhari Hospital, revealed that 91% of all mothers were giving their infants water at age 78 (SD 45) days, 40% of whom started doing so within the first week of life. With regards to complementary feeds, 57% of all mothers were giving predominantly maize meal porridge as opposed to commercial infant cereal at age 78 (SD 45) days. In contrast, this study determined a much lower use of commercial cereal of 5% and maize meal porridge introduction of 1%. It could be explained by the monthly contact of mothers with staff at the Department of Human Nutrition when formula milk is collected, whereby the importance of delaying introduction of complementary feeds until six months of age is reiterated. Conversely, the monthly visits in this study might have prompted mothers to report feeding practices falsely (due to memory loss or because they knew they should not have started giving complementary feeds) and to over-report exclusive formula feeding.

4.4 GROWTH

Nutrition is typically recognised as being essential for the production of energy to meet the needs of the body, and the provision of building blocks for normal growth, progression of development and repair of cells and tissues.^{16, 81} Since growth is the fundamental characteristic of infancy and childhood, sufficient nutrition and energy supply is particularly critical early in life. Infants born with low birth weight are undernourished and therefore at risk of various health conditions; they may not be able to gain sufficient weight, and may suffer compromised long term health and development. About 16% of infants worldwide are born with a low birth weight (< 2500g). In the absence of reliable national data for South Africa, the low birth weight rate is estimated at around 10% to 15%, with lower rates of low birth weight in rural areas than urban areas. In this study, a total of 18 infants (12%) were born with a low birth weight.

Optimum nutrition and feeding of infants support normal growth and development.²⁸ Human milk, a complex blend of nutrients and immunological and various other

bioactive substances, remain the ideal single food for infants. Its variation in composition occurs from woman to woman, by stage of lactation, and for some nutrients, by diet. Fore milk and hind milk differ as well. Malnourished women tend to produce milk of good quality, despite the decreased volume as opposed to well nourished women. There is little agreement in the literature on the energy content of breast milk. Using the standard Atwater figures, it is estimated that the energy content of breast milk is 2.59 kJ/ml (0.63 kCal/ml).⁶¹ Infant formulas are modelled on the chemical composition of breast milk.²⁸ The acknowledgment that infant formulas contain ingredients of lower nutritional quality for the infant (e.g. cow's milk proteins vs. human milk proteins) has led to regulations requiring formulas providing higher levels of all nutrients than those found in breast milk.⁶¹

The infants in this study demonstrated a growth acceleration with regards to weight-for-age, weight-for-length and head circumference-for-age within the first ten weeks of life. A total of nine (6%) infants were overweight-for-length (weight-for-length above 97th percentile) at the third visit only. However, the number of stunted infants (length-for-age below the third percentile) increased from seven (5% at visit 1) to eight (5% at visit 3). These infants were mainly exclusively formula fed. A total of four infants had ailments including cramps, constipation, flu and face rash for which medications were given for up to one week. All, but one mother was unemployed at the time of the study. Though unlikely, these conditions could have possibly contributed to growth faltering.

Higher numbers of infants did not achieve weight gain between visit 2 and visit 3 than between visit 1 and visit 2. This could have been attributed to the introduction of mainly carbohydrate rich maize meal and commercial cereals, with little protein and fat. The supply of water and cereals could satisfy the infant's hunger and delay the intake of formula milk with much needed energy and variety of macronutrients. As infants become older mothers might have become more complacent and less diligent in ensuring that infants receive their required volumes of formula milk.

This study showed how percentiles of growth were shifted among the various anthropometric measurements. For the indices weight-for-age, length-for-age and head circumference-for-age infants aged zero to 10 weeks moved up to two

percentiles. Shifts in growth were more common in terms of catch-up growth with weight-for-age in infants aged two to six weeks. In this study catch-down growth was less common, however 18 (12%) infants moved down one percentile and two (1%) infants moved down two percentiles in length-for-age. A longitudinal analysis of data from the California Child Health and Development Study⁸² showed that shifts in growth rates were very common for children from birth to six months of age. A deceleration of weight across two major percentiles (with major percentiles defined as the 5th, 10th, 25th, 50th, 75th, 90th, and 95th percentiles) is frequently used by health care providers to identify children at risk of undernutrition. Shifts in growth were more common for weight-for-length than for length-for-age or weight-for-age. A study conducted in Durban examined the children born to HIV-1-seropositive women and followed them up from birth to early childhood. There were no significant differences between the two groups (48 infected and 93 uninfected children) at birth, but the infected group had early and continuous lower mean Z-scores for length-for-age (reaching statistical significance at ages three, six and 12 months) and weight-for-age (reaching statistical significance at ages three, six and nine months). Infected children born to HIV-infected women had early and sustained stunting and were malnourished but not wasted.¹⁶

Failure to thrive and obesity are certainly major concerns for health care professionals. One can however, only describe these conditions accurately by comparing weight and length on growth charts over time. The California Child Health and Development Study⁸² suggested that catch-up and catch-down growth during early childhood could affect large numbers of children, especially during infancy, since catch-up or catch-down growth may reflect an adjustment to the genetic potential for growth after intrauterine growth.⁸² Research has shown that lower birth weight and undernutrition in childhood were risk factors for chronic diseases such as elevated glucose concentrations, blood pressure and harmful lipid profiles, suggesting that rapid postnatal weight gain – especially after infancy – is linked to these conditions.⁸³

Various abnormal growth patterns occur in HIV-infected infants and children, ranging from compromised weight and height growth rates to severe wasting with normal length or height.¹⁶ Early infection with HIV may be sub clinical and thus

asymptomatic, but the cumulative effect of a chronic infection coupled with acute infections may substantially impair linear growth.⁸⁴ These growth faltering patterns could be explained by clinical disease patterns associated with HIV-infection. Higher viral load increases the risk of growth failure in infants and children. Lower CD4 T-cell count, infectious complications such as pneumonia and diarrhoea, maternal drug use during pregnancy, and exposure to antiretroviral drug therapy (non-protease inhibitor) have been associated with poor growth.¹⁶ Enteric infections such as diarrhoea can lead directly to malabsorption of nutrients by means of damaged intestinal mucosal epithelial cells which then lead impaired absorption of macro- and micronutrients.⁸⁴ Nutrient requirements may also be increased. Patients with asymptomatic HIV infection have up to 16% greater resting energy expenditure than uninfected patients, rising to 57% in the presence of opportunistic infections.⁸⁴

Epidemiological studies have shown that infants with small size at birth and disproportionate head size, length and weight, or with abnormal placental growth, demonstrate increased rates of coronary heart disease, hypertension and type 2 Diabetes Mellitus (metabolic syndrome) in adulthood.²⁸ Research has furthermore indicated an association between rapid weight gain in infancy and the development of childhood obesity in populations of European, African and Asian descent. It has also been shown that rapid weight gain in the first four months of life is associated with obesity in a sample of young black adults. The cohort study of European American formula fed infants showed a clinically significant association of absolute weight gain in the first week of life with adulthood overweight status.⁶² In interpreting the results it was acknowledged that the weight change in humans from birth to eight days cannot be considered as an accurate "growth parameter". During this period, weight changes mainly reflect the amount of milk ingested, which in turn are dependent on various factors including illnesses, perinatal depression, slow passage of meconium, fluctuation in total body water (affected by over hydration or dehydration at the time of delivery).⁶²

Usually growth is measured from birth, but this study could not take the anthropometric measurements taken at birth into account. The reason was that the birth measurements were taken by nurses and medical staff at the time of birth. Validity and reliability of data could not be ensured and was compromised by the fact

that the measurements were done by more than one health professional and consistency and reliability of the techniques used during measurements could not be verified. Therefore growth was described in terms of the anthropometric measurements taken from the first visit when infants were two weeks old.

Berhane *et al*⁸⁵ studied the effect of HIV infection on pregnancy. Pregnant women attending the antenatal clinic in Kampala, Uganda were enrolled and 450 live born infants were followed for 25 months. The sample contained HIV-infected infants, HIV uninfected infants and seroconverters. Almost 50% of the HIV-infected children died before 25 months of age. The poor outcome in the HIV-infected infants could not be entirely attributed to poverty and underdevelopment, since the control groups shared similar socioeconomic environment. The data have however shown an inverse relationship between early nutritional status and mortality risk. Poor nutritional status accelerated the progression of asymptomatic HIV infection to AIDS.⁸⁵

This study did not aim to investigate the HIV status of the infants. The results might have indicated different growth and weight gain patterns if the HIV status was known and the participants were separated into two groups: i.e. HIV-infected infants and uninfected infants. This should be considered in future studies since polymerase chain reaction (PCR) tests were performed when infants reached six weeks of age at the time when data collection commenced in this study.

Perinatal acquired HIV infection has been shown to be associated with early and progressive deceleration in weight and length.⁸⁵ The severity of an illness or infection is a significant determinant of poor postnatal weight gain.⁸¹ HIV infection has a deleterious effect on linear growth of infants.⁸⁶ HIV infection has become a significant contributor to severe malnutrition, with over 80% of severely malnourished children at some South African hospitals being infected.¹⁶ HIV-infected infants commonly suffer from growth failure.⁷⁷ Growth failure is further more associated with early mortality.⁷⁷ In a longitudinal study conducted by Henderson⁸⁷ in Malawi, it was shown that the difference in mean weight-for-age for HIV-infected and uninfected infants born to HIV-infected mothers was statistically significant from birth. The mean length-for-age was statistically significantly different between the two groups only after five months of age. Furthermore, there was an association between viral load and growth.⁸⁸

Data from a large (1587 children enrolled) prospective European study was used to investigate the growth patterns in the period from birth to the first 10 years of life of HIV-infected ($N = 184$) and uninfected children ($N = 1403$) who were born to HIV-infected mothers. The acquired data were used to do a comparison with British 1990 growth standards. At birth, neither height nor weight was significantly associated with the effects of HIV infection, but differences in growth patterns between infected and uninfected children increased with age. Infected children were significantly shorter and lighter than uninfected children. Differences in growth velocities between infected and uninfected children increased after two and four years of age for height and weight respectively. Furthermore, infected children with mild to serious symptoms of disease lagged behind asymptomatic children with regards to weight and height. Growth faltering, in particular stunting, adversely affects a child's quality of life, especially at the onset of adolescence.⁸⁹

The majority of infants in this study grew well in their first ten weeks of life. They followed their growth curves and thus their energy requirements were met. The results indicated that the majority of infants were obtaining sufficient energy and in some instances too much, as well as too little energy. However, growth accelerated as infants became older and growth faltering improved by ten weeks of age. Despite the benefit of growth achieved by providing sufficient infant formula, the problem of balancing the risks between HIV transmission and the harmful effects of formula feeding remains. This study demonstrated that the practice of formula feeding was burdened with difficulties: women received inadequate information or perhaps did not clearly understand how to make formula milk safe, formula feeds were not always prepared correctly, despite the fact that mothers had access to safe and clean water and free formula and received frequent and regular support from their monthly hospital visits. Apart from the socioeconomic burden of unemployment a number of other factors affected infant feeding practices, such as lack of financial resources to purchase milk or to obtain transport to reach the hospital, lack of support at home in terms of assistance with the care of an infant, lack of basic schooling, erratic and irregular supply of formula milk by the hospitals and the retail sector. Those women who were unable to afford to purchase milk after the free supply had finished, were often those who were most at risk of the harmful and potentially dangerous effects of

formula feeding. Although free supply of formula milk reduced the financial burden of having to buy milk out of their own pocket, mothers still had to render finances for fuel, water, sterilizing and feeding equipment. It could be argued that the provision of free formula milk might have given disadvantaged mothers a false sense of security in being able to provide safe infant feeding. A further concern was the inability to sustain growth of the infant after six months in a household where various basic needs are barely met. The risk of malnutrition could be feared in such circumstances. The PMTCT Programme can certainly serve as a medium to improve the clinical aspects of the health care system in terms of child health care and nutrition. Surveillance and growth monitoring could be performed more effective and sustainable.

4.5 LIMITATIONS OF THE STUDY

- Erratic infant formula supply by Nestlé (in part caused by increased sales and demand for the formula, exacerbated by internal industrial actions at production facilities, customers stockpiling the product), the sole company holding a government tender for providing infant formula to at least 2525 public health facilities countrywide,^{90, 91, 92} restricted efficient execution of the PMTCT Programme. The investigator had to redirect stock from facilities with adequate supplies to Dr George Mukhari Hospital when a shortage was experienced in the pen-ultimate week of follow-up of participants. No clear guidelines exist about what HIV-infected mothers could feed their infants when they do not have access to NAN Pelargon®.
- In spite of the fact that at the time of the study, infant formula was issued to mothers for six months according to the PMTCT protocol, this study only followed participants for 10 weeks. This does not give a comprehensive perspective on the full spectrum of growth of infants on the full PMTCT programme.
- This study focused on dietary intake and growth of infants between two to ten weeks of age and their growth during this period may not be a true reflection of their anthropometric status thereafter. Considerable evidence indicates⁹³ that underweight and stunting increase significantly after six months following the introduction of poor quality complementary feeding.

- The unknown HIV status of the infants limited the associations to be made with growth faltering. At the time of the submission of the research protocol, PCR testing was done at 12 months of age at Dr George Mukhari Hospital. It was only when actual data collection commenced that PCR testing was done routinely at six weeks of age.
- The birth weight was taken by medical personnel in the labour ward. The investigator used the information from the medical files, since the investigator was not present at the time of the infant's birth. The accuracy, reliability and validity of these measurements could not be secured since it was measured by more than one person. Therefore this data could not be used to describe growth from birth, but rather growth from two weeks of age was described.
- The head circumference measurement was performed whilst the infant was held on the mother's lap or when lying down on the changing mat – the use of two body positions might have affected the accuracy of measurements. However, quality control was ensured by duplicating each measurement and repeating every tenth measurement by an independent registered Dietitian.
- The reliability of the dietary intake data in terms of quantification is questionable. The only measure that could contribute to reliable data was the use of an empty feeding bottle by the investigator to assist mothers in indicating the volumes of water and/or powder used in reconstituting the infant formula. In some instances the bottles that mothers used for feeding their infants were marked differently (i.e. fluid ounces instead of metric measurements) from the example bottle and in other cases the infant's bottle was used and washed extensively and subsequently the volume markings were not clearly visible anymore.
- The investigator might have had an influence on the feeding practices of the mothers/caregivers. It may have resulted in staff being more vigilant of maternal/caregiver practices, thereby more actively encouraging exclusive formula/replacement feeding and the delay in the introduction of complementary feeding.
- The lack of a control group (e.g. exclusive breastfeeding) could be a concern in the interpretation of the results. A control group consisting of exclusively breastfed infants was not considered in this study for the following reasons:

the relatively low ($\pm 30\%$) incidence of exclusive breastfeeding as a feeding option at Dr George Mukhari Hospital; mothers who exclusively breastfeed their infants don't visit the hospital for any reason other than their scheduled six-week postnatal appointment (causing difficulty in the follow-up of such infants for ten weeks); the stigma associated with being enrolled into a PMTCT study and being followed-up by the Department of Human Nutrition which is associated with the issue of infant formula to those mother-infant pairs who are involved with the PMTCT programme.

- It was decided to use the CDC 2000³ growth charts in stead of the WHO child growth charts. A difference in the interpretation of the results could have been expected especially in the weight-for-age curves as the mean weight of infants included in the WHO standards⁵⁷ is above the CDC median during the first half of infancy
- This study was conducted at a tertiary health facility, which is probably better resourced than many peripheral/rural clinics. The findings of the study may not be representative of other PMTCT sites.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

The main objectives of the study were to determine weight gain and growth of infants enrolled in the PMTCT Programme between the ages of two and 10 weeks, as well as their feeding practices and dietary intake.

Throughout the study the incidence of underweight, wasting and head circumference-for-age below the third percentile decreased from visit 1 to visit 3, but the number of stunted infants increased towards visit 3.

The energy intake of the majority of males ($N = 65$, 87%) and females ($N = 61$, 80%) was below the DRI⁵⁹ during their first two weeks of life but gradually increased towards the third visit. The majority of infants consumed more than 2g of protein per kg bodyweight by visits 2 and 3. Regarding carbohydrate intake: more than 80% of both male and female infants consumed less carbohydrate than required at visit 1, but carbohydrate consumption improved to such an extent so that males and females consumed on average 69% (at visit 2) and 82% (at visit 3) more carbohydrates than required. Of all the macronutrients, fats were consumed the least by male (89%) and female (87%) infants at visit 1, stabilised at visit 2 and increased towards visit 3.

Mothers generally adhered to good hygiene practices when reconstituting infant formula, although feeds were sometimes made too concentrated or dilute. The introduction of complementary feeds such as commercial cereal and maize meal porridge was determined to be 5% and 1% respectively.

The incidence of underweight, wasting and head circumference-for-age below the third percentile decreased from visit 1 to 3, but the number of stunted infants increased towards visit 3. The majority of infants in this study grew well in their first ten weeks of life. Growth accelerated as infants became older and growth faltering improved by ten weeks of age.

Unfortunately, no infant feeding strategy will ever be totally without risk, either of HIV transmission or mortality. However, current opinion seems to have revisited the importance of breastfeeding for child health. There is a need for better defining of AFASS in each regional setting. Evidence from recent studies and further research in the field should be directed towards a review of current recommendations. The

current policy needs to be reconsidered regarding its stance on infant feeding, especially since the WHO has recently revised its guidance on infant feeding. The revised guidance is based upon two components:

- The evidence supporting the decreased association of exclusive breastfeeding and the risk of HIV transmission compared to non-exclusive breastfeeding.
- The combined risk of HIV and death by 18 months in settings where antiretroviral prophylaxis and free infant formula were provided in the following similar instances i.e. in infants who were replacement fed from birth and infants breastfed for three to six months.⁷

The following challenges need to be addressed to improve the service delivered by the PMTCT Programme and ensure effectiveness regarding prevention:

- The PMTCT Programme should be integrated with mother and infant programmes and/or growth monitoring/immunization services at local clinics to ensure that RthCs⁷¹ are updated regularly. This empowers mothers to take ownership and responsibility of the growth of their infants
- Social support should be instigated and available as early as VCT to ensure continuous financial means to obtain sufficient infant formula upon exit from the PMTCT Programme
- Continuous counselling regarding baby feeding options should be encouraged and improved to ensure that mothers/caregivers stop mixed feeding in the first six months
- Continuous education of mothers/caregivers who are preparing infant formula, to avoid contamination and decrease incidence of diarrhoeal diseases
- Partner/caregiver participation should be encouraged (e.g. via support groups or companionship) to help support exclusive feeding options as well as to improve adherence to follow-up visits
- Monitoring variables such as weight and length, data collection, and reporting practices at the pilot sites as well as other sites should be standardised to enable the use thereof for surveillance purposes. This will aid in the monitoring of the progress of the epidemic and evaluate success of prevention. PMTCT and HAART programmes and antenatal and postnatal

care should be integrated to optimise the quality of support and follow-up provided for HIV-exposed children and their parents

- Although Soshanguve is an urbanized area, unemployment remains a debilitating factor regarding socioeconomic status. It should be ensured that poor mother-infant pairs should benefit from the PMTCT Programme as intended

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APPENDICES

APPENDIX 1

**UNIVERSITY OF STELLENBOSCH: STUDY INFORMATION AND INFORMED
CONSENT FORM**

**STUDY INFORMATION FOR LEGAL GUARDIAN AND INFORMED
CONSENT DOCUMENT**

TITLE OF THE RESEARCH PROJECT:

Growth and nutritional status of formula-fed infants aged 2-10 weeks in the Prevention of Mother-to-Child Transmission (PMTCT) Programme at Dr George Mukhari Hospital.

REFERENCE NUMBER: MP 78/2006
N06/09/172

PRINCIPLE INVESTIGATOR: Caïda Mac Dougall

ADDRESS: Department of Human Nutrition
Dr George Mukhari Hospital
Private Bag X422
Pretoria, 0001

CONTACT NUMBER: 083 556 3624

You and your child are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the dietitian or diet assistant any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how your baby could be involved.

This study has been approved by the Committee for Human Research at Stellenbosch University, as well as the Gauteng Provincial Ethics Committee and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki (a universal code for the conduction of ethical research), South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

DECLARATION ON BEHALF OF PARTICIPANT:

I, the undersigned..... *(name)* in my capacity as mother of the participant*(name of baby)* of *(address)*.

A. HEREBY CONFIRMS AS FOLLOWS:

1. My baby and I were invited to participate in the abovementioned research study which is being undertaken by the Department of Human Nutrition, Faculty of Health Sciences, University of Stellenbosch.
2. The following aspects have been explained to me:

2.1. Aim

The aim of the project is to describe the growth of infants aged 2-10 weeks who have entered the PMTCT Programme at Dr George Mukhari Hospital.

2.2. Procedures

The nature of the project requires infants to be brought to the Department of Human Nutrition at Dr Mukhari Hospital for the usual weight measurement and collection of milk. The project will take place during the baby's first 3 visits to the hospital. The project will last only 8 weeks, but infants should still attend the last 3 follow-up visits until they are 5½ months old. The following procedures will be performed during the first 3 visits:

- Visit 1: Measurement of weight, length and head circumference
- Visit 2: Measurement of weight

- Visit 3: Measurement of weight, length and head circumference. You will be asked to complete a socio-demographic interview schedule and usual intake interview schedule

2.3. Responsibilities

My responsibility is to ensure that the baby is brought to the Department of Human Nutrition at Dr George Mukhari Hospital on the given follow-up dates and times.

2.4. Risks

There are no known risks or detrimental affects that your baby may experience during the study.

2.5. Possible benefits

The results of this project will benefit your baby as well as other babies in the PMTCT Programme with regards to growth monitoring. Problems such as weight loss or poor growth might be identified in early infancy.

2.6. Confidentiality

The information collected (measurements as well as personal information) will be treated as confidential. It will be used in a thesis and the identity of my baby and I will remain anonymous.

2.7. Access to findings

Upon request, the investigator will share the results obtained in the project, but the information pertaining to my baby and I will not be revealed to anyone else.

2.8. Voluntary participation/refusal/discontinuation

Our participation is **entirely voluntary** and I am free to decline to participate. I have not been pressurised to take part. If I say no, this will not affect me negatively in any way whatsoever. I am also free to withdraw him/her from the study at any point, even if I do initially agree to take part. I may choose to leave the study at any time and will not be penalised or prejudiced in any way. My baby may be asked to leave the study before it has finished, if the researcher feels it is in my baby's best interests, or if I do not follow the study plan, as agreed to.

3. The information above was explained to me by (*name of relevant person*) in Afrikaans/*English/*seTswana/*other and I am in command of this language/*was satisfactorily explained to me by (*name of translator*). I was given the opportunity to ask questions and all these questions were answered satisfactorily.
4. No pressure was exerted on me to consent to participation and I understand that my baby and I may withdraw at any stage without any penalization.
5. Participation in this research will not result in any additional costs to myself.

B. HEREBY COSENT VOLUNTARILY TO PARTICIPATE IN THE ABOVEMENTIONED STUDY AS FOLLOWS:

I (*name of mother*)..... hereby voluntarily consent to allow my child (*name of baby*)..... who isweeks old, to take part in the above-mentioned project.

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 will not be penalised or prejudiced in any way.
- My baby may be asked to leave the study before it has finished, if the researcher feels it is in my baby's best interests, or if I do not follow the study plan, as agreed to.

Signed aton2006
(place) (date)

.....
Signature of Mother

.....
Signature of Witness

**Delete where not applicable*

Declaration By Investigator

I (*name*)declare that:-

- I explained the information in this document to..... (*name of mother*).
- 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
- This conversation was conducted in English/*Afrikaans and no translator was used/this conversation was translated into (*language*) by (*name of translator*).

Signed aton2006
(*place*) (date)

.....
Signature of Investigator

.....
Signature of Witness

*Delete where not applicable

Declaration By Translator

I (*name*) declare that:-

- I assisted the investigator (*name*) to explain the information in this document to (*name of mother*) using the language medium of (*language*).
- We encouraged her 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 mother fully understands the content of this informed consent document and has had all her questions satisfactorily answered.

Signed at on2006
(*place*) (date)

.....
Signature of Translator

.....
Signature of Witness

*Delete where not applicable

MESSAGE TO THE PARTICIPANT

Dear mother,

Thank you for your baby's participation in this project.

If you have any further queries or require additional information about the project or you are unable to attend the hospital for your given follow-up visit, please contact **Caïda Mac Dougall** on **083 556 3624** or **012 5293585**.

You can contact the Committee for Human Research at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by the Dietitian or Diet Assistant.

You will receive a copy of this information and consent form for your own records.

APPENDIX 2

UNIVERSITY OF LIMPOPO (MEDUNSA CAMPUS): CONSENT FORM

University of Limpopo (Medunsa Campus) CONSENT FORM

Statement concerning participation in a Clinical Trial/Research Project*.

Name of study:

Growth and nutritional status of formula-fed infants aged 2-10 weeks enrolled into the Prevention of Mother-to-Child Transmission (PMTCT) Programme at Dr George Mukhari Hospital.

I have read the information on */heard the aims and objectives of* the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.

I understand that participation in this study is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular clinic visits neither will it influence the care that I/my baby receive from the dietitian/diet assistant.

I know that this study has been approved by the Research, Ethics and Publications Committee of the University of Limpopo (Medunsa campus)/ Dr George Mukhari Hospital. I am fully aware that the results of this study will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this study.

Name of mother

Signature of mother

Place

Date

Witness

Statement by the Researcher

I provided verbal and/or written* information regarding this study.

I agree to answer any future questions concerning the pre-test as best as I am able.

I will adhere to the approved protocol.

.....
Name of Researcher Signature Date Place

*Delete whatever is not applicable.

APPENDIX 3

DATA ENTRY FORM – VISIT 1

Dr George Mukhari Hospital – PMTCT Programme		VISIT 1						
Patient information:								
1.	Person who prepares the feed(s): <input type="checkbox"/> Mother <input type="checkbox"/> Caregiver							
2.	Study no: _____							
3.	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female							
4.	Date of birth:	<table style="width: 100%; border: none;"> <tr> <td style="border: none; text-align: center;"> _ _ </td> <td style="border: none; text-align: center;"> _ _ </td> <td style="border: none; text-align: center;"> _ _ _ </td> </tr> <tr> <td style="border: none; text-align: center;">day</td> <td style="border: none; text-align: center;">month</td> <td style="border: none; text-align: center;">year</td> </tr> </table>	_ _	_ _	_ _ _	day	month	year
_ _	_ _	_ _ _						
day	month	year						
5.	Birth weight (kg)	_ . _ _						
6.	Birth length (cm)	_ _ . _ _						
7.	Birth head circumference (cm)	_ _ . _ _						
8.	Weight (kg)	1. _ . _ _						
		2. _ . _ _						
		Average: _ . _ _						
9.	Length (cm)	1. _ _ . _ _						
		2. _ _ . _ _						
		Average: _ _ . _ _						
10.	Head Circumference (cm)	1. _ _ . _ _						
		2. _ _ . _ _						
		Average: _ _ . _ _						

<p>11.</p>	<p>How did you mix the milk (Pelargon®)? <i>O kopantse maši jaang (Pelargon®)?</i></p>	<p><input type="checkbox"/> ml water per bottle (<i>tshetse metsi mo lebotlong</i>) <input type="checkbox"/> scoops of milk powder per bottle (<i>maswana a maši mo lebotlong</i>)</p>
<p>12.</p>	<p>How many bottles did your baby drink yesterday? <i>Ngwana wa gago o nwele mabotlolo a le makae maabane?</i></p>	<p><input type="checkbox"/> Number of bottles, and then indicate volume of each bottle: (<i>Palo ya mabotlolo le gore maši mo lebotlolong a ne a le makanakang</i>)</p> <p>-----ml -----ml</p> <p>-----ml -----ml</p> <p>-----ml -----ml</p> <p>-----ml -----ml</p> <p>-----ml -----ml</p>
<p>13.</p>	<p>Amount of NAN Pelargon® issued</p>	<p> _ tins</p>
<p>14.</p>	<p>Follow-up date</p>	<p> _ _ _ _ _ _ _ _ day month year</p>

Comments:

Completed by: ----- Date: -----

APPENDIX 4

DATA ENTRY FORM – VISIT 2

Dr George Mukhari Hospital – PMTCT Programme		VISIT 2
Patient information:		
1.	Person who prepares the feed(s): <input type="checkbox"/> Mother <input type="checkbox"/> Caregiver	
2.	Study no: _____	
3.	Weight (kg)	1. _ . _ _
		2. _ . _ _
		Average: _ . _ _
4.	How did you mix the milk (Pelargon®)? <i>O kopantse maši jaang (Pelargon®)?</i>	<input type="checkbox"/> ml water per bottle (<i>tshetse metsi mo lebotlong</i>) <input type="checkbox"/> scoops of milk powder per bottle (<i>maswana a maši mo lebotlong</i>)
5.	How many bottles did your baby drink yesterday? <i>Ngwana wa gago o nwele mabotlolo a le makae maabane?</i>	<input type="checkbox"/> Number of bottles, and then indicate volume of each bottle: (<i>Palo ya mabotlolo le gore maši mo lebotlolong a ne a le makanakang</i>) -----ml -----ml -----ml -----ml -----ml -----ml -----ml -----ml -----ml -----ml

6.	Amount of NAN Pelargon® issued	_ tins																
7.	Follow-up date	<table style="margin-left: auto; margin-right: auto;"> <tr> <td> _ </td> <td> _ </td> <td> _ </td> <td> _ </td> <td> _ </td> <td> _ </td> <td> _ </td> <td> _ </td> </tr> <tr> <td>day</td> <td>month</td> <td>year</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	_	_	_	_	_	_	_	_	day	month	year					
_	_	_	_	_	_	_	_											
day	month	year																

Comments:

Completed by: ----- Date: -----

APPENDIX 5

DATA ENTRY FORM – VISIT 3

Dr George Mukhari Hospital – PMTCT Programme		VISIT 3
Patient information:		
1.	Person who prepares the feed(s): <input type="checkbox"/> Mother <input type="checkbox"/> Caregiver	
2.	Study no: _____	
3.	Weight (kg)	1. _ . _
		2. _ . _
		Average: _ . _
4.	Length (cm)	1. _ _ . _
		2. _ _ . _
		Average: _ _ . _
5.	Head Circumference (cm)	1. _ _ . _
		2. _ _ . _
		Average: _ _ . _
6.	How did you mix the milk (Pelargon®)? <i>O kopantse maši jaang</i> (Pelargon®)?	<input type="checkbox"/> ml water per bottle (<i>tshetse metsi mo lebotlong</i>) <input type="checkbox"/> scoops of milk powder per bottle (<i>maswana a maši mo lebotlong</i>)

<p>7.</p>	<p>How many bottles did your baby drink yesterday?</p> <p><i>Ngwana wa gago o nwele mabotlolo a le makae maabane?</i></p>	<p><input type="checkbox"/> Number of bottles, and then indicate volume of each bottle: (<i>Palo ya mabotlolo le gore maši mo lebotlolong a ne a le makanakang</i>)</p> <p>-----ml -----ml</p> <p>-----ml -----ml</p> <p>-----ml -----ml</p> <p>-----ml -----ml</p> <p>-----ml -----ml</p>
<p>8.</p>	<p>Amount of NAN Pelargon® issued</p>	<p> _ tins</p>
<p>9.</p>	<p>Follow-up date</p>	<p> _ _ _ _ _ _ _ _ </p> <p>day month year</p>

Comments:

Completed by: ----- Date: -----

APPENDIX 6

USUAL FOOD INTAKE INTERVIEW SCHEDULE

Karolo 6: Dipotso ka dijo tsa tlwaelo

1.	<p>How did you feed your baby yesterday? <i>O jesitse ngwana jang maabane?</i></p>	
2.	<p>How did you mix the milk (Pelargon®)? <i>O kopantse maši jaang (Pelargon®)?</i></p>	<p><input type="checkbox"/> ml water per bottle (<i>tshetse metsi mo lebotlong</i>) <input type="checkbox"/> scoops of milk powder per bottle (<i>maswana a maši mo lebotlong</i>)</p>
3.	<p>How many bottles did your baby drink yesterday? <i>Ngwana wa gago o nwele mabotlolo a le makae maabane?</i></p>	<p><input type="checkbox"/> Number of bottles, and then indicate volume of each bottle: (<i>Palo ya mabotlolo le gore maši mo lebotlolong a ne a le makanakang</i>)</p> <p>-----ml -----ml -----ml</p> <p>-----ml -----ml -----ml</p> <p>-----ml -----ml -----ml</p>

4. Did you give your baby any other drinks yesterday?

A gona le dino dingwe tse ngwana a di nweleng maabane?

Time	Type of drink (including water)	Amount
<i>Nako</i>	<i>Mofuta wa seno (o akaretsa le metsi)</i>	<i>Selekano</i>

5. Did you give your baby any other foods yesterday?

A gona le dijo dingwe tse ngwana a di jeleng maabane?

Time	Type of food	Amount
<i>Nako</i>	<i>Mofuta wa dijo</i>	<i>Selekano</i>

6. Did you give your baby any medication during the past 2 months?

A gona le dithlare tse o di nositseng ngwana mo dikgweding tse pedi tse di fetileng?

Time	Name of medication	Amount
<i>Nako</i>	<i>Leina la setlhare</i>	<i>Selekano</i>

7. Did anybody else give anything else to the baby to eat or drink?

A go mongwe o a fileng ngwana sengwe sa go ja kgotsa go nwa?

Person	Type of food/drink	Amount and date/time period
<i>Motho</i>	<i>Mofuta wa dijo/dino</i>	<i>Selekano/Letlha/Nako</i>

Comments:

Completed by: ----- Date: -----

APPENDIX 7

SOCIO-DEMOGRAPHIC INTERVIEW SCHEDULE

Karolo 7: Dipotso ka Lemorago

Dr George Mukhari Hospital		VISIT 3
PMTCT Programme (<i>Lenaneo la PMTCT</i>)		
Socio-demographic Questionnaire (<i>Dipotso ka Lemorago</i>)		
Patient information (<i>Tshedimose tso ka molwetsi</i>):		
1.	Study no (<i>Tshupo ya molwetsi</i>): _____	
2.	Gender (<i>Bong</i>): <input type="checkbox"/> Male <input type="checkbox"/> Female	
3.	Date of birth (<i>Letlha la matsalo</i>):	_ _ _ _ _ _ _ _ _ day month year

Caregiver Information (<i>Tshedimose tso ka motlhokomedi</i>):		
4.	Physical address (<i>Aterese ya bonno</i>): Telephone (<i>Nomoro ya mogala</i>):	
5.	Age of mother (<i>Dingwaga tsa mme</i>):	_ _ _ years (<i>dingwaga</i>)
6.	Current occupation/employment (<i>Tiro</i>):	
7.	Highest qualification (<i>Thuto e kwa godimo e a e falotseng</i>):	

Hygiene Information (Tshedimosetso ka bophepa):		
8.	<p>What is the source of your drinking water?</p> <p><i>Le gella metsi kae?</i></p>	<input type="checkbox"/> Public taps (<i>Dipompo tsa botlhe</i>) <input type="checkbox"/> River/dam (<i>Noka/Letamo</i>) <input type="checkbox"/> Taps in house/yard/neighbour's taps <i>(Dipompo tsa mo ntlong/mo jarateng/tsa metsi a pula)</i> <input type="checkbox"/> Borehole/rainwater tank/well (<i>Petse/tanka ya metsi a pula/sediba</i>) <input type="checkbox"/> Other (specify) (<i>Tse dingwe – Tlhalosa</i>) -----
9.	<p>Do you use the same water for preparing the baby's bottles?</p> <p><i>A o dirisa metsi a, go direla ngwana lebotlolo?</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
10.	<p>Do you boil the water?</p> <p><i>A o bedisa metsi?</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
11.	<p>How do you clean bottles and teats?</p> <p><i>O tlhatswa mabotlolo le ditami jaang?</i></p>	

General Information (Tshedimosetso ka kakaretso):		
12.	<p>Has the baby had any medical visits? (Indicate name of institution)</p> <p><i>A ngwana o kile a etela kwa ngakeng?</i></p>	<input type="checkbox"/> Doctor (<i>Ngaka</i>) ----- <input type="checkbox"/> Clinic (<i>Kliniki</i>) ----- <input type="checkbox"/> Hospital (<i>Sepetlele</i>) ----- <input type="checkbox"/> Traditional healer (<i>Ngaka ya setso</i>) <input type="checkbox"/> Other (specify) (<i>Tse dingwe – tlhalosa</i>) -----

13.	<p>Has the baby had any of the following ailments?</p> <p><i>A ngwana a kile a tshwarwa ke malwetse a a latelang?</i></p>	<p><input type="checkbox"/> Vomiting (<i>Letlhatso</i>)</p> <p><input type="checkbox"/> Diarrhoea (<i>Letshololo</i>)</p> <p><input type="checkbox"/> Constipation (<i>Pipelo</i>)</p> <p><input type="checkbox"/> Other (specify) (<i>A mangwe - tthalosa</i>)</p> <p>-----</p>
14.	<p>If the baby had any of the above ailments, what did you do?</p> <p><i>O ne wa dirang ge ngwana a lwala ka malwetse a?</i></p>	<p><input type="checkbox"/> Stopped giving milk (<i>O emisitse go fa ngwana maši</i>)</p> <p><input type="checkbox"/> Gave water only (<i>O file metsi fela</i>)</p> <p><input type="checkbox"/> Gave medication only (<i>O file ditlhare</i>)</p> <p><input type="checkbox"/> Gave medication and water (<i>O file ditlhare le metsi</i>)</p> <p><input type="checkbox"/> Gave medication and milk (<i>O file ditlhare le maši</i>)</p> <p><input type="checkbox"/> Other (specify) (<i>Tse dingwe – tthalosa</i>)</p> <p>-----</p>
15.	<p>How long was the baby treated?</p> <p><i>Ngwana o alafilwe sebaka se se kanakang?</i></p>	<p><input type="checkbox"/> Days (<i>Matsatsi</i>)</p> <p><input type="checkbox"/> Weeks (<i>Dibeke</i>)</p>
16.	<p>Have you ever stopped giving the baby milk?</p> <p><i>A o kile wa emisa go fa ngwana maši?</i></p>	<p><input type="checkbox"/> Yes If Yes, for how long? (<i>Sebaka se se kanakang?</i>) -----</p> <p>-----</p> <p><input type="checkbox"/> No</p>

APPENDIX 8**UNIVERSITY OF STELLENBOSCH: STUDY INFORMATION AND INFORMED
CONSENT FORM - SETSWANA****STUDY INFORMATION FOR LEGAL GUARDIAN AND INFORMED
CONSENT DOCUMENT****TITLE OF THE RESEARCH PROJECT:**

Growth and nutritional status of formula-fed infants aged 2-10 weeks in the Prevention of Mother-to-Child Transmission (PMTCT) Programme at Dr George Mukhari Hospital.

REFERENCE NUMBER: MP 78/2006
N06/09/172

PRINCIPLE INVESTIGATOR: Caïda Mac Dougall

ADDRESS: Department of Human Nutrition
Dr George Mukhari Hospital
Private Bag X422
Pretoria, 0001

CONTACT NUMBER: 083 556 3624

Ngwana wag ago o laletswa go tsaya karolo mo projekeng ya dipatlisiso. Ke kopa tseye nako o bale tshedimose tso e e tthagisiwang fa e e tthalosang tsamaiso ya projeke e. Botsa dietitian kgotsa motuusa dietitian ka dintlha tsa projeke tse o sa di tthaloganyeng. Go botlhokwa gore o tthaloganye e bile o kgotsofalele se dipatlisiso di se dirang. Dipatlisiso tse di dume letswe ke komiti ya Human Research kwa University of Stellenbosch le komiti ya Gauteng Provincial Ethics mme e bile tsotlhe di tla dirwa ka tatelo le tsamaiso ya international Declaration of Helsinki, South African Guidelines for good Clinical Practice le Medical Research Council (MRC) Ethical Guidelines for Research.

MAIKANO MO BOEMONG BA MOTSAYA KAROLO:

Nna, yo o saenang fa (*leina*) mo matleng a me jaaka motsadi/motlhokomedi wa semolao wa motsaya karolo..... (*leina la ngwana*) wa ka (*aterese*).

A. KE NETEFATSA KA TSELA E E LATELANG GORE:

6. Nna le ngwaneke re laleditswe go tsa karolo mo dipatlisisong tse di dirwang ke Department of Human Nutrition, Faculty of Health Sciences, University of Stellenbosch.

7. Dintlha tse di latelang ke di tshaloseditswe:

7.1. Maikaelelo

Maikaelelo a projeke ke go tshalosa kgolo ya bana dibeke tse 2-10 ba ba mo lenaneong la PMTCT mo Dr George Mukhari Hospital.

7.2. Tsamaiso

Go ya ka projeke bana ba tshwanelwa ke go tlisiwa mo lefapheng la tsa phepo mo sepetlele go kalwa le go fiwa maši. Projeke e tla tswela dibeke tse tharo tsa ntlha tse ngwana a etelang bookelo. Projeke e e tle go tswela dibeke dile 8 fela bana ba tshwanela go tswela go bonwa dibeke tse 3 tse di latelang tsa bofelo go fitlhela ba le dikgwedi di le 5½. Go tla dirwa tse di latelang:

- Leeto 1: Go kala, meta boleele le tlhogo
- Leeto 2: Go kala
- Leeto 3: Go kala, meta boleele le tlhogo. O thile go kopiwa go araba dipotso tsa maphelo le bonno le dijo tsa tlwaelo tse ngwana a di jang.

7.3. Maikarabelo

Maikarabelo a me ke go bona gore ke tlisa ngwana mo lefapheng la tsa phepo mo Dr George Mukhari Hospital ka matsatsi le nako tse ke di neiwang go busa ngwana.

7.4. Dikotsi

Ga go na dikotsi kgotsa dingwe tse di ka tsonang ngwana mo mathateng ka nako ya dipatlisiso.

7.5. Moputso o o ka bonwang

Dipholo tsa projeke e di tla thusa bana ba bal eng mo lenaneong la PMTCT ka go tlhokomelwa ga kolo.

7.6. Poloko ya tshedimosetso

Tshedimosetso yotlhe e e bonweng e tla bolokwa ka kelotlhoko e dirisetswa thesis e bile leina la ngwanake le ka se phetlhaletswe.

7.7. Go fithelela dipholo

Dipholo tsa dipatlisiso ka ngwanaka ke ka di itsisiwa ga ke dikopa e bile di ka se senolelwe mongwe gape.

7.8. Go ithaopa go tsaa karolo/Go gana/Go se tsewelele

Botsaakarolo ba me bo tswa mo go reng ke ithaopile e bile ke ka gana go tsaa karolo. Ga ke a gapeletswa go tsaa karolo e bile ke ka gana ntle le go amega bobbe ka seo. Ken a le nngwe le ga ken e ke dumetse go tsaa karolo. Ke ka tswa mo dipatlisisong tse ntle le go atholwa kgotsa go kgethollwa. Ngwanake a ka kopiwa go tlogela go tsaa karolo pele dipatlisiso di fela ga mmatlisisi a bona go tshwanelegile go dira jalo.

8. Tshedimosetso ke e tlhaloseditswe ke
 (*leina la motho o o maleba*) ka Afrikaans/*English/*seTswana mme ke tlhaloganya loleme e bile ke tlhaloseditswe mo go kgotsofatsang
 (*leina la toloki*). Ke filwe monyetla wa go botsa dipotso e bile ke arabilwe mo go kgotsofatsang.
9. Ga ke a gatelelwa go tsaye karolo e bile ke a tlhaloganya nna le ngwanake re ka ikogela morago ntle le go otlhaiwa.
10. Ga gona dithaelo tse ke tlo di dirang mo botsaakarolo bo.

C. KE DUMELA BOINEELO BA BOTSAAKAROLO MO THUTONG E E LATELANG:

Nna (*leina la motsadi*)..... ke ithaopa go letlelela ngwanake(*leina la ngwana*) o a leng dikgwedi di lego tsaya karolo mo projekeng e e latelang.

Ke amogela gore:

- Ke badile kgotsa ke baletswe kitsiso leforomo ya tumelo e e kwetsweng ka loleme le ke le buang ka thelelo le ka tokologo.
- Ke bone manyetla wa go bots dipotso e bile di arabilwe ka botlalo.
- Ke tlhaloganya gore botsaakarolo ke boithaopi ba me e bile ga ke a gapelediwa.
- Nna ke ikogela marago nako nngwe le nngwe ntle le go tlhopololwa.
- Ngwanake a ka kopiwa go emisa mo projekeng pele e ka fela ga mmatlisisi a bona go tshwanelegile kgotsa ke sa latelele tsamaiso jaake re dumelone.

Go saenilwe kwa.....ka.....2006

(*lefelo*)

(*letlha*)

.....

Tshaeno ya motsadi

.....

Tshaeno ka paki

*Gontsha tse di sa batlegeng

Declaration By Investigator

I (*name*)declare that:-

- I explained the information in this document to..... (*name of mother*).
- 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
- This conversation was conducted in English/*Afrikaans and no translator was used/this conversation was translated into (*language*) by (*name of translator*).

Signed aton2006
(*place*) (date)

.....
Signature of Investigator

.....
Signature of Witness

*Delete where not applicable

Declaration By Translator

I (*name*) declare that:-

- I assisted the investigator (*name*) to explain the information in this document to (*name of mother*) using the language medium of (*language*).
- We encouraged her 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 mother fully understands the content of this informed consent document and has had all her questions satisfactorily answered.

Signed at on2006
(*place*) (date)

.....
Signature of Translator

.....
Signature of Witness

*Delete where not applicable

MOLAETSA GO MOTSAAKAROLO

Mme,

Ke leboga botsaakarolo ba ngwana wag ago mo projekeng e.

Fa o na le dipotso kgotsa o tlhoka go itse sengwe ka projeke kgotsa o sa kgone go tla bookelong ka malatsi a o a filweng ka kopo leletsa

Caïda Mac Dougall mo **083 556 3624** or **012 5293585**.

O ka ikopanya le komiti ya Human Research mo 021-938 9207 ga o na le dingongorego tse di sa seka sekwang sentle ke ba lefapha la phepo.

O tla fiwa kgatiso ya ditshedimosetso le foromo ya tumelo go ipolokelo tsona.

APPENDIX 9

**UNIVERSITY OF LIMPOPO (MEDUNSA CAMPUS): CONSENT FORM -
SETSWANA**

University of Limpopo (Medunsa Campus) FOROMO YA TUMELO

Statement concerning participation in a Clinical Trial/Research Project*.

Lenaneo la dipatlisiso:

Growth and nutritional status of formula-fed infants aged 2-10 weeks enrolled into the Prevention of Mother-to-Child Transmission (PMTCT) Programme at Dr George Mukhari Hospital.

Ke badile tshedimose tso */ke boleletswe ka maikaelelo a teko e ke neilwe monyetla wa go botsa dipotso, ke tlhaloseditswe tshotlhe e bile ke kgotsofetse. Ga ke a gapelediwa go tsa karolo.

Ke tlhaloganya gore botsaa karolo mo lenaneong ke ka boithaopo ba me e bile ke ka ikogogela morago nako nngwe le nngwe ntle le go fa mabaka. Seo se ka se a me kalafo e o ke e bonong mo bookelong le mo lefapheng la pholo.

Ke a itse le gore thuto e e dumeletswe ke Ethics le Publications Committee of the University of Limpopo (Medunsa campus)/Dr George Mukhari. Ke itse ka botlalo gore dipholo tsa dipatlisiso tse di tla dirisetswa dithuto e bile di ka phatlaletswa. Ke dumela gore se se dirwe go netefatswe gore gankitla ke senolwa e bile dintlha ka ga me di boloketshegile.

I hereby give consent to participate in this study.

.....
Leina la mme

.....
Tshaeno ya mme

.....
Lefelo

.....
Letlha

.....
Paki

Statement by the Researcher

I provided verbal and/or written* information regarding this study.

I agree to answer any future questions concerning the study as best as I am able.

I will adhere to the approved protocol.

.....
Name of Researcher Signature Date Place

*Delete whatever is not applicable.

*Gontsha tse di sa batlegeng

APPENDIX 10

UNIVERSITY OF STELLENBOSCH, ETHICS COMMITTEE APPROVAL



UNIVERSITEIT-STELLENBOSCH-UNIVERSITY
Jou kennisvenoot • your knowledge partner

23 November 2006

Mrs GC Mac Dougall
Discipline of Human Nutrition
Dept of Interdisciplinary Health Sciences

Dear Mrs Mac Dougall

RESEARCH PROJECT : "GROWTH AND NUTRITIONAL STATUS OF FORMULA-FED INFANTS AGED 2-10 WEEKS IN THE PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT) PROGRAMME AT DR GEORGE MUKHARI HOSPITAL"

PROJECT NUMBER : N06/09/172

My letter dated 30 October 2006 refers.

At a meeting that was held on 13 November 2006 the Committee for Human Research ratified the approval of the abovementioned project.

Yours faithfully

CJ VAN TONDER
RESEARCH DEVELOPMENT AND SUPPORT (TYGERBERG)
Tel: +27 21 938 9207 / E-mail: cjvt@sun.ac.za

CJVT/pm



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Fakulteit Gesondheidswetenskappe • Faculty of Health Sciences



Verbind tot Optimale Gesondheid • Committed to Optimal Health
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Tel: +27 21 938 9677 • Faks/Fax: +27 21 931 3352
E-pos/E-mail: rdsinfo@sun.ac.za

APPENDIX 11

**RESEARCH, ETHICS AND PUBLICATIONS COMMITTEE OF THE FACULTY OF
MEDICINE OF THE UNIVERSITY OF LIMPOPO (MEDUNSA CAMPUS)
CLEARANCE CERTIFICATE**

UNIVERSITY OF LIMPOPO
Medunsa Campus



RESEARCH, ETHICS & PUBLICATIONS COMMITTEE

FACULTY OF MEDICINE

CLEARANCE CERTIFICATE

P O Medunsa
Medunsa
0204
SOUTH AFRICA

Tel: 012 - 521 4000
Fax: 012 - 560 0086

MEETING: 06/2006

PROJECT NUMBER: MP 78/2006

PROJECT: Title: Growth and nutritional status of formula-fed infants aged 2-10 weeks enrolled into the prevention of mother to Child transmission (PMTCT) programme at Dr George Mukhari Hospital

Researcher: Mrs C Mac Dougall
Supervisor: Mr RD Kennedy
Co-supervisor: Prof UE MacIntyre
Hospital Superintendent: Prof Holland
Other Involved H.O.D's: Mrs SK Robberts (Head of Human Nutrition Dept, Dr George Mukhari Hospital)

Department: Institute for Human Nutrition
Degree: MSc (Nutrition) University of Stellenbosch

DATE CONSIDERED: August 07, 2006

DECISION OF COMMITTEE:

REPC approved the project.

DATE: August 07, 2006


PROF GA OGUNBANJO
CHAIRMAN (RESEARCH) REPC OF FBM



- | | |
|--------------|--|
| Note: | <p>i) Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee.</p> <p>ii) The budget for the research will be considered separately from the protocol. PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.</p> |
|--------------|--|

APPENDIX 12

EXAMPLE OF SUBJECT IDENTITY CARD

Front

YOUR STUDY NUMBER IS

10

Project title:
Growth and nutritional status of formula-fed infants aged 2-10 weeks
attending the Department of Human Nutrition at Dr George Mukhari
Hospital.

Contact person: Caida Mac Dougall (012) 529 3585 or 083 556 3624

Reverse

FOLLOW-UP DATES AND TIMES:

VISIT 1:

VISIT 2:

VISIT 3:

APPENDIX 14

NUTRITIONAL COMPOSITION OF NAN PELARGON®

Average Composition	Unit	Per 100 g powder	Per 100 ml formula	% RDA per 100 ml
Fat	g	25.9	3.39	-
Linoleic Acid	g	4.13	0.54	-
Alpha Linolenic Acid	mg	506	66	-
Protein	g	11.4	1.49	-
Carbohydrate	g	57.8	7.57	-
Soya Lecithin	g	1.0	0.13	-
Ash	g	1.9	0.25	-
Moisture	g	3.0	-	-
Energy	kcal	510	67	-
	kJ	2130	279	-
Vitamin A	IU	1800	236	11
	mcg RE	540	71	17
Vitamin D	IU	310	41	10
	mcg	7.6	1.0	10
Vitamin E	IU	6.1	0.8	18
Vitamin K	mcg	41	5.4	45
Vitamin C	mg	51	6.7	19
Thiamine (B1)	mg	0.36	0.05	16
Riboflavin (B2)	mg	0.76	0.1	25
Niacin (PP)	mg	5.1	0.7	11
Biotin	mcg	11	1.4	-
Folic Acid	mcg	46	6	20
Pantothenic acid	mg	2.3	0.3	15
Vitamin B6	mg	0.38	0.05	17
Vitamin B12	mcg	1.5	0.2	39
Choline	mg	51	6.7	-
Inositol	mg	25	3.3	-
Taurine	mg	41	5.4	-
Carnitine	mg	8.2	1.1	-
Calcium	mg	320	42	12
Phosphorous	mg	160	21	9
Magnesium	mg	41	5.4	11

Average Composition	Unit	Per 100 g powder	Per 100 ml formula	% RDA per 100 ml
Potassium	mg	500	66	7
Sodium	mg	120	16	-
Chloride	mg	320	42	6
Iron	mg	6.1	0.8	8
Copper	mg	0.31	0.04	6
Iodine	mcg	76	10	25
Manganese	mcg	45	5.9	-
Selenium	mcg	10	1.3	-
Zinc	mg	7.6	1.0	33

Ingredients: Demineralised whey (protein source), maltodextrin, skim milk (protein source), vegetable fat (palm, olein, low erucic rapeseed, coconut, sunflower), potassium caseinate (protein source), lactic acid, soya lecithin, vitamins, zinc sulphate, ferrous sulphate, copper sulphate, potassium iodide and sodium selenate.