AUDIT OF BREECH PRESENTATION DELIVERED VAGINALLY AT CHRIS HANI BARAGWANATH HOSPITAL

Dr B Uzabakiriho

University of the Witwatersrand

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Supervisor: Prof. EJ Buchmann

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DECLARATION

I, Bernard Uzabakiriho, declare that this research is my own work. It is being submitted to the University of the Witwatersrand in the fulfillment for the degree of MMed in Obstetrics and Gynaecology (Wits). It has not been submitted before for any other degree or examination at this or any other university.

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Dr B Uzabakiriho

12th December 2011

DEDICATION

This research report is dedicated to Almighty God, my creator, provider and protector, in whom I trust. I also dedicate this work to my parents for raising me up and sending to school even though they had very limited means. By no means of disrespect, I lastly dedicate this clinical work to my children Esperance Izabayo, Victor Niragire, Pacifique Iraguha and Lael Uwayo together with my wife Alphonsine Narame Uzabakiriho.

ABSTRACT

Background

Vaginal breech delivery can be a difficult obstetric procedure. The well-known Term Breech Trial concluded that planned elective caesarean section at term was safer for the babies than planned vaginal birth. This resulted in widespread adoption of protocols favouring planned caesarean section for breech presentation. However, daily experience shows that vaginal breech deliveries are still conducted in our hospitals.

Objectives and methods

This study was done to: 1) determine the reasons why vaginal breech deliveries still occur with live babies at Chris Hani Baragwanath hospital, despite the adoption of a protocol for elective caesarean section for breech presentation at term; 2) to audit the quality of clinical notes given the potential medicolegal hazards associated with breech delivery; and 3) to describe neonatal morbidity and mortality associated with vaginal breech delivery. This was a retrospective descriptive study and audit of vaginal breech deliveries, using a period sample of vaginal breech births of babies alive at the onset of the second stage of labour, and weighing 800 g or more at birth. Data collection was by review of maternal and neonatal case notes.

Results

There were 90 women with eligible vaginal breech deliveries. Four (4%) were referred from midwife-run antenatal clinics for breech presentation. External cephalic version was not attempted on any of these women. Five (6%) had been booked for elective caesarean

section. On admission in labour, 26 (29%) of these breech presentations were missed, and 23 (26%) had emergency caesarean sections booked. The vaginal deliveries were conducted by registrars in 55 cases (61%) and by midwives in 22 (24%). At delivery, the fetal heart was noted to be present in 28 cases (31%). The method of delivery of the head was stated in 23 deliveries (26%). The median birthweight was 2370 g (interquartile range 1730-3000 g). There were eight babies weighing less than 1000 g (9%). There were eight perinatal deaths (9%), of whom four weighed more than 2500 g. There was one where the aftercoming head could not be delivered with the baby eventually born as a fresh stillbirth.

Conclusion

There may be a problem with clinical skill in detecting breech presentation, and with supervision of vaginal breech deliveries by senior obstetric staff. Note-keeping, with a view to preventing medicolegal risks, was generally poor. However, the majority of vaginal breech deliveries occurred without warning even in the presence of standard antenatal and intrapartum care. This means that vaginal breech deliveries will continue to occur in this institution. Clinicians must remain skilled in vaginal breech delivery and understand the importance of following standard protocols and operating procedures, especially in note-keeping, to prevent poor clinical outcomes and associated medico-legal hazards.

1. LITERATURE REVIEW

1.1. Introduction

Vaginal breech delivery with a live baby is known to be potentially difficult. It has been associated with fetal injury, anoxia, poor neurodevelopmental outcome, death, and medico-legal hazards [1]. However, vaginal breech delivery has until recently been considered to be acceptable obstetric practice. Edward A. Schumann in 1936 classified breech presentation as a pathological presentation [2], requiring a specially trained accoucheur at vaginal delivery. Vaginal delivery for breech presentation at term has been a common practice until recently, for example up to 2002 in France and Belgium [3]. There is a general view that experience counts more in breech delivery than in almost any other obstetric procedure [4]. However, in many institutions, pregnant women will present in advanced labour, sometimes to encounter inadequately trained or inexperienced practitioners who have to conduct a vaginal breech delivery. Even for the average obstetric practitioner, breech delivery remains an uncertain and anxiety-producing event [4]. In the United States of America, some obstetricians are unwilling to perform vaginal breech delivery, and if pregnant women with breech presentations request vaginal birth, such obstetricians may offer the alternative of referral to another obstetrician [5].

A difficult vaginal breech delivery may leave the parturient woman psychologically and physically traumatized, but in the long term, the physical risks for the woman are generally lower with a vaginal delivery than if delivery is by caesarean section [6]. Widespread concerns about the safety of vaginal breech delivery led researchers to

undertake the multicentre Canadian-based Term Breech Trial [7]. The trial, which included a large number of participants from South Africa, found that planned elective caesarean section at term was safer for the babies than planned vaginal birth. [7]. Rates of perinatal death and severe morbidity were significantly reduced in participants allocated to elective caesarean section, and the women allocated to planned caesarean section did not have significantly worse outcomes than those allocated to planned vaginal birth. Although there have been doubts about the validity of the Term Breech Trial results, especially in developing countries, there has been an almost universal shift away from planned vaginal breech delivery. In many institutional protocols, and in South African national guidelines [8,9], it is stated that the best method of delivery for a breech presentation, from the infant's point of view, is elective caesarean section. Alshaheen agrees that caesarean section reduces perinatal mortality among primigravid as well as multiparus women who present with term breech babies [9]. In 2011, in an updated Cochrane review, Hofmeyr *et al* reported that a singleton baby presenting at term with a breech presentation would be more safely delivered by caesarean section than by vaginal delivery [10]. While this seems reasonable and is based mainly on the Term Breech Trial results, it still does not make provision for the possibility of a breech-presenting fetus needing delivery before term, or a term pregnancy that presents in labour with a breech presentation. There are no randomized trials to provide evidence for elective caesarean section before term, or for obstetric management of a term breech that presents during labor.

1.2. Frequency at different gestations

The overall frequency of breech presentation at term in singleton pregnancies varies from 3 to 4%. If external cephalic version is done on all appropriate cases, the incidence decreases to 2.5%. However, at 30 gestational weeks, the frequency of breech presentations is 25%, and at 20 weeks is 40% [1, 11,12]. This explains why preterm pregnancies present relatively frequently as breech. It is known that most breech presenting fetuses at the end of the second trimester will turn to cephalic presentation by 34 weeks of gestation [12].

1.3. Causes of breech presentation

The following factors have been associated with breech presentation:

- Maternal: multiparity, polyhydramnios, oligohydramnios, and contracted pelvis that could interfere with the fetal head being positioned into pelvis. Multiparity leads to increased laxity of the uterus, thereby increasing the risk of breech presentation [13].
- Uterine space occupying lesions such as fibroids, malignancies and bicornuate uterus
- Fetal: multiple pregnancies, hydrocephalus, anencephaly, intrauterine fetal death and any other fetal anomaly
- Placental: either placenta praevia or cornual-fundal placental insertion [14].

However, in the majority of cases, there is no known cause of breech presentation [15]. Women with previous cesarean deliveries have a risk of breech presentation at term twice that of women with previous vaginal deliveries [16]. Both men and women delivered in breech presentation at term contribute to increased risk of breech delivery in their

offspring. Recurrence of breech presentation through the father is thought to be as strong as recurrence through the mother [13].

1.4. Types of breech presentation

With breech presentation, the fetus will have a longitudinal lie, with the buttocks or feet closer to the cervix, and the sacrum will be the dominator.

There are four types of breech presentation:

- Complete: both hips and both knees are flexed
- Frank: there is flexion of both hips and extension of both knees. Frank breech is the most commonly encountered type of breech presentation
- Footling: one or both hips and knees are extended. The foot or feet is the presenting part
- Kneeling: one or both knees are flexed, while the hips are extended. The knee or knees is the presenting part [14].

The complete and frank types of breech presentations have generally been considered favorable for normal vaginal delivery, while footling and kneeling presentations generally require caesarean section because of an increased risk of delivery before the cervix is fully dilated [16, 17].

1.5. Natural history and mechanism of labor

Breech presentation has the following positions in descending order of frequency: left sacrum anterior, right sacrum posterior, right sacrum anterior, left sacrum posterior [14,15]. The bitrochanteric diameter is the widest diameter in breech presentation. Once the bitrochanteric diameter passes through the pelvic inlet, engagement is said to have occurred. Lateral flexion of the body occurs at the waist to allow the fetus to negotiate the birth canal. At the pelvic floor, the anterior hip rotates forward, downward then anterior (internal rotation), and then descent takes place until the breech crowns. In the right sacrum anterior position, for example, engagement of the shoulders is in the right oblique pelvic diameter. The leading shoulder will rotate under the symphysis pubis as the bisacromial diameter turns 45 degrees into the anteroposterior diameter of the outlet. With the anterior shoulder below the symphysis pubis, the posterior shoulder is born over the perineum when the accoucheur lifts the body up. To deliver the anterior shoulder, the baby is lowered again; the shoulder and arms are then brought out. Once the shoulders are delivered, the head descends into the pelvis with the sagittal suture in the oblique diameter, with the occiput being in either the right or left anterior quadrant of the pelvis. The head then rotates internally to allow delivery with the sagittal suture in the anteroposterior diameter, and the occiput under the symphysis pubis [13,15,17].

1.6. Methods used in vaginal delivery of breech presentation

Assisted breech delivery and breech extraction:

Unlike spontaneous breech delivery, as described above, where there is neither traction nor manipulation of the baby, in assisted breech delivery the baby's body is born up to

the umbilicus and then manoeuvres are used to deliver the body, arms and head. It is recommended that a baby be held by the hips during these manoeuvres and never by abdomen, to prevent injury to intra-abdominal structures. Breech extraction is an obstetric procedure in which the accoucheur grasps the baby's feet and pulls the entire baby out, using different manoeuvres that will be described below. This method is not recommended as it may be followed by after-coming head entrapment, because of the cervix not being sufficiently dilated to admit the head, or by extension of the baby's upper limbs and head. Breech extraction is generally done only in emergencies where there is concern over fetal condition or where there is a retained second twin. Some of the manoeuvres used in assisted breech delivery and in breech extraction are described below.

Lower limbs:

1. Pinard Manoeuvre

For flexion of the knees and hip in a frank breech, two fingers are passed along the baby's leg up to the popliteal fossa to bend the knee and flex the hip toward the body [15]. This is also referred to as breaking up the breech [15].

Upper limbs:

1. Løvset Manoeuvre

This method deals with extended arms and was described by Løvset in 1937. The posterior shoulder descends in the pelvis before the anterior shoulder. As the scapulae

appear, the baby is rotated back upwards to bring the posterior shoulder forward for delivery, and then turned back in the opposite direction to bring the anterior shoulder under symphysis pubis for delivery [13].

2. Classical method

The shoulders are delivered, whereby the accoucheur's two fingers slide posteriorly to sweep the baby's arm anteriorly downwards over the baby's chest [14,15].

Head:

1. Wigand-Martin Manoeuvre

The right-handed accoucheur places the baby's body longitudinally on the forearm. The middle finger of that hand goes into the baby's mouth, with the index and ring fingers on the maxillae; this helps to flex the baby's head. The other hand applies suprapubic pressure from above, to assist with flexion of the head [13, 15].

2. Mauriceau-Smellie-Veit manoeuvre

The procedure starts as for the Wigand-Martin Maneuver. The index and ring finger of the left hand are placed on the baby's shoulders whilst the middle finger applies forward pressure on the occipital bone to flex the head further. An assistant may apply suprapubic pressure [13, 16,17].

3. Burns-Marshall technique

The accoucheur stands against the woman's right leg, and lifts the baby's feet using the

left hand. The right hand controls baby's head, as the baby's legs and body are lifted in an arc to bring the baby vertical. The symphysis pubis acts as a fulcrum to encourage flexion of the head [15, 16, 17, 18].

4. Kristellar Manoeuvre

This maneuver is used so that the fetal head can be born in flexion. When the baby's legs are elevated, as in the Burns-Marshall technique, the neck may become extended thereby posing danger to neck fracture. To prevent this, suprapubic pressure is applied to flex the head so that the chin, mouth, nose, forehead, bregma, and vertex can be born in that order [15].

5. Prague Manoeuvre

This is an emergency method used for face-to-pubis births after delivery of the shoulders. With the baby's occiput on the mother's perineum the fingers of the right hand are placed over the baby's shoulders, with the left hand applying traction out and upwards by holding the feet, and swinging the baby in an arc over the mother's abdomen. The method is associated with fracture of the neck, therefore it is rarely used. However, this may be the only available method of delivery if disengagement and forward rotation of the head is not possible [13, 15].

6. Forceps delivery

This is frequently used as a routine for delivery of the after-coming head. After the body and arms are delivered, and the head has descended into the pelvis, an assistant holds the

baby's legs and the body is supported in a warmed dry towel. Classically, Piper forceps are applied on each side of the baby's head, covering the occipitomental diameter. The traction is done slowly. Long forceps such as the Anderson or Simpson varieties can also be used [13, 15, 16, 17].

7. Vaginal retractor

This method is used to provide an airway to the baby's mouth and nose as the baby's face appears at the perineum. Whilst the accoucheur is delivering, an assistant may insert a vaginal retractor against the posterior vaginal wall to allow space for the baby to breathe [15]. Care must be taken not to injure the mother and baby.

There is little published evidence, and specifically, there are no randomized trials to support any of these methods over others. All have been developed over many decades by experience and common-sense. Properly trained and skilled obstetricians should be aware of the correct use and precautions of the methods with which they are familiar.

1.7. Prevention of breech delivery

If a breech presentation is detected at term before the onset of labor, obstetric clinicians may try to avoid breech delivery, and therefore caesarean section, by performing external cephalic version (ECV) [19]. This is a procedure where the fetal lie and presentation are externally manipulated and the fetal buttocks are lifted out of maternal pelvis and turned to the fundus and the head towards the mother's pelvis to

effect a cephalic presentation. This may be facilitated by the use of uterine relaxants such as salbutamol [16,20, 21]. ECV has been shown to be frequently successful, and is considered to be safe for the mother and fetus [20,22,23,24]. The success rate ranges between 40-80% [16]. An updated Cochrane review from 2010, based on data from seven randomized controlled trials, has concluded that ECV done at term reduces the frequency of breech deliveries and caesarean sections [23]. Based on this evidence, ECV is recommended in South African national guidelines for all singleton breech presentations at term, provided that there are no contraindications to the procedure [8]. The cost of caesarean section and the management of associated complications can be reduced by using this simple procedure. ECV is preferred at term or at least at 36 weeks because the baby is ready for delivery in case complications occur related to the procedure, and because there is a greater chance of reversion to breech presentation with preterm ECV [25]. In a study done by Brocks, it was found that when left alone, babies in breech presentation at term would revert to cephalic presentations by the time of delivery in only 14% of cases [26]. It has been noted by Hofmeyr that ECV is less likely to succeed in white than in black women [27]. If ECV is unsuccessful, or not attempted because of contraindications, elective caesarean section is the preferred option locally for avoiding a vaginal breech delivery [8,9]. The following are contraindications to ECV: antepartum haemorrhage, major uterine anomalies, ruptured membranes, if caesarean is indicated as a preferred mode of delivery, scarred uterus, multiple pregnancy, HIV seropositivity (relative), unstable lie and major fetal anomaly [16,28]. ECV has been associated with complications like abruptio placentae, spontaneous rupture of membranes, feto-maternal haemorrhage and uterine rupture [16,28].

1.8. Hazards of breech delivery

Based on the results of the term breech trial, breech-presenting infants delivered vaginally have a higher risk of injury or complications than those delivered by cesarean [7]. The worst outcome is perinatal death from traumatic or hypoxic brain injury. The perinatal mortality rate of breech babies delivered vaginally is three times more frequent than for babies in cephalic presentation, and is especially more common in very low birth weight infants [11, 13], not only because of prematurity related complications. After-coming head entrapment in preterm babies is explained by the fact that the pre-term baby, a fetal head is usually considerably larger than the body, and the body is delivered before the cervix is fully dilated [13]. These risks are especially high in footling breech presentation [14]. Planned cesarean section, at least at term, reduces the risk of perinatal/neonatal mortality or serious neonatal morbidity by 67%, compared to planned vaginal birth [7], as discussed earlier. Hypoxic brain damage in breech presentation may follow umbilical cord prolapse, prolonged labor, constriction of the umbilical cord for a lengthy period while delivering the fetal head, as well as aspiration of amniotic fluid [13]. Breech presentation is considered a significant cause of perinatal death in South African institutions. The sixth South African Saving Babies report for 2006-2007 recorded 45 avoidable perinatal deaths out of a total of 8164 where the babies were alive at the onset of labour (0.6%), in which failure to detect breech presentation was implicated in the death [29]. Presumably, these babies might have had better outcomes if decisions on caesarean section had been made in time. In summary, the factors influencing short-term mortality and morbidity of breech babies are thought to be prematurity, congenital anomalies, cord prolapse, fetal asphyxia, and fetal injuries [12]. Many of these factors

may be avoidable, and this raises the question of medicolegal hazards for practitioners who plan or neglect to prevent vaginal breech delivery, or plan to undertake vaginal breech delivery.

Longer-term follow-up of children from the Term Beech Trial has however provided data that are less convincing for benefit related to caesarean section [30]. Two years after birth, there was found to be no difference in child (including neonatal) mortality or neurodevelopmental delay between planned vaginal and planned caesarean section groups. Despite these findings, policy or practice on breech delivery seems not to have changed in local institutions.

The maternal complications of breech delivery are believed to be related to traumatic delivery resulting in tears and hemorrhage [13]. However, the risks of severe maternal morbidity associated with planned cesarean delivery are likely higher than those associated with planned vaginal delivery [17]. The Term Breech Trial found that short-term minor morbidity was more frequent after planned caesarean section, although urinary incontinence was more frequent following planned vaginal birth at 3 months [7]. However, at follow-up two years after delivery, there were no significant differences in maternal outcomes between the two groups. This included urinary and anal sphincter incontinence [6].

1.9. The place of vaginal delivery for breech presentation

In 1976 Zatuchni and Andros described a scoring system for use when confronted with a breech presentation in labour (Table 1) [14]. This and various modifications have formed the basis for clinical decision-making regarding breech delivery. Since the findings of the Term Breech Trial were released, such methods have become obsolete in institutions that practice routine caesarean section for breech presentation.

It should be expected that in the hands of experienced obstetric clinicians, planned vaginal delivery will be associated with better fetal outcomes, lower morbidity for the mother, will require fewer health-care resources and will therefore be less costly [1]. African hospitals have to deal with a shortage of skilled clinicians who may not be able to deliver a breech-presenting baby safely. However, in such environments, caesarean section may also not be safe, from both an anaesthetic and surgical point of view [31,32]. Interestingly, the Term Breech Trial found that vaginal breech delivery was relatively less hazardous in low and middle income countries [7]. Jadoon has suggested from results from a study in Pakistan that a vaginal breech delivery on a well-counselled mother is an option that does not compromise perinatal or maternal outcome. [33]. Even if caesarean section is chosen, in whatever environment, not all women with breech presentations make it to the operating room in time [34]. There are other reasons why it will be impossible to deliver all term breech pregnancies by caesarean section. The mother may insist on vaginal delivery, breech labour may be precipitate, and there are special situations such as the second twin. Even though the rate of caesarean deliveries for breech rose dramatically after TBT, the impact on PNMR does not seem to change, especially in developing countries [35].

Maternal complications following emergency caesarean section as well as elective caesarean section have been shown to be similar to vaginal deliveries in many respects, with the exception of abdominal and uterine wound problems. Complications of caesarean section include bleeding and blood transfusion, deep vein thrombosis, and infection. However, the maternal mortality rate is 5 times higher in elective caesarean section and 18 times higher in emergency caesarean section compared with vaginal delivery [36] Hence, elective is preferred over emergency caesarean section wherever possible.

It should be stated that even though planned caesarean section for breech presentation has been almost universally adopted, its main pillar of evidence, the Term Breech Trial, has come under severe criticism. Inherent in the results of the Term Breech Trial were the lower protective effect of caesarean section for the baby in developing countries, and the inability to extrapolate the results reliably to preterm breech, and to term breech presenting during labour. More concerning, however, were the methodological problems, highlighted in 2006 by Glezerman [37]. His critique pointed out serious protocol violations, including randomization during labour and the use of inexperienced attendants for vaginal deliveries. There was also bias towards infants with greater birthweight delivering vaginally. Despite these concerns and the lack of long-term benefit from planned caesarean section [6, 30], caesarean section has become firmly entrenched as the delivery method of choice for breech presentation, at least in middle- and high-income countries.

Obstetricians have attempted to predict whether a vaginal breech delivery is likely to be successful. An example is the breech score of Zatuchini and Andros, a numerical figure of the certain parameters (Table 1). Even though a score of less than 3 predicts a poor outcome, the higher scores are less significant as they can not guarantee a successful

vaginal delivery [15]. This score is now of less importance in modern obstetrics as it does not necessarily assist clinicians to make a decision on delivery, especially in this era of rapid recourse to caesarean section for breech presentation.

Table 1. Breech Score of Zatuchini and Andros [15]; interpretation: with a composite score of 3 or less, fetal morbidity with vaginal birth is high, and caesarean section is advised.

	0 Points	1 Point	2 Points
Parity	0	≥1	
Gestational age	≥39 weeks	38 weeks	≤37 weeks or less
Estimated fetal weight	>3630g	3176-3630g	< 3176g
Previous breech>2500g	None	1	≥2
Cervical dilatation on admission by vaginal examination	≤2 cm	3 cm	≥4 cm
Station on admission	-3 or higher	-2	-1 or lower

2. PROBLEM STATEMENT

2.1. Background to the study

Why do vaginal breech deliveries still occur?

Despite the clear shift favoring caesarean section for delivery of breech presentations, vaginal deliveries still occur frequently. For example, at Chris Hani Baragwanath Hospital, 319 vaginal breech deliveries occurred in 2009, the majority for live births. It is reasonable to question why vaginal breech deliveries still occur in this institution.

Possible reasons for the high number of breech deliveries include:

- Women presenting at full dilatation with the breech on perineum, ready to deliver
- Women presenting in advanced labour with a breech presentation and the clinician deciding to proceed with vaginal delivery
- Women presenting in advanced labour with a breech presentation and vaginal birth occurs even after caesarean section is arranged.
- Failure by clinicians to detect breech presentation until the second stage of labour
- Women's choice to have a vaginal breech delivery, or to decline caesarean section.
- Multiple pregnancies, usually with the second twin presenting as a breech.

Factors contributing to these eventualities include:

- Non-attendance or late attendance at antenatal clinic
- Failure to detect breech presentation at antenatal clinic

- Failure to attempt or perform external cephalic version

The need for safe practice in vaginal breech delivery

The fact that breech deliveries for live infants still occur demands a high standard of obstetric skill by the attending clinicians in the Chris Hani Baragwanath labour ward, most frequently registrars. The hazards associated with delivery, with respect to early injury and hypoxia, and to later neurodevelopmental problems, also make it necessary for clear protocols to be followed in the delivery procedure, and for comprehensive notes on the deliveries to be clearly written. Such notes may assist the institution and clinician in defending claims by families of medical negligence. There has been recent concerns about the management of breech presentations in antenatal clinic and labour ward at Chris Hani Baragwanath. Such concerns include failure to use opportunities to perform external cephalic version, failure to detect breech presentation both antenatally and in labour, and reports of injuries and death of babies born by vaginal breech delivery.

Chris Hani Baragwanath Maternity Hospital receives referrals for breech presentation from midwifery clinics in Soweto, Orange Farm and Lenasia. Antenatal clinic midwives from these institutions refer women with suspected breech presentation at 34 to 36 weeks' gestation, and also refer women with breech presentation in labour. The hospital has guidelines in place for management of breech presentation.

These are (quoted *verbatim* from the current guidelines last updated in 2007 [8]):

EXTERNAL CEPHALIC VERSION

External cephalic version (ECV) should be attempted on all mothers with normal singleton breech presentations from 37 weeks gestation, with the following precautions:

1. *Exclude contraindications – hypertension, scarred uterus, antepartum haemorrhage, ruptured membranes, HIV seropositivity*
2. *Give anti-D 100 μg IM to rhesus-negative mothers with no antibodies*
3. *Do not anaesthetise or sedate the mother*
4. *Use hexoprenaline 10 μg IV or salbutamol 0.1-0.2 mg IV to relax the uterus*
5. *Never use excessive force*
6. *Do a CTG tracing before and after ECV, whether successful or not*
7. *Observe the mother for a few hours for complications – labour, rupture of membranes, antepartum haemorrhage, fetal distress*

LABOUR AND DELIVERY

Elective caesarean section is the safest method of delivery for a baby with a breech presentation. Women with breech presentation at 38 weeks should be admitted to hospital for elective caesarean section.

Admission of a woman with breech presentation in labour

1. *Exclude fetal abnormality or multiple pregnancy, by ultrasound if necessary*
2. *Attempt external cephalic version if there are no contraindications*
3. *Estimate fetal weight and pelvic adequacy*
4. *Determine cervical dilatation and station of presenting part*
5. *Perform caesarean section unless suitable for vaginal delivery (below)*

Vaginal breech delivery

Some women may prefer vaginal breech delivery, and some may arrive at hospital in advanced labour. Vaginal breech delivery can be planned for these women provided that all circumstances are favourable. Primigravidae should be strongly advised to have elective caesarean section. Vaginal breech delivery must be personally supervised by the most senior clinician available in the labour ward.

Breech presentation suitable for vaginal delivery

- *Mother understands and accepts vaginal delivery*
- *Clinician experienced and confident with vaginal breech delivery*
- *No signs of pelvic contraction on clinical assessment*
- *Estimated fetal weight less than 3.0 kg*

- *X-ray or ultrasound excludes head extension ('stargazing')*
- *Frank or complete breech*
- *At 6 cm dilatation or more, the presenting part should be at or below the level of the ischial spines*
- *Labour progress ≥1 cm per hour*
- *Epidural anaesthesia is strongly advised*

Technique of delivery

1. *Put the mother in lithotomy position*
2. *Have an assistant and a paediatric doctor in attendance*
3. *Cut an episiotomy after infiltration of the perineum with local anaesthetic*
4. *Allow the breech to deliver itself and only assist in keeping the fetal back facing upwards*
5. *If extended knees prevent easy delivery, assist by flexing at the knees and gently delivering each leg (Pinard maneuver)*
6. *After delivery of the trunk, allow the breech to hang, pull the cord down and cover the delivered parts with a cloth*
7. *As the scapulae appear, be ready to assist with delivery of the arms*
8. *Deliver the arms if necessary by running the fingers from the fetal back over the shoulder and sweeping the arms down in front of the chest, and then out*
9. *The neck will deliver up to the nape*
10. *Deliver the head by lying the fetus over the right forearm (if right-handed) and inserting the right middle finger into the baby's mouth, with the index and ring fingers supporting the cheek (Mauriceau-Smellie-Veit maneuver)*
11. *The left hand exerts suprapubic pressure downwards to flex the head*
12. *Should the fetal back face downwards after delivery of the arms, the head may be trapped. The best chance of delivery is to swing the fetus anteriorly over the maternal abdomen to flex the head*

In addition, the labour ward standard operating procedures (2009) state:

Vaginal breech delivery and vaginal twin delivery

- *Midwives are expected to call doctors to supervise or conduct these deliveries*
- *Record in the patient's file the clinical findings just before delivery, especially the fetal heart rates and the estimated fetal weights.*
- *Record in the patient's file all maneuvers attempted and performed, and their degree of difficulty.*
- *For breech delivery, record in the patient's file the time of delivery of the buttocks and the time of delivery of the head.*
- *For twin delivery, record in the patient's file the time of delivery of each twin, and run a CTG or note the fetal heart rate of the second twin after delivery of the first twin.*

Against this background, it became necessary to perform an audit of vaginal breech deliveries on live babies at Chris Hani Baragwanath Hospital.

2.2. Objectives

The objectives of this study were to determine:

- The reasons why vaginal breech deliveries still occur with normal live babies, in the presence of a protocol favouring elective caesarean section for breech presentation
- Whether best practices and departmental protocols are applied when performing vaginal breech deliveries, including both delivery technique and quality of notes
- The neonatal morbidity and mortality associated with vaginal breech delivery

3. METHODS

3.1. Study design

This was a retrospective cross-sectional descriptive study of vaginal breech deliveries at Chris Hani Baragwanath Maternity Hospital.

3.2. Study population

The inclusion criteria were women giving birth vaginally with:

- Singleton baby with breech presentation
- Fetus considered by the attending clinician to be alive at the time of onset of the second stage of labour.
- Birth weight ≥800 g. The neonatal intensive care unit at Chris Hani Baragwanth Hospital uses a cut-off of about 800g for admission.
- No major fetal anomalies known to the attending clinician at the time of onset of the second stage of labor

3.3. Sampling and sample size

This was a period sample of all eligible vaginal breech deliveries, as described above, from 1 January 2010 to 30 June 2010. It was hoped that at least 100 eligible vaginal breech deliveries would be recorded for meaningful analysis .A sample size of 100 in a descriptive study provides 95% confidence intervals of no less than 10% around observed Percentages.

3.4. Data collection

The labour ward register records mode of delivery and presentation of all babies born vaginally at Chris Hani Baragwanath Maternity Hospital, and provided the names and hospital numbers of women who had vaginal breech deliveries. Using the names and numbers, it was possible to access the full maternal and neonatal case notes from the maternity records room. The files were collected after the women were discharged from hospital postnatally. Explanatory variables recorded included maternal age and parity, demographics, gestational age, antenatal care details including external cephalic version attempts, and obstetric details and note-taking on admission in labour and at delivery. Outcome variables were neonatal outcome, such as birth weight, Apgar scores, injuries, hypoxia, and other complications. For newborn babies admitted to the neonatal unit, these outcomes were recorded in the neonatal admission files, accessed retrospectively from the neonatal unit records room. A complete list of variables collected appears in the data sheet as Appendix A.

3.5. Data analysis

Data analysis was done using Epi-info software. Standard descriptive statistics were used, with means ± standard deviations (SD), medians with ranges and interquartile ranges (IQR), and frequencies expressed in numbers (n) with corresponding percentages. Comparisons of frequences, where necessary, were made using the Chi-square test and Fisher's exact test. Comparisons of continuous variables were made using Student's t-test. A P value <0.05 was considered as statistically significant.

3.6. Ethics

The study was approved by the human research and ethics committee of the University of the Witwatersrand (approval number: **M100315** attached as appendix B).

4. RESULTS

Over a period of 6 months, a total of 90 files of women who delivered breech babies Vaginally, eligible for inclusion, were recorded. The target of 100 could not be reached within the study period. The mean age of mothers was 28.4±7.5 years, and the median parity was 1 (interquartile range 0-2). One woman had a previous breech delivery (1.1%). There were 8 women with previous caesarean sections (8.9%).

4.1. Antenatal care

Eighty-three women (92.2%) had attended antenatal clinic (Table 2). Four were referred from Soweto clinics during antenatal care for breech presentation. Nineteen women (21.3%) had breech presentations on the last antenatal ultrasound scan, but most of these scans were done before term. Thirty-four women (37.8%) attended clinic at a gestation where external version could have been done (37 or more weeks). No external versions were attempted in this group of women. Five women (5.6%) had elective caesarean section booked for breech presentation, but went on to delivery vaginally.

4.2. Care during labour and delivery

Twenty-six breech presentations (28.9%) were missed on first intrapartum examination by the admitting clinicians (Table 3) and only detected later in labour. Sixty-four were detected, and 41 (45.6%) were sent to labour ward for vaginal birth, and 23 (45.6%) booked for emergency caesarean section. The median cervical dilatation on admission was 6.5 cm. Twenty-nine women had a fully dilated cervix (10 cm) and another 11 had a cervical dilatation of 8 cm or 9 cm. No external versions were attempted during labour,

although this could have been done, according to the protocol guidelines, in 7 cases (7.8%). Only a minority of women had fetal weight estimation, ultrasound scan, exclusion of head extension and assessment of the level of head noted in their files.

Table 2. Antenatal care details of women who had vaginal breech deliveries (n=90).

Attended antenatal clinic	83 (92.2%)
Referral from midwifery clinics during antenatal care	34 (37.8%)
Referral from midwifery clinics for breech presentation	4 (4.4%)
Antenatal ultrasound scan done	31 (34.4%)
Breech presentation found on last antenatal ultrasound scan	19 (21.3%)
Median gestation at last ultrasound scan? (IQR)	27 (24-33)
External version could have been done during antenatal care	34 (37.8%)
External version attempted	0
Elective caesarean section booked during antenatal care	5 (5.6%)
Women choosing vaginal breech delivery	0

Table 3: First-stage labour care of women who had vaginal breech deliverie (n=90).

Median gestational age on admission (IQR)	36 (31-38)
Breech presentation not detected on admission	26 (28.9%)
Clinician decided on vaginal delivery	41 (45.6%)
Clinician booked emergency caesarean section	23 (25.6%)
Median cervical dilatation on admission (IQR)	6.5 (4-10)
Opportunity for external cephalic version in first stage of labour	7 (7.8%)
External version attempted	0
Fetal weight estimated in the notes	27 (30.0%)
Emergency ultrasound done	25 (28.1%)
Clinical pelvic assessment	50 (55.6%)
Head extension excluded	0
Level of presenting part	9 (10.0%)

The breech presentation was delivered by a consultant obstetrician in 1 case (1.1%), a registrar in 55 (61.1%), a medical officer in 10 (11.1%), an intern in 1 (1.1%), and a midwife in 22 (24.4%). The staff grade for one birth was impossible to determine from the notes. The notes did not allow determination of whether the accoucheur was supervised by a senior person or not. The method of delivery was described for 40 deliveries (44.4%). Of these, 6 were breech extractions, 23 were assisted breech deliveries, and 11 were spontaneous breech births. Episiotomy was performed in 15 cases (16.7%).

The vaginal breech delivery was written up as a procedure in 85 cases (94.4%) (Table 4). The total duration of the delivery was written down in 3 cases (3.3%). The presence of a fetal heart beat was noted to be confirmed in 19 cases (21.1%). Delivery methods for the lower limbs, upper limbs, and head were mentioned in a minority of deliveries. The qualification or rank of the accoucheur was specifically noted in 3 cases (3.3%).

Table 4: Vaginal breech delivery notes written by accoucheur (n=90).

Specific delivery notes written as an obstetric procedure	85 (94.4%)
Duration of delivery	3 (3.3%)
Fetal heart beat confirmed before delivery	28 (31.1%)
Type of breech	19 (21.1%)
Methods of delivering lower limbs	0
Methods of delivering upper limbs	3 (3.3%)
Methods of delivering head	23 (25.5%)
Time of delivery of the head	8 (8.9%)
Baby's condition at birth	53 (58.9%)
Name of accoucheur	83 (92.2%)
Qualification or rank of accoucheur	3 (3.3%)

4.3. Neonatal outcomes

Thirty-seven babies (41.1%) required neonatal resuscitation (Table 5). Nineteen (21.3%) had Apgar scores of less than 7 at 5 minutes (Table 5). Three babies (3.3%) had significant physical injuries. Two babies had lacerations on anus secondary to vaginal examinations, and one baby had a fractured clavicle. The median birthweight of the newborns was 2370 g with a range of 800 g to 3920 g, and an interquartile range of 1730 g to 3000 g. There were 8 newborns with a birthweight less than 1000 g. Forty-seven (52.7%) babies required admission to the neonatal unit. Neonatal encephalopathy was present in 19 babies (21.3%). Grades of neonatal encephalopathy were not consistently assigned in the notes, so frequencies of encephalopathy grades 1 to 3 could not be determined. There were 8 perinatal deaths (9.1%), each of which is discussed below.

Table 5. Neonatal outcomes after vaginal birth with breech presentation

Median Apgar score at 5 minutes (IQR)	8 (7-9)
5 minute Apgar score < 7	19 (21.3%)
Significant injuries (%)	6 (6.7)
Median birthweight (IQR) in g	2370 (1730-3000)
Resuscitation	37 (41.1%)
Admission to neonatal unit	47 (52.7%)
Respiratory distress	37 (41.1%)
Neonatal encephalopathy (all grades)	19 (21.3%)
Perinatal death	8 (9.1%)

4.4. Perinatal outcome by intrapartum decision on delivery

On admission, as shown in Table 3, the clinicians decided on vaginal delivery in 41 women, and on caesarean section in 23. Neonatal outcomes were compared between these two groups of deliveries. There were no statistically significant differences between the groups in terms of Apgar scores, neonatal admission, respiratory distress, neonatal encephalopathy and neonatal death. There was a trend to lower mean birth weight (2208 g v. 2619 g) with decision to proceed to vaginal delivery (P=0.05) (Table 6).

Table 6. Perinatal outcome by intrapartum decision on delivery

	Decision for vaginal delivery (n=41	**Decision for emergency caesarean section (n=23)**	**P value**
Mean birth weight (± SD) in g	**2208 ± 799**	**2619 ± 738**	**0.05**
Five-minute Apgar score <7	**7 (17%)**	**6 (26%)**	**0.52**
Admission to neonatal unit*	**19 (46%)**	**11 (48%)**	**0.80**
Respiratory distress*	**15 (37%)**	**9 (39%)**	**0.79**
Neonatal encephalopathy*	**7 (17%)**	**5 (22%)**	**0.74**
Perinatal death*	**2 (5%)**	**3 (13%)**	**0.33**

*Analysis excludes one stillbirth in the decision to emergency caesarean section group

4.5.Perinatal deaths

Case 1:

A 29 year old para 1 had seven antenatal visits and she was booked for elective caesarean section for breech presentation at her last visit at 39 weeks gestation. She presented in the active phase of labour at 40 weeks'gestation with the cervix 6 cm dilated. Emergency caesarean was booked but she started bearing down soon after that and a junior registrar started the delivery and called a senior colleague for help. A cord prolapse was also noted. A bilateral episiotomy was done. The head could not be delivered and eventually

the head was decompressed by suprapubic cephalocentesis which drained about 20 ml of fluid. The baby was a fresh stillbirth, weighing 3790 g.

Case 2:

A 29 year old para 1 had four antenatal visits, and presented in labour at 38 weeks' gestation. Her previous visit was at 33 weeks'gestation. Her breech presentation was missed on admission to the labour ward and was only discovered when she was in advanced labour at 8 cm cervical dilatation. An emergency caesarean section was booked but she went into the second stage of labour before caesarean section could be done. The delivery was conducted by a registrar. Episiotomy was not done. The type of breech delivery not recorded. The baby was born with low Apgar scores and developed respiratory distress and severe encephalopathy. The birthweight was 2750 g and the baby died in the neonatal unit.

Case 3:

A 29 year old para 2 had one antenatal visit at 34 weeks. She presented at 36 weeks' gestation in the active phase of labour with the cervix 9 cm dilated. Caesarean section was not booked. The delivery was conducted by a registrar, noted as breech extraction. The 5-minute Apgar score was 3 and the birth weight was 3220g. The baby was resuscitated but died 4 hours later in the neonatal unit from severe asphyxia.

Case 4:

A 17 year old para 0 had two antenatal visits and the last visit was at 33 weeks' gestation. She presented during labour at 37 weeks' gestation with the cervix 4 cm dilated. Breech presentation was detected and she was booked for emergency caesarean section. She progressed to the second stage of labour and the delivery was conducted by a junior medical officer. An assisted breech delivery was done and the birthweight was 2510 g. The 5-minute Apgar score was 2. The baby developed respiratory distress and severe encephalopathy and died in the neonatal unit.

Case 5:

A 15 year old para 0 had 1 antenatal visit, then presented at 27 weeks' gestation in labour with the cervix 4 cm dilated. Tocolysis was started and failed. She went into the second stage of labour and a midwife delivered a baby weighing 980 g. The 5-minute Apgar score was 8. The baby died of prematurity-related complications in the neonatal unit.

Case 6:

A 22 year old para 0 had 1 antenatal visit, then presented at 26 weeks' gestation in labour, with the cervix 5 cm dilated. Tocolysis failed, then she was delivered by a registrar. The birthweight was 800 g, and the 5-minute Apgar score was 6. The baby died from prematurity-related complications in the neonatal unit.

Case 7:

An unbooked 24 year old para 2 presented in spontaneous labour at 26 weeks' gestation and gave birth to a 940 g infant after tocolysis failed. The 5-minute Apgar score was 4. The baby died in the neonatal unit as a result of complications of prematurity.

Case 8:

A 37 year old para 2 had 4 antenatal visits, and presented with suspected preterm labour at 26 weeks' gestation with the cervix closed. She was later found in the second stage of labour, and a registrar delivered a baby that was a fresh stillbirth. The birthweight was 810 g.

5. DISCUSSION

5.1. The results

This study has reported on a very select group of births – vaginal breech with live viable babies at the onset of the second stage of labour – which appear to violate the institution's protocol of planned caesarean birth for breech presentations. The fact that there were 90 such births in a six-month period confirms that such vaginal breech births are not uncommon in this labour ward, occurring about once every 2 days. All of these births were unplanned with not a single woman or clinician choosing vaginal breech delivery during antenatal care. The results confirm that the reasons for these births were spontaneous preterm labour, failure to detect breech presentation during antenatal care, failure to detect breech presentation on admission to labour ward, and advanced or rapidly progressing labour.

It was notable that antenatal care for most of these women played no role in their eventual delivery with breech presentation. Only four were referred for breech presentation and the ultrasound scans showing breech presentations were mostly done before term, at a time when breech presentations can still be expected to turn to cephalic presentations. Only five of these women were booked for elective caesarean section from the antenatal clinic. The fact that not a single woman had an external version attempt suggests either that external version is rarely or never performed in this institution, or that external version, when it was done, was successful or was followed by caesarean section and therefore not recorded in this study. It has been observed at Chris Hani Baragwanath Maternity Hospital that external cephalic version is not frequently performed, and that

registrars have voiced their disappointment with not receiving enough training or experience in the procedure.

On admission in labour, 50% of women were more than 36 weeks pregnant, and breech presentation should have been easily detected. However, the breech presentation was missed in almost 30% of this group of women, suggesting a problem with clinical skills among the medical staff in the labour admission ward. A large number of women were in advanced labour and it was therefore understandable that almost 50% were allowed to labour with a view to vaginal birth. There is some concern about the thoroughness of clinical examination in women where the breech presentation was detected. Relatively few women had basic information recorded such as estimated fetal weight and level of presenting part, and only 25 had an ultrasound scan in labour. Ultrasound scanning is available around the clock in the labour ward and this investigation is necessary to exclude fetal head extension before allowing vaginal delivery. In not a single case, was exclusion of head extension noted in the clinical folders audited.

The accoucheurs for these breech deliveries were mainly registrars and midwives. This may not be surprising because these are the professionals that are available on the labour ward floor. One would however expect that midwives would call registrars to assist at these deliveries. The fact that only one delivery was conducted by a consultant raises the question of supervision and availability of senior staff in the labour ward. It is difficult to comment on these issues here, because the notes did not indicate whether the person conducting the delivery was supervised or not. The delivery notes were also deficient in

detail on the births. According to the department standard operating procedures, reproduced earlier in this report, it is mandatory to write detailed notes on vaginal breech deliveries, especially timing, estimated fetal weight, fetal heart rate, type of breech, method of breech delivery and manoeuvres done. The findings of this audit suggest the contrary, that doctors and midwives include very little of the necessary detail and therefore expose themselves and the hospital to medicolegal risks, should these infants come to harm at any stage after the vaginal breech delivery.

The 23 women who were correctly diagnosed as having breech presentations were booked for caesarean section and ended up delivering vaginally. The reasons for this are unknown in the individual cases, but a deficiency in obstetric theatre facilities is a chronic problem at Chris Hani Baragwanath, and this may have led to excessive waiting times and spontaneous vaginal births (personal communication - Professor E Buchmann)

Neonatal outcomes were poor in a number of cases, with over 20% having some degree of encephalopathy. There were 8 perinatal deaths, 4 of them in babies with birthweights less than 1000 g. These smaller infants primarily died from prematurity-related causes. The 4 larger infants died from intrapartum asphyxia, although in 3 of them, it was difficult to determine if the vaginal breech delivery itself played a role in causing the asphyxia. In only one case, where the baby weighed 3920 g at birth and the aftercoming head became impacted in the pelvis, was there a clear problem with the breech delivery. That case was particularly unfortunate because the woman had been booked for elective caesarean section, albeit somewhat later in the pregnancy, about 40 weeks instead of 39,

than would be expected for elective caesarean section. Analysis of perinatal outcome according to the planned mode of delivery on admission in labour showed no significant differences. However, the sample size may have been too small to detect any associations in this respect.

5.2 Limitations

This audit has certain limitations. The quality of data from the clinical notes, while also being audited, provided in many cases insufficient information about the circumstances surrounding the breech deliveries. An example of this, already mentioned, was the inability to determine whether the accoucheurs were supervised by consultants. Although practically very difficult, a prospective study design involving interviews with the staff involved with each case, would have been more informative. Another limitation was the absence of audit of a 'control' group of women who had optimal care such as external cephalic version and caesarean section for breech presentation. There may be a tendency to be overcritical when confronted with data as it appears in this audit. Knowledge of the circumstances of such pregnancies might provide more reassuring data. Unfortunately, the registers in the antenatal clinic and the operating theatre do not allow complete collection of such data. The other limitation is the fact that we did not look at maternal outcome as well as the duration of hospital stay. The psychological impact on mothers whose babies died is not reflected here. This is because the study was a retrospective audit relying on clinical notes. Finally, a limitation on the neonatal outcome is the lack of long-term follow-up to determine which of the infants went on to develop

neurodevelopmental disability, a major factor in legal claims against obstetric care services.

5.3 Conclusion

There is room for improvement in clinical care and in note-keeping with respect to breech presentation and vaginal breech delivery at Chris Hani Baragwanath Hospital. A significant number of poor neonatal outcomes occurred subsequent to vaginal breech delivery. However, the majority of vaginal breech deliveries occur without warning even in the presence of standard antenatal care. This means that vaginal breech deliveries will continue to occur in this institution. The obstetric department must ensure that clinicians remain skilled in vaginal breech delivery and understand the importance of following standard protocols and operating procedures to prevent poor clinical outcomes and associated medico-legal hazards.

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Appendix A. Data capture sheet

Data sheet

Study number ……. Date……

Age……. Parity before delivery…… Gestation……..wk

Previous breech delivery? Y / N

Previous caesarean section? Y / N

African	White	Indian	Colored	Unknown

Booked	Unbooked
No. of visits: Last visit at …….. weeks?	

Referral during antenatal care? Y / N Reason for referral…….

Was sonar done? Y / N

If yes, what was the presenting part at last sonar?.....At what gestation?.....wk

Stage at which breech diagnosed:

At antenatal clinic	*Latent phase of labour*	*Active phase of labour*	*Second stage of labour*

Antepartum haemorrhage Y/N; Abruptio placentae Y/N

Was there an opportunity to do ECV (referred or noted by Dr)?

Antenatally: Y / N In 1st stage of labour: Y / N

Was ECV attempted? Y / N

Was elective CS booked from antenatal clinic/ward: Y/N

Did the woman choose vaginal breech delivery? Y / N

Cervical dilatation on arrival at CHB: ……. cm

Did the clinician decide on vaginal breech delivery? Y/N

Was breech presentation missed during labour? Y/N

Was emergency CS booked during labour? Y/N

Analgesia in labour: Nil / Epidural / Pethidine

Pre-delivery notes:

	Written	Notes	Nothing written
Mother accepts VD			
Pelvic assessment			
Estimated fetal weight			
Head extension			
Level of presenting part			
Cervical dilatation			
Partogram used			
Emergency ultrasound			

Accoucheur: Consultant / Registrar / MO/ Intern / Midwife

More senior doctor called: Y / N

Episiotomy: Y / N

What type of breech delivery: Spontaneous / Assisted / Extraction / Unknown

Time (how long did it take to extract baby)……..mins./ Not recorded

Any complication? Eg PPH…….

Delivery notes: Written: Y / N. If so……

	Written	Notes	Nothing written
Fetal heart rate before			
Time started – trunk			
Type of breech			
Method for lower limbs			
Method for arms			
Method for head			
Time of delivery of head			
Complications			

Baby's condition at birth			
Name of accoucheur			
Rank / qualification			

Apgar score at 5 minutes……..

Injury: None/……..

Birth weight……g

Resuscitated? Y / N

Admission Y / N If yes, ……days……weeks

Complications: Prematurity / Respiratory distress / Jaundice / HIE / Death/ none

Appendix B. Ethics approval certificate

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

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Bernard Uzambakiriho

CLEARANCE CERTIFICATE	**M10315**
PROJECT	Audit of Breech Vaginal Deliveries at CH Baragwanath Hsopital
INVESTIGATORS	Dr Bernard Uzambakiriho.
DEPARTMENT	Department of Obstetrics & Gynaecology
DATE CONSIDERED	26/03/2010
DECISION OF THE COMMITTEE*	Approved unconditionally

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

DATE 29/03/2010 **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...