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# Intervention for improved newborn feeding and survival where HIV is common

*Perceptions and effects of a community-based  
package for maternal and newborn care in a South  
African township*

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### **Abstract**

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South Africa recently changed infant feeding policy within Prevention of Mother to Child Transmission (PMTCT) of HIV from free formula to recommendation of breastfeeding for all. The country is evaluating the role of Community Health Workers (CHWs) in supporting mothers and newborns.

The aim of this thesis is to explore perceptions of household members on the value given to and the social forces behind formula feeding in light of the recent policy change, and to assess the effect of a community-based package of maternal and newborn care delivered by CHWs on HIV-free survival and exclusive and appropriate infant feeding up to 12 weeks of age.

Studies were conducted in a high HIV prevalence township. Focus group discussions were performed (grandmothers, fathers and teenage mothers) and in-depth interviews with HIV-positive and HIV-negative mothers. Perceptions of household members on the formula policy change were explored and the value household members place on formula feeding and circumstances that drive it. In a cluster-randomized trial (15 intervention, 15 control clusters) CHWs provided two antenatal and five post-natal home visits to support and promote PMTCT activities.

There were misunderstandings by community members on the free formula policy change. Mothers transferred the motherhood role to their mothers while partners provided inadequate financial support, leading to risky mixed feeding. Teenage mothers rarely breastfed their infants due to perceived constraints including embarrassment, sagging breasts and loss of freedom and boyfriends.

At 12 weeks of age the intervention had doubled exclusive breastfeeding (EBF) (28% vs. 14%) and slightly increased infant weight and length. No difference was seen between study arms in HIV-free survival. The effect on EBF at 12 weeks did not differ with maternal education or wealth levels, but was higher among HIV-negative mothers.

Focusing on teenage mothers breastfeeding challenges, involvement of grandmothers and fathers in infant feeding decision-making, improving communication strategies on policy change and breastfeeding to the community and health workers and CHWs home visits supporting PMTCT activities are important for infant feeding and child health.

**Keywords:** Prevention of Mother to Child Transmission of HIV, Community Health Workers, Exclusive breastfeeding, Formula feeding, South Africa

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To Nelson, Ken, Ketrine, and  
Karen for your love and inspiration



# List of Papers

This thesis is based on the following papers, which are referred to in the text by their Roman numerals.

- I Ijumba P, Doherty T, Jackson D, Tomlinson M, Sanders D, Persson LÅ. (2013) Free formula milk in the prevention of mother to child transmission programme: voices of a peri-urban community in South Africa on policy change. *Health Policy and Planning* 28(7): 761-8
- II Ijumba P, Doherty T, Jackson D, Tomlinson M, Sanders D, Persson LÅ. (2014) Social circumstances that drive early introduction of formula milk: an exploratory qualitative study in a peri-urban South African community *Matern Child Nutr* 10(1): 102-11
- III Tomlinson M, Doherty T, Ijumba P, Jackson D, Lawn J, Persson LÅ, Lombard C, Sanders D, Daviaud E, Nkonki N, Goga A, Rohde S, Sitrin S, Colvin M, Chopra M (2014). GoodStart: A cluster randomised effectiveness trial of an integrated, community-based package for maternal and newborn care, with prevention of mother to child transmission of HIV in a South African township. *Trop Med Int Health*. 19(3): 256-66
- IV Ijumba P, Doherty T, Jackson D, Tomlinson M, Sanders D, Swanevelder S, Persson LÅ. Effect of an integrated community-based package for maternal and newborn care on feeding patterns during the first twelve weeks of life: a cluster randomised trial in a South African township (Manuscript)

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# Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
BAN	Breastfeeding, Antiretroviral and Nutrition
CD4	The absolute CD4 cell count measure the number of CD4-T cells in each cubic ml of blood
CDC	Centres for Disease Control and Prevention, Atlanta, United States of America
CHW	Community Health Worker
DREAM	Drug Resource Enhancement against AIDS and Malnutrition
EBF	Exclusive Breastfeeding
FGD	Focus Group Discussion
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
Kesho bora	A better tomorrow in Kiswahili
Mam Bana	Mother baby in Setswana
NGO	Non-Governmental Organisations
OR	Odds Ratio
PROMISE EBF	Promoting Infant Health and Nutrition in Sub-Saharan Africa: Safety and Efficacy of Exclusive Breastfeeding Promotion in the Era of HIV
RR	Relative Risk
SD	Standard Deviation
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
WHO	World Health Organization



# Preface

My involvement in HIV/AIDS dates back to the 1980s when the first AIDS patient in Tanzania was diagnosed from my home village in Kagera Region, bordering Rakai District of Uganda. I was also extremely affected by the epidemic. I lost many relatives, neighbours and friends both in Kagera Region and Rakai District. At the time I was a Lecturer at the then Muhimbili Medical School in the Department of Microbiology and Immunology. The first Reference Laboratory for HIV testing in Tanzania was set up in our department. I was privileged to work with Professor Fred Mhalu and other colleagues in assessing the prevalence of HIV in groups of interest in the country and offering services to the general public.

In the early 1990s, I worked as a Public Health Consultant with World Vision Tanzania on their Kahama Child Survival for Development project funded by World Vision Australia (WVA). The health area focuses were vaccination against measles, (which at the time caused a high number of deaths, particularly, in very remote villages reachable only in dry season), water and sanitation, nutrition, and HIV/AIDS. Despite low income, poor sanitation, lack of potable water and reliable cooking fuel (charcoal or firewood) there was a sizeable number of mothers who practiced formula feeding. This was after the isolation of HIV virus from breast milk and the healthiness of breast milk was being questioned. However, in Kahama formula feeding then was associated with being financially well off. We conducted door-to-door home visits educating mothers on the importance of vaccination, prevention of diarrhoeal diseases, malnutrition and benefits of breastfeeding.

During one of my visits to WVA in Melbourne, I was requested to share my personal experiences and views on HIV/AIDS. At this meeting one participant asked a very controversial question. She wanted to know my views on breastfeeding in the context of HIV. My vast experience of living and working in rural Tanzania had exposed me to challenges associated with formula feeding (including illiteracy, lack of potable water, fuel, refrigeration, time & water to clean infant feeding utensils and money to buy enough formula milk). My firm answer was that breastfeeding was a better choice and this remains my conviction.

In 2008, I was privileged to get a job as a Senior Scientist at the South African Medical Research Council in Durban. I worked as a Project Manager in the Goodstart III community-based randomised trial in Umlazi township

near Durban. I was responsible for the day-to-day management of the trial. I developed the trial operational tools including Standard Operational Procedures, Behaviour Change Communication Booklet and CHW field guides. I trained the CHWs and their supervisors. I contributed to the development of data collection tools, data monitoring, cleaning and analysis; and writing up of manuscripts. I also prepared progress reports and conference presentations in collaboration with the principal investigators. Being interested in HIV and breastfeeding I was keen to keep up to date with research on EBF with ARVs in HIV positive mothers.

When the KwaZulu Natal Provincial Department of Health, Infant and Young Child Feeding Policy was aligned with WHO recommendations for HIV and infant feeding, I was keen to understand the community's perceptions towards the phasing out of the free formula policy. I, therefore, planned additional qualitative studies that could complement the results of the trial on the current policy changes regarding HIV and infant feeding recommendations in South Africa. I am not an isiZulu speaker (the commonly spoken and understood language in KwaZulu Natal); therefore, I needed assistance in the qualitative data collection in the isiZulu language. I did all the analysis of the qualitative data, wrote the manuscripts and led the submission process. My hope is that the results of this study will shed some light on the current implementation of policy change and be of benefit for mothers and their offspring in South Africa and beyond.

This thesis is part of the collaboration in HIV and infant feeding research between Uppsala University, Department of Women's and Children's Health (IMCH) in Sweden; the Medical Research Council (MRC), Health Systems Research Unit (HSRU) and the University of Western Cape, School of Public Health in South Africa. I would like to acknowledge the financial support from the three institutions through my supervisors.



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# Introduction

## MDG-4 progress in sub-Saharan Africa

In 2000 the government leaders of 189 nations came together and committed to a series of goals related to health and poverty reduction by 2015 [1]. This promise was translated into eight interlinked Millennium Development Goals (MDGs). One of these goals (MDG-4) focuses on the health and well-being of the most vulnerable group namely children below five years of age and related to it is MDG-5 which focuses on maternal health [1].

Since 2000 many countries have revised their policies and programmes, and made commitments to achieve MDG-4 as well as the other goals. However, in many sub-Saharan Africa countries including South Africa, progress has been slow [2]. Globally neonatal deaths account for more than 44% of the under-five mortality resulting in 2.9 million deaths per year, mainly in low-income countries [3]. Sub-Saharan Africa carries the second highest burden of neonatal deaths posing a major challenge in achieving MDG-4 of reducing the under-five mortality by two thirds by 2015 [3]. The average reduction in neonatal mortality rate (NMR) in the last decade globally was 2.1% per year, but the sub-Saharan region recorded the lowest reduction rate of 1.5% per year [2]. It is estimated that at the current average decline, the risk of dying within the first four weeks of life in Africa will not match the current level in high-income countries before 2125 [4].

South Africa was one of the twelve countries where the under-five mortality rate was higher in 2005 compared to 1990, the MDG-4 baseline [5]. A review of under-five mortality in South Africa between 1990 and 2011 using different AIDS models (Actuarial Society of South Africa (ASSA) 2008), a model developed by the Centre for Infectious Disease Epidemiology and Research at the University of Cape Town for paediatric HIV (UCT), and the Spectrum's AIDS Impact Module (AIM)) indicated a rapid reduction in AIDS related deaths as a component of under-five mortality since 2005 [6]. This reduction is attributed to improved coverage of prevention of mother-to-child transmission of HIV (PMTCT) services and expanded roll out of antiretroviral therapy (ART) [7]. However, the decline of other causes of under-five mortality such as diarrhoea, pneumonia and neonatal deaths has stagnated over the last decade. Available data indicate that AIDS related deaths in under-five dropped from 50% in 2000 to 28% in 2010 [5] while neonatal deaths, which account for 30% of the under-five mortality remained

unchanged [8]. It is unlikely that South Africa will achieve MDG-4 by 2015. Since non-AIDS deaths contribute an increasing proportion of the under-five deaths, tackling them with the same tenacity is imperative in order to reduce under-five mortality and improve child survival particularly in poor communities [6].

Reduction of under-five mortality rate from 56 deaths per 1,000 live births to the South African 2015 MDG-4 target of 21 deaths per 1,000 live births [9] will require massive scale up of cost effective high impact programmes and practices such as exclusive breastfeeding (EBF) by all mothers regardless their HIV status. Further investments in PMTCT services to eliminate paediatric HIV transmission are crucial as complacency could undermine the recent gains [6].

# Theoretical framework

## Use of theory in cluster randomised trials

There is a need to incorporate a theoretical framework to assist researchers to understand why some interventions work while others fail. Furthermore, there is a need to identify the processes, interactions and ingredients that create the desired outcomes [10]. Equally important, is the understanding of the barriers in relation to contextual social and structural factors within the community [11]. The United Kingdom Medical Research Council document ‘A framework for developing and evaluating Randomised Controlled Trials of complex interventions to improve health’, recommends conducting a process evaluation “to explain discrepancies between expected and observed outcomes, to understand how context influences outcomes and to provide insights to aid implementation” [10].

Increasingly there are suggestions to integrate structural, social and contextual factors when designing and conducting research geared towards promotion of behaviour change. Taking the example of promoting EBF in HIV-positive mothers receiving antiretrovirals (ARVs) for the best outcomes of HIV free child survival [11], this would include considering the barriers women face in cultures where the decision to breastfeed or not is guided mostly by community norms and practices rather than individual choices. Similarly it is important to identify contextual and social barriers associated with HIV disclosure [12].

For this research we adapted the Social and Behaviour Change Communication approach developed by United States Agency for International Development for infant and young children nutrition projects for sub-Saharan African countries [13]. This approach has been used in HIV/AIDS prevention programmes. Its origins are rooted in development communication advocacy and communication as a dialogue rather than a monologue [14]. It draws on principles largely from the socio-ecological model for change that is based on evidence that in order to understand the human behaviour we need to understand the context in which that behaviour occurs [15]. Kippax argues that what is considered “individual behaviour” is nested in a range of influences at different levels, which facilitate or constrain change at the individual level [16]. The two main concepts of social-ecological model for change are that: (a) behaviours are affected by multiple levels of influence and (b) an individual’s behaviour influences and it is influenced by the social

environment [17]. This model emphasises the interaction between and interdependence of factors within and across all levels of health behaviour, recognising that most public health challenges are very complex and cannot be adequately understood and addressed from a single level of intervention [15, 17].

The social and behaviour change communication for health approach is a consultative research-based process that uses communication to promote and facilitate behaviour change in order to improve health outcomes. It argues that a successful approach always necessitates a communication component [14].

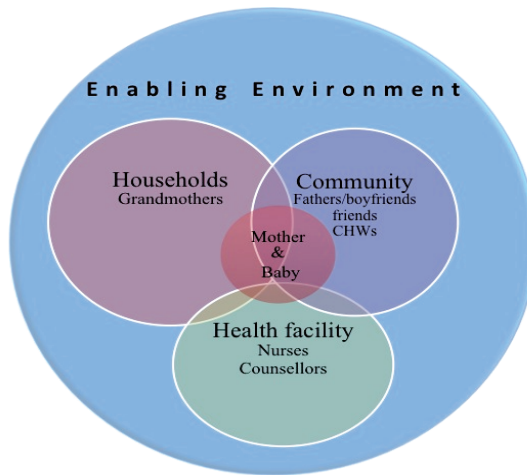


Figure1: The social and behaviour change communication framework of linking exclusive breastfeeding and appropriate infant feeding individual behaviour change to other multiple levels of influence

Adapted from: Infant and Young Child Nutrition social and behaviour change communication approach, 2005 [13].

## Breastfeeding and child survival

Breast-milk is the natural first food for all infants and provides all the energy and nutrients that the infant needs for the first six months [18, 19] and remains a valuable source of nutrients for up to two years [18]. Breastfeeding has the potential to prevent about 800,000 deaths among children under-five years of age each year if all children 0-23 months were optimally breastfed [4, 20]. Breastfeeding is associated with reduction in the risk of acute otitis media, non-specific gastroenteritis and lower respiratory tract infections. It is reportedly also associated with lower risk of necrotizing enterocolitis, sud-



den infant death syndrome, atopic dermatitis, asthma and increased incidence of later diseases and health problems such as obesity, and type 2 diabetes [30]. In low and middle income countries breastfeeding is associated with reduction of mortality from common infectious diseases, particularly diarrhoea and pneumonia [19].

A study conducted in rural Ghana showed that initiation of breast-feeding within the first hour after birth was associated with prevention of 22% of neonatal deaths; 16% if breastfeeding was initiated within the first day [21]. Also infants initiated to breastfeeding within one hour and exclusively breastfed after birth during the neonatal period, were 9 times less likely to die than those who were initiated on infant formula and breast milk within 72 hours after birth [21]. A similar study in Nepal found that 19 % and 8% of deaths could be prevented with universal initiation of breastfeeding within the first hour and within the first day of life, respectively [22]. Early initiation of breastfeeding is also associated with increased breastfeeding success[18]. EBF for the first six months has been shown to play a role in preventing diarrhoea, pneumonia, enhancing nutritional status and thus reducing infant morbidity and mortality [23]. The immunologically active components in breast milk protect newborns against disease and support the maturation of their own immune system and foster optimal growth and development [24].

Although perception of breast sufficiency [25] is quoted by mothers as a cause of mixed feeding [26], several studies have shown that breast milk is all infants need for all their nutritional requirements for the first six months of life [18, 19, 27]. Thus breast milk is regarded as a ‘gold standard’ for protective nutrients [28]. In addition, breastfeeding has a number of intellectual, social, psychological and economic benefits to mother-baby pairs such as mother and child bonding and reduction of postpartum weight retention, enhanced intelligence up to 6 quotations (IQ) points in breastfed babies, and increased birth spacing [29, 30].

## Global infant feeding practices

### Use of infant formula milk

Before the middle of 19th century, breastfeeding was almost universal [31]. However, the development of condensed milk by Borden in 1856 followed by the production of Farine Lactée (milky flour) by Nestlé in 1867 changed infant feeding practices. The availability of these two products marked the beginning of substitute feeding [32]. The increase in the use of breast milk substitutes (BMS) was associated with the increased employment of women away from home mainly in high-income countries [33]. Thus use of breast milk substitutes resulted in a decline in breastfeeding in high-income coun-

tries such as Sweden, Denmark, Norway, Britain and the United States of America [33].

In the 1970s breastfeeding began to increase in high-income countries particularly among older and more educated women [31, 33]. As the sales of breast milk substitutes dropped in these countries, manufacturing companies sought markets in low and middle-income countries [34]. Many of the low and middle-income countries were and are still characterised by low household income, illiteracy and poor access to clean water [35, 36]. In spite of these conditions, the aggressive marketing of formula milk mainly through formula gifts and health professionals, succeeded in convincing some mothers to feed their infants formula milk [35]. However, due to high level of illiteracy and language barriers, many mothers were not able to understand the labels. As a result formula milk preparation instructions were not followed. In addition poor sanitation and lack of money to buy adequate amounts of milk aggravated the poor preparation of formula milk. This resulted in feeding infants over-diluted and contaminated formula milk. Thus many infants who were fed formula milk were at risk of diarrhoeal diseases and malnutrition [37]. Due to lack of immunologically active components found in breast milk these infants were also exposed to respiratory infections such as pneumonia and diarrhoea [24, 38]. The increases in mortality associated with formula feeding were alarming. The historical events summarised in table 1 led to the development of the WHO International Code of Marketing of Breast milk Substitutes (CODE) in 1981[39].

Table: 1 Events that led to the WHO International Code of Marketing Breast milk Substitutes (CODE)

Year	Event
1939	Lecture Singapore Rotary club: Milk and Murder by Cicely Williams [40]
1972	Article: Commerciogenic malnutrition by Jelliffe D B [37]
1974	Book: The baby killer by Muller [41]
1975	Law suit by Nestle against Swiss Third world action group (AgDW) for Nestle kills babies [42]
1978	International boycott of Nestle products by Infant Formula Action Coalition (INFACT [43]
1979	United States of America Senate: Hearing on infant formula. Edward Kennedy [34]  WHO/UNICEF: Meeting - Infant and young child feeding, Geneva [44]
1981	Passing the WHO International Code of Marketing Breast milk Substitutes (CODE) [39]

Adapted from: Judy Pauline Brandy: Marketing breast milk substitutes: problems and perils throughout the world [45].

## WHO International Code of Marketing of Breast Milk Substitutes

The World Health Assembly adopted the WHO Code on 21st May of 1981. By 1984, 130 countries had passed legislation or developed policies to restrict the advertisement of breast milk substitutes [32]. Despite 17 resolutions on the Code between 1981-2010, and the 1990 and 2005 Innocenti declarations (protecting, promoting and supporting breastfeeding), the manufacturing of formula milks and other breast milk substitutes continued to grow [46-48]. In 2010, it was estimated that the annual sales from formula milk was more than US\$31 billion [49].

The Code intentions were to restrict marketing of breast milk substitutes in order to ensure that breastfeeding is promoted, protected and supported

[39]. The Code has been poorly implemented, and its monitoring at international and country levels has been fluid or non-existent [46, 50].

## Consequences of formula feeding

Globally formula feeding increases newborn and infant morbidity and mortality [45]. Lack of access to clean water, poor sanitation, and lack of money to buy adequate amounts of formula milk lead to over-dilution of formula milk and increased risk of diarrhoea [35, 48]. Results from a large cohort study in Philippine's government hospitals involving 9,886 newborn babies showed that infants confined in the nursery, formula fed and subjected to long starvation periods had higher incidence of oral thrush, diarrhoea and clinical sepsis. Also death due to diarrhoea and clinical sepsis were higher in these infants than in those who were exclusively breastfed. In addition, the non-breastfed infants had a 10-fold increase in diarrhoea compared with breastfed infants [51].

The Bellagio child survival study in 42 low-income counties showed that 1.3 million under-five deaths per year could be prevented if universal coverage of breastfeeding was increased to 90% in infants below 6 months of age [19]. A WHO-pooled analysis of data from low-income countries showed that breastfeeding could prevent over 75% of deaths in early infancy and 37% of deaths during the second year of life [52].

A cohort study in Brazil showed that non-breastfed children compared to those exclusively breastfed had 14 times higher risk of dying from diarrhoea, 3.6 times higher risk of dying from pneumonia and 2.5 times the risk of dying from other infections [53]. Other studies show that any diarrhoea morbidity and mortality are significantly reduced even when breastfeeding is not exclusive [30].

## Strategies to improve breastfeeding

In 2002, the World Health Assembly adopted the Global Strategy for Infant and Young Child Feeding [54]. The purpose was to re-focus the world's attention on the impact that breastfeeding practices have on nutritional status growth and development and in achieving optimal health outcomes, hence survival for infants and young children [54]. The strategy was based on earlier achievements such as the Baby-Friendly Hospital Initiative (1991) [55], the International Code of Marketing of Breast-milk Substitutes (1981) [39] and the Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding (1990) [56].

However, the global coverage of EBF among infants aged less than 6 months remains low at 39% [57]. While EBF has been on the increase in some high-income countries such as Sweden, Norway, Denmark and Japan [30] as well as in middle-income countries such as India (46%) and Brazil

(40%), the experience in sub-Saharan Africa with exception of Benin (70%), has been the opposite [57]. Introduction and marketing of breast milk substitutes in low-income countries from the 1960s, cultural barriers, social taboos and lack of adequate support from health services, urbanization and women taking up employment are some of the reasons for this decline [32, 35, 58].

## HIV and breastfeeding

Since the 1980s the decline of breastfeeding in many sub-Saharan countries may be attributed to the fear of HIV transmission through breast milk [59, 60]. The epidemic added unintended consequences that have led to more mothers who could have otherwise breastfed, choosing to use formula milk [61]. Similarly, global efforts to promote breastfeeding were curtailed and blurred by the HIV/ AIDS epidemic in sub-Saharan Africa, especially in countries where formula milk was promoted as part of Prevention of Mother-to-Child Transmission (PMTCT) of HIV programmes [62]. In Africa the proposition of exclusive breastfeeding for 6 months is lower than the global level, estimated at 35% despite many countries being resource poor [36, 57].

Since 1992, the WHO has grappled with the challenge of infant feeding in the context of HIV particularly in low and middle-income countries, mainly in sub-Saharan Africa. For decades a good number of researchers, policy makers and programme managers tried to assess the level of mother-to-child transmission risk attributable to breastfeeding in order to provide appropriate guidelines for HIV infected mothers. Between 1992 and 2009, the WHO developed and/or revised at least 16 different guidelines [63]. The 1992 WHO guidelines recommended breastfeeding by all women including HIV positive mothers [64]. The revised guidelines of 1998 recommended the introduction of replacement feeding, which included home-modified animal milk or commercial infant formula for HIV-exposed infants whose mothers chose not to breastfeed. Secondly, HIV-infected mothers were to be supported in their infant feeding choices. The 1998 WHO/UNICEF HIV and Infant Feeding guidelines stated that replacement-fed HIV-exposed infants were at a reduced risk of dying as long as they had “uninterrupted access to nutritionally adequate breast milk substitutes that are safely prepared and fed to them” [65]. This was seen, as a shift in the WHO’s many years of promoting, protecting and supporting breastfeeding.

Based on WHO/UNICEF guidelines of 1998, Botswana included formula milk provisions in its PMTCT programme in order to eliminate the risk of postpartum transmission of HIV to exposed infants. Botswana is regarded as a middle-income country; therefore it could afford to provide free infant formula for a year to all HIV-exposed infants. In addition Botswana has a good supply of safe water, so formula feeding was seen as an appropriate infant feeding practice [66].

However, this was not the case. Between November 2005 and February 2006, Botswana experienced unusually heavy rains and flooding. These floods were accompanied by a large increase in infant diarrhoea and mortality. In the first quarter of 2006, in just twelve health districts, there were 22,500 cases of diarrhoea, with 532 deaths in children under five (compared to 9,166 cases and 21 deaths for the entire country in the first quarter of 2005) [36]. Centres for Disease Control (CDC) of United States of America, confirmed the contamination of water supplies in 26 villages. The most significant risk factor for children with diarrhoea was not breastfeeding. The risk factors for death included not being breastfed (OR 8.5,  $p = 0.04$ ). Importantly, the HIV status of mothers and infants was not associated with the risk of death. The increased infant deaths challenged the benefits of formula feeding in improving child survival in high HIV prevalent countries. This evidence from Botswana confirmed that breastfeeding avoidance and use of formula milk in high HIV prevalent countries could result in a serious outbreak of diarrhoea in infants [66].

The revised 2006 WHO guidelines were prompted by evidence from three large cohort studies conducted in South Africa, Zimbabwe and Côte d'Ivoire, which showed that EBF for up to 6 months was associated with more than 50% reduction in the risk of transmission of HIV compared to non-exclusive breastfeeding [67-69]. Evidence from these settings showed that the combined risk of HIV infection or death at 18 months of age was similar in infants who were formula fed from birth compared to infants who were breastfed for 3 to 6 months [70-72].

A number of clinical trials conducted in several African countries provided strong evidence that antiretroviral interventions to the mother or the infant significantly reduced the probability of transmitting HIV through breast milk [73]. These studies included the BAN study in Malawi [74], DREAM study in Mozambique [[75], Mma Bana studies in Botswana [76], Mitra study in Tanzania [77] and the Kesho bora studies in South Africa, Burkina Faso and Kenya [78]. In all of these studies the transmission rate was <5% in breastfeeding women who received ARVs during pregnancy and postpartum [73].

The amendments to the 2006 WHO guidelines incorporated evidence showing that antiretroviral (ARV) administration to either the HIV-infected mother or HIV-exposed infant during the breastfeeding period could significantly reduce the risk of postnatal transmission of HIV [79]. In the revised 2009 guidelines WHO recommended that national authorities in each country should decide which single infant feeding practice to recommend and that this should be primarily promoted and supported by Maternal and Child Health services [80].

Using antiretroviral prophylaxis while exclusively breastfeeding for six months and 12 months of breastfeeding has been shown to be the safest feeding modality in HIV infected mothers in resource limited settings [73, 81].

The mechanism by which EBF is associated with lower mother-to-child transmission is not fully understood, however they include: the maintenance of integrity of the infant's gastrointestinal barrier, which is regarded as the primary mode of infection [73]. Secondly, the immunological factors in the breast milk are said to be responsible for the reduction of viral activity in the human milk [24]. Thirdly, EBF maintains the integrity of the mammary epithelial lining and promotes overall breast health [73]. Recently a protein known as Tenascin-C (TNC), an innate mucosal host protein found in milk has been identified and is capable of neutralizing HIV-1 through binding to chemokine core receptor site. This finding potentially explains why the majority of HIV-1 exposed breastfed infants are protected against mucosal HIV-1 transmission [82].

There is scientific evidence to support EBF with antiretrovirals in HIV infected mothers, however the challenge is translating this evidence into practice. A cross-sectional survey of HIV positive mothers in Gaborone Botswana showed that 80.2% of HIV infected mothers opted to formula feed their babies despite this evidence [83]. The authors attribute these findings to poor counselling. Many healthcare workers commonly prescribe or encourage formula feeding despite the availability of evidence supporting EBF where formula feeding is not affordable, feasible, acceptable, sustainable and safe. Poor counselling may not be the only barrier in promoting EBF especially among HIV positive mothers; contextual, structural and social factors need to be considered. In several sub-Saharan countries there is a call for countries to consider context-specific sociocultural understanding in designing effective interventions to promote EBF particularly in HIV positive mothers [84, 85].

## Infant feeding practices in South Africa

### Introduction of formula milk in health facilities

In the 1960s South Africa introduced a subsidised Protein Energy Malnutrition (PEM) strategy as a supplementary feeding scheme [86]. The scheme targeted at risk of malnutrition or malnourished infants over six months and children up to six years of age. The PEM scheme was the starting point for distributing formula milk through public health facilities. While the reasons for longstanding use of formula milk are complex, the distribution of formula milk through the PEM strategy undoubtedly contributed to 'normalising' formula feeding practices. The evaluation of the PEM scheme in the Northern Cape Province indicated that the intervention's objectives of reducing malnutrition in the target groups were not achieved [87]. Also the high number of infants under six months of age who were targeted by the scheme contravened the government's National Breastfeeding Policy, which pro-

moted breastfeeding in this age group [87]. The PEM scheme was promoted nationally as a 'treatment' for malnutrition and food (powdered milk and protein, vitamins and minerals mixture as medicines) by the public health facilities [87].

## Other child nutrition initiatives

Prior to 1994, much of the nutritional research in South Africa focused on nutritional diseases of lifestyle of the higher socio-economic groups. The first ever documented national nutrition survey of children under the age of six years was conducted in 1994/95 [88]. The survey revealed that stunting and Vitamin A deficiency were major problems in children aged 6 to 71 months. The most affected children were from the historically disadvantaged provinces including Northern Cape, Free State, Eastern Cape and KwaZulu Natal [88].

Thus malnutrition in infants and young children was recognized as a key challenge for optimal child survival by the new democratic South African government. As a result the Integrated Nutrition Programme (INP) was initiated and became one of the Department of Health's flagships during the transformation of the health system [89].

One of the Integrated Nutrition Programme's main aims was to enable all women to breastfeed their children exclusively until six months of age. Thereafter, mothers were to introduce their infants to appropriate complementary foods and continue breastfeeding until twenty-four months of age and beyond [90]. Despite this comprehensive initiative the breastfeeding prevalence remained low [91].

The South African Demographic and Health Survey (SADHS) of 1998 showed that only 10% of the infants aged 0-3 months were exclusively breastfed while 48% were formula fed. Also the same survey reported that 17% of infants aged 0-3 months were never breastfed [91]. Mothers with no education were more likely to breastfeed than those who had higher education (median duration 1.1 months for mothers with no education vs. 0.4 months for mothers with more than grade 12 education). The prevalence of EBF in the 0-6 months old infants was 7% [91]. The low prevalence of EBF prompted the Department of Health to adopt the WHO Global Strategy for Infant and Young Child Feeding [90]. However, the results from the South African Demographic and Health Survey of 2003 showed very little improved in EBF as only 8% of the infants aged 0-6 months were exclusively breastfed while 40% of infants less than four months of age were formula fed [92].



## Infant feeding in the HIV era

In 1999, Coutoudis et.al [93] showed that EBF for 3 to 6 months was associated with lower HIV transmission rate compared to mixed breastfeeding, which was the most prevalent feeding practice in South Africa [93]. In a prospective study in 2000 results showed that cumulative probabilities of HIV detection remained similar in never and exclusively breast fed infants up to 6 months, 0.194 (95% CI: 0.136-0.260) and 0.194 (95% CI: 0.125-0.274) respectively, while in mixed feeders the probability was higher; 0.261 (95% CI: 0.205-0.319), by six months [59]. There were no other studies at the time to compliment the South African finding.

The first South African PMTCT guidelines by the National Department of Health in 2002 included free formula milk provisions to HIV-exposed babies [62, 94]. The guidelines also recommended abrupt cessation of breastfeeding at 4 months for infants born to HIV-positive mothers who opted to breast-feed. HIV-positive mothers who opted not to breastfeed were provided with free formula for six months through public health facilities [94]. At the time of introduction of the PMTCT guidelines, there was no sufficient research on the risks of HIV transmission with different infant feeding practices (exclusive or mixed breastfeeding) [95]. Both practices were considered to carry large risks of transmitting HIV. It has also been shown that health workers counselling HIV-positive mothers regularly overestimated the risk of postnatal HIV transmission [60].

Inappropriate use of formula milk can increase the risk of death in children compared to breastfeeding even in HIV-exposed infants. Doherty et.al in their study undertaken in routine PMTCT sites in South Africa found that an inappropriate choice to formula feed (i.e. when WHO criteria acceptable, feasible, affordable, sustainable and safe are not fulfilled) resulted in a higher risk of HIV transmission or death than breastfeeding [96]. Also contamination of infant formula milk, which often results in diarrhoea, is a major threat to child survival. A study in KwaZulu Natal, South Africa indicated that it was difficult to prepare formula milk hygienically in a resource-constrained setting [97]. The study reported that about 80% of the formula milk samples prepared by mothers at home after receiving instructions from the counsellors were found to be contaminated with faecal bacteria [98]. Similarly, about 20% of the formula milk demonstration samples prepared by the counsellors at the clinics to demonstrate to the mothers how formula milk is made were found to be contaminated by faecal bacteria [98]. Thus unhygienic preparation of formula milk compounds the risks of formula feeding in HIV-exposed infants [97].

The increased risk of mother-to-child transmission of HIV associated with mixed feeding and the benefits of EBF was confirmed in large cohort studies carried out in South Africa, Zimbabwe and Côte d'Ivoire [67-69]. The study in KwaZulu Natal, South Africa showed that infants aged 14 weeks who

received formula milk and breast milk, were almost twice as likely to be infected compared to those who were exclusively breastfed [68]. Early introduction of solids to infants who were breastfed led to an 11 times greater risk of HIV infection compared to breast milk only. The reported cumulative postnatal HIV transmission risk in this study was 4.04% after five months of exclusive breastfeeding. Although not statistically significant, mortality in the first 3 months of life was more than doubled in the group receiving replacement feeding compared with the exclusively breastfed group (15% vs. 6%, Hazard ratio, HR 2.06, 1.00 - 4.27,  $P = 0.051$ ). In addition mothers that chose to exclusively formula feed were more likely to have CD4-cell counts below 200 cells per mm (a higher risk group for mother-to-child transmission through breastfeeding) [68]. By 18 months of age, the probability of survival was not statistically significantly different for HIV-uninfected infants, regardless of whether they were breastfed or formula-fed from birth. Also these mothers received intensive counselling support to practice appropriate infant feeding of their choice [68, 70].

The revised 2008 PMTCT of HIV policy launched in April 2008 included: (a) prophylaxis with azidothymidine from 28 weeks' gestation; (b) nevirapine prophylaxis for pregnant women during labour and for their babies within 72 hours of delivery; and (c) HAART for pregnant women with a CD4+ T-cell count  $< 200$  cells/mm [99]. Later in the same year, the Minister of Health launched the national PMTCT accelerated plan (A-plan) which aimed to reduce mother-to-child transmission of HIV from 12% in 2008 to less than 5% by 2011, in accordance with the National Strategic Plan 2007–2011 [100, 101]. However, the infant feeding options remained the same [102].

Between 2002 and 2011 the infant feeding options for South African HIV-infected mothers were either exclusive formula feeding [94] (for the first six months of life where the WHO criteria (acceptable, feasible, affordable, sustainable and safe) were met, or EBF. However, the interpretation of these criteria was problematic at provider-client level [96, 103, 104], and consequently many women ended up mixed feeding. Coutsooudis and colleagues argued that mixed feeding, rather than compliance with exclusive formula feeding, was the result of easy access to formula milk [61]. Concerns about HIV transmission led to more women choosing formula feeding, which may have caused a 'spill over' effect of formula feeding in the general population [61]. South Africa's national breastfeeding rates have stagnated since the emergence of the HIV epidemic largely due to the provision of formula milk for PMTCT as well as mixed messages from health care workers [105]. In a South Africa report poor counselling practices and the above-mentioned WHO criteria were ignored [106]. Furthermore, women might have considered provision of formula milk as a form of cash transfer [102].

In South Africa, mixed feeding is the most practiced mode of infant feeding [61, 107]. Infants are introduced to solids and fluid as early as two

weeks after birth [108], while water and traditional medicine may be introduced much earlier [109]. Goga et. al in their Goodstart cohort study showed that formula use among HIV-negative women was significantly higher than formula use among breastfeeding HIV positive women at all measured time points [106].

Since the late 1990s, South Africa has carried the largest burden of HIV infection in the world [110]. Between 2004 and 2010 the estimated HIV prevalence among women attending antenatal care in public health facilities was hovering between 29.1% - 30.2% [111] and more children were infected mostly through mother-to-child transmission [7]. Despite free formula milk and the largest PMTCT programme in the world, child mortality was increasing [5, 110].

## Reversing the tide

On World AIDS Day, 1st December, 2009 the South African President made major announcements related to curbing HIV/AIDS among women, newborns and children [112]. These are summarised in Figure 2. A month earlier WHO released the 'HIV and Infant Feeding Revised Principles and Recommendations Rapid Advice, November, 2009'. The two events guided the revision of the 2008 South African PMTCT guidelines. The new guidelines 'Clinical Guidelines for the Prevention of Mother-to-Child Transmission of HIV (PMTCT)' were followed by a release of the WHO Guidelines on 'HIV and infant feeding principles and recommendations for infant feeding in the context of HIV and a summary of evidence' [79, 99].

By the time WHO 2010 guidelines were released [113] the new 2010 South African clinical guidelines were operational and were aligned with the WHO guidelines in terms of provision for expanded antiretroviral regimes, including highly active antiretroviral therapy (HAART) for mothers, or nevirapine prophylaxis for infants for the duration of breastfeeding (up to 12 months of infant age) [102]. However, the continued provision of free formula milk in the South African 2010 PMTCT guidelines, caused great concern amongst public health and child health researchers and clinicians [102].

Since 1994 KwaZulu Natal province has reported the highest prevalence of HIV infection in women attending antenatal care in public health facilities [111]. In 2010 the HIV prevalence in some districts in KwaZulu Natal was over 40%. Provincial reports also indicate that there were increases in pneumonia and diarrhoeal diseases morbidity among the under-five children [114]. Due to this challenge the province has been in the forefront in taking up new interventions to curb the HIV epidemic [114]. The KwaZulu Natal provincial Department of Health in this instance was also the first provincial department of health in South Africa to comply with the WHO 2010 guidelines by discontinuing the distribution of free formula milk through public health facilities and promoting breastfeeding [115].

About 8 months later, in August 2011, the South African National Department of Health convened a national breastfeeding consultative meeting where the decision was taken to adopt breastfeeding promotion as the national infant feeding strategy as evidenced in the “Tshwane Declaration of Support for Breastfeeding in South Africa.” After a decade of provision of free formula milk through the PMTCT programme South Africa took a bold decision to promote breastfeeding for all mothers [116].

### Promoting exclusive breastfeeding: concept and practice

Promotion of EBF by peer counsellors is not new in KwaZulu Natal. Between 2006 and 2008 Umlazi was one of the sites in South Africa that participated in a multi-centre cluster randomised, community-based trial known as PROMISE EBF “Promoting Infant Health and Nutrition in the Era of HIV.” Trial sites included South Africa, Zambia, Burkina Faso and Uganda. The objective of the trial was to develop and test an intervention to promote exclusive breastfeeding, to assess its impact on infant health in African contexts where a high prevalence of HIV is a barrier, and to strengthen the evidence base regarding the optimal duration for EBF. The primary outcomes of the trial were prevalence of EBF and diarrhoea at 12 weeks and 24 weeks. This was the first trial undertaken in sub-Saharan Africa to assess the effect of individual home-based EBF peer counselling. Despite utilising single purpose peer counsellors who focused solely on promoting exclusive breastfeeding, the results from the study showed that the South African centre had the lowest prevalence of EBF using 24-hour recall in 12 week old infants. The prevalence was 10% and 6% in the intervention and control clusters respectively compared to Burkina Faso’s 81.6% and 43.9% and Uganda’s 79.1 and 34.6 [105].

Qualitative studies undertaken in conjunction with the PROMISE EBF randomised trial in the South African Umlazi site showed that there were several contextual barriers to practising EBF in a high HIV prevalent peri-urban community. These included fears of not practising expected traditions such as giving infants the ‘Zulu medicines’ and mixed feeding [117]. Women who regarded themselves skilled in infant and young child feeding in the context of the Zulu culture ‘confronted’ the capabilities of the peer counsellors, which made them uncertain to support the women to exclusively breastfeed their infants [118]. On the other hand the peer counsellors failed to identify and address the fears women had about the intentions of counselling visits. Another key concern was that peer counsellors might have felt inferior due to lack of a professional qualification [118]. Other factors that might have rendered peer counselling ineffective include the misinterpretation of exclusive feeding that was understood as “not mixing breast milk and formula milk” but that one could introduce other fluids and solids ranging from water to porridge into infant’s diet [117].

Mothers' belief of milk insufficiency for the infant's food needs whether breastfed or formula fed prompted them to feed their infants other additional foods [26, 107, 117]. Furthermore, when counselling messages were in conflict with the mothers' entrenched beliefs on infant feeding, the messages were quietly dismissed. For example, feeding infants water and traditional medicine is perceived to be necessary for cleansing the infant's gastrointestinal tract and fulfils an important cultural belief [117].

Despite scientific evidence outlining the benefits of breastfeeding even in high HIV prevalent settings, infant-feeding practices in South Africa are still suboptimal. Although from 75 to 97% of infants receive breast milk as their first feed, mixed feeding remained the predominant method of infant feeding [106, 108]. The early introduction (two to four weeks after birth) of solids and fluids in infants diet was common [119] with EBF declining to 12% at the age of three months and only 8% of the infants being exclusively breast fed for the recommended 6 months [92]. The South African national HIV Prevalence, Incidence, Behaviour and Communication Survey carried out in 2008 revealed that a quarter of the children aged 0 to 6 months were exclusively breastfed and about 50% were mixed fed [120]. The prevalence of EBF was much higher than reported in other national surveys. This survey was based on a long recall period of 2 years and lacked supporting in-depth feeding questions. These may be the reasons for the high prevalence of EBF reported [120].

### Supportive environment for promoting breastfeeding

The 2013 revised South African Infant and Young Child Feeding Policy was expected to provide new impetus to protect, promote and support breastfeeding in all mothers regardless of their HIV status [90]. The policy put breastfeeding back on the agenda as the cornerstone of the child survival strategy. The policy detailed the support to be provided to mothers who are known to be HIV infected to exclusively breastfeed their infants for 6 months and continue breastfeeding for 12 months, with appropriate complementary feeding whilst taking antiretroviral treatment as prescribed. HIV negative mothers should exclusively breastfeed their infants for 6 months with continued breastfeeding thereafter for up to 2 years and beyond with appropriate complementary feeding from six months of age. While the guidelines provide sound public health approaches the promotion of breastfeeding in complex social and cultural environments remains a barrier [11, 84, 85]. Secondly, the long history of using formula to 'treat' malnutrition and HIV poses additional challenges [86, 87, 94]. Thirdly, the policy was silent on the continued practical support to mothers particularly HIV positive mothers [90].

## Community-based interventions

### Community-based interventions package for maternal newborn and child health care

In several research settings Community Health Workers (CHWs) have been found to be effective in reducing newborn and child mortality rates [121-123]. A recent meta-analysis of 18 original studies of community-based intervention packages conducted mainly in South Asia, has shown that they were effective in reducing maternal morbidity by 25 % and increasing referrals to health facilities for pregnancy-related complications by 40%. There was also an overall reduction in neonatal deaths of 24%, a 16% reduction in stillbirths and 20% reduction in perinatal mortality [124].

Community-based packages that (a) disseminated education (b) promoted awareness related to birth and newborn care preparedness and (c) were based on building community support groups and women's groups, were most effective in reducing total and early neonatal deaths [124]. On the other hand, packages that comprised community mobilisation and education strategies and home visitation by CHWs managed to reduce neonatal, perinatal deaths and stillbirths significantly [124]. In one study where community mobilisation was added to home-based neonatal care and where 50% of the visits were carried out in the first week of life, a 44% reduction in neonatal deaths was observed [124]. Interventions consisting of antepartum newborn care and breastfeeding education to mothers doubled rates of initiation of breastfeeding [124].

### Country large scale CHW programmes

Probably the best experiences of using CHWs in achieving the MDG-4 are found in Brazil and Bangladesh [125]. It is estimated that the Brazilian CHW programme known as Community Health Agents (CHA) programme established in the 1970s has an estimated 222,300 agents providing services to 110 million people. The agents are the backbone of health teams comprising one family doctor, one nurse, one nurse assistant and 6 Community Health Agents [126]. Each team provides comprehensive care including promotion (i.e. breastfeeding, immunization screening for HIV and tuberculosis (TB) and provision of treatment for HIV/AIDS and TB preventive, recuperative and rehabilitative care to an estimated 150 households. All team members are part of the health system, work full time and are remunerated from the Ministry of Health budget [127]. Brazil achieved its MDG-4 target in 2010, years ahead of schedule. The achievement of the under-five mortality of 14/1,000 live births in 2012 is accredited to the Community Health Agents'

contribution [125, 128]. Other health outcomes are also impressive: only 2% of the under-fives were underweight, immunization coverage was 99%, antenatal coverage of at least four visits was 91%, 93% of family planning demand was met and 90% of eligible women received PMTCT services [125].

Bangladesh provides another successful example where a vibrant non-governmental organization (NGO) sector has successfully implemented CHW programmes. The national non-governmental organisation Bangladesh Rural Advancement Committees (BRAC) has 80,000 CHWs providing comprehensive health services (including community-based maternal and child health, family planning, tuberculosis (TB) specimen collection and observation of directly observed treatment (DOT) to 100 million people. In addition the Bangladesh government has another 50,000 CHWs providing services including family planning, immunisation, vitamin A distribution, birth planning and counselling and management of pneumonia and neonatal sepsis [125]. Between 1989 and 2011 Bangladesh reduced the under-five mortality rate by 60 % and like Brazil it has reached its MDG-4 target of 46/1,000 live births [128].

## CHW initiatives in sub-Saharan Africa

There has been extensive use of CHWs in sub-Saharan Africa including Tanzania, Malawi, Kenya, Uganda, Mozambique and Zimbabwe since attaining health for all by the year 2000 strategy [129]. From 1990, CHW services were sought in prevention and treatment of HIV/AIDS and TB [130]. However, much of the work done by CHWs was based on volunteers and many programmes were not supervised or poorly supervised, uncoordinated and rarely evaluated [131, 132]. Hence it was hard to measure the contributions of the CHWs in improving health outcomes.

The comeback of CHWs was prompted by recommendations for task shifting by the WHO to address the huge shortage of human resources for health (HRH) to achieve the MDGs [133]. According to the 2006 WHO World Health Report, globally, 57 countries (36 in sub-Saharan Africa) had critical shortages of human resources for health i.e. each country had fewer than 23 health workers - doctors, nurses, midwives per 10,000 people). This meant that coverage of basic health care could not be achieved [134]. Sub-Saharan Africa has 11% of the world's population but carries 25% of the global disease burden and its share of global health workforce is only 3% [134]. While South Africa has a better ratio of human resources for health with 49 doctors, nurses, midwives per 10,000 people there is inequitable distribution between the private and public sector. More than 80% of human resources for health are in the private sector serving less than 20 % of the population [135]. Another challenge is that many of the human resources for health in South Africa are not providing primary health care [135].

Ethiopia and Rwanda have in recent years recorded improvements in health outcomes and have credited their successes to the CHW programmes [136]. Rwanda's under-five mortality has been reduced from 182 per 1,000 live births in 2000 to 55 per 1,000 live births in 2012. Similarly, the maternal mortality ratio has been reduced from 530 per 100,000 live births in 2000 to 340 per 100,000 live births in 2010 [3]. In Ethiopia the CHW programme has contributed to reduction of the maternal mortality ratio from 950/100,000 live births in 1990 to 350 per 100,000 live births in 2012, and under-five mortality rate from 204 per 1,000 live births to 68 per 1,000 live births [137].

The one million CHWs campaign for sub-Sahara Africa endorsed by the African Union in 2013 intends to train one million CHWs by the end of 2015, as part of the health system, where they will be remunerated and supervised by the relevant ministries or departments of health. They will also be provided with appropriate technology, such as mobile phones, to reach the poorest communities particularly rural communities. Secondly their work will be linked to achieving particularly MDGs 4 and 5 and developing primary health care services [137].

## CHW initiatives and re-engineered primary health care in South Africa

CHW programmes in South Africa are not new. Sidney and Emily Kark conceived the concept of Community Orientated Primary Care in South Africa in the 1940s and the first project was initiated in Pholela Clinic in rural KwaZulu Natal, in collaboration with Edward and Amelia Jali [138]. The Pholela model was rooted in community empowerment and delivery of health care. Local authorities were involved in planning and decision-making of the project [138]. These innovative ideas were abandoned in 1948 when the Apartheid government came to power. However, in the 1970s and 1980s following the Alma Ata declaration and funding from international donors, CHWs continued to offer services in disadvantaged communities through non-governmental organisations [139].

In 1994 when the democratically elected government of South Africa led by the African Nation Congress (ANC) came into power, CHWs were not included in the human resources planning strategy although Primary Health Care (PHC) was endorsed as the best approach to guide health reform. With less funding from donors and lack of support from government, CHW programmes became small but remained visible in KwaZulu Natal where they had support from NGOs and the provincial Department of Health [131].

In the late 1990s due to the challenge of human resources and the escalating HIV epidemic, the visibility and importance of CHWs came to the fore and they offered crucial services related to HIV prevention, treatment and



care. This was quite evident in KwaZulu Natal with the high prevalence of HIV [131]. However, the contribution of CHWs is not well supported with data in South Africa [132, 139].

As the HIV epidemic intensified in all provinces of South Africa NGOs and community-based organisations (CBOs) were mushrooming. These organisations were mostly contracted by the provincial Departments of Health to train, manage and supervise CHWs. While engaging CHWs in a number of HIV/AIDS services and other developmental activities there was frequently lack of coordination of CHW activities by the different NGOs and community-based organisations resulting in confusion and wastage of resources and to some extent poor service delivery [140, 141]. It was apparent that CHW programmes needed guidelines to avoid wastage of resources and to effectively harness the CHW services.

In 2003, various kinds of CHWs were brought together under the banner of an Expanded Public Works Programme, one of the government's poverty alleviation strategies [132]. This new strategy created an opportunity to register four community worker qualifications in terms of the National Qualifications Framework, creating the possibility for career pathways for CHWs as mid-level health workers [131, 132]. The development of the national CHW programme in South Africa has been influenced by economic and socio-policy platforms of the South African government [132, 142]. However, the relationship between the South African government (National Department of Health) and CHWs is still fluid today, even though for more than a decade South Africa has tried to develop a policy for formal engagement of CHWs into the health system. The latest policy has gone through at least five revisions by 2009 and has yet to be finalised [143].

A recent audit commissioned by the National Department of Health indicates that South Africa has a rich resource of an estimated 65 000 CHWs. They include home-based careers (47 121), lay counsellors (9 243), adherence counsellors (2 010), Directly Observed Treatment, Short-Course (DOTS) supporters (2 740) and peer educators (1 810). Most of them are employed by non-profit organisations, which are funded by provincial departments of health. Payment of stipends to CHWs is largely through NGOs contracted by the provincial departments and others through development partners of the government [144]. This model has been deemed poor by the National Department of Health due to "lack of co-ordination and supervision, poor training and absence of documented evidence of impact" [145]. The model is currently being changed in three key aspects (a) deployment of CHWs is being developed and personal attributes of becoming a CHW have been outlined (b) training manuals are being developed to reinforce standardised training and (c) all CHWs will overtime become part of the Department of Health [146]. Some CHWs are now receiving their stipends through the provincial Departments of Health in Gauteng and North West Provinces [147, 148]. Although there are huge teething problems, for the

first time the government is showing its willingness to take over the CHW programme for effective delivery of primary health care in the country.

### **Why Primary Health Care re-engineering?**

In 1994 the African National Congress government initiated a health sector reform and adopted the primary health care approach and the district health system as a vehicle for delivering health care to all. This was following by building a large number of clinics (3 800) across the country [149]. In addition, health care services for pregnant women and children under 6 years of age were given free of charge in all public facilities and a national school nutrition programme to address malnutrition in children was initiated [86, 150]. However, the implementation of the primary health care approach has been weak and this is mainly attributed to the devastating impact of HIV/AIDS and tuberculosis (TB), which have consumed large amount of resources (time, human, financial) [135, 151]. However, these investments have not been commensurate with favourable health outcomes. Although South Africa is a middle-income country the health indicators are worse or more or less similar to those of low-income countries, such as Malawi, Tanzania, Bangladesh and Nepal [128].

Non-improvement of key health indicators prompted the National department of Health to revisit a number of issues: including (i) the principle of primary health care (community participation, prevention of disease and promotion of health which are linked to intersectoral collaboration) (ii) the functioning of the district health system, (iii) and effective strategies for rolling out Primary Health Care services. The rebirth of Primary Health Care (re-engineered Primary Health Care) has also led to revising how the large workforce of CHWs has to be trained managed and supervised [145, 146, 152]. This process led to finding alternative community-based strategies through consultation with countries that have shown evidence that CHW programmes can improve health outcomes in a relatively short time [126].

The South African Department of health has adapted a three-tier priority approach to re-engineering of Primary Health Care based on the Brazilian model [126] and one of them is deployment of ward based Primary Health Care outreach teams whose backbone is CHWs. Since the vehicle of delivering primary health care is the District Health System, primary health care can only be realised if the District Health System is functioning optimally. Hence, the commitment from the National Department of Health to strengthen the District Health System: planning, budgeting, community participation and inter-sectoral collaboration initiatives; functionality of district hospitals and district management teams and their ability to plan, support implement and provide supportive supervision at all levels of the district [146]. Crucial is also the aligning of PHC delivery to the government's response to the health system challenges namely the Ten Point Plan as well as

the Negotiated Service Delivery Agreement for achieving a long life for all [153, 154].

Ward-based Primary Health Care outreach teams will be constituted and each ward will have at least one Primary Health Care team comprising at least one professional nurse, 2 staff nurses and 6 CHWs. Each CHW will be responsible for 250 households. It is anticipated that there will be at least 4000 Primary Health Care teams in South Africa [146] .

## Rationale for this research

In 2010 an estimated 5.6 million people in South Africa had HIV/ AIDS. The HIV prevalence among women attending antenatal care in public facilities in the country was 32.0% (95% CI: 30.7-33.3%) and in KwaZulu Natal 39.5% (95% CI: 38.0-41.0). An estimated 260,280 women needed PMTCT services [111, 155].

The changes initiated between 2008 and 2011 led to major improvements in PMTCT services and uptake in South Africa. From 2008 to 2011 nurses and midwives at primary care antenatal facilities were trained to provide antiretroviral therapy (ART) for eligible pregnant women. The number of babies tested for HIV before reaching the age of 2 months increased from 36.6% in 2008 to 70.4% in 2011. During the same period the number of HIV positive infants decreased from 9.6% to 2.8%. The first national PMTCT evaluation survey in 2010 found that 3.5% of the HIV-exposed babies were HIV positive and this number dropped in the subsequent national survey to 2.7% in 2011 in infants aged less than 2 months [156]. Also the uptake of PMTCT services was high. More than 98% of the pregnant women were tested for HIV and 91.7% of HIV-positive mothers received ARV treatment or prophylaxis [7, 157].

Despite progress in PMTCT of HIV, there are still major challenges regarding the implementation of evidence-based interventions to improve HIV-free survival of children. For example in 2011, an estimated 70.4% of maternal deaths and 50% of all deaths of children less than 5 years in South Africa were associated with HIV infection [156]. Effective and efficient implementation of the PMTCT programme is crucial for reducing maternal and child mortality.

Recently, access to free infant formula was removed from the PMTCT programme and national infant feeding recommendations now correspond to those of the WHO [80, 90]. Understanding the community perceptions towards this change and what value they give to formula feeding is crucial for designing effective and appropriate community-based strategies to promote the recent government initiative to emphasize breastfeeding as a strategy for infant feeding and improved child survival.

South Africa is evaluating the role of Community Health Workers in supporting and promoting a continuum of mother-and-newborn care and improved PMTCT activities. Community-based home visiting newborn care packages, conducted mainly in South Asia, have demonstrated encouraging evidence of the value of integrating maternal newborn and child health care in community settings delivered by CHWs. However, this evidence is lacking in South Africa especially among the resource-constrained peri-urban settings with high HIV prevalence [158]. Furthermore, evidence for effectiveness of multi-skilled and multitasked as opposed to single purpose CHWs is lacking. This information is crucial in contributing to the formulation of a CHW model for South Africa in supporting and promoting a continuum of mother-and-newborn care and improved PMTCT activities within the context of the reengineered primary health care.

# Aim

The aim of this thesis is to explore the perceptions of household members on the value they give to and the social forces behind the early introduction of formula feeding in light of the recent infant feeding policy change, and to assess the effect of a community-based package of maternal and newborn care delivered by Community Health Workers on HIV-free survival and exclusive and appropriate infant feeding up to 12 weeks of age.

Specific objectives are:

1. To explore the perceptions and understanding of households at community level on the policy decision to phase out free formula milk from the Prevention of Mother-to-Child Transmission of HIV programme in South Africa.
2. To explore mothers' and household members' perceptions, understanding of and the value they place on formula feeding, and the factors that drive its use in a peri-urban settlement.
3. To assess the effect of Community Health Workers visits to pregnant and postnatal women on levels of HIV free survival, exclusive and appropriate infant feeding at 12 weeks postnatally, coverage of care and behavioural indicators and levels of maternal depressed mood at 12 weeks postnatally.
4. To analyse the effects of Community Health Workers' visits and counselling on feeding patterns during the first 12 weeks of age, and to study whether these effect vary by maternal HIV status, educational level, or household wealth.

# Methods

## Study setting

All four papers in this thesis are based on studies conducted in Umlazi township on the periphery of Durban, in KwaZulu Natal province. The township has a population of about 1 million people mostly from the Zulu tribe. Both formal houses and informal shelters are common. The informal sections have very high population density and unemployment rate with frequent incidence of violence and crime. HIV prevalence in 2010 was estimated at 41% amongst women attending antenatal public health facilities [111] and the infant mortality was estimated at 42 per 1,000 live births [159]. The health care services are provided mainly by 10 public clinics and Prince Mshiyeni Memorial Hospital.

## Study design, participants and data collection

The first two studies used qualitative methods while papers three and four used quantitative methods, i.e. a community-based trial. Data were collected as indicated in table 2.

Table 2 Design methods, sample size and analysis of the four papers in this thesis

Paper	Study design	Data collection	Sample size	Main analysis
I	Qualitative research	In-depth interviews	11 HIV- positive mothers	Thematic analysis
		Semi-structured questionnaire FGD Semi-structured questionnaire	9 HIV negative mothers 2 FGD (14 grand-mothers) 2 FGD (13 fathers) 2 FGD (13 teenage mothers)	
II	Qualitative research	In-depth interviews	11 HIV- positive mothers	Thematic analysis
		Semi-structured questionnaire FGD Semi-structured questionnaire	9 HIV negative mothers 2 FGD (14 grand-mothers) 2 FGD (13 fathers) 2 FGD (13 teenage mothers)	
III	Cluster randomised trial	Interviews using structured questionnaire	1659 mother-infant pairs intervention arm	Generalised linear models Linear regression models
		Hospital records Dried blood spots (HIV-exposed infants) Patient held cards Measurements (weight and height of infants at 12weeks). Data captured on mobile phones	1902 mother-infant pairs control arm	
IV	Cluster randomised trial	Secondary analysis of data on feeding patterns collected for paper three	1629 mother-infant pairs intervention arm 1865 mother-infant pairs control arm	Descriptive statistics Logistic regression models Stratified analyses

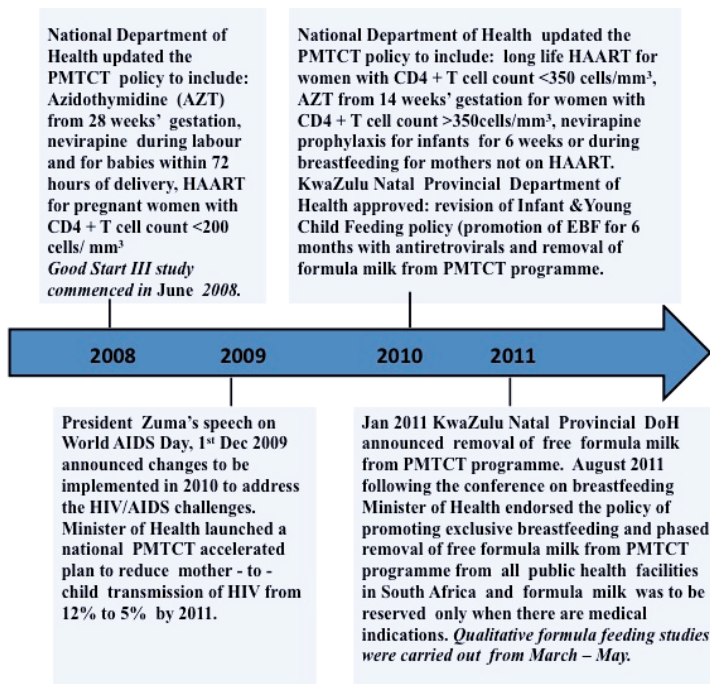


Figure 2. Study timelines in relation to several HIV/AIDS policy changes in South Africa

Figure 2 summarises the major policy change that took place in South Africa during the four studies (context), which may have affected the outcomes of the intervention.

## Papers I & II

### Selection of participants

Participants were purposively selected. We used focus group discussions (FGDs) and in-depth interviews. The applied qualitative research was undertaken to explore the perceptions of the households and community on the free formula policy change and the value they place on the formula feeding. These two issues were considered crucial considering that the study intervention was aimed at promotion of breastfeeding in a country where formula milk was provided free for a decade through public health facilities.

The interviewers recruited participants into the study as per the following recruitment criteria: HIV-positive mothers, HIV-negative mothers, grandmothers and fathers of the babies enrolled in the Goodstart III study were approached for participation. More than 200 participants and their relatives were contacted until the desired sample was recruited. Eleven HIV-positive mothers and 9 HIV-negative mothers, who indicated that they were formula feeding their infants before six months of age participated in in-depth interviews. In addition, 13 teenage mothers (7 HIV-positive and 6 HIV-negative)



from the same trial sample participated in two focus group discussions. Fourteen grandmothers related to the above mothers (seven for HIV-exposed, seven for non HIV-exposed grandchildren) and 13 men (fathers of the babies, seven for HIV-exposed, six for non HIV-exposed infants) participated in four different focus group discussions. This study was conducted from March to May 2011.

## In-depth interviews and focus group discussion tools

Semi-structured guides were developed for the in-depth interviews. These guides were pre-tested in the same community before the start of the study. The in-depth interviews focusing on the knowledge and information about the free formula policy change, source of this information and views of participants on the change, produced data for paper I. For paper II the focus was on the reasons for formula feeding, how mothers accessed formula and challenges and constraints associated with formula feeding. Probing was used to get in-depth information on each of these key questions.

The focus group discussions sought responses to the following key guiding questions: (a) what motivates mothers to use formula milk? (b) How does formula get into the households? (c) What are your views on mothers who formula feed? (d) What do you know or have heard regarding free formula policy change? (e) What are your views on free formula policy change?

Two data collection methods were used because while infant feeding is personal, it is also embedded in the culture and social norms of the community, and hence group discussions were deemed a suitable forum to explore these norms.

## Data analysis

Qualitative data for papers I & II were analysed using thematic analysis as described by Braun and Clarke [160]. Thematic analysis is a systematic yet flexible method for identifying, analysing and reporting patterns and meaning within the data. The analysis was interpretive, with the aim of identifying themes based on the underlying meaning of what the participant had said in opposition to only looking at the surface of the meaning. Data analysis was a continuous process. Analysis was also data driven after each interview or focus group discussion, the interviewers met with the first author Petrida Ijumba (PI) to reflect on the findings. Gaps and new emerging questions were included in subsequent interviews and focus group discussions.

The voice-recorded in-depth interviews and focus group discussions were transcribed verbatim and translated into English. Both the IsiZulu and English versions were read several times by the interviewers/focus group discussion facilitators and Petrida Ijumba (PI) to ensure that the content was retained after translation. The data were then cut into chunks of phrases or sentences and



A baseline survey was carried out in the clusters before randomisation to establish the homogeneity of clusters in key socio-economic indicators as well as to register women of childbearing age in each household. Since no major differences were identified neither stratification nor matching was performed.

## Goodstart III intervention

### **Training of CHWs**

CHWs were trained in Motivational Interviewing [161]. This technique has its origins in psychotherapy and behaviour change theory and it has been used extensively in the addiction field [161]. However, in recent years public health practitioners have drawn on the richness of this technique to address for example, sexual behaviour change, diabetes control, and medical adherence [161].

The strength of this technique lies in assisting individuals to work through their contradictions about behaviour change [161]. The tone of motivational encounter is non-judgmental, empathetic, and encouraging. The counsellor has to establish a non-confrontational and supportive climate in which clients feel comfortable expressing both positive and negative aspects of their current behaviour. The client is expected to do much of the psychological work, and the counsellor to provide guidance [161]. There is generally no direct attempt to dismantle denial, confront irrational or maladaptive beliefs, or convince or persuade. Instead, the goal is to help the client think about and verbally express her own reasons for and against change, how her current health behaviour may conflict with her health as well as that of the infant's and how her current behaviour or health status affects her ability to achieve her health goals or live out their core values. To achieve these ends, the counsellors relied heavily on reflective listening and positive affirmations rather than on direct questioning, persuasion, or advice giving [161].

The CHWs were trained in the intervention over the course of two weeks. The training included the extensive use of role-plays that were video recorded and then used for group reflection teaching and supervision purposes. The intervention was a structured home visiting programme comprising 2 antenatal and 5 postnatal visits with specific content covered at each visit. Infants weighing less than 2500g received two extra visits after discharge from hospital.

The child support grant package in the control arm comprised one visit during the antenatal period to provide the necessary information regarding requirements for a grant application. As grant processing takes a few months, there was a visit at 4-6 weeks postnatally to follow up on the grant application and to assist in resolving any difficulties. At the last visit at 10-

12 weeks CHWs in the control clusters reminded the women to go to the assessment site when their infants were 12 weeks old for data collection.

### **Delivering the intervention**

Women of childbearing age (15 years or older) and pregnant women were identified during the baseline household survey. Women were informed about the study and CHW visits. If the pregnant women agreed to participate in the study then data collectors visited them for signing a written consent form. Inclusion criteria were that women had to be 17 years or older, live in the cluster, be pregnant and intellectually capable of giving consent and willing to be visited by CHWs, supervisors and data collectors. All pregnant women were eligible to receive CHWs visits intervention if they chose to, regardless of whether they agreed to participate in the data collection or not.

Table: 3. Visit schedule and content

Visit no.	Visit contents
Antenatal visit 1	Antenatal care action– immunisations/micronutrient supplementation. Focus on the importance of Voluntary Counselling and Testing (linking this with the PMTCT programme and the benefits of testing to the mother). Emphasise the importance of antenatal care. Key messages on appropriate infant feeding. Encourage EBF in HIV negative women or women of unknown HIV status. For HIV positive women, assist with thinking about infant feeding options. Input regarding infant communication and the mother-infant relationship.
Antenatal visit 2	Birth plan - place of birth, support during labour, care plans if returning to work. Danger signs and emergency plans- this will be done if possible with the family members to elicit their input regarding possible plans in the event of an emergency, including recognising danger signs, emergency transport plan and emergency funds if needed. Home coming arrangements. Follow up and re-emphasis on Voluntary Counselling and Testing, PMTCT, key message on appropriate infant feeding that were provided in antenatal visit one, further discussions in terms of assisting with implementation of chosen feeding option. Additional input on infant communication and the warning signs of post-natal depression.
Postnatal visit1 (24-48 hours)	Assessment of newborn breathing, thermal care, colour, bleeding, neonatal eye care, checklist of danger signs. Assessment of mother-bleeding, signs of infections, mastitis. Early recognition of illnesses (superficial and systemic) and help seeking. EBF and appropriate infant feeding support. Hygienic cord care and what to expect regarding when the cord will fall off. Thermal care, skin-to skin care and Kangaroo care if needed in preterm babies. Ensure that babies of HIV positive mothers have received nevirapine. Information about warning signs for mother and baby and what to do. Support women who have the blues.

Postnatal visit 3 (10-14 days)	Early recognition of illness (superficial or systemic) and help seeking. On going monitoring of breastfeeding or other appropriate feeding. Information about warning signs for mother or baby and what to do. Promote attendance at clinic for 6 week's visit for mother to have access to family planning and baby to receive immunisations and the babies of HIV+ women to receive cotrimoxazole and HIV testing. Mother infant interaction modelling and communication input. Assess for signs of postnatal depression.
Postnatal visit 4 (3-4 weeks)	Early recognition of illness (superficial or systemic) and help seeking. On going monitoring of breastfeeding or other appropriate feeding. Information about warning signs for mother or baby and what to do. Promote attendance at clinic for 6 week's visit for mother to have access to family planning and baby to receive immunisations and the babies of HIV+ women to receive cotrimoxazole and HIV testing. Mother infant interaction modelling and communication input. Assess for signs of postnatal depression.
Postnatal visit 5 (7-8 weeks)	Further input on feeding including advice regarding weaning. Infant weight from clinic card (6 week visit). Mother infant attachment. Checklist of signs of postnatal depression. Has the child been tested for HIV at six weeks and receiving cotrimoxazole? Formula sustainability for HIV positive women using formula milk. Family planning and counselling. Input on milestones and information and specific skills about the stimulation of infants.

## Levels of outcomes assessment

### Primary outcomes

Primary outcomes of the study at 12 weeks after delivery were: levels of HIV-free survival and levels of exclusive and appropriate infant feeding.

### Secondary outcomes

These included: (a) uptake of a postnatal clinic visit within 7 days of life (b) coverage of care and behavioural indicators (antenatal HIV testing, uptake of cotrimoxazole amongst HIV-exposed infants at 12 weeks, family planning uptake at 12 weeks, two-week prevalence of diarrhoea at 12 weeks and (c) post intervention levels of maternal depressed mood at 12 weeks postnatally.

## Data collection procedures, data capture and management

Data collectors received a three-day training on data collection, standard operating procedures specific for data collection and interview techniques.

The study questionnaires were adapted from those used in a previous breastfeeding intervention trial undertaken at the same site [105]. Modifications were also made to allow the data to be collected using mobile phones. Data collectors blinded to arm conducted interviews at 12 weeks postnatally.

Data on HIV test results, CD4 count, and PMTCT medications were extracted from patient held cards (Road to Health Chart and Antenatal Care

Card). Delivery and postnatal data, including date of birth, birth weight, birth complications, access to vitamins, mother's TB and HIV test results, and immunisations were extracted from hospital records.

Dried blood spots were collected from HIV-exposed infants. Each mother or caregiver was requested to provide signed consent to obtain blood from the heel of the infant. Blood was collected using the Standard Operating Procedures developed by the study. All dry blood spots were transported daily to the Global Clinical and Viral Laboratory in Durban for deoxyribonucleic acid polymerase chain reaction (DNA PCR) test. Verbal consent was obtained from each mother or care giver to take the weight and the length of the baby. The weight and the length of babies were measured using Standard Operating Procedures developed by the study. During the interviews data were collected on socio-demographic characteristics, infant illness and hospitalisations and pneumonia and diarrhoea two-week recall. Data were also collected on maternal health and previous child mortality. Depressed mood was determined with the Edinburgh Postnatal Depression Scale [162].

The data collector manager, data quality manager and the project manager conducted daily data quality control. Community health workers received feedback on their work from the supervisors on a regular basis. Separate community health worker (by arm) and data collectors' bi-weekly meetings were held to sort out issues related to data collection and quality. Mobile phones were used to collect data and monitor intervention delivery [163]. Infant feeding pattern was based on dietary recall of 19 foods for the past 24 hours, 7 days and since birth.

Table 4. Definition of variables

<b>Name of variable</b>	<b>Definition</b>
Uptake of a postnatal clinic visit	Mother and infant receiving care from a public health clinic within the first 7 days after delivery
Antenatal HIV testing	Mother receiving an HIV test during her pregnancy
Uptake of cotrimoxazole	Mother reporting having a supply of cotrimoxazole in the house on the day of the 12 week postnatal outcome visit interview
Family planning uptake	Mother reporting using both a hormonal and a barrier (condom) method of family planning at 12 weeks postpartum
Diarrhoea prevalence	Two week maternal recall of three or more loose, watery or liquid stools in the two weeks prior to the 12 week interview
Depressed mood	Mother had a score of 13 or above on the Edinburgh Postnatal Depression Scale

Table 5. Definitions of infant feeding patterns

Type of infant milk / food	Definition
Breast milk	Exclusive breast feeding: Feeding the baby with breast milk or breast milk and medicines but the baby did not receive other food (solids or liquids)
	Predominant breastfeeding: Feeding the baby with breast milk and other fluids including water, water based drinks, fruit juices and medicines but the baby did not receive non- human milk or solids
Formula milk	Exclusive formula feeding: Feeding the baby with formula milk or formula milk with medicines but the baby did not receive other foods (solids or liquids)
	Mixed formula feeding: Feeding the baby with, formula milk, other foods (solids or liquids) but no breast milk (medicines allowed).
Breast milk & formula	Mixed breastfeeding: Feeding the baby with, formula milk, breast milk, and other foods (solids or liquids) (medicines including traditional medicines allowed)
No breast-milk or formula milk	Other feeding: Feeding the baby with solids or liquids, but no formula milk or breast milk (medicines including traditional medicines allowed)

### Data analysis (papers III & IV)

In paper III generalised linear models were used for binary outcomes to estimate risk ratios of the intervention relative to the control arm. Linear regression models were used for the continuous outcomes to estimate mean differences between the arms. To adjust for the cluster design the standard errors of the statistical effect measures of both regression models used were estimated using a robust cluster variance approach. This approach is appropriate given the number of clusters in the study (n=30). The 95% confidence intervals (CI) estimated, therefore, reflect the cluster design. The homogeneity of the intervention effect was evaluated across HIV exposure status of the babies by including an interaction term (group by exposure) in the regression models and estimating exposure specific effects if the interaction effect was significant. Stata 12 was used for the statistical analysis.

In paper IV, a socio economic status variable (asset score) was created with principal component analysis (PCA) based on 16 binary asset items, including access to electricity, piped water in the house, piped water in the yard, piped public water, other water; ownership of a car, refrigerator, radio, television, stove, telephone/cell phone; type of cooking fuel commonly used

by the household i.e. wood, charcoal/gas, paraffin, electricity and the number of people living in the household.

The principal component analysis was performed in order to organize the data by reducing its dimensionality with as little loss of information as possible in the total variation these variables explain. Eigenvectors (weights) were subsequently derived from the correlation matrix. The eigenvalue (variance) for each principal component indicated the percentage of variation the total data explained. The output from the principal component analysis was a table of factor scores/weights for each variable, which was then multiplied with each asset variable and summed to derive the socio economic status score. This socio economic status score was then categorized into tertiles with cut-offs at the 33.33 and 66.67 percentiles creating a socio economic status score with three categories.

The outcome variables assessing feeding methods particularly EBF were described by HIV status, social economic status and level of education or years of education of the mother, in order to evaluate whether the effect of the intervention was similar or differential in these different strata. Pearson's chi-squared odds ratios and Mantel-Haenszel (MH) stratum-specific odds ratios were examined where it was hypothesized that a particular variable might modify the effect of the intervention on the outcome.

Exposure variables (intervention), potential confounders and interaction terms that were found to be significantly associated with EBF in crude and stratified analysis were forward-fitted to a logistic regression model to calculate adjusted odds ratios. The likelihood ratio test was used to test the overall effect of each variable in the model, and those that significantly ( $p < 0.05$ ) improved the fit of the model were retained. The Wald test was used to test the significance of the odds ratios at each level within the variable. Stata 12 (Stata Corporation, College Station Texas, United States of America) was used for computation and analysis.



# Ethical considerations

For papers I & II we obtained ethical approval (10/09/29) from the University of Western Cape Senate Research & Ethics Committee and acquired informed consent for all focus group discussions and in-depth interviews. In order to preserve anonymity, codes were used to identify individuals in focus group discussions and in-depth interviews. In the in-depth interviews, the code denoted the participant's identification letters, the HIV status and age in years. In focus group discussions the code denotes the category of the group, the number, the identification letter for the individual in the group and the age in years. For the teenage mothers their HIV status was used to identify the group. All participants were compensated for time.

The ethics review board of the Medical Research Council (EC08-002) approved the study for papers III & IV. We also established a Community Advisory Board (CAB) that consisted of local stakeholders. The role of the Community Advisory Board members was to understand the operations of the Goodstart III intervention and provide a channel of communicating between Goodstart III and the community, traditional and civil leaders. In addition it held regular meetings with the community to obtain their views on Goodstart III and advise Goodstart III on matters that concerned the project such as crime in the community.

In order to safeguard the participants' identity we used identification numbers instead of names. Data collected on cellphones were downloaded as soon as possible on Goodstart III senior staff Personal Computers. Only designated staff had full access to participants' information. Paper trails containing participants' information was kept under key and lock. We requested both verbal and written consents for different activities, which required participants' approval. Participants were made aware that they could withdraw from the study at any time and that this could not affect their rights to access health care services they were entitled to. HIV disclosure was voluntary and we offered on-going counselling services for mothers who did not want to access the public health services for fear of being blamed or turned away or stigmatised. All participants could access the HIV test results for their infants. Participants in the control clusters received child support grant application information, which benefitted them and their infants. Mothers who were eligible for the child support grant in the intervention arm would have accessed it if they applied for it, but the intervention did not assist them to do so. Similarly, mothers in the control clusters and their families had access to

health care (we had similar health facilities in intervention and control clusters). All participants were compensated for their time.

# Results

The key findings in the first two papers indicated ineffective communication on policy change and social forces that drive early introduction of formula feeding. They were also indicative of the complexity of promoting breast-feeding and why it is necessary to understand the contexts in which breast-feeding takes place. Despite these complexities our findings in the last two papers suggest that the community-based package of home-visits for mothers and newborns had a significant effect on improving EBF, mostly in HIV-negative mothers. Details of each of the four studies are included in the four papers in this thesis. The following is a summary of key findings in each paper.

## Participant characteristics (papers I &II)

The majority of the mothers in the in-depth interviews were aged 20-25 years and a third had a high school education. Five had completed high school, four were in tertiary institutions, three were still in high school and one had dropped out. The majority of the fathers were aged between 24-30 years and two thirds had a high school education and approximately the same proportion was employed. The majority of grandmothers were aged between 50 and 59 and three quarters had some high school. The majority of the mothers lived with their mothers and/or grandmothers. In addition, some of the teenage mothers had mothers who had been teenage mothers as well.

## Communication of free formula policy change (paper I)

This paper demonstrates a missed opportunity to effectively communicate a major policy change in infant feeding in South Africa. The thrust of phasing out free formula milk is to give credibility to promoting, protecting and supporting breastfeeding; which if practised optimally, could maximise not only HIV free infant survival, but also reduce other diseases such as diarrhoea and malnutrition in all infants and reduce under-five mortality. However, mothers and their significant others perceived the policy change to be due to abuse of, and a dysfunctional free formula milk policy. Interpretations of the phasing out free formula policy milk ranged from having too many mothers

who depended on the formula milk, to formula milk being stolen or not delivered to the clinics and to prevent mothers falling pregnant to receive free milk.

Miscommunication was not only at the level of individual mothers or their households; respondents indicated that nurses at several clinics were not well vested in communicating the policy change. Multifaceted communication channels deemed to be appropriate to communicate this policy change were recommended by study participants.

## The social value of formula feeding (paper II)

The second paper highlights the need to engage with communities in understanding the social forces in which infant feeding takes place. Breastfeeding demands engaging many role payers other than the mother-infant dyads, as well as addressing the needs of teenage and working mothers. Secondly, mothers fear in practicing EBF for 6 months remains a major challenge. Thirdly, formula feeding addresses many social and structural needs of the community as illustrated below. Promoting breastfeeding will largely depend on how these key factors are addressed by the health sector in collaboration with other relevant players and communities.

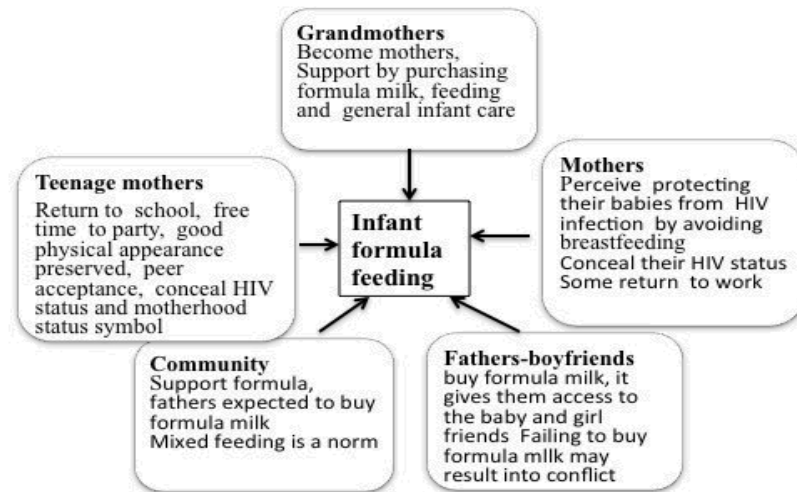


Figure 4. The value of formula feeding as expressed in paper II

## Goodstart III (papers III & IV)

### Description of intervention and control participants

From June 2008 to December 2010, a total of 1894 and 2243 intervention and control women, respectively, were approached in their homes for study participation by CHWs. Of these 65 (28 intervention and 37 control) were deemed not eligible (e.g. false pregnancy, underage, mentally unstable) and 115 (45, 2.4% intervention and 70, 3.2% control) refused participation in CHW visits and/or data collection.

Therefore, 1821 intervention and 2136 control mothers were eligible for participation and signed informed consent for data collection and follow-up. Mothers in both arms had a median age of 23 years, the vast majority were single, and almost all had electricity in their homes and owned mobile phones. A few baseline differences were noted between the intervention and control clusters. Clusters in the intervention arm were slightly wealthier and more households had access to piped water in their homes.

Loss to follow-up prior to delivery was 1.3% in intervention and 0.8% in control clusters for 1798 and 2119 confirmed deliveries, respectively. Of these 1724 live singleton births in intervention and 2017 in control clusters were eligible for 12-week follow-up assessment. Loss to follow-up after singleton live birth until 12-week follow-up was 3.8% in intervention and 5.2% in control clusters. Included in this loss were 8 neonatal deaths, 2 post neonatal deaths and 7 maternal deaths that were confirmed deaths but were not assessed at 12 weeks. A total of 1659 intervention and 1902 control mother-infant pairs were assessed at 12 weeks postpartum (interview, anthropometry, blood testing) of whom 34 were neonatal deaths, 28 post neonatal deaths and 5 maternal deaths, leading to live mother-infant pairs assessed at 12 weeks of 1629 intervention and 1865 control. There were no observations of serious adverse events or unintended effects of the intervention.

### Effect of the intervention on outcomes (paper III)

At baseline there were slight differences between the control and the intervention arms. However, these were marginal and they did not confound the outcomes. The intervention doubled the prevalence of EBF at 12 weeks postpartum, 430/1373 (29%) compared with control 252/1693 (15%), risk ratio (RR 1.92, 95% CI: 1.59-2.33). There was an interaction between mothers HIV status and EBF; therefore, results from this outcome were stratified. The intervention appeared to have a slightly larger significant effect amongst HIV-negative mothers 300/968 (30.1%) (RR 2.16, 95% CI: 1.71-2.73). The intervention had no effect on HIV transmission or HIV-free survival among HIV positive women at 12 weeks. Nevertheless, positive significant effects

in the expected direction were observed in HIV-exposed infants including HIV testing at 6 weeks (67% vs. 74%, RR 1.10) and cotrimoxazole present in the house at 12 weeks postpartum (37% vs. 43%, RR 1.17, 95% CI: 0.99-1.37). In addition, the intervention had some effect on 12-week infant weight-for-age (difference +0.09 SD, 95% CI: 0.00–0.18) and length-for-age z-score (difference +0.11SD, 95% CI: 0.03–0.19) [164].

No differences were found between intervention and control arms regarding antenatal HIV testing. Twelve week maternal report of diarrhoea prevalence was high (20%) in both arms. There was no difference for dual protection methods for family planning, disclosure of HIV status or maternal postnatal mood. Women in the intervention arm were more likely to report making preparations for birth. They were also more likely to have knowledge of newborn danger signs and to take their infant to the clinic within the first week of life.

About 40% of women in the intervention arm received all seven visits from CHWs and 58.7% (957/1629) received the first postnatal visit (72.6% of those were within 48 hours of discharge from hospital after birth). More details on other outcomes can be found in paper III attached to this thesis.

## Effect of the intervention on feeding patterns (paper IV)

As mentioned above, a few baseline differences were noted between the intervention and control clusters. Given the focus on infant feeding outcomes in paper IV, adjustments for these factors were done in order to manage the possible confounding. Control clusters were poorer and intervention clusters had better access to piped water in the house. These differences were adjusted for in all analyses. A total number of 1242/1659 (76 %) in the intervention clusters and 1380/1865 (74%) of the women in the control clusters introduced their babies to breast milk after birth, but only 561(34.4%) in intervention clusters and 607 (32.6%) in control clusters initiated breastfeeding within one hour. There was no difference in the timing of initiation of breastfeeding between study arms.

The intervention resulted in significant effects on infant feeding pattern at 12 weeks post-partum: EBF was doubled, exclusive formula feeding increased, predominant breast-feeding was also increased, mixed formula feeding was reduced as well as mixed breastfeeding. However, the effect of the intervention on exclusive breastfeeding at 12 weeks of age was stronger in the HIV-negative group of mothers as compared to the HIV-positive ones. The reduced risk of mixed formula feeding in the intervention arm was statistically significant only in the HIV-positive stratum.

The intervention did not have any differential effects on infant feeding outcomes at 12 weeks of age in subgroups defined by household asset score levels or maternal education levels (test for interactions, all  $p > 0.10$ ).

# Discussion

The first two papers illustrated the complexities of promoting breastfeeding in a high HIV prevalent community where formula feeding is the norm. They also show the importance of understanding the context of the community in evaluating community-based randomised trials. While paper III and IV indicate that the intervention was effective in doubling EBF and increasing predominant breastfeeding and exclusive formula feeding; and reducing mixed breastfeeding and mixed formula feeding. The misunderstandings of the reasons for the policy change and the social value of formula feeding in the study area may have contributed to the low effect of the intervention among HIV-positive mothers. By identifying and understanding these challenges, it is possible to engage the community in designing strategies to improve the outcomes of the intervention for better planning of maternal, newborn and child health care in South Africa [165, 166].

The discussion sections of the four papers discuss in detail the finding of each study. Therefore, the discussion below will focus mainly on three aspects. First, the methodological considerations, trustworthiness, validity and reliability will be reviewed. Then the following issues will be discussed in the context of the theoretical framework defined earlier,

- a) the importance of effective communication of policy change, and
- b) implications of the social value of formula feeding in promoting breastfeeding.
- c) key findings in papers III & IV

## Methodological considerations

### Relevant policy changes in South Africa 2008-2011

During the study period there were two PMTCT programme policy updates mainly regarding antiretroviral prophylaxis to pregnant women and newborns. The updated 2002 PMTCT guidelines were officially launched in February 2008, and their implementation commenced in April 2008. The 2008 guidelines were updated in 2010 with a switch to WHO option A regime, based on 2009 WHO Guidelines [79] supported by a directive from Present Jacob Zuma in 2009 on World AIDS day [112]. In 2011 the provincial Department of Health in KwaZulu Natal discontinued the provision of

free formula milk in its PMTCT programme (Figure 2). This policy change was based on the 2010 WHO Summary of Evidence for Revised Principles and Recommendations on HIV infant feeding. Studies show that the mortality rates due to mother-to-child transmission of HIV were reducing throughout the study period, particularly in KwaZulu-Natal, from 8% in 2008 to 3.5 in 2010 in infants aged 4-8 weeks [7]. Similarly, in KwaZulu Natal service provider initiated HIV testing increased testing among women attending antenatal care, which reached a coverage of 97.6%. In addition, by 2010 there was 92% coverage for either maternal HAART or prophylaxis in HIV-positive women in South Africa[157]. These changes may have impacted on the cluster randomised trial outcomes particularly the finding of similar HIV free infant survival in both arms.

## Research methods, trustworthiness, validity and reliability

The research carried out in this thesis employed both qualitative and quantitative research.

### Papers I&II

A semi-structured research guide was developed in English by the main author and received inputs from senior researchers. A professional translator as well as the interviewers who were both fluent in English and IsiZulu translated the guide into isiZulu. The two versions were compared and an agreement on the differences was reached; and the agreed on version was piloted using participants from the same area of the study. Any unclear questions were adjusted and a revised version of the research guide was used to collect the data. The data were transcribed into isiZulu and translated by the professional transcribe and translators as well as the interviewers. The daily review of data was based on the feedback and reflection given by the interviewers. The researchers had worked with the two interviewers for more than three years. Also, the author of this thesis is not a born South African, but has lived and worked in KwaZulu Natal for 18 years. Although being still an outsider but being a black African relating to some of the cultural practices and norms is possible, and the author speaks and understands some isiZulu. Being an outsider was also a strength, because it allowed for asking of questions to get clarity on pertinent issues, which were regarded as 'normal' or 'usual' by the interviewers. In addition, the author participated in all in-depth interviews and focus group discussions and gained insights into the responses to the questions.

Qualitative approaches, focus group discussion and in-depth interviewing were deemed suitable for papers I & II because the aim was to explore perceptions of the mothers and their household members as well as the fathers of the infants. This is normally achieved by engaging in a dialogue either with a group of people through focus group discussions or through an indi-



vidual (in-depth) interview. These methods give space to the respondents to talk freely, reflect and engage on issues that are deep rooted and sometimes sensitive and not easily accessible through filling in questionnaires or answering yes /no or counting numbers. For example, we wanted to know how formula gets into the households, why formula feeding is so important and perceptions regarding the policy decision to phase out free formula milk. We combined the focus group discussion with in-depth interviewing to address individual and more personal issues such as mothers' struggle with HIV disclosure and infant feeding, how do their boyfriends treated them, why they avoided breastfeeding and so forth. We also wanted to get personalised views on formula feeding and access to formula milk from the health facilities and how the nurses treated the mothers. In-depth interviews provided an opportunity for mothers to open up and share their perceptions without fear of being victimised.

We explored the understanding and perceptions of the mothers and their households about discontinuation of free formula milk from the PMTCT programme and the value they attached to formula feeding in papers I & II but we did not explore the perceptions of the health facility workers who influence infant feeding. However, at the time it was not possible to obtain an ethical clearance for such a study from the provincial Department of Health.

Throughout the research implementation, care was taken to maintain trustworthiness of the studies. Trustworthiness in qualitative research includes maintaining credibility, dependability, conformability and transferability [167-169]. In order to achieve credibility the researcher engaged regularly with the interviewers throughout the research period. Numerous formal and informal discussions were held to reflect on the findings. Where there were ambivalent understandings clarity was sought from resource persons such as grandmothers, fathers and mothers who participated in the study. The author also spent quality time in the study site interacting with different people in their homes, in shops and on the streets. In addition, all interviews and focus group discussions were recorded and were backed up with hand written notes. After each interview or focus group discussion the researcher and the interviewers had reflection sessions to sort out any challenges and to inform the next in-depth interview or focus group discussions. Being part of the entire research cycle (inception, design, data collection, analysis and interpretation and write up) increased the credibility of the studies.

Dependability was achieved by having the same researcher team (one principle investigator) and interviewers throughout the study. We also used the same transcribes and translators. The semi- structured research guides were only modified to include emerging questions deemed important to strengthen the research. The data were transcribed verbatim and translated into English. Both isiZulu and English versions were read several times by

the translators and the interviewers to confirm that content was retained throughout the translation processes. Interviewers had more than five years of data collection experience in both qualitative and quantitative research.

Conformability was ascertained by trying to remain as neutral as possible during data collection and sticking to the perception displayed in participants research responses. We also used open-ended questions, which allowed participants to debate some of the issues that were hard to agree upon. Furthermore, triangulation processes used in the two studies reconfirmed credibility, transferability and dependability. Firstly, triangulation of the results from in-depth interviews and focus group discussions were used to compare findings across data collection methods. In addition, four different groups of participants were included (mothers, fathers, grandmothers, and teenage mothers) and information was compared across these four groups. Finally, the first author Petrida Ijumba (PI) and Tanya Doherty (TD) identified themes independently.

We have described the context of the study area in detail as well as the selection processes for participants and data collection. Reading and studying these processes can guide those who intend to transfer these findings to similar setting.

### **Papers III & IV**

In community-based studies such as health promotion interventions a cluster-randomised trial is considered the most valid approach to investigate the effectiveness of such interventions and to minimise contamination associated with individual randomisation [170]. Therefore we used a cluster-randomised trial design to test the effectiveness of the CHW home visit intervention. Cluster-randomised trials are considered the gold standard for measuring the effectiveness of a community or health system interventions because: (i) this design is superior to other alternatives e.g. individual randomisation) in estimating an intervention's true effect; and (ii) other common study designs-including "pre-post" studies and "comparison-group" or "quasi-experimental" studies without careful matching have a higher risk of producing erroneous conclusions [170-172]. Other strengths of using a cluster-randomised trial include having independent and similar measurement of outcomes in intervention and control areas and a large study population. In addition we used data collectors who understand the Zulu culture, and are isiZulu and English speakers.

The weaknesses of using a cluster-randomised trial design include reduced precision since randomisation is done at cluster level, but data analysis is at an individual level. This means that there is lack of independence among the individuals due to the 'relatedness' within the pre-existing groups, which leads to some loss of statistical efficiency [171]. However, this was adjusted for when calculating the sample size and during data analysis.

Data on infant feeding behaviour is usually collected through self-reporting. Therefore, there is always a possibility that participants may report what they think the researcher wants to hear. However, there was a significant difference in EBF and this suggests that these differences could not be attributed solely to reporting bias. We recruited more participants in the control compared to the intervention clusters. This was mainly due to resignation of CHWs in the intervention arm who found better opportunities elsewhere, during which there were breaks in recruitment.

In order to limit loss-to-follow up and high costs of running the study, infants were followed up for three months and data were collected at a single point. Therefore, the EBF data are not suitable for analysing trends or reflecting on EBF at 6 months. Furthermore, we did not include questions on timing of introduction of solids and other liquids although this knowledge is crucial in developing strategies to support mothers to breastfeed and it is still lacking. The study was conducted in a peri-urban community with a high number of participants having a cellphone and electricity, thus the results may not be generalised to rural setting. Generalisability may be limited to similar township settings in Southern Africa.

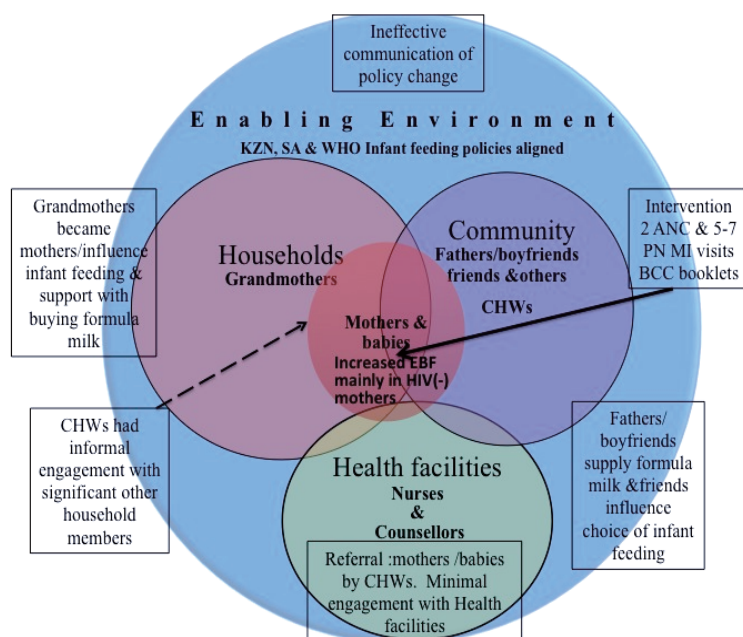


Figure 5. Summary of findings showing the levels of influence of infant feeding in the study and main outcomes

Key for Figure 5: KZN- Kwazulu Natal, BCC- Behaviour Change Communication, ANC- Antenatal Care, PN- Postnatal, MI-Motivational Interviewing, SA- South Africa, HIV (-)- HIV-negative

## Communication of policy change

In order to reduce under-five mortality in South Africa it is imperative that neonatal deaths and paediatric HIV, which drive mortality in children below the age of five years, are addressed with the same tenacity [6, 173]. One of the evidence-based effective interventions is breastfeeding, particularly exclusive breastfeeding by all mothers for the first 6 months regardless of their HIV status [174, 175]. The removal of free formula from the PMTCT programme in South Africa was a land-mark change in the infant feeding history of South Africa during the HIV/AIDS era. It is supposed to create an enabling environment for promoting breastfeeding since the provincial, national and international policies are now aligned (Figure 5). However, despite the scientific evidence of multiple studies in several sub-Saharan Africa countries showing that EBF with antiretrovirals to the mother or the mother and the infant offer the best infant feeding option in HIV-exposed babies, this change in policy has been received with mixed views. On the one hand, there is optimism of getting mothers to optimally breastfeed regardless of their HIV status using public health approaches [90] or more innovative strategies [176]. On the other hand, there is scepticism about operationalizing the change due to the momentous task of addressing other pertinent issues linked to EBF [11, 84]. The challenges cited include the social structural and contextual factors that drive formula feeding, adherence to infant antiretroviral regimes, as well as the cultural barriers to practise EBF [11, 84]. Our study found similar challenges. These are real challenges that need to be discussed by policy makers and implementers and addressed and shared with the public as part of the policy change implementation.

While planning and consultations at policy-making level is of vital importance for policy change, so is the harnessing of buy-in from communities and in particular, the primary members affected by the change [166, 177]. Effective communication on policy change should engage all stakeholders as illustrated in Figure 5. Research shows that effective communication on policy change should be done at the right time. Stakeholders should communicate similar and accurate messages that are appropriate for the different audiences, as well as use appropriate channels of communication [178].

Results from our study show that policy change communication was ineffective at all levels illustrated in Figure 5 (i.e. households, community, health facilities and more importantly, to the mothers whether enrolled in PMTCT programmes or not). The communicated messages through newspapers, radio and TV were not explicit and were not followed by a dialogue between mothers in the PMTCT programme or their households or their communities by the policy change implementers (i.e. health facility personnel).

It seems there was a big gap in understanding the objectives of the discontinuation of free formula milk (policy change) between the policy makers at

the KwaZulu Natal Provincial Department of Health and policy implementers notably the frontline health workers in the health facilities and the communities they serve (Figure 5). The nurses and the breastfeeding counsellors at each health facility were not equipped with clear and similar messages on the rationale for policy change. For example while it was clear at a policy level that all mothers who were already receiving free formula milk could continue to receive it until their babies were 6 months old and that formula milk was not to be issued to new mothers [179], the interpretation at the operational level (clinics) was different. Mothers of newborns in the PMTCT programme were given free formula milk after the policy change while mothers of older babies but less than 6 months were told to purchase formula milk for their babies.

At the household level (i.e. mothers, grandmother and fathers or boy-friends) the reasons for discontinuation of free formula milk from the PMTCT programme were not clear even though the households were the primary beneficiaries of free formula milk and grandmothers and fathers in these households were key influencers of infant feeding. Thus mothers, household members and the communities at large resorted to their own interpretation of why the policy was changed. Other studies show that suspicions and mistrust may derail the policy change implementation [180]. Lack of effective communication was possibly due to the sensitivity attached to the policy change at the time. While the intention behind the issuing of free formula milk was to assist HIV positive mothers who chose not to breastfeed and could not afford to purchase formula milk over the years issuing of formula milk was plagued with corruption [181].

This was also a missed opportunity to market “the breast milk brand” proposed by Coutsooudis, Coovadia, & King, by reflecting and debating the consequences of formula feeding and mixed breastfeeding and their relationship to diarrhoeal diseases, malnutrition, pneumonia and as well as the benefits of exclusive breastfeeding for the first six months of life and its relationship to child survival even in the context of HIV [93].

The challenge of understanding the policy change does not only create confusion among mothers or their households and communities, but among health workers as well. In Malawi the challenge of translating the policy change into practice was met by poor knowledge and understanding of the policy. It was also difficult to find enough time to engage very busy health workers in information crucial for implementing the policy change. Another challenge was that it created tension among health workers who found difficulties in implementing a policy, which was shallow in terms of contextual issues that force HIV positive mothers to breastfeed beyond 12 months subjecting them to social exclusion and stigmatisation [182, 183].

While this thesis did not assess the perceptions of health workers, the scenario in South Africa may be similar to that of Malawi. The scientific evidence, which is the basis of change remains mainly in the domain of re-

searchers and may not be clear to many of the frontline workers who are the agents of change in their communities [184]. Thus, there is a need to simplify and communicate the change in an understood language to harness the contributions of frontline workers in policy change.

Overestimation of the risk of mother- to- child transmission during breastfeeding in HIV positive mothers by nurses and by HIV positive mothers has been reported [185, 186]. In South Africa, some health workers may be complacent to embrace change due to the perceived risk of HIV transmission coupled with a long period of counselling HIV positive mothers to use formula milk. Thus workers may require systematic supportive supervision in order to implement policy change [184]. The lack of role models in the households and among health workers in health facilities to support the policy implementation creates another challenge.

South Africa's new infant and young child feeding policy has incorporated the 2010 WHO's recommendations and the 2013 South African "Regulations Relating to Foodstuffs for Infants and Young Children, based on the International Code of Marketing of Breast milk Substitutes and World Health Assembly Resolutions" [90, 187]. However, frontline workers will most likely require a guide on steps to take in handling the complex social, structural and contextual issues, which are likely to challenge EBF in general and in particular among HIV positive mothers (for example what strategies and support are available to assist mothers to EBF in the absence of disclosing or resistance to change by grandmothers). Similarly the day-to-day practical challenges that come with breastfeeding such as what to do if the mother gets ill and is unable to breastfeed, or develops breast problems or has to leave her child with someone else. These challenges may need to be addressed by both the health facilities and the communities they serve in collaboration with the policy makers and leaders at all levels of the health system [140].

Giving a chance to communities and health workers, particularly those working in the clinics, to share their experiences, to have their voices heard and their concerns addressed, is another way of creating buy in and accessing vital information needed to design culturally appropriate strategies for change [85, 165, 184]. Steps to be followed in implementing policy change need to be planned not from the top to the bottom but from the bottom to the top as well in order to manage the change process as illustrated in Figure 6 [179, 180, 188].



Figure 6. Cycle of managing the change process

A comprehensive user-friendly communication strategy using principles from social marketing [177, 178] to inform health workers and the communities of the basis for change is needed. The communication strategy should cover key points such as: (a) why formula milk is not the same as breast milk (b) why formula milk was introduced in the PMTCT programme (c) why it took 10 years to discontinue provisions of free formula milk (d) what lessons we have learned in those 10 years (e) why we are promoting breastfeeding now (f) why women should not breastfeed and formula feed at the same time in the first 6 months of life, (g) what EBF is and (h) who should exclusively breastfeed for 6 months? Similarly information on risks and benefits associated with different feeding patterns would be useful.

## Social value of formula feeding

Breastfeeding is an intimate behaviour and there are many personal factors that influence its practice such as confidence, commitment and HIV status [119, 189]. The paradox is that many mothers acknowledge the benefits of breastfeeding, however their knowledge is not translated into practice [58, 109, 190]. While initiation of breastfeeding is common in South Africa [108], many studies conducted in the country show that EBF like exclusive formula feeding are concepts that are not well understood or many mothers have difficulties in accepting them to be viable infant feeding strategies for 6 months [25, 96, 106, 107, 117].

Most likely these difficulties arise because they contradict the norms and practices of mixed feeding at the household and community levels [11, 84, 85]. Similarly, many health care providers work within the context of culture that strongly believes in mixed feeding. Thus most of the nurses also tend to agree with the mothers regarding milk insufficiency, early introduction of solids, and formula feeding [83, 185, 186]. Our study indicates that both health care workers and the communities they serve need support in addressing the barriers associated with EBF.

In our study we found that due to social circumstances such as teenage pregnancy, returning to school or work, maintaining teenage life styles and physical looks (avoiding sagging breasts), fear of postnatal HIV transmission through breastfeeding as well as expectations of the community (i.e. mixed feeding is a norm), fathers are tasked with purchasing formula milk) were some of the reasons why formula feeding is highly valued as illustrated in Figure 4. Similar findings have been reported elsewhere [191, 192].

While counselling on infant feeding by health care workers in South Africa involves mothers and occasionally fathers, our study shows that grandmothers, fathers or boyfriends and peers (particularly among teenage mothers) play a major role in influencing infant feeding practices as illustrated in Figures 4&5. This influence is translated by the role of infant feeding and general caring being taken over by grandmothers and the role of purchasing formula milk taken over by fathers/boyfriends. This means that strategies geared to promoting EBF ought to engage the significant others in households and communities (Figure 5) [190].

A small study of 14 mothers undertaken in the Eastern Cape in 2013 indicated that with continuous reliable and trusted support mothers can EBF [176]. The study investigated the concept of 'feeding buddy' as a support system for mothers. The key message from that study was that the pregnant woman was responsible for selecting the 'buddy' she trusted and the buddy had to commit to be available to attend antenatal care with the pregnant woman and provide practical support in breastfeeding as well as advocating for the mother in the household or community [176]. The mothers who participated in this study identified three categories of people as possible buddy candidates; the mother or sister of the pregnant woman and boyfriend.

Although South Africa's fertility rate (2.34 children per woman of child bearing age) [193] is one of the lowest in Africa, teenage pregnancy is still a major concern particularly in black and coloured teenagers [194]. It is estimated that 30% of all pregnancies are teenage pregnancies [195]. Many reasons have been associated with teenage pregnancy, ranging from lack of a father figure in a household to gender violence and prevailing gender norms [195-197]. Recent studies show that, although teenage pregnancy is viewed negatively in the townships, parents uphold the ideal of not discussing sex with their teenage daughters creating a fertile ground for teenage pregnancies [194]. It is also possible that teenage mothers may be put off from seek-



ing support on use of contraceptives, care in pregnancy and infant feeding from health professionals due to fear of being ridiculed or reprimanded [198].

Our results show that out of the 3957 pregnant women who participated in the community-based trial approximately 910 (23%) were teenagers. Teenage mothers influence each other to formula feed. They equally influence each other in taking up the role of motherhood, which ends up being grandmother's and/or great grandmother's role (Figure 5). Similar finding have been reported by Nelson & Sethi [192]. Teen girls' returning to school constitutes another reasons for formula feeding. While the South African Constitution and Schools Act of 1996 as well as the 2007 Department of Education guidelines advocate for the right of pregnant girls to remain in school, they are silent on the best way to protect the nutritional needs of the infant for the first 6 months of life [199, 200]. In our study, some girls returned to schooling as early as one month after delivery and for them, this justified formula feeding.

It is possible for teenage mothers to breastfeed particularly if they have their mothers' continuous support [201]. The role of grandmothers in infant feeding in sub-Saharan Africa is well documented [202-204]. In South Africa this role is even greater as mentioned above. Grandmothers frequently take over this role completely as illustrated in Figures 4 & 5. Therefore, there is a good opportunity to use the grandmothers to support breastfeeding instead of supporting formula feeding. This also means that the current model of infant feeding counselling by health care workers which is directed at mothers and excludes grandmothers and fathers who often provide crucial support for infant feeding needs to change.

The community has influence on households and the mother's infant feeding decisions as shown in Figure 5. Studies in South Africa and Malawi show that implementation of WHO recommendations on infant feeding in the context of HIV is not easy due to the influences of households and communities [96, 119, 182, 183]. Community norms, social and structural set up may challenge the confidence of the mother to exclusively breastfed [11]. Community members' breastfeeding behaviour and reactions to breastfeeding influence the infant feeding choices made by households. For example, a cultural practice of giving an enema with soapy water to infants to cleanse the infants 'insides' or traditional medicine (muthi wenyoni) to protect the infant against evil spirits may interfere with mother's intentions to EBF [117]. It is also important to acknowledge that the concept of exclusivity in infant feeding is not rooted in cultural norms of Umlazi. Therefore regular and sustained practical support may be needed. Despite these challenges, promotion of EBF for the first 6 months of life remains a viable and effective intervention for child survival in all mothers regardless of their HIV status. Therefore, strategies that can engage mothers, their households (grandmothers and fathers/boyfriends), the community at large and the

health facilities that serve them in a dialogue on infant feeding and child survival are needed.

### Effect of the intervention on outcomes (paper III)

In paper III results showed that a community-based trial, which used the services of CHWs to conduct door-to-door home motivational interviewing visits almost doubled the prevalence of exclusive breastfeeding. The intervention however, had no impact on HIV-free survival. We recorded improvements in secondary outcomes, such as infant weight-for-age and length-for-age, knowledge of newborn danger signs, clinic visits within the first week of life, testing for HIV-exposed infants at 6 weeks and availability of cotrimoxazole in the house at 12 weeks postnatally [164].

The high and similar rates of HIV-free survival at 12 weeks in the intervention and control arms may be due to several HIV/AIDS and PMTCT policy changes that took place from 2008 to 2010, which are summarised in Figure 2 and discussed in detail in the methodological consideration section in this thesis. Research carried out in Kwazulu Natal province in 2009-2010 reported that 97.6% of women who were attending antenatal care had an HIV test. In addition, many HIV positive women (92%) had access to either highly active antiretroviral therapy or prophylaxis in South Africa [157].

The prevalence of exclusive breastfeeding in this study was three times the prevalence reported by the latest South Africa Demographic Health Survey and higher than that reported from the PROMISE-EBF trial where peer supporters focused entirely on breastfeeding counselling [105]. The higher EBF prevalence may be explained by the fact that the intervention commenced contacts with women during pregnancy and we paid extra attention to the early postnatal visits particularly the 24-48hours after a mother's return to her home (58% of women receiving the first postnatal visit, 72.8% of those in the first 48 hours) while PROMISE-EBF started counselling visits later in the first week after birth [105, 164]. Studies have shown that a home visit as soon as possible after a mother and baby return home is crucial for maternal and neonatal health and survival [205]. Since South Africa has a high rate of health facility deliveries and more than 90% of the women own a cell phone it is possible to institute a notification system between the health facility and the CHWs as part of discharge protocol in all facilities [164].

Also motivational interviewing may have increased the behaviour change outcome possibly due to its client centeredness and dialogue approach [161]. Furthermore, CHWs informal contacts with significant others in the households as illustrated in Figure 5, may have assisted the mothers to sustain their infant feeding choice. The higher prevalence of EBF attained by multi-purpose CHWs (they delivered an integrated package of care) implies that CHWs can be efficient and effective in providing continuum of care in ma-

ternal newborn and child health care services. They can also provide a needed crucial link between the community and the health facilities in the envisaged re-engineered primary health care programme [144, 146, 151]. In this intervention we tried to strengthen the links between the health system and the community, through creating a referral system where CHWs referred pregnant women, mothers and their infants with danger signs to the clinics using a standard referral letter (Figure 5). While the compliance with the referrals by mothers was good [206] the follow up on the referrals by the health facility (clinic) or the CHWs was not formalised. This component of community-based maternal, newborn and child survival strategy needs further investigation.

Given the findings of this study, the scale up of this approach through the new proposed re-engineered primary health care programme with Ward-based Primary Health Care Outreach Teams should be considered [146].

In summary, the community-based trial package was effective most notably in increasing EBF. This model can contribute to informing and improving the effectiveness, efficiency and sustainability [207] of the maternal/newborn home visit component of the re-engineered primary health care programme in South Africa and similar settings in Southern Africa.

## Effect of the intervention on feeding patterns (paper IV)

In paper IV detailed analysis of the data from the intervention showed that an integrated package delivered by systematically supervised, remunerated, full time CHWs produced significant and favourable effects on infant feeding patterns at 12 weeks of age in a poor semi-urban South African area, with high HIV prevalence among mothers. However, the positive effect on exclusive breastfeeding was more pronounced among HIV-negative mothers, which may reflect the difficulties of current evidence-based feeding recommendations in a setting of high HIV prevalence and recent drastic infant feeding policy changes [90, 116, 208].

However, more than 70% of HIV negative mothers practiced infant feeding patterns other than exclusive breastfeeding. This may indicate that motivational interviewing targeting primarily mothers may not be sufficient to change what has become a predominantly formula feeding culture in South Africa. We may need to formalise the motivational interviewing for the significant others in consultation with the pregnant women so they can get regular and sustained support within their households [161].

A recent systematic review indicated that studies combining individual (one-on-one counselling and support) and group counselling (counselling in groups of mothers or other members of their families) were superior in increasing EBF and breastfeeding rates at birth, during the first month and between 1 and 5 months in low and middle income countries [209]. In our

trial we included in the motivational interviewing sessions other household members related to the mother who were willing to take part in the dialogue, such as participants' mothers, grandmothers, sisters, husbands /boyfriends. However, the trial was not designed to systematically measure the extent of their participation in these sessions nor their contribution [158].

Another factor associated with low prevalence of EBF in HIV-positive mothers or mothers with unknown HIV status may be related to CHWs beliefs. An exit interview with CHWs who carried out the intervention revealed that none of them had exclusively breastfed their babies although they were given the responsibility to influence behavioural change. Studies conducted in Southern Africa discuss challenges of counselling that go beyond training[103]. Thus it is most likely that CHWs were not convinced that these women should practice breastfeeding.

While breastfeeding initiation rates were high (76% intervention versus 74% control) and were similar to those reported elsewhere in South Africa [108] they are below the WHO target of 90%. More ever, less than 35% of the mothers in both intervention and control clusters experienced timely initiation of breastfeeding, i.e. within one hour after delivery, despite 98% of the deliveries taking place in a hospital with Baby Friendly Hospital Initiative credentials. Timely initiation of breastfeeding is crucial [21]. A study conducted in rural Ghana in 2006 showed that initiation of breast-feeding within the first hour after birth was associated with prevention of 22% of the neonatal deaths [21]. Infants initiated to breastfeeding and who exclusively breastfed within one hour after birth were nine times less likely to die than those who were initiated on infant formula and breast milk within 72 hours of birth [21]. Late initiation of breastfeeding may be related to fear of HIV transmission through breast milk as well as poor or lack of support from hospital nurses [185].

Education level and socio-economic status of the mother has been found to have an effect on the prevalence of EBF, particularly in high and middle-income country settings such as Sweden and the United Kingdom [210, 211]. The experience in African countries is mixed. In two studies (Nigeria and Ghana) neither maternal age nor education level had an effect on practicing EBF [212, 213], while a study in Uganda showed a positive association between EBF and maternal level of education [214]. However, in our study the intervention had no differential effect in groups of women defined by the educational level or household asset scores.

Studies conducted in sub-Saharan Africa show that social factors such as community norms, the role of significant others in breastfeeding decision-making and structural factors such as single motherhood and teenage pregnancy are key factors associated with choices related to infant feeding and to a larger extent fear of HIV transmission [61, 96, 119, 215]. Participants in our study were relatively young mothers (average age of 23 years), single or divorced (87%) and 23% were teenage mothers and mainly attending school.

The demographic characteristics in our study population may be different from those observed in high and middle-income countries such as Sweden and the United Kingdom and [210, 211] this could explain the differences obtained in our study.

## Conclusion & implications

We have shown that an integrated package delivered by systematically supervised, remunerated and full time CHWs resulted in doubling the frequency of EBF. It also had significant and favourable effects on infant feeding patterns at 12 weeks of age in a poor semi-urban South African area, where HIV is prevalent among mothers. The size of the effect was relatively modest, but larger than in previous comparable trials [105]. The positive effect on exclusive breast-feeding was more pronounced among HIV-negative mothers, which may reflect the difficulties of current evidence-based feeding recommendations in a setting of high HIV prevalence and recent drastic feeding policy changes.

The removal of free formula milk from the PMTCT programme gives South Africa another opportunity to promote an evidence-based single infant feeding policy. Also, there is optimism that both HIV-positive and HIV-negative mothers could practise optimal EBF and reduce child morbidity and mortality associated with HIV/AIDS, malnutrition, diarrhoea and pneumonia the four major causes of child mortality. However, there are momentous challenges that need to be addressed before optimal breastfeeding can become a reality in South Africa.

Capitalising on policy change for improved infant feeding requires integration of public health approaches and well thought through socio-cultural strategies to address the complexities discussed earlier. Thus the development of implementation strategies need to involve public health specialists working hand in hand with interdisciplinary teams possibly comprising sociologists, psychologists, ethnographers, policy makers, gender specialists; and local and traditional authorities to look into viable strategies for addressing the social, cultural and structural challenges which impact on the uptake of EBF. Equally important would be monitoring, supervision and evaluation of the policy change implementation to provide a platform for lessons learned and experiences for scale up as well as informing policy makers of the progress made so that they can provide support.

Currently, research on infant feeding in the context of on HIV/AIDS is often unshared or not translated for frontline workers or community use. The policy and implementation strategies need to be translated so that the frontline workers as well as the communities they serve have a full understanding of what they mean.

It is crucial to design programmes to address the needs of teenage mothers. A policy that supports teenage mothers to return to school after delivery needs to consider the rights of the newborns of teenage mothers as well [199, 200]. High schools may have to consider introducing in their curricula infant care programmes including infant feeding for expecting mothers. Teenage mothers face a lot of challenges in accessing health care facilities due to cultural norms that contradict each other: For example on one hand they are not supposed to be sexually active and yet need to prove their fertility before marriage [194, 198]. More engagement with teenage mothers may yield useful information on what to include in strategies geared towards supporting them to breastfeed. The upheld ideal of mothers not talking about sex to their daughters also needs further investigation.

It is also time to review policies that hinder EBF for six months such as the current paid maternity leave, which is only four months. Also mothers in informal or casual employment do not enjoy this right, as they cannot risk losing their jobs and livelihood. Such mothers are most likely to return to work as soon as possible without any maternity leave compensation from the state. Revising and amending this policy and providing financial support to breastfeeding mothers will go a long way to improve child survival [216]. Some of these challenges have now been brought to the fore and are being debated in the media which may be a good start [217].

The challenges of formal engagement of CHWs in the South African health system has been documented and debated for more than a decade [143]. Evidence from other countries as well as our current study show that, CHWs can make a valuable contribution in delivering maternal newborn child health care and improve PMTCT of HIV activities. It is important that the processes of engaging CHWs in the health systems are not allowed to stagnate. A programme with trained, supervised, and coordinated CHWs linked to the health system is most likely to improve maternal and child health and survival even in high HIV prevalent settings.

## Summary in isiZulu

Ijumba, P 2014. Uhlelo lwezindlela ezingcono zokondliwa kwezingane ezisanda-kuzalwa nokwandisa isikhathi sempilo yazo, ezindaweni ezinabantu abaningi abaphila negciwane lesandulela-ngculazi. Imibono nemithelela yezifundiso ezenziwa emphakathini ngokukakekelwa komama nezingane ezisanda-kuzalwa elokishini laseMzansi-Africa.

Noma isekhoma inqubekela-phambili ekuvimbeleleni ukuthelelwa kwezingane ngomama abanegciwane lesandulela-ngculazi eMzansi Afrika, zisekhona izinkinga ezininkulu mayelana nokusetshenziswa kolwazi oluqoqiwe lwezindlela ezingcono zokuthuthukisa inani lezingane eziphila zingathelelekile ngegciwanesandulela-ngculazi.

Esikhathini esifushane esidlule kuqediwe ukunikezela mahhala kobisi lwebhodlela ezinhlelweni zokuvimbela omama ukuthelelela izingane ngegciwane lesandulela-ngculazi; futhi nezincwadi zezwe ngokondliwa kwezingane seziyavumelana nalezo zenhlangothi yamazwe yezempilo(WHO). Umzansi-Africa ubheka iqhaza elibanjwe ngonompilo ekuxhaseni nasekuthuthuzeni ukuxhumana phakathi kwezihlelo zokunakekelwa komama nalezo zokunakekela izingane ezisanda-kuzalwa, nokwenza-ngcono izindlela zokuvimbela ukutheleleka kwezingane yigciwane lesandulela -ngculazi lisuka komama

Inhloso yalolucwaningo ukuqonda ngemibono yamalunga omndeni ngokubaluleka kanye nomthelela umphakathi onayo mayelana kokushesha ukuqala ukunika ubisi lwebhodlela; ikakhulu emva-nje kokushintsha komgomo wokondliwa kwezingane; kanye nokubheka imiphumela yezifundiso ezethulwa ngonompilo emphakathini zokunakekela omama nezingane ezisanda-kuzalwa eziphathelene nokwandisa kwenani lezingane eziphila zingathelelekanga ngegciwane lesandulela-ngculazi, ukungaxubi izindlela ezahlukeneyo zokondla ingane, nokondla izingane ngendlela efanele zize ziqede amaviki ayishumi-nambili ubudala.

Lolucwaningo lwenziwe elokishini eliseduze neTheku emzantsi-Afrika, lapho izinga labantu abaphila negciwane lesandulela-ngculazi lilikhulu nobuphophu bubukhulu. Amaphepha amabili okuqala abeqxile ezingxoxweni ezenziwa nogogo, omkhulu, nomama abasebancane kanye nasemibuzweni ejulile eyenziwe komama abaphila negciwane lesandulela-ngculazi kanye nomama abangenalo igciwane lesandulela-ngculazi.

Imibono yamalunga omndeni mayelana nomgomo obeka ukuqedwa kokunikezwa mahhala kobisi lwebhodlela yaqoqwa ngokubuza imibuzo.



Iphepha lesibili lihlola ukuthi amalunga omndeni akubona kubaluleke kangakanani ukondla izingane ngobisi lwebhodlela, libuye libheke izimo eziphoqa ukuthi kusetshenziswe loluhlobo lokondla ingane. Amaphepha amabili okugcina agxile ocwaningweni oluyi cluster-randomised trial(kusetshenziswa izigodi/amaqoqo awu 15 afundiswa ngokunakekela/intervention, nawu 15 angafundiswanga/ control sites) - lapho onompilo basebenzisa izifundiso ezihlangene futhi ezikwazi ukusabalaliseka, bevakashela omama emakhaya kabili ngesikhathi bekhulelwe, nakahlanu emva kokubeletha ngenhloso yokubaxhasa futhi bathuthukise izindlela abangazenza ukuvimbela ukuthetheleka kwegciwane lesandulela-ngculazi lisuka kumama liya enganeni. Imiphumela eqavile kwakuwukubheka izinga labantwana abangaxutshelwa uma bondliwa futhi nabondliwa ngendlela efan-ele baze baqede amasonto ayishumi nambili ubudala; kanye nokubheka izinga lezingane ezizalwa zingathelekile igciwane lesandulele-ngculazi.

Kwaba nomahluko omkhulu nokungaqondisisi emphakathini mayelana noshintsho olusanda kwenziwa kumgomo wokondla izingane ophathelene nobisi lwebhodlela. Omama bezingane badlulisela umsebenzi wokuba umama komama nakogogo babo ; kanti abalingani ababaniki uxhaso olwanele ngemali yokondla, lokhu kuholela ezindleleni ezinobungozi zokondla izingane ngobisi lwebhodlela. Omama abasebancane baba-mbalwa abancelisa ibele ngenxa yokucabangela izingqinamba; ezinjengokuthi kuyihlazo, akum-niki umama inkululeko, nokuthi amabele ayawa; okhu bakuhlanganisa nokungabukeki kahle emzimbeni nokulahlekelwa amasoka.

Emasontweni ayishumi-nambili zizelwe izingane, uhlangothi lweqoqo lomama locwaningo olufundisiwe ngokunakekelwa komama nezingane lubonise ukukhula kwezinga lisishe liphindwe kabili inani lezingane ebe-sezinceliswa ubisi lwebele kuphela (28% vs. 14%, RR 1.92; 95% CI 1.59–2.33) futhi kwabakhona nentuthuko kwizisindo nobude bezingane (umehluko kwizisindo 0.09; 95% CI 0.00–0.18, umehluko ebudeni 0.11; 95% CI 0.03–0.19). Awukho umehluko obonakele emaqoqweni omabili ahlukene ocwaningo uma kuqhathaniswa amanani ezingane ezingathelekile yigciwane lesandulela-ngculazi. Omama abaseqoqweni ebelikhuthazwa lifundiswa ngokunakekelwa komama nezingane bebezihambisa kangcono izingane emtholampilo ngesonto lokuqala zizelwe uma beqhathaniswa neqoqo lomama abebengafundiswa ngokunakekelwa komama nezingane (RR 1.10; 95% CI 1.04–1.18). Awukho umehluko ezinganeni ezinamasonto ayishumi nambili kulezozingane ezondliwa ngobisi lwebele kuphela zingaxutshelwa uma uqhathanisa amaqoqo ngokwezinga lemfundo kamama, nangezinga lomcebo, kepha izinga lomphumela yokunika ubisi lwebele kuphela laliphakeme komama abangaphili negciwane lesandulela-ngculazi uma kuqhathaniswa nomama abaphila negciwane lesandulela-ngculazi (interaction,  $p=0.01$ ).

Kunesidingo sokuthuthukisa izinga lezindlela zokuxhumana kucaciswe ngezizathu zokuguqulwa kwemigomo ebhekene nokondliwa kwezingane

kanye nokuthuthukisa indlela entsha yokunceliswa kwezingane ubisi lwebele lungaxutshwa nalutho. Kufanele kugxilwe kakhulu komama abasebancane, futhi ogogo nobaba bezingane babeyingxenye yokuthatha izinqumo ngezindlela zokunceliswa kwezingane, ukuze bakwazi ukuxhasa nokugququzela ukunceliswa kwezingane ibele kuphela ukuze izingane zibe nempilo engcono. Uhlelo lonompilo lokuvakashela emakhaya ngenhloso yokuvikela izingane zingatheleleki ngegciwane lesandulela-ngculazi, libenomthelela omuhle ekuthuthukiseni inani lezingane ezinceliswa ibele kuphela zize zibe namasonto alishumi-nambili ubudala. Ukungabonakali komthelela waloluhlelo lokufundisa kwinani lezingane ezingathelelekile yigciwane lesandlela-ngculazi kungenziwa ukwandiswa kohlelo lokunikezelwa kwemishanguzo (ART) njengengxenye yohlelo lokuvikela ukutheleleka kwezingane ezizalwa ngomama abanegciwane lesandulela-ngculazi. Umthelela omncane obonakalayo wezinga lokuncelisa ibele lodwa eqoqweni lomama abanegciwane lesandulela-ngculazi abafundisiwe kungaba izinkomba zomphumela wokuguqulwa komgomo ovimbela ukunikezwa kobisi lwebhodlela mahhala, futhi kungakhombisa nesidingo sokusabalalisa ulwazi ngezinkomano zamanje zokondliwa kwezingane ezisanda kuzalwa kumalunga omphakathi nakubasebenzi bezempilo .

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