

**UTAH MEDICAL INSURANCE ASSOCIATION
INSURANCE REQUIREMENTS**

**UTAH MEDICAL INSURANCE
ASSOCIATION**

INSURANCE REQUIREMENTS

FOR

OBSTETRICAL PRACTICE



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THERE ARE ONLY TWO OPTIONS FOR DELIVERY:

**AN EASY VAGINAL DELIVERY OR AN EASY
CESAREAN SECTION.**

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FOR OBSTETRICAL PRACTICE**

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Revised Edition**

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FOREWORD

In the mid-1980's, the Utah Medical Insurance Association (UMIA), like professional insurers throughout the country, experienced an unprecedented increase in the number and severity of claims arising from the practice of obstetrics. While physicians providing obstetrical care comprised only 25% of the UMIA insureds, they accounted for nearly half of the known losses. A continuation of that trend would have made the practice of obstetrics uninsurable at any cost and would have dramatically affected the availability of medical care to the public.

Consequently, the UMIA is compelled to offer coverage for obstetrical practice only to those physicians who comply with the insurance requirements contained in this booklet. Failure to abide by the insurance requirements in the absence of the patient's written consent will not affect coverage provided under a policy then in effect, but may result in non-renewal of the policy or renewal with an exclusion of the coverage for obstetrical care.

The UMIA insurance requirements have been formulated by a committee of perinatologists, obstetricians, family practitioners, claims personnel, defense counsel and chaired by the medical director of UMIA to enhance the defensibility of claims arising from areas of obstetrical care that have resulted in substantial losses. The insurance requirements are not intended to define the minimum standard of care applicable to all practitioners of obstetrics in this community. To the contrary, in some instances the requirements may exceed acceptable standards or may not incorporate alternatives some authorities advocate. Nevertheless, the UMIA believes uniform adherence to these requirements by its insureds will reduce the incidence of claims and will substantially improve the defensibility of those pursued.

If compliance with a requirement is not feasible in a particular facility or locality, upon written consent of those providing obstetrical care in that area, the UMIA may grant an exception to the requirements. In addition, patients may request care inconsistent with these insurance requirements. In both instances, UMIA insureds are required to obtain the patient's written consent to such non-compliance.

The UMIA intends to continuously review these requirements and invites the comments and recommendations of all its members.

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UTAH MEDICAL INSURANCE ASSOCIATION

DEFINITION

OF

OBSTETRICS

The rendering of prenatal and/or intrapartum care, management or consultation to a pregnant woman, except for the care, management, or consultation for acute ectopic pregnancy and first or second trimester terminations.

PRENATAL CARE RECORD FORM

The UMIA will not require the use of any single type of prenatal record. We do, however, recommend the forms developed by ACOG, *Intermountain Health Care* or the University of Utah Medical Center as examples. Any *risk assessment* form which allows a comparable level of record keeping will be acceptable. When complications arise, please expand comments on additional Progress Notes.

CRITERIA FOR CONSULTATION AND REFERRAL FOR FAMILY PRACTITIONERS PROVIDING OBSTETRICAL CARE

Patients meeting any of the following criteria should be referred for obstetrical care to an obstetrician. A ** denotes those clinical conditions which require consultation and/or co-management by a maternal fetal medicine specialist. This in no way disallows subsequent shared or concurrent care of these patients:

1. **Insulin dependent diabetes mellitus
2. **Multiple gestation
3. **Previous cerclage or needing a cerclage in current pregnancy
4. **Serious cardiac, renal, collagen vascular or hematologic disease
5. Hydatidiform mole

Patients meeting the following criteria should have consultation and/or consultation and examination by an obstetrician:

1. Hypertension: chronic or pregnancy induced except for **severe preeclampsia and **eclampsia
2. Abnormal carbohydrate intolerance (defined as two abnormal values on a three hour glucose tolerance test and managed by diet alone)
3. Repetitive pregnancy loss (3 or more conceptions not ending in birth of a live child)
4. Positive antibody screen (Rh or other significant)
5. Pre-term labor less than 35-weeks
6. **Pre-term rupture of membranes (<35-weeks)
7. Prolonged ruptured membranes (>24-hours)
8. Vaginal bleeding after 20-weeks
9. Previous stillbirth
10. Previous pre-term birth (<35-weeks)
11. **Previous child or present fetus with significant congenital anomaly

12. Post-term pregnancy (≥ 41 -weeks)
13. *Chorioamnionitis including postpartum fever $\geq 100.4^\circ$ (excluding the first 24-hours postpartum). Advise early referral of antepartum cases
14. Previous C-section other than low transverse or any C-section for family practitioners who do not have privileges to perform C-sections
15. *Postpartum hemorrhage exceeding 700 cc
16. +Second stage exceeding one hour in a multiparous patient or two hours in a nulliparous patient with one additional hour allowed for patients with an epidural
17. Previous shoulder dystocia
18. All malpresentations. (breech, transverse, etc)
19. +Labor arrest
20. Hyperthyroidism
21. Seizure disorder
22. Current addictive drug abuse
23. Other significant chronic medical illness
24. Confirmed intrauterine growth *restriction*
25. **Diagnosed placenta previa beyond 24 weeks

*Does not apply in communities in which obstetrics is performed exclusively by Family Practitioners/General Practitioners.

+Does not apply when the Family Practitioner involved in the care has privileges for C-section.

DATING CRITERIA AND OBSTETRICAL ULTRASOUND

All pregnant patients presenting for prenatal care prior to 20 weeks must have a basic diagnostic ultrasound performed according to ACOG criteria (*reference ACOG Practice Bulletin, Number 101, February 2009*) including complete biometric assessment. Such an examination is performed ideally between 18 and 20 weeks gestation, but may be performed at any stage prior to 20 weeks.

AMNIOCENTESIS

1. All amniocenteses should be done with *continuous real-time ultrasound guidance*.
2. All persistently bloody taps should be followed by a period of careful fetal monitoring to assure fetal well being.
3. It is recommended that amniocentesis be done in close temporal proximity to a delivery suite.
4. *All genetic amniocentesis should be performed by the specialty of Maternal-Fetal Medicine.*
5. Given the availability of maternal serum screening and targeted high resolution sonography, it is inappropriate to counsel a woman that she is at high risk for Down syndrome simply on the basis of her age, as this may or may not be true. Adequate counseling is only possible with the use of serum screening. It is inappropriate to discuss serum screening in terms of “false positives.” Rather, this should be offered to all pregnant women in order to determine whether or not they are at increased risk for Down syndrome, and the absolute magnitude of this risk.

HYPERTENSION & PREGNANCY

Chronic Hypertension

1. If the patient is on an antihypertensive medication prior to pregnancy, leave her on it. The exception would be patients using angiotensin converting enzyme (ACE) inhibitors. Such medications are contra-indicated in pregnancy.
2. There is no evidence to suggest benefit in initiating antihypertensive therapy during pregnancy for women with chronic hypertension unless the diastolic blood pressure exceeds 100-mmHg. In such patients, drugs such as Nifedipine, Atenolol, or **Labetalol**, may be appropriate.
3. IT IS CATEGORICALLY UNACCEPTABLE TO INITIATE OUTPATIENT ANTIHYPERTENSIVE THERAPY OF ANY TYPE IN PATIENTS WITH PREGNANCY-INDUCED HYPERTENSION/PREECLAMPSIA. Because the distinction between worsening chronic hypertension and superimposed pregnancy induced hypertension is often difficult, take great care in initiating antihypertensive therapy in any pregnant woman beyond 20 weeks gestation. Maternal-fetal medicine consultation is often helpful in such patients.
4. Patients with chronic hypertension are at great risk for developing superimposed pregnancy induced hypertension. SUCH PATIENTS MUST BE FOLLOWED VERY CLOSELY, ESPECIALLY IN THE THIRD TRIMESTER. ANY SIGNIFICANT ELEVATIONS IN BLOOD PRESSURE GENERALLY ARE BEST EVALUATED BY ADMITTING THE PATIENT TO THE HOSPITAL FOR SERIAL BLOOD PRESSURE ASSESSMENT AND THOROUGH LABORATORY WORKUP, TO EXCLUDE SUPERIMPOSED PREECLAMPSIA.

Pregnancy Induced Hypertension/Preeclampsia

1. MOST ERRORS ARE MADE BY IGNORING OR NEGLECTING NEW ELEVATIONS IN BLOOD PRESSURE THAT OCCUR IN THE SECOND HALF OF PREGNANCY.
2. Take any new elevations in blood pressure seriously – they are not normal. Multiple attempts to re-take a blood pressure in different positions in order to get a “normal” reading only courts disaster.
3. The ultimate treatment for this condition is delivery. Thus, a diagnosis of pregnancy-induced hypertension/preeclampsia must be followed by prompt delivery, unless considerations of prematurity outweigh the risk of continuing the pregnancy. THE DIAGNOSIS OF THIS CONDITION AT OR BEYOND 37 WEEKS MANDATES DELIVERY. WAITING FOR A FAVORABLE CERVIX IS NOT JUSTIFIED. A CESAREAN SECTION FOR FAILED INDUCTION IS FAR PREFERABLE TO A MATERNAL OR FETAL DISASTER. Except in very mild cases, diagnosis beyond 34 weeks generally should lead to delivery.

4. In cases of apparently mild disease, with significant prematurity, inpatient management should be considered the default mode of treatment. In select cases, careful outpatient management is acceptable if the following conditions are met:
 - ✦ Blood pressure < 150/100
 - ✦ <1+ proteinuria
 - ✦ Careful home BP monitoring is possible
 - ✦ The patient is sufficiently educated and reliable to take and act upon home BP measurements **and follow up with the physician as instructed**
 - ✦ The patient has had a careful laboratory evaluation to exclude severe disease (platelets, AST, ALT, 24 hour urine for creatinine clearance and protein). These labs should be repeated on at least a weekly basis.
 - ✦ The patient has no symptoms suggesting severe disease (headache, epigastric pain, visual disturbances)
 - ✦ Twice weekly antepartum testing can be accomplished
 - ✦ The fetus does not have IUGR
5. During hospitalization, both pre, intra and postpartum, a systolic blood pressure >180 mmHg, a diastolic blood pressure >110 mmHg or a mean arterial pressure $(2S + D)/3$ >125 mmHg requires prompt administration of an antihypertensive medication such as IV hydralazine or IV **labetalol**. In many situations, administration of such drugs is also indicated for a diastolic pressure between 105-110 mmHg. For patients not on MgSO₄, PO nifedipine is also an excellent choice.

In all other cases, inpatient management or transfer to a tertiary center is mandatory.

ANTEPARTUM TESTING (APT)

Indications for Antepartum Testing:

- ★ Type I diabetes mellitus
- ★ Type II or gestational diabetes requiring either insulin or oral hypoglycemic agents.
- ★ Hypertension, chronic or pregnancy induced
- ★ Post term pregnancy (more than 41 weeks)
- ★ Previous stillbirth
- ★ Cyanotic maternal cardiac disease
- ★ Hyperthyroidism
- ★ Decreased fetal movement
- ★ IUGR, or suspected IUGR, prior to ultrasound confirmation of diagnosis
- ★ Multiple gestation
- ★ Twins with significant growth discrepancies.
- ★ Advanced maternal age.
- ★ Artificial reproductive techniques.
- ★ Medical problems that increase the risk of placental insufficiency (antiphospholipid syndrome etc.).

All patients evaluated after 32 weeks gestation in labor and delivery must have a FHR tracing meeting criteria for a reactive NST or negative CST or biophysical profile of 8.

Although initial evaluation of APT may be performed by a nurse, all APT's must be evaluated by a physician in a timely fashion. Evaluation must be by standard criteria, i.e., REACTIVE or non-REACTIVE (NST) or POSITIVE or NEGATIVE (CST). "Adequate" or "OK" does not constitute proper evaluation.

NST "REACTIVE" is defined as 2 accelerations above baseline, of at least 15 bpm, lasting 15 seconds within any of the standard time frames. Significant variable decelerations are also important and should lead to prompt sonographic evaluation of amniotic fluid volume, and/or delivery, if at term.

CST "NEGATIVE" is defined as no late decelerations in response to 3 uterine contractions (spontaneous or evoked) within 10 minutes.

"POSITIVE" is defined as repetitive late decelerations in response to uterine contractions, regardless of their frequency.

No patient should be discharged with suspicious or equivocal NST results. Further testing is required, such as a biophysical profile or CST.

RECOMMENDED FREQUENCY OF NON-STRESS TESTING

| <u>INDICATION</u> | <u>FREQUENCY</u> |
|---|------------------|
| ✦ Diabetes mellitus requiring insulin or oral therapy | 2 X / week |
| ✦ Post-dates (<i>weekly amniotic fluid determination</i>) | 2 X / week |
| ✦ I.U.G.R. prior to term (<i>weekly amniotic fluid determination</i>) | 2 X / week |
| ✦ Hypertension (<i>weekly amniotic fluid determination</i>) | 1-2 / week |
| ✦ Previous fetal demise | 1 X / week |
| ✦ Medical complications of pregnancy known to be associated with an increased risk of still birth or birth asphyxia | 1-2 X / week |
| ✦ Decreased fetal movement | 1 X only |
| ✦ Premature membrane rupture | Daily |
| ✦ Hemorrhage | Variable |

Notes:

- ★ *Significant* variable or any late decelerations are grounds for further evaluation or delivery. The presence or absence of oligohydramnios may aid in the above assessment.
- ★ With IUGR, hypertensive or post dates pregnancies; amniotic fluid volume assessment must be done at least once per week.

The beginning of NST testing depends upon the clinical setting and specific indications.

INTRAPARTUM FETAL SURVEILLANCE

All patients in labor beyond 24-weeks gestation must undergo continuous electronic fetal heart rate monitoring. For patients receiving oxytocin or misoprostol, we recommend checklists such as those described in appendix A be instituted.

FORCEPS AND VACUUM EXTRACTION DELIVERY

Introduction:

The application of forceps or vacuum extractors requires the following:

- A properly trained operator with privileges for this procedure
- Descent of the fetal skull to at least +2/5 station with documentation
- A fully dilated cervix with documentation
- Precise knowledge of the fetal position (i.e., OA, LOA, etc.) with documentation
- Adequate clinical pelvimetry with a note to that effect
- Adequate anesthesia
- An estimated fetal weight of <4250-g with documentation of this estimate
- A documented indication

All operative vaginal deliveries should be approached as trials. All operative vaginal deliveries should be abandoned if delivery does not proceed easily with the use of the instrument. The only exception is a life threatening maternal or fetal emergency while preparations for cesarean section are underway. In addition, the following considerations apply:

- *Progressive descent must occur with each pull*
- *Sequential use of vacuum and forceps is contraindicated*
- *Repeated applications of forceps is generally inappropriate*
- *Vacuum delivery may proceed in the face of “pop-offs” only if the cause of the “pop-off” is documented equipment failure or air leak*
- *After two such pop-offs, the vacuum attempt should be abandoned*
- *Cesarean section is almost always the appropriate route of delivery for lack of progress in labor, unless criteria for outlet forceps are met.*

A cesarean section is preferable to a damaged fetus delivered vaginally. Cesarean section is the delivery method of choice for fetal distress if a forceps delivery is not predictably easy.

Definitions:

1. ***Outlet Forceps:** The application of forceps when a) the scalp is visible at the introitus without separating the labia, b) the fetal skull has reached the pelvic floor, c) the sagittal suture is in the anterior-posterior diameter or in the right or left occiput anterior or posterior position, and d) the fetal head is at or on the perineum. According to this definition, rotation cannot exceed 45-degrees. There is no difference in perinatal outcome when deliveries involving the use of outlet forceps are compared with similar spontaneous deliveries and, furthermore, there is no data to support the concept that

rotating the head on the pelvic floor 45-degrees or less increases morbidity. Forceps delivery under these conditions may be desirable to shorten the second stage of labor.

2. ***Low Forceps:** The application of forceps when the leading point of the skull is at station +2 or more. Low forceps have two subdivisions: a) rotation 45-degrees or less (e.g., left occipito-anterior to occiput anterior, right occipito-posterior to occiput posterior), and b) rotation more than 45-degrees. A low forceps operation is appropriate, for example, when the patient has an adequate pelvis, the vertex fills the hollow of the sacrum, the fetus is not macrosomic and the anesthesia is adequate. Under these conditions, low forceps delivery may be completed without trauma, if the application of the forceps is easy and traction is not difficult. If the forceps is not accomplished without excessive force, a prudent approach is to proceed with a cesarean section. Protraction and arrest disorders of labor have an adverse impact on perinatal outcome that appears to be enhanced by low or mid forceps delivery as currently defined.
3. ***Mid Forceps:** The application of forceps when the head is engaged, but the leading point of the skull is above station +2. Under very unusual circumstances, such as the sudden onset of severe fetal or maternal compromise, application of forceps above station +2 may be attempted while simultaneously initiating preparations for a cesarean delivery in the event that the forceps maneuver is unsuccessful. Under no circumstances, however, should forceps be applied to an unengaged presenting part or when the cervix is not completely dilated.

*The same criteria applies to vacuum extraction with the Silastic cup. The use of any other type of vacuum extractor is unacceptable.

Indications:

The indications for the forceps operation, including the position and station of the vertex at the time of application of the forceps, should be specified in a detailed operative description in the patient's medical record.

The following must be documented in the medical record at the time of instrument delivery:

- | | |
|---------------|----------------------------------|
| * Indications | * Position |
| * Station | * Time of instrument application |

A "Procedure Note" describing and summarizing the forceps or vacuum extraction delivery should be documented at completion of the procedure.

It is essential to document, prior to forceps/vacuum placement, the station and position of the fetal head and indication for instrumental delivery. Do not place forceps or vacuum above a +2 station. Sequential use of forceps and vacuum is associated with a high risk of fetal injury and is not acceptable. If the head does not descend readily and easily, stop and perform a cesarean section.

MANAGEMENT OF SINGLETON BREECH

All singleton breech fetuses (24+ weeks gestational age) should be delivered by cesarean section unless they are non-viable or suffer from grave fetal defects.

PROTOCOL FOR OXYTOCIN ADMINISTRATION

If the following checklist cannot be completed by the nursing staff or the physician, Oxytocin should not be initiated. The recommended dose is 1 mU/min with increases at 30 minute intervals if needed. Chart documentation for doses exceeding this recommendation explaining the medical need offsetting the increased maternal/fetal risk are required.

1. Physician or Midwife Order on chart
2. Current history and physical on the chart (for scheduled induction)
3. Prenatal Record on chart (for scheduled induction)
4. Indication for induction is documented
5. Pelvis is documented by physician to be clinically adequate (should be on prenatal record)
6. Estimated fetal weight within past week (clinical or ultrasound) less than 4500-grams in a non-diabetic woman or less than 4250-grams in a diabetic woman
7. Gestational age documented
8. Consent signed (General L&D consent)
9. Physician with C-section privileges is aware of the induction and readily available and this is documented in the medical record
10. Status of the cervix is assessed and documented
11. Presentation is assessed and documented (physician required to come in if nurse unable to determine)
12. Fetal Assessment completed and indicates:
 - A minimum of 20-minutes of fetal monitoring is required prior to starting Oxytocin
 - * At least 2-accelerations (15 bpm x 15 sec) in 30-minutes are present, or a biophysical profile of 8 is present within the past 4-hours
 - Adequate variability
 - No late decelerations
 - No more than 2 Variable deceleration exceeding 60-seconds and decreasing greater than 60-bpm from baseline within the previous 30-minutes prior to starting Oxytocin infusion

* This document does not apply to a formal Oxytocin challenge test without the intent to induce or augment labor.

If deviation from policy occurs, physician documentation will include an explanation of a reason for the deviation.

OXYTOCIN CHECKLIST

Checklist will be completed by nursing staff every 30-minutes. Oxytocin should be stopped or decreased if the following checklist cannot be completed.

Fetal Assessment indicates:

- At least 1 acceleration of 15-bpm x 15-seconds in 30-minutes or adequate variability for 10 of the previous 30-minutes
- No more than 1 late deceleration occurred
- No more than 2 Variable decelerations exceeding 60-seconds in duration and decreasing greater than 60-bpm from the baseline within the previous 30-minutes

Uterine Contractions

- No more than 5-uterine contractions in 10-minutes for any 2 consecutive 10-minute intervals
- No two contractions greater than 120-seconds duration
- Uterus palpates soft between contractions
- If IUPC is in place, MVU must calculate less than 300-mm Hg and the baseline resting tone must be less than 25-mm Hg.

Note: If Oxytocin is stopped, the Pre-Oxytocin Checklist will be reviewed before Oxytocin is reinstated.

GUIDELINES FOR VAGINAL BIRTH AFTER CESAREAN DELIVERY (VBAC)

For any woman undergoing a **trial of labor** after cesarean section, the following must be documented in the chart, preferably in both the office and the labor and delivery chart.

- ★ She understands her chances of successful vaginal delivery is about 50% if the prior indication was failure to progress in labor, and about 80% for other indications.
- ★ She understands her chances of a catastrophic uterine rupture is 0.5-1% and that a significant number of babies whose mothers suffer ruptured uterus during labor will incur permanent brain damage or death.
- ★ Unsuccessful trial of labor is associated with more complications for the mother than elective repeat cesarean section.
- ★ She may elect repeat cesarean section at any time.
- ★ Induction of labor is associated with an increased risk of uterine rupture compared to spontaneous labor.
- ★ Obesity both reduces the likelihood of successful trial of labor and increases the likelihood of maternal complications.

For women considering a trial of labor after cesarean section, it is acceptable to delay the final decision regarding route of delivery until later in pregnancy, when changing clinical conditions such as estimated fetal weight and station of the presenting part are known.

The following are contraindications for **a trial of labor following cesarean section**:

- A vertical or fundal uterine scar
- Twins
- More than 1 prior cesarean section
- Suspected macrosomia

The following should also be noted:

A physician capable of performing cesarean section, an anesthesiologist or CRNA capable of performing emergency general anesthesia and adequate OR staff must be within 5-minutes of the operating room at all times during labor. Many hospitals will not be able to comply with this rule, thus contraindicating VBAC in these facilities.

Also note the following:

- Elective induction is contraindicated
- The use of prostaglandin ripening agents is contraindicated
- Continuous electronic fetal monitoring is mandatory throughout labor
- The only acceptable oxytocin regimen is a starting dose of 1 mU/min, increasing by 1 mU every 30-minutes. **The panel, however, believes that oxytocin use in these patients will be banned at some point in the not to distant future.**

Remember that most cases of uterine rupture will be heralded by the appearance of new, significant variable decelerations. A low threshold for intervention in the presence of such decelerations, even with good variability and accelerations, is mandatory in the VBAC patient.

HOSPITAL STANDARDS *

ACOG Minimum

- ✦ Identification of high-risk mothers and fetuses
- ✦ Continuous electronic fetal monitoring
- ✦ Cesarean delivery capabilities within 30-minutes, *including anesthesia*
- ✦ Blood and fresh frozen plasma for transfusion
- ✦ Provision of real-time ultrasound examination on a 24-hour basis for labor and delivery use
- ✦ Neonatal resuscitation
- ✦ Laboratory services on a 24-hour basis
- ✦ Consultation and transfer agreement
- ✦ Nursery
- ✦ Data collection and retrieval

VBAC – *All personnel required for cesarean delivery must be in house.*

* Community/hospital exceptions to the above must be documented with proper informed consent.

MISOPROSTOL USE IN PREGNANCY

When Misoprostol (cytotec) is used with a living fetus, which is potentially viable ex utero, the following precautions are mandatory:

1. The dose is 0.25 mcg vaginally or orally.
2. The dose cannot be repeated more frequently than every 4-hours.
3. Continuous electronic fetal heart rate monitoring is essential during Misoprostol use.
4. No oxytocin can be given unless 4-hours has elapsed from the time of the last Misoprostol dose.
5. Written informed consent should be considered. An appropriate consent form is included.
6. Elective induction with misoprostol is contraindicated.

Misoprostol should not/must not be used:

1. If the cervix is >2 cm dilated.
2. If the patient is already in labor or is having regular uterine contractions.
3. If the patient has a uterine scar.
4. With twins.
5. With hydramnios.

Misoprostol Supplemental Informed Consent

There are certain drugs (Prostaglandins) that are helpful in the following ways:

- ✦ Preparing the cervix (the opening of the womb) for delivery
- ✦ For starting labor in pregnant women

Your doctor/midwife has ordered a type of these drugs called Misoprostol. The most common use of the drug is for the treatment of stomach ulcers. The FDA has NOT approved this drug for use in pregnancy. Also, the manufacturer recommends NOT using this drug during pregnancy. However, the manufacturer of Misoprostol has recognized that the drug may be appropriate for non-FDA approved purposes if your doctor feels that it is appropriate based on:

- ✦ Experience
- ✦ Published research
- ✦ Expert clinical opinion

This drug has become widely used by doctors/midwives for preparing the cervix and for starting labor. Based on extensive use and study of Misoprostol within the obstetrical community, your doctor/midwife believes that it is safe for use in your situation.

The American College of OB/GYN has issued a statement in favor of the use of Misoprostol for preparing the cervix and starting labor. Recent studies show that this drug is more effective in encouraging vaginal delivery within 24-hours than the other drugs more commonly used. It also reduces the need for, and the amount of, other drugs used to start labor. The studies do show that use of Misoprostol may result in a higher chance of prolonged contractions and other possible complications. These problems seem to be much more common with doses higher than will be used for your delivery (higher than 25 micrograms). No study has ever shown any long-term harmful health effect to a fetus that did not have fetal distress.

Even though there have been many studies in which Misoprostol has been used to start labor, such studies have never been submitted formally to the FDA. However, the FDA has found it to be safe and effective for other uses and it is available by prescription in the United States. A large body of scientific knowledge and the documented experience of many doctors/midwives support your doctor/midwife's choice of this drug to start labor and/or prepare your cervix. Your doctor/midwife does not believe this drug's use is experimental or investigational in your case.

The American College of OB/GYN has written guidelines that will be followed in your care for the use of Misoprostol.

| Benefits to the use of Misoprostol may include the following: | Risks to the use of Misoprostol may include, but are not limited to: |
|---|---|
| <ul style="list-style-type: none"> ✦ Misoprostol is at least as effective, if not more effective, than the other drugs available. ✦ It is given by mouth or vaginally and can be placed by an RN. ✦ It has fewer side-effects for the mother compared to other drugs. ✦ The rate of C-section, fetal distress, and newborn ICU admissions are about the same as with other drugs used for the same purpose. | <ul style="list-style-type: none"> ✦ Not FDA approved at this time. ✦ The drug's manufacturer does not recommend its use (but they have stated that such use may be appropriate when recommended by a doctor/midwife). ✦ You may have frequent contractions and/or prolonged contractions. Frequent contractions happen most often after the second dose. ✦ Increased chance of meconium stained fluid. ✦ Fetal heart rate changes ✦ Fetal distress |

Remember that most of these risks can also occur with other drugs used to start labor or to prepare the cervix for delivery.

* SHOULDER DYSTOCIA

Despite the fact that shoulder dystocia is rarely predictable or preventable, it remains a major source of litigation today. This is because the injury may be caused by inappropriate traction by the physician on the baby's head, and by the willingness of a handful of "experts," unfamiliar with the medical literature, to testify that any brachial plexus injury means that the doctor must have pulled too hard. Pound for pound, infants of diabetic mothers have an increased likelihood of shoulder dystocia. For these reasons, the following measures are essential, both to protect your patient and yourself:

1. All **pregnant** women with any form of diabetes must have an ultrasound to estimate fetal weight at 37-39 weeks gestation. If a woman enters labor prior to this ultrasound, the physician must perform and document a careful manual estimation of fetal weight in early labor, or within a week of labor. Keeping in mind that an infant of a diabetic mother may gain ½ pound per week in late pregnancy (i.e., after such an ultrasound exam), the clinician must document an estimated weight in the first stage of labor in the chart for all diabetic women. If the estimated weight is >4500-g, the physician must recommend cesarean section because of the high risk of shoulder dystocia. This weight is from ACOG guidelines. However, many clinicians feel a more reasonable weight cut off is 4250-g. The physician must at least discuss with the patient the risk of shoulder dystocia and the option of primary cesarean section. *Reference ACOG Practice Bulletin, No. 40, November 2002.*
2. If the fundal height exceeds the gestational age in weeks by more than 2-cm beyond 37-weeks in a non-diabetic patient, the clinician must document an estimated fetal weight either by ultrasound or clinically in the first stage of labor. Primary cesarean should generally be recommended for non-diabetic women with estimated fetal weight exceeding 5000-g and, depending upon delivery history and the size of the pelvis, should generally be considered with estimated fetal weights in excess of 4500-g.
3. Forceps or vacuum delivery (other than true outlet procedures) is contraindicated for women with arrest of descent and an estimated weight in excess of 4000-g.
4. Patients with a history of shoulder dystocia should undergo cesarean delivery, whether or not injury occurred during the prior shoulder dystocia.

Once shoulder dystocia is encountered, there are 4 essentials:

1. DO NOT EXERT TRACTION ANY GREATER THAN WOULD BE USED FOR ANY UNCOMPLICATED VAGINAL DELIVERY.
2. USE THE DESCRIBED MANEUVERS (McRoberts, Woods, etc.) IN ANY ORDER DESIRED. WE NOTE THAT McROBERTS AND SUPRAPUBIC PRESSURE ARE THE MOST COMMONLY USED INITIAL MANEUVERS.
3. DO NOT APPLY, AND DO NOT LET ANY NURSE, APPLY FUNDAL PRESSURE.

4. DOCUMENT IN DETAIL ALL THAT WAS DONE. A sample ideal delivery might read:

“Once shoulder dystocia was encountered: all traction ceased until the obstruction was relieved. Suprapubic pressure and McRoberts maneuvers were performed and were (were not) successful. A proctoepisiotomy was performed, but was not effective. Posterior arm release was attempted and was unsuccessful. Woods maneuver was then attempted and was successful in releasing the shoulder. AT NO TIME WAS ANY AMOUNT OF FORCE APPLIED TO THE BABY’S HEAD IN EXCESS OF THAT REQUIRED FOR A NORMAL DELIVERY. The baby was delivered LOA.”

UMIA notes that accuracy and honesty in all record keeping is essential. The above note is provided as a reminder of how a shoulder dystocia might be properly handled, to achieve the best outcomes for our patients.

We note that, if you leave any fact up to the imagination, the patient and family, coached by the plaintiff attorney, will be happy to fill in the blanks. Remember that many cases of Erbs Palsy occur unrelated to shoulder dystocia and are pre-delivery events.

* Community/hospital exceptions to the above must be documented with proper informed consent.

Shoulder Dystocia Delivery Note addendum

Time head delivered _____

Time body delivered _____

Initial Traction:

Gentle attempt at traction, assisted by maternal expulsive forces

Explain if above box not checked _____

Any/all maneuvers that apply and the order in which they were utilized. The order is not specified by the standard of care

| Maneuvers utilized | In which order (circle) | By whom |
|--|-------------------------|---------|
| <input type="checkbox"/> McRoberts | 1 2 3 4 5 6 7 | _____ |
| <input type="checkbox"/> Suprapubic pressure | 1 2 3 4 5 6 7 | _____ |
| <input type="checkbox"/> Episiotomy | 1 2 3 4 5 6 7 | _____ |
| <input type="checkbox"/> Episiotomy extension | 1 2 3 4 5 6 7 | _____ |
| <input type="checkbox"/> Posterior arm release | 1 2 3 4 5 6 7 | _____ |
| <input type="checkbox"/> Rubin's Maneuver | 1 2 3 4 5 6 7 | _____ |
| <input type="checkbox"/> Woods maneuver | 1 2 3 4 5 6 7 | _____ |
| <input type="checkbox"/> Other (list) _____ | 1 2 3 4 5 6 7 | _____ |

Verify that fundal pressure was not applied after the head delivered:

_____ Not Applied

_____ Applied

If applied, by whom: _____

If applied, reason: _____

The arm under the symphysis at the point the head was delivered was: Right Left

Comments: _____

Primary Care Provider*

Registered Nurse*

Other Care Providers in attendance*

Other Care Providers in attendance*

MANAGEMENT OF PRETERM LABOR

USE OF 17 ALPHA HYDROXY PROGESTERONE:

Preterm birth affects 12% of all births in the United States. Recent studies support the hypothesis that progesterone supplementation reduces recurrent preterm birth in a select group of women. Progesterone supplementation for the prevention of recurrent preterm birth is recommended by the American College of Obstetricians and Gynecologists' Committee on Obstetric Practice and the Society for Maternal Fetal Medicine (Use of Progesterone to Reduce Preterm Birth; ACOG Committee on Obstetric Practice; #419; October 2008). It should be offered to women with a singleton pregnancy and a prior spontaneous preterm birth due to spontaneous preterm labor or premature rupture of membranes. Current evidence does not support the routine use of progesterone in women with multiple gestations. Progesterone supplementation for asymptomatic women with an incidentally identified very short cervical length (less than 15 mm) may be considered; however, routine cervical length screening is not recommended.

Despite the apparent benefits of progesterone, the ideal progesterone formulation is unknown. Dosage administration schedules that have been shown to be efficacious in recent randomized clinical trials include:

1. 17-alpha-hydroxyprogesterone caproate 250 mg IM weekly
2. Vaginal progesterone 100 mg daily
3. Micronized progesterone capsules (200 mg vaginally daily)

The American College of Obstetricians and Gynecologists' Committee on Obstetric Practice and the Society for Maternal Fetal Medicine believe that further studies are needed to evaluate the optimal preparation, dosage, route of administration, and other indications for the use of progesterone for the prevention of preterm delivery. Based on current knowledge, it is important to offer progesterone for pregnancy prolongation to only women with a documented history of a previous singleton spontaneous birth at less than 37 weeks of gestation.

USE OF MAGNESSIUM SULFATE:

Several recent clinical trials, both individually and in meta-analysis, have confirmed that preterm infants exposed to magnesium sulfate at the time of labor have a reduced risk (by 30-45%) of cerebral palsy (CP) at age 18-24 months. This benefit occurs without an increased risk of death. These effects are primarily seen before 28-30 weeks gestation, where the number needed to treat to prevent one case of CP is 51-56. However, these studies have used varied magnesium sulfate regimens at variable gestational ages of intervention and in varied study populations (preterm labor with intact membranes, preterm PROM, multifetal pregnancies).

The American College of Obstetricians and Gynecologists has not yet endorsed the use of magnesium sulfate for the prevention of cerebral palsy in preterm deliveries (August 2009). However, the University of Utah and Intermountain Healthcare Maternal-Fetal Medicine group has established the following evidence-based guidelines:

1. Women with imminent risk of delivery at < 28 weeks should be considered for magnesium sulfate neuroprophylaxis:
 - a. Preterm labor (active contractions, > 4 cm dilated), preterm ruptured membranes, abruption, concerning fetal status (absent end-diastolic flow in umbilical artery, intrauterine growth restriction, etc)
 - b. No contraindications to magnesium sulfate
2. Offer magnesium sulfate prophylaxis:
 - a. Advise women of temporary side effects
 - b. Advise women that the risk of moderate-severe CP in surviving babies is reduced by approximately 50% (RRs = 0.45 – 0.55)
3. Initiate magnesium sulfate therapy:
 - a. Bolus: 6 gm IV over 20-30 minutes
 - b. Maintenance: 2 grams/hour
 - c. Continue until delivery or until 12 hours of therapy
4. Reassess if undelivered after 12 hours of therapy:
 - a. Risk of imminent delivery remains – continue maintenance infusion
 - b. Low risk of imminent delivery – d/c magnesium sulfate infusion
5. If risk of imminent delivery returns:
 - a. > 6 hours but < 28 weeks gestation – re-treat
 - b. > 28 weeks gestation – do not retreat.