

EVALUATION OF A QUALITY IMPROVEMENT CYCLE INTERVENTION IN THE PROVISION OF PMTCT AT A REGIONAL HOSPITAL

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ABSTRACT

The vast majority of new Human Immunodeficiency Virus (HIV) infections in infants and young children occur through mother-to-child-transmission (MTCT), either during pregnancy, labour or delivery or by breastfeeding. Without access to perinatal MTCT (PMTCT) programmes approximately 30% of all babies born annually will be infected with HIV.

OBJECTIVES

The aim was to implement and audit a quality improvement cycle at the Worcester Obstetric Unit, which comprises of Worcester Hospital, a regional hospital in the Western Cape Province and its level one midwife obstetric Unit (MOU), in order to improve the quality of the PMTCT programme. The intervention included the implementation of easy changes and tools in the Antenatal Clinic, Infectious Diseases Clinic and Labour ward.

METHODS

The files and antenatal records of all HIV positive patients and patients with an unknown HIV status, who delivered at the Worcester Obstetric Unit during January, February and March of 2010 and 2011, were reviewed. All HIV negative patients and patients that had stillbirths and miscarriages were excluded. The pre-interventional findings of 2010 were compared with the post-interventional findings of 2011.

RESULTS

At the Worcester Obstetric Unit, for the study time period, there were 907 deliveries in 2010, of which 102 (11.2%) patients were HIV positive and 4 (0.4%) had an unknown HIV status compared to 2011, with 865 deliveries of which 108(12.5%) patients were HIV positive and no patients had an unknown HIV status. Significantly more patients were diagnosed with HIV before they fell pregnant than during pregnancy in the 2011 group, when compared with the 2010 group. A CD4 count was done on 94% of patients who were newly diagnosed with HIV and those with an unknown CD4 count result in the 2010 group, compared to 92% in 2011. There was a significant improvement after

the intervention in the time it took from when blood was drawn for a CD4 count until the result was followed up, the median time decreased from 34 to 8 days ($p=0.000001$). Significantly more patients qualified for highly active antiretroviral therapy (HAART) after the guidelines were changed and the CD4 cut off was increased to 350 cells/ μl ($p=0.001$). Prior the intervention 18 patients did not receive the correct management before delivery due to preventable reasons, compared to one at the MOU. After the intervention this decreased significantly to only one patient at Worcester Hospital and none at the MOU ($p=0.000001$). Before the intervention adherence to the PMTCT protocol at the MOU was significantly better than at the hospital ($p=0.0005$) and after the intervention there was no significant difference ($p=1.0$).

CONCLUSION

Although the audit and quality improvement cycle was performed at a single hospital, with specific changes geared towards their needs, the basic principles can be applied to any Unit in the country providing a PMTCT service. Educating staff, creating awareness and reminding staff of the basic principles of PMTCT, implementing small changes and streamlining processes and setting specific goals or timelines, can lead to significant improvements in care, which ultimately will lead to a decrease in PMTCT of HIV and HIV related maternal and infant morbidity and mortality.

OPSOMMING

Die oorgrote meerderheid (>90%) van nuwe Menslike Immuniteitsgebreeksvirus (MIV) infeksies in babas en jong kinders vind plaas deur middel van moeder-na-kind-oordrag, hetsy gedurende swangerskap, die kraamproses of borsvoeding. Sonder toegang tot perinatale voorkomingsprogramme (PMTCT) sal ongeveer 30% van alle babas jaarliks met MIV geïnfekteer word.

DOELWITTE

Die doel van die studie was om 'n gehalteverbeteringsiklus by die Worcester Verloskunde Eenheid, wat bestaan uit Worcester Hospitaal, 'n streekshospitaal in die Wes-Kaapprovinsie en sy vlak een vroedvrou verlossingseenheid (VVE), te implementeer en daarna te evalueer, om sodoende die gehalte van die PMTCT-program te verbeter. Die intervensie het bestaan uit die implementering van eenvoudige veranderinge en prosesse in die voorgeboortekliniek, infeksiesiekte-kliniek en kraamsaal.

METODES

Die lêers en voorgeboorte rekords van alle MIV-positiewe pasiënte en pasiënte met 'n onbekende MIV-status, wat gedurende Januarie, Februarie en Maart van 2010 en 2011 verlos het by die Worcester Verloskunde Eenheid, is nagegaan. Alle MIV-negatiewe pasiënte en pasiënte met doodgebore babas en miskrame is uitgesluit. Die pre-intervensie bevindings van 2010 is vergelyk met die post-intervensie bevindings van 2011.

RESULTATE

By die Worcester Verloskunde Eenheid was daar 907 geboortes gedurende die studietydperk in 2010, waarvan 102 (11,2%) pasiënte MIV-positief was en 4 (0,4%) met 'n onbekende MIV-status. In 2011 was daar 865 geboortes waarvan 108 (12,5%) pasiënte MIV-positief was en geen met 'n onbekende MIV-status. In die 2011-groep is beduidend meer pasiënte gediagnoseer met MIV voor as tydens swangerskap. In die 2010-groep is daar 'n CD4-telling gedoen vir 94% van nuut gediagnoseerde pasiënte en diegene met 'n onbekende CD4-telling, in vergelyking met 92% in 2011. Daar was 'n

beduidende verbetering na die intervensie in die tyd wat dit geneem het vandat bloed getrek is vir 'n CD4-telling totdat die resultaat opgevolg is. Die mediane tyd het verminder vanaf 34 na 8 dae ($p = 0.000001$). Nadat die riglyne vir kwalifisering vir hoogs aktiewe antiretrovirale terapie (HAART) verander is na 'n CD4 telling ≤ 350 selle/ μl het daar beduidend meer pasiënte gekwalifiseer vir HAART. By Worcester Hospitaal het 18 pasiënte voor die intervensie nie die korrekte behandeling intrapartum ontvang nie weens voorkombare redes, in vergelyking met slegs een pasiënt by die VVE. Na die intervensie was daar 'n beduidende afname na slegs een pasiënt by Worcester Hospitaal en geen by die MOU ($p = 0.000001$). Voor die intervensie was die korrekte uitvoering van die PMTCT-protokol by die MOU beduidend beter as by die hospitaal ($p = 0,0005$) en na die intervensie was daar geen beduidende verskil ($p = 1.0$).

GEVOLGTREKKING

Alhoewel die oudit en gehalteverbeteringsiklus uitgevoer is by 'n enkele hospitaal, met spesifieke veranderinge gerig tot hul behoeftes, kan die basiese beginsels toegepas word in enige eenheid in die land wat 'n PMTCT diens verskaf. Opvoeding van personeel en bewusmaking rakende die basiese beginsels van PMTCT, klein veranderinge en die vaartbelyning van prosesse by die voorgeboorte klinieke en die stel van spesifieke doelwitte of tydlyne, kan lei tot aansienlike verbeteringe in pasiënte sorg. Dit sal uiteindelik lei tot 'n afname in die MIV oordrag van moeder na kind, asook MIV- verwante morbiditeit en mortaliteit in moeders en kinders.

BACKGROUND AND LITERATURE REVIEW

According to the 2011 World Health Organization (WHO) statistics there were approximately 34 million Human Immunodeficiency Virus (HIV) positive people worldwide, of which 16.7 million were women and 3.3 million were children under the age of 15 years.¹ Only 50 percent of people worldwide know their HIV status. The United Nations Millennium Development Goals (MDG) were instituted to, amongst others, combat the HIV/Acquired Immunodeficiency syndrome (AIDS) epidemic.² Member countries agreed to put into place certain actions to halt and reverse the spread of HIV by 2015 and to provide treatment when needed. The aim of MDG number 6 (MDG-6) is to combat HIV/AIDS, malaria and other diseases. It has two targets applicable to HIV/AIDS: Target A is to halt and reverse the spread of HIV/AIDS by 2015 and Target B was to provide universal access to treatment for HIV/AIDS when needed, by 2010.

The HIV infection rate currently shows the most rapid increase in the female population. In Sub-Saharan Africa more than 60% of all new HIV infections are in women, infants and children.³ As a mode of transmission, mother-to-child-transmission (MTCT) is the cause of more than 10% of all new HIV infections worldwide. During 2010 2.5 million people were newly diagnosed with HIV, 330 000 were children younger than 15 years.⁴ The number of newly infected children in 2010 was 22% less than in 2001. In sub-Saharan Africa, between 2009 and 2011, the number of children newly infected with HIV fell by 28%.⁵ The reduction in newly infected children with HIV is the result of MTCT programs.

More than 90% of new HIV infections in infants and young children occur through MTCT, either during pregnancy, labour, delivery or breastfeeding.³ In a non-breastfeeding HIV positive woman the risk of transmission (in the absence of any intervention) is 15-30%, while breastfeeding increases the transmission rate to between 20-45%. Without proper care and treatment 50% of newly infected children will die before their second birthday.

In the 2011 population CENSUS it was estimated that there were 50.59 million people in South Africa, with the overall HIV prevalence rate of approximately 10.6%.⁶ About one-fifth of South African women in their reproductive years are HIV positive. The total number of people living with HIV was estimated at more or less 5.38 million. In South Africa the HIV prevalence rate among pregnant women in 2011 was 30.2%.⁷ Roughly 300 000 of the approximately 1 million babies born yearly in South Africa are exposed to HIV.⁸ Without access to a perinatal MTCT (PMTCT) programme about 90 000 or 30% of these babies born will be infected with HIV.

The use of rapid HIV testing with same-day results is recommended by the WHO since this contributes to an increase in the uptake of HIV testing. Rapid HIV testing is simple, cost effective, highly sensitive and specific, and gives instant, same-day results.⁹ A study in Uganda found that rapid HIV testing with same-day results had many advantages compared to standard enzyme-linked immunosorbent assay (ELISA) testing, including increased notification rates (96% vs. 65%).¹⁰ Rapid testing has also been shown to be cost effective when compared with ELISA and Western blot tests.

The use of Anti-retroviral (ARV) drugs for PMTCT has been proven to be effective by multiple clinical trials since the mid-nineties. The Cochrane collaboration published a review in 2010 of randomized controlled trials and observational studies.¹¹ They concluded that ARVs were safe in pregnant women with HIV infection who qualify for treatment, that it effectively suppresses the virus and decreases MTCT and infant mortality. According to the WHO the risk for MTCT in non-breastfeeding women can be reduced to less than 2% and in breastfeeding women to less than 5% with proper implementation of the PMTCT program protocols.¹² In South Africa this relates to the prevention of HIV infection in approximately 75 000 babies annually.⁸

From these statistics the extent of HIV/AIDS as a disease is clear, as well as the importance of the correct implementation of the PMTCT protocols to aid in reaching MDG6 by 2015. Two major weaknesses were identified in the implementation of the PMTCT program at Worcester Hospital by Dr Andrew Liebenberg, a Family Medicine registrar, as part of one of his second year MFamMed assignments in 2010¹³:

1. *The time interval from the diagnosis of HIV to the availability of the CD4 count and the implementation of Highly Active Anti-Retroviral Therapy (HAART).*
2. *Poor adherence to the protocol of single dose ARVs administered intrapartum.*

An audit of a regional hospital in KwaZulu-Natal, by Moodley et al., showed similar problems in the implementation of PMTCT as identified for Worcester Hospital.¹⁴ At the specific hospital there was a high uptake of HIV testing, but a delay in obtaining CD4 count results as well as in the initiation of HAART during pregnancy. This indicated that there were certain barriers in service delivery that prevented the integration of PMTCT into routine antenatal care.

A study was done by Coetzee et al. on the efficacy of the first routine PMTCT programme in South Africa, implemented in the Khayelitsha subdistrict of the Western Cape Province in 1999.¹⁵ The results of this study, done in 2003, demonstrated that implementing a large-scale PMTCT programme in an urban public-sector setting was feasible. The majority of the pregnant women accepted HIV testing and were prepared to join the PMTCT programme which was relatively unknown at the time. The overall rate of MTCT in this study was < 10%. This reflects the effectiveness of the PMTCT programme delivered within routine health-care services.

In Zambia, an audit by Mandala et al. concluded that efficient PMTCT regimes, beyond single dose Nevirapine (NVP), could be implemented in primary health care settings with few resources.¹⁶ There also was a high uptake for HIV testing, however 83% of HIV positive pregnant women's CD4 counts were not done. When blood samples were drawn and dispatched, the results were followed up in only 11.3% of cases. Problem areas identified were the time interval between diagnosis and of blood being drawn for CD4 count, follow-up of the results and the capacity to initiate anti-retroviral therapy (ART).

The findings of the studies conducted in KwaZulu-Natal and Zambia reflect similar problem areas identified in the *Action Framework for 'No child born with HIV by 2015 &*

Improving the health and wellbeing of mothers, partners and babies in South Africa' published by the Western Cape Department of Health in 2012.^{14,16-17}

In the PMTCT Action Framework one of the prioritised strategic objectives is the prevention of vertical transmission of HIV to reduce MTCT to, at least, less than 2% at six weeks and less than 5% at 18 months by 2016.¹⁷ The Provincial Workshops identified certain problem areas in the Western Cape Province, including: Low family planning uptake rate, late antenatal clinic bookings, inadequate rate of antenatal women tested for HIV, low rate of repeat HIV testing at 32 weeks, low rate of adherence to antenatal Zidovudine (AZT), inadequate number of HIV infected pregnant women initiated on ART, low NVP coverage of infants born to HIV positive pregnant women, inappropriate infant feeding practices (e.g. mixed feeding) and low rate of infant testing at 18 months.

According to the data collected and analysed for the Western Cape Province in 2010: 52.7% of pregnant women booked before 20 weeks, 91.6% were tested for HIV at the first antenatal visit, in 98.2% of patients who tested HIV positive a CD4 test was done and 85% of antenatal clients were initiated on AZT or HAART. The aim of the Action Framework's strategic plan is to have 90% of women in the Western Cape book before 20 weeks and 100% for the rest of the parameters, by 2015.

This was the motivation behind doing a quality improvement cycle intervention at Worcester Hospital, as well as the adjacent level one midwife obstetric Unit (MOU), with the aim of improving the identified problem areas. The intervention included the implementation of simple changes and tools in the Antenatal Clinic (ANC), Infectious Diseases Clinic (IDC) and labour ward. An audit was done of the PMTCT program before and after the intervention.

The study is relevant and it will contribute to the Western Cape Department of Health's strategic plan and action framework in reaching its goals for 2015, as well as, when taking the global picture into consideration, the United Nations MDG-6 for 2015.

PMTCT GUIDELINES

The WHO published PMTCT guidelines in 2010: *Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants - Recommendations for a public health approach – 2010 version*, which were due for an update in 2012.³ These guidelines were a revision of the 2006 guidelines and are based on new evidence regarding the use of ARV's in preventing MTCT. The guidelines were developed to provide international standards in PMTCT protocols in low and middle income countries. The 2010 National PMTCT Guidelines were implemented by the Western Cape Department of Health on 1 September 2010.¹⁸ In the revised 2010 PMTCT protocol several changes were made regarding ARV drug regimens for mother and infant, eligibility for lifelong ART and infant feeding. The new regimen was implemented at Worcester Hospital on 1 October 2010.

The 2010 National PMTCT Guidelines¹⁸:

Antenatal

- HIV positive pregnant patients with WHO stage 3 & 4 or CD4 count ≤ 350 cells/ μ l qualify for lifelong ARV treatment. HIV positive pregnant patients who do not qualify for ART should be started on AZT 300mg 12hrly from 14 weeks gestation.
- Laboratory Haemoglobin (Hb) concentration must be done on all patients before AZT is started and repeated monthly. The Hb concentration needs to be ≥ 8 g/dl.

Intrapartum

- Patients on AZT prophylaxis must receive a single dose AZT 300mg, NVP 200mg and Truvada® (Tenofovir 300mg/Emtricitabine 200mg) when in labour and then AZT 300mg every 3 hours until delivery.
- Patients on lifelong ART do not require NVP or Truvada, but must continue their medication throughout labour and delivery.

SETTING OF THE STUDY

The study took place at Worcester Hospital, a 269 bed regional hospital in the Cape Winelands East district of the Western Cape Province.¹⁹ Worcester Hospital labour ward currently has 14 beds where all level 2 high risk obstetric cases from the Winelands East and Overberg regions are managed and high risk deliveries are performed. Low risk cases are managed at the Community Health Centre (CHC) MOU with a 10 bed labour ward, which is adjacent to the hospital. Together the two form the Worcester Obstetric Unit.

Antenatal clinic booking of all pregnancies and low risk antenatal clinic care is done at various fixed and mobile clinics in the area, these include: Worcester CHC (also known as GGS40 day hospital), Empilisweni, Maria Pieterse, Somerset Street, Rawsonville, De Doorns, Orchard, Touwsriver and Sandhills clinics. A high risk antenatal clinic is held twice weekly at Worcester hospital. The IDC, where all HIV positive patients who require ART are counselled and managed, is held daily at Worcester Hospital. The district hospitals which refer high risk patients to Worcester Hospital are at Ceres, Robertson, Bredasdorp, Montagu, Swellendam, Caledon, Hermanus and Laingsburg.

According to the 2010 Antenatal HIV and Syphilis Prevalence Survey, the estimated HIV prevalence for the Western Cape Province was 18.5%.¹⁷

QUALITY IMPROVEMENT CYCLE

The aim of a quality improvement cycle is to improve the quality of care in a specific setting, by identifying areas that need improvement and implementing changes.²⁰

Improvements can be done in two ways:

- By improving the process itself and/or
- By improving the outcomes of the process

The four steps that define a quality improvement cycle are: plan, do, check and act.

1. Plan – *the change*:
 - Identifying the need to implement change
 - Describe the current process and the opportunities for improvement
 - Documentation of goals and objectives
2. Do – *implement the changes or new practices*
3. Check – *monitor and review the change*:
 - Monitor the progress and effectiveness of the implemented plan
 - Record the results and compare with the original data or project goals
 - Studying the results – what was achieved?
4. Act – *revise and plan how to use the information gained*:
 - Were the implemented changes successful?
 - Can the process be improved even more?
 - What lessons were learned and can they be implemented elsewhere?

METHODS

Two major problem areas were identified at Worcester Hospital in the implementation of the National Guidelines for PMTCT. The following easy interventions were implemented at the Worcester Obstetric Unit and the referring clinics to improve the problem areas identified. An audit was done before the intervention and afterwards.

PROBLEM ONE:

Too long a time interval between making the diagnosis of HIV, getting the CD4 count and referring to the IDC in order to start HAART.

INTERVENTION:

A meeting was held with all personnel involved with ANC bookings, as well as IDC staff to inform them of the problems identified, planned interventions, as well as to remind them of the PMTCT guidelines. The following changes were implemented:

1. All pregnant patients must receive HIV counselling and testing at their first visit to the ANC.

2. Blood must be drawn immediately for a CD4 count in all pregnant patients who test positive on the initial HIV rapid blood test (at the same ANC visit) and all patients more than 14 weeks gestation must be started on AZT.
3. Follow-up for CD4 count results must be done within one week after the first ANC visit.
4. All pregnant patients with a CD4 count ≤ 350 cells/ μ l must be referred to IDC immediately and the following bloods must be taken: full blood count (FBC), creatinine and alanine aminotransferase (ALT).
5. IDC staff must give priority to pregnant patients and their appointments must be within one week.
6. Only a two week interval is allowed between the initial ANC booking visit, making the diagnosis and attending the first IDC appointment.
7. IDC personnel must be asked to expedite initiating HAART, in order to avoid further delays.

PROBLEM TWO:

Poor administration of single dose ARVs intrapartum

INTERVENTION:

The quality improvement cycle that was implemented at the Worcester Obstetric Unit included:

1. All labour ward personnel, including doctors, were reminded of the PMTCT guidelines.
2. A specially designed stamp was added to a designated area of the patient's admission notes. (see Addendum A) The stamp provided a space to add information regarding the patient's HIV status, whether the patient is on HAART or AZT. In addition, when the 3 hourly AZT and single dose NVP and Truvada were given for the patients on AZT prophylaxis.
3. The stamp must be completed on admission by the doctor or sister on duty in the labour ward.

Patients whose files were missing or empty were excluded from the analysis.

DATA COLLECTION

As stated, the Worcester Obstetric Unit consists of the Worcester Hospital antenatal (high risk) clinic and labour ward, and the Worcester CHC MOU antenatal (low risk) clinic and labour ward. Thus any quality improvement cycle or audit had to include both and the intervention had to be performed at both sites.

The files and antenatal records (antenatal card, partogram, birth record, nursing notes, prescription chart and doctor's notes) of all HIV positive patients and patients with an unknown HIV status, who delivered at the Worcester Obstetric Unit during January, February and March of 2010 and 2011 respectively, were reviewed with permission of the relevant heads of departments and medical superintendents. A data capturing form was completed for each (see Addendum B). Included in the study population were all normal vertex deliveries, breech deliveries, assisted deliveries and caesarean sections. All the patients with babies who were born before arrival at the obstetric Unit (BBA's), were included in the study. All HIV negative patients and women with stillbirths and miscarriages were excluded from the study.

STATISTICAL ANALYSIS

A data analysis was done of all data collected from deliveries at the Worcester Obstetric Unit during the specified time period. General data was collected for the antenatal period, including:

- Total patients HIV positive versus negative versus unknown
- Total patients booked versus unbooked
- Age of the patient at the time of booking
- Gestational age at booking
- Methods used to determine gestational age
- HIV diagnosis made before or during pregnancy
- CD4 count

The pre-interventional findings of 2010 were compared with the post-interventional findings of 2011 for the Worcester Obstetric Unit. Aspects audited included:

- Was there a CD4 count done in all HIV positive patients?
- Time period from booking until CD4 count was done.
- Was the CD4 result given to the patient?
- Time period from performing CD4 count until the result was given to the patient.
- Was an IDC appointment given to patients who qualified for HAART?
- Time period from when CD4 result was available until when IDC appointment was given.
- Was any treatment given (AZT or HAART) to the patient?
- Time period from IDC appointment until HAART was started.
- Was the patient on AZT until HAART was started?
- Was the HAART regimen noted on the ANC card?

For the intra partum and postpartum period the pre-interventional findings at Worcester CHC MOU was compared with the pre-interventional findings at Worcester Hospital in 2010. The post-interventional findings at the two settings in 2011 were compared with each other as well as with the pre-interventional findings. Aspects audited included:

- Time period from when treatment was started to delivery
- Was the correct treatment given before delivery?
- If the incorrect treatment was given, where was the mistake made?
- Any avoidable or unavoidable reasons that incorrect treatment was given?

General data collected for the intra- and postpartum period:

- Gestational age at delivery
- Mode of delivery (only at Worcester Hospital)
- Infant feeding methods
- ARV's provided to the infant
- Methods of contraception

Proportions were compared with Chi-square tests and normally distributed quantitative data with Student's t-test. Medians of quantitative data not normally distributed were compared with the Mann-Whitney U-test. Proportions with small numbers were compared with Fisher's Exact tests. Probability values of less than 0.05 were regarded as significant. The statistical package used for calculations was Statistica version 11 of 2012.

ETHICAL ASPECTS

Approval to conduct the audit was obtained from the Committee for Human Research of the Faculty of Medicine and Health Sciences, Stellenbosch University (Ethics reference number: N10/12/403, see Addendum C). Approval for the intervention and audit were also obtained from the Chief Executive Officer of Worcester Hospital and the Director of Health Services in the Boland Region.

- The study was a retrospective audit and no questionnaires were completed.
- The study was a step-up of the present routine data collection of the provincial PMTCT programme.
- The routinely collected data presently do provide information on the efficiency of the provincial PMTCT program.
- The researcher personally collected additional data (i.e. type of ARV intervention and CD4 counts).
- Improving the quality and detail of data collected on the patients on the provincial PMTCT programme will enable adjustments to the provincial PMTCT programme to reduce the HIV transmission rates to lower levels than what is projected within the National Strategic Plan 2007-2011. ²¹
- Patient confidentiality was not compromised in any way.

Waiver of obtaining consent from patients was granted by the Committee of Human Research taking above considerations in account as well as the fact that the researcher was never in contact with the study patients at any time.

BUDGET

There was no need to make any budget provision for this study by the Western Cape Government Department of Health, Worcester Hospital or Stellenbosch University.

RESULTS

The audit was done at the Worcester Obstetric Unit where a quality improvement cycle intervention was implemented in 2010 and reviewed in 2011. The months January, February and March of 2010 and 2011 were audited.

The total number of deliveries for the Worcester Obstetric Unit for the year 2010 were 3284 and for 2011 it was 3274. For the two entities forming the Unit, Worcester Hospital (WH) and the Worcester CHC MOU (MOU), the total number deliveries for 2010 and 2011 are shown in Table 1.

Table 1: Total deliveries for 2010 and 2011

Total deliveries for the year	2010 (%)	2011 (%)	p-value
WH	1694 (51.6)	1676 (51.2)	0.750
MOU	1590 (48.4)	1598 (48.8)	
TOTAL	3284	3274	

The total number of deliveries for the Worcester Obstetric Unit for the months that were reviewed in the audit; January, February and March of 2010 and 2011, are shown in Table 2.

Table 2: Total deliveries at Worcester Obstetric Unit for January, February, March 2010 and 2011

Total deliveries January, February and March	2010 (%)	2011 (%)	p-value
WH	442 (48.7)	426 (49.2)	0.85
MOU	465 (51.3)	439 (50.8)	
TOTAL	907	865	

At the Worcester Obstetric Unit, the number of patients who delivered at the Unit during the months of January through March of 2010 and 2011, and who were tested or known to be HIV positive or negative, as well as the untested or HIV unknown patients are shown in Table 3.

In tables 3, 4 and 5 all HIV positive, negative and status unknown were included in calculating the p-value for the comparison between 2010 and 2011.

Table 3: HIV status of patients who delivered at Worcester Obstetric Unit in January, February and March of 2010 and 2011

Total deliveries (January, February, March) at Unit:	2010(%)	2011 (%)	p-value
HIV+	102 (11.2)	108 (12.5)	0.109
HIV-	801 (88.3)	757 (87.5)	
HIV unknown	4 (0.4)	0 (0)	
TOTAL	907	865	

During the audit period there were three patients who delivered at Worcester Hospital who were never tested for HIV ante- or postnatally in 2010, compared to none in 2011 (Table 4). At the MOU only one patient was not tested during the audit period in 2010 and all patients were tested in 2011 (Table 5).

Table 4: HIV status of patients who delivered at Worcester Hospital in January, February and March of 2010 and 2011

Worcester Hospital (January, February, March)	2010 (%)	2011 (%)	p-value
HIV +	44 (10.0)	53 (12.4)	0.124
HIV -	395 (89.4)	373 (87.6)	
HIV unknown	3 (0.7)	0 (0)	
TOTAL	442	426	

Table 5: HIV status of patients who delivered at Worcester CHC MOU in January, February and March of 2010 and 2011

MOU (January, February, March)	2010 (%)	2011 (%)	p-value
HIV +	58 (12.5)	55 (12.5)	0.623
HIV -	406 (87.3)	384 (87.5)	
HIV unknown	1 (0.2)	0 (0)	
TOTAL	465	439	

Initially the study population consisted of all the HIV positive patients, as well as the patients with an unknown HIV status, who delivered at the Unit. The files of these patients who delivered at the Unit during the months of January, February and March of 2010 and 2011 were reviewed, some of these files were missing and some of the files were empty, not containing the antenatal card and/or the admission, delivery and postpartum notes by the health personnel. These patients were removed from the study population, thus the new smaller population with complete files and all information available, was used in the analysis (Figures 1-4).

For the audit of the antenatal period the study population was further divided into two groups, namely patients who received antenatal care (booked) and those who received no antenatal care (unbooked). The subgroup of patients that booked at the antenatal clinic during their pregnancy's files were reviewed. Certain general aspects, as previously noted, were reviewed in this group and the pre-interventional findings of 2010 were compared with the post-interventional findings of 2011. (Figures 1-4)

As demonstrated in Figures 1-4, the unbooked group of patients were further divided into two groups. The first group was the patients that were unbooked and never tested for HIV, not ante-, intra- or postpartum. They were discharged with their HIV status still unknown. The second group included the unbooked patients who were tested at delivery and found to be HIV positive, as well as those known to be HIV positive before pregnancy. This second group of unbooked patients were included back into the study population with the review of the intra- and postpartum period. General data, as well as pre- and post-interventional findings for the time period were compared between the two years as well as the hospital and MOU. (Figures 1-4)

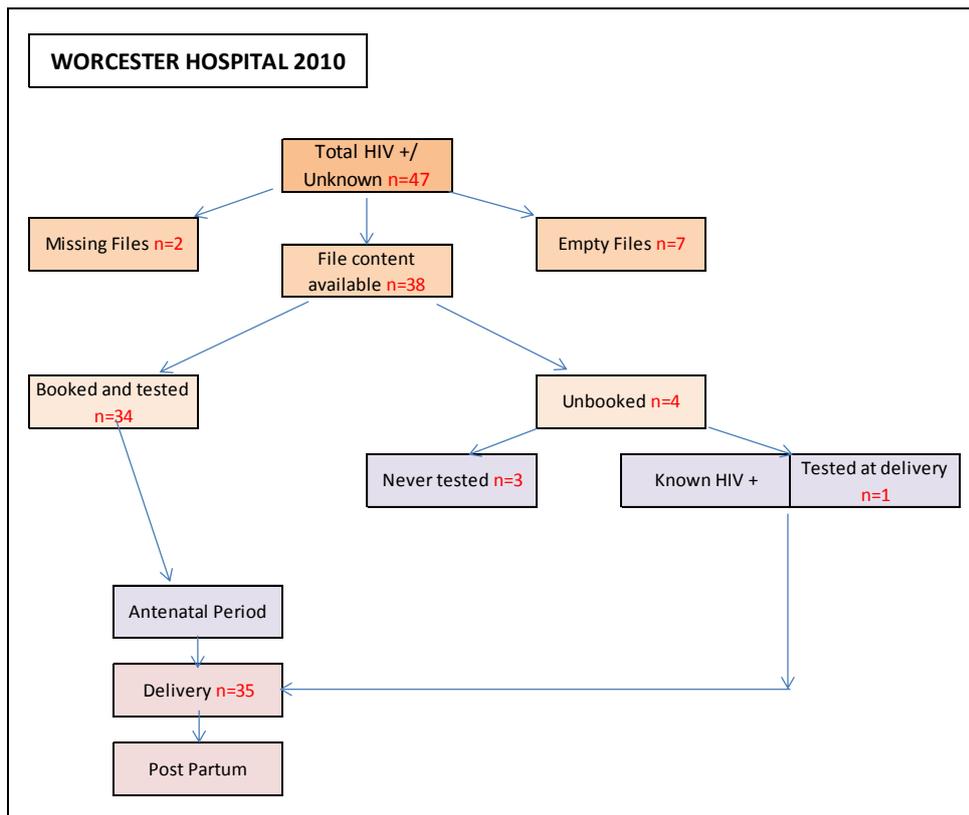


Figure 1: Worcester Hospital Study Group January, February, March 2010

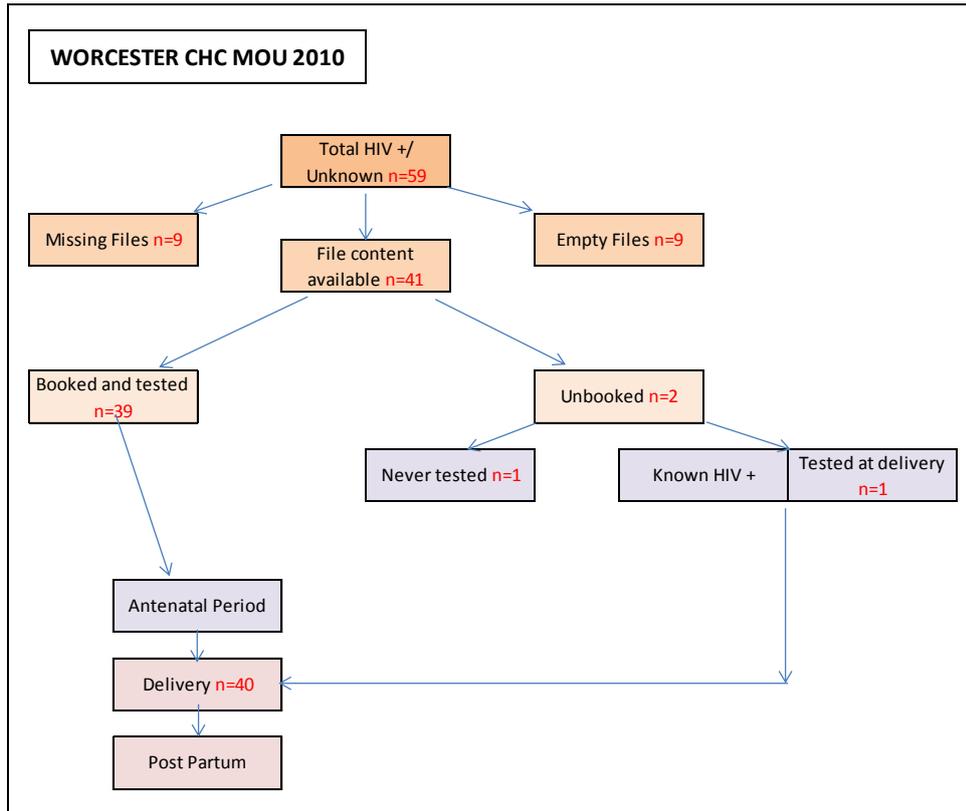


Figure 2: Worcester CHC MOU Study Group January, February, March 2010

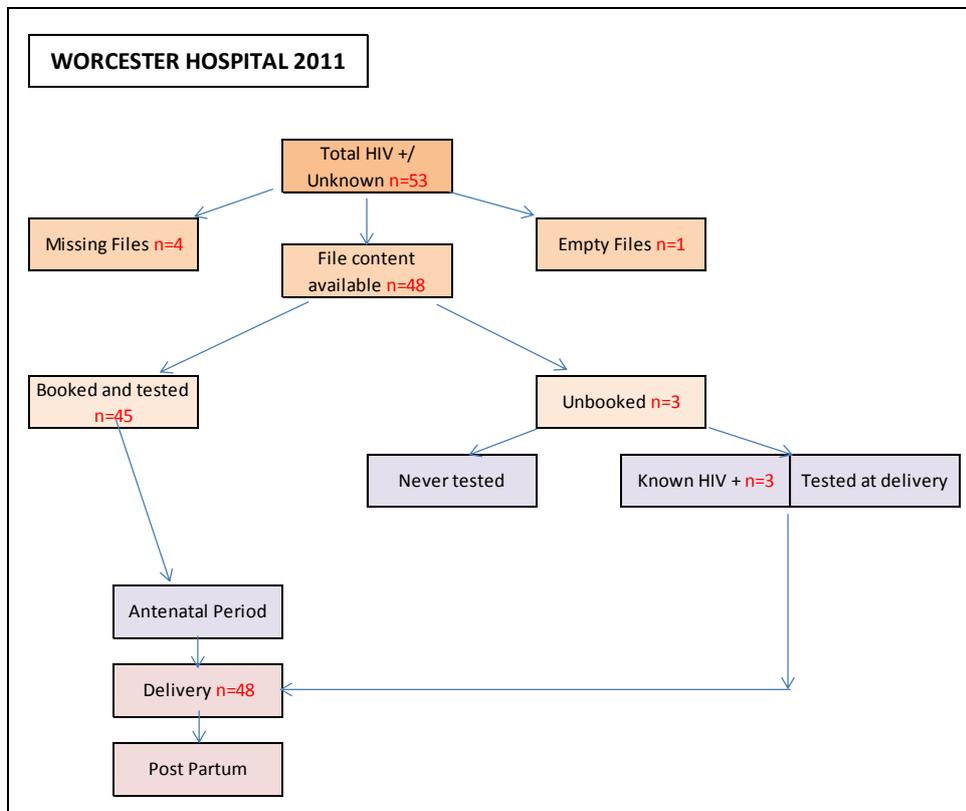


Figure 3: Worcester Hospital Study Group January, February, March 2011

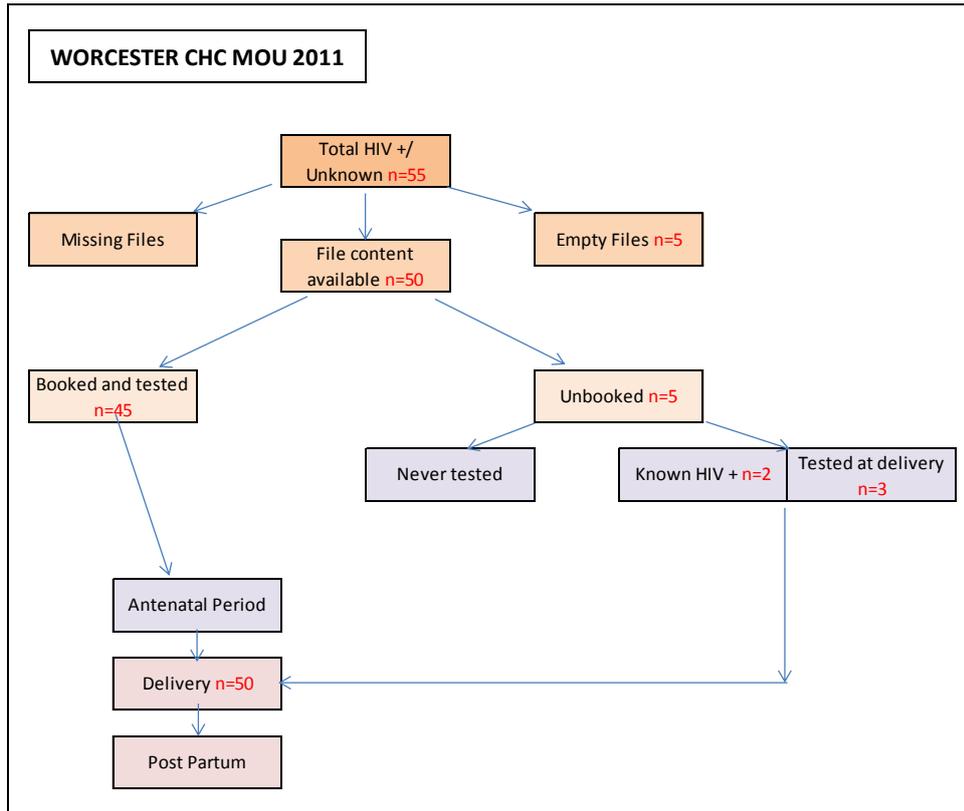


Figure 4: Worcester CHC MOU Study Group January, February, March 2011

Antenatal period

The study population used in this part of the audit, as explained (Figures 1-4), consists of all the HIV positive and status unknown patients with files that were available and complete.

For the entire study population (2010 and 2011) the median age at booking was 27 years, with the range 15 to 45 years. 50% of the study population were between 23 and 30 years of age.

In 2010 six patients were unbooked compared to eight in 2011 (Table 6).

Table 6: Total HIV positive/unknown patients who delivered at Worcester Obstetric Unit

BOOKED versus UNBOOKED	2010 (%)	2011 (%)	p-value
Booked	73 (92.4)	90 (91.8)	0.889
Unbooked	6 (7.6)	8 (8.2)	
TOTAL	79	98	

The unbooked patients were excluded from the study population for the rest of the audit of the antenatal period.

The median gestational age at which patients booked at the antenatal clinic (in 2010 and 2011 combined) was 20 weeks, with a range of 6 to 39 weeks. 50% of the patients' gestational age was between 14 and 27 weeks. For the study time period the methods used to determine the gestational age at booking are shown in Table 7.

Table 7: Methods used to determine gestational age at ANC

Method used to determine gestation		%
Last Menstrual Period	54	33.1
Ultrasound	64	39.3
Booking Symphysis-pubis Height	45	27.6
TOTAL	163	

Data collected to determine if patients were mostly diagnosed with HIV during pregnancy or whether the diagnosis was made before pregnancy are shown in Table 8.

Table 8: HIV diagnosis made before or during pregnancy

HIV diagnosed :	2010 (%)	2011 (%)	p-value
Before pregnancy	23 (31.5)	50 (55.6)	0.002
During pregnancy	50 (68.5)	40 (44.4)	
TOTAL	73	90	

The median CD4 count of the study population was 364 cells/ μ l, with a range between 54 and 1313 cells/ μ l.

One of the outcomes that formed part of the audit was whether a CD4 count was done in all HIV positive patients. The study population was divided into two groups, firstly patients who were known to be HIV positive before pregnancy and secondly patients who were diagnosed as HIV positive at their booking visit at the antenatal clinic. Both of these groups were reviewed as to whether a CD4 count was done in the cases where it was not available or known and if there was any significant difference made after the intervention was implemented.

Table 9 indicates the number of the patients known to be HIV positive before booking, who had a known or unknown CD4 count.

Table 9: Patients known to be HIV positive before pregnancy

<i>CD4 count known?</i>	2010	2011	p-value
Yes	7	14	1.0
No	16	36	
TOTAL	23	50	

There were also patients known to be HIV positive before pregnancy who had an unknown CD4 count. Table 10 shows the number of patients in whom a CD4 count was done.

Table 10: Patients known to be HIV positive before pregnancy with unknown CD4 count

<i>Unknown CD4 count - was a CD4 done?</i>	2010	2011	p-value
Yes	15	33	1.0
No	1	3	
TOTAL	16	36	

Patients who were diagnosed with HIV at their booking visit. Table 11 shows how many of these patients had CD4 counts done.

Table 11: Patients who were diagnosed with HIV during pregnancy

<i>Was a CD4 done?</i>	2010	2011	p-value
Yes	47	40	0.25
No	3	0	
TOTAL	50	40	

The time period from when the diagnosis of HIV was made or the patient identified as known to be HIV positive, but without a CD4 result, until the CD4 count was done, was a mean of 17.1 days before the intervention and after the intervention it was reduced to a mean value of 4.4 days. The median was zero before and after the intervention (p-value= 0.57).

The results as to whether the CD4 count was followed up and recorded on the antenatal clinic card before the intervention and after the intervention are shown in Table 12.

Table 12: CD4 result followed up and recorded on ANC card

CD4 result followed up	2010 (%)	2011 (%)	p-value
Yes	54 (87.1)	61 (83.6)	0.56
No	8 (13.0)	12 (16.4)	
TOTAL	62	73	

The days that passed from when blood was drawn for the CD4 count until the result was given to the patient and documented on the ANC card, was a median of 34 days in the pre-intervention group and a median of eight days in the post-intervention group (p-value = 0.000001).

From the group of patients who were newly diagnosed as HIV positive as well as the group known to be positive before pregnancy but not on treatment, the patients who qualified for HAART were identified (Table 13). Patients with a CD4 count of less than 200 cells/ μ l qualified for HAART before 1 September 2010, thereafter the cut off value increased to 350 cells/ μ l. In both groups there were 11 patients where the CD4 count was not documented or followed up, these patients potentially missed the opportunity to be started on HAART.

Table 13: Patients newly diagnosed as HIV positive and patients known to be HIV positive but not on HAART

Qualified for HAART	2010	2011	p-value
Yes	11	31	0.001
No	49	31	
Unknown	11	11	
TOTAL	71	73	

All the patients in the 2010 group, and all except one patient from the 2011 group, who qualified to be started HAART were given an appointment at the IDC (Table 14).

Table 14: All patients who qualified to be started on HAART was supposed to receive an IDC appointment.

ID clinic appointment given	2010	2011	p-value
Yes	11	30	1.0
No	0	1	
TOTAL	11	31	

Before the intervention, the time period from the day the CD4 result was checked and the patient identified as someone who qualified for HAART, until the day of the IDC appointment, was a median of 34.5 days, with a range of 4 to 90 days. After the intervention this time period had decreased to a median of 8 days with a range of 0 to 22 days (p-value = 0.03).

All patients in the pre- and post-intervention groups were reviewed to see if they received any form of treatment, either HAART or AZT, during the antenatal period according to the PMTCT guidelines (Table 15).

Table 15: Prescription of antiretroviral treatment (AZT or HAART) to all patients for the antenatal period

ART prescribed	2010 (%)	2011 (%)	p-value
Yes	68 (93.2)	90 (100)	0.017
No	5 (6.8)	0 (0)	
TOTAL	73	90	

Table 16 shows the number of patients who received HAART before the PMTCT guidelines were revised (2010 group) compared to the number who were on HAART after change in the guidelines (2011 group). The percentage of patients on HAART increased significantly ($p=0.0006$).

Table 16: Treatment method received by HIV positive patients antenatally before (2010) and after (2011) PMTCT guidelines changed

Treatment	2010 (%)	2011 (%)	p-value
AZT	59 (86.8)	56 (62.2)	0.0006
HAART	9 (13.2)	34 (37.8)	
TOTAL	68	90	

The number of patients who were on HAART before they fell pregnant compared to those who were commenced on HAART during the antenatal period is shown in Table 17.

Table 17: HAART commenced before pregnancy or during the antenatal period

HAART commenced	2010	2011	p-value
Before pregnancy	2	17	0.3
During pregnancy	7	17	
TOTAL	9	34	

The time period from when the patient attended the IDC for the first time until the date HAART was actually started was reviewed for the pre and post intervention groups. Before the intervention it was a median of 15 days (range 0 to 37 days) and after a median of 42 days (range 0 to 69 days) (p-value = 0.25).

It was audited whether patients that were started on HAART antenatally, received AZT according to the PMTCT guidelines, until HAART was started (Table 18).

Table 18: Patients who were started on HAART during the antenatal period and received AZT before HAART was commenced.

On AZT until HAART was started	2010	2011	p-value
Yes	4	16	0.065
No	2	0	
TOTAL	6	16	

Another aspect assessing the intervention was whether the HAART regimen was documented on the antenatal clinic card (Table 19).

Table 19: HAART regimen documented on ANC card.

HAART regimen on card	2010	2011	p-value
Yes	7	27	1.0
No	2	7	
TOTAL	9	34	

The time period that patients received antiretroviral therapy before delivery was audited. Before the intervention the median treatment time was 55 days (range 1 to 113

days). This increased to a median of 91 days (range 7 to 228 days) after the intervention was implemented (p-value = 0.09).

Intrapartum and postpartum period

The study population used in this part of the audit, as explained (Figure 1-4), includes all the patients included in the antenatal period, as well as unbooked patients who were known to be HIV positive (diagnosed before pregnancy) as well as those patients tested before delivery.

The median gestational age at delivery for the study population (2010 and 2011) was 39 weeks with a range between 26 and 43 weeks. All patients at the MOU had normal vertex deliveries, but at Worcester Hospital caesarean sections and breech deliveries were also performed (Table 20).

Table 20: Mode of delivery Worcester Hospital and Worcester Obstetric Unit

Mode of delivery HIV+ patients Worcester Hospital*	2010 (%)	2011 (%)	*p-value
Vaginal deliveries (NVD & Breech deliveries)	14 (36.8)	19 (39.6)	0.80
Caesarean section	24 (63.2)	29 (60.4)	
Mode of delivery HIV+ patients Worcester Obstetric Unit	2010 (%)	2011 (%)	
Vaginal deliveries (NVD & Breech deliveries)	55 (69.6)	69 (70.4)	
Caesarean section	24 (30.4)	29 (29.6)	

The correct administration of antiretroviral treatment before delivery, which included patients on HAART as well as PMTCT was assessed. Patients needed to be on HAART or receive three hourly AZT when in labour and a single dose NVP and Truvada before delivery, in order for treatment to be correct.

At Worcester Hospital, the number of patients who received the correct treatment before and after the interventions were implemented is shown in Table 21.

Table 21: Worcester Hospital: Patients that received the correct antiretroviral treatment (HAART or AZT/NVP/Truvada) before delivery

<i>Worcester hospital:</i>			p-value
Correct treatment given before delivery	2010 (%)	2011 (%)	
Yes	18 (47.4)	43 (89.6)	0.00002
No	20 (52.6)	5 (10.4)	
TOTAL	38	48	

The number of patients who received the correct treatment before and after the interventions were implemented, for the Worcester CHC MOU, are shown in Table 22.

Table 22: At Worcester CHC MOU: Patients that received the correct antiretroviral treatment (HAART or AZT/NVP/Truvada) before delivery

<i>Worcester CHC MOU:</i>			p-value
Correct treatment given before delivery	2010 (%)	2011 (%)	
Yes	28 (68.3)	39 (78.0)	0.30
No	13 (31.7)	11 (22.0)	
TOTAL	41	50	

Certain unpreventable factors were identified that prevented the health care personnel from administering the correct treatment. The two main unpreventable factors were: Patients delivering in the ambulance or before arrival in the labour ward (BBA's) and patients who were fully dilated on admission with imminent delivery; in these cases there was not enough time to administer treatment. Preventable reasons that were identified for not administering treatment were: HIV status was never tested, these patients were treated as HIV negative, and health care workers missed out on the fact that the patient was on HAART. In most cases no reason could be identified as to why patients had not received any treatment (Tables 23 and 24).

Table 23: Worcester Hospital: Preventable and unpreventable reasons why patients did not receive the correct ART before delivery

<i>Worcester Hospital:</i>		
Reasons why patients received incorrect treatment	2010	2011
No reason identified	14	1
BBA	1	2
Fully dilated on admission	1	2
HIV not tested	3	0
Missed that patient was on HAART	1	0
TOTAL	20	5

Table 24: Worcester CHC MOU: Preventable and unpreventable reasons why patients did not receive the correct ART before delivery

<i>Worcester CHC MOU:</i>		
Reasons why patients received incorrect treatment	2010	2011
No reason identified	2	0
BBA	10	7
Fully dilated on admission	0	4
HIV not tested	1	0
Missed that patient was on HAART	0	0
TOTAL	13	11

In calculating how many patients were incorrectly managed, the unpreventable factors were subtracted from the total patients incorrectly managed, to give new, adjusted totals for the incorrectly managed patients. These adjustments are shown in Tables 25 and 26.

Table 25: Worcester Hospital: Actual number of patients incorrectly managed

ADJUSTED incorrect management	2010	2011
Total patients incorrectly managed	20	5
MINUS Non-preventable reasons (BBA+Fully dilated)	2	4
Actual incorrect management	18	1

Table 26: Worcester CHC MOU: Actual number of patients incorrectly managed

ADJUSTED incorrect management	2010	2011
Total patients incorrectly managed	13	11
<i>MINUS</i> Non-preventable reasons (BBA+Fully dilated)	10	11
Actual incorrect management	3	0

After the patients who were managed incorrectly due to non-preventable reasons were removed, the new results to review whether patients received correct treatment before and after the intervention are shown in Tables 27 and 28. There was a significant improvement in the treatment of patients at Worcester Hospital after the intervention ($p=0.000001$), while there was no significant change in patient management at the MOU ($p=0.08$).

Table 27: Worcester Hospital: Adjusted figures with non-preventable reasons excluded

<i>Worcester Hospital:</i>	2010 (%)	2011 (%)	p-value
Correct treatment given before delivery			
Yes	18 (50)	43 (97.7)	0.000001
No (excluding non-preventable reasons)	18 (50)	1 (2.3)	
TOTAL	36	44	

Table 28: Worcester CHC MOU: Adjusted figures with non-preventable reasons excluded.

<i>Worcester CHC MOU:</i>	2010 (%)	2011 (%)	p-value
Correct treatment given before delivery			
Yes	28 (90.3)	39 (100)	0.08
No (excluding non-preventable reasons)	3 (9.7)	0 (0)	
TOTAL	31	39	

Worcester Hospital was compared with the Worcester CHC MOU before the intervention (Table 29). The administration of ART to patients before delivery was significantly better before the intervention at the MOU, compared to Worcester Hospital ($p=0.0005$).

Table 29: Results of patients receiving the correct treatment. Worcester Hospital compared with Worcester CHC MOU before the intervention

Correct treatment given before delivery	WH 2010	MOU 2010	p-value
Yes	18	28	0.0005
No (excluding non-preventable reasons)	18	3	
TOTAL	36	31	

Worcester Hospital was compared with the Worcester CHC MOU after the intervention (Table 30). After the intervention, there was no significant difference in the administration of ART to patients before delivery at the MOU, compared to Worcester Hospital ($p=1.0$).

Table 30: Results of patients receiving the correct treatment. Worcester Hospital compared with Worcester CHC MOU after the intervention

Correct treatment given before delivery	WH 2011	MOU 2011	p-value
Yes	43	39	1.0
No (excluding non-preventable reasons)	1	0	
TOTAL	44	39	

The specific treatment regime given to patients, either correctly according to the protocol or incorrectly due to preventable reasons, was reviewed before and after the intervention (Table 31).

Table 31: Treatment regime given before delivery, correctly according to protocol or incorrectly due to preventable reasons

Treatment regime given before delivery	2010		2011	
	correct	incorrect	Correct	incorrect
HAART	8	1	33	0
AZT & sdNVP or AZT/sdNVP/Truvada	38	16	49	1

In the patient group who received the incorrect treatment or management before delivery. The mistakes mostly made were identified. These mistakes were reviewed to also see whether there were any improvements made after the intervention (Tables 32 and 33).

Table 32: Worcester Hospital: Most common mistakes made when patients were incorrectly managed before delivery

<i>Worcester Hospital:</i>	2010	2011
Incorrect treatment given before delivery		
No medication given/prescribed (PMTCT/HAART)	12	1
Only sdNVP only, no 3hrly AZT	5	0
AZT only	1	0
TOTAL	18	1

Table 33: Worcester CHC MOU: Most common mistakes made when patients were incorrectly managed before delivery

<i>Worcester CHC MOU:</i>	2010	2011
Incorrect treatment given before delivery		
No medication given/prescribed	2	0
Only sdNVP given, no 3hrly AZT	1	0
AZT only	0	0
TOTAL	3	0

Reviewing data for the Unit revealed that most infants received formula milk as feeding method. Excluded from the results for 2010 (Table 34), there was one patient where the feeding method was not documented and another where the baby passed away shortly after delivery (early neonatal death). Excluded from the results for 2011, was an early neonatal death (Table 34).

Table 34: Feeding methods used in HIV positive patients

Feeding methods	2010	2011
Formula milk	68	89
Breastfeeding	9	8
TOTAL	77	97

Most of the babies were started on ART according to the PMTCT guidelines, shortly after delivery. The provision of ART for the infants after delivery is shown in Table 35.

Table 35: Antiretroviral therapy prescribed to infant of HIV positive mother

ART prescribed for baby	2010	2011
Yes, treatment was given	72	97
No, nothing was prescribed for infant	1	0
Nothing documented in file regarding treatment	1	0
ENND	1	1
Mother was never tested for HIV	4	0
TOTAL	79	98

The methods of contraception chosen by the study population following delivery and counselling by healthcare personnel are shown in Tables 36 and 37.

Table 36: Contraception methods chosen at Worcester Hospital

<i>Worcester Hospital:</i> Contraception method	2010	2011
Petogen	27	32
Sterilization	6	16
IUCD	0	0
Nothing	0	0
Not documented	5	0
TOTAL	38	48

Table 37: Contraception methods chosen at Worcester CHC MOU

<i>Worcester CHC MOU:</i> Contraception method	2010	2011
Petogen	36	49
Sterilization	0	0
IUCD	0	0
Nothing	0	0
Not documented	5	1
TOTAL	41	50

DISCUSSION

Worldwide there is agreement that countries must strive towards keeping mothers, partners and children living with HIV alive and healthy and to eliminate new HIV infection in babies and children, especially through vertical transmission. This motivated the WHO/UNAIDS' *Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive*²², aiming to reduce the number of new HIV infections in children by 90% and to reduce the number of AIDS related maternal deaths by 50%, worldwide by 2015. PMTCT is the cornerstone of the plan to reach these goals. South Africa's response to the WHO Global Plan is the *National Action framework for 'No Child Born with HIV by 2015 & Improving the Health and Wellbeing of Mothers, Partners and Babies in South Africa'*⁷, with the goal to align all strategies in order to maximise efforts to reach specific national and provincial goals. The aim of the Quality Improvement Cycle implemented at the Worcester Obstetric Unit, was to assist in reaching the goals set by the Western Cape Province's Action Plan¹⁷, and ultimately the goals of the WHO/UNAIDS Global Plan. The key elements of a successful PMTCT program are: primary prevention of HIV, prevention of unplanned pregnancies, and the focus of this study, the prevention of the transfer of HIV infection from mother to child and the provision of ART to women and infants.

This audit not only compared general findings for the Worcester Obstetric Unit before and after the intervention, but it also compared findings for its two components, i.e. the regional hospital, Worcester Hospital and the MOU, Worcester CHC MOU, with each other, before and after the intervention.

The audit showed that the total deliveries did not differ significantly between 2010 and 2011 (Table 1, $p=0.75$). Thus meaningful statistical comparisons can be made between the two years. The number of deliveries for the three months audited per year also did not differ significantly between the years (Table 2, $p=0.85$). The results show that all patients who delivered at the Unit during the study periods, and who booked at the antenatal clinics, received HIV counselling and testing and no patients declined testing.

This is in line with the goals set by the Provincial Strategic Plan Action Framework: Testing 100% of patients who book at an antenatal clinic by 2015.¹⁷

Four of the patients who delivered at the Unit before the intervention had an unknown HIV status and were not tested prior to discharge. After the intervention all patients were tested (Table 3). All four patients' pregnancies were unbooked and they were never tested by the nursing staff on admission to the delivery Unit or postpartum. Three of these patients delivered at the regional hospital, where the doctor who admitted the patient also did not request an HIV test. The rate of HIV status unknown for the Unit for 2007 to 2009 was, 11.2%, 8.5% and 6.5% respectively, for the drainage area the rates for the same years were 8.4%, 4.2% and 2.8%.¹⁹ The reason for the high rates at the Unit compared to the region, were attributed to poor record keeping and documentation in the birth register at Worcester hospital and MOU, rather than patients actually not being tested, according to the head of the Unit. A possible reason for the improved rates during the study period is the greater awareness created regarding HIV testing due to implementation of the strategies. The issue of poor record keeping was eliminated regarding all patients included in the study, since we not only relied on information from the birth register, but also from the stamp on the patients' medical records.

The HIV prevalence rate for the Western Cape was 18.5% in 2010, this is the second lowest HIV prevalence when compared to the rest of the provinces in South Africa.¹⁷ The HIV prevalence rate for the Worcester hospital drainage area for 2007 to 2009 were 9.1%, 10.4% and 11.1% annually and for the Unit, 8.4%, 9.5% and 10.9%.¹⁹ The prevalence rates for the study population's time period were in keeping with the increase in the percentages seen, 11.2% for the 2010 group and 12.5% for the 2011 group (Tables 4 and 5).

The median gestational age at which patients booked at the antenatal clinic was 20 weeks, with 50% of the patients between 14 and 27 weeks. This is below the aim of the Provincial Action Framework that 90% of patients must book before 20 weeks by 2015; the baseline for the Western Cape District for 2010 was 52.7%.¹⁷ The number of

patients who booked versus who were unbooked did not differ significantly between the 2010 and 2011 groups (Table 6). In 2010 92.4% were booked versus 91.8% in 2011.

The method used to determine gestational ages was almost equally distributed between ultrasound, the date of the first day of the last menstrual period (LMP) and Symphysis Fundus Height (SF) measurement, with ultrasound the most used method, but only in 6.13% more patients than LMP and 11.65% more patients than SF-measurement (Table 7). This is an alarming finding, since it is known that ultrasound dating is the most accurate method and ultrasound services are readily available in the region, for dating and detail scans, especially since the median booking gestation was 20 weeks. 27% of patients were dated by using SF measurements and 33.13% by LMP, the reason for this could be either that patients booked late and did not qualify for ultrasound dating or due to missed opportunities, either patients missing appointments or health care workers not booking them for ultrasounds. In the patient group who were dated by LMP, there could be patients included who received early dating scans which fitted in with their LMP. The optimal utilization of the antenatal ultrasound services in the region needs to be addressed. The study illustrates how the audit of a specific aspect of medical care can also identify other unexpected problem areas in the study population. By addressing these issues it can lead to an overall improvement in the provision of medical care in general.

Significantly more patients were diagnosed with HIV before they fell pregnant than during pregnancy in the 2011 group, when compared with the 2010 group (Table 8, $p=0.002$). This could be due to greater awareness regarding HIV testing in the region.

A CD4 count was done for most of the patients who were newly diagnosed with HIV and those known to be positive before pregnancy but with an unknown CD4 count (Tables 10 and 11). There was no significant difference before and after the intervention. These figures are better than the baseline of 64% for South Africa in 2010.⁷ The goal of the National Action Framework is 80% by 2011 and 100% by 2016. In order to reach 100% a strict “same day protocol” must be implemented, which means it must become routine

to do a CD4 count on the same day as when the diagnosis of HIV was made, this was also illustrated in research done by Mandala et al. in Zambia.¹⁶

One of the aims of the study was to improve the time lost between a patient being diagnosed with HIV, or identified as known to be positive but with an unknown CD4 result, and a CD4 count being done. Ideally this should happen on the same day as discussed above. The “same day protocol” was already followed in most cases before the intervention with a median of zero days both before and after the intervention.

The results of the blood drawn for CD4 count were not followed up in 13% of patients before the intervention and in 16.4% of patients afterwards (Table 12), this is not a significant change ($p=0.56$). After the intervention, the reason that these patients were not followed up could be attributed to the patients themselves, only one patient was identified where the antenatal clinic personnel did not check the CD4 result. All of the 11 remaining patients defaulted antenatal care after booking until delivery.

A significant improvement was made with the intervention in the time that it took from when blood was taken for CD4 count until the result was given to the patient ($p=0.000001$). After the intervention the median time decreased from 34 to 8 days which is a significant reduction in time. Ideally the interval should be one week. Most of the mobile clinics only do fortnightly visits, and financially patients would not be able to afford their own transport to the clinic in town. It is already difficult for most patients to get time off from work and getting time off two weeks in a row would probably be more difficult than having their appointments spaced further apart, two weeks would be a more realistic goal to set. Before the intervention the nursing staff placed the blame for the prolonged time between taking the blood specimen and following up the CD4 result, on the laboratory services. After contacting the Tygerberg and Greenpoint laboratories it was confirmed that all results were actually available within a day, but it depended on the date the specimen was received.

There were significantly more patients who qualified for HAART in the 2011 group when compared with the 2010 group (Table 13, $p=0.001$). This result was a reflection of the change in PMTCT protocol. More patients were eligible for HAART since the increase

in the cut off value to 350 cells/ μ l. In both groups there were eleven patients where the CD4 count was not documented, this was a missed opportunity since these patients potentially could have qualified for HAART. The importance of documenting results need constant emphasis during training sessions and should be included in interventions to improve care.

The patients who qualified for HAART were all, except for one, given an appointment at the IDC, there was no significant difference before and after the intervention with regards to patients receiving appointments (Table 14). After the intervention there was a significant shortening of the time from when a patient was identified as qualifying for HAART and the date given for the IDC appointment ($p=0.03$), from a median of 35 to 8 days.

All patients were audited whether they were started on some form of treatment during the antenatal period, either HAART or AZT, after the intervention significantly more patients received treatment than before (Table 15, $p=0.017$). Before the intervention 93% of patients received antiretroviral therapy, this figure improved to 100% afterwards (Table 15). This fulfils the goals of the Western Cape Action Plan and the National Action Framework of providing 100% of patients with AZT and if they qualify, HAART, antenatally by 2015/2016.^{7,17} The reason for the success can be attributed to the greater awareness made at the antenatal clinics regarding HIV testing and treatment and the PMTCT program.

Significantly more patients received HAART in the 2011 group compared to the 2010 group (Table 16, $p=0.0006$). This reflects the impact of the change in the PMTCT protocol. Since the CD4 cut off was increased to 350 cells/ μ l significantly more patients qualified for HAART.

The time period from when patients attended the IDC for the first time until the date HAART was started, did not differ significantly before and after the intervention, it took a median of between 15 and 42 days for a patient to be started on HAART. The time it takes to start a patient on HAART depends on many variables which could not be

influenced by factors outside the IDC. The IDC functions independently from the antenatal clinic and the obstetrics and gynaecology department did not have any influence in fast tracking our patients, apart from getting earlier appointments for them. The intervention also did not include the IDC personnel and no change was expected. Future interventions should be more comprehensive and include the IDC personnel. With closer cooperation between the two departments this problem can be addressed better.

Another aspect audited was whether patients who qualified for HAART received AZT until HAART was commenced (Table 18). This was the case for all patients after the intervention, but it did not differ significantly from before the intervention ($p=0.065$). The numbers however were small and this could be a Type 2 error. With larger numbers the difference should be significant. Documentation of the HAART regime on the antenatal card did also not differ significantly between the two groups, probably due to the fact that it was already done in seven out of nine patients (Table 19). The aim, however, should be the documentation of the HAART regime on the antenatal cards of all patients, since patients rarely know their specific drug names. The IDC personnel should take responsibility for the documentation on the card.

The median gestational age at delivery was 39 weeks, with 50% of patients between 37 and 40 weeks. 100% of patients delivered vaginally at the MOU since all their patients who required caesarean sections were referred to Worcester hospital. At Worcester hospital 63.2% and 60.4% of patients delivered via caesarean section during the study period for 2010 and 2011 respectively. The overall caesarean section rate including the MOU deliveries was 30.4% in 2010 and 29.6% in 2011.

One of the most important aspects audited, in which we aimed to make a difference with the implementation of the interventions, was the correct administration of ART. The initial figures found in the analysis were misleading, since when assessing the reasons why patients received the incorrect treatment, certain factors had to be excluded. The reasons identified why patients did not receive the correct management before delivery can be divided into two groups, preventable and non-preventable reasons (Tables 23

and 24). The preventable reasons were related to omissions by health care personnel, including doctors and nursing staff, and were addressed in the intervention. The preventable reasons were: patients were never tested for HIV and these patients were managed as HIV negative, patients on HAART were not recognised and in the case of most patients no reason could be identified. In these cases, the medication was not prescribed by the doctor who admitted the patient, the mistake was not noticed by the nursing staff and nothing was administered.

The non-preventable reasons were related to situations where patients did not receive the correct treatment, but due to factors that could not be attributed to the medical personnel. This included: delivery before arrival in the labour ward, for example at home or in the ambulance and cases where the patient was fully dilated on admission to the labour ward with insufficient time to administer medication. The patients who did not receive the correct management due to non-preventable reasons were excluded from the analysis. Before the intervention, 18 patients at Worcester Hospital did not receive the correct management for no apparent reason, compared to three at the MOU (Tables 25 and 26). At the hospital, in 12 of the 18 patients, no drug was prescribed and no treatment was given at all before the delivery (Table 32). After the intervention this decreased significantly to only one patient (Table 27, $p=0.000001$). Overall, before the intervention, significantly more patients received the incorrect management at Worcester Hospital due to non-preventable reasons, compared to the MOU. Before the intervention management at the MOU was significantly better than at the hospital (Table 29, $p=0.0005$).

The improvement at Worcester Hospital can be attributed to the greater awareness made by the intervention regarding the documentation of the patient's HIV status and treatment method (HAART or AZT) and prescribing the ARV's on admission, especially the three hourly AZT when in labour and the single dose NVP and Truvada before delivery. After the intervention, when comparing the administration of treatment at Worcester Hospital with the MOU, there was no significant difference (Table 30, $p=1.0$). This is also indicative of the positive change and improvement in management after the intervention, with previously a significant difference between the two.

Another interesting finding was that most patients opted for the formula feeding, between 8 and 12% of the patients opted for breastfeeding (Table 34). A reason for this may be that patients are not aware that exclusive breastfeeding is a feeding option for HIV positive patients. A lot of work needs to be done in the promotion of breastfeeding in order to reach the goals set by the Action Framework of more than 50% of babies of HIV positive women being breast fed exclusively for up to six months by 2015.⁷ Changes need to be implemented since the Minister of Health announced in 2011 that South Africa would promote exclusive breastfeeding for all mothers and that the provision of free formula milk to all HIV positive mothers should be phased out and only provided on a needs-based basis.

Contraception was provided to all patients, mostly in the form of Petogen (Depot medroxyprogesterone acetate) on the day of discharge (Tables 36 and 37). At Worcester Hospital postpartum sterilizations were done on 16% of the HIV positive patients during the study period in 2010 and 33% in 2011. None of the patients at the MOU were referred for sterilizations and Petogen was the only method of family planning provided. The option of inserting an intra-uterine contraceptive device (IUD) was not given to any of the patients at the hospital or MOU. This is another missed opportunity since IUD's are first tier effective contraceptive methods with less than 2% pregnancies at five years compared to Petogen as a second tier effective method.²³ Family planning is essential and unintended pregnancies should be avoided.²⁴ Family planning counselling should be integrated into all PMTCT services with the promotion of dual contraception methods (barrier contraception in addition to another method).⁷ There is definitely room for improvement in the counselling services provided at both the hospital and MOU to include different options of contraceptive methods, including sterilization and IUD's, compared to just providing Petogen. This must be included in future quality improvement cycle interventions.

The limitations of the study include the short time period and limited number of patients included in the study population. A follow up audit of the provision of PMTCT services at the Unit should be performed within a few years to see whether the

interventions implemented during the study period were sustainable and whether the intervention had any long term effect.

CONCLUSION

The audit revealed that by implementing small changes in the process of providing PMTCT significant improvements in efficacy could be made at a regional hospital and MOU. The time interval from when blood was drawn for a CD4 count until the result was followed up and then, until the appointment for the IDC was given, was significantly decreased. The implication of this decrease in time wasted is that patients are seen at the IDC earlier in pregnancy and can potentially be on HAART for a longer time during pregnancy. This contributes to improve maternal health and a decrease in transmission rates to the fetus.

Significantly more patients qualified for HAART following the PMTCT regime was changed in 2010. This could also lead to a decrease in HIV related morbidity and mortality.

By creating more awareness under health care workers regarding PMTCT, patients HIV status and prescribing correct treatment before delivery, significant changes can be made to patients' management and ultimately wellbeing. The audit highlighted significant improvements in the correct administration of ART intrapartum after the intervention.

Although the audit and quality improvement cycle was performed at a specific hospital, with specific changes geared towards their needs, the basic principles can be applied to any Unit in the country providing a PMTCT service. Educating staff, creating awareness and reminding staff of the basic principles of PMTCT, implementing small changes and streamlining processes and setting specific goals or timelines, can lead to significant improvements in care, which ultimately will lead a decrease in PMTCT of HIV and HIV related maternal and infant morbidity and mortality.

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- Dr J Harvey, statistician
- Dr CA Oettlé, consultant, Worcester Hospital
- Mrs H Hanmer, ward clerk, Worcester Hospital

ADDENDUM A: Stamp

RVD: Reactive/Non-Reactive

HAART: Y/N

Regime.....

AZT: Y/N when in labour:

AZT 3hrly.....

sdNVP..... Truvada.....

ADDENDUM B: Data Capturing Form

STUDY NUMBER: WH / MOU

Booking information:	<ul style="list-style-type: none"> • Date: • Gestation: • Method: U/S, LMP, SFH
HIV status:	+ / - / unknown
Date diagnosis of HIV was made:	<ul style="list-style-type: none"> • Before pregnancy: • During pregnancy:
CD4 count:	<ul style="list-style-type: none"> • Date blood was taken: • Date result given to patient: • Result: • If indicated, date for 1st ID clinic visit:
ARV Therapy:	<ul style="list-style-type: none"> • Treatment: AZT / HAART / unsure / no treatment given • Date treatment started: • Gestation treatment started: • HAART regimen noted on ANC card: <input type="checkbox"/>
Intrapartum:	<ul style="list-style-type: none"> • Duration of treatment before delivery: • Treatment given before delivery: <ol style="list-style-type: none"> 1. Only sdNVP 2. AZT/NVP/Truvada 3. Nothing documented
Postpartum:	<ul style="list-style-type: none"> • Type of neonatal feeding: Breast milk / Formula milk • Neonatal ARV therapy commenced: <input type="checkbox"/>
Family planning:	

ADDENDUM C: Copy of Ethics Approval Letter



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16 May 2011 **MAILED**

Dr E van Niekerk
PO Box 5556
Worcester West
6862

Dear Dr van Niekerk

Evaluation of Quality Improvement Cycle Intervention in the Provision of PMTCT at a Regional Hospital.

ETHICS REFERENCE NO: N10/12/403

RE : APPROVAL

A panel of the Health Research Ethics Committee reviewed this project on 7 February 2011; the above project was approved on condition that further information is submitted.

This information was supplied and the project was finally approved on 15 May 2011 for a period of one year from this date. This project is therefore now registered and you can proceed with the work.

Please quote the above-mentioned project number in ALL future correspondence.

Please note that a progress report (obtainable on the website of our Division: www.sun.ac.za/rds) should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly and subjected to an external audit. Translations of the consent document in the languages applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239
The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Hélène Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

Approval Date: 15 May 2011 Expiry Date: 15 May 2012

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Yours faithfully,

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14 October 2011 12:42

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