Women's Patient Care Center – Ambulatory Services
Evidence-Based Protocol and Policy

Gestational Age Estimation:
Accuracy, Precision, Reliability, and Safety Regarding:
Documentation & Scheduling of Elective Cesarean Section & Scheduling of Induction

**Recommendations:**

The Cut-Off for reliability is US performed before 24w6d. (because US performed at 25 weeks estimates the GA +/- 2 weeks, patients scheduled after 39 weeks GA will be beyond 37 weeks in more than 95% of cases).

In other words, if the method used to calculate the EDD is based upon an ultrasound performed prior to 24w6d gestation, then an elective Cesarean section may be scheduled after the estimated GA of 39w0d without any additional testing.

Other patients who could be scheduled without additional testing are: documented fertilization and embryo transfer dates for ART patient [+/- 0 days]; or highly reliable patient records of regular menses over at least 6 months, including LMP [+/- 5 days].

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**Manual:** WPCC Ambulatory Services

**Categories:** Clinical Care

**Section:** Prenatal Care

**Review responsibility:** Medical Director of Ambulatory Services

**Effective date:** July 6, 2006

**Last revised date:** July 6, 2006

**Team members performing:** All care team members for prenatal care in the Obstetrics & Gynecology Clinic in the TVC

**Guidelines applicable to:** Patients receiving prenatal care from the OB care team in the TVC

**Specific education requirements:** Review and comprehension of this protocol and policy

**Physician order requirements:** According to content
If the method used to calculate the EDD is based upon an ultrasound performed after 25 weeks gestation, then an amniocentesis for fetal lung maturity testing must be scheduled prior to the scheduled elective Cesarean section.3

(Evidence Grade: Moderate Quality, Benefit/risk Trade-offs)

Safety:
Prevention of human error should primarily be achieved with policies and procedures directed at human factors, and not routinely through additional technology and interventions.
In this modern era, the primary cause of a miscalculated EDD is human error. In the interest of patient safety and the reduction of error, it is critical that:
1) the EDD be properly calculated
2) a decision is made after the first Ultrasound whether it is indicated to adjust the EDD and this decision is documented (affirmative or negative) - (see rank order of reliability – select higher order method)
3) a change to the EDD is confirmed within the medical record documentation
4) a changed EDD within the medical record documentation thereafter becomes the sole determinant of all interventions that depend upon GA for interpretation or medical decision-making
5) the EDD calculation is repeated (double-checked) prior to making a decision about an intervention that is GA-dependent (like elective Cesarean section)

Elective Cesarean in the 39th week:
When scheduling an elective repeat Cesarean section, the recommendation is to schedule this during the 39th week.1,3,5 (For patients with a history of prior Cesarean who decline the option of trial of labor and request a scheduled Cesarean.)

Use best clinical information to estimate 39th week:
The objective is to use best clinical information to estimate when the patient will be 39 weeks, understanding that there is a range of accuracy surrounding this estimate.1 3 If the range (95th %ile) includes a GA less than 37 weeks, then an additional test for fetal lung maturity is indicated before proceeding with elective delivery.

Additional considerations:
- maternal diabetes: not covered by this protocol
  (the fetus of a diabetic patient may have delayed fetal lung maturity; the fetus of a diabetic patient is at higher risk of complications – including stillbirth near term)
- planning for the induction or elective Cesarean of a patient with maternal diabetes should be individualized, with consideration of the benefits and risks for both the maternal and the fetal/neonatal patients

- twins6 and higher multiples: not covered by this protocol
  (there is a rationale for acting earlier than 39 weeks, due to concerns about likelihood of labor and placental insufficiency)
- planning for the induction or elective Cesarean of a patient with twins should be individualized, with consideration of the benefits and risks for the maternal and the fetal/neonatal patients

-HIV/AIDS\(^2\): not covered by this protocol
- Amniocentesis to determine fetal lung maturity in pregnant women infected with HIV should be avoided whenever possible

-previus Classical Cesarean section\(^4\): not covered by this protocol
- (there is a rationale for acting earlier than 39 weeks, due to the increased risk of uterine rupture if the patient enters active labor and particularly if this is obstructed labor)
- if the clinical decision is made to intervene earlier (37-38 weeks) then the information about precision of the dating in the particular patient should be reviewed, and based upon the likelihoods, a decision be made whether FLM testing is indicated

**Rationale**

Fact: The OB Care Team and the pregnant patient estimate the due date (EDD) and use that to calculate the estimated Gestational Age (GA) on any given date during the pregnancy.
Fact: The EDD may change due to the acquisition of new data with greater reliability or due to a correction of a previous calculation.

Rank order from best to worst of reliability of methods for estimating EDD and GA:
1) documented fertilization and embryo transfer dates for ART patient [+/- 0 days]
2) documented first trimester ultrasound [+/- 3-7 days]
3) highly reliable patient records of regular menses over at least 6 months, including LMP [+/- 5 days]
4) documented early second trimester ultrasound (13-20 weeks) [+/- 7-11 days]
5) documented late second trimester ultrasound (21-26 weeks) [+/- 12-15 days]
6) documented early third trimester ultrasound (27-33 weeks) [+/- 15-18 days]
7) patient’s best recollection of LMP, with a background of ‘regular’ cycles [+/- 14-28 days]
8) newborn estimate of age by qualified provider [+/- 18-21 days]
9) documented late third trimester ultrasound (34-40 weeks) [+/- 19-22 days]
10) number of weeks elapsed since report of ‘quickening’ [+/- 42 days]
11) number of weeks elapsed since documented positive pregnancy test (can be reliable for estimating >39 weeks if >36 weeks have transpired since the positive test – this assumes that there has not been an intervening miscarriage and a new pregnancy)
Ultrasound-derived EDD is common: Since our routine management includes an ultrasound to confirm dates (and for other indications), we usually have an ultrasound document dated shortly after the first comprehensive prenatal visit.

In the absence of good ‘dates’, the precision shortcomings of ultrasound estimate of GA, based upon biometry are:

1) inaccurate placement of sensor to do measurement
2) incorrect calculation of GA based upon measurement
3) use of tables for determining GA which were developed from a racial/ethnic population different from this patient
4) the fetus could have growth restriction, and therefore biometric measurements would tend to underestimate the true GA
5) twins and higher multiples
6) normal biologic variation, even among normally growing fetuses from a matched population with certain dates
7) decreasing accuracy (increasing range of error) with GA

A good rule of thumb:
If ultrasound has been used to set the EDD and to calculate the GA, then the accuracy (or range of error around the estimate) can be estimated as follows:
If we assume a fetus is growing normally, (all measurements are consistently estimating the same GA), we can use the average to estimate the gestational age, and the accuracy will be +/- 8% (includes 95% of population, or 2 Standard Deviation [SD]).

Elective Cesarean in the 39th week:
When scheduling an elective repeat Cesarean section, the recommendation is to schedule this during the 39th week. (For patients with a history of prior Cesarean who decline the option of trial of labor and request a scheduled Cesarean.)
It is very important to avoid an unplanned preterm delivery, and the sequela, which include RDS. The longer the scheduled date is set in the pregnancy, the more likely that the patient will enter spontaneously labor, come to hospital at that time, and require the Cesarean at that time. Our L&D is prepared for this eventuality. The planning of an elective Cesarean achieves a convenience for the patient and her family, a convenience for the care team, and permits Cesarean procedures to be done at a planned time with planned staff – rather than competing for resources at other times of the day, could be argued to improve overall safety by reducing the chance of a saturation of active/urgent cases at an unplanned time. By the way, there’s not been any outcome advantage to the newborn demonstrated by allowing the pregnant patient to go into labor for awhile before a CS is performed.

Use best clinical information to estimate 39th week:
The objective is to use best clinical information to estimate when the patient will be 39 weeks, understanding that there is a range of accuracy surrounding this estimate. If the range (95th %ile) includes a GA less than 37 weeks, then an additional test for fetal lung maturity is indicated before proceeding with elective delivery. For patients where the best clinical information for EDD is an ultrasound performed after 25 weeks, this would
mean that for that subset of patients, if elective Cesareans were scheduled at 39 weeks, in 1% of these cases the neonate would be 36 weeks or less and have an attendant risk of RDS (of about 7%). Therefore, the number needed to test (test to rule out fetal lung immaturity) would be about 150-1500 to prevent 1 case of RDS. Although it would be possible to do a detailed Markov analysis using the continuous data from US accuracy and the 95th and 99th %iles, and the risks of mild RDS, severe RDS, and TTN and calculate the trade-off points for recommending amnio & FLM testing, this seems beyond what is required at this moment for our internal policy.

Why should we try to minimize the number of amniocentesis procedures and FLM tests?

Amniocentesis cost and risk issues:
- invasive procedure
- unpleasant for patients
- risk of complication in up to 4% of patients
- bed and nursing utilization in a busy care area
- prolonged LOS
- cost of equipment and human resources

Fetal Lung Maturity cost and risk issues
- cost of processing test
- interpretation of FLM test results depend upon the GA – cut-offs are GA-dependent
  and this is the uncertainty problem
- false positive and negative predictions

Footnotes:

1 The American College of Obstetricians and Gynecologists generally recommends that scheduled cesarean deliveries not be performed before 39 completed weeks of gestation. Best clinical estimates of gestational age should be used for planning cesarean delivery. ACOG Committee Opinion Number 234, May 2000 (Replaces No. 219, August 1999) Scheduled Cesarean Delivery and the Prevention of Vertical Transmission of HIV Infection

2 In women with HIV infection for whom a Cesarean is planned, delivery at 38 completed weeks of gestation is recommended to reduce the likelihood of onset of labor or rupture of membranes before delivery. Best clinical estimates of gestational age should be used for planning cesarean delivery. ACOG Committee Opinion Number 234, May 2000 (Replaces No. 219, August 1999) Scheduled Cesarean Delivery and the Prevention of Vertical Transmission of HIV Infection
Before elective repeat cesarean delivery, the maturity of the fetus should be established. For patients with an indication for an elective repeat cesarean delivery, fetal maturity may be assumed if one of the following criteria is met:
- 36 weeks have elapsed since documented positive results were obtained from a serum or urine BHCG test performed at our or other reliable laboratory
- US measure of CRL obtained between 6-11 weeks of gestation supports a current GA of 39 weeks or more on scheduled date
- clinical history and physical exam and US exams from 12-20 weeks support a GA of 39 weeks or more on the scheduled date

From ACOG Guidelines for Prenatal Care 5th Edition
( viewed at www.acog.org on 5/30/06)

Many clinicians choose to deliver patients with a history of prior Classical Cesarean section (by elective repeat cesarean delivery) before 39 weeks of gestation to reduce the risk of spontaneous uterine rupture. However, early delivery may lead to complications of prematurity for the neonate, including a small risk of respiratory distress syndrome (RDS). Our model suggests that early delivery (at 36 weeks of gestation) is preferable to strategies that delay delivery to ensure fetal lung maturity. Although rare, the catastrophic outcomes that are associated with uterine rupture tip the balance toward favoring early delivery. Complications of prematurity after 36 weeks of gestation are generally thought to be minor and transient; therefore, although complications of prematurity are more frequent than uterine rupture, they are not nearly as detrimental to maternal quality of life. Thus, in our model, we saw no benefit of offering fetal lung maturity testing because it would lead, in cases of negative results, to further expectant management in a risky situation.

The gold standard to address a clinical controversy is a randomized, controlled trial. Because of the small number of patients with a classic uterine scar and the even smaller number of uterine ruptures, tens of thousands of patients would have to be randomized to have adequate power to determine the best strategy. Decision analysis is not intended to replace randomized controlled trials; however, when none are available, it can provide insight to clinical conundrums. Our model is intended to aid clinicians in understanding the relative risks and benefits of the various strategies. Although there is uncertainty associated with the results of any decision analysis, this model strongly suggests that a strategy of elective delivery at 39 weeks of gestation (strategy 1) for women with a previous classic cesarean delivery is not optimal with regard to maternal and fetal outcomes.


Gestational age for a planned CS
Pregnant women should be offered information that current research evidence suggests a planned CS should not be carried out before 39 weeks because of the increased risk of
respiratory problems for babies born by planned CS before 39 weeks. This applies to instances where there are no other clinical indications for early delivery.

NICE Caesarean Section Clinical Guideline. April 2004. <accessed online>

Scheduling elective CS at GA of not less than 38 weeks may decrease the frequency of TTN.


Elective cesarean section at term, in an obstetric population without prenatally identified risk factors, remains associated with increased resuscitation risk with related implications for the neonate compared with vaginal delivery. A significant reduction in neonatal resuscitation risk would be obtained by waiting until week 39(+0) before performing elective cesarean section.


An elective cesarean section before the onset of labor early in the 37th week of gestation should not be routinely undertaken.


Timing of planned CS for twin pregnancy:

Pregnant women should be offered information that current research evidence suggests that planned CS for twin pregnancy should not be carried out before 38 weeks because of the increased risk of respiratory problems for babies from multiple pregnancies born by planned CS before 38 weeks.

We identified a cohort study conducted in the US in which 79 sets of twins delivered by CS between 36 weeks and 37 weeks 6 days’ gestation were compared to 47 sets of twins delivered by CS between 38 weeks and 40 weeks 2 days’ gestation. The outcome was the incidence of respiratory disorders-namely respiratory distress syndrome and transient tachypnoea of the newborn. Eleven pregnancies were affected by respiratory disorders. Ten out of these (90.9%) had been delivered before 38 weeks compared to 69 out of 115 unaffected pregnancies (60.0%). Thus patients with pregnancies in which one or both neonates were diagnosed with respiratory disorders were more likely to have undergone CS before 38 weeks’ gestation than those without affected neonates. (p=0.04)
We did not identify any other studies that looked at the optimal gestational age for planned CS for other multiple pregnancies as the study described above only included twins and not triplets and therefore is not generalisable to all multiple pregnancies. Multiple pregnancy is an established risk factor for preterm birth and data from the NSCSA1 showed that 29% of twin pregnancies went into spontaneous labour before 37 weeks.

Summary
For twin pregnancies, the risk of neonatal respiratory disorders is reduced after 38 weeks gestation. This study did not include triplet pregnancy and therefore is not generalisable to all multiple pregnancy, only twin pregnancy.


*Risk assessment for neonatal respiratory distress syndrome with FLM II combined with gestational age. On the basis of gestational age alone, most fetuses <30 weeks of gestation will be at risk of RDS, whereas few fetuses after 36 weeks of gestation will experience RDS. Obtaining FLM results at 39+ and <30 weeks of gestation is arguably not very useful.*


Predicted Risk of Neonatal Respiratory Distress Syndrome by Gestational Age and TDx-FLM II Surfactant-to-Albumin Ratio Value

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Values are expressed as percentages.

TDx-FLM II surfactant-to-albumin (Abbott Laboratories, Abbott Park, IL).
# Neonatal Morbidity According to Gestational Age

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<th>Gestational Age (weeks)</th>
<th>Incidence of RDS (%)</th>
<th>Incidence of grade III and IV IVH (%)</th>
<th>Incidence of NEC (%)</th>
<th>Incidence of sepsis (%)</th>
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<td>Incidence of sepsis</td>
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REFERENCE
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