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INFANT FEEDING PRACTICES IN RURAL SOUTH AFRICA AND RECOMMENDATIONS TO PREVENT POSTNATAL TRANSMISSION OF HIV

A thesis presented for the degree of Doctor of
Medicine

University of Glasgow

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ABSTRACT

BACKGROUND

Breastfeeding makes a major contribution to child health and is also recognised as a significant factor in child survival. Exclusive breastfeeding (EBF) from 0 to 6 months of age is recommended by the World Health Organization (WHO) as the optimal feeding method for infants, including infants of HIV-infected women from developing countries who, after appropriate counselling, choose to breastfeed. Whilst there is evidence that EBF may be associated with less risk of postnatal HIV transmission than mixed feeding, it is still uncommonly practised for reasons that are poorly understood.

Both the patterns and duration of breastfeeding are important determinants of health outcomes. In vertical HIV transmission research, reliable documentation of early breastfeeding practices is important in order to correctly attribute postnatal transmission to feeding patterns.

AIMS

The work of this thesis formed the preparatory phase of work for the Wellcome-funded Vertical Transmission Study (VTS) in rural KwaZulu Natal, South Africa. The aim of the VTS was to examine the postnatal transmission risks associated with infant feeding, specifically exclusive breastfeeding.

The aim of this thesis was to undertake three specific areas of work to inform the design of the VTS:

1. Breastfeeding practices in the study area. To assess exclusive breastfeeding rates, other infant feeding practices, and impediments to exclusive breastfeeding in a cohort of infants.
2. Use of non-prescribed medications. To describe the variety, and frequency of administration, of non-prescribed medications given to infants in the first three months of life in the study area.
3. Methodology of collection of breastfeeding data. To validate methods of collecting data on the duration of exclusive breastfeeding in the study area.

POPULATION AND METHODS

Two studies were conducted: a cross-sectional survey and a longitudinal study.

In the cross-sectional survey 445 consecutive mothers and care-givers of infants aged one day to 12 months, attending immunisation clinics, were interviewed using a structured questionnaire in August and September 1999.

In the longitudinal study, 130 women attending three clinics, chosen for their disparate socio-economic characteristics, were interviewed about feeding practices at weekly postnatal intervals to 16 weeks, from September 1999 to February 2000. At every interview a 48 hour and a 7 day recall breastfeeding history were taken. A subset of 70 mothers also received two intermediate visits per week during which additional 48 hour, non-overlapping, recall interviews were conducted. 93 infants were revisited at 6-9 months of age when mothers' recall of exclusive breastfeeding duration from birth was documented.

In addition, mothers were visited at 6 and 12 weeks postnatally and any medications given to their infants was recorded.

RESULTS

In the longitudinal study all mothers initiated breastfeeding but 46% of infants received non-breastmilk fluids or feeds within 48 hours of birth; only 10% were exclusively breastfed for 6 weeks and 6% for 16 weeks. Supplements, most commonly formula milk, were introduced for perceived milk insufficiency. 43% of women made their own decisions about feeding, but health staff (22%) and grandmothers (16%) were cited as sources of advice. In the cross-sectional survey caregivers reported that 47% of infants aged 2 weeks, 40% aged 6 weeks and 33% aged 12 weeks had been exclusively breastfed since birth.

A total of 107 (97%) of infants received non-prescribed medications in the first 3 months of life: 89% rectally and 58% orally. The most common enema contained traditional Zulu medicine made from herbs, given more than once weekly, usually for perceived constipation; the most common oral medication was gripe water, given once daily, mainly for 'colic' or 'wind'. Twenty-nine (26%) mothers had consulted a traditional healer, most commonly regarding concerns about a capillary naevus. Mothers with a clean water supply were more likely to give non-prescribed oral medications than those without (OR 2.7; p 0.02), whilst those who had no education were less likely to administer them than those who had completed school (OR 0.19, p 0.03).

Reported breastfeeding practices over the previous 48 hours did not reflect exclusive breastfeeding practices since birth (specificity 65-89%; positive

predictive value 31-48%). Six month exclusive breastfeeding duration recall was equally poor (sensitivity at 2 weeks 79%; specificity 40%). Seven day recall accurately reflected exclusive breastfeeding practices compared with thrice weekly recall over the same time period (sensitivity 96%; specificity 94%).

CONCLUSIONS

Exclusive breastfeeding is uncommon despite a Baby-friendly Hospital Initiative in the district. Any strategy to promote exclusive breastfeeding should target women antenatally, involve other influential members of the family, provide relevant information about the physiology of breastfeeding and breastmilk production, and support mothers in the important first two weeks post delivery.

Non-prescribed medications are given almost universally to young infants, irrespective of socio-economic class. These medications interfere with exclusive breastfeeding, and their effect on postnatal mother-to-child transmission of HIV is not known. Health professionals need to be aware of the extent of, and reasons for, administration of non-prescribed medications to young infants, so that effective health messages can be targeted at mothers and caregivers.

The study compared different methods for measuring the recollection of duration of exclusive breastfeeding in the same cohort of women, in which the WHO definitions of early infant feeding were consistently applied. If an infant ever received a fluid or feed other than breastmilk s/he was removed from the EBF category, and was classified as a mixed feeder from that time. This is crucial when documenting breastfeeding patterns in relation to mother-to-child transmission of HIV. In this study, 48 hour exclusive breastfeeding status did not accurately reflect

feeding practices since birth. Long term recall data on exclusive breastfeeding were even more inaccurate. Studies examining duration of exclusive breastfeeding, particularly in HIV transmission research, should be collected prospectively at intervals of no longer than a week.

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CHAPTER 1: BACKGROUND

1.1 THE GLOBAL HIV EPIDEMIC

Over the past 25 years, HIV (Human Immunodeficiency Virus) has been responsible for one of the most destructive epidemics in recorded history. HIV has been isolated from virtually all body fluids, including blood, semen, vaginal secretions, tears, urine, saliva and breast milk. Transmitted through sexual contact, parenterally through needle-sharing drug abusers, via blood transfusions and through mother-to-child transmission (MTCT), the number of people living with HIV in 2005 reached 40.3 million (36.7 – 45.3 million), and Acquired Immunodeficiency Syndrome (AIDS), the end stage of the disease caused by HIV, has killed more than 25 million people over the past 25 years world-wide¹.

Sub-Saharan Africa remains undoubtedly the area most devastated by the epidemic¹. It has just over 10% of the world's population, but more than 60% of all people living with HIV live there – 25.8 million (23.8 – 28.9 million), of whom 13.5 million (12.1 – 14.6 million) are women¹. There is little evidence of declining epidemics in countries in southern Africa, apart from Zimbabwe¹. In South Africa a national adult HIV prevalence of less than 1% in 1990 rose to almost 25% within 10 years, and HIV prevalence amongst pregnant women has reached the highest levels recorded: 29.5% (28.5 – 30.5%) of women attending antenatal clinics were HIV-positive in 2004, with prevalences reaching 40% in the hardest-hit province, KwaZulu Natal¹.

Due to MTCT of HIV, the epidemic among women of childbearing age is associated with a parallel epidemic in children, with an estimated 700,000 (630,000 – 820,000) new infections in children under 15 years worldwide in 2005¹. MTCT of HIV can occur before, during and after delivery (see Section 1.4). In sub-Saharan Africa the majority of HIV-infected children die before their fifth birthday and HIV is already contributing to increased rates of childhood mortality². Breastfeeding contributes to this increase, with an estimated 5-20% of infants born to HIV-positive women acquiring the infection through this route, and this mode may be responsible for 30-50% of HIV infections in infants and young children in Africa^{3,4}. Avoidance of all breastfeeding exposes children to different risks – exposure to other life-threatening infections⁵ and malnutrition due to inadequate replacement feeding⁶. Thus arises the significant public health dilemma – how should HIV infected women feed their children, and what is the effect of the HIV epidemic on infant feeding practices, particularly in areas of the world with high HIV prevalences and high rates of breastfeeding?

1.2 THE BENEFITS OF BREASTFEEDING

Breastfeeding makes a major contribution to child health and is also recognized as a significant factor in child survival^{5,7-11}. Exclusive breastfeeding (Table 1) is the best form of feeding for the infant during the first six months of life¹². The crucial benefit of exclusive breastfeeding for six months (versus exclusive breastfeeding for four months followed by partial breastfeeding to six months), in developing-countries, is the decreased morbidity and mortality associated with infectious diseases, particularly diarrhoea¹³. The advantages of breastfeeding over formula feeding have been well described¹⁴⁻¹⁶, and are more than just the advantages of

the constituents of breastmilk. Breastfeeding also protects a mother's health and has economic and emotional benefits¹⁷⁻¹⁹.

Table 1: Definitions of breastfeeding patterns²⁰⁻²²

Breastfeeding pattern	Definition
Exclusive breastfeeding	Means giving the infant no other food or drink, not even water, apart from breastmilk (including expressed breastmilk), with the exception of drops or syrups consisting of vitamins, mineral supplements or prescribed medicines
Predominant breastfeeding	The infant's predominant source of nourishment is breastmilk. However, the infant may also have received water or water-based drinks (sweetened or flavoured water, teas, infusions, etc); fruit juice; Oral Rehydration Salts (ORS); drop and syrup form vitamins, minerals and medicines; and folk fluids (liquids used for non-nutritional purposes e.g. oil for constipation or tea for relief of colic). With the exception of fruit juice and sugar-water, no food based fluid is allowed under this definition
Partial breastfeeding	Means giving a baby some breastfeeds, and some artificial feeds, either milk or cereal, or other food
Mixed breastfeeding	Means giving a baby both breastmilk and other foods or liquids (i.e. includes predominant and partial breastfeeding)

1.2.1 Biochemical composition of human milk

The unique composition of breastmilk provides the ideal nutrients for human growth, particularly brain development, in the first months of life^{13,23-25}. The balance of macronutrients and micronutrients and the bioavailability of essential nutrients ensure that digestion and absorption are highly efficient¹⁶. For example, greater than 50% of iron from human milk is absorbed compared with typically less than 12% of iron from cow milk-derived formula²⁶. Values of 7% to 12% appear to be most representative for term infants fed cow milk formula²⁶. In addition the lactoferrin in breastmilk binds with iron to make it unavailable to the pathogen *Escherichia coli* which depends on iron for its growth¹⁶. Lactoferrin appears in very low amounts in cow's milk. The protein composition of mature breastmilk is approximately 8-10g/l. The quantity and quality of protein in the breastmilk are important. The protein of breastmilk consists of micellar caseins and aqueous whey proteins²⁵. The ratio of whey proteins to casein is 1.5 for breastmilk and 0.25 for cow's milk; that is 40% of human milk protein is casein and 60% whey, and 80% of cow's milk is casein and 20% whey¹⁶. The predominant casein of human milk is β -casein, which forms micelles of relatively small volume and produces a soft, flocculent curd in the infant's stomach¹⁶. α -lactalbumin, lactoferrin, secretory IgA, and serum albumin are the major whey proteins in breastmilk^{16,25}.

The proteins in human and animal milks contain a different balance of amino acids¹⁶. Cow's milk contains very little taurine and, therefore, is found in lower quantities in formula fed infants compared to those who are breastfed¹⁶. Taurine performs a neuro-transmitter or neuromodulator role in the brain and retina in addition to being generally involved in the stability of membranes²⁷. Infants

conjugate bile acids predominantly with taurine immediately after birth, but quickly change to conjugate with glycine¹⁶. Cysteine levels are also high in human milk; whilst levels of phenylalanine and tyrosine are low¹⁶. Premature infants do not have the enzymes necessary for metabolism of phenylalanine or tyrosine¹⁶.

Human milk contains numerous immunoglobulins, particularly secretory IgA which protects the infant from bacteria and viruses which invade the mucosa^{28,29}. Other factors found in breastmilk include mucins and sialic acid-containing glycoproteins, which have been shown to inhibit rotavirus replication and prevent experimental gastroenteritis¹⁶, and lysozyme - a specific protein with lytic properties which has low levels in cow's milk¹⁶ and is bacteriolytic against Enterobacteriaceae and gram-positive bacteria and helps maintain the characteristic intestinal flora of the breastfed infant¹⁶.

Human milk not only provides passive protection but can also directly modulate the immunological development of the infant^{30,31}. The thymus of a breastfed infant is considerably larger compared to a formula-fed infant, and this is likely to be caused by immune modulating factors in breastmilk^{30,31}. Breastfed infants have a reduced incidence of later allergic diseases³² and conditions associated with auto- or dysregulated immunity, for example Crohn's disease^{33,34}, insulin dependent diabetes mellitus³⁵ and lymphomas³⁶. The immuno-modulatory properties of breastmilk are thought to contribute to this protection^{32,37}. Cytokines, chemokines and colony-stimulating factors have been found in human milk³⁸.

These molecules are described as pluripotent polypeptides that act in autocrine/paracrine ways through binding to specific cellular receptors³⁸.

Cytokines, including IL-1 (insulin-like growth factor 1), IL-1 β and TNF- α (tumour

necrosis factor), function by forming networks and produce a cascade effect which helps the immune system to develop and function well³⁸. Colony-stimulating protein factors have been discovered in breast milk, including G-CSF (granulocyte colony stimulating factor), M-CSF (macrophage colony stimulating factor) and GM-CSF (granulocyte-macrophage colony stimulating factor)³⁸. They are responsible for control of cell proliferation and differentiation during haematopoiesis³⁸. Chemokines are small chemotactic cytokines which activate leucocytes and mediate inflammation³⁸.

Epidermal growth factor (EGF), a small polypeptide mitogen found in human milk, also helps to protect the gut of the infant³⁹. EGF has many functions and is reported to stimulate the proliferation of epidermal and epithelial tissues, accelerate the growth and maturation of the fetal pulmonary epithelium and improve healing of wounds of the corneal epithelium³⁹.

Lipids are essential for energy and neurodevelopment of the infant. Trial data reports more advanced development at 8-18 years in children, born preterm, who were breastfed in infancy as compared to those who were formula fed⁴⁰; and at 18 months and 8 years in children born preterm who received breastmilk as opposed to preterm formula^{41,42}. Triacylglycerols, phospholipids and their component fatty acids, the sterols, are the most important lipids in breastmilk²⁵. The lipids contribute about 50% of the calories in breastmilk and also provide essential fatty acids and cholesterol. Linoleic and linolenic acids in breastmilk are transformed into longer-chain polyunsaturates which have important roles in prostaglandin synthesis and maintaining the fluidity of membrane lipids³⁷. The fatty acids, arachidonic acid and DHA, are components of the grey matter and are

synthesized from linoleic and linolenic acids³⁷. Cholesterol is an essential component of all membranes and is required for growth, replication and maintenance¹⁶. Breastfed infants have higher plasma cholesterol levels than those fed formula¹⁶. There are some studies from animals which show that infants who receive a high cholesterol diet early in life are protected from high levels of cholesterol when they are older¹⁶.

Finally, the first milk produced, colostrum, is particularly important for the infant both nutritionally and immunologically. Protein, fat-soluble vitamins (particularly vitamin A, carotenoids, sodium and vitamin E) and minerals are found in greater quantities than in mature milk²⁵. Colostrum is rich in immunoglobulins, particularly secretory IgA, and contains anti-oxidants (an ascorbate-like substance and uric acid) which might trap neutrophil-generated reactive oxygen metabolites⁴³. Colostrum promotes bifidus flora in the gastro-intestinal tract and the excretion of meconium¹⁶. The high protein and fat levels are appropriate for the requirements and reserves of the newborn infant¹⁶.

1.2.2 Protection against disease

Breastfeeding is associated with significant reduction in the incidence and duration of many childhood illnesses⁵ including diarrhoea⁴⁴, pneumonia⁴⁵, otitis media⁴⁶, bacteraemia⁴⁷ and meningitis⁸.

Globally, most of the deaths attributable to artificial feeding are due to diarrhoeal illnesses. The WHO reported that in 1995 3 million deaths annually occur from diarrhoea in children less than 5 years of age⁴⁸. A study from rural Bangladesh reported that one third of all deaths in children from 18 to 36 months of age were

attributable to failure to breastfeed⁴⁹. In Malaysia the attributable mortality rate for artificial feeding was reported to be between 28 and 153 per 1000 infants depending, respectively, on the presence or absence of piped water and toilet facilities in the home⁵⁰. A meta-analysis of available data from six studies, with data on all-cause death for 1123 children under two years of age showed that non-breastfed infants are at higher risk of mortality than those who are breastfed. There was a six-fold increased protection against diarrhoeal deaths by breastfeeding and a 2.4 fold protection against respiratory deaths in the first six months of life⁵.

In a study from the Philippines deaths from diarrhoeal diseases were ten times more common for infants under six months of age who were never breastfed or where breastfeeding was stopped, compared to those who had been breastfed⁵¹. Even in settings with better resources, increased breastfeeding rates were associated with a significantly reduced risk of diarrhoeal diseases in the first year of life^{9,52}.

Pneumonia is one of the leading causes of death in children under 5 years, worldwide. In Brazil, infants who were not breastfed had a significant and substantially increased risk of hospitalization for pneumonia (risk of admission was 17 times greater among infants who were not being breastfed) compared with breastfed infants, while among breastfed infants the risk of hospitalisation was associated with mixed feeding with solids, but not fluids⁴⁵. Even for children who received both breast and formula milk the risk was about four times greater than for children who received breastmilk alone. In a further study of infant deaths from infectious diseases in Brazil, non-breastfed Brazilian infants were 3.6 times more

likely to die of acute lower respiratory tract infections than those who received breastmilk and no artificial milk. Infants receiving both human and artificial milk had an intermediate odds ratio of 1.6^{10,53}.

These benefits of breastmilk are not limited to the developing world. A study from Dundee, Scotland, showed that the probability of respiratory illness occurring at any time during childhood was significantly reduced if the child was exclusively breastfed for 15 weeks and no solid foods were introduced during this time⁵⁴. Furthermore, children who were given solids before 15 weeks of age were heavier, fatter, and had higher systolic blood pressure in childhood⁵⁴.

A study of North American infants showed that avoidance of breastfeeding leads to a 4- to 16-fold risk of *Haemophilus influenzae* bacteremia and meningitis⁸. In Finland, where more women initiate and practise prolonged breastfeeding compared to women in the USA, *H. influenzae* meningitis is much less frequent during the first year and infants who receive breastmilk beyond six months are only one third as likely to develop meningitis during the second year of life⁵⁵.

Breastfeeding protects against acute otitis media, partly because of the protective constituents of human milk and also because the process of suckling at the breast helps to protect the inner ear⁴⁶.

In a multicentre study on 926 preterm infants, necrotizing enterocolitis developed in 5.5%⁵⁶. Infants fed solely on formula milk were six to ten times more likely to develop the disease compared to exclusively breastfed infants, and three times more likely compared to those fed on formula plus breastmilk⁵⁶. Furthermore, among babies born at more than 30 weeks gestation, confirmed necrotizing

enterocolitis was rare in those who received some breastmilk and was 20 times more common in infants receiving formula milk only⁵⁶.

Carpenter et al observed in British neonatal units that breastmilk is the single most effective method of preventing necrotising enterocolitis, preventing 100 deaths annually⁵⁷. In a prevention programme in Sheffield, England, the post-perinatal mortality rate was reduced from 5.2 to 1.9 per 1000. Breastfeeding accounted for an estimated 24% of the reduction in the mortality rate⁵⁷.

Sudden infant death syndrome is more common amongst infants fed on formula milk⁵⁸. Formula-fed infants aged 0-3 months, from families with an excellent standard of home care, had a relative risk of sudden death 7.7 times higher than for infants who were breastfed during the previous three weeks⁵⁸.

There is some evidence that if an infant is ever breastfed there is some protection against urinary tract infections in infancy⁵⁹.

In addition, there are several studies which suggest that breastfeeding is associated with a reduced frequency of certain chronic diseases later in life^{16,32}, including lymphoma³⁶, Crohn's disease^{33,34,60} and celiac disease⁶¹. Formula feeding may result in lymphoid hypertrophy and some of the immunologic phenomena associated with autoimmune disease^{62,63}. It is known to accelerate the development of celiac disease⁶⁴ and is a risk factor for Crohn's disease and ulcerative colitis in adulthood^{33,34}. Immunologic damage to pancreatic beta cells is thought to cause insulin-dependent diabetes mellitus and studies suggest that formula feeding is a risk factor accounting for 2% to 26% of cases³⁵. It is thought that breastfeeding is protective against pancreatic β -cell destruction⁶⁵.

Furthermore, if diabetes does develop in breastfed children they are less likely to have anti-thyroid antibodies⁶⁶. There are reports of a decreased incidence of food allergies in infants who are exclusively breastfed, and breastfeeding appears to delay the development of atopic dermatitis, particularly in allergic families^{67, 68}.

Many earlier studies looked only at whether infants breastfed or not. There have been several recent studies looking at breastfeeding patterns and morbidity. These have focused more on the pattern of breastfeeding, and have looked at the protection afforded by exclusive breastfeeding. In a randomised controlled trial, women who received either six counselling visits or three counselling visits were compared with a control group that had no supportive intervention⁶⁹. Exclusive breastfeeding, at three months post-partum, was practised by 67% of six-visit, 50% of three-visit and 12% of control mothers (intervention groups vs controls, $p < 0.001$; six-visit vs three-visit, $p = 0.02$). Fewer intervention than control infants had an episode of diarrhoea (12% vs 26%, $p = 0.03$)⁶⁹. In another randomized trial in the Republic of Belarus, hospitals and polyclinics were randomly assigned to receive an experimental intervention modelled on the Baby-friendly Hospital Initiative of the World Health Organization⁵². Infants from the intervention sites were significantly more likely than control infants to be exclusively breastfed at three months (43.3% vs 6.4%; $p < 0.001$) and at six months (7.9% vs 0.6%; $p = 0.01$), and had a significant reduction in the risk of one or more gastrointestinal tract infections (9.1% vs 13.1%; adjusted OR, 0.60; 95%CI, 0.40-0.91) and of atopic eczema (3.3% vs 6.3%; adjusted OR, 0.54; 95%CI, 0.31-0.95). A recent community-based study promoting exclusive breastfeeding in India reported increases in exclusive breastfeeding rates at three months in the intervention compared to control communities (79% vs 48%; OR 4.02, 95%CI 3.01-5.38,

$p < 0.0001$); and a reduction in the 7-day diarrhoea prevalence in infants in the intervention compared to control communities at three months (0.64, 0.44-0.95, $p = 0.028$) and at six months (0.85, 0.72-0.99, $p = 0.04$)⁷⁰.

1.2.3 Psychological and developmental benefits

Breastfeeding has important psychological benefits for both the mother and the infant^{71,72}. Some consider that the relationship a breastfeeding mother has with her infant is the strongest human bond. If a healthy infant is delivered to a mother who did not receive medication and placed on her abdomen immediately after birth, the infant crawls to the breast on its own and latches on and suckles⁷³.

There has been increasing interest over the past decade in breastfeeding and improved cognitive outcome in infants. Studies have found that premature infants who received breastmilk by tube feeding were more advanced developmentally at 18 months and 7-8 years than those of comparable gestational age and birthweight who had received formula by tube⁴¹. Such observations suggest that breastmilk has a significant impact on the growth of the central nervous system. This is further supported by studies of visual acuity in premature infants who were fed breastmilk compared with those who were formula fed⁷⁴.

Horwood et al reported on an 18-year longitudinal study which examined the association between the duration of breastfeeding and childhood cognitive ability and academic achievement over 18 years⁴⁰. It demonstrated a small but detectable increase in childhood cognitive and educational achievement (assessed by a cumulative test score for various outcomes) in infants who were breastfed, even when confounding variables were accounted for⁴⁰. A variety of

measures showed these effects which were relatively long-lived, extending throughout childhood into young adulthood⁴⁰. Children who were breastfed for 8 months or longer had a mean test score at age 18 that was 0.11 to 0.30 standard deviation units higher than those not breastfed⁴⁰.

One of the criticisms of studies looking at breastfeeding and cognitive function is the concern related to confounding covariables such as socioeconomic status and maternal education. A meta-analysis²³, which included studies of children between six months and 15 years, indicated that after adjustment for appropriate key cofactors, breastfeeding was associated with significantly higher scores for cognitive development than was formula feeding, with an overall effect of 3.2 IQ points after controlling for potential confounders. The analysis showed that enhanced cognitive development was demonstrated early in development and was seen through childhood and adolescence²³. Developmental benefit was demonstrated with increasing duration of breastfeeding and low birth weight infants showed greater gains from breastfeeding compared to normal weight infants²³. The analysis suggested that normal weight infants who were breastfed have a cognitive developmental advantage of 2.66 points ($p < 0.001$) whereas low birth weight infants have an advantage of 5.18 points ($p < 0.001$) compared to formula fed infants²³.

1.2.4 Maternal benefits

Women who breastfeed return to their pre-pregnancy state faster than women who do not, and are less likely to develop obesity later in life⁷⁵. Breastfeeding protects against osteoporosis, due to greater increases in fractional calcium absorption during lactation^{17,76,77}. Breastfeeding promotes the involution of the

uterus and improves child spacing thus preventing anaemia as iron stores are less depleted^{19,78}. On a population basis breastfeeding may contribute more to birth spacing than all family planning use combined in many countries¹⁹. A woman who exclusively, or almost exclusively, breastfeeds during the first six months, and who has not resumed menstruation has a less than 2% risk of becoming pregnant⁷⁹.

The risk of ovarian cancer is reduced by increasing cumulative months of pregnancy, increasing length of oral contraceptive use and increasing duration of lactation which cause ovulation suppression^{18,80}. In addition there is compelling evidence that breastfeeding protects against premenopausal breast cancer⁸¹.

1.3 BREASTFEEDING PRACTICES

Exclusive breastfeeding (Table 1) is recommended, by the World Health Organization, as the ideal way to feed infants for the first six months of life to achieve optimal growth, development and health¹². Thereafter, to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues for up to two years of age or beyond^{12,13,24}. These recommendations apply to all populations and were endorsed by the World Health Assembly in 2001 (World Health Assembly resolution 54.2, 2001). Exclusive breastfeeding from birth is possible except for a few medical conditions, and unrestricted exclusive breastfeeding results in ample milk production.

Despite the nutritional adequacy²⁴ and benefits of exclusive breastfeeding, this pattern of feeding is only practised by a minority of women both in Africa⁸²⁻⁸⁵ and

worldwide^{69,86-88}, even in countries where the rates of breastfeeding initiation are high. Overall, an estimated 41% of infants under four months and 25% under six months are exclusively breastfed and in sub-Saharan Africa 23% of infants under six months of age are exclusively breastfed⁸⁹. A strict definition of exclusive breastfeeding was used (see Table 1), but the rates of exclusive breastfeeding at four and six months were based on a 24-hour history and not a lifetime rate.

UNICEF⁹⁰ reported low rates of exclusive breastfeeding and low rates of mothers still breastfeeding their children between 20-23 months in many parts of the world (Tables 2 and 3).

Table 2: Exclusive* and sustained breastfeeding patterns worldwide.
Adapted from UNICEF⁹⁰

Country	% of children(1995-2001 [#]) who are exclusively breastfed <6 months	% of children (1995-2001 [#]) who are still breastfeeding at 20-23 months
Angola	11	37
Botswana	34	11
Cambodia	12	59
Cameroon	12	29
Colombia	32	25
Comoros	21	45
Cuba	41	9
Egypt	57	30
Ethiopia	84	77
Gambia	26	54
India	37 (<4 months data only available)	66
Kazakhstan	36	17
Kenya	5	24
Lebanon	27 (<4 months data only available)	11
Malawi	44	77

Country	% of children(1995-2001[#]) who are exclusively breastfed <6 months	% of children (1995-2001[#]) who are still breastfeeding at 20-23 months
Mozambique	30	58
Nicaragua	22	29
Pakistan	16 (<4 months data only available)	56
Papua New Guinea	59	66
Rwanda	84	71
Saudi Arabia	31 (<4 months data only available)	30
Senegal	24 (<4 months data only available)	49
Sierra Leone	4	51
Tanzania	32	48
Thailand	4 (<4 months data only available)	27
Vietnam	31 (<4 months data only available)	21
Zambia	11 (<4 months data only available)	39

*Definitions: Strict definition of exclusive breastfeeding used (see Table 1) but the rates of exclusive breastfeeding at four and six months were based on a 24-hour history and not a lifetime rate.

[#] Data refer to the most recent year available during the period specified in the column heading

Table 3: Regional summaries of exclusive* breastfeeding for the first 3 months and sustained breastfeeding. Adapted from UNICEF⁹⁰

Region	% of children (1995-2000 [#]) exclusively breastfed from 0-3 months	% of children (1995-2000 [#]) still breastfeeding at 20-23 months
Sub-Saharan Africa	27	50
Middle East and North Africa	41	30
South Asia	36	67
East Asia and Pacific	54	Unavailable
Latin America and Caribbean	Unavailable	25
CEE/CIS and Baltic States	13	21
Industrialised countries	Unavailable	Unavailable
Developing countries	39	52
Least developed countries	34	64
Worldwide	39	52

*Definitions: Strict definition of exclusive breastfeeding used (see Table 1) but the rates of exclusive breastfeeding at four and six months were based on a 24-hour history and not a lifetime rate.

[#] Data refer to the most recent year available during the period specified in the column heading

A limitation to the promotion and support of exclusive breastfeeding for the first six months of life, in many populations, is the lack of understanding of reasons for the fall in exclusive breastfeeding rates during the first six months, even amongst highly motivated women and in societies where the majority of women initiate breastfeeding, even if not exclusively. In particular it is recognized that there is marked attrition of exclusive breastfeeding between four and six months¹³. The World Health Organization has identified as a research priority determining the biological and social constraints to exclusive breastfeeding for the first six months in different geographical and cultural settings¹³.

Common reasons for breastmilk supplementation include perceived insufficiency of milk and concerns over a crying baby^{21,91-94}. In a study in Mexico⁹⁴ perceived insufficiency of milk was common with 80% of women reporting this problem within the first four months post-partum. Perceived insufficiency of milk was the reason mentioned most often for the premature termination of breastfeeding and/or introduction of supplementary bottles.

Family pressures, beliefs and traditions surrounding feeding play important roles in a woman's confidence in, and ability to, exclusively breastfeed⁹⁵. In fact there are few physiological constraints on a successful outcome for breastfeeding, but a wealth of factors interact on the individual woman from family, friends and health care workers.

Early technical difficulties, including cracked nipples, engorgement and mastitis also play important roles in a woman's ability to initiate and sustain exclusive breastfeeding^{21,95,96}.

Although programmes that increase breastfeeding do not necessarily increase exclusive breastfeeding⁹⁷⁻⁹⁹ there is increasing evidence from around the world that it is possible to increase the rates of exclusive breastfeeding^{52,69,87}. To improve breastfeeding practices, global initiatives have concentrated on hospital policies and procedures⁹⁸⁻¹⁰⁰ for example the Ten Steps to Successful Breastfeeding (see Table 4)¹⁰¹. These interventions have shown significant impact on breastfeeding outcomes, but often these effects are not sustained in the community⁹⁸⁻¹⁰⁰. However, a facility-based breastfeeding intervention trial in Belarus, based on the WHO Baby-friendly Hospital Initiative (BFHI) did increase the duration and exclusivity of breastfeeding in the first year of life⁵². Thirty-one maternity hospitals and polyclinics in the Republic of Belarus were randomly assigned to receive an intervention based on the BFHI or a control intervention of continuing usual infant feeding policies and practices. Infants from the intervention sites were significantly more likely than control infants to be breastfed to any degree at 12 months (19.7% vs 11.4%), and were more likely to be exclusively breastfeeding at 3 months (43.4% vs 6.4%; $p < 0.001$) and at 6 months (7.9% vs 0.6%; $p < 0.01$).

Table 4: The Ten Steps to Successful Breastfeeding¹⁰¹

Every facility providing maternity services and care for newborn infants should:

1. Have a written breastfeeding policy that is routinely communicated to all health care staff
 2. Train all health care staff in skills necessary to implement this policy
 3. Inform all pregnant women about the benefits and management of breastfeeding
 4. Help mothers initiate breastfeeding within a half-hour of birth
 5. Show mothers how to breastfeed, and how to maintain lactation even if they are separated from their infants
 6. Give newborn infants no food or drink other than breastmilk, unless medically indicated
 7. Practise rooming-in - allow mothers and infants to remain together - 24 hours a day
 8. Encourage breastfeeding on demand
 9. Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants
 10. Foster the establishment of breastfeeding support groups and refer others to them on discharge from the hospital or clinic
-

There are several studies showing the impact of community-based support of breastfeeding which have been published over the last five years. A study from Mexico reported on the use of peer counselling using trained lay community members to contact and advise peers from the same community⁶⁹. Peer counsellors provide early counselling and follow-up and a potentially less costly outreach model. This study randomized women to two intervention groups with different counselling frequencies – one with six visits and one with three visits and a control group with no intervention. At three months post-partum, exclusive breastfeeding was practiced by 67% of 6-visit, 50% of 3-visit and 12% of control mothers (intervention groups vs controls $p < 0.001$; 6-visit vs 3-visit $p < 0.02$).

A similar study in Bangladesh reported on the effect of peer-counsellors in Dhaka⁸⁷. In Bangladesh 95% of mothers have home deliveries, so any strategy for increasing breastfeeding rates in hospitals and facilities fails to reach most mothers. Women were randomized to intervention or control groups. Peer counselling significantly improved breastfeeding practices - 70% of mothers were exclusively breastfeeding their infants at 5 months compared to 6% for the control group (difference = 64%; 95% CI 57% - 71%, $p < 0.0001$). Mothers in the intervention group initiated breastfeeding earlier than control mothers and were less likely to give prelacteal and postlacteal feeds. In this study WHO definition of feeding were used (see Table 1); data were collected at monthly intervals when a 24-hour recall in addition to a cumulative history over the past month were obtained by trained field workers. Mothers were asked at each monthly visit if they had fed her baby anything other than breastmilk since the last visit. A mother could be classified as partly breastfeeding at, for example, month four, but

exclusively breastfeeding at month five; the feeding history collected was not, therefore, a cumulative rate since birth.

More recently, a study assessed the feasibility, effectiveness and safety of an educational intervention to promote exclusive breastfeeding for the first six months of life in India⁷⁰. The approach used multiple counselling opportunities through existing primary health care services. At three months the exclusive breastfeeding rates were 79% (381) in the intervention and 48% (197) in the control communities (OR 4.02, 95% CI 3.01-5.38, $p < 0.0001$). In addition the 7-day diarrhoea prevalence was lower in the intervention than in the control communities at three months (OR 0.64, 0.44-0.95, $p = 0.028$) and six months (0.85, 0.72-0.99, $p = 0.04$). This study used strict WHO definitions for feeding (see Table 1); feeding data were collected at three months by 24 dietary recall, and at nine months when mothers were asked to recall the duration of time they exclusively breastfed their infant.

1.4 MOTHER-TO-CHILD TRANSMISSION OF HIV

The HIV pandemic in sub-Saharan Africa threatens to reverse the significant gains made in infant and child mortality over the last decades and the promotion of breastfeeding which has undoubtedly contributed to improved child health¹⁰²⁻¹⁰⁴.

Transmission of HIV infection from mother-to-child was first recognized in the 1980's soon after the recognition of acquired immune deficiency in adults. Both HIV type 1 and HIV type 2 can be transmitted from mother to child, but HIV-2 is

transmitted much less frequently^{105,106}. MTCT of HIV can occur before, during or after delivery, but rarely in early pregnancy.

Prolonged breastfeeding by an HIV-infected mother can double the overall risk of MTCT of HIV from less than 20% to about 40%⁴. Without specific interventions to reduce the risk of transmission of HIV estimated rates of MTCT range from 14% to 25% in Europe and America, and 13% to 42% in developing countries¹⁰⁷. Different characteristics in the populations reported on, and differences in the duration of breastfeeding, are considered to be responsible for these differences². In the absence of interventions, the estimated risk of timing of mother-to-child transmission is: 5-10% antenatally, 10-15% during labour and delivery and 5-20% in the postpartum period if the mother breastfeeds (Table 5).

Table 5: Estimated risk and timing of MTCT in the absence of interventions. Adapted by WHO from De Cock KM et al²⁰

Timing	Transmission rate
During pregnancy	5-10%
During labour and delivery	10-15%
During breastfeeding	5-20%
Overall without breastfeeding	15-25%
Overall with breastfeeding to six months	20-35%
Overall with breastfeeding to 18-24 months	30-45%

Studies have identified preventive regimens to substantially reduce perinatal transmission of HIV. In 1994, zidovudine (AZT) given to non-breastfeeding American and French women in the ACTG 076 trial regimen achieved a reduction of MTCT of HIV of 67%¹⁰⁸. One hundred mg of AZT was given orally five times daily starting at 14-34 weeks gestation and during labour 2mg/kg intravenous infusion over 1 hour, followed by a continuous infusion of 1mg kg⁻¹ hr⁻¹. Postpartum the infant was given 2mg/kg orally for every 6 hours for 6 weeks.

Regimes have since been reported which are simpler and more affordable¹⁰⁹⁻¹¹¹. These have reduced MTCT of HIV by approximately 35-50%: Thailand 50%¹⁰⁸; Cote d'Ivoire 37% at 3 months post-partum¹⁰⁹; Cote d'Ivoire/Burkina Faso 38% at 6 months¹¹⁰; West Africa 30% at 15 months¹¹¹.

The HIVNET 012¹¹² and SAINT¹¹³ studies reported an approximate 50% reduction in transmission using a single dose of nevirapine during labour to the mother, and to the infant¹¹² or mother and infant¹¹³ within 72 hours of birth. The potential for wide implementation of such regimens has become increasingly feasible.

Breastmilk transmission has, therefore, become an even more significant mechanism of MTCT, as it reduces the overall efficacy of peripartum interventions. In the Petra study¹¹⁴, a multicentre study conducted at five sites in Africa, a reduction of efficacy of the three anti-retroviral regimens used (A, B, C or placebo) was evident at 18 months: the HIV infection rates at 6 weeks and 18 months were 5.7% compared to 15% in Group A, 8.9% compared to 18% in Group B, 14.2% compared to 20% in Group C and 15.3% compared to 22% in the placebo group. The infants enrolled in the HIVNET 012 study were nearly all breastfed¹¹².

Significant differences in infant infection rates were confirmed at 3, 12 and 18 months.

The complete avoidance of breastfeeding by HIV-infected women in Africa is not realistic for many reasons apart from cost. The choices HIV-infected women make are a balance of risks between HIV transmission and increased morbidity and mortality due to the loss of protection by breastfeeding to diseases such as diarrhoea and pneumonia. A modelling exercise looked at optimal breastfeeding, complete avoidance of breastfeeding and early cessation of breastfeeding in the context of the HIV epidemic¹⁰³. The three categories of breastfeeding were weighed in terms of HIV transmission and infant mortality. Avoidance of breastfeeding by the whole population always produces the worst outcome. The lowest frequency of adverse outcomes occurs if none of the HIV-infected women breastfeed and all of the HIV-uninfected women breastfeed optimally if the infant mortality rate is less than 100 per 1000. In many parts of the world this is not the case. More recently, mathematical simulation modelling was used to estimate the effects on HIV-free survival at 24 months in three different scenarios: replacement feeding from birth by HIV-positive mothers, exclusive breastfeeding up to six months followed by early breastfeeding cessation, and no postnatal intervention. The simulation suggests that exclusive breastfeeding up to six months followed by early cessation produces the best outcome where $IMR > 25/100$ live births¹⁰⁴. IMR-based analyses can help guide policy makers about appropriate feeding strategies for HIV-positive mothers in different settings¹⁰⁷.

In trials in different parts of Africa, more than 70-90% of HIV-infected women chose breastfeeding, after receiving counselling about the implications of both

formula feeding and breastfeeding¹⁰⁹⁻¹¹². In a controlled trial conducted in Kenya, HIV infected women were randomised to either exclusive formula feeding or breastfeeding¹¹⁵. Compliance in the breastfeeding group was 96% compared to 73% in the formula arm, and the dropouts were greater in number in the formula arm. This study highlighted the problems of trying to randomise feeding behaviour. Many rural African women are likely to be stigmatised for not breastfeeding and, in context of high HIV infection rates, formula feeding becomes a social marker for infection⁹¹.

Rather than abandoning breastfeeding altogether in areas of the world where HIV is prevalent, the most urgent public health research question in mother-to-child transmission is how to make breastfeeding by HIV-positive mothers safer with regard to transmission risk given the possible adverse risks of refraining from breastfeeding.

1.5 RISK FACTORS ASSOCIATED WITH POST-NATAL TRANSMISSION

1.5.1 Duration of Breastfeeding

HIV transmission can take place at any point during lactation. There is strong evidence that the longer the duration of breastfeeding the greater the risk of transmission¹¹⁶⁻¹²⁰. A prospective study in Malawi followed breastfed infants of HIV-infected mothers to 24 months¹¹⁶. After the first month of life, the cumulative risk of infections was 3.5% at five months, 9% at 18 months and 10% at 24 months. There was some evidence in this study of a declining risk with increasing infant age. However, a recent meta-analysis from sub-Saharan Africa¹¹⁷ showed children are at continued risk throughout the breastfeeding period and the risk is

constant as long as breastfeeding continues: the cumulative probability of becoming HIV-infected after four weeks was 1.6% at three months, 4.2% at six months, 7.0% at 12 months and 9.3% (95% CI 3.8 – 14.8) at 18 months.

1.5.2 Pattern of breastfeeding

Another important risk factor, of particular relevance at the population level, and for the aims of this thesis, is the mode of infant feeding. Many earlier studies examining postnatal transmission did not look specifically at the pattern of breastfeeding^{84,115,116,121,122}. However, it can be assumed that most of the women mixed fed, as exclusive breastfeeding is only practised by a minority of women world-wide and mixed feeding is the norm in most populations. In a study in Kenya infected women were randomized to either breastfeed or formula feed¹¹⁵.

Transmission at 6 weeks was 9.7% and continued to rise thereafter, to 36.7% at 24 months. Although women in the breastfeeding arm were advised to breastfeed exclusively, they were not supported to do this. 90% gave some breastmilk to their infants, whether they breastfed exclusively or not was not monitored rigorously, so feeding patterns in this group are unknown. In the formula group there was also a continued increase in transmission from 6 weeks to 24 months. There was only 70% compliance in this group and 30% of women were mixed feeding¹¹⁵.

For the first time in 1999 a study was reported which compared MTCT rates in each of 3 feeding groups: exclusive breastfeeding for at least 3 months; partial or mixed breastfeeding; and exclusive formula feeding^{123,124}. Strict WHO definitions of exclusive breastfeeding were used for this study (see Table 1). Of 551 HIV-positive mothers, 157 exclusively formula fed, 118 exclusively breastfed and 276 mixed fed. At three months, the MTCT in exclusively breastfeeding mothers was

similar to that in mothers giving only formula feeds and significantly lower than in those mixed breastfeeding (14.6% vs 24.1%). At 6 months the MTCT in exclusively breastfeeding mothers was the same as that in mothers giving only formula feeds (19.4% [95%CI 11.9-26.9] vs 19.4% [95%CI 13.1-25.6]); MTCT in exclusively breastfeeding mothers was significantly lower than in those who mixed fed (26.1% [95%CI 20.3-31.8]). At 15 months, infants who had been mixed fed were more likely to be infected (36%) than those who had been exclusively breastfed (25%) or exclusively formula fed (19%). Exclusive breastfeeding carried a significantly lower risk of HIV infection than mixed feeding (Hazard ratio 0.56, 95% CI 0.32-0.98) and was similar in this respect to never breastfeeding (Hazard ratio 1.19, 95% CI 0.63 – 2.22). This suggested that exclusive breastfeeding may carry no additional risk of MTCT of HIV over formula feeding. However, these promising findings were obtained from a trial whose main purpose was to test the efficacy of vitamin A in reducing MTCT.

Recent results from the Zvitambo study group in Zimbabwe show that, compared with exclusive breastfeeding, early mixed breastfeeding was associated with a 4.03 (95%CI 0.98-16.61), 3.79 (95%CI 1.40-10.29) and 2.6 (95%CI 1.21-5.55) greater risk of postnatal HIV transmission at 6, 12 and 18 months respectively¹²⁵. Predominant breastfeeding was associated with a 2.63 (9%CI 0.59-11.67), 2.69 (95%CI 0.95-7.63) and 1.61 (95%CI 0.72-3.64) trend towards greater postnatal HIV transmission risk at 6, 12 and 18 months, compared with exclusive breastfeeding. In this study, detailed feeding information was collected from mothers at six weeks, three months and six months. At these interviews mothers were asked to recall whether or not any of 22 liquids, milks, medicines or solid foods had ever been given to the infant. A strict WHO definition of exclusive

breastfeeding was used (see Table 1). Predominant breastfeeding was defined as the infant's predominant source of nourishment was breastmilk, but non-milk liquies (e.g. water, tea, juice, cooking oil) were also consumed according to mothers' reports at all three timepoints (six weeks, three months, six months), or at two of three timepoints.

Several other studies are in progress which aim to answer this question more fully, including the Vertical Transmission Study in KwaZulu Natal.

1.5.3 Maternal immune status and viral load

In a recent analysis of data from two West African AZT trials, a low CD4 count (<500/mm³ in plasma) was associated with a 3-fold increase in risk compared to counts >500¹¹⁸. Studies from Kenya¹²⁶ and Durban¹²⁷ have shown a strong correlation between low CD4 counts and the concentration of breastmilk DNA. In a meta-analysis of data from trials in sub-Saharan Africa, the risk of postnatal infection was correlated with CD4 counts with an 8-fold increase in transmission with CD4 cell counts lower than 200/mm³ and 3.5 times with a CD4 cell count between 200-500/mm³ compared to those with CD4 cell counts >500/mm³ ¹¹⁷.

It has been observed that the risk of transmission through breastmilk is increased if the mother is infected postnatally¹²⁸. However there is some evidence that RNA viral load is only partially correlated with breastmilk viral load and that this viral load varies both over time and between breasts¹²⁹. A low blood CD4 cell count (<200/mm³) during pregnancy and a raised Na/K ratio (indicative of sub-clinical mastitis) were significantly associated with increased milk RNA viral load at all times.

Semba et al reported, from their findings in Malawi, that women in whom RNA virus had been detected in breastmilk samples taken at six weeks post-partum, had a 5-fold increased risk of transmission of HIV to their infant¹³⁰.

1.5.4 Breast health

Breast lesions which cause inflammation, bleeding or oozing of pus, for example mastitis and sub-clinical mastitis, are associated with postnatal HIV transmission¹³⁰⁻¹³². In a Kenyan study¹³² breastfeeding (OR, 1.7; 95% CI, 1.0-2.9) and mastitis (relative risk 3.9; 95% CI, 1.2-12.7) were associated with increased transmission overall, and mastitis (RR, 21.8; 95% CI, 2.3-211.0) and breast abscess (RR, 51.6; 95% CI, 4.7-571) were associated with late transmission (occurring >2 months postpartum). In a second observational cohort study in Nairobi¹³³ identified risk factors for postnatal transmission included mastitis (OR = 2.7, 95% CI, 1.1-6.7) and maternal nipple lesions (OR = 2.3, 95%CI, 1.1-5.0). Sub-clinical mastitis may occur at initiation of breastfeeding when it can be associated with poor technique, inadequate attachment and emptying of the breast. It is also seen at the time of weaning, especially when rapid, with milk stasis and incomplete emptying of the breast or when the infant is ill with less vigorous suckling. Subclinical mastitis is thought to increase the 'leakiness' in the breast duct cell lining; thus the infant is exposed to increased quantities of the virus^{20,130,131}. RNA viral load in breastmilk has been associated with evidence of sub-clinical mastitis¹³¹.

Studies from Africa have shown that approximately 10% of women have nipple lesions, mastitis or breast abscesses – but this is in women who are presumed to be mixed feeding, as this is the norm in most parts of the world. On clinical

examination 7-11% had mastitis or sub-clinical mastitis¹³³. On calculating the Na/K ratio, estimates of sub-clinical mastitis were 11-12% at 6 and 14 weeks¹³¹. Nipple lesions were reported to be 11-13%¹³³ and 10%¹³⁴ on clinical examination. Finally abscesses on clinical examination were reported to be 12%¹³² and 3%¹³⁴. In the cohort of breastfeeding HIV-infected women in Abidjan, Cote d'Ivoire, 11% reported cracked nipples and 3.5% described breast abscesses¹³⁴. Approximately 16% of both the HIV-infected and uninfected women in Malawi had elevated breastmilk sodium levels measured at 6 weeks postpartum¹³⁰.

1.5.5 Integrity of mucous membranes

Factors resulting in disruption of the infant's mucous membranes are postulated to be a risk factor for transmission¹³³. The OR if the infant had oral thrush below 6 months of age was 2.8 (95%CI 1.3 – 6.2).

It has also been postulated that the intestinal permeability of the young infant may be affected by the mode of feeding, with infants who receive only breastmilk having a less permeable gut lining than those who also receive other foods¹³⁵. However, in the one study which has looked at this, the feeding mode of infants of HIV-positive mothers, was not associated with intestinal permeability in the infants¹³⁶.

1.5.6 Other factors

In a meta-analysis of late postnatal transmission, the sex of the child was found to be significantly associated with transmission. Females were 40% less likely than males to become infected through breastfeeding after four weeks of age (Hazard ratio 0.6, 95% CI 0.4-0.9, p=0.014). This difference may be due to males receiving

complementary feeds at an earlier age, and this mixed feeding of breastmilk and other fluids/solids exposing them a greater risk of becoming infected with HIV^{20,117}. However, it is of interest that in the European Collaborative Study, girls were at a 1.5 times increased risk of MTCT overall, but the sex effect was limited to elective caesarean section deliveries, suggesting that girls may have an increased risk of intrauterine transmission compared with boys¹³⁶.

1.5.7 Gaps in knowledge

There are many research questions, as yet, unanswered in the area of postnatal transmission of HIV. Studies in South Africa and Zambia are examining the risk of postnatal transmission of HIV with different feeding modes. The pilot work of this thesis has been used to design and implement the Vertical Transmission Study, South Africa, which is looking at this question.

A study in Zambia (the ZEBS study) is looking at the feasibility of shortening the length of time women breastfeed with abrupt cessation at six months and the introduction of nutritionally adequate, locally prepared replacement feeds¹³⁷.

Trials evaluating the use of antiretrovirals during breastfeeding are underway¹³⁸. These include antiretroviral therapy given to the mother to reduce viral load in plasma and breastmilk as well as antiretroviral regimens providing prophylaxis to uninfected infants during the period of breastfeeding.

There is conflicting evidence on the effect of breastfeeding on HIV infected mothers and more work needs to be carried out to look at morbidity and mortality amongst breastfeeding women.

Further work is being carried out looking at other methods of making breastmilk safer, e.g. heat-treating breastmilk. There is little information relating to the benefits of breastfeeding for infected children. Studies to date have been contradictory or inconclusive.

Further studies are necessary to determine whether abrupt cessation of all breastfeeding by HIV-infected mothers at six months results in an overall gain in child survival compared to continuing breastfeeding beyond six months with the introduction of complementary feeds.

1.6 BIOLOGY OF POSTNATAL TRANSMISSION

Various biological mechanisms have been postulated to explain the protection exclusive breastfeeding may afford in mother-to-child transmission of HIV¹³⁹⁻¹⁴². These are discussed in detail in the excellent reviews by Smith¹⁴² and Kourtis¹⁴¹, which are summarised below.

1.6.1 The maintenance of the integrity of the gastro-intestinal mucosal barrier

It has been postulated that stimuli that lead to breaches in mucosal integrity or enhance immune activation may facilitate transmission of HIV infection to the infant¹⁴¹. The systemic circulation is protected from the entry of damaging macromolecules, bacteria and viruses, by the intestinal mucosa which acts as a barrier^{140,142}. Exclusive breastfeeding reduces exposure of the infant to environmental pathogens in contaminated water, foods and feeding utensils¹³⁹. Exclusive breastfeeding also reduces exposure of the infant to dietary antigens.

Reduced antigen and pathogen exposure may facilitate early closure of the enterocyte junctions in the intestinal mucosal barrier¹⁴².

Permeability of the intestinal mucosa is temporarily increased soon after birth; thereafter this permeability decreases to the levels found in adults^{140,142}. This early increased transmission may enhance the capacity of the immature immune system from the passive transfer of mother's antibodies present in the breastmilk¹⁴². If the tight junctions of the intestinal mucosal cells do not firmly close, thereafter, foreign proteins may cross over into the systemic circulation; such mechanisms can increase the passage of HIV across the gastro-intestinal barrier¹⁴².

Intestinal permeability, measured by the differential sugar absorption test, decreases faster in breastfed infants than in those fed with non-human milks^{142,143}¹⁴⁴. This suggests that either exclusive human milk facilitates gut closure or dietary antigens delay closure¹⁴². There is evidence that TGF-beta 1, a cytokine, which is found in large quantities in breastmilk, maintains or enhances intestinal barrier function^{141,145}.

Infection and inflammation can alter the permeability of the intestinal mucosal barrier^{142,146}. If mixed feeding is introduced early to the infant's diet (i.e. before six months), the immature immunological system of the infant is exposed to potentially damaging pathogens and dietary antigens¹⁴². These challenges to the infant's gut may result in activation or sensitization of the immune responses¹⁴².

Smith et al postulate that if the infant is given only breastmilk and not exposed to non-human antigens in the diet and environmental pathogens, then the intestinal

mucosal barrier will be protected through reduction in the incidence or severity of diarrhoeal episodes¹⁴². Increased intestinal permeability and mucosal damage is associated with acute gastroenteritis and chronic diarrhoea^{147,148}. The application of computer-assisted quantitative morphological techniques to intestinal mucosae from children with persistent diarrhoea have revealed a spectrum of changes consistent with a cell-mediated immune form of damage¹⁴⁹. Smith et al go on to observe that the foods or fluids that the infant is exposed to influence the risk of diarrhoea¹⁴² with infants under six months of age given fluids such as water or teas having a 2-3.2 fold increase in diarrhoeal episodes compared with exclusively breastfed infants¹⁵⁰; and more episodes of diarrhoea being noted if the water is not clean^{142,150}. Non-exclusive younger infants (under two months of age) are at most risk of diarrhoea^{142,150-152}.

1.6.2 The promotion of beneficial intestinal microflora

There are differences in the intestinal microflora of exclusively breastfed and mixed fed babies¹⁶. The normal flora of the intestinal tract of the breastfed infant is *Lactobacillus bifidus*, with few gram-negative bacteria whilst the microflora of infants receiving formula milk consists mainly of gram-negative bacteria, including enterobacteria, bacteroides and enterococci^{142,153}. *L. bifidus* metabolizes milk saccharides, producing acetic and lactic acid which create the low pH of the stool of breastfed infants¹⁶. The pH of stools in the first week of life in breastfed infants is lower than that of formula fed infants^{142,154}. The flora of bifid bacteria is inhibitory to bacteria, including *Staphylococcus aureus*, *Shigella*, *Salmonella*, *Vibrio cholerae*, *Escherichia coli*, rotavirus and *Campylobacter*^{16,155}.

The introduction of solid food to the breastfed infant causes a major disturbance in the microbial patterns of the large bowel, with numbers of enterobacteria and enterococci rising sharply, and colonisation by *Bacteroides* species, clostridia and anaerobic streptococci occurring¹⁵⁶. It has been suggested by Smith¹⁴² that the altered intestinal flora in infants receiving breastmilk substitutes or mixed feeding may be analogous to the disturbed vaginal flora associated with bacterial vaginosis which has been linked to HIV acquisition^{142,157,158}. In bacterial vaginosis anaerobic flora flourish in response to the increased pH in the vagina and the low levels of lactobacilli; mechanisms thought to be responsible for increased HIV entry into the female reproductive tract¹⁴². In normal circumstances, in the absence of bacterial vaginosis, the vagina has a low pH which is responsible for reducing the activation of CD4 lymphocytes and thereby inhibiting the numbers of HIV target cells in the vagina^{142,159}. If the pH of the vagina is increased, this might lead to increased attraction between the HIV virus and the eukaryotic cells present in the vagina^{142,160}.

1.6.3 Immune factors in human milk

It has been postulated that there are immune factors in human milk which exhibit targeted action against HIV. Human breastmilk is rich in antibodies, chemokines, cytokines, helper and cytotoxic T lymphocytes, Natural Killer cells and macrophages, together with a range of non-immune factors, all directed against HIV¹⁴¹. HIV-1 induces specific humoral as well as cellular immune response against viral antigens in breastmilk¹⁴¹. Colostrum of HIV-infected women contains secretory IgA, secretory IgM and IgG against HIV antigens, including the envelope-encoded surface glycoproteins¹⁶¹. Recently, cytokines and chemokines have been discovered in breastmilk and have highlighted gaps in our knowledge

regarding the immunological responses around HIV and breastfeeding^{38,141}. The recent discovery that the CC chemokines, RANTES, MIP-1 α and MIP- β are the major human immunodeficiency virus suppressive factors released by CD8+ T lymphocytes have highlighted the potential role that these factors play in postnatal HIV transmission through breastfeeding^{38,141}. Lactoferrin, glycosaminoglycans, secretory leukocyte protease inhibitor and specific immunoglobulins all demonstrate action against HIV^{142,162,163}.

Smith¹⁴² et al have postulated that "breastmilk composition may differ when breastfeeding is exclusive or a threshold level may exist for certain protective factors that may not be achieved during non-exclusive breastfeeding"¹⁴². Lower maternal serum IgG concentrations, higher maternal serum IgA and IgM concentrations and higher maternal serum prolactin levels are documented in women who breastfeed frequently; exclusive breastfeeding is intrinsically more frequent than other types of breastfeeding^{142,163}. These changes influence the levels of these factors in breastmilk¹⁴². The immunoglobulin reaction in breastmilk has been linked to mother-to-child transmission of HIV^{38,142}.

1.6.4 Mammary epithelial permeability.

It has been postulated that exclusive breastfeeding helps maintain the integrity of the mammary epithelial permeability and thus reduces the HIV viral load in breastmilk¹⁴². As in the intestinal mucosa, there are tight junctions in breast tissue between neighbouring epithelial and endothelial cells that limit transfer of blood components into breastmilk^{141,142}. After delivery, the permeability of the mammary epithelia is increased as breastfeeding is established, and permeability also increases when complementary feeds are introduced to the infant's diet^{142,164}.

Lactation, when fully in process, is accompanied by closed tight junctions^{142,164}. During mastitis, the inflammatory reactions lead to increased permeability and the passage of pericellular sodium into breastmilk^{142, 165,166}. If the integrity of the mammary epithelium is damaged pericellular sodium can move into breastmilk^{142,167}. In several studies, the level of sodium in breastmilk has been used to demonstrate "leakiness" in the mammary epithelium which can occur in inflammatory conditions such as mastitis or even breastmilk stasis^{141,142,165}.

The pattern of breastfeeding may have a direct effect on mammary epithelial permeability, and in turn on HIV viral levels in breastmilk and risk of transmission¹⁴². Exclusive breastfeeding may lead to a shorter period of time between initiation of breastfeeding and established lactation, thus reducing the duration of increased permeability of the mammary epithelia¹⁴². Exclusive breastfeeding on demand, with good attachment of the infant to the breast, leads to fewer breast health difficulties, including blocked milk ducts and mastitis²¹. In turn, decreased permeability of the mammary epithelial tight junctions may reduce levels of HIV virus in breastmilk and, therefore, the risk of transmission¹⁴¹. Furthermore, fewer breast health difficulties, such as bleeding cracked nipples, will lead to less opportunities for the baby to come directly into contact with maternal blood. Two studies have reported higher proportions of HIV-infected infants among mothers reporting cracked or bleeding nipples^{122,134,142}.

In one study, elevated sodium samples were reported in breastmilk samples from HIV-infected women^{131,142}. This indicated potential defects in the epithelial cells of the mammary gland^{131,142}. These women had significantly higher HIV loads compared to the breastmilk from the women with normal sodium levels^{131,142}. Two

further studies reported a significant association of elevated sodium levels in breastmilk and increased HIV transmission^{130,131,142}.

Increased levels of lactoferrin, SLPI, interleukin 8, and RANTES and immunoglobulins have been found in the breastmilk of women with mastitis^{141,165}. Further more, the risk of HIV transmission from mother to infant was increased in those with higher levels of lactoferrin in breastmilk¹⁶⁸. Periodic local replication of HIV may be responsible for activating mammary epithelia thereby influencing transmission of the virus¹⁶⁸.

1.7 CURRENT FEEDING RECOMMENDATIONS

The Global Strategy for Infant and Young Child Feeding¹², adopted by the WHO and UNICEF, states that the optimal feeding pattern for overall child survival is exclusive breastfeeding for the first six months, and continued breastfeeding for up to two years and beyond, with complementary feeding from age six months, together with related maternal nutrition and support. The Global Strategy contains specific recommendations for children in exceptionally difficult circumstances, including those born to HIV-positive women.

An estimated 1.6 million children are born to HIV-infected women each year, mainly in low-income countries. The Global Strategy for Infant and Young Child Feeding¹² states that the absolute risk of HIV transmission through breastfeeding for more than one year needs to be balanced against the increased risk of morbidity and mortality when infants are not breastfed. The strategy goes on to state that all HIV-infected mothers should receive counselling, which includes

provision of general information about meeting their own nutritional requirements and about the risks and benefits of various feeding options and specific guidance in selecting the option most likely to be suitable for their situation. Adequate replacement feeding is needed for infants born to HIV-infected mothers who choose not to breastfeed. A mother's choice should always be respected.

Given the need to reduce the risk of HIV transmission to infants HIV-infected mothers are recommended to avoid all breastfeeding and use replacement feeding when it is acceptable, feasible, affordable, sustainable and safe. The WHO/UNAIDS guidelines are clear about the feeding choices facing women with HIV¹⁶⁹. If these children cannot be assured uninterrupted access to acceptable, feasible, affordable, sustainable and safe breastmilk substitutes then artificial feeding substantially increases the risk of illness and death. Regardless of potential transmission benefits, exclusive breastfeeding in these situations may be the most favourable option¹⁶⁹.

At six months HIV-infected women are recommended to cease breastfeeding as quickly as possible when complementary feeds are added. The infant will still require milk in the diet and so replacement milk should be introduced. However, as at birth, mothers need further counselling at this stage as many women will not have the finances to provide replacement milks to their infants. Breastmilk continues to provide a valuable source of energy, protein and micronutrients throughout the second year of life, when the high prevalence of food-borne pathogens, poor nutritional quality of complementary feeds and reduced immunologic protection from breastfeeding contribute to diarrhoea and failure to thrive at this stage. Abrupt cessation of breastfeeding may increase malnutrition

and risk of non-HIV infectious diseases as well as cause discomfort in both mother and child.

The WHO/UNAIDS guidelines recommend that women of unknown HIV status are counselled as if they were HIV-negative – i.e. to exclusively breastfeed for six months, to introduce complementary feeds at six months and to continue breastfeeding into the second year of life.

1.8 COLLECTING BREASTFEEDING DATA

Collecting breastfeeding data is fraught with difficulties. Prior to the HIV epidemic, infant feeding data were collected largely to answer research questions associated with diarrhoea, respiratory illness and growth. There are a lot of difficulties with collection of these type of data. Data collected retrospectively from cross-sectional surveys or longitudinal studies with long time intervals between interviews may be biased by maternal recall^{51,170,171}. Current breastfeeding status based on a previous 24 hour history may not accurately reflect the feeding pattern since birth¹⁷²⁻¹⁷⁴. Data from demographic health surveys and maternal and infant cluster surveys often use 24-hour recall to provide national estimates of the percentage of infants under four months who are exclusively breastfed. However, information is not available regarding the cumulative proportion of infants who exclusively receive breastmilk through four to six months of age.

Infants are often grouped by imprecise criteria depending on whether they have 'ever' or 'never' received breastmilk and rarely by the pattern of breastfeeding which can be exclusively breastfed, predominantly breastfed and partially breastfed¹⁷⁵⁻¹⁷⁷. In addition, since many researchers do not use standardised

definitions for breastfeeding patterns (Table 1), comparability of results between studies is impaired.

Usually the greatest differences are reported when exclusive breastfeeding is compared with exclusive formula feeding^{46,52,178}. Furthermore, there is the problem of assignment of feeding mode. If the feeding of a child directly before he/she becomes ill is used, this results in the most accurate morbidity comparisons. Only sometimes is this achieved in feeding-morbidity studies¹⁰.

Interesting questions relate to these problems of definition and assignment. Is breastfeeding protective after it has been discontinued? Some studies suggest that this the case for respiratory illnesses^{179,180}.

An important illustration of the need for accurate breastfeeding practices data is in HIV transmission research. The HIV pandemic has raised dilemmas about infant feeding recommendations¹⁶⁹ and highlights the importance of accurate and consistent documentation of early infant feeding practices, in order to correctly estimate the risks of breastfeeding in mother-to-child transmission of HIV¹⁸¹.

Whilst many studies have documented postnatal transmission of HIV in breastfeeding populations, few have attempted to describe feeding practices in detail yet^{84,115,116,121,122,182,183}. The definition of exclusive breastfeeding has been incorrectly used in some studies, referring to a diet with no infant formula milk, but not excluding other liquids¹²¹ or foods⁸⁴. In a study from Durban the authors failed to consider either water or complementary foods in the diet¹²². The trial by Nduati et al in Kenya did not record infant feeding practices in detail¹¹⁵.

This is not surprising as the exclusively breastfed baby is a rarity. There is some evidence that exclusive breastfeeding may carry minimal additional risk of postnatal MTCT of HIV compared to exclusive replacement feeding, but a significantly lower risk than mixed feeding¹²³. In order to make the distinction between exclusive breastfeeding and other patterns of breastfeeding it is important to document the frequency, volume and description of all other fluids and feeds given, including non-prescribed medications. Inaccurate data may falsely attribute postnatal transmission to a particular feeding pattern e.g. exclusive breastfeeding, when, in reality, the mother has been mixed feeding. In addition it is, as yet, unknown whether mixed feeding with different fluids (e.g. water or dilute porridge) carries the same risks for MTCT of HIV, whether these risks vary with the degree of mixing, and whether they are constant postnatally. The WHO recently published an assessment tool to improve standardisation of collecting infant feeding practices and breast health data in the context of HIV transmission research¹⁸³. This tool was based on the experience of several field studies including the one reported here.

1.9 NON-PRESCRIBED MEDICATIONS

The WHO definition of exclusive breastfeeding (Table 1) states that an infant may only receive human milk with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines. This definition was made in 1991 at a meeting on breastfeeding indicators. It is an indicator, to be used in surveys or research, and not a recommendation, which is the optimal practice. In surveys, if a baby has medicines or vitamins this does not invalidate the exclusive breastfeeding status. However, when supporting women to exclusively breastfeed

it is recommended that they give only breast milk to their baby, and only medicines if they are prescribed by a doctor or nurse – i.e. non prescribed or over-the-counter medications²².

Non-prescribed medications are used by people throughout the world, including rural societies in sub-Saharan Africa^{184,185}. Here, ancestral spirits and witchcraft are perceived to be part of life and ill-health is thought to be related to a disturbance of this environment¹⁸⁶. Anthropologists have reported that the purchase of non-prescribed medication is not limited to the rural, uneducated or elderly and that African people move comfortably between Western and indigenous medicines¹⁸⁷.

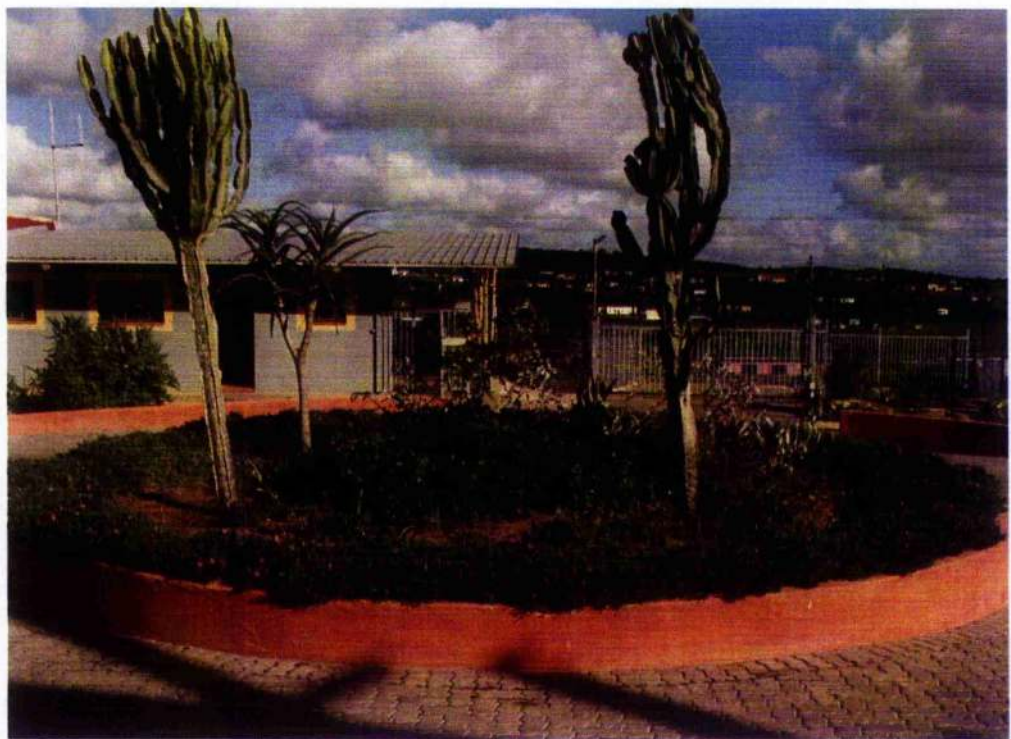
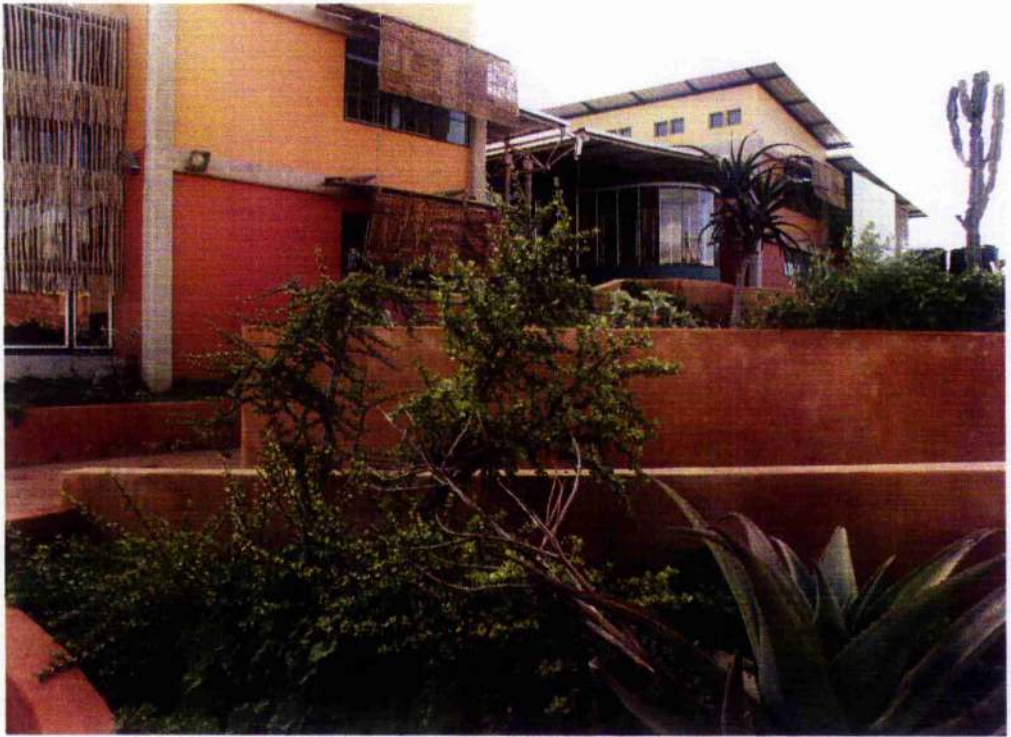
Children in South Africa are known to be the recipients of non-prescribed medication¹⁸⁵⁻¹⁸⁷. Whilst many illnesses may be successfully managed at home, these remedies are not always without hazard. Enema administration in KwaZulu Natal has been associated with severe metabolic or organic dysfunction including acute onset of respiratory distress, abdominal distension and hypotonia¹⁸⁸. Electrolyte disturbances may be caused by water enemas¹⁸⁹ and mortality due to renal and hepatic failure has been reported following herbal enema administration¹⁹⁰. Treating young infants at home may delay seeking professional help for potentially life-threatening conditions such as gastro-enteritis. Furthermore, giving non-prescribed medicines precludes the recommendation to exclusively breastfeed.

Data collected on patterns of breastfeeding usually report whether infants were given non-nutritive fluids (e.g. tea and water) and nutritive fluids and solids (e.g.

formula or cow's milk), but rarely report on non-prescribed medications. This may be important with regard to HIV transmission. Non-prescribed medications may be given in moderately large quantities (e.g. two teaspoons three times daily gives a total of 30mls per day, which is equivalent to one feed for a newborn infant). Non-prescribed medications may be irritant to the infant's gut, particularly if prepared unhygienically.

1.10 SUMMARY

Unfortunately HIV is most prevalent in areas of the world where most women partially breastfeed and the availability of safe replacement feeds is not a realistic option for the majority. There is, therefore, an urgent need to understand how breastfeeding can be made more safe, to examine methods to accurately collect infant feeding and breast health data, and to explore whether exclusive breastfeeding can be promoted as a public health intervention in an area of high HIV prevalence in a rural and traditional society in Africa.



Africa Centre for Health and Population Studies

CHAPTER 2: AIMS

2.1 OVERALL AIMS OF THESIS AND RELATIONSHIP TO THE VERTICAL TRANSMISSION STUDY

The work for this thesis formed the preparatory work for a large, on-going Wellcome-funded study, called the Vertical Transmission Study (VTS), 2001-2007. The VTS was established to examine the risk of post-natal transmission of HIV in relation to infant feeding practices, specifically exclusive breastfeeding.

Approximately 3,500 pregnant women (HIV-infected and uninfected) were enrolled into the VTS, and over 2,000 infants followed from birth until two years of age, documenting daily feeding practices, infant morbidity and maternal breast health, and monthly infant HIV status.

Prior to the commencement of the VTS in 2001, various questions had to be answered to inform the design of the VTS (data collection forms, frequency of visits, design of a breastfeeding support strategy). The Wellcome Trust awarded a grant for a phase of pilot work, which forms this thesis. There were three areas about which little was known in the study area:

- Breastfeeding practices in the study area
- The use of non-prescribed medications in the study area
- Methods of collecting breastfeeding data in the context of HIV transmission research, not only in the study area, but also generally in areas of high HIV prevalence.

A cross-sectional survey and a longitudinal study were conducted, each with specific research questions to inform the three areas listed above.

2.2 BREASTFEEDING PRACTICES

At the time of this study, little was known about breastfeeding practices, particularly exclusive breastfeeding practices, in areas of high HIV prevalence, and the effect that the promotion of formula feeding, which has accompanied this pandemic, has had on breastfeeding patterns and duration^{191,192}. In particular, no work had been carried out in the study area on current breastfeeding practices and barriers to exclusive breastfeeding. Formative research is invaluable to understand values, beliefs and practices that significantly affect breastfeeding behaviour in a community^{92,193-196}. In addition it can help target clear and effective messages to specific populations or community groups. The formative research in Mexico⁹² found that mothers believed they should give something in addition to breastmilk when the baby was 'thirsty', the baby or mother were ill, or if the mother was emotionally upset. Using these findings the researchers developed breastfeeding training materials and messages targeting this issue. Two of the key messages they developed were: 'Breastmilk is sufficient to quench a baby's thirst, even in hot weather' and 'Mother's milk is better than any other method of feeding a young infant, even when a mother is emotionally upset'.

Furthermore, despite the baby-friendly status¹⁰¹ of the local hospital, there were large gaps in knowledge about breastfeeding and HIV and infant feeding amongst local health workers in the area¹⁹⁷.

As part of the VTS, a community-based breastfeeding counselling and support intervention was going to be implemented, in the area, to help women, who had chosen to breastfeed, to do so exclusively. In order to design this intervention, train counsellors appropriately, and anticipate when mothers may experience difficulties, it was necessary to understand feeding practices in the local area.

The aims of this section of work were:

- to describe infant feeding practices in a rural community
- to determine the reasons for supplementation of breastmilk, and when supplements are introduced to the diet
- to understand the difficulties perceived by mothers in feeding their infants
- to determine the barriers to exclusive breastfeeding in this population.

A number of hypotheses were tested related to breastfeeding practices:

- most mothers in the cohort will initiate breastfeeding
- cumulative exclusive breastfeeding from birth to 16 weeks in the cohort of mothers followed will be expected to be low (less than one quarter)
- the time at which other fluids or feeds are added to the infant's diet will be less than three months post partum.

The purpose of this section of work in preparation for the VTS was to design a breastfeeding counselling and support strategy for women who choose to breastfeed in an area of high HIV prevalence, taking into account the barriers and constraints to exclusive breastfeeding in the area.

2.3 NON-PRESCRIBED MEDICATIONS

The second area of work was on non-prescribed medications. Anecdotally it was known that mothers in this area administer non-prescribed medications to their children. However, the extent of this practice and the types of medications given to infants were not documented and little was known about this in the district medical services.

Whilst the WHO definition of exclusive breastfeeding permits the use of non-prescribed medications for surveys and research studies, this is not the recommended or optimal practice for women who are exclusively breastfeeding²². When supporting women to exclusively breastfeed it is recommended that they give only breast milk to their baby and only medications if they are prescribed by a doctor or nurse (i.e. no non-prescribed or over-the-counter medications). In addition it is not known whether the administration of non-prescribed medications to otherwise exclusively breastfeeding infants increases the risk of postnatal HIV transmission²⁰.

Little has been published in the medical literature on the range of non-prescribed medications given to children under six months of age in South Africa and the reasons they are administered¹⁸⁵⁻¹⁸⁷.

The aims of this section of work were:

- to describe the variety, and frequency of administration, of non-prescribed medications given to a cohort of infants in the first three months of life in rural kwaZulu Natal
- to describe why mothers give non-prescribed medications to their infants in the first few months of life
- to estimate the proportion of women not exclusively breastfeeding attributable to non-prescribed medications.

In the absence of any published literature on the subject in infants in KwaZulu Natal, a number of hypotheses were tested related to non-prescribed medications:

- the majority of infants under three months of age will not receive oral non-prescribed medications or enemas
- the level of maternal education will be related to the administration of non-prescribed medications, with more educated women giving fewer of these medications to their infants.

The purpose of this section of work in preparation for the VTS was to:

- determine the use of non-prescribed medications in infants in the study area and the potential for this to interfere with exclusive breastfeeding

- design counselling messages to be used in the breastfeeding support strategy around the issue of non-prescribed medications.

2.4 METHODOLOGY OF COLLECTION OF BREASTFEEDING DATA

The third area of work was to explore methods of collecting accurate data on infant feeding practices and breast health in this population and to compare different methods of collecting breastfeeding data.

Earlier studies looking at postnatal HIV transmission through breastfeeding have been criticised for a number of methodological reasons. The definitions of breastfeeding are not consistent and the intensity of breastfeeding is not defined^{84,116,121,122,181}. It is difficult to compare studies where, in one report, the infant is considered to be breastfed if s/he has one feed of breastmilk per day, whereas in another study the infant is considered to be breastfed only if s/he is predominantly or exclusively breastfed.

The aims of this section of work were:

- to determine the most appropriate methods of collecting feeding data in this population
- to determine the validity of maternally kept diaries of infant feeding practices as an effective way of improving infant feeding data collection.

The hypotheses tested were that:

- the 7-day recall of breastfeeding practices will reliably reflect feeding practices over the preceding week and will be as reliable as a series of 48-hour recall histories taken over the same time period
- the maternal recall of cumulative exclusive breastfeeding from birth, at six to nine months post delivery will not be reliable
- maternal diaries will accurately reflect feeding practices of the preceding week.

The purpose of this section of work in preparation for the VTS was to:

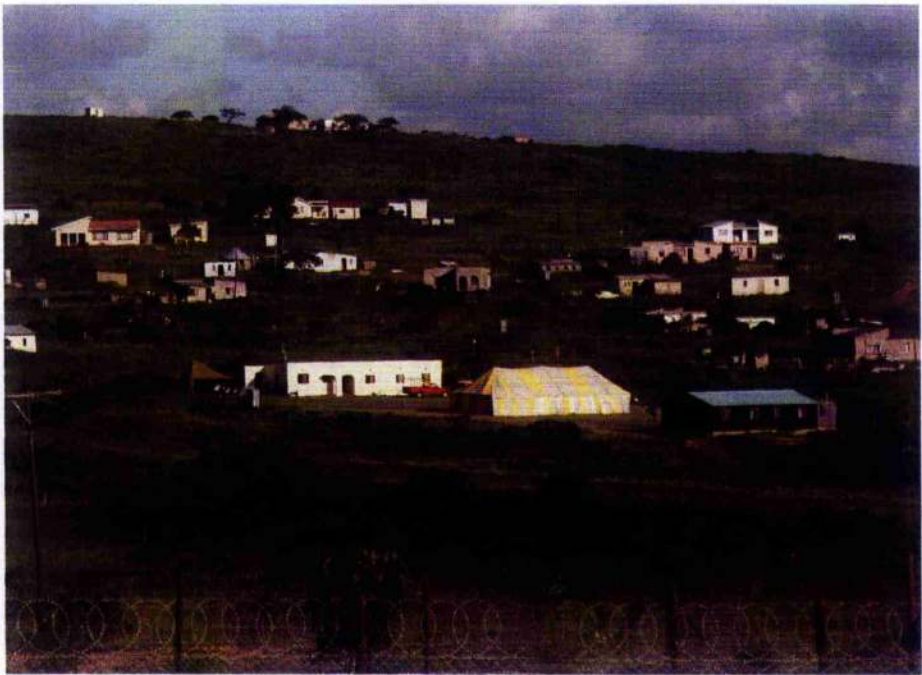
- design an accurate method of collection of breastfeeding data for the first nine months of life in this study population, in order to accurately attribute HIV rates, morbidity and mortality to different infant feeding practices
- design a diary that would improve the accuracy of infant feeding recall.

I set out to achieve these aims by conducting two studies: a cross-sectional survey followed by a longitudinal study. The cross-sectional survey was completed two weeks before the longitudinal study began. The results of this survey were used to inform the final design of the questionnaire for the longitudinal study, in addition to providing information on feeding practices of infants living in the wider community of the district (see Section 3.8.1).

2.5 MY ROLE IN THIS STUDY

I was the lead researcher in the pilot work which forms the content of this thesis. I arrived in South Africa in March 1999 and designed the pilot studies, funded by the Wellcome Trust. I designed the questionnaires, gained permission from the local ethics committee and the local tribal leaders to proceed with the studies, and recruited and trained the team of field workers. I was responsible for the day-to-day running of the project, maintaining the quality of data collection and data entry. I designed the data base and was responsible for analysing the results. In addition, I carried out field visits on all the study participants at six and 12 weeks post-partum.

Since the completion of this pilot work I have been involved in the implementation of the VTS, and am a co-investigator in this study. I have been the VTS project leader on site, since 2002.



Mpukunyoni tribal area

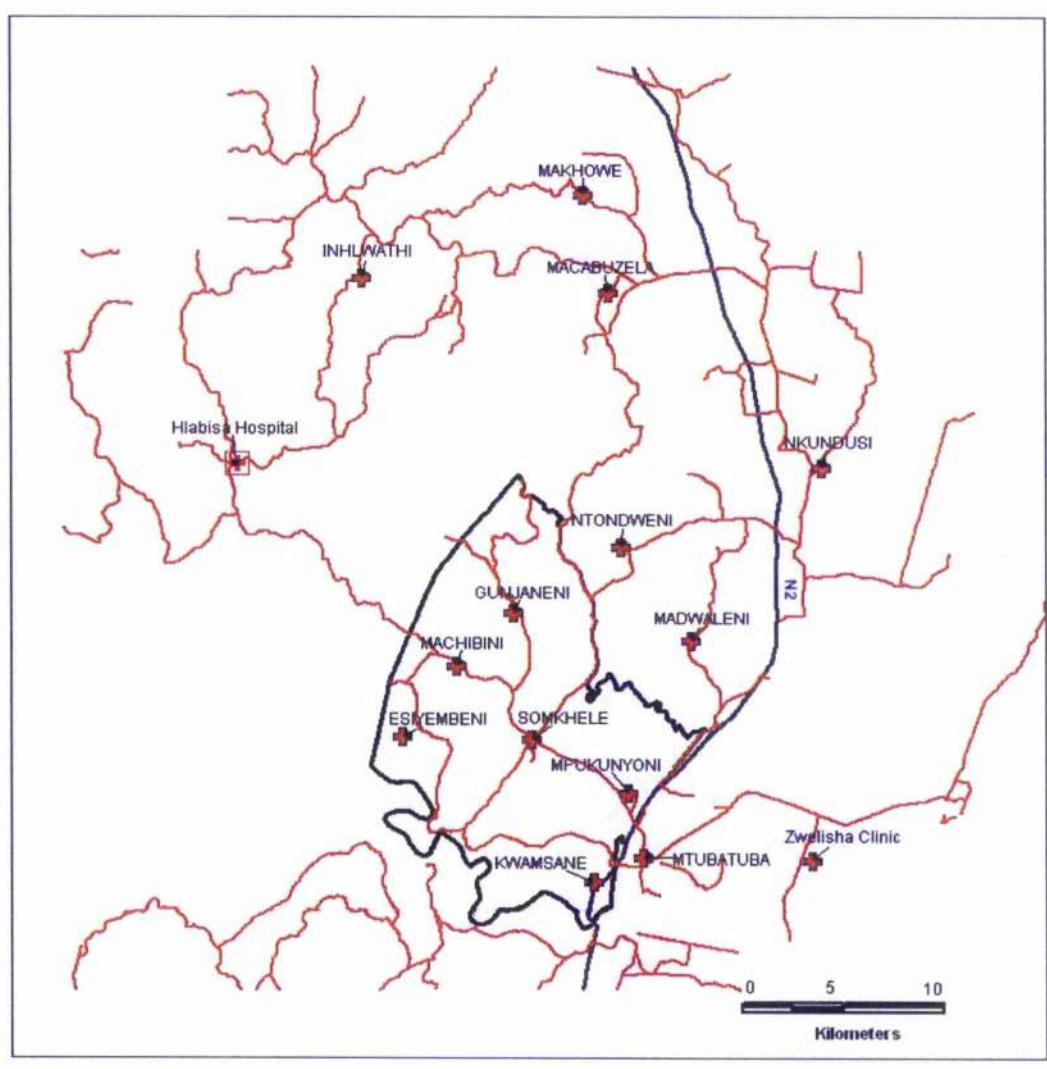
CHAPTER 3: POPULATION AND METHODS

3.1 AFRICA CENTRE FOR HEALTH AND POPULATION STUDIES

This study was conducted at The Africa Centre for Health and Population Studies in the Umkhanyakude District of KwaZulu Natal. The Africa Centre is a community-based research initiative established, jointly, in 1997 by three leading research institutions in South Africa – the Medical Research Council, the University of Natal and its medical school, The Nelson R. Mandela School of Medicine, and the University of Durban Westville. The two universities have since merged to become the University of KwaZulu Natal. The office infrastructure of the Africa Centre is situated on land which was donated by the local Traditional Authority.

The mission of the centre is to conduct policy-related health and population research, in an ethical manner, in partnership with the community in which we work; and to enhance the capacity of the people of sub-Saharan Africa to do research.

Figure 1: Map of Fixed Clinics in the Hlabisa sub-district



3.2 PHYSICAL GEOGRAPHY OF THE STUDY AREA

The study was conducted in the Hlabisa sub-district of the Umkhanyakude District municipality, located in northern KwaZulu-Natal, South Africa. The study area is 1430 km² with altitudes ranging from 20 to 500 m above sea level¹⁹⁸. The terrain is flat to undulating, to mountainous, and vegetation ranges from sparse grassland to thick forest¹⁹⁸. The area has one formal township, KwaMsane, in the southern part of the District and increasingly rural and isolated areas further north¹⁹⁸ (Figure 1). Mtubatuba and KwaMsane are under the jurisdiction of the Transitional Local Council. Local tribal authorities govern the rest of the district. There is, accordingly, a broad socio-demographic profile¹⁹⁸.

The Africa Centre operates a Demographic Surveillance System (DSS) in the southeastern section of the district in the tribal area of Mpukunyoni, the most populous and least mountainous part of the Hlabisa district, and including the township of KwaMsane¹⁹⁸. The surveillance population is thought to be representative of rural populations in KwaZulu Natal, and to a lesser extent of rural black populations elsewhere in the country¹⁹⁸.

3.3 POPULATION

Before the change of government in 1994 the district formed part of the KwaZulu home-land. The resident Zulu ethnic population numbers 217 750¹⁹⁹. The Hlabisa sub-district is made up of four tribal areas, each under the local authority of a tribal chief, known as inkosi¹⁹⁸. Although residents of the tribal area owe allegiance to, and fall under the local jurisdiction of, the chief, they are not necessarily members

of his traditional clan or tribe¹⁹⁸. The majority of people are Christians, approximately one third belong to established denominations (e.g. Lutheran, Catholic and Anglican); one third to African-initiated churches (e.g. Zionist); and one third are Shembes (a religious group primarily restricted to Zululand)(personal communication, Victoria Hosegood, Population Studies, Africa Centre for Health and Population Studies, 2006).

Persons live in scattered multigenerational homesteads of varying size (1-100 people), as opposed to definable villages as in other parts of Africa¹⁹⁸. The mean number in a household is 7.4²⁰⁰. The area is characterized by large variations in populations density (0-6500 people per km²)¹⁹⁸. The political and economic history of South Africa and its neighbouring countries has led to frequent physical separation of household members¹⁹⁸. The recent political history of the country, including the Apartheid Group Areas Act, and the labour migration system, have resulted in members of many rural households residing elsewhere during most of the year to be closer to their place of work, to accompany other labour migrants, to obtain care and support, or to attend school²⁰¹. There is substantial migration of people both within the area and outwith the area to industrial towns such as neighbouring Richard's Bay or further afield, for example Johannesburg^{198,202}. Approximately 40% of adult men aged 18 or older reside outside the area²⁰¹, but migration is not limited to adults. A large number of children are also non-resident in their households, either for schooling or because their parents have died²⁰².

Wide differentials appear in living standards, literacy rates and access to electricity and clean water, although overall social and environmental conditions are substantially better than in many other countries in sub-Saharan Africa¹⁹⁸. Annual

per capita income is \$1730, the literacy rate is 69%, and life expectancy at the beginning of the AIDS epidemic averaged 63 years¹⁹⁸. Subsistence agriculture is not common; the economy is mainly a cash economy and most people try to find work either in the neighbouring towns of Richard's Bay and Empangeni, or on the surrounding commercial farms (sugar cane and forestry)¹⁹⁸. There are many professionals (e.g. nurses and teachers) residing in the township, KwaMsane. Families in the remainder of the district are usually supported either by a member working away or by a grant or pension to another family member¹⁹⁸. In 2001, 25% of those aged 15-65 years reported that they were unemployed and actively seeking work²⁰³.

The main stores are located in the market town of Mtubatuba. In addition there are approximately 139 Spaza shops (small road side stalls) scattered throughout the district, which those in the more rural area utilize regularly²⁰⁴. In 2001 only 8% of households had access to piped water inside their dwellings²⁰³ in contrast to 30% for KwaZulu Natal and 32% for the country as a whole¹⁹⁹. Fifty percent of households had no electricity supply and 39% of households had no toilet facilities²⁰³.

Marriage rates are very low in the area and have been declining for many decades. Thirty-four percent of women and 39% of men reaching the end of their reproductive years (45-59 years) have never been married²⁰⁵. Despite the low incidence of marriage, regular or casual sexual partnerships are common, especially for the population younger than 40 years²⁰⁵. Hosegood reports that child-bearing in this context appears to have become increasingly de-linked from

the process of marriage, as indicated by over 50% of women giving birth outside of marriage²⁰⁵.

3.4 HEALTH SERVICES

The health infrastructure of Hlabisa is typical of many other rural health districts in KwaZulu Natal¹⁹⁸. At the time of the study there were thirteen government clinics in the District, all of which provide immunisation services, and twelve of which provide ante-natal care. The clinics are run by nurses, who provide all patient care, including family planning, preventive child-health services, treatment for TB, sexually-transmitted diseases and non-communicable diseases such as diabetes and hypertension; and a wide range of minor complaints. For areas not covered by these clinics there are mobile health clinics which visit specific areas in the district.

Clinics are well attended, with 95% of pregnant women attending an antenatal clinic at least once during their pregnancies and up to 80% of children achieving full primary vaccination, up to measles vaccination at nine months of age²⁰⁶. In addition, substantial use is made of the many general practitioners in Mtubatuba and neighbouring towns such as Richard's Bay. At the time of the study there were 4-5,000 pregnancies per year in the district¹⁹⁸. Within the entire Hlabisa district, 25-30% of women deliver at fixed clinics, 35-40% at the Hlabisa hospital and 18% at home. An additional 10-15% deliver at hospitals outside of the district or with GP's in town. Approximately 14% of first antenatal bookings occur at the mobile clinics. The average gestational age of women attending for first antenatal booking is similar between primigravid (24.5 weeks) and parous women (25

weeks). The average age of all pregnant women booking in the district is 24.5 years, and 19.5 years for primigravids.

Hlabisa hospital is the central fixed health facility in the district run by general physicians and nursing staff (Figure 1). It provides a wide range of services, including surgical and obstetrical care and primary health services. The majority of pregnant women deliver their infants at one of the clinics or the Hlabisa hospital, which was declared Baby-friendly in 1999¹⁰¹.

The mean distance travelled by any individual in the population to their nearest clinic is 4.72 km (range 2.4 – 5.9 km)²⁰⁰. In addition there are an estimated 349 fixed, registered, traditional healers, and an unknown number of unregistered traditional healers, serving this population²⁰⁴. Traditional medicines may be purchased from the traditional healers and also from road-side stalls and shops.

KwaZulu Natal is the province of South Africa with the highest HIV prevalence rate among antenatal attendees. Anonymous antenatal surveillance showed that 42% of women attending the antenatal services in 1999, at the time of the study, were HIV infected²⁰⁷. This is in contrast to 4.2% (95%CI 3.0-5.7) in 1992 and 14% (95%CI 10.4-18.4) in 1995²⁰⁸. By 2000 the probability of dying between the ages of 15 and 60 years was 58% for women and 75% for men. AIDS, with or without tuberculosis, was the leading cause of death in adulthood (48%)²⁰⁹.

In 1999, at the time of this study, UNICEF accredited Hlabisa hospital as baby-friendly (see Table 4)¹⁰¹. As part of this all pregnant women and mothers attending the hospital and local clinics, both HIV-infected and uninfected, received the same general infant feeding recommendations i.e. to exclusively breastfeed for the first

six months of life and continue breastfeeding thereafter until at least two years postnatally¹². At the time of this study antenatal counselling and testing for pregnant women was not offered routinely.

3.5 COMMUNITY ENTRY

Prior to the commencement of the work for this thesis, consultations were held with traditional and other leaders in the district. The study was described to them and opportunities given for questions to be asked. The local tribal authority granted permission for the study. All field workers carried letters from the Inkosi (chief) giving them permission to carry out home visits in the area.

At the time of this study the Africa Centre was establishing a Community Advisory Board (CAB), composed of elected members of the community. Members of the CAB were consulted about the feasibility and acceptability of conducting this work and were kept informed of the progress of the study. In addition, since the study was being conducted in the government clinics and hospital, meetings were held with the hospital and community matrons and the medical director, and approval was sought and granted from the Provincial Health Department.

3.6 RECRUITMENT OF STAFF

The following staff were recruited: eight clinic assistants; one driver to collect forms from the clinics; one data entry clerk and eight field workers. The field workers were recruited from the local area. In this area with high unemployment²⁰³, and a history of unfair labour practices, transparency in recruitment policy is important. The Africa Centre had previously placed advertisements in local schools, clinics and at the tribal courts, in a process to recruit field staff for the large demographic surveillance system (DSS). Over 2,000 young people had applied, and all underwent written tests for literacy and numeracy. The required criteria for consideration for posts as a field worker were:

Female – many men in the area are migrant and a male field worker visiting a mother every week could raise suspicion.

Candidates should have completed school and obtained a school leaving certificate – a matriculation certificate.

Candidates should live in the area in which the study was being conducted.

Those applicants not taken by the DSS were placed on a list from which other projects in the centre could recruit. The next 20 persons on the list, ranked in order of ability in numeracy and literacy, were tracked at their homes by myself and invited to come for a selection process.

A two-day selection workshop was designed and conducted by myself. None of the candidates had ever worked in a research setting previously so the first day of

the workshop was dedicated to introductions and expectations of the successful candidates (see Appendix 1 for programme). During the workshop, candidates were asked to take part in a number of assessments and objective exercises.

The group of 20 applicants was divided into four teams. A video on HIV, produced locally, was shown to the groups. The groups were then asked to discuss the video and its implications. They were asked to select one member of the group to present the views of the group to the rest of the teams. During this exercise I rotated around the groups, listening to the discussion and observing how the individuals participated in this group exercises.

The applicants were then shown examples of data forms similar to those which would be used in the study (Appendix 2). Training for one hour took place on the first day on how to complete a data form. Practice scenarios were conducted with mothers, and applicants were asked to complete the questionnaires. The correct answers were then explained afterwards, with ample opportunity for people to ask for further clarification and help. On the second day of the workshop there was a revision session and participants were given the opportunity to ask for further clarification. Then three test exercises were conducted. Three scenarios were acted out, with an HIV counsellor playing the part of a mother and another counsellor playing the part of the researcher. The interviews were conducted in Zulu, the language used in the clinics and field. In each scenario a set of information was given which would enable the researcher to fill in the form completely. Participants listened to the interview and completed two individual data forms whilst listening to the scenario - Exercise 2a and 2b (Appendix 1).

For exercise 3 the participants were taken individually and had to conduct an interview with an 'acting' mother, who gave the same information to each participant. The participant again was asked to complete the form, and was able to ask as many questions as they felt was necessary in order to obtain the required information. The forms were collected and marked by myself.

Each participant was given 4 different scores which were weighted equally (Appendix 1). The first score was a general impression gained during the 2-day workshop – ability to work in a team, ability to interact with others, initiative. The other 3 scores were based on the questionnaire scores. Eight successful field workers were chosen.

3.7 TRAINING

Training was conducted over a six week period by myself and a Zulu member of the community. Training included the following elements:

Community entry. All members of the team were trained in aspects of community entry – how to approach the community, how to approach the traditional leaders, how to represent the Africa Centre for Health and Population Studies.

Household entry. All members of the team were trained in household entry²¹⁰. I was assisted in this by a retired Zulu hospital matron, who was employed at the Africa Centre in the Community Liaison Office. The manner in which a homestead is entered and whom to speak to first have a specific protocol in Zulu culture and are sensitive issues. Training included: how to enter a homestead, who to ask for,

correct introductions to the household head and other members of the family, where to sit for the interviews.

Numeracy. Training in mathematics was not consistent across all schools in the district prior to 1994. Many schools had no mathematics teachers so the level of numeracy is generally low. Good numeric skills are necessary for accurate data collection. A 10-day course on simple addition and subtraction, percentages, simple fractions, multiplication, and units used for weighing and measuring was conducted by myself.

Data forms. Two full weeks were spent on training on the data forms. Role plays, scenarios and written exercises were used to consolidate knowledge and check for accuracy and consistency in those being trained.

Definitions. Two days were spent going over definitions used in the forms. Working definitions were developed for breast health problems, for example mastitis, which were used throughout the study.

Ethics and consent. Sessions on the ethics of research and informed consent were conducted with all the recruited staff, but most particularly with the clinic assistants who would be enrolling women into the study.

Field workers were not trained in breastfeeding or infant feeding, but were trained to document exactly what was reported by the mother, without making any judgement on the information given.

A half-day course on anti-hijacking techniques and safety in the field was conducted by a local security officer.

3.8 STUDIES

Two studies were conducted for this thesis: a cross-sectional survey and a longitudinal study. These are described in detail below.

3.8.1 Cross-sectional survey

A cross-sectional survey was conducted at the twelve clinics in the Hlabisa sub-district which provide ante-natal services.

Mothers and care-givers of infants, aged one day to 12 months, attending immunisation clinics at the twelve clinics, were surveyed using a structured questionnaire (Appendix 2). The survey was conducted over three consecutive weeks in August and September 1999. All women bringing infants to the clinic were considered eligible. The questionnaires were administered by the trained study workers. Information was obtained on feeding practices since birth and in the preceding 48 hours, based on maternal or caregiver recall. Specifically, the women were asked whether they had breastfed their infants during these time intervals and what other supplements, if any, had been given. All women (n=445) were approached and none declined to participate.

The cross-sectional survey looked at breastfeeding practices, and did not seek to provide information on non-prescribed medications or the methodology of collection of breastfeeding practices.

3.8.2 Longitudinal study

The longitudinal study was the main study of this thesis.

Three clinics were selected from the Mpukunyoni tribal area of the Hlabisa sub-district in order to represent the socio-economic heterogeneity of the area: one in the township of KwaMsane where most homes have piped water, waterborne sanitation and where most persons have regular employment, either in the government service or as self-employed professionals; a second rural clinic, Mpukunyoni, accessed by a tar road; and a third clinic, Gunjaneni, in the deep rural area accessible only by a dirt road. Most women in these rural areas obtain their water from rivers or ponds, and families use pit latrines or have no toilet facilities whatsoever. Households are supported by incomes from migrant labour, old-age pensions and subsistence farming.

Enrolment in the longitudinal study was from September 1999 to February 2000. Women attending antenatal clinics were eligible for the survey if they were at least 30 weeks gestation, lived in the catchment area of one of the three clinics included in the survey, and did not intend to move out of the area in the following four months. Consecutive women were approached and none declined to participate.

The aim was to recruit 50 women per clinic, which would allow a detection of a difference in exclusive breastfeeding rates between the three clinics of approximately 25%. It was decided that if the observed differences between clinics were less than 25% then a pooled analysis would take place. With a total sample size of 150 the 95% confidence interval surrounding the observed exclusive breastfeeding rates would be $\pm 5\%$ to 8%, depending on the frequency of exclusive

breastfeeding. This sample size would allow accurate enough evaluation of trends of exclusive breastfeeding over time²¹¹.

Women were interviewed antenatally to document how they intended to feed their infant over consecutive periods: from 0 to 6 weeks of age, and from 7 to 12 weeks of age. Definitions of the different patterns of breastfeeding were not given to the mothers. All mothers were visited at home between 2 and 4 days post delivery and then at weekly intervals by the trained field staff until 16 weeks post-delivery. In addition to the weekly visits, a subset of women received two intermediate visits during the week (that is, a total of three visits per week). These women were randomly selected at delivery using a computer generated random number system which allocated odd or even numbers.

At the weekly interviews, a 48 hour recall history and then a seven day recall history were obtained from each mother. The subgroup of mothers who received two additional visits per week had additional 48 hour, non-overlapping, recall interviews. Follow up was to 16 weeks post-delivery (Appendix 2).

As a quality control measure 5% of questionnaires were repeated by a different field worker on the same day as the original interview. Discrepancies were reconciled by myself and sometimes involved a revisit to the home.

All mothers were asked to keep simple diaries in which they marked days of non-exclusive breastfeeding. The diaries consisted of a square to represent each weekday. The women made a mark in the appropriate square if they gave anything in addition to breast milk on that day. If the square remained empty it was assumed that the baby had been exclusively breastfed for that day. Neither the

mothers nor the field workers looked at the diaries at the time when the structured questionnaires were being completed. The diaries were collected and brought back to the research centre weekly, with the questionnaires, and were only looked at by the data capturers.

This study was designed to provide information on three distinct areas of work: (1) breastfeeding practices, (2) the use of non-prescribed medications and (3) the methodology of collecting breastfeeding data, and to test the hypotheses stated in the aims (see page 55). Specific methodology relating to each of these three areas is detailed below.

3.8.2.a Breastfeeding practices

Women were asked what they had given to their infant to eat/drink over the period of time examined (that is, 48 hours or seven days). Anything other than breast milk was documented using a structured questionnaire. The field workers probed the mother using a list of commonly given foods/fluids, which included (glucose) water, formula milk and porridge. Mothers were probed about the different fluids in case they did not realise the importance of mentioning fluids such as water. The same approach of an open question followed by a list of prompted responses was used for questions on breastfeeding difficulties and reasons for introducing other fluids or feeds. If nothing else had been given to the infant for the previous week, the infant was recorded as being exclusively breast fed for that period. Anything other than breast milk given was documented and the infant was coded as not exclusively breast feeding for that recall period.

It was hypothesized that most mothers in the cohort will initiate breastfeeding, but that cumulative exclusive breastfeeding from birth to 16 weeks of follow-up will be

low (less than a quarter of mothers). In addition it was hypothesized that the time at which other fluids or feeds will be added to the infants' diet will be less than three months post partum. The questionnaires, with daily feeding data collected on a weekly basis, were designed in order to collect the data necessary to support or refute these hypotheses.

In addition, bivariable logistical regression analyses were performed²¹² to look for determinants of exclusive breastfeeding from 0-6 weeks, including maternal age, parity, education, gender of baby, episiotomy, time to first breastfeed, fuel and water supply, owning a fridge and delivery site. $P < 0.05$ was considered statistically significant.

One extra visit was carried out when the infant was between 6 and 9 months of age by myself, during which the mothers' recall of duration of exclusive breastfeeding from birth was documented. Mothers were asked when (if ever) they first introduced water, when (if ever) they first introduced non-human milk, and when (if ever) they first introduced (semi-) solids to their infants' diet. Whichever was introduced first was taken as the time when exclusive breastfeeding was discontinued. The exclusive breastfeeding recall histories of twins were considered separately to take into account their possible different feeding patterns.

3.8.2.b Non-prescribed medications

I interviewed the mothers, at their homes, twice in the first three months after delivery: when their infant was approximately six weeks old and again at 12 weeks. I was accompanied by the field worker who normally visited the mother, who translated for me. As part of the visit mothers and caregivers were asked whether their infant had received any medications at all, whether from a doctor,

nurse or purchased by the mother since their last visit. The type of medication and the frequency of administration were recorded. If the medication was still present in the home the container was examined. Intermittent use of paracetamol was not included as a non-prescribed medication as clinic staff or community health workers often recommend this for fever or pain.

Mothers were specifically asked whether any enemas had been given to the infant, what type of enema was used, how often it was given and the reason it was administered. This question was asked in case mothers did not view enemas as a medication^{185,186}. Finally the mothers were asked whether the infant had been taken to a traditional healer and the reason help was sought.

A medication was considered to be non-prescribed if it had not been prescribed by either a medical doctor or nurse at one of the government facilities or by a private general practitioner. Although many of the traditional healers are registered, any medications prescribed by them were considered 'non-prescribed' for the purposes of this study.

It was hypothesized that the majority of infants under three months of age will not receive oral non-prescribed medications or enemas, and that the more educated women will give fewer of these medications to their infants. As non-prescribed medication administration to young infants is thought to be low in this area, this method of collecting data at two specific time-points (six and 12 weeks) will allow each infant to be categorized as receiving or not receiving non-prescribed medications during these time periods.

3.8.2.c Methodology of collecting breastfeeding data

Various methods were used in the longitudinal study to assess the optimum way of collecting breastfeeding data in this population: 7-day recall by interview; a series of 48-hour recall by interview; maternally kept diaries.

In order to validate the various approaches to assess duration of exclusive breastfeeding (EBF), the following questions were validated:

Is 48 hour EBF status (= 'current EBF feeding status') representative of the entire preceding feeding history?

The 48 hour recall EBF status at 2, 4, 6, 8, and 16 weeks will be compared with the cumulative EBF history from birth, determined from consecutive seven day recall histories. An infant will be removed from the EBF category as soon as something other than breast milk is introduced to the diet.

Do maternal recall interviews at 6-9 months post-delivery provide accurate information on EBF duration and what are the determinants of recall accuracy?

The duration of EBF recalled by mothers, revisited between six and nine months post-delivery, will be compared with the cumulative data from birth, obtained from seven day recall at the weekly visits. Mothers will be asked at this 6-9 month visit to recall for how long their infant received EBF. From this, the recalled EBF status

when the infant was 2, 4, 6, 8 and 16 weeks will be categorised. From the cumulative longitudinal data the week at which the infant was no longer receiving EBF will be determined. One week range on either side of this time point will be allowed, and this will be compared with the duration of EBF recalled by the mother at 6-9 months.

Multiple logistical regression analyses will be carried out to look at determinants of accurate recall of EBF to within one week, including the following socioeconomic determinants: maternal education, ownership of fridge, types of water, fuel and sanitation used, and clinic catchment area. Other possible determinants of breast feeding recall accuracy include: parity, gravidity, age, people who influenced feeding practices and helped with breast feeding, history of breast health problems, the infant's sex and birth weight, and the elapsed time since the mother had stopped EBF.

Is 48 hour EBF recall representative of the previous seven day EBF recall?

The 48 hour EBF recall data obtained at the weekly visit will be compared with the seven day EBF recall data obtained at the same weekly visit from all mothers.

Do feeding practices, as recorded in maternal diaries, accurately represent recent breastfeeding history?

The number of women reporting EBF in their diaries over the previous seven days will be compared with both the seven day recall data (collected from all mothers) and the thrice weekly recall (collected from the subset of mothers).

How accurate is seven day recall compared to a series of 48 hour recalls?

Seven day EBF recall will be compared with 48 hour recall collected thrice weekly (twice from the intermediate visits and once from the weekly visit) from the subset of women. The number of women who say they had EBF over the previous seven days will be compared with the number of women who say they had EBF at each of the thrice weekly visits. A woman will only be counted to have EBF from the thrice weekly data if she reports EBF on each of the three occasions.

For each of the above validations the sensitivity, specificity, positive predictive value and negative predictive value of the index method against the corresponding 'best comparison' will be computed.

3.9 DATA ANALYSIS

The data from the cross-sectional study were entered into a MS Access database. All questionnaires were double-entered, and discrepancies reconciled by myself.

Questionnaires from the longitudinal study were brought to the centre daily and data entered into a MS Access database. Ten percent of questionnaires were double-entered for quality control.

Analysis was performed using SPSS version 8.0 (SPSS Inc, Chicago, Ill). Basic descriptive analyses of the data were carried out using frequency distributions. Baseline data between the clinics were tested for significance using independent Student's t-tests for independent groups and Chi-square tests. P values <0.05 were considered significant, and all tests of significance were two-sided.

Bivariable and multiple logistical regression analyses²¹² were performed to look at determinants of administration of non-prescribed medications and visits to a traditional healer. The infant's gender, the mother's age and education, and socio-economic determinants including the household's ownership of fridge, source of drinking water, and area of home were analysed. Variables were chosen for inclusion in the multiple logistical regression analysis after checking for multicollinearity. P<0.05 was considered statistically significant.

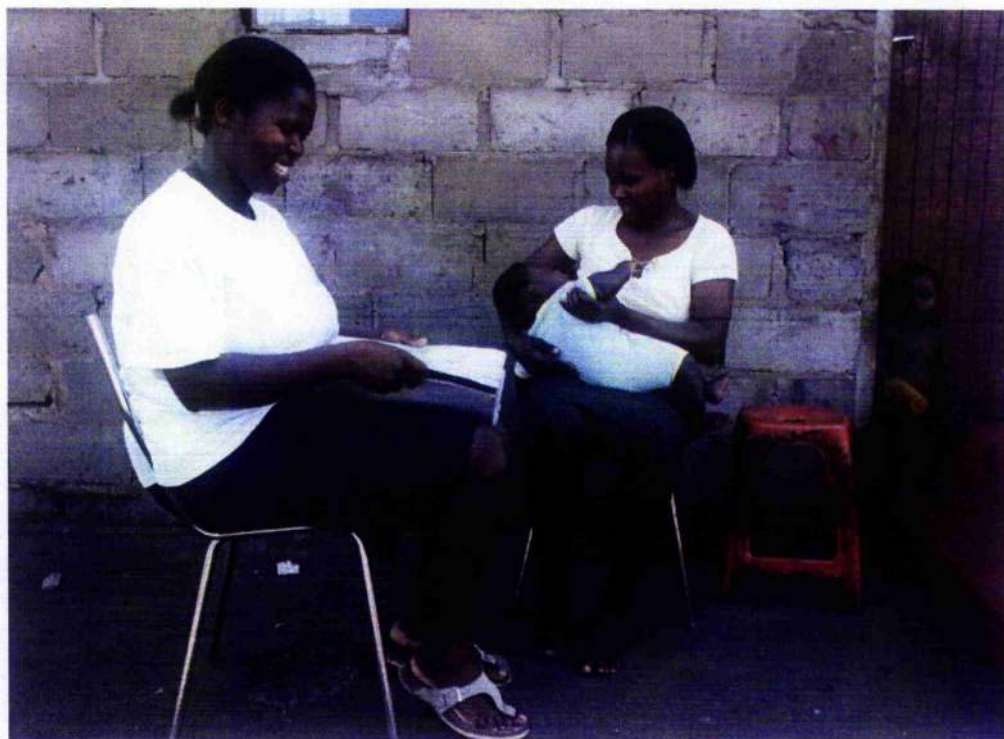
Multiple logistical regression analyses were performed to look at determinants of accurate recall of EBF to within one week, including the following socioeconomic determinants: maternal education, ownership of fridge, types of water, fuel and sanitation used, and clinic catchment area. Other possible determinants of breast

feeding recall accuracy include: parity, gravidity, age, people who influenced feeding practices and helped with breast feeding, history of breast health problems, the infant's sex and birth weight, and the elapsed time since the mother had stopped EBF.

For both studies WHO definitions as documented in Table 1 were used.

3.10 ETHICAL APPROVAL

Ethical approval for the study was obtained from the Ethics Committee of the University of Natal, Durban. Verbal informed consent was obtained from women participating in the cross-sectional survey and written informed consent from those participating in the longitudinal study (Appendix 3).



(above) Clinic visit

(below) Home visit

CHAPTER 4: RESULTS

4.1 GENERAL

The results of the longitudinal study are reported in three distinct sections, relating to the different areas of work detailed in the methods section. Each of the three sections of work has been published in peer-reviewed journals:

Breastfeeding practices

Breastfeeding practices in an area of high HIV prevalence in rural South Africa.

Bland RM, Rollins NC, Coutsooudis A, Coovadia HM. Acta Paediatrica

2002;91(6):704-11

Use of non-prescribed medications

The use of non-prescribed medication in the first 3 months of life in rural South

Africa. Bland RM, Rollins NC, Van den Broeck J, Coovadia HM. Trop Med Int

Health 2004;9(1):118-24

Methodology of collecting breastfeeding data

Maternal recall of exclusive breastfeeding duration. Bland RM, Rollins NC, Solarsh

G, Van den Broeck J, Coovadia HM. Arch Dis Child 2003;88(9):778-83

The results of the cross-sectional survey are reported in the section on breastfeeding practices, as this survey did not seek to answer questions related to the other two areas of work.

In the longitudinal study the three clinics referred to are as follows (see Figure 1):

KwaMsane – township

Mpukunyoni – rural

Gunjaneni – deep rural

The results are divided into three sections to reflect the three published manuscripts.

4.2 BREASTFEEDING PRACTICES

4.2.1 Longitudinal study

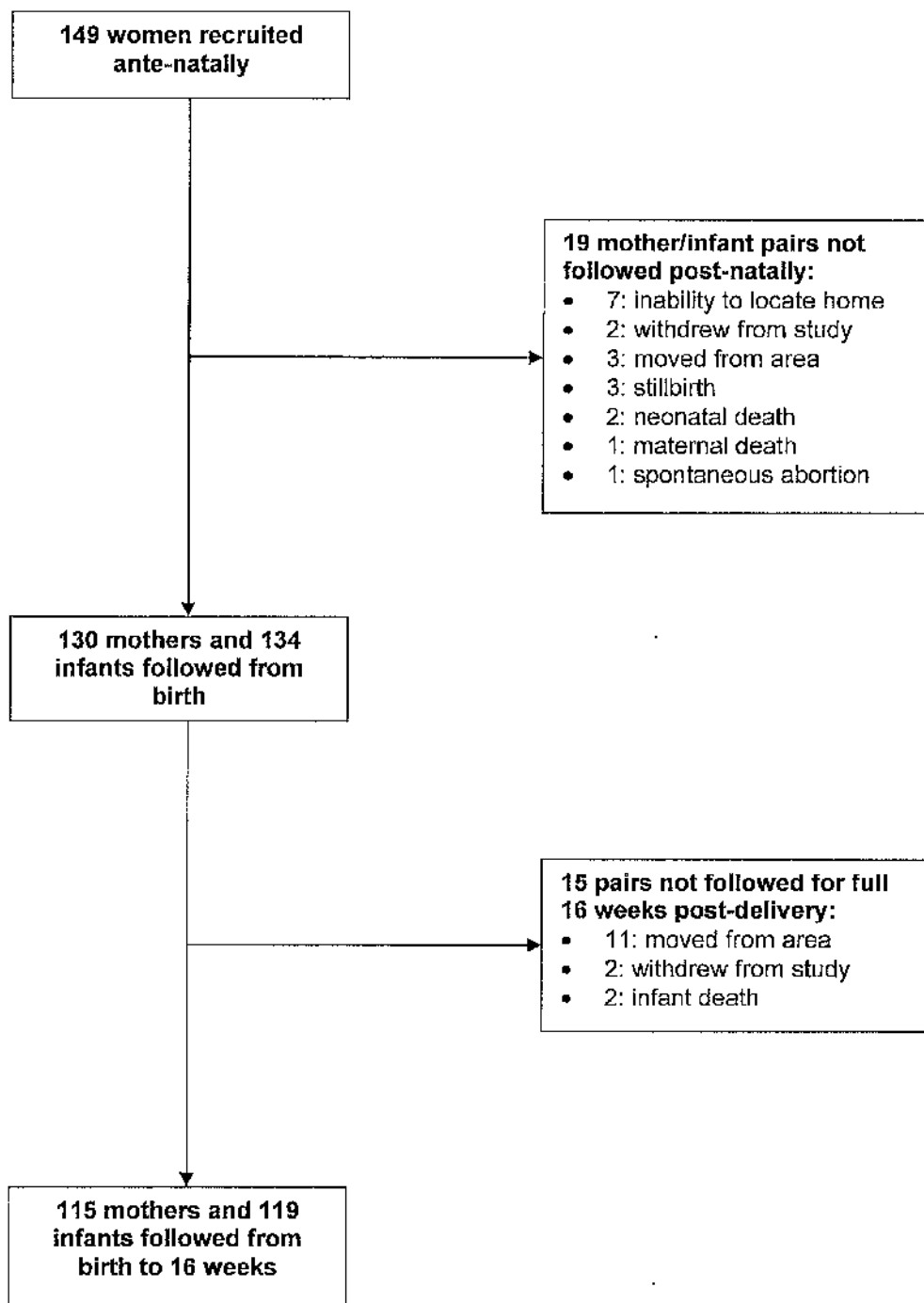
4.2.1.a Cohort profile

One hundred and forty-nine women were recruited antenatally (Figure 2).

Nineteen mother/infant pairs were lost to initial follow-up due to: inability to locate the home (7), stillbirth defined by a fetal loss \geq 24 weeks gestation (3), moved out of study area (3), withdrawal of consent to participate in the study (2), neonatal death (2), maternal death (1) and spontaneous abortion defined as a fetal loss \leq 24 weeks gestation (1). One hundred and thirty mothers and 134 infants (including four sets of twins) were followed from birth, and of these 119 infants were followed for all 16 weeks of the study. Fifteen mother/infant pairs were lost to follow-up

during the course of the study due to: moved out of study area (11), withdrawal of consent to participate in the study (2), and infant death (2). The results of the remaining 15 mother/infant pairs were included in the data analysis for the period they were in the study.

Figure 2: Cohort profile of women in feeding study



4.2.1.b Socio-demographic and perinatal characteristics of mothers and infants

Table 6 shows the socio-demographic and perinatal characteristics of mothers enrolled (n = 130) and infants delivered (n = 134) for the three clinics (Kwamsane – township; Mpukunyoni – rural; Gunjaneni – deep rural). There were no significant differences for many of the variables between the three clinic areas (maternal age, parity, completion of final year of secondary school, proportion of Caesarian sections and episiotomies, female infants, mean birth weight and low birth weight infants). However, there were significant differences between the township (Kwamsane) and rural/deep rural (Gunjaneni and Mpukunyoni) for water supply, fuel supply, toilet facilities and the proportion of home births. Those mothers enrolled from the township were more likely to have clean water (i.e. not river water), to have access to electricity, to have access to a toilet facility, and to deliver their baby at a facility rather than home.

Table 6: Sociodemographic and perinatal characteristics of mothers and infants followed from birth

Characteristic	Township Kwamsane	Rural Mpukunyoni	Deep rural Gunjaneni
Maternal socio-demographics (n=130)	n = 36	n = 55	n = 39
Age at delivery (mean)*	26.7	26.3	25.2
Parity (median)*	3	2	2
Completion of final year of secondary school*	38.2%	29%	31%
River water as main water supply ^a	8%	38%	59%
Fuel supply ^b :			
Wood as main fuel supply	8%	18%	54%
Electricity as main fuel supply	72%	33%	13%
No toilet facilities, including a pit latrine ^c	0%	13%	33%
Delivery (n = 130)	n = 36	n = 55	n = 39
Home delivery ^d	3%	20%	15%
Caesarian section*	8%	16%	10%
Episiotomy*	44%	36%	43%
Infant characteristics (n = 134)	n = 36	n = 57	n = 41

Characteristic	Township	Rural	Deep rural
	Kwamsane	Mpukunyoni	Gunjaneni
Infant female*	58%	56%	38%
Mean birth weight (kg)*	3.28	3.70	3.23
Infant birth weight <2.5 kg*	0	0	0

* no significant differences between the 3 areas ($p > 0.05$)

a: $p < 0.001$ between deep rural and township; $p = 0.002$ between rural and township; $p = 0.06$ between rural and deep rural

b: $p < 0.001$ between deep rural and township; $p = 0.003$ between rural and township; $p = 0.002$ between rural and deep rural

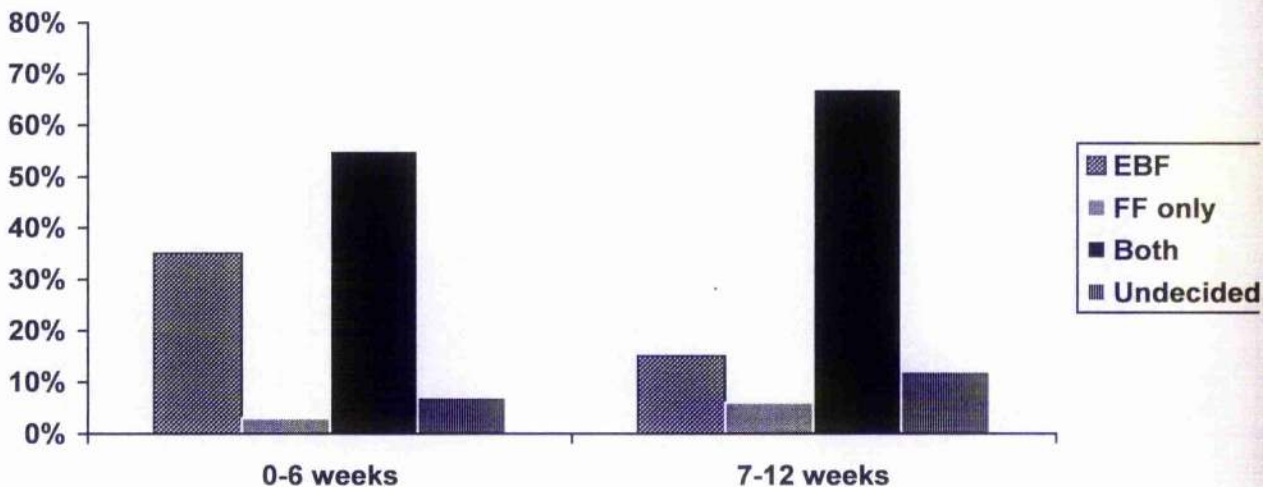
c: $p < 0.001$ between deep rural and township; $p < 0.001$ between rural and township; $p = 0.43$ between rural and deep rural

d: $p = 0.109$ between deep rural and township; $p = 0.024$ between rural and township; $p = 0.601$ between rural and deep rural

4.2.1.c Antenatal feeding choices

Thirty-five percent of women (n = 46 of 130) stated that they would exclusively breastfeed their infant from birth to six weeks of life and 15% (n = 19 of 130) between weeks seven and twelve (Figure 3). Fifty-five percent (n = 71 of 130) and 67% (n = 87 of 130) of women planned to mix feed (i.e. to give both breast milk and formula milk during these time periods). A small proportion of women planned to exclusively formula feed their infants: 3% (n = 4 of 130) from birth to six weeks and 6% (n = 8 of 130) between weeks seven and twelve. Seven percent of women (n = 9 of 130) were undecided as to how to feed their infant from birth to six weeks, and 12% (n = 16 of 130) between seven and twelve weeks.

Figure 3: Antenatal feeding decisions



4.2.1.d Breastfeeding patterns

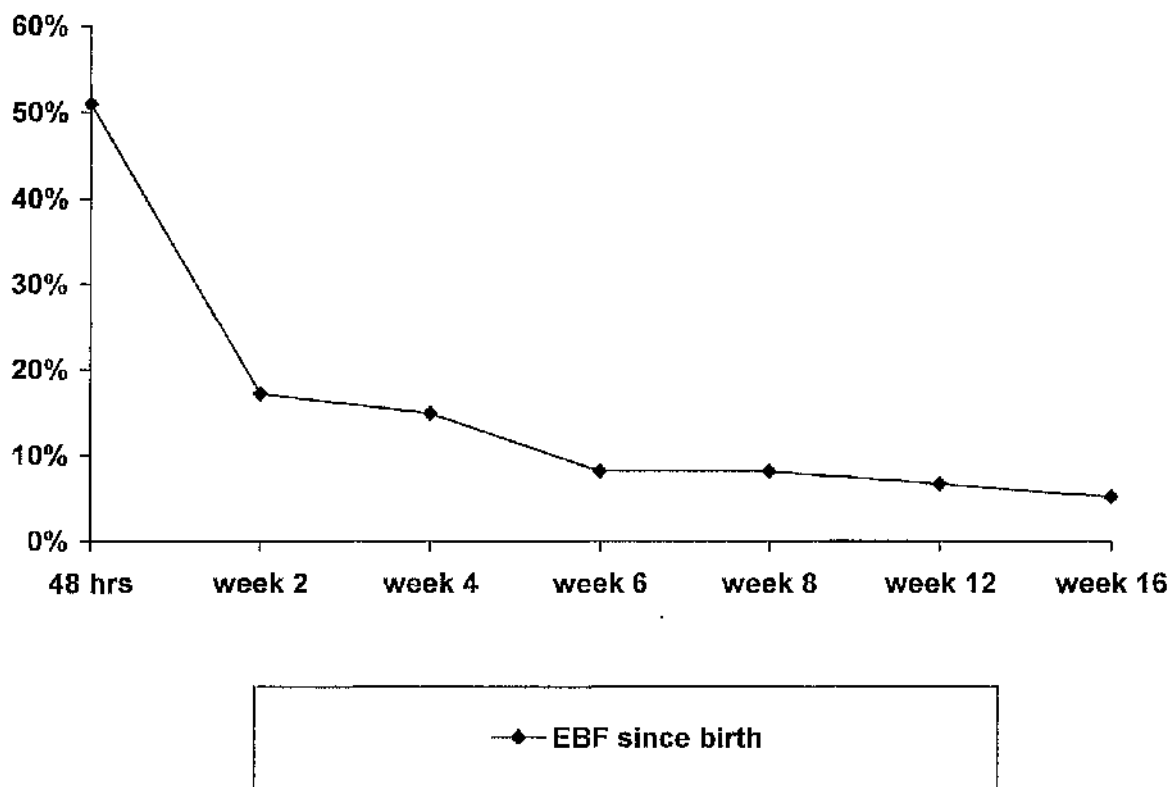
Breastfeeding patterns were similar in all three areas studied. All mothers initiated breastfeeding, including the four women who intended to exclusively formula feed from birth. Fifty one percent (n=21) of infants from Gunjaneni Clinic, 53% (n=30) from Mpukunyoni Clinic and 50% (n=18) from KwaMsane Clinic were exclusively breastfed for the first 48 hours of life. In addition, there were no significant differences between the three areas in those still exclusively breastfeeding at 16 weeks post delivery, although the numbers were very small: 7% (n=3) from Gunjaneni, 7% (n=4) from Mpukunyoni, and 3% (n = 1) from Kwamsane (p=0.87). The feeding data of the cohort were therefore analysed collectively.

4.2.1.e Proportion of infants who were exclusively breastfed from birth to 16 weeks

The proportion of infants (n = 134) who were exclusively breastfeeding from birth is shown in Figure 4, showing a sharp decrease in exclusive breastfeeding within the first two weeks. Sixty-eight infants (51%) were exclusively breastfed for the first 48 hours; 23 (17%) from birth until two completed weeks; 20 (15%) until four completed weeks; 11 (8%) until six completed weeks; 11 (8%) until eight completed weeks; 9 (7%) until 12 completed weeks and 7 (5%) until 16 completed weeks of age.

There was an association between the mother's intended feeding practice and the feeding pattern at 6 weeks of age (p=0.05). However, only 20% (9/46) of mothers who intended to 'breastfeed only' from birth to six weeks carried out their intention. The remaining 80% (37/46) mixed fed.

Figure 4: Maintained exclusive breastfeeding rate from birth to 16 weeks. Women were counted as not adhering to exclusive breastfeeding on the first day of giving something other than breastmilk.



4.2.1.f Proportion of infants who were exclusively breastfed excluding feeding patterns in the first 48 hours of life

Almost 50% of infants received something in addition to breast milk in the first 48 hours of life, thus excluding them thereafter from the cumulative 'exclusive breastfeeding' category. Therefore, the proportion of infants who were exclusively breastfed excluding what happened in the first 48 hours of life was calculated to ascertain whether this would make a difference to the overall proportion of infants who were exclusively breastfed. Excluding the feeding patterns in the first 48 hours:

25% of infants were exclusively breastfed at two weeks (compared to 17%)

24% at four weeks (compared to 15%)

17% at six weeks (compared to 8%)

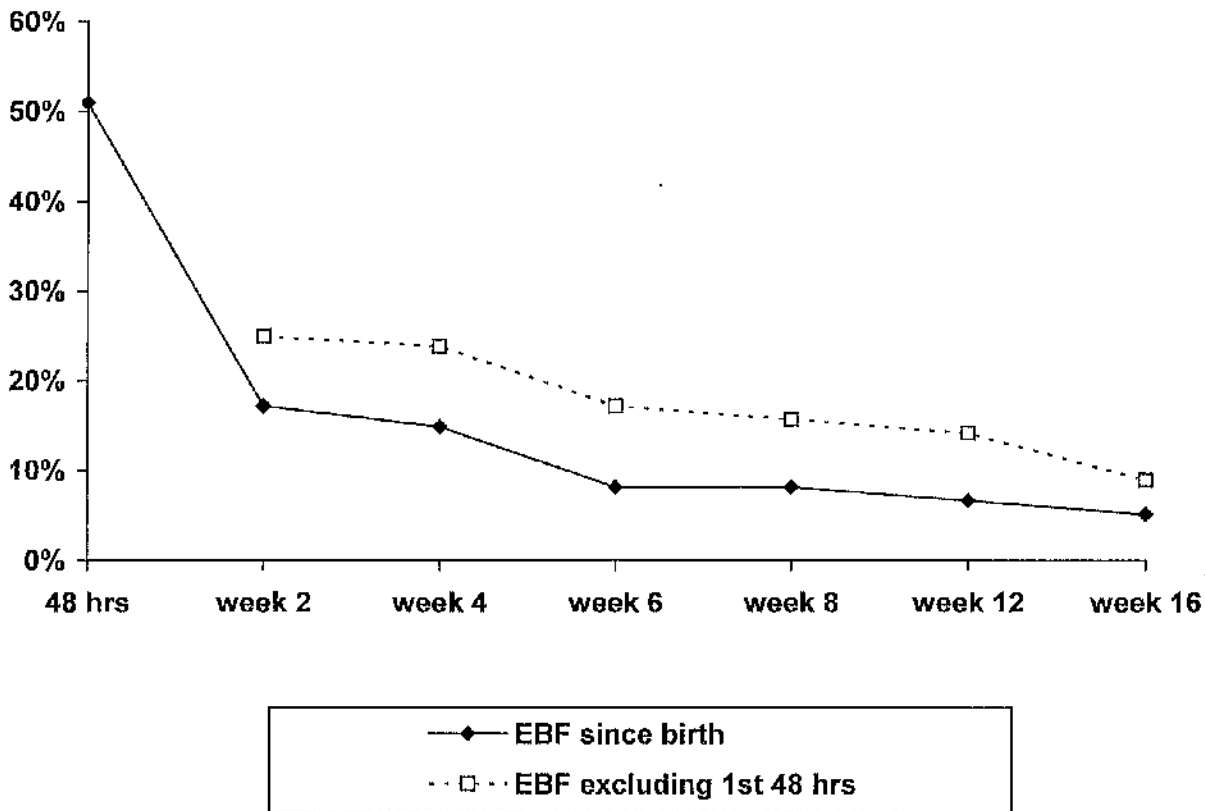
16% at eight weeks (compared to 8%)

14% at twelve weeks (compared to 7%)

9% at sixteen weeks (compared to 5%)

There was little difference in the overall proportion of infants who were exclusively breastfed from day three of life (i.e. excluding the first 48 hours of life) to 16 completed weeks (Figure 5).

Figure 5: Maintained exclusive breastfeeding rate excluding the first 48 hours of life. The proportion of mothers who maintained exclusive breastfeeding, excluding what happened in the first 48 hours of life, is represented, and includes infants who received an early feed after delivery but were exclusive breastfeeding thereafter.

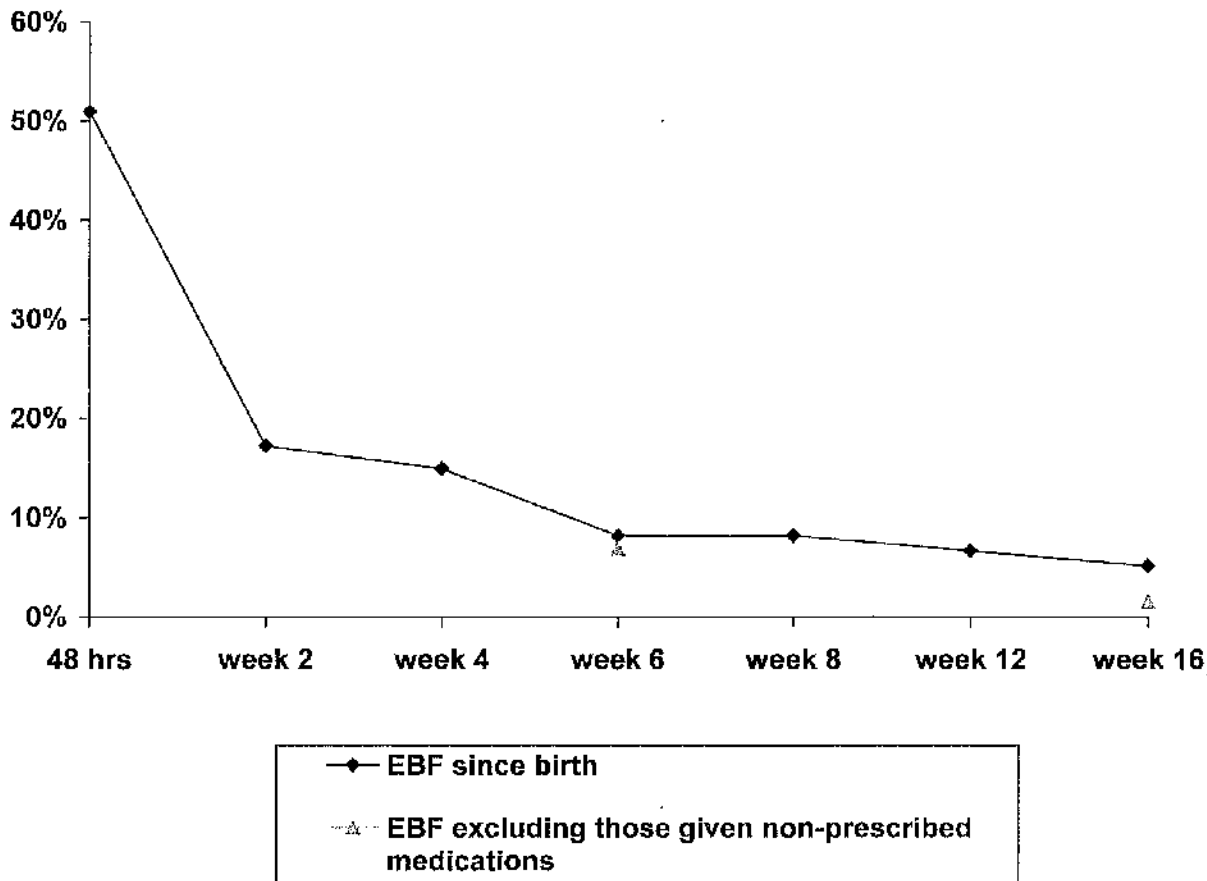


4.2.1.h Proportion of infants who were exclusively breastfed if non-prescribed medications are considered

If infants who received non-prescribed oral medications are also excluded from the exclusively breastfed group, the number who were continuously exclusively breastfed from birth falls from 10% (n=14) to 8% (n = 11) at 6 weeks, and from 6% (n=7) to 3% (n = 4) at 16 weeks (Figure 6). Thirty-seven percent (n = 41) of infants

received non-prescribed medications by the age of six weeks and 36% (n = 40) by the age of 12 weeks (See Section 4.3 on non-prescribed medications).

Figure 6: Maintained exclusive breastfeeding rate including non-prescribed medications. The proportion of women who were excluded from the exclusive breastfeeding category at six and 16 weeks as they gave non-prescribed medication.



4.2.1.i Determinants of exclusive breastfeeding

Delivery in the district hospital, as compared to a clinic or at home, was the only factor associated with exclusive breastfeeding from 0-6 weeks in a univariable logistic analysis: 21.4% of those born at the hospital and 4.8% of those born at a clinic or home were exclusively breastfed from 0-6 weeks ($p = 0.006$). Twelve women were giving no breastmilk at all by 16 weeks post delivery; in univariable analysis these women were 8.7 times more likely to own a fridge than not own a fridge (95% CI 1.0 – 73.7; $p = 0.016$). Women who had completed schooling were 7.7 times more likely to give no breastmilk than those who had not completed schooling (95% CI 1.8 – 32.4; $p = 0.001$).

4.2.1.j Supplementation and reasons for supplementation

Eighteen percent ($n=24$ of 134 infants) of infants were put to the breast within 1 hour of birth but 44% ($n=59$ of 134 infants) had a delay of at least four hours. During the first 48 hours of life the most frequently given supplements were water or glucose water (35%; 47 of 134 infants), and commercial formula milk (15%; 20 of 134 infants), mainly given for a perceived insufficiency of breastmilk (36%; 49 of 134 infants).

From week one to week 16, a total of 1597 infant weeks of feeding data were recorded. The most commonly given supplements were commercial formula feed (840 weeks; 52%) and semi-solids (335 weeks; 21%) given for an 'unsatisfied baby' or perceived milk insufficiency (852 weeks; 53%) (Table 7).

Table 7: Types of, and reasons for, introducing supplemental feeds

	Rank order of supplemental feeds given	Rank order of reason for introduction of supplemental feed
First 48 hours of life	Glucose water	Perceived insufficient milk
	Formula feed	Crying/unsatisfied baby
>48 hours of life - 16 weeks	Formula feed	1. Baby 'unsatisfied'
	Glucose/water / semi-solids	2. Perceived insufficient milk

4.2.1.k Breast health problems

During the first 48 hours post-partum, 31% (n=41/130) of mothers complained of breastfeeding difficulties, of which 93% (n = 38/41) were 'milk let down' problems. Between weeks one and 16, 19% (n=25/130) of women complained of some difficulty, most commonly sore nipples (n = 11) and poor milk supply (n = 10). Sixty-four percent (16/25) of mothers reporting breast health problems had introduced supplements by the end of week one. None of the mothers who reported breast health difficulties exclusively breastfed for the 16 weeks of follow-up.

4.2.1.l Source of feeding advice

At the first postnatal visit mothers were asked about their source of infant feeding advice (Table 8). The feeding advice for twins was recorded separately as difficulties may arise with only one twin, particularly if s/he was low birth weight. In addition different advice may be given for male, as opposed to female, infants.

Almost half of the mothers stated that no-one had influenced their feeding decision (n = 58/134; 43%) and that no-one had helped them with breastfeeding (n = 61/134; 45%). Approximately one fifth of mothers had been influenced by medical or nursing staff (n = 29/134; 22%) and a similar proportion had been helped with initial breastfeeding by someone medically trained (n = 26/134; 19%). The maternal grandmother of the infant was another influential person, but community health workers, other relatives and husbands or partners did not appear to influence feeding decisions (Table 8).

Table 8: People whom mothers identified as sources of infant feeding advice at first postnatal visit.

Source of infant feeding advice	Person who influenced feeding decision (n = 134)*	Person who helped with initial breastfeeding (n = 134)	Person who will give future advice (n = 134)
No-one	58 (43%)	61 (45%)	16 (12%)
Medical/nursing staff	29 (22%)	26 (19%)	49 (36%)
Maternal grandmother	22 (16%)	27 (20%)	22 (16%)
Don't know	12 (9%)	9 (7%)	22 (16%)
Other relative	4 (3%)	5 (4%)	4 (3%)
Mother-in-law	1 (1%)	1 (1%)	1 (1%)
Community health worker	1 (1%)	2 (1%)	12 (9%)
Husband/partner	1 (1%)	0 (0%)	0 (0%)
Other	6 (4%)	3 (2%)	8 (6%)

* feeding advice for twins was recorded separately as difficulties may arise with only one twin (particularly if LBW) and different advice may be given for male, as opposed to female, infants.

When mothers were asked who they would turn to for advice in the future regarding feeding their current infant, the most common response was medical or nursing staff (n = 49/134). However, 12% of mothers said they would not seek help from anyone, and 16% stated they did not know who they would ask. Nine percent of mothers stated they would ask for advice from their community health worker and no-one said that they would ask their husband or partner (Table 8).

The final feeding outcome was not significantly associated with the source of feeding advice (p=0.26). Of the eight women who exclusively breastfed for 16 weeks, 62% (n=5) stated that they themselves chose how to feed their infant. Ninety-two percent (n=11 of 12) of women who were not breastfeeding at 16 weeks post-delivery stated that they had been advised by someone else on the mode of infant feeding.

4.2.2 Cross sectional survey

Three hundred and ninety-six mothers and 51 care-givers were interviewed, giving a total of 447 interviews. These mothers and care-givers were all different from those who took part in the longitudinal study. The dates of birth of two infants were not recorded and these questionnaires were excluded from analysis, leaving results for 445 interviews. The ages of the infants ranged from one day to one year, with a median age of 19 weeks (Interquartile range, 25th percentile-75th percentile: 12-33). Sixty-two percent (n = 276) of respondents surveyed used lakes, rivers or ponds as their main water source. Thirty-one percent (n = 140) had no toilet facilities and 45% (n = 201) used wood as their main fuel source for boiling water. There were no differences in feeding pattern by water source, sanitation or fuel supply.

Table 9 summarises the results of the feeding practices of these infants divided into age groups. The proportion of infants who were being breastfed at the time of the interview; the recall of exclusive breastfeeding practices over the previous 48 hours; and the most common supplemental feeds given to those who were mixed feeding over the previous 48 hours are documented. The majority of infants were receiving some breast milk in all age groups (26 of 28 in the first three weeks of life; 139 of 168 between six months and one year of age). For infants under six months of age, under 50% of them in all age groups had been exclusively breastfed over the previous 48 hours. For those infants between six months and one year of age, 19 of 198 (11%) had only received breast milk over the previous 48 hours. From birth to six months the most common supplements given were commercial formula milk and glucose water.

Table 9: Clinic-based, cross-sectional survey of breastfeeding practices in rural kwaZulu Natal (n = 445)

Age in weeks	n	Breastfeeding currently	Exclusive breastfeeding past 48 hours	Supplemental feeds most frequently given to those breastfeeding, but not exclusively [#]
0 - 3	28	26 (93%) CI: 76-99%*	11 (39%)	Commercial formula milk (30%) Glucose water (30%) (n = 15)
4 - 6	16	16 (100%) CI: 79-100%	7 (44%)	Commercial formula milk (78%) Glucose water (33%) (n = 9)
7 - 9	39	31 (79%) CI: 64-91%	14 (36%)	Commercial formula milk (88%) Solids other than porridge(41%) (n = 17)
10 - 12	33	31 (94%) CI: 80-99%	10 (30%)	Commercial formula milk (62%) Solids other than porridge(38%) (n = 21)

Age in weeks	n	Breastfeeding currently	Exclusive breastfeeding past 48 hours	Supplemental feeds most frequently given to those breastfeeding, but not exclusively [#]
13 - 16	60	56 (93%) CI: 84-98%	13 (22%)	Commercial formula milk (74%) Porridge (32%) (n = 43)
17 - 24	101	89 (88%) CI: 80-94%	22 (22%)	Commercial formula milk (64%) Porridge (42%) (n = 67)
25 - 52	168	139 (83%) CI: 76-88%	19 (11%)	Porridge (62%) Commercial formula milk (51%) (n = 120)

* 95% CI showed percentages not significantly different from previous and following age groups

[#]Multiple supplements may be recorded for the same child. Only the 2 most commonly given supplements have been recorded. Few infants receive porridge before 12 weeks, but it becomes more frequent from 13 weeks onwards.

Typical additions to porridge are margarine, peanut butter, eggs and powdered milk.

Table 10 shows the mother's antenatal intentions and those from the longitudinal study who managed to exclusively breastfeed, at two, six and 12 weeks postnatally. In addition the proportion of infants from the cross-sectional survey whose mothers/caregivers stated that they had been exclusively breastfed for the corresponding time periods (up to two, six or 12 weeks postnatally) is included to allow comparison with the longitudinal data, although different mothers and infants were enrolled into the two studies. In the cross-sectional survey 47% of mothers said their infant had been exclusively breastfed from birth to two weeks, whereas in the longitudinal study only 17% of infants were exclusively breastfed from birth to two weeks. At 12 weeks, 33% of mothers in the cross-sectional study said their infants had been exclusively breastfed from birth to 12 weeks of age, whereas in the longitudinal study 7% of infants had been cumulatively breastfed from birth to 12 weeks.

Table 10: Intended duration of exclusive breastfeeding antenatally compared with the number who did so since birth at 4 different ages based on longitudinal data. Data on EBF recall since birth is provided from the cross-sectional survey for comparison.

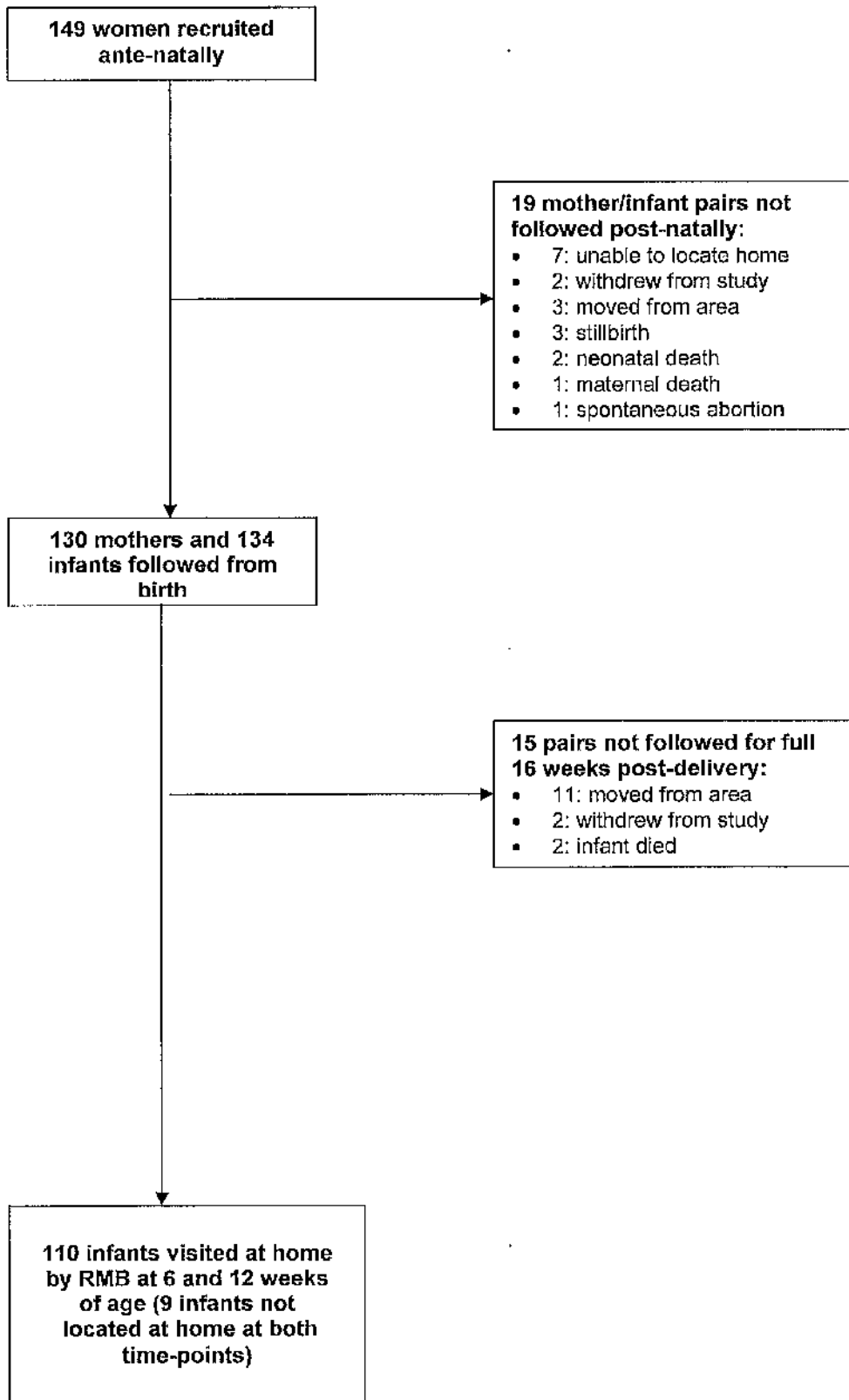
	Longitudinal study		Cross-sectional survey
	Antenatal intention to EBF	Cumulative EBF from birth	Maternal recall of EBF from birth
2 weeks	34% (n = 46)	17% (n = 23)	47% (n = 8/17)
6 weeks	34% (n = 46)	10% (n = 14)	40% (n = 4/10)
12 weeks	15% (n = 20)	7% (n = 10)	33% (n = 3/9)
16 weeks	-----	6% (n = 8)	15% (n = 2/13)

4.3 NON-PRESCRIBED MEDICATIONS

4.3.1 Cohort profile

One hundred and ten infants were visited, at around six and 12 weeks, at their homes by myself for the purposes of this section of the study (Figure 7). Nine infants were not located at both time points so were excluded from analysis.

Figure 7: Cohort profile of women interviewed about non-prescribed medications.



4.3.2 Socio-demographic characteristics of those followed for this section of work

The characteristics of the mothers of the 110 infants followed for this section of the study were similar to the characteristics of the mothers of the total 130 mothers enrolled in the study (Table 6).

The median age of mothers at delivery was 25.2 years (P10 – P90: 18.2 – 36.9 years); the median years of school completed was 8 (P10 – P90: 0 – 12); 42 (38%) women owned a fridge; 43 (39%) had access only to 'dirty' water (from a river, pond or stream); 54 (49%) of infants were male; 31 (28%) were recruited from the KwaMsane clinic in the township, 46 (42%) from Mpukunyoni clinic in a rural area and 33 (30%) from Gunjaneni clinic in a deep rural area.

4.3.3 Proportion of infants who received non-prescribed medications

Almost all infants ($n = 107/110$, 97%) received some form of non-prescribed medication in the first three months of life, either orally or via an enema (Table 11). Enema use was more common than oral non-prescribed medications. Eighty-three percent ($n = 91/110$) of infants received an enema in the first six weeks of life; and 74% ($n = 81/110$) between weeks six and twelve.

Overall, 58% of infants ($n = 64/110$) received some form of non-prescribed medication orally: 37% ($n = 41/110$) in the first six weeks of life and 36% ($n = 40/110$) between weeks six and twelve.

Table 11: Proportion of infants who received non-prescribed medication, either orally or rectally, during the first 6 weeks of life, the second 6 weeks of life, and at any time during the first 12 weeks of life.

Mode of administration of non-prescribed medication	Birth - 6 weeks of age	6 - 12 weeks of age	Any time from 0 – 12 weeks of age
	n = 110	n = 110	n = 110
Enema	91 (83%)	81 (74%)	98 (89%)
Oral	41 (37%)	40 (36%)	64 (58%)
Enema and/or oral	101 (92%)	93 (84%)	107 (97%)

4.3.4 Types of non-prescribed medications administered

The different types of non-prescribed medications are shown in Table 12.

Enemas containing traditional Zulu medicine, water and sunlight soap were all commonly given to infants. A significant proportion of infants who received either enemas or oral medications did so on more than one occasion.

The most commonly given non-prescribed oral medications given were gripe water, or 'muthi wenyoni'. Gripe water, purchased from pharmacies or stores, contains sodium bicarbonate and alcohol and the label states it is used to 'comfort infants with colic, wind or perceived abdominal pain'. Muthi wenyoni is an antacid purported by the manufacturers to make the baby healthy and energetic and believed by users to cleanse the system from evil influences which may harm the child. It contains calcium carbonate, magnesium carbonate, sodium bicarbonate, sodium citrate and alcohol (3.7% v/v).

Table 12: Types and frequencies of non-prescribed medications administered to infants, both orally and rectally, in the first 3 months of life.

Type of medication	Frequency	Birth – 6 weeks n = 110	6 – 12 weeks n = 110
ENEMAS		n = 91	n = 81
Traditional Zulu medicine ¹		35 (38%)	38 (46.9%)
	More than once weekly	22	19
	Weekly or less	13	19
Water only		29 (32%)	16 (19.8%)
	More than once weekly	19	8
	Weekly or less	10	8
Sunlight soap ² and water		19 (21%)	19 (23.5%)
	More than once weekly	10	9
	Weekly or less	9	10

Type of medication	Frequency	Birth – 6 weeks n = 110	6 – 12 weeks n = 110
Other		8 (10%)	8 (9.8%)
	More than once weekly	7	3
	Weekly or less	1	5
ORAL MEDICATION		n = 41	n = 40
Gripe water ³		17 (41%)	14 (35%)
	More than once weekly	14	9
	Weekly or less	3	5
Muthi Wenyoni ⁴		8 (19%)	3 (8%)
	More than once weekly	6	3
	Weekly or less	2	0
Traditional Zulu Medicine ¹		4 (10%)	7 (18%)
	More than once weekly	2	4
	Weekly or less	2	3

Type of medication	Frequency	Birth – 6 weeks n = 110	6 – 12 weeks n = 110
Combinations of the above medications		6 (15%)	8 (20%)
	More than once weekly	4	6
	Weekly or less	2	2
Other (including cough mixture)		6 (15%)	8 (20%)
	More than once weekly	0	1
	Weekly or less	6	7

¹Traditional Zulu medicines contain many ingredients including herbs and animal extracts. They can be bought from local street traders or obtained from traditional healers themselves

²Sunlight is a brand of washing powder

³Contains sodium bicarbonate and alcohol (4.4% v/v). Used to comfort infants with 'colic', 'wind' or perceived abdominal pain

⁴An antacid purported by the manufacturers to make the baby healthy and energetic and believed by users to cleanse the system from evil influences which may harm the child. Contains calcium carbonate, magnesium carbonate, sodium bicarbonate, sodium citrate and alcohol (3.74% v/v)

4.3.5 Reasons for administration of non-prescribed medications

The most commonly given reasons for enema administration at any time during the first 12 weeks of life were perceived constipation (n = 45/98, 46%) or a belief that the infant needed to be 'cleaned out' (n = 30/98, 31%). Other reasons included healing of 'inkaba' (an internal wound thought to be caused by severance of the umbilical cord), stomach pains, protection of the baby against evil spirits and because 'the weather was changing'.

The most frequently given reasons for administering oral medications were 'wind', 'colic' or perceived abdominal pain.

4.3.6 Consultations with a traditional healer

Twenty-nine mothers (29/110 = 26%) said they had consulted a traditional healer at some point in the first 12 weeks of life. The most common reason for consulting a traditional healer was for 'ibala', the Zulu word for a capillary naevus, especially found on the back of the neck in infants (15/29; 52%). Women also sought advice for 'inkaba', stomach pains and inyoni (perceived as the vulnerability of all infants to supernatural elements which may cause illness. If untreated, inyoni may lead to a sunken fontanelle and diarrhoea). Table 13 shows the reasons mothers sought help from a traditional healer.

Table 13: Main reason cited by mother for administration of non-prescribed enemas to infants and for visits to a traditional healer during the first 12 weeks of life.

Reason	Number (%)
For administration of non-prescribed medication by enema	n = 98
Perceived constipation	45 (46)
Baby needs to be 'cleaned out'	30 (31)
No reason given	11 (10)
For healing of the umbilicus internally 'inkaba**	4 (4)
Stomach pains	2 (2)
Protection of baby	2 (2)
Capillary naevus	1 (1)
Baby crying	1 (1)
Baby hot	1 (1)
For 'mouth wound'	1 (1)
As the weather changing	1 (1)
For visit to traditional healer	n = 29
Capillary naevus	15 (52)
For healing of the umbilicus internally 'inkaba**	3 (11)

Reason	Number (%)
Perceived stomach pains	3 (11)
Inyoni**	2 (7)
No reason given	2 (7)
Mouth wound	1 (3)
To 'clean the stomach'	1 (3)
'Wind'	1 (3)
Diarrhoea	1 (3)

* 'Inkaba' is an internal wound thought to be caused by severance of the umbilical cord

** 'Inyoni' is a condition which may be associated with diarrhoea and dehydration

4.3.7 Determinants of administration of non-prescribed medications and visits to a traditional healer

There was a significant interaction between those with a clean water supply and those who owned a fridge ($p=0.001$), therefore ownership of a fridge was omitted from the multiple logistical regression analysis. No other associations were noted.

Table 14 presents the univariable logistic regression analyses of associations with administration of non-prescribed medications and visits to a traditional healer. The number of infants who received any enemas at all in the first 12 weeks of life was so high that I could not examine for determinants in this group. However, I looked at determinants of those mothers who administered enemas more frequently than once weekly to their infants. Completion of school, access to a 'clean' water supply and living in the township were significantly associated with the administration of non-prescribed oral medications to infants.

Multiple logistical regression analysis showed that mothers who had a 'clean' water supply were more likely to give non-prescribed oral medication than those without (OR = 2.7 and $p = 0.0223$). Women who had no education were less likely to give non-prescribed medication than those who had completed education (OR = 0.19 and $p = 0.0326$). There were no significant determinants identified for mothers who visited traditional healers or those who gave enemas more frequently than once weekly.

Table 14: Univariable analysis of associations with administration of non-prescribed oral medications, visits to a traditional healer and enemas given more frequently than once weekly (compared to weekly or less) during the first 12 weeks of life.

Determinant	n	Non-prescribed oral medication n (%)	P-value*	Visit to traditional healer n (%)	P-value*	Enema administered more than once weekly n = 71	P-value*
Maternal age							
<20y	25	14 (56)		10 (40)		17 (68)	
20 – 29y	50	31 (62)		12 (24)		32 (64)	
>29y	31	15 (48)	0.485	6 (19)	0.190	19 (61)	0.873
Maternal education							
None	13	5 (38)		2 (15)		10 (77)	

Determinant	n	Non-prescribed oral medication		Visit to traditional healer		Enema administered more than once weekly	
		n (%)	P-value*	n (%)	P-value*	n = 71	P-value*
1 - 9yrs	57	28 (49)		15 (26)		34 (60)	
>9 yrs	39	29 (74)	0.018	12 (30)	0.552	26 (67)	0.465
Clinic							
1 (Township)	31	24 (77)		10 (26)		16 (52)	
2 (Rural)	46	24 (52)		11 (24)		31 (67)	
3 (Deep rural)	33	14 (42)	0.014	10 (30)	0.814	24 (73)	0.183
Fridge							
Yes	68	42 (62)		19 (28)		41 (60)	

Determinant	n	Non-prescribed oral medication		Visit to traditional healer		Enema administered more than once weekly	
		n (%)	P-value*	n (%)	P-value*	n = 71	P-value*
No	42	20 (48)	0.146	10 (24)	0.633	30 (71)	0.236
Water source							
Tap or well	65	42 (65)		17 (26)		42 (65)	
River, pond or stream	43	18 (42)	0.020	12 (28)	0.841	28 (65)	0.957
Infant sex							
Male	54	31 (57)		16(30)		35 (65)	
Female	56	31 (55)	0.828	13(23)	0.445	36 (64)	0.954

* Chi-square test

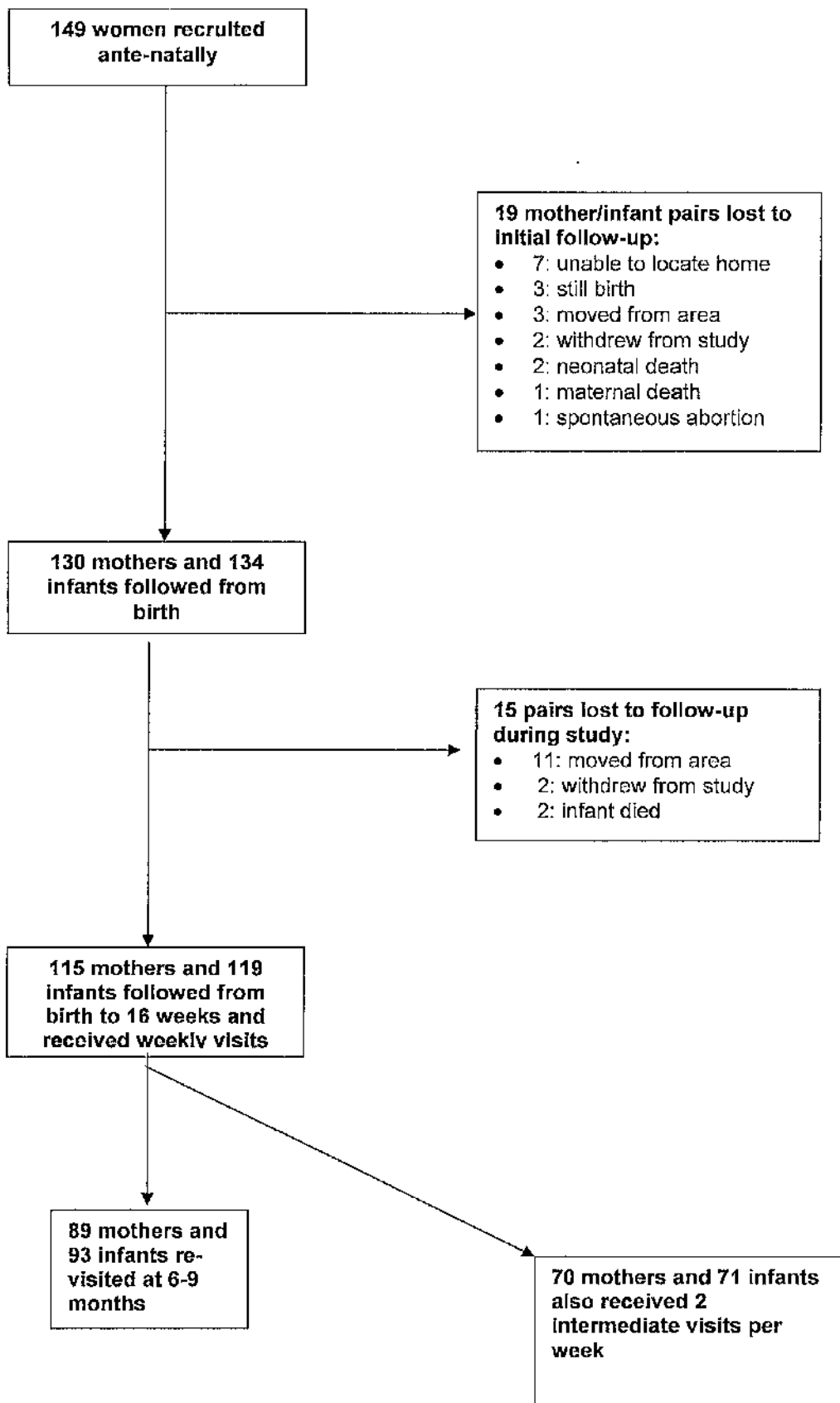
4.4 METHODS OF COLLECTING BREASTFEEDING DATA

4.4.1 Cohort profile

One hundred and forty-nine women were recruited antenatally (Figure 8). Data for this part of the study were collected on all the 119 infants who were followed for the complete 16 weeks of the study. The results of the remaining 15 mother/infant pairs were included in the data analysis for the period they were in the study. Seventy mothers and 71 infants also received the two intermediate visits per week. Eighty-nine mothers and 93 infants were traced and re-visited when the infants were between six and nine months of age. Of these 93 infants, an exclusive breastfeeding recall history was obtained on 81 infants; mothers could not recall a feeding history for the other 12 infants.

As the breastfeeding patterns were similar in all three areas (see section on breastfeeding patterns) the feeding data of the cohort were analysed collectively.

Figure 8: Cohort profile of mothers revisited at six to nine months



4.4.2 Comparison of collection of feeding data

Table 15 shows the different methods of recalling exclusive breastfeeding (EBF) status against a 'best comparison' in each case. In most cases the 'best comparison' is the cumulative feeding history since birth. However, in the case of 48 hour recall, the 'best comparison' is the weekly recall including the 48 hour of recall. Weekly recall is compared to thrice weekly recall (the series of overlapping 48 hour recall interviews).

In each case the number of complete records available for each comparison is documented, in addition to the sensitivity, specificity, positive and negative predictive values.

The meaning of sensitivity in this analysis is the ability of the methods to correctly identify infants who are EBF, whilst the specificity is the ability of the methods to correctly identify those who are not EBF.

Is 48 hour EBF status (= 'current EBF feeding status') representative of the entire preceding feeding history?

The data on 48 hour recall at the different time points ('current EBF feeding status') showed high sensitivities at all time points. In other words, the 48 hour recall accurately identified those who had exclusively breastfed from birth to the time point specified (Table 15).

However, 48 hour recall showed low specificities and poor positive predictive values for the entire exclusive breastfeeding history. In other words, some infants were classified as EBF from the 48-hour recall when, in fact, the entire feeding history indicated that they had received fluids/feeds other than breastmilk at some time. More specifically, using our 48-hour assessment method, one would conclude that 31% of infants were EBF at 6 weeks whereas if cumulative assessments are taken into account this estimate is only 10%.

Table 15: Comparison of methods of determining EBF versus non-EBF. 48-hour recall, diary and weekly recall compared against a specified 'best comparison'. Sensitivity is the ability of the methods to correctly identify infants who are EBF, whilst the specificity is the ability of the methods to correctly identify those who are not EBF

EBF recall	'Best comparison'	No. of records compared	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
48 hour recall ('current EBF status') at:						
2 weeks	Cumulative feeding history since birth	94	100	65	48	100
4 weeks	Cumulative feeding history since birth	89	100	74	47	100
6 weeks	Cumulative feeding history since birth	96	100	77	33	100
8 weeks	Cumulative feeding history since birth	95	100	79	31	100
16 weeks	Cumulative feeding history since birth	88	100	89	47	100

EBF recall	'Best comparison'	No. of records compared	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Recall at 6-9 months for EBF status at:						
2 weeks	Cumulative feeding history since birth	81	79	40	52	70
4 weeks	Cumulative feeding history since birth	81	76	46	41	79
6 weeks	Cumulative feeding history since birth	81	86	70	36	96
8 weeks	Cumulative feeding history since birth	81	80	70	26	96
16 weeks	Cumulative feeding history since birth	81	100	82	30	100

EBF recall	'Best comparison'	No. of records compared	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
48 hour recall [#]	Weekly recall	1051	100	96	92	100
Diary	Thrice weekly recall*	436	96	88	73	98
Diary	Weekly recall	1199	94	86	74	97
Weekly recall	Thrice weekly recall*	546	96	94	86	98

* Interview carried out at same time as weekly interview on each woman

* Sub-sample of women

Do maternal recall interviews at 6-9 months post-delivery provide accurate information on EBF duration and what are the determinants of recall accuracy?

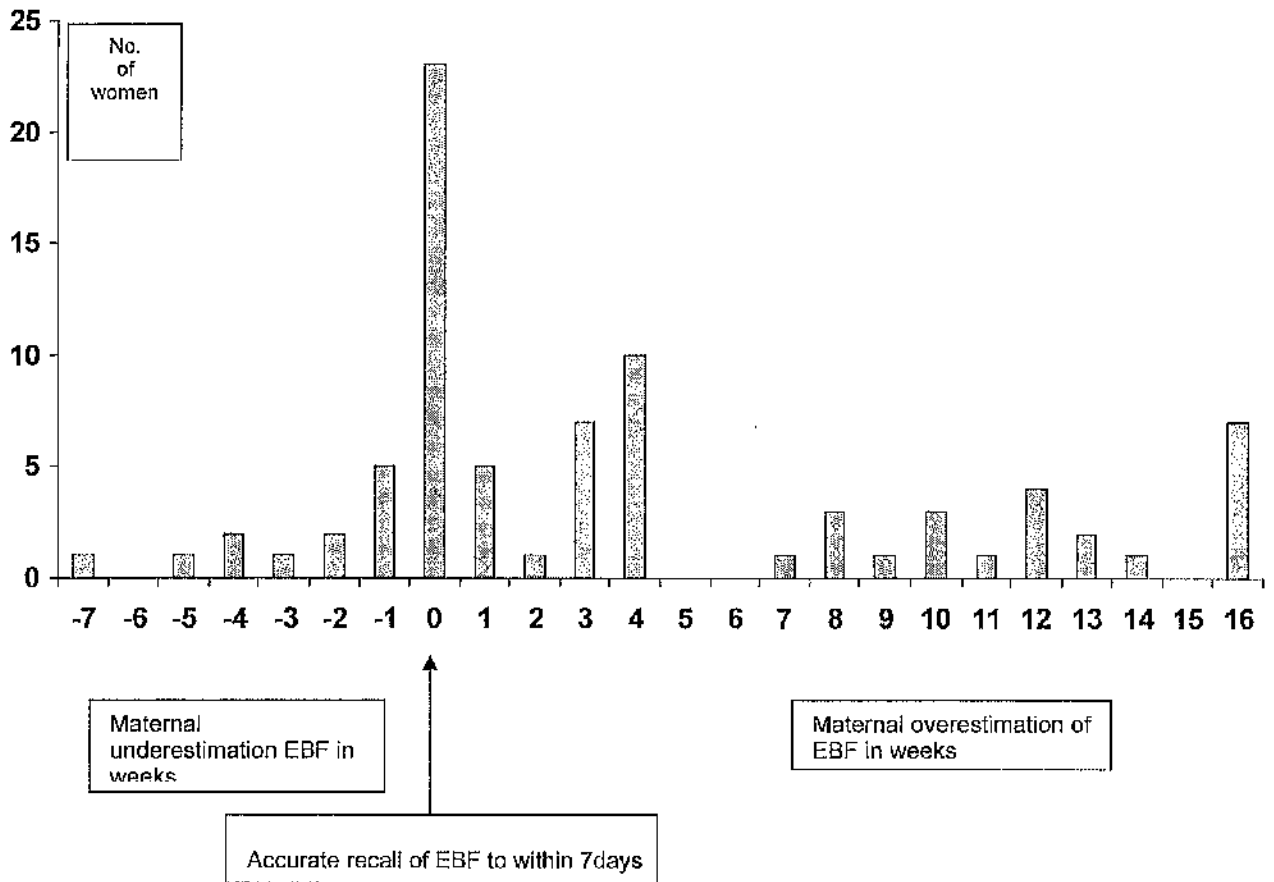
Recall at 6- 9 months post-delivery was poor, particularly for the early weeks of infant life (Table 15). The few mothers who had maintained EBF for the study duration, however, recalled this accurately.

Multivariable logistic regression analyses revealed no other significant determinants of accurate recall of EBF to within one week. Specifically,

educational level achieved, economic advantage (indicated by water and fuel supply and ownership of a fridge) and a history of breast health problems did not significantly influence long-term recall.

Figure 9 shows the difference between the length of EBF, in weeks, recalled by the mother when she was re-visited between 6 and 9 months post delivery and the length of EBF collected from the weekly interviews. The mean age of the infants when the mother was interviewed was 31 weeks (standard deviation 4.8 weeks; range: 22-47 weeks). 13% (n = 12) of mothers could not remember when they gave something other than breastmilk to their infant, so infant breastfeeding data are only available for 81 mother-infant pairs. Among those who did remember seventy-two percent (n = 58) inaccurately recalled the length of time, to within one week, that they exclusively breastfed: 57% (n = 46) overestimated the duration of EBF (mean 7.6 weeks); 15% (n = 12) underestimated the duration of EBF (mean 2.7 weeks).

Figure 9: Maternal recall of duration of exclusive breastfeeding by mothers interviewed 6-9 months post delivery compared to the longitudinal data collected at weekly intervals



Is 48 hour EBF recall representative of the previous seven day EBF recall?

High positive (92%) and negative (100%) predictive values were obtained when 48-hour recall was compared to weekly recall obtained at the same interview showing that recall over 48 hours predicted reliably the breastfeeding history over the preceding week (Table 15).

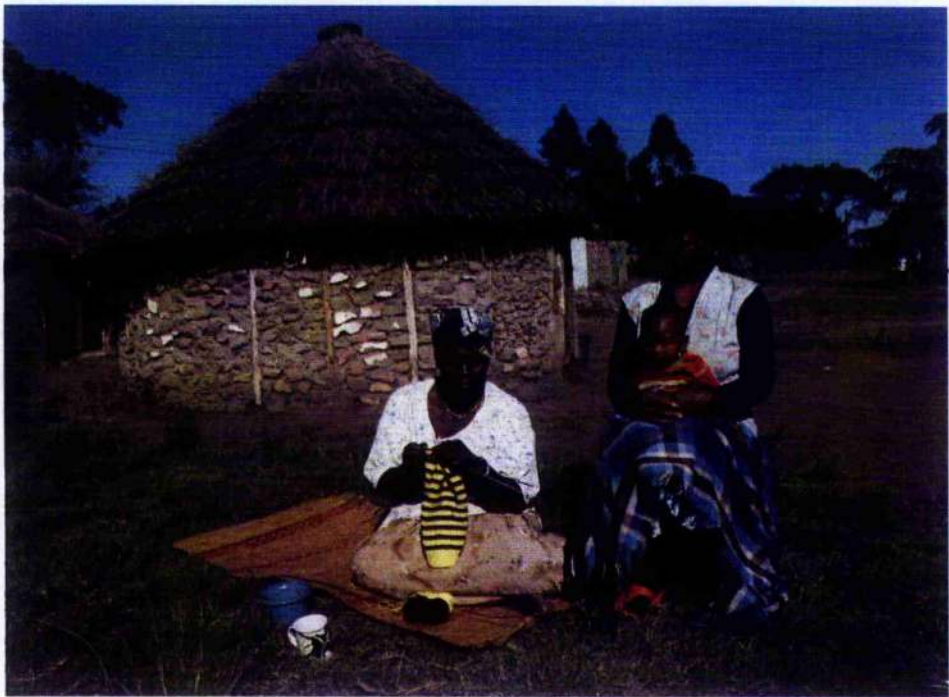
How accurate is seven day recall compared to a series of 48 hour recalls?

High sensitivities (96%) and specificities (94%) were obtained when weekly histories were validated against thrice weekly recall. In other words, 7-day recall accurately identified those infants who had been EBF and those who had not been EBF over the preceding week, when compared to the three 48-hour interviews over the same time period (Table 15).

Do feeding practices, as recorded in maternal diaries, accurately represent recent breastfeeding history?

Diaries also showed high sensitivities and negative predictive values compared to both weekly (sensitivity 94%; negative predictive value 97%) and thrice weekly interview (sensitivity 96%; negative predictive value 98%) recall. Diaries accurately recorded infants who were EBF (sensitivity) but were not so reliable at identifying infants who were not EBF (specificity). If mothers forgot to fill in the diary that they

gave something other than breast milk to their infant, the data would be interpreted as 'exclusively breastfed' for that time period (Table 15).



Local families

CHAPTER 5: DISCUSSION

5.1 SUMMARY OF THE RESULTS

Breastfeeding practices

- All women in the longitudinal study initiated breastfeeding.
- Breastfeeding patterns were similar in the three areas studied.
- 55% and 67% of women intended, antenatally, to mix feed their infants from birth to six weeks, and six to twelve weeks respectively.
- There was a sharp decrease in exclusive breastfeeding within the first two weeks post partum, with 17% of the cohort still being exclusively breastfed at two weeks of age. Only 5% of infants were exclusively breastfed from birth to 16 weeks of age.
- There was a sharp decrease in exclusive breastfeeding within the first two weeks post-partum, even when feeding patterns in the first 48 hours were excluded.
- 44% of babies had a delay of at least 4 hours before being put to the breast, contrary to the recommendations of the baby-friendly hospital initiative.
- The most commonly given supplements were glucose water in the first 48 hours of life and formula milk from day three to 16 weeks post partum.

- The most commonly given reasons for supplementing feeds were a maternal perception of insufficient milk, and an unsatisfied baby.
- A third of women complained of breast health problems. None of the mothers who reported breast health difficulties exclusively breastfed for the 16 weeks of follow-up.
- Most mothers stated that no-one had influenced them in their feeding decision and that no-one had helped them to breastfeed.

Non prescribed medications

- 97% of infants received some form of non-prescribed medication in the first three months of life, either orally or via enema.
- The most commonly given enemas were traditional Zulu medications.
- The most commonly given oral medications were gripe water or an antacid called 'muthi wenyoni'.
- The most commonly given reasons for enema administration were perceived constipation or a belief that the baby needed to be 'cleaned out'.
- The most commonly given reasons for administering oral medications were 'wind', 'colic' or perceived abdominal pain.

- 26% of mothers had consulted a traditional healer in the first 12 weeks of life, most commonly regarding a capillary naevus.
- Mothers who were less educated were less likely to administer non-prescribed medications.
- Mothers who had a clean water supply were more likely to give non-prescribed medications.

Methods of collecting breastfeeding data

- The 48 hours recall accurately identified those who had exclusively breastfed from birth to the time specified. However, it did not accurately identify those who had mixed fed at some point since birth, and overestimated the duration of exclusive breastfeeding.
- Maternal recall of exclusive breastfeeding, at 6-9 months post-partum, did not accurately represent the feeding history since birth. 57% overestimated, and 15% underestimated, the duration of exclusive breastfeeding.
- The 48 hour recall predicted reliably the breastfeeding history over the past week.
- The 7-day recall predicted reliably the breastfeeding history over the past week.

- Maternal diaries accurately recorded infants who were exclusively breastfed, but were not so reliable at identifying infants who were not exclusively breastfed.

5.2 CONTEXT OF THE STUDY

The Global Strategy for Infant and Young Child Feeding¹² states that as a public health recommendation, infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development and health. Thereafter, to meet their evolving nutritional requirements infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues for up to two years of age or beyond.

However, there are exceptional circumstances where families in difficult situations require special attention and practical support to be able to feed their children adequately¹². These are listed as: children who are severely malnourished, low birth weight infants, infants and children of natural or human-induced emergencies, orphans, and children born to HIV-infected women.

The Strategy states that all HIV-infected mothers should receive counselling which includes provision of general information about meeting their own nutritional requirements and about the risks and benefits of various feeding options, and specific guidance in selecting the option most likely to be suitable for their situation. Current evidence suggests that HIV-infected mothers should avoid mixed feeding and, for the first six months, practise either exclusive replacement feeding (if this is 'acceptable, feasible, affordable, sustainable and safe') or

exclusive breastfeeding^{20,22,193}. From six completed months of age, HIV-infected mothers should introduce complementary feeds and avoid breast milk altogether. However, some form of milk in the diet is recommended until the child is two years of age⁶.

This study was conducted before HIV-testing for pregnant women was available in the study area, before the Global Strategy was published, and before individual counselling on feeding for women, depending on their HIV status was conducted. Free formula feeds for HIV-infected women were not available in the district. However, the hospital at Hlabisa had achieved baby-friendly status¹⁰¹ and, in theory, all women were encouraged to exclusively breastfeed for the first six months of life.

Prior to the introduction of a district PMTCT (Prevention of mother-to-child transmission programme) in the area, and the initiation of the Vertical Transmission Study to examine the postnatal transmission risks of exclusively breastfeeding, this study was conducted to inform the design of a breastfeeding support strategy for women who choose to breastfeed, and the design of data collection instruments.

5.3 THE DILEMMA OF INFANT FEEDING IN THE CONTEXT OF HIV

Rural African women who are HIV-infected and have received appropriate counselling face a dilemma about how they should feed their infants. They are encouraged to choose between exclusive replacement feeding (if this is acceptable, feasible, affordable, sustainable and safe) or exclusive breastfeeding.

However, exclusive breastfeeding is uncommon and avoidance of breastfeeding is not a realistic option for many mothers who cannot afford formula milk, have inadequate access to clean water and are concerned about stigmatization if they completely avoid breastfeeding. In addition, there is a serious risk that promotion or provision of formula feeds may result in a 'spillover effect' to women who are HIV-negative or who do not know their HIV status.

5.4 CROSS-SECTIONAL SURVEY VERSUS LONGITUDINAL STUDY

I hypothesized that most mothers in the cohort would initiate breastfeeding but that cumulative exclusive breastfeeding rates would be low, and most infants would receive other fluids or feeds whilst they were under three months of age.

In the cross-sectional survey most infants received breast milk from birth throughout the first year of life. These findings support the first hypothesis that most mothers in this area initiate breastfeeding.

Whilst the cross-sectional survey indicates that exclusive breastfeeding from birth was more common than that reported in the longitudinal study (Table 10), the longitudinal study shows that exclusive breastfeeding from birth was uncommon. Cross-sectional surveys, relying on maternal recall over 24 hours, or even over the preceding month remain common tools for assessing the feeding practices of infants in studies measuring MTCT of HIV^{115,116,181}. The present cross-sectional survey had limitations as there were few infants at each time point compared with the longitudinal data. While these findings need to be confirmed in a larger study,

it is suggested that longitudinal data should be used in any similar preparatory, or follow-up, situational analyses of breastfeeding practices.

5.5 FEEDING PATTERNS

There were no significant differences between the infant feeding practices in the three areas studied. It is interesting that even mothers from the deep rural area of Gunjaneni, where homes are isolated and water is mainly collected from rivers and ponds, did not exclusively breastfeed for longer than those in the socially advantaged township where access to clean water and stores to purchase formula milk is more readily available. The data show that both in the township and in the more remote areas, mixed feeding is the socially and culturally accepted mode of infant feeding in this area.

As hypothesized, all mothers in the longitudinal study initiated breastfeeding, including those who had intended to exclusively formula feed from birth. This is not surprising as the hospital is baby-friendly, and the nurses in the clinics have all received some training on breastfeeding promotion. Free formula milk was not available in the clinical facilities, nor are rooms to prepare replacement feeds.

It was hypothesized that the cumulative breastfeeding rate from birth to 16 weeks of follow-up would be less than a quarter of all infants. This was based on exclusive breastfeeding rates from other surveys⁶³. Almost half the infants in this study were mixed fed as early as the first 48 hours of life and most babies dropped out of the EBF category by two weeks of age. Similar proportions of non-exclusively breastfed babies were found even if the feeding history of the first 48

hours of life were excluded, suggesting that mixed feeding is common at all time points in the first few weeks of life, rather than a pattern of early introduction of, for example, glucose water, immediately after birth followed by a sustained period of exclusive breastfeeding.

It was hypothesized that the time at which other feeds of fluids would be added to the infants' diet would be less than three months of age. This was true, with glucose water, formula milk and porridge all being introduced as early as the first week of life.

The most common mode of feeding was found to be mixed feeding, which is associated with increased mortality and morbidity, and the highest rates of MTCT^{102,104,169}.

5.5.1 Antenatal intentions and subsequent feeding practices

Although it is not known whether the mothers in the study intended to be as strict in how they fed their infants as the WHO definition requires, of those who intended to 'breastfeed only' for the first six weeks, 80% actually mixed fed. Some proportion of this difference may also be due to unexpected postnatal events.

This study identifies a number of major impediments to exclusive breastfeeding and risk factors for mixed feeding in this population. Many women had made the choice, antenatally, to mix feed. How a woman chooses to feed her infant is influenced by many factors, including the influence of family, friends and health staff. Although the majority of women reported that they decided for themselves how they would feed their baby, and had no help with the initiation of

breastfeeding, the maternal grandmother and health staff were cited as important influences, particularly for future feeding advice.

5.5.2 Reasons for mixed feeding

Most infants had dropped out of the 'exclusive breastfeeding' category by two weeks of age. Mother's perceptions of 'insufficient milk' and an 'unsatisfied baby' are consistent with reports from other parts of the world^{91,92,94}. However, almost all mothers can produce enough milk if help is given with positioning and attachment in the early days, and if breastfeeds are given often enough²¹. Data from a study in Soweto, South Africa, found that women base their conclusions about breast milk sufficiency mainly on infant crying⁹¹.

Although the numbers were small, mothers were significantly more likely to have stopped giving breast milk altogether by 16 weeks postnatally if they were economically advantaged (owned a fridge) and had completed school education. Education may allow increased exposure to media messages on alternatives to breastfeeding.

Any strategy to promote exclusive breastfeeding should target women antenatally and involve other influential members of the family. Relevant information about the physiology of breastfeeding and the importance of colostrum helps mothers to understand how breastfeeding works. Information about infant crying patterns helps families to interpret infants' fretfulness and may delay unnecessary premature supplementation with non-human milk or other fluids²¹. Messages should emphasise that exclusive breastfeeding is recommended for all infants, globally, regardless of socio-economic circumstances.

5.5.3 Breast health problems

Breast health problems were not uncommon. None of the women who reported difficulties maintained exclusive breastfeeding for 16 weeks. It is likely that in many cases the early introduction of other fluids or feeds caused the breast health problems. Reported milk let-down problems during the first 48 hours after delivery were consistent with mothers' concerns about insufficient milk and lack of understanding about colostrum. These problems can be overcome if mothers are supported in the critical early postpartum period by health staff who have been trained in breastfeeding counselling, have the appropriate knowledge and technical skills, and are committed to promoting and supporting breastfeeding.

5.5.4 Resources needed to support exclusive breastfeeding

There is evidence that women who choose to breastfeed exclusively can sustain this chosen feeding practice within their community^{52,69,87}. However, to substantially increase and sustain exclusive breastfeeding rates, resources are required, for example to fund lay counsellors^{69,87}. This type of investment has been shown to be cost-effective. Although the mothers in this study were significantly more likely to breastfeed exclusively to six weeks if they had delivered at the baby-friendly district hospital, the rates of exclusive breastfeeding in this district remain low at two weeks post-partum, despite follow-up by community health workers. In addition, few infants were breastfed within one hour of birth, as recommended by the Baby-friendly Hospital Initiative¹⁰¹. Such delayed breastfeeding has been identified as an important obstacle to successful breastfeeding practice²¹.

5.5.5 Feasibility of replacement feeding

Although this study did not specifically look at the feasibility of replacement feeding, the data show that none of the women initiated formula feeding at birth, and only a small proportion were giving no breast milk at all at 16 weeks postpartum. Two-thirds of the women had access only to dirty water, and almost half used wood as their source of fuel for cooking. These data are consistent with national statistics which report that in rural areas of South Africa more than 75% of poor households have no access to piped water or sanitation²¹³. Since this study was completed, formula feeds are provided free of charge to HIV-infected women for six months. However, many women do not have the resources to prepare feeds safely and consistently.

5.6 NON-PRESCRIBED MEDICATIONS

The use of non-prescribed medications play an important role in the care-giving practices of mothers in this area. Interpreting young children's behaviour, crying patterns and symptoms is complex, and it is not surprising that mothers resort to remedies which are commonly perceived to help or prevent illness.

Both enema use and the administration of oral non-prescribed medications were common in the cohort. 97% of infants received some form of non-prescribed medication during the first 12 weeks of life. I did not expect that medication use would be this high in this age group. There is very little in the literature on this subject in South Africa, particularly in children. People do not talk about this subject, and often deny the administration of such medications and the influence of spiritual and cultural beliefs on infant health. It was of interest that even the

group of field workers who took part in this study were surprised at the high rates of use of these medications for young babies. The hypothesis that the majority of infants under the age of three months of age would not receive oral non-prescribed medications or enemas was refuted.

5.6.1 Enemas

Enema administration was more common in the cohort than oral medications with 53% (n = 58/110) of infants receiving enemas more frequently than once weekly during the first week of life. All households use water, and most use sunlight soap, so enemas containing these ingredients are cheap and readily accessible.

Traditional Zulu remedies are also conveniently purchased either from one of the many traditional healers in the area, or from local traders. Zulu remedies are made from a variety of products including extracts from plants.

Although 46% of infants were given enemas for perceived constipation, it is unlikely that the majority of them were clinically constipated, especially as all of them were receiving some breast milk. It is more likely that caregivers erroneously perceived that the baby was constipated if stools had not been passed for 24-48 hours²¹. Mothers need reassurance about the normal pattern of stooling in the breastfed baby which varies considerably from once weekly to defecation after each feed²¹⁴.

Enemas were also given to 'clean the baby out', a process which is believed to cool the baby down and protect him or her by purging harmful evil influences. Simple explanations about how to keep infants cool in hot and humid weather would be appropriate in this situation in addition to education about the useful

factors in breast milk (and particularly in colostrum) which help to 'clean' the bowel of meconium and protect the baby from illnesses.

Enemas are not always harmless, and sometimes cause preventable deaths. In our study area in the year 2000 there were 156 deaths in infants aged 0-12 months, identified by the Africa Centre verbal autopsy unit. For four children no obvious cause of death was evident other than that death followed the administration of an enema (personal communication, Annamie Vanneste, Verbal Autopsy Unit, Africa Centre for Health and Population Studies, 2000).

The number of infants who received any enemas at all in the first 12 weeks of life was so high that I could not examine for determinants in this group. Even when I looked at those who administered enemas more frequently than once weekly, there were no significant associations (Table 14).

5.6.2 Oral non-prescribed medications

Fewer infants received oral medications than enemas. Possible reasons for this include costs and accessibility. A 100ml bottle of Muthi Wenyoni costs 9.45 South African rands and a 150ml bottle of Gripe Water costs 16 South African rands, whereas a loaf of bread costs 2.4 rands (at the time of the study 8 ZA rands = \$1).

I hypothesised that women who were more educated would be less likely to administer non-prescribed medications to their infants. As there is so little literature around this subject, this assumption was based on discussions with staff (nurses and field workers) at the Africa Centre who were, themselves, mothers.

However, this study shows that educated women are more likely to administer oral medications. They may be influenced by the marketing strategies of manufacturers of medications and by their peer group. Mothers with a 'clean' water supply were also more likely to give oral medications to their infants. Those with a 'dirty' water supply are more likely to live in rural areas, inconveniently located for shops and chemists which stock medications. Both educated women and those with 'clean' water are likely to be financially advantaged and so more able to afford non-prescribed medications.

It is interesting to postulate why the people I had spoken to prior to the study seemed to think that the administration of oral non-prescribed medications would be uncommon and limited to the more rural, uneducated, women. It is possible that people who are better informed about the health system and recommendations for managing their infants (e.g. giving oral rehydration solution for diarrhoea) are more likely to deny the existence of this practice both to people like myself and the health services.

Surprisingly when I visited the homes the mothers seemed to be happy to produce the containers of non-prescribed medications and tell me about their usage. I phrased the question in an open-ended way: "What medications have you given to your baby by mouth?" and "What medications have you given to your baby by enema?" rather than "Have you given any non-prescribed medications to your baby?" Although the documentation of non-prescribed medications could be an underestimation, the study still shows its widespread use.

Oral medications were most frequently given for 'colic' and perceived abdominal pain. As there is no proven medical cure for colic, mothers need an explanation about the universality of the condition, the fact that it is usually self-resolving, and ways that they can comfort a colicky baby^{16,21}.

Muthi Wenyoni is very popular in this area and other parts of South Africa¹⁸⁷. The condition known as inyoni may be associated with diarrhoea and dehydration. It is problematic if infants with potentially life-threatening diarrhoea and dehydration are being given Muthi Wenyoni rather than having prompt access to medical help. Interestingly, both Muthi Wenyoni and Gripe Water contain varying amounts of alcohol (3.74% v/v and 4.4% v/v respectively), and it is possible that their perceived benefits may be partially caused by the relaxation and sleep-inducing properties of the alcohol.

5.6.3 Consultations with a traditional healer

Consultation with a traditional healer was not significantly associated with any of the determinants I examined. The 349 traditional healers in the district are widely scattered, easily accessible and widely trusted for their skills at diagnosis and treatment. Although only a quarter of mothers reported consulting a traditional healer, it is possible to buy traditional remedies from many outlets in this area, for example markets and Spaza shops, without actually paying to visit a traditional healer in person.

5.6.4 Hazards of non-prescribed medications

Child rearing can be a daunting task, particularly in areas with high infant mortality and morbidity. It is important for health professionals to understand why mothers

administer non-prescribed medications, and which medications are commonly used, so that they can ask about their use. Whilst the administration of non-prescribed medications may not cause any clinical problems, they may be dangerous, may interfere with appropriate health-seeking behaviour and preclude compliance with exclusive breast feeding.

Mothers who are concerned about their infant's welfare should be encouraged to seek help from health professionals who empathise with their concerns, do not criticize them, give clear and consistent explanations about their infant's problems, and reassurances about perceived difficulties which do not require medical treatment.

5.7 MATERNAL RECALL OF EXCLUSIVE BREASTFEEDING DURATION

This study compared different recall methods of (duration of) exclusive breastfeeding in the same cohort of women in which the WHO definitions of early infant feeding were consistently applied. If an infant ever received a fluid or feed other than breast milk they were immediately removed from the exclusive breastfeeding category, and I classified them as mixed feeders from that time.

This is crucial when documenting breast feeding patterns in relation to mother-to-child transmission of HIV. If researchers discount small deviations from exclusive breastfeeding (e.g. 10 ml of glucose water after delivery) and use their personal judgement to change definitions of feeding patterns as studies continue, then comparisons between studies become difficult and confused. More specifically, studies may underestimate a benefit of exclusive breastfeeding if small deviations

from exclusive breastfeeding do, indeed, increase the risk of HIV transmission and these have not been documented¹⁸².

5.7.1 'Current exclusive breastfeeding status'

'Current status' dietary assessments, most commonly obtained from a 24 hour recall, but in this study from a 48 hour recall, are not intended to capture lifelong feeding histories. In this study 48 hour recall did not accurately reflect exclusive breastfeeding history since birth. Clearly, the 'current exclusive breastfeeding status' showed 100% sensitivity for those mothers who were exclusively breastfeeding at the given time points. However, mothers who had exclusively breastfed over the previous 48 hours had not necessarily exclusively breastfed consistently since birth as reflected by the lower specificities (65% at 2 weeks, 74% at 4 weeks, and 77% at 6 weeks of infant age).

Studies have reported the phenomenon of infants moving in and out of feeding categories^{172,215} changing from mixed feeding at some time points to exclusive breastfeeding at other times. In this study area salaries are paid monthly and it is not unusual for families to run out of money at the end of the month. A mixed fed baby might, therefore, be exclusively breastfed at the end of the month if there is no commercial formula milk left in the household because of inadequate finances.

In addition, sick infants are often exclusively breastfed, which would be reflected in the 'current EBF status' but does not necessarily reflect the entire breastfeeding history.

Using these methods in studies examining MTCT of HIV may lead to substantial misclassification of lifelong feeding patterns and confuse and obscure relations

between breastfeeding patterns and the risk of postnatal transmission of HIV. I recommend that 'current EBF status' is inadequate when attributing feeding practices to the acquisition of HIV from birth.

5.7.2 Maternal recall 6-9 months post delivery

When mothers were interviewed between six and nine months post-delivery, I found that recall of feeding practices from birth to 16 weeks was inaccurate, as hypothesised. It has previously been documented that mothers overestimate the duration of breast feeding²¹⁶. In this study I show that mothers also overestimate the duration of exclusive breastfeeding and, therefore, recommend that studies intending to correlate postnatal transmission and feeding practices need to collect prospective, longitudinal data rather than rely on cross sectional surveys. Cross sectional surveys may be more appropriate for describing population trends rather than individual practice.

5.7.3 48 hour recall versus seven day recall

When the 48 hour exclusive breastfeeding recall was compared with the seven day exclusive breastfeeding recall obtained at the same visit for each mother, the recall of EBF practices over the previous 48 hours showed high positive and negative predictive values compared to their recall of events over the preceding seven days (positive predictive value of 92% and negative predictive value of 100%). It is concluded that 48 hour recall methods can accurately capture EBF patterns over the preceding week (although some overestimation will still occur) and are suitable for cross sectional surveys of current feeding practices. One of the shortcomings of this study is that I did not look at 24 hour recall to assess

'current status' of breastfeeding, and cannot, therefore, comment whether 24 hour and 48 hour recall are equivalent.

5.7.4 Weekly recall versus thrice weekly interviews

The seven day recall of exclusive breastfeeding practices showed both a high sensitivity and specificity compared to the thrice weekly recordings (sensitivity of 96%; specificity of 94%). The hypothesis that weekly recall reliably reflects the feeding pattern over the preceding seven days and is as reliable as a series of 48-hour recall histories taken over the same time period is supported.

5.7.5 Maternal diaries

Mothers found the simple diaries easy to use. The sensitivity was high when compared with both the weekly and the thrice weekly recall obtained from the structured interviews. However, it was not 100% sensitive – that is, while some diaries reported exclusive breastfeeding, the information from the interviews reported mixed feeding over the same time period. This was most likely a result of diary design. No mark on any day of the diary indicated a week of exclusive breastfeeding. Therefore, if a mother forgot to fill in her diary it was assumed, sometimes falsely, that her infant had received exclusive breastmilk for that week. A better design would be for the mother to make a mark in different columns (with pictures), depending on how she had fed her infant that day. Nevertheless, the results of this study suggest, as hypothesised, that simple diaries, when designed and used appropriately, are a useful adjuvant to data collection exercises in the field and can be used to corroborate data from longitudinal studies based on weekly visits.

5.7.6 Implications for design of data collection tools for the Vertical Transmission Study

In conclusion 'current EBF status' based on 48 hour EBF recall, does not accurately represent the feeding pattern since birth, and long term exclusive breastfeeding recall tends to overestimate the duration of EBF.

I concur with the WHO document^{182,183} that feeding data should, ideally, be collected by prospective longitudinal studies, with frequent contact, in order to assemble a lifetime feeding history. Based on the data from this study I recommend seven day recall methods for prospective studies. However, given the accuracy of the seven day recall period it would be useful, in future studies, to compare this with other methods, for example, two weekly recall.

I recommend that investigators use the standardized WHO definitions of breast feeding (Table 1) and that they adhere strictly to these during the period of research, recording any deviation in terms of frequency and volume of other fluids or feeds given. Studies reporting on MTCT of HIV can then be compared and the crucial issue of whether exclusive breastfeeding is safe for infants of HIV-infected women can be answered consistently and accurately.



(above) Grandmother with child

(below) Breastfeeding mothers at clinic

CHAPTER 6: CONCLUSIONS

6.1 POLICY IMPLICATIONS

6.1.1 Breastfeeding practices

HIV has the highest rates of prevalence in areas of the world where most women practise breastfeeding^{1,3,4}. The *Lancet* series on child survival highlights the crucial role that breastfeeding plays in reducing mortality and stresses the need to consider overall survival and not just avoidance of HIV infection^{102,151}. Even in high HIV prevalence countries breastfeeding could prevent 13% of under-5 deaths; in low HIV prevalence countries 15% of under-5 deaths¹⁰². However, most women, worldwide, do not breastfeed their infants exclusively for the first six months of life.

This study was conducted in an area with one of the highest HIV prevalences in the world, in preparation for a large prospective cohort study to estimate HIV transmission rates associated with infant feeding, particularly exclusive breastfeeding. This study was conducted to inform the design of a breastfeeding intervention to support women to exclusively breastfeed for six months. Despite the presence of a baby-friendly hospital in the district, early mixed feeding with water and commercial formula milk, premature introduction of solids, and long delays in the baby being put to the breast, are common. The early introduction of other fluids and feeds, particularly solids, is worrying given the differential transmission risks recently reported¹²⁵. Whilst many women intended to breastfeed exclusively, they were not able to fulfill this postnatally, and many women complained of insufficient milk, a crying baby or an unsatisfied baby.

The Ten Steps to Successful breastfeeding¹⁰¹ are the foundation of the WHO/UNICEF Baby-friendly Hospital Initiative (see Table 4). They detail the practices necessary in maternity services to support breastfeeding. Step 2 of this policy states that all healthcare staff should be trained in the skills necessary to implement breastfeeding. However, breastfeeding training is often voluntary, poorly structured and inconsistent, leaving large gaps in the knowledge and skills of those caring for mothers and infants. This is something we documented in the local area¹⁹⁷. Studies throughout the world have emphasized that health professionals' knowledge, attitudes and practices are often not supportive of breastfeeding^{217,218}.

Furthermore, training on, and promotion of, breastfeeding has been complicated by the HIV pandemic, and confusion has arisen over the role of breastfeeding in countries with high HIV prevalences²¹⁹. There is concern that support for breastfeeding in sub-Saharan Africa has declined, with a 'spill-over' of replacement feeds to HIV-negative women and those who do not know their HIV status²²⁰.

There is no doubt that the Baby-friendly Hospital Initiative has been instrumental in directing necessary resources to improve the quality of feeding care in maternity services. As a result there is an upward trend in breastfeeding rates in various countries^{194,221}. However, initiating exclusive breastfeeding is not enough. A mother will return to her family environment which must support her to sustain appropriate feeding practices and to access skilled support if required.

Step 10 of the Ten Steps to Successful Breastfeeding¹⁰¹ includes the establishment of breastfeeding support groups connecting mothers to community support after discharge; Step 3 includes antenatal care ('Inform all pregnant women about the benefits and management of breastfeeding') and Step 5 breastfeeding guidance ('Show mothers how to breastfeed, and how to maintain lactation even if they should be separated from their infants'), which both involve maternal access to support and may reach beyond the health facility to the community.

It is clear, however, that women need support postnatally if they are to be successful in exclusively breastfeeding. There is growing evidence that community-based breastfeeding promotion and support can improve breastfeeding practices in developing countries^{69,87,194}. This is even more critical in areas of HIV prevalence where research suggests that increased transmission risks are associated with the early introduction of formula milk or solids^{123,125}. In addition, since in this study so many women dropped from the exclusive breastfeeding category in the first 48 hours of life, additional counselling sessions antenatally to explain to the mother about initiation of breastfeeding, what to expect around delivery, and the advantages of colostrum for the infant may be helpful in this area.

6.1.2 Non-prescribed medications

Non-prescribed medications are much more common than I had anticipated, even in very young infants. Administration of oral medications will interfere with the practice of exclusive breastfeeding. Home-made traditional medications have the potential to cause diarrhoea due to inadequate hygiene and dirty water.

Given that non-prescribed medications are so common in this part of the world, one would expect such frequency to occur elsewhere in both South Africa and southern Africa.

Health workers should at the very least ask about the use of these medications during interviews with mothers; should understand the range of medications administered in their local areas, and the reasons they are given; and try to design health messages that address the causes of concern that lead mothers to give these medications.

In every culture specific beliefs that impede optimal breastfeeding need to be identified through formative research and addressed through effective, well-designed behaviour change communication to promote and support optimal breastfeeding practices.

6.1.3 Methodology of collection of breastfeeding data

Women overestimate the length of time they exclusively breastfeed. For studies looking at HIV transmission a cumulative breastfeeding history is necessary, with careful documentation of all other solids, fluids and possibly medications given. Collecting these data by cross-sectional methods may result in misclassification of feeding type with more mothers being included in an exclusive breastfeeding category.

Daily feeding patterns collected at weekly intervals provide a reliable feeding history, particularly when corroborated with maternal diaries.

Strict definition of feeding categories should be set beforehand, and ideally universal definitions (e.g. those recommended by the WHO) should be used to allow comparisons between studies.

6.2 IMPLICATIONS FOR THE DESIGN OF THE VERTICAL TRANSMISSION STUDY

Formative research is invaluable to guide effective action on breastfeeding and to shape messages and approaches that are likely to result in positive breastfeeding behaviour change.

6.2.1 Breastfeeding practices

Based on this formative research, the design of a breastfeeding intervention in this area, for the purpose of examining postnatal transmission associated with exclusive breastfeeding, involving lay breastfeeding counsellors should include (Appendices 4 and 6):

- Antenatal home visits to: support the woman in her feeding choice, involve other influential family members, listen to any concerns the woman has, explore previous feeding experiences and discuss specific breastfeeding issues including initiating early breastfeeds, the importance of colostrums and the advantages of breastfeeding.
- Early home visits in the first two weeks postnatally, to ensure good positioning and attachment of the baby, to support the mother and to problem-solve around any difficulties the mother has experienced. During these visits feeds should be observed by the counsellor, looking specifically for the four key points of positioning and the four key points of attachment

to the breast^{21,214}. Technical help should be offered where needed. A breastfeeding woman does not typically make decisions alone.

Communication strategies must address not only individual behaviour change of the mother but also the beliefs of those who influence her at all levels.

- Thereafter, regular home visits until six months of age to support exclusive breastfeeding. Specific topics should be included for discussion at different ages. These visits should include talking with other influential family members, where appropriate^{69,87,194}.
- If a woman has a specific difficulty, for example a breast health problem (e.g. cracked nipple) visits should be offered more regularly, and there should be a well organised system of referral for women with problems which need medical assistance, for example, mastitis.
- Lay counsellors should be trained in the theoretical aspects of breastfeeding and milk production, counselling, and be competent at and comfortable with the technical aspects of breastfeeding (helping a mother to position her baby at the breast, cup feeding, milk expression).
- HIV-positive women who choose replacement feeding need special support and assistance in hygienic preparation of milk feeds, measuring amounts of formula powder and water, cleaning of utensils and cup feeding. The local hospital should be aware that replacement feeding is permitted by HIV-infected women even though the hospital is baby-friendly.

- A study form which allows counsellors to record breastfeeding technique and practice, and also document breast health problems.

6.2.2 Non-prescribed medications

The design of a breastfeeding intervention in this area, involving lay breastfeeding counsellors should include:

- Messages about the benefits of breastfeeding which include advantages currently perceived to be associated with non-prescribed medications. For example: non-prescribed medications are considered necessary to 'clean the baby out'. Strong messages about the value of colostrum in 'cleaning out' the meconium from the baby should be given to pregnant women. Non-prescribed medications are considered necessary to 'protect the baby from inyoni' (spiritual forces which harm the baby in the first few weeks of life). Strong messages about the protective value of breastfeeding against common childhood illnesses, and talking about colostrum in terms of the baby's first immunisations should be given to pregnant women.
- Non-prescribed medications are often given as the mother is concerned about her baby crying, her baby being ill, or her baby being constipated. Providing relevant information to mothers during these periods of concern may reduce the frequency and amount of non-prescribed medications administered (Appendix 5).
- Health workers in the study should be aware of the universality of these medications, the types of them and the reasons that they are given, so they can ask about them during consultation.

- Traditional healers are often ignored, or left out of health strategies, yet they are respected members of the community and deal with sick infants and adults on a daily basis. They should be brought on board for any strategy to improve breastfeeding practices.

6.2.3 Methodology of collection of breastfeeding data

The design of the data collection part of the Vertical Transmission Study by field workers should include (Appendix 4):

- A form which allows daily feeding data to be recorded at weekly intervals.
- A form which includes details of different foods and fluids (including water) that infants may be given, including medications used in the area.
- A form which contains all the data needed to assign infants to different feeding categories.
- A diary which is simple enough to be used by women with no education to record feeding and morbidity data.

6.3 AREAS FOR FUTURE RESEARCH

6.3.1 Breastfeeding practices

Current research suggests that exclusive breastfeeding carries a lower risk of HIV transmission compared to mixed feeding^{123,125}. Current feeding guidelines reflect these studies, in that if replacement feeding is not acceptable, feasible, affordable, sustainable and safe, then exclusive breastfeeding is recommended for the first

few months of life^{169,12}. In addition, the considerable mortality associated with not breastfeeding highlights the importance of developing feeding policies appropriate to the background infant mortality rates^{102,151}.

However, is it possible for women to sustain exclusive breastfeeding for six months? There is evidence that individual women can do this and there is certainly evidence that EBF rates can be improved^{69,87}, but these studies did not document cumulative days of EBF. In addition, these studies were not conducted in areas of high HIV prevalence.

The Global Strategy for Infant and Young Child Feeding¹² includes community-based interventions to promote and support infant and young child feeding as a new operational target. It calls on governments to promote development of community-based support networks to help ensure appropriate infant and young child feeding, for example mother-to-mother support groups and peer or lay counsellors, to which hospitals and clinics can refer mothers on discharge; and to ensure that community-based support networks are not only welcome within the health care system but also participate actively in the planning and provision of services.

There is an urgent need to demonstrate whether cumulative exclusive breastfeeding is possible, what are the important aspects of a breastfeeding support strategy to enable women to sustain exclusive breastfeeding, and whether it is possible for lay counsellors to provide this support, given that the health services in developing countries are already overburdened.

Breast health problems are relatively common in reported studies^{131,133,134}. In order to reduce postnatal HIV transmission and enable women to maintain exclusive breastfeeding to six months, research is needed to determine whether it is possible to reduce these problems, in HIV infected women, if they are given sufficient support to position and attach their babies, initiate early good feeding practices, and feed on demand. Furthermore, is it possible for lay counsellors to support women with early feeding problems, such as sore or cracked nipples, before these problems progress and develop into mastitis?

There is conflicting evidence about maternal mortality amongst HIV-infected women who breastfeed^{222,223}. Studies are required to determine whether it is possible or advisable for women with low CD4 counts, low BMI, and who are sick to sustain six months of breastfeeding.

Operational research on the effects of HIV-positive women choosing formula milk in communities and the 'spill-over' that this may have on women who are HIV-negative or of unknown status is needed. Whilst there is evidence that breastfeeding rates are improving globally²²¹, will the introduction of free formula feeds into countries with high HIV prevalences lead to reduced rates of exclusive breastfeeding and increased rates of mix feeding?

The promotion, protection and support of breastfeeding is an exceptionally cost-effective strategy for improving child survival and reducing the burden of childhood disease, particularly in developing countries. What are the key elements of a community-based strategy to improve exclusive breastfeeding rates for six

months, and how much would this cost? This will help policy makers to assess the costs and benefits of such an intervention.

6.3.2 Non-prescribed medications

The effects of non-prescribed medications on HIV transmission are not known, although evidence suggests that mixed feeding carries a higher risk of postnatal HIV transmission than exclusive breastfeeding^{123,125}.

Non-prescribed medications were found to be extremely common in this study area. Is it possible to reduce the use of non-prescribed medications in a community where they are so widely used, and can key messages about these medications be incorporated into a community-based strategy to improve exclusive breastfeeding rates?

6.3.3 Methodology of collection of feeding data

Previous studies examining postnatal HIV transmission have been criticised for their methodology^{116,121,181}. Is it possible to visit large numbers of women frequently to collect feeding data in a sufficiently rigorous manner to enable transmission risks of HIV to be determined?

6.3.4 Vertical Transmission Study

In conclusion, The Vertical Transmission Study (2001-2007), which started enrolment of HIV-infected and uninfected women *after* completion of the pilot work which forms the basis of this thesis, will be in a position to answer many of these questions. The main aim of the VTS is to determine the risks of postnatal HIV transmission associated with different infant feeding patterns, specifically exclusive breastfeeding. In addition, the effectiveness of a home-based feeding

intervention, to support women to exclusively breastfeed to six months postnatally, which was based on the formative research of this thesis, will be assessed. The patterns of feeding, including the use of non-prescribed medications, in both HIV-infected and uninfected women will be documented using data collection forms, based on the findings of this pilot work. Breast health problems in both HIV-infected and uninfected women will be determined. Finally, the morbidity and mortality of mothers and children will be examined.

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APPENDICES

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12. What toilet facilities do you have at home?

Record one answer only

Flush toilet	
Pit latrine	
None	
Other	
Don't know	

13. What is your main water supply?

Record one answer only

Piped water into homestead	
Piped water to a public tap	
Well water into homestead	
Well water to a public tap	
River	
Pond	
Other	
Don't know	

Feeding

14. In the past week has your baby only received breast milk?

Yes	
No	
Don't know	

15. In addition to breast milk what other feeds did the baby receive?

Record Yes, No or Don't know = DKN for each choice

	Y,N	DKN
Glucose/sugar water		
Water		
Cow's milk		
Formula milk		
Porridge		
Maas		
Other		

16. If you answered "other" to the above question please specify

--

17. Who influenced your decision on how to feed your baby?

Record one answer only

Mother	
Mother-in-law	
Other relative	
Nurse	
Decided myself	
Other	
Don't know	

18. If you need advice in the future about feeding your baby, who are you most likely to ask?

Record one answer only

Mother	
Mother-in-law	
Other relative	
Nurse	
No-one	
Don't know	

Candidate	Impression	Exercise 2a	Exercise 2b	Exercise 3
Cynthia Ndlovu	85%	100%	80%	42%
Thandeka Sosibo	70%	95%	80%	75%
Bongekile Mthethwa	85%	74%	100%	58%
Thandazile Sangweni	55%	100%	100%	58%
Cynthia Ngema	80%	89%	80%	67%
Fanele Mbuyazi	55%	74%	70%	50%
Khanyisile Nkwanyona	60%	89%	90%	42%
Thulisile Magwaza	55%	100%	80%	58%
Samukelisiwe Mtshali	90%	100%	100%	83%
Bongi Matavele	80%	100%	80%	58%
Zanele Ntima	85%	100%	100%	75%
Nompumelelo Myeni	50%	95%	90%	58%
Jabu Gumede	60%	97%	70%	58%
Cynthia Sikhakane	95%	100%	100%	67%
Zonke Shandu	70%	95%	60%	67%

Recruitment Mamanengane Sept 1999-09-26

1. Selected candidates from list

Candidate	Register number	School test total
Cynthia Ndlovu	26	61%
Thandeka Sosibo	60	59%
Bongekile Mthethwa	241	56%
Cynthia Ngema	6	56%
Samukelisiwe Mtshali	67	56%
Zanele Ntlma	105	57%
Bongi Matavele	35	57%

2. Not selected candidates from list

Candidate	Register number	School test total
Thandazile Sangweni	243	56%
Fanele Mbuyazi	200	55%
Cynthia Khanyisile Nkwanyoma	4	54%
Nompumelelo Myeni	21	54%
Jabulile Gumede	145	41%

3. Invited but did not come

Candidate	Register number	School test total
Sharon Patty Khuzwayo	211	
Fikile Phumzile Mthembu	53	
Charity Mtshali	41	
Thabi Primrose Zwane	154	

4. Not invited but came

Jabulile Gumede (see above: not selected but took part in the course with equal chance for selection)

Khomzeni Prudence Mkhwamazi: left course at start and evidently went to her work

APPENDIX 2: STUDY DATA COLLECTION FORMS

Cross-sectional survey:

- Feeding survey of infants aged 6, 10, 14 and 36 weeks

Longitudinal study:

- Recruitment form
- Detailed locator form
- Primary information sheet
- Initial feeding history
- Nurses initial feeding questionnaire
- Weekly feeding interview
- Maternal feeding diary
- Intermediate questionnaire
- Six week check
- Six month check
- Maternal details

Feeding survey of infants aged 6,10,14 and 36 weeks

1. Clinic name / Igama le-Clinic

--	--	--	--	--	--

2. Date of interview / Usuku lokuhlolwa

d	d	m	m	y	y
---	---	---	---	---	---

3. DOB of baby/Usuku lomntwana lokuzwala

d	d	m	m	y	y
---	---	---	---	---	---

4. Age of baby / Ubudala bomntwana

amasonto / weeks	
------------------	--

5. Relationship of respondent to infant / Uhlobo lakanjani nomntwana

--	--

6. Reason for coming to clinic?

Immunisation / Umgomo	
-----------------------	--

Isizathu esenza ukuba uze E-clinic?

Other / okunye	
----------------	--

7. If attending for immunisation, which immunisation?

--	--

Uma uzogoma umntwana hlolo luni lomgomo ozomgoma ngalo?

8. What water supply do you have at home?

Piped water into homestead / Umpompi ongena okhaya	
Piped water to a public tap / Umpompi womphakathi	
Well water into the homestead/Amanzi asemadanyini oza ekhaya	
Well water to a public tap/Amanzi asemadanyini awo wonke umphakathi	
River / Umfula	
Stream / umthombo	
Lake / Ichibi	
Pond / Ichibi	
Other / okunye	

Niwathola kuphi amanzi?

9. What fuel do you use for cooking?

Paraffin / uphalafini	
-----------------------	--

Usebenzisani okwenza umlilo wokupheka?

Electricity / ugesi	
---------------------	--

Wood / ukhuni	
---------------	--

Other / nokunye	
-----------------	--

10. What toilet facilities do you have?

Flush toilet / Ithoyilethi elishawayo	
---------------------------------------	--

Hloboluni lwendlu yangasase onayo?

Pit latrine / Ithoyilethi langaphandle	
--	--

Nii / Alikho	
--------------	--

Other / Nokunye	
-----------------	--

11. Is your baby receiving any breast milk?

Yes/Yebo		Go to 12 / Dlulela embuzweni No. 12
----------	--	-------------------------------------

Umntwana wakho uyancela yini lbele?

No / Cha		Go to 15 / Dlulela embuzweni No. 15
----------	--	-------------------------------------

12. Has your baby received any other fluid/food in addition to breast milk in the past 48 hours?

Yes / Yebo	
------------	--

Umntwana wakho uko wathola okuphuzwayo noma ukudfa phezu kwebele kulama hora angu 48 edlule?

No / Cha	
----------	--

13. Has your baby ever received any other fluid/food in addition to breast milk?

Yes / Yebo	
------------	--

Umntwana wakho uke wathola okuphuzwayo noma okudlwayo - phezu kobisi lwebele?

No / Cha	
----------	--

14. If you answered "yes" to questions 12 & 13 above, what has your baby received in addition to breast milk?

Glucose/sugar water / Amanzi anoshukela	
---	--

Water / Amanzi	
----------------	--

Formule milk / Ubisi lwethini	
-------------------------------	--

Cow's milk / Ubisi lwenkomo	
-----------------------------	--

Maas / Amasi	
--------------	--

Porridge / Iphallsht	
----------------------	--

Other / Nokunye	
-----------------	--

Uma impendulo yakho "yebo" embuzweni ongenhla uyacelwa ukuba usho lokho okunika umntwana wakho phezu kwobisi lwebele?

If your baby is not receiving any breast milk: uma umntwana wakho engaluthozi ubisi lwebele

15. Has your baby ever received breast milk?

Yes / Yebo	
------------	--

Ngabo umntwana wakho wake waluncinta ubisi lwebele?

No / Cha	
----------	--

16. When did you first give formula milk?

amasonto/weeks	
----------------	--

Waqala nini ukunikeza ingane yakho ubisi olusemathlinini?

17. When did you stop all breast milk?

amasonto/weeks	
----------------	--

Wamnyokisa nini umntwana wakho ubisi lwebele unomphela?

Recruitment Form

Eligibility Form: to be filled in at recruitment

1. Code of isigodi | | |

2. Isigodi catchment area

Kwamsane	
Mpukunyoni	
Gunjaneni	

3. Main clinic attended for ante-natal care

Kwamsane	
Mpukunyoni	
Gunjaneni	
Other	
Don't know	

4. Clinic to be attended for immunisations

Kwamsane	
Mpukunyoni	
Gunjaneni	
Other	
Don't know	

5. Eligibility for study (2 + 3 or 4)

Yes	
No	

6. Date of recruitment

y	y	y	y		m	m	d	d

7. Place of recruitment

Kwamsane	
Mpukunyoni	
Gunjaneni	

8. Signature of clinic assistant

Detailed locator form: to be filled in at recruitment

1. Area for follow-up

Kwamsano	
Mpukunyoni	
Gunjaneni	

2. Study number

--	--	--	--	--	--	--	--

3. Name of baby's mother

Surname	First names
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4. Maiden surname of baby's mother

Maiden surname

5. Name of baby's father

Surname	First names
---------	-------------

6. Name of head of household

Surname	First name
---------	------------

7. Occupation of head of household

--

8. isigodi (code)

--	--	--	--

9. Africa Centre tag number

--	--	--	--	--	--	--	--

10. If no tag number record the address

--

11. Colour of house

--

12. Nearest store to home

--

13. Nearest bus stop / taxi rank to home

--

14. Nearest school to home (code)

--	--	--	--	--	--	--	--

15. Local area name

--

16. Best way to reach home

--

17. Contact telephone number

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

18. Induna

--

19. Expected date of delivery

y	y	y	y	m	m	d	d				

To be filled in after delivery

20. Name of baby

Surname	First name
---------	------------

21. Date of birth of baby

y	y	y	y	m	m	d	d
---	---	---	---	---	---	---	---

22. Sex of baby

	Female
	Male

23. Time of delivery
24 hour clock

		:		
--	--	---	--	--

Primary information sheet: to be filled in at recruitment

Previous pregnancies

1. How many live children have you had?

Usube nabantwana abangaki?

Record number or Don't know = 99

--	--

2. When was your last child born?

Wazatwa nini umntwana wakho?

y	y	y	y		

m	m

d	d

This pregnancy

3. Which clinic did you mostly attend for ante-natal care?

Iliphi iclinic owawulhamba kakhulu ngenkathi uxukuzi?

Record one answer only

Kwamsane	
Mpukunyoni	
Gunjaneni	
Other	
Don't know	

4. Where do you intend/plan to deliver your baby?

Uzimisela ukubelethela kuphi?

Record one answer only

Kwamsane	
Mpukunyoni	
Gunjaneni	
Hlabisa	
Other	
Don't know	

5. Where will you take your baby for immunisations?

Uzoza komgomela kuphi umntwana wakho?

Record one answer only

Kwamsane	
Mpukunyoni	
Gunjaneni	
Other	
Don't know	

Intentions to feed

6. How do you intend to feed your baby for the first 6 weeks of life?

Uzimisela ukumupha kanjani umntwana wakho ukudla, kulamasonto awu 6 okuqala?

Record one answer only

Breast feed only/ibela kuphela	
Formula feed only/ubisi lwethini kuphela	
Probably give both/mhlawumbe kokubili	
Not decided/awukacabangi	
No response given/akunampendulo	
Other/okunye	

7. How do you intend to feed your baby from 7 to 12 weeks?

Uzimisela ukumupha kanjani umntwana wakho ukudla kusukela emasontweni ayi 7 - 12?

Record one answer only

Breast feed only/ibela kuphela	
Formula feed only/ubisi lwethini kuphela	
Probably give both/mhlawumbe kokubili	
Not decided/awukacabangi	
No response given/akunampendulo	
Other/okunye	

8. When will you mix either phulo or bread with milk/maas?

Uzoxuba nini uphuthu noma isinkwa nobisi/amasil?

Record age in weeks

Don't know = 99, Never = 77

		weeks of age/amasonto obudala
--	--	-------------------------------

9. When will you first give spoon feeds?

Uzoqala nini ukumnika ukudla kwesipunu?

Record age in weeks or Don't Know = 99

		weeks of age/amasonto obudala
--	--	-------------------------------

10. What is the first type of spoon feed you will offer?
 Hlobo luni lokudla kwesipunu ozoqala
 umnike kona?
 Record one answer only

Pap/Iphalishi	>Q12
Nestum/Nestum	>Q12
Purity/IPurity	>Q12
Cerelac/icerelac	>Q12
Other/okunye	>Q11
Don't know/angazi	>Q12

11. If other, what type of spoon feed will you offer?
 Uma okunye, hlobo luni lokudla kwesipunu
 ozonika kona?

12. When do you think you will offer water, juice or
 other liquids in addition to milk?
 Ucabanga ukuthi uzoqala nini ukunika
 amanzi, jusi nokunye kokuphuzwa, ngaphezu
 kobisi?
 Record age in weeks or Don't Know = 99

 weeks of age/amasono obudala

13. What is the main reason you will introduce any
 fluid/feed other than breast milk?
 Yisiphi isizathu esingadala unike umntwana
 okunye kokuphuzwa/ukudla okungesikho
 ubisi lwebele?
 Record one answer only

Baby thirsty/Umntwana womile	>Q15
Baby not satisfied/Umntwana akanelisiwe	>Q15
Insufficient breast milk/Ubisi lwebele alwonele	>Q15
Make baby bigger/Ukwenza umntwana abe mkhulu	>Q15
Mother returning to work/Umama ubuyela emsebenzini	>Q15
Mother returning to school/Umama ubuyela esikoleni	>Q15
Complementary feeds/ukumqalisa ukudla	>Q15
Other/okunye	>Q14
Don't know/angazi	>Q15

14. If other, what is the reason?
 Uma okunye, isiphi isizathu?

15. Do you intend to go back to work?
 Uzimisele ukubuyela emsebenzini?

Yes	<input type="checkbox"/>	>Q16
No	<input type="checkbox"/>	>Q17
Don't know	<input type="checkbox"/>	>Q17

16. How many weeks old will your baby be when you return to work?
 Uzobe esenamasono amangaki umntwana uma usubuyela
 emsebenzi?
 Record age in weeks or Don't Know = 99

 weeks of age/amasono obudala

17. Do you intend to go back to school?
 Uzimisele ngokubuyela esikoleni?

Yes	<input type="checkbox"/>	>Q18
No	<input type="checkbox"/>	>Q19
Don't know	<input type="checkbox"/>	>Q19

18. How many weeks old will your baby be when you return to school?
 Uzobe esenamasono omangaki umntwana uma usubuyela
 esikoleni?
 Record age in weeks or Don't Know = 99

 weeks of age/amasono obudala

Amenities

19. What is your main water supply?

Niwathola kuphi amanzi?

Record one answer only

Piped water into homestead / Umpompi ongena ekhaya	>Q21
Piped water to a public tap / Umpompi womphakathi	>Q21
Well water into homestead / Amanzi asemadanyini cza ekhaya	>Q21
Well water to a public tap / Amanzi asemadanyini awo wonke umphakathi	>Q21
River / Umfula	>Q21
Stream / Umthombo	>Q21
Lake / Ichibi	>Q21
Pond / Ichibi	>Q21
Other / Okunye	>Q20
Don't know/Angazi	>Q21

20. If other, what water supply do you have?
Uma akunye, niwathola kuphi?

--

21. Do you have a fridge?
Ninayo ifriji (isibandisi)?

Yes
No
Don't know

22. What is the main fuel you use for cooking?
Usebenzisanl okwenza umlilo wokupheka?
Record one answer only

Paraffin / uphatafini	>Q24
Electricity / ugesi	>Q24
Wood / Ukhuni	>Q24
Other / okunye	>Q23
Don't know / Angazi	>Q24

23. If other, what is the main fuel you use for cooking?
Uma okunye, usebenzisanl ukuze upheke?

--

24. What toilet facilities do you have at home?
Hlobotuni lwendlu yangasese onayo?
Record one answer only

Flush toilet / Ithoyilethi elshawayo	End
Pit latrine / Ithoyilethi langaphandle	End
None / Alikho	End
Other /okunye	>Q25
Don't know / Angazi	End

25. If other, what toilet facilities do you have?
Uma okunye, usebenzisa luphi uhlobo lwethoyilethi?

--

Initial Feeding History

Feeding history first 48 hours of life: to be completed at first home visit

Signature of field worker _____

Initial information

Sex

Male	
Female	

1. Study number _____

2. Name of baby _____
Surname
First name

3. Date of birth of baby? _____
y y y y
m m
d d

4. Date of interview _____
y y y y
m m
d d

5. Code of interviewer _____

6. Name of informant _____
Surname
First name

7. Relationship of informant to baby
Record one answer only

Mother	
Care-giver living in same homestead	
Care-giver living in different homestead	
Other	
Don't know	

8. Is the informant the main care-giver of the baby?

Yes	
No	
Don't know	

9. Method of delivery
Record one answer only

Spontaneous delivery		>Q11
Forceps delivery		>Q11
Vacuum extraction		>Q11
Caesarian section with local anaesthetic		>Q11
Caesarian section with general anaesthetic		>Q11
Other		>Q10
Don't know		>Q11

10. If other, what was the method of delivery? _____

11. Birth weight of baby _____
Please record in Kg or Don't know = 99.9

12. Was an episiotomy performed at delivery?

Yes	
No	
Don't know	

Feeding history

13. When was the baby first put to the breast?

Waqala nini umntwana ukufunzwa ibele?

Record one answer only

	<1 hour	>Q14
	1-2 hours	>Q14
	2-3 hours	>Q14
	3-4 hours	>Q14
	>4 hours	>Q14
Check!	Never	>Q15
	Don't know	>Q14

14. Did you give the baby colostrum?

Wamnika umntwana ubisi lokuqala lwebele?

	Yes	
	No	
	Don't know	

15. Apart from breast milk, were any other fluids

given orally in the first 48 hours?

Ngaphandle kobisi lwebele, kukhona yini okunyo

okuphuzwayo okunikwe umntwana kumahora angu 48 okuqala?

	Yes	>Q16
	No	>Q24
	Don't know	>Q24

16. When were the additional fluids given?
Okuphuzwayo kokwengezelela kwanikwa nini?
Record one answer only

1 - 6 hours	
6 - 12 hours	
12 - 24 hours	
24 - 48 hours	
Don't know	

17. What additional fluids were given in first 48 hours ?
Okuphuzwayo kokwengezelela kwaba yini?
Record Yes, No or Don't know for each choice and number of feeds given, 0 = none, Don't know =99 Check if "anything else" until respondent says "no"

	Y/N/ DKN	No of Feeds	
Glucose/sugar water/Amanzi anoshukela			>Q19
Water/Amanzi			>Q19
Formula milk/Ubisi lwethini			>Q19
Cow's milk/Ubisi lwenkomo			>Q19
Other/Okunye			>Q18
Unknown feed/ ukudla ongakwazi			>Q19

18. If other, what fluids were given?
Uma okunye, yini okuphuzwayo akunikwayo?

19. Who gave the additional fluids?
Ubani onike ukudla okwengezelayo?
Record Yes, No or Don't know for each choice Check if "anything else" until respondent says "no"

	Y,N DKN	
Nurse/medical staff/umhlengikazi/udokotela		>Q21
Relative/sihlobo		>Q21
Yourself/uwe		>Q21
Other/Okunye		>Q20
Unknown person/ umuntu ongamazi		>Q21

20. If other, who gave the fluids?
Uma okunye, ubani omnikile (owamnika ukudla)

21. Why did the baby receive other fluids?
Kungani umntwana athola nokunye ukudla?
Record Yes, No or Don't know for each choice. Check if "anything else" until respondent says "no"

	Y,N DKN	
Baby thirsty/Umntwana womile		>Q24
Baby unsatisfied/Umntwana akanelisiwe		>Q23
Baby crying/Umntwana uyakhala		>Q24
Insufficient breast milk/Ubisi lwebele olungenele		>Q24
Breast problems/Izinkinga zebele		>Q24
Mother unwell/Umama akaphilile		>Q24
Other/Okunye		>Q22
Unknown reason/sizathu ongasazi		>Q24

22. If other, what was the reason?
Uma okunye, kwakuyini isizathu?

23. If you answered "baby unsatisfied" please describe what you mean.
Ucelwa uchaze usho ukuthini uma uhl umntwana akenele?

24. How often was your baby given milk (breast or formula) in the first 24 hours?

Kukangaki umntwana enikwa ubisi lwebele noma lwethini ema horeni angu 24 okuqala?

Record one answer only

24 hours = 24 hours since delivery

Whenever baby wanted		>Q26
1 hourly		>Q26
2 hourly		>Q26
3 hourly		>Q26
4 hourly		>Q26
Other		>Q25
Don't know		>Q26

25. If other, how often?

Uma okunye kangaki?

--

26. Does your baby ever suckle at nights?

Umntwana wakho uyadonsa ubisi ebeleni ebusuku?

Check	Yes	
	No	
	Don't know	

27. Where does your baby usually sleep at night?

Ulalaphi umntwana wakho ebusuku?

Record one answer only

In bed with mother/embhedeni nomama		>Q29
In own cot/embhedeni wayo		>Q29
Other/okunye		>Q28
Don't know/angazi		>Q29

28. If other, describe where?

Uma kwenye indawo ujoye ukulalaphi?

--

29. Were any fluids apart from breast milk given at night?

Ngaphandle kobisi lwebele ngabe okunye okuphuzwayo ukunikiwe ebusuku?

	Yes		>Q30
	No		>Q32
	Don't know		>Q32

30. What additional fluids were given at night?

Kwabayini enye ayiphuza ebusuku?

Record Yes, No or Don't know for each choice

and number of feeds per night 0 = none, Don't know =99

Check if "anything else" until respondent says "no"

	Y,N DKN	No Feed	
Glucose/sugarwater/amanzi anoshukela			>Q32
Water/Amanzi			>Q32
Formula milk/ubisi lwethini			>Q32
Cow's milk/ubisi lwenkomo			>Q32
Other/okunye			>Q31
Unknown feed/ukudla ongakwazi			>Q32

31. If other, what additional fluids were given at night?

Uma okunye kwaba yini ayiphuza ebusuku

--

32. Have you had any problems with breast feeding?

Wake waba nezinkinga ngokuncelisa lbele?

	Yes		>Q33
	No		>Q34
	Don't know		>Q34

33. What problems have you had?

Zinkingazini owake waba nazo?

Record Yes, No or Don't know for each choice

Check if "anything else" until respondent says "no"

	Y,N DKN	
Sore nipples/Izingono ezibufungu		>Q35
Inverted nipples/Izingono ezishonile		>Q35
Cracked nipples/Izingono ozichachambilo		>Q35
Milk let-down problems/Izinkinga zokungabi nalubisi		>Q35
Problems with positioning/Ukungahlangi kahle		>Q35
Mastitis/Ukuvuvuka kwebele		>Q35
Breast abscess/Amathumba emabeleni		>Q35
Other/Okunye		>Q34

34. If other, please describe

35. Had you decided how to feed your baby prior to delivery?

Wabe usucabangile ngokupha umntwana wakho ukudla ungakabelethi?

	Yes	
	No	
	Don't know	

36. Who mainly influenced your decision on how to breast feed?

Isikakhulu/isakhulukazi ubani noma yini eyakwenza ukabange ukumncelisa lbele?

Record one person only

Mother/Umama	>Q38
Mother-in-law/Umamezala	>Q38
Husband/partner/Umkhwenyana	>Q38
Other relative/Esinye isihlobo	>Q38
Medical/nursing staff/Abahlengi	>Q38
Community health worker/Unompilo	>Q38
Local birth attendant/Umbelethisi wendawo	>Q38
Decided myself/Ngizicabangole	>Q38
Other/omunye	>Q37
Don't know/Angazi	>Q38

37. If other, who influenced you?

Uma omunye ubani owakwcutuleka?

38. If anyone helped you to breast feed who was the main person?

Uma bekhona abakusiza, ubani ikakhulukazi/Isikakhulu ubani?

Record one person only

Mother/umama	>Q40
Mother-in-law/Umamezala	>Q40
Other relative/Esinye isihlobo	>Q40
Medical/nursing staff/Abahlengi/dokotola	>Q40
Community health worker/Unompilo	>Q40
Local birth attendant/Umbelethisi wendawo	>Q40
No-one/akekho	>Q40
Other/omunye	>Q39
Don't know/Angazi	>Q40

39. If other, who helped you?

Uma omunye, ubani?

40. If you need advice in the future about feeding your baby, who are you most likely to ask?

Uma udinga iseluleko ngokulandelayo ngokondla ingane yakho, ubani ongamlalela kakhulu?

Record one person only

Mother/Umama	>Q42
Mother-in-law/Umamezala	>Q42
Other relative/Esinye isihlobo	>Q42
Medical/nursing staff/Abahlengi/dokotola	>Q42
Community health worker/Unompilo	>Q42
Local birth attendant/Umbelethisi wendawo	>Q42
No-one/akekho	>Q42
Other/Omunye	>Q41
Don't know/Angazi	>Q42

41. If other, who will you ask?

Uma omunye, ngubani oyomlalela?

42. How do you know when your baby wants to feed?

Wazi kanjani uma umntwana esefuna ukudla?

Record one answer only

When baby cries/Uma umntwana ekhala	End
At a certain time interval/Ngezikhathi ezechukene	End
Rooting for breast/Umntwana ufuna lbele	End
Looks in pain/Umntwana ubukeka esaziblungwini	End
Other/okunye	>Q43
Don't know/Angazi	End

43. If other, please explain

Uma okunye uyacelwa uchaze

Initial Feeding History from nursing staff

To be taken from nursing staff if mother still in hospital after delivery
(Questions relate to first 48 hours of life)

Signature of field worker

1. Study number

2. Name of baby

Surname

First name

4. Date of interview

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
y	y	y	y	m	ni	d	d

5. Code of Interviewer

6. Name of nurse

Surname

First name

7. Apart from breast milk, were any other fluids given orally in the first 48 hours?

Yes	>Q8
No	End
Don't know	End

Ngaphandle kobisi lwebefe, kukhona yini okunye okuphuzwayo okunikwe umntwana kumahora angu 48 okuqala?

8. What additional fluids were given in first 48 hours?

Okuphuzwayo kokwengezela kwaba yini?

Record Yes, No or Don't know for each choice

and number of feeds given, 0 = none, Don't know =99

Check if "anything else" until respondent says "no"

	Y/N DKN	No of Feeds	
Glucose/sugar water/Amanzi anoshukela			>Q10
Water/Amanzi			>Q10
Formula milk/Ubisi lwethini			>Q10
Cow's milk/Ubisi lwenkomo			>Q10
Other/okunye			>Q9
Unknown feed/ ukudla ongakwazi			>Q10

9. If other, what fluids were given?

Uma okunye, yini okuphuzwayo akunikwayo?

10. Who gave the additional fluids?

Ubani onike ukudla okwengezelayo?

Record Yes, No or Don't know for each choice

Check if "anything else" until respondent says "no"

	Y,N DKN	
Nurse/medical staff/umhlangikazi/udokotela		>Q12
Relative/Isihlobo		>Q12
Other/Okunye		>Q11
Unknown person/ umuntu ongamazl		>Q12

11. If other, who gave the fluids?

Uma omunye, ubani omnikile (owamnika ukudla)

12. Why did the baby receive other fluids?

Kungani umntwana athola nokunye

ukudla?

Record Yes, No or Don't know for each

choice. Check if "anything else" until

respondent says "no"

	Y,N DKN	
Baby thirsty/Umntwana womile		End
Baby unsatisfied/Umntwana akanolisiwo		End
Baby crying/Umntwana uyakhala		End
Insufficient breast milk/Ubisi lwebefe olungenele		End
Breast problems/izinkinga zebele		End
Mother unwell/Umama akaphilile		End
Other/Okunye		>Q13
Unknown reason/Isizathu ongasazi		End

13. If other, what was the reason?

Uma okunye, kwakuyini Isizathu?

End

Weekly feeding interview

Questions refer to the 7 days since the last weekly visit / Initial feeding visit if this is 1st weekly visit

Signature of field worker

--

Initial information

1. Study number

--	--	--	--	--	--	--	--

2. Name of baby

Surname	First name
---------	------------

3. Date of interview

y	y	y	y	m	m	d	d
---	---	---	---	---	---	---	---

4. Code of Interviewer

--	--	--	--

5. Name of Informant

Surname	First name
---------	------------

6. Relationship of informant to baby
Record one answer only

Mother	
Care-giver living in same homestead	
Care-giver living in different homestead	
Other	
Don't know	

7. Is the informant the main
care-giver of the baby?

Yes	
No	
Don't know	

Feeding history

8. Is the baby receiving any breast milk?
Umntwana wakho uyaluthola yini ubisi lwebele?

	Yes	
Check!	No	>Q9
	Don't know	>Q23 End

For a baby receiving breast milk

9. How many breast feeds does the baby receive in 24 hours?

Ulincela kangaki ibele emahoreni angu 24?

Please record approx no. or Don't Know = 99; continuous = 88

--	--

10. Approximately how many minutes is the baby at the breast (both breasts) per feed?

Ngabe imizuzu emingaki umntwana encele ibele?

Record approx time in minutes or Don't Know = 99

--	--

11. Have there been any problems with breast feeding?
Zike zaba khona yini izinkinga ngokuncellsa ibele?

Yes		>Q12
No		>Q14
Don't know		>Q14

12. What problems have there been?
Zinkingazini ezabakhona?

Record Yes, No or Don't know

for each choice

Check if "anything else" until respondent says "no"

	Y,N	
	DKN	
Sore nipples/izingono ezibuhlungu		>Q14
Inverted nipples/izingono ezishonile		>Q14
Cracked nipples/izingono ezichachamble		>Q14
Problems with milk supply/izinkinga zokungabi naiubisi		>Q14
Problems with positioning/Ukungahlangi kahle		>Q14
Mastitis/Ukuvuvuka kwebele okubuhlungu nokushisayo		>Q14
Breast abscess/Amathumba emabeleni		>Q14
Other/Okunye		>Q13

13. If other, what has the problem been?
Uma okunye, kubekingazi yini?

--

14. In the past 48 hours has the baby ONLY received breast milk?

Emahoreni angu 48 adlule-umntwana uke wathola ubisi lwebele lodwa?

Check!	Yes		>Q15
	No		>Q16
	Don't know		>Q15

15. In the past week has the baby ONLY received breast milk? (No other fluids /food at all)

Esontweni eledule umntwana uke wathola ubisi lwebele lodwa?

(Akukho okunye akudlile nakuphuzile)

Check!	Yes		End
	No		>Q16
	Don't know		End

For a baby receiving breast milk and other fluid/food

	Y,N DKN
16. Why has the baby received other fluids/feeds? Yini okwenze umntwana anikwe okunye okuphuzwayo/ nokudlwayo? Record Yes, No, DKN for each choice Check if "anything else" until respondent says "no"	
Baby thirsty/Umntwana womile	>Q18
Baby unsatisfied/Umntwana akanelisiwe	>Q18
Insufficient breast milk/Ubisi lwebele alwenale	>Q18
Make baby bigger/ Ukwenza umntwana abe mkhulu	>Q18
Breast problems/Izinkinga zebele	>Q18
Mother unwell/Umama akaphilile	>Q18
Mother at school/umama uye esikoleni	>Q18
Mother working/umama uyasebenza	>Q18
Complementary feeds/ukumqalisa ukudla	>Q18
Other/Okunye	>Q17

17. If other, please give the reason.
Uma okunye nika isizathu

	Y,N DKN
18. In addition to breast milk what other fluids/ feeds did the baby receive? Phezu kwebele yini okunye akudlile/nakuphuzile? Record Yes, No, Don't know for each choice Check if "anything else" until respondent says "no"	
Glucose/sugar water/Amanzi anoshukela	>Q20
Water/Amanzi	>Q20
Formula milk/Ubisi lwethini	>Q20
Cow's milk/Ubisi lwenkomo	>Q20
Porridge/phalishi	>Q20
Maas/amasi	>Q20
Other/okunye	>Q19

19. What other fluids/feeds were given?
Yini okunye akuphuzile/nakudlile?

20. In addition to breast milk did the baby receive any other fluids/feeds at night? Phezu kobisi lwebele, ngabe umntwana uyakithola okunye ukudla/okuphuzwayo ebusuku? Remember questions refer to past 7 days	Yes	>Q21
	No	End
	Don't know	End

	Y,N DKN
21. In addition to breast milk, what other fluids/ feeds did the baby receive at nights? Phezu kobisi lwebele,ziphuzozini/kudlakoni okunye akutholile ebusuku? Record Yes, No or Don't know for each choice Check if "anything else" until respondent says "no"	
Glucose/sugar water/Amanzi anoshukela	End
Water/Amanzi	End
Formula milk/Ubisi lwethini	End
Cow's milk/Ubisi lwenkomo	End
Porridge/phalishi	End
Maas/amasi	End
Other/okunye	>Q22

22. What other fluids/feeds were given?
Yini okunye akuphuzile/akudlile?

For a baby receiving no breast milk

23. How many formula feeds has the baby received in 24 hours?

Kungaki okobisi lwethini umntwana akuphuzile ku 24 hrs?

Please record approximate number or Don't Know= 99

--	--

24. Is the baby only receiving formula milk?

Umntwana uthola ubisi lwethini lodwa yini?

Check!	Yes	End
	No	>Q25
	Don't know	End

For a baby receiving formula feeds and other fluid/food

25. In addition to formula feeds what other feeds did the baby receive?

Phezu kobisi lwethini yini okunye akudlile/akuphuzile?

Record Yes, No or Don't know

for each choice

Check if "anything else" until respondent says "no"

	Y,N DKN	
Glucose/sugar water/Amanzi anoshukela		>Q27
Water/Amanzi		>Q27
Cow's milk/Ubisi lwenkomo		>Q27
Porridge/Phallshl		>Q27
Maas/amasi		>Q27
Other/Okunye		>Q26

26. What other fluids/feeds were given?

Ziphuzozini/kudla kuni okunye akunikiwe?

--

27. Why did the baby receive other fluids/feeds?

Yini eyenze umntwana anikwe

ezinye iziphuzo/okunye ukudla?

Record Yes, No or Don't know

for each choice

Check if "anything else" until respondent says "no"

	Y,N DKN	
Baby thirsty/Umntwana womile		End
Baby unsatisfied/umntwana akanelelwiwe		End
Make baby bigger/Ukwenza umntwana abe mkhulu		End
Complementary feeds/ukumqalisa ukudla		End
Other/Okunye		>Q28

28. If other, please explain the reason

Uyacelwa uchaze isizathu

--

Baby's name:

Study number: _ _ _ _ _

Date of weekly visit: / / **20 00**
 d d m m y y y y

Uyacelwa ukuba ubhale njalo uma ngabe umntwana wakho ethole okunye ngaphandle Kwebele.

Msombuluko	Lwesibili	Lwesithathu	Lwesine	Lwesihlanu	Mgqibelo	Sonto

Baby's name:

Study number: _ _ _ _ _

Date of weekly visit : / / **1 9**
 d d m m y y y y

Uyacelwa ukuba ubhale njalo uma ngabe umntwana wakho ethole okunye ngaphandle Kwebele.

Msombuluko	Lwesibili	Lwesithathu	Lwesine	Lwesihlanu	Mgqibelo	Sonto

Intermediate Questionnaire: Questions refer to previous 48 hours

Signature of field worker _____

1. Study number _____

2. Name of baby

 Surname First name

3. Date of birth of baby

 y y y y m m d d

4. Date of interview

 y y y y m m d d

5. Code of interviewer _____

6. Name of informant

 Surname First name

7. Relationship of informant to baby
Record one answer only

Mother	
Care-giver living in same homestead	
Care-giver living in different homestead	
Other	
Don't know	

8. Is the informant the main care-giver of the child?

Yes	
No	
Don't know	

9. Has the baby received any breast milk over the past 48 hours?
Umntwana uke wathola ubisi lwebele kulama hora angu-48?
 Check!

Yes		>Q10
No		>Q12
Don't know		End

10. Has the baby **ONLY** received breast milk over the past 48 hours?
Emahoreni angu 48 adlule-umntwana uke wathola ubisi lwobelo LODWA yini?
 Check!

Yes		End
No		>Q11
Don't know		End

11. In addition to breast milk what has the baby received?
Phezu kwebele yini okunye akudlile?
Record Yes, No or Don't know for each choice
Check if "anything else" until respondent says "no"

	Y,N	DKN
Glucose/sugar water/Amanzi anoshukela		End
Water/Amanzi		End
Formula milk/Ubisi lwethini		End
Cow's milk/Ubisi lwenkomo		End
Porridge/lphalishi		End
Maas/Amasi		End
Other/okunye		End

12. If the baby has not received breast milk, what has the baby received over the past 48 hours?
Uma umntwana engathofanga ubisi lwebele yini umntwana ayitholile kulama - hora angu-48?
Record Yes, No or Don't know for each choice
Check if "anything else" until respondent says "no"

	Y,N	DKN
Glucose/sugar water/Amanzi anoshukela		End
Water/Amanzi		End
Formula milk/Ubisi lwethini		End
Cow's milk/Ubisi lwenkomo		End
Porridge/lphalishi		End
Maas/Amasi		End
Other/okunye		End

6 Week Check

Baby's name

Study number

Date of examination
y y y y m m d d

Name of examiner

History:

Visits to clinic/doctor/hospital since birth (maternal recall)

Visits to traditional healer since birth (maternal recall)

History of medicines given since birth (maternal recall)

oral

rectal

Immunisations since birth, with dates if possible (maternal recall)

Systematic enquiry:

	Current (past 7 days)	From birth
General		
Oral thrush		
Fever		
Other		
Feeding		
Good/poor		
Respiratory		
Cough		
Fast breathing		
Indrawing		
CVS		
Cyanosis		
GI		
Diarrhoea*		
Diarrhoea* + blood		
Constipation*		
CNS		
Seizures		
Development		
Smiling		
Fixing/following		
Hearing		

*Diarrhoea = 3 or more stools, which are looser than normal, on 2 or more days

*Constipation = mother's perception of constipation

Examination

General:

Weight =

Length=

OFC=

Adenopathy:

Cervical R =

Axillary R =

Cervical L =

Axillary L =

Inguinal R =

Epitrochlear R =

Inguinal L =

Epitrochlear L =

Clinical anaemia:

BCG scar:

Rash:

Napkin:

Eczema:

Other:

Oral candidiasis:

Conjunctivitis:

Other:

CVS:

HS:

Additional sounds:

Resp:

RR:

Recession:

Breath sounds:

Added sounds:

GI:

Hepatomegaly* :

Splenomegaly* :

Masses:

CNS:

Tone/power:

Ventral suspension:

Position prone:

Head lag:

Fixing & following:

Reflexes:

* Hepatomegaly and splenomegaly defined as >2cm below R and L costal margin respectively

6 Month Check

Baby's name

Study number

Date of examination
y y y y m m d d

Name of examiner

History:

Visits to clinic/doctor/hospital since birth (maternal recall)

Visits to traditional healer since birth (maternal recall)

Current medicines

oral

rectal

What age did you first give spoon feeds?

What age did you first give formula milk?

What age did you first give glucose water?

What did your baby weigh at birth?

Systematic enquiry:

	Current (past 7 days)	From birth
General		
Oral thrush		
Fever		
Other		
Feeding		
Good/poor		
Respiratory		
Cough		
Fast breathing		
Indrawing		
CVS		
Cyanosis		
GI		
Diarrhoea*		
Diarrhoea* + blood		
Constipation*		
CNS		
Seizures		
Development		
Gross motor		
Speech		
Fine motor		
Social		

*Diarrhoea = 3 or more stools, which are looser than normal, on 2 or more days

*Constipation = mother's perception of constipation

Examination

General:

Weight =

Length=

OFC=

Skin fold thickness=

Adenopathy:

Cervical R =

Axillary R =

Cervical L =

Axillary L =

Inguinal R =

Epitrochlear R =

Inguinal L =

Epitrochlear L =

Clinical anaemia:

BCG scar:

Rash:

Napkin:

Eczema:

Other:

Oral candidiasis:

Conjunctivitis:

Other:

CVS:

HS:

Additional sounds:

Resp:

RR:

Recession:

Breath sounds:

Added sounds:

GI:

Hepatomegaly* :

Splenomegaly* :

Masses:

CNS:

* Hepatomegaly and splenomegaly defined as >2cm below R and L. costal margin respectively

Maternal details

Study number

1. Parity and

2. Gravidity

3. Married Yes
No

4. Highest standard passed at school

5. Date of birth of mother
y y y y m m d d

6. Place of delivery

Gov clinic	<input type="text"/>
Hlabisa	<input type="text"/>
NPA	<input type="text"/>
Private hospital	<input type="text"/>
Home	<input type="text"/>
GP	<input type="text"/>
Other	<input type="text"/>

APPENDIX 3: CONSENT FORM LONGITUDINAL STUDY

Information sheet for infant feeding study

Sifisa ukwenza ucwaningo lokuthola ulwazi ngendlela okondliwa ngayo abantwana, nokukhula kwabo kulendawo. Silangazelela ukwazi izinhlobo zeziphuzo nokudla omama abakunika abantwana phezu kokuncelisa ibele. Kuvamlise ukubanzima ukukhumbula ukuthi umntwana udleni waphuzani ezinsukwaneni ezedlule.

Sithanda ukubuka izindlela ezahlukene okungaqoshwa ngazo lolulwazi. Uma ungathanda ukungena kulolucwaningo sothanda ukuba kesibuze imibuzwana elula yokuthi ngabe uzilungiselele ukumondla kanjani umntwana wakho.

Uma umntwana wakho usumbelethile, siyokuvakashela ekhaya kanye ngesonto. Siyobuza ukuthi umntwana wakho ufunzweni kulezizinsuku ezimbalwa ezedlule. Sophinde sicele ukuba ugcwalise encwajananeni lokhokudla okungesilo ubisilwebele, umntwana akuthole usuku ngosuku. Siyolanda lencwajana enalemibhalo kanye ngesonto uma sivakashele lapho kwakho.

Uyophinde uvakashelwe ekhaya ngomunye wawodokotela njalo emva kwamasono ayisithupha, ubuzwe ukuthi umntwana ubefunzwa kanjani. Umntwana uyokalwa ahlolwe akuyuthathwagazi nanani engalimaza umntwana wakho.

Ulwazi ngomntwana wakho logcinwa luyimfihlo. Kuphela imiphumela eyokhishwa isihlanganiswe yonke engatholakala. Uma ungathandi ukubambisana kuilucwaningo, awuyukube - kwa cala ngalokho - ukhululekile ukusebenzisa umtholampilo wakho njengakuqala - ungesabi lutho.

We wish to conduct a research project to learn about infant feeding and growth in this area. We are interested to know what fluids and food mothers give to their infants in addition to breast milk.

It is often difficult to remember what infants had to eat or drink several days ago. We want to look at different ways of recording this information.

If you agree to take part in this study we would like to ask you some simple questions about how you intend to feed your baby. After your baby is born, we will visit you at home, at least once a week. We will ask you questions on how your baby has been fed over the previous few days.

We will also ask you to fill in a diary recording what feeds, other than breast milk, your baby has each day. We will collect these from you once a week when we come to visit you.

You will also be visited at home by one of the medical team every 6 weeks. You will be asked questions on how your baby has been fed, your baby will be weighed and examined. No blood tests will be taken, and nothing will be done to hurt your baby.

Your child's information will be kept entirely confidential and only the results of everybody together will be made available to others. If you chose not to participate it will not be held against you and you can still continue to come to clinics for regular care as before.

Imvume Yocwaningo Lokondliwa Kwengane
Consent Form for Feeding Project

Mina, _____ **(Igama)**
I, _____ **(Name)**

Nginikeza imvume ukungena kucwaningo lokondliwa kwengane
Hereby consent to take part in the feeding project

Ngitsheliwe ngalolucwaningo ngu i
I have been informed about this research project by

_____ **(Igama lika msizi wasemthola mpilo)**
(Name of clinic assistant)

Ngifundile ngaqondisisa ngolwazi olungemuva
I have read, and understand, the information overleaf

Ngiyazi ukuthi ngingayeka nomanini uma ngingasathandi ukuqhubeka kulolucwaningo. Ngaphandle kokubandlululeka ekunakekelekeni kwami nengame yami emtholampilo.

I understand that I may withdraw my consent at any time, and without prejudice to further care for myself or my baby.

Signed _____
Umama/Ubaba
Mother/father

Signed _____
Umsizi wasemtholampilo
Clinic assistant

Date ___/___/___
 Year Month Day

APPENDIX 4: VERTICAL TRANSMISSION STUDY FORMS BASED ON THIS FORMATIVE WORK

Breastfeeding antenatal visits – topics to cover

Field monitoring form – first week

Field monitoring form – after first visit

Breastfeeding form – first week

Breastfeeding form – after first week



BAF - BCSS Antenatal Form

Form Completion Details - FIRST VISIT

Field worker Place

Site: Hlabisa Cato Manor

Form completion date / /

Y Y Y Y M M D D

1. Woman's Details (Check preprinted details)

1a. Surname 1b. Maiden name 1c. Date of birth

1c. First name 1d. Second name 1f. Estimated age years

If new residence complete Africa Centre TAG

Study number

2. Past experience and intention

2a. Have you ever had any children? Yes No **If yes, go to 2d.** **If yes, 2b. Did you breastfeed any of your children?** Yes No

2c. Until what age did you breastfeed? months
(record longest duration for any child)

2d. What milk do you intend to give your new baby during the first 4 weeks?
 Breastfeed only (BFO) Breastfeed and other milks/fluids (BAF) Commercial formula feeds only (FFO) Undecided (DKN)
 Other replacement milk only (ORM) specify,

2e. Have you discussed this with anyone? Yes No **If yes, who** 2f. Mother/Mother-in-law Other family member Clinic/hospital staff Community health worker BF support group
 Other specify,

2g. Is there anyone at home who will be able to support you with feeding the baby? Yes No **If no, go to 2k**

2h. Home support - Surname

2i. Home support - First name

2j. Relationship of home supporter Mother/Mother-in-law Family/Household member Friend Other

2k. Where do you plan to stay immediately after your baby is born? This residence Other residence

2l. **If other, specify name and directions**

3. Study introduction checklist - Must cover all points

3a. Introduce study	<input type="radio"/> Yes <input type="radio"/> No	3c. What to expect around delivery	<input type="radio"/> Yes <input type="radio"/> No	3e. Practical ways for the family to support	<input type="radio"/> Yes <input type="radio"/> No
3b. Routines and schedules	<input type="radio"/> Yes <input type="radio"/> No	3d. What to do if home delivery or OOD	<input type="radio"/> Yes <input type="radio"/> No	3f. Identify woman's and family's concerns	<input type="radio"/> Yes <input type="radio"/> No
3g. Other	<input type="radio"/> Yes <input type="radio"/> No	Other, specify <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			

4. Date of next BCSS HOME visit (approx. 36 weeks gestation) / /

5. Infant feeding counselling

5a. Infant feeding counselling visit (Clinic) Yes No **If Yes, date** / /

5b. Feeding intention (1st 4wks) (See codes above - #2d.)

6. BCSS antenatal visit #2

6a. Date - -

6b. Field worker 6c. Site Home Clinic

6d. Colostrum/First feed Attach/Position Replacement feeds Milk production Express BM Experience/Concerns

6e. Feeding intention (1st 4wks) (See codes above - #2d.)

6f. Planned residence after delivery This home Other, specify

7. BCSS antenatal visit #3

7a. Date - -

7b. Field worker 7c. Site Home Clinic

7d. Colostrum/First feed Attach/Position Replacement feeds Milk production Express BM Experience/Concerns

7e. Feeding intention (1st 4wks) (See codes above - #2d.)

7f. Planned residence after delivery This home Other, specify

8. BCSS antenatal visit #4

8a. Date - -

8b. Field worker 8c. Site Home Clinic

8d. Colostrum/First feed Attach/Position Replacement feeds Milk production Express BM Experience/Concerns

8e. Feeding intention (1st 4wks) (See codes above - #2d.)

8f. Planned residence after delivery This home Other, specify

Form Check

Supervisor code

Signature / /

FMF - Field Monitoring Form

Form Completion Details

Field worker Place

Form completion date / /

Y Y Y Y M M D D

Informant

Mother

Main care-giver (other than mother)

Household head

Household member

Other **Do not continue**

New BSID (if new homestead)

AC TAG not visible

Child's study number

FMF number page 1



Complete 'Date details' on next form

Name of informant (if not mother)

Date of last visit / / Week day

Date of intended visit / / Week day

Y Y Y Y M M D D

1. Missed visit (absent after 2 repeat visits)

1a. Missed visit Yes

If yes,

1b. Reason for missed visit

Moved away temporarily In hospital

Moved away permanently Poor weather

No informant at home Other

1c. Diary used for missed visit data?

Yes No

2. What food and drink has your baby received since the day of the last visit?

Date											Today	
	Week day										Do not complete if 'Missed visit'	
(Mark if respondent gives information or diary used) Reported	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Number of breastfeeds yesterday	
Breastmilk (day + evening)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Breastmilk (after going to bed)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Expressed breastmilk	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Average no. units per day	Average times per day
Unsure if other food/fluid given	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Water / Glucose water	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Tea / Juice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Formula	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Powdered milk (not commercial formula)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Cow's milk (incl maas, yoghurt)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Cereals or Porridge (home prepared or commercial)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Mashed vegetables or fruit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Other family foods (Other foods prepared for all of family)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Other food - unspecified	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Other food - specified	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Other specified 1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	1 Code	<input type="text"/>
Other specified 2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	2 Code	<input type="text"/>
Other specified 3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	3 Code	<input type="text"/>

2b. What container was most frequently used for giving the milk / fluids? Cup Bottle Other Don't know N/A

3. Water Usage (if EBF, go to question 4)

3a. If water was used to prepare feeds or fluids for the baby, what was the water source most frequently used?

Piped - internal (PIN) Borehole/Well with handpump (BWP) Water carrier/tanker (CAR) Don't know (DKN)

Piped - yard tap (PYA) Flowing river/stream (FLR) Rainwater tank (RWT)

Piped - public tap/kiosk (PPK) Dam/Pond (STG) Other (OTH)

3b. Was the water sterilised (boiled/bleach) before preparing the milk/fluids? Yes No Don't know N/A

3c. Was the container sterilised (boiled/bleach) before preparing the milk/fluids? Yes No Don't know N/A

BFF - BCSS Checklist Form - First Week

Form Completion Details

Field worker Place

Form completion date / /

Y Y Y Y / M M / D D

Informant

Mother
 Main care-giver
 Household head
 Household member
 Other **Do not continue**



BCF number page 1

Mother's Details - self adhesive label

Complete 'Date details' on next form

Name of informant (if not mother)

3. Check maternal and breast health

	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	
Date									
Week day									
Reported	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Action
Blocked duct L	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
R	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Engorgement L	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
R	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Painful nipple L	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
R	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Cracked nipple L	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
R	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Bleeding nipple L	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
R	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Nipple oozing pus L	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
R	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Mastitis/Abscess L	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
R	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Breast oozing pus L	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
R	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Breast thrush L	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
R	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
NOT Feeding from L breast	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
R	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Unsure of difficulty	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

1. Missed visit (absent after 2 repeat visits)

1a. Missed visit Yes
 If yes, 1b. Reason for missed visit
 Moved away temporarily In hospital
 Moved away permanently Poor weather
 No informant at home Other
 If yes, 1c. Diary used? Yes No

2. General

	Yes	No	
Baby well?	<input type="checkbox"/>	<input type="checkbox"/>	If any 'No' then go direct to area of concern and then complete others.
Mother well?	<input type="checkbox"/>	<input type="checkbox"/>	
Baby EBF?	<input type="checkbox"/>	<input type="checkbox"/>	

Action:

S=Support and encourage;
 T=Counsel and treat;
 R=Refer to supervisor;
 C=Refer to clinic;
 U=Urgent referral to clinic

3b. DRF Completed

Yes No

3c. Other comments related to mother's health

BCF - BCSS Checklist Form

BCF number page 2

4. School and work

4a. Do you intend to return to school or work within the next 4 weeks?
 Yes No Don't know

*If yes, check if intends to change/stop breastfeeding practice
 If yes, refer to clinic team*

5. Document Feeding Practices

5a. Baby's study number

Baby 1

					1
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5b. Is the mother feeding the baby on demand?

Yes No Don't know

Day Night

5c. How many feeds did the baby have yesterday?
If unsure, or too many to count, record as 'DK'

6am-6pm		6pm-6am	

Observe the positioning of the baby

5d. Does the mother appear relaxed and comfortable? Yes No Not observed

5e. Are baby's head and body aligned/straight? Yes No Not observed

5f. Is the baby facing the breast and nose opposite nipple? Yes No Not observed

5g. Is baby's body close to mother's body? Yes No Not observed

5h. Is baby's bottom/body supported? Yes No Not observed

Observe the baby's attachment

5i. Is more of the areola above than below the baby's mouth? Yes No Not observed

5j. Is baby's mouth wide open? Yes No Not observed

5k. Is the lower lip turned outward? Yes No Not observed

5l. Is baby's chin touching the breast? Yes No Not observed

Observe the baby suckling

5m. Does baby take slow, deep sucks? Yes No Not observed

5n. Do the baby's cheeks appear round (not indrawn)? Yes No Not observed

Baby 2

					2
--	--	--	--	--	---

Yes No Don't know

Day Night

6am-6pm		6pm-6am	

Yes No Not observed

Yes No Not observed

Yes No Not observed

Yes No Not observed

Yes No Not observed

Yes No Not observed

Yes No Not observed

Yes No Not observed

Yes No Not observed

Yes No Not observed

Yes No Not observed

6. Record Feeding Difficulties i.e. resulting in less effective feeding

Positioning and attachment

6a. Difficulty with positioning Yes No Don't know

6b. Difficulty with attachment Yes No Don't know

Mother's reported difficulties

6c. Milk insufficiency Yes No Don't know

6d. Baby thirsty Yes No Don't know

6e. Baby hungry/not satisfied Yes No Don't know

6f. Baby refusing Yes No Don't know

6g. Baby generally unwell (always refer to clinic if 5+ days) Yes No Don't know

6h. Baby constipated Yes No Don't know

6i. Baby needs cleaning out Yes No Don't know

6j. Baby crying Yes No Don't know

6k. Baby has/had blocked nose in past week Yes No Don't know

Dummy

6l. Baby receiving dummy Yes No Don't know

Oral thrush

6m. Baby has/had oral thrush in past week Yes No Don't know

6n. Nystatin given Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

Yes No Don't know

7a. DRF Completed?

No Yes

8a. Final BCSS visit

No Yes

If Yes, 8b. Reason for final visit

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7b. Other comments related to baby's health

7c. Action taken
(on any feeding difficulty or baby health)
 If more than one response, then record highest level of response

Action:
 S=Support and encourage;
 T=Counsel and treat;
 R=Refer to supervisor;
 C=Refer to clinic;
 U=Urgent referral to clinic

Action:
 S=Support and encourage;
 T=Counsel and treat;
 R=Refer to supervisor;
 C=Refer to clinic;
 U=Urgent referral to clinic

Supervisor code

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Have you completed the 'Date details' on the next form?

Signature _____

2	0	0	/		/		
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