THE DEVELOPMENT OF A TOOL TO EVALUATE THE QUALITY OF PREVENTION OF MOTHER TO CHILD TRANSMISSION PROGRAMMES OFFERED TO THE HIV EXPOSED INFANTS IN A PRIMARY HEALTH CARE FACILITY SETTING IN CAPE TOWN

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Quality of Care

Prevention of Mother to Child Transmission (PMTCT)

Programme Effectiveness

Evaluation

Efficiency

Quality Assurance

Audit

Development of tool

Quality Improvement

ABBREVIATIONS:

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Treatment
ARV	Antiretroviral/s
AZT	Zidovudine
CoCT	City of Cape Town
EPI	Expanded Programme on Immunisations
FHI	Family Health International
HAART	Highly Active Antiretroviral Treatment
HAST	HIV, AIDS, STI and TB
HCT	HIV Counselling & Testing
HIV	Human Immunodeficiency Virus
MDHS	Metro District Health Services
MOU	Maternity & Obstetrics Units
MTCT	Mother to Child Transmission
NPO	Non-Profit Organisation
NVP	Nevirapine
PCR	Polymerase Chain Reaction
PR	Participatory Research
PHC	Primary Health Care
PMTCT	Prevention of Mother to Child Transmission
SA	South Africa
SSA	Sub-Saharan Africa
STI	Sexually Transmitted Infections
TB	Tuberculosis
UNAIDS	United Nations AIDS
WCDoH	Western Cape Department of Health
WCP	Western Cape Province
WHO	World Health Organisation

ABSTRACT

Introduction

Mother to Child Transmission is a significant route of HIV infection in children and in South Africa (SA) the median HIV prevalence rate among pregnant women is 30, 2% and in the Western Cape Province (WCP) it is 18, 2%. Although Prevention of Mother to Child Transmission (PMTCT) programmes are now available at 100% of all health care facilities and 95% of women attend antenatal care, these programmes are complex and outcome data reveals fluctuations in transmission rates as well as pockets of high transmission within well performing sub-districts. The careful management of programme processes thus requires more than coverage and outcome data. It also requires a clear picture of process indicators related to access to PMTCT services, the quality and continuity of care within the PMTCT programme and integration of PMTCT service into the comprehensive package of health care services.

Aims and objectives

To develop a tool that will measure the quality of care of HIV exposed infants in the PMTCT programme at primary care setting in Cape Town, by engaging local programme managers in a participatory process to develop a tool that is locally applicable and relevant, and captures local management expertise. To identify the evaluation domains, to develop a set of indicators for each domain and to pilot the tool to assess its feasibility and usefulness of the data generated.

Methodology

Study design: The study design for developing this tool was Participatory Research and the knowledge of local experts formed the basis of the research and planning. This study design best suited the four phases of tool development and validation.

Population and sample: The participants in the tool design (the 'core task team') were purposefully selected as provincial and district HIV, AIDS, STI and TB (HAST) programme managers and academics who had been involved in the development of a previous integrated HAST audit. A second group of participants involved in piloting and validating (the 'implementers') were purposefully selected as end-users of the tool: facility managers and sub district HAST coordinators. The target population for which the tool was developed was the HIV exposed infants on the PMTCT programme within the primary care setting in Cape Town.

Data collection process: The literature review revealed that a tool that would serve this purpose was not available. The 'core task team' and 'implementers' developed the tool using the steps

proposed by Benson and Clark (1982) in a continuous analysis process involving panel discussions and post pilot sessions. The researcher facilitated each of the sessions in a manner that afforded each of the group members an equal opportunity to express their opinion. At each of these sessions, robust discussions on each of the tracer indicators within the agreed domains took place, until a decision was taken on the best way forward.

Ethics

Procedural ethics was provided by the Higher Degrees Research Committee at UWC. Confidentiality of all client records reviewed during the piloting of the tool was maintained. Each participant received an information sheet and completed a consent form. During this study the contributions made by the HAST experts and facility level staff were equally respected and this contributed towards improved quality assurance and health system strengthening.

Results

Following this series of sessions, a tool that could evaluate the quality of the PMTCT programmes offered to the HIV exposed infant in the primary health facility setting, was developed. The piloting of this PMTCT Baby tool showed that the tool was feasible and provided useful information that would guide decision-making at facility, sub-district, sub-structure and provincial level, in order to effect quality improvement. The tool has been considered to be valid and reliable and is applicable to the primary setting across the Western Cape Province.

Conclusion:

The PMTCT Baby tool has captured the expertise and experience of programme HAST managers responsible for developing, monitoring and strengthening the local PMTCT programme, as well as those responsible for implementing the programme. It is recommended for inclusion into the Integrated HAST audit tool by the implementers and will become part of all future auditing of the HAST programmes. It is evident that implementation guidelines are essential in order to ensure that the PMTCT policy is implemented as intended.

DECLARATION

I declare that this thesis titled, "***THE DEVELOPMENT OF A TOOL TO EVALUATE THE QUALITY OF PREVENTION OF MOTHER TO CHILD TRANSMISSION PROGRAMMES OFFERED TO THE HIV EXPOSED INFANTS IN A PRIMARY HEALTH CARE FACILITY SETTING IN CAPE TOWN"*** is my own work, that it has not been submitted for any degree or examination in any other university and that all sources I have used or quoted have been indicated and acknowledged by complete references.

Signed by: ……

Date: ……

Dedication:

My Heavenly Father who gave me the wisdom and grace to be able to do this amidst all the competing demands of working, being a wife, mother, sister and daughter. To my amazing husband Ricardo, for his eternal support of me during this MPH and all my studies over the last 22 years. My son Dominic, who decided to grow over 30 cm while I was doing this programme and my daughter Jordan who agreed for me to start this programme as she started Grade 1, so that we would make all the major changes at the same time. The three of you have made endless sacrifices, never complained and just gave support! I am eternally grateful and will now make up for all of this. To my mum, dad, sister, brother and extended family who saw far less of me than they had been accustomed to and for understanding that it was all for a greater cause, I appreciate your support and love. Dr Vera Scott for her patience, support and always accommodating my circumstances. To Corinne & Janine, thank you for turning every perceived mountain into a mole-hill.

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Vera Scott:	Senior Researcher: School of Public Health: UWC
Patti Olckers:	Deputy Director: Comprehensive Health Programmes: Mitchell's Plain / Klipfontein Sub-Structure
Gilboni Matiso:	HAST Coordinator: Khayelitsha / Eastern Sub-Structure

Facility Managers, facility level staff, PHC Managers and PMTCT coordinators who participated in the training and piloting of this tool.

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CHAPTER 1: INTRODUCTION

1.1 Problem

HIV is a major disease burden in Sub-Saharan Africa (SSA), with South Africa (SA) having one of the highest community prevalences of 10, 2% of the total population according to the Statistics South Africa (Stats SA, 2011) mid-year estimates. Mother to Child Transmission (MTCT) is a significant route of infection in children with between 10-40% transmission rates in the absence of medical intervention. The median HIV prevalence rate among pregnant women in SA is 30, 2% and 18, 5% in the Western Cape Province (WCP) (DoH, 2011).

Ninety percent of the world's 800 000 paediatric cases of AIDS are in SSA, an area that is challenged by a high HIV prevalence among pregnant women within an under-resourced health care infrastructure (UNAIDS, 2010). Prevention of Mother to Child Transmission (PMTCT) is one of the key interventions implemented in order to achieve a two thirds reduction in the under 5 mortality by 2015 (the 4th Millennium Development Goal). Before PMTCT programmes had been implemented, the MTCT rate from HIV positive breastfeeding mother to her infant ranged from 22, 2% to 30, 2% (UNAIDS, 2005). According to the South African National HIV Household Prevalence Survey conducted in 2008 (AVERT, 2009), 2, 5% of children aged 2 – 14 years are already HIV positive.

PMTCT programmes are efficacious (PETRA, 2002) and in SA these services are now available at all health care facilities (Goga *et al*, 2010). Since 95% of women attend antenatal care, it should be feasible to implement and track the PMTCT programme (Jackson *et al*, 2007). However the PMTCT programmes are complex and require a number of high quality health system interventions across the service platform ranging from antenatal, intra-partum, post-natal, baby follow-up at well baby clinics and follow-up for the mother after delivery (Jackson *et al*, 2007).

Rollins, *et al* (2002) emphasise the imperative for thorough monitoring of PMTCT interventions. They state that surveys, sentinel site reports, cohort studies and routine data are often costly and

lack information that would guide decision-makers and funders. According to Stringer *et al* (2008) there is a lack of consensus on how to monitor the effectiveness of PMTCT programmes, since it involves a complex critical pathway.

1.2 Local Setting

1.2.1 The Metro District

This research is set in the WCP which has 6 districts of which the Metro District is the largest. Within the Metro District there are 2 health authorities that render primary care services to the uninsured population at 147 primary care facilities. These are the Provincial Government – Metro District Health Services (MDHS) and Local Government - City of Cape Town: Health (CoCT). The Metro District consists of eight health sub-districts and within the MDHS, two health sub-districts form a health sub-structure. There are thus four health sub-structures which each function as a complete management unit, equivalent to that of a health district. Within the CoCT, each health sub-district comprises of a management unit for the local government health services, but with a strategic and clearly defined link into each of the four health sub-structures.

Services across this primary care platform are predominantly nurse-driven and doctor-supported and are seen as the entry point into health care. Referrals for further management are made into the secondary and tertiary level of care, from the primary care platform.

1.2.2 Health Programmes Support to the Metro District

The Western Cape Department of Health (WCDoH) provincial level comprises of a Chief Directorate: Health Programmes, which provides support to all the health districts including the sub-structures within the Metro District with regards to:

- policy development,
- provision of relevant guidelines, tools and standard operating procedures,
- monitoring and evaluation of health programmes, health outputs and outcomes,
- programme management and financial and human resource acquisition and allocation.

At the sub-structure level, programme managers are in place for various health programmes. They are responsible for providing technical programme support to the sub-district programme

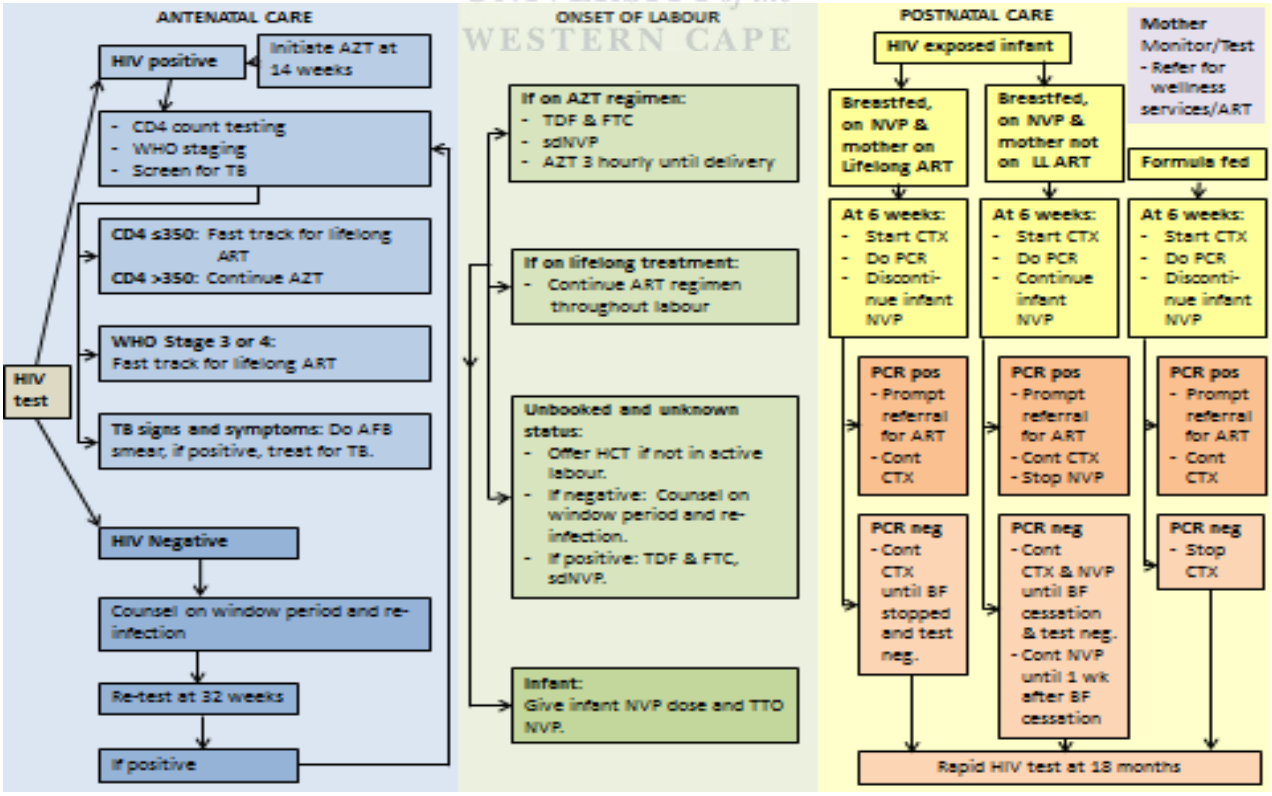
coordinators on the operationalization of policy; feed into policy development at the provincial level; ensure human and financial resource prioritisation and allocation; contract manage the external health care providers including non-profit organisations (NPO) and monitor and evaluate sub-structure level health programmes.

On sub-district level there are two HIV, AIDS, STI and TB (HAST) programme coordinators who provide direct support to all facility managers in the actual implementation of policy; monitor and evaluate health programme outputs and provide training related to the implementation and sustaining of health programmes. There is also a PMTCT coordinator who functions across the Sub-Structure providing direct support to facility management with regards to PMTCT specifically.

1.2.3 The PMTCT Programme

The WCP has the flagship PMTCT programme in SA (WCDoH, 2009). One of the sub districts within the WCP was the first to pilot PMTCT in SA and by 2003 all maternal and infant service sites in the WCP had PMTCT service coverage.

Diagram 1.1: PMTCT programme summary (Developed by C. Goosen: WCP PMTCT Manager, May 2012)



AZT:	Zidovudine, an antiretroviral drug used to prevent MTCT of HIV
CD4:	Number of T-helper lymphocytes per cubic millilitre of blood. A test conducted to determine the number of fighter cells in the blood of an HIV infected individual
WHO Stage:	World Health Organisation Stage. The different stages of HIV infection
TB:	Tuberculosis. A contagious bacterial infection that involves the lungs
ART:	Antiretroviral treatment. A variety of drugs that reduce the amount of HI Virus in the body fluid
AFB:	Acid-fast bacilli. A test to detect TB in sputum
sdNVP:	Single dose Nevirapine. Antiretroviral drug used to prevent mother to child transmission of HIV
TDF and FTC:	Tenofovir and Emtricitabine otherwise known as Truvada®. Antiretroviral drug used to prevent MTCT of HIV
LL:	Lifelong. As long as the person lives
CTX:	Co-Timoxazole. An anti-bacterial drug that is used prophylactically in HIV exposed infants to prevent bacterial infection
Pos:	Positive. The presence of HIV in the blood.
Neg:	Negative. The absence of HIV in the blood.
TTO:	To Take Out. Medication given on discharge from hospital to be continued at home
BF:	Breastfeeding. Infant feeding from the mother's breast.
PCR:	Polymerase Chain Reaction. A test conducted to detect HIV in the infant's blood at 6 weeks age.

Based on the PMTCT policy guidelines (WCDoH, 2011), diagram 1.1 provides a summary of the PMTCT programme. The mother is introduced to the PMTCT programme on testing HIV positive during the antenatal booking visit, registered onto the Antenatal HIV Counselling and Testing (HCT) register and monitored throughout her pregnancy. Her immune status is determined by her CD4 count and based on this the mother is either commenced on dual antiretroviral treatment (ART), which is referred to as PMTCT ART, for the duration of her pregnancy or lifelong ART. In the labour ward, the mother on PMTCT ART will receive a short course of prophylactic antiretroviral (ARV) drugs to prevent transmission while the mother on lifelong ART will continue with her regimen as prescribed. The new born infant is started on a single ARV drug as prophylaxis to prevent HIV infection and is continued on this drug for 6 weeks when an HIV Polymerase Chain Reaction (PCR) test is conducted and then commenced on Co-trimoxazole, a drug to prevent opportunistic infections. If the infant is breastfeeding, then the drugs are continued until one week after breastfeeding has stopped. With an HIV PCR positive result, the infant is either fast tracked for referral and commencement on ART and with an HIV PCR negative result, the infant is followed up and tested for HIV after cessation of breastfeeding. All infants who test HIV PCR negative are tested at 18 months with an HIV rapid test.

Paper based registers in the antenatal setting, labour ward and baby clinics, track all clients (mothers and infants) registered on the PMTCT programme and provide programme coverage and outcome indicators as follows:

- Proportion of HIV positive pregnant women receiving adequate Zidovudine (AZT) antenatally
- Proportion of HIV positive pregnant women receiving NVP stat intra-partum
- Proportion of HIV positive mothers accessing adequate dual therapy
- HIV transmission rate to the HIV exposed infant at 6 weeks

(Personal communication with Brenda Smuts, previous Director HIV & AIDS, STI and TB Programme, for the WCDoH, 3 March 2010).

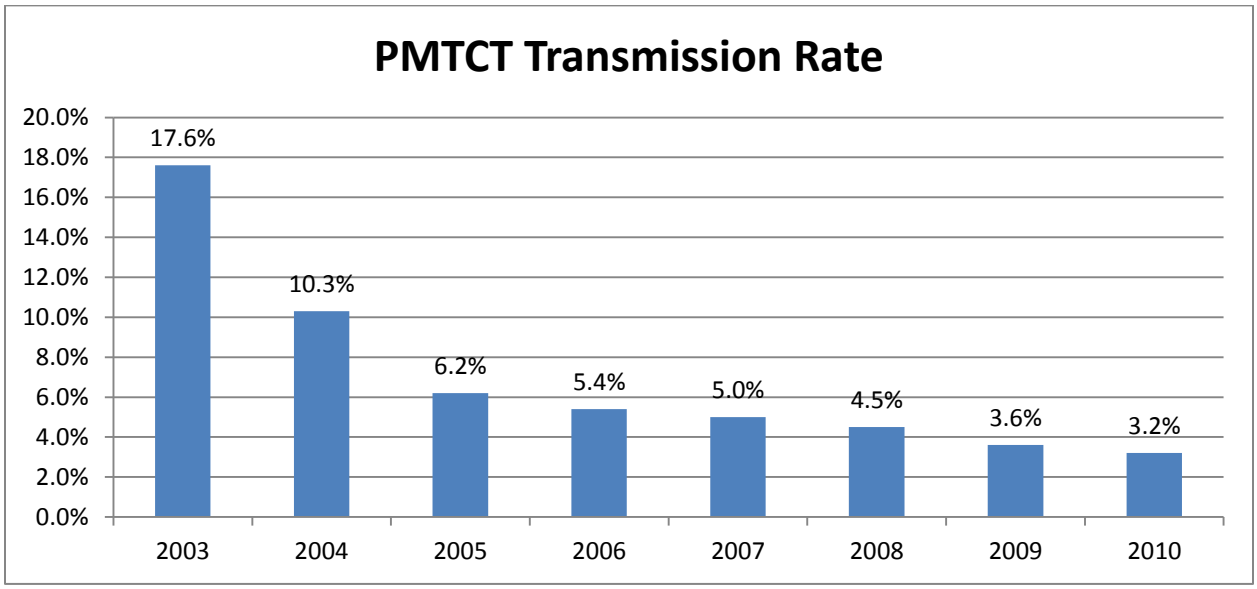
1.2.4 Purpose of the Study

The strength of the HIV programme within the WCP is due to the fact that the health authorities and academic institutions placed significant emphasis on managing and improving the programme through monitoring and evaluation. As far back as 2002 the local and provincial health department programme managers and academics within the Metro District, saw the need to audit or evaluate the quality of care that clients receive within the Tuberculosis (TB) services in the Primary Health Care (PHC) setting. A tool was developed to look at the quality of care that the TB client received and was subsequently piloted in one sub district. The findings were utilized to improve service delivery through identifying areas for re-training, re-enforcement and improved management of services. However, the tool had required too much qualitative work and was thus deemed too detailed to apply throughout the entire Metro District.

This experience then informed the approach to developing an integrated tool to evaluate a much broader scope of services: TB care, HCT, general HIV care, ARV care and STI services. The integrated tool made use of tracer indicators and was predominantly quantitative.

In 2007 a PMTCT component was added which focussed on the quality of PMTCT care rendered in the antenatal unit and labour ward to HIV positive pregnant women on the PMTCT programme.

Graph 1.1: Mother to Child Transmission Rate from 2003 to 2010 (WCDoH Data set, 2011)



In the WCP the PMTCT transmission rates, according to the WCDoH official data set, has shown a marked reduction in mother to child transmission from 17, 6% in 2003 down to 3, 2% in 2010 (refer to Graph 1.1). Although this may paint a picture that the PMTCT programme within the WCP is well functioning and efficacious, analysis of quarterly coverage and outcome data reveals fluctuations within the year as well as pockets of high transmission within moderate to well performing sub-districts. PMTCT programmes are complex and there is a risk of suboptimal implementation which makes careful programme monitoring and management essential. This requires more than just process and outcome evaluation. In addition to this, the current official data set provides coverage and outcome data that predominantly focuses on the mother, with only minimal focus on the infant. Based on this, PMTCT programme managers felt that there was still room for improvement in the Metro District and an opportunity to learn lessons from the Metro District could also be shared with other provinces.

An audit tool is currently in place to measure the quality of the PMTCT programmes rendered within the Antenatal Setting and the Labour Ward. The purpose of the development of the tool to evaluate the PMTCT services rendered to the HIV exposed infant was to measure the quality of care this infant received and in-so-doing contribute to the quality improvement of the PMTCT service offered within the primary care facility setting.

The WCP had developed considerable expertise in managing the implementation of the PMTCT programme, and an opportunity presented itself to capture this in a monitoring and evaluation tool which could be used to locally improve performance in the areas where transmission was still high, as well as in other provinces. A PMTCT tool to evaluate the services rendered to the HIV exposed infant has thus been designed to dovetail with existing HAST tools for the following reasons:

- One package evaluating all HAST programmes, could provide a uniform approach to quality assurance across the HAST programmes;
- It would be easier for users to apply this tool, since they would be familiar with using the tool with the same design;
- As with cause and effect, it would be beneficial to identify gaps within the quality of the other HAST programmes as a result of integration of services, that may reveal causes of poor performance within this particular programme area;
- Certain aspects that would require evaluation could simply be latched onto existing components of the existing Integrated HAST audit tool.

1.2.5 Outline of the study

The literature review was conducted with a specific focus on process evaluation, programme effectiveness, the research process of developing a tool and a search for existing tools that would serve this purpose. The chapter on methodology includes a process flow of the study outlining the 4 sessions held with the HAST experts and the two pilots that were conducted (including the training session) in order to develop the three drafts of the tool. This is followed by a chapter which focuses on the results from the second pilot which ultimately informed the final tool. The chapter on discussion unpacks the process of developing the PMTCT baby tool, highlights the challenges in interpreting policy and determines the usefulness and applicability of the PMTCT baby tool. In the last chapter recommendations for the use of the tool are made, as well as actions that would improve the PMTCT programme.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This literature review first looked at process evaluation and its stages and then it focused in more detail on quality assessment as a specific form of process evaluation. A further look ensued into defining programme effectiveness and its six stages, which was followed by a review of the most appropriate research processes for developing a tool. The last leg of the search located all published PMTCT tools internationally as well as unpublished PMTCT tools in SA that were available for use.

2.2 Process Evaluation

An evaluation is a process of systematically determining the effectiveness and impact of a set of activities as it relates to its goal/s (Bonita, Beaglehole & Kjellstrom, 2006). A process evaluation is the use of empirical data to assess health programme delivery and, unlike an outcome evaluation that assesses the impact of a programme, a process evaluation verifies whether the programme is being implemented according to designed or protocol (Bliss & Emshoff, 2002). The questions that must be answered when conducting process evaluation are: "*what is the programme intended to be; what is delivered in reality and where are the gaps between programme design and delivery?"* (Bliss & Emshoff, 2002:1). In order to answer these questions, use is made of qualitative and quantitative methods in process evaluation, since no one method can provide the same rich information (Linnan & Steckler, 2003).

The main reasons for conducting process evaluation include the following (Bliss & Emshoff, 2002):

- The comparison of multiple sites with regards to fidelity
- To provide validity for the relationship between programme intervention and the resultant outcomes
- To provide managers with information on the quality surrounding implementation
- To provide programme accountability to sponsors, the public, clients and funders

- Ultimately to improve the quality of the programme through evaluation which is also considered an intervention

The proposed stages of process evaluation are as follows (Bliss & Emshoff, 2002):

- Form strong collaborative relationships with the appropriate programme delivery and management staff and determine programme components
- Develop logical model and evaluation questions
- Determine the methodology and consider the management information system
- Implement data collection and analysis and write the report

Quality assessment is another form of process evaluation that is spoken of in the literature. In the context of Primary Health Care (PHC) it has been defined as a process whereby services are evaluated against a set of norms for quality care (AKF, 1993). These norms are often in the form of policies, guidelines and protocols. Katzenellenbogen *et al* (1997: 147), state that *"evaluation is a systematic way of learning from experience"*. This in essence means reflecting on work done and past experiences, in order to determine where problems lie and whether goals have been achieved. Planned activities are thus changed based on lessons learned and recommendations made from the evaluation process. Comparison standards are required which refer to the programme goals that are being evaluated. Without these stated goals, evaluating a service or programme is futile, since a comparison between action and its impact cannot be derived. In order to ultimately improve the quality of health care, evaluation research aims to measure and improve the various components that will guide movement in the direction of achieving this. In order to make service quality assessments most effective, the information that it elicits should be used to analyse, interpret, feedback and plan remedial actions (AKF, 1993) which then in turn is re-assessed.

2.3 Programme Effectiveness

The concept of "programme effectiveness" also relies heavily on process evaluation principles. Knippenberg (1986) suggests that programme managers are often faced with situations where it would be desirable to measure the impact (such as reduced numbers of babies born with HIV) but that this may be too difficult or expensive to do. In this scenario he advocates that programme managers should at least measure the conditions for a programme to be effective. In

other words, Knippenberg suggests that if a programme is well designed, then effectiveness (and impact) can be assumed if a set of conditions are met. He has put forward six 'conditions of programme effectiveness framework' which, in addition to access, cover processes: availability of key resources, capacity, initial use of the service, quality of care and continuity of care. UNICEF and WHO have used this approach to evaluate PMTCT in low and middle income countries (2001).

In the literature the PMTCT programme's effectiveness has also been tracked by using coverage indicators, such as what proportion of the infected mothers had access to ART and care and what proportion of HIV exposed infants have access to ART, HIV testing and appropriate referrals (Stringer, Chi, Chintu, Creek, Ekouevi, Coetzee, Tih, Boulle, Dabis, Shaffer, Wilfert & Stringer, 2008). Stringer *et al* (2008) further state that in order to ensure coverage, the complete sequence of events must be in place and delivered for prophylaxis to be delivered. This critical pathway is made up of process indicators that are collected routinely from facilities as part of the PMTCT programme reporting. Client fall-out along this critical pathway can also be significant, with mothers falling out after HIV testing and then not accessing ART; or HIV exposed infants not returning for HIV testing following all interventions within the antenatal, labour and postnatal periods. Although the aforementioned evidence exists with regards to which proportions of women and infants access care, the literature search does not produce reasons as to why women did not access care or why they dropped off along the care pathway (Stringer *et al*, 2008).

2.4 Research process of Developing a Tool

Various scientific articles published on health-instrument or tool development and validation make reference to "A Guide for Instrument Development and Validation" by Benson & Clark (1982). For example, Boyce, Gowland, Hardy, Rosenbaum, Lane, Flews, Goldsmith and Russel (1991) used this guide for the development of a quality of movement measure for children with cerebral palsy. The development of the short musculoskeletal function assessment questionnaire with regards to validity, reliability and responsiveness was based on Benson and Clarks guide (Swintokowski, Engelberg, Martin & Agel, 1999). Zarc, Pawlowski, Allen, Bryant-Stephens, Winston, Angusco and Shea (2006) developed and validated a tool to measure asthma symptom control in children using Benson and Clarks guide.

The guide depicts a 4 phase step by step (13 steps) guide to health-related tool development and validation. The 4 phases according to Benson & Clark (1982) are as follows:

- Planning (Steps 1-2) – this includes defining the content area that will be measured and the target group for which the tool is intended.

  During the planning phase the literature is reviewed to ensure that an appropriate, reliable and valid tool does not already exist. Out of this phase, the key concepts for item generation are developed and open-ended questions are presented to the judges.

- Construction (Steps 3-6) – the objectives of the tool that define the purpose of the tool will be stated. The objectives will lend itself to preparing the table of specifications, which are two-way grids reflecting content areas and categories. Item writing follows and the process ultimately intends on linking items to set objectives. A flow chart is then developed which defines each step in the process. This is followed by defining the format for responses, e.g. ranging from "strongly agree" to "strongly disagree"; or "Yes", "No" and "N/A" (Not Applicable). Once all items and objectives have been linked and consensus is reached with the judges (experts in health), content validation has been achieved.

- Quantitative Evaluation (Steps 7-11) - validity and reliability, through quantitative evaluation of the tool is conducted during the piloting phases. Estimating the reliability of the tool, will follow through field work with 2 sets of observers who will apply the tool within the same settings and use the same clients, so that the findings can be compared. The group of testers will be allowed an opportunity to feedback on the experiences with regards to applying the tool, so that ease of use can be determined

- Validation (Steps 12-13) – validation of a newly developed tool may be an ongoing process which requires ongoing research efforts and may not be concluded in one research paper. Validation is essential because it allows one to be confident with regards to what the tool is actually measuring (Benson & Clark, 1982: 798).

  As part of the validation process, the study sample will be calculated so that it is representative of the study population. This will facilitate the process of comparing routine data with information that is found within the registers and folders of the study sample.

2.5 Available PMTCT tools

The further review of existing literature aimed at determining whether a checklist or assessment tool already exists, that would help to elicit the information required with regards to the quality of the PMTCT service that is rendered to the HIV exposed infant within the PHC setting. Based on this, the need for further development of such a tool would be determined.

A literature search was conducted using the following key words: PMTCT, Assessment Tool, Evaluation, Quality of Care, Effectiveness of PMTCT programme and Development Validation Tool. This search yielded a set of tools that have been used to evaluate certain aspects of the PMTCT programme and services.

The following 10 tools were produced out of this process and are described in Appendix A:

- Labour Ward Monthly Data Summary and Antenatal Data Validation Tool (Smit, in press)
- Module 9 PMTCT Programme Monitoring Tool for Antenatal Care and Maternity Ward Register Tool (CDC, n.d.)
- Western Cape Provincial PMTCT Checklist (WCDoH, 2008)
- Volunteers Follow-up Schedule for Expectant Mothers on Highly Active Antiretroviral Treatment (HAART) and Volunteers Follow-up Schedule for Expectant Mothers on PMTCT (Kroon, 2011)
- Family Health International (FHI) Institute for HIV/AIDS (2003) published a health manager's toolkit called, Baseline Assessment Tools for PMTCT of HIV
- Evaluation of the Scale up of the PMTCT Infant feeding Counselling Training Programme in Tanzania (Luceno *et al*, 2010)
- PMTCT Folder Review of Antenatal Services - Integrated HAST audit Tool and PMTCT Folder Review of Labour Ward - Integrated HAST audit Tool (WCDoH, CoCT & UWC, unpublished)

Of the ten tools, eight are applicable to the primary care setting, four of which focus on the hospital setting as well. The tools focus predominantly on the labour ward and antenatal setting and make use of the registers and interviews in order to gain the information required.

Although most of the tools focus in some way on the elements of the PMTCT programme that are rendered to the HIV exposed infant. Two of these three 3 tools are applicable to the community setting (rather than the facility setting) for use by community field workers and the source of information is through conducting interviews and support visits. The third tool focuses on the HIV exposed infant and is applicable to the primary care setting. It has been used by PMTCT and project managers and the information is gathered through interviews. The focus of this tool is predominantly on protocol and drug availability, infant feeding counselling questions aimed at the facility staff and staff competency in rendering the PMTCT service to the infant. This tool does not focus on the infant folder or PMTCT register in order to verify that the PMTCT programme is implemented according to policy. It will therefore not be possible to adapt this tool for the SA context. It is thus evident that a tool that will focus specifically on the quality of the PMTCT programme that is rendered to the HIV exposed infant in the primary setting is needed and will add value within the framework of process evaluation.

There are also tools that have been developed in various quality improvement initiatives, such as the 3 interview questionnaires used in the study conducted in improving the coverage of the PMTCT programme through a participatory quality improvement intervention (Doherty, Chopra, Nsibande & Mngoma, 2009) and the tools used to conduct interviews in the study on an evaluation of PMTCT implementation and integration into routine maternal, child and women's health services (Horwood *etal*, 2010). However for the purpose of this study, the inquiry was limited to tools used to evaluate the quality of the actual PMTCT service rendered to the HIV exposed infant.

CHAPTER 3: METHODOLOGY

3.1 Introduction

A predominantly qualitative strategy was used, since this study was aimed at developing the tool through acquiring the input and experiences of experts in the field of HIV and AIDS within the Western Cape Province. This facilitated a process of understanding (Katzenellenbogen *et al*, 1997) what experts in the field required to be included in the tool.

3.2 AIM

To develop a tool that would measure the quality of care of HIV exposed infants in the PMTCT programme in the primary care facility setting in South Africa.

3.2.1 OBJECTIVES

- To engage local programme managers in a participatory process to develop a tool that is locally applicable and relevant, and that captures local management expertise
- To identify the evaluation domains required to measure quality of care of HIV exposed infants in the PMTCT services at primary care level
- To develop an indicator set for each evaluation domain
- To conduct a small pilot of the tool to assess its feasibility and the usefulness of the information generated

3.3 Study Design

Participatory Research (PR) was the study design that was applied. According to Breitbart (2003, 161) "*Participatory Research seeks to democratise research design by studying an issue or phenomenon with the full engagement of those affected by it"*. The focus was on collaboration with regards to developing the research agendas and designing actions that would ultimately improve the outcomes of care rendered to the HIV exposed infant. This type of research is increasingly being used in health research (Cornwall & Jewkes, 1995) and it in essence breaks the mould of conventional research and focuses on the process of sequential reflection and action. In this research, the action was the development of the tool. Local knowledge of

programme experts or those managing the health services formed the basis of the research and planning. This study design suited all four phases of tool development and validation (Benson & Clark, 1982) most appropriately.

As stated by Baum et al (2006) the researcher and participants developed a blurred line between them, as the power was deliberately abdicated by the researcher within the relationship. During the sessions, the researcher allowed all opinions of the HAST experts to be expressed and did not steer the discussion in any particular direction, i.e. the researcher posed questions and deliberately allowed the discussions to flow. Therefore, for this study the experts in the HAST field played an active role in deciding on the content of the tool, the piloting thereof and the appraisal of the tool. Although this was very time-consuming, the experts were involved throughout the entire cycle of tool development. The managers of the health services were involved in the piloting and refinement of the tool.

The process of tool design was built on the approach suggested by Benson & Clark (1982) as described in the literature review and the tool content was informed by what others had already done in developing a tool of this nature, but with the intent of addressing the context specific requirements in the Western Cape. Broadly the process of tool development consisted of:

- Planning: Panel discussion with experts to reflect on the existing Integrated HAST audit tool, the steps taken to develop it and the gaps that exist within it. The target audience and populations, as well as the domains were defined.
- Construction: The purpose of the tool was defined, a draft tool with indicators was developed over 2 sessions with the HAST experts, so as to gain a degree of content validation.
- Quantitative evaluation: A small pilot was done by one of the HAST experts to achieve a greater sense of whether the content was valid and reliable. Revision of the tool with the panel of HAST experts done to further refine the indicators. A second pilot was conducted by a broader team including facility staff, their supervisors and HAST experts to determine validity and reliability of the tool.
- Validation: This is an ongoing process. The write up of the thesis contributes to this process. The tool will be used widely as part of application of the Integrated HAST audit

tool on an annual basis throughout the WCP. The provincial integrated HAST audit tool task team will remain responsible for further reviewing and refining of the PMTCT Baby tool along with all other tools.

Throughout this process of tool development, diversity of views was revealed and opportunities presented, that required further exploring (UWC, 2002).

Diagram 3.1: Methodological process flow for this study

Research activities	Steps of tool development	Phases of tool development
Preparation: Researcher	Step 1: Select the HAST experts: core task team members and implementers	Planning
	Step 2: Define role of session facilitator	
Session 1: Core task team	Step 3: Reflect on the Integrated HAST audit tool with the core task team members	
	Step 4: Define the purpose of the tool, the target audience and target population	Construction
	Step 5: Define the domains for the Integrated HAST audit tool	
	Step 6: Develop the indicators for the PMTCT Baby Tool	
Session 2 and 3: Core task team	Step 7: Present the review of the current PMTCT tools that were identified in the literature review	
	Step 8: Develop draft indicator set and sampling and present draft 1 of the PMTCT Baby tool	
	Step 9: Core task team to comment on tool and draft 2 of the PMTCT Baby tool	
Pilot 1: One core task team member	Step 10: Conduct first pilot at Langa and Wynberg clinics, to test	Quantitative Evaluation
Session 4: Core task team	Step 11: Feedback from pilot to evaluate tracer indicators	

Session 4: Core task team	Step 12: Refine data collection tools	Quantitative Evaluation
	Step 13: Draft 3 of tool developed and planning for second pilot of tool with implementers	
Pilot 2: Core task team and implementers	Step 14: Conduct training for second pilot	
	Step 15: Second Pilot the tool	
Feedback workshop: Core task team and implementers	Step 16: Results collated and presented to core task team and implementers at feedback session	
	Step 17: Determine feasibility and usefulness of this tool.	Validation
	Step 18: Finalise the PMTCT Baby tool	

3.4 Selection of the HAST Experts

Two groups of HAST experts were involved in this process, i.e. the core task team and the implementers. The core task team were involved in all the phases of the actual development of the tool and the implementers were involved in the second piloting and feedback sessions.

For the core task team, experts within the HAST arena within both local and provincial health authorities, HAST Non-Profit Organisation (NPO) partners and public health academics were invited to participate according to the criterion sampling strategy (Rice & Ezzy, 1999). For this study the following criteria was applied:

- Individuals actively working within the HAST arena within the WCP for at least 5 years.
- Individuals previously involved in the development and application of the Integrated HAST audit Tool within the WCP.
- Individuals of a diverse opinion. The experts represented HAST health service delivery within the provincial government and local authority settings, public health academic arena and HAST health programmes within both provincial and local government settings.
- Individuals involved in managing and coordinating HAST programmes or in researching the management of HAST programmes.

Within the WCP, a quarterly meeting exists where the Integrated HAST audit tool is discussed with regards to its current state, relevance to the services, alignment with dynamic protocol and policy. At this meeting amendments to the Integrated HAST audit tool are made if required. All the members who attend this forum met the criteria to be core task team members. Although ten core task team experts were invited to participate in the development of this tool, of these, seven individuals participated in all the sessions and the remaining three were able to attend on an adhoc basis when their schedules permitted.

The selected core task team who had met the specified criteria represented the HAST arena within the WCP as follows:

- 2 District HAST Coordinators working within the MDHS,
- 1 HAST Clinician and Programme Support Medical Officer from the CoCT,
- 2 HAST experts and consultants to the HAST programme within the WCP, from the Desmond Tutu TB Centre [NPO] focussing on PMTCT system strengthening,
- 2 HAST programme managers from the CoCT,
- 1 Provincial DoH HAST programme manager,
- 1 Comprehensive Health Programme manager from the MDHS and
- 1 Academic from the School of Public health at the University of the Western Cape.

The second group of experts were the implementers and were defined as health staff within the HAST service delivery arena within both local and provincial health authorities. The following criterion sampling strategy (Rice & Ezzy, 1999) was used:

- Individuals active within the HAST service delivery arena within the WCP for at least 2 years.
- Individuals previously involved in the application of the Integrated HAST audit tools when auditing other HAST programmes.
- Individuals involved in rendering and supervising HAST service delivery.
- Individuals were facility staff willing to have their facilities participate in the pilot, or were the supervisors of these facilities

Seven implementers were purposefully selected to give input into the structure and content of the tool during the training and pilot phase. The selected seven implementers were as follows:

- 2 facility managers of the two sites who met the criteria for piloting and indicated their willingness to have their facilities included in said pilot. The two selected sites were based on being a low burden clinic with no ART services and a high burden clinic with an ART service on site,
- 2 of the professional nurses who render PMTCT services within the selected facilities,
- 1 PMTCT coordinator for the sub-structure and
- 2 PHC managers for the geographical area where the piloting would take place.

3.5 Ethics

Participation of the HAST experts, PMTCT coordinators, facility managers, supervisors and facility staff in this research process was completely voluntary. Each of the participants provided informed consent and was informed that he or she could withdraw from this study at any time during the process. Every effort was made to respect the dignity of each of the participants, by allowing them to express their opinion and not allow any one member to dominate a discussion or refute another's opinion. The time away from their workplace did not exceed 3 hours per session or per pilot, with the exception of the training session, which took the participants out of their workplace for 5 hours. The impact on the time of the core task team members was mitigated by the fact that they were mandated to conduct monitoring and evaluation and ensure quality as part of their core function.

The development of this tool provided programme and facility managers with a tool to improve the quality of the PMTCT service rendered to the HIV exposed infant which not only measured what they achieved against expected standards, but which also sets clear standards and was aligned to the policy. The development and piloting of this tool took place at no cost to the WCDoH and local government health authorities, other than staff time as described above.

There was no breach of confidentiality since the names of mothers and infants did not form part of the data that was collected. None of the patient folders or registers were removed from the

facilities. All participants involved in the piloting of the tool were reminded that professional secrecy was to be maintained and this was adhered to.

Higher Degrees Research Committee at the University of the Western Cape provided procedural ethics for this research.

3.6 Role of group / session facilitator

The sessions were facilitated by the researcher to ensure that all participants had an equal opportunity to express their opinions. One of the researcher's main tasks was to ensure that no one member dominated any of the discussions. Other tasks included note taking, voice recordings and clarifying that the core task team contributions were correctly understood and captured for the purpose of this research and further development of the tool.

3.7 Development of the Baby PMTCT Tool

The core task team contributed to the development of the tool from planning through to indicator construction, the training and the two rounds of piloting. The implementers contributed to the second pilot and the assessment of feasibility, validity and usefulness of the tool. All decisions with regards to inclusions in the tool were by discussion, debate and ultimately reaching consensus.

3.7.1 Session 1

The purpose of session one was firstly to reflect on the content of the existing Integrated HAST audit tool to inform the decision on whether it would be necessary to develop a new component (to be called the PMTCT Baby tool) to evaluate the service rendered in the HIV exposed infant on the PMTCT programme until the 6 week HIV PCR test has been conducted and in terms of feeding choices for the entire period that the infant was in care. Secondly, the purpose was to reflect on the structure of the existing Integrated HAST audit tool to decide whether this was suitable for the new component.

Review of current Integrated HAST audit Tool

In order to make the afore-mentioned key decisions, the core task team needed to be familiarised with the content and structure of the Integrated HAST audit tool. This tool is a management tool consisting of evaluation domains and programme components. The nine evaluation domains are contained within the matrix, consisting of 152 indicators covering the following HAST programme components: HCT, HIV Care, STI, TB, ARV Care, PMTCT antenatal HCT and HIV Care and PMTCT labour ward and immediate post natal care.

Table 3.1: Structure of current tool showing evaluation domains and programme components

	General	TB	STI	HCT	HIV Care	ARV Care	PMTCT antenatal HCT and HIV Care	PMTCT Labour ward
Access								
Availability								
Capacity: Staffing								
Capacity: Systems								
Capacity: Management								
Quality								
Integration								
Continuity of Care								
Outcome								

This table depicts the matrix that serves as a management tool. The columns in the tool represents the HAST programme components that are being evaluated and each of the rows reflect the evaluation domains, i.e. the conditions of effectiveness. In each cell there is then a set of tracer indicators (not shown here) to evaluate the domain for each of the HAST programme components.

It was noted that the existing tool already evaluates PMTCT care given in the antenatal setting with regards to HCT and HIV care and in the labour ward with regards to intra-partum and immediate post-partum care to the mother and infant. The indicators related to this are shown in

Table 1.2. The core task team decided that it was necessary to develop a Baby PMTCT Tool to evaluate care given to the HIV exposed infant when he or she is registered at the local primary care facility for on-going prophylactic care until an HIV PCR is conducted at 6 weeks of age and in terms of infant feeding and on-going care thereafter. It was decided that existing Integrated HAST audit tool would be utilised as a template for the development of the new tool and in particular that the same evaluation domains and criteria for the selection of tracer indicators would be used.

Table 3.2: Existing PMTCT indicators included in the Integrated HAST Audit tool

	PMTCT Antenatal HCT and HIV Care	**PMTCT Labour ward**
Access	Early bookings (<20weeks)	-
	HCT uptake	-
Availability	-	-
Capacity: Staffing	Clinical staff trained in HIV/AIDS clinical training	Clinical staff trained in HIV/AIDS clinical training
Capacity: Systems	Antenatal folders retrievable	-
Capacity: Management	-	-
Quality	Counselling form used	Standard HIV/ART stationery
	Consent taken	EDD recorded
	Risk reduction discussed	Received NVP in labour
	Received adequate AZT antenatally	Received ART regimen in labour
	Condom issued	Condoms issued
	Feeding options discussed	Delivery protocol followed
	RPR done and results noted	Baby received ART regime at delivery and discharge
	Weight, BP, urinalysis done	-
	Correct data transfer; folder to Antenatal HCT register	Correct data transfer, folder to labour ward register
Integration	Symptomatic TB screen	Contraception on discharge
	Symptomatic STI screen	-
Continuity of Care	On-going counselling	Appropriate HAART commencement / referral (folder review)
Outcome	-	-

The core task team noted that the Integrated HAST audit was accompanied by a manual as well as a data capturing template in Excel format which automatically generates graphs, allowing for easy feedback to service providers and programme implementers. The Integrated HAST audit has developed a feedback process which takes place in a structured manner. Each facility has to select 3 actions or areas for improvement within each programme area and formulate action plans. During the following audit, which is conducted 6 months later, these action plans are revisited in order to determine whether any improvements have taken place or not. (Own experience of the sequence of events, having been employed in the Child Health & HAST programmes within the MDHS from 2002 – 2010). The core task team decided to recommend this same process be used in giving feedback to facilities on the results of the PMTCT Baby tool.

Review of current data collection tools

Time was taken to reflect on these data collection tools and particular attention was given to how sampling was done in the various folder reviews (inclusive of paper based registers). The data collection tools are: the routine health information sheet, a facility manager's questionnaire, the consulting and counselling room observation from and the series of folder reviews. The folders reviews address the following programmes within HAST:

- HIV Counselling and Testing,
- HIV General Care,
- STI,
- TB,
- ARV Care,
- PMTCT Antenatal HCT and HIV care and
- PMTCT Labour Ward and Postnatal HIV Care (WCDoH, CoCT & UWC, in press).

Annexures to the data collection tools include a list to collate the different training courses that the staff had attended and a folder sampling form for each of the folder reviews, to record the folders had been accessed as well as those sampled but not found.

It was decided that a new folder review for the HIV exposed infant would be added and that an amendment to the facility manager questionnaire would be made in terms of the ART drug and consumable availability for the PMTCT programme.

Purpose of the tool:

It was agreed that the purpose of the tool was to evaluate both the routine PMTCT data and the care provided by the staff within the health facilities to the HIV exposed infant who registered for PMTCT services. The evaluation would be for the period commencing at the time that the infant is registered at the public health clinic until the 6 week HIV PCR test is conducted and following that with regards to infant feeding and continuity of care, for the sampling period not exceeding 6 months in age. It was agreed that the development of the PMTCT Baby tool was indeed required to dovetail with the current Integrated HAST audit tool.

Target audience

The user of this tool was defined as being the middle level health managers, who would be equipped with adequate information to facilitate decision-making, determine programme effectiveness and promote programme improvement at facility level. The middle level health managers would include the Provincial HAST Coordinators, District / Sub-Structure and sub-district level HAST co-ordinators, Facility Managers and other facility level staff, PHC Managers and other programme coordinators / managers.

Target population

The target population has been defined as the HIV exposed infants who are enrolled onto the PMTCT programme, irrespective of whether or not the mother had received antenatal or intra-partum ART. These infants would be assessed from date of registration at the clinic, until an HIV PCR is conducted at 6 weeks and beyond that for the sampling period, not exceeding 6 months of age.

In the event of infants testing PCR positive or negative after being on the PMTCT programme, the tool would allow one to track whether or not the PMTCT policy was adhered for the mother and infant and thus determine the level of programme effectiveness.

Domains for the Integrated HAST audit tool

For the Integrated HAST audit tool to be effective, a monitoring and evaluation framework was developed. In order for a programme to be effective, a set of critical conditions had to be met within this framework.

During the development of the Integrated HAST Audit tool, evaluation domains were agreed upon and at this session, the current domains were presented, discussed and re-assessed with regards to its relevance for the PMTCT Baby tool. The domains presented were as follows:

Table: 3.3. Domains for the Integrated HAST audit Tool

- **Access** to the programme must be ensured
- **Availability** of key resources and capacity to conduct the programme
- **Continuity of Care** is a key issue to ensure that the care pathway for the client is seamless and maintained
- **Quality of care** provided is the major element of final effectiveness of the intervention. Adherence to standard protocols and procedures must be in place and have to be followed.
- **Integration of Services** increases access across the HIV/TB/STI cluster and can be seen as part of a holistic approach to the client. This domain is essentially an aspect of quality of care, but has been separated from that domain so as to provide managers with an integration lens

Source: **(Scott *et al,* 2010)**

The core task team agreed that the same set of domains would be applicable, against which the indicators for the PMTCT Baby tool would be based.

Selection Criteria for the Tracer Indicators for the PMTCT Baby Tool

Based on the fact that selection criteria for the tracer indicators have previously been established with the development of the Integrated HAST audit tool (Scott *et al, 2010),* it was decided that these criteria would be applied for the selection of the tracer indicators for the PMTCT Baby tool. The criteria adopted for this tool has been modified from Scott *et al* (2010):

- Measure similar implementation aspects to a set of programme elements so that, by measuring the tracer, it is possible to deduce the performance of the other elements
- Be an essential part of the programme.
- Be realistic in relation to current best practice in the HIV and TB programmes.
- As far as possible, align to National and Provincial guidelines.
- Be possible to measure in a valid, reliable and interpretable way.
- Provide information that one can use to improve the management of HIV/TB/STI programmes at sub-district, district and provincial level.
- Preference is given to indicators that can be drawn from current routine monitoring systems or that can be incorporated into such systems without undue burden to staff involved in the collection of routine data.

This session ended with a decision that the researcher would draft a set of indicators which would set the basis for the data collection tool that would dovetail the Integrated HAST audit tool and that it would align to the 5 domains and the criteria for the selection of the tracer indicators. This first draft would be distributed for comment to the core task team and would take discussion at the next session.

3.7.2 SESSION 2 and 3: Discussion of sampling techniques and tracer indicators

Review of PMTCT Tools identified during the Literature Review

The literature review which had been conducted by the researcher was tabled and reviewed by the group at session 2. It was then unanimously agreed that all available tools were not suitable to be utilised as the PMTCT Baby tool. The domains used with the tools that were found in the literature review were not compatible with those that were required for this tool. The indicators used were either not applicable or already part of the PMTCT indicators contained in the antenatal and intra-partum folder reviews in the Integrated HAST audit tool.

See **appendix A** for detail on the tools that were found during the literature search.

Review of draft indicator set and sampling

Draft 1 (**appendix B**) of the PMTCT Baby tool that had been compiled and distributed for comment to the HAST experts after session 1 formed the basis for further discussion in session 2 and 3. In this section of the write up of the research process, the discussion on sampling of folders is described as well as the discussion on a small subset of the indicators. Not all the discussions are reported here as there was considerable overlap in issues relevant to each indicator. The subset of discussions have been chosen to illustrate how the core task team debated together the relevance, feasibility and validity of the indicators.

Sampling

Although the process of developing this tool was a predominantly qualitative study, the tool itself was a quantitative tool. For the folder review it was of value to identify the distribution of quality of care, but since ten folders were too small a number to provide reliable results (the 95% confidence intervals are very large), the intention was to identify main problems that may exist.

Since the PMTCT programme had been designed to keep the HIV exposed infant HIV negative at 6 weeks PCR testing, it was decided that folders of 5 infants who tested HIV PCR positive and 5 who tested HIV PCR negative would be required per facility. The selection of folders (infants) was retrospective since this would allow the opportunity to track whether there was an association between adherence to protocol and the HIV PCR result, i.e. the outcome.

Following discussion with regards to the most appropriate time to commence sampling, it was decided that for this evaluation, it would be adequate to commence sampling 3 months prior to the audit date in order to access recent folders. This would mean that the infant was registered onto the programme 3 months ago and had received care according to the PMTCT policy for at least 3 months. The infants of mothers, who had refused HIV PCR testing, would be excluded from the sampling. The core task team agreed on the exclusion since it would be fruitless tracking programme effectiveness without a programmatic outcome. The tracer indicator "Proportion of folder found" was agreed to by the core task team members and it was agreed that since this indicator determines the availability of sampled folders, that it would reside within the availability and capacity domain.

The PMTCT register would be used to select the sample of infant's folders. In the session there was a further debate on whether folders of the HIV positive mothers of the selected infants should be drawn and reviewed. It was decided that information related to the mothers HIV care would be included, since care to the mother can influence the HIV PCR result of the infant in a positive or negative manner, as follows:

- The WHO staging and CD4 count of the mother would reflect the mother's clinical state during the antenatal and breastfeeding period and thus have a positive or negative bearing on the HIV PCR result of the infant
- Inappropriate or inadequate management plan in terms of HIV care or ART in accordance with clinical guidelines, could negatively impact the infants outcomes.
- Poor continuity of care for the mother would negatively impact the outcome for the infant, but also affect that the chances of survival of the mother

Since this information on the mother, which ties into infant care, was not always accessible in the PMTCT baby register, it was agreed that the mother's folder should be retrieved in order to access this. It was also deemed opportune to look at another aspect of the PMCTC programme which is not strictly postnatal care but relevant to the longer-term well-being of the infant, i.e. whether the mother accesses on-going care or not. In conclusion, the folders of all the mothers of the sampled infants would be retrieved for evaluation, irrespective of the infants HIV PCR outcome.

Some of the challenges that were raised in terms of sampling included were as follows:

- In a setting where the burden of HIV exposed infants is very low, there would be challenges in obtaining the sample size of 10 folders when applying the suggested sampling frame.
- In facilities with low MTCT rates, finding 5 sequential HIV PCR positive folders may span across 1 – 3 years and 5 sequential PCR negative folders may span across a few months or even weeks.

In these circumstances, another dynamic is introduced of evaluating different staff (as they often rotate) over a long period of time, resulting in the two groups of infants (those who test positive and those who test negative) not being properly comparable. The Integrated HAST audits are conducted as often as 6 monthly, with the focus on recent change after action plans had been put

in place for improvement. Since the agreed sampling in the afore-mentioned circumstances would pre-date any of the agreed interventions, the core task team agreed to re-visit sampling.
During session three, the routine data set for the PMTCT programme was tabled and discussed and a very good example was raised by one of the core task team members. The data for the Klipfontein sub-district for the previous 6 months revealed none of the infants registered on the PMTCT programme at any of the sites, had tested HIV PCR positive. It was noted that this sub-district has the second highest number of infants registered on the PMTCT Baby register in the entire WCP. The concern was heightened that we may not obtain any HIV PCR positive infants in the sampling period.

The core task team then further deliberated options on whether to use 5 folders of HIV PCR positive infants in the prior 6 months and then an additional 10 HIV PCR negative folders. The rationale was based on the fact that 5 HIV PCR folders may not be available for sampling within the sampling period, but that a greater chance existed with obtaining the HIV PCR negative folders for the specified sampling period.

Towards the end of discussions on sampling in session three, the core task team questioned whether it would make a difference whether the baby was HIV PCR positive or negative and whether the focus should not just remain on the quality of care that the baby received at the facility in terms of PMTCT programme. In essence, whether we should use 10 folders irrespective of PCR result?

After all of the afore-mentioned deliberation, the core task team decided as follows:

- Since the aim of the tool is to evaluate the quality of the PMTCT programme offered to HIV exposed infants and their mothers, the PCR result would not be taken into account when sampling the 10 folders.
- The number of infants on the PMTCT register would depict the sampling sequence used, starting on a date 3 months ago, select the infants as follows for all infants who had an HIV PCR done:
    i) <100 PMTCT babies / year – then select 10 sequential folders;
    ii) 101 – 300 babies / year – select consecutive folders;

iii) 301+ PMTCT babies / year – select every 5th PMTCT folder.

- The folders of the mothers of the sampled infants would be selected to answer the questions that pertain to their postnatal HIV related care.

Although the core task team agreed that it would be ideal to link the mother's folder to that of her infant in practices (i.e. one folder for both), they acknowledged that in most instances it would still remain difficult to find the mothers clinical information. This was predominantly due to the fact that ~50% of the facilities do not offer all HAST services and the mothers clinical information would often be at another facility where she may be accessing life-long ART. It was then concluded that a section be added to the sampling of the PMTCT Baby tool, where the user could state the number of mother folders found that did or did not meet the criteria to be included in this audit and the number of mother's folders that could not be found. In this instance the concern would however remain whether we could be sure that the mother is accessing HIV care or ART elsewhere.

Counselling and Consent Form Used

It is a Western Cape and National policy requirement that written consent is taken when conducting an HIV test. When it relates to children and infants, the parent or legal guardian must provide written consent for the HIV test.

The "HIV Consent and Testing Record for Adults and Children" is the standardised recording form, for use within the WCP in all public health facilities and at all non-medical HIV testing sites that are funded by the public sector. This form is used for capturing client details, recording of written consent, post HIV test advice, screening for TB, STI, PMTCT and family planning and to track counselling across 3 follow-up sessions. Since this form provides prompts and guidance to its users, it essentially improves the quality of services delivery through ensuring alignment to policy when used accurately. The core task team felt it was reasonable to expect the use of this form to ensure quality through alignment to policy and to promote desired outcomes in practice.

Following significant discussion, the core task team agreed that the indicator "Proportion of clients counselling form used and consent taken" would be included in the Quality domain since it elicits adherence to policy, and that the following two questions should be included in the PMTCT Baby tool to gather the information for the indicator:

- Has an HIV consent and testing form been used for the HIV PCR test?
- Was consent taken for the HIV PCR test?

The rational use of this as a tracer indicator was debated and tested against the selection criteria. The group agreed that as a tracer indicator it was able to deduce performance of other programme elements, i.e., screening for other HAST related conditions (TB, STI, PMTCT) ensuring the follow-up of clients after a positive HIV test result and facilitating integration e.g. access to contraceptives. This indicator was considered to be realistic and feasible since the information that is required to feed into the indicator, is easily derived from the form that is filed in the infants folder. It was also agreed that it was possible to measure this indicator in an interpretable manner. Managers and HAST programme coordinators would be able to use this information to identify gaps and respond accordingly in order to improve quality of service.

Feeding practices discussed

Feeding practices play a pivotal role when it comes to MTCT of HIV since transmission can occur through breast-feeding. Although this risk of transmission during the post-natal period is eliminated when the mother chooses to formula feed and is substantially reduced when the mother chooses to exclusively breast-feed, cultural pressures and various circumstances may cause the mother to mix-feed, which presents an opportunity for HIV transmission. Counselling clients about feeding practice is therefore important in reducing MTCT of HIV. The importance of this makes it imperative that feeding practices would be discussed at every visit in order to check that no mixed feeding takes place and to discuss current feeding practice and its related challenges.

It was agreed that the indicator should be "Proportion of mothers with feeding practices discussed". Initially the core task team agreed to include two questions i.e., "Is there a record that feeding options and mixed feeding were discussed at each visit" and "Was the full quota of

infant feeding formula issued with each visit". With further discussion it was agreed that "each visit" should be changed to "last visit" since it would be a cumbersome process to go through the folder to access this information in events where the record-keeping was not reflected in the PMTCT register

The domain Quality was selected since it was agreed that these questions elicit adherence to policy. Quality is ensured with adherence to policy or protocol. Responding to the identified gaps would improve quality of service and reduce the risk of MTCT through mixed feeding.

Following deliberations, the core task team still agreed that the tracer indicator does not provide information that is required with regards to stock outs or non-availability of infant feeding formula (Pelargon or Melegi). The concern was that a stock out or non-availability of the formula could result in mixed feeding as well and not just the presence or absence of counselling on a monthly basis. We decided to add another tracer indicator to the facility manager's component of the Integrated HAST audit tool that would enquire into possible stock outs of the required formula feeding. The tracer "Proportion of facilities with stock outs of tracer drugs (ART) or consumables (infant feeding formula)" would reside under the domain availability and capacity.

The tracer was measured against the criteria for selecting a tracer indicator and found that on a large scale it could measure the extent of stock out and possibly even the impact on PCR results. The required information is easily derived from the facility manager and can be confirmed on the bin card. Bin cards are expected to be in place for pharmaceutical and non-pharmaceuticals within all public health facilities. This information that the tracer indicator provides can be used by the PHC managers and facility manager to track ordering patterns and related gaps in these.

PCR result available

The HIV PCR result at 6 weeks of age is the measured outcome indicator that reflects the effectiveness of the antenatal, intra-partum and post-partum interventions in the PMTCT programme in the WCP. All efforts during the antenatal, intra-partum and post-partum period are in vain when the HIV PCR result is not known. It is this indicator that is tracked and reflects the

culmination of the PMTCT programme offered to that point. Both National and Provincial Policy define that a PCR must be taken at 6 weeks and it has been considered to be standard practice, so it is a realistic programme expectation.

The core task team agreed that the tracer indicator would be, "Proportion of HIV PCR results available". This tracer element was measured against the selection criteria for tracer indicators and it was agreed that since it was standard practice for the National Health Laboratory Services to send the results sheet to each facility and that it is standard practice that all laboratory investigation results are filed in the clients folders, it would not be unreasonable to expect to have the results available. A pre-requisite for the PMTCT programme is that the HIV PCR results are also recorded in the PMTCT Baby register, resulting in this indicator being considered realistic and feasible.

The core task team decided on the question "Is the HIV PCR test result available in the folder", since it was agreed that if no result exists, then an assumption could be made that the test was not done (as is the case with all record-keeping). If the HIV PCR test was done (at this or another facility), the expectation is that the result would be in the infants folder so that the appropriate future action can be taken. The laboratory HIV PCR result sheet should be in the infant's folder or result recorded in continuation notes in the folder or in a referral letter (if the HIV PCR was conducted at another facility).

The quality domain was selected, since this question elicits adherence to policy which ensures quality and is a critical part of the PMTCT programme since it has a direct link with the outcome measure of the programme.

Infant fully immunised

The Expanded Programme on Immunisations (EPI) is the National and Provincial policy which guides the immunisation schedule. A fully immunised infant has a significantly reduced risk of contracting communicable diseases and access to immunisation reflects whether the infant has received comprehensive care. There is data to show that full immunisation will reduce under 5 mortality rates by 15%: 13% as a result of Pneumonia and 2% as a result of TB (Groenewald,

Bradshaw, Msemburi, Neetheling, Matzopolous, Naledi, Daniels & Dombo, 2009). Infant and under 5 mortality rates in the WCP were confirmed at 21 and 26 per 1000 live births respectively in 2009 (Groenewald *et al*, 2009) and have been projected to be 19 and 26, 5 per 1000 live births respectively for the WCP (ASSA, 2008) in 2011.

Since immunisations is standard practice, it was not considered to be an unrealistic expectation to have each infant immunised and immunisations is included within the routine monthly reporting of all public health facilities within WCP. Irrespective of the infants HIV PCR result, being fully immunised would be beneficial to any infant.

The core task team agreed that the tracer indicator would be "Proportion of HIV exposed infants fully immunised". The tracer indicator was measured against the selection criteria and found to be a proxy indicator for access to comprehensive health care, frequency of access to wellness services, but that it would in essence not be able to measure any other PMTCT related programme elements.

The core task team decided on the question "did the baby receive the birth, 6 and 10 week immunisations as per schedule" to be included in this tool. The rationale for the schedule to include until 10 weeks only is due to the agreed sampling that commences 3 months ago, which would result in some infants not being eligible for the 14 week immunisations as yet. This information is easily found in the immunisation section of the "Paediatric Record" or in the continuation notes.

This indicator resides within the Integration domain since it facilitates integration into the general or comprehensive service platform.

Baby weighed at last visit

The core task team deliberated on whether or not to include an indicator assessing whether the infant's weight was being checked and recorded and if so, how frequently this should be conducted. A decision was taken to go back into the PMTCT policy to identify whether a need for regular weight checks existed, other than for early detection of growth faltering. The PMTCT Policy stipulates that the dosage of the prophylactic drug prescribed (Nevirapine - NVP) should

be administered according to the weight of the infant and since most infants gain a significant amount of weight (enough to affect the dosage of NVP) during the first 6 weeks of life, the core task team agreed that the only way to ensure that an accurate NVP dose is calculated and adjusted, is by ensuring that the weight is checked and recorded.

The tracer indicator "Proportion of infants with NVP supply checked and dosage adjusted" was first proposed but in the third session it was decided that the "Proportion of infants weighed at last visit". Weighing the infant is not just current and expected practice within the PMTCT programme, but is also a standard of care provided to all infants, irrespective of the HIV exposure or HIV PCR status as it facilitates early detection of growth faltering. The information is retrievable from the continuation sheets in the infant's folders and is an indicator that will allow for quick wins when re-establishing poor performance of this indicator. Since this indicator again elicited the quality of care aligned to policy, it was placed under the quality domain

Although the weight should be checked with every visit, the core task team agreed that to make the indicator feasible, evidence of a weight at the last visit recorded in the folder would be adequate. The question decided upon was, "Was the infant weighed and weight recorded at the last visit".

Discussion furthered on whether it would be expected for the mother to bring the balance of the baby's NVP along with each visit so that the difference in what is required could be issued. It was however decided that this would be of little value and was not considered essential to track.

Appropriate management plan

Should a medical condition be chronic or of a nature that requires regular visits to the health services, it is considered standard practice to document a management plan and to provide the client with a follow-up appointment. The core task team deliberated this issue extensively across session 2 and 3 and finally concluded that the indicator should be included and should in essence be deemed essential for both the infant and the mother.

This indicator resides within the continuity of care domain, since on-going care would be promoted. The core task team decided on the tracer indicator, "Proportion of clients with future

management plan noted at last visit" and was measured against the selection criteria for tracer indicators and found that this indicator is essential and not nice-to-have as future management of the client would be compromised. The PMTCT policy expects that the infant and mother are followed up until such time that either are transferred to an ART or other appropriate site, or the infant is discharged when HIV PCR negative. The information required for this indicator is easily retrievable under the "Plan and Treatment" section of the HIV/ART visit summary form or it would be accessible within the clinical folder on the continuation sheets. This information would definitely improve the management of the client within the HAST programme in general and would provide management with information to identify gaps in care and to address them accordingly.

The question decided upon "was an appropriate management plan noted at the last visits". The rationale was that if any problems have been noted for either the mother or the infant, there must be a management plan recorded to further investigate, monitor or treat the problem. Should no new problems be noted, the management plan needs to record current treatment and dates for future visits. The management plan should also include a follow-up appointment date or time period (e.g. in 1 month).

PMTCT Baby Register review

The PMTCT baby register is an official document that is contained within the National and Provincial PMTCT policy. Although there is a slight variation between the expected data that is recorded in the WCP and National registers, the information that it yields produces all the Division of Revenue Act indicators that are required for reporting on a monthly basis to the NDoH and the Provincial Treasury. The core task team thus agreed that it is imperative that all the elements that are recorded in the PMTCT baby register are deemed as essential in order to make appropriate management decisions and to track progress towards closing the gaps that have been identified.

The data that is recorded cover all aspects of post natal care within the PMTCT programme to the infant and the mother and it is the responsibility of all staff who record data in the register to

ensure that data integrity is maintained through accurate recording, ensuring that all fields are completed and that the data is aligned to that of the infant and mothers folder.

Following discussions across the 2 sessions, the core task team agreed to two tracer elements as follows:

- "Proportion of correct entries in PMTCT Baby register": The measuring of this element would definitely deduce the performance of other programme elements related to the care of the infant within the PMTCT programme, i.e. frequency of visits to the facility, potential for mixed feeding, etc. This tracer indicator is important since it reveals various programme elements that management can respond to, based on the gaps identified, which will improve the rendering of services within the PMTCT programme.
- "Proportion of HIV exposed infants whose mothers are registered in the PMTCT Baby Register": This tracer indicator aims to measure the care offered to the HIV positive mother would either be of benefit to, or be detrimental to the HIV exposed infant. Ultimately this would ensure that the mother of the infant is appropriately managed according to the HAST policies and is aligned to Provincial policy. This is a realistic expectation and is current practice within the WCP.

Both tracer indicators reside within the quality domain since adherence to the policy for the PMTCT programme is tracked which would reflect quality care was provided to the infant and the mother. It would also reflect that the Information Management Data Flow Policy (WCDoH, 2009) was adhered to, since this commences with accuracy at the facility level before the data flows up to sub-district level, district, provincial and ultimately national level, would be dependent on this.

The core task team then selected 3 questions that would be included in the PMTCT Baby tool, to evaluate the use of the register. The three questions and the rationale for the use of each of them were as follows:

- "Is the 6 week PCR, test result, Cotrimoxazole at 6 weeks, initial and on-going feeding choice and provision of milk formula to date (where applicable) correctly entered from the clients folder into the PMTCT Baby Register?"

This question helps to assess the accuracy of the PMTCT Baby Register. Data from the PMTCT register is used to monitor programme performance and it is important that all the elements in the register correctly reflect information from the clinical records. The register should be used to ensure that the appropriate care has been provided.

- "Does the mother of the infant have her PHC folder number recorded in the PMTCT Baby Register?"

  If the mothers PHC folder number is reflected it allows maternal and infant care to be linked more readily. Ideally, all PMTCT mothers should also have a folder at this facility. However, the folder number could also be from this or another facility, e.g. an ART site where the mother receives care.
- "Does the mother of this infant have a CD4 result recorded in the PMTCT Baby Register?"

  Both a CD4 count and WHO Clinical Staging are required to determine the appropriate package of HIV care required by the mother. CD4 counts are monitored 6 monthly for the HIV positive clients not on ART and 12 monthly for those on ART.

Mother identified as HIV positive in clinical notes

A long standing struggle within the WCP according to the core task team of HAST experts, is that the PMTCT programme tracks and supports the infant until 6 weeks HIV PCR results, onto 6 months after breastfeeding has ceased or the formula feeding is no longer issued as part of the programme. During that period appropriate referral of infants occurs and quality care for the infant becomes the focus, with little consideration for the care of the mother after child birth.

The following concerns were expressed by the core task team:

- these HIV positive women are accessing other health care services (family planning, TB screening, etc.) and the attending clinicians are often not aware of their HIV status;
- that they breastfeed their infants exclusively with CD4 counts and WHO staging that is not tracked and the infant runs the risk of HIV transmission and
- that all efforts are made to save the infant, who is then orphaned since the mother dies due to poor clinical care.

The tracer indicator "Proportion of mothers identified HIV positive in the clinical folder" was decided upon. It will measure that the mother is treated with the consideration that she is HIV positive and although this indicator cannot be routinely tracked, during the application of the tool the information is retrievable. The indicator will help to improve the provision of general HIV wellness care when acted upon by managers and supervisors. Since the HAST Programme at Provincial level have put stationery in place that must be used with each client who tests HIV positive, it is not unrealistic to expect that this indicator can be achieved.

The core task team decided to add the question "Is the mother identified as HIV positive in the clinical folder" to the PMTCT Baby tool. It is expected that the mothers HIV status be indicated in continuation notes or that there is some indication of the mother accessing HIV care, e.g. use of the standard HIV/ART stationery or a CD4 count done and result recorded or filed.

Standard HIV/ARV Clinical Stationery used

It is a Western Cape and National policy requirement that the HIV / ART stationery is utilised with all clients on an HIV positive diagnosis in a public health facility. Irrespective of whether the clients is counselled and tested for HIV by the HIV counsellor or a clinical person, the HIV/ART stationery should be used with immediate effect.

The use of the standard "HIV/ART stationery" improves the quality of services as it provides a prompt and guide to clinicians. The stationery facilitates recording and review of information, promoting continuity of care. If the mother receives ART elsewhere, it would be acceptable to not have complete records at the facility where the infant receives care. This form is used for capturing client details, WHO staging, CD4, social assessment, adherence to treatment counselling, clinical visits and explanatory notes. It comprises of an A3 white folded card called the "HIV/ART Patient Summary folder" and an A3 folded paper summary for clinical notes which allows for numerous follow-ups per sheet. Since this form provides prompts and guidance to its users, it essentially improves the quality of services delivery through ensuring alignment to policy when used accurately. It is thus realistic to expect the use of this form to ensure quality through alignment to policy and essentially to promote desired outcomes in practice. This form is

a crucial non-negotiable piece of stationery that must be used with all HIV positive clients irrespective of whether they are on ART or within general HIV wellness care.

The core task team decided on the tracer indictor, "Proportion of HIV positive mothers with HIV / ART stationery used"**.** The tracer indicator made it possible to deduce the performance of other programme elements, i.e. continuity of care for the HIV positive mother, access to counselling and clinical care. This indicator is considered to be realistic and feasible since the information that is required to feed into the indicator, is easily derived from the "HIV / ART stationery that is found in the clients folder. It was also agreed that it was possible to measure this indicator in an interpretable manner and that management would be able to use the information to make systems related decisions to improve quality of service. Since this indicator elicits adherence to policy, it was decided that it was best suited within the Quality domain.

Following a brief discussion, the core task team decided to include the question: "has the standard HIV / ART stationery been used?", to the PMTCT baby tool.

Mothers CD4 count and WHO staging recorded

According to the HIV Wellness and ART policy at National and Provincial level, both a CD4 count and WHO clinical staging are required to determine the appropriate package of care to the client and should thus both form part of the baseline assessment for all HIV positive mothers. The WHO clinical stage should be updated when the new stage defining illnesses are noted and a CD4 count is required 6 monthly pre-ART, to assess disease progression and every 12 month for those on ART.

The core task team decided on the tracer indicator "Proportion of HIV positive mothers WHO staged and CD4 count recorded" and agreed that it would also measure or indicate adequate access to HIV care. This information is easily accessible and measuring this indicator would allow management to respond to the gaps identified. Since this is current practice within the HAST programme in the WCP and on a national level, expecting this indicator to be achieved is realistic.

Again the core task team raised concerns related to the care of the infant's mother and agreed to add the following two questions:

- "Is the mother's baseline / current WHO clinical stage recorded?"
- "Has a CD4 count been done and are the results available?"

The information can be accessed in the general folder for the standard HIV/ART Patient Summary folder or in the general clinical notes in the event that the official stationery had not been used. The apt domain was decided to be quality, again due to adherence to policy being indicative of quality of care being rendered.

Social Assistance and PAP smear

It is standard practice to conduct a social assistance evaluation and a PAP smear on all HIV positive women as a component of HIV Care and ART service delivery. Since this is both national and provincial policy it is expected as standard practice, but the core task team deliberated in terms of whether it was applicable to include this in this particular tool.

The tracer indicator 'proportion mothers with evidence of general HIV care' was decided upon. This indicator would also suggest that all other programme elements aligned to HIV care would be in place and not just social assistance and PAP smears. This information is accessible within the standard HIV/ART stationery or the continuation notes.

It was decided that the following two questions would be added to the PMTCT Baby tool:

- "Was social assistance evaluation completed?"

  This section assesses social support needs. It assesses support available to the mother at home, source of income and alcohol and drug use, all of which may influence adherence to treatment and require intervention. It also assessed whether there are vulnerable children, whether the infant is placed at risk and if the family is eligible for any grants.
- "Has client had a PAP smear done and results recorded?"

  Cervical cancer presents in younger women and progresses much more rapidly with HIV infection. The protocol for routine PAP smears in HIV positive women has not yet been finalised, however we work on current best practice that HIV positive women should

have at least one PAP at baseline, irrespective of their age and whether a PAP has already been done in the last 10 years.

This indicator resides within the quality domain since it speaks into adherence to the relevant policy.

Commenced on HAART

The HIV care and ART policy stipulates the medical criteria for commencing ART and these criteria should be adhered to in all clinical settings. The HIV/ART stationery is used from time of confirmation of the HIV status and allows for tracking of the client so that it is clear when the client meets the medical criteria for commencement onto life-long ART.

The tracer indicator selected, was "Proportion of mothers commenced who require ART". This indicator is very easy to track since the information is easily accessible in the HIV/ART stationery and the continuation notes (should the stationery not be used). This indicator responds to policy and thus the quality domain is most suited.

The core task team agreed that the following two questions should be asked since it elicits whether or not the mother of the HIV positive infant has been assessed for ART eligibility and whether she had been referred accordingly if the criteria were met.

- "Does the mother currently meet the medical criteria for ART? "

  The rationale is that the review of the CD4 count result and WHO clinical stage to determine whether the mother has met the medical criteria for ART in post-natal women is crucial.
- "Has the mother commenced on ART post-delivery?"

  This question assesses appropriate access to ART for those who meet the medical criteria for ART and who have not commenced on ART previously. Clients who meet the criteria should be timeously commenced on ART provided at the facility or formally referred to an ART site for treatment. It is the responsibility of the facility to monitor the clients access to ART for all PMTCT mothers.

Contraceptives

The core task team agreed that access to contraception is linked to the PMTCT programme and general HIV Care. Dual protection against pregnancy and sexually transmitted diseases is recommended for sexually active women. Since the core task team agree that the move towards HIV and Family planning integration is not Provincial policy, it has however been included in Standard Operating Procedures based on research that has been in progress within the Metro District.

The tracer indicator "% HIV positive mothers assessed for contraception" was measured against the selection criteria and found to be a proxy indicator for access to comprehensive health care, but it would in essence not be able to measure any other PMTCT related programme elements.

The core task team members decided that the question "were contraceptives needs assessed at the last visit and due date for repeats recorded?" would be appropriate to assess contraceptives another than condoms. Many women will say they are on contraceptives, even though they have missed their last appointment for repeat contraception, therefore due dates for the next visit for contraceptives should always be noted.

The information required to respond to this question is found in the HIV/ART Visit Summary Form and if this form was not used then it should be found within the general clinical notes. The indicator resides within the integration domain since it facilitates integration into the general or comprehensive service platform.

It was agreed that it would be a realistic to include this question and that the results would stimulate management to move more towards achieving a better place on integration. However with regards to standard practice of care for maternal health, all women who are sexually active should be offered contraceptives and condoms as a routine.

Sequence of questions

In draft 1 and 2 of the tool development, the focus was predominantly on questions and tracer indicators. However in session 3 the core task team deliberated on the sequence of the questions

and its alignment to the rest of the folder reviews contained within the Integrated HAST audit tool so as to effect uniformity. This would facilitate the data collection in terms of the data collection template and how the sheets have been constructed in order to ultimately tally through to provide a summary of the evaluation of audit that had been conducted.

Draft 2 of the tool

Following sessions two and three, draft 1 of the data collection tool was amended rather significantly to include the questions that would speak into the preliminary set of tracer indicators. The tool was divided into 3 sections:

- Sampling section: in this section the numbers of folders that were sampled for both infant and mother was recorded, as well as those sampled but not found.
- Infant section: eleven questions were included to address the tracer indicators relevant to the infant and the PMTCT Baby register
- Mother section: thirteen questions were included to address the tracer indicators relevant to the mother, infant and PMTCT baby tool

Draft 2 of the tool (**Appendix C**) was agreed to by the core task team members.

3.7.3 PILOT OF TOOL

The core task team decided that a small pilot would help to define or strengthen the tracer indicators and the data collection tools. The understanding was that this would make the tool more robust for formal piloting. It was decided that this small pilot would be conducted by the Clinician who was a core task team member and that Wynberg and Langa clinic would be utilised.

Wynberg Clinic is a low burden clinic with no ART services. Only 24 HIV exposed babies were recorded on the PMTCT register for the entire year. It took 2hr to conduct the pilot, from the time of sampling out of the PMTCT register until completion of the tool. In general a very poor link between the mother and infant was found. The PMTCT care according to policy was rather unstructured (and all over the place) with poor record keeping especially with regards to the mother. There was also no dedicated PMTCT clinic and mothers brought their infants at any time

and at any session and any available nurse would see the infant. This clinic did not offer an ART service and mothers accessed this elsewhere.

Langa Clinic is a high volume site with 137 HIV exposed infants on the PMTCT register at the time when the small pilot was conducted, averaging between 270 and 320 HIV exposed infants on the PMTCT programme per annum. It took 1hr 50mins to conduct the pilot, from the time of sampling from the PMTCT register until completion of the tool, since the register was extremely well completed, due to excellent oversight from the facility manager, who also provides input in terms of standard of care. This pilot therefore presents the best scenario in terms of care given.

Feedback of the pilot was provided at session four.

3.7.4 SESSION 4: Feedback from pilot to evaluate the tracer indicators

The results of this pilot were shared electronically with the core task team members before session four and then formally tabled at the session. The HAST Clinician / Programme Support Medical Officer who conducted the small pilot, decided that it would be best to present the feedback by facility since the facilities were very different in terms of HAST services offered and the burden of disease.

Lessons from the pilot at Langa Clinic

All the infants registered had corresponding mother's folders completed in the PMTCT baby register. This may have been due to Langa having their own ART site and the mothers were on treatment at the same facility. In essence a very good link existed between the care for the mother and the infant.

Sampling

The HAST Clinician / Programme Support Medical Officer reported that the sampling was found to be remarkably difficult since the mother's often have different surnames to their infants and in addition to this the sampling instructions were found to be ambiguous, as follows:

- As recommended the sampling 3months ago and she worked backwards for 6 months. The numbers of registered infants were counted and it was then noted that the sampling

options had suggested the sampling against the number of infants per year. It was suggested that the core task team discuss and amend this to number of infants registering on the PMTCT programme per month, for the next draft.

- It was not quite clear what was meant with consecutive folders. Every second baby was then sampled, but this would require clarification.

Based on this method of sampling the HAST Clinician / Programme Support Medical Officer managed to access all 10 infants folders including two additional folders, in the event that any of the folders could not be found. All of these came from the same page within the PMTCT baby register.

Key Results

Feeding practices were not discussed at the last visit for 90% of the babies. In 80% of infants the counselling form was used and consent taken. 100% of information in the PMTCT register was accurately recorded and complete.

Of the mothers' folders sampled, 3 mothers were found to be on ART prior to pregnancy, 4 of them started ART at Langa during pregnancy, 2 moms were in HIV wellness care at Langa prior to the delivery and 1 mother was admitted to HIV care at Langa, because she presented at the PMTCT programme with a baby.

Collection of the data on the infant

In terms of **feeding options**, looking into tracer indicator 'proportion of mothers with feeding practices discussed', two questions were included in the tool, i.e. 'is there a record that feeding options and mixed feeding were discussed at each visit' and 'was the full quota of infant feeding formula issued with each visit'. The HAST Clinician / Programme Support Medical Officer suggested that the question, 'is there a record that feeding options and mixed feeding were discussed at each visit' should either change or be omitted? The reason for this suggestion is that although the feeding choice was clearly recorded at the last visit, when the child is 3 months and older it is no longer appropriate to discuss feeding options at every visit. For most babies it was clearly recorded that feeding options were discussed at the first visit. It was suggested that the question rather ask if there is a record that feeding options were discussed at some point or whether the feeding choice has been clearly recorded.

As for the second question, 'was the full quota of infant feeding formula issued with each visit', it was suggested that N/A be added into the response columns, since some of the mothers prefer to buy their own formula (of which there were quite a few in the register).

As for the indicator, 'proportion of mothers **counselling form used and consent** taken', it was suggested that N/A be added to the tool when answering the two questions aligned to this tracer indicator, i.e. 'has an HIV consent and testing form been used for the HIV PCR test' and 'was the consent taken for the HIV PCR test'. This is due to the fact that many infants test at another institution, e.g. a hospital and are referred to the health facility for further management. In these instances, the consent forms will not be included, but the result would be written in the folder or included in the referral letter from the referring institution.

The tracer indicator 'proportion of HIV exposed infants fully immunised' could be skewed in the event of a stock-out. Discussion followed on whether to record immunisations is up to date in the event of a stock or not. It was decided that the immunisation schedule would be added to the guidelines manual and that N/A would be included for legitimate reasons, i.e. stock outs that prevented the infant from being fully immunised.

Collection of data on the Mother

The tracer indicator 'proportion of mothers with evidence of general HIV care' and its related question took significant discussion at the feedback session. It was decided that the question 'was a social assistance evaluation completed', that this question is asked HIV care tool (recent positive diagnosis) and the ARV tool (recent ARV started). In the sample for the PMTCT Baby tool, many of the mothers had been known to the clinic for years before the baby was born and therefore the fact that their social assistance was filled in or not, did not seem to be relevant to current care. It was suggested that this question be omitted.

Further discussion continued on the question 'has mother had a PAP smear done and results recorded', that this question was very out of date for some patients, since some PAPs are delayed during pregnancy and for 3 months thereafter because of hormonal changes during pregnancy. So although many mothers did not have a PAP smear, it would be inappropriate to do so at that

time. In addition to that, if we decide to keep this question should we not be adding a N/A for moms who are ineligible and those who are at another institution for colposcopy? This question would also be omitted in the next draft.

Lessons from the pilot at Wynberg Clinic

Sampling

Since the numbers are small, sequential folders were sampled which made it easy to complete the mother and infant sampling form without getting confused. Only 12 babies registered in the last 5 mnths and out of this only 1 folder could not be found, while another was intentionally omitted from the sampling since the mother repeatedly defaulted from bringing the baby for a HIV PCR even after counselling.

The mothers name and other details were recorded in the PMTCT register, but none of the folder numbers of the mothers were recorded. Twenty mother folders were selected for sampling dating 13 months back and out of these only six folders were found. As a point of interest, CLINICOM (an electronic patient data base / system) was checked to see whether these mothers were elsewhere in the primary health care system, since CLINICOM should show all the deliveries that take place at the Maternity and Obstetrics Units (MOU). It was found that only six mothers attended at Wynberg, one mother at Matthew Goniwe and one mother at Crossroads clinic. The other 12 mother folders could not be traced at all.

Results

In only 30% of mother, the Counselling form was used and consent taken for the infants HIV PCR. The monthly columns in the PMTCT register were not marked off for formula feeding or breastfeeding. Therefore 0% of the mothers had there feeding practice discussed. Poor use of stationery was also found, with only one out of six mothers folders found, i.e. 17%.

Collection of the data on the infant

With the tracer indicator 'Proportion mothers with feeding practice discussed', it was also noted that since the sampling commenced at 3 months ago and since the numbers of infants registered for PMTCT are small, infants who were six months old already had been sampled. At this age

formula is no longer dispensed and this was apparent with two infants in the sample at Wynberg clinic. The core task team needed to consider either adding N/A to the formula question or changing the question to focus on the last PMTCT related visit, rather than the last visit.

It is also noted that breastfeeding and formula purchasing babies do not attend the clinic regularly. One question that arose was in terms of the baby being exclusively breastfed until 2mnths and successfully changed to formula and in an abrupt manner, whether this is considered mixed feeding? Although these could be clarified in the manual, the core task team deliberated with regards to the value of the question on 'was the full quota of infant feeding formula issued with each visit" when we already ask the question 'is there a record that feeding options and mixed feeding were discussed at each visit' and whether the information that is received from both questions are essential.

Two decisions were taken by the core task team:

- Remove the question 'was the full quota of infant feeding formula issued with each visit', since the tracer indicator can still remain through the use of the remainder question "is there a record that feeding options and mixed feeding were discussed at each visit".
- Change the sampling to commence 2 months ago and work backwards to accommodate the facilities with smaller numbers.

Collection of data on the Mother

The HIV status of only one of the six mothers was recorded in the folder. Only three of the six mothers have been seen at the clinic post-delivery. There is evidence that the mothers, of all twenty folders that were sampled, had attended the clinic when registering the baby on the PMTCT programme and 19 out of the 20 had a CD4 count which was recorded in the register. However, the recording in the folder suggests that no on-going care is provided to the mothers.

The core task team agreed that in order for this tool to provide the robust information that is necessary to change practice, the tracer indicators, with the exception of the two questions removed on PAP smears and social assistance would remain.

One recommendation that the core task team would want to make into practice based on the findings from this small pilot is that the mother and infant should be seen together at the initial

PMTCT visit. This would facilitate the fact that the mother gets some form of baseline care, it will also allay perceptions that the care is just for the infant and it will allow recording that will clarify the links between mother and infant. However, should the mother access HIV care elsewhere, then this will still allow for the recording of the relevant information that would contextualise the infant's care and allow for a folder to be ready for when the mother accesses care for anything other than ART or HIV care.

As for the sampling it was decided that if any of the folders of mothers of any of the infants were not be available at the facility, no replacement mother folders would be retrieved. In addition to this it was agreed that if the mother was last seen in the antenatal period or no HIV status is recorded anywhere in the folder, then further auditing of the folder would stop. It was agreed that a row would be included in the data collection tool that states whether or not the folder would qualify for further auditing. At this point the new denominator would be recorded for the rest of the audit.

Draft 3 of the PMTCT Baby tool

After the small pilot conducted at Langa and Wynberg, the core task team agreed on the indicator set and amended the data collection tools. Draft 3 (**Appendix D**) was produced, which was used for the second pilot.

3.7.5 The Second Pilot

Selection of pilot sites

The core team wanted to determine whether the tool would be valid and reliable when applied by different users and within different settings, having made the suggested adjustments after the small pilot. A site with low volume PMTCT clients, in a setting without an onsite ART service, and a site with high volume PMTCT clients with an onsite ART service were again decided upon. In essence the selection would be similar to that of the small pilot, but with different users and a more refined tool. The following sites were selected:

Sarepta clinic

The clinic is situated in the Eastern sub-district. It has a fairly even distribution of clients that range from middle income to lower income socio-economic groups. The facility manager agreed that the site could be piloted

Kuyasa clinic

The clinic is situated in the Khayelitsha sub-district and it services a population that is predominantly, but not entirely low socio-economic group. The facility manager also agreed that the facility could be used for this pilot.

Selection of the implementers

In order to select the implementers group, PHC managers and comprehensive health programme managers who had previously been involved in HAST audits were approached and enquired with regards to which facilities within their area of supervision would suit the site selection criteria.

Once a few sites were identified that met the agreed criteria, facility managers were approached in order to determine whether they would agree to participate in this pilot. The first two sites that met the criteria, where the facility managers agreed to partake in the pilot, were then selected to be the pilot sites.

Facility level staff with more than with more than 2 years' experience in the HAST arena at facility level and with previous involvement in HAST audits were then selected. The PMTCT coordinator for the sub-structure within which both sites were located was included in the implementers group.

Training Session

A half day training session was held for the implementers and the teams were established for the second pilot. Each team was allocated a core task team member, who remained available to

answer questions and support data collation. The training aimed to ensure that all users applied the tool in the same manner so that reliability would be ensured.

The training covered the following:

- An overview of the entire Integrated HAST audit tool was provided
- Draft 3 of the PMTCT Baby tool was presented and comments taken
- Mock folders and register sheets were utilised so that the tool could be completed
- Difficulties and confusing areas were discussed and clarified
- Discussion on potential usefulness and feasibility of the tool. The implementers were informed that this level of information would be required with the post pilot feedback.
- Dates for the pilot were confirmed.

Each team conducting a pilot comprised of a core task team member, the facility manager, a facility level staff member working in the HAST services, the PHC manager of the relevant sub-district and a sub-district or sub-structure HAST or PMTCT coordinator. All these members had been involved in the application of the Integrated HAST audit tool in the past.

The pilot at Kuyasa and Sarepta proceeded according to plan, with each facility being audited in less than 2 hours from the time of sampling until completion of the data collection tools. All designated team members participated as planned. In general sampling for the infant was very clear and did not require any further clarification. However the availability of the mother folder care at the same facility and no evidence existed that the mother was receiving any form of HIV care or ART elsewhere. The core task team members who were on the teams were able to clarify these and agreed that the guide for this data collection will need to be explicit in clarifying when a mother folder does and does not meet the criteria for inclusion and in what instances it should be recorded as ‘N/A’ and ‘not found’.

3.7.6 Data Analysis

The notes from the sessions held with the core task team were voice recorded and captured in writing. These notes were then captured in the form of reports and minutes and were used to update the next draft of the tool.

An Excel template was designed with built in formulas, to capture the data from the pilots. This spread-sheet had built-in graphs which provided a graphic representation of the data and painted an immediate picture on potential errors.

3.7.7 Feedback workshop and final review of tool

On completion of the pilot, the researcher collated the results and calculated proportions (most of the data is likely to be categorical). The results were presented back to the core task team and implementers to assess whether the tool produced information which was considered useful to improve the PMTCT programme to HIV exposed infants at facility level.

During the training session, the application of the tool with the second pilot and at the feedback session, the implementers were afforded the opportunity to comment on the data collection tool and the user-friendliness of the tool. The feedback workshop was a special session arranged to review the pilot to ensure that each of the implementers expressed their opinion in terms of whether the tool was found to be feasible, whether it produced useful results and in essence whether it could be used to improve service rendering to the HIV exposed infant at facility level.

At this feedback workshop both groups deemed the pilot successful and agreed that the data collection tool elicited the information required to feed into the tracer indicators.

The users also agreed that the data collection tools were useful and that it provided clear indications in terms of where policy was adhered to and where the PMTCT service rendered to the HIV exposed infant required further support. It was decided that the PMTCT Baby Tool (folder review) should be incorporated into the Integrated HAST audit tool.

The results of the second audit and the final PMTCT Baby tool are presented in Chapter 4.

CHAPTER 4: RESULTS

4.1 Results of the second pilot of the PMTCT Baby Tool

The full set of results from the second pilot was collated by the researcher and is shown in Table 4.1. These results demonstrate the usefulness of the information which the Baby PMTCT Tool collects.

Table 4.1 Results of the second pilot

Domain	**Tracer Indicator**	**Sarepta** Infant N=10 Mother N=8	**Kuyasa** Infant N=10 Mother N=10
Access	% Mothers identified HIV positive in the clinical folder	75%	100%
Availability and capacity	% Facilities with stock outs of tracer drugs (ARTs) or consumables (infant formula)	0%	0%
	% Folders found – Infant	100%	100%
	- Mother	80%	70%
Quality	% Mothers counselling form used and consent taken (at 6 weeks)	0%	40%
	% HIV PCR results available	60%	70%
	% Mothers with feeding practices discussed	20%	0%
	% Babies weighed at last visit	90%	100%
	% Correct entries in PMTCT Baby register	20%	0%
	% HIV exposed infants whose mothers are registered in the PMTCT Baby register	30%	100%
	% HIV +ve mothers with HIV / ART stationery used	38%	33%
	% HIV +ve mothers WHO staged and CD4 count recorded	19%	33%
	% Commenced who require ART - Needed ART	33%	0%
	- Commenced on ART	0%	0%
Continuity	% Clients with future management plan noted at last visit - Infant	40%	20%
	Mother	0%	67%
Integration	% HIV exposed infant fully immunised	80%	0%
	% HIV +ve mothers assessed for contraception	13%	100%

Access

Maternal access to ongoing HIV care was measured by the *proportion of mothers identified as HIV positive in the clinical folder*. This indicator and question was included, since concerns were raised that mothers who are HIV positive are not accessing on-going HIV care. The only way to ensure that on-going care is being provided is by identifying them as HIV positive in their folders, so that when these mothers access other health services they can be managed holistically by the attending clinician, since their HIV status would be available.

All (n=3) of the mother folders that met the criteria for inclusion at Kuyasa clinic were found to indicate that the mother was HIV positive. Out of the 8 (N-8) mothers found eligible at Sarepta, 75% (n-6) of them specified that the mother was HIV positive. This means that, while the infant is accessing care by being registered on the PMTCT programme, their mothers are not known to be HIV positive and so are not accessing ongoing care for HIV.

Availability and Capacity

The availability of infant feeding formula and ART drugs for rendering the PMTCT programme, was measured by the *proportion of facilities with stock outs of tracer drugs (ARTs) or consumables (infant formula)*. This indicator and question was included in the facility manager's questionnaire to identify whether stock outs had been experienced, since mixed feeding and the non-availability of ART drugs would negatively impact on the HIV status of the HIV exposed infant.

None of the two facilities had any tracer drug or consumable stock outs related to the PMTCT programme, i.e. AZT, NVP, Truvada and Pelargon or Melegi. These items were available and the evidence for this was found in the bin cards. Should any of the infants at the 2 sites test HIV PCR positive at 6 weeks, this would not be as a result of poor access to ART drugs and infant feeding formula.

Availability of the mother and infants medical records was measured by the *proportion of folders found – infant and mother.* In order to ensure that HIV care provided to the mother and infant is continuous, the folders should be accessible. Each facility should have a filing system in place

that would facilitate access to all folders. All (N=20) infant folders that were sampled, were found and reviewed between the 2 sites. Of the 10 (N=10) folders that were sampled at Sarepta clinic, 20% (n=2) of the folders were not found. All (N=8) of the mothers folders that were found at Sarepta clinic, met the criteria for sampling.

At Kuyasa clinic out of the total number of (N=10) folders that were selected, 40% (n=4) failed to meet the criteria for sampling, since these mothers were not seen at the health facility post-delivery. The remaining 6 folders met the criteria for sampling (N=6), but only 50% (n=3) of them were found.
Since a standard filing system for health facilities is in place, it was not expected that these many folders would not be accessible.

Quality

The quality of counselling is measured by the *proportion of mothers counselling form used and consent taken (at 6 weeks)*. A standard recording form, the "HIV Consent and Testing Record for Adults and Children" has been in use since 2009 for the recording of all counselling provided and consent taken for HIV. This form contains prompts that facilitates accurate record keeping and serves as the legal document for consent. At Sarepta clinic none (n=0) of the babies tested (N=10) for HIV PCR had evidence that the mother was counselled or that consent for the test was taken. At Kuyasa, only 40% (n=4) of the total sampled infants (N=10) had evidence that the prescribed form was used. This reflects that the use of this form is poor and requires intervention. The National and Western Cape policy requirement that written consent for HIV testing should be taken, was not adhered to.

The quality of the entire PMTCT programme is measured by the outcome of the HIV PCR results of the infant and this is *measured by the proportion of HIV PCR results available.* The National Health Laboratory Services send all results to the facilities where the tests are conducted and it is standard practice that these results are filed in the client folder. At Sarepta clinic 60% (n=6) of HIV PCR results of the infants (N=10) were found in the folder and 70% (n=7) of the total infants (N=10) were found at Kuyasa clinic. None of the HIV PCR tests were conducted at other facilities. The absence of a test result means that no evidence of the outcome

of the HIV exposed infant exists after the mother and infant have been on the PMTCT programme.

The quality of infant feeding practices was measured by the *proportion of mothers with feeding practices discussed* at the last visit. Mixed feeding increases the infant's chance of testing HIV PCR positive at 6 weeks. It is thus imperative that in order to ensure that the policy is adhered to, that infant feeding practices are discussed. Only 20% (n=2) of the total (N=10) infants at Sarepta clinic had evidence in the folder that infant feeding was discussed with their mother. At Kuyasa clinic none (n=0) of the infant folders reflected that infant feeding was discussed with their mothers at the last visit. This indicator was very poorly achieved at both clinics and a huge risk for mixed feeding thus presents itself.

In order to ensure that the dosage of the ART drug NVP was prescribed according to the infant's weight, as the policy stipulates, the *proportion of babies weighed at last visit* was measured. Quality care to the infant is ensured by weighing the infant so that the correct drug dosage can be prescribed and also to determine whether growth faltering is taking place. Sarepta clinic achieved 90% (n=9) of all infants (N=10) being weighed at the last visit and Kuyasa clinic achieved 100% (n=10) for this indicator. The quality of care in terms of drug prescription and drug issue was well achieved.

Quality record-keeping is ensured by measuring the *proportion of correct entries in the PMTCT Baby register*. It was expected that the 6 week HIV PCR test result, Co-trimoxazole at 6 weeks, initial and on-going feeding choice and provision of milk formula to date (where applicable), is correctly entered from the infants folder into the PMTCT Baby register. At Sarepta clinic the register entries were only 20% (n=2) correct of the total (N=10) entries sampled and none (n=0) of the entries at Kuyasa clinic were completed correct from the infant folders (N=10). Poor translation of information from the infant folders to the PMTCT Baby register was noted and this translated into poor information flowing from the register into the departmental reporting system.

The quality of care offered to the HIV positive mother could be detrimental or beneficial to the HIV exposed infant. In order to ensure that the mother is adequately managed, this is measured by the *Proportion of HIV exposed infants whose mothers are registered in the PMTCT Baby*

register. The aim was to be able to track that the mother was managed according to HAST policies.

At Sarepta clinic 50% (n=5) of the mothers of HIV exposed infants were recorded in the PMTCT Baby register with regards to their PHC number at 30% (n=3) and CD4 at 70% (n=7) being recorded. Since 30% (n=3) of the maternal folder numbers were recorded in the PMTCT Baby register, but 80% (n=8) of the mothers folders were located, it reflects that other mechanisms for locating these folders had to be used, i.e. other electronic patient record system. At Kuyasa clinic this indicator was 100% (n=10) achieved with regards to the PHC folder and the CD4 count recorded. Also note that maternal folder number and CD4 recorded in the PMTCT register would speak to the quality of care domain directly for the mother and indirectly for the infant.

Quality of care to the mother is ensured through adherence to policy and this was measured by the *proportion of HIV positive mothers with HIV / ART stationery used*. The standard HIV / ART stationery is a National and Provincial policy requirement and its use facilitates adherence to the HIV treatment policy. Of the mother folders (N=8) that were found and used at the Sarepta clinic, only 38% (n=3) of them had the standard HIV/ART stationery used in the mothers folder. In the Kuyasa clinic, only 3 of mother folders that were eligible (N=6) could be found and only 33% (n=1) of these folders had the standardised HIV/ART stationery used. So in summary at Kuyasa clinic out of the total infants (N=10) sampled, only 6 mothers met the criteria for inclusion and of these only 3 of the folders were found. Then of the 3 that were found, only 1 used the standard HIV/ART stationery. Again since Kuyasa clinic is an ART site, it was expected that the standard HIV/ART stationery would be in use in all HIV positive clients. This would require intervention.

The quality of care to the mother was measured by the *proportion of HIV positive mothers who were WHO staged and had there CD4 count recorded* in their folders. The WHO staging should be updated when new stage defining illnesses are noted and a CD4 count is required 6 monthly pre-ART, to assess disease progression and every 12 months for those on ART. Only 13% (n=1) of the total (N=8) mothers at Sarepta clinic were WHO staged and 25% (n=2) of the total (N=8) mothers had a CD4 count recorded. This indicator was then calculated at 19% achieved. At

Kuyasa clinic the WHO staging and CD4 count of 33% (n=1) of the eligible mothers (N=3) was achieved. This reflects poor adherence to policy with regards to HIV care at both sites.

The quality of care provided to the mother is further measured by the *proportion of HIV positive mothers commenced on ART, who require ART,* i.e. needed ART and commenced on ART. Medical eligibility criteria for commencement on lifelong ART are set out in the HIV Treatment policy guideline and in order to ensure that quality care is provided to the mother, evidence of this should be accessible in the mother's folder. Thirty three percent (n=1) of the total number of mothers (N=3) was recorded as eligible for ART at Sarepta clinic. However, this mother was never commenced on ART nor is there record that she was referred for ART. At Kuyasa clinic, only 1 mother of those folders that were eligible for sampling (N=6) was not on ART and this mother was not yet eligible for lifelong ART.

Continuity

The continuity of care for the mother and infant was measured by the *proportion of clients with future management plan noted at last visit – infant and mother*. It is expected standard practice that the mother and infant are followed up until such time that they are either referred for care elsewhere, commenced on ART or that the infant is discharged with a HIV PCR negative result.
Of all (N=10) the infants at Sarepta clinic, 40% (n=4) of them had a management plan noted at the last visit. At Kuyasa clinic 20% (n=2) of infants (N=10) had a management plan noted. As for the mothers, none (n=0) of them (N=8) had a management plan noted at Sarepta clinic and 67% (n=2) of the total eligible mothers (N=3) was achieved at Kuyasa clinic. Both facilities have achieved poorly in this indicator and continuity of care to both mother and infant was compromised.

Integration

In order to integrate service delivery for the infant in comprehensive package of care, the measure of the *proportion of HIV exposed infant fully immunised*, was used. Immunisations are seen as a proxy indicator for access to comprehensive health care since all infants should be fully immunised unless a medical reasons exists that indicates otherwise. Immunisation of all infants should be up to date according to the infant's age. Of the total infants (N=10) sampled at Sarepta

clinic, 80% (n=8) were fully immunised. At Kuyasa clinic none (n=0) of the total infants (N=10) sampled were fully immunised. This could arguably be due to the fact that the volume of infants seen at the Sarepta clinic is lower and the staff are thus able to address standard care better. However, this could also be a recording-keeping gap at Kuyasa clinic, since it seems highly unlikely that all of the infants were missed opportunities with regards to immunisations.

The integration of the care for the mother into the comprehensive service was measured by the *proportion of HIV positive mothers assessed for contraception*. This would reflect access to dual protection against pregnancy and STIs, as well as being a proxy indicator for access to comprehensive health care. At Sarepta clinic only 13% (n=1) of the total number of mothers sampled (N=8) were assessed for contraception and at Kuyasa clinic all (n=3) the mothers were assessed for contraception. Integration of the care for the mother at Sarepta clinic, into comprehensive care and in terms of access to dual protection requires some attention.

4.2 Final version of the tool

Following feedback of the results to the core task team and implementers and final discussions, it was agreed that the questions in the draft 3 of the Baby PMTCT Tool, which was piloted, would remain unchanged. The final tool (Appendix D) which only differs from draft 3 in terms of formatting, responds to the five evaluation domains and a set of 15 indicators, as shown in Table 4.2. It was felt that this tool would give programme and facility managers' sufficient information to improve the quality and coverage of the PMTCT service rendered to the HIV exposed infant. The facility manager's questionnaire was also amended in order to feed into these indicators.

Table 4.2. Domains and Indicators for the PMTCT Baby Tool

Domain	Tracer Indicator	Rationale	Questions
Access	Proportion of Mothers identified HIV positive in clinical folder	Postnatal women on the PMTCT programme may attend clinic for different reasons and to ensure access to HIV care, an HIV status must be indicated.	Is the mother identified as HIV positive in the clinical folder?

Availability and Capacity	Proportion of facilities with stock outs of tracer drugs (ARTs) or consumables (infant formula)	To ensure access to essential ART drugs and infant feeding formula to provide quality care according to the PMTCT policy	Facility Manager's Questionnaire covers all tracer drugs and consumables, including Pelargon Formula Feeding for the PMTCT baby
	Proportion of folders found	For both infant and mother, it is important that clinical information is available so that quality of care and continuity of care can be ensured	Number of infant folders retrieved. Number of infant folders requested for review but not found.
			Number of mother folders found that meet criteria. Number of mother folders found that fail criteria Number of mother folders not found
Quality	Proportion of mothers counselling from used and consent taken	Use of the standard "HIV Consent and Testing record for Adults and Children" improves the quality of services as it provides a prompt and guide to users	Has an HIV consent and testing form been used for the HIV PCR test?
		It is WCP policy requirement that written consent is taken for an HIV test. The requirement for infants is consent from the parent or legal guardian.	Was consent taken for the HIV PCR test?

Quality	Proportion of HIV PCR results available	If a PCR was done, the expectation is that that result would be in the infants folder so that the appropriate future action can be taken	Is the HIV PCR test result available in the folder?
	Proportion of mothers with feeding practice discussed	It is expected that feeding is discussed at every visit since HIV transmission can occur through mixed feeding.	Is there a record that feeding practice was discussed at the last visit?
	Proportion of Infants weighed at last visit	Weight will determine the correct dose for medication and early detection for growth faltering. Infant should be weight at every visit.	Was the infant weighed and weight recorded at the last visit?
	Proportion of correct entries in PMTCT register	Helps to assess the accuracy of the PMTCT register. Data from register is used to monitor programme performance and it is important that all elements correctly reflects information from the folders. It also ensures that appropriate care is provided.	Is the 6 week PCR test result, cotrimoxazole at 6 weeks, initial and ongoing feeding choice and provision of milk formula to date (where applicable) correctly entered from the clients folder into the PMTCT baby register?
	Proportion of HIV exposed infants whose mothers are registered in the PMTCT register	If the mothers PHC folder number if reflected it allows maternal and infant care to be inked more readily.	Does the mother of this infant have her PHC folder number recorded in the PMTCT register?

Quality		CD4 counts are monitored 6 monthly for those not on ART and annually for those on ART. This result is needed to determine if the mother is receiving the appropriate package of care.	Does the mother of this infant have a CD4 result recorded in the PMTCT register?
	Proportion of HIV +ve mothers with HIV/ART stationery used	Use of standard HIV/ART stationery improves the quality of services as it provides a prompt and guide to clinicians	Has the standard HIV/ARV stationery been used?
	Proportion of HIV +ve mothers WHO staged and CD4 count recorded	Both WHO staging and CD4 are required in order to provide an appropriate package of care	Is the mother's baseline / current WHO clinical stage recorded?
			Has a CD4 count been done as per CD4 protocol and are results available?
	Proportion of mothers commenced who require ART	Assesses the appropriate access to ART for those who meet the medical criteria and who have not commenced previously	Does the mother currently meet the medical criteria for ART?
			Has mother been commenced on ART post-delivery?

Continuity	Proportion of clients with future management plan noted at last visit	If any problem is noted for either the mother or infant, there must be a management plan recorded to investigate, monitor or treat the problem.	Was an appropriate management plan noted at the last visit? (Infant)
			Was an appropriate management plan noted at the last visit? (Mother)
Integration	Proportion of HIV exposed infants fully immunised	It also reflects whether the infant has received comprehensive package of care. Fully immunised infants have a significantly reduced risk of contracting communicable diseases.	Did the baby receive the Birth, 6 and 10 week immunisations as per schedule?
	Proportion of HIV +ve mothers assessed for contraception	To ensure that the HIV +ve client is accessing a comprehensive package of care and offer dual protection against pregnancy and sexually transmitted infections.	Were the contraceptive needs assessed at the last clinical visit and due dates for repeats recorded?

CHAPTER 5: DISCUSSION

Introduction

The researcher set out to develop a tool, pilot it and in-so-doing engaged local programme managers in a participatory process to develop a tool that would be locally applicable and relevant, and captures the local management expertise. Through this process the evaluation domains have been identified that were required to measure quality of care of HIV exposed infants in the PMTCT services at primary care level. An indicator set for the evaluation domains has been developed. The tool was piloted twice and through feedback from the core task team and implementer groups, it could be established whether or not the tool was deemed feasible and whether the information that it generated was considered useful.

5.1 The process of developing the PMTCT Baby tool

The use of Benson and Clarks steps in developing the PMTCT Baby tool

The approach for developing the PMTCT Baby tool was in accordance with the four steps in the Guide for Instrument Development and Validation as proposed by Benson & Clark (1982). All thirteen steps within the four phases were directly applicable and provided a helpful structure for the development of this tool. The use of the Benson & Clarks phases and steps also facilitated content development, as noted by Hasdai, Jessel & Weiss (1997), in their study on the development of an instrument to measure the use of a computer simulator in training children with disabilities.

Having used the four phases in this study, it was noted that the steps of the second pilot and the feedback of the results of the pilot fell between the third and fourth phases of Construction and Quantitative Evaluation in Benson & Clarks flowchart (1982). This was due to the fact that the second pilot was seen as both a form of quantitative evaluation and validation of the tool. Although other users of this framework have collapsed these two phases when applying the approach due to this blurred line (Desrosiers, Hebert, Dutil & Bravo, 1993 and Boyce, Gowland, Hardy, Rosenbaum, Lane, Plews, Goldsmith & Russell, 1991), the researcher decided that in

order maintain the structure that this approach provided, the PMTCT Baby tool would be developed using all four phases of tool development.

Capturing the local programme managers expertise

In engaging the core task team in a participatory research process, the researcher allowed them to own the tool through all the stages of its development, thus breaking the conventional mould of research. The core task team was responsible for deciding that the tool needed to dovetail the Integrate HAST audit tool and that the same set of domains would be used, determining what the tracer indicators would be, developing the data collection tool and piloting the tool through two rounds. The core task team will continue to be part of the process of further validation and amendment.

The strengths displayed by the core task team, was evident in the fact that they were involved in the development and use of previous folder review data collection tools that formed part of the Integrated HAST audits. They thus understood the basic principles around developing and using these data collection tools. These experts were familiar with challenges previously experienced and were thus able to flag these challenges early in the process of developing the PMTCT Baby tool.

Weaknesses that came to the fore were that the members were previously accustomed to focusing on the questions that should be included in the data collection tools and then worked their way back to the tracer indicators. This would often result in a question having to be drafted and re-drafted until it could feed into an indicator. This delayed the agreement on the indicator set. As the sessions progressed this process became easier as the point of departure for the discussion became clearer.

Participatory research remained the process that was followed when engaging the implementers in piloting and modifying the tool. The strength of including the users in the process of tool development, allowed for them to clearly state what did and did not make sense when interpreting the questions on the data collection tool.

In order to allow the entire spectrum of HAST programme to be audited at the same time, using the same resources (human and financial), it was agreed that the PMTCT Baby Tool will be incorporated into the Integrated HAST audit tool. This process will be supported by the core task team which will continue to meet beyond this research process as a Provincial HAST audit task team and which will also facilitate the integration of quality improvement methods (action plans) to be implemented and monitored simultaneously.

5.2 Challenges in Interpreting Policy

According to both HAST expert groups – the core task team and the implementers - the biggest lesson learnt from the developing indicators was that policy interpretation and implementation is not as clear and straight-forward as had been assumed. For example, the PMTCT policy states that the dose of Nevirapine prescribed must be calculated according to the weight of the infant; however it does not specify how frequently an infant should be weighed. As they debated the frequency that an infant should be weighed, the core task team recognised the need for policy to be accompanied with an implementation guide. The policy also stipulates that the mother should be counselled in preparation for the infants HIV PCR and that she should provide consent, but it does not clearly define that the use of the standard 'HIV Consent and Testing Record for Adults and Children' form is compulsory. As provincial and Cape Town (MDHS and CoCT) programme managers, the core task team used the opportunity afforded by the tool development to set guidelines and standards for the Western Cape Province.

There is a body of literature in the field of policy analysis which explores how and why implementers often interpret and implement policy differently from what the policy designers intended (for example, Gilson and Raphaely, 2008; Gill, Shiffman, Schneider, Murray, Brugha & Gilson, 2008). This literature suggests that the implementation of policy is highly influenced by the front line staff. For example, in Tanzania the implementation of the exemptions policy for the community health fund, varied significantly between the various wards since the policy was not deemed to be explicit enough (Kamuzora & Gilson, 2007).If policy is not clear and mindful of service delivery level realities, this could influence the degree to which policy is changed at the implementation level (Gill *et al*, 2008; Hill & Huppe, 2002). In a meta-analysis conducted on the implementation of clinical policy guidelines (Francke, Smit, deVeer & Mistiaen, 2008) it was

revealed that policy implementation varied from one clinical setting to another, when the policy neglected to clearly define which clinician/s it was intended for.

5.3 Local applicability, relevance and usefulness of the PMTCT Baby tool

According to Nuefeld, Stet, Riviera, Valle, Grados, Uriega & Lopez (2011), although evaluation is an integral part of the design and implementation of health programmes, the use of evaluation results for improving programme implementation and decision-making is limited in developing countries. Habicht, Victora & Vaughan (1998), further state that the main objective of an evaluation is to influence decision-making and the evaluation design should thus be based on the level of decision-making that is required.

At facility level, the facility managers take the ultimate responsibility for all activities performed, services rendered and programmes offered. They have to make decisions with regards to all implementation aspects in all programmes. These programmes include all HAST, chronic diseases of lifestyle, maternal child and women's health policies, the expanded programme on immunisations, amongst others. The facility managers have agreed that they could gain better control over the PMTCT programme with this tool, since it helps them to identify various gaps and to respond to them appropriately, through making informed management decisions. For example the following facility level actions are suggested by the pilot results and would improve the quality of the PMTCT programme:

- There are quick wins to be made in terms of record-keeping and transfer of data from the client's folders into the PMTCT Baby register. This would improve the achievement of two of the indicators in the quality domain. With the auditing of pre-determined objectives, which is an annual Information Management quality assurance audit, the evidence in the registers would not be in-keeping with that of the records in the folder. It is thus imperative that the register should accurately reflect the applicable information contained in the folder.
- Ensuring that the filing of HIV PCR results at the registry of the facility is conducted as soon as possible after receipt, will improve the access to HIV PCR results for the attending clinician and also provide evidence of the outcome of the entire PMTCT programme.

- Formalising the use of the standard HIV Consent and Testing record for adults and children and the HIV / ART stationery when conducting an HIV PCR test and when the mother tests HIV positive, respectively, will improve record-keeping and with the prompts contained in these stationery, the quality of care to both mother and infant would be improved.
- Evaluating the filing system at the facility and ensuring that this is aligned to the prescribed departmental filing system, will ensure that folders are located. Available folders will facilitate continuity of care for mothers and infants.
- Conduct an assessment of staff training and levels of experience in order to make decisions with regards to appropriate placement of staff within the health facility and to identify the need for training, in order to render quality care. The gaps identified in the results of this tool, could be significantly reduced if the most appropriately trained clinical staff are placed in the best suited clinical setting.

The information generated by the tool not just found to be of use at facility level, but also revealed various areas that could be improved at sub-district and provincial level. The tool identified actions which could be implemented at sub district and provincial level to strengthen the PMTCT programme. For example, at sub district level the pilot identified that there is a need to expand training on the PMTCT policy, a responsibility of the HAST coordinators, and at a provincial level, to add implementation guidelines on the importance of weighing infants to determine the Nevirapine dosage and on ensuring good feeding practices and the absence of mixed feeding. The pilot also identified that the general child health stationery does not make provision for regular recording of infant feeding practices; this will require attention at provincial level.

The PMTCT coordinators provide PMTCT programme support to the sub-structure and were part of the 'implementers' and thus included in the training and piloting of the tool. They agreed that the tool was an excellent aid in assisting them with their core function of system strengthening of the PMTCT programme and the delivery of support at the coal-face. They have to trace the infant with an HIV PCR positive result retrospectively, in order to identify if and where the delivery of the PMTCT programme failed the mother and infant. Since data collection

tools already exists for the PMTCT services rendered antenatally and during the intrapartum period, the PMTCT baby tool would now provide guidance in terms of the process of tracing the PMTCT service rendered to the HIV exposed infant. The role of the PMTCT coordinators also includes ensuring that the PMTCT Baby register is correct and complete and that the appropriate stationery is utilised. The PMTCT baby tool elicits this information which the PMTCT coordinators can respond to.

Feasibility of the use of this tool and information

Programme and facility managers have agreed that it is feasible to conduct the evaluation of the PMTCT programme on an annual basis when conducting the Integrated HAST audit tool in order to compare performance improvement from one year to the next. The application of the PMTCT Baby tool will thus not require any additional human resources. They also stated that through by applying this tool they felt that they became more familiar with the content of the programme, since they are responsible for various programmes that require their focus.

Use of the tool for quality improvement

The perceived quality of the health service rendered to the public cannot be easily defined, but a general sense from health service users (Schneider & Palmer, 2002), is that their symptoms are not always addressed and they also perceive a sense of prejudice to different class and race groups. This raises the fact that a constant attempt towards quality improvement should be made. Quality improvement is defined by Batalden & Davidoff (2007) as a combined effort of all role-players (healthcare professionals, researchers, clients and their family members) that strives towards improved system performance, better professional development and better patient outcomes. The PMTCT baby tool has shown that it can produce information that will identify the need for professional training, reveals areas where the system can be improved and ultimately improve patient outcomes through facilitating adherence to policy.

In the five evaluation domains, fifteen new tracer indicators have been added to evaluate the service rendered to the HIV exposed infant and nine of these tracer indicators belong to the quality domain. The core task team agreed that in order to improve quality, significant emphasis

had to be placed on the quality indicators and in-so-doing enhance the clients experience within the public sector.

Øvretveit (2004) describes the four approaches to quality improvement. One approach is to take corrective action in instances where practice has fallen short of the expected standard, through using the problem solving method. This is the approach used in the application of the Integrated HAST audit that the PMTCT Baby tool will be part of. Since facility managers play a critical role in assuring quality at facility level, it is essential that they are familiar with the PMTCT programme. According to Øvretveit (2004), an important way to improve quality is through developing the facility manager's skills, which would ultimately skill them in more appropriate resource utilisation. Facility managers were included in the development of this PMTCT Baby tool to ensure that it would be useful and understandable for this management cadre. The facility managers involved in the pilot described the training experience as 'eye-opening' experience voiced how this in itself allowed for them to engage practice and personnel and finance allocation differently.

CERPOD (2003) reveals a series of scenarios that show how the use of available data in registers, folders and monthly tally sheets, can be used to evaluate the service being rendered and establish the capacity for improvement in order to improve quality. Similarly in a participatory quality improvement intervention, Doherty, Chopra, Nsibande & Mngoma (2009) show how, through the development and use of data collection tools to assess the PMTCT service rendered in KwaZulu-Natal, information was used to improve the quality of the service through the development of action plans to address areas of weakness. Evidence exists to substantiate that an evaluation of a service in a well thought through manner, does produce results that can be used to improve the quality of the service being rendered (Doherty *et al*, 2009)

Audit and feedback can be effective in improving professional practice (Rowe, de Savigny, Lanata, & Victora, 2005; Jamtvedt, Young, Kristoffersen, O'Brien, Oxman, 2006) and in resource poor settings, where the adherence to policy baseline was low, a review suggested that an audit and its feedback had positively influenced adherence to policy (Pattinson, 2006).

5.4 Validity of measure

It is acknowledged that a valid tool for a first world setting will not necessarily be valid in a developing world, so measurement validity reflects the extent to which a tool measures what it intends on measuring in a particular context (Portney & Watkins, 2000). In this instance local experts and local users have been involved in defining the purpose of the tool and developing it to make it relevant to the local context. A valid test must be reliable, which means that the measurement is relatively free from error according to Portney & Watkins (2000). There are various approaches to validity testing and "*all types of validity testing address the degree of confidence that we have in the inferences we draw from"* this tool (Portney & Watkins, 2000: 81). For the purpose of the development of this tool the team of experts looked at face and content validity. It was not possible to look at criterion validity because no gold standard tool currently exists.

Face Validity

According to Portney & Watkins (2000: 82), *"face validity indicates that an instrument appears to test what it is supposed to and that it is a plausible method for doing so*". Face validity was ensured through the involvement of the core task team and the implementers groups. Since face validity is deemed weakest of all measures of validity, it was imperative that this was strengthened by the involvement of the relevant experts and stakeholders who were knowledgeable in the field of HAST and instrumental in determining whether or not this tool would be useful.

Feedback at the workshop after the second pilot with regards to the tools usefulness came predominantly from the facility managers and the PMTCT coordinators. They accepted the indicators as valid measures of the PMTCT programme to HIV exposed infants.

Content Validity

According to Portney & Watkins (2000: 83) content validity is the "*adequacy with which the universe is sampled by a test"* and in this instance the test refers to the PMTCT Baby tool that has been developed. Content validity in this study was ensured by reviewing the literature and through having engaged the core task team in defining the domains to be measured so that the

"content universe" of PMTCT care to HIV exposed infants could fully be assessed. Although this was essentially a subjective process, it evolved out of a process of planning, construction and quantitative evaluation to ultimately ensure validation of the tool.

Portney & Watkins (2000) state that the theoretical basis for a tool are reflected through its component parts and this can only be achieved following a thorough, rational evaluation of the tool's objectives. Since the purpose of the tool was to evaluate the PMTCT service offered to the HIV exposed infant, the tool had to reflect the level to which the PMTCT policy and protocol have been adhered to.

When developing the PMTCT Baby tool, no comparisons could be made with other instruments which meant that it was not possible to measure criterion validity (Portney & Watkins, 2000).

5.5 Reliability

Joppe (as cited by Golafshani, 2003: 598) defines reliability as "*the extent to which results are consistent over time and an accurate representation of the total population under study is referred to as reliability and if the results of the study can reproduce under similar methodology, then the research instrument is considered to be reliable"*.

To strengthen reliability, the implementers who were involved in the pilot were trained on the rationale and use of the tool. They were provided with a guide which explained how to use the data collection tool and a core task team member was provided to support them. The presentations used in the training session will serve as a model for the future development of a training package to accompany the tool.

The pilot helped to identify a tracer indicator that that did not measure what it had intended to measure: "proportion of HIV exposed infants whose mothers are registered in the PMTCT Baby register". In order to be considered registered the mother had to have both their own folder number and their CD4 count recorded in the register. The pilot showed that the quality of record-keeping in the register was too poor to assess this reliability.

5.6 Limitations:

In hindsight both groups of HAST experts felt that the second pilot should have included a larger sample size but it was also clear that in order to remain within the sampling period (not exceeding six months) that this would not always be possible at some of the facilities.

The PMTCT Baby tool is a quantitative tool and not a qualitative tool. Also, it makes use of tracer indicators rather than a full set of indicators to assess programme performance. When a tracer indicator indicates an area of poor performance it is necessary to do a fuller investigation which might need to include qualitative approaches.

The tool does not track the care rendered to the infant between delivery and the time that the mother accesses care at the health facility. Experience within the PMTCT programme in Cape Town suggests that this time period could be anywhere between 1 and 4 weeks. The tool also will not be able to track the quality and gaps in care that is rendered to the infant and mother beyond 6 months when breastfeeding and formula feeding would stop. PMTCT policy advocates for tracking the HIV exposed infant, who tested HIV PCR negative at 6 weeks, until 18 months of age. The PMTCT baby tool does not make provision for this. The core task team agreed that since the routine data has not sufficiently responded to this policy position as yet, the tool would be amended at a later stage.

Most of the core task team members have been involved in the development of the Integrated HAST audit tool and this presents a degree of researcher bias in making decisions on appropriate evaluation domains and the purpose of the tool. Yet it is also not unreasonable to argue that the most appropriate local PMTCT tool would be one that dovetails with the existing Integrated HAST audit tool.

5.7 Generalisability:

Vaismoradi (2009) defines generalizability as the extent to which findings from a study apply to a wider population. This tool evaluates the PMTCT programme as it is offered to the HIV exposed infant at primary care facility setting in Cape Town. It will be applicable to the HIV exposed infant in a Primary Care setting elsewhere in the Western Cape Province, since the

policy remains the same. It will however not be applicable for use at secondary and tertiary institution due to protocol variances at these levels of care, especially since specialist care is provided at that level and since pre-term infants are cared for at these levels with different drug regimens. The tool however is adaptable and could be adapted for these settings, should the need be expressed.

CHAPTER 6 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

A tool to evaluate the PMTCT service rendered to the HIV exposed infant was developed in a participatory manner along with experts in the HAST programme arena and key users of the tool. Benson & Clarks (1982) approach to tool development proved to be exceptionally useful in providing structure to the process. Face and content validity was ensured, but criterion validity could not be measured. Reliability was ensured in the pilot through training all users on how to apply the tool, by providing them with a guide for the data collection tool and by allocating a core task team member to support each pilot team.

The usefulness of the tool at facility, sub-district and provincial level was evident with regards to facilitating decision-making and quality improvement and establishing programme effectiveness. The tool allowed for the identification of weakness in current programme support and delivery and suggested actions that could be taken at a facility, sub-district and provincial level. This tool can be used in the same or similar settings throughout the Western Cape Province and with minor adaptations, it will be applicable to secondary and tertiary settings as well. The tool makes explicit, a set of standards that are implicit in the current PMTCT policy. Programme managers involved in the development of the tool have realised the need for policy implementation guidelines to accompany the policy.

6.2 Recommendations

6.2.1 The use of the tool

The PMTCT baby tool dovetails with the existing Integrated HAST audit tool that is used throughout the Western Cape Province in the primary care setting. Since the evaluation of the PMTCT service rendered to the HIV exposed infant is the only HAST programme that does not have a data collection tool as part of the Integrated HAST audit tool, it is recommended that it be incorporated as a component.

A training package will have to be developed for the PMTCT baby tool and this will include mock folders, registers and stationery so that participants can become familiar with where to find the data that is being reviewed. A manual will be developed that will serve as a guiding document for the user in preparation for and when conducting the review. It will provide information on sampling, where to search for the data that is required and how to complete the data collection tool. This will ensure reliability with the application of the tool.

The Provincial HAST Audit task team will take responsibility for on-going review of the data collection tool. After each audit cycle they will assess validity of the tool and keep up to date with policy changes.

6.2.2 Actions to improve PMTCT programme based on pilot

Various recommendations that will ultimately improve the quality of the PMTCT service rendered to the HIV exposed infant, are put forward for implementation at the different service delivery levels and by different role-players.

At facility management level

At facility level, the staff should commence with the consistent implementation of the HIV Testing and Consent form for use with all mothers who must provide consent for the infant to have an HIV PCR test at 6 weeks. On testing HIV positive, the HIV / ART stationery should be implemented with immediate effect for the infant. The use of these two stationery items should be deemed non-negotiable and essential in order to ensure quality of care.

The PMTCT Baby register makes provision for feeding practices to be recorded with every visit. Staff should be encouraged to make use of the register columns to record infant feeding with each visit. The register however, does not make provision for specific discussion around the feeding practices that should take place at each of these sessions. The stationery in the infant's folder also lacks prompts in terms of the detail around infant feeding. Staff must also be reminded that some infants are breastfed and that some mothers prefer to purchase their own formula, so in these instances formula milk will not be issued. In the event where the mother chooses to breastfeed, facility level staff needs to be mindful of the fact that the mother must be

Viral Load Suppressed and on ART. Should the mother select formula feeding, due consideration should be given in terms of her access to clean water, the knowledge on how to mix the formula, the ability to clean the infants bottles adequately and the understanding that inadequate hygiene practices do pose the risk of diarrhoea for the infant.

In order to respond to the infant in an effective manner and in order to track the outcomes of all the PMTCT interventions (according to the policy), the HIV PCR result must be available in the infant folder. All efforts must be instituted at facility level to file the HIV PCR results within 24 hours and to draw the clinical staff's attention to all HIV PCR positive results immediately.

HAST programme staff at sub-structure level

The data from the PMTCT Baby register is collated monthly to feed into the routine information system of the department of health. The accurate transfer of data from the folder to the register and the completeness of all the register data fields are crucial in order to facilitate programme reporting. The PMTCT coordinator should conduct training across the sub-structure on how to complete the register and then monitor the quality of register record-keeping on a monthly basis.

Provincial HAST programme responsibility

The coordination of training with regards to infant feeding for clinical staff and HIV counsellors must be prioritised. This will ensure standardisation of the message to the mother and reduce the risk of mixed feeding.

A policy implementation guideline in terms of defining what is expected in the management plan for the PMTCT infant in terms of follow-up care, on-going care of the HIV positive mother and care of the infant post 6 week HIV PCR until 18 month HIV rapid test, is required.

A group in collaboration with the Maternal, Child and Women's health programmes directorate, to address the cross-cutting issues that are covered in this tool, must be convened as a matter of urgency.

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Appendix A: Comparison of PMTCT tools						Level at which applicable			For use by				
	Name of Tool	Area of PMTCT	Number of Indicators	Domains covered	Source of Information	Community	PHC Facility	Hospital Setting	Community Field Worker	Nurse / Doctor	HIV Facility Counsellor	Other - Specify	Comment
1	Labour Ward Monthly data Summary	Labour Ward	11	Quantity Data & Service Quality	Registers		X	X		X			Unpublished
2	Antenatal Data Validation Tool	Antenatal Care	11	Quantity Data & Service Quality	Registers		X			X			Unpublished
3	Module 9 PMTCT Programme Monitoring Tool fir Antenatal Care & Maternity Ward Register Tool	Antenatal Care Labour Ward	16	Quantity Data & Service Quality	Registers		X	X	X				
4	Western Cape Provincial PMTCT Checklist	Antenatal Care Labour Ward	14	Quality	Folders		X	X		X			Tool that serves as a checklist to enhance data quality & record-keeping. Outdated!
5	Volunteers Follow-up Schedule for Expectant Mothers on HAART	Antenatal Care Labour Ward Baby Follow-up	12	Quality	Interviews Support visits	X			X				Evaluating the impact of CHWs on the PMTCT programme coverage and health outcomes. The focus is system strengthening and quality improvement.
6	Volunteers Follow-up Schedule for Expectant Mothers on PMTCT	Antenatal Care Intrapartum Baby Follow-up	12	Quality	Interviews Support visits	X			X				
7	FHI Baseline assessment tools for PMTCT of HIV	Antenatal Care Intrapartum Baby Follow-up	97	Access Integration	Interviews		X					PMTCT OR Project Manager	
8	Evaluation of the Scale up of the PMTCT Infant feeding Counselling Training Programme in Tanzania	Antenatal Care Baby Care	14	Access Capacity: Staffing Availability	Interviews		X					Researchers	Large scale evaluation of all facilities in Tanzania wrt PMTCT in relation to Infant Feeding
9	PMTCT Folder Review of Antenatal Services - Integrated Audit Tool	Antenatal Care	19	Access Quality Capacity: Systems Integration Continuity of Care Outcomes	Registers Folders		X			X			Unpublished
10	PMTCT Folder Review of Labouw Ward - Integrated Audit Tool	Intrapartum	6	Access Quality Capacity: Systems Integration Continuity of Care Outcomes	Registers Folders		X	X		X			Unpublished

Appendix B:

PMTCT: HIV Exposed Infants Care Folder Review Facility name:_____ Date:_____

Sampling procedure: PMTCT Baby Register, starting on a date 2 months ago and working backwards, select sequential folders until you have 5 PCR-negative and 5 PCR-positive Baby-folders. Exclude Babies where the Mother declined PCR testing. Use the 10 folders to answer questions 1 to 10. Using a similar method, select an additional 5 HIV+ client folders for mother of babies irrespective of the babies PCR result. The ten folders from HIV+ clients will be used to answer questions 11 to 17. Note any folders that are not possible to locate in the process. Answer Yes (Y), No (N) or Not Applicable (N/A) for each question. Record any relevant other information on the back of the form.

Number of folders retrieved from the folder system _____ Number of folders requested for review but not found in the folder system _____

			PCR NEGATIVE FOLDERS					PCR POSITIVE FOLDERS										SUMMARY RESULTS		
Ref			Folder 1	Folder 2	Folder 3	Folder 4	Folder 5	Folder 6	Folder 7	Folder 8	Folder 9	Folder 10	Folder 11	Folder 12	Folder 13	Folder 14	Folder 15	Total Yes	Total No	Total N/A
Q	1	Has a counselling form been used?																		
Q	2	Was consent for an PCR test taken?																		
Q	3	Is the PCR result available in the folder?																		
Q	4	Is there a record that feeding options and mixed feeding were discussed at each visit?																		
Access	5	Was the full quota of infant feeding formula issued with each visit?																		
Access / Q	6	Was NVP supply checked and dosage adjusted with each visit?																		
Q	7	Is the information from the client's folder correctly entered into the PMTCT Baby register?																		
Q	8	Has the standard HIV/ARV stationery been used?																		
Q	9	Was a follow-up appointment and appropriate management plan noted at the last visit?																		
Q	10	Has the baby been referred for HAART																		
Q	11	Is there a record that weight and urinalysis was done at the last clinical visit?																		
Cont	12	Is there a record that the mother is receiving HAART?																		
Q / Cont	13	Did the mother have a CD 4 count done and are results available?																		
Q / Cont	14	Did the mother have WHO staging done?																		
Q / Cont	15	Has client been commenced on HAART?																		
Q / Int	16	Were condoms issued at the last clinical visit?																		
Cont	17	Was a follow-up appointment and appropriate management plan noted at the last visit?																		

Appendix C

PMTCT: HIV Exposed Infants Care Folder Review Facility name:_____

Sampling procedure: PMTCT Baby Register, starting on a date 2 months ago and working backwards, select sequential folders until you have 7 PCR-negative and 3 PCR-positive Baby-folders. Exclude Babies where the Mother declined PCR testing. Use the 10 folders to answer questions 1 to 10. Select the folders of the 10 Mothers of the same babies to answer questions 11 to 17. Note any folders that are not possible to locate in the process. Answer Yes (Y), No (N) or Not Applicable (N/A) for each question. Record any relevant other information on the back of the form.

Number of folders retrieved from the folder system _____ Number of folders requested for review but not found in the folder system _____

			PCR NEGATIVE FOLDERS							PCR POSITIVE FOLDERS			SUMMARY RESULTS		
Ref			Folder 1	Folder 2	Folder 3	Folder 4	Folder 5	Folder 6	Folder 7	Folder 8	Folder 9	Folder 10	Total Yes	Total No	Total N/A
		Folder Number													
Q	1	Has a counselling form been used?													
Q	2	Was consent for an PCR test taken?													
Q	3	Is the PCR result available in the folder?													
Q	4	Has the standard HIV/ARV stationery been used?	N/A	N/A	N/A	N/A	N/A								
Q	5	Has the baby been commenced on HAART? [Evidence of start date]	N/A	N/A	N/A	N/A	N/A								
Q	6	Is there a record that feeding options were discussed at last visit?													
Access	7	Was the full quota of infant feeding formula issued at the last visit?											>10 tins	8-10 tins	<8 tins
Q		Was the baby's weighed and weight recorded at last visit?													
Access / Q	8	Was Co-trimoxazole issued at last visit and dosage adjusted according to weight?	N/A	N/A	N/A	N/A	N/A								
Access / Q	9	Was a follow-up appointment and appropriate management plan noted at the last visit?													
Q	10	Is the information from the client's folder correctly entered into the PMTCT Baby register?													
H-Q	1	Has the standard HIV/ARV stationery been used?													
H-Q	2	Was a social assistance evaluation completed?													
H-Q	3	Has a RPR been done and are results available in the folder?													
H-Q	4	Has client had a pap smear done and results recorded?													
H-Q	5	Did client undergo WHO clinical staging? (Baseline and if there has been a change *******in what? According to new stationery?? Check with david p)													
H-Q	6	Adult: Has a CD4 count been done as per CD4 protocol and are results available?													
H-Q	7	Did client meet the medical criteria for ARVs?													
H-Q	8	Has client been commenced on ARVs?													
H-Q	9	Were condoms issued at the last clinical visit? (either male or female condoms)													
H-Int	10	Were the contraceptive needs assessed at the last clinical visit & due date for repeats recorded?													
H-Int	11	Is there a record of screening for TB at the last clinical visit? (minimum symptom screen of weight loss and cough; appropriate tests done and recorded if symptomatic)													
H-Int	12	Is there a record of screening for STI and appropriate treatment, if required, at the last clinical visit?													
H-Cont	13	Was a follow-up appointment and appropriate management plan noted at the last visit?													

Appendix D

PMTCT: Postnatal Review Facility name:_____ Date:_____

Sampling procedure:

1. From the PMTCT Baby Register, start on a date 3 months ago and work backwards. Select sequential baby folders as follows: If the clinic registers <10 babies per month, select every sequential folder; if the clinics registers 10 or more babies per month select alternative folders. Note the names of infants and their mothers in Annexure 9.
2. If any folder cannot be found, select a replacement using the same method until you have 10 baby folders to evaluate or have exceeded the 6 month cut-off. Use these to answer questions 1 to 7. Answer questions 8-10 from the register for these babies and their mothers.
3. For each baby whose folder has been found, draw the mother's folder. Exclude folders of mothers who were not see at the facility post-delivery. Note the number of folder retrieved that meet criteria (seen post-delivery at the facility), the number of folders found that fail criteria (not seen post-delivery) and the number of folders not found. Use the maternal folders that meet crieria to answer questions 11-18.
4. Answer Yes (Y), No (N) or Not Applicable (N/A) for each question. Record any relevant other information on the back of the form.

Number of baby folders retrieved from the folder system _____ Number of baby folders requested for review but not found in the folder system _____

Number of mother folders found that meet criteria:_____ Number of mother's folders found that fail (do not meet) criteria:_____ Number of mother folders not found:_____

												SUMMARY RESULTS		
		Infant Folder Reviews	Folder 1	Folder 2	Folder 3	Folder 4	Folder 5	Folder 6	Folder 7	Folder 8	Folder 9	Folder 10	Total Yes	Total No	Total N/A
PMTCT-Q	1	Has an HIV consent and testing form been used for the HIV PCR test?													
PMTCT-Q	2	Was consent taken for the HIV PCR test?													
PMTCT-Q	3	Is the HIV PCR test result available in the folder?													
PMTCT-Q	4	Is there a record that feeding practice was discussed at the last visit?													
PMTCT-Q	5	Was the baby weighed and weight recorded at the last visit?													
PMTCT-Q	6	Did the baby receive the birth, 6 and 10 week immunisations as per schedule?													
PMTCT-Cont	7	Was an appropriate management plan noted at the last visit?													
		PMTCT Baby Register Review	Folder 1	Folder 2	Folder 3	Folder 4	Folder 5	Folder 6	Folder 7	Folder 8	Folder 9	Folder 10	Total Yes	Total No	Total N/A
PMTCT-Q	8	Is the 6 week PCR test result, cotrimoxazole at 6 weeks, initial and ongoing feeding choice and provision of milk formula to date (where applicable) correctly entered from the client's folder into the PMTCT Baby Register?													
PMTCT-Ac	9	Does the mother of this infant have her PHC folder number recorded in the PMTCT register?													
PMTCT-Ac	10	Does the mother of this infant have a CD4 result recorded in the PMTCT register?													
		Maternal Folder Reviews	Folder 1	Folder 2	Folder 3	Folder 4	Folder 5	Folder 6	Folder 7	Folder 8	Folder 9	Folder 10	Total Yes	Total No	Total N/A
H-Ac	11	Is the mother identified as HIV-positive in the clinical folder?													
H-Q	12	Has the standard HIV/ARV stationery been used?													
H-Q	13	Is the mother's baseline / current WHO clinical stage recorded?													
H-Q	14	Has a CD4 count been done as per CD4 protocol and are results available?													
H-Q	15	Does the mother currently meet the medical criteria for ART?													
H-Q	16	Has mother been commenced on ART post-delivery?													
H-Int	17	Were the contraceptive needs assessed at the last clinical visit & due date for repeats recorded?													
H-Cont	18	Was an appropriate management plan noted at the last visit?													

APPENDIX E

UNIVERSITY OF THE WESTERN CAPE

School of Public Health

Private Bag X17 ● **BELLVILLE** ● 7535 ● South Africa
Tel: 021- 959 2809, Fax: 021- 959 2872

PARTICIPANT INFORMATION SHEET
Development of a Tool to Evaluate the Quality of the Prevention of Mother to Child Transmission programme offered to the HIV exposed infants in the primary care facility setting in Cape Town

Dear

I am Juanita Olivia Arendse, a student at the University of the Western Cape. I am consulting experts in the HIV & AIDS, STI and TB arena so as to gather information related to the development the instrument that will evaluate the quality of the PMTCT services offered to the HIV exposed infants in the primary care setting.

Why am I doing this?

I am required to undertake a research project and submit a mini-thesis in partial fulfilment of the requirements for the degree Masters in Public Health in the School of Public Health (SOPH), University of the Western Cape. I will be carrying out expert panel discussions and am accountable to **Dr Vera Scott (Supervisor, SOPH) who is contactable on +27 21 959 2630 or c/o SOPH Fax: +27 21 959 2809 or by email at vscott@mweb.co.za**

Who are the participants?

The participants are a group of local experts in the field of public primary care sector management of HIV services who will comprise the Core Task Team.

What is expected from the participants in the study?

I will ask you to attend a set of four group meetings (scheduled at the mutual convenience of the group). You will be asked to contribute your expertise on the subject of managing HIV programmes through structured, facilitated discussions with other group members. This will cover the purpose of the tool that is being developed, operational definitions, defining what the tool will and will not cover, desirable criteria for the tool, the choice of evaluation domains and indicators and the approach and content to be covered wrt training on the tool. Each expert panel discussion will last approximately 60 - 90 minutes. All the information collected will be treated confidentially, and only the researcher and supervisor will have access to it.

What can participants expect?

Once the research project is completed, feedback will be provided to all participants in the form of summarised and detailed reports as well a copy of the final tool.

Can you withdraw from the study?

Certainly, you may withdraw from the study at anytime, without having to give a reason. You are free to ask questions during the expert panel discussions. You do not have to talk about anything you do not want to, and you may exit from the expert panel discussion at any time. The study is voluntary and if you refuse to participate this will not influence your employment in any way.

Any further questions?

Are there any questions about what I have just explained? More information may be obtained from Juanita Olivia Arendse: who is contactable on +27 21 483 5751 or Fax: +27 21 483 6033 or by email at juani.mosesarendse@gmail.com. If you are willing to participate in the study, please read and sign the consent form below.

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School of Public Health

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Consent Form

Development of an Instrument to Evaluate the Quality of the Prevention of Mother to Child Transmission services offered to the HIV exposed infants in the primary care setting in Cape Town

Participant's agreement

I have been informed about the purpose of the study, and what my participation involves. I also understand that I can withdraw from the study at any time, without having to give a reason and that the study is voluntary. I also understand that confidentiality will be maintained and that the findings of the study will be used for research purposes and service development.

Researcher's agreement

I shall keep all the information collected during the research confidential and use a pseudonym of your choice in all documents. The contents will be used for the purposes referred to above, but may be used for published or unpublished research at a later stage without further consent. Any change from this agreement will be renegotiated with you.

Participant's Signature: _____ Date: _____

Interviewer's Signature: _____ Date: _____

Dr Vera Scott (Supervisor, SoPH) is contactable on +27 21 959 2630 or c/o SOPH Fax: +27 21 959 2809 or by email at vscott@mweb.co.za

Appendix G

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Who are the participants?

The participants are a group of facility managers, supervisors, HAST coordinators and facility level staff experienced in the HAST arena and willing to partake in piloting the tool at their facilities. These participants will comprise the group referred to as implementers.

What is expected from the participants in the study?

I will ask you to attend a half day training session whereby you will comment on the tool that will evaluate the quality of the PMTCT programme offered to the HIV exposed infants in the South African primary care facility setting be piloted. You will also have the opportunity to comment on the need / usefulness for such a tool and its content. The training then aims to present the rationale and purpose of the tool, as well as clear any areas of ambiguity. You will then be required to be involved in the piloting of the tool and to provide feedback at the review session.

All the information collected will be treated confidentially, and only the researcher and supervisor will have access to it.

What can participants expect?

Once the research project is completed, feedback will be provided to all participants in the form of summarised and detailed reports as well a copy of the final tool.

Can you withdraw from the study?

Certainly, you may withdraw from the study at anytime, without having to give a reason. You are free to ask questions during the training session and piloting stage. You do not have to talk about anything you do not want to, and you may exit from the study at any time. The study is voluntary and if you refuse to participate this will not influence your employment in any way.

Any further questions?

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