April 23, 2014

Ohio Department of Health
Regulations and
Noncompliance Findings

Shannon Richey, R.N.
Assistant Bureau Chief
Bureau of Community Health Care Facilities and Services
Ohio Department of Health
Types of Surveys Conducted Since January 1, 2012

- 5 Initial Inspections
- 86 Triennial Inspections
- 52 Complaint Inspections
- 8 Capacity Increase Inspections
- 3 Monitoring Inspections
Top Ten Maternity Licensure Deficiencies and Frequency

- **Tag M0713** – Polices and Procedures – Admission, Infection Control, Individual Patient Care Plans (99)

Maternity units and newborn care nurseries shall develop and follow policies and procedures that address:

  1. Admission;
  2. Infection control, consistent with current infection control guidelines issued by the United States centers for disease control and prevention; and
  3. Individual patient care plans.
Tag M0713 - Policies and Procedures - Admission, Infection Control, Individual Patient Care Plans (99)

Failure to develop and follow policies related to:
- Pitocin Administration (reducing or stopping Pitocin when non-reassuring fetal heart rate tracings occur)
- Non-Reassuring Fetal Heart Rate Tracings (repositioning, oxygen administration, fluid bolus, notification of physician)
- Magnesium Sulfate Administration (monitoring of reflexes and vital signs)
- Neonatal Resuscitation (intubation to view cords and suctioning prior to stimulation of a non-vigorous infant)
- Resident Physician to Attending Physician Communication (patient’s condition worsens, non-reassuring fetal heart rate tracings, complaints of continued pain, lack of progress and/or prolonged labor)
Tag M0713 - Policies and Procedures - Admission, Infection Control, Individual Patient Care Plans (99) - Continued

- Standard Care Arrangements between Midwives and Physicians (notification by midwife to physician when a patient’s condition becomes complicated, of non-reassuring fetal heart rate tracings, of prolonged labor, of lack of progress, of meconium stained fluid)
- Vacuum Extraction (prolonged amount of time or exceeding number of pop-offs)
- Pain Management (adequately assessing, appropriately managing)
- Intrapartum nursing practice related to the communication of the maternal/fetal status assessment
- Use of chain of command when care of a patient by a physician, resident physician, or certified nurse midwife is in question
- Monitoring and evaluation of preterm labor patients
Tag M0602 – Safety and Security Policies (40)
The maternity unit, newborn care nursery, or maternity home shall develop and follow policies for ensuring the safety and security of all patients, including infant security drills for locating missing newborns. The policies shall be reviewed at least annually, and practice infant security drills shall be conducted on each shift at least once every six months.
Tag M0602 – Safety and Security Policies (40)

- Failure to conduct infant security drills as required
- Failure to ensure medications are kept secured (locked)
- Failure to monitor and replace expired medications and/or supplies
Tag M0601 – Disaster Preparedness Plan (15)
The maternity unit, newborn care nursery, or maternity home shall develop and follow a disaster preparedness plan including evacuation in the event of a fire. Evacuation procedures shall be reviewed at least annually, and practice drills shall be conducted quarterly on each shift.
Tag M0601 – Disaster Preparedness Plan (15)

- Failure to conduct fire drills as required (Hospital wide fire drills only count if the maternity unit staff participates in the drill on the maternity unit and maternity unit staff are evaluated during each drill)
Top Ten Maternity Licensure Deficiencies and Frequency

Tag M1503 – QA/PI Requirements (12)

The quality assessment and improvement program shall do all of the following:

1. Monitor and evaluate all aspects of care including effectiveness, appropriateness, accessibility, continuity, efficiency, patient outcome, and patient satisfaction;
2. Establish expectations, develop plans, and implement procedures to assess and improve the quality of care and resolve identified problems;
3. Establish expectations, develop plans, and implement procedures to assess and improve the maternity unit and newborn care nursery's governance, management, clinical and support processes;
Top Ten Maternity Licensure Deficiencies and Frequency

Tag M1503 – QA/PI Requirements (12) - Continued

(4) Establish information systems and appropriate data management processes to facilitate the collection, management, and analysis of data needed for quality improvement;

(5) Internally document and report findings, conclusions, actions taken, and the results of any actions taken to the health care service's management and medical director;

(6) Document and review all unexpected complications and adverse events, being serious injury or death resulting from medical management, which arise during the provision of the service or during the hospital stay; and
Tag M1503 – QA/PI Requirements (12) - Continued
(7) Hold regular meetings, chaired by the medical director of the maternity unit or newborn care nursery, or designee, as necessary, but at least within sixty days after a death or complication, to review all deaths and complications and to report findings. Any pattern that might indicate a problem shall be investigated and remedied, if necessary.
Tag M1503 – QA/PI Requirements (12)

- Failure to hold a meeting, chaired by the medical director of the maternity unit, within sixty days after a complication to review and report findings
Tag M0908 – Level I – Emergency C/S, Fetal Monitor, Resuscitation (11)
Each provider shall have the ability to perform all of the following:
(1) An emergency cesarean delivery within thirty minutes of the time that
the decision is made to perform the procedure on a twenty-four hour per
day basis;
(2) Fetal monitoring; and
(3) Resuscitation and stabilization of newborns and emergency care for
the mother and newborn in each delivery room.
Failure to perform an emergency cesarean section within 30 minutes from the time that the decision was made to perform the procedure.
Top Ten Maternity Licensure Deficiencies and Frequency

Tag M1203 – Level III A, B, C Performance Requirements (6)

Using licensed health professionals acting within their scope of practice, each freestanding children's hospital with a level IIIA, level IIIB, or level IIIC neonatal care service shall:

(1) Develop and follow a written service plan for the care of patients;
(2) Provide for the range of services for the patient population it serves consistent with the "Guidelines for perinatal care";
(3) Provide or have a written referral policy for obtaining public health, dietetic, genetic, and toxicology services not available in-house;
(4) Establish criteria for determining those conditions that can be routinely managed by the service. The criteria shall be based on staff education, competence, and experience with the conditions, and the support services available to the service;
Top Ten Maternity Licensure Deficiencies and Frequency

- **Tag M1203** – Level III A, B, C Performance Requirements (6) - Continued
  5. Provide a formal education program for staff that includes the neonatal resuscitation program and a post resuscitation program;
  6. Conduct risk assessments for identification of and appropriate consultation for high risk patients;
  7. Provide follow-up services to patients or refer patients for appropriate follow-up;
  8. Provide consultation and accept newborn referrals on a twenty-four hour basis;
  9. Have the capability to resuscitate and stabilize newborns in the nursery consistent with the neonatal resuscitation program;
  10. Coordinate and facilitate high risk neonatal transports from referring services consistent with the "Guidelines for perinatal care";
Top Ten Maternity Licensure Deficiencies and Frequency

Tag M1203 – Level III A, B, C Performance Requirements (6) - Continued

(11) Develop and follow policies and procedures for the transport of newborns to another neonatal care service when medically appropriate. This may include newborns that are below the gestational age and weight limitations for the receiving service;

(12) Provide developmental follow-up of at-risk newborns in the service or refer such newborns to appropriate programs;

(13) Provide or coordinate ongoing continuing education for referring services;

(14) Provide opportunities for clinical experience for purposes of graduate nursing education, or continuing education, or both;

(15) Participate on an ongoing basis in basic or clinical neonatology research; and
Top Ten Maternity Licensure Deficiencies and Frequency

- **Tag M1203** – Level III A, B, C Performance Requirements (6) - Continued
  
  (16) Provide multidisciplinary planning related to management and therapy for newborn care.
Tag M1203 – Level III A, B, C Performance Requirements (6)

- Failure to provide a formal post resuscitation program for all nursing staff
Top Ten Maternity Licensure Deficiencies and Frequency

- **Tag M0706** – Minimum Competency Requirements for Staff (6)

Each service provider shall:

Establish minimum competency requirements for staff in accordance with recognized national standards and ensure that all staff are competent to perform services based on education, experience and demonstrated ability. Services that allow for the use of advanced practice nurses, anesthesiologist assistants, or physician assistants, shall develop and follow written policies and procedures.
Tag M0706 – Minimum Competency Requirements for Staff (6)

- Failure to ensure that all staff were competent to perform services based on successful completion of their orientation
- Failure to ensure all staff were competent to perform services based on demonstrated ability (related to scrub duties during cesarean sections; neonatal resuscitation including intubation; clamping of umbilical cords (CNM), accurately analyzing and interpreting fetal heart tracings; appropriate and safe care of newborns)
- Failure to ensure that medical staff followed current standards of practice related to neonatal resuscitation
- Failure to ensure staff followed the current facility midwife standard care agreement, specifically addressing midwife collaboration with the covering physician
Top Ten Maternity Licensure Deficiencies and Frequency

Tag M0907 – Level I - Service Performance Requirements (5)
Each provider shall, using licensed health care professionals acting within their scopes of practice:
(1) Develop and follow a written service plan for the care of patients;
(2) Provide for the appropriate range of services for the patient population it serves;
(3) Provide or have a written referral policy for obtaining public health, dietetic, genetic, and toxicology services;
(4) Establish written criteria for determining those conditions that can be routinely managed by the service. The criteria shall be based on staff education, staff competence, the amount of staff experience with the listed conditions, and support services available to the service;
(5) Provide a formal education program for staff, including the neonatal resuscitation program and a post resuscitation program;
Top Ten Maternity Licensure Deficiencies and Frequency

- **Tag M0907** – Level I - Service Performance Requirements (5) - Continued
  6) Conduct a risk assessment of obstetric and newborn patients to ensure identification of appropriate consultation requirements or referral for high-risk patients;
  7) Provide follow-up services to patients or refer patients for appropriate follow-up;
  8) Provide education for mothers regarding personal care and nutrition, newborn care and nutrition, and newborn feeding;
  9) Provide for consultation or referral of obstetric transports as needed. A system shall be in place to prepare and efficiently transport the patient consistent with the "Guidelines for perinatal care";
  10) Provide for consultation or referral of neonatal transports as needed. A system shall be in place to prepare and efficiently transport the patient consistent with the "Guidelines for perinatal care";
Top Ten Maternity Licensure Deficiencies and Frequency

Tag M0907 – Level I - Service Performance Requirements (5) - Continued

(11) Establish criteria for the acceptance of neonatal transports from other services based on demonstrated capability to provide the appropriate services consistent with the "Guidelines for perinatal care," including the acceptance of newborns from level II or level III neonatal care services who otherwise do not meet the gestational age and weight restrictions; and

(12) Have the capability to resuscitate and stabilize newborns in the nursery consistent with the neonatal resuscitation program.
Tag M0907 – Level I - Service Performance Requirements (5)

- Failure to establish minimum competencies and provide education to ensure staff were competent to care for patients experiencing drug withdrawal
- Failure to provide a formal post resuscitation program for all nursing staff
- Failure to ensure staff follow written service plans for the care of patients, requiring nurses to follow physician orders
Top Ten Maternity Licensure Deficiencies and Frequency

- **Tag M1111** – Level III – Emergency C/S, Fetal Monitor, Resuscitation (4)

  Each provider shall have the ability to perform all of the following:
  
  1. An emergency cesarean delivery within thirty minutes of the time that the decision is made to perform the procedure on a twenty-four hours basis;
  2. Fetal monitoring; and
  3. Resuscitation and stabilization of newborns and emergency care for the mother and newborn in each delivery room.
Tag M1111 – Level III – Emergency C/S, Fetal Monitor, Resuscitation (4)

- Failure to perform an emergency cesarean section within 30 minutes from the time that the decision was made to perform the procedure
Top Ten Maternity Licensure Deficiencies and Frequency

- **Tag M1008** – Level II – Emergency C/S, Fetal Monitor, Resuscitation (4)
  
  Each provider shall have the ability to perform all of the following:
  
  1. An emergency cesarean delivery within thirty minutes of the time that the decision is made to perform the procedure on a twenty-four hour basis;
  2. Fetal monitoring; and
  3. Resuscitation and stabilization of newborns and emergency care for the mother and newborn in each delivery room.
Tag M1008 – Level II – Emergency C/S, Fetal Monitor, Resuscitation (4)

Failure to perform an emergency cesarean section within 30 minutes from the time that the decision was made to perform the procedure
Other Tags Resulting in Enforcement Action

- **Tag M0915 – Level I – Physician to Assist in High Risk Delivery** – Failure to maintain the ability to obtain the services of a physician to assist the primary physician or certified nurse midwife in the case of an unavoidable delivery of a high risk patient, emergency cesarean section delivery, or unexpected fetal or neonatal distress.

- **Tag M1103 – Level III – Management of Newborns** – Failure to ensure that a Level IIIB neonatal care service was staffed with personnel to provide continuous life support and comprehensive care for extremely high risk newborn infants and those with complex and critical illness, specifically those personnel who have been identified as the person responsible for neonatal resuscitation.

- **Tag M1001 – Level II – Intrapartum Care Admission Limits** – Failure to transfer an obstetrical patient who was less than thirty-two weeks gestation who displayed signs of labor following a surgical procedure.
Infant and Maternal Death Reports

Please ensure that you are reporting all infant and maternal deaths using the most current reporting form dated 01/20/13

Infant Death - Report the death of all fetuses of twenty weeks gestation or greater that showed evidence of life at any point from the mother’s admission through delivery; all liveborn neonates before twenty-eight days of age, from delivery or admission through transfer or discharge; or all liveborn infants twenty-eight days of age through one year of age, from delivery or admission through transfer or discharge

Maternal Death - This includes reporting any maternal death that occurs from any cause related to or aggravated by pregnancy or its management from the woman’s admission and care at delivering hospital through transfer or discharge

Form can be found on the ODH Web Site: www.odh.ohio.gov – Use A-Z index – Click on “M” – Click on Maternity Units – Click on Forms – Click on MF5 (Reporting of Infant or Maternal Death)
Contact Information:

Shannon M. Richey, R.N.
Assistant Bureau Chief
CLIA Laboratory Program
Bureau of Community Health Care Facilities and Services
Division of Quality Assurance
Ohio Department of Health
(614)728-3329
Shannon.Richey@odh.ohio.gov
QUESTIONS