

Reducing Obstetrical Liability:



Amniocentesis

Preventive Action & Loss Reduction Plan



First Professionals Insurance Company

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Amniocentesis

Most malpractice claims entailing amniocentesis are attributed to diagnostic error and involve timing factors rather than performance issues. Because amniocentesis provides valuable diagnostic evidence of many serious birth defects, measuring fetal maturity, and determining the status of blood incompatibilities, it presents as a high-risk obstetrical procedure in terms of claim severity. Catastrophic outcomes, when attributed to diagnostic error as a result of timing factors or acts of omission, can be avoided by implementing simple, yet effective, loss prevention measures. In this section, the associated risks and related errors entailing amniocentesis are reviewed and serve as the predicate for the risk management strategies designed to minimize risk, prevent error and successfully defend the unavoidable claim. Throughout the text, documentation tools are presented to facilitate a proactive approach and to validate the quality of care.

Associated Risks

Amniocentesis is regarded as a low-risk procedure in terms of patient injury. Risks associated with amniocentesis include a 1 in 200 risk of miscarriage, hemorrhage, mixing of maternal and fetal blood (if bleeding occurs), infection of the amnion (amnionitis), excessive leakage of amniotic fluid, and very rarely, injury to the infant with the needle. Although the incidence of such complications is relatively low, the injury severity levels are high, and thus are often a precipitating factor of malpractice claims.

Errors can occur predicated upon a failure to diagnose birth defects or genetic problems due to performing amniocentesis prematurely (prior to the 12th week) or beyond the 18th week of pregnancy. Specific misdiagnoses include Down's syndrome, cystic fibrosis, and neural tube defects.

Other significant errors related to the performance of amniocentesis can result from the failure to recognize complications of the procedure, such as an infection of the amniotic fluid, mixing of maternal and fetal blood, and injuries to the fetus. Failure to respond appropriately to the diagnosis of Rh-negative mother by not administering immune globulin can result in claims as well. Inadequate informed consent is often a precipitating factor in claims arising out of amniocentesis.

Risk Management

Loss preventive measures regarding amniocentesis begin with a customized informed consent process (Fig. 1). It is efficacious to implement an educational component for the patient at the time of the discussion and consent. Such education should specify the risks, benefits, and alternatives to the amniocentesis, as well as the limitations of the procedure (*normal results do not equal a normal baby*) (Fig. 2).

Create a high-risk follow-up tracking mechanism to monitor diagnostic test results and scheduled repeat or serial testing. The tracking mechanism is necessary to validate completion and the timely receipt by the physician of all test results. It should also include documentation of the physician's response and any follow-up orders (Fig. 3).

CLAIM ANALYSIS SUMMARY

PIAA Neurologically Impaired Newborn Study

- The aspect of maternal obesity shows an association of an increased risk of adverse outcomes in pregnancy. Obese patients are at much greater risk of maternal complications, such as hypertension and diabetes, which could increase the risk of infant neurological impairment.
- The interpretation of antepartum tests or procedures was a factor in 17% of all cases. The failure to perform the test or procedure was alleged in 20% of cases. Diagnostic ultrasound was the most frequent test at issue.
- At least one intrapartum complication was reported in 70% of claims entailing neurologically impaired newborns. The failure to recognize a complication was reported in 44% of those cases. Cord complications and abruptio placentas were the two most common types of intrapartum complications.
- An abnormality in EFM results was recorded in 93.5% of all cases in which a C-section was performed. 96% of claims alleging a delay in performance of C-section revealed an EFM abnormality.
- Fetal distress was noted in 88% of claims.
- Meconium staining was found in 34% of cases.
- Neonatal complications were reported in 96% of claims entailing neurological impairment with 60% reporting two or more complications, notably anoxia (59%), seizures (19%), and pulmonary problems (19%).
- Physician documentation was often incomplete and/or did not correspond to information recorded by others involved in the care and treatment of the patient.
- The inability of providers to recognize problems during labor, particularly when the second stage was prolonged, led to allegations of improper management.
- Delay in consulting with the obstetrician during labor was a prevalent allegation, primarily when managed by a nurse midwife, and when signs of fetal distress were or should have been apparent.
- The failure to recognize nuchal cord or other cord compression problems was a significant issue.

Schedule appropriate follow-up office visits frequently enough to provide adequate monitoring. Document compliance/non-compliance. If the patient breaks an appointment or fails to obtain the necessary diagnostic studies, consider the “two phone calls and a letter” process. Two phone calls to reschedule are made, and, when no acceptable result has occurred, a formal letter is generated (Fig. 4). This system is also helpful if one must address patient noncompliance or defend claims alleging failure to treat or diagnose in a timely manner. Because the time parameters relative to gestational age are essential, follow-up efforts and notification to the patient must be promptly diaried and documented. Document patient follow-up in the chart (Fig. 4).

Promptly refer the patient for consultations with specialists when indicated. When consultations are requested, be sure that they are formalized in writing, and that the management of the patient is clearly defined as to total or partial responsibility of each physician. Be sure the patient is made aware of new relationships and accountabilities.

Informed Refusal

Patients who refuse amniocentesis, delay undergoing the procedure or who are otherwise noncompliant should be fully informed about the potential consequences (Fig. 5). Document your discussions with the patient, and send written confirmation of their non-compliance certified mail (Fig. 6). In most cases, such a letter will prevent pursuit of a claim or become persuasive evidence before a jury in the event of an unavoidable claim. To further reduce your liability exposure, consider terminating the physician-patient relationship of non-compliant patients (Fig. 7).

Legal Protection

Contact FPIC immediately should you encounter an untoward event that could become the subject of a claim or suit. Seek legal or risk management guidance whenever you are uncertain as to how to proceed from a liability standpoint. Doing so is in your best interest and often pivotal for claim avoidance, mitigation, and enhanced defensibility.

AMNIOCENTESIS Risk Management Guidelines

- Provide patient education regarding amniocentesis.
- Set realistic patient expectations – normal results do not equal a normal baby.
- Schedule amniocentesis with specificity and in conjunction with gestation age.
- Initiate a diary system to ensure adequate serial amniocenteses.
- Utilize a customized informed consent process.
- Require that patients execute informed consent form(s).
- Create a high-risk follow-up tracking system to monitor diagnostic test results.
- Schedule follow-up visits to facilitate adequate monitoring.
- Document patient non-compliance and confirm in writing.
- Consider terminating the physician-patient relationship of non-compliant patients.
- Promptly refer patients for consultations with specialists when indicated.
- Seek legal or risk management guidance whenever uncertain how to proceed from a liability standpoint.

Informed Consent of Pregnancy

1. The obstetricians and certified nurse midwives of (*NAME OF PRACTICE*) wish to welcome you to our practice. We consider this to be a very enjoyable specialty because our patients are generally healthy women eagerly awaiting the arrival of their babies. We believe that good communication and an environment of mutual respect and cooperation help ensure a healthy mother and baby.
2. As you may be aware, there has been a rise in malpractice claims against doctors, some valid and some frivolous. This increase in lawsuits has resulted in a huge increase in malpractice insurance rates for all obstetricians. Because of often impossibly high malpractice insurance rates, some obstetricians have stopped delivering babies. The climate of medical malpractice today demands that the patient be as informed as possible of potential, but unlikely, problems that may occur from pregnancy. Pregnancy is a normal process for women, but there is always the possibility of complications. These infrequent problems may happen with or without warning, often despite our best efforts to prevent them. We want to educate you and your partner about these possibilities so that you may be more prepared in the very unlikely event that you develop such a problem.
3. The patient's lifestyle is an important part of her health, pregnant or not. Obesity, smoking, poor eating habits, drug use, and not getting enough exercise may cause complications in both the mother and her developing child. The patient is responsible for her lifestyle choices. About 3% to 4% of all babies are born with birth defects. Smoking, medications, street drugs, over the counter medicines, alcohol, viruses and fevers, complications of other medical conditions such as diabetes, and problems passed on in families are some of the causes of these. Often there is no identifiable reason. Stillbirth is rare, but when it does happen there is often no obvious cause.
4. During the first few months of pregnancy, nausea and vomiting are a common problem. Occasionally, it becomes severe enough for a hospital stay. Miscarriage occurs in about 20% of pregnancies. Bleeding may or may not be a sign of this. Pregnancy loss after the first trimester is less common and may occur for reasons that are unknown and unavoidable. The loss of an early pregnancy may require surgery, such as a D & C, to prevent infection or blood loss.
5. Ectopic pregnancy is a pregnancy that remains and grows in the fallopian tube instead of the uterus. If this is allowed to proceed, rupture of the tube will occur. Abdominal pain, vaginal bleeding, and even shoulder pain, occurring in the first trimester of pregnancy, may be indications of ectopic pregnancy. This should be promptly reported to your physician. Medication can treat this condition in the very early stages. However, sometimes surgery to remove the tube and ovary is necessary to prevent serious hemorrhage or death.
6. Medical problems such as diabetes, heart disease, high blood pressure, and herpes require special attention in pregnancy. Pregnancy can make some of these problems worse. It is important for the patient who has a medical condition to work with her doctors to become as healthy as possible before becoming pregnant. This may include exercising, losing weight and/or changing medications. Infections of the bladder or kidney can be common in pregnancy. Less common are infections within the uterus during pregnancy. Any infection that can happen before pregnancy can happen during pregnancy.

Fig. 1

7. Preeclampsia is a complication of pregnancy characterized by high blood pressure, protein in the urine, and retention of fluid, which causes swelling of the hands and feet and headache. These symptoms should be promptly reported to your physician. This condition can usually be managed as an outpatient, but sometimes, hospitalization is required. The treatment is delivery of the infant. Strict management includes bed rest, diet, and medications. This is necessary to allow time for the unborn infant to sufficiently mature for a safe delivery. Eclampsia is the more serious complication, which can develop from preeclampsia. It is characterized by uncontrollable high blood pressure, convulsions, and coma. Hospitalization, medication, and delivery of the infant are the treatments
8. Problems later in pregnancy can include heavy bleeding due to problems with the placement of the placenta (afterbirth) or an early separation of the placenta from the inside of the uterus. Other problems that can only happen in pregnancy include problems with the baby's growth, babies born too early, and problems with interactions between the baby's blood and the mother's. Pregnant women are prone to veins, phlebitis, and blood clots.
9. Cesarean section is major surgery that can be life saving when necessary. Cesarean section may be needed for many reasons: the baby may not do well in labor, the baby may not be head first, the baby may not be fitting through the birth canal properly. Many of the problems mentioned earlier can result in cesarean section. Cesarean section can be associated with infectious complications and/or injury to surrounding organs that may require further surgery or treatment. Occasionally forceps or a vacuum cup is needed to help deliver the baby's head. When indicated they can be life saving for the baby. Properly used they usually cause no problems but can leave a mark on the baby that will go away. It is very rare, but there can be injuries to the baby's head, even with proper use. These instruments are not used unless the benefits outweigh any risk. Any women can have tears of the vagina, rectum or uterus in the childbirth process. Sometimes women develop a large bruise of the pelvic area that may require surgery for proper healing. The afterbirth usually comes out in one piece; however, small fragments can remain inside and cause bleeding and infection. Very rarely, there is such heavy bleeding after delivery, either vaginal or by cesarean section, that a blood transfusion or hysterectomy may be needed to save a life. Usually, stitches of the vagina and bottom heal quickly. Occasionally there may be an infection or poor healing in that area that requires treatment.
10. Anesthesia also has risks. Women may be allergic to or have reactions to the medications used. General anesthesia can result in aspiration pneumonia. Patients receiving medicines of any kind can have a reaction, allergic or otherwise. Blood transfusions (given only when absolutely needed) can result in bad reactions or infections transmitted by blood.

To attempt to list every single emergency or complication is impossible. This "informed consent" is not intended to alarm the patient, only to remind the patient that life and pregnancy are not without risk. We ask that you and your partner acknowledge the receipt of this information with your signatures. This document will become part of your record. We shall be happy to answer any questions you might have. You may request a copy of this document for your personal records.

Signature: _____ Date: _____
Partner: _____ Witness: _____
_____ I give permission to discuss test results with my partner or parent or _____

Fig. 1 (cont'd)

AMNIOCENTESIS

I acknowledge that Dr. _____ has recommended that I undergo a procedure called amniocentesis.

I acknowledge that the following information has been provided to me:

Amniocentesis is a test to analyze the liquid (amniotic fluid) that surrounds a fetus. This procedure is done by inserting a needle through the pregnant woman's abdomen into her uterus. Approximately 2 tbsp (29.57 ml) of the amniotic fluid is collected and examined.

Amniocentesis in Early Pregnancy

Amniocentesis may be done to determine whether the fetus has certain types of birth defects. Amniocentesis can also determine the sex of the fetus. Amniotic fluid can be tested for more than 100 types of defects that are associated with inherited (genetic) diseases (such as Down's syndrome or cystic fibrosis) or neural tube defects. However, amniocentesis cannot detect many common birth defects, such as cleft lip and palate, heart problems, and some types of mental retardation.

Amniocentesis can also be done during the second trimester if blood type incompatibilities are present (such as Rh sensitization). Repeated amniocentesis testing may be needed to monitor how much the fetus is affected by sensitization.

Amniocentesis may be done late in pregnancy (during the third trimester) to determine whether the fetus' lungs are mature enough for early delivery. Amniocentesis may also be done later in pregnancy if an infection of the amniotic fluid (amnionitis) is suspected.

Risks

Amniocentesis is usually very safe. Usually the risk of having an abnormal baby is greater than the risk of the procedure in high-risk pregnancies. However, there is a slight chance (about 1 in 200) that this procedure may cause a miscarriage. There is also a slight risk of excessive bleeding (hemorrhage), infection of the amniotic fluid (amnionitis), or excessive leakage of the amniotic fluid, which could harm the fetus or mother. Rarely, the fetus may be injured by the needle during the procedure.

Amniocentesis has a very small risk of causing bleeding that could lead to mixing the blood of the mother and fetus. Therefore, a pregnant woman with Rh-negative blood will be given the Rh immune globulin vaccine (such as RhoGAM) to prevent Rh sensitization (which could harm her fetus if it has Rh-positive blood).

Normal results from amniocentesis do not guarantee that the baby will be healthy.

Further, I acknowledge that I have had full opportunity to discuss this information with the doctor(s) concerned and I have received answers to all of my questions and to my satisfaction. I hereby consent to undergo amniocentesis procedure(s) as directed.

Signature of Patient or Authorized Representative

Date

Fig. 2

Sample Letter Confirming Informed Refusal

Date

Dear (Patient name):

This will confirm my medical recommendation that you undergo amniocentesis and your refusal to do so. As I have explained to you, amniocentesis is a relatively low-risk diagnostic procedure, which involves a test to analyze the liquid (amniotic fluid) that surrounds a fetus. This procedure is done by inserting a needle through the pregnant woman's abdomen into her uterus. Approximately 2 tbsp (29.57 ml) of the amniotic fluid is collected and examined.

Because of your obstetrical history, including _____, the indications for amniocentesis include _____

The effectiveness of amniocentesis is dependent upon narrow time parameters relative to the infant's age. In your case that time period begins on _____ (date) and ends after _____ (date).

Despite my advising you that _____

You have refused to undergo amniocentesis. I again urge you to reconsider your refusal to undergo this important diagnostic procedure.

Very truly yours,
_____, M.D.

Send certified mail, return receipt requested as well as via regular mail, and keep a copy in the chart.

Fig. 5

Sample Letter of Physician's Notification of Non-compliance

Date

Dear (Patient name):

This letter is to inform you that I am concerned with your failure to comply with my recommendations for diagnostic testing and treatment, and/or your failure to keep scheduled appointments necessary for me to provide medically necessary care. The appointments on (list dates) were not kept. The recommended diagnostic tests and treatment, specifically, (list) have not been completed.

I urge you to contact my office and schedule the testing, treatments, and appointments that I have recommended in the interest of your health. Your continued delay could further compromise your prognosis.

Very truly yours,
_____, M.D.

Send certified mail, return receipt requested as well as via regular mail, and keep a copy in the chart.

Fig. 6

Sample Letter of Physician's Intent to Withdraw

Date

Dear (Patient name):

This letter is to inform you that I am no longer able to continue as your physician due to your failure to comply with my recommendations for diagnostic testing and treatment, and/or your failure to keep scheduled appointments necessary for me to provide medically necessary care.

As you are aware, your condition requires further medical attention. I strongly recommend that you contact a physician to provide those services to you without delay. During the interim, but not beyond 30 days from the date of this letter, I will continue to provide you with emergency medical care.

At your request, I will provide you, or the physician you select, a copy of your complete medical record. Please sign and return to me the attached medical record authorization. If you have a problem selecting a physician, I suggest you contact the medical society for a list of physicians practicing in your local area.

Very truly yours,

_____, M.D.

Send certified mail, return receipt requested as well as via regular mail, and keep a copy in the chart.

Fig. 7

References

A Reference Tool For Risk Management. (2002). First Professionals Insurance Company, Inc. Jacksonville, FL.

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