# PRIMARY OBSTETRIC ULTRASOUND: COMPARING A DETAIL ULTRASOUND ONLY PROTOCOL WITH A BOOKING ULTRASOUND PROTOCOL

by

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A dissertation submitted for the degree of Master of Reproductive Medicine at the University of Stellenbosch

December 2009

# “DECLARATION

I, the undersigned, hereby declare that the work contained in this thesis is my original work and that I have not previously in its entirety or in part submitted it at any university for a degree.

**Signature ___________________** **Date __________________”**

# ABSTRACT

**Background** The current obstetric ultrasound service in the Tygerberg hospital (TBH) drainage area provides only routine early scans with follow-up for selective clinical indications. Patients who book at and after 24 weeks gestational age do not receive an ultrasound unless clinically indicated. Therefore fetal abnormalities and or pregnancy complications in this group could go undetected.

**Aims** The primary aim of the study was to compare 2 ultrasound referral protocols in respect of the number of clinically relevant abnormalities detected prior to delivery and their gestational age (GA) at diagnosis:

- The current protocol of routine early ultrasound scans (18 – 23 weeks) and scans for selective clinical indications (Control Group/ Group A)
- The new protocol of booking scans for all, regardless of GA, and follow-up for selective clinical indications protocol (Study Group/ Group B).

Secondary aims of the study were:

- To compare the number of patients receiving an ultrasound and the total number of scans performed in each group, including all follow-up scans.
- To compare the number of patients receiving an ultrasound between 18 and 23 weeks GA since this is regarded as the most appropriate for a detailed scan.
- To calculate and compare the percentages of (presumed) postdates or preterm pregnancies and small for gestational age (SGA) babies between both groups.
- To determine which of the three dating methods (ultrasound, last menstrual period (LMP) dates and fundal height (FH) measurements) estimates the date of delivery most accurately.
- To determining the influence of the body mass index (BMI) on the accuracy of GA estimation by means of a FH measurement.

- To obtain more accurate data on booking tendencies by calculating the GA at booking, confirmed by ultrasound.

**Methods** An analytical audit was done on a low-risk population attending 2 public sector antenatal care facilities in the Cape Town metropolitan area. Firstly the audit was done with the current, routine early ultrasound and selective referral protocol for specific clinical indications in place. Following this audit the ultrasound protocol was changed to a booking scan and selective referral protocol for specific clinical indications and another audit was done. The study followed a participatory action research model. Seven hundred and fifty consecutive patients were recruited into each group.

**Results** There were 631 (84.1%) patients in Group A and 629 (83.9%) patients in Group B with known pregnancy outcome. The two groups were comparable with regard to age, gravidity, parity, mean birth weight (BW), number of low BW cases and cases of intra-uterine death. Although the two groups differed significantly in the median 5 minute Apgar scores ($p$ = 0.001), the difference was concluded to be of no clinical significance. No difference was found in the number of cases with Apgar scores below 7 ($p$ = 0.12).

A significant difference was found between the groups with regard to the number of complications and abnormalities detected antenatally with ultrasound [$p$ = 0.02 OR (95%CI): 0.62(0.41 - 0.94)]. This is mainly due to significantly more early fetal loss cases detected in Group B [$p$ = 0.03 OR (95%CI): 0.12 (0.01 – 0.96)]. There was however no difference between the number of congenital fetal abnormalities ($p$ = 0.33), twin pregnancies ($p$ = 0.53) and the number of early low lying placentas ($p$ = 0.41).

The two groups were comparable with regard to the number of abnormalities and complications at birth ($p$ = 0.29) even though 93.7% of cases with abnormalities or complications at birth had a scan in Group B as opposed to the 62.3% of

cases in Group A. In total, three cases with fetal abnormalities were overlooked at Bishop Lavis Community Health Centre.

No difference was found between the groups with regard to the number of congenital fetal abnormalities (8 vs 6, $p = 0.79$), the number (5 vs 12, $p = 0.14$) or mean GA at diagnosis (21w4d vs 18w4d, $p = 0.30$) of twin pregnancies or the number of cases with placenta praevia at 32 weeks (1 vs 1), detected with ultrasound. Combining these complications also yielded no difference between the groups with regard to the number of complications (14 vs 19, $p = 0.47$) nor the mean GA at diagnosis (22w4d vs 19w1d, $p = 0.07$).

Significant differences between groups A and B were shown in the median (1 vs 1, $p < 0.001$) and average (0.81 vs 1.41) number of scans performed per patient. Differences were also shown in the number of scans performed between 18 weeks 0 days and 23 weeks 6 days [330 vs 382, $p = 0.003$ OR (95%CI): 0.71 (0.56 – 0.89)], the number of scans performed prior to 24 weeks GA [336 vs 412, $p < 0.001$ OR (95%CI): 0.60 (0.47 – 0.76)] and the number of patients receiving at least one scan [390 vs 567, $p < 0.001$ OR (95%CI) 0.18 (0.13 – 0.24)]. A 74% increased workload was observed with Group B.

A significant difference was found when comparing the groups with regard to the number of requested follow-up ultrasound examinations by the ultrasound departments [105 vs 313, $p < 0.001$ OR (95%CI): 0.20 (0.15 – 0.26)]. This was mainly due to the significant increase in requested follow-up examinations for fetal detail in Group B [42 vs 212, $p < 0.001$ OR (95%CI): 0.32 (0.20 – 0.51)] and is also responsible for the significant differences found in the number of requests for follow-up for possible fetal abnormality [14 vs 11, $p < 0.001$ OR (95%CI): 4.22 (1.73 – 10.38)] fetal growth and Doppler [29 vs 54, $p = 0.03$ OR (95%CI): 1.83 (1.05 – 3.17)] and placenta localization at 32 weeks GA [10 vs 10, $p = 0.02$ OR (95%CI): 3.19 (1.19 – 8.58)].

The two groups were comparable for all clinical reasons for ultrasound referrals ($p$ = 0.60). The change in referral protocol for certain high risk patients from TBH to Karl Bremer hospital on the 1st of July 2008 did not have a negative effect on the study as the number of patients delivering at Elsiesriver Midwife Obstetric Unit remained unchanged ($p$ = 0.23). No difference was found between the groups with regard to all types of labour and modes of delivery.

No difference was found between the groups in the number of preterm deliveries ($p$ = 0.64) and SGA babies ($p$ = 0.42). A significant difference was found with regard to the number of postdates deliveries [$p$ = 0.01 OR (95%CI): 1.64 (1.11 – 2.41)]. When combining these complications related to the accurate dating of pregnancies, no difference was found ($p$ = 0.50). In order to determine the impact of ultrasound at and after 24 weeks GA the number of patients who did not receive an ultrasound in Group A was compared to the number of patients in Group B who received an ultrasound at and after 24 weeks GA. No difference was found with regard to the preterm deliveries ($p$ = 0.30) and SGA babies ($p$ = 0.86). A significant difference was found in the postdates pregnancy category [$p$ = 0.001 OR (95%CI): 2.28 (1.34 – 3.89)] and when these complications were combined [$p$ = 0.003 OR (95%CI): 1.65 (1.17 – 2.31)].

Comparing the 3 pregnancy dating methods (ultrasound, LMP dates and FH measurements), revealed that ultrasound predicted the estimated due date within 10 days in 89.8% of cases in comparison to the 66.5% predicted by using the LMP dates and the 54.6% predicted by using the FH measurements. Significant differences were found when ultrasound was compared to LMP ($p$ < 0.001), ultrasound compared to FH ($p$ < 0.001) and LMP compared to FH ($p$ = 0.01).

The mean BMI of Group A was found to be significantly ($p$ = 0.004) less than the mean BMI observed for Group B. This was concluded to be of no clinical significance. Data from the two groups were combined in the calculation to determine the impact of BMI on FH measurements. All patients who received an ultrasound and had a known FH measurement were included in the calculation. Ultrasound was set to naught and the difference in weeks between GA as determined by ultrasound and FH was determined. With a BMI of up to 39.9kg/m$^2$, GA as determined by ultrasound and FH agreed within 3 weeks in 75 to 80% of cases. With a BMI of 40kg/m$^2$ and over the agreement within 3 weeks decreased to less than 46% of cases.

In Group B, 444 patients (78.2%) attended their ultrasound appointment within 7 days of booking. Of these 23.4% were found to be less than 18 weeks, 42.3% between 18 weeks 0 days and 23 weeks 6 days and 34.2% were at and over 24 weeks GA. Therefore, 65.7% of patients were eligible for a detail scan. In this group the clinically determined GA prior to ultrasound agreed within 2 weeks and 3 weeks with the GA as determined with ultrasound in 69.6% and 82.8% of cases respectively.

**Conclusions** In this population only approximately 34% of patients benefited from the booking scan protocol. This protocol would probably be better suited for a population with a higher percentage of patients booking at and after 24 weeks GA. The booking scan protocol increased the workload significantly with no significant benefits except for the reduced number of postdates pregnancies.

A booking scan is also recommended for all patients with body mass indexes of 40 or greater as the GA as determined by fundal height and ultrasound correlated within 3 weeks in less than 50%. A travelling ultrasound service will aid in improving the attendance rate in a population that is in general socio-economically deprived.

A combination of both protocols is likely to be more cost-effective: patients booking with a FH of less than 26 cm are scheduled for a detail scan between 18 and 24 weeks clinically estimated GA while patients booking later than this (either all of them or at least those with a BMI of 40 $kg/m^2$ or more) are scanned as soon as possible after booking. This protocol would probably still demonstrate the benefit of reduced postdates pregnancies while significantly reducing the total workload. This could be the topic of a subsequent study.

# ABSTRAK

**Agtergrond** Die huidige obstetriese sonar diens in die Tygerberg hospital (TBH) dreineringsarea voorsien slegs roetine vroeë sonars met opvolg vir selektiewe kliniese indikasies. Pasiënte wat na 24 weke gestasie ouderdom bespreek ontvang slegs 'n sonar indien dit klinies aangedui is. Fetale abnormaliteite en of komplikasies van swangerskap in hierdie groep kan ongediagnoseerd bly.

**Doelwitte** Die primêre doelwit van die studie was om 2 sonar verwysings protokolle te vergelyk ten opsigte van die hoeveelheid klinies relevante abnormaliteite geïdentifiseer voor geboorte en die gestasie met diagnose:

- Die huidige roetine vroeë sonar (18 – 23 weke) protokol en sonars vir selektiewe kliniese indikasies (Groep A).
- Die nuwe besprekings sonar vir almal protokol, onafhanklik van gestasie en opvolg vir selektiewe kliniese indikasies (Group B).

Sekondêre doelwitte van die studie was:

- Om die hoeveelheid pasiënte wat 'n sonar ontvang het te vergelyk asook die totale hoeveelheid sonars wat gedoen is in elke groep insluitend die opvolg ondersoeke.
- Om 'n vergelyking te tref tussen die hoeveelheid pasiënte wat 'n sonar ontvang het tussen 18 en 23 weke gestasie sienende dat hierdie tydsgleuf as die mees ideale tyd vir 'n detail sonar geag word.
- Om die persentasies van vermoedelike post-mature en pre-mature swangerskappe asook klein vir gestasie babas te bepaal en te vergelyk tussen die 2 groepe.
- Om te bepaal watter een van die 3 gestasie bepalende metodes (sonar, laaste menstruele periode (LMP) datums en fundale hoogte (FH) mates) die datum van verlossing die beste voorspel.
- Om te bepaal wat die invloed is van die liggaams massa indeks (BMI) op die akkuraatheid van gestasie bepaling deur middel van die FH mate.

- Die verkryging van meer akkurate inligting oor die besprekings neigings deur die gestasie by bespreking te bepaal, bevestig met sonar.

**Metodes** ‘n Analitiese oudit was gedoen op ‘n lae risiko populasie wat voorgeboorte sorg ontvang by 2 publieke sektor fasiliteite in die Kaapstad metropolitaanse area. Die oudit was eers gedoen met die huidige roetine vroeë sonar en selektiewe verwysings protocol vir spesifieke kliniese indikasies in plek. Dit was gevolg deur ‘n verandering in die protokol na ‘n besprekings sonar en selektiewe verwysings protokol vir spesifieke kliniese indikasies en nog ‘n oudit is gedoen. Die studie het ‘n deelnemings aksie navorsings model gevolg. Sewe honderd en vyftig opeenvolgende pasiënte was gewerf vir elke groep in die studie.

**Resultate** Daar was 631 (84.1%) pasiënte in Groep A en 629 (83.9%) pasiënte in Groep B waarvan die swangerskapsuitkomste bekend was. Die twee groepe was vergelykbaar in terme van ouderdom, graviditiet, pariteit, gemiddelde geboortegewig, hoeveelheid lae geboortegewig en intra-uteriene sterfgevalle. Alhoewel die twee groepe betekenisvol verskil het in die mediaan 5 minute Apgar tellings ($p$ = 0.001), was die verskil bevind om van geen kliniese belang te wees nie. Geen verskil was gevind in die hoeveelheid gevalle met Apgar tellings onder 7 nie ($p$ = 0.12).

‘n Betekenisvolle verskil was gevind tussen die groepe met betrekking tot die hoeveelheid komplikasies en abnormaliteite wat opgespoor is voor geboorte met sonar [$p$ = 0.02 OR (95%CI): 0.62(0.41 - 0.94)]. Dit is hoofsaaklik as gevolg van die betekenisvolle meer vroeë fetale verliese wat opgespoor is in Groep B [$p$ = 0.03 OR (95%CI): 0.12 (0.01 – 0.96)]. Daar was geen verskil gevind tussen die hoeveelheid kongenitale fetale abnormaliteite ($p$ = 0.33), tweeling swangerskappe ($p$ = 0.53) en die hoeveelheid vroeë laag liggende plasentas ($p$ = 0.41) nie.

Die twee groepe was vergelykbaar in die hoeveelheid abnormaliteite en komplikasies by geboorte ($p = 0.29$) ten spyte daarvan dat 93.7% van gevalle met abnormaliteite en komplikasies by geboorte 'n sonar gehad het in Groep B in teenstelling met die 62.3% van gevalle in Groep A. In totaal was 3 fetale abnormaliteite oorgesien by die Bishop Lavis Gemeenskaps Gesondheid Sentrum.

Geen verskil was gevind tussen die groepe in die hoeveelheid kongenitale fetale abnormaliteite (8 teen 6, $p = 0.79$), die hoeveelheid (5 teen 12, $p = 0.14$) en gemiddelde gestasie met diagnose (21w4d teen 18w4d, $p = 0.30$) van tweeling swangerskappe of die hoeveelheid van gevalle met plasenta praevia teen 32 weke (1 vs 1), soos bevind met sonar, nie. Die kombinasie van hierdie komplikasies het ook geen verskil opgelewer tussen die groepe met betrekking tot die hoeveelheid komplikasies (14 teen 19, $p = 0.47$) of die gemiddelde gestasie met diagnose nie (22w4d teen 19w1d, $p = 0.07$).

Betekenisvolle verskille was gevind tussen die groepe in die mediane (1 teen 1, $p < 0.001$) en gemiddelde (0.81 teen 1.41) hoeveelheid sonars wat gedoen is per pasiënt. Verskille is ook gevind in die hoeveelheid sonars wat gedoen is tussen 18 weke 0 dae en 23 weke 6 dae [330 teen 382, $p = 0.003$ OR (95%CI): 0.71 (0.56 – 0.89)], die hoeveelheid sonars wat gedoen is voor 24 weke gestasie ouderdom [336 teen 412, $p < 0.001$ OR (95%CI): 0.60 (0.47 – 0.76)] en die hoeveelheid pasiënte wat ten minste 1 sonar ontvang het [390 teen 567, $p < 0.001$ OR (95%CI) 0.18 (0.13 – 0.24)]. 'n 74% verhoogde werkslading was waargeneem in Groep B.

'n Betekenisvolle verskil was gevind met die vergelyking van die hoeveelheid opvolg ondersoeke wat aangevra is deur die sonar departemente [105 teen 313, $p < 0.001$ OR (95%CI): 0.20 (0.15 – 0.26)]. Dit was hoofsaaklik as gevolg van die aansienlike verhoging in opvolg ondersoeke wat aangevra is vir fetale detail in Groep B [42 teen 212, $p < 0.001$ OR (95%CI): 0.32 (0.20 – 0.51)] en is ook verantwoordelik vir die betekenisvolle verskille wat gevind is in die hoeveelheid opvolg ondersoeke wat aangevra is vir moontlike fetale abnormaliteite [14 teen 11, $p$ < 0.001 OR (95%CI): 4.22 (1.73 – 10.38)] fetale groei en Doppler [29 teen 54, $p$ = 0.03 OR (95%CI): 1.83 (1.05 – 3.17)] en bepaling van plasentale ligging teen 32 weke gestasie ouderdom [10 teen 10, $p$ = 0.02 OR (95%CI): 3.19 (1.19 – 8.58)].

Die twee groepe was vergelykbaar vir alle kliniese redes vir sonar verwysings ($p$ = 0.60). Die verandering in verwysingsprotokol vir sekere hoë risiko pasiënte van TBH na Karl Bremer hospitaal vanaf die 1$^{ste}$ Julie 2008 het nie 'n negatiewe effek gehad op die studie nie sienende dat die hoeveelheid pasiënte wat by Elsiesrivier vroedvrou obstetriese eenheid gekraam het, onveranderd gebly het ($p$ = 0.23). Geen verskil was gevind tussen die groepe vir alle tipes kraam en metodes van verlossing nie.

Geen verskil was gevind tussen die groepe in die hoeveelheid voortydse verlossings ($p$ = 0.64) en klein vir gestasie babas nie ($p$ = 0.42). 'n Betekenisvolle verskil was gevind in die hoeveelheid post-mature geboortes [$p$ = 0.01 OR (95%CI): 1.64 (1.11 – 2.41)]. Die kombinasie van hierdie komplikasies wat verband hou met die akkurate gestasie bepaling van swangerskappe het geen verskil tussen die groepe opgelewer nie ($p$ = 0.39). Om die impak te bepaal van sonar na 24 weke gestasie was die hoeveelheid pasiënte wat nie 'n sonar ontvang het in Groep A vergelyk met die hoeveelheid pasiënte in Groep B wat 'n sonar ontvang het op en na 24 weke gestasie. Geen verskil was gevind in terme van voortydse verlossings ($p$ = 0.30) en klein vir gestasie babas nie ($p$ = 0.86). 'n Betekenisvolle verskil is wel gevind in die post-mature geboorte kategorie [$p$ = 0.001 OR (95%CI): 2.28 (1.34 – 3.89)] en wanneer die komplikasies gekombineer was [$p$ = 0.003 OR (95%CI): 1.65 (1.17 – 2.31)].

Vergelyking van die 3 swangerskaps duurte bepaling metodes (sonar, LMP datums en FH mates), het getoon dat sonar die geskatte datum van verlossing binne 10 dae in 89.8% van gevalle akkuraat voorspel het in teenstelling met die 66.5% voorspel deur die gebruik van die LMP datums en die 54.6% voorspel deur die gebruik van die FH mates. Betekenisvolle verskille was gevind tussen sonar en LMP datums ($p < 0.001$), sonar en FH mates ($p < 0.001$) en LMP datums en FH mates ($p = 0.01$).

Die gemiddelde BMI van Groep A was betekenisvol minder ($p = 0.004$) as die gemiddelde BMI soos gevind in Groep B. Dit was bevind om van geen kliniese belang te wees nie. Data van die twee groepe was gekombineer om die impak van BMI op FH mates te bepaal. Alle pasiënte wat ‘n sonar ontvang het en ‘n bekende FH mate gehad het was ingesluit in die berekening. Sonar was gestel op nul en die verskil in weke tussen die gestasies soos bepaal deur sonar en FH mate was bereken. Met ‘n BMI tot en met 39.9kg/$m^2$ is gevind dat die gestasie soos bepaal deur sonar en FH mates ooreengestem het binne 3 weke in 75 – 80% van gevalle. Met ‘n BMI van 40kg/$m^2$ en meer het die ooreenstemming verlaag na minder as 46% van gevalle.

In Groep B het 444 pasiënte (78.2%) hul sonar afspraak binne 7 dae van bespreking nagekom. Van hierdie pasiënte was 23.4% se gestasie onder 18 weke, 42.3% tussen 18 weke 0 dae en 23 weke 6 dae en 34.2% se gestasie was op en oor 24 weke gestasie. Dit wil sê 65.7% van pasiënte sou kwalifiseer vir ‘n detail sonar. In hierdie groep het die gestasie soos klinies bepaal voor sonar binne 2 en 3 weke ooreengestem met die gestasie soos bepaal deur sonar in 69.6% and 82.8% van gevalle onderskeidelik.

**Gevolgtrekkings** In hierdie populasie het slegs ongeveer 34% van pasiënte voordeel getrek uit die besprekings sonar protokol. Hierdie protokol kan moontlik beter gepas wees vir ‘n populasie met ‘n hoër persentasie van pasiënte wat op en na 24 weke gestasie ouderdom bespreek. Die besprekings sonar protokol het die werkslading merkwaardig verhoog met min betekenisvolle voordele behalwe vir die verminderde hoeveelheid vermoedelike post-mature swangerskappe.

‘n Besprekings sonar word aanbeveel vir alle pasiënte met ‘n liggaams massa indeks van 40 of meer sienende dat die gestasie ouderdom soos bepaal deur die fundale hoogte en sonar ooreengestem het binne 3 weke of minder in minder as 50% van gevalle. ‘n Mobiele sonar diens sal help om die bywonings tempo te verbeter in ‘n populasie wat in die algemeen sosiaal-ekonomies minderbevoorreg is.

‘n Kombinasie van beide protokolle sal heel moontlik meer koste effektief wees: pasiënte wat bespreek met ‘n FH van minder as 26cm word geskeduleer vir ‘n detail sonar tussen 18 en 24 weke volgens klinies geskatte gestasie terwyl pasiënte wat later as 24 weke bespreek (almal of ten minste daardie met ‘n BMI van $40kg/m^2$ of meer) ‘n sonarondersoek kry so gou as moontlik na bespreking. Hierdie protokol sal moontlik steeds die voordele inhou van die verlaging van vermoedelike post-mature swangerskappe asook die aansienlike verlanging van die totale werkslading. Dit kan ‘n onderwerp wees vir ‘n volgende studie.

# ACKNOWLEDGEMENTS

The researcher would like to thank Professors GB Theron and LTGM Geerts for their guidance and support, the nursing staff at Elsiesriver and Bellville South Community Health Centres for their co-operation and Mrs. Debbie Grové for the statistical analysis.

Thanks are due to the Harry Crossley fund for providing funds for the study as well as the Department of Health of the Western Cape for their interest and support.

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# LIST OF ABBREVIATIONS

| | |
|---|---|
| AC: | Abdominal circumference |
| AFI: | Amniotic fluid index |
| AGA: | Appropriate for gestational age |
| ANC: | Antenatal clinic |
| AVSD: | Atrial-ventricular septal defect |
| BBA: | Birth before arrival |
| BL: | Bishop Lavis |
| BMI: | Body mass index |
| BPD: | Biparietal diameter |
| BW: | Birth weight |
| CA: | Chorio-amnionitis |
| CHC: | Community Health Centre |
| CI: | Confidence interval |
| CPI: | Chronic placental insufficiency |
| CRL: | Crown-rump-length |
| D: | Days |
| DP: | Deepest pool |
| EDD: | Expected date of delivery |
| EFW: | Estimated fetal weight |
| ELBW: | Extremely low birth weight |
| ENND: | Early neonatal death |
| E/R: | Elsiesriver |
| FH: | Fundal height |
| FL: | Femur length |
| G: | grams |
| GA: | Gestational age |
| GDM: | Gestational diabetes mellitus |
| HC: | Head circumference |
| HIV: | Human immunodeficiency virus |

| | |
|---|---|
| IUD: | Intra-uterine death |
| IUGR: | Intra-uterine growth restriction |
| KBH: | Karl Bremer Hospital |
| LBW: | Low birth weight |
| LGA: | Large for gestational age |
| LMP: | Last menstrual period |
| MC: | Monochorionic |
| MOU: | Midwife obstetric unit |
| ND: | Not diagnosed on scan |
| NS: | No scan |
| OR: | Odds ratio |
| PE: | Pre-eclampsia |
| PH: | Pulmonary hypoplasia |
| PIH: | Pregnancy induced hypertension |
| PlHypo: | Placental hypoperfusion |
| PPROM: | Preterm prelabour rupture of membranes |
| SD: | Standard deviation |
| SGA: | Small for gestational age |
| SROM: | Spontaneous rupture of membranes |
| TBH: | Tygerberg hospital |
| TOP: | Termination of pregnancy |
| TTTS: | Twin-to-twin transfusion syndrome |
| VLBW: | Very low birth weight |
| W: | Weeks |

# LIST OF DEFINITIONS

**Abruptio placenta:** Premature separation or detachment of the placenta from the chorion.

**Agenesis:** Congenital absence of an organ or part, usually caused by a lack of primordial tissue and failure of development in the embryo.

**Amniotic fluid index:** Measured after 28 weeks gestational age. The maternal umbilicus is used to divide the uterus into quadrants and the deepest vertical pocket in each measured. The four values are added together. Values between 5 and 25cm are regarded as normal.

**Body mass index (BMI):** A formula for determining obesity. It is calculated by dividing a person's weight in kilograms by the square of the person's height in centimeters.

**Chorionicity:** Determining how many placentas are present in a multiple pregnancy. Monochorionicity pertaining to a single placenta and dichorionic to two placentae.

**Deepest pool:** A means of assessing amniotic fluid volume. Usually calculated prior to 28 weeks gestational age. The deepest unobstructed pocket of amniotic fluid is selected and measured vertically. Values of between 2 and 8cm are regarded as normal.

**Doppler:** A technique for detecting the movement of blood flow.

**Ectopic pregnancy:** An abnormal pregnancy in which the conceptus implants outside the uterine cavity.

**Extremely low birth weight:** Birth weight below 1000g.

**Fundal height:** The height of the fundus, measured in centimeters from the top of the symphysis pubis to the highest point in the midline at the top of the uterus.

**Gestational age:** Duration of pregnancy expressed in weeks. Weeks stated include the days of the week up to and including the $6^{th}$ day.

**Gestational diabetes mellitus:** A disorder characterised by an impaired ability to metabolise carbohydrates usually caused by a deficiency of insulin, occurring in pregnancy. It disappears after delivery of the infant but, in a significant number of cases, returns years later.

**Growth restriction:** Is diagnosed when the growth rate deviated significantly from an established norm. Intra-uterine growth restriction may be implied from the presence of other features, such as reduced amniotic liquor, diminished fetal activity and abnormal Doppler waveforms.

**Hypoperfusion:** Decreased passage of fluid, like blood, through a specific organ or an area of the body.

**Level II hospital:** A hospital with general specialist services.

**Level III hospital:** A hospital with sub-specialist care where invasive ultrasound procedures are performed by maternal fetal medicine specialists.

**Low lying placenta:** Placenta inserted into the lower segment of the uterus within 2cm of the internal cervical os prior to 24 weeks gestational age. The placenta can also cover the internal cervical os partially or completely.

**Low birth weight:** Birth weight below 2500g.

**Obstetric ultrasound protocol:** Guidelines used by doctors and nursing staff for the referral of obstetric patients for ultrasound.

**Placental insufficiency:** An abnormal condition of pregnancy, manifested clinically by a decreased rate of fetal and uterine growth. One or more placental abnormalities cause dysfunction of maternal-placental or fetal-placental circulation sufficient to compromise fetal nutrition and oxygenation.

**Placenta praevia:** Diagnosed after 28 weeks gestational age. Placenta implants in the lower segment of the uterus less than 5cm from the internal cervical os. The placenta can also cover the internal cervical os partially or completely.

**Postmaturity:** Beyond the normal date of maturity, beyond 41 weeks or 294 days gestational age.

**Pre-eclampsia:** An abnormal condition of pregnancy characterised by the onset of acute hypertension and proteinuria after the twenty-fourth week of gestation.

**Pregnancy induced hypertension:** Hypertension occurring during and caused by pregnancy and resolves after birth.

**Preterm labour:** Labour commencing after viability (27 weeks or 800g) and before 37 weeks GA.

**Prophylactic:** Preventing the spread of disease.

**Pulmonary hypoplasia:** Incomplete or underdevelopment of the lungs.

**Small for gestational age (SGA):** A baby with a birth weight below the $10^{th}$ percentile for gestational age is regarded as being small for gestational age.

**Vascular anastomoses:** Communication of blood vessels.

**Very low birth weight:** Birth weight below 1500g.

# Chapter 1

# INTRODUCTION

Obstetric ultrasound is valuable in determining accurate gestational age (GA) and detecting abnormalities or complications, before it is clinically suspected. Ultrasound is often regarded as a luxury and not recognised as a very useful investigation that should form part of routine practice. The three standard referral protocols used are:

- Selective scan (only if clinically indicated)
- Routine scan (everyone booking before 24 weeks GA)
- Booking scan for all (regardless of GA)

Depending on the population group and availability of an ultrasound service, a selective scan protocol only, a routine early scan together with a selective scan protocol or a booking scan together with a selective scan protocol are usually used. In the Tygerberg region the current protocol includes a routine early ultrasound examination and selective referral protocol for specific clinical indications, regardless of whether women received a previous scan or not (Appendix A).[1] Patients are referred for a detail scan between 18 and 23 weeks GA. If they are less than 18 weeks pregnant, a detailed scan is scheduled for approximately 21 weeks GA. Low lying placentas are followed up at 32 weeks GA. Patients who attend clinic for the first time beyond 23 weeks (clinical estimation) do not receive an ultrasound unless it is clinically indicated. Clinical indications for ultrasound beyond 23 weeks GA are increased fundal height (FH) at the second or subsequent antenatal visits, clinical suspicion of twins, FH measurement at the second or subsequent antenatal visits falling below the 5$^{th}$ centile for GA as determined by the use of the locally derived FH centile chart and suspected malpresentation at and beyond 36 weeks GA [in respect of patients from the local antenatal clinic at Bishop Lavis Community Health Centre (CHC)](Appendix B).[2] The other 4 clinics, which are being serviced by the ultrasound department at Bishop Lavis CHC, refer patients for fetal presentation directly to TBH to avoid unnecessary travelling costs should the fetus be in a breech position requiring referral to Tygerberg Hospital (TBH).

With the use of this protocol, patients who book after 24 weeks GA do not receive an ultrasound unless clinically indicated. This is problematic because the dating of pregnancies with ultrasound at and after 24 weeks GA is not regarded as very accurate and the detection of fetal abnormalities is more difficult. However, some complications of pregnancy are detectable with ultrasound after 24 weeks GA including congenital fetal abnormalities, multiple pregnancies and placenta praevia.[3-5] The frequencies with which these complications occur at term are 2–3% (for major anomalies), 1% and 0.5–1.5% respectively. These complications could be life threatening to both the mother and baby/ies if the delivery is planned at a primary hospital, without prior knowledge of the condition. A booking scan with follow-up for selective clinical indications, could result in the earlier detection of these complications and lead to appropriate antenatal care and delivery management at a level 2 or 3 hospital. At the Bishop Lavis CHC an abnormality or complication is detected in approximately 5.4% of all patients scanned.[6]

The management of obstetric patients relies heavily on the accurate determination of GA. The majority of patients in this region do not recall the first day of their last menstrual period (LMP) with great accuracy.[7] This leaves health practitioners to determine GA from the FH measurement or ultrasound. There is literature evidence suggesting that ultrasound is superior to certain LMP dates in determining GA irrespective of the trimester in which the ultrasound examination was done.[8] It has also been suggested that ultrasound performs better in determining GA than FH measurements and that FH measurement accuracy increases with GA.[9] FH is usually used to assess fetal growth rather than GA and there is a lack of research determining FH accuracy in determining GA. It would be of value to compare the three different GA determination methods throughout pregnancy. The advantages would be more accurate scheduling of elective caesarean sections, planned inductions of labour necessitated by obstetric factors, anti-retroviral therapy initiation as well as a possible reduction in incorrectly diagnosed postdates and preterm deliveries.

A booking scan policy would mean that an ultrasound will be done as soon as possible after the date of first attendance with follow-up examinations for detail, placenta location or clinically relevant indications. Some potential advantages of this protocol would include more accurate dating and earlier detection of fetal abnormalities as well as pregnancy complications in patients booking after 24 weeks GA. However, this may result in a drastic increase in workload and it is unclear whether such a protocol is warranted in an already strained health care environment in South Africa.

Bishop Lavis CHC acts as the centre for primary level obstetric ultrasound examinations for five antenatal clinics (ANC) in the TBH drainage area (Belhar, Bellville South, Bishop Lavis, Delft and Elsiesriver). The study was conducted at two of these clinics, Bellville South and Elsiesriver.

In order to qualify as an ultrasonographer in South Africa a 3 year national diploma or 3 year degree in diagnostic radiography needs to be completed prior to doing an additional 2 year degree in ultrasound. Ultrasonography is regarded as a very scarce skill in South Africa. Ultrasound has many branches or subdivisions and most ultrasonographers working in government hospitals choose a subdivision like obstetrics and gynaecology. An ultrasonographer in a primary hospital could screen fairly large numbers of patients in order to detect as many fetal abnormalities or pregnancy complications as possible and refer them to a level 2 or 3 hospital for appropriate management. An ultrasonographer also serves as an additional check-point for the detection of high risk factors such as increased body mass index and abnormal outcome of pervious pregnancies, that referring staff might have overlooked.

# Chapter 2

## Tygerberg region obstetric service

The Bishop Lavis CHC ultrasound service deals almost exclusively with patients at low obstetric risk and was started in 1996 with ultrasonography students scanning patients from one antenatal clinic. The student-based service was later expanded to a full-time service for all 5 antenatal clinics and in 2004 a qualified ultrasonographer was appointed.

## LITERATURE REVIEW

Numerous studies have been conducted comparing selective and routine ultrasound referral protocols.[10-13] It was found that there was a reduction in the number of suspected postdates pregnancies, inductions for postdates, perceived preterm labours and referrals for fetal surveillance when a routine ultrasound protocol was used. Routine obstetric ultrasound examinations had no significant impact on pregnancy outcome and were associated with a significant increase in the number of scans performed.[12,13]

Major congenital fetal abnormalities are defined as those which have an adverse outcome on either the function or social acceptability of the individual and have an incidence of approximately 2 – 3%.[3] These abnormalities could be life threatening to both mother and baby and should be managed at a tertiary institution as soon as possible after detection. In some cases, termination of pregnancy (TOP) will be offered until 24 weeks GA. However, in more serious cases TOP may be offered even beyond this GA in South Africa, in cases where there is a substantial risk of suffering from serious handicap or the abnormality is known not to be compatible with meaningful survival after birth.[14] Some conditions, such as congenital diaphragmatic hernia can be treated in-utero with a procedure called fetal endoscopic tracheal occlusion.[15] It has been previously reported that early detection of fetal anomalies during routine scanning, reduced the perinatal mortality rate due to an increase in TOP for the anomalies.[16] However, the abnormal fetuses were merely excluded from the calculation of perinatal mortality and did not improve the overall pregnancy outcomes. As with most conditions, the earlier the abnormality is detected, the earlier management can be planned and treatment implemented if needed.

The incidence of twin pregnancies is approximately 1% at birth.[3] Fetal risks associated with multiple pregnancies are growth restriction, congenital abnormalities and intrauterine death.[14] Monochorionic (MC) (monozygotic) twins as opposed to dichorionic (DC) twins, have a higher incidence of complications.[14] This is mainly due to the shared placenta in MC twin pregnancies leading to blood volume shifts between the fetuses. The antenatal mortality rate for MC twins is nearly twice as high as in DC twin pregnancies and approximately four times as high as in singleton pregnancies.[14] It is therefore critical to determine chorionicity correctly. Prior to 14 weeks, chorionicity determination is very accurate with a sensitivity of 100% and specificity of 99%.[14] However, the ultrasound signs disappear as the pregnancy progresses. MC twin pregnancies require much more frequent follow-up visits and closer surveillance to improve outcome.[14] In some cases as with twin-to-twin transfusion syndrome (TTTS), twin reversed arterial perfusion and acute fetal transfusion after a single intrauterine death, treatment may involve separating the vascular anastomoses within the placenta with laser.[14] This greatly reduces the risk of losing both fetuses, however timing of treatment is essential. Numerous authors have found that the earlier detection of multiple pregnancies is not associated with an improved outcome.[10,11,16,17] However, the earlier a twin pregnancy is identified, the better chance of correctly determining chorionicity and subsequently planning the management of the pregnancy or treatment if required.[14] Even though MC twins carry a higher complication rate than DC twin pregnancies, more than three quarters of twin pregnancies are DC.[18] When compared with singleton pregnancies, DC twin pregnancies demonstrate an increased risk for preterm birth, intrauterine growth restriction (IUGR) and perinatal mortality. The presence of a twin pregnancy will also lead to an incorrect GA determination by FH if an ultrasound is not performed.

Placenta praevia occurs in approximately 0.5 – 1.5% of pregnancies.[4] The placenta is inserted partially or completely into the lower segment with varying degrees of obstruction of the internal cervical os. The aetiology is unknown, however age, parity and previous caesarean delivery have been identified as possible factors of association.[14] Other risk factors include cigarette smoking, drug abuse, previous abortion and previous placenta praevia.[14] The mother runs the risk of severe haemorrhage and even death if left untreated. Fetal risks include preterm birth, fetal growth restriction in up to 16% of cases, an almost double increased incidence of serious fetal malformations and umbilical cord complications such as cord prolapse or compression.[14] The overall perinatal mortality rate due to placenta praevia causing preterm birth has lowered from approximately 126 per 1000 nearly 23 years ago to 42 to 81 per 1000.[14] This is mostly due to conservative management and improved neonatal care. Based on the literature approximately 28% of women have a low lying placenta at the time of their detail scan.[14] This percentage lowers to 18% at 24 weeks and to 3% at term. Most centres, including TBH, rescan patients who have a low lying placenta at 20 to 23 weeks at 32 weeks.[14] Placenta localisation is not currently checked in patients who book after 24 weeks GA. With a booking scan protocol more cases of placenta praevia could be detected before complications arise, the pregnancy can be managed expectantly with the aim to prolong the pregnancy and antenatal steroids can be administered to enhance fetal lung maturity and thereby reducing the antenatal mortality further.

Polyhydramnios or hydramnios is defined as an ultrasonographically measured deepest pool (DP) of 8cm or greater, an amniotic fluid index (AFI) of 25cm or greater or above the 95$^{th}$ centile for GA.[14,19] This condition affects approximately 0.2% of pregnancies with various known causes.[14,19] Of these causes, maternal diabetes mellitus, inability of the fetus to swallow, various fetal anomalies, TTTS, fetal anaemia and congenital infections are the most significant. The most frequent maternal complications encountered are due to uterine distention.[14,19] There is also an increased incidence of caesarean section due to placental abruption and unstable fetal lie.[14] Antenatal mortality rates associated with polyhydramnios are approximately 5%.[14] This is mainly due to preterm prelabour rupture of membranes (PPROM) and subsequent preterm delivery as well as the presence of fetal malformations. The aim of general management of patients with polyhydramnios is to alleviate maternal symptoms and to prolong the pregnancy as far as possible.[14] Treatment is usually only indicated in those cases with moderate to severe polyhydramnios. Treatment will usually be directed at the underlying cause, however therapeutic amniocentesis may be indicated.[14] This procedure carries various risks, however it has been proven to prolong pregnancies and improve survival. In cases where FH is used to determine GA, polyhydramnios will only be suspected in those cases where the FH increases rapidly. The presence of polyhydramnios will also lead to an incorrect GA determination if an ultrasound is not performed.

Oligohydramnios is defined as a DP of 2cm or less, an AFI of 5cm or less or below the 5$^{th}$ percentile for GA.[14,19] The most common causes of oligohydramnios are PPROM, IUGR, chronic placental insufficiency, postmaturity and fetal anomalies.[14,19] Oligohydramnios is associated with an increased risk of caesarean section for fetal distress due to IUGR, fetal anomalies or umbilical cord compression.[14] Prematurity with subsequent low birth weight is a risk factor as well as pulmonary hypoplasia (PH) and skeletal deformities due to prolonged oligohydramnios.[14,19] The aims of managing patients with oligohydramnios will be to establish the aetiology and if the fetus is viable to monitor the fetal condition thus reducing perinatal mortality.[14] The presence of oligohydramnios will complicate GA determination if an ultrasound is not performed. The condition will only be suspected at the follow-up antenatal clinic visit if poor increase in FH is present and the 10$^{th}$ centile is crossed on the FH centile chart (Appendix B).[2] Timing of treatment in this condition is critical.

Subsequent to the detection of abnormal findings on ultrasound the patients need to be referred to the appropriate level of care for further management. The frequency of antenatal visits will be higher, compared to the low frequency (4 – 8 week intervals) of visits appropriate for low risk patients.

In combination, the above mentioned conditions constitute approximately 4 – 5% of pregnancies indicating that 5 out of every 100 patients who book after 24 weeks GA could have one of these conditions. With the current scanning protocol patients booking after 24 weeks do not routinely receive an ultrasound. Therefore, unless the condition worsens or the patient presents with symptoms like bleeding or with excessive or very poor growth in FH, the medical staff will never be aware of the condition being present.

**Hypothesis:**

Providing a booking scan to patients booking at or after 24 weeks GA, far more cases with pregnancy complications will be detected, leading to improved antenatal care and possibly pregnancy outcome.

Accurate dating of pregnancies is essential to make clinical decisions and to evaluate the fetus for growth disturbances during the pregnancy. Most centres, including TBH and the primary care antenatal clinics within the Tygerberg region, use the following method for dating at the first antenatal clinic visit.

- When the first day of the last LMP is sure and the ultrasound findings are in keeping with the GA according to the LMP (within 7 days in the first trimester, 10 – 14 days between 15 and 24 weeks and 21 days from 24 weeks onwards) the GA according to the LMP is used as the correct GA.[14]
- If the GA according to ultrasound in the first and second trimesters (up to 24 weeks) is not in keeping with the GA according to the LMP or the LMP dates are unsure, the average GA according to the ultrasound is used.[20]

- In cases where the LMP dates are sure and where the GA is more than 24 weeks and the GA by FH correlates within equal or less than 4 weeks, the GA according to the LMP is used as the correct GA.[20]
- If the LMP dates are unsure in the third trimester or are not in keeping with the GA according to the FH, the GA according to the FH will be regarded as the correct GA.[20] FH can be used to determine GA from a measurement of 18cm which corresponds to a gestation of approximately 20 weeks. The FH in centimetres is plotted on the 50th centile on the FH centile chart compiled on the same patient population as the index study.[2] According to the ultrasound protocol followed in the Tygerberg Region Obstetric service and approved by the department of Obstetrics and Gynaecology at TBH, if the LMP is uncertain and the FH measures 23cm or more a routine scan will not be done (Appendix A).[1] On the FH centile chart 23cm corresponds to 24 weeks if plotted on the 50th centile. This protocol was followed during the index study for the routine ultrasound group.

Accurate dating of pregnancies with ultrasound starts at 7 weeks GA. Patients who are less than 7 weeks pregnant are provided with a follow-up appointment for accurate dating at approximately 12 weeks GA. GA determination by ultrasound between 7 weeks 0 days and 11 weeks 6 days is achieved by measuring the crown-rump length (CRL), between 12 weeks 0 days and 13 weeks 6 days by measuring the CRL, biparietal diameter (BPD), head circumference (HC) and abdominal circumference (AC).[21-23] Beyond 13 weeks 6 days GA determination by ultrasound is done by measuring BPD, HC, AC and femur length (FL).[22-24] The ultrasound machine determines the average of the GA according to the different individual measurements and this is then used as the GA, on condition that the measurements are concordant and the fetus not anomalous. Determining GA with ultrasound at and after 24 weeks GA is not regarded as being very accurate and the clinical information (FH measurement and or LMP dates) on GA estimation should be taken into consideration.

The CRL is measured from the head of the fetus to its buttocks with the fetus in a neutral position, excluding the limbs and yolk sac.[21] The fetal head is measured on a transverse plane of the head at the level where the midline is continuous and interrupted by the cavum septum pellucidum in the anterior third.[22] The BPD is measured from the outer edge of the parietal bone nearer the transducer to the inner edge of the opposite parietal bone (outer-inner). The HC is measured on the BPD plane as the perimeter around the outer edge of the skull excluding the skin. The AC is measured as the outer perimeter of the fetal abdomen on a transverse plane at the level of the stomach and the intra-hepatic portion of the umbilical vein situated in the anterior third of the abdomen, including the skin.[23] The spine is identified posteriorly with the descending aorta located anterior to this. Both the HC and AC are measured by the use of an expanding ellipse. The FL is measured on an image demonstrating a femoral diaphysis in its entirety in a plane as close as possible to right angles to the ultrasound beam.[24] The femoral head and distal epiphysis are not included in the measurement and a straight measurement is made, disregarding the curvature of the femur.

Other investigators working in Africa found that patients do not recall the date of their LMP with great accuracy and routine antenatal ultrasound is not widely available.[7,25] In our setting, a routine ultrasound protocol is in use and patients who book at or after 24 weeks 0 days GA will only receive a scan if clinically indicated. Therefore, dating pregnancies, especially in the third trimester relies heavily on an accurate FH measurement. It has been suggested previously that ultrasound performs better in determining the GA throughout pregnancy when compared to certain LMP dates and predicts GA more accurately than FH measurements.[8,9,26] A study conducted in the Central African Republic in 1995 revealed that 45% and 63% of patients delivered within 2 and 3 weeks respectively of the estimated due date (EDD) as predicted by the FH.[25] However, there has been very limited research done on the accuracy of FH measurements in GA determination and the effect of increased body mass index (BMI) on FH measurements.

Birth weight (BW) is classified as low (<2500g), very low (<1500g) or extremely low (<1000g).[14] In the TBH region, 23.9% of babies born in 2008 had low BW.[27] This percentage includes live as well as still births. Of live births, 21.4% were classified as having low BW.[27] Major causes of low BW include prematurity and growth restriction [or small-for-gestational age (SGA)]. Preterm labour refers to labour that commences after viability (in our setting 27weeks or 800g if GA is unknown) and before 37 weeks GA. The incidence of preterm labour in developed countries is around 5 to 10%.[14] It is often caused by and associated with intrauterine infections, placental abruption or placenta praevia and cervical incompetence.[14] One of the biggest risk factors for the fetus is the risk of prematurity which could lead to respiratory distress syndrome, intracranial haemorrhage or pulmonary haemorrhage.[14] The percentage of patients with suspected preterm labour increases when GA is not accurately determined. This could lead to an increased number of deliveries being incorrectly considered to be preterm and more patients being referred unnecessarily to higher levels of care.[13] When a baby is born without prior knowledge of the GA at which birth took place, the BW together with the Ballard score is used to determine GA.[28] This method shows a 92% agreement with antenatal ultrasound for all postnatal gestational weeks (equal or greater than 28 weeks) up to 96 hours after birth. A centile chart for birth weights compiled on the same patient population as the index study is used for this purpose.[29] SGA babies have lower birth weights however they follow their own growth curve and may just be constitutionally small. SGA babies have a higher risk of perinatal compromise and of developing adult disease. A larger percentage of babies will be labelled SGA (or large for GA) if the GA is determined incorrectly and an incorrect diagnosis will result in undue anxiety.[30]

Postdates pregnancy is defined by The International Federation of Gynaecologists and Obstetricians as a pregnancy that continues for more than 294 days or 42 weeks after the last menstrual period.[14,31] This definition was used for the purposes of this study and labour is traditionally induced when 42 weeks is reached because the risk of stillbirth from 42 weeks onward is 1 in 1000 pregnancies and at 43 weeks 1 in 500. There is also an increased risk of birth asphyxia and trauma.[14] The most prominent maternal risk of induction of labour for postdates pregnancy is an increased risk of caesarean section.[14] The benefits of providing a booking scan for every patient regardless of GA in order to reduce the number of false preterm and postdates pregnancies by a better estimation of GA needs to be investigated to confirm the results found by other authors.[10-13] Postdates pregnancies are routinely referred from primary level of care to the next level of care for possible induction. Because a large proportion of patients in this area tend to book late, do not receive an ultrasound and do not recall their LMP dates with great accuracy, a conservative induction policy is used. If a postdates pregnancy is suspected, an AFI scan and cardiotocogram (CTG) are performed. The patient will be considered for induction if the AFI is less than 5cm or the CTG gives a poor result.[32] The fetal evaluation clinic at TBH examined approximately 600 patients for suspected postdates pregnancies in 2008.[33] A booking scan for all patients may significantly reduce the number of unnecessary referrals to the fetal evaluation clinic for suspected postdates pregnancy.

Accurate fetal size determination could be problematic in an overweight or obese patient. According to the World Health Organization normal weight is defined as a BMI of 20 – 25 $kg/m^2$, overweight as more than 25 $kg/m^2$ and a BMI greater than 30 $kg/m^2$ is known as obesity.[34] Obesity (outside of pregnancy) is divided into 3 categories or grades: I = BMI 30 – 34.9 $kg/m^2$, II = BMI 35 – 39.9 $kg/m^2$, III = BMI equal or more than 40 $kg/m^2$. Obesity in pregnancy holds a number of risks for both the mother as well as the fetus including pregnancy induced hypertension and gestational diabetes.[14,35] Due to the increased risk of complications during pregnancy as well as the birth, patients with a BMI of 40 and greater are referred as level II patients to TBH for high risk management. An area of interest was the influence of BMI on the accuracy of FH measurements in determining GA after 18 weeks.

Approximately 16.1% of pregnant women in the Western Cape are infected with the Human Immunodeficiency Virus (HIV).[36] Preventing perinatal transmission of the virus from mother to child is a high priority within this health service. Transmission will occur in 20 – 30% of women who do not receive treatment and do not breastfeed. Approximately half of transmissions in untreated women occur during delivery and 20% during the third trimester of pregnancy.[37] A HIV-infected woman who breastfeeds has a further 30% risk of transmitting the virus to her child. With treatment, the perinatal transmission rates have decreased to 1 – 2% in developed countries.[14,38] In the Cape Town Metropolitan area the transmission rate was approximately 4.8% in 2008.[39] According to the then current antenatal retroviral treatment protocol, HIV-infected patients with CD4 counts of 250 cells per cubic millilitre or more started their prophylactic treatment at 28 weeks GA or at booking if it took place after 28 weeks GA.[40] Patients with lower CD4 counts starts highly active anti-retroviral treatment as soon as feasible. Again, dating after 24 weeks GA will depend on an accurate FH measurement. A more accurate dating method, ultrasound in the third trimester, could contribute to commencing anti-retroviral treatment timeously.

Additional information regarding the correct obstetric ultrasound policy to improve maternal care and perinatal outcome is required. A comprehensive study was therefore planned to investigate two different ultrasound screening protocols.

# Chapter 3

# AIMS OF THE STUDY

The primary aim of the study was to compare 2 ultrasound referral protocols regarding the number of clinically relevant abnormalities (congenital fetal abnormalities, multiple pregnancies, placenta praevia, suspected abnormal fetal growth, pregnancy loss and abnormal liquor) detected prior to delivery and their GA at diagnosis:

- The current protocol of routine early ultrasound scans (18 – 23 weeks) and scans for selective clinical indications (Control Group / Group A)
- The new protocol of booking scan for all, regardless of GA, and follow-up for selective clinical indications (Study Group / Group B).

The following were the secondary aims of the study:

1. Comparing the number of patients receiving an ultrasound and the total number of scans performed in each group, including all follow-up scans. The above information can be used to determine the workforce and resources that would be required to implement the different ultrasound referral protocols.
2. Comparing the number of patients receiving an ultrasound between 18 and 23 weeks GA since this is regarded as the most appropriate time interval for a detailed scan. The detail scan is one of the most important scans to be performed for obstetric management and the higher the rate of scanning during this period, the better the expected detection rate for fetal abnormalities and complications.
3. Comparing the percentages of (presumed) postdates or preterm pregnancies and SGA babies between both groups, both in cases who received an early ultrasound (less than 24 weeks GA) and cases in Group A that did not have an ultrasound examination (because the GA was estimated to be equal or more than 24 week 0 days) or cases that had a GA of 24 weeks 0 days or more when they had their first ultrasound

examination in Group B. This information will indicate whether late ultrasound scanning contributes to more accurate GA determination. These outcomes will be noted in the study population if:

- A patient delivered beyond 41+6 weeks GA or before 37 weeks
- A baby was diagnosed to be SGA according to the GA used in the management and the local BW reference range.

4. Determining which of the three dating methods (LMP, FH measurement or ultrasound) estimates the date of delivery most accurately. A comparison of GA at delivery was made in patients with a spontaneous onset of labour and normal BW (defined as falling within the 10$^{th}$ and 90$^{th}$ centiles for GA according to the locally derived BW centile chart[29]) who had sure LMP dates and a known FH measurement and who received an ultrasound scan.
5. Determining the influence of the BMI on the accuracy of GA determination by means of a FH measurement. The BMI of those patients who received an ultrasound was categorised. FH must have been known at the time of the ultrasound examination. Ultrasound GA estimation was used as the reference.
6. Obtaining more accurate data on booking tendencies by calculating the GA at booking, confirmed by ultrasound.

# Chapter 4

# METHODOLOGY

An analytical audit was done on a low-risk population attending 2 public sector antenatal care facilities in the Cape Town Eastern metropolitan area. Firstly the audit was done with the current referral protocol in place consisting of a routine early ultrasound with selective scans for specific clinical indications. Following this audit the ultrasound protocol was changed to a booking scan for all with selective scans for specific clinical indications and another audit was done. The study followed a participatory action research model.

The study was conducted at the Elsiesriver CHC and Bellville South CHC for recruitment and Bishop Lavis CHC, Karl Bremer Hospital (KBH) and TBH for the ultrasounds. Recruitment commenced in October 2007. At that time TBH was the only referral hospital for the two antenatal clinics in question. In July of 2008, the referral system for certain high risk cases was changed and patients were also referred to KBH for antenatal care and delivery.

The study population consisted of all low-risk patients booking at Elsiesriver CHC and Bellville South CHC for antenatal care. Patients were excluded if they had any maternal medical condition or historical risk factor that would categorise them into a high risk group that requires referral to the high risk clinics at KBH and TBH, or ultrasound unit at TBH. Patients who received an ultrasound prior to booking were also excluded.

Waiver of informed consent was granted by the Committee of Human Research of the University of Stellenbosch since the proposed research tested accepted routine referral policies and posed no more than minimal risk or cost to the subjects.

The first time period to collect data for Group A commenced on 8 October 2007 and continued until 28 January 2008. Recruitment was interrupted between 10 December 2007 and 4 January 2008 to compensate for the decreased booking rate during the festive season. Data was collected by the researcher on a daily basis on all patients who came for booking on the day. Patients were referred for ultrasound on the basis of the current ultrasound referral protocol by the antenatal nursing staff. Only patients who were thought to be less than 24 weeks pregnant were referred for a detailed ultrasound between 18 and 24 weeks GA. The first time period continued until 750 patients, who met the inclusion criteria, booked.

The second time period to collect data for Group B commenced on 4 February 2008 and continued until 28 April 2008. The ultrasound referral protocol was changed to the booking scan policy, whereby all patients were referred for an ultrasound regardless of their GA. This time period also continued until 750 consecutive low-risk patients booked. An ultrasound was arranged for them within 7 days of booking. This allowed the patients to make arrangements at home and at work in order to attend the ultrasound department.

Ultrasound examinations were performed at Bishop Lavis CHC on a Toshiba Justvision 400, at KBH on a Toshiba Eccocee (Toshiba, Japan) and on an Aloka 3500 (Aloka, Mitaki-Shi, Tokyo) and a Siemens Antares Sonoline (Siemens, Germany) at TBH. All machines used 3.5 MHz curvilinear probes. The Toshiba Justvision 400 does not have Doppler capabilities.

Scans for clinical indications were performed on patients from both groups, regardless of GA and whether they received a previous scan or not. Patients from both groups, who were found to be less than 18 weeks pregnant, had a low lying placenta or any condition that requires follow-up, were given a follow-up date for a detailed scan at 18 to 23 weeks GA or placentography at 32 weeks GA. The referring nursing staff used the Perinatal Education Program criteria to calculate GA prior to ultrasound (Appendix C).[20] GA was not altered if the GA according to ultrasound corresponded with the LMP determined GA within the variation calculated by the ultrasound machine prior to 16 weeks GA, within 2 weeks between 16 and 23 weeks 6 days GA and within 3 weeks at and after 24 weeks GA.

The following clinically relevant information was noted during the ultrasound examinations. Lie of the fetus, position and distance of the placenta from the internal cervical os, number of fetuses, amniotic fluid volume and presence or absence of fetal abnormalities. A placenta was regarded as being low lying if its cervical margin was within 2cm from the internal cervical os prior to 24 weeks GA. Thereafter, a distance of less than 5cm was required for a placenta to be regarded as being low-lying or placenta praevia after 28 weeks GA. Low-lying placentas were followed up at 32 weeks. If it was praevia at that time the patient was referred to the high risk clinic at TBH.

The following was regarded as ultrasound evidence of fetal growth abnormalities:

- Growth restriction – reduced liquor, head measurements normal with AC under the 5$^{th}$ centile for GA (asymmetric growth), HC/AC ratio above the 95$^{th}$ centile for GA and estimated fetal weight (EFW) below the 10$^{th}$ centile for GA.
- Macrosomia – late in the third trimester, AC above the 95$^{th}$ percentile for GA, liquor volume normal or increased.

Ultrasound evidence of amniotic fluid volume abnormalities included:

- Polyhydramnios – deepest pool measuring more than 8cm or AFI more than 25cm.
- Oligohydramnios – deepest pool measuring less than 2cm or AFI less than 5cm.

When fetal abnormalities or complications were detected, the patient was referred to the ultrasound unit at TBH. Abnormal ultrasound findings do not always have an impact on antenatal management or pregnancy outcome. An example of this is a finding of isolated club feet. Termination of pregnancy will not be offered in such a case and obstetric management will remain the same as if the abnormality was not present.

The FH centile chart of all recruited patients was checked within 2 weeks of booking to confirm inclusion and to determine clinical GA. Ultrasound results were gathered by the researcher and the personnel at the TBH and KBH ultrasound units. The Astraia database at the TBH ultrasound unit was checked for GA at time of first ultrasound, multiple pregnancies, confirmation of abnormalities or complications detected at Bishop Lavis CHC and follow-up results. Uncomplicated deliveries took place at Elsiesriver Midwife Obstetric Unit (MOU) and both patients from the Elsiesriver and Bellville South antenatal clinics delivered there. The birth registries at Elsiesriver MOU, TBH and KBH were checked for date of delivery, spontaneous onset of labour and mode of delivery, BW and 5 minute Apgar score of the baby. Complications during delivery were also noted. Medical records were reviewed in cases of neonatal or intensive care unit admission, delivery prior to 37 weeks GA, BW less than 2500 grams, intra-uterine death (IUD), neonatal death, any antenatal admission, presence of abnormalities and poor perinatal outcome. The last patient delivered in January 2009.

The required sample size was calculated with the $\alpha$-value at 0.05 and the $\beta$-value at 20% (power 80%), assuming a 10% complication detection rate in the group prior to the change in policy and a 15% complication detection rate thereafter. Seven hundred and fifty patients (total 1500) were required for each group. These calculations assumed a 40% scanning rate prior to change in policy and a 90% scanning rate thereafter. The SPSS version 16 statistical package for social science was used to analyze the data. Continuous variables with a normal distribution were analyzed with Student's *t*-test. In case of a skewed distribution, medians were compared with the Mann Whitney *U*-test. Discrete data was analyzed using Chi-square and small numbers using Fisher's exact test. Chi-square and Fisher's exact tests were performed using Epi Info version 3.5.1, August 13, 2008. A probability (*p*) level of less than 0.05 was regarded as significant.

# Chapter 5

# RESULTS

A total of 1500 low risk patients who booked consecutively were recruited in the study, with groups A and B each comprising of 750 patients. Outcome of pregnancy was known in 631 cases in Group A and in 629 cases in Group B.

Table 1 contains a summary of the population characteristics and pregnancy outcome. Patients were confirmed to be not pregnant with a strip pregnancy test (U – Test pregnancy®) provided by Humor Diagnostica. Miscarriages consisted of all cases where pregnancy failed prior to viability (27 weeks / 800g), including one ectopic pregnancy in Group B, early negative fetal heart action as diagnosed with ultrasound and patients who were confirmed not to be pregnant anymore after a previous positive pregnancy test followed by vaginal bleeding. Some of these patients did not have a scan. The 3 TOP cases in Group A were all performed for fetal abnormalities. The 1 TOP in Group B was on the patient's request. IUD was confirmed with ultrasound in all but one case in Group B. Cases of IUD was excluded from the calculations for mean BW and Apgar score. The maternal death in Group A occurred at 26 weeks 3 days GA and is not included in the miscarriage sub-group.

**Table 1** Population characteristics and pregnancy outcome in groups A and B. Values are number (%), mean (standard deviation) or median (range) as appropriate

| | Group A | Group B | *p* | OR (95% CI) |
|---|---|---|---|---|
| **Pregnancies with known outcome*** | **631 (84.1)** | **629 (83.9)** | **0.94** | |
| **Infants with known outcome** | **623** | **616** | | |
| Age (years) [^] | 25.74 (5.49) | 25.32 (5.49) | 0.18 | |
| Gravidity[^] | 2.03 (1 – 6) | 1.94 (1 – 6) | 0.17 | |
| Parity[^] | 0.9 (0 – 5) | 0.83 (0 – 5) | 0.23 | |
| BMI[^] | 26.59 (6.27) | 25.91 (5.71) | 0.004 | |
| **Live born infants[¥]** | **616 (98.9)** | **610 (99.0)** | **0.98** | |
| Mean BW[#] | 3055.3(558.5) | 2996.1(582.3) | 0.07 | |
| *LBW* [¥] | 84 (13.5) | 98 (15.9) | 0.29 | |
| *VLBW* [¥] | 2 (0.3) | 14 (2.3) | 0.006 | 0.14(0.02–0.65) |
| *ELBW* [¥] | 1 (0.2) | 0 (0) | 1.00 | |
| *LBW excl. Twins,IUD*[¥] | 77/618 (12.5) | 79/612 (13.0) | 0.77 | |
| **Women delivered^** | **618 (97.9)** | **605 (96.2)** | | |
| Mean GA at delivery [Φ] | 39.1 (2.68) | 38.9 (2.47) | 0.10 | |
| < 37 weeks [Φ] | 96 (15.5) | 101 (16.7) | 0.64 | |
| ≥ 42 weeks [Φ] | 81 (13.1) | 51 (8.4) | 0.01 | 1.64(1.11–2.41) |
| 5min Apgar[#] | 10 (1 – 10) | 10 (3 – 10) | 0.001 | |
| 5min Apgar below 7[#] | 11(1.8) | 4(0.7) | 0.12 | |
| Twin pregnancy | 5 | 12 | 0.14 | |
| Miscarriages | 6 | 14 | 0.11 | |
| Not pregnant | 3 | 9 | 0.15 | |
| TOP | 3 | 1 | 0.62 | |
| IUD | 7 | 6 | 1.00 | |
| ENND[$] | 1 | 1 | 1.00 | |
| Maternal death[$] | 1 | 1 | 1.00 | |

BMI: body mass index; BW: birth weight in grams; LBW: low BW < 2500 grams; VLBW: very LBW < 1500 grams; ELBW: extremely LBW < 1000 grams; TOP: termination of pregnancy; IUD: intra-uterine death; ENND: early neonatal death; *: % of patients recruited; ^: % of patients with known pregnancy outcome; ¥: % of infants with known outcome; #: live born infants only; Φ: % of women delivered; OR: odds ratio; CI: confidence interval; $: cases of ENND and maternal death are discussed on pages 35 and 36

Table 2 contains a summary of the ultrasound findings at both locations, Bishop Lavis CHC and TBH. The ultrasound findings refer to the complications or fetal abnormalities detected. The early pregnancy loss rate and the number of non-pregnant cases for Group A were probably much higher. Patients in Group A received an appointment for ultrasound between 18 and 23 weeks GA at which time the early pregnancy losses and non-pregnant cases would have been recognised already and lost to follow-up as patients tend not to report a pregnancy loss or absence of pregnancy to the antenatal clinic. If the early pregnancy losses and non-pregnant cases were disregarded in both groups the difference of complications and abnormalities detected antenatally between the two groups were found not to be significant ($p = 0.57$). In Group A 1 case of talipes and another with fibroids were overlooked at Bishop Lavis CHC and later diagnosed at TBH. One case in Group A with suspected fetal heart defect diagnosed at TBH was not confirmed with post-natal ultrasound. There were 5 cases in group B where complications or abnormalities were suspected at Bishop Lavis CHC and then not confirmed at TBH.

**Table 2** The complications and abnormalities detected with ultrasound in both groups

| | Group A<br>BL / Total | Group B<br>BL / Total | *p* | OR (95%CI) |
|---|---|---|---|---|
| **Total (%)*** | **34/44 (7.0)** | **59/68 (10.8)** | **0.02** | **0.62** (0.41 – 0.94) |
| Not pregnant^ | 1/1 (2.3) | 9/9 (13.2) | 0.09 | |
| Early pregnancy loss^ | 1/1 (2.3) | 11/11 (16.2) | 0.03 | 0.12 (0.01 – 0.96) |
| Gynaecological findings^ | 8/9 (20.5) | 5/5 (7.4) | 0.08 | |
| Increased liquor^ | 3/4 (9.1) | 3/7 (10.3) | 1.00 | |
| Decreased liquor^ | 0/0 | 0/2 (2.9) | 0.52 | |
| Abnormal fetal findings^ | 7/9 (20.5) | 6/8 (11.8) | 0.33 | |
| Twins^ | 4/5 (11.4) | 12/12 (17.6) | 0.53 | |
| Malpresentation > 36 weeks^ | 0/1(2.3) | 0/0 | 0.40 | |
| Early low placenta^ | 9/10 (22.7) | 10/10 (14.7) | 0.41 | |
| Placenta praevia > 32 weeks^ | 0/1 (2.3) | 1/1 (1.5) | 1.00 | |
| Suspected growth restriction^ | 1/3 (6.8) | 2/3 (4.4) | 0.68 | |

BL / Total: number of cases detected at Bishop Lavis CHC / Total number of cases; OR: odds ratio; CI: confidence interval; *: % of pregnancies with known outcome; ^: % of complications and abnormalities detected

Table 3 contains a summary of the abnormalities or complications at birth in both groups. The performance of an ultrasound examination would not have made a difference in antenatal management in the cases with acute neonatal morbidity, acute maternal post-partum morbidity, birth before arrival, intra-uterine death, spontaneous fetal loss or maternal death. In the one case of fetal loss, a negative fetal heart action was noted at 21 weeks GA without the knowledge or suspicion of the mother or the nursing staff. In the one case of early neonatal death (ENND) in Group A ultrasound would not have altered the antenatal management as the baby died due to sepsis. In the one case of ENND in Group B ultrasound could have had an impact on antenatal management as the baby died due to a renal abnormality. One case of talipes in Group A was overlooked at Bishop Lavis CHC. In Group B one case of talipes and one case of atrial-ventricular septal defect was overlooked at Bishop Lavis CHC. None of the early (before 20 weeks GA) miscarriages or the termination of pregnancy on the patient's request were included.

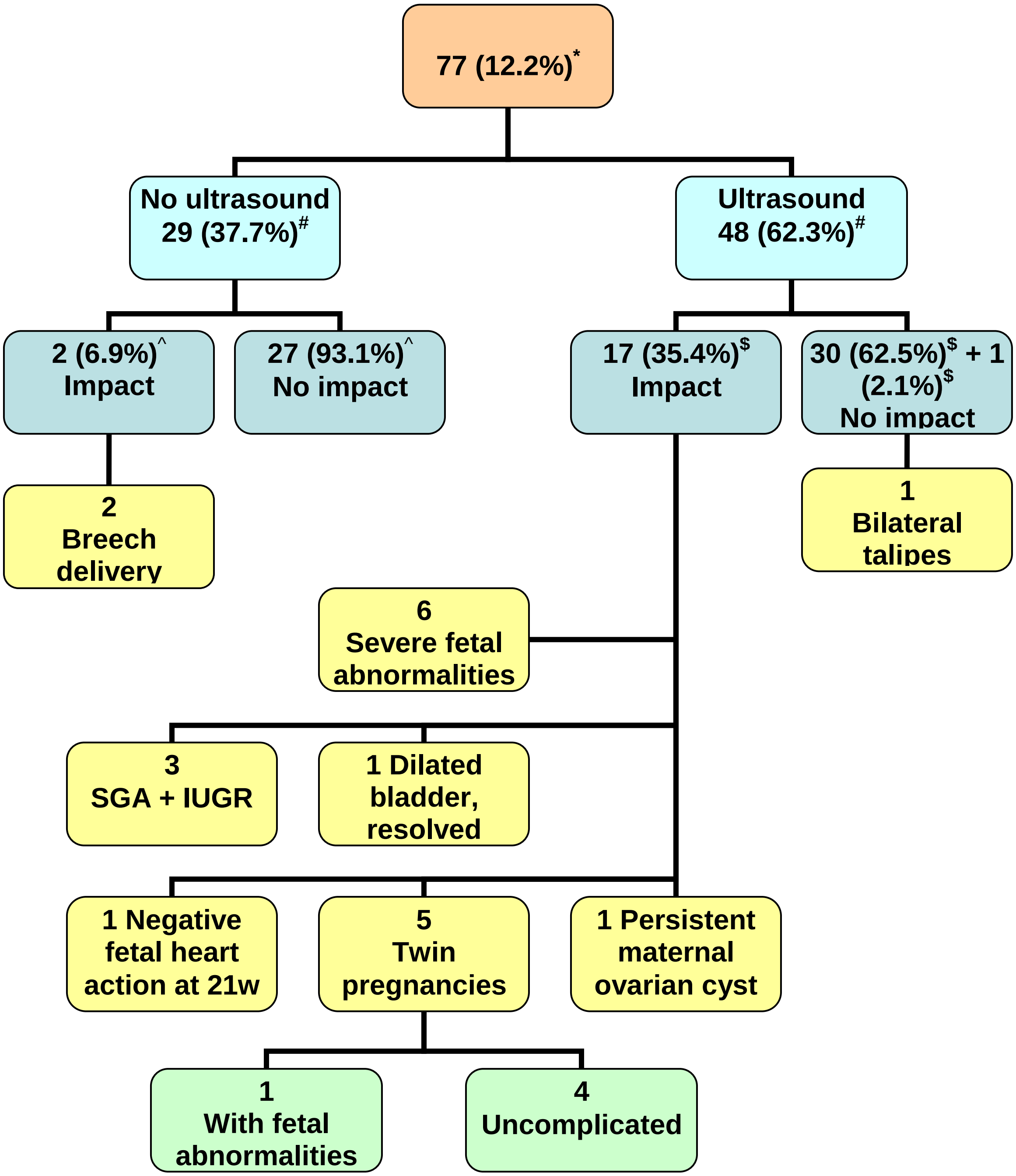
**Table 3** Abnormalities or complications at birth in groups A and B

| Abnormalities or Complications | Group A No scan / Total | Group B No scan / Total | *p* |
|---|---|---|---|
| **Number*** | **29/77**(12.2) | **4/64** (10.2) | **0.29** |
| Acute neonatal morbidity^ | 8/25(32.5) | 0/24(37.5) | 1.00 |
| Acute maternal post-partum morbidity^ | 3/6(7.8) | 0/4(6.3) | 0.75 |
| Breech delivery^ | 2/2(2.6) | 0/0 | 0.50 |
| Birth before arrival^ | 8/16(20.8) | 2/12(18.8) | 0.57 |
| Early neonatal death^ | 1/1(1.3) | 1/1(1.6) | 1.00 |
| Intrauterine death^ | 4/7(9.1) | 1/6(9.4) | 1.00 |
| Twins^ | 0/5(6.5) | 0/11(17.2) | 0.21 |
| Miscarriage after 20 weeks^ | 2/3(3.9) | 0/0 | 0.25 |
| Fetal abnormalities^ | 1/8(10.4) | 0/5(7.8) | 0.58 |
| TOP for fetal abnormalities^ | 0/3(3.9) | 0/0 | 0.25 |
| Maternal death^ | 0/1(1.3) | 0/1(1.6) | 1.00 |

No scan / Total: cases that did not receive an ultrasound / total number of abnormalities or complications; OR: odds ratio; CI: confidence interval; *: % of pregnancies with known outcome; ^: % of abnormalities or complications at birth; TOP: termination of pregnancy

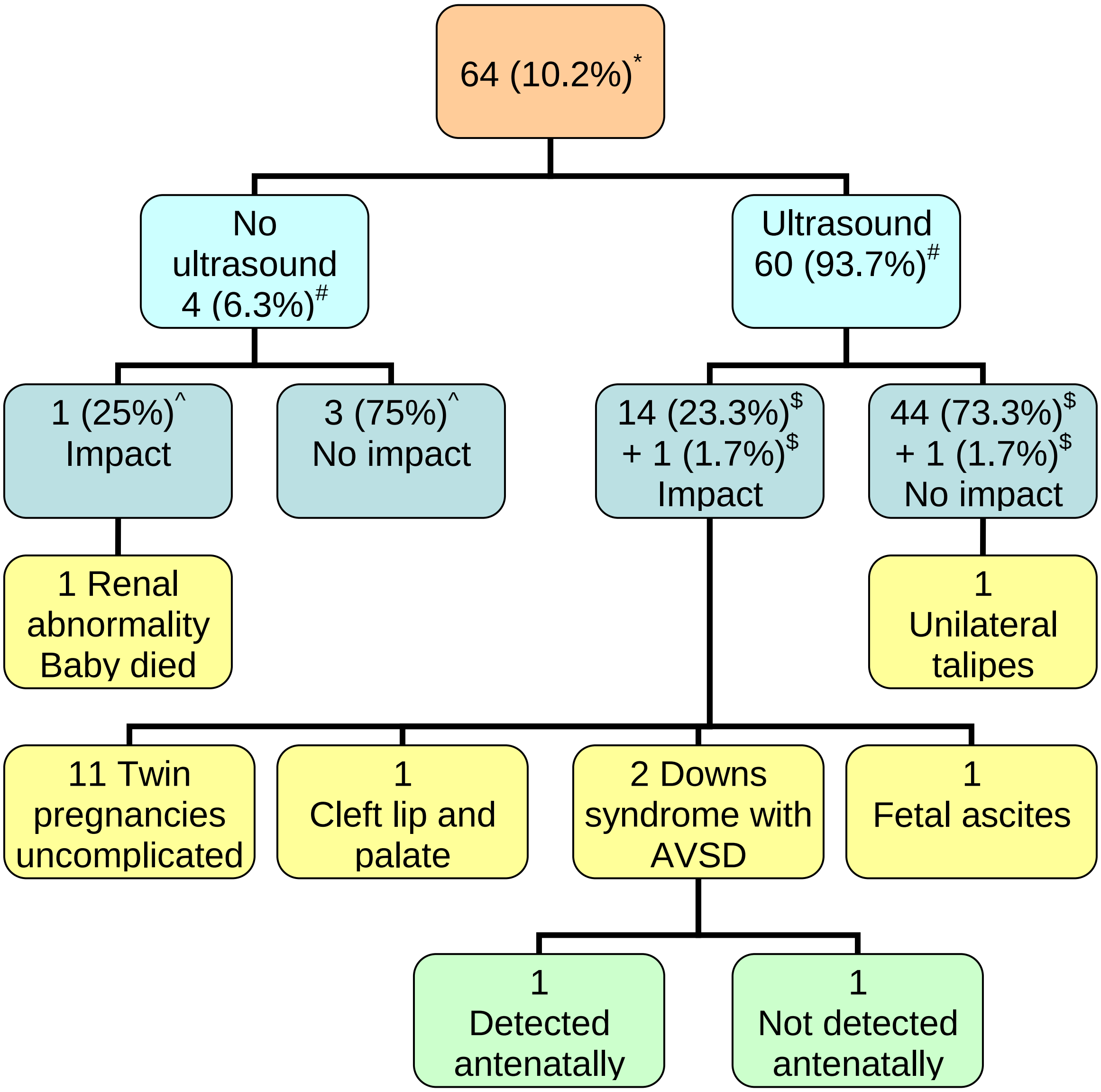
Flow diagrams 1 and 2 and table 4 aids in demonstrating the impact ultrasound had on the birth complications in both groups.

**Flow diagram 1** Impact of ultrasound on the birth complications in Group A




*: % of patients with known outcome; #: % of birth complications; ^: % of patients with birth complications that did not receive an ultrasound; $ : % of patients with birth complications that received an ultrasound

**Flow diagram 2** Impact of ultrasound on birth complications in Group B




*: % of patients with known outcome; #: % of birth complications; ^: % of patients with birth complications that did not receive an ultrasound; $ : % of patients with birth complications that received an ultrasound

**Table 4** Birth complications and the impact of ultrasound on the outcome

| | Group A | Group B | *p* | OR (95% CI) |
|---|---|---|---|---|
| **Birth complications*** | **77 (12.2)** | **64 (10.2)** | **0.29** | |
| No scan done# | 29 (37.7) | 4 (6.5) | <0.001 | 9.06 (2.77–32.8) |
| • No difference^ | 27 (93.1) | 3 (75.0) | 0.33 | |
| • Difference^ | 2 (6.9) | 1 (25.0) | 0.33 | |
| Scan done# | 48 (62.3) | 60 (93.7) | <0.001 | 0.11 (0.03–0.36) |
| • No difference$ | 30 (62.5) | 44 (73.3) | 0.32 | |
| • Difference$ | 17 (35.4) | 14 (23.3) | 0.24 | |
| Abnormalities missed$ | 1 (2.1) | 2 (3.3) | 1.00 | |

*: % of patients with known outcome; #: % of birth complications; ^: % of patients with birth complications that did not receive an ultrasound; $: % of patients with birth complications that received an ultrasound

Table 5 contains a summary of the congenital fetal abnormalities in groups A and B. The difference in prenatal detection (7/8 vs. 3/6) was not significant ($p = 0.1$).

**Table 5** Congenital fetal abnormalities and the gestational age (GA) at diagnosis for groups A and B

| Group A | GA | Group B | GA |
|---|---|---|---|
| Bilateral talipes | ND | Unilateral talipes | ND |
| Bilateral talipes | 19w0d | Trisomy 21 with AVSD | ND |
| Amnion band syndrome | 20w2d | Renal abnormality | NS |
| Diaphragmatic hernia | 20w6d | Trisomy 21 with AVSD | 23w0d |
| Spina bifida | 22w0d | Unilateral renal agenesis | 23w1d |
| Bilateral talipes | 24w3d | Cleft lip and palate | 25w3d |
| Craniofacial abnormalities incl. cleft lip and palate, eye abnormality, brain dysplasia, bilateral talipes | 25w6d | | |
| Unilateral talipes | 28w6d | | |

w: weeks; d: days; ND: Not diagnosed on scan; NS: No scan; AVSD: atrial-ventricular septal defect

Table 6 consists of a comparison between the two groups with regard to the percentages and mean GA at diagnosis of congenital fetal abnormalities, twin pregnancies and placenta praevia at 32 weeks GA. These complications were also evaluated together.

**Table 6** Comparison of mean gestational age (GA) at diagnosis of congenital fetal abnormalities, twin pregnancies and placenta praevia in groups A and B

| | Group A | Group B | *p* - value |
|---|---|---|---|
| **Fetal abnormalities*** | **8** (1.3) | **6** (1.0) | **0.79** |
| *Mean GA at diagnosis* | 23w0d | 23w6d | |
| *Range* | 19w0d–28w6d | 23w0d–25w3d | |
| *Diagnosed < 24 weeks* | 4 | 1 | 0.2 |
| *No scan done* | 0 | 1 | |
| *Not diagnosed on scan* | 1 | 2 | |
| **Twin pregnancies*** | **5** (0.8) | **12** (1.9) | **0.14** |
| *Mean GA at diagnosis (SD)* | 22w2d(6w4d) | 18w0d(5w0d) | 0.30 |
| *Median* | 20w1d | 18w2d | |
| *Range* | 16w1d–32w0d | 9w6d–26w3d | |
| *Diagnosed < 24 weeks* | **3** (0.5) | **11** (1.7) | 0.20 |
| **Placenta praevia*** | **1** (0.16) | **1** (0.16) | **1.00** |
| *GA at diagnosis* | 20w1d | 21w4d | |
| **All complications*** | **14** (2.2) | **19** (3.0) | **0.47** |
| *Mean GA at diagnosis (SD)* | 22w4d(4w4d) | 19w1d(5w0d) | 0.07 |
| *Median* | 20w6d | 18w4d | |
| *Range* | 16w1d–32w0d | 9w6d – 26w2d | |
| *Diagnosed < 24 weeks* | 8 | 13 | 0.5 |

*: % of pregnancies with known outcome; w: weeks; d: days; SD: standard deviation

Table 7 contains a summary of the IUD cases in both groups and indicates whether they received an ultrasound and if so at what GA. BW and GA at time of IUD were also noted.

**Table 7** Summary of the intra-uterine death (IUD) cases in groups A and B

| Scan done at | BW | LGA/AGA/SGA | GA at IUD | Cause |
|---|---|---|---|---|
| **Group A** | | | | |
| No | 2800g | AGA | 40w | PE/CPI |
| No | 2600g | SGA | 40w | CA |
| No | 4000g | LGA | 41w | CA |
| No | 2600g | SGA | 40w | Abruptio |
| No | 4170g | LGA | ? | ? |
| 19w4d | 2000g | AGA | 34w | CA |
| 27w0d | 2300g | SGA | 37w | CPI/CA |
| **Group B** | | | | |
| No | 1850g | AGA | 33 | CA |
| 23w5d* | 1620g | AGA | 30 | ? |
| 31w5d | 2360g | SGA | 39 | CA |
| 17w1d | 1760g | SGA | 38 | CA/PlHypo |
| 20w5d | 3800g | AGA | 40 | CA |
| 22w1d | 1400g | SGA | 33 | CPI |

BW: birth weight; LGA: large for gestational age; AGA: appropriate for gestational age; SGA: small for gestational age; g: grams; w: weeks; d: days; PE: pre-eclampsia; CPI: chronic placental insufficiency; CA: chorio-amnionitis; ?: uncertain; PlHypo: placental hypoperfusion; *: not confirmed IUD with ultrasound

Table 8 describes the ultrasound examinations for both groups. The category before 18 weeks includes all cases with negative fetal heart action as identified by ultrasound, miscarriages, ectopic pregnancy, TOP and cases where no pregnancy was identified with ultrasound and who were later confirmed not to be pregnant. Of the 629 patients with known pregnancy outcome in Group B, 492 (78.2%) attended the ultrasound department within 7 days of booking.

**Table 8** Number and timing of ultrasound examinations in groups A and B

| | Group A | Group B | *p* | OR (95%CI) |
|---|---|---|---|---|
| **Women recruited** | 750 | 750 | | |
| **Pregnancies with known outcome** | 631 (84.1)[@] | 629 (83.9)[@] | 0.94 | |
| *Scans / patient** | | | | |
| *Median (range)* | 1 (0 – 11) | 1 (0 – 12) | <0.001 | |
| *Mean (SD)* | 0.81 (0.91) | 1.41 (1.04) | | |
| *Women scanned 18-24w** | 330 (52.3) | 382 (60.7) | 0.003 | 0.71 (0.56–0.89) |
| *Women scanned < 24 w** | 336 (53.2) | 412 (65.5) | <0.001 | 0.60 (0.47–0.76) |
| *Women scanned at least once** | 390 (61.8) | 567 (90.1) | <0.001 | 0.18 (0.13–0.24) |
| **Of women scanned** | | | | |
| *Not pregnant^* | 3 | 9 | 0.14 | |
| *1$^{st}$ scan < 18w0d^* | 44 (11.3) | 233 (41.1) | <0.001 | 0.13 (0.09–0.18) |
| *1$^{st}$ scan 18 - 24w^* | 292 (74.9) | 179 (31.6) | <0.001 | 2.17 (1.70–2.75) |
| *1$^{st}$ scan < 24w0d^* | 336 (86.2) | 412 (72.7) | <0.001 | 3.28 (2.32–4.63) |
| *1$^{st}$ scan ≥ 24w0d^* | 51 (13.1) | 146 (25.7) | <0.001 | 0.29 (0.20–0.41) |
| *Any scan 18 - 24w^* | 330 (84.6) | 382 (67.4) | <0.001 | 2.66 (1.90–3.74) |
| *Number of scans* | 512 | 890 | | |
| **Of scans performed** | | | | |
| *Not pregnant* | 4 | 9 | 0.14 | |
| *N < 18w0d*[$] | 46 (9.0) | 245 (27.5) | <0.001 | 0.38 (0.29–0.50) |
| *N 18 – 24w*[$] | 353 (68.9) | 392 (44.0) | <0.001 | 2.82 (2.23–3.51) |
| *N ≥ 24w0d*[$] | 109 (21.3) | 244 (27.4) | 0.013 | 0.72 (0.55–0.93) |

OR: Odds ratio; CI: Confidence intervals; SD: standard deviation; [@]: % of patients recruited; *: % of pregnancies with known outcome; ^: % of women receiving at least 1 scan; [$]: % of total number of scans

Table 9 contains a summary of the reasons for requested follow-up examinations. These are only cases who received follow-up appointments at the ultrasound departments and do not include the cases who developed clinical reasons for ultrasound referral. Patients were given follow-up dates for dating if the pregnancy was found to less than 7 weeks GA and proper dating by ultrasound was not possible.

**Table 9** Reasons for requested follow-up ultrasound examinations for groups A and B

| Number (%) | **Group A** | **Group B** | *p*-value | OR (95% CI) |
|---|---|---|---|---|
| **Total requests** | **105** | **313** | | |
| | (20.5)@ | (35.2)@ | <0.001 | 0.48 (0.37– 0.62) |
| | (16.6)* | (49.8)* | <0.001 | 0.20 (0.15 – 0.26) |
| Patients attending for follow-up^ | 93 (88.6) | 289 (92.3) | 0.32 | |
| Dating^ | 0 (0) | 9 (2.9) | 0.12 | |
| Gynaecology^ | 2 (1.9) | 1 (0) | 0.16 | |
| Fetal detail^ | 42 (40.0) | 212 (67.7) | <0.001 | 0.32 (0.20 – 0.51) |
| Possible fetal abnormality^ | 14 (13.3) | 11 (3.5) | <0.001 | 4.22 (1.73 – 10.38) |
| Fetal growth and Doppler^ | 29 (27.6) | 54 (17.3) | 0.03 | 1.83 (1.05 – 3.17) |
| Placenta localization^ | 10 (9.5) | 10 (3.2) | 0.02 | 3.19 (1.19 – 8.58) |
| Liquor volume^ | 4 (3.8) | 4 (1.3) | 0.11 | |
| Twin pregnancy^ | 5 (4.8) | 12 (3.8) | 0.77 | |

OR: odds ratio; CI: confidence intervals; @: % of total number of scans; *: % of pregnancies with known outcome; ^: % of total number of requests

A summary of the clinical reasons that developed as an indication for ultrasound referral to TBH is shown in Table 10. These referrals were made by the nursing staff following clinical assessment.

**Table 10** Clinical reasons for ultrasound referral for groups A and B

| | Group A | Group B | *p* - value |
|---|---|---|---|
| **Total number of referrals*** | **29** (4.6) | **34** (5.4) | **0.60** |
| Fetal growth^ | 21 (72.4) | 22 (64.7) | 0.70 |
| Liquor^ | 2 (6.9) | 5 (14.7) | 0.44 |
| Fetal growth & Doppler^ | 5 (17.2) | 5 (14.7) | 1.00 |
| Placenta localization^ | 1 (3.4) | 0 (0) | 0.46 |
| Fetal presentation^ | 0 (0) | 2 (5.9) | 0.50 |

*: % of patients with known pregnancy outcome; ^: % of total number of referrals

Table 11 contains information on place of birth, labour and mode of delivery. Some patients delivered elsewhere and were telephonically contacted to collect the information. Cases of IUD in both groups and maternal death in Group B were included. Cases of TOP were not included. The referral policy for high risk patients changed during the course of the study. Where patients in certain high risk categories requiring level I care were previously referred to TBH, they were referred to KBH.

The maternal death in Group A occurred at 26 weeks 3 days GA. The baby died intra-uterine. The patient received scans at Bishop Lavis CHC and TBH with unilateral talipes suspected at Bishop Lavis CHC, diagnosed as bilateral talipes at TBH. Cause of death was acute respiratory distress and the patient had tuberculosis. The maternal death in the Group B occurred during birth, the baby was a breech delivery. The patient collapsed unexpectedly following the delivery with respiratory distress and subsequent cardiac arrest. The patient could not be resuscitated. The patient did not have a postpartum haemorrhage. The most likely cause of death was pulmonary embolism. The patient did not have an autopsy. The baby was healthy. One set of twins in Group B was diagnosed at 26 weeks and 3 days, however one of the fetuses did not have a positive fetal heart action.

In the one case of ENND in Group A the patient did not receive an antenatal ultrasound. The baby was born at 26 weeks GA and died 2 days later. The primary cause of death was stated to be congenital syphilis and the final cause of death as severe prematurity. In the one case of ENND in Group B the patient also did not receive an antenatal ultrasound and delivered at 39 weeks 2 days GA according to FH. The 5 minute Apgar score was 3. The baby was born with a renal abnormality and died on day 1.

**Table 11** Place of birth, labour and mode of delivery for groups A and B. *: % of number of deliveries; E/R: Elsiesriver; MOU: midwife obstetric unit; TBH: Tygerberg hospital; KBH: Karl Bremer hospital; BBA: birth before arrival

| | | Group A | Group B | *p*-value |
|---|---|---|---|---|
| **Number of deliveries** | | **618** | **605** | |
| Place of birth: | E/R MOU | 317 (51.3)* | 332 (54.9)* | 0.23 |
| | TBH | 261 (42.0)* | 158 (26.1)* | |
| | KBH | 21 (3.4)* | 101 (16.7)* | |
| | TBH + KBH | 282 (45.4)* | 259 (42.8)* | 0.35 |
| | BBA | 17 (2.7)* | 12 (2.0)* | 0.49 |
| | Other | 2 (0.3)* | 2 (0.3)* | 1.00 |
| Labour: | Spontaneous | 522 (84.4)* | 517 (85.5)* | 0.91 |
| | Induced | 72 (11.7)* | 72 (11.9)* | 0.96 |
| Elective caesarean section | | 24 (3.9)* | 16 (2.6)* | 0.30 |
| Mode of delivery: | Vaginal | 535 (86.6)* | 528 (87.3)* | 0.78 |
| | Caesarean section^ | 83 (13.4)* | 77 (12.7)* | 0.78 |

^: Including the elective caesarean sections

Table 12 contains the reasons for induction of labour and caesarean sections for both groups and Table 13 describes the complications that would be affected by inaccuracies in GA determination (postdates and preterm deliveries, small-for-gestational age fetuses).

**Table 12** Reasons for induction of labour and caesarean sections for groups A and B

| N (%) | Group A | Group B | *p* | OR (95%CI) |
|---|---|---|---|---|
| **Women delivered** | **618** | **605** | | |
| **Induction of labour*** | **72** (11.7) | **72** (11.9) | **0.96** | |
| *Postdates*^ | 16 (22.2) | 8 (11.1) | 0.12 | |
| *IUD*^ | 5 (6.9) | 4 (5.6) | 1.00 | |
| *SROM* ^ | 29 (40.3) | 32 (44.4) | 0.74 | |
| *PIH*^ | 7 (9.7) | 5 (6.9) | 0.74 | |
| *PE*^ | 6 (8.3) | 20 (27.8) | 0.004 | 0.24 (0.08–0.68) |
| *GDM*^ | 1 (1.4) | 1 (1.4) | 1.00 | |
| *Other*^ | 8 (11.1) | 2 (2.8) | 0.10 | |
| **Caesarean section*** | **83** (13.4) | **77**(12.7) | **0.78** | |
| Fetal distress$ | 39 (47.0) | 26(33.8) | 0.15 | |
| Breech presentation$ | 8 (9.6) | 11(14.3) | 0.61 | |
| Poor progress$ | 15 (18.1) | 20(26.0) | 0.31 | |
| Failed induction$ | 5 (6.0) | 8(10.4) | 0.55 | |
| Elective$ | 10 (12.0) | 8(10.4) | 0.85 | |
| Other$ | 6 (7.2) | 4(5.2) | 0.75 | |

OR: odds ratio; CI: confidence intervals; *: % of women delivered; ^: % of labour inductions; $: % of number of caesarean sections; IUD: intrauterine death; SROM: spontaneous rupture of membranes; PIH: pregnancy induced hypertension; PE: pre-eclampsia; GDM: gestational diabetes mellitus

**Table 13** Post-dates deliveries (≥42 weeks), preterm deliveries (< 37 weeks) and SGA infants (less than 10th centile for gestation) for groups A and B, categorised according to the timing of the ultrasound examination

| | **Group A** | **Group B** | ***p*** | **OR (95%CI)** |
|---|---|---|---|---|
| **Post-dates deliveries**^ | **81** (13.1) | **51** (8.4) | **0.01** | **1.64** (1.11–2.41) |
| *Scan < 24 weeks*^ | 19 (3.1) | 18 (2.9) | 0.95 | |
| *Scan ≥ 24 weeks*^ | 11 (1.8) | 23 (3.8) | 0.032 | 0.46 (0.21-0.99) |
| *No scan*^ | 51 (8.3) | 10 (1.6) | <0.001 | 5.35 (2.60-11.34) |
| *No scan < 24 weeks*^ | 62 | 33 | 0.003 | 1.32 (1.13-1.55) |
| **Preterm deliveries**^ | **96** (15.5) | **101** (16.7) | **0.64** | |
| *Scan < 24 weeks*^ | 41 (6.6) | 49 (8.1) | 0.38 | |
| *Scan ≥ 24 weeks*^ | 8 (1.3) | 36 (6.0) | <0.001 | 0.21 (0.09–0.47) |
| *No scan*^ | 47 (7.6) | 16 (2.6) | <0.001 | 3.03 (1.65–5.64) |
| *No scan < 24 weeks*^ | 55 | 52 | 0.93 | |
| **Pregnancies with SGA**^ | **52** (8.4) | **60** (9.9) | **0.42** | |
| *Scan < 24 weeks*^ | 39 (6.3) | 46 (7.6) | 0.44 | |
| *Scan ≥ 24 weeks*^ | 3 (0.5) | 10 (1.7) | 0.09 | |
| *No scan*^ | 10 (1.6) | 4 (0.7) | 0.19 | |
| *No scan < 24 weeks*^ | 13 | 14 | 0.8 | |
| **SGA infants** | **54** | **63** | | |
| *Singleton alive* | 47 | 46 | | |
| *1 of twin alive* | 3 | 8 | | |
| *2 of twins alive* | 4 | 6 | | |
| *Singleton iud* | 0 | 3 | | |
| **Total complications related to dating**^ | **229** (37.1) | **212** (35.0) | **0.50** | |
| *Scan < 24 weeks*^ | 99 (16.0) | 113 (18.7) | 0.25 | |
| *Scan ≥ 24 weeks*^ | 22 (3.6) | 69 (11.4) | <0.001 | 0.29 (0.17–0.48) |
| *No scan*^ | 108 (17.5) | 30 (5.0) | <0.001 | 4.06 (2.61–6.33) |
| *No scan < 24 weeks*^ | 130 | 99 | 0.043 | 1.36 (1.01-1.84) |

^: % of number of deliveries; *: % of live births; SGA: small for gestational age; IUD: intra-uterine death

The two groups were compared in order to determine the impact of ultrasound at or after 24 weeks 0 days with regard to the percentage of suspected postdates deliveries. The number of suspected postdates cases in Group A patients who did not receive an ultrasound (51) was significantly higher than suspected postdates cases in Group B patients who received an ultrasound at or after 24 weeks 0 days GA (23). [$p = 0.001$ (OR -95% CI) 2.28 (1.34 – 3.89)].

The same calculations were performed on the preterm deliveries as well as the SGA cases. The number of preterm delivery cases in Group A who did not receive an ultrasound (47) was not different from the number of preterm delivery cases in Group B who received a scan at or after 24 weeks GA (36) ($p = 0.30$).

The number of pregnancies with SGA babies in Group A patients who did not receive an ultrasound (10) was not different from patients in Group B who received an ultrasound at and after 24 weeks GA (10) (p = 0.86). In order to determine the impact of ultrasound at or after 24 weeks GA on the total number of complications related to the accurate dating of pregnancies, the number of cases in Group A patients who did not receive an ultrasound (108) was significantly higher than in Group B patients who received a scan at or after 24 weeks GA (69) [$p = 0.003$ OR (95%CI): 1.65 (1.17 – 2.31)].

There were 354 (56.1%) patients in Group A and 313 (49.8%) patients in Group B who were sure about the date of their LMP. This difference was statistically significantly different [$p = 0.03$; OR (95%CI): 1.29 (1.03 – 1.62)]. Comparing only FH measurement at booking, the mean GA as determined by FH measurement showed a trend towards a statistical difference (24.50 weeks SD 4.89 vs. 25.17 weeks SD 4.99, $p = 0.05$). Clinically determined GA at the booking visit (based on information from LMP and FH combined) was 21.63 weeks SD 6.20 for group

A and 22.64 SD 6.48 for group B ($p = 0.01$). Four hundred and forty four patients in Group B attended their ultrasound appointment within 7 days of booking. The average clinical GA of these patients prior to ultrasound (22.35 weeks SD 6.21) was not different from after ultrasound (21.72 weeks SD 6.14)($p = 0.14$) but in 135 patients (30.4%) the difference between ultrasound dating and clinical dating was 3 weeks or more and in 81 (18.3%) the difference was even 4 weeks or more. Overestimations of 3 weeks or more (84) were significantly more common than underestimations of 3 weeks or more (51) [$p = 0.002$, OR (95%CI) 1.80 (1.21-2.67)].

Ultrasound, LMP dates and FH were compared in order to determine which method predicts the date of delivery most accurately. The two groups were combined and 218 patients had sure LMP dates, received an ultrasound (at any GA), had a known FH measurement prior to ultrasound, had a spontaneous onset of labour and normal BW. FH resulted in an average GA of 39.8 weeks (SD: 3.21), ultrasound in 39.1 weeks GA (SD: 1.93) and LMP dates in 38.5 weeks GA (SD: 3.21). A statistically significant difference was found between all three groups with *p* – values of 0.02, 0.01 and $< 0.001$ when comparing ultrasound with LMP dates, ultrasound with FH and LMP dates with FH respectively. Table 14 contains a summary and comparison of the number and percentage of patients with the difference between the EDD as determined by the three dating methods and the actual date of birth.

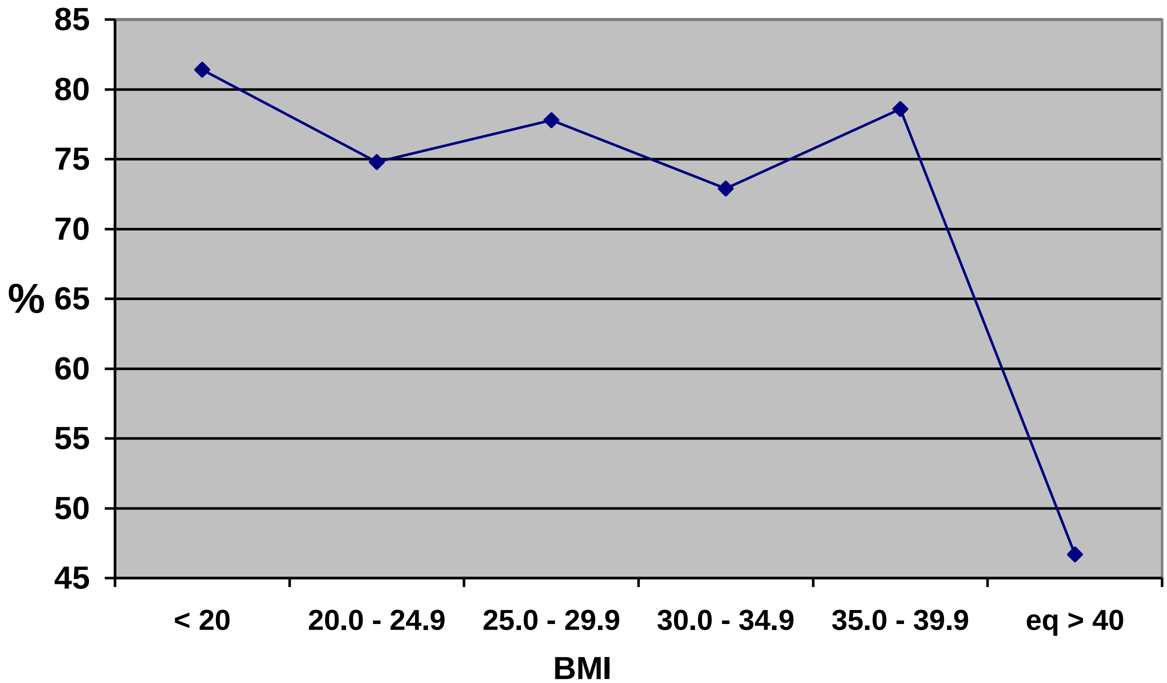
**Table 14** Number (%) of patients with difference (in days) between expected date of delivery predicted according to the three dating methods (Ultrasound, LMP and FH) and actual date of birth, calculated in 218 patients with data on all 3 parameters

| **Difference** | **U/S** | **LMP** | **FH** | **U/S vs LMP *p*–value** | **U/S vs FH *p*–value** | **LMP vs FH *p*–value** |
|---|---|---|---|---|---|---|
| 0 – 3 | 119 (54.6) | 143 (65.6) | 53 (24.3) | 0.02 | <0.001 | <0.001 |
| 0 – 7 | 167 (76.6) | 144 (66.1) | 93 (42.7) | 0.02 | <0.001 | <0.001 |
| 0 – 10 | 196 (89.8) | 145 (66.5) | 119 (54.6) | <0.001 | <0.001 | 0.01 |
| > 10 | 22 (10.1) | 73 (33.5) | 99 (45.4) | <0.001 | <0.001 | 0.02 |

U/S: ultrasound; LMP: last menstrual period, FH: fundal height

Data from the two groups were combined to determine the impact of BMI on the accuracy of FH measurements. All patients who received an ultrasound and had a known FH measurement prior to the ultrasound were included in the calculation. The difference in weeks between GA as determined by ultrasound and FH was determined for the different BMI categories. In Figure 1 this difference is expressed as the percentage of cases agreeing within 3 weeks or less.

**Figure 1** Percentage of patients with gestational age determined by ultrasound and fundal height differing by 3 weeks or less divided into categories by body mass index (BMI)




In order to determine booking tendencies, we evaluated the GA of 444 patients from Group B who received their ultrasound examination within 7 days of booking: 104 (23.4%) were found to be less than 18 weeks pregnant, 188 (42.3%) between 18 weeks 0 days and 23 weeks 6 days and 152 (34.2%) 24 weeks or more. Therefore 65.7% of patients booked prior to 24 weeks GA and would have been eligible for a detailed scan.

# Chapter 6

# DISCUSSION

This study investigated the impact of expanding an obstetric ultrasound service from a policy of routinely providing a scan between 18 and 23 weeks 6 days with further scans offered for a selected list of clinical indications to a policy where an ultrasound examination within 7 days of booking is offered in addition. This would result in ultrasound examinations also being offered to women booking for antenatal care after 24 weeks gestation, who are not routinely offered a scan with the current protocol. The main finding of the study is that the booking scan protocol is associated with a 74% increase in total workload, but that this did not lead to improved pregnancy outcome or higher and/or earlier detection rates for congenital fetal abnormalities, twin pregnancies or placenta praevia.

The selection of participants for our study differed from previous studies investigating different ultrasound protocols and services in the TBH drainage area.[12,13] In the index study patients were excluded if they had any maternal medical condition or historical high risk factor that would require referral to the high risk clinics at KBH and TBH or the ultrasound unit at TBH. The results are therefore only applicable to low-risk patients.

The two groups were comparable with regard to patient age, gravidity, parity and average birth weight and these findings were in concordance with results from other studies previously conducted in the TBH drainage area (Table 1).[12,13] There was no difference in the number of live births, miscarriages, terminations or perinatal losses. The non-significant difference in the number of miscarriages between the two groups can be explained by the higher early scanning rate in group B leading to 8 times as many findings of absent fetal heart action while in Group A most miscarriages were probably identified prior to the routine ultrasound examination, which was scheduled between 18 and 23 weeks GA.

Patients tend not to return to the antenatal clinic to report pregnancy losses and were therefore lost to follow-up. There was no difference in mean GA at delivery, proportion of babies with low birth weight or a 5 minute Apgar less than 7. The statistically significant difference in median 5 minute Apgar scores was probably a type one error and not of any clinical significance. There was no difference in type of labour and mode of delivery or reasons for caesarean section. The indications for induction of labour remained unchanged during the study apart from an unexplained increase in inductions for pre-eclampsia in group B. The proportion of patients who delivered at Elsiesriver CHC was comparable between the two groups (Table 11) in spite of rerouting of level I patients to KBH instead of TBH from 1st July 2008. The change in referral protocol during the study might be seen as a disadvantage of our study, however, since the proportion of patients delivering at Elsiesriver CHC was unchanged it would seem that it did not have a perceivable impact.

***Birth complications and fetal abnormalities:*** No difference was found in the number of birth complications between the two groups (Table 3, p = 0.29). There were 14 congenital fetal abnormalities in total (1.1%) which is lower than accepted percentages of between 2 and 3% and a reflection of the low-risk nature of the cohort studied.[3] One case in Group A and two cases in Group B were overlooked at the Bishop Lavis ultrasound department but the ultrasound equipment used at this facility during the study was approximately 9 years old with limited image quality. The incidence of Down's syndrome was 1.6 per 1000 live births and for congenital diaphragmatic hernia, spina bifida, cleft lip and palate and unilateral renal agenesis the incidence was 0.8 per 1000 which is in concordance with published data.[3,41] For talipes the incidence was 4 per 1000 which is twice as high as the published data of 1 to 2 per 1000 births.[3] Talipes shows multifactorial inheritance with both genetic and environmental factors playing a role. The reason for the increased incidence in our study population is uncertain but may be a chance finding. The introduction of a booking scan protocol did not result in a higher number of fetal abnormalities being detected or an earlier average GA at diagnosis. Significantly more of follow-up scans were requested because of possible fetal structural abnormalities in Group A (Table 9; $p < 0.001$) but this is merely a reflection of a much higher number of follow-ups for other reasons in Group B since the difference is not significant when compared to the total number of patients scanned.

***Twins:*** There were 16 (1.3%) twin pregnancies, an incidence which is in concordance with the literature of approximately 1%.[3] There were more than twice as many twin pregnancies in Group B than in Group A but this was not significant and the reason for this is uncertain (Table 1). All cases in both groups were known prior to birth and the difference in average GA at diagnosis of the twin pregnancies, albeit four weeks earlier in Group B, was not statistically significant due to small numbers. In the clinical setting however, four weeks could make a difference in the correct diagnosis of chorionicity as the ultrasound features disappear with advancing GA or in the recognition of early complications in MC twins.

The average GA of diagnosis of fetal abnormalities, twin pregnancies and placenta praevia was regarded as one entity for both groups and was not statistically different ($p = 0.07$), demonstrating no benefit of a booking scan policy in earlier diagnosis of these pregnancy complications. The numbers are however very small and influenced by a significant outlier in group A (twins detected at 32 weeks). The % of complications detected before 24 weeks was not different.

At the time when the sample size for this study was determined, the referral rate from the ultrasound unit at Bishop Lavis CHC to TBH was used. However, the 10% referral rate included patients who were referred for the detection of single soft markers for chromosomal abnormalities. Between the writing of the protocol and the start of the study, this unwarranted referral policy was ended. This resulted in a drop in referral rate to approximately 5.4%. We also presumed a scan rate of approximately 40% in Group A and a 90% scan rate in Group B. The scan rate in Group A was in fact 61.8% and in 90.1% in Group B. These factors attributed to the fact that the presumed detection rate prior to and after the change in policy were not reached in groups A and B respectively.

***Postdates deliveries:*** The incidence of postdates pregnancies (10.8%) in our study was in concordance with a previous study conducted on a similar population in the TBH drainage area.[13] There were significantly more suspected postdates pregnancies in Group A ($p = 0.01$) resulting from a significant difference in the women who were not scanned (Table 13; $p < 0.001$). The introduction of a booking scan for all women reduced the incidence of suspected postdates pregnancies in Group B as a whole and in the sub-group who received an ultrasound at or after 24 weeks 0 days GA. This is probably due to more accurate GA determination with ultrasound, both before and after 24 weeks 0 days GA.

***Preterm deliveries:*** A previous study performed on a similar population demonstrated the same incidence of preterm deliveries as in our study (16.1%).[13] The two groups, as well as the subgroups who were scanned before 24 weeks GA, were comparable with regard to the percentage of preterm deliveries but a significant difference was found in the women who were scanned at or after 24 weeks GA (Table 13; $p < 0.001$) and in those who did not receive an ultrasound ($p < 0.001$). There was no difference between patients in Group A who were not scanned and patients in Group B who received a scan at and after 24 weeks ($p = 0.30$). This would indicate that performing an ultrasound at and after 24 weeks GA does not reduce the number of perceived preterm deliveries when compared to not performing a scan at all.

***SGA:*** The incidence of SGA babies (9.6%) in our study was comparable with a previous study conducted on a similar population in the TBH drainage area.[12] No significant difference was found between the two groups with regard to the percentage of SGA cases, both in the groups as a whole or the subgroups of women who had a scan before or after 24 weeks or women who had no ultrasound examination. The introduction of a booking scan regardless of GA did not change the incidence of infants being regarded as SGA.

The number of suspected postdates deliveries, preterm deliveries and SGA cases in the sub-groups who received ultrasound examinations before 24 weeks GA as well as the overall incidence of low birth weight babies in both groups being no different indicates that the population did not change from the first to the second time period.

Postdates deliveries, preterm deliveries and SGA cases are all complications that could be influenced by inaccuracies in the dating of pregnancies. When grouped together the impact of ultrasound at and after 24 weeks was determined by comparing patients in Group A who were not scanned to patients in Group B who received a scan at and after 24 weeks GA. This yielded a significant difference ($p = 0.003$) which was mainly due to the big impact of late ultrasound on the incidence of suspected postdates delivery.

***IUD:*** The incidence of IUD after 27 weeks in this study was 1.1% and the introduction of a booking scan protocol did not reduce this, which is in line with the literature.[42] No difference was found when comparing the percentage of IUD cases who received an ultrasound in the two groups and since the predominant cause of death was chorio-amnionitis the demise could not have been expected to be prevented by an ultrasound examination. Almost half of the babies born in the IUD cases were SGA which would reflect the accompanying chronic placental insufficiency.

***Ultrasound exposure and workload:*** Significantly more patients ($p < 0.001$) had at least one scan in Group B (Table 8). In Group A 61.8% of patients received at least 1 scan and an average of 0.81 scans was performed per booked patient. With a booking scan for all women regardless of GA and follow-up scan for selective clinical indications 90.1% of patients received at least 1 scan and an average of 1.41 scans were performed per booked patient. Therefore when comparing the two protocols per 100 booked patients, 28 more patients would receive at least one scan and 60 extra scans would need to be performed in total with the new protocol.

The booking scan policy significantly increased the number of patients receiving their first ultrasound examination before 24 weeks GA (8% increase, $p < 0.001$) and a detailed scan between 18 and 23 weeks 6 days GA (12% increase, $p = 0.003$) (Table 8). This could be due to more accurate early pregnancy dating in Group B with resultant more accurate timing of detailed scans. The GA period between 18 and 23 weeks is regarded as the most opportune time to perform a detailed scan and detect fetal abnormalities.

There was a significant ($p < 0.001$) increase in the number of follow-up scans requested as well as in the total number of scans performed in Group B (Tables 9 and 10). The increased number of follow-up scans is mainly due to the higher scanning rate prior to 18 weeks with subsequent request for follow-up detailed scans. The significant differences in the proportion of follow-ups requested for low-lying placenta and fetal growth and Doppler (Table 9) are merely a reflection of more follow-ups for other reasons in Group B since they became non-significant when follow-ups for routine detailed scans were excluded.

***Dating:*** Only about half of patients were sure about the date of their LMP, this is similar to observations by other authors working in developing countries.[7,25] Statistically significant differences in GA at spontaneous onset of labour were found when the 3 pregnancy dating methods (FH, ultrasound and LMP) were compared. Determining the predictive value for the EDD of each of the dating methods revealed that ultrasound performed significantly better than LMP and FH measurement (Table 14). Ultrasound predicted the EDD within 10 days in

89.8% of cases while LMP and FH predicted this in only 66.5% and 54.5% of cases respectively and all these percentages were significantly different from one another. Four hundred and forty four patients in Group B were scanned within 7 days of booking and although their average GA before and after ultrasound was comparable, this difference was 3 weeks or more in 135 patients (30.4%) and 4 weeks or more in 81 (18.3%) and serious overestimations were significantly more common than underestimations [$p$ = 0.002, OR (95%CI) 1.80 (1.21-2.67)].

***BMI and FH:*** A small (0.51) but statistically significant difference in BMI was found between the two groups but this is probably a type one error and not of clinical significance. GA by FH agreed with ultrasound within 3 weeks in 75 to 80% of cases with a BMI up to 39.9 $kg/m^2$. This agreement fell to approximately 46% in cases with BMI equal or greater than 40 $kg/m^2$ (Figure 1). Although the results of the study may not support the implementation of a protocol with booking scans in all women, in cases with a BMI of 40 $kg/m^2$ or greater a booking scan may be recommended for dating purposes as there is poor agreement between FH and fetal size as determined by ultrasound.

***Booking tendencies:*** Booking tendencies were determined in patients from Group B who were scanned within 7 days of booking: 23.4% of patients booked prior to 18 weeks GA, 42.3% between 18 weeks 0 days and 24 weeks GA and 34.2% booked at or after 24 weeks 0 days GA. This indicates that approximately 66% of patients were eligible for a detail scan before 24 weeks and it is unclear therefore why only 53% of patients in group A received a detailed scan before 24 weeks according to the existing policy. A possible explanation is the systematic serious overestimation of the GA (with more than 3 weeks) by clinical methods (LMP combined with FH) in 19% of patients, which would lead to non-referral in a number of women who are truly less than 24 weeks pregnant. An alternative explanation would be the non-attendance for ultrasound appointments, which occurred for approximately 22% of booking scans in group

B. In view of the coinciding of the festive season, group A may have been at some disadvantage in this regard since appointments were not available on public holidays and non-attendance may have been higher. Even if this had been a source of potential bias though, the results of the study would not have been different since the current results do not show overall benefit of a booking scan policy.

The reasons for this lack of overall benefit are multiple. Since 66% of patients booked before 24 weeks, only 34% of women could have benefited from an additional booking scan and this small number may have limited the potential of this study to show the benefits of booking scans. It is questionable whether the additional work load of booking scans justifies the small gains in cohorts with similar patient characteristics as the index study but in communities where fewer women book before 24 weeks, a booking scan policy may be of greater benefit. The fact that 22% of women did not attend for the booking scan appointment may also have limited the impact of the new protocol and this puts in question the utilisation of available services by the patients. Currently a single ultrasonographer at the Bishop Lavis CHC serves 5 primary care antenatal clinics in the TBH drainage area. Patients from 4 of these clinics need to travel some distance to receive their ultrasound examinations (Elsiesriver and Bellville South CHC are located approximately 6 and 11 kilometres away). Most patients rely on public transport which may be infrequent and many patients are socio-economically deprived and not able to afford the travelling costs involved. Different results might therefore have been obtained if the ultrasound service had coincided with the booking clinic in each facility.

# Chapter 7

# CONCLUSION

The two groups were comparable with regard to baseline data and site of delivery supporting the assumption that the study population did not change between the two periods in spite of a change in referral pattern for certain high risk patients.

No difference in any of the pregnancy outcome parameters was found between the two groups. The booking scan protocol did not affect the number of infants considered to be SGA at birth, nor the number of fetal abnormalities, twins or placenta praevia detected prior to delivery. It did not significantly affect the GA at which the fetal abnormalities and twins were detected but caused a significant reduction in suspected postdates pregnancies not only for the whole group but especially in the sub-group that was scanned at and after 24 weeks GA. This would prevent unnecessary referrals to level II and III facilities for fetal surveillance because of suspected postdates pregnancies. No difference was found in the number of birth complications between the two groups. This was expected as the booking scan protocol did not result in the detection of significantly more problems that would have altered antenatal management and improved the outcome.

The three pregnancy dating methods (FH measurement, ultrasound and LMP dates) were found to be significantly different. Ultrasound predicted the EDD within 10 days in significantly more cases than LMP or FH measurements and FH performed significantly worse than LMP. In the large majority (75-80%) of women with BMI less than 40 $kg/m^2$, the estimated GA as determined by FH and ultrasound agreed with 3 weeks but with higher BMI the agreement fell under 50%. A high BMI would therefore in our opinion justify a booking scan for dating.

The booking scan protocol increased exposure of patients to ultrasound but the associated 74% increase in total workload did not result in clinical benefit and is in our opinion not justified. Possible reasons for the negative findings in this study were the high rate of booking before 24 weeks (66%) and non-attendance (22%). It may therefore still be worthwhile to investigate the value of a booking scan protocol in a population where more patients book after 23 weeks GA, where the incidence of obesity is higher or where the scan is offered in the clinic and on the day of booking itself.

## RECOMMENDATIONS

Most populations in the Tygerberg drainage area are socio-economically deprived and travelling costs can be a barrier to adherence to appointments. A travelling ultrasonographer who visits antenatal clinics with good quality portable equipment could help to improve patients' access to ultrasound services by avoiding travel to centrally located ultrasound department.

Since very few women in the study population recall the first day of their LMP with accuracy (only 50% recall the date), FH is often relied upon to estimate GA. While FH seems to be fairly accurate in a large proportion of leaner women, its agreement with ultrasound is too poor to be clinically useful in patients with a BMI of 40 $kg/m^2$ or more. A booking scan for these obese women would aid substantially in determining GA more accurately and should therefore be supported. Since even in leaner women, the clinical dating methods are much more likely to overestimate the true GA than to underestimate it, it may also be of benefit to increase the cut-off value of FH for offering a detailed scan to possibly 26 cm instead of the current 23 cm.

A combination of both protocols is likely to be more cost-effective: patients booking with a FH of less than 26 cm are scheduled for a detailed scan between 18 and 24 weeks clinically estimated GA while patients booking later than this (either all of them or at least those with a BMI of 40 $kg/m^2$ or more) are scanned as soon as possible after booking. This protocol would probably still demonstrate the benefit of reduced postdates pregnancies while significantly reducing the total workload. This could be the topic of a subsequent study.

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APPENDIX A

# ULTRASOUND DEPARTMENT
# BISHOP LAVIS COMMUNITY HEALTH CENTRE

## REFFERAL PROTOCOL
## Effective from 09/07/2007

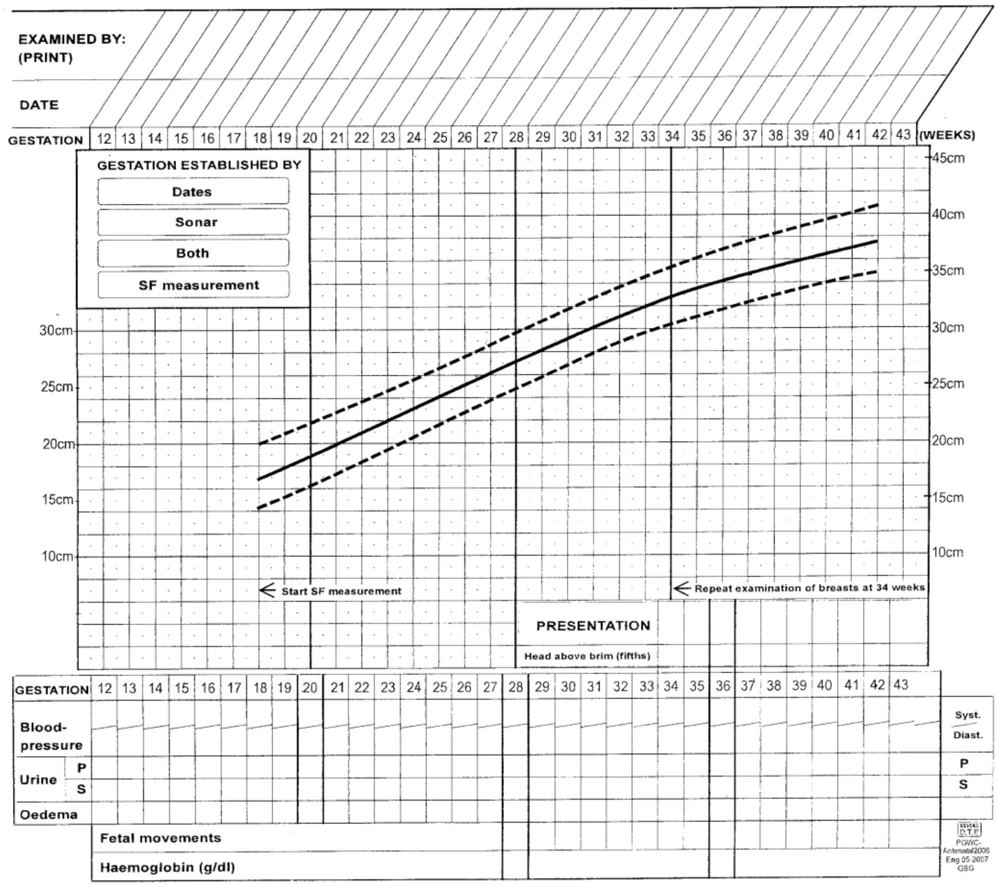
- **No dating scans**
- Refer for a detail scan between 18 weeks 0 days and 23 weeks 6 days (Preferably at 21 weeks) SF=18 to 23cm
- Increased SF at 2nd or subsequent visits or after an ultrasound (? twins, ? Polyhydramnios)
- Patients with chronic hypertension, controlled with one drug and patients with pregnancy induced hypertension, <34weeks, diastolic <110 mmHg, controlled with one drug:
  - Detail scan between 18 and 23 weeks 6 days
  - Doppler examination at 24 weeks (no earlier) or as soon as possible after booking in cases of late bookers
- Patients who conceived when 37 years of age or older should be referred directly to Tygerberg Hospital for genetic counseling (Tel: 021 938 5572)

  **Make an appointment for:**
  - Nuchal Translucency scan between 11 and 13 weeks 6 days
  - Genetic counseling at 16 weeks
- Decreased SF measurement at 2nd or subsequent visits or after an ultrasound (? IUGR) = Refer to Fetal Evaluation Clinic (FEC) at Tygerberg Hospital with a FEC referral letter.

Kind Regards
Sonographer, Bishop Lavis Community Health Center
021 934 6127

## APPENDIX B

### Fundal height centile chart for the Tygerberg region



## APPENDIX C

### CORRECT USE OF THE NEW SYMPHYSIS-FUNDUS CURVE

The new curve was compiled using women in the Tygerberg Hospital drainage area. The curve is easily recognizable as it starts at 18 weeks and continues until 42 weeks gestational age. The previous curve that was compiled in Argentina starts at 20 weeks and continues until 40 weeks.

### HOW DOES UTRERINE SIZE COMPARE TO GESTATIONAL AGE?

1. Up to 12 weeks uterine size can reasonably accurately be determined with a bimanual examination. If there is uncertainty about gestational age before 12 weeks the patient should be examined bimanually by a doctor.
2. Between 13 and 17 weeks the abdominal examination is the more accurate method to determine gestational age. The fundal height is more than 2 fingers below the umbilicus.
3. From 18 weeks onwards symphysis-fundus measurement is the more accurate measurement. The fundal height is 2 fingers below the umbilicus or higher.

### HOW MUST GESTATIONAL AGE BE DETERMINED IF THE UTERINE SIZE DIFFERS FROM THE GESTATIONAL AGE AS DETERMINED BY USING THE LAST NORMAL MENSTRUAL PERIOD?

1. With the fundal height below the umbilicus (less than 22 weeks pregnant):
   - i) With a difference of 3 weeks and more the uterine size must be used as the more likely correct gestational age.
   - ii) With a difference of less than 3 weeks the last menstrual period must be used as the more likely correct gestational age.

2. With the fundul height at the height of the umbilicus or higher (22 weeks pregnant or more):
   - i) With a difference of 4 weeks and more the uterine size must be used as the more likely correct gestational age.
   - ii) With a difference of less than 4 weeks the last menstrual period must be used as the more likely correct gestational age.

### HOW MUST THE SF-MEASUREMENT BE USED TO DETERMINE GESTATIONAL AGE?

The SF-height in centimeters on the $50^{th}$ centile from 18 to 42 weeks is used to determine gestational age in weeks. A SF-measurement of 26cm corresponds to a gestational age of 27 weeks.

**A DIFFERENCE BETWEEN UTERINE SIZE AND GESTATIONAL AGE AS DETERMINED BY THE LAST NORMAL MENSTRUAL PERIOD IS MOST LIKELY THE RESULT OF INCORRECT DATES**

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GB Theron