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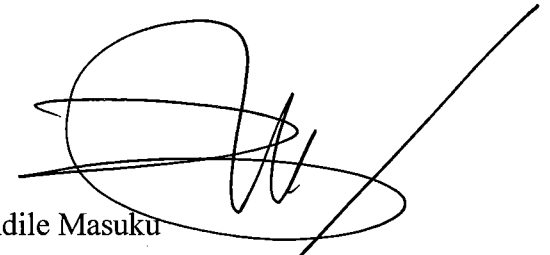
Dissertation for M Med (Obstetrics and Gynaecology)

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Supervisor: Prof Eckhart Buchmann

DECLARATION

I, Bandile Masuku, declare that this research report is my own work. It is being submitted to the Colleges of Medicine of South Africa in partial fulfilment of the requirements for the qualification of Fellowship of the College of Obstetrics and Gynaecology. It is also being submitted for the degree of Master of Medicine in the branch of Obstetrics and Gynaecology in the University of the Witwatersrand, Johannesburg.



Bandile Masuku

Date 1 | 2 | 16

DEDICATION

I dedicate this work to my fiancée Loyiso Lugayeni, my parents especially my late father Raymond Musa Masuku and my sons Amukelani and Zibuse, for their patience and support.

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ABSTRACT

Background

A pregnant woman is considered to have a prolonged pregnancy when her pregnancy has extended beyond 42 gestational weeks. The diagnosis of prolonged pregnancy is difficult to make especially when these women are not sure of their last menstrual period or never had early pregnancy ultrasounds scan.

Objectives

The aim of this study was to determine the appropriateness of referral and the pregnancy outcomes of women referred to CHBAH for prolonged pregnancy.

Methods

This was a secondary analysis of data from a cross sectional study on "***predictive ability of clinical palpation for estimating amniotic fluid volume in suspected prolonged pregnancy"***, considering the gestational age at the time of referral.

Results

One hundred women were recruited. Fifty-five of them were found to be inappropriately referred while 45 were found to be appropriately referred with no statistical difference between the two groups.

Conclusion

The majority of the referrals were inappropriate.

1. BACKGROUND AND LITERATURE REVIEW

1.1 Introduction

The diagnosis of a post-term pregnancy is made when a pregnancy extends beyond 42 weeks or 294 days of gestation from the first day of the last menstrual period (LMP) or beyond 14 days of the best determined obstetric estimate of the date of delivery (EDD).[1,2] Prolonged pregnancy is used interchangeably as synonyms to post-term.

Categorization of gestational age has been a subject of debate for many years. Though recently there has been consensus in the definitions, which are as follows ***"term"*** is defined as 37 to 41 completed weeks, ***"preterm"*** as less than 37 weeks and ***"post-term"*** as 42 or more completed weeks. Recently, there has been better insight into foetal physiology and the realisation of gestational age as a continuum, and it has been noted that infants born before 39 weeks may suffer significant morbidity. Therefore, the descriptions of ***"late preterm"*** as 34 completed weeks to 36 weeks 6 days, and **"*early term"*** from 37 weeks completed weeks to 38 weeks 6 days have been suggested; "**full term"** being 39 weeks through 40 weeks 6 days and "**late term"** being 41 weeks through 41weeks 6 days. [3,4,5,6]

The term "***post-dates"*** has no robust definition, and will be avoided altogether in this research report.

The frequency of post-term pregnancy varies from country to country, and has changed with time. In the United States, for example, the frequency of pregnancies at 41 weeks or more fell from 19.6% to 13.9% from 1997 to 2007. Similarly, the frequency of pregnancies at 42 weeks or more fell from 7.8% to 5.6 % in the same time period.[2,3,5]

This drop could have occurred for a number of artefactual reasons, including better ascertainment of gestational age using early pregnancy ultrasound, more frequent delivery

at 38 to 39 weeks for primary elective caesarean section, and greater numbers of inductions of labour before 41 weeks.[3] There are few reports of the frequency of post-term or prolonged pregnancy in South Africa.

Of note, the National Basic Antenatal Care guidelines instruct midwives in MOU to refer all the pregnant women who have an estimated gestational beyond 40 weeks 6 days for further management in hospital either for induction of labour or for conservative management. [7]

Unpublished data from a study of 416 women in Gauteng Province who had early second-trimester ultrasound scans, found that the proportion of post-term pregnancies by LMP was 3.6%, and by ultrasound scans, 1.4%.[8]

The influence of gestational age estimation using various methods and the chance of erroneous diagnosis of prolonged pregnancy will be discussed further.

1.2 Causes and risk factors

The most common cause of apparent prolonged pregnancy is wrong dates where the LMP is used for gestational age estimation. This information is usually given by the pregnant woman at the first antenatal visit, although the "true" causes of prolonged pregnancy are poorly understood. Some of the rare causes have a sound physiological basis, such as placental sulphatase deficiency characterised by low circulating estriol levels, fetal adrenal hypoplasia, and fetal anencephaly. In all these cases, there is failure at some stage of the fetal-placental steroid hormone release and synthesis.[2] Prolonged pregnancy has been found to be more commonly associated with male fetus including paternal genes expressed in the fetoplacental unit.[2,3]

Obesity and primiparity have also been implicated in causing prolonged pregnancy. Obesity would appear to have an endocrine element in the causation of prolonged pregnancy.[9-11] Hilder, et al. concluded that being parous appeared to have a protective effect on fetal mortality in prolonged pregnancy.[9]

There is evidence to suggest that women who are born from a prolonged pregnancy are more likely to have prolonged pregnancies themselves with a relative risk of 1.3. Those who have had a prolonged pregnancy are also more likely to have another in a subsequent pregnancy, with the incidence being calculated to increase 2.7 fold for a second pregnancy and 3.9-fold after two successive prolonged pregnancies.[1,10,11]

1.3 Adverse perinatal outcomes

Prolonged pregnancy is associated with increased risks of adverse perinatal outcomes.[1,2] These risks were initially underestimated, as earlier studies were done before the increased use of ultrasound to determine EDD, and were likely to include pregnancies that were not truly prolonged, thus giving a falsely low complication rate. The other reason for underestimation relates to definitions of stillbirth rates that were calculated using all pregnancies delivered at given gestational age as the denominator, forgetting that the newborn, having been delivered, is no longer at risk of stillbirth. The correct denominator now used is ongoing pregnancies.[12-17]

Using ongoing pregnancies as the denominator, Hilder, et al. demonstrated a six-fold increase in stillbirth rate from 0.35 at 37 weeks of gestation to 2.12 per 1000 at 43 weeks.[17] Stillbirths in these figures account for more perinatal deaths than sudden infant death syndrome and prematurity, thus suggesting that delivery of these babies would have resulted in reduced total mortality. Perinatal mortality exponentially increases from 40

weeks; for example, at 42 weeks it is twice that of 40 weeks, and is similarly fourfold at 43 weeks and 5 to sevenfold at 44 weeks.[5,17-19] The high rates of perinatal death result from uteroplacental insufficiency, intrapartum asphyxia, fetal macrosomia, meconium aspiration syndrome, intrauterine infection, and, to a small extent, anencephaly.[2,19]

1.3.1 Fetal effects

a. Macrosomia

Macrosomia, when defined as birth weight of 4500 g or more, occurs three times more frequently at 42 weeks than at 40 weeks, resulting from continuing placental function and fetal growth beyond term. "Big baby", as macrosomia is known, is associated with maternal anxiety, cephalopelvic disproportion, and shoulder dystocia with resultant orthopaedic and neurological injury.[2,20] With shoulder dystocia, the most serious neurological concern, with potential for significant permanent disability, is brachial plexus injury.[20]

b. Oligohydramnios and intrapartum asphyxia

Oligohydramnios in post-term pregnancy occurs due to placental insufficiency and becomes more frequent as pregnancies prolong. Intrapartum asphyxia is associated with underlying placental insufficiency resulting in inadequate placental perfusion associated with uterine contractions. Oligohydramnios may result in umbilical cord compression, meconium passage and meconium aspiration syndrome. Consequently, there is an increased risk for further neonatal complications such as seizures, hypoglycaemia and respiratory distress. Prolonged pregnancy is an independent risk factor for neonatal encephalopathy and infant death.[17-19, 22]

c. Foetal dysmaturity syndrome

Fetal dysmaturity syndrome occurs in 20% of prolonged pregnancies. The condition is the post-term equivalent of intra-uterine growth restriction. Such newborns appear similar to growth-restricted babies, but in addition give the impression of being very alert, tall and thin with dry scaly skin and long nails, often chronically stained with meconium[2,5]. Extreme cases may have advanced skull ossification.[22] Antenatal care with fetal surveillance has contributed to the condition becoming rare in recent years, with these babies being delivered before they reach this advanced stage.

1.3.2 Maternal effects

The maternal risks of prolonged pregnancy are often interlinked with fetal risks; for example, with macrosomia increasing the likelihood of dystocia with need for caesarean section or severe perineal injuries, especially third and fourth degree tears. Haemorrhage, infection and thromboembolic disease may result.[2] Maternal morbidity as is measured by chorioamnionitis, severe perineal laceration, caesarean section delivery rates, postpartum haemorrhage endomyometritis also show an increase with prolonged pregnancy.[23]

The psychological aspects of prolonged pregnancy are often underestimated. Maternal anxiety, confusion and frustration are common.[20,22]

1.4 Management

Timely and appropriate management of prolonged pregnancy determines the perinatal outcomes, and should, in theory, reduce the risks discussed above. By and large, the management of prolonged pregnancy depends on the best estimation of the gestational age, as this would impact on the decision whether to deliver electively or wait for spontaneous labour. The well-being of the fetus also plays a role in that decision. As discussed above,

accurate determination of the gestational age is central in the diagnosis of prolonged pregnancy.

1.4.1 Determination of gestational age

Determining gestational age is crucial to the general management of the pregnant woman. This applies in many clinical situations, whether it should be the decision on when to give Rh immune globulin, when to perform a glucose tolerance test, or when to give antenatal corticosteroids for lung maturity or when to time elective delivery.[23] The diagnosis of a prolonged pregnancy relies very heavily on accurate determination of gestational age. Different methods have been formulated to accurately derive gestational age.

a. Last menstrual period

The commonly used Naegele's rule was developed in the 19th century to calculate the EDD in pregnant women with a normal 28-day menstrual cycle by counting back three calendar months from the first day of the LMP and then adding one week.[18,25-27] However, Naegele's rule does not consider different lengths of months and consequently suffers from some imprecision. Furthermore, the rule has been found to be somewhat unreliable because it depends on several factors: 1) the woman's memory to recall her LMP; 2) the woman's knowledge of her menstrual cycle regularity and length; 3) the presence of early or light bleeding; and 4) factors that influence ovulation such as breast feeding and contraception use.[25-27]

Gestational calculators have advanced over the years modifying Naegel's rule; the most popular of them all is the obstetric 'wheel'. The obstetric 'wheel', commonly used by obstetricians and midwives to determine the gestational age and EDD, uses the first day of the LMP as its reference point and then counts days through the calendar to an EDD at 280

days. This eliminates the imprecision of Naegele's rule in terms of different lengths of months, but still suffers from inaccuracies related to the LMP, cycle length, and irregular bleeding.

A problem specific to obstetric wheels is that there may be up to five day differences between different wheels as they are manufactured by different pharmaceutical companies.[25,28,29] Obstetric wheels should be carefully checked before use. In the age of technology, the obstetric wheels are giving way to downloadable applications on smart phones designed to calculate gestational estimation with more precision. The smart phones applications have been found to be more precise than obstetrics 'wheels' and are abundantly accessible to many health professionals as they already possess them.

There are other methods and formulae developed to determine an accurate EDD like the PREM Rule. In this rule, a pregnant woman has to determine the first day of the upward thermal shift in body temperature minus seven days plus nine months. Nonetheless, this rule cannot be applied to most pregnant women as very few would be aware of, or even be interested in, their thermal shift or let alone own thermometers.[30, 31]

There is also a suggested formula by Parikh that is meant to supplement Naegele's Rule to make it more accurate. Naegele's rule is dependent on the duration of the menstrual cycle which averages 28 days, but ranges from 20 to 45 days even in healthy women.[32] As mentioned above, there is inherent potential for error when determining EDD with Naegele's Rule (or using an obstetrical wheel or smart phones applications), whenever cycle length is not 28 days.

The Parikh formula takes the duration of the cycle as a variable. The adjusted formula is as follows: the EDD is the LMP plus 9 months plus a difference between the duration of the

previous cycle and 21 days. For example, if the cycle length was 34 days, the formula would read: EDD = LMP + 9 months + (34-21) days. This is based on the fact that the luteal phase remains more or less constant in all cycles at around 14 days and the duration of the follicular phase in longer or shorter cycles varies making it equal to duration of the previous cycle minus 14 days. Although the formula seems to make sense, it still requires validation.[32-34]

b. Ultrasound scanning

Ultrasound scanning has become the most popular and best-validated method of determining gestational age in high-income countries and is highly recommended by different professional authorities such as ACOG and RCOG through NICE Guidelines. The earlier the ultrasound scan is done in pregnancy, the more precise is the gestational age estimate. In the first trimester, gestation is determined by measuring crown-rump length (CRL). The benefit of early gestational age estimation is based on the assumption that human embryos have parallel growth in early pregnancy, meaning first trimester embryos of the same size have the same age.[37, 38]

Not only is there parallel growth in early pregnancy, but ultrasound gestational age estimation is very time-exact, with an 8% margin of error irrespective of the gestational age, according to the regression analysis by Hadlock.[39-41] Therefore, variation of ultrasound calculated gestation by LMP is accepted to be ±7 days up to 20 weeks, ±14 days between from 20 to 30 weeks and ±21 days beyond 30 weeks of gestation. Knowledge of the 8% rule is helpful when trying to assess the approximate error in individual cases where there is discrepancy between LMP and ultrasound gestational age. For example, if the LMP is 13/01/2012 then the EDD is 20/10/2012 by Naegele's rule. An ultrasound scan done on 1/07/2012 makes the gestation 21 weeks and one day with an EDD of 10/11/2012 and a

discrepancy of 20 days. In this case, the ultrasound gestational age can be converted to 148 days and multiplied by 0.08 to yield a margin of error of 11.8 (=12 days).

The conclusion is that the EDD obtained from LMP is unlikely to be correct, as the discrepancy falls outside the margin of error of 12 days. Therefore, the ultrasound gestational age is accepted, and the LMP-based gestational age is rejected.

In the United Kingdom, the National Institute of Clinical Excellence (NICE) guidelines recommend that an ultrasound scan be done for a pregnant woman between clinically estimated gestational age of 10 and 13 weeks, to determine gestational age. The next-best estimate for gestation is in the second trimester, using foetal biparietal diameter (BPD).

This measure was first introduced in 1969 by Campbell, as a reliable best estimate of the gestational age in the second trimester. Several studies have since confirmed the CRL, BPD or even the femur length (FL) as reliable best estimates of gestational age.[43]

Taipale, et al.[44] found that early ultrasound scanning was more accurate in determining gestational age than using LMP. Several studies have confirmed the accuracy of ultrasound in determining EDD, among others, the Swedish Birth Registry study which included over 1.2 million births, and showed that performance of early dating ultrasound reduced the rate of post-term birth from 13.3% to 7.4%, thanks to more accurate gestational age estimation.[45] In a study comparing pregnancy dating by last menstrual period, ultrasound scanning or their combination, Savitz, et al., found that using early pregnancy ultrasound scanning for dating was far more accurate, particularly where doubt exists.[46]

The use of early ultrasound in determining EDD reduces the number of pregnant women diagnosed with prolonged pregnancy,[44] as compared to the ones using LMP. In addition, it

reduces false-positive diagnosis, thereby reducing the overall rate of prolonged pregnancy from 10 % to around 3% and minimizing intevention.[45]

A recent meta-analysis concurred on the overall reduction of inductions of labour for prolonged pregnancy, for women who had ultrasound dating before 24 weeks.[47]

Standard clinical criteria, as proposed in the American College of Obstetrics and Gynaecology (ACOG) Practice Bulletin No 146 which replaced Practice Bulletin No 55 of 2004 recommends the utilisation of both LMP and ultrasound to best estimate gestational age and the ultrasound being the one that is more accurate[6].

1.4.2 Prolonged pregnancy management

After determining the gestational age, the next important issue is the management of the period towards delivery and the timing of delivery. These two decisions are dependent on the risks to the fetus if the pregnancy is prolonged, as discussed earlier. These concerns motivate the belief that pregnancies should not be allowed to progress to 42 weeks. Delivery is therefore favoured, at the very latest, 41 weeks of gestation.[2]

A Cochrane systematic review by Gulmezoglu, et al., involving 16 trials with a total of 6588 participants, showed that routinely inducing labour at 41 weeks reduces the risk of perinatal death of normally formed fetuses.[48] The Cochrane systematic review found that the absolute risk reduction in terms of perinatal death was however small, with 500 inductions required in women after 41 weeks of gestation to prevent one perinatal death. It should be noted that labour induction is not done to reduce prolonged pregnancies *per se*, but it is meant to improve perinatal outcomes[49].

The question that always arose is: "When the induction should be performed? Historically, the single largest randomized trial on management of post-term pregnancy was the Canadian Multicenter study, which randomly assigned 3407 women with low risk, uncomplicated, singleton pregnancies at or after 41 weeks gestation to either induction of labour or expectant management, up to 44 weeks.[50] The results showed that the induction of labour group had a statistically significant lower incidence of intrapartum fetal distress and a lower caesarean rate than the expectant management group. Hence, and given the results of systematic reviews, [48,51] it has become common practice that induction of labour, in low risk patients, where there are no contraindications to induction, should be done at 41 weeks. This has been affirmed recently by Oros, et al. in their paper entitled Low-risk pregnancy at 41 weeks: When should we induce labour? They concluded that induction of labour from 41 weeks reduces the proportion of babies born with small-for-gestational age though it increases hospital stay as well as delivery by caesarean section especially for failed induction.[52]

The alternative to induction of labour beyond 41 weeks is expectant management. This involves frequent repeat assessments with ultrasound scans and cardiotocography, making it costly.[50] Patient inconvenience, with bi-weekly visits to the clinic with the accompanying anxiety, must also be considered. Where available, expectant management can however be regarded as an appropriate alternative to induction in low-risk pregnancies that have passed 41 weeks of gestation.[53] Women should be counselled carefully about the benefits and risks of expectant management so that they can make truly informed choices.

Antenatal fetal surveillance, while not a preventative strategy, is intended to detect uteroplacental insufficiency so that those women who need induction or early delivery can be detected. When there is evidence of fetal compromise such as, non-reassuring non-stress

testing (NST), or oligohydramnios, delivery should be advised immediately, as these findings are associated with poor perinatal outcomes.[2,6]The surveillance package for expectant care of prolonged pregnancy may include NST, amniotic fluid volume assessment, biophysical profile and sometimes the oxytocin challenge test. These tests can be performed individually or in combination, and there is no consensus over the superiority of each test or a combination of tests.[6] Invasive procedures such as, amnioscopy and amniocentesis, have been largely abandoned.

However, expectant management is associated with an increased risk the intrauterine death and neonatal death overall increasing perinatal mortality. The results of the Scottish population analysis show that waiting for spontaneous labour is associated with perinatal mortality than for induction of labour.[54]

There is no validated published method for determining oligohydramnios clinically by palpation. This was the subject of the primary study from which this secondary data was collected. The primary study found that clinical palpation is a poor predictor for oligohydramnios, but that presenting part ballottement inside the lower part of the uterus, if found, gives 90% assurance of normal liquor volume (defined as an amniotic fluid index (AFI) greater than 5 cm).[55]

On ultrasound scanning, there is no consistent definition for oligohydramnios in prolonged pregnancy. Suggested definitions are most frequently the deepest vertical pool less than 2 cm, or an AFI less than 5 cm.[56] Morris, et al. in their double-blind cohort study of 1584 women after 40 weeks' gestation found that an AFI less than 5 cm, not the deepest vertical pool less than 2 cm, was associated with birth asphyxia and meconium aspiration, although the sensitivity was low.[57] Other authors contend that the deepest vertical pool is the better

measurement, because of the high false positive rate of the AFI, which appears to over-diagnose oligohydramnios.[58]

There is no enough evidence that finding a cervical Bishop score of more than six (6) for favourability would yield a better outcome for women that undergo induction of labour. In the setting of an unfavourable cervix, both expectant management and induction of labour are associated with low complications rates in low risk women with prolonged pregnancy. However, there seems to be an advantage for induction of labour using cervical ripening agents in the absence of contraindications to induction, regardless of parity or method of induction.

Ultrasound measurements of cervical length was found to be a useful predictor of the successful induction of labour suggesting that measurements of the cervical length at 37 weeks gestation can predict the likelihood of the prolonged pregnancy and risk of emergency caesarean section.[59]

Historically, it has been has been believed that induction of labour potentially increases the caesarean section rate. However, results of recent randomised trials have contradicted this belief by showing either decreased or equivalent caesarean delivery rates in women undergoing induction compared with expectant management.[50,60,61]

1.5 Management of prolonged pregnancy in poorly-resourced settings

South African government health institutions serve indigent patients and patients from working class backgrounds. Given the resource problems in these institutions, the local setting is typically poorly-resourced. There is no published work on the management of prolonged pregnancies in South Africa; so, the comments here represent local experience only.

Prolonged pregnancies present a dilemma because many of the women continue to be referred from clinics to hospital for this reason and it is uncommon for them not to have certain gestational dates and have not had ultrasound scans early in their pregnancies. Therefore, clinicians may regard a history of prolonged pregnancy with suspicion. Even the calculations of gestational age made by staff at community clinics are sometimes inconsistent and erroneous owing to poor history taking that will assist in estimating the gestational age. In most instances, a detailed history with appropriate recalculation or re-evaluation of the last menstrual period eliminates a large portion of these women as having a prolonged pregnancy. A number of strategies are available to minimise prolonged pregnancy and its sequel.

Membrane sweeping performed during early term is a procedure which has been found to reduce the prevalence and the incidence of prolonged pregnancy especially in low resource settings. Of note though it would require performing the procedure in 8 women to prevent one prolonged pregnancy.[62]

A common practice in South Africa in women with unconvincing evidence of prolonged pregnancy is to assess foetal movements, amniotic fluid volume and cervical favourability including membrane sweeping. If the movements and amniotic fluid volume are normal and the cervix is unfavourable, ask the woman to observe her foetal movements and re-evaluate weekly if delivery has not occurred. Reduced movements, reduced amniotic fluid volume or a favourable cervix would be indications for induction.[63] This practice has not been scientifically evaluated.

Even when a decision has been made that a woman is most likely to be at 41 or more weeks of gestation, the management dilemma moves to induction or expectant management. Induction may be hazardous because of shortage of foetal monitoring equipment or

overcrowding in the labour ward, and expectant care may be difficult, again because of shortage of monitoring equipment.

2. PROBLEM STATEMENT

Chris Hani Baragwanath Academic Hospital (CHBAH) is a high-risk referral unit that manages women referred from midwife-run clinics in and around Soweto. Such referrals include women suspected to have prolonged pregnancy. According to the National 'Basic Antenatal Care' (BANC) Protocol, referrals are made when a woman reaches 41 completed weeks of gestation. The referrals may be based on ultrasound evidence, on menstrual dates, or on clinical palpation and measurement of the uterus. Local experience suggests that many of these referrals are inappropriate, with errors made in gestational age estimation by the referring staff. Clinicians at CHBAH frequently have to correct these estimates, often causing anxiety or disappointment to the pregnant women who are told at the clinics that their pregnancies are 'overdue'.

It would be useful to quantify the extent of inappropriateness of referrals for prolonged pregnancy, and determine how gestational age is determined, and if necessary, corrected at referral. This would assist in training and retraining of staff in terms of referral for prolonged pregnancy.

3. AIMS AND OBJECTIVES

The aim of the study was to determine the appropriateness of referrals made to CHBAH of women suspected to have prolonged pregnancy and further evaluate the management and the perinatal outcomes of those women. An "appropriate" referral was one where the best estimate of gestational age was 41 weeks or more.

The specific objectives were:

- to describe demographic and obstetric characteristics of women referred to CHBAH for suspected prolonged pregnancy.
- to determine the best estimate of gestational age in women referred to CHBAH for suspected prolonged pregnancy, and the method of estimation in each case, with reference to amniotic fluid volume and cervical Bishop score.
- to describe the clinical outcomes of the pregnancies: mode of delivery, neonatal admission and perinatal death.

4. METHODS

4.1 Study design

This was a secondary analysis of data from a prospective cross-sectional study on "***The predictive ability of clinical palpation for estimating amniotic fluid volume in suspected prolonged pregnancy".*** The primary study was conducted at CHBAH with data collection from 1 July 2011 to 30 September 2011. The aim of that study was to determine if clinical estimation of amniotic fluid volume in prolonged pregnancies would provide the same results as ultrasound estimation of amniotic fluid volume. The findings have been published.[54] The primary researcher also collected data on gestational age assessment, clinical management, and final perinatal outcome. These data were used in the secondary analysis.

4.2 Setting

CHBAH provides referral facilities to about 58 midwife-run antenatal clinics in the surrounding areas of Soweto, Orange Farm and Lenasia. Routine antenatal care is conducted at the clinics, and problem cases are referred to the unit at CHBAH. All pregnancies suspected to have passed 41 completed weeks of gestation are referred as problem cases. The antenatal clinic services in the district do not offer routine early pregnancy ultrasound scanning. However, private medical practitioners are sometimes consulted by pregnant women, and frequently perform pregnancy ultrasound scans.

The CHBAH obstetric protocol on "postterm pregnancy" states that:[61]

This is pregnancy exceeding 41-42 weeks. The most serious associated problems are intrapartum related birth asphyxia and meconium aspiration. Many suspected post-term pregnancies are referred to hospital from their local clinics.

The management is as follows:

- ***Ensure that the gestational age has been correctly calculated;***
- ***A report from an early ultrasound scan (≤24 weeks) provides convincing evidence of correct gestational age;***
- ***If there is certainty about gestational age, induce labour; and***
- ***If there is uncertainty about gestational age:***
    - ***Induce labour if there is reduced foetal movement, reduced liquor volume, or a favourable cervix;***
    - ***Do not induce labour if foetal movement and liquor volume are normal, and the cervix is unfavourable for induction.***

Protocol points 3 and 4 are not specific, but intend to state that if there is certainty about gestational age being ≥41 weeks, induction of labour should be considered, and that if there is certainty about gestational age being <41 weeks, induction should not be considered (personal communication - Prof E Buchmann).

Induction of labour is performed using low-dose two-hourly titrated oral misoprostol if the cervix is unfavourable on Bishop score (<6-8), or oxytocin infusion in the labour ward, with artificial rupture of membranes of the woman is HIV-uninfected. **The low dose oral misoprostol is prepared by using 200 microgram of misoprostol diluting in 200 millilitres (ml) and give 10 millilitre of the solution every 2 hours for 24 hours. This is performed with foetal monitoring being done 4 hourly with a cardio-tocograph.**

Whereas oxytocin infusion is prepared by diluting 2 international units of syntocinon in 1 litre of ringer lactate, starting it off from 60ml increasing it every 15 minutes till 240ml is reached and is continued till delivery.

4.3 Study population

These were all women referred from midwife-run clinics for the sole reason of a suspicion of prolonged pregnancy (41 or more completed weeks of gestation), irrespective of parity. Only singleton pregnancies with living babies were included. Women under the age of 18 years, or who had diabetes mellitus or pre-labour rupture of the membranes, or previous caesarean sections, were also excluded. These women were excluded in the primary study on the basis that they require specific management protocol that is different for prolonged pregnancy and have determined indications and the timing of delivery and including the mode of delivery. All participants were recruited at the CHBAH antenatal clinic.

4.4 Sampling and sample size

A sample of eligible women was drawn on days that the researcher of the primary study was attending the antenatal clinic. On each morning, the researcher recruited the first four women presenting as referrals for prolonged pregnancy. On some days, there were not sufficient women in the referral queue at recruitment, so less than four women were at times recruited. Recruitment to participate in the study took place for 28 days. The total sample size was 100 women, based on a power calculation for significance of expected sensitivity and specificity of clinical palpation for amniotic fluid volume in the primary study.

4.5 Data collection

In the primary study, the researcher verified or refuted prolonged gestation by interrogation of the history of the LMP, and by asking about ultrasound examinations done (private doctors or public service), and by studying the antenatal records. As much as these women are referred from clinics, some have had ultrasound examination from independent general practitioners to confirm pregnancy and sometime for dating.

Estimates of gestational age based on LMP were done using Naegel's rule. For each woman, a "best estimate" of gestation was made as follows:

- The presence of an early ultrasound scan result (≤24 weeks) was taken as the best gestation;
- In the absence of early ultrasound scan, sure menstrual dates were accepted;
- In the absence of either LMP or early ultrasound scan, a late ultrasound scan (>24 weeks but <36 weeks) was accepted as a best estimate; and failing that,
- the initial clinical assessment of the midwives at the first antenatal visit was used. Women's self-reporting of private ultrasound scans was accepted in the absence of documentation of such scans. At the prolonged pregnancy referral visit in the primary study, ultrasound scans were done by a qualified ultrasonographer in all cases to determine estimated fetal weight and amniotic fluid volume, but not gestational age. Amniotic fluid volume was estimated using the four-quadrant amniotic fluid index (AFI), measured twice and averaged. An AFI <5 cm was considered as oligohydramnios. A cervical assessment was made for the Bishop favourability score and, where the cervix was sufficiently open, a "stretch and sweep" procedure was done in the hope of bringing forward the onset of labour. The researcher decided on a management plan, based on the CHBAH clinical protocols, either admission for elective delivery, or continued antenatal care with delivery either at CHBAH or the clinic.

The date of giving birth, the mode of delivery, the birth weight and the immediate perinatal outcome was determined by tracking data in the birth registers at CHBAH and the midwife obstetric units (MOUs) in Soweto, Orange Farm and Lenasia. Additional detail, if needed, was obtained from the neonatal unit records or the maternal case-files. A copy of the data sheet is attached as Appendix A.

4.6 Data analysis

For the secondary analysis, the data were extracted from the primary data and analysed in Stata 11 software (Statacorp, College Station, Texas). Descriptive data analysis was done using means ± standard deviations, medians with ranges and interquartile ranges where appropriate, and frequencies presented as percentages. Where comparisons of frequencies were made, Fisher's exact test was used. Where necessary, comparison of frequency distributions was done using Student's t-test for normally distributed variables or the Wilcoxon ranksum test for non-normal distributions. P values of less than 0.05 were considered to indicate statistical significance.

4.7 Ethics Approval

This secondary study received approval from the University of the Witwatersrand's Human Research and Ethics Committee, approval number **M 111133** attached as **Appendix B,** separately from the primary study which received its own approval.

5. RESULTS

5.1 Demographic and obstetric characteristics

The data were obtained from 100 eligible women from the primary study. The mean age of the women was 25.7±6.0 years, with a range of 18-45 years. Forty-four women were nulliparous and the highest parity was 5 (Table 1). The mean body-mass index was 28.1±4.9 kg/m^2 with a range of 19.3-45.8. Twenty women were HIV-infected, of whom 13 were receiving highly-active antiretroviral therapy (HAART). Although all women were referred for the sole reason of prolonged pregnancy, 10 were found to be hypertensive (systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg). One of these women had severe pre-eclampsia and required immediate admission to the obstetric high care unit.

Table 1. Parity of women referred for suspected prolonged pregnancy (n=100)

Para	**Number**
0	44
1	36
2	14
3	3
4	2
5	1

5.2 Gestational age estimation

The mean gestational age by LMP was 40.2±2.2 weeks with a range of 29-48 weeks (Table 2). Fourteen women could not recall their LMP. Thirty-eight women were 41 or more weeks' pregnant according to their LMP.

Table 2. Gestational age by LMP in women referred with suspected prolonged pregnancy (n=86)

Gestational age in weeks	Number	%
29	1	1.2
36	1	1.2
37	2	2.3
38	10	11.6
39	11	12.8
40	23	26.7
41	26	30.2
42	1	1.2
43	8	9.3
44	1	1.2
45	1	1.2
48	1	1.2

The methods for best estimate of gestational age are shown in Table 3. Early pregnancy ultrasound (≤24 weeks) was available in 26 women. In 13 women, there was no ultrasound scan and the LMP was uncertain, so that "other methods" were used. Other methods include the first symphysis fundal height (first palpation) noted by midwives in the antenatal cards. It is an acceptable method of estimating gestational age and sometimes quickening is used.

Sixty-five of the women did not have any form of ultrasound done in their pregnancies. Out of the 35 who had ultrasound scans, 23 had their scans done by private doctors, and 12 by practitioners in public hospitals. The mean gestational age from the best estimation was

39.9±1.5 weeks with a range of 34-43 weeks. Forty-five women had best estimate gestation ≥41 weeks, with five of these ≥42 weeks. These 45 were considered as 'appropriate' referrals, judged only on the grounds of the reason for referral being prolonged pregnancy. Twenty-seven women were 40 weeks pregnant, and the remaining 28 were 39 weeks pregnant or less.

Table 3. Method of best estimate of gestational age in women referred for prolonged pregnancy (n=100)

Method	**Number**
Early ultrasound	26
LMP	52
Late ultrasound	9
Other	13

Twenty-two of the 26 women who had a best estimate by early ultrasound had their scans done by private doctors. Sixteen of the 26 women (61.5%) with early ultrasound scan results had gestational ages less than 41 weeks on the day of referral (Table 4).

Table 4. Gestation age determination on the day of referral for prolonged pregnancy, using early pregnancy ultrasound scans (n=26).

Best estimate of gestation age in weeks	Number	%
35	1	3.9
36	1	3.9
37	1	3.9
38	2	7.7
39	3	11.5
40	8	30.8
41	9	34.6
42	1	3.9

In the women whose best estimate of gestational age was based on LMP (n=52), 32 (62%) had gestational ages of 40 or less completed weeks on the day of referral (Table 5). Conversely, in women whose best estimate of gestational age was based on late pregnancy ultrasound scan (>24 weeks) (n=9), five (56%) were 40 or less weeks pregnant on the day of referral (Table 6). For women whose gestation was determined by "other" methods (n=13), two (15.4%) had best estimates of gestational age of 40 weeks or less (Table 7).

Table 5. Gestational age determination on the day of referral for prolonged pregnancy, using last menstrual period (n=52)

Best estimate of gestational age in weeks	Frequency	%
37	2	3.9
38	6	11.5
39	8	15.4
40	16	30.8
41	18	34.6
42	1	1.9
43	1	1.9

Table 6. Gestational age determination on the day of referral for prolonged pregnancy, using late ultrasound scan (24 weeks) (n=9)

Best gestation age	Frequency	%
34	1	11.1
36	1	11.1
39	1	11.1
40	2	22.2
41	4	44.4

Table 7. Gestational age determination on the day of referral for prolonged pregnancy, using methods other than ultrasound scan or last menstrual period (n=13)

Best gestation age	Frequency	%
39	1	7.7
40	1	7.7
41	9	69.2
42	2	15.4

The mean AFI measurement was 8.1±4.3 cm, with a range of 0-22.5 cm. Twenty-three women had oligohydramnios (AFI <5 cm). Amniotic fluid volume was not statistically significantly associated with gestational age at a cut-off of 41 weeks, either as a mean AFI or as oligohydramnios. A trend to lower AFI in pregnancies ≥41 weeks was however observed (Table 8).

Table 8. Comparison of amniotic fluid index (AFI) findings according to best estimate of gestational age

Best estimate of gestational age in weeks	**Mean AFI (cm)**	**Oligohydramnios (AFI <5 cm)**
<41 (n=55)	7.3 ± 4.5	9 (16.4%)
≥41 (n=45)	8.7 ± 4.0	14 (31.1%)
P value for difference	0.08 (Student's t-test)	0.10 (Fisher's exact test)

The Bishop score could be determined in 90 women, with 10 women resisting or declining cervical assessment on vaginal examination. The median Bishop score was 5 (interquartile range 4 – 6). Eleven women (12.2%) had a Bishop score of 8 or more (Table 9). There was no difference in Bishop scores between women who were ≥41 weeks and <41 weeks on best estimate of gestational age. In both groups, the median Bishop score was 5 (Wilcoxon ranksum test, P=0.20).

Table 9. Bishop cervical favourability score findings in women referred for suspected prolonged pregnancy (n=90)

Bishop Score	Frequency	%
2	2	2.2
3	15	16.7
4	16	17.8
5	24	26.7
6	13	14.4
7	9	10.0
8	5	5.6
9	4	4.4
10	1	1.1
11	1	1.1

5.3 Obstetric management and outcomes

Forty-four women were admitted for delivery at the referral visit, with 10 of them because of co-existent hypertension. Of the remaining 34 who were admitted, 25 had a best estimate of gestational age of ≥41 weeks and nine had either a reduced AFI, reduced fetal movements, or a poor obstetric history. The 56 women who were not admitted included 15 who had a best gestation of ≥41 weeks but had no early pregnancy ultrasound scan and had normal AFI, and one who was 41 weeks pregnant on early ultrasound scan but declined induction of labour. The remaining 41 who were not admitted were <41 weeks pregnant by best estimate with normal AFI and no co-morbidities or other risk factors.

Of the 44 women admitted, 4 were or went into spontaneous labour on the same day and did not require induction. Another 12 women were admitted at subsequent visits by the obstetric staff for elective delivery. The median interval from day of referral visit to delivery was 2 days

with a range of 0-38 days. Those admitted on the day of referral (n=44) had a median interval of 1 day with a range of 0-5 days. In contrast, those not admitted had a median interval of 6 days with a range of 0-38 days. Eighty-five women delivered their babies at CHBAH, and 15 gave birth at MOUs in Soweto, Orange Farm and Lenasia. There were 35 caesarean sections, with the most frequent indication being fetal distress in 24 cases (68.6%) (Table 10). The woman who required an elective caesarean section was 38 years old and 41 weeks pregnant by a late pregnancy ultrasound scan. She had a previous stillbirth and no living children.

Table 10. Indications for caesarean section in women referred for prolonged pregnancy (n=35)

Indication	**Number**	**%**
Poor labour progress	6	17.1
Fetal distress	24	68.6
Breech presentation	2	5.7
Failed induction of labour	2	5.7
Elective caesarean section	1	2.9

The mean birth weight was 3305±414 g, with eight infants weighing ≥4000 g. All babies were born alive. Intrapartum fetal heart rate changes and meconium passage were not recorded in the primary study data. The five-minute Apgar score was ≥9 in 96 of the 100 babies born (Table 10). There were 5 neonatal admissions, three for mild respiratory distress (one with possible meconium aspiration syndrome) and two for mild birth asphyxia. Neither of the latter two babies developed evidence of neonatal encephalopathy. No neonatal deaths were recorded. However, there was no information about newborns after their discharge from hospital.

Table 11. Apgar scores at 5 minutes for infants born of women referred for suspected prolonged pregnancy (n=100)

Apgar score	Frequency
6	2
7	1
8	1
9	16
10	80

Table 12. Comparison table of appropriate VS inappropriate

Category	Inappropriate (n=55)	Appropriate (n=45)	P value
Parity 0 1 2 3 4 5	 28 15 9 1 1 1	 16 21 5 2 1 0	0.33
Age	25.5±6.3	26.0±	0.69
Public sector scan	4	10	0.04
Private sector scan	22	15	0.54
Gestational age by 1 2 3 4	 16 32 5 2	 10 20 4 11	0.02
HIV infected	10	10	0.63
Weight (n=96) {kg}	70.9±12.6	74.0±12.1	0.23
Height (cm)	159.2±5.4	162.0±4.1	0.006
Body-mass index (n=96) kg/m^2	28.0±5.1	28.2±4.7	0.85
Mid-upper arm circumference (cm)	29.3±3.4	29.4±3.4	0.84
Abdominal circumference (cm)	101.5±6.9	102.4±6.7	0.52
Symphysis-fundal height (cm)	37.8±2.4	38.0±3.0	0.63

Amniotic fluid index	8.7±4.0	7.3±4.5	0.08
Bishop score	5.0±1.5	5.6±2.2	0.20
Spontaneous labour	32	16	0.02
Caesarean section	22	13	0.25
Birth weight (grams)	3269±395	3349±437	0.34
Male baby (n=99)	26/54	27/45	0.24

6. DISCUSSION

The study looked at 100 participants sampled from a population of women referred to CHBAH for suspected prolonged pregnancy. This sample was not necessarily intended in the primary study to be representative of the population. The women sampled were those who arrived early in the morning at CHBH. It is plausible, although not necessarily likely, that late arrivals differ systematically in demographic and obstetric characteristics from early arrivals. Nevertheless, this sample should give an approximate picture of all women referred for prolonged pregnancy.

Most notable among the general obstetric findings was the prevalence of hypertension (10%) in the women. Hypertension was not observed before referral in any of these women, and yet provided a valid reason for induction of labour. A lesson from this finding is that blood pressure measurement, and also a thorough physical examination, should not be neglected in women referred for prolonged pregnancy. The HIV seropositivity rate of 20% was lower than the 29% currently thought to be the population seroprevalence in Soweto pregnant women (personal communication, Prof E Buchmann). While this could be attributed to chance, this would not be surprising, as HIV infection is associated with preterm birth and could therefore be inversely associated with prolonged pregnancy.[62]

The difficulty with assessing prolonged pregnancy referrals was well illustrated by the wide range of gestational ages found. Gestational age by LMP varied widely from 29-48 weeks, but even the gestational age by best estimation had a wide range, with a range of 34-43 weeks. The mean best estimate was 39.9 weeks, much less than the 41 weeks at which midwife-run antenatal clinics are supposed to refer women. Only 45 women were 41 weeks or more pregnant at referral, suggesting that the remaining 55 were inappropriately referred. Even among the women who had ultrasound scans done at 24 weeks or less (n=26), the majority (n=16) were not yet 41 weeks pregnant on the day of referral. This begs the question of whether the

midwives at the clinics were aware of or could interpret the ultrasound scans. Since the majority of ultrasound scans at 24 weeks or less were done by private doctors, it is possible that the clinic midwives did not see these scan reports or ask about them. Even where LMP was the basis for the best estimate of gestational age (n=52), only 38% pregnancies were of 41 or more weeks' duration. These findings suggest a systematic and frequent failure by the referring clinic midwives to assess gestational age correctly. Gestational age assessment from the LMP should be a simple matter, and prior ultrasound evidence of gestational age should be actively pursued in all women booking for antenatal care. In the case of early ultrasound scans, calculation of the EDD is usually not necessary as the EDD appears on the ultrasound report, or the pregnant woman has been told her EDD. Therefore, incorrect gestational age assessment results in a majority of referrals for prolonged pregnancy being inappropriate. This may be an educational problem for midwives in the clinics, and will require further training. It could also be suggested that before a woman is referred for prolonged pregnancy: 1) she must be asked if she has private ultrasound scan results; and 2) her gestational age should be carefully and systematically recalculated from the LMP and other available evidence.

Most of the clinics referring to CHBAH are poorly resourced and have no ultrasound scanners. Availability of early pregnancy ultrasound in midwife-run clinics would theoretically reduce the numbers of prolonged pregnancies, by preventing misclassification, and therefore reduce the numbers of referrals and inductions. This has been shown to be true in randomised controlled trials.[47-50] However, the costs and benefits of ultrasound scanning at midwife-run clinics would have to be evaluated before instituting such technology at this level of care. Not only would ultrasound equipment have to be procured, but midwives or sonographers would be needed to do the scanning. Also, the technology would not be of lesser value for women who book late (after 24 weeks) for antenatal care. Performing membrane sweeping from early

term would also decrease a number of referrals for prolonged pregnancy and the results also demonstrate that fact. There are 48 (32 from the inappropriate group and 16 from the appropriate group) who did not undergo induction of labour and delivered spontaneously as a result of membrane sweeping done by the primary investigator upon the estimation of their gestational age.

The place of ultrasound assessment of amniotic fluid volume in prolonged pregnancy is not questioned here, but scanning for AFI would not be necessary in all referred women. In those with early ultrasound-based dates of 41 weeks or more, induction can be offered without resorting to assessment of AFI. AFI assessment would be necessary only in women who request pregnancy continuation. In the women whose best estimate is less than 41 weeks at referral, an AFI assessment makes no sense because such women should not even have been referred. This study included routine AFI assessment for all women, and some were, rightly or wrongly, admitted for induction of labour because of reduced AFI, despite being less than 41 weeks pregnant by best estimate of gestational age.

Even in the absence of good information on gestational age and inappropriate referral, the management of prolonged pregnancy in CHBAH is in line with recommended international best practice. The management of referrals at CHBAH involves best estimation of gestational age, determining fetal well-being using markers such as fetal movements and amniotic fluid volume and, where necessary, NST. The state of maternal and fetal well-being, and the wishes of the pregnant woman, will define the course of management where there is doubt about gestational age.

The perinatal outcomes proved to be good in this study, with no cases of neonatal encephalopathy, severe meconium aspiration syndrome, or neonatal death. However, caesarean section rates were high (35%) and the dominant indication for caesarean section was fetal

distress. While the details of each of these cases were not available in the study data, local experience is that doctors have a low threshold for surgical intervention in inductions done using misoprostol, an agent known to cause tachysystole and sometimes fetal hypoxia.[63]

Comparing the two groups, the inappropriate referred group and the appropriate one, reveals not much of a difference except that the 55 out of hundred were indeed inappropriately referred. There seems to be more women who are primigravidas who were referred inappropriately. This could suggest that primigravidas tend not to recall their LMP than those who are parous and gravid, which increases inappropriate referrals for prolonged pregnancy in primigravidas.[11] Hilder, et al. concluded that being parous appeared to have a protective effect on fetal mortality in prolonged pregnancy.[9]

Similar number of women in both groups had ultrasound done either in private or public sector with more done in private. BMI and the gender of the fetus were not different within the two groups.

There were more caesarean sections done in the inappropriate group than in the appropriate group which had lesser caesarean sections. As mentioned above, the main indication for the caesarean section was fetal distress in both groups.

One statistical significant finding with an odds ratio of 0.006 is the height; it has no scientific basis. Height does not seem to influence the risk of prolonged pregnancy.

Some limitations need to be acknowledged. As this was a secondary analysis, and the study was not originally designed for the listed objectives, the selection of the study population could not be manipulated in a manner that eliminates bias. There was a restriction on the data that was available. No detail could be obtained regarding the duration and complications of induction of labour. Also, hypotheses could not be tested as the sample was small and its size

was not calculated for the objectives of this secondary analysis. The strength of the study was the 100% follow-up of all women to delivery, including delivery at MOUs. However, late neonatal outcome data, to 28 days, was not available.

7. CONCLUSION

The study has shown that the majority of referrals for prolonged pregnancy were inappropriate because of a failure by referring antenatal clinic staff to assess gestational age accurately. This failure involves the use of both early antenatal ultrasound results and evidence of gestational age based on the LMP. The most appropriate responses would be a tightening of the protocol for referral to ensure systematic and careful recalculation of gestational age before referral, and re-education of midwives at clinic level on gestational age and referral for prolonged pregnancy.

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Appendix A

Data collection sheet

Date.....

Study no……..... Age…… Parity…… Previous C/section……

Gestation (LMP)……Best gestation…….. by early scan(1), dates(2), late scan(3), other 4)……..

Smoking(0,1)…….. HIV status……CD4……..HAART……..Weight…… kg

Height…….. cm MUAC..... cm AC……. cm SFH…… cm

Head in fifths……..... OP position(0,1) .....… Irritability(0,1,) ……

Fundal ballottement…….

Midportion ballottement……..

Suprapubic ballottement……..

Fetus free.....…….

Foetal parts obscured (limbs)……

Uterine compressibility ……

Cervical forewaters……..

General impression……

Impression of colleague..... Rank of colleague(1=con, 2=reg).....

Cervix (Bishop):

Dilatation……=……. Length……=…….

Consistency……=……. Position……=……

Station……=……. TOTAL.....

Sonar:

MVP1..... MVP2…….. AFI1…… AFI2...… AFI mean…… EFW..... g

Labour spontaneous(0,1)……. Meconium staining(0,1,2)…….

Variable decelerations(0,1)……. Date of delivery..... Hospital(0,1).....

Caesarean section(0,1)…… Birthweight……. g

Stillbirth(0,1)…….. 5-minute Apgar……..

Neonatal admission(0,1)…….. Neonatal death(0,1)..……

Where to deliver..... Notes:

Appendix B

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Bandile Masuku

CLEARANCE CERTIFICATE	M111133
PROJECT	Appropriateness, Management and Pregnancy Outcomes of Pregnant Women Referred to Chris Hani Baragwanath Academic Hospital for Prolonged Pregnancy
INVESTIGATORS	Dr Bandile Masuku.
DEPARTMENT	Department of Obstetrics & Gynaecology
DATE CONSIDERED	25/11/2011
M1111330DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 25/11/2011 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Prof E Buchmann

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**
PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...