

# Development of an implementation tool for a breast milk bank in the North West Province

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Mini-dissertation submitted in *partial* fulfilment of the requirements for the degree *Magister Scientiae* in Dietetics at the Potchefstroom Campus of the North-West University

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## **PREFACE AND DECLARATION**

The article format has been selected for this study. The research was conducted by the Magister Scientiae student, Mrs. Maria Pretorius, who wrote the mini-dissertation under the supervision of the co-authors, Doctors Robin Dolman, Welma Lubbe and Namukolo Covic. Dr. Dolman acted as supervisor, Dr. Lubbe as co-supervisor and Dr. Namukolo as assistant supervisor. The article “An implementation tool for breast milk banking” was written according to the instructions of the Journal of Human Lactation and the article is yet to be submitted.

### **DECLARATION FROM STUDENT THAT PLAGIARISM HAS BEEN AVOIDED**

I, Maria Pretorius, ID: 8502010006085, student number: 13001051, hereby declare that I have read the North-West University’s “Policy on Plagiarism and other forms of Academic Dishonesty and Misconduct” (NWU, 2011).

I did my best to rephrase the authors’ information that I have cited in such a manner that it still reflected what the authors wanted to portray. I acknowledge that some of the information may have been adapted into my trend of thought, but that I tried to incorporate the information to the best of my ability to still reflect what the original authors intended.

I declare that this dissertation is my own work; although I respect the professional contribution made by my supervisors and I would like to give due recognition to them.

Mrs. Maria Pretorius

April 2015

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Hereby I would like to thank the following people for their assistance during this research project.

First of all, I would like to thank the Lord for giving me the talents and opportunity to do a Magister Scientiae degree and for the knowledge that He is always there through every step of my life.

Secondly, I would like to thank my supervisors, Doctors Robin Dolman, Welma Lubbe and Namukolo Covic for guiding me through this process.

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Finally, I would like to thank my husband, Barend Pretorius, for believing in me, my son, Sebastian Pretorius, for motivating me to finish, and my family who supported me wherever they could.

## ABSTRACT

**Background:** Breast milk banks (BMBs) provide human donor breast milk to preterm infants when mothers are not able to provide breast milk themselves (Arslanoglu *et al.*, 2010:20). Breastfeeding is the single most effective intervention to saving the lives of millions of children in developing countries (Bhutta & Lobbok, 2011:378-380). BMBs form an integral part of the millennium development goals (MDGs) (Dempsey & Miletin, 2010:2) on reducing infant mortality and morbidity and are being implemented all over the world (Hartmann *et al.*, 2007:667, Arslanoglu *et al.*, 2010:20, Eidelman & Schanler 2012:827).

**Problem statement:** BMBs can be established more effectively with an implementation tool in place. Currently, there is no tool available to guide the implementation of a BMB in South Africa; the only guidelines that could be found are those describing the operation of BMBs in other countries. Some of the BMBs already established in South Africa were implemented with the help of the South African Breast Milk Bank Reserve (SABR), but without a formalised guideline to provide implementation guidance.

**Aims and objectives:** The purpose of this study was to adapt a current Kangaroo mother care (KMC) progress-monitoring tool and to adjust it according to the BMB setting in South Africa in order to provide a final suggested implementation tool for the implementation of BMBs.

**Method:** An explorative, descriptive design with multiple phases was used. Different data sets were audited; including patient files, written reports, working files, research articles and policies. Observations were also made with regards to available equipment and designated BMB space. During phase one, a critical analysis was performed on research articles and websites regarding BMBs. The qualitative data was analysed by using content analysis. This information was adapted and contextualised in phase two. This phase entailed applying the adapted tool to the BMB setting of the selected regional hospital, which then led to phase three, in which the audited data was incorporated into the final suggested implementation tool resulting from this study.

**Results:** The suggested tool, the North West Province BMB implementation tool, shared the six main constructs with the KMC progress-monitoring tool. The constructs are creating awareness, adopting the concept, taking ownership, evidence of practice, evidence of routine and integration and sustainable practice. However, some of the progress markers and instrument items were specifically relevant to the KMC setting and others to the BMB setting. On the other hand, some constructs overlapped, being relevant to both settings: for instance awareness by management, conscious decision to implement, mobilisation of resources (human, space and equipment), information about mothers' other resources such as budget, patient records, staff orientation,

evidence of discharge, policies and other written documents, and 1-2 year audit evidence and staff development.

**Conclusion:** Adapting the KMC progress-monitoring tool led to the development of a suitable tool to guide BMB implementation. The tool is called the North West Province BMB implementation tool. This tool could be used to guide the implementation of a BMB in other hospitals in South Africa.

**Key terms:** implementation, donor milk bank, breast milk bank, protocol, human milk bank, procedures

## OPSOMMING

**Agtergrond:** Borsmelkbanke (BMB'e) verskaf menslike skenkerborsmelk aan premature babas wanneer moeders nie self die borsmelk kan voorsien nie (Arslanoglu *et al.*, 2010:20). Borsvoeding is die mees effektiewe intervensie om die lewens van miljoene kinders in ontwikkelende lande te red (Bhutta & Lobbok, 2011:378-380). BMB'e vorm 'n integrale deel van die millennium ontwikkelingsdoelwitte (MOD'e) (Dempsey & Miletin, 2010:2) betreffende die afname van kindersterftes en morbiditeit en word regoor die wêreld geïmplementeer (Hartmann *et al.*, 2007:667, Arslanoglu *et al.*, 2010:20, Eidelman & Schanler 2012:827).

**Probleemstelling:** BMB'e kan meer effektief gevestig word aan die hand van 'n implementasie-instrument. Daar is tans geen beskikbare instrument om die implementasie van 'n BMB in Suid-Afrika te rig nie; die enigste riglyne wat gevind kon word, is dié wat die werking van BMB'e in ander lande beskryf. Sommige van die BMB'e wat reeds in Suid-Afrika gevestig is, is geïmplementeer met die bystand van die Suid-Afrikaanse Borsmelkbank Reserwe (SABR), dit was egter gedoen sonder geformaliseerde riglyne wat implementasieleiding verskaf.

**Doelstellings en doelwitte:** Die doel van hierdie studie was om 'n huidige Kangeroe moedersorg (KMC) vorderingsmoniteringsinstrument aan te pas en te verander volgens die BMB-omgewing in Suid-Afrika, om sodoende die finale voorgestelde implementeringsinstrument vir die implementering van BMB'e te verskaf.

**Metode:** 'n Verkennende, beskrywende ontwerp met verskeie fases is gebruik. Verskillende datastelle is geouditeer wat pasiëntlêers, geskrewe verslae, werklêers, navorsingsartikels en beleide insluit. Waarnemings is ook gedoen ten opsigte van beskikbare toerusting en aangewese BMB-ruimtes. In fase een is 'n kritiese analise van navorsingsartikels en webwerwe aangaande BMB'e gedoen. Die kwalitatiewe data is geanaliseer deur van inhoudsanalise gebruik te maak. Hierdie inligting is aangepas en gekontekstualiseer in fase twee. Hierdie fase het die toepassing van die aangepaste instrument vir die BMB-omgewing van die gekose plaaslike hospitaal behels, wat aanleiding gegee het tot fase drie waarin die geouditeerde data in die finale voorgestelde implementasie-instrument, wat die resultate van hierdie studie vorm, geïnkorporeer is.

**Resultate:** Die voorgestelde instrument, die BMB implementeringsinstrument van die Noordwes-Provinsie, het die ses hoofkonstrukte met die KMC vorderingsmoniteringsinstrument gedeel. Die konstrukte is bewustheidskepping, aanneming van die konsep, eienaarskap, bewys van praktyk, bewys van roetine en integrasie en volhoubare praktyk. Sommige vorderingsmerkers en instrumentitems was egter relevant tot spesifiek die KMC-omgewing en ander tot die BMB-omgewing. Daar was egter meer konstrukte wat oorvleuel het en relevant vir beide omgewings was; byvoorbeeld bewustheid by bestuur, bewuste besluit om te implementeer, mobilisasie van

hulpbronne (menslik, ruimte en toerusting), inligting in verband met moeders, ander hulpbronne soos begroting, pasiëntverslae, personeeloriëntasie, bewys van ontslag, beleide en ander geskrewe dokumente, en bewys van 1-2 jaar se ouditte en personeelontwikkeling.

**Gevolgtrekking:** Die aanpassing van die KMC vorderingsmoniteringsinstrument het tot die ontwikkeling van 'n instrument wat geskik is om die implementering van BMBe te lei. Dit word die Noordwes-Provinsie se BMB-implementeringsinstrument genoem. Die instrument kan ook gebruik word om die implementasie van 'n BMB in ander hospitale in Suid-Afrika te lei.

**Sleuteltermes:** implementasie, skenkermelkbank, borsmelkbank, protokol, menslike melkbank, prosedures

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## LIST OF ABBREVIATIONS

AFASS	Acceptable, Feasible, Affordable, Sustainable and Safe
AIBLUD	Italian Association of Human Milk Banks
BMB	Breast Milk Bank
ELBW	Extremely Low Birth Weight
EMBA	European Milk Bank Association
EMTCT	Elimination of Mother-to-Child Transmission
HIV	Human Immunodeficiency Virus
HMBANA	Human Milk Banking Association of North America
IQ	Intelligence Quotient
IYCF	Infant and Young Child Feeding
KMC	Kangaroo Mother Care
LBW	Low Birth Weight
MDGs	Millennium Development Goals
MMB	Mothers' Milk Bank
NEC	Necrotizing Enterocolitis
NICE	The National Institute for Health and Clinical Excellence
NMAA	Nursing Mothers' Association of Australia
PREM Bank	Perrron Rotary Express Milk Bank
REDEBLH	Rede de Bancos de Leite Humano
SABR	South African Breastmilk Reserve
UK	United Kingdom
UKAMB	United Kingdom Association for Milk Banking

UNICEF	United Nations International Children's Emergency Fund
VLBW	Very Low Birth Weight
WBTi	World Breastfeeding Trends Initiative
WHO	World Health Organization

## DEFINITIONS

Breast Milk Bank (BMB): A facility established with the purpose of selecting, collecting, checking, processing, storing, and distributing donor human milk, which is to be used for specific medical requirements (Arslanoglu *et al.*, 2010:4). It can also be referred to as donor milk banking or human milk banking.

Constructs: Is an idea or theory containing various conceptual elements, typically one considered to be subjective and not based on empirical evidence.

Contextualised: To put (a linguistic element, an action, etc.) into a context, especially one that is characteristic or appropriate, as for the purposes of a study (Dictionary.com, 2015).

Donor milk: Human milk given voluntarily and freely to a BMB (Arslanoglu *et al.*, 2010:4).

Exclusive breastfeeding: Infant receives only breast milk (including expressed breast milk from a wet nurse) and nothing else, except for oral rehydration solution, medicines, vitamins and minerals if prescribed by a medical practitioner (Dictionary.com, 2015).

Guideline: any guide or indication of a future course of action (Dictionary.com, 2015).

Implementation: The process of putting a decision or plan into effect (Dictionary.com, 2015).

Instrument items: Items used as a way to achieve or cause something (Dictionary.com, 2015).

Operating: Control of the functioning of a process/system (Dictionary.com, 2015).

Pasteurised human milk: Human milk that has undergone a pasteurisation process (Arslanoglu *et al.*, 2010:4).

Pooled human milk: A mixture of human milk obtained from one or more than one donor (Arslanoglu *et al.*, 2010:4).

Progress markers: Markers indicating the movement to a more developed state (Dictionary.com, 2015).

Tool: Anything used as a means of accomplishing a task or purpose (Dictionary.com, 2015).

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# CHAPTER 1: OVERVIEW OF THE STUDY

## 1.1 Background

The leading causes of infant mortality in children younger than five years, include pneumonia, preterm birth complications, diarrhoea, complications during birth, malaria, neonatal sepsis and others (UNICEF, 2012a:1). Breastfeeding is the most effective intervention in reducing the risk of neonatal infections such as pneumonia and diarrhoea globally, thus it has a significant effect on the reduction of mortality (UNICEF, 2012a:1). Furthermore, breastfeeding plays a crucial role in child survival, growth and development (UNICEF, 2012a:1). According to the Human Sciences Research Council (HSRC) who conducted the South African National Health and Nutrition Examination Survey in 2012 and found that South Africa's exclusive breastfeeding rate of infants below the age of six months was only at an alarming low 7,4 percent in 2012 (DOH, 2003a:114).

The Tshwane declaration of support for breastfeeding was signed by the minister of Health in August 2011 and symbolises the government's commitment and political will to ensure the promotion, protection and support of breastfeeding which would contribute to improving maternal and child health in South Africa (DOH, 2011:214). The Tshwane declaration stated that promoting, protecting and supporting breastfeeding would reduce child mortality. The declaration includes the use of donated breast milk as one of the effective strategies to reduce mortality and morbidity in preterm and vulnerable infants (DOH, 2011:214). The concern was also raised, during the development of the Tshwane declaration, that the infant and child mortality rates in South Africa remained unacceptably high at 47 deaths per 1 000 live births, and that the target rate of 20 deaths per 1 000 live births will not be reached before the end of 2015 (DOH, 2011:214; UNICEF, 2012a:1).

A breast milk bank ensures that donated breast milk is available for preterm and vulnerable infants whose mothers are not able to provide breast milk during the first fourteen days of life (Arslanoglu *et al.*, 2010:2). The terms used for breast milk banking vary between countries. The words "donor milk banking" or "human milk banking" are also used, but to avoid confusion the term breast milk banking (BMB) will be used in this study.

One of the first BMBs in Africa was established in Durban in South Africa in December 1980 (Dempster, 1982:951). Forty four BMBs were opened in South Africa between 2003 and 2014 with the assistance of the South African Breastmilk Reserve (SABR). Many more are being established in South Africa in order for breastfeeding mothers to be able to donate breast milk to preterm infants in need. The first BMB in the North West Province was established in the Kenneth Kaunda district in July 2012.

Available guidelines from various countries such as Italy, America, the United Kingdom, Norway and Australia concerning BMB implementation only discuss some of the aspects that are needed to implement a BMB, but do not indicate the entire implementation process. With this in mind, an implementation tool guiding the entire process of implementing a BMB would benefit institutions that need to implement a BMB in other parts of South Africa.

## **1.2 Problem statement**

There are numerous publications from various countries that have published guidelines on the operation of a BMB and discuss what is needed during the operation of a BMB. These guidelines include various aspects like donors, milk, pasteurisation machine, fridges, personnel, funds, etc., but they do not indicate a step-by-step manner in which to implement a BMB from the pre-implementation phase or how to ensure institutionalisation (Hartmann *et al.*, 2007:667, Arslanoglu *et al.*, 2010:1). It can therefore be said that no implementation tool discussing all that is needed during each step of implementing of a BMB is available.

Although there are several established BMBs in South Africa, there was no available tool in literature (at the time of research) on how to implement a BMB in South Africa. During the search for implementation tools, the progress-monitoring tool consisting of progress markers and instrument items for implementing Kangaroo mother care (KMC) was identified (Bergh *et al.*, 2005:1102-1108). This tool was developed for the South African setting and seemed suitable to be adapted to a different context according to the author of the KMC progress monitoring tool (Bergh *et al.*, 2005:1102-1108), however, the progress markers and instrument items were specific to the KMC set-up and needed adaptation and contextualisation to suit the BMB setting.

### **1.3 Research aim and objectives**

#### **1.3.1 General aim**

The general aim was to develop and audit a tool to guide breast milk bank implementation in the South African context.

#### **1.3.2 Objectives**

Objective 1: To adapt a current KMC progress-monitoring tool to guide the development of a BMB implementation draft tool.

Objective 2: To audit the developed implementation draft tool by auditing the implementation of a BMB at a selected regional hospital.

Objective 3: To adjust and refine the developed implementation draft tool according to the results of the auditing process to provide the North West Province BMB implementation tool.

### **1.4 Study Design**

#### **1.4.1 Method**

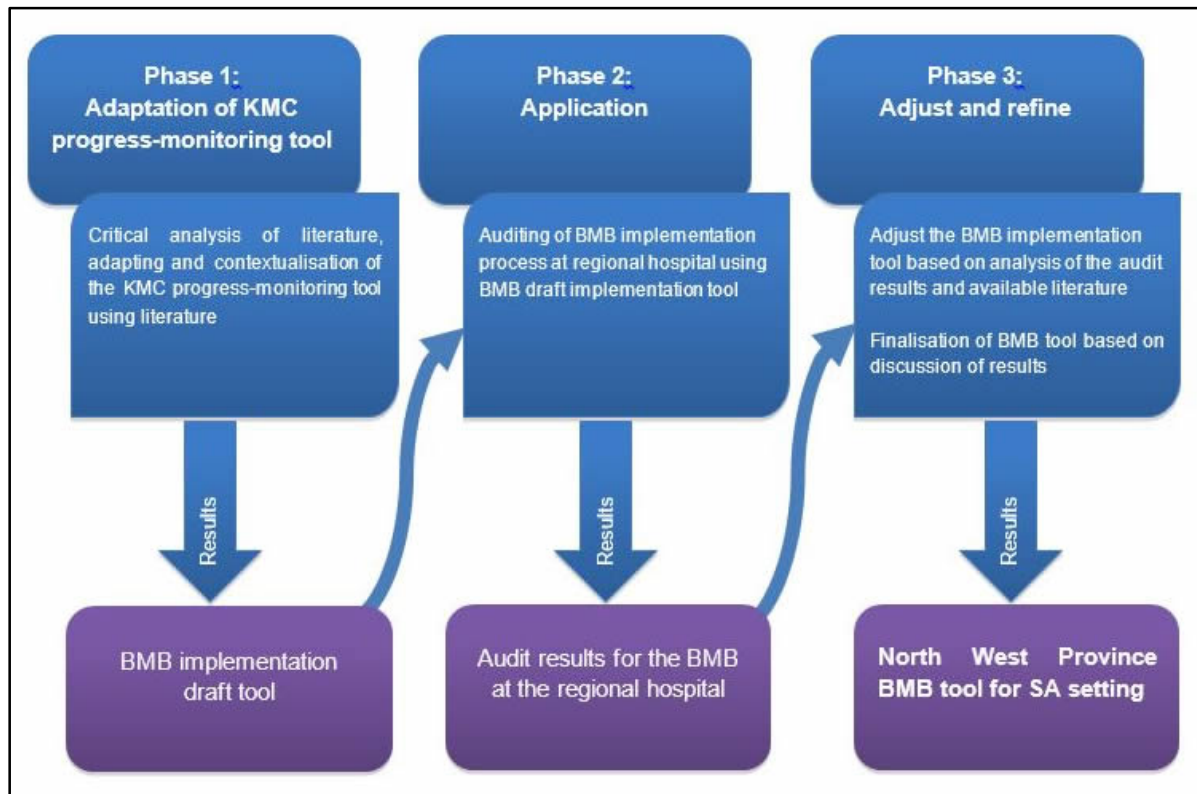
A qualitative study design that was exploratory in nature was used. The KMC progress-monitoring tool was adapted and audited in order to develop an implementation tool for BMBs.

### **1.5 Data collected for the auditing process**

The researcher collected data from articles, grey literature, patient files, written reports, policies, documents and by observation as determined by the adapted draft tool. This was done from February to April 2014 at a selected regional hospital in the Kenneth Kaunda district with 350 beds. The specific regional hospital was selected because the first BMB in the North West Province was opened at this hospital and the researcher is on the staff that was involved in the implementation of the BMB.

## 1.6 Methodology

The study was done in three phases as shown below in Figure 1-1.



**Figure 1-1: Study phases used in the development of the breast milk banking implementation tool**

### **Phase 1: Adaptation of KMC progress-monitoring tool**

The constructs included in the original KMC progress-monitoring tool were presented in a cumulative manner and are: creating awareness, adopting the concept, taking ownership, evidence of practice, evidence of routine and integration and sustainable practice. Additional progress markers were identified by means of a content analysis of the KMC progress-monitoring tool, peer-reviewed articles and grey literature on BMBs and are discussed in more detail in the article (Chapter 3). Grey literature in combination with peer-reviewed articles was used in this study because it provided a more comprehensive view of the information that is available on the implementation of BMBs. The researcher will refer to these datasets as documents. The additional progress markers that were identified for the successful implementation of a BMB included: evidence of donor milk screening, evidence of quality control, research documenting benefits and continued funds (Chapter 3, Figure 3). The original KMC progress-monitoring tool was adapted to form a BMB draft tool to be used in phase 2.

## **Phase 2: Application of the draft tool by auditing the breast milk bank implementation process of a regional hospital**

During phase 2, the adapted draft tool was audited by applying it to the collected data of the BMB implementation process at the selected regional hospital. The data was collected from patient files, documents including the service agreement document and control forms, written reports, policies and through observation.

Exploratory studies are often used in qualitative research when little is known about the phenomenon with the purpose to explore and describe it (Botma *et al.*, 2010:50). A qualitative system was therefore used to analyse the data and it was audited by comparing and categorising it according to the progress markers and the instrument items of the adapted BMB draft tool. The auditing was mostly done by identifying which documents or forms were available and the type of information it entailed. This information was then checked against the KMC progress-monitoring tool and drafted BMB implementation tool. The results of the analysis were used to refine and adjust the North West Province BMB implementation tool in phase 3.

## **Phase 3: Adjustment of the draft tool and refinement based on the audit results**

Based on the experience of using the draft BMB implementation tool to evaluate the implementation process at the selected regional hospital, the tool was adjusted and refined in order to provide the North West Province BMB implementation tool that can be tested in other BMB implementations in the province.

The adjustment and refinement were done by comparing the progress markers and instrument items relevant to the progress markers, to the data gained from phase 1 and phase 2. Although the progress markers remained the same, it became evident that there were differences in the instrument items between the data obtained in the peer-reviewed articles and grey literature on the one hand, and that of the selected regional hospital on the other hand. The final suggested BMB implementation tool (Chapter 3, Figure 4) was designed; this tool can be tested in other sites in the province under study

### **1.7 Ethical consideration**

The study protocol was submitted to the Faculty of Health Science, Health Research Ethics Committee of North-West University for ethical approval and approval was obtained (NWU-00083-13-S1) (Annexure A). Approval to conduct the research at the selected regional hospital was also obtained from the North West Department of Health as well as from the hospital (Annexures B, C and D). Furthermore, approval was obtained from the author of the study "Measuring implementation progress in kangaroo mother care", Dr. Anne-Marie Bergh for the use



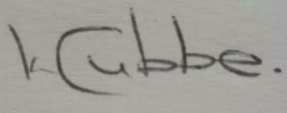
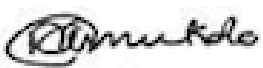
and adaptation of the progress-monitoring tool (Bergh *et al.*, 2005:1102). The European Milk Bank Association (EMBA) also granted their approval for the use of their figure (Figure 2-3 in the Literature Review chapter) that indicates the active and planned breast milk banks supported by the European Milk Bank Association (Annexure E). No human subjects were used during this study.

### 1.8 Structure of mini-dissertation

This mini-dissertation is presented in article format. Chapter 1 is the introductory chapter that explains the need for a breast milk bank implementation tool and provides the aims and objectives for the study. In Chapter 2, the literature review, the history of breast milk banking and the motivation for the use of donor milk and how it is relevant to the initiatives in South Africa are discussed. Chapter 3 contains the article that was prepared for submission to the Journal of Human Lactation. The reference style used for Chapter 3 is according to the requirements of the journal, whilst the reference style of the North-West University was used throughout the rest of the document. The last chapter, Chapter 4 entails the conclusions and recommendations.

### 1.9 Authors' contributions

The article included in this mini-dissertation was prepared by several authors and their contributions are listed below.

Name	Qualification	Role in this study	Signature
Mrs. M. A. Pretorius	BSc Dietetics	Responsible for the literature searches, data analysis and interpretation and text drafting	
Dr. R.C. Dolman	PhD Dietetics	Supervisor and critical reviewer of study, review of data interpretation and final draft	
Dr. W. Lubbe	PhD Nursing	Co-supervisor and critical reviewer of study review of data interpretation and final draft	
Dr. N. Covic	PhD Nutrition	Assistant supervisor and critical reviewer of study review of data interpretation and final draft	

## **1.10 Conclusion**

With the revival of the establishment of BMBs throughout the world as well as in South Africa, it can only be seen as beneficial to have a BMB tool to guide the implementation of BMBs in South Africa. Guidance can be provided by this BMB tool to the hospitals throughout the North West Province needs to establish BMBs seeing that this BMB tool that was developed within the province.

## **CHAPTER 2 LITERATURE REVIEW**

### **2.1 Introduction**

Breast milk has great advantages for term and preterm infants (Eidelman *et al.*, 2012:827) and is recommended by the World Health Organization (WHO) as the most optimal way of feeding infants. When mothers are unable to provide breast milk to their infants in special need, for instance preterm infants at risk of developing necrotizing enterocolitis (NEC), the WHO recommends that these infants receive donor milk as first alternative (WHO, 2003:12). Breast milk banks (BMBs) need to be available in order to provide these preterm infants with donor milk. The terms used for breast milk banking vary between different countries, as some may refer to BMBs as “donor milk banking” or “human milk banking”; the term breast milk banking (BMB) will be used in this study to avoid confusion. BMBs were first established in the eighteenth century, but their popularity varied due to influential factors such as the availability of formula milk, financial implications and the emergence of the human immunodeficiency virus (HIV) (Jones, 2003:313). In recent years, a revival in the establishment of BMBs is evident all over the world as countries became more aware of how beneficial breast milk is for infants in need (Jones, 2003:313).

This literature review discusses the importance of breast milk feeding by indicating some of the general benefits of breast milk, followed by those specific to the preterm infant. The global situation concerning infant mortality and breastfeeding rates, and more specifically the situation in South Africa, will also be explored. Thereafter, some initiatives that are currently in place to address the improvement of breastfeeding rates are discussed. Although there are different initiatives to promote the increase in the usage of breast milk, emphasis will be on the use of BMBs in this study. The history of, and as far possible the current situation concerning the establishment of these BMBs and their situation in other countries, as well as in South Africa, are discussed. Available implementation tools are then explored and the KMC progress-monitoring tool is discussed, specifically because it was found to be the most relevant tool to use for the guidance of a BMB implementation tool.

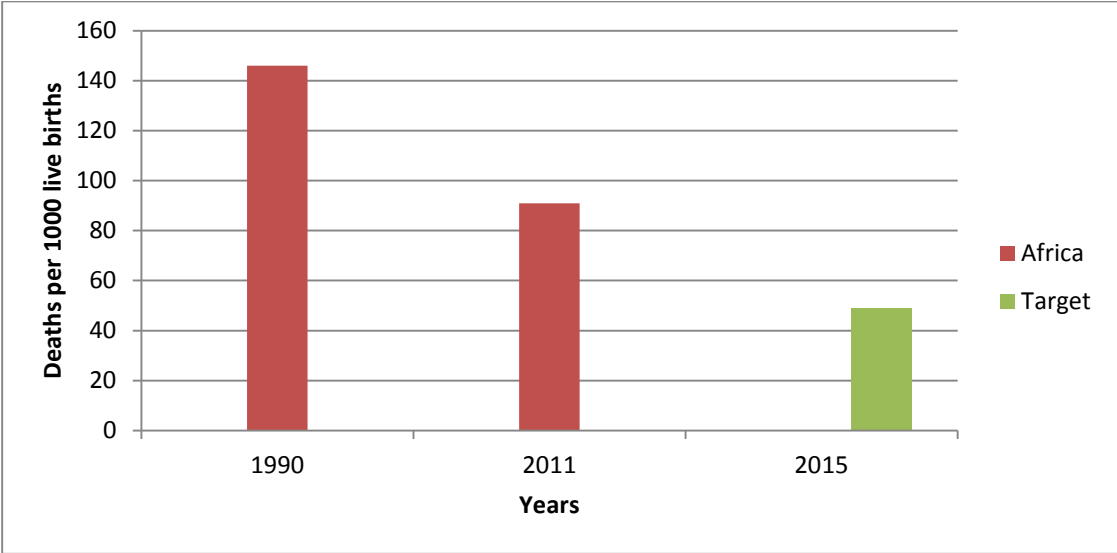
### **2.2 The millennium development goals (MDGs)**

The millennium declaration was endorsed in New York in September 2000 when leaders of 198 countries met for committed cooperation in order to build a more prosperous and safe world. Eight time-bound and measurable goals were set that needed to be reached by 2015 and they are known as the MDGs. The eight goals are:

1. Eradicate extreme poverty and hunger
2. Achieve universal primary education

- 3. Promote gender equality and empower women
- 4. Reduce child mortality
- 5. Improve maternal health
- 6. Combat HIV/AIDS, malaria and other diseases
- 7. Ensure environmental sustainability
- 8. Develop a global partnership for development (UNICEF, 2005:4-5).

The MDGs declaration was an inspiring development to improve the lives of hundreds of millions of people around the world. The target of MDG number four was to reduce the mortality rate of children under the age of five by two thirds between 1990 and 2015 (UNICEF, 2005:18). Substantial progress has been made globally towards achieving MDG number four. The global infant mortality rate has decreased by 49 percent, in other words from 90 deaths per 1 000 live births in 1990 to 46 deaths per 1 000 live births in 2013 (UNICEF, 2014b:1). Regions such as North Africa, Latin America and the Caribbean, South East Asia, West Asia and East Asia, reduced their infant mortality rates by more than 50 percent. In other parts of Africa, on the other hand, despite strategies to reduce under-five mortality in the continent, the rate has only decreased by 54 percent from 146 deaths per 1 000 live births in 1990 to 91 deaths in 2011 (see Figure 2-1; UNICEF, 2013:49). It is therefore unlikely that Africa will reach the target rate of 48 deaths per 1 000 live births in 2015.



**Figure 2-1: Infant deaths per 1 000 live births trend since 1990 (UNICEF, 2013:49)**

The burden of under-five deaths is concentrated in the world’s poorest regions and countries. These regions are Sub-Saharan Africa and South Asia, where more than four fifths of all global under-five deaths occur. Demographically, South Africa forms part of Sub-Saharan Africa. The under-five mortality rate varies across African countries. However, not all African countries fail to

reach the target rate (UNICEF, 2013:49), Liberia, Tunisia and Egypt for example, have already exceeded the target rate. These countries' successes are due to multiple factors, which include the focus on high-impact interventions such as strengthened health systems, investing more in health and related social determinants of health (such as nutrition), making gains in medical technology, improving education, child protection and economic growth (UNICEF, 2013:49).

On the other hand, countries such as Botswana, Lesotho, Zimbabwe and Swaziland have had an increase in the under-five mortality rate since 1990 due to HIV/AIDS related deaths (UNICEF, 2014:56). Other factors that also contribute to the lack of achieving the MDGs, include weak health systems, poor conditions with regards to education, and income, insufficient and inappropriate nutritional practices and poor sanitation facilities. These aspects lead to poor health (UNICEF, 2013:49).

North Africa was the most successful, when comparing to African regions; since the region reduced its infant mortality rate by 54 percent. When comparing the mortality rate in 1990 with that of 2011, Southern Africa has the second best rate in Africa with a 46 percent reduction. West and East Africa both reduced the death rate by 42 percent (UNICEF, 2013:49). Central Africa is the only African region with an increase in their under-five infant mortality rate, but this might be due to the high mortality rates (more than 18 percent) caused by malaria (UNICEF, 2013:49). About 64 percent of under-five deaths in Africa occur within the first year of life, and more than half of these are neonatal deaths, which occur within the first 28 days following birth. High-impact interventions during the post-natal period that can reduce neonatal morbidity and mortality drastically, include skilled attendance at birth and exclusive breastfeeding (UNICEF, 2013:52).

### **2.2.1 Infant mortality and morbidity**

Globally, the leading causes of death among children under five are pneumonia, preterm birth complications, diarrhoea, intrapartum related complications during birth, malaria, neonatal sepsis and others (UNICEF, 2012b:a). NEC remains one of the leading causes of mortality and morbidity among preterm infants in the United States (Hunter *et al.*, 2008:117). In contrast, infectious diseases such as pneumonia, malaria, meningitis, tetanus, HIV, diarrhoea, and measles account for about 41 percent of under-five deaths in Africa (UNICEF, 2012b:1). These infectious diseases are preventable and global efforts to address these diseases have been made (UNICEF, 2012a:2).

Easy and inexpensive, but high-impact solutions to decrease infant mortality, include the early initiation of breastfeeding and exclusive breastfeeding (UNICEF, 2012a:21). The initiation of breastfeeding within the first half hour following birth can reduce infant mortality by up to 20 percent, but unfortunately more than half of the world's newborn infants are not breastfed within

half an hour after birth (UNICEF, 2012a:21). Less than 40 percent of children younger globally than six months are exclusively breastfed despite the fact that non-breastfed infants are 14 times more likely to die in the first six months as a result of pneumonia and diarrhoea when compared to exclusively breastfed infants (DOH, 2011:3). Therefore it is of extreme importance that exclusive breastfeeding for the first six months must be emphasised and promoted.

One in three infants are exclusively breast fed during the first six months in the developing world; taking into consideration that variation exists across regions (Haroon *et al.*, 2013:1). The exclusive breastfeeding rates in developing countries have increased from 33 percent in 1995 to 39 percent in 2010 with an exceptional increase in the rates in West and Central Africa from 12 percent in 1995 to 28 percent in 2010 (Haroon *et al.*, 2013:1). The exclusive breastfeeding rates of low-income countries are higher than those of high income countries. This might be due to the wider availability of formula, social perceptions and work constraints in high income countries (Cattaneo & Quintero-Romero, 2006:48). The potential benefits of exclusive breastfeeding practices have a great impact on developing countries with a poor socio-economic status such as South Africa, due to the high burden of disease, including HIV, and low access to clean water and sanitation (UNICEF, 2014a:1).

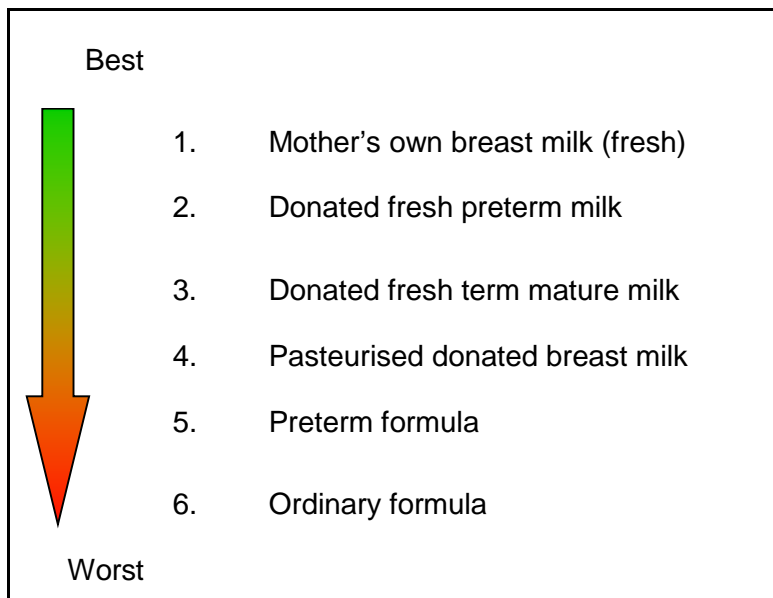
Globally, preterm birth is the direct cause of 27 percent of the four million neonatal deaths annually, and low birth weight (LBW) directly or indirectly contributes to 60 to 80 percent of all neonatal deaths. The World Health Organization (WHO, 2011:1) defines LBW as a weight of less than 2.5 kg at birth. Infants born with LBW can further be categorized into infants with a very low birth weight (VLBW) weighing less than 1,5 kg and infants with an extremely low birth weight (ELBW) weighing less than one kilogram (WHO, 2011:1). Infants born with LBW, preterm and small for gestational age (SGA), are at a disadvantage when compared to infants with a normal birth weight. These LBW infants have a high risk of developmental delay, infection, early growth retardation and death during infancy and childhood (WHO, 2011:1).

### **2.3 Preterm infant feeding problems and alternative recommendations**

The WHO developed guidelines for the optimal feeding of LBW infants, because the quality of care that LBW infants receive in low- and middle income countries is inadequate (WHO, 2011:1). Some of the main reasons why mothers of preterm infants struggle with the initiation of breastfeeding or establishing proper milk expression are due to amongst others inadequate breast stimulation, side effects of certain medications, poor support and lack of privacy (Sisk *et al.*, 2010:368; Corvaglia *et al.*, 2013:5).

The benefits of breastfeeding are clear, but not all mothers are able to breastfeed. If a mother is unable to breastfeed, the following alternatives are recommended: the mother can express her

own milk, a healthy wet nurse can breastfeed the infant or milk from a human milk bank can be used, depending on the circumstances (WHO, 2003:10). The WHO ranking for feeding choices for low birth weight infants are illustrated in Figure 2-2.



**Figure 2-2: Milk for low birth weight infants: WHO hierarchy of feeding choices (Arnold, 2006:26)**

#### **2.4 Breast milk benefits**

Studies have shown that the promotion of breastfeeding influences breastfeeding and exclusive breastfeeding influences practices positively (Lutter *et al.*, 2013:1418). Breastfeeding has many advantages and should not only be seen as a lifestyle choice, but as a public health issue (Eidelman *et al.*, 2012:e827; Schanler *et al.*, 1999:1150). Exclusive breastfeeding results in reduced respiratory tract infections, otitis media and serious throat infections. This protective effect increases with the duration of exclusive breastfeeding (Chantry *et al.*, 2006:425; Ip *et al.*, 2007:1; Ip *et al.*, 2009:S17). Furthermore, breastfeeding also reduces the prevalence of nonspecific gastrointestinal tract infections as well as the risk of inflammatory bowel disease (Barclay *et al.*, 2009:421; Penders *et al.*, 2006:511; Duijts *et al.*, 2010:e18; Ip *et al.*, 2007:1; Ip *et al.*, 2009:S17; Quigley *et al.*, 2007:e837). The sudden infant death syndrome risk can also be reduced by 36 percent with breastfeeding (Ip *et al.*, 2007:1). Exclusive breastfeeding for three to four months has a protective effect pertaining to allergic diseases such as asthma, atopic dermatitis and eczema (Greer *et al.*, 2008:183; Ip *et al.*, 2007:1). The long-term benefits of breastfeeding include a decreased risk of being overweight, developing diabetes type one and two, developing an allergy and possibly better neurodevelopmental outcomes and improves bonding between mother and infant (Ip *et al.*, 2009:S17; Ip *et al.*, 2007:1).

The obesity rates worldwide have more than doubled since 1980, with more than 1.9 billion adults, 18 years and older, being overweight in 2014. South African women have the highest prevalence of obesity in the world at an alarming 42 percent, and the obesity rate of the South African men was 38 percent in 2013 (Ng *et al.*, 2014:9). However, research has indicated that the obesity rates of breastfed infants in adulthood are significantly lower (Ip *et al.*, 2009:S17; Ip *et al.*, 2007:1). The duration of breastfeeding is inversely related to the risk of being overweight, but with the confounding factor is whether the breast milk was given via breastfeeding or bottle feeding, because breastfed infants self-regulate the intake and this self-regulating habit affects weight gain in adulthood (Ip *et al.*, 2009:S17; Ip *et al.*, 2007:1).

The risk for diabetes type one and two is reduced by up to 30 percent and 40 percent respectively when an infant is breastfed exclusively for at least three months (Ip *et al.*, 2007:1).

Controversy still exists whether preterm infants fed breast milk have higher intelligence quotients (IQ) when compared to preterm infants receiving formula milk. Several studies indicated that there is a positive effect on neurodevelopmental outcomes in LBW infants (Lucas *et al.*, 1998:1481, Isaacs *et al.*, 2010:357). One of these studies that specifically compared donor breast milk (DBM) with formula milk, found that the IQ scores of the DBM fed children were significantly higher, with an average 8.3 point IQ increase. The advantage of having a higher IQ score is dose-dependent on the proportion of DBM received (Lucas *et al.*, 1998:1481). The results of other studies are not conclusive, and more research is needed to clarify this. The impact of a higher IQ score may lead to potentially important medical, biological and social implications (Isaacs *et al.*, 2010:1).

Breast milk provides short- and long-term benefits to preterm infants. For example the lower rate of sepsis and NEC in breast fed infants indicates that breast milk helps to develop the host defence of the preterm infant (Furman *et al.*, 2003:66; Meizen-Derr *et al.*, 2009:57; Schanler *et al.*, 1999:1150; Sisk *et al.*, 2007:808). The lower incidence of NEC in infants when breast milk is provided, contributes to lower mortality rates and lower neurodevelopmental disabilities and long-term growth impairment (Hintz *et al.*, 2005:696; Shah *et al.*, 2008:170; Vohr *et al.*, 2006:e115; Vohr *et al.*, 2007:e953). Breast milk can be considered as a preventative “medicine”; because formula fed infants have a higher risk for developing NEC when compared to infants that receive breast milk, regardless of whether it is the mother’s own milk or donor milk (Arnold, 2006:26; Boyd *et al.*, 2007:F169; McGuire & Anthony, 2003:F11). Other benefits include the improvement of feeding tolerance, reaching full enteral feeds quicker and a decreased incidence of re-admission (Schanler *et al.*, 1999:1150; Vohr *et al.*, 2006:e115; Vohr *et al.*, 2007:e953). Although controversy previously existed about the effect of human milk on the reduction of NEC, two meta-analysis studies concluded that human milk reduces the incidence of NEC, irrespective of whether it is donor milk or the mothers own milk (Ip *et al.*, 2007:1; Sullivan *et al.*, 2010:562).

Breast milk improves rapid gastric emptying and gut motility, which contribute to more frequent passing of stools and an improved gastrointestinal tract system (Tudehope, 2013:S19). Breast milk also protects preterm infants from foreign proteins by providing hormones, peptides, amino acids, nucleotides, growth factors and inhibitors of pro-inflammatory cytokines, which lead to enhanced maturation of the mucosal barrier (Tudehope, 2013:S19). The enhanced mucosal barrier has numerous benefits, with studies indicating that preterm infants who receive breast milk have lower rates of: late onset sepsis, upper respiratory tract infections, urinary tract infection and diarrhoea (Tudehope, 2013:S19).

Breastfeeding also forms part of the interventions to prevent non-communicable diseases (Eidelman *et al.*, 2012:830). Long-term studies indicate that preterm infants receiving breast milk have lower rates of factors contributing to non-communicable diseases such as metabolic syndrome, lower blood pressure and low-density lipoprotein concentrations as well as improved leptin and insulin metabolism (Lucas, 2005:S2; Singhal, *et al.* 2001:413).

## **2.5 Global strategies for promoting and protecting breastfeeding**

When it comes to protecting, promoting and supporting breastfeeding, it is important that politicians, health care providers and employers, should form part of the support system for mothers who decide to breastfeed (Lutter *et al.*, 2013:213). A study done by Lutter *et al.* (2013) indicated that there is a positive correlation between exclusive breastfeeding rates and duration of breastfeeding. They did this by quantifying the relationship between breast feeding promotion and changes. Due to the fact that over two thirds of infant deaths are related to poor feeding during the first year of life, it is extremely important for individual countries to establish proper feeding strategies (Lutter *et al.*, 2013:213). Table 2-1 indicates the interventions that improve and promote breastfeeding practices, as adapted from UNICEF 2012. These interventions targets various areas of effectiveness such as the improvement of early initiation of breastfeeding, extended duration of breastfeeding, improved practices regarding breastfeeding and an improved attitude towards breastfeeding. A BMB would support the interventions promoting breastfeeding practices.

**Table 2-1: The interventions which improve and promote breastfeeding practices adapted from UNICEF 2012**

Intervention	Area of effectiveness			
	Improve early initiation of BF	Extend duration of BF	Improve BF practices	Improve attitude towards BF
Maternity care practices	✓	✓		
Professional support		✓		
Lay and peer support	✓	✓		
Community-based breastfeeding promotion and support			✓	
Media and social marketing	✓			✓
Support for breastfeeding in the workplace		✓		

The factors known to promote successful breastfeeding include the interventions already described in Table 2-1 as well as implementations of the International Code for Marketing of Breast-milk Substitutes, the Baby Friendly Hospital Initiative and human BMBs (Lutter *et al.*, 2013:218). The Government of Brazil supports the implementation of BMBs and there are one or more BMBs in each of the 26 states. These BMBs provide milk to ill newborn infants and it fosters a culture of breastfeeding in hospitals (Lutter *et al.*, 2013:218).

National breastfeeding policies should also protect, promote and support breast milk banking, because it is a reasonable and effective way of providing infants with breast milk (Arnold, 2006:5). The establishment of BMBs is severely impaired in countries where there is no public health policy that supports donor milk banking or the regulation of its operations (Arnold, 2006:5). The WHO/UNICEF policies pertaining to breast milk banking have been consistent over the years. In 1980, the WHO recommended donor milk as the “first alternative” when the mother is unable to breastfeed, and in 1992, donor milk was accepted as an alternative feeding choice if the mother tested positive for HIV (WHO, 2003:12). The use of banked donor milk was reaffirmed in 1998 and in 2003 in a publication on HIV and infant feeding (Arnold, 2006:5). The WHO awarded the Sasakawa Prize to Dr. Joao Aprigio Guerra de Almeida of Brazil in 2001 for his work in organising the largest and most important breast milk banking system in the world (Arnold, 2006:5). The Sasakawa Prize that was established in 1984, is intended for one or more persons, institutions or NGOs that have accomplished outstanding work in health developments. Brazil is unique in the sense that with the promotion, protection and support of breast milk banking, they have found

ways to promote, protect and support breastfeeding, resulting in breastfeeding becoming a cultural norm (Arnold, 2006:5).

## **2.6 Strategies for promoting breastfeeding in South Africa**

South Africa has a variety of strategies for promoting breastfeeding and optimal feeding for infants. These strategies include the Elimination of Mother-to-Child Transmission of HIV (EMTCT) program and the Tshwane declaration of Support for Breastfeeding in South Africa, amongst others.

### **2.6.1 The Elimination of Mother-to-Child Transmission of HIV program**

South Africa implemented the Elimination of Mother-to-Child Transmission of HIV (EMTCT) program, which was developed by the WHO in 2001, as a strategy to decrease the HIV incidence rate in infants. The Preventative Mother-to-Child Transmission of HIV (PMTCT) program, as it was previously named, entailed that HIV positive mothers could receive free formula milk for the first six months of the infants' life at all public health facilities. They could only receive the formula if the following criteria concerning the use of formula milk were met: acceptability, feasibility, affordability, sustainability and safety (AFASS) (Ijumba *et al.*, 2012:2). Exclusive breastfeeding was recommended if the mother did not meet the AFASS criteria. The rationale behind this decision was that mothers could feed their infants optimally without exposing them to HIV. The general population also began opting for formula milk due to the concerns for HIV transmission (Ijumba *et al.*, 2012:2). Unfortunately, due to the misinterpretation of the AFASS criteria on the provider-client level, the mothers started to mix feed or abstained from breastfeeding and this led to the increase in the incidence of diarrhoea due to the poor access to safe, clean water (Doherty *et al.*, 2007:1791). This provision of free formula milk and mixed messages from health care workers, kept the South African breastfeeding rate low (Doherty *et al.*, 2012:105). It was also found that there is an increase in infant mortality rate associated with formula feeding (Doherty *et al.*, 2011:4).

The WHO revised their recommendations of recommending formula milk for HIV positive mothers after three large cohort studies were done in South Africa, Cote d'Ivoire and Zimbabwe. These studies concluded that exclusive breastfeeding reduces the risk of HIV transmission by more than 50 percent when compared to infants not fed breast milk exclusively (Becquet *et al.*, 2006; Coovadia *et al.*, 2007:1107; Iliff *et al.*, 2005:699). The 2009 WHO guidelines were adjusted for a second time after studies showed a significant reduction in the risk of post-natal HIV transmission if either the HIV-infected mother or HIV-exposed infant received antiretroviral therapy (Bedri *et al.*, 2008:300). The updated 2009 WHO guidelines subsequently recommended that the national authorities in each country should decide which single infant feeding practice to recommend

(WHO, 2010:3). In 2010, South Africa already had new clinical guidelines on the implementation of the new ARV therapy guidelines. These new clinical guidelines stated that if the HIV positive mother uses ARV therapy and/or the infant receives nevirapine prophylaxis, he/she can breastfeed for up to one year (WHO, 2010:108). There was, however, great concern about the 2010 Preventative Mother-to-Child Transmission of HIV guidelines, as these still recommended providing free formula milk, which resulted in confusion amongst mothers due to receiving mixed messages. (Doherty *et al.*, 2011:8). The mothers did not know if they should breastfeed while they use ARV therapy or rather use the formula milk that was still provided. Another concern was the mixing in unsafe settings which led to the increase in the incidence of malnutrition (WHO, 2010:22). KwaZulu-Natal was the first provincial department in South Africa to discontinue the distribution of free formula milk in 2012 (Ijumba *et al.*, 2012:762).

### **2.6.2 The Tshwane declaration**

The most recent available statistics on exclusive breastfeeding (EBF) in South Africa was obtained during a survey in 2003; this survey found that South Africa's prevalence of EBF was at only 7,4 percent (HSRC, 2012:144). This issue was therefore raised during the development of the Tshwane declaration, since the infant and child mortality rates in South Africa remain unacceptably high at 47 deaths per 1 000 live births. For this reason, South Africa might not achieve the MDG of reducing the rate of under-five mortality by two-thirds or a target rate of 20 deaths per 1 000 live births (DOH, 2011:214; UNICEF, 2012:1).

To address the above, the Tshwane declaration noted that promoting, protecting and supporting breastfeeding, irrespective of maternal HIV status, will reduce child mortality. This reduction of child mortality is a priority of the South African Government. This new declaration created an opportunity to promote EBF, irrespective of the mothers' HIV statuses, or years of poor feeding practices (Ijumba *et al.*, 2012:1). Some of the key points of the declaration concluded that infants that were not breastfed exclusively for the first six months had a six- to tenfold increase in the possibility of death from diarrhoea and pneumonia, two of the leading causes of infant death; furthermore, almost all mothers can breastfeed with success; and breastfeeding improves an infant's chance on survival.

The Tshwane declaration of Support for Breastfeeding in South Africa, which was signed by the national Department of Health in August 2011, is an initiative that shows South Africa's commitment to improving maternal and child health (DOH, 2011:214). South Africa adopted the 2010 WHO guidelines on HIV and Infant feeding in 2011 and the main focus of the health services changed to that of support and counselling for mothers known to be HIV infected. These mothers using ARVs were encouraged to breastfeed exclusively for six months and to continue with breastfeeding for up to one year after complimentary foods have been introduced (DOH,

2011:214). The mothers that are HIV negative or do not know their status, should exclusively breastfeed their infants for six months and continue breastfeeding for up to two years or longer. These guidelines are in accordance with the Global strategy for Infants and Young Child Feeding (IYCF) (DOH, 2013:11).

The Tshwane declaration resolved that the issuing of free formula milk should be discontinued and phased out from April 2012. The declaration also came to the conclusion that BMBs should be promoted and supported as an effective approach to reduce early neonatal and post-natal morbidity and mortality for infants who cannot be breastfed. The 2013 IYCF Policy recommends that high risk infants in need of donor human milk, should be prioritised as follows: very low birth weight infants (<1 500 g), very pre-term infants (Infants born at less than 32 weeks of gestational age), low birth weight infants (<2 500 g) and HIV exposed infants who are not able to suckle or whose mothers are too sick to breastfeed (DOH, 2013:23). A BMB ensures that there is donated breast milk available for these high-risk infants (Arslanoglu *et al.*, 2010:1).

## **2.7 History and background of BMBs globally and nationally**

### **2.7.1 History of Breast milk banks**

The Human Milk Banking Association of North America (HMBANA) defines “a donor human milk bank as a service established for the purpose of collecting, screening, processing, storing, and distributing donated human milk to meet the specific needs of individuals for whom human milk is prescribed by health care providers who are licensed to prescribe” (Updegrave, 2005:27).

The first recorded BMB was established in Vienna, Austria, in 1909, with the second opening in Boston and the third in Germany (Jones, 2003:313). With regards to the African continent, some articles report that Cape Verde opened the first BMB in Africa in 2011 with the help of Brazil. Other literature states that the first BMB in South Africa was already opened in Durban in December 1980 (Villanueva, 2011:d5179).

BMBs are established and being established in South Africa in order for breastfeeding mothers to be able to donate breast milk to preterm infants in need. There are three BMB non-profit organisations in South Africa, namely Milk Matters, the South African Breast Milk Reserve (SABR) and Ithemba Lethu. SABR supports hospitals in setting up milk banks in eight of the nine provinces, whereas Ithemba Lethu provides support in Kwazulu-Natal and Milk Matters in the Western Cape. Milk Matters has opened three BMBs and the SABR 18 BMBs. The first BMB in the North West Province was opened in the Kenneth Kaunda district in July 2012 with the support of the SABR.

## 2.7.2 Implementation of breast milk banks

Countries such as the United States of America, Australia, Brazil and Italy, to name a few, have published guidelines on the operation of a BMB.

The guidelines from the various countries listed above, discuss some of the aspects that are needed to implement a BMB, but a tool guiding the establishment of a BMB or the implementation process has not been documented yet. The United Kingdom's guidelines focus on the period following the establishment of the human milk banks, and they address the following topics: lifestyle, medication, infections, collection of milk, storage of milk, bacteriological testing of milk, heat treatment of donor breast milk, handling of breast milk and archiving samples of breast milk (Baumer, 2004:ep27). The guidelines of the Italian association of human milk banks (AIBLUD) for the operation of a donor human milk bank, discuss donor selection, procedures for collection and storage of the milk and the operative procedures. The AIBLUD guidelines are very similar to that of the United Kingdom (Arslanoglu *et al.*, 2010:347). These published guidelines provide the vital information that is needed to operate a BMB successfully. The Human Milk Banking Association of North America (HMBANA) also provides guidelines, but it is not freely available and is mainly relevant to the American setting. The HMBANA also addresses some of the required aspects needed by an institute to qualify to open and operate a BMB.

The mentioned guidelines discuss some of the aspects or progress-markers that are needed to operate a BMB, but they do not address the implementing process, namely the pre-implementation process and the institutionalisation of a BMB. The lack of implementation process guidelines in the current literature, especially in the South African context, clearly indicates that there is a need for a tool to guide the implementation of a BMB in South Africa.

Additional to the discussed guidelines, there is a Kangaroo mother care (KMC) progress-monitoring tool, which was developed for the South African setting. Further investigation showed that this tool can be used to guide the implementation process of a BMB (Bergh *et al.*, 2005:1102). Bergh *et al.* (2005) conducted a study with the aim to develop and test a monitoring tool with quantitative indicators or progress markers that could measure the progress of individual hospitals in the implementation of KMC in the South African setting. Feedback is easily achieved with the KMC progress-monitoring tool because it leads itself to visual presentation and also does not need to progress linearly and allows for one step to continue without the previous step being fully completed. They concluded that their KMC progress-monitoring tool also has the potential to be adapted and will be discussed in chapter 3 to measure progress in other interventions, such as in the implementation of a BMB.

## **2.8 Situation with implementation of BMBs in different countries**

### **2.8.1 European Countries**

#### **2.8.1.1 United Kingdom**

The first milk bank in the United Kingdom (UK) was established at Queen Charlotte's Hospital in London in 1939 (Baumer, 2004:ep27). This milk bank is the longest standing milk bank in the world. The UK currently has 17 BMBs, one in Scotland, one in Ireland and 15 in England. During 2013, the only milk bank operating in Scotland, moved to a new site and has since become a centre offering a national service to Scotland. All countries in Europe are members of the European Milk Bank Association (EMBA) as can be seen in Figure 2-3. The EMBA is a non-profit organisation with the aim of promoting BMBs in Europe and encouraging international cooperation between BMBs in the European countries. The EMBA was established in 2010. The UK follows the National Institute for Health and Care Excellence (NICE) guidelines in establishing and operating a donor milk bank. The National Institute of Health and Clinical Excellence (NICE) published a best practice guideline on the operation of donor milk bank services. This guideline discusses the recruitment of donors, the duration of donation, collection and transport of the milk, processing donor milk at the milk bank, tracking and tracing donor milk and the quality assurance of the milk (NICE, 2010:6). The NICE guidelines recommend that milk should not be pooled and that it should be pasteurised. The donors do not pay to donate and they also do not receive any financial incentive for donating. The NICE guidelines for operating a donor milk bank (NICE, 2012:1), which were developed in 2010, do not make recommendations for the configuration of services, but do make recommendations for the safe and effective operation of donor milk services, as this is their main focus. The NICE guidelines provide guidelines on how donors should be recruited, screened and supported and on how to handle and process the milk they receive. It does not, however, discuss what happens to the milk as soon as it leaves the bank and how to care for and treat the infants receiving donor milk or how mothers should handle and store breast milk for their own infants.

The managers of the donor milk are a senior midwife and a paediatrician or a senior scientist, and the staff members that handle the donor milk are mostly nurses, although some BMBs use trained staff members that have other designations. Some BMBs also have volunteers that collect the milk. Preterm infants and infants recovering from gut surgery are the main recipients of the donor milk. A study performed in the UK by Renfrew *et al.* (2009:4), aimed to determine whether the availability of donor milk influenced the promotion, initiation and duration of breastfeeding. They concluded that if it was handled correctly, it would be influential (Renfrew *et al.*, 2009:4).

### **2.8.1.2 Norway**

Norway experienced a decrease in breastfeeding after the Second World War due to scheduled feeds and the availability of formula milk. The Germans opened the first BMB in Norway in 1941 during the Second World War and it is currently located at the Ullevål University Hospital in Oslo. Norway currently has 12 BMBs. The Norwegian National Board of Health published guidelines on the operation of donor milk banks in 2002. These guidelines define the organisational structure of the milk banks, the equipment, donor qualifications and exclusion criteria, and procedures for screening, handling, and dispensing the milk (Grøvslien & Grønn, 2009:206). Norway screens their donors carefully and dispense the donor milk raw rather than pasteurised, while pasteurisation is the norm in all the other countries. The main difference regarding the operation of their BMBs is that they use raw, unpasteurised milk for preterm infants. There is only one milk bank that pasteurises the milk it provides to preterm infants <1 500 g, and that this bank is the only bank that reimburses donors for expenses (Grøvslien & Grønn, 2009:207). Norway also joined the EMBA.

### **2.8.1.3 Italy**

The first BMB in Italy opened in 1965 and there are currently 30 BMBs in Italy. Italy also belongs to the EMBA with their office situated in Milan. Within the European Union, the organization in Italy (The Italian Association of Human Milk Banks (AIBLUD)), however, have their own guidelines to use as a tool to optimise the functioning of all the milk banks in Italy, by guiding milk banking rather than being a rigid or prescriptive tool. These guidelines were compiled by a Working Group in 2002. This association is also a NGO. A multidisciplinary team, consisting of neonatologist, dietitian, nutritionist, parents of infants, nurses working in NICUs and representatives of the Islamic community developed this guideline (Arslanoglu *et al.*, 2010:2). Donor milk is also not

pooled and are pasteurised; donors do not pay to donate or receive financial incentive when donating.



**Figure 2-3: Active and planned breast milk banks supported by the European Milk Bank Association (Reprinted with permission)**

**2.8.2 Brazil**

BMBs in Brazil are coordinated by the Ministry of Health and this coordinating organisation is called the National Network of Human Milk Banks (Rede de Bancos de Leite Humano – REDEBLH). The BMBs assist in the promoting of breastfeeding and therefore form part of the national public health policy in Brazil (Almeida & Dorea, 2006:335). The Brazilian Ministry of Health provide training in the management of a BMB. As mentioned earlier, the REDEBLH received the Sasakwa Health Award for the best public health project in 2001.

The first BMB was opened in 1978 at a regional hospital called Hospital Regional de Taguatinga (Almeida & Dorea, 2006:335). There are currently numerous BMBs in public as well as private hospitals in Brazil. The REDEBLH website that was updated in 2014, indicates that there are an astounding 213 BMBs located within the 26 Brazilian states.

The amount of litres of donor milk dispensed, the number of infants that benefits from this milk and the amount of money saved by providing donor milk, make Brazil's donor milk banking system one that should be imitated (Arnold, 2006:7); especially by other developing countries such as South Africa.

### **2.8.3 Australia**

Donating breast milk to preterm infants or supplementing full-term infants during the night was a common practice in maternity hospitals in Australia in the 1940s. The use of mothers' milk in hospitals was replaced with the use of artificial infant milks in the late 1950s. When the hospitals needed EBM, they sought donations from the community (Thorley, 2012:247).

In the early 1980s, the milk bank of the Royal Alexandra Hospital for Children in Sydney made use of donated milk from mothers in the community. One of the sources of donor milk was the Nursing Mothers' Association of Australia (NMAA), now called the Australian Breastfeeding Association; a non-government organisation. The NMAA established one of the formal BMBs in 1978 and used trained volunteers as counsellors. The NMAA developed their own policy statement in 1975 stipulating that a variety of forms needs to be filled in and recorded for the purposes of the group leader. After the second volunteer that acted as the coordinator of this BMB relinquished her position, the BMB had to close, because there was no one to replace her. The NMAA withdrew from milk banking due to their concern about legal liability. They developed a new policy in 1978, stating that they are not responsible for the establishment or maintenance of breast milk banks (Thorley, 2012:250). The NMAA completely withdrew from milk banking by 1979. Not only the legal liability was a direct reason for the failure of the milk bank, but also the fact that sustaining the milk bank revolved around the involvement of and time that volunteers had available (Thorley, 2012:250). There is another milk bank on the Gold Coast of Queensland that is still operating, but they are struggling with a lack of funding.

The Perron Rotary Express Milk Bank (PREM Bank) was established at the King Edward Memorial Hospital in Western Australia. This organisation established the first formal milk bank since the revival of BMBs in Australia in 2006, and they developed a best practice guideline that addresses safety, quality and good manufacturing practices (Hartmann *et al.*, 2007:667). Their intention was that these best practice guidelines should be used when a national standard for the operation and management of donor human milk banks in Australia is developed.

The procedures and management practices that the Perron Rotary Express Milk Bank (PREM) developed, are based on the internationally recognised practices of other operating milk banks and is consistent with blood and tissue donation in Australia (Hartmann *et al.*, 2007:669). Australian human milk banks are not regulated under a specific legislation. There is also no specific standard in screening human milk donors, when compared to the standard screening process of EMBA and HMBANA. These two associations have developed guidelines for donor screening that Australia has applied in their context. However, the microbiological standards that the PREM bank uses are based on the United Kingdoms' guidelines. The PREM Bank pools the milk of one specific donor before pasteurisation and tests the pooled milk for bacterial growth (Hartmann *et al.*, 2007:667).

Australia has five formal milk banks to date of which the non-profit organisation, Mothers' Milk Bank (MMB), is the first community based milk bank. Volunteers, including health professionals and other volunteers, run the MMB. All the BMBs in Australia are operated by NGOs and they are dependent on volunteers and donations.

#### **2.8.4 United States**

The United States does not have a federal public health policy in place to support donor milk banking or the regulation thereof. For this reason, breast milk banking services are severely impaired (Arnold, 2006:2). The Human Milk Banking Association of North America (HMBANA) is the association regulating the milk banks in Canada, Mexico and the United States and was founded in 1985. HMBANA is a non-profit organisation that standardises and facilitates the establishment and operation of BMBs (Updegrave, 2005:27; Bronwell *et al.*, 2014:48). They have opened 18 BMBs that rely on donations and payments from donor milk recipients and hospitals.

HMBANA defines donor milk banking as 'a service established for the purpose of collecting, screening, processing, storing and distributing donated human milk to meet the specific needs of individuals for whom milk is prescribed by health care providers who are licensed to prescribe'. Although there were BMBs in the United States that operated as described in the definition, there were still BMBs that closed. The various factors which led to the closing of many BMBs included the marketing of formulas, decreased breastfeeding rates, and fears of viruses and other illnesses that could be spread through breast milk (Jones, 2003:313). The screening process for donors followed by HMBANA, is the same than the process described in the USA human blood bank guidelines and is reviewed and updated annually (Jones, 2003:313). They do not have a centralised data repository yet, and in 2010 the Food and Drug Administration suggested that they develop a data repository (Brownell *et al.*, 2014:52). HMBANA' guidelines recommend pooling three to five donors' milk before pasteurisation.

### 2.8.5 Taiwan

Taiwan opened their first hospital based BMB in Taipei in 2005. Taipei City Hospital followed the guidelines of HMBANA and the United Kingdom Association for milk banking (UKAMB) and are also a non-profit organisation (Chang *et al.*, 2013:28). Therefore, it can be presumed that Taipei City Hospital pasteurise the milk, do not pool any milk, do not give any financial incentives to donors, to name a few comparative guidelines. The concept of donor milk has been accepted by the general population and the expectation and processing capacity of the Taiwanese Ministry of Health have been exceeded. The BMBs in Taiwan are funded by the Taipei City Hospital and the Department of Health of Taipei City Government.

As can be seen from the discussion, there are numerous BMBs worldwide. Not all countries have published guidelines concerning their BMBs, however, most countries do have websites and contact information.

The various countries all have basic principles in common: for instance recruiting donors, a donor screening form, a place to store the milk, and guidelines for the recipients. There are, however, other areas where there are differences, for example: pasteurising the milk or not, pooling the milk or keeping it separate, paying donors for milk or not (see Table 2-2). These principles influence the way in which the specific BMB of that institution is operated, but that does not necessarily mean that a BMB may be more or less successful.

**Table 2-2: Comparison of breast milk banks**

	<b>United Kingdom</b>	<b>Norway</b>	<b>Italy</b>	<b>Brazil</b>	<b>Australia</b>	<b>United States</b>	<b>Taiwan</b>
Date of 1 <sup>st</sup> formal recorded BMB	<b>1939</b>	<b>1941</b>	<b>1965</b>	<b>1978</b>	<b>1978</b>	<b>1985</b>	<b>2005</b>
Relevant BMB associations	European milk bank association (EMBA)	Norwegian National Board of Health	European milk bank association (EMBA) and Italian Association of Human Milk Banks Associazione Italiana Banche del Latte Umano Donato (AIBLUD)	Rede de Bancos de Leite Humano (REDEBLH)	Mothers milk bank (MMB) Mercy Health Breastmilk Bank KEMH PREM (Perron Rotary Express Milk) Bank	Human Milk Banking Association of North America (HMBANA)	Human Milk Banking Association of North America (HMBANA) and United Kingdom association for milk banking (UKAMB)
Funded by	Donations	Donations	Donations	Government	Donations	Payments made by donor milk recipients and hospitals Donations	Government
Volunteers/staff in hospital	Staff in hospital and volunteers	Staff in hospital and volunteers	Staff in hospital and volunteers	Staff in hospital	Volunteers and staff in hospital	Staff in hospital	Staff in hospital

	<b>United Kingdom</b>	<b>Norway</b>	<b>Italy</b>	<b>Brazil</b>	<b>Australia</b>	<b>United States</b>	<b>Taiwan</b>
Type of guideline	NICE: Donor breast milk banks: operation of donor milk bank services	Guidelines on the operation of donor milk banks.	Guidelines for the establishment and operation of a donor human milk bank	Instituto Fernandes Figueira/Fundacao Oswaldo Cruz (FIOCRUZ) developed their own guidelines	Developed their own best practice guideline. Microbiological standards are based on UK's guidelines	Developed their own guidelines: Guidelines for the Establishment and Operation of a Donor Human Milk Bank	Guidelines for the Establishment and Operation of a Donor Human Milk Bank and NICE guidelines: Donor breast milk banks: operation of donor milk bank services
Pooling	No	No	No	No	Yes, pools (one donor at a time)	Yes, pools (3-5 donors at a time)	No
Financial incentive for donors	None	Reimburses donors for expenses	None	None	None	None	None
Number of banks	17	12	30	213	5	18	1
Regulating authority				Federal quality control	No specific legislation	None	Government
Pasteurisation	Pasteurise	Unpasteurised except for one BMB which pasteurises the milk	Pasteurise	Pasteurise	Pasteurise	Pasteurise	Pasteurise

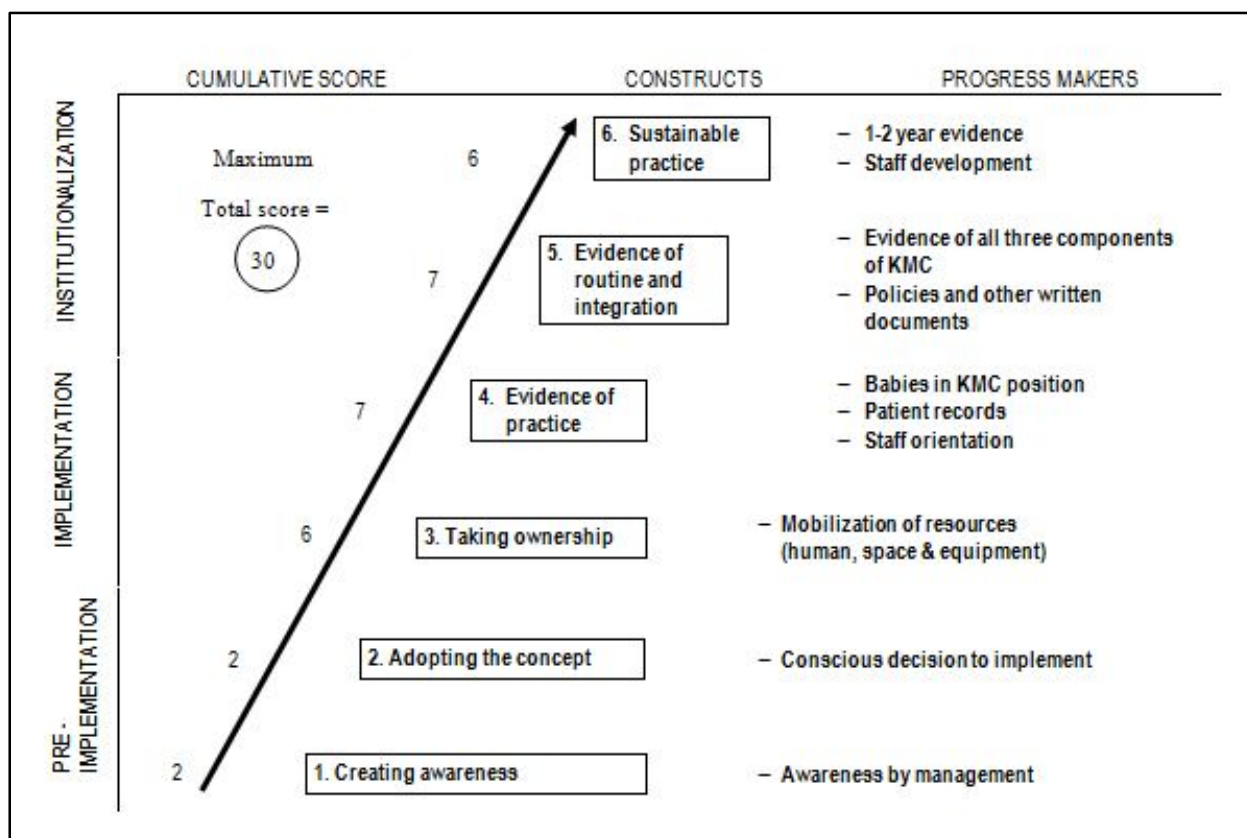
	<b>United Kingdom</b>	<b>Norway</b>	<b>Italy</b>	<b>Brazil</b>	<b>Australia</b>	<b>United States</b>	<b>Taiwan</b>
Non-profit organisation or government funded	Non-profit organisation	Government funded	Non-profit organisation	Government funded	Non-profit organisation	Non-profit organisation	Non-profit organisation
Failed/succeeded	Succeeded	Succeeded	Succeeded	Succeeded	First BMBs failed due to legal liability and struggling due to lack of funding, current BMB struggling due to lack of funding	Succeeded	Succeeded

## 2.9 Implementation tools

Implementation tools are needed to create change in an orderly fashion. There are various tools that can be used when a new process needs to be implemented (Aarons *et al.*, 2011:4). The different tools summarise factors with different focus areas at multiple levels, for example, some tools focus on the importance of developing alignments among stakeholders in the community (Aarons *et al.*, 2011:5) and other tools focus on the significance of extensive and ongoing partnerships with consumers and agencies (Aarons *et al.*, 2011:5). The contextual levels help to form an organised frame. The process of implementing evidence practices can be challenging, therefore this process can sometimes lead to a service not meeting its full potential (Aarons *et al.*, 2011:4).

There are core themes that are apparent in all the implementation tools, such as phases like pre-implementation, implementation and maintenance. There is consensus that the implementation phases do not always happen in an undeviating manner (Aarons *et al.*, 2011:4). Although implementation phases consists of many components, there may be different focuses on specific factors in the tool, depending on the significance of these components.

A search of the available literature for a suitable implementation tool for the implementation of a BMB in the South African setting or within other countries was performed. Unfortunately, an implementation tool that provided guidance from pre-implementation to institutionalisation could not be found for the BMB setting. There were some peer-reviewed articles that provided some guidance for the operation of a BMB, but the data within those articles was not sufficient to guide the whole implementation process of a BMB. Consequently, a search was done to find the most relevant tool within the health sector that could be adapted to the BMB setting. The only tool found that could be used in the BMB setting was the Kangaroo mother care (KMC) progress-monitoring tool that was developed by Berg *et al.* (2005). The KMC progress-monitoring tool was developed by using three different data sets and they aimed at identifying important implementation issues in hospitals in South Africa, experiences and barriers to the implementation. Bergh *et al.* (2005) found that this tool, depicted in Figure 2-4, also had the potential to be adapted because it addresses the same concerns for measuring progress in other interventions (Bergh *et al.*, 2005:1104). This KMC progress-monitoring tool has the advantage that it was developed within the South African health sector setting.



**Figure 2-4: The KMC progress-monitoring tool (Bergh, *et al.*, 2005:1102-1108) (Reprinted with permission)**

Bergh, *et al.* (2005) developed the “KMC progress-monitoring tool” by including different data sets that were obtained from amongst others interviews, observations and field notes, as well as relevant documents and questionnaires. The data was analysed and conceptualised in three main phases: pre-implementation, implementation and institutionalisation. Six constructs to depict the progress of implementation were described: creating awareness, adopting the concept, mobilisation of resources, evidence of practice, evidence of routine and integration and sustainable practice. These main phases, constructs and progress markers could either be adapted or contextualised to the BMB setting to provide a BMB implementation tool.

Due to the fact that there are so many different aspects to take into consideration when developing an implementation tool, it is important to try and make sure that all the necessary constructs and progress makers in the different phases are included and addressed (Aarons *et al.*, 2011:4). The researcher concluded that there are many successful BMBs worldwide, and although not all of them operate in exactly the same manner, they all have similar constructs. The development of an implementation tool for a BMB in the North West Province will therefore take the constructs and progress makers of other BMBs into consideration as well as those identified for the implementation tool that Bergh *et al.* (2005) developed, seeing that this tool is relevant to the

South African health care system. With the revival of the interest in BMBs and the increasing number of BMBs that still need to be opened, there is need for clear guidance on how to implement these BMBs.

## **2.10 Conclusion**

From this literature review the benefits of breast milk in general and specifically to preterm infants were discussed as well as the initiatives to promote breastfeeding in general and specific to the South African setting. These initiatives included the history of BMBs and a general overview of the situation of the implementation of BMBs worldwide. It became clear that there is a need for the development of a tool to guide BMB implementation, due to the lack of such a tool guiding the step-by-step implementation of BMBs in South Africa. This lack was identified and led to the aim of developing and auditing a tool to guide BMB implementation.

## **CHAPTER 3: ARTICLE**

Manuscript prepared for submission to Journal of Human Lactation

### **A tool to guide breast milk bank implementation**

#### **Authors:**

Maria Pretorius

Robin Dolman


Welma Lubbe

Namukolo Covic

### 3.1 Permission to submit this article for examination purposes

I, the supervisor, hereby declare that the research done by Maria Pretorius reflects her input and effort in the exploration of this topic.

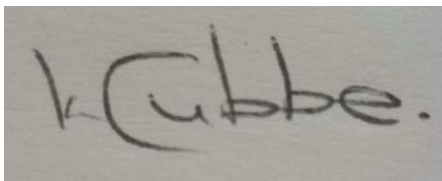
I hereby grant permission that she may submit this article not only for publication, but also for examination purposes in partial fulfilment of the requirements for the degree Magister Scientiae Dietetics.



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Supervisor: Robin Dolman


Date: 29 April 2015



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Co-supervisor: Welma Lubbe

Date: 29 April 2015



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Assistant supervisor: Namukolo Covic

Date: 29 April 2015

### 3.2 Declaration by the researcher

I hereby declare that this research 'A tool to guide breast milk bank implementation' is my own work and that all sources have been fully referenced and acknowledged.



---

M. A. Pretorius

Date: 29 April 2015

### **3.3 Declaration by the language editor**

I hereby confirm that I have language edited the article titled 'A tool to guide breast milk bank implementation'.

\_Elma de Kock\_\_\_\_\_

Date: 27 April 2015

## 3.4 Journal of Human Lactation: Submission guidelines

Updated 3/19/14

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#### Article Categories

- Reviews
- Original Research
- Original Research (Brief Reports)
- Student Research
- Case Reports
- Insights in Practice
- Insights in Policy
- Commentaries
- Special Reports
- Inside Track
- Letters to the Editor

**IMPORTANT:** Authors must follow both the "General Requirements for Manuscripts Submitted" and the "Requirements for Article Categories" sections below. Manuscripts that do not adhere to the following instructions will be returned to the corresponding author for technical revision before undergoing peer review.

#### GENERAL REQUIREMENTS FOR MANUSCRIPTS SUBMITTED

##### Preparation of Manuscript

Manuscripts should be prepared according to the guidelines set forth in the *American Medical Association Manual of Style, 10th Edition*. All text should be double-spaced. Font size should be 12 pt. Margins should be set at 1 inch. Do not include page numbers as these will automatically be added when the manuscript is submitted and converted to a PDF file. The main manuscript file should be a Word document (.doc or .docx). Tables can be created in Word or Excel. Charts and graphs should be provided in whatever format they were created in, such as Word or Excel. Photographs should not be copied into a Word or PowerPoint document; they should be provided in whatever format they were originally made in (eg. jpg, tiff, eps). For photographs, please ensure that they are high-resolution (at least 300 dpi).

Acceptable English usage and syntax are expected. Do not use slang, medical jargon, or obscure abbreviations or phrasing. Metric measurement is preferred; equivalent measurements may be included in parentheses. Always provide the complete form of an acronym/abbreviation the first time it is presented in the abstract and text. Write breast milk as two words, breastfeeding as one. Use generic names for drugs or devices; put trade names in parentheses.

##### Title Page

ALL submissions require a Title Page. This is the only file which should include the authors' names. The Title Page must be uploaded as a separate file to ensure blind peer-review. The Title Page must include: (a) Complete manuscript title; (b) Authors' full names, academic degrees, and affiliations; (c) Name and address of corresponding author, including fax and telephone

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numbers, and email address; (d) Address for reprints if different from that of corresponding author; (e) Word counts for the abstract, and for text independent of abstract; (f) keywords which will be used for PubMed reference (always include "breastfeeding" as a keyword); and (g) Acknowledgments, if the authors wish to include them. Authors may acknowledge persons who have contributed to the research or manuscript development. Participation of research subjects may be acknowledged, but subjects must not be specifically named. Limit acknowledgments to 50 words.

#### **Ethical Approval / Protection of Human Subjects and Animals in Research**

When reporting research activities involving human or animal subjects, please include a statement in the Methods section of the article, indicating that all procedures followed were in accord with the ethical standards of the responsible institutional council, committee, or review board. Please specify which institution(s) granted approval. For example: "This study was approved by the Boston University Medical Center Institutional Review Board." If the research was exempt from ethical approval, please include a statement indicating that and an explanation. For example: "This study was exempt from ethical approval because it was a secondary analysis of a publicly available dataset." Research articles without a clear statement of such approval will be returned without review. For research involving animals, authors should indicate whether the procedures followed were in accordance with the standards set forth in the *Guide for the Care and Use of Laboratory Animals* (published by the National Academy of Science, National Academy Press, Washington, DC).

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When including participant photographs, please try to avoid making them recognizable (for example, do not show a face). If a photograph is recognizable, please include a statement in your manuscript indicating that written consent for using the photograph(s) was obtained. If your manuscript is accepted for publication, you will be asked to have the person in the photograph sign an additional *Journal of Human Lactation* photo consent form.

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*JHL* is now accepting audio/video files. The following file types can be handled by our manuscript submission Web site, Sage Track. Audio/Video: asf, avi, flv, mov, mp3, mp4, mpeg, mpg, wav, wma, wmv. For optimal viewing, videos should be 480x360 pixels. If it is a different size/aspect ratio, it will be resized upon upload. There is no limit to the length of the video, although the maximum file size allowed is 1GB. Videos hosted elsewhere (such as YouTube), can be included as links. Once uploaded, the videos will only be viewed in the HTML version of an article.

#### **Tables, Figures and Images**

Each table/figure/image must be uploaded as a separate file, not as part of the main text document. If there are multiple tables/figures/images, please upload each one as a separate file. Number tables/figures/images consecutively as referred to in the text. Provide each table/figure/image with a brief title above the table/figure/image. Place explanatory matter or data incorporated from another source in footnotes. Indicate footnotes with lowercase letters (a, b, c, etc.); do not use symbols. Presentation of the results from logistic regression, Poisson

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imaging studies; observational studies, and economic evaluations. The formatted manuscript should include the following sections:

**Well Established/Newly Expressed:** Two brief summary paragraphs stating what is already known on this topic (Well Established; 40 words max) and what this study adds (Newly Expressed; 40 words max). Please label each section separately and write clearly in layman's terms.

**Abstract:** A structured abstract (250-word limit) with the following headings: (1) Background, (2) Objective(s), (3) Methods, (4) Results, (5) Conclusion(s).

**Text:** 3500-word limit. Must include the following sections: (1) Background with clearly stated objective(s); (2) Methods; (3) Results; (4) Discussion; (5) Conclusion and (6) Funding and Conflict of Interest.

1. Background: should succinctly summarize the literature with regards to the objective(s).
2. Methods: must state the study design, and should include setting and dates of study, subject selection criteria, data collection methods, and statistical methods used. Statistical analysis should include the following items, as appropriate: pre-study calculation of sample size; statements adequately describing or referencing all statistical procedures used; confidence intervals given for the main results. **IMPORTANT:** please include a statement regarding which institution(s) granted ethical approval (see Ethical Approval section above).
3. Results: should clearly state the final sample size(s), participation and exclusions, and primary analyses that are parallel to the Objectives.
4. Discussion: should address the importance of the findings reported in the results section and how they compare to other published reports of a similar nature. A limitations section is expected.
5. Conclusion: should briefly summarize conclusions based on the content of the paper.
6. Funding and Conflict of Interest: Should comprise a brief summary of all funding sources and any conflict of interest that exists (for example funds or honoraria paid from any source that stands to gain financially from the outcomes described in the study.) This is included in the manuscript to ensure the information is visible to reviewers. When not applicable, the authors should state that no conflict of interest exists.

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1500-word limit excluding Abstract, tables, figures, and references; limit to 1 table and 1 figure. Brief reports on new, interesting findings will meet the same criteria as Original Research but will be reported in shorter format reflecting a less complex study design or original findings not requiring an extended manuscript. A title page, Well Established/Newly Expressed section, and structured abstract (250 words) are required. Manuscripts should be formatted using the same headings as Original Research articles (see above). **IMPORTANT:** please include a statement regarding which institution(s) granted ethical approval (see Ethical Approval section above).

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### **Insights in Practice**

1500-word limit, excluding tables, figures, and references. Innovative teaching aids and procedures, charting, and referral forms specific to a lactation workup are appropriate for this article category. We also invite general discussions about running a lactation consultant practice, hospital-based management and service issues, and contemporary insights related to clinical experience. The manuscript should include an unstructured abstract (limit 250 words), a background stating the issue/problem, a presentation of the recommendations, a summary of the information presented, and a conclusion. Include subheadings as necessary.

### **Insights in Policy**

2000-word limit, excluding tables, figures, and references. This article category is designed to feature new steps in policymaking, for example, innovative policies on lactation-related, hospital clinical practice, or steps forward in national or international policymaking, such as development of national guidelines for implementation of the Baby-Friendly Hospital Initiative. We also invite general discussion and contemporary insights on policymaking and ways in which policies can be changed or implemented. The manuscript should include an unstructured abstract (limit 250 words), a background stating the issue/problem, a presentation of the recommendations, a summary of the information presented, and a conclusion. Include subheadings as necessary.

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#### **Inside Track**

##### **What is an *Inside Track*?**

Each *Inside Track* is a 2-page handout written for breastfeeding mothers. The concept is to provide a resource that IBCLCs and other clinicians working with breastfeeding mothers can share with their clients.

##### **How does *Inside Track* differ from other *JHL* papers?**

All other papers in *JHL*, from Editorials and Commentaries to Original Research and Independent Study Modules, are aimed at lactation professionals (clinicians, researchers, educators, etc.). By contrast, *Inside Track* is for mothers. It is written in a low-literacy style to be readable by most breastfeeding mothers.

##### **How is *Inside Track* similar to other *JHL* papers?**

Like all other articles in *JHL*, *Inside Track* must be based on the latest evidence and research. Information needs to be referenced to a reliable, independent source or research publication (see References below). The fact that *Inside Track* is published in *JHL* lends it credibility that requires it to go beyond the average patient handout and include up-to-date, evidence-based information.

##### **What topics are suitable for *Inside Track*?**

Any topic that is practically applicable to a breastfeeding family. For example, milk supply, expressing and pumping for a premie, toddler nursing, returning to work, etc. It is important that topics are narrow enough in focus to incorporate into a single-page, double-sided handout. It is recommended that authors read past *Inside Tracks* and choose a topic that has not been previously addressed.

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At least 1 of the authors must be an IBCLC, and the lead author must be an ILCA member. If the lead author is not an ILCA member when the *Inside Track* is submitted, he or she must join ILCA prior to its publication. *Inside Track* seeks to promote the IBCLC and to foster new writers among ILCA’s membership.

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**Specifics:**

- Maximum word length: 650 words.
- Writing must be clear and use layman's terms; this would be a reading level of around age 10 (for example in the US – grade 5; approximating the reading level of WIC materials). This is not “talking down” to women but rather ensures accessibility for the widest possible audience, including women with lower literacy skills, women with limited English, and tired, new mothers!
- To achieve this, use short words and sentences, an active voice and conversational style, avoid double negatives, reduce use of words with 3 or more syllables and use bullets.
- *JHL* is an international journal, with readers from all levels of society all over the world. Avoid phrases that portray a narrow frame of cultural reference (such as “5<sup>th</sup> grade” or “here in the US”); avoid making assumptions about socioeconomic status (“use a private office to pump” or “be sure to sign up for WIC”). If you do need to use examples that might not be universal, qualify them (“In the US and some other countries...” or “If you can, ask for a private space to pump...”) As for all *JHL* articles, American spellings are used.
- Provide 2 relevant photographs. You will be asked to obtain written permission from the photographer(s) to use the photos. If a photo is recognizable (i.e., if a face is shown), you will also be asked to obtain written permission from the person (or parent of the person) photographed. High-resolution (at least 300 dpi) images are required and .jpg images are preferred. Tiff and .pdf images are also acceptable. Upload images separately from main text and title page files. In the main text file, indicate where you would like to place each photograph and provide captions.
- Include 1 or 2 bulleted lists to break down information into an easy-to-read format.
- Include information about the role of the IBCLC in relation to the topic presented in the *Inside Track*.
- Consider including a list of 1-5 relevant websites to provide mothers with helpful resources.

**References**

There is no need to reference well-known, evidence-based statements, for example, that breastfeeding is healthier than formula feeding, or that the BFHI improves hospital practices for breastfeeding women. Statements or claims that are not common knowledge, however, need to be referenced. So as (random!!) examples, the following would need to be referenced:

- Breastfeeding reduces ovarian cancer
- Premies born in Baby-Friendly hospitals breastfeed longer
- Breastfeeding moms cannot use Drug X
- Most newborns cry at least 2 hours a day

**Questions / Editorial Assistance**

If you have any questions about the manuscript submission process, please contact our editorial staff at [jhleditorialoffice@gmail.com](mailto:jhleditorialoffice@gmail.com).

References should be included for the benefit of the authors and the reviewers. They will not be published in the final *Inside Track*. References should be *primary sources*, that means, a (recent) paper from academic literature, a (recent) book, etc. Websites designed for popular reading are not valid reference sources, but websites by highly credible sources such as the CDC or the WHO are appropriate as references. References do not count in your word limit.

**Title page:**

*Inside Track* submissions require a Title Page. This is the only file that should include the authors' names. The Title Page must be uploaded as a separate file to ensure blind peer-review. The Title Page must include: (a) Complete manuscript title; (b) Authors' full names, academic degrees, and affiliations; (c) Name and address of corresponding author, including fax and telephone numbers, and email address; (d) Address for reprints if different from that of corresponding author; (e) Word counts for the abstract, and for text independent of abstract; (f) keywords which will be used for PubMed reference (always include "breastfeeding" as a keyword).

**Submission and peer review:**

All *Inside Tracks* should be submitted directly to *JHL* via the submission site at <http://mc.manuscriptcentral.com/jhl>. When the site prompts Manuscript Type, select *Inside Track* as the option. Reviewers will be chosen by *JHL* editorial staff, and will be alerted to the fact that this is an *Inside Track*, because the criteria for (readability, applicability, etc.) are different from other papers. Comments to the author will go directly to the author. As with other *JHL* papers, authors should allow a lead-time of approximately 4-6 months between submission and the article going into print. Not all submissions are guaranteed acceptance.

**Before submitting your *Inside Track*:**

- Is at least 1 author an IBCLC and is the lead author a member of ILCA?
- Is the word count 650 words or less?
- Is it written in a low-literacy style and have you included 2 photographs and 1-2 bulleted lists?
- Have you considered including a list of 1-5 helpful websites?
- Is the information based on the latest evidence and research?
- Have you included references to statements that are not common knowledge?
- Have you included information about the role of the IBCLC in relation to the topic presented?
- Have you uploaded separate main text, title page, and photograph files?

**Questions / Editorial Assistance**

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## **A tool to guide breast milk bank implementation**

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## **A tool to guide breast milk bank implementation**

Maria A. Pretorius, Robin C. Dolman, Welma Lubbe, Namukolo Covic

### **Abstract**

#### **Background:**

South Africa has several established breast milk banks (BMBs), but at the time of the study, no tool could be found to guide the step-by-step implementation process of a BMB from pre-implementation to institutionalisation. Bergh, *et al.* (2005) did however design a ‘progress-monitoring tool’ for the implementation of Kangaroo mother care (KMC) in the South African setting, and this implementation tool was considered suitable for adaption to BMB implementation.

#### **Objective:**

The aim was to adapt the KMC progress-monitoring tool in order to develop and provide a tool to guide BMB implementation.

#### **Methods:**

The study design was exploratory in nature. A qualitative approach to data collection and analysis was used, since a document audit of amongst others patient files, statistical control forms, guidelines and service agreement documents, minutes of meetings, policies and structured observation using a checklist from the service agreement document, was performed. The data was analysed by means of content analysis and by thematically organising the data into different categories.

**Results:**

The KMC progress-monitoring tool was adjusted by comparing data from documents to the KMC progress-monitoring tool to provide a suggested BMB draft tool. Thereafter, the data obtained from the selected regional hospital was compared to the suggested BMB tool to structure the final tool, the North West Province BMB implementation tool.

**Conclusion:**

An implementation tool was adapted to provide a tool to guide BMB implementation in North West Province and other settings in South Africa.

***Well Established:*** BMBs have been and are being established with the help of non-governmental organisations (NGOs) worldwide as well as in South Africa. These NGOs have systems in place to implement BMBs, but these systems vary.

***Newly Expressed:*** Currently, there are no published articles discussing the implementation process of a BMB in the North West Province to guide institutions to establish a new BMB. This article provides a suggested implementation tool for the establishment of a BMB.

## Background

Breastfeeding is the single most effective intervention to save the lives of millions of children in developing countries (Bhutta & Lobbok, 2011:379) and this intervention supports the fourth millennium development goal set by UNICEF to reduce the mortality rate of children under five by two thirds between 1990 and 2015 (UNICEF, 2005:18). The global infant mortality rate has dropped by 49% between 1990 and 2013, decreasing from 90 to 46 deaths per 1 000 live births. In South Africa, the infant mortality rate dropped from 61 to 44 deaths per 1 000 live births between 1990 and 2013; a decrease of only 28% (UNICEF; 2014a:1; Eidelman, *et al.*, 2012:827). South Africa's target rate is 20 deaths per 1 000 live births in 2015 and it is unlikely that South Africa will reach its target rate (UNICEF, 2005:18). The benefits of breast milk, such as amongst others, decreased risk of developing necrotising enterocolitis (NEC), improving gut motility, possible higher intelligence quotient, decreased risk of diabetes and being overweight, have been documented extensively (Furman *et al.*, 2003:66, Sisk *et al.*, 2007:808; Tudehope, 2013:S17).

Breast milk banks (BMBs) are used in many countries to provide donor milk to vulnerable infants in need. By providing donor milk, BMBs can contribute towards reducing infant mortality rates by preventing the prevalence of diseases such as NEC. This disease is one of the most common gastrointestinal diseases and the second most common cause of mortality in preterm infants (Lin & Stoll; 2006:1271; Panigrahi; 2006:151). Donor milk is essential in South Africa, with the high prevalence of HIV, in order to provide donor milk to preterm infants whose mothers are not able to provide breast milk initially and are therefore vulnerable to infections (DOH; 2013:22).

The Department of Health in South Africa made a declaration to improve the promotion, protection and support of breastfeeding to contribute towards reducing infant mortality and morbidity, by amongst others promoting the establishment and regulation of BMBs (DOH; 2011:1). South Africa has three non-profit organisations (NGOs) focusing on BMBs, namely Milk Matters, the South African Breastmilk Reserve (SABR) and Ithemba Lethu. These NGOs provide support through

initial training, and providing equipment and donor milk to hospitals interested to establish BMBs. However, currently there is no specific standardised tool to guide the process of establishment and implementation. The only guidelines that could be found are on the operation of a BMB that has already been established. These guidelines come from the United States, Italy, Brazil, Australia, and the United Kingdom. Numerous factors must be taken into account in order to establish BMBs effectively. The need for a tool specifically designed to address the implementation process of establishing a BMB in the South African setting, was identified by Bergh *et al.* (2005).

Bergh *et al.* (2005:1102) developed an implementation tool, the Kangaroo mother care (KMC) progress-monitoring tool for the South African setting, and concluded that this tool also had the potential to be adapted for measuring progress in other interventions in the South African setting (Bergh *et al.*, 2005:1102). This KMC progress-monitoring tool (Figure 2) was therefore used as the starting point for the development of the North West Province BMB implementation tool.

The aim of this study was to adapt the KMC progress-monitoring tool to the BMB setting and develop an implementation tool for BMBs in the North West Province. The regional hospital used in this study established the first BMB in the North West Province with the help of SABR. Based on the study aim, the objectives for this research were: to adapt the KMC progress-monitoring tool to develop a draft BMB implementation tool; use the draft tool to audit the BMB implementation process at the regional hospital where the BMB has been established; and adjust the tool based on the results of the auditing to provide the final BMB implementation tool. The implementation tool developed can contribute to more effective implementation of BMBs in South Africa and other developing countries.

## **Methods**

As no specific BMB implementation tool was identified in the available literature, an exploratory design was adopted to develop a preliminary appreciation of the phenomenon (Botma *et al.*, 2010:50) and to describe what the BMB implementation tool should entail. Qualitative approaches

to data collection and analysis were used to guide the development of the implementation tool. The KMC progress-monitoring tool (Figure 2) was adapted and used to audit the BMB implementation process at a regional hospital in the North West Province. Ethical approval was obtained from the Faculty of Health Science, Human Research Ethics Committee of the North-West University (clearance number NWU-00083-13-S1). Further approval to conduct the research at the selected hospital was obtained from the North West Department of Health as well as the hospital authorities. The BMB tool was developed in three consecutive phases, as depicted in Figure 1, and will be described according to these phases.

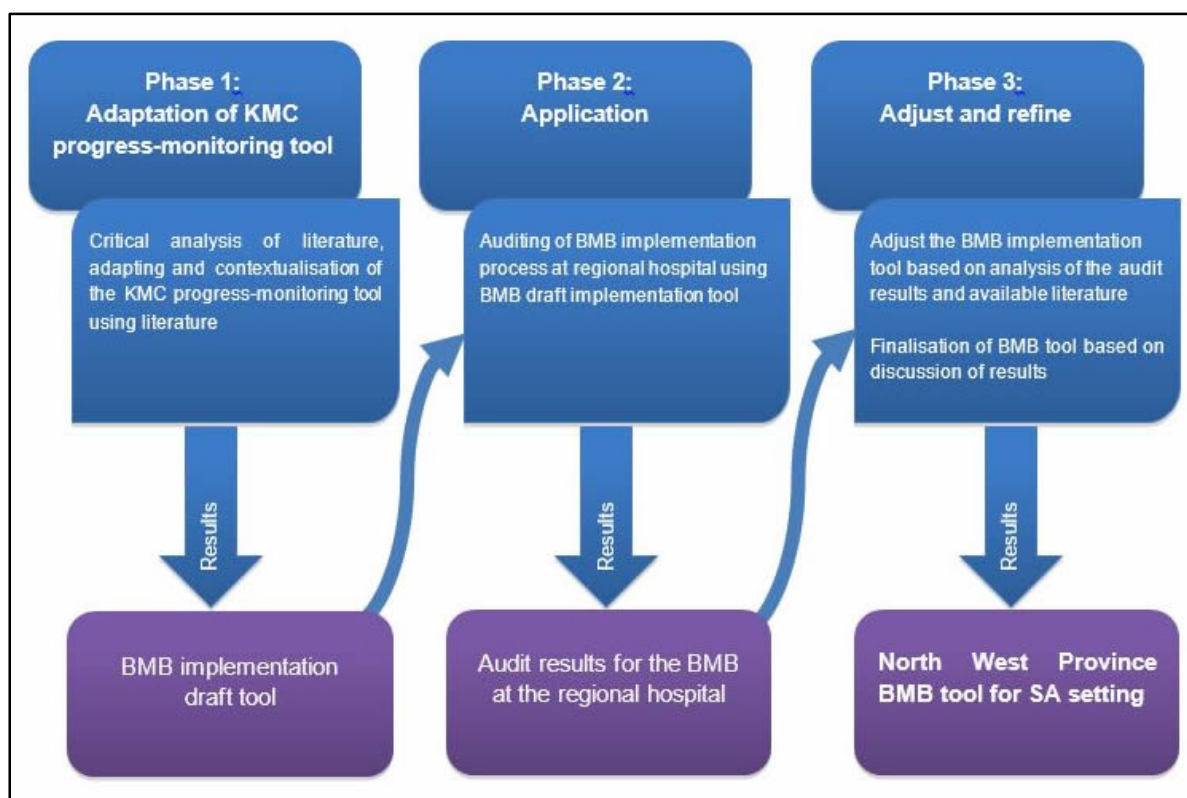


Figure 1: Study phases used in the development of the breast milk banking implementation tool

*Phase 1: Adaptation of KMC tool*

A literature survey was performed on aspects relevant to the establishment and implementation of BMBs using the following key words: implementation, donor milk bank, breast milk bank, protocol, human milk bank and procedures. The search engines used included Ebscohost, Science

Direct and Scopus; these are comprehensive databases of articles that would have been published on the given topics. The literature search and auditing was done over a period of three months, February - April 2014. Grey literature was also included in the literature survey; this was important since grey in addition to peer-reviewed articles provide a more comprehensive perspective on the available information on the implementation of BMBs. The various types of documents and articles will simply be referred to as documents in the rest of the article. Criterion sampling was used to identify all the documents that met the inclusion criteria. The inclusion criteria set to determine which documents to include, required that the document should provide information addressing at least three of the six constructs provided by the KMC progress-monitoring tool: creating awareness, adopting the concept, taking ownership, evidence of practice, evidence of routine and integration and sustainable practice (Bergh *et al.*, 2005:1102). Only documents available in English were included because if it was not available in English information could be lost in translation or articles that did not meet the inclusion criteria to prevent the possibility of taking data out of context as those articles would not have been intended for BMB implementation purposes.

All available and accessible BMB websites of identified organisations in certain countries whose documents met the inclusion criteria, were searched for additional information that could be categorised under the six constructs used by the KMC progress-monitoring tool to provide a more comprehensive base from which to develop the BMB implementation tool.

A phenomenological approach was used to assess and extract relevant data from the retrieved and included documents. This methodological approach was preferred, since it would lead to the identification of relevant categories of information that needed to be taken into account (Botma *et al.*, 2010:188) in the drafting of the BMB tool, based on the information from the reviewed documents. To obtain data extraction credibility and validity, two dietitians, who were involved in the implementation of the BMB of the regional hospital, were used to extract the relevant data

from the retrieved documents. The two dietitians extracted the data independently and the information they extracted yielded the same results without exception. Because the two dietitians assisted in the implementation and institutionalisation phases of the BMB at the regional hospital, the BMB implementation process was quite familiar to them and they could therefore identify relevant constructs and progress markers among those reflected in the included documents. The dietitians were also in a position to identify additional constructs or progress markers that were deemed necessary and detailed description of the progress markers are listed in Text box 1. Further credibility was ensured by prolonged engagement by the researcher, as the researcher was a member of the implementation team since July 2012 and was involved in the meetings, trainings, pasteurisation, signing up of donors, compilation of statistical information and recordkeeping of the documents described in phase 2.

The data collected was assessed and analysed against the constructs of the KMC progress-monitoring tool, to determine if these were sufficient or if more categories or constructs were needed. Relevant information in the retrieved documents was also used to determine which constructs could be adapted or contextualized to the BMB setting. The adaptation was done by rephrasing or removing information that was specific to a KMC setting; this information was then contextualised by using the appropriate terminology pertaining to BMBs.

*Phase 2: Application of the draft tool by auditing the breast milk bank implementation process of a regional hospital*

During phase 2, the draft tool developed in phase 1 was used to audit the implementation process at the regional hospital. This process required access to various documents that reflected on the implementation process that was followed. An all-inclusive, purposive sampling of qualitative data sets, including documents, checklists, files, and records, was used. The researcher obtained permission from the North West Province Department of Health and the Regional Hospital Patient Safety Group Committee to access these documents, as part of the ethics approval process for the

study described above. The two dietitians independently divided the data sets into the categories provided by the constructs and progress markers, to ascertain credibility and reproducibility of the results obtained from the audit. The data sets were kept in their respective files in the designated BMB room and in the researcher’s office. Privacy and confidentiality was ensured as the researcher did not use any names or identifying information in capturing the data.

The categorisation process of the data sets retrieved and the audit results provided information for further refinement of the adapted draft tool in phase 3.

*Phase 3: Adjustment of the draft tool and refinement based on the audit results*

Based on the results obtained from using the drafted tool to audit the implementation process at the hospital, the draft tool was adjusted and refined to provide the final North West Province BMB implementation tool. This adjustment and refinement could also provide additional constructs and progress markers that may not have been adequately addressed by the draft tool.

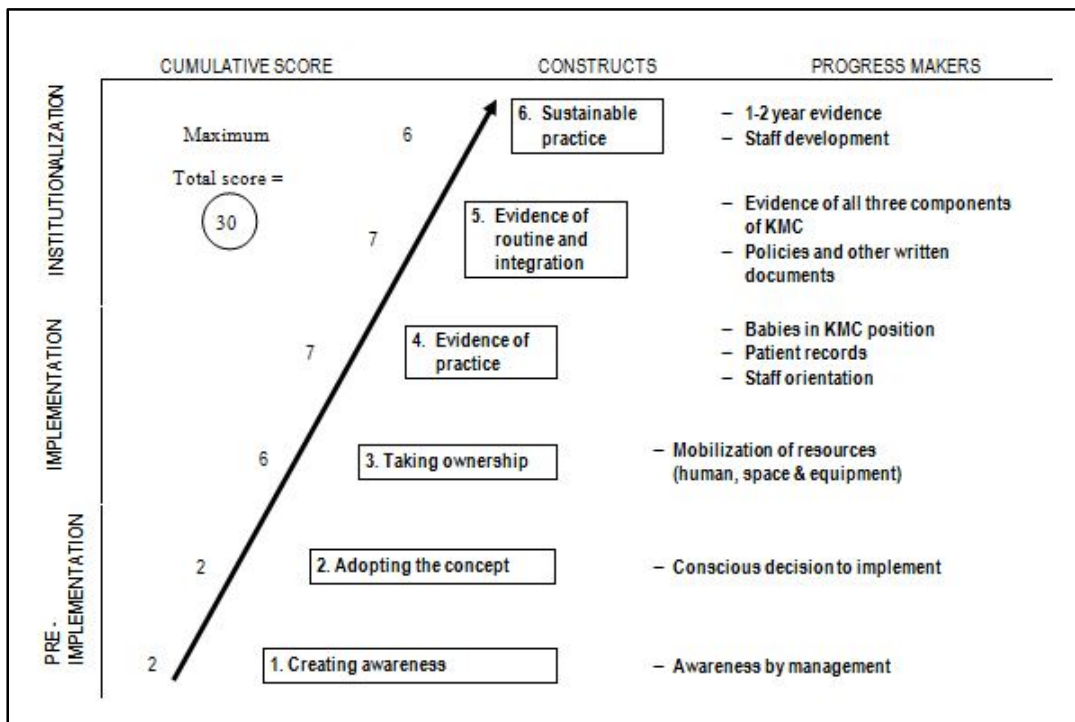


Figure 2: The KMC progress-monitoring tool (Bergh, *et al.*, 2005:1102-1108) (Reprinted with permission)

## **Results**

### *Phase 1: Adaptation of KMC tool*

Twenty documents, including peer-reviewed articles and grey literature, were retrieved in the literature search. Eight of the 20 documents did not provide enough information to address at least three of the six constructs and were excluded and therefore 12 documents were included. The documents included information of the BMB settings of five countries: Australia, Brazil, Italy, United Kingdom and United States of America. The relevant information from the 12 documents is summarised under the six constructs and progress markers of the KMC progress-monitoring tool and is provided in Table 1. None of the included documents contained information on all the constructs of the KMC progress-monitoring tool.

Section A and B (Figure 3) reflect on how the KMC tool was adapted to develop the BMB draft tool, with sections A and B representing the KMC constructs and progress markers respectively. During the analytical process of developing the BMB draft tool, it was clear that the constructs remained the same than those included in the KMC progress-monitoring tool, but additional progress markers were needed for BMB implementation (see Figure 3, Section B). Progress markers specific to KMC and not relevant to BMB were also identified and omitted from the developed draft tool (see Figure 3, Section B). Examples of omitted progress markers include evidence of all three components of KMC, infants in KMC position and evidence of KMC nutrition and were subsequently omitted during phase 3.

Section C (Figure 3) provides the additional information included in the adaptation to develop the BMB draft tool. Based on the literature review, additional information was included in the developed BMB draft tool to address the specific types of staff needed and the decisions documented in minutes taken on the adoption of the concept. Gaps were identified in the addressing of required funds, taking ownership on which type of equipment was procured, and the

form in which the mothers received information. The BMB draft tool items regarding evidence of practice included the evidence that research were published regarding all aspects pertaining to breast milk banking, specific records kept for monitoring purposes, as well as the need for routine bacteriological screening of the milk.

Concerning the evidence of routine, it was necessary to identify whether there was routine sampling of the pasteurised milk, recording of other information regarding the pasteurisation cycle and everything it entails, including hazard analysis and critical control points (HACCP), and standard operating procedure documents on the day-to-day operation of the BMB. Finally, for the last construct of sustainable practice, evidence of audited documents, staff development policies and records of staff trainings as a standard process, is needed (Figure 3, Section C).

The relevant constructs and progress markers of the KMC progress-monitoring tool and the additional information derived from the analysis described above provided guidance on the type of data that would be collected during the phase 2 audit. This data was then used to develop the North West Province BMB tool.

Table 1: Summary of relevant construct information from peer-reviewed articles and other documents used to develop the breast milk bank implementation tool based on the KMC progress-monitoring tool

Article	Type of article	Country	Constructs of KMC progress-monitoring tool reflected by the document					
			Creating awareness	Adopting the concept	Taking ownership	Evidence of practice	Evidence of routine	Sustainable practice
Almeida <i>et al.</i> , 2006.	Peer-reviewed	Brazil	√⊙	√□	√■	√§#	√π†	
Jones, F. 2003.	Peer-reviewed	North America		√*□	√■	√§	√π	
Hartmann, <i>et al.</i> , 2007.	Peer-reviewed	Australia		√*□	√■	√#	√π†	√ç
Arslanoglu <i>et al.</i> , 2010.	Peer-reviewed	Italy		√*	√■	√#	√π†	
Baumer, J.H. 2004.	Peer-reviewed	United Kingdom		√*	√■β		√π†	
Gorry, C. 2014.	Document	Brazil	√⊙	√*□	√Δ■	√#	√π	
Updegrove, K. 2005.	Peer-reviewed	North America		√*□	√Δ■		√†	
Brownell <i>et al.</i> , 2014.	Peer-reviewed	North America		√*□	√■	√§		
Rosenbaum, K.2012.	Document	North America	√⊙	√*□	√Δ■	√#§	√†	
NICE, 2010.	Peer-reviewed	United Kingdom		√*□	√■β	√#§	√π	√ΣçΨ
Geraghty <i>et al.</i> , 2010.	Peer-reviewed	North America	√⊙	√*□	√Δ■	√#		√ç
Kamholz <i>et al.</i> , 2012.	Peer-reviewed	North America	√⊙	√*□	√Δ■β	√#		√Σç

These articles were used during the next phase (Phase 2). Instrument items related to progress markers: # Statistics are kept, \* policies and documents exist regarding BMBing, § research was done on the information available within the BMB,★ mentioned funds, ■ mentioned some of the equipment needed, ⊙ mentioned type of personnel involved in the BMB, β had educational documents, leaflets available, Δ a specific space was identified for the BMB, † microbiological testing is done on samples, Ω mentioned staff development, π safety measures and practices are discussed, ç mentioned staff training, Ψ NICE guidelines discussing staff development policies.

	Section A: Constructs	Section B: Progress markers	Section C: Instrument items
Institutionalisation	6. Sustainable practice	<ul style="list-style-type: none"> <li>• 1-2 years of evidence</li> <li>• Staff development</li> <li>• Evidence of staff training</li> </ul>	<ul style="list-style-type: none"> <li>• Audit results should be kept for at least 1 year</li> <li>• A staff development policy must be in place</li> </ul>
	5. Evidence of routine and integration	<ul style="list-style-type: none"> <li>• Evidence of all three KMC components</li> <li>• Evidence of KMC position</li> <li>• Evidence of KMC nutrition</li> <li>• Policies and other written documents</li> <li>• Evidence of donor milk screening</li> <li>• Evidence of quality control</li> </ul>	<ul style="list-style-type: none"> <li>• Keep record of patient discharge, e.g. date discharged, weight, age, length of stay, if the patient received breast milk or formula on discharge, total days that patient received donor milk as recorded in patient file</li> <li>• Statistics presentations and DBM receipt control sheet, new donor protocol, recipient of DBM, nursing control form, statistics of infants receiving DBM, control sheet of defrosting freezers, control sheet of freezer temperatures, control form of pasteurisation of DBM</li> <li>• HACCP guidelines should be available and followed</li> </ul>
Implementation	4. Evidence of practice	<ul style="list-style-type: none"> <li>• Infants in KMC position</li> <li>• Patient records and statistics</li> <li>• Staff orientation</li> <li>• Research documenting benefits</li> <li>• Continuous funds</li> </ul>	<ul style="list-style-type: none"> <li>• Monthly statistics should be done and records should be kept regarding infants receiving donor milk as well as donors and the temperatures of the freezers</li> <li>• Research to be done on benefits of donor milk</li> <li>• Funds must be available</li> </ul>
	3. Taking ownership	<ul style="list-style-type: none"> <li>• Mobilisation of resources (human, space, equipment)</li> <li>• Information for mothers</li> <li>• Removal of cribs</li> <li>• Allocation of funds</li> </ul>	<ul style="list-style-type: none"> <li>• A space should be identified and allocated for the BMB The equipment needed: 2 chest freezers, pasteurise machine, bottles, foil caps for bottles, iron, refrigerator, pamphlets, permanent marker pens, plastic bags, files, transport/cooler boxes, breast pumps</li> <li>• Mothers received pamphlets, SABR and other BMBs in South Africa have websites that mothers can visit, and mothers received donor forms</li> </ul>
Pre-implementation	2. Adopting the concept	<ul style="list-style-type: none"> <li>• Conscious decision to implement</li> </ul>	<ul style="list-style-type: none"> <li>• Guidelines and policies or service agreements must be available and signed by facility</li> </ul>
	1. Creating awareness	<ul style="list-style-type: none"> <li>• Awareness by management</li> </ul>	<ul style="list-style-type: none"> <li>• Coordinator, volunteers, milk bank employees, executive committee, group leader, Ministry of Health, Senior midwife, a paediatrician or a senior scientist, nurses, administration, personnel from the university, risk management department, accounting department, materials management department, neonatologists, neonatal nursing staff, international board-certified lactation consultants, dietitians</li> </ul>

Constructs only relevant to KMC progress-monitoring tool    Constructs only relevant to BMB tool

Figure 3: BMB draft tool.

*Phase 2: Application of the draft tool by auditing the breast milk bank implementation process of a regional hospital*

In Phase 2, the auditing of the BMB implementation process of a regional hospital was done using the developed draft tool (Figure 3) from phase 1. The findings of the auditing process, in relation to the constructs that were given in Table 1 and Figure 2, are reflected in Text Box 1.

**Text box 1: Summary of information obtained from the auditing process of the breast milk banking process at the regional hospital**

<p>Creating awareness</p> <ul style="list-style-type: none"><li>• Various staff members were identified as being stakeholders in awareness creation</li><li>• Coordinator, Volunteers, Milk bank employees, Executive committee, Group leader, SA Department of Health, Senior midwife, a Paediatrician, Nurses, Risk management department, Accounting department, Neonatal nursing staff, Dietitians</li></ul> <p>Adopting the concept</p> <ul style="list-style-type: none"><li>• Documented minutes of decisions to adopt the concept and funding needed observed</li><li>• Various guidelines including the service agreement and policies were available</li><li>• Funds needed for equipment, bottles, caps, marker pens, leaflets, etc.</li></ul> <p>Taking ownership</p> <ul style="list-style-type: none"><li>• This was indicated by allocating dedicated space, procurement of equipment and information provision to mothers</li><li>• Specific spaces/facilities were identified</li><li>• Pasteurisation machine, freezers, file of temperatures, milk containers, refrigerators, foil caps, bottles, iron, plastic bags, transport/cooler boxes were also provided</li><li>• Provision of leaflets, educational documents, internet website, breast milk donor forms</li><li>• Allocation of funds</li></ul> <p>Evidence of practice</p> <ul style="list-style-type: none"><li>• Evidence of screening of donors and recipients</li><li>• Evidence of research/Articles of previous research done, or being done</li><li>• Records of all storage and processing conditions kept as well as individual donor and recipient information based on monthly statistics</li><li>• New staff members were orientated and trained</li></ul> <p>Evidence of routine</p> <ul style="list-style-type: none"><li>• Evidence of milk donor screening, and patient discharge records and quality control of donor milk</li><li>• Samples were taken after pasteurisation, microbiological testing is done on samples</li><li>• Evidence of discharge of patients records, e.g. date discharged, weight, age, length of stay, if the patient received breast milk or formula on discharge, total days that patient received donor milk as recorded in patient file, etc.</li><li>• Statistics presentations to the Department of Health, and donor breast milk receipt control sheet, new donor protocol, recipient of DBM, nursing control form, statistics of infants receiving DBM, control sheet of defrosting freezers, control sheet of freezer temperatures, control form of pasteurisation of DBM</li><li>• Hazard analysis and critical control points (HACCP)</li></ul> <p>Sustainable practice</p> <ul style="list-style-type: none"><li>• Evidence of staff development and training apparent</li><li>• Statistics kept for at least a year</li><li>• Staff trained and records must be kept</li></ul>
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The results of the audit indicated the types of managerial staff and driving forces needed for the pre-implementation, implementation and institutionalisation phase. Some personnel were only needed during some of these phases. Minuted documentation and a service agreement indicated that the concept was adopted. When it came to taking ownership, a space was allocated and all the necessary information provided on forms and pamphlets was available to mothers. SABR was paid by the North West Provincial Department of Health for the set up and everything it entailed, including the purchase of all necessary equipment. There was an agreement that the North West Provincial Department of Health was responsible to pay SABR, and that SABR handled the rest of the financial responsibilities. Statistics were kept of all the infants receiving donor milk, the donors, and the temperatures of the pasteurisation process and freezers; these statistics provided evidence of practice. In terms of evidence of routine practice, the SABR does not require specific hazard analysis and critical control points (HACCP) guidelines, but it is enforced in their training manual where the handling and processing of the donor milk is discussed. Finally, statistical records (Table 2), from 2011 until the time that the audit was done in 2014, were available. Although there was no staff development policy, it was evident from attendance registers that the staff members were trained (Text Box 1).

Table 2: Selected examples of audit results using the BMB draft tool and auditing methods used for the regional hospital case study

<u>Constructs</u>	<u>Method to determine how construct was applied</u>	<u>Sample</u>	<u>Case study evidence</u>
<ul style="list-style-type: none"> <li>Evidence that awareness was created</li> </ul>	<ul style="list-style-type: none"> <li>Auditing of minutes by documenting the personnel involved during the pre-implementation process</li> </ul>	<ul style="list-style-type: none"> <li>Minutes documented all personnel involved</li> </ul>	<ul style="list-style-type: none"> <li>4 minutes of meetings held within a period of 8 months in 2012</li> </ul>
<ul style="list-style-type: none"> <li>Evidence that the concept was adopted</li> </ul>	<ul style="list-style-type: none"> <li>Establish existence of formally documenting the conscious decision to implement BMB</li> </ul>	<ul style="list-style-type: none"> <li>Service agreement document with SABR</li> </ul>	<ul style="list-style-type: none"> <li>1 service agreement document available stating the establishment and time frame</li> </ul>
<ul style="list-style-type: none"> <li>Taking ownership</li> </ul>	<ul style="list-style-type: none"> <li>Structured observation using a checklist based on literature</li> </ul>	<ul style="list-style-type: none"> <li>Space provided by the hospital, staff provided</li> <li>All types of equipment and pamphlets</li> </ul>	<ul style="list-style-type: none"> <li>1 checklist of equipment specified by SABR available</li> <li>2 pamphlets</li> </ul>
<ul style="list-style-type: none"> <li>Evidence of practice</li> </ul>	<ul style="list-style-type: none"> <li>Auditing of working file (file with the forms and sheets used to record handling of donor milk), receiver file, donor file by determining which documents/forms were available in the files</li> </ul>	Statistics available <ul style="list-style-type: none"> <li>receiver forms</li> <li>DBM receipt control sheet</li> <li>new donor protocol</li> <li>nursing control form</li> <li>statistics of infants receiving donor breast milk</li> <li>control sheet of defrosting freezers</li> <li>control sheet of freezer temperatures</li> <li>control form of pasteurisation of DBM</li> </ul>	<ul style="list-style-type: none"> <li>32 presentations reporting on information regarding donor milk recipients</li> <li>120 receiver forms</li> <li>22 DBM receipt control sheets</li> <li>13 new donor protocol forms</li> <li>25 nursing control forms</li> <li>16 statistic forms of infants receiving donor breast milk</li> <li>2 control sheets of defrosting freezers</li> <li>11 control sheets of freezer temperatures</li> <li>20 control forms of pasteurisation of DBM</li> </ul>

<u>Constructs</u>	<u>Method to determine how construct was applied</u>	<u>Sample</u>	<u>Case study evidence</u>
<ul style="list-style-type: none"> <li>• <b>Evidence of routine</b></li> </ul>	<ul style="list-style-type: none"> <li>• Auditing of the sample report through establishing the existence of such a report</li> <li>• Auditing of information of PowerPoint presentations to indicate if routine was established</li> </ul>	<ul style="list-style-type: none"> <li>• Laboratory Sample report, certificate of analysis as requested by SABR and health and safety officer</li> <li>• Statistics available</li> </ul>	<ul style="list-style-type: none"> <li>• 1 laboratory sample report, 1 certificate of analysis as requested by SABR and health and safety officer in 3 years</li> <li>• 32 presentations reporting on information regarding donor milk recipients</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Sustainable practice</b></li> </ul>	<ul style="list-style-type: none"> <li>• Auditing of trainings to determine if the staff attended the trainings</li> <li>• Auditing of working file, receiver file, donor file to determine the number of donors and recipients of the donor milk over time</li> </ul>	<ul style="list-style-type: none"> <li>• Staff training attendance registers and statistics power points</li> <li>• Statistics available on donors and recipients</li> </ul>	<ul style="list-style-type: none"> <li>• 3 attendance registers and 32 statistic PowerPoints</li> <li>• 22 DBM receipt control sheets and 13 new donor protocol forms,</li> </ul>

### *Phase 3: Adjustment of the draft tool and refinement based on the audit results*

The results of the audit were used to refine the BMB draft tool. The resulting North West Province BMB tool with the suggested progress markers is provided in Figure 4. Although there were no additional progress markers, additional instrument items arose following the identification of a gap in the audit process of phase 2. These items were the documents minuting the decision to implement the BMB and the type of personnel involved during the pre-implementation phase. During the implementation phase other and additional equipment were needed and there was a need for the orientation of new staff. Finally, in the institutionalisation phase, there was evidence of information of the donor milk recipient after discharge, but there was no specific HACCP document. To take into account possible variability between BMB sites, the North West Province BMB tool has been structured generically to allow for the adaptation to different contexts. The merits of doing this will be covered in the discussion section.

A variety of personnel is needed in the different stages of implementation, e.g. pre-implementation, implementation and institutionalisation. Some staff members are involved during the whole process, e.g. the dietitians, coordinator and nursing manager, and other only during certain stages. Academics from the university, for example, took part in the pre-implementation phase and conducted research that would inform the implementation process and this research study. The type of managers involved in the implementation process, may also differ from hospital to hospital. This depends on the type of managers that work in the facility, since each hospital does not necessarily have a neonatologist for example. This section in the BMB tool has been structured generically to take this variability into account.

The North West Province BMB tool should be used as a guide and it should be kept in mind that a facility does not need to follow the exact examples of the instrument items of Text box

1 to implement a BMB, but they do need to follow the constructs and BMB progress markers. In order to adopt the concept, a guideline, policy or written commitment signed by the leaders of the implementation in the specific facility is needed. For the physical implementation, ownership must be taken to allocate a physical space for the procured equipment. The equipment may differ slightly, since some countries use glass bottles whereas others use plastic bottles to store the milk. Some countries provide breast pumps to mothers and other countries do not have the finances to provide all the mothers with breast pumps; these mothers are then encouraged to hand express. This method is also believed to be more hygienic. The bacteriologic screening of milk should always be done at a BMB; but differences occur in sample size and frequency of screening.

Receiving funds for BMBs are crucial, because there are constant expenses such as bottles, caps, pamphlets, etc. A new initiative can only be successful if the community are aware of it, since awareness leads to involvement; therefore it is crucial that the public receives information regarding donating and infants receiving donor milk. There must be clear evidence that the BMB is operating successfully and statistics, with ample information for research, must be provided to the relevant BMB affiliation whether it is SABR or any other BMB NGO to determine the effect of donor milk on the infants in the facility. With the BMB implemented, it must be institutionalised by having evidence of routine in the records kept by the hospital and ensuring quality control by following HACCP guidelines.

The final step is sustainable practice, consisting of a staff development policy and staff training to ensure that the process is completed thoroughly and that the facility is able to provide audit results of all the previous months/years.

	Section A: Constructs	Section B: Progress markers	Section C: Instrument items
Institutionalisation	6. Sustainable practice	<ul style="list-style-type: none"> <li>• 1-2 years of evidence</li> <li>• Staff development</li> <li>• Evidence of staff training</li> </ul>	<ul style="list-style-type: none"> <li>• Audit results should be kept for at least 1 year</li> <li>• A staff development policy must be in place</li> </ul>
	5. Evidence of routine and integration	<ul style="list-style-type: none"> <li>• Policies and other written documents</li> <li>• Evidence of donor milk screening</li> <li>• Evidence of quality control</li> </ul>	<ul style="list-style-type: none"> <li>• Keep record of patient discharge, e.g. date discharged, weight, age, length of stay, if the patient received breast milk or formula on discharge, total days that patient received donor milk as recorded in patient file</li> <li>• Statistics presentations and DBM receipt control sheet, new donor protocol, recipient of DBM, nursing control form, statistics of infants receiving DBM, control sheet of defrosting freezers, control sheet of freezer temperatures, control form of pasteurisation of DBM</li> <li>• HACCP guidelines should be available and followed</li> </ul>
Implementation	4. Evidence of practice	<ul style="list-style-type: none"> <li>• Patient records and statistics</li> <li>• Staff orientation</li> <li>• Research documenting benefits</li> <li>• Continuous funds</li> </ul>	<ul style="list-style-type: none"> <li>• Monthly statistics should be done and records should be kept regarding infants receiving donor milk as well as donors and the temperatures of the freezers</li> <li>• Research to be done on benefits of donor milk</li> <li>• Funds must be available</li> </ul>
	3. Taking ownership	<ul style="list-style-type: none"> <li>• Mobilisation of resources (human, space, equipment)</li> <li>• Information for mothers</li> <li>• Allocation of funds</li> </ul>	<ul style="list-style-type: none"> <li>• A space should be identified and allocated for the BMB The equipment needed: 2 chest freezers, pasteurise machine, bottles, foil caps for bottles, iron, refrigerator, pamphlets, permanent marker pens, plastic bags, files, transport/cooler boxes, breast pumps</li> <li>• Mothers received pamphlets, SABR and other BMBs in South Africa have websites that mothers can visit, and mothers received donor forms</li> </ul>
Pre-implementation	2. Adopting the concept	<ul style="list-style-type: none"> <li>• Conscious decision to implement</li> </ul>	<ul style="list-style-type: none"> <li>• Guidelines and policies or service agreements must be available and signed by facility</li> </ul>
	1. Creating awareness	<ul style="list-style-type: none"> <li>• Awareness by management</li> </ul>	<ul style="list-style-type: none"> <li>• CEO, coordinator, volunteers, milk bank employees (SABR), executive committee, group leader, Ministry of Health, senior midwife, a paediatrician or a senior scientist, nurses, administration, personnel from the university, risk management department, accounting department, materials management department, neonatologists, neonatal nursing staff, international board-certified lactation consultants, dietitians</li> </ul>

Figure 4: North West Province BMB implementation tool

## Discussion

The objectives of this study were the adaptation of the KMC progress-monitoring tool to develop a BMB implementation draft tool, auditing the implementation of a BMB at a regional hospital using the developed draft tool, and using the audit results to refine the BMB implementation tool termed the North West Province BMB implementation tool.

In phase 1, the constructs of the KMC progress-monitoring tool were found to be useful for the BMB draft tool. The six constructs, creating awareness, adopting the concept, taking ownership, evidence of practice, evidence of routine and integration and sustainable practice, (Bergh *et al.*, 2005:1102) were all found to be useful for the BMB tool. None of the 12 documents from literature reviewed addressed all six constructs. This served to confirm the need for the development of a BMB implementation tool that would be comprehensive enough to provide adequate guidance, not only for the implementation process, but also for continued monitoring and evaluation of implemented BMBs. The importance of these constructs and their values are described by the progress markers that will be discussed later.

From phase 1, the relevant progress markers were also identified (Figure 3). These are important, as they would provide guidance on the types of data that must be collected to signify progress or appropriate implementation when used for monitoring and evaluation purposes. The progress markers relating to the abovementioned constructs were found to be useful (Figure 3).

Creating awareness is an important construct, because it identifies the role players that are needed to implement and institutionalise the BMB. Once these role players have been identified, the next step of adopting the concept by signing some sort of an agreement or developing a policy on the implementation of a BMB, can be performed. When this pre-implementation phase is completed, the implementation phase, in which ownership is taken to identify a specific space, funds are made available for the procurement of equipment, and donors can be provided with information and

signed up, can commence. During evidence of practice, statistics are kept on all the processes and procedures from signing up a donor, receiving the milk, freezing it, pasteurising it, providing it to the recipient, capturing the necessary information regarding the donor and recipient, until the recipient is discharged or not receiving donor milk anymore as recommended by NICE. With all the statistics captured during the abovementioned procedures, research can and should be done as this can provide evidence of the benefits of donor milk and identify any shortcomings that need further research. During evidence of routine and integration, control forms, policies and quality control guidelines must be available to ensure that a routine is followed in which all personnel is aware of how to follow the procedures. During the final step of sustainable practice, it is important to be able to provide a staff development policy and continuous staff training to ensure that staff members understand the technical processes of how the BMB is organised, how its health and safety and quality systems work and the regulatory and ethical aspects (NICE, 2010:6). The audit results must be available in order to determine the amount of donors and recipients. This can indicate whether the BMB is succeeding in reaching the community and infants in need of donor milk as well as indicating supply and demand.

However, not all the progress markers of the KMC progress-monitoring tool were found to be useful. The following markers, the evidence of all three KMC components, KMC position and KMC nutrition, and removal of cribs, were found to only apply to the KMC setting (Bergh *et al.*, 2010:1106). These were therefore omitted from the North West Province BMB tool (Figure 4). Some progress markers not mentioned in any or most of the documents reviewed, included the conscious decision to implement a BMB in the form of a signed agreement, a staff development policy or training staff. These were added to the draft tool based on the experience of the dietitians involved in the implementation process and the literature reviewed. It is important to have a signed agreement or policy to implement a BMB in order to know who the role players are and what is expected of them in starting such an endeavour. Evidence of a staff development policy and staff

training must exist to ensure that all staff members are aware of the procedures and are competent in these procedures (NICE, 2010:6).

In phase 2, the draft tool was used to audit the implementation process of the BMB at a regional hospital. The auditing provided information about the implementation process, both in terms of where the process was successful, but also where the process was less successful. A variety of managers were involved at the start of the process, but some personnel are involved throughout the process, for example the coordinator who has a variety of responsibilities, the dietitians who train the personnel and pasteurise the milk, the doctors that prescribe the milk and the nurses that provide the milk (Rosenbaum, 2012:206). The other personnel, such as the quality control officer, were only involved in the process once. Other countries, such as the United States, Italy and Australia, rely more on quality control officers and do more microbiological testing on donor milk (Hartmann *et al.*, 2007:669, Baumer, 2004:1, Arslanoglu *et al.*, 2010:11) than the selected regional hospital. This can be seen as a shortcoming that can be addressed by the selected regional hospital.

The funding needed for sustaining the BMB was one of the issues that needed to be dealt with. It was decided that the Provincial Department of North West would be responsible for the initial set-up and administrative costs for the first year and that the selected regional hospital will be responsible for the continued administrative costs. The statistics recorded were provided to SABR on a weekly basis, but unfortunately, apart from this study, none of the statistics have been used by the selected regional hospital thus far to obtain any specific research outcomes.

Based on the auditing process, some deficiencies that needed refining were identified. There was for instance no existing implementation policy, no specific control forms to document necessary statistics in order to provide evidence of practice, routine and integration, no research was performed to enhance the knowledge pertaining to the different facets of and the improving of the process of BMBing, no HACCP guidelines to ensure quality control and no staff development policy to ensure that all staff members are aware of the procedures.

After refinement, the North West Province BMB implementation tool is composed of the six constructs, namely creating awareness, adopting the concept, taking ownership, evidence of practice, evidence of routine and integration and sustainable practice, and a comprehensive list of progress markers. This tool can be used to guide the implementation process by providing the implementation actions needed. Challenges were the cultural barriers of accepting and using donor milk, training the staff working with preterm infants and convincing these staff members to buy into the concept of prescribing and using donor milk (Rosenbaum, 2012:206; Kamholz, 2012:129). The criteria for donor milk recipients must be incorporated into the policies to prevent the extensive use of donor milk in unnecessary cases, such as cases of mothers that do not provide night feeds and want to use donor milk instead. The selected regional hospital like BMBs in Cuba and the United States, is also confronted with the challenge of increasing the supply of donor milk to meet the demand. This challenge can be addressed by creating more awareness in the public sector (Gorry, 2014:15; Updegrave, 2005:32). Another challenge experienced by countries such as the United States is funding; some BMBs rely on donations alone and some charge the donor milk recipients a processing fee (Rosenbaum, 2012:206; Kamholz, 2012:129). A facility that wants to implement a BMB must take definite decisions about the management of the financial side of the BMB. If these challenges are addressed by a tool guiding the implementation process, that can also create a greater awareness of possible challenges ahead. The North West Province BMB implementation tool can also be used for the monitoring and evaluation of the BMB implementation process.

Finally, it is important to recognise that situations may vary in different contexts, even in the same country. For this reason, it is recommended that the developed tool must only be used as a guide that should be adapted to the local context. One aspect that may need adaptation is concerned with the type of personnel involved, since all hospitals do not have an international board-certified lactation consultant or a neonatologist. The type of bottles that facilities use may differ it can be

glass or plastic bottles; some facilities might provide breast milk pumps and others not; the type of documents they use to document statistics may differ; the area in which the equipment is placed will differ from facility to facility depending on where they have space available.

The limitations of this study are that only one hospital was used to evaluate the drafted implementation tool. The study did not consider attitude, such as the attitude of the personnel, donors and recipients into consideration, although they play a role in the successful implementation of such an endeavour. These limitations were not addressed during the study, because this study was not designed to incorporate the emotional side of breast milk banking.

## **Conclusion**

It was possible to adapt the KMC progress-monitoring tool to develop a BMB implementation tool that was successfully used to audit the implementation process of a BMB at a regional hospital. The audit revealed areas of weakness that could have been better addressed during the implementation process had there been such an implementation tool available. We recommend that the developed BMB tool must be adapted to address the needs of different BMB contexts before using it. When used appropriately, this tool would contribute not only to more effective implementation of BMBs, but also to the monitoring and evaluation of implementation processes.

## **Funding and Conflict of Interest**

Bias may have occurred, because the researcher was involved in the implementation process of the BMB at the selected regional hospital. However, the other members of the research team were not employees of the hospital, a fact that assisted in avoiding any bias.

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## **CHAPTER 4: CONCLUSION AND RECOMMENDATIONS**

### **4.1 Introduction**

This final chapter provides the conclusions that the researcher made with regards to the three objectives posed in Chapter 1, subsequently this chapter also discusses the limitations of the study and provides recommendations to other hospitals and for further study. To achieve the aim of developing and auditing an implementation tool for the implementation of a breast milk bank (BMB), three objectives were set:

Objective 1: To adapt a current KMC progress-monitoring tool to guide the development of a BMB implementation draft tool.

Objective 2: To audit the developed implementation draft tool by auditing the implementation of a BMB at a selected regional hospital.

Objective 3: To adjust and refine the developed implementation draft tool according to the results of the auditing process to provide the North West Province BMB implementation tool.

### **4.2 Developing and auditing a BMB implementation tool**

During this study it became evident that there are various aspects of BMBs to take into consideration and it was a challenge not to incorporate aspects that discussed the finer details of operating a BMB instead of the steps needed to implement a BMB. Although there might be differences between BMBs, the constructs of creating awareness, adopting the concept, taking ownership, evidence of practice, evidence of routine and integration and sustainable practice must be in place for the successful implementation of a BMB. This North West Province BMB implementation tool gives guidance on the steps from pre-implementation to institutionalisation whereas the service agreement provided by the non-profit BMB organisations provides the finer details of operating a BMB. With this in mind there are always some aspects that can only be addressed as the situation arises and will not necessarily be relevant for the different BMBs such as the different responsibilities of the staff regarding the handling of the donor milk and what the steps that should be taken in case of noncompliance. Other issues that arised during this study was that there were periods of shortage of donor milk and that the coordinator had to think of initiatives to motivate possible donors to donate and continue donating.

The implementation tool unfortunately does have some aspects that it does not address such as the struggling to find donors that qualify to donate and the attitudes of the personnel working with the donor milk and the community receiving donor milk. In South Africa, there is also the double

burden of high preterm infant rates and a smaller population that can provide donor milk seeing that HIV positive women are not allowed to donate. This just emphasises the need for a BMB that could provide donor milk.

Hospitals from the provincial government of Health North West that want to implement a BMB can use the North West Province BMB implementation tool as the main guideline during their process, although they still need to adapt it to their unique circumstances, such as the type of personnel involved and the physical set-up of the BMB. The North West Province BMB implementation tool checklist, developed in this study, can be used for guidance and provides questions that are required to be answered in order to determine if the various constructs have been met (Table 4-1). As was seen in the literature, lessons learnt from BMBs around the world showed that not all attempts at implementing BMB were successful and sustainable. A tool such as this could assist in ensuring that the various constructs required for a successful BMB are planned for and in place to enable success and sustainability in the long run.

**Table 4-1: North West Province BMB implementation tool checklist**

	<b>Constructs</b>	<b>Progress markers of BMB</b>	<b>Examples of instrument items for BMB</b>	<b>Question</b>	<b>Done (Y/N)</b>
Pre-implementation	1. Creating awareness	Awareness by staff	Evidence of meetings attended by staff such as the coordinator, volunteers, milk bank employees, executive committee, group leader, Ministry of Health, senior midwife, a paediatrician or a senior scientist, nurses, administration, personnel from the university, risk management department, accounting department, materials management department, neonatologists, neonatal nursing staff, international board-certified lactation consultants, dietitians	Which staff does the facility have available to create awareness, implement and operate the BMB?	
	2. Adopting the concept	Conscious decision to implement	Guidelines and policies or service agreements must be available and signed by facility	Is there a policy or service agreement that has been signed by the facility?	
Implementation	3. Taking ownership	Mobilisation of resources (human, space and equipment) Information for mothers	A space should be identified and allocated for the BMB The equipment needed: 2 chest freezers, pasteurise machine, bottles, foil caps for bottles, iron, refrigerator, pamphlets, permanent marker pens, plastic bags, files, transport/cooler boxes, breast pumps  Mothers received pamphlets, SABR and other BMBs in South Africa have websites that mothers can visit, and mothers received donor forms	Is there a specific space allocated for the BMB and are all the resources such as the equipment mobilised?  Are there any forms providing evidence that donors receive information?	
	4. Evidence of practice	Patient records Research documenting benefits Funds	Monthly statistics should be done and records should be kept regarding infants receiving donor milk as well as donors and the temperatures of the freezers  Research to be done on benefits of donor milk Funds must be available	Are all the documents in place to record all processes and statistics?  Is research done using the statistics?  Are funds available?	

	<b>Constructs</b>	<b>Progress markers of BMB</b>	<b>Examples of instrument items for BMB</b>	<b>Question</b>	<b>Done (Y/N)</b>
Institutionalisation	5. Evidence of routine and integration	Evidence of discharge Policies and other written documents Evidence of donor milk screening Evidence of quality control	Keep record of patient discharge, e.g. date discharged, weight, age, length of stay, if the patient received breast milk or formula on discharge, total days that patient received donor milk as recorded in patient file Statistics presentations and DBM receipt control sheet, new donor protocol, recipient of DBM, nursing control form, statistics of infants receiving DBM, control sheet of defrosting freezers, control sheet of freezer temperatures, control form of pasteurisation of DBM HACCP guidelines should be available and followed	Are all records kept and statistics presented? Are all the quality control points guidelines followed?	
	6. Sustainable practice	1-2 year audit evidence Staff development	Audit results should be kept for at least 1 year A staff development policy must be in place	Are there results available for the last year? Is staff trained continuously and is there any evidence?	

### **4.3 Limitations**

The fact that only one hospital was used to guide the implementation process, can be seen as a limitation. If more than one hospital's experience could have been used, it could have contributed to an implementation tool that was more sound. The attitudes of the staff involved plays a crucial role in the successful implementation and institutionalisation of a BMB and this tool does not address this fact and can therefore also be seen as a limitation.

### **4.4 Recommendations**

- Any health facility based institution that wants to implement a BMB should be made aware of this guiding tool and use it in collaboration with all the information that they receive from the non-profit milk bank organisation.
- The implementation tool should be reviewed and adjusted to ensure that it is user-friendly and used for its intended purpose.
- Advocacy and education to milk bank associations regarding availability and benefits of the implementation tool to ensure that it is used more widely.
- The implementation tool can be adjusted to develop a progress-monitoring tool for BMBs.

### **4.5 Summary**

The North West Province BMB implementation tool is a useful guide for the implementation of a BMB within the South African setting to help infants in need. Donor milk is the second best option to mothers own milk and should be seen as a valuable contribution to infant health. Numerous preterm infants may have positive outcomes with a BMB to ensure that donor milk procedures are followed correctly and provided to those in need.

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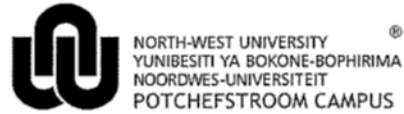
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# ANNEXURE A: ETHICAL APPROVAL LETTER FROM NWU



Private Bag X6001, Potchefstroom  
South Africa 2520

Tel: 018 299-1111/2222  
Web: <http://www.nwu.ac.za>

To whom it may concern

Faculty of Health Sciences  
Tel: 018 2992092  
Fax: 018 2992088  
Email: [Minrie.Greeff@nwu.ac.za](mailto:Minrie.Greeff@nwu.ac.za)

30 July 2013

Dear Dr. Covic

## Ethics Application: NWU-00083-13-S1 Summary Report

### "Breast milk bank implementation attitudes and acceptability in the North West Province"

All ethical concerns were addressed in this application and ethical approval is recommended.

Yours sincerely



Prof. Minrie Greeff  
Ethics Sub-committee Vice Chairperson

Original details: Prof. Minrie Greeff(10187308) C:\Users\13210572\Documents\ETIEK\2013 ETHICS\NWU-00083-13-S1 Summary Report.docm  
30 July 2013

File reference: NWU-00083-13-S1

# ANNEXURE B: PERMISSION FROM THE NATIONAL DEPARTMENT OF HEALTH TO CONDUCT THE RESEARCH IN FACILITIES



**health**  
Department of  
Health  
North West Province  
REPUBLIC OF SOUTH AFRICA

2<sup>nd</sup> Floor Tirolo Building  
Dr. Albert Lutuli Drive  
Mafikeng, 2745  
Private Bag X2068  
MMABATHO, 2735

Tel: (018) 387 1786  
Fax: 018 392 5710  
kshoo@nw.gov.za  
www.nwhealth.gov.za

## POLICY, PLANNING, RESEARCH, MONITORING AND EVALUATION

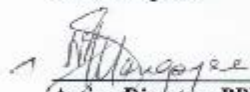
**To** : Ms C.S Oosthuizen & Ms M.A Pretorius  
**From** : Policy, Planning, Research, Monitoring & Evaluation  
**Subject** : Approval Letter- Breast milk bank implementation, attitudes and acceptability in the North West Province.

### Purpose

To inform the researcher that permission to undertake the above mentioned study has been granted by the North West Department of Health. The researcher is expected to arrange in advance with the chosen districts or facilities, and issue this letter as proof that permission has been granted by the provincial office.

Upon completion, the department expects to receive a final research report from the researcher.

Kindest regards

  
Acting Director: PPRM&E  
Mr. L. Moaisi

08/01/2014  
Date



# ANNEXURE C: APPROVAL TO CONDUCT THE RESEARCH FROM THE TLOKWE SUB-DISTRICT



**health**

Department of  
**Health**  
North West Province  
REPUBLIC OF SOUTH AFRICA

Private Bag 12528  
Pretoria 0001  
2520

Tel: (0)6 2975060 & 104  
Fax: (0)6 294 6680  
E-mail: amchule.ca@nwpg.gov.za  
E-mail: Awa.Monyamane

OFFICE OF THE PHC MANAGER: TLOKWE SUB DISTRICT

07 March 2014

**To : Ms C.S Oosthuizen & Ms M.A Pretorius**  
**From : FROM TLOKWE SUB-DISTRICT DR KENNETH KAUNDA**

**RE: Approval to conduct your research**

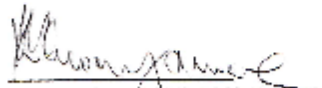
This communiqué serve to inform you that your request to conduct research at the following facilities in the sub-district of Tlokwe is approved based on the proof that you submitted to show that both the University and Department of Health have granted you approval


The above mentioned facilities will be notified but you can take this approval letter with you to the facilities

Contact details for facilities are as follows

Boiki Tlhabi: Acting Operational Manager Tloome  
:018 295 3352

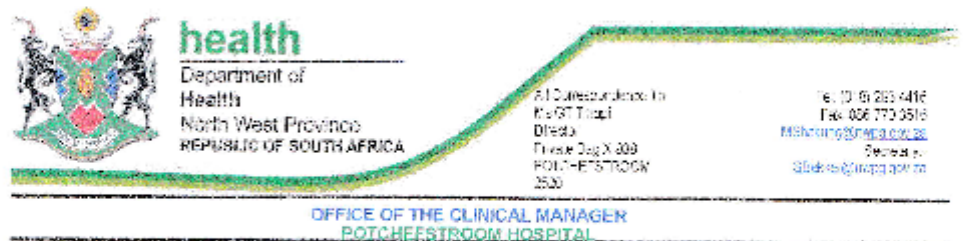
Steve Tshwete: Operational Manager Ledimo  
: 018 295 6570

  
ACTING : PHC MANAGER  
K. MONYAMANE

  
Healthy Living for All

1

# ANNEXURE D: APPROVAL GRANTED BY THE OFFICE OF THE CLINICAL MANAGER



**TO: MS C OOSTHUIZEN AND MS M PRETORIUS**

**FROM: DR JMM SHAKUNG**

**DATE: 2014-05-15**



**RE: APPROVAL GRANTED BY PSG COMMITTEE**

This serves to inform you that the PSG Committee has approved your research study on the Breast Milk Bank Implementation, Attitudes and Acceptability.

Kindly provide us with the written outcome upon completion of your research study.

Sincerely,

  
**DR JMM SHAKUNG**  
**CLINICAL MANAGER**

## **ANNEXURE E: APPROVAL FROM EUROPEAN MILK BANK ASSOCIATION**

Approval from European Milk Bank Association (EMBA) for the use of their figure (Figure 2-3 in Literature Review chapter) that indicated the active and planned breast milk banks supported by the European Milk Bank Association

On 17 Feb 2015, at 12:05, Maria Pretorius <[maria.vanderwalt@gmail.com](mailto:maria.vanderwalt@gmail.com)> wrote:

Good day,

I am currently doing my masters degree on implementing a breast milk bank in South Africa. I want to ask permission to use the picture that is on the website that displays how many milk banks there are within each country as part of my literature study.

Thank you for considering my request.

Kind regards

Maria Pretorius

**From:** Gillian Weaver <[gillian.weaver@yahoo.com](mailto:gillian.weaver@yahoo.com)>

**Date:** 17 February 2015 at 10:17:52 PM SAST

**To:** Maria Pretorius <[maria.vanderwalt@gmail.com](mailto:maria.vanderwalt@gmail.com)>

**Subject: Re: Permission**

Dear Maria

You are very welcome to use the map. Thank you for asking. However do please ensure you acknowledge EMBA as the source.

Very best wishes with your Masters.

Gillian Weaver