

# **GUIDELINES FOR PERINATAL SERVICES**

*EIGHTH EDITION, 2008*

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## II. PREFACE

This document represents the Eighth Edition of what formerly was called *Standards for Perinatal Centers*. Since then, the name has changed to *Guidelines for Perinatal Services*, because use of the term “standards” connotes an inflexibility of application that is not intended. As noted in the preface to an earlier edition, so-called standards that apply to major urban areas are not always practical in rural America. Unfortunately, when a bad outcome occurs and litigation ensues, the differences between urban and rural are frequently ignored. These guidelines are not meant to hold Iowa hospitals and Iowa perinatal professionals to an impractical ideal.

Although the *Guidelines for Perinatal Services* are clearly not intended to serve as standards, they do specify particulars when feasible. For example, specification of a designated level of care for a hospital should be clearly evident from the descriptions. In this regard, one of the changes from the earlier editions is a broader designation of levels of care. This was done to empower hospitals rather than to restrict them.

In the past, the Perinatal Guidelines Advisory Committee chose to keep the designation of levels of care as simple as possible, i.e., Levels I, II, and III. Levels II and III were designated only if the hospital was a referral center. All other hospitals were designated as Level I facilities. During the 1997 revision, the committee thought this approach was no longer reasonable. As a result, levels of care were designated by the functional capacity of the hospital. Thus, it may be possible to have a number of Level II and Level III perinatal centers in one city.

The Committee is very much aware of the need for organization of limited resources in a rural state. Accordingly, the *Guidelines for Perinatal Services Eighth Edition*, is designed to encourage and support the presence of a Level II Regional Center and Level II Regional Neonatal Centers where the area is not populous enough to support a Level III perinatal center.

This Eighth Edition also includes the new provisions from *Iowa Code Chapter 141 A* governing HIV testing during pregnancy which took effect on July 1, 2007.

The members of the Perinatal Guidelines Advisory Committee are commended and thanked for generously sharing their time and talent to compile the *Guidelines for Perinatal Services*. The contributions of the Committee, ex officio members as well as the Iowa Department of Public Health staff, were invaluable. A list of the committee members may be found on page v.

Comments or questions regarding the *Guidelines for Perinatal Services* may be addressed to:

Perinatal Guidelines Advisory Committee  
Iowa Department of Public Health  
Bureau of Family Health  
321 East 12th Street, Lucas Building  
Des Moines, Iowa 50319-0075  
Telephone: 1-800-383-3826

Sincerely,



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### III. ACKNOWLEDGEMENTS

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## IV. BACKGROUND

### A. History

*In 1973, the Iowa Statewide Perinatal Care Program began under the auspices of the Regional Medical Program and the University of Iowa.*

Iowa's first neonatal intensive care unit opened in Dubuque in 1971. This unit, located at Mercy Medical Center, was the result of private efforts representing Dubuque's entire medical community. Soon thereafter, in 1973, the Iowa Statewide Perinatal Care Program began under the auspices of the Regional Medical Program and the University of Iowa.

In 1974, the Regional Medical Program was incorporated into a joint Maternal and Child Health Program at the Iowa Department of Public Health and the University of Iowa. This statewide program continued to evolve through the joint efforts of the Iowa Department of Public Health and the University of Iowa.

The perinatal team of the Iowa Statewide Perinatal Care Program visited every hospital with an obstetrical service in Iowa during the first two years of the project. The information gained through these hospital visits identified those hospitals which could serve, or were already in the process of serving, as Level II Centers of care. With the assistance of the perinatal team, hospitals which had expanded their services were recognized by the Iowa Statewide Perinatal Care Program. Current level designation of hospitals in Iowa with an Obstetrical Service may be found on the Iowa Department of Public Health Web site: [www.idph.state.ia.us/hpcdp/statewide.perinatal.care.asp](http://www.idph.state.ia.us/hpcdp/statewide.perinatal.care.asp), or by calling 1-800-383-3826 .

These guidelines were specifically created to address hospitals with obstetrical and neonatal services. They do not include hospitals that do not participate in obstetrical care and non-hospitals are not covered in these guidelines.

### B. Process for Level Designation

*In 1998, Iowa Administrative Code officially established the Iowa Regionalized System of Perinatal Health Care.*

In 1977, the Iowa Department of Public Health established an Advisory Committee for Perinatal Standards which formulated the first edition of *Standards for Perinatal Centers*. A process for designation of centers was developed by this and subsequent standards committees. In 1998, the *Iowa Administrative Code* (Chapter 641, Section 150) established the Iowa Regionalized System of Perinatal Health Care, which defines the purpose and function of regionalized perinatal care for the state.

The issue of designation of level of care is potentially contentious and requires further clarification of the intent of designation. The primary purpose of designation is to ensure Iowa perinatal patients receive appropriate care as close to their homes as possible. In an ideal situation, no community hospital

would be more than 50 miles from a perinatal center. Unfortunately, Iowa's low population density precludes this. Accordingly, Iowa developed a network of regional perinatal centers. Based on well-documented outcome statistics, this system has served the state very well.

Currently, many physicians and hospitals are operating in an environment quite removed from the era when the *Standards for Perinatal Centers* were first offered to the state. Now, physicians do not always have a choice of hospitals when admission is required. Rather, they are encouraged to admit to the hospital specified by the patient's health insurance policy. This may serve the patient's needs very well if the care available at the hospital is appropriate, but that is not always the case. Because of health insurance changes and because the state's rural character has not changed, the committee continues to strongly support the concept of regionalized perinatal services for Iowa.

The intent of *Guidelines for Perinatal Services* is to assure that when a hospital markets itself at a particular level of perinatal care, it is capable of providing that care. The public is entitled to know the level of functioning. A hospital having determined to participate in the regionalized system of perinatal care shall comply with the guidelines appropriate to the level of participation selected by the hospital and approved by the advisory committee for perinatal guidelines. The statewide parental health care program shall also perform periodic on-site verification surveys of established perinatal service programs to verify the continued ability of each hospital to meet the criteria for the level of designation selected by the hospital. The results of each survey shall be submitted to the Department, along with a recommendation to continue, suspend, or revoke the hospital's certification of verification. The *Guidelines for Perinatal Services* provides the framework to be used in defining and evaluating the level of perinatal services being offered.

In metropolitan areas, where Level III Centers are found, the natural evolution of competition is such that multiple centers can and will exist. The indigenous and referral bases are sufficient to warrant more than one Level III Center in these cities. In less populous communities, the referral resources will continue to be lower-level hospitals and centers.

Review and evaluation of a hospital's established or developed perinatal service program cannot be made without consideration of available resources sufficient to support that service at the level of designation being sought. Questions to ask may include:

- Are there sufficient numbers of transports to justify the need for another neonatal transport team?
- Does the community have sufficient pediatricians to adequately staff two neonatal intensive care centers?

These are only two illustrations of the many issues that will be considered in determining the appropriateness of a request.

The following steps describe the process for a hospital to be reviewed for a new designation:

1. Submit the following information to the Perinatal Guidelines Advisory Committee:
  - a) Description of the geographic area to be served
  - b) Identification of the target population to be served
  - c) Identification of Level I Hospitals to be served

- d) Identification of any overlap with existing higher level hospitals and/or centers
- e) Identification of unmet needs of the area to be served
- f) Demonstration of the ability to meet the most recent perinatal guidelines

2. Mail the package to: Perinatal Guidelines Advisory Committee  
 Iowa Department of Public Health  
 Bureau of Family Health  
 321 East 12th Street, Lucas Building  
 Des Moines, Iowa 50319-0075

Upon receipt of the information, the hospital's request will be reviewed by the Statewide Perinatal Care Program team members and the Perinatal Guidelines Advisory Committee to determine if all guidelines are met.

## C. Regulatory Considerations

*EMTALA regulations and interpretative guidelines relating to women in labor apply to all levels of hospitals.*

### EMTALA REGULATIONS

The Perinatal Guidelines Advisory Committee is aware of active enforcement of the Examination and Treatment for Emergency Medical Conditions and Women in Labor (EMTALA) law. EMTALA regulations and interpretative guidelines relating to women in labor apply to all levels of hospitals. Since 1986 the federal government enacted legal requirements detailing how Medicare-participating hospitals with emergency services must handle clients with emergency medical conditions or women who are in labor. Regulations relating to patient screening and transfer have undergone numerous changes since 1986.

They may be referenced in the following documents:

- the 1985 Consolidated Omnibus Budget Reconciliation Act (COBRA)
- related regulations at 42 CFR 489.24 and 42 CFR 489.20 (l)(m)(q)(r) and its related amendments
- the Social Security Act, section 1866, Agreements with Providers of Services, 42 U.S.C. §1395cc
- the Social Security Act, section 1867, Examination and Treatment for Emergency Medical Conditions and Women in Labor, 42 U.S.C. §1395dd
- Centers for Medicare and Medicaid Services position of the Born-Alive Protection Act as it relates to EMTALA. The Survey and Certification letter, S&C-05-26, can be found at the following Web site:

<http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter05-26.pdf>

Hospitals must be aware of the requirements that pertain to EMTALA regulations.<sup>1</sup>

For questions or further information, please contact:

Iowa Department of Inspections and Appeals  
321 East 12th Street, Lucas Building  
Des Moines, Iowa 50319  
Telephone: (515) 281-4115

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<sup>1</sup> American Academy of Pediatrics and American College of Obstetricians and Gynecologists (2002). *Guidelines for Perinatal Care (5th Edition)*. Elk Grove Village, 2002, pgs 369-375 or <http://www.cms.hhs.gov/EMTALA/>

## V. IOWA'S REGIONALIZED PERINATAL HEALTH SYSTEM

### A. Purpose

*This Guidelines for Perinatal Services addresses how various Iowa hospitals relate to the regionalized system and suggests a level of functioning which should identify the role each hospital plays in the system.*

Iowa's regionalized perinatal health system helps practitioners in rural Iowa to rapidly access specialty services for their patients even though such services may not exist in the local community. This is predicated on several factors, including the willingness of certain hospitals in moderate-to-large Iowa cities to provide specialty services and the presence of a functional system of patient transportation.

This *Guidelines for Perinatal Services* addresses how various Iowa hospitals relate to the regionalized system and suggests a level of functioning which should identify the role each hospital plays in the system.

The following pages present a description of the levels of care among Iowa perinatal hospitals. The levels are as follows:

- Level I Hospital
- Level II Hospital
- Level II Regional Center
- Level II Regional Neonatology Center
- Level III Center

To be effective, the system must have complete cooperation. For example, although Level III Perinatal Centers will assist with responsibility for coordinating transfer of patients among the hospitals, each hospital with transport capability must be willing to assist when the transport capabilities of the Level III Perinatal Centers are overtaxed. This situation has happened in the past. However, the emergence of managed care networks could draw allegiances away from the state system and into a more restricted regional focus. The Iowa Department of Public Health recognizes its responsibility for monitoring changes in the health care delivery system and preserving the capabilities of the regionalized perinatal system for all Iowans

## **B. Level I Hospitals**

### **DEFINITION**

**L**evel I Hospitals provide basic inpatient care for pregnant women and newborns without complications; manage perinatal emergencies, including neonatal resuscitation; provide leadership in early risk identification before and after birth; seek consultation or referral for high-risk patients; and provide public and professional education.<sup>1</sup>

### **FUNCTIONS**

Level I Hospitals have a family-centered philosophy regarding sibling visitation. Parents have reasonable access to their newborns 24 hours a day within all functional units and are encouraged to participate in the care of their newborns. Generally, parents can be with their newborns in the mother's room. Noninfectious siblings may visit in the mother's room or in a designated space.<sup>2</sup>

Level I Hospitals have the capability to:

- Provide surveillance and care of all patients admitted to the obstetric service with an established triage system for identifying high-risk patients who should be transferred to a facility that provides Level II or higher care, prior to delivery
- Provide proper detection and supportive care of unanticipated maternal-fetal problems that occur during labor and delivery
- Perform emergency cesarean sections as soon as possible after the decision to do the operation has been made
- Provide transfusions of blood and fresh frozen plasma on a 24-hour basis
- Provide anesthesia, pharmacy, radiology, respiratory support, electronic fetal heart-rate monitoring, and laboratory services on a 24-hour basis
- Provide care of postpartum conditions
- Evaluate the condition of healthy neonates and their continuing care until discharge
- Resuscitate all neonates using the neonatal resuscitation program guidelines as established by the American Heart Association/American Academy of Pediatrics
- Stabilize all neonates, including unexpectedly small or sick neonates, before transfer
- Consult and arrange transfers in conjunction with the obstetrician, pediatrician or neonatologist at the referral center
- Maintain a nursery for normal term or near-term newborns

### **PHYSICAL FACILITIES**

Physical facilities for perinatal care in hospitals should be conducive to care that meets the normal physiologic and psychosocial needs of mothers, neonates, fathers, and families. Special facilities should be available when deviations from the norm require uninterrupted physiologic, biochemical, and clinical observations of patients throughout the perinatal period. Labor, delivery, and newborn care facilities should be located contiguously.

The following recommendations are intended as general guidelines and are meant to be flexible enough to meet local needs. It is recognized that individual limitations of physical facilities for perinatal care may impede strict adherence to the recommendations. Furthermore, not all

hospitals will have all the functional units described. Provisions for individual units should be consistent within the framework of a regionalized perinatal care system and the state and local public health regulations.<sup>3</sup>

For more specific guidelines for new construction or remodeling, refer to the current edition of *Guidelines for Construction and Equipment of Hospital and Medical Facilities*. To order this book or request a catalog, call The American Institute of Architects Press in Washington, D.C. at 1-800-365-2724 or visit the Web site at <http://www.archINFORM.net/info/index.htm>.

### Obstetric Functional Units

#### **Labor**

Areas used for women in labor are equipped with the following components:

- Adequate space for support persons, personnel, and equipment
- Adequate ventilation and temperature control
- A labor or birthing bed
- A storage area for the patient's clothing and personal belongings
- Adjustable lighting that is pleasant for the patient and adequate for examinations
- An emergency signal and an intercommunication system
- A sphygmomanometer and stethoscope
- Mechanical infusion equipment
- Fetal monitoring equipment
- Oxygen, ventilation bag and mask and suction outlets
- Access to at least one shower for use of labor patients
- Storage facilities for supplies and equipment

#### **Delivery**

Delivery rooms should be close to the labor rooms in order to afford easy access and to provide privacy to women in labor. A waiting area for families should be adjacent to the delivery suite, and restrooms should be located nearby.

Traditional delivery rooms and cesarean birth rooms are similar in design to operating rooms. Vaginal deliveries can be performed in either room, whereas cesarean birth rooms are designed especially for that purpose and are thus larger. Each type of birthing room is well lighted and environmentally controlled to prevent chilling of the mother and neonate.

It is desirable that cesarean deliveries be performed in the obstetric unit. However, if this is not possible due to cost and space, equipment for neonatal stabilization and resuscitation must be available during delivery.

Each delivery room is maintained as a separate unit with the following equipment and supplies necessary for normal delivery and for the management of complications:

- Delivery/operating table that allows variation in position for delivery
- Instrument table and solution basin stand
- Instruments and equipment for vaginal delivery, repair of laceration, cesarean delivery, and the management of obstetric emergencies
- Solutions and equipment for the intravenous administration of fluids
- Equipment for administration of all types of anesthesia, including equipment for emergency resuscitation of the mother
- Individual oxygen, air, and suction outlets for mother and neonate
- An emergency call system
- Mirrors for patients to observe the birth
- Wall clock with a second hand
- Equipment for fetal heart rate monitoring
- Scrub sinks with controls strategically placed to allow observation of the patient

Trays containing drugs and equipment necessary for emergency treatment of both mother and neonate are kept in the delivery room area. Equipment necessary for the treatment of cardiac or respiratory arrest is easily accessible.<sup>4</sup>

### **Postpartum Care**

The postpartum unit is flexible enough to permit comfortable accommodation of patients when the patient census is at its peak and use of beds for alternate functions when the patient census is low. Ideally, single-occupancy rooms should be provided; however, not more than two patients should share one room. If possible, each room in the postpartum unit should have its own toilet and hand washing facilities. When this is not possible and it is necessary for patients to use common facilities, patients should be able to reach them without entering a general corridor. When the newborn rooms-in with the mother, the room should have hand washing facilities, a mobile bassinet unit, and supplies necessary for the care of the newborn.<sup>4</sup>

### **Combined Units (Labor/Delivery/Recovery or Labor/Delivery/Recovery/Postpartum room)**

Comprehensive obstetric and neonatal care can be provided to the low-risk and the high-risk mother, infant and the family in a single room. A homelike, family-centered environment with the capability for providing high-risk care is a key design criterion for both the labor/delivery/recovery (LDR) and labor/delivery/recovery/postpartum (LDRP) rooms. Each room is equipped for all types of delivery except cesarean deliveries or those that may require general anesthesia.

During the labor, delivery, and recovery phases, care can be provided in an LDR room or can be extended to include the postpartum period in an LDRP room.

Nurses providing care in combined units are knowledgeable in antepartum care, labor and delivery, postpartum care, and neonatal care, making the use of staff cost-effective and increasing the continuity and quality of care.<sup>4</sup>

## Neonatal Functional Units

### **Resuscitation/Stabilization**

A resuscitation and stabilization bed should be available in the immediate area of delivery for those neonates who require it. Contingent upon their condition, neonates are moved from this area to the nursery for admission and stabilization and/or transfer to a Level II Regional Center, Level II Regional Neonatology Center or Level III Center.

The resuscitation area contains the following items:

- Overhead source of radiant heat that can be regulated based on the infant's temperature - radiant warmers with accommodations for X-ray capabilities are recommended
- Thin resuscitation/examination mattress that allows access on three sides
- Wall clock (Apgar timer is beneficial)
- Equipment and medications as recommended by the Neonatal Resuscitation Program. This includes but is not limited to a laryngoscope with infant-sized blades, endotracheal tubes, and resuscitation bags with masks for full-term and preterm neonates
- Oxygen, compressed air and suction sources that are separate from those for the mother
- Equipment for examination, immediate care, and identification of the neonate

### Neonatal Resuscitation Program

The resuscitation area is usually within the delivery room, although it may be in a designated, contiguous, separate room. If resuscitation takes place in the delivery room, the area is large enough to ensure that the resuscitation of the neonate can be achieved without interference of the ongoing care of the mother. Following stabilization of the neonate, the newborn's vital signs must be maintained (e.g., by using prewarmed blankets). The room temperature is kept at a level higher than that customary for patient rooms or operating suites. Qualified nursing staff is available to assess the newborn during this period.<sup>4</sup>

### **Admission/Observation (Transitional Care Stabilization)**

The admission/observation area is for careful assessment of the neonate's condition during the first 24 hours after birth (i.e., during the period of physiologic adjustment to extrauterine life). This assessment may take place within one or more functional areas (e.g., the room in which the mother is recovering, the LDRP room, the newborn nursery, or a separate admission/observation area). In some hospitals, the newborn nursery is the primary area for transitional care, both for neonates born within the hospital and for those born outside the hospital.

The admission/observation area should be near the delivery/cesarean birth room. If it is part of the maternal recovery area, which is preferable, physical separation of the mother and newborn during this period can be avoided.

The capacity of the admission/observation area depends on the size of the delivery service and the duration of close observation. The admission/observation area is well lighted, has a wall clock, and contains emergency resuscitation equipment similar to that in the designated resuscitation area.

The physicians' and registered nurses' assessments of the neonate's condition determine the subsequent level of care. Most neonates are transferred from the admission/observation area to the newborn nursery or to the postpartum area for rooming-in. Some neonates may require transfer to another facility. Consultation with a pediatrician or neonatologist and/or referral to a hospital offering a higher level of care should be initiated for infants with respiratory distress or those infants requiring oxygen therapy for more than two hours.

Respiratory distress is defined as tachypnea (respiratory rate of 60 or more per minute), grunting, tugging, retracting, nasal flaring, or cyanosis. Any or all of these may constitute respiratory distress.<sup>4</sup>

### **Newborn Nursery**

Routine care of apparently normal full-term neonates who have demonstrated successful adaptation to extrauterine life may be provided either in the newborn nursery or in the area where the mother is receiving postpartum care. The nursery should be relatively close to the postpartum area. The newborn nursery is well lighted, has a large wall clock, and is equipped for emergency resuscitation.<sup>4</sup> There also should be a quiet room for testing newborn hearing.

### **MEDICAL PERSONNEL**

The obstetric/newborn care area is under the supervision and/or direction of an American board certified obstetrician-gynecologist, a American board-eligible or American board-certified pediatrician, or a physician with special interest and experience in obstetrics or pediatrics.

Adequate anesthesia coverage under the supervision of a licensed physician is available in a timely fashion for emergency situations on a 24-hour-a-day, seven-days-a-week basis.

For cesarean sections or if neonatal problems are anticipated during vaginal delivery, a second physician or attendant who is skilled in resuscitation and care of the neonate should be in attendance.

### **NURSING PERSONNEL**

Nurses assigned to the obstetrical/neonatal service demonstrate competency in the care of the mother and infant.

#### Staffing

Registered nurses assigned to the obstetrical/neonatal service must be licensed to practice in Iowa, complete an obstetrical and/or neonatal orientation and demonstrate obstetrical and/or neonatal competencies as defined by each hospital. At least one of these registered nurses must be available at all times. His/her primary responsibility is the delivery of nursing care.

### **Labor/Delivery/Immediate Postpartum/Newborn**

A registered nurse is responsible for the admission assessment of the gravida in labor, as well as continuing assessment and support of the mother and fetus during labor, delivery and the early postpartum period.

A registered nurse is responsible for the admission assessment of the newborn, as well as continuing assessment during the stabilization period.

Licensed practical nurses, nursing assistants and other appropriate technical personnel may assist in the care of the gravida in labor, but should be under the direct supervision of the registered nurse.

Hospital staff are educated in providing assessment and support to breastfeeding women.

### **Later Postpartum Period/Newborn Care**

Nursing care of the mother and newborn is directed and supervised by a registered nurse. A licensed practical nurse may provide care for patients without complications.

Nurses have a supporting and teaching role in assisting mothers to care for their infants. This should be recognized and fostered.

Staff educated in providing assessment and support to breastfeeding women.

### **OUTREACH EDUCATION**

Level I Hospitals should assume an active role in the development and coordination of wellness and preventive programs concerning maternal/child health at the community level (e.g., programs on family planning, family-life education, parenting, childbirth education, breastfeeding, cessation of smoking, etc.), and are encouraged to communicate with the local board of health.

Hospitals are also encouraged to work with IDPH funded Maternal Health Centers. Enhanced services to promote prenatal education, nutritional support, and oral health care to pregnant women who qualify. Call or refer women to the Maternal Health Center in their county of residence. To find the Maternal Health Center in your area, contact IDPH at 1-800-383-3826.

### **ALLIED HEALTH PERSONNEL AND SERVICES**

Level I Hospitals have available, but are not limited to, the following allied health personnel and services:

- Registered dietitian with knowledge of maternal and neonatal nutrition management
- Social worker
- Bioengineer-safety and environmental control
- Pharmacy
- Radiology
- Laboratory
- Pathology

### **INFECTION CONTROL**

Each hospital establishes written policies and procedures for assessing the health of personnel assigned to the perinatal care services and those who have significant contact with the newborn. This includes restricting their contact with patients when necessary. These policies and

procedures include screening for tuberculosis and rubella. Routine culturing of specimens obtained from personnel is not useful, although selective culturing may be of value when a pattern of infection is suspected.

No special or separate isolation facilities are required for neonates born at home or in transit to the hospital. Detailed descriptions of the isolation categories and requirements should be available in each hospital's infection control manual.

For more detailed information, refer to (American Academy of Pediatrics and American College of Obstetricians and Gynecologists . (2002). *Guidelines for Perinatal Care (5th Edition)*. Elk Grove Village, 2002, Chapter 10, pp. 331-352 on Infection Control).

## **NEWBORN SAFETY**

The protection of infants is the responsibility of all personnel in a facility. Infants are to be transported in a bassinet rather than be carried. Infants are transported one at a time, and should not be kept in the hallway or nurses station without direct supervision. Infants should always be within the sight and supervision of staff, the mother, or other family members/friends designated by the mother. Each hospital has a policy established that addresses strategies to promote infant safety.

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*Iowa Administrative Code 641—Chapter 150 – Iowa Regionalized System of Perinatal Health Care*

<sup>1</sup> March of Dimes Birth Defects Foundation, Committee on Perinatal Health. *Toward Improving The Outcome Of Pregnancy: The 90s And Beyond*. White Plains (NY):MDBDF; 1993, p. 35

<sup>2</sup> American Academy of Pediatrics and American College of Obstetricians and Gynecologists (ACOG). (2002). *Guidelines for Perinatal Care (5th Edition)*. Elk Grove Village, 2002, pp. 23-27.

<sup>3</sup> American Academy of Pediatrics and American College of Obstetricians and Gynecologists (2002). *Guidelines for Perinatal Care (5th Edition)*. Elk Grove Village, p. 30

<sup>4</sup> American Academy of Pediatrics and American College of Obstetricians and Gynecologists (2002). *Guidelines for Perinatal Care (5<sup>th</sup> Edition)*. Elk Grove Village

## C.

## Level II Hospitals and Level II Regional Centers

*Because the Level II Regional Centers have made a special effort to provide services to a region, they are recognized as referral or Regional Centers.*

Iowa's regional perinatal health system was formalized in 1973. Because of Iowa's rural character, the Iowa Regionalized System of Perinatal Health Care Program (IRSPHCP) recognized that neonatologists and maternal-fetal medicine specialists would not be prevalent in the state. In order to provide specialty care for pregnant women and neonates on a regional basis, it was necessary to enlist obstetricians and pediatricians to provide special types of obstetric and newborn services. As a result, the IRSPHCP developed a strategy of special training for physicians and the nurses that worked with them, through hospital visitations by the Statewide Perinatal Care Program (SPCP).

It is impractical in Iowa to have neonatologists and maternal-fetal medicine specialists in all referral centers. Thus, the system of Level II Regional Centers continues to be important to Iowa's regional perinatal concept. Because the Level II Regional Centers have made a special effort to provide services to a region, they are recognized as referral or Regional Centers.

Many of Iowa's hospitals, particularly those that deliver approximately 500 or more babies annually, have pediatricians and obstetricians on staff. This allows them to offer a higher level of care than facilities staffed exclusively by family physicians. The designation of Level II Regional Center is reserved for those hospitals that have been designated as referral centers. Other differences in the hospitals will be delineated in separate sections.

Level II Regional Centers represent an attempt to support the provision of special services for the women and newborns. It is unlikely that two such units would exist in one community. If this were the case, the community would be better served by one tertiary center.

All Level II Hospitals and Level II Regional Centers maintain a Perinatal Care Committee. Members of this committee should represent, but not be limited to, the fields of obstetrics, pediatrics, family practice, nursing, administration, laboratory, respiratory therapy, anesthesia and social services.

Responsibilities of the Perinatal Care Committee include the following:

- Develop policies for the unit including provisions to ensure adequate patient care by qualified providers
- Conduct meetings at least semi-annually to resolve problems related to the unit
- Review educational activities conducted by the unit
- Serve as a general liaison between the various groups represented on the committee

## **LEVEL II HOSPITALS**

### **Definition**

Level II Hospitals provide the same care and services as Level I Hospitals plus they provide management of certain high-risk pregnancies and services for newborns with selected complications. These hospitals deliver approximately 500 or more babies annually and have an obstetrician and pediatrician on staff. The perinatal unit is under the co-direction of a pediatrician and an obstetrician.

### **Functions**

In addition to the functions of Level I Hospitals, Level II Hospitals have the capability to:

- Manage selected high-risk pregnancies
- Manage neonates 34 weeks and greater gestation
- Manage mildly ill newborns with problems which are expected to resolve rapidly
- Manage recovering neonates who can be appropriately transferred from the referral center
- Maintain a special area designated for the care of sick neonates
- Maintain nursing personnel with training in the care of sick neonates
- Maintain nursing personnel with training in the care of high risk mothers

Consultation with a pediatrician or neonatologist and/or referral to a higher level perinatal center should be initiated for infants requiring oxygen therapy for more than six hours and/or ventilatory care for more than two hours.<sup>1</sup>

Consultation with an obstetrician-gynecologist or a maternal fetal medicine subspecialist should be obtained for patients who meet the criteria state in Appendices B and C of the American Academy of Pediatrics and American College of Obstetricians and Gynecologists. (2002). *Guidelines for Perinatal Care (5th Edition)*. Elk Grove Village, pages 365-368.

### **Physical Facilities**

Level II Hospitals have the same physical facilities as Level I (see pages 5-10 of this document). Please also refer to *Guidelines for Construction and Equipment of Hospitals and Medical Facilities*. To order this book or request a catalog, call The American Institute of Architects Press in Washington, D.C. at 1-800-365-2724.

### **Medical Personnel**

Level II Hospitals have the same medical personnel as Level I Hospitals. In addition, the perinatal units in Level II Hospitals are under the co-direction/supervision of an American board-eligible or American board-certified obstetrician/gynecologist and an American board-eligible or American board-certified pediatrician for their respective areas. Allied medical specialists in various disciplines are on staff, including specialists in internal medicine, radiology, and pathology. Psychiatric services are available.

### **Nursing Personnel**

Level II Hospitals have the same minimal requirements for nursing personnel as Level I Hospitals. Nursing orientation and competencies in a Level II Hospital are specific to the patient population they serve. A registered nurse with advanced training and experience in routine and

high-risk obstetric and/or neonatal care should be assigned to the labor and delivery area or NICU at all times.

### **Outreach Education**

Level II Hospitals have the same responsibility for outreach education as Level I Hospitals.

### **Allied Health Personnel and Services**

Level II Hospitals have the same allied health personnel and services available as a Level I, with the addition of the following:

- Respiratory therapy
- Ultrasound

### **Infection Control**

Infection control guidelines are the same as for Level I Hospitals.

### **Newborn Safety**

Level II Hospitals have at least the same requirements for newborn safety as Level I Hospitals.

## **LEVEL II REGIONAL CENTERS**

### **Definition**

Level II Regional Centers have a developed neonatal intensive care unit (NICU). The sizes of the units vary because of the differing demands in the various regions in Iowa. Accordingly, a Level II Regional Center may have as few as four neonatal intensive care beds.

The obstetric service in a Level II Regional Center provides services for maternity patients at higher risk than those in Level II Hospitals because of the presence of an NICU. However, reasonable efforts should be expended to transfer those patients whose newborns are likely to require a higher intensity of care as offered in a Level III Center.

Level II Regional Centers provide the same care and services as Level II Hospitals. In addition, Level II Regional Centers have the following differentiating characteristics:

- Designation as a Level II Regional Center by the Perinatal Guidelines Advisory Committee and the Iowa Regionalized System of Perinatal Health Care program of the Iowa Department of Public Health
- A defined referral area
- A defined relationship with Level II Regional Neonatal Center or Level III Center either in Iowa or a contiguous state
- A minimum of three pediatricians and three obstetricians on staff
- Manages patients at higher risk than Level I or Level II Hospitals
- Complexity of care is determined by the training and experience of physicians and nursing staff and extent of support services available
- The medical staff of the Level II Regional Center may include neonatologists (pediatricians with subspecialty certification in the care of ill newborns). These centers may have

capabilities for the care of ill newborns that exceed those of centers staffed exclusively by pediatricians without such subspecialty training (see Level II Regional Neonatology Center)

## **Functions**

Level II Regional Centers have the same functions as Level II Hospitals. In addition, Level II Regional Centers have the capability to:

- Accept selected maternal transports based on criteria developed in conjunction with the Level III Perinatal Center
- Maintain specially trained nursing personnel in the care of high risk mothers
- Maintain a defined neonatal intensive care unit
- Maintain specially trained nursing personnel for the neonatal intensive care unit
- Provide care for infants requiring ventilatory support
- Maintain a functioning neonatal transport team for the regional area served (see Appendix K)
- Provide for follow-up care of high-risk newborns as per the Iowa High Risk Infant Follow-up Program (see Appendix M)

Consultation with an obstetrician-gynecologist or a maternal fetal medicine subspecialist should be obtained for patients who meet the criteria state in Appendices B and C of the American Academy of Pediatrics and American College of Obstetricians and Gynecologists. (2002). *Guidelines for Perinatal Care (5th Edition)*. Elk Grove Village, pages 365-368.

## **Physical Facilities**

Level II Regional Centers have the same physical facilities as Level II Hospitals with the addition of the following.

### Obstetric Functional Units

#### **Labor/Delivery**

Patients who have significant medical or obstetric complications are cared for in a room especially equipped with cardiopulmonary resuscitation equipment and other monitoring equipment necessary for observation and special care. It is preferable that this room be located in the labor and delivery area and meet the physical requirements of any other intensive care room in the hospital. When patients with significant medical or obstetric complications are cared for in the labor and delivery area, the unit has the same capabilities as an intensive care unit.<sup>2</sup>

#### **Postpartum**

Larger services may have a specific recovery room for postpartum patients with a separate area for high-risk patients. Required equipment is similar to that needed in any surgical recovery room and includes equipment for monitoring vital signs, suctioning, administering oxygen, and infusing fluids intravenously. Cardiopulmonary resuscitation equipment must be immediately available.<sup>2</sup>

### Neonatal Functional Units

Continuous cardiopulmonary monitoring and constant nursing care and other support for severely ill infants are provided in the intensive care area. Because emergency care is provided in this area, laboratory and radiology services are readily available 24 hours a day. The results of blood gas analysis are available soon after blood sample collection.

The neonatal intensive care area should be near the delivery/cesarean birth room and should be easily accessible from the hospital's ambulance entrance. It should be away from routine hospital traffic.

The amount and complexity of equipment is considerably greater than that required in Level I and Level II nurseries. Equipment and supplies in the intensive care area include the same items as needed in the resuscitation and intermediate care areas. Immediate availability of emergency oxygen is essential. Continuous monitoring of delivered oxygen concentrations, patient oxygenation, body temperature, ECG, respirations and blood pressure should be available. Supplies should be kept close to the patient station so that nurses are not away from the neonate unnecessarily and may use their time and skills efficiently.

### **Medical Personnel**

Level II Regional Centers have the same medical personnel as Level II Hospitals with the addition of a American board-eligible or American board-certified pediatrician or neonatologist serving as director of the NICU. This physician maintains a consultative relationship with Level III Center physicians. Additionally, Level II Regional Centers have a minimum of three pediatricians and three obstetricians on staff.

If an infant is placed on mechanical ventilation, a physician, nurse practitioner, physician's assistant, or appropriate person capable of airway management and experienced in diagnosis is available in-house on a 24-hour basis.

### **Nursing Personnel**

Level II Regional Centers have the same minimal requirements for nursing personnel as Level II Hospitals. Additionally, Level II Regional Center registered nurses have advanced training and experience in high-risk obstetrics and/or neonatal care.

### **Outreach Education**

Provide outreach education to each hospital in the referral area at least once per year (see Appendix N). This can be achieved by one or more of the following:

- a. Sponsoring an annual conference
- b. Visiting Level I and Level II Hospitals
- c. Providing educational programs at the Regional Center for the staff members of the Level I and Level II Hospitals
- d. Sending written educational materials to the Level I and II Hospitals

## Allied Health Personnel and Services

Level II Regional Centers have the same allied health personnel and services available as Level II Hospitals, with the addition of the following:

- A respiratory therapist, certified lab technician/blood gas technician and an X-ray technologist should be in-house on a 24-hour basis when a neonate is being managed on mechanical ventilation
- Allied personnel should have special training and an interest in high-risk mothers and infants

## Infection Control

Infection control guidelines are the same as for Level II Hospitals.

## Newborn Safety

Level II Regional Centers have at least the same requirements for newborn safety as Level II Hospitals.

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*Iowa Administrative Code 641—Chapter 150 – Iowa Regionalized System of Perinatal Health Care*

<sup>1</sup> March of Dimes Birth Defects Foundation, Committee on Perinatal Health (1993). *Toward Improving the Outcome of Pregnancy: The 90s And Beyond*. White Plains (NY):MDBDF.

<sup>2</sup> American Academy of Pediatrics and American College of Obstetricians and Gynecologists. (2002). *Guidelines for Perinatal Care (5th Edition)*. Elk Grove Village.

## D. Level II Regional Neonatology Centers

### DEFINITION

**L**evel II Regional Neonatology Centers have all of the attributes and capabilities of Level II Regional Centers with the addition of a demonstrated commitment to providing a higher level of neonatology care. The Level II Regional Neonatology Centers must become a Level II Regional Center first before becoming eligible to be a Level II Regional Neonatology Center. The Level II Regional Neonatology Center (Level II RN) will manage many high-risk pregnancies and neonates under 34 weeks gestation. Exceptions will be cases for which surgical intervention or maternal or pediatric subspecialty care is needed or anticipated. Exceptions will also include pregnancies that require the care of a maternal fetal medicine specialist.

Level II RN Centers provide the same care and services as Level II Regional Centers. In addition, Level II RN Centers have the following differentiating characteristics:

- Designation as a Level II Regional Neonatology Center by the Perinatal Guidelines Advisory Committee and the Statewide Perinatal Care Program of the Iowa Department of Public Health
- A minimum of two American board-eligible or American board-certified neonatal/perinatal medicine sub-specialists on staff
- Neonatology care is available on a continuous (24/7) basis

- The medical director of the neonatal intensive care unit is a full-time, specialist with American board eligibility or American certification in neonatal/perinatal medicine
- A pediatric cardiologist is active on staff
- Neonatal diagnostic imaging and laboratory capabilities should be available 24 hours a day
- Level II RN Centers have respiratory therapists, certified lab technicians/blood gas technicians, x-ray technologists and ultrasound technicians with neonatal/perinatal experience, available on a 24-hour basis. Level II RN Centers also have social work services with social workers assigned specifically to the maternal and neonatal units
- Registered nurses in the NICU should have specialty certification or advanced training and experience in the nursing management of high-risk neonates and their families
- Centers that routinely provide care to infants less than 34 weeks gestation or less than 1500 grams birth weight will maintain a report of all NICU admissions that includes an accounting of patient mortality and morbidities for the benchmarking of results against other centers (national or statewide) and for the purpose of continuous review and quality improvement
- Consultation with an obstetrician-gynecologist or a maternal fetal medicine subspecialist should be obtained for patients who meet the criteria as stated in Appendices B and C of the American Academy of Pediatrics and American College of Obstetricians and Gynecologists. (2002). *Guidelines for Perinatal Care (5th Edition)*. Elk Grove Village, pages 365-368.

## PHYSICAL FACILITIES

Level II RN Centers have the same physical facilities as Level II Regional Centers; however, they have more equipment and staffing to facilitate the prolonged care and ventilation of their patients. The Level II RN center may have more than ten neonatal intensive care beds.

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## **E. Level III Centers**

### DEFINITION AND FUNCTIONS

**L**evel III Centers provide the same care and services as Level II Regional Centers, plus they manage the most high-risk pregnancies, and high risk neonates. The Level III Center is an extension of the Level II Regional Center and serves the same regional functions. The differentiating factor between them is primarily one of additional professional staff and more extensive physical facilities. There may be multiple Level III Perinatal Centers in the same city.

Level III Centers maintain a Perinatal Care Committee with additional representation by surgical specialties.

### PHYSICAL FACILITIES

Level III Centers have the same physical facilities as Level II Regional and Level II Regional Neonatology Centers; however, they have more equipment and serve a more complicated patient population.

## **MEDICAL PERSONNEL**

- The medical director of the maternal/fetal intensive care unit is a full-time, American board certified obstetrician and American board eligible or American board certified in maternal fetal medicine.
- The medical director of the neonatal intensive care unit is a full-time, American board-eligible or American board certified in maternal fetal medicine or American board-certified pediatrician with American board eligibility or certification in neonatology
- Anesthesiologists on staff have special training or experience in obstetric and pediatric anesthesia, and are available in the hospital 24 hours a day
- A pediatric surgeon is active on staff
- A pediatric cardiologist is active on staff
- Obstetric and neonatal diagnostic imaging should be available 24 hours a day
- All surgical patients in the intensive care nursery will be on the medical service of a neonatologist

These physicians must be immediately available to the Level III Center and reside in the same metropolitan area as the hospital. A neonatologist should be in-house when unstable critically ill infants are being managed on a ventilator.

## **NURSING PERSONNEL**

Level III Centers have the same minimal requirements for nursing personnel as Level II Regional Centers except the nurse managers of the perinatal units in Level III Centers have prior experience in maternal or pediatric nursing and have a minimum of a bachelor of science in nursing degree. Registered nurses in the NICU should have specialty certification or advanced training and experience in the nursing management of high-risk neonates and their families.

## **OUTREACH EDUCATION**

Level III Centers have the same responsibilities for outreach education as Level II Regional Centers (see Appendix N).

## **ALLIED HEALTH PERSONNEL AND SERVICES**

Level III Centers have the same allied health personnel and services as Level II Regional Centers. Additionally, Level III Centers have respiratory therapists, certified lab technicians/blood gas technicians, x-ray technologists and ultrasound technicians with neonatal/perinatal experience, available on a 24-hour basis. Level III Centers also have social work services with social workers assigned specifically to the maternal and neonatal units.

## **INFECTION CONTROL**

Infection control guidelines are the same as for Level II Regional Centers.

## **NEWBORN SAFETY**

Level III Centers have at least the same requirements for newborn safety as Level II Regional Centers.

## **QUALITY IMPROVEMENT**

Centers will maintain a patient database of all NICU admissions that includes an accounting of patient mortality and morbidities for the benchmarking of results against other centers (national or statewide) and for the purpose of continuous review and quality improvement.

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## F. Differentiation of Levels of Care

	Level I	Level II	Level II Regional	Level II Regional Neonatology	Level III
Definition & Functions	Page 5	Provides all services as Level I, plus deliveries of 500 or more. Has a Perinatal Care Committee. Manages high-risk pregnancies, neonates 34 wks and greater, mildly ill newborns, and recovering neonates transferred from referral centers. Infants on oxygen for more than 6 hrs and/or ventilator care for more than 2 hrs require consult with pediatrician or neonatologist at a higher level of care. Transfer should be considered.	Provides all services of Level II, plus manages patients at higher risk. The complexity of care is determined by the training and experience of the physicians and nursing staff and extent of support services. Has a defined referral area & defined relationship with a Level III center. Accepts maternal transports, provides care for infants requiring ventilatory support, maintains a neonatal transport team, and provides for follow-up care of high-risk newborns.	Provides all services as Level II Reg., plus manages high risk neonates less than 34 wks. Extension of Level II Reg with additional professional staff & more extensive physical facilities.	Provides all services as Level II Reg., plus manages high-risk pregnancies and neonates less than 34 wks. Extension of Level II Reg with additional professional staff & more extensive physical facilities.
Physical Facilities	Pages 5-9	Special area designated for care of sick neonates.	Neonatal intensive care unit with as few as 4 beds.	More equipment, serve more complicated patient population.	More equipment, serve more complicated patient population.
Medical Personnel	Supervised or directed by OB/GYN, pediatrician or physician with special interest & experience.	Perinatal unit under co-direction/supervision of OB/GYN and pediatrician.	Pediatrician serves as director of NICU. Minimum of 3 pediatricians and 3 obstetricians on staff.	Director of NICU is full time pediatrician with certification in neonatal/perinatal medicine, pediatric cardiologist on staff. Neonatologist is in house when unstable critically ill infants on ventilator.	Director of maternal/fetal ICU is full time obstetrician with certification in maternal-fetal medicine; director of NICU is full time pediatrician with certification in neonatal/perinatal medicine; pediatric surgeon on staff, and pediatric cardiologist on staff. Neonatologist in house when unstable critically ill infants on ventilator.
Nursing Personnel	Registered nurses with demonstrated ob and/or neonatal competencies.	Registered nurses with training in care of sick neonates.	Registered nurses have special in high-risk obstetrics and/or neonatal care.	Registered nurses have special training in high-risk neonatal care.	Nurse manager has prior experience in maternal or pediatric nursing with minimum of BSN.
Outreach	Page 10	Same as Level I.	Provide education to each hospital in referral area at least once per year.	Same as Level II Reg.	Same as Level II Reg.
Allied Health	Page 10	Same as Level I, plus respiratory therapy, ultrasound & physical therapy services.	Same as Level II, plus RT, certified lab tech and x-ray tech in house 24 hrs/day when infant on ventilator. Personnel have special training and interest in high-risk mothers and infants.	Same as Level II Reg, plus RT, certified lab tech/blood gas tech, x-ray tech and ultrasound tech with neonatal experience on 24/hr basis. Social workers available to neonatal units.	Same as Level II Reg, plus RT, certified lab tech/blood gas tech, x-ray tech and ultrasound tech with neonatal/perinatal experience on 24/hr basis. Social workers assigned to maternal and neonatal units.
Infection Control	Page 10	Same as Level I.	Same as Level I.	Same as Level I.	Same as Level I.
Safety	Page 11	Same as Level I.	Same as Level I.	Same as Level I.	Same as Level I.

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## VI. APPENDICES

### Appendix 1. Vital Statistics Terms Defined

**Fetal death:** means death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy. Death is indicated by the fact that after expulsion or extraction the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. In determining a fetal death, heartbeats shall be distinguished from transient cardiac contractions, and respirations shall be distinguished from fleeting respiratory efforts or gasps.<sup>1</sup> (Commonly referred to as “stillbirth”)

**Infant death:** death of a liveborn infant under one year of age; includes both neonatal and postneonatal deaths<sup>3</sup>

**Live birth:** means the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which, after such expulsion or extraction, breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. In determining a live birth, heartbeats shall be distinguished from transient cardiac contractions, and respirations shall be distinguished from fleeting respiratory efforts or gasps.<sup>1</sup>

**Maternal Death:** A maternal death is any death occurring while a woman is pregnant or of a woman within one year after delivery. This includes but is not limited to deaths resulting from abortions, ectopic pregnancies and all deaths during pregnancy, childbirth, puerperium or deaths from complications of childbirth. In the event of a maternal death, the certifying physician shall indicate that circumstance on the certificate of death.<sup>2</sup>

**Neonatal death:** death of a liveborn infant occurring within the first 27 days of life<sup>3</sup>

**Perinatal death:** death of a fetus of greater than 20 weeks’ gestation or death of a liveborn infant under 28 days of life<sup>3</sup>

**Postneonatal death:** death of a liveborn infant after the first 27 days of life, but before one year of age<sup>3</sup>

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1. *Iowa Code 144.1/Title IV Public Health/Subtitle 2 Health-Related Activities Definitions*  
641.4—IAC/Genetics/Definitions
  2. 641—5.1(135) *Iowa Administrative Code*
  3. 2005 Vital Statistics of Iowa, Iowa Department of Public Health, Center for Health Statistics. Available at: [http://www.idph.state.ia.us/apl/common/pdf/health\\_statistics/2005/vital\\_stats\\_2005](http://www.idph.state.ia.us/apl/common/pdf/health_statistics/2005/vital_stats_2005). Accessed June 4, 2013.

## Appendix 2. Maternal—Fetal Transport

Maternal-fetal transport is an essential component of modern perinatal care. All facilities in the state providing obstetrics need to be familiar with their own resources and capabilities in dealing with obstetrical and neonatal complications. In most instances, maternal-fetal transport is preferable to neonatal transport. Each hospital, when transporting or accepting a transport, needs a system in place to facilitate a smooth transition of care in the most expeditious manner possible. The majority of maternal-fetal transports can be carried out by ground transportation. It is important for ambulance services to be equipped for maternal-fetal transport and have appropriately trained staff.

Maternal-fetal transports must be conducted and accomplished in compliance with EMTALA rules and regulations; see the EMTALA reference on page 3 of these guidelines. Particular attention must be given to areas regarding appropriate medical screening as it relates to women in labor and transfer requirements. EMTALA rules do not preclude appropriate transfer of women in labor with careful documentation of the need for transport.

The transferring hospital and physician must *ensure* that the skills and equipment available during transport will meet the anticipated needs of the maternal-fetal dyad rather than assume that everyone onboard an ambulance or aircraft is adequately trained. Specific attention should be placed on neonatal resuscitation skills. If the referring hospital chooses to set up its own transport for the purpose of “saving time” and getting the patient to the receiving hospital sooner, it must understand that it is *fully* responsible for the patient until arrival at the receiving institution. It is important that when a referring hospital refuses a transport team after it has been recommended, the receiving hospital document the refusal in writing.

Communication between the referring and accepting physicians is critical to ensure safe maternal-fetal transport. Record keeping and transfer of records is also an important element of maternal-fetal transport. Centers for Medicare and Medicaid Services (CMS) requires that “the transferring hospital send to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer...other records (e.g., test results not yet available or historical records not readily available from the hospital’s files) must be sent as soon as practicable after transfer.”<sup>1</sup>

Although hospitals designated as Level II and higher are expected to accept patient referrals, Level II Regional Centers, Level II Regional Neonatology Centers, and Level III Centers are expected to provide transportation services. A critical function of providers at Level II designated and higher hospitals is to communicate with the providers at Level I Hospitals in deciding whether a particular patient should be transported to the Level II Hospital, Level II Regional Center, Level II Regional Neonatology Center or directly to a Level III Center. Careful assessment of the hospital’s capabilities for perinatal management will be critical in these decisions. This information will need to be disseminated among the hospital staff. Providers of obstetric care need to know the critical gestational age limitations for their particular nursery. Below this gestational age, maternal-fetal transport should be utilized if delivery is anticipated and the circumstances permit.

Level III Centers are capable of providing ground and air transportation with fully staffed crews. Important decisions to be made jointly will include the appropriateness of transport, the best mode of transportation, the need for additional personnel accompanying the transport, and appropriate medical management to initiate prior to transport.

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1. American Academy of Pediatrics and American College of Obstetricians and Gynecologists (2012). *Guidelines for Perinatal Care (7<sup>th</sup> Edition)*. Chapter 4. Elk Grove Village, IL.

### Appendix 3. Antenatal Administration of Steroids

The American College of Obstetricians and Gynecologists, (ACOG), Committee on Obstetric Practice issued an updated *ACOG Committee Opinion* on antenatal administration of corticosteroids in 2011.<sup>1</sup>

The Committee on Obstetric Practice makes the following recommendations regarding the use of corticosteroid therapy for fetal maturation during pregnancy:

- Treatment should consist of one of the following corticosteroid courses:  
Betamethasone 12 mg given intramuscularly 24 hours apart for two doses
- OR
- Dexamethasone 6 mg given intramuscularly 12 hours apart for four doses
- A single course of corticosteroids is recommended for pregnant women between 24 and 34 weeks of gestation who are at risk of preterm delivery within 7 days.
- A single course of antenatal corticosteroids should be administered to women with PROM before 32 weeks of gestation to reduce the risks of respiratory distress syndrome, perinatal mortality, and other morbidities.
- The efficacy of corticosteroid use at 32–33 completed weeks of gestation for preterm PROM is unclear based on available evidence, but treatment may be beneficial, particularly if pulmonary immaturity is documented.
- There are no data regarding the efficacy of corticosteroid use before viability, and it is not recommended.
- A single rescue course of antenatal corticosteroids may be considered if the antecedent treatment was given more than 2 weeks prior, the gestational age is less than 32 6/7 weeks, and the women are judged by the clinician to be likely to give birth within the next week.
- Regularly scheduled repeat courses or multiple courses (more than two) are not currently recommended.
- Further research regarding the risks and benefits, optimal dose, and timing of a single rescue course of steroid treatment is needed.

Since infants born at 22-24 weeks are now surviving, it follows that there is no contraindication for antenatal steroid use in this population based on gestational age. Although the use of antenatal steroids for infants between 22-24 weeks gestation has been controversial in the past, this therapy should be strongly considered based upon a recent study suggesting improvements in the survival of these infants.<sup>2</sup>

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1. American College of Obstetricians and Gynecologists (2011). (Practice Bulletin No. 130). Washington D.C. Available at: [http://www.acog.org/Resources\\_And\\_Publications/Committee\\_Opinions/Committee\\_on\\_Obstetric\\_Practice/Antenatal\\_Corticosteroid\\_Therapy\\_for\\_Fetal\\_Maturation](http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Obstetric_Practice/Antenatal_Corticosteroid_Therapy_for_Fetal_Maturation). Accessed June 4, 2013.
  2. Muri R, Kusuda S, Fujimura M, Neonatal Research Network Japan. Antenatal Corticosteroids Promote Survival of Extremely Preterm Infants Born at 22 to 23 Weeks of Gestation. *J Pediatr*. 2011; 159(1):110-114.

## Appendix 4. Maternal—Fetal Vital Signs in Labor

After the patient in labor has been admitted and her status evaluated, ongoing intrapartum surveillance is necessary. The level of surveillance may vary according to predetermined risk factors. General care during labor should provide optimal patient comfort in addition to optimal fetal and maternal safety. There is no comparative data that supports optimal time intervals for maternal-fetal assessments for low risk clients. Therefore, determining frequency of assessments is based on individual clinical situations, guidelines and standards from professional organizations and unit policies.

- Assessment of the quality of uterine contractions is recommend to occur at the same time intervals as fetal heart rate (FHR) assessment intervals defined below, in conjunction with vaginal examinations: this should be adequate to monitor the progress of labor and to detect abnormalities.
- Maternal temperature, pulse and blood pressure should be assessed and recorded every four hours until membranes have ruptured and then every 1-2 hours thereafter (Ricci & Kyle, 2008 p.335).
- Maternal pain and interventions for pain should be assessed and recorded regularly.
- The frequency and method (intermittent auscultation or continuous electronic fetal monitoring) of fetal heart rate monitoring used during labor should be based on risk factors and delineated by departmental policy.
- If there are no risk factors at the time of the patient's admission, a standard approach to intermittent auscultation of the fetal heart rate is to determine and record the auscultated FHR just after a contraction at least every 15-30 minutes in active phase, of the first stage of labor and at least every 5-15 minutes in the second stage of labor. Intermittent auscultation may not be appropriate for all pregnancies. Most of the clinical trials that compare electronic fetal monitoring (EFM) with intermittent auscultation have excluded subjects at high risk for adverse outcomes, and the relative safety of intermittent auscultation in such cases is uncertain.
- When using electronic fetal monitoring during the active phase of the first stage of labor, the fetal heart rate should be assessed at 15-30 minute intervals and during the active pushing phase of the second stage of labor, at 5-15 minute intervals.
- Interpretations of the fetal heart rate patterns during labor cannot occur without the evaluation of uterine contractions. Assessment of the intensity, duration, frequency and resting tone of uterine contractions is recommended to occur at the same time intervals as fetal heart rate (FHR) assessments intervals.
- If risk factors are present on admission or appear during labor continuous electronic fetal monitoring is recommended.
  - ▶ During the active phase of the first stage of labor, the FHR should be determined and recorded at least every 15 minutes.
  - ▶ During the second stage of labor, the FHR should be determined and recorded and documented at least every 5 minutes if auscultation is used. If continuous fetal monitoring is used the fetal heart rate tracing should be evaluated at least every 5 minutes.
- Intermittent auscultation may not be appropriate for all pregnancies. Most of the clinical trials that compare electronic fetal monitoring (EFM) with intermittent auscultation have

excluded subjects at high risk for adverse outcomes, and the relative safety of intermittent auscultation in such cases is uncertain.

- When electronic fetal heart rate monitoring is selected as the method of fetal assessment, the physician and obstetric personnel attending the patient should be qualified to identify and assess the fetal monitor tracing.
- When interpreting the FHR pattern consider the gestational age, prior fetal assessment, medications and obstetric and medical conditions (e.g. suspected intrauterine growth restriction, preeclampsia, and diabetes).
- A detailed and graphic documentation of the course of events during labor should be noted, such as: physician or nurse presence, the patient's position in the bed, cervical status, oxygen or drug administration, hypertension or hypotension, fever, amniotomy, color of the amniotic fluid, and maternal pushing.
- Laboring down or delayed pushing is an approach to second stage management of labor that allows for passive descent of the fetus with no maternal effort despite complete dilation. Usually this technique is initiated with women who have regional anesthesia. Typically this is two hours for the nulliparous woman or until the urge to push (also known as the Ferguson reflex) and one hour for the multiparous woman. Delayed pushing has been associated with preventing negative fetal effects, a decrease in instrumental deliveries, a decrease in maternal fatigue, and a decrease in third and fourth degree lacerations and episiotomies. There is no standard guideline for the frequency of FHR assessment for the patient who is complete but not actively pushing, this should be defined in your hospital policy.
- Tachysystole is defined as greater than 5 contractions in 10 minutes, contractions that last longer than 90 seconds, or increase in baseline uterine tone.

### **Electronic Fetal Monitoring (EFM) Nomenclature Update**

The National Institute of Child Health and Human Development (NICHD) held workshops in 2008 for the specific purpose of developing standardized and clear-cut definitions for fetal heart rate (FHR) tracings. The definitions that came from these workshops have now been adopted by the American College of Obstetricians and Gynecologists (ACOG)<sup>2</sup> and the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN). The Joint Commission (TJC), formerly called the Joint Commission on Accreditation of Healthcare Organizations (JACHO), also recommended standardized terminology for fetal monitoring in the July 2004 Sentinel Event Alert #30.<sup>5</sup> The purpose for this adoption is to have all care providers using the same terminology for interpretation of fetal monitor strips to ensure safe and consistent patient care. The new definitions are listed in the tables that follow.

### **Three Tier Fetal Heart Rate Interpretation System**

**Category I** FHR tracings include all of the following:

- Baseline rate: 110-160 beats per minute
- Baseline FHR variability: moderate
- Late or variable decelerations: absent
- Accelerations: present or absent

**Category II** FHR tracings include all FHR tracings not categorized as category I or category III. Category II tracings may represent an appreciable amount of those encountered in clinical care. Examples of Category II FHR tracings include any of the following:

Baseline rate-

- Bradycardia not accompanied by absent variability
- Tachycardia

Baseline FHR variability-

- Minimal baseline variability
- Absent baseline variability not accompanied by recurrent decelerations
- Marked baseline variability

Accelerations-

- Absence of induced accelerations after fetal stimulation

Periodic or episodic decelerations-

- Recurrent variable decelerations accompanied by minimal or moderate baseline variability
- Prolonged deceleration >2 minutes but <10 minutes
- Recurrent late decelerations with moderate baseline variability
- Variable decelerations with other characteristics, such as slow return to baseline, “overshoots,” or “shoulders”

**Category III** FHR tracings include either:

- Absent baseline FHR variability and any of the following
  - Recurrent late decelerations
  - Recurrent variable decelerations
  - Bradycardia
- OR
- Sinusoidal pattern

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1. American Academy of Pediatrics and American College of Obstetricians and Gynecologists (2012). *Guidelines for Perinatal Care (7<sup>th</sup> Edition) Chapter 6*. Elk Grove Village, IL.
  2. American College of Obstetricians and Gynecologists, Practice Bulletin. *Intrapartum Fetal Heart Rate Monitoring*. Vol.116, No.5, November 2010.
  3. Mayberry LJ, Hammer R, Kelly C, True-Driver B, De A. Use of Delayed Pushing with Epidural Anesthesia: Findings from a Randomized Controlled Trial. *J Perinatol*. 1999; 19(1):26-30.
  4. Ricci S, Kyle T. Nursing management during labor and birth. *Maternity and Pediatric Nursing*. New York, NY: Lippincott, Williams & Wilkins, Ch.14, p.335.
  5. Joint Commission on Accreditation of Healthcare Organizations. *Preventing Infant Death and Injury during Delivery. Sentinel Event Alert No. 30*. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations; 2004:1-3.

**Table 1. Definitions of Fetal Heart Rate Patterns**

Pattern	Definition
Baseline	<ul style="list-style-type: none"> <li>• The mean FHR rounded to increments of 5 beats per min during a 10 min segment, excluding: <ul style="list-style-type: none"> <li>– Periodic or episodic changes</li> <li>– Periods of marked FHR variability</li> <li>– Segments of baseline that differ by more than 25 beats per min</li> </ul> </li> <li>• The baseline must be for a minimum of 2 min in any 10 min segment</li> </ul>
Baseline variability	<ul style="list-style-type: none"> <li>• Fluctuations in the FHR of two cycles per min or greater</li> <li>• Variability is visually quantitated as the amplitude of peak-to-trough in beats per min <ul style="list-style-type: none"> <li>– Absent—amplitude range undetectable</li> <li>– Minimal—amplitude range detectable but 5 beats per min or fewer</li> <li>– Moderate (normal)—amplitude range 6-25 beats per min</li> <li>– Marked—amplitude range greater than 25 beats per min</li> </ul> </li> </ul>
Acceleration	<ul style="list-style-type: none"> <li>• A visually apparent increase (onset to peak in less than 30 sec) in the FHR from the most recently calculated baseline</li> <li>• The duration of an acceleration is defined as the time from the initial change in FHR from the baseline to the return of the FHR to the baseline</li> <li>• At 32 weeks of gestation and beyond, an acceleration has an acme of 15 beats per min or more above baseline, with a duration of 15 sec or more but less than 2 min</li> <li>• Before 32 weeks of gestation, an acceleration has an acme of 10 beats per min or more above baseline, with a duration of 10 sec or more but less than 2 min</li> <li>• Prolonged acceleration lasts 2 min or more but less than 10 min</li> <li>• If an acceleration lasts 10 min or longer, it is a baseline change</li> </ul>
Bradycardia	<ul style="list-style-type: none"> <li>• Baseline FHR less than 110 beats per min</li> </ul>
Early deceleration	<ul style="list-style-type: none"> <li>• In association with a uterine contraction, a visually apparent, gradual (onset to nadir 30 sec or more) decrease in FHR with return to baseline</li> <li>• Nadir of the deceleration occurs at the same time as the peak of the contraction</li> </ul>
Late deceleration	<ul style="list-style-type: none"> <li>• In association with a uterine contraction, a visually apparent, gradual (onset to nadir 30 sec or more) decrease in FHR with return to baseline</li> <li>• Onset, nadir, and recovery of the deceleration occur after the beginning, peak, and end of the contraction, respectively</li> </ul>
Tachycardia	<ul style="list-style-type: none"> <li>• Baseline FHR greater than 160 beats per min</li> </ul>
Variable deceleration	<ul style="list-style-type: none"> <li>• An abrupt (onset to nadir less than 30 sec), visually apparent decrease in the FHR below the baseline</li> <li>• The decrease in FHR is 15 beats per min or more, with a duration of</li> </ul>

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	15 sec or more but less than 2 min
Prolonged deceleration	<ul style="list-style-type: none"><li>• Visually apparent decrease in the FHR below the baseline</li><li>• The deceleration is 15 beats per min or more, lasting 2 min or more but less than 10 min from onset to return to baseline</li></ul>

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## Appendix 5. Vaginal Birth after Cesarean and Trial of Labor after Cesarean

The changing views in the US related to VBAC over the past decade have been considered in *The Iowa Perinatal Letter* (“VBAC Revisited: Déjà Vu All Over Again,” vol. XIX, no. 3, p. 11, 1998 and “VBAC: The Pendulum Swings,” vol. XXI, no. 1, p. 4, 2000) and by the American College of Obstetricians and Gynecologists (ACOG) in the Practice Bulletin #5 published in July, 1999, “Vaginal Birth After Previous Cesarean Delivery.”<sup>1</sup> On July 10, 2010 new guidelines were released by ACOG. These guidelines are less restrictive than those previously issued.

### **The following recommendations are based on good and consistent scientific evidence (Level A):**

- Most women with one previous cesarean delivery with a low-transverse incision are candidates for trial of labor after cesarean (TOLAC). They should be counseled about vaginal birth after cesarean (VBAC) and offered a trial of labor.
- Epidural anesthesia may be used for TOLAC.
- Misoprostol (Cytotec) should not be used for third trimester cervical ripening or labor induction in patients who have had a cesarean delivery or major uterine surgery.
- A previous uterine incision extending into the fundus is a contraindication for TOLAC.

### **The following recommendations are based on limited or inconsistent scientific evidence (Level B):**

- Women with two previous low-transverse cesarean deliveries and no contraindications who wish to attempt VBAC may be allowed a trial of labor. They should be advised that the risk of uterine rupture increases as the number of cesarean deliveries increases.
- Use of oxytocin or prostaglandin gel for TOLAC requires close patient monitoring.
- Women with a vertical incision within the lower uterine segment that does not extend into the fundus are candidates for TOLAC.
- Women with one previous cesarean delivery with a low transverse incision, who are otherwise appropriate candidates for twin delivery, may be considered candidates for TOLAC.
- External cephalic version for breech presentation is not contraindicated in women with a prior low transverse uterine incision who are not at risk for adverse maternal or neonatal outcomes from external cephalic version and TOLAC.
- Those at high risk for complications (e.g. those with previous classical or T-incision, prior uterine rupture, or extensive transfundal uterine surgery) and those in whom vaginal delivery is otherwise contraindicated (e.g., those with placenta previa) are not generally candidates for planned TOLAC.
- Induction of labor for maternal or fetal indications remains an option in women undergoing TOLAC.
- TOLAC is not contraindicated for women with previous cesarean delivery with an unknown uterine scar type unless there is a high clinical suspicion of a previous classical uterine incision.

**The following recommendations are based primarily on consensus and expert opinion (Level C):**

- Because uterine rupture may be catastrophic, TOLAC/VBAC should only be attempted in institutions equipped to respond to emergencies with physicians immediately available to provide emergency care.
- After thorough counseling that weighs the individual benefits and risks of TOLAC, the ultimate decision to attempt this procedure or undergo a repeat cesarean delivery should be made by the patient and her physician. Documentation of counseling and the management plan should be included in the medical record.

**Other considerations:**

- The statement that physicians should be “immediately available to provide emergency care”<sup>1</sup> for the woman undergoing TOLAC has had very significant implications for Iowa hospitals. ACOG points out that, as opposed to other obstetric complications which may arise without warning, TOLAC attempts represent elective procedures. If a service plans on offering TOLAC to its patients, surgical, anesthetic, and nursing support should be available when a woman attempting TOLAC is in active labor so that prompt cesarean delivery can be undertaken should it be required.
- In making plans for delivery, physicians and patients should consider a woman’s chance of a successful VBAC as well as the risk of complications from trial of labor, all viewed in the context of her future reproductive plans.
- Approximately 60-80% of appropriate candidates who attempt VBAC will be successful. A VBAC avoids major abdominal surgery, lowers a woman’s risk from having multiple cesarean deliveries such as hysterectomy, bowel and bladder injury, transfusion, infection, placenta previa and placenta accreta.
- There are trade-offs here as a woman desiring VBAC may have to travel from her local facility to a center hospital in order to be afforded this opportunity. The delays inherent in additional travel time to the hospital for the woman in labor may present additional risks. As ACOG states in the last statement in the summary, the ultimate decision to attempt VBAC or undergo a repeat cesarean delivery is an individual one made by the patient and her physician based on individual risks, benefits, and values.
- Prostaglandins, especially misoprostol (Cytotec), are not recommended in any woman with a prior uterine scar, regardless of gestational age or clinical situation due to the increased risk of uterine rupture.

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1. American College of Obstetricians and Gynecologists, Practice Bulletin. *Vaginal Birth After a Previous Cesarean Delivery*. Vol.116, No.2, Part 1, August 2010.

## Appendix 6. Oxytocin for Induction and Augmentation of Labor

Oxytocin is a synthetic hormone used to stimulate rhythmic contractions of the uterus that produce cervical changes and fetal descent, while avoiding uterine tachysystole and fetal intolerance to labor. Complications from the use of oxytocics are ever present, especially when used in the antepartum and intrapartum phases of pregnancy.

Labor may be induced or augmented with oxytocin only after a thorough examination of both mother and fetus and indications for and methods of induction or augmentation have been documented. A physician who has privileges to perform cesarean deliveries should be readily available to respond should problems arise.

### Prior to the initiation of oxytocin infusion:

- A physician or qualified nurse should perform a vaginal exam on the patient to assure the adequacy of the maternal pelvis as well as the position of the fetus.
- A 20-minute baseline fetal monitoring strip is recommended before initiation of oxytocin.
- A primary line of intravenous solution is established.
- Before an induction for any indication, ACOG (2009)<sup>2</sup> recommends that the benefits of labor induction be weighed against the potential maternal and fetal risk. An induction of labor has merit as a therapeutic option when the benefits of delivery outweigh the risks of continuing the pregnancy.
- Oxytocin following pre-induction cervical ripening agent appears to be more effective than oxytocin alone as a method of induction.
- The likelihood of success of induction of labor is significantly increased in women with a Bishop score of six or more compared with women who have an unfavorable cervix.
- Prepare oxytocin intravenous solutions using a physiologic electrolyte-containing solution to prevent water intoxication. **Oxytocin is a high risk medication** and should be prepared by pharmacy personnel.
- Oxytocin is administered as a dilute solution intravenously via an infusion pump. The Oxytocin tubing should be inserted as close to the IV site as possible.

### During Oxytocin infusion:

- Although there is no consensus in the literature on the ideal oxytocin dosage regimen, available data support a lower dosage rate of infusion. The Society of Obstetricians and Gynaecologists of Canada (SOGC) recommends “using the minimum dose to achieve active labor, increasing the dosage no more frequently than every 30 minutes and reevaluating the clinical situation if the oxytocin dosage rate reaches 20 mU/min.”<sup>5</sup> The **Statewide Perinatal Care Program supports a lower dosage approach to oxytocin use, e.g., 1-2 mU/min., increasing by 1-2 mU/min. every 30-40 minutes.**
- The exact half-life of oxytocin is unknown, but is thought to be 3-10 minutes. The physiological steady state is believed to be approximately 40 minutes, therefore advancing oxytocin in increments of less than 30 minutes is not recommended.
- Continued increases in oxytocin rates over a prolonged period can result in oxytocin receptor desensitization or down regulation, making oxytocin less effective in producing uterine contractions.

- The uterus should relax for at least one minute between contractions.
- The most common side effect of oxytocin is tachysystole and is dose related. Tachysystole is defined as greater than 5 contractions in 10 minutes, contractions that last longer than 90 seconds, or increase in baseline uterine tone. Fifty percent of tachysystole cases will have nonreassuring fetal heart rate tracings. Therefore, when tachysystole is present, oxytocin should be discontinued (see tachysystole algorithm).
- Physiologic doses (low dose) of oxytocin may be safer in patients at high risk for tachysystole, fetal distress, or both. Examples include: preeclampsia, chronic hypertension, oligohydramnios, multiple gestation, prematurity, fetal growth restriction, placental abruption or any fetus that is already compromised and has little reserve.
- Fetal heart rate and uterine activity should be evaluated every 15 minutes in the first stage of labor and every 5 minutes in the second stage of labor while oxytocin is infusing. This is most easily accomplished with continuous electronic fetal monitoring but may be done by auscultation. Establish protocols for your institution and follow them.
- Assess and document maternal pulse, respirations and blood pressure every 30 to 60 minutes depending on stage of labor and presence of associated complications and hospital protocol.
- Assess and document maternal temperature every 4 hours or more often if indicated.

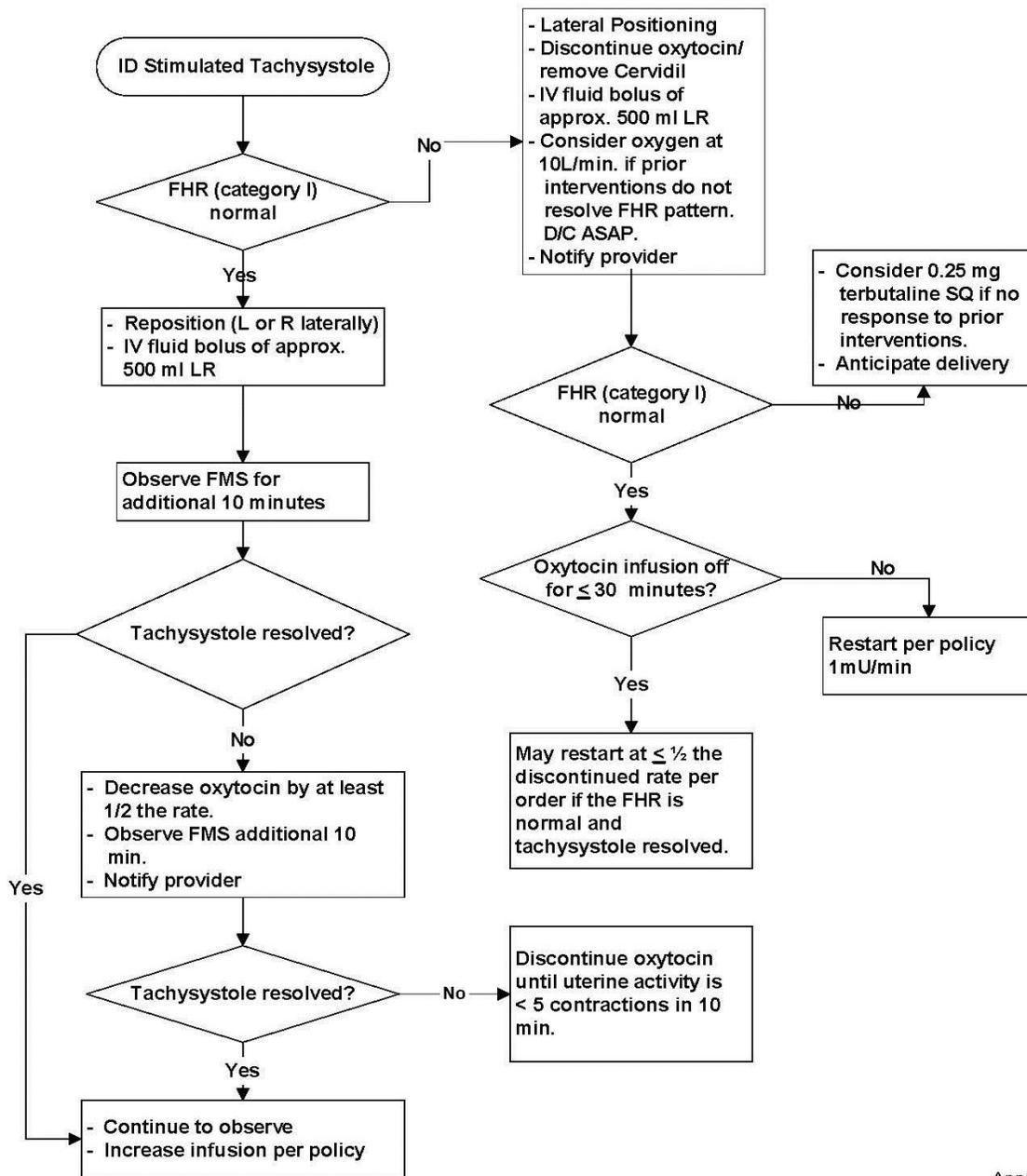
Refer to American College of Obstetricians and Gynecologists' (ACOG) Practice Bulletin on Induction of Labor and to recent literature when developing protocols and procedures.<sup>2</sup>

Each hospital must have policies, procedures, and protocols developed by nursing and medical staff. These should be evaluated and revised on an ongoing basis. If the physician requests deviation from the institution's policy, procedures, or protocol, ensure that the physician writes the order.

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1. American Academy of Pediatrics and American College of Obstetricians and Gynecologists (2012). *Guidelines for Perinatal Care (7<sup>th</sup> Edition)*. Chapter 6. Elk Grove Village, IL.
  2. American College of Obstetricians and Gynecologists, Practice Bulletin. *Induction of Labor*. Vol.114, No.2, Part 1, August 2009.
  3. Association of Women's Health, Obstetric, and Neonatal Nurses, Practice Resource, 3<sup>rd</sup> Edition. Cervical Ripening and Induction and Augmentation of Labor. Washington D.C. 2008.
  4. Simpson KR, Knox GE. Oxytocin as a High Alert Medication: Implications for Perinatal Patient Safety. *MCN*. 2009; 34(1):8-15.
  5. Society of Obstetricians and Gynaecologists of Canada. Induction of labour at term. (Clinical Practice Guideline No. 107). Ottawa, Canada. 2001
  6. Miller L. Excessive Uterine Activity, and Patient Safety: Time for a Collaborative Approach. *J Perinat Neonatal Nurs*. 2009; 23(1):52-58.

Stimulated Tachysystole Definition and Management Algorithm

Stimulated uterine contractions that occur more often than 5 in a 10-minute segment (averaged over 30 minutes), contractions lasting 2 minutes or more or contractions of normal duration occurring within one minute of each other. No change in FHR is necessary. The woman's perception of pain is not included in the definition.



Approved by  
Dr. Faust 01/30/07  
BCQI Committee 2/27/07  
Revised 5/09

## Appendix 7. Neonatal Assessment

At every delivery there should be at least one person whose primary responsibility is the neonate and who is certified in NRP and capable of initiating resuscitation. Either that person or someone else who is immediately available should have the skills required to perform a complete resuscitation including endotracheal intubation. During the stabilization period immediately following the delivery, temperature; heart and respiratory rates; skin color; adequacy of peripheral circulation; type of respiration; level of consciousness; tone and activity should be monitored and recorded at least once every 30 minutes until the neonate's condition has remained stable for two hours. For newborns with pallor or poor perfusion blood pressures should be obtained every 30 minutes until stable for two hours. Once the infant is determined clinically stable, and remains clinically stable, observations should be made and recorded according to the routine of the hospital nursery or at least every eight hours until discharge.

The American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG) recommend that if the five minute Apgar score is less than seven, additional scores should be assigned every five minutes for up to 20 minutes.<sup>2</sup> Any conditions that require special attention, such as vacuum assisted delivery; respiratory distress; hypoglycemia; temperature instability; change in activity (including poor feeding); unusual skin color; abnormal cardiac and respiratory findings, including abnormal blood pressure; delayed/abnormal voiding or stooling; or any degree of neonatal depression should be noted. Actions taken to correct the problem should be documented in the infant's record. For infants awaiting transport, vital signs including temperature, heart and respiratory rates, blood pressure, oxygen saturation, and fraction of inspired oxygen should be documented at least every 30 minutes.

It is advisable to develop nursery guidelines to delineate those conditions that are associated with increased risk for neonatal illness and warrant close observation and frequent assessment. These include delivery prior to 37 weeks gestation, low birth weight, small for gestational age (SGA), large for gestational age (LGA), maternal drug abuse, maternal fever or infection, low Apgar scores, operative vaginal delivery (forceps or vacuum extraction), or any questionable clinical status.

### Gestational Age Classification

In August 2001, the American Academy of Pediatrics published an article by Kramer et al entitled, "A New and Improved Canadian Reference for Birth Weight for Gestational Age."<sup>3</sup> This reference provides sex-specific growth curves and percentile cutoffs for defining small- and large-for-gestational-age births that reflect the trend toward increasing birth weight at or near term. Data from each neonate should be plotted on a birth weight-gestational age chart that indicates whether the neonate is small, appropriate, or large for gestational age.

The determination of gestational age and its relationship to weight can be used in the identification of neonates at risk for illness. For example, neonates who are either large or small for gestational age are at relatively increased risk for hypoglycemia and polycythemia, and appropriate tests are indicated. Newborn exam to determine gestational age should be done as soon as possible after birth or within the first 12 hours of life using the New Ballard Score sheet.

Guidelines for performing the gestational age assessment are available at, <http://www.ballardscore.com>, accessed June 26, 2013.

### **Risk for Hypoglycemia**

Neonatal hypoglycemia, a common metabolic disorder, may result in significant neurologic sequelae, especially in the symptomatic infant, if left untreated. In certain groups of high-risk infants who have a higher incidence of hypoglycemia than the normal population, neonatal glucose screening is highly recommended. These groups include the following infants: preterm infants; infants of diabetic mothers; infants who are small for gestational age (SGA) or large for gestational age (LGA); infants with a history of substance exposure; infants with limited or no prenatal care; infants with a five-minute Apgar score of six or less; infants with meconium staining or other symptoms of fetal distress; infants with polycythemia; and infants with severe erythroblastosis fetalis.

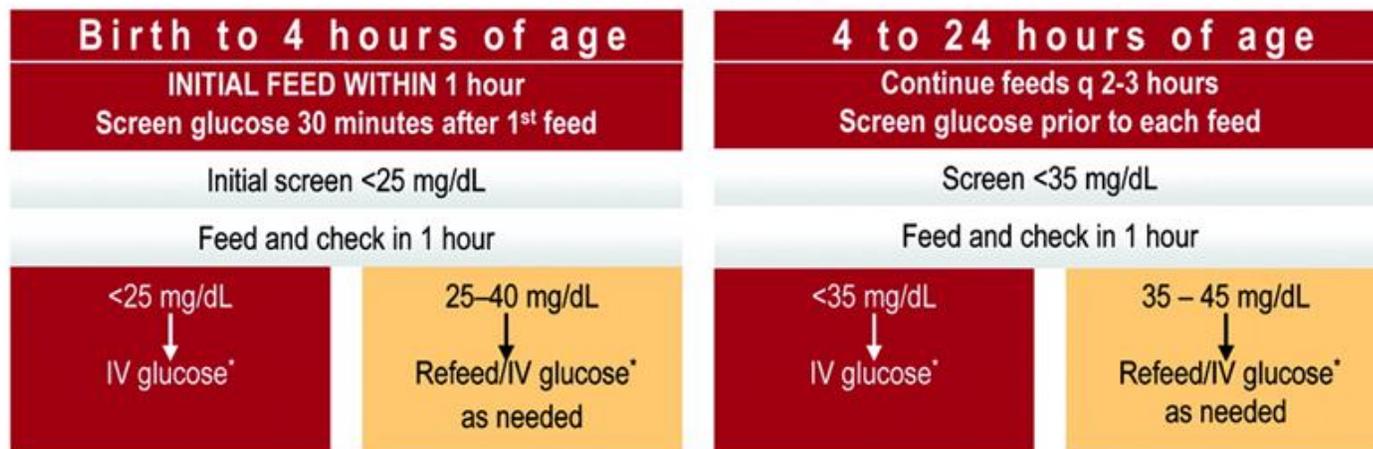
In 2011, the AAP published a clinical report, “Postnatal Glucose Homeostasis in Late Preterm and Term Infants.”<sup>4</sup> This guideline includes an algorithm for the screening and management of neonatal hypoglycemia (Fig 1). Hospitals are encouraged to refer to this clinical report when establishing their own written policy for screening and treatment of newborns at risk for hypoglycemia. Protocols should include specific guidelines for treatment with intravenous D10W, particularly for those infants with symptoms of hypoglycemia. Symptoms include irritability, tremors, jitteriness, exaggerated Moro reflex, high-pitched cry, seizures, lethargy, floppiness, cyanosis, apnea and poor feeding. Blood glucose concentration should be measured as soon as possible (minutes, not hours) in any infant who manifests clinical signs of hypoglycemia.

# Screening and Management of Postnatal Glucose Homeostasis in Late Preterm and Term SGA, IDM/LGA Infants

[(LPT) Infants 34 – 36<sup>6/7</sup> weeks and SGA (screen 0-24 hrs); IDM and LGA  $\geq$ 34 weeks (screen 0-12 hrs)]

**Symptomatic and  $<40$  mg/dL  $\longrightarrow$  IV glucose**

## ASYMPTOMATIC



**Target glucose screen  $\geq 45$  mg/dL prior to routine feeds**

\* Glucose dose = 200 mg/kg (dextrose 10% at 2 mL/kg) and/or IV infusion at 5–8 mg/kg per min (80–100 mL/kg per d). Achieve plasma glucose level of 40-50 mg/dL.

Symptoms of hypoglycemia include: Irritability, tremors, jitteriness, exaggerated Moro reflex, high-pitched cry, seizures, lethargy, floppiness, cyanosis, apnea, poor feeding.

**Figure 1:** Reprinted with permission from the American Academy of Pediatrics<sup>4</sup>

Screening for and management of postnatal glucose homeostasis in late-preterm (LPT 34-36 <sup>6/7</sup> weeks) and term small-for-gestational age (SGA) infants and infants who were born to mothers with diabetes (IDM)/ large-for-gestational age (LGA) infants. LPT and SGA (screen 0-24 hours), IDM and LGA  $\geq$ 34 weeks (screen 0-12 hours). IV indicates intravenous.

1. American Academy of Pediatrics and American College of Obstetricians and Gynecologists (2012). *Guidelines for Perinatal Care (7th Edition)*. Chapter 8. Elk Grove Village, IL.
2. American Academy of Pediatrics, Committee on Fetus and Newborn, American College of Obstetricians and Gynecologists, Committee on Obstetric Practice. *Pediatrics*. 2006; 117(4):1444-1447.
3. Kramer MS, Platt RW, Wen SW, Joseph KS, Allen A, Abrahamowicz M, Blondel B, Bréart G for the Fetal/Infant Health Study Group of the Canadian Perinatal Surveillance System. A New and Improved Population-Based Canadian Reference for Birth Weight for Gestational Age. *Pediatrics*. 2001; 108(2):e35. Available at: <http://pediatrics.aappublications.org/content/108/2/e35>. Accessed June 9, 2013.
4. American Academy of Pediatrics, Committee on Fetus and Newborn. Clinical report—Postnatal Glucose Homeostasis in Late Preterm and Term Infants. *Pediatrics*. 2011; 127(3):575-579.

**Appendix 8. Statute and Rules for Ophthalmia Prophylactics*****Code of Iowa 139 A.38: Medical treatment of newly born***

Each physician attending the birth of a child, shall cause to be instilled into the eyes of the newly born infant a prophylactic solution approved by the Iowa department of public health. This section shall not be construed to require medical treatment of the child of any person who is a member of a church or religious denomination and whose religious convictions, in accordance with the tenets or principles of the person's church or religious denomination, are against medical prophylaxis or treatment for disease.

***Iowa Administrative Code 641-1.7(139 A): Treatment of infant eyes***

The Iowa department of public health approves one percent silver nitrate solution in single-dose ampules or single-use tubes of an ophthalmic ointment containing one percent tetracycline or 0.5 percent erythromycin in each conjunctival sac as an ophthalmia prophylactic for newborn infants' eyes. Prophylaxis should be given after birth, but in no instance delayed for more than one hour after delivery. Once applied none of the above agents used for prophylaxis shall be flushed from the eyes following installation.

## Appendix 9. Center for Congenital and Inherited Disorders

### ***Code of Iowa 2004, Volume I, 136A.1: Purpose***

To reduce and avoid adverse health conditions of inhabitants of the state, the Iowa department of public health shall initiate, conduct, and supervise screening and health care programs in order to detect and predict congenital or inherited disorders. The department shall assist in the translation and integration of genetic and genomic advances into public health services to improve health outcomes throughout the life span of the inhabitants of the state.

### ***Iowa Administrative Code defines the responsibilities of the Center for Congenital and Inherited Disorders as follows:***

641—4.1(136A) Program overview. The center for congenital and inherited disorders within the department of public health provides administrative oversight to the following: Iowa newborn screening program, expanded maternal serum alpha-fetoprotein screening program, regional genetic consultation service, neuromuscular and related genetic disease program and Iowa registry for congenital and inherited disorders.

The Iowa Department of Public Health has designated the State Hygienic Laboratory (SHL) as the central testing laboratory for the Iowa Newborn Screening Program (INSP) and the Maternal Prenatal Screening Program (MPSP). The SHL is responsible for testing specimens submitted by providers and reporting the test results to the facility/provider of record.

All newborn blood spot forms and maternal serum specimens for Iowa patients shall be submitted to the SHL for testing.

The Center for Congenital and Inherited Disorders (CCID) also provides oversight for the Iowa Stillbirth Surveillance Project and the Family Health History initiative.

Contact information:                   Center for Congenital and Inherited Disorders  
                                                   Iowa Department of Public Health  
                                                   321 E. 12<sup>th</sup> Street  
                                                   Lucas State Office Building  
                                                   Des Moines, IA 50319-0075  
                                                   1-800-383-3826

Information about CCID programs, *Iowa Code*, *Iowa Administrative Rules* and genetics resources may be found on the Iowa Department of Public Health website, available at: [www.idph.state.ia.us/genetics](http://www.idph.state.ia.us/genetics), accessed June 6, 2013.

## Appendix 10. Newborn Hearing Screening

### Goal and Outcomes of Newborn Hearing Screening

This protocol is intended to provide guidelines for personnel providing newborn hearing screening in order to be in compliance with *2003 Iowa Code* and *Iowa Administrative Rules*, legislation mandating newborn hearing screening and reporting.<sup>3</sup> It has long been recognized that unidentified hearing loss at birth can adversely affect speech and language development as well as academic achievement and social-emotional development.<sup>1</sup> The goal of universal hearing screening of all newborns and infants in Iowa is early detection of hearing loss to allow children and their families the earliest possible opportunity to obtain appropriate early intervention services.

National recommendations are to have infant's hearing screened before one month of age, hearing loss identified by three months of age and early intervention services in place by six months of age.

### Goal of Iowa Newborn Hearing Screening Protocol

This protocol is intended to provide guidelines to personnel providing newborn hearing screening in Iowa in accordance with *2003 Iowa Code* and *Iowa Administrative Rules*, legislation mandating newborn hearing screening and reporting in Iowa.

### Personnel

Every birth hospital or birth center shall designate an employee to be responsible for the newborn hearing screening program in that institution.

Newborn hearing screen shall be performed by an audiologist, audiology assistant, audiometrist, registered nurse, licensed physician, or other person for whom newborn hearing screening is within the person's scope of practice.

### Responsibility of Birth Facility

If the infant is born in a birthing hospital, hearing screening shall be performed prior to discharge, except in the following circumstances:

1. The newborn is transferred for acute care prior to completion of the hearing screening.
2. The newborn is born with a condition that is incompatible with life.

If the infant is born in a birthing center, that center shall refer the newborn to an audiologist, physician or hospital for newborn hearing screening. Before discharge of the newborn, the birth center shall arrange an appointment for the newborn hearing screening and report to the parent the appointment time, date and location. The newborn hearing screen should take place no later than one month of age.

If the infant is born in a location other than a birthing hospital or birthing center, the physician or other health care professional who undertakes primary pediatric care of the newborn shall refer the newborn to an audiologist, physician, or other hospital for completion of the newborn hearing screen no later than one month of age. The health care professional who undertakes primary pediatric care of the newborn shall arrange an appointment for the newborn hearing screening and report the appointment time, date, and location to the parent.

**Technology**

All newborns and infants born in Iowa, except those born with a condition that is incompatible with life, shall be screened for hearing loss using at least one of the following procedures:

1. Automated or screening auditory brainstem response (ABR), or
2. Evoked otoacoustic emissions (OAE)

**Test Parameters and Pass Criteria for DPOAE, TEOAE, and ABR****DPOAE****Collection Parameters**

Stimulus type: 2 primary pure tones, response measured at  $2f_1-f_2$  for each stimulus tone pair

Stimulus intensity: L1 65 dB SPL, L2 55 dB SPL

Frequency ratio ( $f_2/f_1$ ): 1.22

F2 Frequency region: 2-5 kHz

**Pass Criteria**

Response presence can be determined by examining response level or by examining the response level relative to the noise floor (SNR) (ASHA 2004). SNR should be at least 6 dB, with a minimum response level of -5 to -8 dB SPL and an acceptably low noise floor (-4 dB SPL or less) at a minimum of 3 of 4 F2 frequencies.

**TEOAE****Collection Parameters**

Stimulus type: click

Click rate: 50-80 per second

Stimulus intensity: 78-82 dB SPL

Frequency region: 1-5 kHz

**Pass Criteria**

Common clinical practice defines presence of a response as a SNR of at least 6 dB, or an overall minimum amplitude (wideband) response of 6 dB, with a reproducibility of 50 percent or greater.

**ABR****Stimulus Parameters**

Stimulus type: 0.1 msec click

Intensity: 35 dB HL

**Stopping Criteria for Newborn Hearing Screening**

Many factors influence the outcome of a hearing screen, such as technology used, skill of the screener, the state of the baby, the noise level in the room, the age at which the infant is tested, and the hearing sensitivity of the baby. To reduce the refer rate at the time of discharge, babies who refer on the first screen are often tested again. While this is a viable means of reducing the false positive rate (referring babies with normal hearing), excessive retesting can increase the false negative rate (passing babies with actual hearing loss).

No guidelines are currently available that address the number of times a hearing screen should be repeated on a baby before hospital discharge or at outpatient follow-up. The following guidelines can be used until published data are available. Because birthing debris in the ear canal is the primary cause of false positive results, the preferable age of initial testing is at least 24 hours of age in the well-baby nursery and no less than 12 hours unless the family is planning to leave. The recommended age for children in the NICU for a longer period of time is at least five days of age. Ear canal massage between tests is recommended.

### **OAE Screening in the Well-baby Nursery**

Assuming that test conditions are adequate (quiet baby, quiet room, acceptable probe fit) two test sessions of no more than three tests per ear are recommended, for a total of six tests per ear. The test sessions should be conducted several hours apart.

### **ABR Screening in the Well-baby Nursery**

Assuming that test conditions are adequate (quiet baby with little or no muscle movement, quiet room, acceptable electrode impedance and headphone placement), no more than two tests per ear are recommended. The tests should be conducted several hours apart.

### **Two-stage Screening in the Well-baby Nursery (OAE followed by ABR)**

Assuming that test conditions are adequate (see above), no more than three OAE's followed by one ABR per ear are recommended. Testing should be conducted in one to two sessions. If a child does not pass with ABR, the child must be referred to a hospital/audiology clinic that is able to rescreen the child with ABR as recommended by the Joint Committee for Infant Hearing Screening.<sup>1</sup>

### **ABR Tests in the NICU**

It is recommended that all NICU babies be tested with ABR. The baby should be tested close to the time of discharge. If test conditions are adequate and the baby is at least five days of age, recommended stopping criteria are one test per ear. If the baby is less than five days old, follow the well-baby protocol.

### **Outpatient Follow-up**

Outpatient follow-up screening can be accomplished at some birthing hospitals, Area Education Agency (AEA) offices, audiology clinics, or Child Health Specialty Clinics in Iowa. Assuming that the babies are at least five days of age and test conditions are adequate, recommended stopping criteria for OAE's are three tests per ear. If a baby passes on the third attempt, the test should be immediately repeated. If the pass result cannot be replicated, the result should be recorded as "a refer." Proceed to ABR. **Scheduling a second outpatient OAE rescreen is not recommended.** Stopping criteria for screening ABR is one test per ear. Scheduling a second outpatient screening ABR is not recommended. Instead, proceed to a comprehensive evaluation following Recommended Guidelines for Pediatric Audiologic Assessment.

### **Guidelines for Children with Risk Factors for Delayed Onset or Progressive Hearing Loss**

Iowa's Early Hearing Detection and Intervention (EHDI) program follows children who pass their birth screen and are identified with Risk factors for delayed onset or progressive hearing loss based on Joint Committee on Infant Hearing (JCIH) indicators. Known risk factors) (e.g.

cranio-facial anomalies, exchange transfusion for elevated bilirubin, family history of hearing loss, NICU > 5 days) are listed by JCIH at:

<http://pediatrics.aappublications.org/content/120/4/898.full.pdf+html>, accessed June 26, 2013.

Some risk factors are of greater concern for delayed onset hearing loss and require closer monitoring. Families and Primary Care Providers (PCPs) receive risk factor letters from EHDI when the child is 3 months old as a reminder that the child needs to have an audiological assessment by 6 or 24-30 months of age depending on risk indicated. An audiologist with skills and expertise in evaluating newborns and young infants with hearing loss should conduct the assessment. In addition, if caregiver or parental concerns arise about speech, hearing or communication development, the child should be referred for an audiology assessment. Staff at Child Health Specialty Clinics are available to answer questions about risk factors and can provide locations offering audiology assessment; call (319) 356-3570.

### **Parental Notification**

If at the time of hearing screening a child is known to have risk factors for delayed onset hearing loss (as set forth in the recommendations of JCIH), the parents should be notified about the risk factors present along with the results of the birth screen. Although not required by law, it is strongly recommended that hospital staff discuss the results verbally in language the parents can understand and assist the family with scheduling recommended follow up screening. The parents and primary care provider will also be notified by written letter from EHDI about the risk factors present along with the results of the birth screen.

### **Parental Refusal**

Although parental consent is not necessary to perform newborn hearing screening, parental objection to the screening is valid. If a parent refuses the newborn hearing screen, obtain a written refusal from the parent or guardian, the form is available at:

<http://www.idph.state.ia.us/IAEHDI/>, accessed June 26, 2013. Maintain the original copy in the infant's medical record. A copy of the refusal should be sent to the Iowa Department of Public Health within six days of the infant's birth.

### **Reporting Hearing Screening Results and Information to the Iowa Department of Public Health**

Iowa law provides that birthing hospitals, birth centers, physicians, any facility including Area Education Agencies (AEAs), audiologists and other health care professionals are legally required to report to the Iowa Department of Public Health (IDPH) the results of a hearing screen, re-screen, or diagnostic assessment for any child under three years of age.<sup>3</sup>

The following information shall be reported to the Iowa Department of Public Health within six days of the birth of the newborn, utilizing the department's designated reporting system:

1. The name and date of the birth of the newborn.
2. The name, address and telephone number, if available, of the mother of the newborn. If the mother is not the person designated as legally responsible for the child's care, the name address and telephone number of the guardian shall be reported.
3. The name of the primary care provider for the newborn at the birthing hospital or birth center.

4. The results of the newborn hearing screening, either ‘pass’, ‘refer’, or ‘not screened’, for each ear separately.
5. The results of any rescreening, either ‘pass’ or ‘refer’, and the diagnostic audiologic assessment procedures used for each ear separately.
6. Known risk indicators for hearing loss of the newborn or infant.

### **Confidentiality**

Reports, records, and other information collected by or provided to the Iowa Department of Public Health relating to a child’s newborn hearing screening, rescreen, and diagnostic audiologic assessment are confidential records. The confidentiality of all the information and records used in its review shall be maintained by the personnel of the department. No individual or organization providing information to the department in accordance with its rules shall be deemed to be or held liable for divulging confidential information.

If you have questions about the Iowa EHDI system or where you can find hearing-related services for children, please contact: State EHDI Coordinator, Iowa Department of Public Health; phone: (515) 242-5639 or (800) 383-3826; EHDI website available at: <http://www.idph.state.ia.us/iaehdi/default.asp>, accessed June 26, 2013.

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1. American Academy of Pediatrics, Joint Committee on Infant Hearing. Policy Statement—Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs. *Pediatrics*. 2007; 120(4):898-921. Available at: <http://pediatrics.aappublications.org/cgi/content/full/120/4/898>. Accessed June 5, 2013.
  2. *Iowa Administrative Code 641*, Chapter 3. Early Hearing Detection and Intervention.
  3. *2003 Iowa Code*, Chapter 135.131. Available at: [http://www.idph.state.ia.us/iaehdi/common/pdf/iaehdi\\_law.pdf](http://www.idph.state.ia.us/iaehdi/common/pdf/iaehdi_law.pdf). Accessed June 9, 2013.

**Appendix 11. Neonatal Transport-Medical and Legal Concerns**

Neonatal transport teams are involved in very high-risk transport situations; therefore, prior attention to potential legal problems is advisable. The institution that employs the team is responsible for its actions, and a physician at that institution directs the team's activities. The goals of a neonatal transport team include stabilization of the neonate and initiation of advanced care at the referring hospital with continuation of critical care therapies and monitoring en route to the receiving facility. Transport services should have detailed job descriptions, policies and procedures that guide transport personnel in the care of critically ill newborns. In 2007, the American Academy of Pediatrics' Section on Transport Medicine published the "Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients, 3<sup>rd</sup> Edition."<sup>1</sup> This revised and updated resource provides comprehensive guidelines for health care professionals on emergency interfacility transport of neonates and children.

The referring hospital is responsible for coordinating the transfer. EMTALA requires the transferring physician to certify in writing that at the time of the transfer: 1) the benefits of the transfer outweigh the risks; 2) the patient (parent or surrogate) has given informed consent for the transfer; 3) and appropriate transfer has been arranged. If no parent or surrogate is available to provide consent, the transfer may proceed under implied consent. The physician should be as thorough as possible when documenting the benefits and risks of transfer. EMTALA does not require transporting services to obtain a separate consent.

Before transport, the referring institution should understand the degree of its responsibility to the patient being transported. During a transport, there is a gradual shift in responsibility from the referring facility to the transport team and then to the receiving facility. The transport team should lead the process of preparing the patient for transfer. However, the referring physician and medical personnel share the responsibility for the patient's medical care until the patient physically leaves the hospital. If the transferring physician disagrees with the plan of the transport team, the team must defer to the transferring physician while the patient is still in the referring hospital. The departure of the transport team from the premises of the referring hospital may be considered the official point of transfer of responsibility from the referring physician to the transport team. The receiving facility and staff begin to acquire medical responsibility for a patient when the patient arrives at the hospital and they become aware of his presence, even if the patient is being attended to by the transport team.

An institution should always perform within its capability and should not accept patients whose care exceeds that capability. Hospitals in each region should determine their level of commitment to emergency or specialty care. They should operate within those boundaries and within their designated level of service in Iowa's regionalized system of perinatal care. Hospitals that are designated as a Level II Regional, Level II Regional Neonatology and Level III referral center are required to maintain a functional neonatal transport team. In general, transport of neonates should not be done by Level I or Level II facilities. If a referring hospital refuses a transport team after it has been recommended, it is important for the receiving hospital to document the refusal in writing.

The medical control physician should make a decision regarding the acceptance of a neonatal transport promptly after the initial request. The availability of neonatal inter-facility transport services does not preclude the need to provide resuscitation and emergency care at the referring facility. The receiving facility and medical control physician must ensure that the skills and equipment available during transport will meet the anticipated needs of the patient. If the referring hospital chooses to perform its own transport for the purpose of “saving time” and getting the patient to the receiving hospital sooner, they must understand that they are *fully* responsible for the patient until arrival at the receiving institution. The referring physician and hospital may be held liable for using inappropriate transport services.

An appropriate transfer occurs when the:

- Transferring hospital has provided medical care within its capacity to minimize risk to the patient’s health (or to unborn child of a woman in labor)
- Receiving hospital has agreed to accept the patient and has the space and resources available for treatment
- Transferring hospital sends available medical records with the patient
- Transfer is effected by qualified personnel and transportation equipment

#### Transport Supervision

The medical director should be a specialist in pediatrics and sub-specialist in pediatric critical care, pediatric emergency medicine or neonatology. The medical director should be available to the team 24 hours a day or should clearly designate an appropriate physician for alternative coverage. The transport coordinator is a registered nurse who coordinates the day-to-day activities of the transport team. This position is often the equivalent of a head nurse for the transport team. A designated medical control physician (MCP) should be available 24 hours a day and be able to respond promptly to transport or consultation requests. This person must be experienced in handling transport calls and in offering management suggestions for the period before the arrival of the transport team. The MCP should be knowledgeable about the availability or resources such as beds and transport teams, and must have authority to accept transferred patients without further consultation. The MCP must be able to triage and activate back-up systems when necessary and is responsible for team composition, selection of carrier, and the clinical care provided during transport. The MCP should communicate with the referring physician when necessary, especially in the period between the initial call and the arrival of the transport team at the referring institution.

#### Experience and Background Training of Staff

Each transport nurse will be currently licensed as a registered nurse by the Iowa Board of Nursing. Specific training and experience in the care of critically ill neonates is necessary. This background should include a minimum of one year of full time staff nurse experience in a Level IIR, Level IIRN or Level III NICU. The transport nurse must be able to provide appropriate care for the patient being transported by air/ground from the time of arrival at the referring hospital, while the patient is loaded on the aircraft/ground transport vehicle and during the transport until the time the patient is admitted to the neonatal center.

#### Guidelines for Training of Personnel Involved in Transport

Each transport nurse shall be able to provide care necessary for life support and/or stabilization of the patient during transport. Responsibilities shall include a working knowledge of all equipment used during transport. All transport nurses should have successfully completed and be current in Basic Life Support (BLS) and Neonatal Resuscitation Program (NRP). Certification by the S.T.A.B.L.E. Program is highly recommended. Continuing education, training, competency and quality review should be documented to ensure that the team members remain qualified to perform necessary services and procedures.

All transport nurses should be proficient in the following procedures:

- Bag-mask ventilation
- Intubation
- Insertion of laryngeal mask airway (LMA)
- Operation of transport ventilator (if available)
- Use of oxygen therapy devices (e.g., masks, nasal cannula)
- Intravenous line placement.
- Umbilical catheter placement.

The development of an effective neonatal inter-facility transport service requires multiple resources, but in particular, needs skilled healthcare professionals trained and experienced in neonatal transport. In order to maintain these resources in a cost-effective manner, a minimum volume of neonatal transport patients is required. Substantial commitment from hospital administration is necessary to provide a system that will meet the goal of safe, skilled neonatal transport.

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- American Academy of Pediatrics (2007). Guidelines for Air and Ground transport of Neonatal and Pediatric Patients (3<sup>rd</sup> Edition). Elk Grove Village, IL.

## Appendix 12. Discharge Planning and Health Education

The following are guidelines for minimum discharge education that should be provided to parents or care taker prior to discharge of mother and baby from the hospital:

1. **Umbilical cord care.** Research has shown that umbilical cord drying time is decreased with as needed cleaning of the cord with water rather than alcohol. Parents should notify their physician if the cord or skin around the cord is reddened or has foul-smelling drainage.
2. **Voiding and stooling patterns.**
3. **Breastfeeding education.** Position, latch-on, and adequacy of swallowing. Breastfed babies should be fed every 1-1/2 to 3 hours to total 8-12 feedings in a 24-hour period. Parents should understand that 6-8 wet diapers/day indicate adequate oral intake.
4. **Formula preparation.**
5. **Newborn skin care/rashes.**
6. **Jaundice.** Recent research has shown that even moderate degrees of hyperbilirubinemia are associated with an increase in minor neurologic dysfunction throughout the first year of life. Follow-up should be provided within two days of discharge for all neonates discharged < 48 hours after birth. Early follow-up is particularly important for infants of < 38 weeks' gestation. Parents should be taught to notify the baby's physician if jaundice extends to the lower extremities, if the baby is not eating well, or if the baby is lethargic.
7. **Bathing.**
8. **Positioning.** To reduce the risk of SIDS, infants should be placed on their backs to sleep. All babysitters and daycare providers need this instruction as well. It is necessary to provide supervised "tummy time," that is, time when the baby is awake and observed by the parents or caregivers at all times, to help prevent head-positioning deformities, and encourage development of upper body, trunk and neck strength.
9. **Smoking.** Parents should be taught that smoking around their baby increases the risk of SIDS and some respiratory ailments. Parents who smoke should be provided with information on smoking cessation programs. One evidence based program free to all Iowans is Quitline Iowa, a toll free telephone tobacco cessation program that can be reached by dialing 1-800-QUIT NOW (1-800-784-8669). Parents should be encouraged to leave the house to smoke, and to not smoke in the car. They should ask child care providers to not smoke around the baby as well. All children benefit from smoke free environments. For more information go to [www.quitlineiowa.org](http://www.quitlineiowa.org).
10. **Bed-sharing.** Parents should be aware that bed-sharing increases the risk of SUID/SIDS (for definition of these terms and more information see appendix X) and death from suffocation, overlying and entrapment.
11. **Warning signs for the infant.** Parents should be encouraged to call their physician for any of the following signs in the newborn:
  - Breathing difficulties
  - Seizures, loss of consciousness
  - Lethargy, irritability
  - Decreased feeding for 24 hours
  - Vomiting more than one to two entire feeds in one day, or projectile vomiting
  - No urine output for more than 12 hours
  - Bowel movements that are black, watery, loose, or of increased frequency

- Reddened umbilical site
  - Redness, drainage, swelling, foul odor around circumcision site
  - Jaundice covering abdomen/extremities
  - Pustules/rashes other than normal newborn rashes
  - White patches on the mouth that remain after the mouth is gently wiped with a wet cloth or that cannot be removed with gentle scraping
  - Axillary temperature under 97.7°F (36.4°C) or over 100°F (37.8°C). Demonstrate temperature taking and reading a thermometer
  - Any baby who appears “ill”
12. **Importance of regular medical checkups.** The first newborn visit should be two to three days after discharge in infants discharged at < 48 hours of age. Those infants discharged at > 48 hours should be seen at one to two weeks of life by a health care practitioner, unless conditions exist that require a visit sooner.
13. **Infant safety concerns.** Includes the following:
- Car seat safety<sup>5</sup>
  - Crib safety<sup>6</sup>
  - Sun safety
  - Infection control (limiting contact)
14. **Discharge follow-up.** All infants discharged prior to 72 hours should be followed for newborn jaundice and weight check within 48 hours of discharge.
15. **Instruction in self-care for the mother.** Includes the following:
- Perineal self-care and hand washing
  - Involution, lochial flow and breast changes
  - Signs of hemorrhage
  - Recognition of signs of infection
  - Introduction to family planning and contraception principles
  - Introduction to stress management and strategies for coping with parenting responsibilities
  - Maternal depression
  - Follow-up care
16. **Warning signs for the mother.** Includes the following:
- Fever over 100.4°F (38°C)
  - Reappearance of bright red color in lochia that has turned brownish
  - Vaginal discharge with a foul odor or accompanied by irritation
  - Excessive bleeding or large clots
  - Swelling of legs, particularly if this is painful, red, or warm to touch
  - Burning or painful sensation upon urination, frequent urination or inability to urinate
  - Pain in the pelvic or perineal area
  - Severe headache, blurred vision
  - Swelling in the face or around the eyes
  - Persistent or severe mood swings
  - Thoughts of harming herself or the baby

### Early Discharge of the Mother and Infant

The Newborns' and Mothers' Health Protection Act of 1996 provides minimum federal standards for health plan coverage for mothers and their newborns, including those who are discharged from the hospital in less than 24 hours. Under the act all health plans are required to allow the new mother and newborn to remain in the hospital for a minimum of 48 hours after a normal vaginal birth and for 96 hours after a cesarean birth unless the attending provider, in consultation with the mother, decides upon an earlier discharge. Discharge planning should begin with the first contact with the health care provider.

When discharge is considered before 48 hours, the American Academy of Pediatrics (AAP) recommends limiting this practice to singleton infants who are born between 38 and 42 weeks of gestation, who are birth-weight appropriate for gestational age, and who meet the following criteria:

- Uncomplicated antepartum, intrapartum and postpartum course for both the mother and the infant
- Physical exam completed by physician, nurse midwife, nurse practitioner, or physician's assistant prior to discharge of both mother and the infant.
- Vaginal birth
- Newborn vital signs are documented as within normal limits and stable for 12 hours before release:
  - ▶ Respiratory rate below 60 breaths per minute
  - ▶ Heart rate of 100-160 beats per minute
  - ▶ Axillary temperature of 97.7° to 99.3° (36.5° C to 37.4°C) measured in an open crib with appropriate clothing
- Newborn has spontaneously passed at least two successful feedings and can coordinate suck, swallow and breathing with feeding
- Infant has voided and passed one stool
- Evaluation of clinically significant jaundice, if present, has been completed and follow-up plans are in place
- Physical assessment shows no abnormalities requiring continued hospitalization
- Bleeding at circumcision site is not excessive for at least two hours post procedure
- All immediately necessary vaccines have been administered, e.g., hepatitis B, according to current immunization schedules
- Screening tests have been performed as required by state regulations, including HIV
- Newborn hearing screening has been completed per state regulations
- Cord or infant blood type and direct Coombs test results, as indicated, have been reviewed
- Pulse-oximetry screening for Critical Congenital Heart Disease (CCHD) is complete, and baby has a negative (normal) screen. (See Appendix EE, *Guidelines for Newborn Screening for Critical Congenital Heart Disease*)

In their compendium of postpartum care the Association of Women's Health Obstetric and Neonatal Nurses (AWHONN) recommends the following for preparing the mother for discharge<sup>8</sup>:

- Maternal vital signs are documented as within normal limits and stable:
  - ▶ Temperature less than 100.4°F (38°C)
  - ▶ Pulse less than 100 beats per minute

- ▶ Blood pressure more than 90/60 mmHg and less than 140/90 mmHg, and/or consistent with the prenatal course
- ▶ Fundus firm without excessive bleeding
- ▶ Able to void without difficulty
- ▶ Rh status of mother determined and RhoGam given if indicated
- ▶ Ambulation tolerated
- Follow-up for medical care is documented.
- Mother's knowledge, skill and confidence to provide adequate care for baby are documented by the fact that she has received education regarding the following:
  - ▶ Breastfeeding or bottle feeding (The breastfeeding mother-infant dyad should be assessed by trained staff regarding nursing position, latch-on, feeding frequency, and adequacy of swallowing)
  - ▶ Knowledge of infant's urine and stool frequency
  - ▶ Cord, skin and infant genital care
  - ▶ Recognition of signs of illness and common infant problems, particularly jaundice
  - ▶ Proper infant safety (i.e., proper use of a car seat and positioning for sleep)
- Mother has received instruction in self-care about:
  - ▶ Perineal self-care and hand washing
  - ▶ Involution, lochial flow and breast changes
  - ▶ Signs of hemorrhage
  - ▶ Recognition of signs of infection
  - ▶ Introduction to family planning and contraception principles
  - ▶ Introduction to stress management and strategies for coping with parenting responsibilities
  - ▶ Maternal depression
  - ▶ Follow –up care
- Laboratory data were available and reviewed, including:
  - ▶ Maternal syphilis and hepatitis B surface antigen status
  - ▶ Cord blood (Type, RH, direct Coombs')
  - ▶ Other tests as clinically indicated
- A source of continuing health care (Medical Home) for the mother and infant has been identified.
- Family, environmental and social risk factors have been assessed.
- Family members or other support person(s), including health care providers who are familiar with newborn care, are available to the mother and baby the first few days after discharge.
- Prior to discharge from the hospital verify the identification tags of both mother and the infant.

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1. American Academy of Pediatrics and American College of Obstetricians and Gynecologists (2012). *Guidelines for Perinatal Care (7th Edition)*. Chapter 8. Elk Grove Village, IL
  2. American Academy of Pediatrics, Subcommittee on Hyperbilirubinemia. Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation [published correction appears in *Pediatrics*. 2004; 114(4):1138]. *Pediatrics*. 2004;114(1):297-316. Available at: <http://pediatrics.aappublications.org/content/114/1/297>. Accessed June 5, 2013.
  3. Dore S, Buchan D, Coulas S, Hamber L, Stewart M, Cowan D, Jamieson L. Alcohol Versus Natural Drying for Newborn Cord Care. *JOGNN*. 1998; 27(6):621-627.
  4. Thureen P, Deacon J, O'Neill, Hernandez J (1999). *Assessment and Care of the Well Newborn*. Philadelphia, PA: W.B. Saunders Co.
  5. American Academy of Pediatrics, Committee on Injury, Violence, and Poison Prevention, Committee on Fetus and Newborn, Bull MJ, Engle WA. Clinical Report—Safe Transportation of Preterm and Low Birth Weight Infants at Hospital Discharge. *Pediatrics*. 2009; 123(5):1424-1429. Available at: <http://pediatrics.aappublications.org/content/123/5/1424>. Accessed June 11, 2013.
  6. US Consumer Product Safety Commission. Crib Information Center. Available at: <http://www.cpsc.gov/info/cribs/index.html>. Accessed June 11, 2013.
  7. American Academy of Pediatrics, Council on Environmental Health, Section on Dermatology, Balk SJ. Technical Report—Ultraviolet Radiation: A Hazard to Children and Adolescents. *Pediatrics*. 2011; 127(3):e791-e817. Available at: <http://pediatrics.aappublications.org/content/127/3/e791>. Accessed June 11, 2013.
  8. Association of Women's Health, Obstetric and Neonatal Nurses (2006). *The Compendium of Postpartum Care*, Washington D.C.: AWHONN.
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## Appendix 13. Iowa High Risk Infant Follow-up Program

Iowa High Risk Infant Follow-up Program screening evaluations are recommended for high-risk NICU patients at ages 4, 9, and 18 and 30 months of age. The screening evaluation consists of a developmental, neurological and physical assessment performed by a physician or pediatric nurse practitioner that has had training in developmental assessment. See below for the admission criteria.

Level II Regional Centers and higher-level perinatal services are expected to participate in the Iowa High Risk Infant Follow-up Program, or develop an independent high-risk infant follow-up program. Assistance with the program may be obtained from:

Iowa High Risk Infant Follow-up Program  
The University of Iowa  
200 Hawkins Drive, 8900 JPP  
Iowa City, IA 52242-1011  
(319) 353-6880

### Admission criteria for the Iowa High Risk Infant Follow-up Program:

1. Birth weight < 1500 grams or less than 33 weeks gestation
2. Respiratory Distress Syndrome requiring mechanical ventilation for  $\geq 2$  hours
3. Other forms of respiratory distress requiring mechanical ventilation for  $\geq 2$  hours
4. Clinical diagnosis of central nervous system infection
5. Perinatal depression as evidenced by a five-minute Apgar score of  $\leq 6$
6. Hypoglycemia as proven by two consecutive true blood glucose levels of  $\leq 30$  mg/dl
7. Neonatal seizures as documented by physician observation with concurrence of a staff neonatologist, or by an attending pediatrician in a Level II-Regional, Level II- Regional Neonatal, or Level III Center
8. Infants demonstrating hypotonia on discharge examination
9. Polycythemia - central hematocrit of  $\geq 65\%$  or 60-64% with signs and partial exchange transfusion, with resolution of signs occurring within the first 24 hours of life
10. Maternal substance abuse during pregnancy
11. Infants not included in criteria 1-10, but felt to be at risk by an attending physician:

Examples include:

- a) Sepsis
- b) Small for gestational age (SGA)
- c) Severe hyperbilirubinemia (total bilirubin of 20mg/dl or greater)
- d) Chorioamnionitis
- e) Intraventricular hemorrhage
- f) Multiple birth, if one sibling meets criteria
- g) Intrauterine transfusion
- h) Babies entering living environments that present severe psychosocial concerns
- i) Other as defined locally
- j) Physician request

Infants moving into Iowa from other states are accepted if one or more of the above criteria occurred within the neonatal period.

## Appendix 14. Outreach Education

Each Level II Regional and higher hospital provides outreach education to the referral area it serves. The purpose of the outreach education is to meet the needs of the hospitals being served and is based on a needs assessment of those hospitals. It is recommended that Level II Regional, Level II Regional Neonatology Centers, and Level III Centers have contact at least once each year with each referring hospital. This contact may consist of:

- direct visits
- visits by referring hospital personnel
- an annual regional program
- written materials prepared by Level II Regional Center, Level II Regional Neonatology Center and Level III Center personnel with distribution to the referral area

The Statewide Perinatal Care Program (SPCP), through the Iowa Regionalized System of Perinatal Health Care (IRSPHC) with oversight and funding from the Iowa Department of Public Health, provides outreach education to the state of Iowa. The content of the educational contacts is as outlined above.

The Statewide Perinatal Program keeps a record of educational contacts with its surrounding areas and provides this record to the IRSPHC upon request.

## Appendix 15. Pregnancy and HIV (Human Immunodeficiency Virus)

Since 1994, the United States Public Health Service has recommended universal, voluntary testing of pregnant women. The decrease in mother-to-child (perinatal) HIV transmission is a public health achievement in HIV prevention in the United States. Nationally, the number of infants infected with HIV through perinatal transmission has decreased from 1,650 cases during the early- to mid-1990s to fewer than 240 cases in 2002. This decline is attributed to multiple interventions, including routine, voluntary HIV testing of pregnant women, the use of rapid HIV tests at delivery for women of unknown HIV status, and the use of antiretroviral therapy by HIV-infected women during pregnancy and by infants after birth.

While the need for pregnant women to know their HIV status was recognized early in the epidemic as a key step to preventing perinatal transmission, testing efforts to date have often focused on risk-based screening or voluntary, opt-in systems of testing. These types of systems have been shown to be only moderately successful at achieving testing of pregnant women, in part because they depend on the ability of a health care provider to discern potential risk behaviors and on the enthusiasm with which the provider recommends the testing.<sup>1</sup>

In September 2006, the Centers for Disease Control and Prevention (CDC) released the *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*, available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>, accessed June 11, 2013. These new recommendations, which replace CDC's 1993 *Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings*, advise universal, opt-out testing for pregnant women. The CDC recommendations include the following:

- All pregnant women in the United States should be screened for HIV infection.
- Health care providers should test women for HIV as early as possible in the pregnancy.
- Screening should occur after the patient is notified that:
  - a) HIV screening is recommended for all pregnant patients; and
  - b) She will receive an HIV test as part of the routine panel of prenatal blood tests, unless she declines (i.e., opt-out screening).
- HIV testing must be voluntary and free of coercion.
- Pregnant women should receive oral or written information that includes an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant, and the meanings of positive and negative results.
- No additional process or written documentation of informed consent should be required for HIV tests beyond that for other routine prenatal tests.
- Pregnant women should be given the opportunity to ask questions and to decline testing. If a patient declines testing, this decision should be documented in the medical record.
- Health care providers should discuss and address reasons for declining an HIV test (e.g., lack of perceived risk, fear of the disease, and concerns regarding partner violence or potential stigma or discrimination).
- Women who decline the test early in prenatal care should be encouraged to be tested at a subsequent visit.

- A second HIV test during the third trimester, preferable <36 weeks of gestation may be considered for all pregnant women, and is recommended for women with risk factors (e.g., injection drug users and their sex partners, women who exchange sex for money or drugs, women who are sex partners of HIV-infected persons, and women who have had a new or more than one sex partner during this pregnancy) or who have signs or symptoms consistent with acute HIV infection.
- Any woman with an undocumented HIV status at the time of labor should be screened with a rapid HIV test unless she declines (opt-out screening).
- When a woman's HIV status is still unknown at time of delivery, she should be screened immediately postpartum with a rapid HIV test unless she declines (opt-out screening).
- Immediate initiation of appropriate antiretroviral prophylaxis should be recommended to women on the basis of a reactive rapid test result without waiting for the result of a confirmatory test.
- When the mother's HIV status is unknown postpartum, rapid testing of the newborn as soon as possible after birth is recommended so antiretroviral prophylaxis can be offered to HIV-exposed infants. Women should be informed that identifying HIV antibodies in the newborn indicates that the mother is infected.

<p><b><i>IOWA REQUIREMENTS AND GUIDELINES FOR HIV TESTING DURING PREGNANCY</i></b></p>
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*Iowa Code Chapter 141A* governs HIV testing. On July 1, 2007, new provisions took effect. The following requirements and guidelines are consistent with Iowa Code. Requirements of Iowa Code are indicated by a code citation following the entry.

#### **A. Pretest Education**

*Required:*

- Information about HIV prevention, risk reduction, and treatment opportunities to reduce the possible transmission of HIV to a fetus shall be made available to all pregnant women. (141A.4)
- Prior to undergoing an HIV test, information shall be available concerning testing and how to obtain additional information about HIV infection and risk reduction. (141A.6)

*Recommended:*

- All health care providers of pregnant women should be knowledgeable about HIV in pregnancy, the treatment needed to protect infants of HIV-positive mothers, how to discuss HIV and risk factors with patients, and how to refer HIV-positive and high-risk patients for other support services.
- All pregnant women should receive the required information as early as possible during the prenatal period.
- The opportunity for the woman to ask questions about HIV should be provided in a supportive manner by the health care provider.

#### **B. Consent**

*As part of routine prenatal testing:*

The State of Iowa deems consent for all pregnant women when tested as part of routine prenatal testing (Iowa Code 141A.4). No written or oral consent is required. However, special provisions for minors apply. A pregnant minor must be informed by the health care provider that the minor's legal guardian will be notified by the health care provider if the HIV test is confirmed as positive. Minors are not required to sign a separate consent to this effect.

### **C. Testing**

#### *Required:*

- All pregnant women shall be tested for HIV infection as part of the routine panel of prenatal tests. (141A.4)
- A pregnant woman shall be notified that HIV screening is recommended for all prenatal patients and that the pregnant woman will receive an HIV test as part of the routine panel of prenatal tests unless she objects to the test. (141A.4)
- If a pregnant woman objects to and declines the test, the decision shall be documented in her medical record. (141A.4)

#### *Recommended:*

Testing should occur as early in the pregnancy as possible.

- Health care providers should discuss and address reasons for declining an HIV test (e.g., lack of perceived risk, fear of the disease, and concerns regarding partner violence or potential stigma or discrimination), and encourage women who decline the test early in prenatal care to be tested at a subsequent visit.
- A second HIV test during the third trimester, preferable <36 weeks of gestation may be considered for women with risk factors (e.g., injection drug users and their sex partners, women who exchange sex for money or drugs, women who are sex partners of HIV-infected persons, and women who have had a new or more than one sex partner during this pregnancy) or who have signs or symptoms consistent with acute HIV infection.

### **D. Post-test Counseling**

#### *Required:*

Post-test counseling is required only if the test is positive.

- At any time that the subject of an HIV test is informed of confirmed positive test results, counseling concerning the emotional and physical health effects shall be initiated. Particular attention shall be given to explaining the need for the precautions necessary to avoid transmitting the virus. The subject shall be given information concerning additional counseling. (141A.7)

#### *Recommended:*

- The HIV-positive patient should be referred to an HIV specialist for follow up.
- Partner notification should be explained to the patient at this time. Newly diagnosed persons will be contacted by a state or local health department disease prevention specialist to assist them in notifying partners who may also be infected with HIV.

### **E. Testing of the Newborn When the Mother's HIV Status is Unknown**

#### *Not Consistent with Iowa Code:*

The CDC recommends HIV testing of newborns immediately after birth when the HIV status of the mother has not been determined. However, testing of a newborn without the consent of a legal guardian is not consistent with Iowa Code 141A.6 unless the legal guardian cannot be

located or is unavailable and the test results are necessary for diagnostic purposes to provide appropriate urgent medical care.

### ***RECOMMENDATIONS FOR PREGNANT HIV-INFECTED WOMEN***

The Public Health Service Task Force issued revised *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States* on October 12, 2006. It is emphasized that concepts relevant to HIV management evolve rapidly. The Task Force has a mechanism to update recommendations on a regular basis, and the most recent information is available on the **AIDSinfo Web site**, available at: <http://AIDSinfo.nih.gov> , accessed June 11, 2013.

#### **Resources**

For questions regarding the clinical management of HIV/AIDS, contact:

- *Iowa Department of Public Health*  
Bureau of HIV, STD, and Hepatitis: (515) 242-5150  
HIV Partner Notification Assistance Program: (515) 242-5141
- *National Perinatal HIV Hotline*  
(888) 448-8765

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1. Royce RA, Walter EB, Fernandez MI, Wilson TE, Ickovics JR, Simonds RJ. Barriers to universal prenatal HIV testing in 4 US locations in 1997. *Am J Public Health.* 2001; 91:727-733.

## Appendix 16. Group B Streptococcal Disease

In November 2010, the CDC released updated guidelines for the prevention of early onset neonatal GBS infections.<sup>1</sup> This update replaces the 2002 CDC guidelines. Due to efforts to decrease GBS related disease, the incidence of early-onset GBS disease in the newborn has decreased significantly from 1.7 cases per 1000 live births to 0.34-0.37 cases per 1000 live births. Because rates of maternal colonization remain unchanged since the 1970s, we need to continue to be vigilant in our efforts to prevent GBS disease. Therefore, the updated guidelines, endorsed by ACOG and AAP, continue to recommend screening of all pregnant women between 35 and 37 weeks' gestation but they clarify many issues that were left unaddressed in the 2002 guidelines, including new methods for identifying GBS, a new definition of GBS bacteriuria, clarified screening and treatment algorithms for women with preterm labor and preterm premature rupture of membranes (PPROM), dosing information of penicillin, revised prophylaxis regimens for penicillin allergic women as well as a new algorithm for management of potentially affected newborns. We review these changes, as well as unchanged key aspects of the 2002 guidelines.

### Identifying GBS

Proper identification of GBS first relies upon correct collection techniques. Specimens should be collected from the inside of the lower vagina (introitus) and through the anal sphincter. The same swab can be used, or 2 different swabs can be used, if desired. However, they should be treated as 1 sample. A speculum should not be used during the collection. If lab processing is not immediately available, transport media can be used for samples. The highest specificity occurs if the sample is stored at 4°C and is processed within 24 hours of collection. Typically after enrichment, GBS is isolated on blood agar plates and then identified by the CAMP test or by a latex agglutination assay. If chromogenic media is used, a negative result must be confirmed by subculturing to an appropriate agar plate or the media can be directly tested for GBS.<sup>2</sup> The CDC recommends that laboratories report GBS results in concentrations of  $\geq 10^4$  colony forming units/ml from urine specimens of pure or mixed organism cultures. However, many labs report GBS at lower concentrations. For example, the University of Iowa Clinical Microbiology Lab reports *any* GBS isolate in urine culture in any reproductive age woman regardless of colony count according to recommendations from the American Society for Microbiology. Any urine culture reported as GBS positive, *regardless of the colony count*, should be considered positive as any positive urine culture is considered a marker of heavy GBS colonization. Therefore, *any GBS positive urine culture regardless of colony count* should be considered GBS positive for the entire pregnancy and the pregnant woman should receive intrapartum antibiotic prophylaxis.<sup>3</sup>

Antibiotic sensitivities should be performed on any GBS isolate from urine or rectovaginal swab if the patient is known to be allergic to penicillin and is at high risk of anaphylaxis. The CDC 2010 guidelines clearly define “high risk of anaphylaxis” as: a history of anaphylaxis, angioedema, respiratory distress or urticaria following the administration of penicillin or a cephalosporin.

Susceptibility testing must include testing for inducible clindamycin resistance, such as a D zone test. In the “D zone test,” or double-disk diffusion method, a clindamycin disk is away from the edge of an erythromycin disk. The sample is incubated overnight and strains that have inducible

resistance will show flattening of the clindamycin zone in the area next to the erythromycin disc “D zone.”

While the 2010 guidelines acknowledge some of the limitations of identification of GBS by PCR based nucleic acid amplification tests (NAAT), including test complexity, costs, availability, and staffing requirements, the updated guidelines do expand the options for the laboratory to include NAAT. NAAT directly from the swab may be used for women at term with an unknown GBS status who have no other risk factors. If GBS is identified by NAAT, then intrapartum antibiotic prophylaxis (IAP) should be given. However, if a patient develops *any* risk factor, then IAP should be given regardless of the NAAT results. For prenatal NAAT tests, the test must be done from an enrichment broth. Availability for this testing in the state of Iowa is limited. At the University of Iowa, a rapid PCR technique to detect GBS is limited and is only available as a mail out assay.

### **Screening and Treatment Algorithm** (Figure 1 on page 41)

In regards to screening, all pregnant women should be screened at 35-37 weeks’ gestation. The only exceptions are women who had GBS isolated from urine *at any time* in the current pregnancy or who had a previous infant with invasive GBS disease. As previously stated, a pregnant woman with a urine culture positive for GBS *regardless of the colony count and gestational age of collection* should be considered GBS colonized. While these women do not need third trimester screening, they should receive intrapartum antibiotic prophylaxis. IAP should be given to these GBS bacteremic patients even if repeat urine cultures are negative.

With regard to GBS urinary tract infection (UTI), primary treatment for GBS UTI should occur if the colony count is greater than 10,000 colony forming units/mL. If the patient is *asymptomatic* and has a colony count *less than* 10,000 colony forming units/mL, then they do *not* need to be primarily treated for the GBS UTI. Women should also be screened if they experience preterm labor or PPRM. Any woman, who screens positive for GBS, should be given IAP with the exception of women who are having a cesarean section performed prior to the onset of labor and rupture of membranes. Although a risk does exist for transmission of GBS from a colonized mother to her infant during a planned cesarean delivery performed before onset of labor in a woman with intact amniotic membranes, it is extremely low, based on a retrospective study at a single hospital and a review of CDC active, population-based surveillance data from the 1990s. Thus, in this specific circumstance, in which the risk for disease is extremely low, the individual risks to a mother and her infant from receiving intrapartum antibiotic prophylaxis may balance or outweigh the benefits. Intrapartum antibiotic prophylaxis to prevent perinatal GBS disease is, therefore, not recommended as a routine practice for women undergoing planned cesarean deliveries. Patients expected to undergo planned cesarean deliveries should nonetheless still undergo routine vaginal and rectal screening for GBS at 35--37 weeks because onset of labor or rupture of membranes may occur before the planned cesarean delivery. In rare situations in which patients or providers opt for intrapartum prophylaxis before planned cesarean deliveries, administration of antibiotics at the time of incision rather than at least 4 hours before delivery may be reasonable. Unless they have a urinary tract infection, these women *should not* be given antibiotics to clear the GBS infection.

IAP is indicated if the GBS status is unknown at the onset of labor and at least one of the following occur: delivery will occur <37 weeks' gestation, ROM  $\geq$  18 hours, intrapartum temperature  $\geq$  100.4°F, and/or a positive GBS result by intrapartum nucleic acid amplification tests. The new guidelines clearly highlight that GBS screening should be performed and that prophylaxis is indicated if these patients are likely to deliver and should be discontinued if it is decided that the woman is not in true labor. For women who experience PPRM, GBS screening should be performed and latency antibiotics should be given if they are not in labor. If they are in labor, then GBS prophylaxis should be administered. IAP is not indicated solely for the reason of colonization by GBS in a previous pregnancy or GBS bacteriuria in a previous pregnancy. Regardless of intrapartum risk factors, IAP is also not indicated if a negative rectovaginal screening culture was obtained in late gestation of the current pregnancy. A vaginal-rectal GBS screening result is valid for 5 weeks if done prior to 35 weeks' gestation. After 35 weeks, GBS screening does not need to be repeated.

### **Prophylaxis Regimens** (Figure 2 on page 42)

Penicillin G remains the drug of choice for IAP; an initial dose of 5 million units should be given IV, then 2.5 to 3.0 million units administered IV every 4 hours until delivery. This range provides flexibility based on what formulation is available. The same degree of protection is provided by this range. Ampicillin can also be given as an initial dose of 2 grams IV followed by 1 gram IV every 4 hours until delivery. In the case of women who are allergic to penicillin and are *not* at high risk for anaphylaxis such as those who *do not* have a history of anaphylaxis, angioedema, respiratory distress syndrome, or urticaria with penicillin or cephalosporin administration, then cefazolin is the antibiotic of choice; an initial dose of 2 grams should be given IV, then 1 gram administered IV every 8 hours until delivery. Cefazolin has similar pharmacokinetics to penicillin and concentrates well in amniotic tissues. In contrast, clindamycin does not concentrate well in fetal tissue or amniotic fluid. If a woman is at high risk for anaphylaxis, then clindamycin should be used if their GBS is susceptible to clindamycin and erythromycin, and the D-zone test was negative if the isolate was erythromycin resistant. Clindamycin 900 mg should be given IV every 8 hours until delivery. Erythromycin is no longer listed as an alternative for penicillin-allergic women. For a penicillin-allergic, high anaphylaxis risk women with unknown GBS sensitivity results, then vancomycin, 1 gram should be administered IV every 12 hours until delivery. Vancomycin should be used prudently because it is not as effective for IAP as clindamycin and is a “drug of last resort” for gram positive bacterial infections.

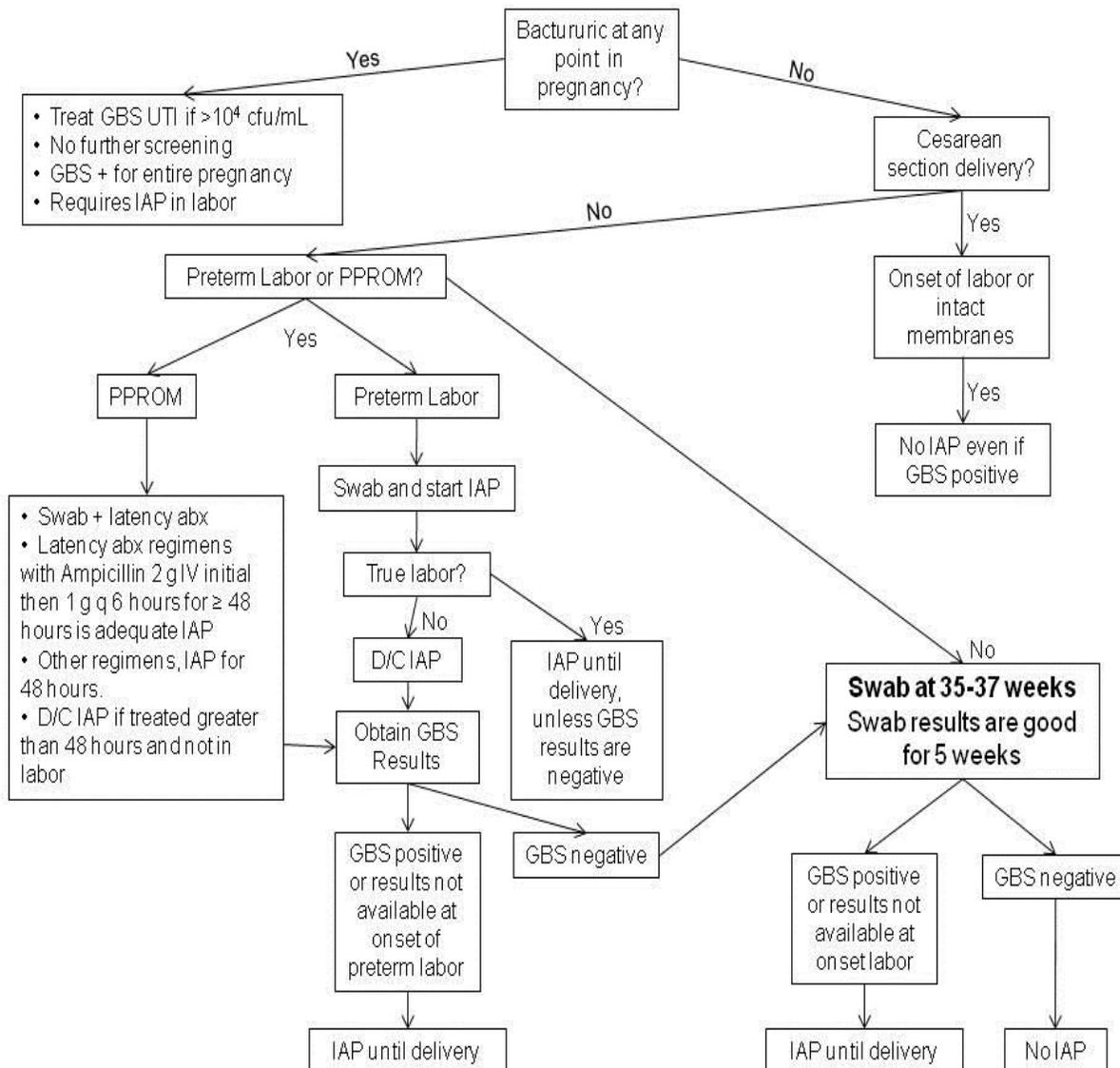
Regarding the duration of IAP with respect to delivery, there is insufficient data regarding the timing of intrapartum procedures, such as amniotomy for labor progression, and length of IAP administration. *Ideally*, IAP should be administered at least 4 hours before delivery. However, obstetrically necessary procedures, such as amniotomy for the placement of a fetal scalp electrode in the setting of nonreassuring fetal heart tones, should not be delayed to achieve the 4 hours of IAP.

The 2010 changes to the CDC guidelines are summarized in Table 1 on page 43. Overall, the incidence of early-onset invasive GBS disease in newborns is low. However, the rates of GBS colonization are unchanged and the maternal rates of resistance to clindamycin and erythromycin

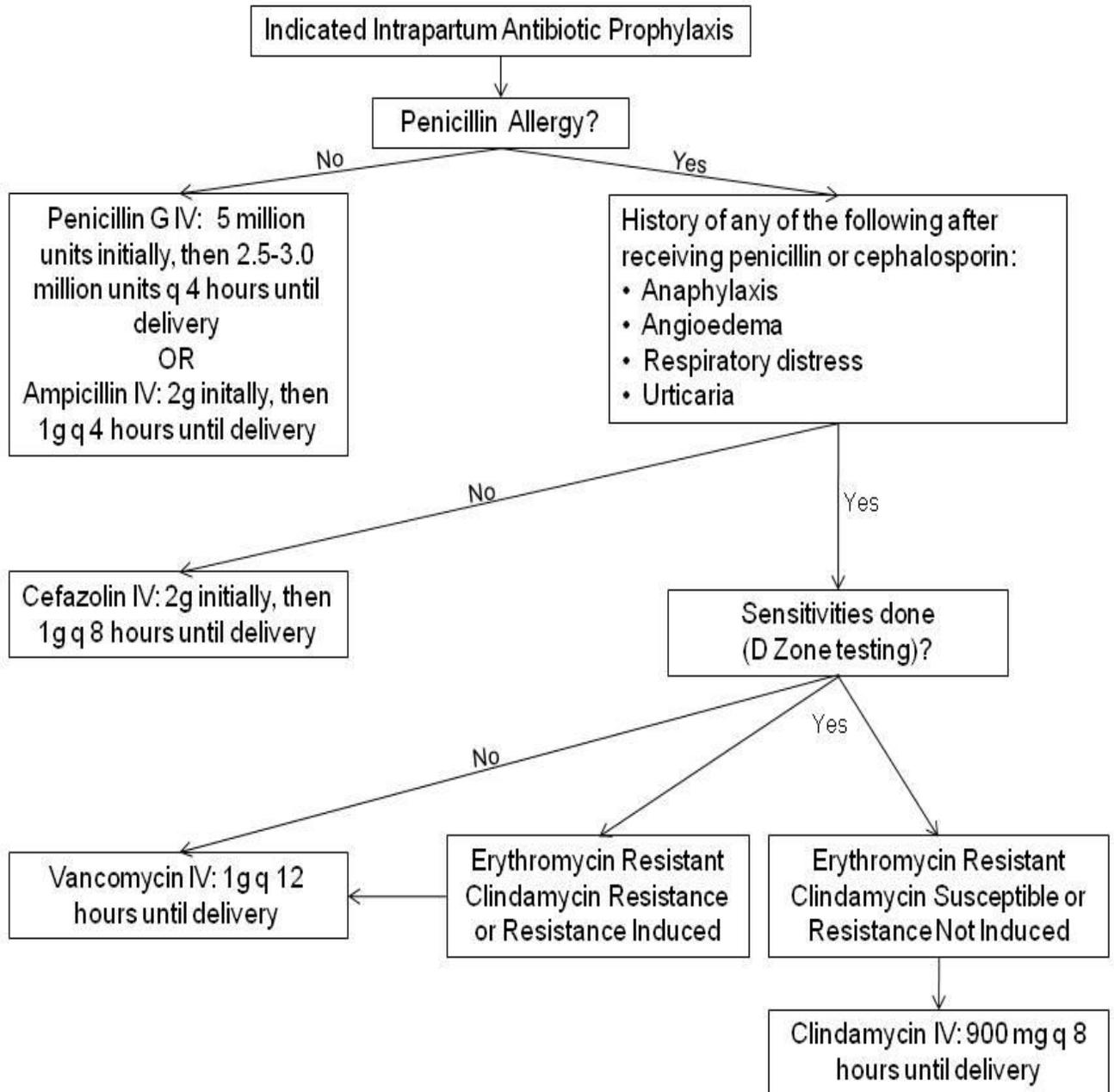
are high. And, there is a higher rate of early-onset GBS disease in different racial populations. Therefore, obstetric and pediatric providers in Iowa must be vigilant in the implementation of these updated guidelines.

1. Prevention of Perinatal Group B Streptococcal Disease -- Revised Guidelines from CDC, 2010. *MMWR Recomm Rep.* Nov 19 2010; 59(RR-10):1-36.
2. National Center for Immunization and Respiratory Diseases, Division of Bacterial Diseases. Q&As About Implementing the 2010 Guidelines for Laboratorians. 2010; Available at: <http://www.cdc.gov/groupbstrep/lab/QAs-lab.html>. Accessed June 11, 2013.
3. National Center for Immunization and Respiratory Diseases, Division of Bacterial Diseases. Q&As About Implementing the 2010 Guidelines for Obstetric Providers. 2010. Available at: <http://www.cdc.gov/groupbstrep/clinicians/QAs-obstetric.html>. Accessed June 5, 2013.

**Figure 1: GBS Screening and Treatment Algorithm**



**Figure 2: Intrapartum Antibiotic Prophylaxis Regimen Algorithm**



**Table 1: 2010 CDC Updates to the 2002 CDC Group B Strep Recommendations**

Category	Key Updates to 2002 Recommendations
Screening for GBS	<ul style="list-style-type: none"> <li>• Guidance regarding to cesarean delivery before labor and no ROM is applied to all gestational ages</li> <li>• New screening protocols with PCR (NAAT) based techniques</li> </ul>
Screening in the setting of threatened pre-term labor	<ul style="list-style-type: none"> <li>• Separate algorithms for spontaneous preterm labor and PPROM</li> <li>• Discontinuation of GBS prophylaxis if not truly in labor</li> <li>• PPROM latency antibiotic regimens including Ampicillin x 48 hours are adequate for GBS prophylaxis. Yet, oral antibiotics <i>alone</i> not adequate.</li> </ul>
GBS Specimen Processing	<ul style="list-style-type: none"> <li>• In clindamycin susceptible, erythromycin resistant GBS isolates, inducible clindamycin resistance (D-Zone) testing should be performed.</li> <li>• If available, clarified use of PCR (NAAT) based techniques</li> <li>• Labs should report GBS in urine cultures in concentrations <math>\geq 10^4</math> cfu/mL</li> </ul>
Intrapartum Antibiotic Prophylaxis	<ul style="list-style-type: none"> <li>• Definition for high risk for anaphylaxis clarified as a history of anaphylaxis, angioedema, respiratory distress or urticaria after penicillin or a cephalosporin.</li> <li>• Dosing of penicillin G to be 2.5-3.0 million units IV every 4 hours for appropriate drug levels and allow flexibility in penicillin G formulations.</li> <li>• Erythromycin is NOT an alternative antibiotic in penicillin-allergic women.</li> </ul>
Secondary Prevention of GBS in Neonates	<ul style="list-style-type: none"> <li>• Recommendations apply to <i>all</i> newborns.</li> <li>• Adequate IAP strictly defined as <math>\geq 4</math> hours of IV penicillin, ampicillin, or cefazolin.</li> <li>• Well appearing infants with moms with indication for IAP, but did not receive IAP can be observed for <math>\geq 48</math> hours <i>unless</i> <math>&lt; 37</math> weeks or <math>\geq 18</math> hours of membrane rupture <math>\rightarrow</math> limited evaluation and <math>\geq 48</math> hours observation</li> <li>• Well appearing infants born between 35-36 weeks and mothers received IAP do not require diagnostic evaluations.</li> </ul>

## Appendix 17. Male Newborn Circumcision

Male circumcision, surgical removal of some or all of the foreskin (prepuce) from the penis is one of the most common surgical procedures in the world. In the United States, circumcision is most often performed in the newborn period. In 2007, the American Academy of Pediatrics (AAP) formed a multidisciplinary task force to evaluate the recent evidence regarding male circumcision. An updated policy statement was subsequently released on August 27, 2012. The Circumcision Policy Statement<sup>1</sup> has been endorsed by the American College of Obstetricians and Gynecologists (ACOG). Findings from the systematic evaluation of the evidence are available in the accompanying Technical Report, “Male Circumcision.”<sup>2</sup>

### Preventive Health Benefits

The AAP task force on circumcision evaluated English-language peer-reviewed literature from 1995 through 2010. They concluded that the preventive health benefits of elective circumcision for male newborns outweigh the risks of the procedure. These benefits include prevention of urinary tract infections, penile cancer and transmission of some sexually transmitted diseases, including HIV. The procedure is well tolerated when performed by trained and competent professionals under sterile conditions with appropriate pain management.

The preventive health benefits are not great enough to recommend routine circumcision for all male newborns. However, the benefits are sufficient to justify access to this procedure and third-party reimbursement for the cost of the procedure if families choose to have their newborns circumcised. Clinicians should routinely inform parents of the potential benefits and risks of newborn circumcision in a nonbiased manner and make sure they understand that it is an elective procedure. Parents should weigh the medical information in the context of their own religious, ethical and cultural beliefs and practices. For some families, the medical benefits alone may not outweigh these other considerations.

### Potential Complications

The true incidence of complications with newborn male circumcision is unknown due to differing definitions and standards for determining the timing of when a complication occurred. The AAP task force has grouped potential complications in terms of the timing of the procedure. “Acute” complications are defined as those present in the immediate post-procedural time frame. They are rare, occurring in approximately 1 in 500 newborn male circumcisions. The most common complication is bleeding. Other acute complications include infection, penile injury and an imperfect amount of tissue removed during circumcision. “Late” complications are still present during infancy but not in the immediate post-procedural period. Adhesions (natural and vascularized skin bridges) and meatal stenosis are the most common late complications. Other late complications with newborn circumcision include excessive residual skin (incomplete circumcision), excessive skin removal, phimosis and epithelial inclusion cysts. Circumcision of premature infants and infants with a prominent suprapubic fat pad or penoscrotal webbing is associated with an increased risk of later-occurring complications, including poor cosmesis, trapped/buried penis and adhesions. Male circumcision performed during the newborn period has significantly lower complication rates than circumcision performed later in life. After review of the current literature, the AAP task force concluded that male circumcision does not adversely

affect penile sexual function, sensitivity or satisfaction, regardless of how these factors are defined.

### **Contraindications**

Newborn circumcision is contraindicated for the following infants: significantly premature infants; infants with blood dyscrasias or those who have a family history of bleeding disorders; infants with congenital abnormalities such as hypospadias or congenital chordee; and infants with deficient shaft skin such as penoscrotal fusion or congenital buried penis.

### **Circumcision Procedure**

Circumcision is an elective procedure and should be performed only if the infant is stable and healthy. Practitioners should confirm that vitamin K has been administered prior to the procedure in accordance with the standard of newborn care.<sup>3</sup> The three most common techniques used for male circumcision in the United States involve use of the Gomco clamp, the Plastibell device or the Mogen clamp. There is no significant difference in the risk of complications between the specific techniques. All three involve the following steps: 1) estimation of the amount of external skin to be removed; 2) dilation of the preputial orifice so the glans can be visualized to ensure that the glans itself is normal; 3) bluntly freeing the inner preputial epithelium from the epithelium of the glans; 4) placing the device; 5) leaving the device in place long enough to produce hemostasis; and 6) surgical removal of the foreskin.

#### *Gomco clamp:*

- Device specifically designed for performing circumcisions
- Procedure: The foreskin is cut lengthwise through the stretched tissue (dorsal slit) to allow space to insert the device; the bell of the Gomco clamp is placed over the glans and the foreskin is pulled over the bell; the base of the Gomco clamp is then placed over the bell and the arm of the clamp is fitted; after confirming correct fitting and placement of the clamp and the amount of foreskin to be excised, the surgeon tightens the nut on the Gomco clamp; the clamp is left in place for 3-5 minutes to allow for hemostasis; then the foreskin is removed using a scalpel and the Gomco base and bell are removed.<sup>4</sup>

#### *Plastibell device:*

- Procedure: A plastic ring is inserted under the foreskin and a tie is placed over the ring to provide hemostasis; the ring remains on the penis for several days until the tissue necroses and the ring falls off spontaneously.

#### *Mogen clamp:*

- Device consisting of 2 flat blades that have a limited (slit-like) space between them and a mechanism that draws the blades together and locks them into place
- Slit is limited to 3mm to allow the foreskin, but not the glans to cross the opening
- Procedure: The preputial adhesions are taken down gently using a probe and the glans is pushed downward, protecting it from the blades; the prepuce distal to the glans is drawn into the slit between the blades and positioned; the blades are locked together, crushing the skin and creating hemostasis; the skin is excised from above the clamp; then the clamp is removed and the skin is pushed proximally into proper position.

## **Analgesia and Anesthesia**

Adequate analgesia/anesthesia should be provided whenever newborn circumcision is performed. The AAP recommends both nonpharmacologic and pharmacologic techniques for reducing the procedural pain associated with newborn circumcision. Nonpharmacologic techniques (positioning, sucrose pacifier) are not recommended as the sole method of analgesia during circumcision as they do not prevent procedural or post-procedural pain. They should be used as analgesic adjuncts to improve comfort during the procedure. The administration of oral Acetaminophen has been demonstrated to reduce postoperative pain scores 6 hours after the procedure.<sup>5</sup> However, there is no evidence that the newborn experiences persistent pain after the local pre-procedure anesthetic wears off.

### *Nonpharmacologic techniques:*

- Physiologic positioning of the infant (swaddling upper extremities) in a padded environment may decrease distress during circumcision.
- Nonnutritive sucking on a pacifier dipped in sucrose has been demonstrated to decrease crying during circumcision.

Penile nerve block techniques are highly effective in reducing the behavioral and physiologic indicators of pain caused by male newborn circumcision. The most commonly used method is the dorsal penile nerve block (DPNB). With this technique systemic lidocaine levels reach peak concentrations about 60 minutes after injection and are generally well below toxic ranges.<sup>6</sup> Minor complications may include bruising and hematomas at the injection site which do not require any change in management. The subcutaneous circumferential ring block is also effective in relieving the procedural and post procedural pain of newborn circumcision. No complications have been reported with this technique. There is evidence that both the DPNB and subcutaneous ring block are superior to EMLA cream in relieving pain during and after circumcision.<sup>7</sup> For newborns the maximum dose of 1% lidocaine without epinephrine is 4.5-5 mg/kg/dose in a 2-hour period (1% lidocaine equals 10 mg/ml).<sup>8</sup>

### *Nerve blocks:*

- Dorsal penile nerve block (DPNB): Consists of two subcutaneous injections of 0.4 ml of 1% lidocaine without epinephrine administered below Buck's fascia at the 10 and 2 o'clock positions, 0.5 to 1 cm distal to the base of the penis using a 27-gauge needle
- Subcutaneous ring block: Consists of one subcutaneous injection of 0.8 ml of 1% lidocaine without epinephrine administered at the base or midshaft of the penis and infiltrated in a band or ring around the penis using a 27-gauge needle

Topical anesthetic preparations require the use of an occlusive dressing or plastic wrap to keep the cream in place prior to the procedure. Infrequent complications such as erythema, swelling and blistering have been associated with the use of topical anesthetics. These occur more commonly with lidocaine-prilocaine cream (EMLA) than 4% lidocaine cream (LMX4). LMX4 cream has the advantage of faster onset to anesthesia when compared to EMLA cream. Topical anesthetics may cause more skin irritation in low birth weight infants, and penile nerve block techniques are preferred for these infants. There have been no reports in the literature of systemic toxicity such as seizures or cardiovascular instability with the use of these products for newborn circumcision. There have been isolated case reports of clinically significant methemoglobinemia with EMLA

cream that involved prolonged application time or use in premature infants. EMLA should not be used in neonates who are receiving other drugs known to induce methemoglobinemia.<sup>9</sup> There is no risk of methemoglobinemia with the use of LMX4 cream.

*Topical local anesthetics:*

- Eutectic mixture of 2.5% lidocaine & 2.5% prilocaine (EMLA cream): 1-2g applied 60-90 minutes before circumcision
- Topical 4% lidocaine (LMX4 cream): 2g applied 30 minutes before circumcision

### **Discharge Instructions**

Parents of newborn boys should be instructed in the care of the penis at the time of hospital discharge, whether the newborn is circumcised or not. The uncircumcised penis should be washed with soap and water. The foreskin should not be forcibly retracted. Adhesions present at birth usually disappear by age 2 to 4 months. When the adhesions have resolved the foreskin can be easily retracted, and the whole penis can be washed with soap and water. The circumcised penis should be washed gently without aggressive pulling back of the skin.

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## Appendix 18. Managing Newborn Hyperbilirubinemia and Preventing Kernicterus

Bilirubin is the yellow breakdown product created from the destruction of hemoglobin in circulating red blood cells. Red cells have a shortened lifespan in the newborn. Approximately 35 mg of unconjugated bilirubin is formed from each gram of hemoglobin, and newborns produce up to 10 mg/dl/day. Bilirubin production is elevated in the first 24-48 hours of life. Unconjugated bilirubin is lipid-soluble and must be transported to the liver in plasma, reversibly bound to albumin. In the liver, bilirubin is transported across hepatic cell membranes where it is bound to ligand for conjugation. A liver enzyme conjugates bilirubin, converting it to water-soluble bilirubin pigments that can be excreted into the bile and urine. It is eliminated from the body via the intestines and to a lesser degree through the renal system. Bilirubin pigments that are not eliminated can be reabsorbed into the circulation as unconjugated bilirubin, a process called enterohepatic recirculation. In term newborns, conjugation is delayed during the first hours after birth but increases by about 24 hours of age. Hemolysis or bruising at birth can increase the bilirubin load. Elimination of bilirubin is often delayed in preterm infants. Other factors can impair its elimination, such as poor feeding, bowel obstruction or immature liver conjugation. Breastfed babies typically have higher bilirubin levels than formula fed infants. Babies with reduced conjugation or elimination of bilirubin are at risk for hyperbilirubinemia.

### Definitions

*Total serum bilirubin (TSB):* bilirubin is the catabolic product of heme metabolism, which is formed by the breakdown of heme present in hemoglobin, myoglobin, cytochromes, catalase, peroxidase, and tryptophan pyrrolase. Several laboratory techniques have been developed for measuring the serum bilirubin concentration. The specific technique used has implications for the interpretation of serum values.

*Direct or conjugated bilirubin:* concentration of bilirubin conjugated with glucuronic acid.

*Indirect or unconjugated bilirubin:* the lipid-soluble form of bilirubin that circulates in loose association with the plasma proteins.

*Transcutaneous bilirubin (TcB):* noninvasive measure of the yellow color of blanched skin and subcutaneous tissue; used as screening tool to help determine whether the TSB should be measured; provides an estimate of the TSB value expressed in mg/dl; measurements can be plotted on the same nomogram as TSB measurements

*Hyperbilirubinemia:* TSB level of <13 mg/dl or a TSB rise of <0.5 mg/dl/hour; results in physiologic jaundice

*Physiologic jaundice:* yellow color in skin and sclera that appears as bilirubin levels increase; begins cephalically, usually seen in face first and progresses caudally to trunk and extremities

*Severe hyperbilirubinemia:* TSB above the 95<sup>th</sup> percentile for age in hours; requires treatment with phototherapy

*Phototherapy*: visible light delivered in measurable doses; causes photoisomerization whereby bilirubin present in superficial capillaries and interstitial spaces of the skin and subcutaneous tissues is converted to water-soluble isomers that are excretable without further metabolism by the liver

*Intensive phototherapy*: implies irradiance in the blue-green spectrum (wavelength band of approximately 430-490 nm) of at least 30  $\mu\text{W}/\text{cm}^2$  per nm (measured at the infant's skin directly below the center of the phototherapy unit) and delivered to as much of the infant's surface area as possible; the most efficient units positioned for maximum skin coverage can lower TSB by as much as 5 mg/dl/hour

*“Bronze baby syndrome”*: complication of phototherapy where a grayish-brown discoloration of the skin occurs; seen exclusively in infants with an elevated direct-reacting or conjugated bilirubin level (cholestatic jaundice)

*Acute bilirubin encephalopathy (ABE)*: acute and reversible clinical manifestations of bilirubin neurotoxicity caused by an accumulation of unconjugated bilirubin in the brain; seen in the first weeks after birth; presenting signs are subtle and nonspecific; early signs include lethargy, hypotonia and poor suck; intermediate phase is characterized by moderate stupor, irritability and hypertonia manifested by backward arching of the neck (retrocollis) and trunk (opisthotonos); infant may develop fever and high-pitched cry which alternates with drowsiness and hypotonia; advanced phase may be irreversible and is characterized by pronounced retrocollis-opisthotonos, shrill cry, no feeding, apnea, fever, deep stupor to coma, possible seizures and death

*Kernicterus*: yellow staining of specific areas of brain tissue caused by an accumulation of unconjugated bilirubin in the brain; results in bilirubin neurotoxicity and chronic bilirubin encephalopathy

*Chronic bilirubin encephalopathy*: chronic and irreversible clinical neurologic sequelae associated with bilirubin neurotoxicity, including severe choreoathetoid cerebral palsy, sensorineural hearing loss, dental- enamel dysplasia, paralysis of upward gaze and intellectual deficits

### **Background and Scope of the Problem**

More than 60% of healthy full term and late preterm infants will develop hyperbilirubinemia during the first week of life. Most are discharged from their birth hospital before the peak of TSB occurs, usually at 72-120 hours of age. Hyperbilirubinemia typically resolves by 7-10 days of life. Approximately 5-11% of infants will develop severe hyperbilirubinemia. Without intervention, TSB levels can progress to values greater than 25 or 30 mg/dl (above the 99<sup>th</sup> percentile for age in hours) which puts the infant at risk for acute bilirubin encephalopathy and kernicterus. It is estimated that about one in seven infants with TSB levels greater than 30 mg/dl will develop kernicterus, resulting in chronic bilirubin encephalopathy.<sup>1,2</sup> The relationship between extremely high TSB levels and bilirubin neurotoxicity is not known because routine surveillance is not available. Cases of extremely high levels of serum bilirubin in infants with no apparent sequelae have been reported. Conversely, infants without documented high serum bilirubin levels have been found to have kernicterus.<sup>3</sup> The critical level in otherwise healthy

newborns is likely influenced by postnatal age, maturity, duration of hyperbilirubinemia and rate of TSB rise.

In April 2001, The Joint Commission (formerly known as the Joint Commission on Accreditation of Hospitals, JCAHO) issued a sentinel event alert notifying hospitals and healthcare providers that recent cases of kernicterus in otherwise healthy newborns had been reported.<sup>4</sup> One registry includes 90 cases in the United States from 1984 to 2001.<sup>5</sup> Studies suggest that several factors contributed to the resurgence of kernicterus in the US, including early discharge, an increase in home births and an increase in exclusive breastfeeding. A warning on the danger of kernicterus was also issued by the Centers for Disease Control and Prevention (CDC).<sup>6</sup> In 2002, the National Quality Forum declared kernicterus and TSB concentrations greater than 30 mg/dl to be “never events” or preventable, adverse medical occurrences that should never happen.<sup>7</sup>

The current incidence of bilirubin encephalopathy in the US is unknown; however, kernicterus is still being reported. The majority of these affected infants are term and late-preterm infants who are discharged from the hospital as healthy newborns, yet subsequently develop extreme hyperbilirubinemia and the neurodevelopmental findings associated with kernicterus.

### **Current Guidelines for Management and Follow-Up After Discharge**

In July 2004, the American Academy of Pediatrics (AAP) released a clinical practice guideline, “Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation.”<sup>8</sup>

The focus of this guideline was to reduce the incidence of severe hyperbilirubinemia and bilirubin encephalopathy while minimizing the risks of unintended harm, such as maternal anxiety, decreased breastfeeding and unnecessary costs and treatment through appropriate identification, follow-up and therapy.

The key elements of the AAP guideline are summarized in the following recommendations:

1. Promote and support successful breastfeeding.
2. Establish nursery protocols for the identification and evaluation of hyperbilirubinemia.
3. Measure the total serum bilirubin (TSB) or transcutaneous bilirubin (TcB) level on infants jaundiced in the first 24 hours.
4. Recognize that visual estimation of the degree of jaundice can lead to errors, particularly in darkly pigmented infants.
5. Interpret all bilirubin levels according to the infant’s age in hours. (Figure 1)
6. Recognize that infants less than 38 weeks’ gestation, particularly those who are breastfed, are at higher risk of developing hyperbilirubinemia and require closer surveillance and monitoring.
7. Perform a systematic assessment on all infants before discharge for the risk of severe hyperbilirubinemia. (Table 1)
8. Provide parents with written and verbal information about newborn jaundice.
9. Provide appropriate follow-up based on the time of discharge and the risk assessment.
10. Treat newborns, when indicated, with phototherapy or exchange transfusion. (Figure 2, 3)

In 2009, a panel of experts reviewed the relevant literature including the report on screening for neonatal hyperbilirubinemia by the Tufts-New England Medical Center Evidence-Based Practice Center<sup>9</sup> and the current report by the US Preventive Services Task Force.<sup>3</sup> New evidence suggests

that combining a predischarge measurement of TSB or TcB with clinical risk factors including gestational age might improve the prediction of the risk of subsequent hyperbilirubinemia. In October 2009, Maisels et al published their commentary article, “Hyperbilirubinemia in the Newborn Infant  $\geq 35$  Weeks’ Gestation: An Update With Clarifications.”<sup>10</sup> In addition to clarifying several areas addressed in the 2004 AAP guideline, the authors introduced new recommendations for management and follow-up testing, according to predischarge screening. Their recommendations are summarized in Figure 4.<sup>10</sup> The gestational age and the predischarge TSB or TcB level are the most important factors that help to predict the risk of hyperbilirubinemia. The risk increases with each decreasing week of gestation from 42-35 weeks.

### **TcB Measurement**

TcB or transcutaneous bilirubin measurement is being performed more frequently in hospitals and outpatient settings. This noninvasive screening tool provides a good estimate of the TSB expressed in mg/dl and helps to determine whether the TSB should be measured. As with any point-of-care testing, regular monitoring for quality assurance by comparing TcB measurements with the TSB is necessary. Studies in term and late preterm infants have indicated that the TcB tends to underestimate the TSB, particularly at higher TSB levels. In the 2009 updated guidelines, Maisels et al provide specific evidence-based strategies for determining when TSB measurement is indicated.

Measurement of the TSB should be performed if:

- The TcB value is at 70% of the TSB level recommended for the use of phototherapy<sup>11</sup>
- The TcB value is above the 75<sup>th</sup> percentile on the Bhutani nomogram (Fig 1) or the 95<sup>th</sup> percentile on a TcB nomogram<sup>12</sup>
- At follow-up after discharge, the TcB value is  $>13\text{mg/dl}$  ( $222\mu\text{mol/L}$ )<sup>13</sup>

### **Treatment**

In 2011, the AAP published a technical report to standardize the use of phototherapy in the management of hyperbilirubinemia, “Phototherapy to Prevent Severe Neonatal Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation.”<sup>14</sup> The most important intervention for infants with severe hyperbilirubinemia is to initiate phototherapy without delay. The clinical response to phototherapy depends on the efficacy of the phototherapy device, as well as the infant’s rates of bilirubin production and elimination. The following characteristics contribute to the effectiveness of the phototherapy device: emission of light in the blue-to-green range that overlaps the in vivo plasma bilirubin absorption spectrum ( $\sim 460\text{-}490\text{ nm}$ ); irradiance of at least  $30\ \mu\text{W}/\text{cm}^2$  per nm (confirmed with an appropriate irradiance meter calibrated over the appropriate wavelength range); illumination of maximal body surface; and demonstration of a decrease in total bilirubin concentrations during the first 4 to 6 hours of exposure. Serial measurements of bilirubin concentrations are recommended to monitor the effectiveness of phototherapy treatment.

The efficacy of commercial neonatal phototherapy devices varies widely. These devices can be categorized according to their light source as follows: gallium nitride light-emitting diodes (LED), halogen spot lights (metal halide bulbs), fiberoptic blankets and fluorescent tube devices. The performance characteristics of the most commonly used phototherapy devices are summarized in Table 2.<sup>14</sup> The AAP has recommended that the irradiance for intensive phototherapy be at least 30

$\mu\text{W}/\text{cm}^2$  per nm over the wavelength band interval of 460-490 nm.<sup>8</sup> Devices that emit lower irradiance may be supplemented with auxiliary devices. The AAP further recommends that ***“All nurseries and services treating infants should have the necessary equipment to provide intensive phototherapy.”***<sup>8</sup>

The AAP recommendations for exchange transfusion are summarized in Figure 3, “Guidelines for exchange transfusion in infants 35 or more weeks’ gestation.”<sup>8</sup> During birth hospitalization, exchange transfusion is recommended if the TSB rises to these levels despite intensive phototherapy. The following guidelines are provided for infants readmitted to the hospital with severe hyperbilirubinemia: if the TSB concentration is above the exchange level, repeat TSB measurement every 2 to 3 hours and consider exchange transfusion if the TSB remains above the levels indicated after intensive phototherapy for 6 hours. Immediate exchange transfusion is recommended if the infant with hyperbilirubinemia shows signs of acute bilirubin encephalopathy: hypertonia, arching, retrocollis, opisthotonos, fever, high-pitched cry.

In cases of isoimmune hemolytic disease, the AAP recommends administration of immunoglobulin (IgG, 0.5-1.0 g/kg over 2 hours) if the TSB is rising despite intensive phototherapy or the TSB level is within 2 to 3 mg/dl (34-51  $\mu\text{mol}/\text{L}$ ) of the exchange level (Fig 3). If necessary, this dose can be repeated in 12 hours.<sup>8</sup>

Several pharmaceutical agents have been investigated for their ability to prevent or treat neonatal hyperbilirubinemia. Tin mesoporphyrin, a potent inhibitor of heme oxygenase, has been shown to effectively reduce TSB levels in term and preterm infants. It is currently being investigated for use in infants with severe hyperbilirubinemia.<sup>16</sup>

### **Parent Education and Resources**

Before the infant is discharged from the hospital, parents should be given both written and verbal information about newborn jaundice, including risk factors, identification and treatment. As part of their Safe and Healthy Beginnings program, the AAP offers a resource toolkit for hospitals and providers. *“Safe & Healthy Beginnings: A Resource Toolkit for Hospital and Physician’s Offices”* is based on the key aspects of the revised AAP hyperbilirubinemia guideline, including 1) the assessment of a newborn’s risk for severe hyperbilirubinemia, 2) support for breastfeeding mother, and 3) coordination of care between newborn nursery and primary care practice. It is available for purchase at the AAP Bookstore. This on-line resource includes tools for clinicians and parent handouts. An on-line demo is available at, <http://www2.aap.org/pubserv/shb/index.html>, accessed June 26, 2013.

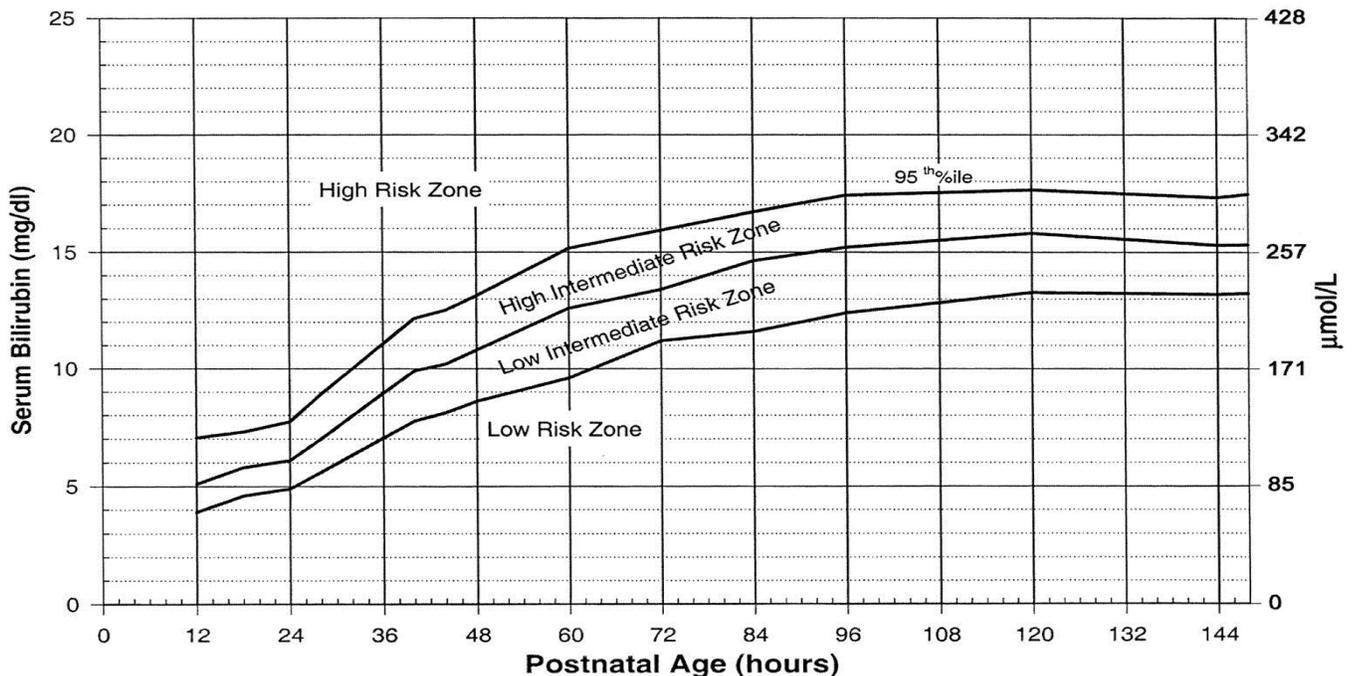
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**Table 1: Risk Factors for the Development of Severe Hyperbilirubinemia in Infants of 35 or More Weeks' Gestation (In Approximate Order of Importance).**

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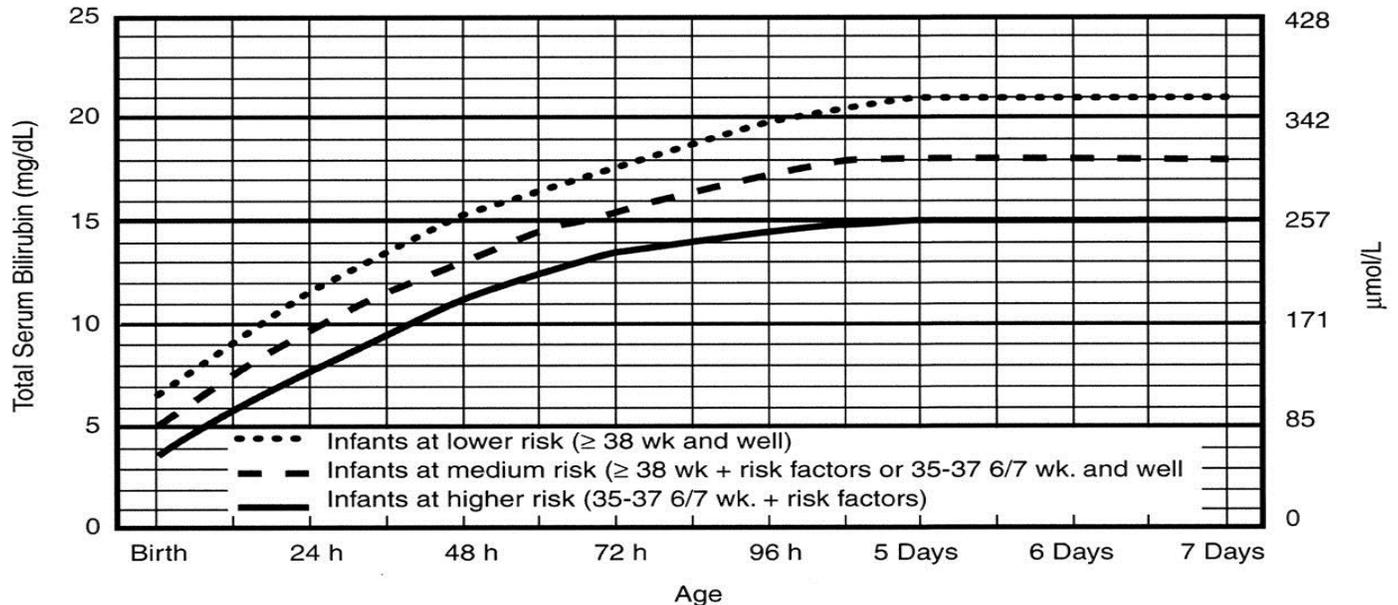
<p>Major Risk Factors</p> <ul style="list-style-type: none"> <li>Predischarge TSB or TcB level in the high-risk zone (Fig 2)<sup>25,31</sup></li> <li>Jaundice observed in the first 24 h<sup>30</sup></li> <li>Blood group incompatibility with positive direct antiglobulin test, other known hemolytic disease (eg, G6PD deficiency), elevated ETCO<sub>c</sub></li> <li>Gestational age 35-36 wk<sup>39,40</sup></li> <li>Previous sibling received phototherapy<sup>40,41</sup></li> <li>Cephalhematoma or significant bruising<sup>39</sup></li> <li>Exclusive breastfeeding, particularly if nursing is not going well and weight loss is excessive<sup>39,40</sup></li> <li>East Asian race<sup>39*</sup></li> </ul>
<p>Minor Risk Factors</p> <ul style="list-style-type: none"> <li>Predischarge TSB or TcB level in the high intermediate-risk zone<sup>25,31</sup></li> <li>Gestational age 37-38 wk<sup>39,40</sup></li> <li>Jaundice observed before discharge<sup>40</sup></li> <li>Previous sibling with jaundice<sup>40,41</sup></li> <li>Macrosomic infant of a diabetic mother<sup>42,43</sup></li> <li>Maternal age <math>\geq 25</math> y<sup>39</sup></li> <li>Male gender<sup>39,40</sup></li> </ul>
<p>Decreased Risk (these factors are associated with decreased risk of significant jaundice, listed in order of decreasing importance)</p> <ul style="list-style-type: none"> <li>TSB or TcB level in the low-risk zone (Fig 2)<sup>25,31</sup></li> <li>Gestational age <math>\geq 41</math> wk<sup>39</sup></li> <li>Exclusive bottle feeding<sup>39,40</sup></li> <li>Black race<sup>38*</sup></li> <li>Discharge from hospital after 72 h<sup>40,44</sup></li> </ul>

\* Race as defined by mother's description.



**Figure 1: Nomogram for Designation of Risk.** Reprinted with permission from the American Academy of Pediatrics<sup>8</sup>

Nomogram for designation of risk in 2840 well newborns at 36 or more weeks' gestational age with birth weight of 2000 g or more or 35 or more weeks' gestational age and birth weight of 2500 g or more based on the hour-specific serum bilirubin values. The serum bilirubin level was obtained before discharge, and the zone in which the value fell predicted the likelihood of a subsequent bilirubin level exceeding the 95th percentile (high-risk zone) as shown in Appendix 1, Table 4. Used with permission from Bhutani et al.<sup>31</sup> See Appendix 1 for additional information about this nomogram, which should not be used to represent the natural history of neonatal hyperbilirubinemia.



- Use total bilirubin. Do not subtract direct reacting or conjugated bilirubin.
- Risk factors = isoimmune hemolytic disease, G6PD deficiency, asphyxia, significant lethargy, temperature instability, sepsis, acidosis, or albumin  $< 3.0\text{g/dL}$  (if measured)
- For well infants 35-37 6/7 wk can adjust TSB levels for intervention around the medium risk line. It is an option to intervene at lower TSB levels for infants closer to 35 wks and at higher TSB levels for those closer to 37 6/7 wk.
- It is an option to provide conventional phototherapy in hospital or at home at TSB levels 2-3 mg/dL (35-50mmol/L) below those shown but home phototherapy should not be used in any infant with risk factors.

**Figure 2: Guidelines for phototherapy in hospitalized infants of 35 or more weeks' gestation.** Reprinted with permission from the American Academy of Pediatrics<sup>8</sup>

Note: These guidelines are based on limited evidence and the levels shown are approximations. The guidelines refer to the use of intensive phototherapy which should be used when the TSB exceeds the line indicated for each category. Infants are designated as "higher risk" because of the potential negative effects of the conditions listed on albumin binding of bilirubin,<sup>45-47</sup> the blood brain barrier,<sup>48</sup> and the susceptibility of the brain cells to damage by bilirubin.<sup>48</sup>

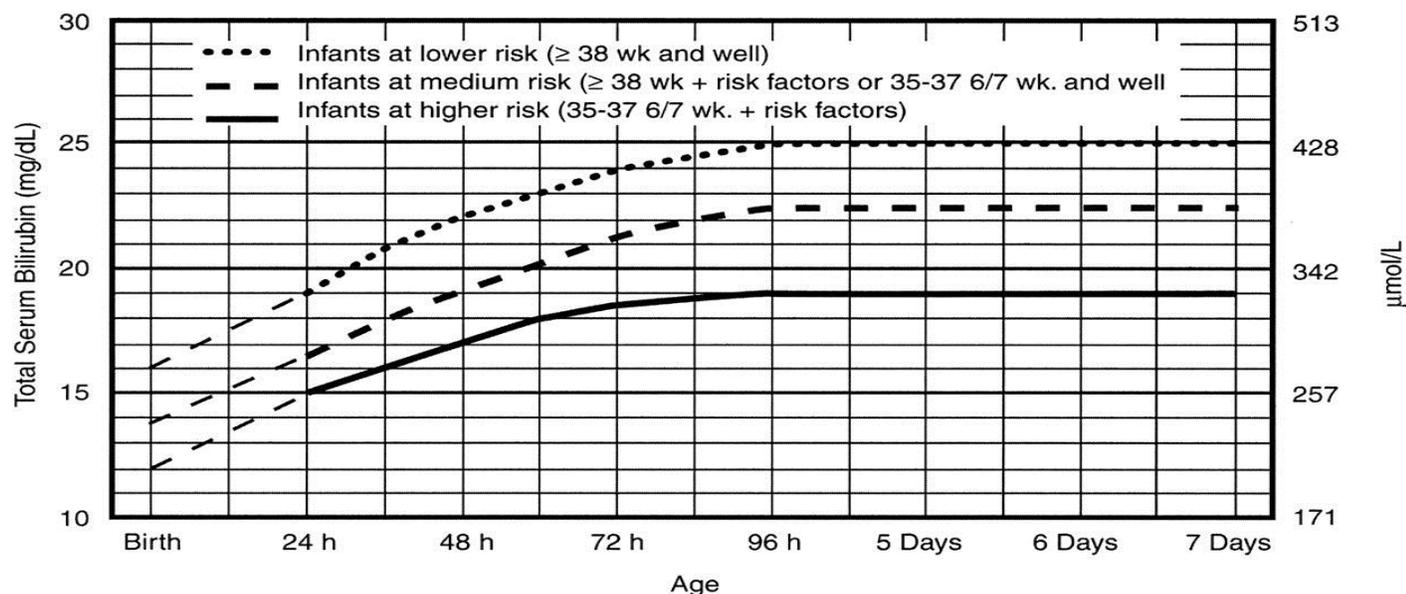
"Intensive phototherapy" implies irradiance in the blue-green spectrum (wavelengths of approximately 430-490 nm) of at least  $30\mu\text{W}/\text{cm}^2$  per nm (measured at the infant's skin directly below the center of the phototherapy unit) and delivered to as much of the infant's surface area as possible. Note that irradiance measured below the center of the light source is much greater than that measured at the periphery. Measurements should be made with a radiometer specified by the manufacturer of the phototherapy system.

See Appendix 2 for additional information on measuring the dose of phototherapy, a description of intensive phototherapy, and of light sources used. If total serum bilirubin levels approach or exceed the exchange transfusion

line (Fig 4), the sides of the bassinet, incubator, or warmer should be lined with aluminum foil or white material.<sup>50</sup> This will increase the surface area of the infant exposed and increase the efficacy of phototherapy.<sup>51</sup>

If the total serum bilirubin does not decrease or continues to rise in an infant who is receiving intensive phototherapy, this strongly suggests the presence of hemolysis.

Infants who receive phototherapy and have an elevated direct-reacting conjugated bilirubin level (cholestatic jaundice) may develop the bronze-baby syndrome. See Appendix 2 for the use of phototherapy in these infants.



- The dashed lines for the first 24 hours indicate uncertainty due to a wide range of clinical circumstances and a range of responses to phototherapy.
- Immediate exchange transfusion is recommended if infant shows signs of acute bilirubin encephalopathy (hypertonia, arching, retrocollis, opisthotonos, fever, high pitched cry) or if TSB is  $\geq 5$  mg/dL ( $85 \mu\text{mol/L}$ ) above these lines.
- Risk factors - isoimmune hemolytic disease, G6PD deficiency, asphyxia, significant lethargy, temperature instability, sepsis, acidosis.
- Measure serum albumin and calculate B/A ratio (See legend)
- Use total bilirubin. Do not subtract direct reacting or conjugated bilirubin
- If infant is well and 35-37 6/7 wk (median risk) can individualize TSB levels for exchange based on actual gestational age.

### Figure 3: Guidelines for exchange transfusion in infants 35 or more weeks' gestation.

Reprinted with permission from the American Academy of Pediatrics<sup>8</sup>

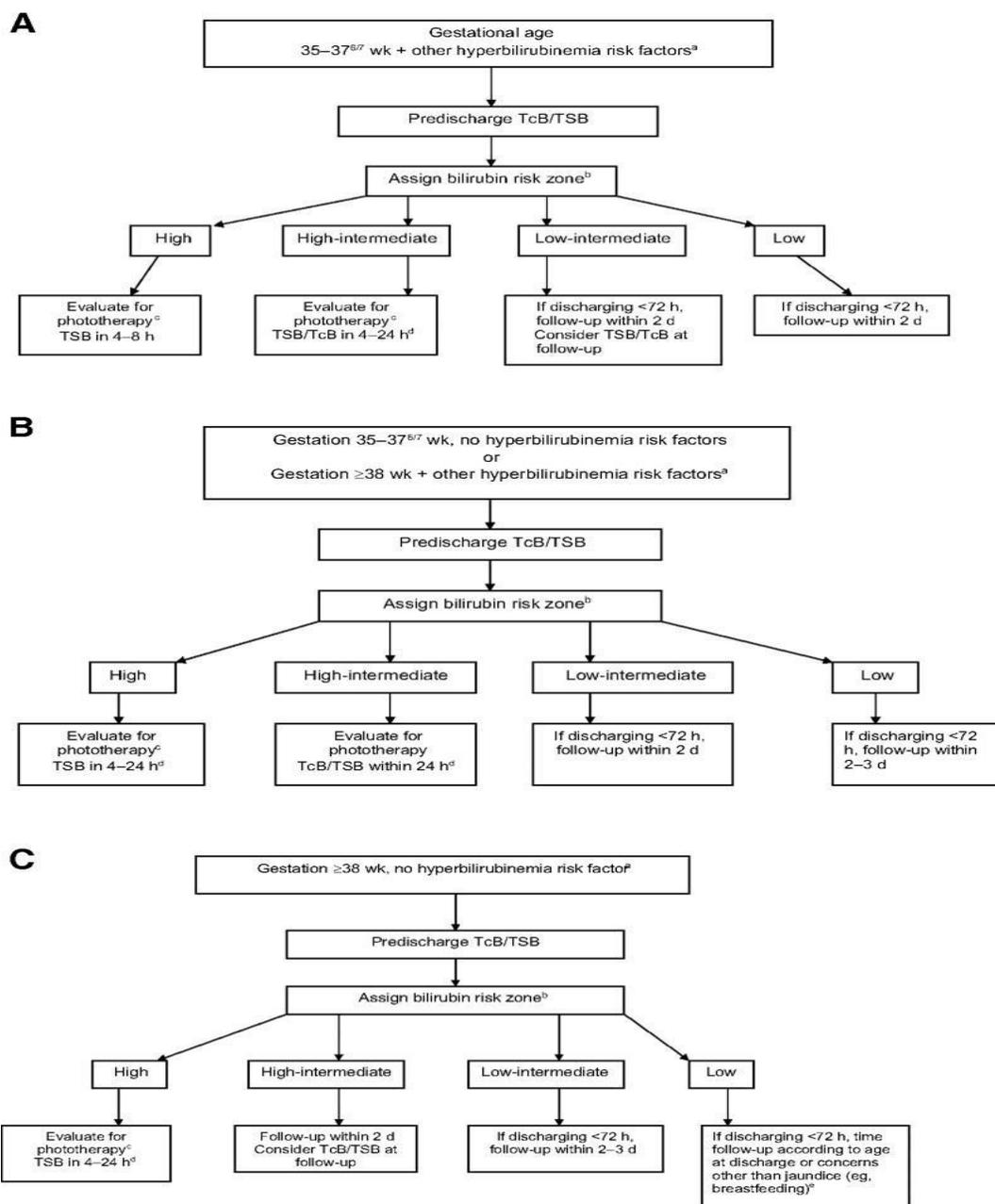
Note that these suggested levels represent a consensus of most of the committee but are based on limited evidence, and the levels shown are approximations. See ref. 3 for risks and complications of exchange transfusion. During birth hospitalization, exchange transfusion is recommended if the TSB rises to these levels despite intensive phototherapy. For readmitted infants, if the TSB level is above the exchange level, repeat TSB measurement every 2 to 3 hours and consider exchange if the TSB remains above the levels indicated after intensive phototherapy for 6 hours.

The following B/A ratios can be used together with but not in lieu of the TSB level as an additional factor in determining the need for exchange transfusion<sup>52</sup>:

Risk Category	B/A Ratio at Which Exchange Transfusion Should be Considered	
	TSB mg/dl/Alb, g/dl	TSB $\mu\text{mol/L}$ /Alb, $\mu\text{mol/L}$
Infants $\geq 38$ 0/7 wk	8.0	0.94
Infants 35 0/7-36 6/7 wk and well or $\geq 38$ 0/7 wk if higher risk or isoimmune hemolytic disease or G6PD deficiency	7.2	0.84

Infants 35 0/7-37 6/7 wk if higher risk or isoimmune hemolytic disease or G6PD deficiency	6.8	0.80
-------------------------------------------------------------------------------------------	-----	------

If the TSB is at or approaching the exchange level, send blood for immediate type and crossmatch. Blood for exchange transfusion is modified whole blood (red cells and plasma) crossmatched against the mother and compatible with the infant.<sup>53</sup>



**Figure 4: Algorithm providing recommendations for management and follow-up according to predischARGE bilirubin measurements, gestation, and risk factors for subsequent hyperbilirubinemia.** Reprinted with permission from the American Academy of Pediatrics<sup>10</sup>

- Provide lactation evaluation and support for all breastfeeding mothers.
- Recommendation for timing of repeat TSB measurement depends on age at measurement and how far the TSB level is above the 95th percentile (Fig 2). Higher and earlier initial TSB levels require an earlier repeat TSB measurement.
- Perform standard clinical evaluation at all follow-up visits.
- For evaluation of jaundice see 2004 AAP guideline.<sup>1</sup>
- Table 3.<sup>b</sup> Fig 2.<sup>c</sup> Fig 1.<sup>d</sup> In hospital or as outpatient.<sup>e</sup> Follow-up recommendations can be modified according to level of risk for hyperbilirubinemia; depending on the circumstances in infants at low risk, later follow-up can be considered.

**Table 2: Phototherapy Devices Commonly Used in the United States and Their Performance Characteristics.**  
Reprinted with permission from the American Academy of Pediatrics<sup>14</sup>

Device	Manufacturer	Distance to Patient (cm)	Footprint Area (Length x Width, cm <sup>2</sup> )	% Treatable BSA	Spectrum, Total (nm)	*Bandwidth (nm)	Peak (nm)	Footprint Irradiance (μW/cm <sup>2</sup> /nm)		
								Min	Max	Mean ±SD
<b>Light Emitting Diodes [LED]</b>										
neoBLUE	Natus Medical, San Carlos, CA	30	1152 (48 × 24)	100	420–540	20	462	12	37	30 ± 7
PortaBed	Stanford University, Stanford, CA	≥5	1740 (30 × 58)	100	425–540	27	463	40	76	67 ± 8
<b>Fluorescent</b>										
BiliLite CW/BB	Olympic Medical, San Carlos, CA	45	2928 (48 × 61)	100	380–720	69	578	6	10	8 ± 1
BiliLite BB	Olympic Medical, San Carlos, CA	45	2928 (48 × 61)	100	400–550	35	445	11	22	17 ± 2
BiliLite TL52	Olympic Medical, San Carlos, CA	45	2928 (48 × 61)	100	400–626	69	437	13	23	19 ± 3
BiliBed	Medela, McHenry, IL	0	693 (21 × 33)	71	400–560	80	450	14	59	36 ± 2
<b>Halogen</b>										
MiniBiliLite	Olympic Medical, San Carlos, CA	45	490 (25 diam)	54	350–800	190	580	<1	19	7 ± 5
Phototherapy Lite	Philips Inc, Andover, MA	45	490 (25 diam)	54	370–850	200	590	<1	17	5 ± 5
<b>Halogen fiberoptic</b>										
BiliBlanket	Ohmeda, Fairfield, CT	0	150 (10 × 15)	24	390–600	70	533	9	31	20 ± 6
Wallaby II Preterm	Philips, Inc, Andover, MA	0	117 (9 × 13)	19	400–560	45	513	8	30	16 ± 6
Wallaby II Term	Philips, Inc, Andover, MA	0	280 (8 × 35)	53	400–560	45	513	6	11	8 ± 1
SpotLight 1000	Philips, Inc, Andover, MA	45	490 (25 diam)	54	400–560	45	513	1	11	6 ± 3
PEP Model 2000	PEP, Fryeburg, ME	23	1530 (30 × 51)	100	400–717	63	445	12	49	28 ± 11
Bili Soft	GE Healthcare, Laurel, MD	0	825 (25 × 33)	71	400–670	40	453	1	52	25 ± 16

Data in Table 1 are expanded and updated from that previously reported by Vreman et al.<sup>15</sup> The definitions and standards for device assessment are explained below.

**EMISSION SPECTRAL QUALITIES:** Measured data of the light delivered by each of the light sources are presented as the minimum, maximum and range. Light source emission spectra within the range of 300–700 nm were recorded after the device had reached stable light emission, using a miniature fiberoptic radiometer (IRRAD2000, Ocean Optics, Inc, Dunedin, FL). For precision based device assessment, the spectral bandwidth (\*), which is defined as the width of the emission spectrum in nm at 50% of peak light intensity, is the preferred method to distinguish and compare instead of the total range emission spectrum (data usually provided by manufacturers). Emission peak values are also used to characterize the quality of light emitted by a given light source.

**IRRADIANCE:** Measured data are presented as mean ± standard deviation (SD), representing the irradiance of blue light (including spectral bandwidth), for each device's light

footprint at the manufacturer-recommended distance. To compare diverse devices, the spectral irradiance ( $\mu\text{W}/\text{cm}^2/\text{nm}$ ) measurements were made using calibrated BiliBlanket Meters I and II (Ohmeda, GE Healthcare, Fairfield, CT), which were found to yield identical results with stable output phototherapy devices. This type of meter was selected from the several devices with different photonic characteristics that are commercially available, because it has a wide sensitivity range (400–520 nm with peak sensitivity at 450 nm), which overlaps the bilirubin absorption spectrum and which renders it suitable for the evaluation of narrow and broad wavelength band light sources. The devices have been found exceptionally stable during several years of use and agree closely after each annual calibration.

**FOOTPRINT:** The minimum and maximum irradiance measured (at the intervals provided or defined) in the given irradiance footprint of the device (length  $\times$  width). The footprint of a device is that area which is occupied by a patient to receive phototherapy. The irradiance footprint has greater dimensions than the emission surface, which is measured at the point where the light exits a phototherapy device. The minimum and maximum values are shown to indicate the range of irradiances encountered with a device and can be used as an indication of the uniformity of the emitted light. Most devices conform to an international standard to deliver a minimum/maximum footprint light ratio of no lower than 0.4.

**BSA: BODY SURFACE AREA** refers to percent (%) exposure of either the ventral or dorsal planar surface exposed to light and Irradiance measurements are accurate to  $\pm 0.5$ . All of the reported devices are marketed in the United States except the PortaBed, which is a non-licensed Stanford-developed research device and the Dutch Crigler-Najjar Association (used by Crigler-Najjar patients).

## Appendix 19. Perinatal Illicit Substance Exposure in Infants and Pregnant Women

### Scope of the problem

The National Survey on Drug Use and Health (NSDUH) reports that in 2002 and 2003, 4.3 percent of pregnant women aged 15 to 44 had used illicit drugs including opiates, marijuana, cocaine, hallucinogens, inhalants, tranquilizers, stimulants, and sedatives in the past month. Also 4.1 percent reported binge alcohol use and 18.0 percent reported smoking cigarettes.<sup>1</sup> The rate of drug use for pregnant teenagers was approximately 15 percent.<sup>2</sup> The NSDUH data also suggest that women increased their substance use during the year *after* giving birth.

Illicit substance use/abuse (and legal substance use/abuse including alcohol and tobacco) may impact a pregnant woman's health, the course of her pregnancy, and the development of her fetus. Fetal effects of illicit substances include teratogenesis, intrauterine growth retardation, prematurity, low birth weight, birth complications, and central nervous system damage. Exposed newborns are at risk for neonatal abstinence effects and developmental and behavioral abnormalities.

Increasing rates of substance abuse during pregnancy translate into higher numbers of drug-exposed infants. In 2004 and 2005 DHS confirmed in utero drug exposure on 549 and 306 newborns, respectively, in Iowa.<sup>5</sup> However, this number is lower than the expected 1500-1750 newborns based on ~ 37,000 infants being delivered in Iowa annually. This discrepancy is mainly due to poor screening/testing practices. The unrecognized infants are discharged to their homes where mothers are likely to continue to use/abuse illegal substances. These infants continue to be exposed to illegal substances and the associated chaotic life style, health degradation, violence, child abuse and neglect, and family dysfunction.

Research shows that intervention works. Treatment for substance abuse during pregnancy is significantly more effective than at other times in a woman's life. Treatment also has a positive effect on fetal outcome (fewer intensive care admissions due to greater gestational age and birth weight).<sup>6</sup> Early recognition, early intervention, timely entry into treatment, and a sustained, long-term treatment regimen minimize the fetal impacts of perinatal maternal illicit drug use and improve a woman's prognosis for successful, ongoing recovery from addiction. A screening and intervention protocol developed by a panel of experts from across Iowa will help medical care providers to make objective decisions regarding their screening/testing/intervention practices for substance abuse in women during pregnancy and for their offspring.<sup>7,8</sup>

### Purpose

- Develop a community practice guideline for perinatal illicit substance use screening and testing
- Identify illicit substance using patients during pregnancy and their exposed infants
- Provide a screening tool to identify the patients and infants at risk for use and exposure
- Provide guidelines for referral and intervention both for the mother and the infant
- Increase secondary and tertiary prevention efforts to reduce pregnancy related illicit drug use/abuse

The sole goal of identification is to provide early access to assessment and treatment for the mother/infant dyads without application of punitive measures. Identification efforts should start at the first prenatal visit. Screening for maternal substance abuse must begin with a thorough but non-judgmental and compassionate interview. History taking should include questions about the pregnant woman's and her immediate family members' use of prescribed and un-prescribed drugs, tobacco, and alcohol.

### **Consent for Testing**

Specific consent should be sought from the pregnant woman to perform urine toxicology testing if any risk factor is recognized via risk assessment form. Urine testing history including testing offer dates, maternal responses (consented versus declined), test dates, results, and positive testing drug(s) should be documented in the chart. Any concerning result should be shared with the hospital social worker and the pediatric team.

Maternal consent is not needed to test a newborn as long as one or more of the risk indicators related to maternal and infant history or presentation are present; if the risk factors equate to the conditions stated in Iowa law that is "if a health practitioner discovers in a child physical or behavioral symptoms of the effect of exposure to cocaine, heroin, amphetamine, methamphetamine, or other illegal drugs including marijuana, or combination or derivatives that were not prescribed by a health practitioner or if the health practitioner has determined through examination of the natural mother of the child that the child was exposed in-utero." However, the mother should be informed of the decision to test the newborn. Urine/meconium or umbilical cord testing with testing dates and results should be documented in the chart.

### **Risk assessment in Prenatal Clinic, Labor & Delivery, and Neonatal Units**

This tool consists of two assessments; one to assess the risk status of the pregnant/delivering woman, the other of the infant.

- Prenatal clinic/delivery room risk assessment form: Prenatal clinic and labor and delivery staff will fill out this form. This risk assessment should take place at the first encounter with the pregnant woman and at delivery. At other encounters the staff should document that the pregnant woman continues to be abstinent.
- Neonatal risk assessment form: This form will be filled out by the newborn staff who will also review the above listed form and maternal drug testing results.
- Labor and delivery staff should share the maternal risk assessment and testing results with the medical team providing care to the newborn. If prenatal care and delivery take place at different hospitals, the delivery hospital should request maternal consent to obtain the prenatal records from where prenatal care was obtained.
- Each hospital is encouraged to either adopt these attached forms or develop a system to incorporate the risk assessment forms into the prenatal/neonatal records. Prenatal clinic/labor and delivery staff, hospital substance abuse management team, hospital social worker(s), psychiatry staff, and pediatric team should review these forms in their assessment of their client (infant and/or the mother).

### **Test specimens**

- Urine: 10 ml urine; if submission to the lab is to be delayed it should be kept refrigerated until testing.

- Umbilical Cord: 6-8 inch segment; cord blood should be drained from the cord segment and discarded, rinse exterior with normal saline, place cord segment in specimen container; sample is shipped to testing laboratory without preservative at room temperature.
- Meconium: 5 grams of meconium is necessary. It may be refrigerated up to 48 hours after collection.
- Urine is the test of choice for the mother; either umbilical cord testing OR urine and meconium testing should be done to test the newborn.
- Every institution should have a procedure for documentation according to their policies and procedures in handling all specimens obtained for the purpose of newborn toxicology testing.

### **Institutional response to addiction in Prenatal Clinic/Labor & Delivery Unit**

Hospitals are recommended to establish an in-house team to respond to the needs of pregnant women using illicit drugs. This team may include staff from prenatal clinic, newborn unit, hospital social services, hospital/community chemical dependency unit/agency, and psychiatry department. Staff becoming aware of substance abuse or positive test results should have this team or the hospital social worker involved to improve the referral process for treatment at any time during pregnancy. Information on referral centers for substance abuse treatment can be found at, [www.idph/state.ia.us](http://www.idph/state.ia.us) under Bureau of Substance Abuse/Online Resources/Licensed Substance Abuse Treatment Programs.

### **Notification Guidelines**

Any staff becoming aware of an infant testing positive for illicit substances as defined in Iowa code is required by law to file a report with DHS for “Presence of Illegal Drugs.” Any staff becoming aware of maternal substance abuse, positive test result and/or multiplicity of risk indicators for perinatal illicit substance exposure should have the hospital social worker get involved to assess for a need to file a report for “denial of critical care” with DHS for child protection.

### **Resources**

- *National Institute on Drug Abuse (NIDA): Commonly Abused Drugs Chart* (revised March 2011)  
Lists substances of abuse, including tobacco, alcohol, illicit and prescription drugs; Provides information on their common and street names, how they are generally administered and their potentially harmful health effects; Website available at: <http://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs/commonly-abused-drugs-chart>, accessed June 4, 2013.
- *Iowa Substance Abuse Information Center (ISAIC)*  
Provides information for parents, teens, college students, educators and health professionals on substance abuse prevention and recovery; Provides specific age-appropriate information on club drugs, Crack/Cocaine, Heroin/opiates, inhalants, Marijuana, Methamphetamine, prescription and OTC drugs, steroids, synthetic drugs (K2, Bath Salts) and Tobacco; Provides contact information for prevention and treatment programs in Iowa to anyone seeking a referral; Website available at: <http://www.drugfreeinfo.org/drugs/>, accessed June 4, 2013. Helpline is staffed 24/7, (866) 242-4111.

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1. Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *The National Survey on Drug Use and Health Report, Substance Use During Pregnancy: 2002 and 2003 Update*. Washington, DC: US Department of Health and Human Services; June 2005.
  2. Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *National Household Survey on Drug Abuse, 2001*. Washington, DC: US Department of Health and Human Services; February 2003.
  3. Eyler FD, Behnke M, Conlon M, Woods NS, Wobie K. Birth outcome from a prospective, matched study of prenatal crack/cocaine use: II. Interactive and dose effects on neurobehavioral assessment. *Pediatrics*. 1998; 101(2), 237-241.
  4. Walsh C, MacMillan HL, Jamieson E. The relationship between parental substance abuse and child maltreatment: findings from the Ontario Health Supplement. *Child Abuse Negl*. 2003; 27(12):1409-25.
  5. DHS database system: Personal communication.
  6. Little BB, Snell LM, Van Beveren TT, Crowell RB, Trayler S, Johnston WL. Treatment of substance abuse during pregnancy and infant outcome. *Am J Perinatol*. 2003; 20(5):255-62.

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## SAMPLE--Perinatal Illicit Substance Exposure Risk Assessment Tool\*

### A. Obstetrics Clinic and Labor and Delivery Unit

#### ► Risk Factors Related to Current Pregnancy

Maternal urine drug screen positive .....	Yes	No
Maternal report of illicit drug use .....	Yes	No
No prenatal care or late prenatal care (> 16 weeks gestation) .....	Yes	No
Poor prenatal care (≤ 4 prenatal visits) .....	Yes	No
Abruptio placenta.....	Yes	No
Unexplained premature delivery.....	Yes	No
Unanticipated out-of-hospital delivery .....	Yes	No
Unexplained discrepancy between delivery/prenatal care facilities (hospital hopping) .....	Yes	No
Presented at hospital in second stage of labor .....	Yes	No
Precipitous labor (<3 hours) .....	Yes	No
Unexplained episode of acute hypertension (≥140/90 mmHg) .....	Yes	No
Unexplained seizures, stroke, or myocardial infarction.....	Yes	No
Tobacco/Alcohol use or prescription drug (i.e. Vicodin, Oxycotin) abuse .....	Yes	No
Physical attributes suggesting illicit drug use such as IV track marks, visible tooth decay, sores on face, arms or legs.....	Yes	No
Altered mental status suggesting influence/withdrawal from illicit drugs .....	Yes	No
Unexplained stillbirth.....	Yes	No

#### ► Risk Factors Related to Maternal Medical History

Unexplained hepatitis B or C, syphilis or HIV within the last 3 years .....	Yes	No
Untreated maternal depression or major psychiatric illness within the last 3 years	Yes	No
Ever used illegal drugs during any pregnancy.....	Yes	No
Ever delivered an infant who tested positive for illicit drugs .....	Yes	No

#### ► Risk Factors Related to Maternal Social History

History of illicit drug use by mother or partner within the last 3 years .....	Yes	No
History of illicit drug rehabilitation by mother or partner within the last 3 years ..	Yes	No
History of domestic violence by partner within the last 3 years.....	Yes	No
History of child abuse, neglect, or court ordered placement of children outside of home .....	Yes	No

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 Physician/CNM/Nurse Signature

---

 Date

**This risk assessment should take place at the first encounter with the pregnant woman and at delivery. At other encounters the staff should document that the pregnant woman continues to be abstinent. If any of the above questions is answered with a YES, please do the following:**

- Request informed consent from the mother to order urine screening for illicit drugs
- Contact the unit social worker to initiate detailed psychosocial assessment
- Request Chemical Dependency Services consult if the social worker and the physician believe it is warranted
- Request Psychiatry consult if mental health problems recognized
- Communicate the risk status with Newborn Nursery or NICU staff verbally (for L&D staff)
- Attach copy of this form to Labor and Delivery Form and send to the Newborn Nursery or NICU along with the baby

**B. Newborn Nursery/NICU (please review maternal risk assessment from L&D unit)**

**► Risk Factors Related to Newborn Assessment**

Maternal risk factor(s) present .....	Yes	No
Mother was tested during this pregnancy or labor for illicit drugs .....	Yes	No
Mother tested positive for illicit drugs during this pregnancy .....	Yes	No
Gestation $\leq$ 37 weeks from unexplained preterm delivery .....	Yes	No
Unexplained birth weight less than 10 <sup>th</sup> percentile for gestational age .....	Yes	No
Unexplained head circumference less than 10 <sup>th</sup> percentile for gestational age .....	Yes	No
Unexplained seizures, stroke, or brain infarction .....	Yes	No
Unexplained symptoms that may suggest drug withdrawal/intoxication: high pitched cry, irritability, hypertonia, lethargy, disorganized sleep, sneezing, hiccoughs, drooling, diarrhea, feeding problems, or respiratory distress.....	Yes	No
Unexplained congenital malformations involving genitourinary tract, abdominal wall, or gastrointestinal systems .....	Yes	No

\_\_\_\_\_  
Physician/Nurse Practitioner Signature

\_\_\_\_\_  
Date

**► Staff should order meconium and urine screening tests for illicit drugs if the answer is Yes to one or more questions under the Risk Assessment Tool parts A or B.**

\*Tool developed by task force of statewide perinatal experts in collaboration with the Iowa Perinatal Care Program

EFFECTS OF MATERNAL SUBSTANCE ABUSE ON THE FETUS/NEONATE <sup>9</sup>			
SUBSTANCE	PREGNANCY EFFECTS	NEONATAL EFFECTS	WITHDRAWAL SYMPTOMS
Cocaine Amphetamines Methamphetamine	Spontaneous abortion Abruptio placenta Stillbirth Premature delivery (most common effect)	Growth: Low birth weight Smaller head circumference  Malformations: Urogenital Ocular Vascular disruption (limb reduction, intestinal atresia) Skull defect, encephaloceles Midline defects (agenesis of corpus callosum, septo-optic dysplasia)  Neurodevelopmental: Hypertonia Tremulous Porencephaly Impaired organizational state	<u>Onset:</u> <i>At birth or a few days thereafter</i>  Neurobehavioral: Depressed state occurring immediately after birth and lasting 3-4 days Late-emerging hyperirritable phase (onset 3-30 days) Abnormal crying, sleeping, and feeding patterns Possible seizures  Other symptoms: Tachycardia, tachypnea, and apnea Elevated cardiac output, stroke volume, mean arterial blood pressure, and cerebral artery flow velocity resolving by day 2
Opiates (heroin, opium, morphine)	Appetite suppression Iron-deficiency anemia Spontaneous abortion Premature delivery Preterm labor Abruptio placenta Chorioamnionitis Fetal distress Fetal loss Increased C/S related to breech presentation	Growth: Intrauterine growth restriction Smaller head circumference  Other effects: Longer duration of membrane rupture Increased rates of meconium staining Lower Apgar scores Increased incidence of syphilis and HIV infection at birth	<u>Onset:</u> <i>At birth</i> <b>NEONATAL WITHDRAWAL SYNDROME</b> Central Nervous System: Irritable, excessive crying Jittery, tremulous Increased tone Autonomic Dysfunction: Excessive sweating Hypertension Respiratory Symptoms: Nasal stuffiness Gastrointestinal and Feeding Disturbances: Diarrhea Hyperphagia Excessive sucking Hyperactive reflexes Sleep disturbances Seizures Hyperthermia Mottling Tachypnea
Hallucinogens (PCP)	Precipitous delivery Out of hospital delivery	Growth: Small for gestational age	<u>Onset:</u> <i>At birth or shortly after birth</i> <b>PCP-ASSOCIATED SYNDROME</b> Neurological: Severe hypertonicity Sudden episodes of agitation Fluctuating levels of consciousness Early alterations in state lability and consolability <i>Spontaneous clonus persisting for several weeks</i> Gastrointestinal: Abdominal distention Vomiting Diarrhea
Marijuana		Growth: Intrauterine growth restriction	Neurological: Hypertonicity Irritability Jitteriness

## Appendix 20. Hepatitis B

### Maternal Hepatitis B Surface Antigen (HBsAg) Testing

All pregnant women should be tested routinely for HBsAg during an early prenatal visit (e.g., first trimester) in each pregnancy, even if they have been previously vaccinated or tested. Women who were not screened prenatally, those who engage in behaviors that put them at high risk for infection and those with clinical hepatitis should be tested at the time of admission to the hospital for delivery.

If the woman has a positive HBsAg, the case must be reported to the Iowa Department of Public Health, Center for Acute Disease Epidemiology (EPI) within one week per *Iowa Administrative Code* 614 Chapter 1. The case may be reported by phone (1-800-362-2763), by secure fax (515-281-5698), or in writing. The form for reporting a Hepatitis B case is located in the EPI Manual, Hepatitis B section, available at:

[http://www.idph.state.ia.us/idph\\_universalhelp/main.aspx?system=IdphEpiManual](http://www.idph.state.ia.us/idph_universalhelp/main.aspx?system=IdphEpiManual), accessed June 6, 2013.

### Vaccination of Infants at Birth

Birth Dose: Only single-antigen hepatitis B vaccine should be used for the birth dose.

For all medically stable infants weighing >2,000 g at birth and born to HBsAg negative mothers, the first dose of vaccine should be administered before hospital discharge. On a case-by-case basis and only in rare circumstances, the first dose may be delayed until after hospital discharge for an infant who weighs >2,000 g and whose mother is HBsAg negative. When such a decision is made by the physician to withhold the birth dose and a copy of the original laboratory report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant's medical record.

Infants born to mothers who are HBsAg positive should receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) <12 hours of birth.

Infants born to mothers whose HBsAg status is unknown should receive hepatitis B vaccine <12 hours of birth. The mother should have blood drawn as soon as possible to determine her HBsAg status; if she is HBsAg positive, the infant should receive HBIG as soon as possible (no later than one week of age).

Preterm infants weighing <2,000 g and born to HBsAg negative mothers should have their first vaccine dose delayed until one month after birth or hospital discharge. For these infants, a copy of the original laboratory report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant's medical record.

Preterm infants weighing <2,000 g and born to HBsAg positive mothers should receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) <12 hours of birth. The initial vaccine dose (birth dose) should not be counted as part of the vaccine series because of the potentially reduced immunogenicity of hepatitis B vaccine in these infants; three additional doses of vaccine (for a total of four doses) should be administered beginning when the infant reaches one month of age.

### **After the Birth Dose—Completion of Vaccine**

All infants should complete the hepatitis B vaccine series with either single-antigen vaccine or combination vaccine, according to the recommended vaccination schedule.

Administration of four doses of hepatitis B vaccine to infants is permissible in certain situations (e.g., when combination vaccines are administered after the birth dose).

### **Post-vaccination Testing**

For infants born to mothers who are HBsAg positive, post-vaccination testing for anti-HBs and HBsAg should be performed after completion of the vaccine series, at age 9–18 months (generally at the next well-child visit). Testing should not be performed before age 9 months to avoid detection of anti-HBs from HBIG administered during infancy and to maximize the likelihood of detecting late HBV infection. Anti-HBc testing of infants is not recommended because passively acquired maternal anti-HBc might be detected in infants less than 24 months of age born to HBV infected mothers.

### **Resource**

Maternal Hepatitis B Coordinator  
Bureau of Disease Prevention & Immunization  
Iowa Department of Public Health  
321 East 12th Street  
Des Moines, IA 50319  
Phone: (515) 281-7228  
Fax: (800) 831-6292

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1. Iowa Department of Public Health. The Epi Manual: Guide to Surveillance, Investigation, and Reporting. Available at: [http://www.idph.state.ia.us/idph\\_universalhelp/main.aspx?system=IdphEpiManual](http://www.idph.state.ia.us/idph_universalhelp/main.aspx?system=IdphEpiManual). Accessed June 6, 2013.
  2. Iowa Department of Public Health. Bureau of HIV, STD, and Hepatitis: Hepatitis Program. Available at: <http://www.idph.state.ia.us/HivStdHep/Hepatitis.aspx?prog=Hep&pg=HepResources>. Accessed June 6, 2013.
  3. Centers for Disease Control and Prevention (CDC). *MMWR*, December 23, 2005. Vol.54/ No. RR-16. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States. Available at: <http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf>. Accessed June 6, 2013.
  4. Immunization Action Coalition. Available at: <http://www.immunize.org/>. Accessed June 6, 2013.
  5. Centers for Disease Control and Prevention: Viral Hepatitis. Available at: <http://www.cdc.gov/ncidod/diseases/hepatitis/b/>. Accessed June 6, 2013.
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## Appendix 21. Induced Therapeutic Hypothermia for Newborns with Moderate to Severe Hypoxic Ischemic Encephalopathy

Hypoxic ischemic encephalopathy (HIE), also known as birth asphyxia, is the most common cause of brain injury in the newborn. In the United States, perinatal asphyxia and resulting hypoxic ischemic encephalopathy occurs in 1 to 3 per 1,000 births. HIE is defined as acute brain injury that is evidenced by clinical signs of encephalopathy and laboratory findings indicating fetal acidemia. The clinical criteria for defining moderate and severe encephalopathy are described in Table 1. Brain injury occurs as the result of an intrapartum event that disrupts cerebral blood flow and leads to decreased oxygenation in the brain, most often in term or late preterm infants. Events that may lead to HIE include uterine rupture, abruptio placenta, cord prolapse, cord rupture, maternal trauma, hemorrhage, shoulder dystocia, maternal hypotension and fetal heart rate decelerations. Accumulating evidence supports the thinking that this is an evolving process of brain injury which begins with the initial hypoxic-ischemic insult, but then extends into the recovery period. After resuscitation where cerebral perfusion and oxygenation are restored, a secondary reperfusion injury occurs from 6 to 48 hours after the initial event. This second phase of injury involves irreversible cell death. About half of all neonates with severe HIE will die in the newborn period, and most of the survivors experience significant disability.

Table 1

Category	Moderate Encephalopathy	Severe Encephalopathy
1. Spontaneous Activity	Decreased activity	No activity
2. Posture	Distal flexion or complete extension	Decerebrate
3. Autonomic System: Pupils Heart Rate Respirations	Constricted Bradycardia Periodic breathing	Skew deviation/dilated/NR Variable heart rate Apnea
4. Tone	Hypotonia (focal or general)	Flaccid
5. Primitive Reflexes: Suck Moro	Weak Incomplete	Absent Absent
6. Level of Consciousness	Lethargic	Stupor or coma

### Induced Therapeutic Hypothermia

Until recently, treatment for neonates with hypoxic-ischemic encephalopathy has been limited to supportive care and treatment of seizures. However, research has emerged with new treatment options that have great potential for improving outcomes. *Induced hypothermia*, therapy aimed at minimizing the secondary reperfusion injury associated with HIE has been shown to reduce the incidence of death and disability for infants with moderate to severe encephalopathy. Brain cooling has a favorable effect on multiple pathways contributing to ischemic brain injury. Studies suggest that cooling the deep regions of the brain can provide some neuro protection for the newborn at risk for severe brain injury. The Neonatal Resuscitation Program, 6<sup>th</sup> Edition guidelines recommend that infants born at  $\geq 36$  weeks gestation with evolving moderate to severe hypoxic ischemic encephalopathy should be offered therapeutic hypothermia.<sup>2</sup> Treatment should be initiated within 6 hours of birth using an established study protocol in a tertiary facility that is capable of managing the adverse effects of cooling. The potential adverse effects of induced hypothermia include hypoglycemia, decreased myocardial contractility, ventilation-perfusion mismatch, increased blood viscosity, acid-base and electrolyte imbalances, and an increased risk for infection. The cooling process should continue for 72 hours followed by slow rewarming

over at least 4 hours. Cooling centers must have the capability for multidisciplinary care and longitudinal follow-up.

### Cooling Techniques

Induced hypothermia has been studied using two methods of treatment: *selective head cooling and whole-body cooling*. Selective head cooling is accomplished using a cooling cap. For whole-body cooling, the infant is placed on a cooling blanket. Both methods have been associated with a reduction in brain injury following a hypoxic-ischemic event. Although selective head cooling has been associated with fewer systemic effects of hypothermia, it has not been proven effective in cooling the deep regions of the brain where the greatest potential for neuro protection exists. Whole-body cooling involves lowering the core body temperature and is associated with more adverse systemic effects. But, this method provides more consistent regulation of the brain temperature and more effective cooling of the deep brain structures.<sup>3</sup> It is important to note that clinical trials for both cooling techniques are ongoing.

### Induced Whole-Body Cooling in Iowa

Induced whole-body cooling for infants with moderate to severe hypoxic ischemic encephalopathy is currently available at the following perinatal centers in Iowa:

- University of Iowa Children’s Hospital, Iowa City  
NICU, Bay 1: (319) 356-1671
- Mercy Medical Center, Des Moines  
NICU: (515) 358-4000
- Blank Children’s Hospital, Des Moines  
NICU: (515) 241-4490
- St. Luke’s Hospital, Cedar Rapids  
NICU: (319) 369-7247

Practitioners have collaborated in these centers to develop a treatment protocol that mirrors the original NICHD Neonatal Research Network randomized trial comparing whole-body cooling and usual care (control) for term infants with hypoxic-ischemic encephalopathy.<sup>4</sup> Potential candidates for cooling must be <6 hours of age,  $\geq 36$  weeks gestation, and have a birth weight that is >1800 grams. There must be physiologic evidence of acute perinatal depression: a cord blood gas or first postnatal blood gas indicating severe acidemia,  $\text{pH} \leq 7.0$  or base deficit  $\geq 16$  mmol/L. In cases where a blood gas is not obtained or there is moderate acidemia,  $\text{pH} 7.01-7.15$  or base deficit 10-15.9 mmol/L, infants will be considered for treatment if their 10-minute Apgar score is  $\leq 5$  or they require prolonged resuscitation with intubation and ventilation for more than 10 minutes. Neurologic criteria for cooling include the presence of seizures *or* an abnormal neurological exam that is defined by the presence of signs in 3 of 6 categories from Table 1. The general guidelines for identifying potential candidates for induced hypothermia treatment are outlined in the attached algorithm (Figure 1), “Whole Body Cooling for Hypoxic Ischemic Encephalopathy.” **Eligible patients may be excluded from treatment if cooling therapy cannot be initiated by 6 hours of life.** So, it is imperative that practitioners identify potential candidates for cooling soon after birth and initiate transfer to a cooling center.

Clinical trials supported by the Neonatal Research Network are ongoing at the University of Iowa, information is available at: <https://neonatal.rti.org/>, accessed June 26, 2013. Practitioners are encouraged to contact a cooling center to discuss the care of *any* infant at risk for HIE, even those who fail to meet the general guidelines for cooling.

### Temperature Management Prior to Cooling

In an observational study within the NICHD trial, Laptook et al<sup>5</sup> demonstrated that an elevated body temperature is associated with worse outcomes among term infants with hypoxic ischemic encephalopathy. The risk of death or moderate/severe disability was increased with the duration and total time of elevated esophageal temperatures >38.0°C. Death or moderate/severe disability was also associated with the longest duration of skin temperatures >37.5°C. More research is needed to determine the implications for passive cooling prior to induced hypothermia treatment. For newborns with suspected HIE, frequent monitoring of axillary temperatures prior to transfer is recommended. The goal for managing these patients prior to cooling is to maintain a normal temperature, 36.0-37.0°C (96.8-98.6°F) and avoid hyperthermia, temperature >37.5°C (99.5°F).

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## Appendix 22. Progesterone Therapy to Prevent Preterm Birth

Women with a history of preterm delivery are at two to three times greater risk of having a recurrent preterm delivery. For these women, there is one option available to decrease their risk of prematurity—17 alpha-hydroxyprogesterone caproate (17-P). The exact mechanism by which 17-P works is not clearly understood, but it is thought to be related to a reduction of gap junction formation and therefore decreased uterine contractions.<sup>1</sup> It has recently been proposed that the effect of 17-P may also be anti-inflammatory in nature and that it may preserve cervical integrity. Initially studied as a 250mg weekly injection, 17-P was found to decrease the rate of preterm delivery (less than 37 weeks) from 55% in the placebo group to 36% in the treatment group.<sup>2</sup> In addition, infants of the treatment group were significantly less likely to have necrotizing enterocolitis, intraventricular hemorrhage, or need supplemental oxygen. Administration of 17-P was initiated a 16-20 weeks gestation in the initial study. However, the optimal timing to initiate therapy has not been well established.

Follow-up studies have evaluated the use of 17-P with different routes of administration and study populations. Since many women would like to avoid injections, other routes of administration have been investigated. 17-P is not widely marketed by any particular pharmaceutical company. Prophylactic administration of progesterone in the form of a vaginal suppository, 100mg administered every night at bedtime was found to significantly reduce the risk of prematurity (by approximately 50%) in women with a prior preterm delivery.<sup>3</sup> Although this may be a more convenient form for patients due to self-administration, the vaginal suppository is not widely available and must be formulated by individual pharmacies.

A study is currently underway to evaluate the use of vaginal progesterone suppositories in women with a history of prior preterm birth, but with normal cervical lengths during the current pregnancy. For women with no history of a preterm birth, but a shortened ( $\leq 15$  mm) cervix, it appears that progesterone suppositories may be beneficial.<sup>4</sup> As for twin gestations, treatment with prophylactic 17-P does not seem to reduce the risk of preterm delivery.<sup>5</sup> This is likely due to the different mechanism, possibly uterine over distension which many twin premature deliveries are thought to be attributed.

Currently, the American College of Obstetricians and Gynecologists (ACOG) recommends that the use of progesterone supplementation in pregnancy to prevent preterm birth be restricted to women with a history of a prior spontaneous preterm delivery.<sup>6</sup> However, the ideal population, route and timing of progesterone therapy are yet to be determined.

On January 3, 2013 the Iowa Department of Human Services, Iowa Medicaid Enterprise (IME) sent Informational Letter No. 1203 to Iowa Medicaid physicians, nurse practitioners, nurse midwives, hospitals, clinics, maternal health centers and family planning agencies. It provides information regarding Medicaid coverage of 17HP. It is available at, <http://secureapp.dhs.state.ia.us/IMPA/Information/ViewDocument.aspx?viewdocument=af825d92-12fc-4284-af1b-aa75d053f819>, accessed June 26, 2013. For questions about filing claims, please contact the IME Provider Services Unit at 1-800-338-7909, or locally in Des Moines at 515-256-4609 or email at, [imeproviderservices@dhs.state.ia.us](mailto:imeproviderservices@dhs.state.ia.us).

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## Appendix 23. Preventing Shaken Baby Syndrome and Abusive Head Trauma

Shaken Baby Syndrome is a highly preventable form of child abuse which occurs when an infant or young child is violently shaken or slammed into a surface. It is usually triggered by inconsolable infant crying. An infant's neck muscles are very weak and his head is disproportionately large for his body. So, when shaken, the head will violently rotate in a figure eight pattern, causing blood vessels to tear and brain damage to occur.

### Background and Scope of Problem

From 1995 – 2007, 51 Iowa infants died from Shaken Baby Syndrome (SBS). Many more survived with injuries, some of them life-altering. Immediate effects of SBS may include vomiting, seizures, breathing difficulties, lethargy, limpness or stiffness of arms and legs, and bleeding in the eye. Long-term effects may include cognitive and learning disabilities, paralysis, speech impairments, hearing loss, vision problems, and behavior disorders. In approximately 20% of cases the victim dies.

The Iowa Prevent SBS Team, comprised of representatives from Iowa Department of Public Health, Prevent Child Abuse Iowa, Iowa Department of Management and Blank Children's Hospital worked collaboratively to plan and implement a statewide program to prevent Shaken Baby Syndrome. Through a scholarship opportunity, the team attended the PREVENT Institute for Child Maltreatment at University of North Carolina to receive six days of training by experts in the field and coaching toward the development of a five-year plan for Shaken Baby Prevention in Iowa.

Efforts by child abuse prevention advocates and victims' families led to the passage and signing of a bill during the 2009 legislative session, directing the Iowa Department of Public Health to develop and implement a statewide SBS prevention plan. With work from the PREVENT Institute as a foundation, the plan was developed and is currently in the implementation phase. Funds received through Heartland Area Education Agency (American Recovery and Reinvestment Act) have allowed for a pilot SBS prevention program to serve birthing hospitals in a 12-county region in central Iowa. Additional hospitals throughout the state were supported through grant funds from the University of Iowa Children's Hospital. Prevent Child Abuse Iowa received funding from other donors. Many Iowa hospitals have located independent funding and implemented the program as well.

### Period of PUPLE Crying<sup>®</sup>

The educational program selected for use is the *Period of PURPLE Crying<sup>®</sup>*, the only SBS prevention program having undergone randomized, clinical trials to measure its effectiveness. Program development drew from more than 25 years of research on normal infant crying. Using a child development education approach, the *Period of PURPLE Crying<sup>®</sup>* program helps parents and caregivers understand the features of crying in normal infants that can lead to shaking or abuse. The program teaches these crying characteristics in a 10-minute DVD which is available in ten languages. Education is provided to new parents by nurses at the time of discharge from the hospital. The word PURPLE is an acronym representing the prominent characteristics of

inconsolable infant crying: **Peaks** at 2 months; **Unexpected**; **Resists** soothing; **Pain-like** face; **Long** lasting; **Evening** (baby may cry more in late afternoon or evening) Figure 1.



Figure 1

### Behavioral Component

There are **3 action steps** outlined in the *Period of PURPLE Crying*<sup>®</sup> program. They guide the caregiver to respond in a way that reduces crying as much as possible while preventing shaking and abuse. These action steps are:

1. Caregivers should respond to their baby with **“Comfort, carry, walk and talk”** behaviors. This encourages caregivers first to increase contact with their infant to reduce some of the fussing, to attend to their infant’s needs, and to not neglect them.
2. It is **“OK to walk away”** if and when the crying becomes too frustrating. When this happens, caregivers should put the baby in a safe place and then walk away.
3. It is **“Never OK to shake or hurt”** your baby to stop his crying under any circumstances.

The *Period of PURPLE Crying*<sup>®</sup> program is unique because:

- It approaches prevention through educating parents and the community about **normal infant development**, specifically that crying for infants is normal. The program focuses on education and coping skills, rather than on the negative consequences of shaking.
- It uses highly attractive, **positive** messages for caregivers rather than negative warnings about bad consequences.
- It aims to bring about a **cultural change** in our understanding of infant crying both for caregivers and the general public.
- It is designed to increase program “penetration rates” to new parents and be widely acceptable to health care professionals and groups disseminating the intervention.
- Each family of a new baby gets their own set of materials so they can review it as needed and relevant. They can also share it with others who care for their baby.

## **Minimum Requirements for Hospital Implementation**

### **1. Each Family Needs to Receive Their Own Set of Materials**

The tested model requires that each parent of a new infant receives both the *PURPLE* program DVD and booklet to take home with them. Parents may not realize how relevant the material is until baby is a few months old. People learn in different ways; some learn best through reading the brochure, and others learn through viewing the DVD. Families are encouraged to share the information with all caregivers.

### **2. Consistent Messages and Fidelity of the Program**

It is critically important that consistent, clear and correct (evidence-based) messages are given to the parents and the public.

### **3. Triple Dose Strategy**

#### *Dose One: Birthing Hospitals*

The *PURPLE* program is given to families of new babies, both mothers and fathers, in the hospital after the birth of their baby. Maternity nurses are trained and provided with a script to use when presenting the materials to families of new babies. Each family receives from the nurse the 10-minute DVD and 11-page full color booklet about *PURPLE Crying* to take home with them. When possible, the parents should watch the DVD in the hospital and be able to ask the nurse questions. Additionally, the nurse should give the DVD/Booklet to the parent, have them open it and read the booklet at the hospital before they leave. It is very important that the parents receive the program from a person in a position of authority or influence, like a maternity nurse, doctor, midwife or health educator. It is equally important that the person delivering the *PURPLE* program encourages parents to review the materials and encourages them to share the materials with other caregivers of their baby. Users of the program can add a certificate or commitment statement if they wish. These are also available at no cost from the NCSBS.

#### *Dose Two: Prenatal and Postnatal Primary Health Care Units or Public Health Visiting Nurses*

Public health nurse home visitors, pediatricians, family doctors or public health clinics should reinforce the message by talking to parents about the concepts taught in the *Period of PURPLE Crying*<sup>®</sup> program.

#### *Dose Three: Public Education and Media Campaign*

A public education campaign provides this information to everyone, especially to those who did not receive it through the previous two methods. This is an important part of bringing about a cultural change in our understanding of the normality of early increased crying. It is important to educate grandmothers, temporary caregivers, boyfriends, neighbors and relatives about the *PURPLE* program. Understanding of the *Period of PURPLE Crying*<sup>®</sup> among the general population can help ease the stress, and even criticism, of parents dealing with the inconsolable crying of their babies. It also enables mothers and fathers to receive support and reinforcement from those who understand the *Period of PURPLE Crying*<sup>®</sup> concept.

**Resources**

For more information on the *Period of PURPLE Crying*<sup>®</sup>, visit: [www.purplecrying.info](http://www.purplecrying.info).

The program has undergone several years of randomized controlled trials in the United States and Canada. Refer to Randomized Controlled Trials and Research accepted for publication at:

<http://www.dontshake.org/sbs.php?topNavID=4&subNavID=32&navID=345>. Accessed June 6, 2013.

The program is also based on over three decades of research on normal infant crying. Refer to the SBS and Infant Crying Bibliography attributed to this program, available at:

<http://www.dontshake.org/sbs.php?topNavID=4&subNavID=32&navID=332>. Accessed June 6, 2013.

For more information about the *PURPLE* program, contact the National Center on Shaken Baby Syndrome (NCSBS) by email at: [purple@dontshake.org](mailto:purple@dontshake.org); Visit the website at: [www.dontshake.org](http://www.dontshake.org); Call the center at (801) 447-9360) or write to: 1433 North 1075 West, Suite #110, Farmington, Utah 84025.

The *Period of PURPLE Crying*<sup>®</sup> is a registered trademark and all content is copyright protected. All Rights Reserved, Ronald G. Barr, MDCM and the National Center on Shaken Baby Syndrome (2004–2009).

## Appendix 24. Sudden Unexpected Infant Death and Sudden Infant Death Syndrome

Sudden unexpected infant death (SUID), also known as sudden unexpected death in infancy (SUDI), is a term used to describe any sudden and unexpected death in infants less than 1 year of age, where the cause of death is not immediately obvious prior to investigation. With a thorough case investigation, many of these sudden, unexpected infant deaths can be explained.

Explainable causes for SUID include poisoning, metabolic disorders, hyper or hypothermia, suffocation, neglect and homicide (Fig.1).<sup>1</sup> When cases of SUID remain *unexplained* after a complete autopsy, examination of the death scene and review of the clinical history the death is classified as sudden infant death syndrome (SIDS). Ninety percent of SIDS deaths occur before 6 months of age, and the peak incidence occurs between 1 and 4 months. SIDS is uncommon after 8 months of age. It is the leading cause of death in infants from one month to one year of age. Historically, SIDS deaths were observed more often in the colder months of the year, but a pattern of seasonality is no longer apparent.

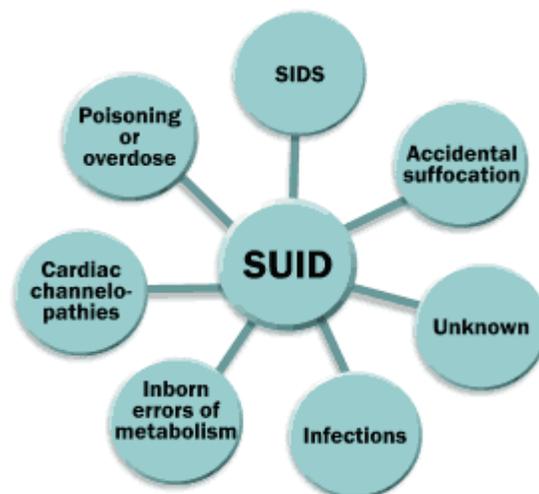


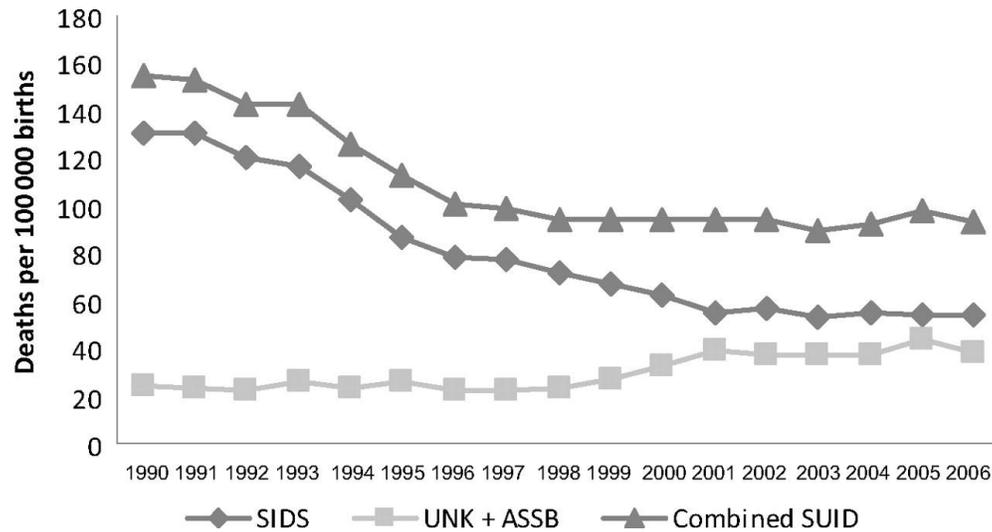
Figure 1. Possible causes of SUID<sup>1</sup>

### Background and Scope of the Problem

In the United States there are approximately 4600 SUID cases every year. Of those deaths, about 2300 are classified as SIDS. In 2006, the latest year from which data are available, 2327 infants died of SIDS.<sup>2</sup> There is a higher incidence among African American infants (99 per 100 000 live births) and American Indian/Alaskan Native infants (112 per 100 000 live births) than non-Hispanic white infants (55 per 100 000 live births).<sup>3</sup> However, no ethnic, religious or socioeconomic group is immune to SIDS.

In their annual report to the governor and general assembly, Iowa's Child Death Review Team reported 91 sleep-related infant deaths (death of a child 1 year of age or less) for the years 2008 and 2009.<sup>3</sup> A sub-committee was formed to explore and analyze data from those 2008 and 2009 deaths. Of those 91 deaths, 22 infants died of SIDS, 42 deaths were classified as SUID, 25 infants died of asphyxia and in 2 cases the cause of death was undetermined. In a majority of these cases the sub-committee found identifiable risk factors in the baby's sleep environment that increased the risk of SIDS and accidental death. The two most common sleep surfaces were adult beds and couches (28/91 and 21/91). Other significant factors included soft bedding (65/91), prone sleep position (34/91 placed prone to sleep and 48/91 found deceased in prone position), co-sleeping with adults or older children (40/91), exposure to tobacco products (53/91) and exposure to alcohol or illicit drugs either in utero, environmentally or their caretakers at the time of death were under the influence of these substances (45/91).

In 1992, the American Academy of Pediatrics (AAP) first recommended that infants be placed in a non-prone position for sleep as a strategy to reduce the risk of SIDS.<sup>4</sup> The "Back to Sleep" campaign was initiated in 1994.<sup>5</sup> Subsequently, the incidence of SIDS in the US declined from 120 deaths per 100 000 live births in 1992 to 56 deaths per 100 000 live births in 2001, a decrease of 53% over 10 years (Fig.2)<sup>1</sup> However, in recent years that decline has plateaued.



**Figure 2: Trends in SIDS and other SUID mortality: United States 1990-2006. UNK indicates ill-defined or unspecified deaths.<sup>1</sup>**

In 2005, the AAP published a policy statement on SIDS.<sup>6</sup> Since then, sleep-related infant deaths due to suffocation, asphyxia, entrapment and other ill-defined or unspecified causes of death have increased. In October 2011, the AAP expanded its recommendations regarding SIDS to focus on a safe sleep environment to reduce the risk of all sleep-related infant deaths. These recommendations are published in their policy statement, “Sudden Infant Death Syndrome and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment.”<sup>7</sup> The background literature review and data analyses on which this policy statement is based are included in the accompanying technical report.<sup>8</sup> Case-control studies are the standard regarding SIDS and other sleep-related deaths as there have been no randomized controlled trials.

The AAP recommendations were developed to reduce the risk of SIDS and sleep-related suffocation, asphyxia and entrapment among infants in the general population. They are intended for parents, health care providers and others who care for infants. Some recommendations are directed toward women who are pregnant or may become pregnant. Most of the epidemiologic studies that established the risk factors for SIDS/SUID include infants up to one year of age. Therefore, the AAP recommendations for sleep position and sleep environment should be used consistently for infants throughout the first year of life.

### **Summary of Evidence and AAP Recommendations for Reducing the Risk of SIDS/SUID<sup>8,9</sup>** **Back to sleep for every sleep.**

- Infants should be placed supine, wholly on their back for every sleep until one year of age. Once an infant is able to independently roll from supine to prone he can remain in whatever sleep position he assumes. Supine sleeping does not increase the risk of choking and

aspiration, even in infants with gastroesophageal reflux. The rare exception is the infant with an upper airway disorder where protective mechanisms are impaired.

- Side sleeping increases the infant's risk of rebreathing expired gases, resulting in hypercapnia and hypoxia. Recent studies have found the risk of SIDS with side sleeping to be similar to prone sleeping.
- Prone sleeping puts the infant at high risk for SIDS. It increases the risk of rebreathing expired gases and overheating. A recent study suggests that prone sleeping alters the autonomic control of the infant's cardiovascular system during sleep which can result in decreased cerebral oxygenation. Compared to back sleepers, babies who sleep on their stomach experience less movement, higher arousal thresholds and longer periods of deep sleep. For unaccustomed stomach sleepers (babies who usually sleep supine), their risk of SIDS when placed prone to sleep is increased by 20%.
- Elevating the head of the crib is not recommended. This is not effective in reducing gastroesophageal reflux and might result in the infant sliding to the foot of the crib into a position that compromises respiration.
- Preterm infants and other infants in the NICU should be placed supine for sleep as soon as they are "medically stable and significantly before the infant's anticipated discharge, by 32 weeks' postmenstrual age."

#### **Use a firm sleep surface.**

- Appropriate sleep surfaces include a crib, bassinet or portable crib/play yard that conforms to the current safety standards.\* The crib mattress should be firm and maintain its shape so that there are no gaps between the mattress and the side of the crib, bassinet or play yard. Soft materials such as pillows, cushions, quilts, comforters or sheepskins should not be placed under the infant. The mattress should be covered only with a fitted sheet.
- Sitting devices such as car safety seats, strollers, swings and infant carriers are not recommended for routine sleep in the hospital or at home. If an infant falls asleep in a sitting device, he should be moved from the seat to a crib or other appropriate flat surface as soon as is practical.
- In 2010, the Consumer Product Safety Commission (CPSC) issued a statement warning consumers about the suffocation hazard to infants, particularly those younger than 4 months, who are carried in an infant sling. When using a sling or cloth carrier, the baby's head should be up and above the fabric so that his face is visible and the nose and mouth are not obstructed.

\*Beginning June 28, 2011 the Consumer Product Safety Commission requires that all cribs manufactured and sold in the US (including resale) must comply with new and improved federal safety standards. The new rules, which apply to full-size and non-full-size cribs, prohibit the manufacture or sale of traditional drop-side rail cribs, strengthen crib slats and mattress supports, improve the quality of hardware, and require more rigorous testing. The details of the rule are available on the CPSC website at, <http://www.cpsc.gov/info/cribs/index.html>, accessed June 26, 2013. By December 28, 2012, child care centers must use only compliant cribs that meet the new federal safety standards.

#### **Room-sharing without bed-sharing is recommended.**

- In 2011, a meta-analysis of 11 studies confirmed that bed sharing, an infant sleeping on the same surface with another person, is a significant risk factor for SIDS. Bed-sharing, puts the baby at risk for accidental injury and death from suffocation, asphyxia, entrapment, falls and strangulation. Younger infants <12 weeks old and those born prematurely or with low birth weight are at greatest risk for SIDS while bed-sharing, possibly because they lack the motor skills to escape potential danger in their sleep environment. The risk of SIDS is higher, the longer the duration of bed-sharing during the night. There is a higher risk of SIDS when the infant is bed-sharing with someone who is not a parent and when there are multiple bed sharers. Epidemiologic studies have not found bed-sharing to be protective of SIDS for any subgroup of the US population. This includes the subgroup of breastfeeding mothers who do not smoke and have not consumed alcohol, drugs or arousal-altering medications.
- The AAP recommends that infants sleep on a separate sleep surface (crib, bassinet, play yard) in the parents' bedroom close to their bed. This arrangement is safer than bed-sharing or solitary sleeping (infant sleeping in a separate room), and it decreases the risk of SIDS by as much as 50%. Room-sharing allows the parents to sleep in close proximity to their infant which facilitates feeding, comforting and nurturing.
- Devices promoted to make bed-sharing "safe" are not recommended (eg, in-bed co-sleeper).
- Multiple studies have demonstrated an extremely high risk of SIDS and suffocation for infants sleeping with adults on couches and armchairs. The AAP recommends that infants not be held for feeding on a couch or armchair when there is a high risk that the parent might fall asleep.
- Co-bedding twins and higher order multiples is not recommended in the hospital or at home.

**Keep soft objects and loose bedding out of the crib to reduce the risk of SIDS, suffocation, entrapment and strangulation.**

- Pillows, quilts, comforters, sheepskins, soft toys and loose blankets in the baby's sleep environment are hazardous and increase the risk of suffocation and rebreathing exhaled gases. In many SIDS cases, the infant was found with his head covered by loose bedding. These objects should be kept out of the crib.
- As an alternative to loose blankets, parents should consider using wearable blankets or sleep sacks.
- Bumper pads and similar products are not recommended.

**Pregnant women should receive prenatal care.**

- Several epidemiologic studies have demonstrated a lower risk of SIDS for infants whose mothers obtained early and regular prenatal care.

**Avoid smoke exposure during pregnancy and after birth.**

- Maternal smoking before, during and after pregnancy continues to be a major risk factor for SIDS in many epidemiologic studies. Exposure to second-hand tobacco smoke adversely affects infant arousal and increases the risk for SIDS in a dose-dependent manner. Third-hand smoke refers to residual contamination after the cigarette has been extinguished. There has been no research to date that demonstrates a risk for SIDS with third-hand smoke. In 2010, Dietz et al estimated that one third of SIDS deaths could be prevented if all maternal smoking during pregnancy was eliminated.
- Mothers should not smoke during pregnancy or after birth.

- Families are encouraged to set strict rules for smoke-free homes and cars to prevent exposure of infants and children to second-hand tobacco smoke.

#### **Avoid alcohol and illicit drug use during pregnancy and after birth.**

- Several studies have demonstrated an increased risk of SIDS with prenatal and postnatal exposure to alcohol and illicit drugs. In 50% of SIDS cases in Iowa in 2008 and 2009 (45/91), the infant was exposed to drugs in utero, environmentally or was being cared for by someone under the influence of drugs or alcohol at the time of death.
- Mothers should not use alcohol or illicit drugs before and during pregnancy.
- Parents should be advised that alcohol and/or illicit drug use in combination with bed-sharing places the infant at particularly high risk of SIDS.

#### **Breastfeeding is recommended.**

- Several recent studies support the protective role of breastfeeding for SIDS; however, they do not distinguish between nursing and feeding expressed human milk. In 2011, researchers reported that *any* breastfeeding was more protective of SIDS than no breastfeeding. And, the protective effect is increased with exclusivity for any duration. In the largest and most recent case-control study of SIDS, German researchers found that exclusive breastfeeding at 1 month of age halved the risk of SIDS. At all ages, the SIDS rate was lower for breastfed infants, partially or exclusively breastfed.
- If possible, infants should be exclusively fed breast milk (breastfeeding or feeding expressed human milk) for the first 6 months of life.

#### **Consider offering a pacifier at nap time and bedtime.**

- Several studies have demonstrated a protective effect of pacifier use on the incidence of SIDS. In two meta-analyses the risk of SIDS was decreased by 50-60%. Even when the pacifier falls out of the baby's mouth the protective effect continues throughout that sleep period. The mechanism of protection is unclear, but the following theories have been proposed: lowered arousal thresholds, favorable modification of autonomic control during sleep, and maintaining airway patency during sleep.
- The AAP recommends that a pacifier be offered when placing the infant down to sleep. Once he falls asleep, it is not necessary to reinsert the pacifier. If the baby refuses the pacifier, he should not be forced to take it.
- Pacifiers should not be attached to clothing or stuffed toys when the infant is sleeping as this may pose a strangulation or suffocation risk.
- To avoid disruption in breastfeeding, pacifier introduction can be delayed until breastfeeding is well established, usually by 3-4 weeks of age.
- There is currently no evidence that thumb-sucking or finger-sucking is protective for SIDS.

#### **Avoid overheating.**

- Studies have shown an increased risk of SIDS with overheating, but the definition of overheating varies.
- Infants should be dressed appropriately for the environment, with no more than 1 layer more than an adult would wear to be comfortable.
- Over-bundling and covering the infant's face and head should be avoided. Caregivers should watch for signs of overheating, such as sweating or the baby's chest feeling hot to the touch.

- It has been suggested that improving/increasing room ventilation with a floor fan or ceiling fan may decrease the risk of SIDS. However, after reviewing the current data the AAP task force concluded that there is insufficient evidence to recommend the use of fans as a strategy to reduce the risk of SIDS.

**Infants should be immunized in accordance with recommendations of the AAP and the Centers for Disease Control and Prevention.**

- There is no evidence of a causal relationship between immunizations and SIDS. And, recent evidence suggests that immunizations may have a protective effect against SIDS. In a 2007 meta-analysis researchers found the risk of SIDS to be halved for those infants who were immunized.

**Avoid commercial devices marketed to reduce the risk of SIDS.**

- In September 2010, the FDA and CPSC issued a joint press release urging parents and caregivers to *stop* using infant sleep positioners because of the risk of suffocation with their use, [www.fda.gov/medicaldevices/safety/alertsandnotices/ucm227301.htm](http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm227301.htm), accessed June 26, 2013. They reported 12 infant deaths related to these devices in the past 13 years. Sleep positioners are devices intended to keep a baby in a desired position during sleep. The two most common types of positioners are the sleeping bolster and the wedge-style positioner. There is no evidence that any benefits of these devices outweigh the risk of suffocation.
- Commercial devices including wedges, positioners, special mattresses, and special sleep surfaces should be avoided as there is no evidence that these devices are safe or reduce the risk of SIDS.

**Do not use home cardiorespiratory monitors as a strategy to reduce the risk of SIDS.**

- Home cardiorespiratory monitors can be useful for detecting apnea or bradycardia in cases where the infant has had an apparent life-threatening event. However, there is no evidence that home monitors are effective for preventing SIDS.

**Supervised, awake tummy time is recommended to facilitate development and to minimize development of positional plagiocephaly.**

- Positional plagiocephaly refers to the persistent flat spot that develops on the back or one side of a baby's head when he sleeps in the same position repeatedly.
- Supervised, awake tummy time is recommended for infants on a daily basis, beginning as early as possible to promote motor development and minimize the risk of positional plagiocephaly.
- Other preventive strategies include routinely changing the baby's orientation in the crib and avoiding excess time spent in sitting devices.
- For detailed information regarding diagnosis, management and prevention strategies see the recent AAP clinical report, "Prevention and management of positional skull deformities in infants."<sup>10</sup>

**Health care professionals, staff in newborn nurseries and neonatal intensive care nurseries, and child care providers should endorse the SIDS risk-reduction recommendations as soon as the infant is clinically stable and significantly before anticipated discharge.**

- Healthcare providers in neonatal intensive care units and newborn nurseries are encouraged to implement and model all of the recommendations to reduce the risk of SIDS.
- All physicians, nurses, other health professionals and child care providers should receive education on safe infant sleep practices.
- Child care providers should implement these safe sleep practices, and it is preferable that they have a written safe sleep policy.

**Media and manufacturers should follow safe sleep guidelines in their messaging and advertising.**

- In a recent study, investigators examined magazines targeted toward child-bearing women. They found that one-third of the sleeping infants pictured and two-thirds of the sleeping environments portrayed unsafe sleep positions and sleep environments.
- “Safe sleep messages should be reviewed, revised and reissued every 5 years to address the next generation of new parents and products on the market.”

The AAP recommends that the national campaign to reduce the risks of SIDS be expanded to include a major focus on the safe sleep environment and ways to reduce the risks of *all* sleep-related infant deaths, including SIDS, suffocation, and other accidental deaths. Pediatricians, family physicians, and other primary care providers should actively participate in this campaign.

**Resources**

*Iowa SIDS Foundation*, a statewide, nonprofit, voluntary health organization dedicated to providing emotional support to SIDS and SUID families residing in Iowa, educating professionals and the general public about SIDS and risk reduction, and funding medical research into the causes of SIDS. Visit website at: [www.iowasids.org](http://www.iowasids.org); Call toll free at, (866) 480-4741.

*First Candle*, a national nonprofit organization dedicated to eliminating stillbirth, SIDS and other sudden unexpected infant deaths. Visit website at: <http://www.firstcandle.org/>.

*National Institutes of Health, Safe to Sleep® Public Education Campaign*. Information and materials available at: <http://www.nichd.nih.gov/sids/>, accessed June 26, 2013; Call toll free at: (800) 505-CRIB (2742).

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## Appendix 25. Cocooning for Pertussis

Diseases do not have age limits. Vaccines are not just for kids, adults need protection too. Parents of newborns need to ensure their vaccinations are up to date to keep themselves healthy and to prevent spreading disease to their infants.

One important vaccine is Tdap (tetanus, diphtheria and acellular pertussis) which protects adults from contracting pertussis and spreading it to others.<sup>1</sup> Infants are at greatest risk of having severe complications from getting pertussis, including death.

Pertussis, also known as whooping cough, is a highly contagious and vaccine-preventable disease that has made a startling comeback in recent years. Immunity from childhood pertussis vaccinations wanes over time, therefore the pertussis immunizations most adults received as children may no longer fully protect them. In infants younger than 1 year of age who get pertussis, more than half must be hospitalized. The younger the infant, the more likely treatment in the hospital will be needed. Of those infants who were hospitalized with pertussis from 2000-2004, approximately 1 in 4 developed pneumonia and 1 in 100 died.<sup>1</sup>

In Iowa, according to the Iowa Department of Public Health, there are approximately 502% more persons with pertussis disease in calendar year 2012 compared to the average of the past five years (the five year average is 179 and 1121 cases have been reported as of Sept 14, 2012). Historically, pertussis activity has been cyclical with increased activity observed every three to five years; therefore the current activity is not unexpected. High levels of activity last occurred in 2004 (1066 cases reported) and 2005 (1106 cases reported), and the number of cases also increased moderately in 2010.

The Advisory Committee on Immunization Practices (ACIP) voted in October of 2012 to recommend that health care professional should administer a dose of Tdap during each pregnancy irrespective of the patient's prior history of receiving Tdap. This is done to maximize the maternal antibody response and passive antibody transfer to the infant. The optimal timing for Tdap administration is between 27 and 36 weeks gestation. For women not previously vaccinated with Tdap, if Tdap was not administer during pregnancy, Tdap should be administered immediately postpartum<sup>3</sup>.

The strategy of protecting infants from pertussis by vaccinating those in close contact with them (e.g. parents, siblings, grandparents, caregivers, etc.) is known as "cocooning." ACIP has recommended cocooning with Tdap vaccine since 2005 and continues to recommend this strategy for all those with expected close contact with newborns. Cocooning enhances maternal vaccination to provide maximum protection to the infant.<sup>4</sup>

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## Appendix 26. Breastfeeding Term & Late Preterm Infants

According to the Centers for Disease Control and Prevention (CDC), Breastfeeding is a priority because we know that this is one way we can positively affect the health of mothers and babies. Evidence shows that several specific practices in medical care settings can significantly affect rates of breastfeeding initiation and duration among women. Birth facility policies and practices that create a supportive environment for breastfeeding should begin prenatally and continue through discharge.

In an effort to improve breastfeeding policy and practice in hospitals, with the goal of increasing the number of babies breastfed in Iowa, the Department of Public Health has implemented a statewide breastfeeding initiative, “6 Steps 4 Success.” The Initiative includes face-to-face meetings with key maternity staff in birthing hospitals to identify and evaluate current breastfeeding policy and offer resources to promote development and improvement of policies. Also, training on basic breastfeeding support and management for staff directly assisting mothers and babies with breastfeeding is offered to all birthing hospitals. To date, there have been face-to-face meetings with key maternity staff in 65 birthing hospitals and 34 staff trainings have been conducted.

The Academy of Breastfeeding Medicine, Protocol #7: Model Breastfeeding Policy (Revision 2010) is included as an addendum to these guidelines. This model breastfeeding protocol provides guidelines for the care of breastfeeding mothers and infants at term. It includes the “Ten Steps to Successful Breastfeeding” as defined by the Baby-Friendly Hospital Initiative. Guidance for each step can be found at, <http://www.babyfriendlyusa.org>, accessed June 26, 2013. The Academy of Breastfeeding Medicine, Protocol #10: Breastfeeding the Late Preterm Infant (34<sup>0/7</sup> to 36<sup>6/7</sup> Weeks Gestation), revised June 2011 provides guidelines specific to the late preterm infant.<sup>8</sup>

### WHO/UNICEF Ten Steps to Successful Breastfeeding

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in the skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within the first hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation even if they are separated from their infants.
6. Give newborn infants no food or drink other than breast milk, unless medically indicated.
7. Practice rooming-in (allow mothers and infants to remain together) 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no artificial nipples or pacifiers to breastfeeding infants.\*
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital.

### Professional Counseling Guides

Counseling Guides for Health Care Professionals, developed by the Iowa Breastfeeding Coalition, are one-page guidelines intended for use by health care professionals when counseling

mothers. The following guidelines are available on the Iowa Department of Public Health website, <http://www.idph.state.ia.us/wic/Breastfeeding.aspx>:

- Prenatal Breastfeeding Promotion
- Breastfeeding in the 1<sup>st</sup> Week (included in these guidelines)
- Breastfeeding at 2 Weeks
- Breastfeeding at 4 Months
- Breastfeeding at 6 Months
- Breastfeeding at 9 Months

## **Breastfeeding in the 1st Week**

### **A Counseling Guide for Health Care Professionals**

#### **Counseling Message for Mothers**

It is important to hold your baby skin-to-skin after birth and breastfeed within the first hour. There are many benefits to breastfeeding skin-to-skin for several weeks. It has been shown to increase breastfeeding duration, enhance growth and development, and builds your confidence.

Offer the breast at least 8-12 times every 24 hours and let your baby feed until baby is satisfied, falls asleep and releases the breast.

Babies have been fed continuously in utero and therefore need to learn the sensation of hunger and be able to communicate this to you. Feeding cues may include:

- Rooting reflex
- Small fussing sounds
- Hand-to-mouth activity
- Smacking lips
- Pre-cry facial grimaces

Crying is a late signal of needing to be fed and babies cry for many other reasons beside hunger. Proper position and latch helps get breastfeeding off to a good start. The following steps tell how:

- Turn baby's whole body toward you.
- Bring baby's chest close to your chest and baby's nose and chin close to your breast.
- Hold baby so that baby's nose is across from your nipple (pillow or folded blanket may help).
- Touch baby's upper or lower lip gently with your nipple so baby will open mouth. Your baby may not open wide enough if both lips are touched at the same time.
- Hold your baby close so when baby's mouth is wide open baby can latch on.

#### **Background for Professionals**

Skin-to-skin contact (i.e., no clothing or bedding between mother and baby) helps baby transition to extrauterine life, stabilizes baby and facilitates the first feeding. Routine medications and the initial weight can be delayed for an hour.

Colostrum, the first milk, is available in small amounts. Colostrum provides everything healthy newborns need. Newborns need to nurse often because their stomachs are small and breastmilk is quickly digested. Frequent feeding and skin-to-skin contact also helps to prevent hypoglycemia, minimize jaundice, and stimulate milk supply. Limited and scheduled feedings may prevent establishment of a good milk supply. By day 3, babies are more alert and have longer periods of wakefulness. Babies usually nurse every 1½ to 3 hours for a total of at least 8-12 feedings every 24 hours. If baby breastfeeds less than 8 times per day, evaluate the feeding pattern to make sure baby is feeding often enough. Information on appropriate intake and weight gain on the other side.

Both mother and baby should be comfortable during feedings. Encourage mothers to support their breasts during feeding. Hold the breast with the thumb across from baby's nose and four fingers below the breast and behind the areola.

Help mothers to learn several feeding positions: side-lying, laid-back, cradle, cross-cradle and football.

Many mothers experience gentle tugging or tenderness during the early days. However, breastfeeding should not hurt. Pain that causes a woman to question whether to continue breastfeeding is not normal and she should be referred to an individual who has been trained to help mothers with breastfeeding problems.

Most prescriptions and over the counter medicines can be taken during breastfeeding.

- Check with health care providers (yours and your baby's) before taking anything.
- Tell your provider how important breastfeeding is to you and ask them to help you continue.

The Infant Risk Center at 806-352-2519 takes calls from parents and professionals on questions about medicines and herbs. The website, [www.infantrisk.org](http://www.infantrisk.org) is a good resource as well.

### Counseling Message for Mothers

Avoid pacifiers and bottles for the first month of your baby's life.\*

Look for signs that baby is getting enough:

- Listen for swallowing.
- Count the number of wet and dirty diapers.

The minimum number of wet and dirty diapers per day for the first week is listed below.

<u>Day</u>	<u>Wets</u>	<u>Stools</u>
1	1	1 dark color
2	2	2 dark to greenish-brown
3-4	3+	1-2 greenish-brown to yellow
5-7	6+	3-4 yellow

Have your baby's weight checked at 3 to 5 days of age by one of the following:

- Baby's health care provider
- Certified lactation consultant
- The hospital nursery
- A visiting nurse
- A well child clinic
- A WIC clinic

The only thing your baby needs other than breastmilk is vitamin D.

Prescribe medications that will expose the baby to the least amount of drug; i.e., those with the shortest half life, lowest dose possible and time the dose related to the baby's typical feeding schedule.

Check credible resources like Thomas Hale's book, *Medications and Mother's Milk* and the website Lactmed. If temporary weaning is necessary, provide instructions about how to maintain a full milk supply with a quality electric breast pump.

### Background for Professionals

Breastmilk is all that healthy babies need. It takes some practice for breastfeeding to go smoothly. Encourage mothers to wait until milk supply is established before introducing bottles or pacifiers. Babies suck differently on bottle nipples and pacifiers which may make it hard for baby to go back to the breast. Early supplemental feedings decrease mother's milk supply and negatively affect baby's intestinal flora. Teach mothers to evaluate how baby is feeding.

- When milk begins to flow, mother should be able to hear the soft "ka, ka" sound as baby swallows.
- Wet and dirty diapers are an excellent indicator of how much breastmilk baby is getting. The stool changes in color and consistency as mature milk replaces colostrum. Once the meconium is eliminated, stools will be loose and unformed, with a consistency of seedy mustard. After 4 weeks of age, stooling patterns change. The volume of stool usually increases and the frequency decreases, however, each baby is different.

An early weight check gives a new mother confidence in her ability to produce enough milk and an opportunity for you to answer questions and provide support. Babies discharged with a weight loss >7% should be seen by their health care provider within 2 days of discharge.

Babies lose weight the first 4 days after birth. Then most breastfed babies begin gaining weight at the rate of ½ to 1 ounce per day. By 2 weeks of age, babies should be at or over birth weight. If not, careful assessment is needed and a referral to someone knowledgeable on breastfeeding management. For further information see the Academy of Breastfeeding Medicine's clinical protocol #3 on supplementation, at [www.bfmed.org](http://www.bfmed.org).

All healthy newborn breastfed infants should receive 400 IU of vitamin D per day beginning in the first few days of life to prevent rickets and vitamin D deficiency.

Questions? Call one of the following:

- Certified breastfeeding educator/counselor
- Certified lactation consultants (IBCLC)
- Health care professionals
- La Leche League
- Peer support groups
- Physicians
- WIC staff

Mothers and babies are not born knowing how to breastfeed. It takes patience and practice to learn and recognize each other's signals. Identify sources of support from family, friends, and the community. Encourage mothers to call with questions or for advice.

*Developed by the Iowa Breastfeeding Coalition, Distributed by the Iowa WIC Program, Revised 2011<sup>6</sup>*

\*In their 2011 Policy Statement on SIDS and other sleep-related infant deaths, the American Academy of Pediatrics makes the following recommendation: "Consider offering a pacifier at nap time and bedtime. Although the mechanism is yet unclear, studies have reported a protective effect of pacifiers on the incidence of SIDS...For breastfed infants, delay pacifier introduction until breastfeeding has been firmly established, usually by 3 to 4 weeks of age."<sup>9</sup>

### **Contraindications to Breastfeeding<sup>10</sup>**

#### *Medical Conditions:*

-Conditions where the mother **should not** breastfeed **OR** feed expressed breast milk:

- Mother is HIV positive
- Mother is positive for human T-cell lymphotropic virus type I or II (HTLV-1 or HTLV-2)
- Mother has untreated brucellosis
- Infant has classic galactosemia

-Conditions where the mother may **partially** breastfeed or **partially** feed expressed breast milk:

- Infant has phenylketonuria (PKU): may alternate breastfeeding with special protein-free or modified formula, provided that appropriate blood monitoring is available

-Conditions where the mother **should not** breastfeed, but **can** feed expressed breast milk:

- Mother has active (infectious) untreated tuberculosis: can resume breastfeeding after treated for minimum of 2 weeks and documented that mother is no longer infectious
- Mother has active herpes simplex lesions on her breast: may breastfeed using other breast if not affected
- Mother develops varicella in period of 5 days before through 2 days after delivery: mother should be separated from infant, but expressed milk can be used for feeding
- Mother is acutely infected with H1N1 influenza: mother should be separated from infant until she is afebrile

#### *Maternal Medications:*

- There are a limited number of agents that are contraindicated with breastfeeding, and usually an appropriate substitute can be found.
- LactMed, an internet resource published by the National Library of Medicine/ National Institutes of Health is the most comprehensive, up-to-date source of information regarding the safety of maternal medications when the mother is breastfeeding.<sup>11</sup> This resource is available at, <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT>, accessed June 26, 2013.

- Breastfeeding is not recommended when the mother is receiving medication from the following classes of drugs: amphetamines, chemotherapy agents, ergotamines, and statins.

#### *Maternal Substance Abuse: Drugs, Alcohol, Tobacco*

- Narcotic-dependent mothers can be encouraged to breastfeed if they are enrolled in a supervised methadone maintenance program and have negative screening for HIV and illicit drugs.
- Breastfeeding is contraindicated with use of the following street drugs: PCP (phencyclidine), cocaine, and cannabis.
- Alcoholic beverages should be limited to an occasional intake but no more than 0.5g alcohol per kg body weight, which for a 60kg mother is approximately 2oz liquor, 8oz wine, or 2 beers.<sup>12</sup>
- Nursing should take place 2 hours or longer after the mother consumes alcohol to minimize its concentration in the breast milk.
- Maternal smoking is not an absolute contraindication to breastfeeding, but should be strongly discouraged as it is associated with an increased incidence of infant respiratory allergy and SIDS.

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## ABM Clinical Protocol #7: Model Breastfeeding Policy (Revision 2010)

The Academy of Breastfeeding Medicine Protocol Committee

*A central goal of The Academy of Breastfeeding Medicine is the development of clinical protocols for managing common medical problems that may impact breastfeeding success. These protocols serve only as guidelines for the care of breastfeeding mothers and infants and do not delineate an exclusive course of treatment or serve as standards of medical care. Variations in treatment may be appropriate according to the needs of an individual patient.*

### Purpose

**T**HE PURPOSE OF THIS PROTOCOL is to promote a philosophy and practice of maternal–infant care that advocates breastfeeding. Care should support the normal physiologic functions involved in the establishment of this maternal–infant process and assist families choosing to breastfeed with initiating and developing a successful and satisfying experience.

This policy is based on recommendations from the most recent breastfeeding policy statements published by the Office on Women’s Health of the U.S. Department of Health and Human Services,<sup>1</sup> the American Academy of Pediatrics,<sup>2</sup> the American College of Obstetricians and Gynecologists,<sup>3</sup> the American Academy of Family Physicians,<sup>4</sup> the World Health Organization,<sup>5</sup> the Academy of Breastfeeding Medicine,<sup>6</sup> and the UNICEF/World Health Organization evidence-based Ten Steps to Successful Breastfeeding.<sup>5,7–10</sup>

In addition to evidence supporting each of the Ten Steps improving breastfeeding exclusivity or duration, there is also documentation of a dose-responsive effect: Women at hospitals implementing six of seven studied steps in one report were six times more likely to meet their exclusive breastfeeding goals than those from hospitals implementing no or only one of the steps.<sup>11</sup> The degree of compliance is also important: Breastfeeding duration is longer when hospitals’ self-reported compliance with the steps is better.<sup>12</sup>

### Policy Statements

1. The “name of institution” staff will actively support breastfeeding as the preferred method of providing nutrition to infants. A multidisciplinary, culturally appropriate team comprising hospital administrators, physician and nursing staff, lactation consultants and specialists, nutrition staff, other appropriate staff, and parents shall be established and maintained to identify and eliminate institutional barriers to breastfeeding. On a yearly basis, this group will compile and evaluate

data relevant to breastfeeding support services and formulate a plan of action to implement needed changes.

2. A written breastfeeding policy will be developed and communicated to all healthcare staff. The “name of institution” breastfeeding policy will be reviewed and updated biannually using current research as an evidence-based guide.
3. All pregnant women and their support people as appropriate will be provided with information on breastfeeding and counseled on the benefits of breastfeeding, contraindications to breastfeeding, and risk of formula feeding.<sup>13</sup>
4. The woman’s desire to breastfeed will be documented in her medical record.
5. Mothers will be encouraged to exclusively breastfeed unless medically contraindicated. The method of feeding will be documented in the medical record of every infant. (Exclusive breastfeeding is defined as providing breastmilk as the sole source of nutrition. Exclusively breastfed babies receive no other liquids or solids with the exception of oral medications prescribed by a medical care provider for the infant.)
6. At birth or soon thereafter all newborns, if baby and mother are stable, will be placed skin-to-skin with the mother. Skin-to-skin contact involves placing the naked baby prone on the mother’s bare chest. The infant and mother can then be dried and remain together in this position with warm blankets covering them as appropriate. Mother–infant couples will be given the opportunity to initiate breastfeeding within 1 hour of birth. Post-cesarean-birth babies will be encouraged to breastfeed as soon as possible, potentially in the operating room or recovery area (Table 1). The administration of vitamin K and prophylactic antibiotics to prevent ophthalmia neonatorum should be delayed for the first hour after birth to allow uninterrupted mother–infant contact and breastfeeding.<sup>14–16</sup>
7. Breastfeeding mother–infant couples will be encouraged to remain together throughout their hospital stay,

TABLE 1. BEST PRACTICES FOR BREASTFEEDING SUPPORT FOLLOWING CESAREAN DELIVERY

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Early mother–infant contact. Avoidance of separation unless dictated by medical indications
Early breastfeeding <1 hour after delivery. Can occur in delivery suite or recovery room
Regional anesthesia for cesarean delivery
Infant positioning to minimize incision discomfort. Use of side-lying, football breastfeeding position. Use of pillow to protect incision site
Use of regional medication after cord clamping to decrease the need for postoperative narcotics
Preferential use of narcotics with less adverse effects on neonatal behavior
Frequent breastfeeding and rooming-in such as would be routine for vaginal delivery
Protocols for early breast pumping and expression if infant separation is dictated because of medical indication such as prematurity. Should be initiated day of delivery
Easy availability of lactation expert for further support and assistance if needed
Monitoring for delayed onset of lactation in mother and excessive weight loss in the newborn
Education and encouragement of family members in methods of supporting breastfeeding in the new family

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including at night (rooming-in). Skin-to-skin contact will be encouraged as much as possible.

8. Breastfeeding assessment, teaching, and documentation will be done on each shift and whenever possible with each staff contact with the mother. Each feeding will be documented, including latch, position, and any problems encountered in the infant's medical record. For feedings not directly observed, maternal report may be used. Every shift, a direct observation of the baby's position and latch-on during feeding will be performed and documented.
9. Mothers will be encouraged to utilize available breastfeeding resources, including classes, written materials, and video presentations, as appropriate. If clinically indicated, the healthcare professional or nurse will make a referral to a lactation consultant or specialist for additional education and assistance.
10. Breastfeeding mothers will be instructed about:
  - a. Proper positioning and latch-on
  - b. Nutritive suckling and swallowing
  - c. Milk production and release
  - d. Frequency of feeding/feeding cues
  - e. Hand expression of breastmilk and use of a pump if indicated
  - f. How to assess if infant is adequately nourished and
  - g. Reasons for contacting the healthcare professional

These skills will be taught to primiparous and multiparous women, provided in written form,<sup>17</sup> and reviewed before the mother goes home.

11. Parents will be taught that breastfeeding infants, including cesarean-birth babies, should be put to breast a minimum of eight to 12 times each 24 hours, with some infants needing to be fed more frequently. Infant feeding cues (e.g., increased alertness or activity, mouthing, or rooting) will be used as indicators of the baby's readiness for feeding. *Breastfeeding babies will be breastfed at night.*
12. Time limits for breastfeeding on each side will be avoided. Infants can be offered both breasts at each feeding but may be interested in feeding only on one side at a feeding during the early days.
13. No supplemental water, glucose water, or formula will be given unless specifically ordered by a healthcare professional (e.g., physician, certified nurse midwife, or

nurse practitioner) or by the mother's documented and informed request. Prior to non-medically indicated supplementation, mothers will be informed of the risks of supplementing. The supplement should be fed to the baby by cup if possible and will be no more than 10–15 mL (per feeding) in a term baby (during the first 1–2 days of life). Alternative feeding methods such as syringe or spoon feeding may also be used; however, these methods have not been shown to be effective in preserving breastfeeding. Bottles will not be placed in or around the breastfeeding infant's bassinet.<sup>18–20</sup>

14. This institution does not give group instruction in the use of formula. Those parents who, after appropriate counseling, choose to formula feed their infants will be provided individual instruction.
15. Pacifiers will not be given to normal full-term breastfeeding infants. The pacifier guidelines at "name of institution" state that preterm infants in the Neonatal Intensive Care or Special Care Unit or infants with specific medical conditions (e.g., neonatal abstinence syndrome) may be given pacifiers for non-nutritive sucking. Newborns undergoing painful procedures (e.g., circumcision) may be given a pacifier as a method of pain management during the procedure. The infant will not return to the mother with the pacifier. "Name of institution" encourages "pain-free newborn care," which may include breastfeeding during the heel stick procedure for the newborn metabolic screening tests.<sup>21</sup>
16. Routine blood glucose monitoring of full-term healthy appropriate-for-gestational-age infants is not indicated. Assessment for clinical signs of hypoglycemia and dehydration will be ongoing.<sup>22</sup>
17. Antilactation drugs will not be given to any postpartum mother.
18. Routine use of nipple creams, ointments, or other topical preparations will be avoided unless such therapy has been indicated for a dermatologic problem. Mothers with sore nipples will be observed for latch-on techniques and will be instructed to apply expressed colostrum or breastmilk to the areola/nipple after each feeding.
19. Nipple shields or bottle nipples will *not* be routinely used to cover a mother's nipples, to treat latch-on problems, or to prevent or manage sore or cracked nipples or used when a mother has flat or inverted nipples. Nipple shields will be used only in conjunction

- with a lactation consultation and after other attempts to correct the difficulty have failed.
20. After 24 hours of life, if the infant has not latched-on or fed effectively, the mother will be instructed to begin to massage her breasts and hand express colostrum into the baby's mouth during feeding attempts. Skin-to-skin contact will be encouraged. Parents will be instructed to watch closely for feeding cues and whenever these are observed to awaken and feed the infant. If the baby continues to feed poorly, hand expression by the mother or a double set-up electric breast pump will be initiated and maintained approximately every 3 hours or a minimum of eight times per day. Any expressed colostrum or mother's milk will be fed to the baby by an alternative method. The mother will be reminded that she may not obtain much milk or even any milk the first few times she expresses her breasts. Until the mother's milk is available, a collaborative decision should be made among the mother, nurse, and healthcare professional (e.g., physician/nurse practitioner/certified nurse midwife) regarding the need to supplement the baby. Each day the responsible healthcare professional will be consulted regarding the volume and type of supplement. Pacifiers will be avoided. In cases of problem feeding, the lactation consultant or specialist will be consulted.<sup>14</sup>
  21. If the baby is still not latching on well or feeding well when discharged to home, the feeding/expression/supplementing plan will be reviewed in addition to routine breastfeeding instructions. A follow-up visit or contact will be scheduled within 24 hours. Depending on the clinical situation it may be appropriate to delay discharge of the couplet to provide further breastfeeding intervention, support, and education.
  22. All babies should be seen for follow-up within the first few days postpartum. This visit should be with a physician (pediatrician or family physician) or other qualified healthcare practitioner for a formal evaluation of breastfeeding performance, a weight check, assessment of jaundice, and age-appropriate elimination: (a) For infants discharged at less than 2 days of age (<48 hours), follow-up at 2-4 days of age; and (b) for infants discharged between 48 and 72 hours, follow-up at 4-5 days of age. Infants discharged after 5-6 days may be seen 1 week later.
  23. Mothers who are separated from their sick or premature infants will be:
    - a. Instructed on how to use skilled hand expression or the double set-up electric breast pump. Instructions will include expression at least eight times per day or approximately every 3 hours for 15 minutes (or until milk flow stops, whichever is greater) around the clock and the importance of not missing an expression session during the night.
    - b. Encouraged to breastfeed on demand as soon as the infant's condition permits
    - c. Taught proper storage and labeling of human milk and
    - d. Assisted in learning skilled hand expression or obtaining a double set-up electric breast pump prior to going home
  24. Before leaving the hospital<sup>23</sup> breastfeeding mothers should be able to
    - a. Position the baby correctly at the breast with no pain during the feeding
    - b. Latch the baby to breast properly
    - c. State when the baby is swallowing milk
    - d. State that the baby should be nursed a minimum of eight to 12 times a day until satiety, with some infants needing to be fed more frequently
    - e. State age-appropriate elimination patterns (at least six urinations per day and three to four stools per day by the fourth day of life)
    - f. List indications for calling a healthcare professional
    - g. Manually express milk from their breasts
  25. Prior to going home, mothers will be given the names and telephone numbers of community resources to contact for help with breastfeeding, including (the support group or resource recommended by "name of institution").
  26. "Name of institution" does not accept free formula or free breastmilk substitutes. Nursery or Neonatal Intensive Care Unit discharge bags offered to all mothers will not contain infant formula, coupons for formula, logos of formula companies, or literature with formula company logos.
  27. "Name of institution" health professionals will attend educational sessions on lactation management and breastfeeding promotion to ensure that correct, current, and consistent information is provided to all mothers wishing to breastfeed.<sup>24</sup>

#### Application

All breastfeeding patients.

#### Exceptions

Breastfeeding is contraindicated<sup>2,25</sup> in the following situations:

- Mothers who are human immunodeficiency virus-positive in locations where artificial feeding is acceptable, feasible, affordable, sustainable, and safe<sup>26</sup>
- Mothers currently using illicit drugs (e.g., cocaine, heroin) unless specifically approved by the infant's healthcare provider on a case-by-case basis
- Mothers taking certain medications. Most prescribed and over-the-counter drugs are safe for the breastfeeding infant. Some medications may make it necessary to interrupt breastfeeding, such as radioactive isotopes, antimetabolites, cancer chemotherapy, some psychotropic medications, and a small number of other medications. The references used at "name of institution" are *Medications and Mothers' Milk* by T. Hale,<sup>27</sup> the drugs and lactation database of the U.S. National Library of Medicine, TOXNET: Toxicology Data Network (LactMed),<sup>28</sup> *Breastfeeding: A Guide for the Medical Profession* by R.A. Lawrence and R.M. Lawrence,<sup>29</sup> *Drugs in Pregnancy and Lactation* by G.G. Briggs, R.K. Freeman, and S.J. Yaffe,<sup>30</sup> and the American Academy of Pediatrics Statement on the Transfer of Drugs into Human Milk.<sup>31</sup> (NB: Alternative local references and resources may be substituted if available.)

- Mothers with active, untreated tuberculosis. A mother can express her milk until she is no longer contagious.
- Infants with galactosemia
- Mothers with active herpetic lesions on the breast(s). Breastfeeding can be recommended on the unaffected breast. (The Infectious Disease Service will be consulted for problematic infectious disease issues.)
- Mothers with onset of varicella within 5 days before or up to 48 hours after delivery, until she is no longer infectious
- Mothers with human T-cell lymphotropic virus type I or type II

### The Ten Steps to Successful Breastfeeding

1. Have a written breastfeeding policy that is routinely communicated to all healthcare staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within 1 hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants.
6. Give newborn infants no food or drink other than breastmilk, unless medically indicated.
7. Practice rooming-in—allow mothers and infants to remain together—24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no artificial teats or pacifiers to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them, on discharge from the hospital or clinic.

### Other Related Policies

- Policy #
- Other references/resources<sup>32–35</sup>

### Initiated by

List appropriate names, departments.

### Contributing Departments

List all departments involved in developing policy.

### Research Needs

Change in the hospital setting is hard. A comprehensive hospital breastfeeding policy that is clearly communicated to maternity staff may be a key step in the change process to support breastfeeding dyads. Rosenberg et al.<sup>36</sup> reported that the presence of a written breastfeeding policy was independently associated with a statistically significant increase in the rate of breastfeeding.

Certain maternity care practices like The Ten Steps to Successful Breastfeeding (Table 2), the framework of the WHO-UNICEF Baby-Friendly Hospital Initiative, have been shown to influence breastfeeding outcomes. An analysis of the Infant Feeding Practices Study II (IFPS II) found that

breastfeeding women who did not experience any of the Steps were 13 times more likely to stop breastfeeding early compared to those who experienced at least six Steps. In addition, the more steps practiced, the higher the duration and exclusivity of breastfeeding at 2 months.<sup>37</sup> As only 8% of women surveyed in the IFPS II reported experiencing all six of the Baby-Friendly efforts measured, a great deal of work remains to be done.

Recommendations for further research include:

1. What are effective strategies to increase implementation of Baby-Friendly practices in the hospital setting?
2. How best to monitor staff adherence to a hospital's breastfeeding policy?
3. What are the effects of additional practices, not included in the original Ten Steps, on breastfeeding initiation and duration?

### Acknowledgments

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- ABM protocols expire 5 years from the date of publication. Evidence-based revisions are made within 5 years or sooner if there are significant changes in the evidence.

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## Appendix 27. Tobacco Cessation

Women should not initiate smoking cigarettes, and current smokers should pursue smoking cessation. There is no known level of smoking that is considered a safe consumption level. Parents who smoke often expose their children to secondhand smoke, with associated adverse health consequences and economic costs, and model smoking behavior to their children, potentially increasing the likelihood that their children will become smokers

### Background

In 2011, approximately 2,800 Iowa deaths were directly attributable to tobacco use. Another 1,600 deaths were identified as likely being due to tobacco use. Estimated annual health care costs in Iowa directly related to tobacco use now total \$1 billion. Cigarette smoking is the leading cause of preventable death and poses one of the most significant threats to public health in the United States. Approximately 173,940 women died in the U.S. during 2000-2004 due to smoking. The CDC estimates that 18.1% of adult U.S. women aged 18 years or older are current cigarette smokers (CDC 2009).

### Smoking and Childbearing

Smoking is harmful to the health of pregnant women and their fetuses. However, despite evidence of these harmful effects, Iowa Vital Records data for 2011 indicate that 12.7% of pregnant women in their third trimester of pregnancy stated that they were smokers. Iowa women on Medicaid were more than four times as likely to smoke in the last 3 months of pregnancy when compared to women with private insurance. Smoking during pregnancy presents major, avoidable health risks to both the woman and her fetus. Smoking has been linked to doubling a woman's risk of having a low birth-weight baby, slowing fetal growth, and increasing the risk of preterm delivery. Compared to babies of nonsmokers, babies whose mothers smoked during pregnancy are up to three times more likely to die from sudden infant death syndrome (March of Dimes, 2009).

### Health Care Professional

Health care professionals should educate all women about the risks of tobacco use and second-hand smoke, screen women for tobacco use, and support cessation efforts. Focusing attention on these efforts before, during and after pregnancy is critically important because of the harmful effects of smoking and exposure to second hand smoke on the fetus and newborn. See ACOG's 2011 Smoking Cessation During Pregnancy – *A Clinician's Guide to Helping Pregnant Women Quit Smoking* at the following link:

[http://www.acog.org/About\\_ACOG/News\\_Room/~media/Departments/Tobacco%20Alcohol%20and%20Substance%20Abuse/SCDP.pdf](http://www.acog.org/About_ACOG/News_Room/~media/Departments/Tobacco%20Alcohol%20and%20Substance%20Abuse/SCDP.pdf), accessed June 26, 2013.

One evidence based model for brief tobacco cessation intervention is “2 A’s and a R”. This model was developed by the American Dental Hygienists Association visit, [www.askadviserefer.org](http://www.askadviserefer.org), accessed June 26, 2013.

Providers are encouraged to talk to each patient about quitting, but the time to perform this intervention is limited so this intervention is very brief. Providers are educated to ask about tobacco use as well as identify and document tobacco use status for each patient at every visit.

1. **Ask about tobacco use.** Ideally health care practitioners should implement an office-wide system that ensures that tobacco use status is queried and documented at each visit
2. **Advise to quit.** In a clear strong and personalized manner, urge ever tobacco user to quit. The provider should emphasize the importance of quitting before health problem arise. Once the patient has been advised to quit, the provider is encouraged to ask probing questions to determine readiness to quit before making a fax referral. This could be as simple as asking the patient, “How do you feel about quitting” or “Have you ever tried quitting before?” “How did it go?”
3. **Refer patient to Quitline Iowa.** If a patient expresses and interest in quitting, the provider recommends participation with Quitline Iowa. The provider’s is then encourage to ask the patient to sign a fax referral form, making sure the patient fills in contact information and preferred call-back times.

Quitline Iowa will provide cessation assistance including helping patient set a quit date and develop a plan to quit. Quitline counselors will help identify strategies for coping with cravings, withdrawal symptoms, smoking triggers, and other challenges, including providing information about pharmacotherapy. A variety of printed materials covering health information, quit tips, relaxation techniques, and other helpful advice can also be mailed to patients. In addition, Quitline counselors will identify and refer patients to other resources, such as community support groups or smoking cessation classes, for those patients who would prefer such services.

### Smoking Cessation Coverage Available to Medicaid Members

When providers are working with Medicaid eligible women a helpful tool is located on the Iowa Department of Public Health’s website. It has tips on making a fax referral to the Quitline, Nicotine Replacement Therapy (Medicaid Prior Authorization form) and Cessation Medication Fax referral form, available at:

<http://www.idph.state.ia.us/TUPAC/Cessation.aspx>, accessed June 26, 2013.

Iowa Medicaid Enterprise has an Informational Letter no. 1048 released in 2011 to assist you. It is available at the following link:

[http://www.ime.state.ia.us/docs/1048\\_SmokingCessationCoverageAvailabletoMedicaidMembers.pdf](http://www.ime.state.ia.us/docs/1048_SmokingCessationCoverageAvailabletoMedicaidMembers.pdf), accessed June 26, 2013.

### For Clients

#### Quitline IOWA



Quitting is about more than just not smoking. When patients join the Quitline program, a Quit Coach® will help them become an expert in living without tobacco using "The 4 Essential Practices to Quit For Life," based on 25 years of research and experience helping people quit tobacco.

### Web Coach

Another new option from the Iowa Department of Public Health the “**Web Coach**” is an interactive online program that provides each participant with a personalized experience. The Web Coach focuses on four essential practices to enable smokers to quit for life:

- Quit at their own pace
- Conquer urges to smoke
- Use medications so they really work
- Don’t just quit; become a non-smoker

Each of these practice areas includes articles, videos, e-lessons and interactive worksheets to help participants successfully quit tobacco. Progress toward that goal includes a spending calculator, to help a participant compare the cost of tobacco vs. the cost of medication; a tobacco usage tracker, which allows a participant to track when and where they smoke to identify patterns and triggers; and discussion forums and online groups for more personalized social support. After quitting, participants can track how long they’ve been tobacco-free and see how much money they’ve saved and time that has been added back to their daily life since quitting tobacco. For more information about **Web Coach**, call Quitline Iowa 1-800-784-8669 or visit, [www.quitlineiowa.org](http://www.quitlineiowa.org).

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## Appendix 28. Influenza Immunization for Pregnant Women & Health Care Workers

Influenza is a highly contagious viral infection that affects mainly the nose, throat, chest and lungs. Influenza may cause mild to severe illness, and may even lead to death. In the very young, the elderly, and those with other serious medical conditions, infection can lead to severe complications such as pneumonia.

Everyone unless contraindicated, 6 months and older should get a influenza vaccine each year. This recommendation has been in place since February 24, 2010 when CDC's Advisory Committee on Immunization Practices (ACIP) voted for "universal" influenza vaccination in the U.S. to expand protection against influenza to more people. While everyone should get a vaccine each influenza season, it's especially important that those at high risk of having serious influenza-related complications and for those who live with or care for people at high risk for developing influenza-related complications. Those in greatest need of being vaccinated include:

- Pregnant women
- Children younger than 5, but especially children younger than 2 years old
- People 50 years of age and older
- People of any age with certain chronic medical conditions
- People who live in nursing homes and other long-term care facilities
- People who live with or care for those at high risk for complications from flu, including Health care workers, Household contacts of persons at high risk for complications from the flu, Household contacts and out of home caregivers of children less than 6 months of age (these children are too young to be vaccinated).<sup>1</sup>

Receiving an influenza vaccine is the first and most important step in protecting against influenza. When given during pregnancy, the influenza vaccine has been shown to protect both the mother and her baby (up to 6 months old) from influenza. Influenza is more likely to cause severe illness in pregnant women than in women who are not pregnant. Changes in the immune system, heart, and lungs during pregnancy make pregnant women more prone to severe illness from influenza as well as hospitalizations and even death. Pregnant women with influenza also have a greater chance for serious problems for their unborn babies, including premature labor and delivery.<sup>2</sup>

To prevent influenza and complications in pregnant women, in 2004 the Centers for Disease Control and Prevention's (CDC) Advisory Committee for Immunization Practices (ACIP) began recommending routine immunization of pregnant women with the influenza vaccine at any stage of pregnancy. The nasal spray vaccine is not recommended for use in pregnant women. Influenza vaccine will protect pregnant women, their unborn babies, and protect the baby after birth.<sup>3</sup>

In 2010 the American Academy of Pediatrics released a policy statement to recommend implementation of a mandatory influenza immunization policy for all health care workers. Immunization rates of health care workers are unacceptably low and health care associated influenza outbreaks are common. Employees of health care institutions have both ethical and professional obligation to act in the best interests of the health of their patients. Medical and

religious exceptions can be granted on an individual basis. Hospitals should develop policies regarding influenza immunization policy for all health care workers to ensure patient and staff safety.

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## Appendix 29. Eliminating Elective Delivery Prior to 39 Weeks Gestation

Despite long standing recommendations from the American College of Obstetricians and Gynecologist (ACOG), the practice of elective inductions at less than 39 weeks of gestation is common practice in the United States and may account for 10-15% of all deliveries.<sup>1</sup> This practice is associated with more unplanned cesarean births, operative vaginal deliveries, longer length of stay in labor and delivery and significant newborn morbidity. Newborn morbidity, caused by iatrogenic prematurity, is significant enough of an issue to warrant inclusion as a national perinatal quality benchmark both by the National Quality Form and the Joint Commission.<sup>1</sup>

Following the ACOG recommendations for no elective inductions, primary or repeat cesarean births prior to 39 0/7 weeks is a practice where obstetric providers may intervene to decrease the rate of prematurity. Infants born between 37-39 weeks gestation are at increased risk for temperature instability, feeding problems and infection. Significant brain and neurologic development continues to occur in the last month of pregnancy, with the fetal brain nearly doubling in weight.<sup>2</sup> The confirmation of fetal lung maturity through amniocentesis can minimize the risk of respiratory distress syndrome but, fetal lung maturity testing does not assess for any other risk of prematurity.

ACOG practice bulletin #107 (2009) on induction of labor has prescribed indications and contraindications for induction of labor before 39 weeks (Table 1).<sup>3</sup> With adequate surveillance and treatment, both chronic hypertension and diabetes can often be managed until 39 weeks gestation. Repeat cesarean sections should be completed 39 weeks or after, unless a prior classical cesarean section was performed.<sup>2</sup> A woman with contractions prior to 39 weeks should clearly be in labor (cervical change with contractions), prior to proceeding to a repeat cesarean section.

**Table 1**

<b>Examples of Indications and Contraindications for Induction of Labor</b>	
<b>Indications</b>	<b>Contraindications</b>
Abruptio Placenta Chorioamnionitis Fetal Demise Gestational Hypertension Preeclampsia, eclampsia Postterm Pregnancy Maternal medical conditions( diabetes mellitus, renal disease, chronic pulmonary disease, chronic hypertension, antiphospholipid syndrome) Fetal compromise ( severe IUGR, isoimmunization. Oligohydramnios)	Vasa previa or complete previa Transverse fetal lie Umbilical cord prolapse Pervious classical cesarean delivery Active genital herpes infection Previous myomectomy entering the endometrial cavity
<b>Confirmation of Term Gestation</b>	
<ul style="list-style-type: none"> <li>• Ultrasound measurement at less than 20 weeks of gestation supports gestational age of 39 weeks or greater.</li> <li>• Fetal heart tones have been documented as present for 30 by Doppler ultrasonography.</li> <li>• It has been 36 weeks since a positive serum or urine human chorionic gonadotropin pregnancy test result.</li> </ul>	

From ACOG Bulletin # 107, 2009<sup>3</sup>

One of the principles of quality process improvement is that process uniformity will generally improve outcomes. Therefore, a checklist based protocol for the management of induction of labor is recommended for standardization and patient safety. An example of a checklist from ACOG is included in this hard copy of the appendix. Please check the ACOG website if viewing this appendix online as well as for frequently for updates on checklist and other bulletins at the link below.

<http://www.acog.org/~media/Patient%20Safety%20Checklists/psc002.pdf?dmc=1&ts=20130307T1011029875>. Accessed June 6, 2013.

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1. Clark S, Frye D, Meyers J, Belfort M, Dildy G, Kofford S, Perlin. Reduction in elective delivery at <39 weeks of gestation: comparative effectiveness of 3 approaches to change and the impact on neonatal intensive care admission and stillbirth. *American Journal of Obstetrics & Gynecology*. 2010; 203(5):449.e1-6.
  2. Day L, Hunter S (2008). The rising pre-term delivery rate in Iowa—Three things we can do now. *The Perinatal Letter*, XXIX (1), pp.1-6.
  3. American College of Obstetricians and Gynecologists, Practice Bulletin. *Induction of Labor*. Vol.114, No.2, Part 1, August 2009.
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# Patient Safety Checklist ✓

Number 2 • November 2011

## INPATIENT INDUCTION OF LABOR

Date \_\_\_\_\_ Patient \_\_\_\_\_ Date of birth \_\_\_\_\_ MR # \_\_\_\_\_  
 Physician or certified nurse-midwife \_\_\_\_\_ Last menstrual period \_\_\_\_\_  
 Gravidity/Parity \_\_\_\_\_  
 Estimated date of delivery \_\_\_\_\_ Best estimated gestational age at delivery \_\_\_\_\_  
 Indication for induction \_\_\_\_\_

**Fetal Presentation (1)**

- Vertex
- Other \_\_\_\_\_
  - If other, physician or certified nurse-midwife notified

Estimated fetal weight \_\_\_\_\_

- Patient has a completed medical history and physical examination
  - Known allergies identified \_\_\_\_\_
  - Medical factors that could effect anesthetic choices identified \_\_\_\_\_
  - Pertinent prenatal laboratory test results (eg, group B streptococci or hematocrit) available (2, 3)
  - Other special concerns identified (eg, medical problems and special needs): \_\_\_\_\_
- Patient counseled about risks and benefits of induction of labor (1)
  - Consent form signed as required by institution

Bishop Score (see below) (1): \_\_\_\_\_

**Bishop Scoring System**

Score	Factor				
	Dilation (cm)	Position of Cervix	Effacement (%)	Station*	Cervical Consistency
0	Closed	Posterior	0-30	-3	Firm
1	1-2	Midposition	40-50	-2	Medium
2	3-4	Anterior	60-70	-1, 0	Soft
3	5-6	—	80	+1, +2	—

\*Station reflects a -3 to +3 scale.  
 Modified from Bishop EH. Pelvic scoring for elective induction. *Obstet Gynecol* 1964;24:266-8.

- Orders received (1)
  - Oxytocin
  - Cervical ripening

## Appendix 30. Intimate Partner Violence

Homicide is an infrequent event, but it is the leading cause of death for women of reproductive age. In Iowa, between the years of 2000 and 2003, there was an average of 12.2 deaths yearly due to domestic violence.<sup>1</sup> Each year, more than 6 million American women become pregnant; unfortunately, pregnancy does not exempt women from being victims of homicide.<sup>2</sup> For every 100,000 live births in the United States during 1991 through 1999, there were at least 2 women who died as a result of homicide during pregnancy or within one year of pregnancy.<sup>2</sup> Of the 6-8% of women (20-25% of pregnant adolescents) who experience abuse during pregnancy, intimate partners have been the perpetrators. Intimate Partner Violence (IPV) is not just a social problem anymore; it has gradually been acknowledged as one of the most severe threats to a woman's health. Preventing violence against women was listed as one of the top priority health issues for the United States in the Department of Health and Human Services' campaign, "Healthy People 2010."

All nurses who provide care to women will inevitably encounter a patient affected by IPV. This gives nurses and other health care providers a unique opportunity to have discussions about IPV and for referrals and possible interventions. Violence during pregnancy may be more common than some conditions (gestational diabetes, placenta previa or pre-eclampsia.) for which most pregnant women are routinely screened. Along with screening for risk factors such as smoking and alcohol use, screening for intimate partner violence could be incorporated into routine prenatal care.

Nurses and other clinicians need to be aware of Iowa's Mandatory reporting statutes. Iowa Code 147.111 mandates "that any person who administers any treatment to persons suffering from a gunshot, stab wound, or other bodily injury, which may have resulted from a criminal offense, must be reported to a law enforcement agency." Iowa code 135B.7 requires each hospital to establish protocols for treating victims. Under the Iowa Administration Code (IAC 481.51.7), hospitals must interview victims in privacy, ensure confidentiality, educate emergency department staff to identify victims of domestic violence. It also specifies certain information that must be included in the victim's medical record as well as giving out referral information.

### Definitions

- Intimate Partner Violence (IPV) has been defined as a pattern of coercive behavior designed to exert power and control over a partner (or ex-partner) in an intimate relationship through the use of intimidating, threatening, harmful, or harassing behavior.<sup>4</sup> IPV takes on many forms, ranging from serious physical injury and sexual assault to progressive social isolation, emotional abuse, humiliation, intimidation, economic abuse and progressive coercion and control. IPV occurs in all cultures, races, ages, sexes, educational levels and socioeconomic groups.
- Physical violence is the intentional use of force with the potential to cause injury, harm, or death. Physical violence can be actual or threatened. It includes, but is not limited to, these acts: slapping, pushing, shaking, biting, scratching, choking, burning, hitting, and using a knife, gun or other weapon against another person.
- Sexual violence is the actual or threatened use of physical force to compel a person to engage in a sexual act against her/his will. An attempted or completed act with a person

who is unable to avoid participation, communicate unwillingness or understand the nature of the act. Examples of abusive sexual contact include unwanted touching, fondling or other sexual contact that does not necessarily involve intercourse.

- Forms of emotional abuse may be as effective at controlling a victim as a physical injury. There are many behaviors that may be perceived by the victim as emotionally abusive including, but not limited to: humiliating name calling, deliberately embarrassing the victim, especially in public, controlling the victim's movements and activities, isolating victims from friends and family, and/or controlling financial resources.

### **Intimate Partner Violence and Pregnancy**

IPV may vary throughout a relationship. It may occur only prior to conception or during pregnancy; but, most often, it is continuous. The strongest predictor of IPV during pregnancy is IPV before pregnancy. However, pregnancy is in itself an especially high risk time for IPV to begin or reoccur. The physical, emotional and financial changes associated with pregnancy often provide an opportunity for an abusive partner to establish power and control over the woman. Similarly, women who experience IPV during the postpartum period are likely to have experienced it during pregnancy.

Abuse during pregnancy is responsible for poor perinatal outcomes. Violence during pregnancy may result in miscarriage, poor maternal weight gain, anemia, second and third trimester bleeding, and abruption. Controlling partners may prevent or prohibit prenatal care; therefore, abused women may start prenatal care late in the pregnancy or have frequent missed appointments. This behavior has two effects: the woman (1) may find it difficult to fulfill the basic prenatal care requirements, such as taking prescribed supplements, screenings for sexually transmitted diseases, diabetes, and pre-eclampsia and (2) may have limited access to referral and follow-up care. In an attempt to deal with the stress of physical or emotional abuse in her life, the woman may continue to smoke or self-medicate by using alcohol or other drugs during her pregnancy. These behaviors may lead to preterm labor and/or preterm delivery, low birth weight term infants, intrauterine growth restriction and fetal alcohol syndrome.

Abusive partners sometimes prohibit their partners from using birth control, take away her contraception or intentionally break or refuse to use condoms. This can lead to a large number of unwanted pregnancies, pregnancies in close intervals and transmission of sexually transmitted infections and HIV.

Many women experiencing IPV may suffer from both anxiety and depression. Even when the pregnancies result in healthy birth outcomes, abused women may be at an increased risk for postpartum depression, especially because women who are abused during their pregnancy are likely to be abused after delivery as well. Severe cases of physical abuse to a pregnant woman have direct effects on the fetus. For example, physical injury to fetus or fetal death associated with trauma to the mother.

### **Caring for pregnant women experiencing IPV**

A study by Sharps et al in 2001 reported that within a year of her murder, 41% of women experiencing IVP had used health care agencies.<sup>5</sup> Each contact with the healthcare system represents an opportunity for intervention by health care providers to increase that woman's

awareness of her and her child's risk of injury or death. It provides an opportunity to help the woman develop a safety plan and to receive services to address her personal needs. Routine screening establishes that the problem of intimate partner violence is medically relevant.

Screening should be done for all women, especially those of childbearing age. Steps in screening and interventions can be summarized in the acronym **RADAR**, which was developed by the Massachusetts Medical Society. **R**outinely screen, **A**sk directly, **D**ocument your findings, **A**ssess the patient's safety and **R**eview options and provide referrals. The steps of the RADAR process for screening/intervention are as follows:

**-R**outinely screen for violence. Most women will not disclose violence in their relationships without being asked. Screening should occur at various times over the course of the pregnancy, at the first prenatal visit, at least once per trimester and at postpartum checkup, as well as during the intranatal (labor) admission assessment. This is important because some women may need to be asked more than once about abuse and abuse may begin later in pregnancy. Many women will respond eventually if the questioning is sensitive and caring and the environment feels safe. Also, screen women and adolescents when they present to your unit with injuries (especially to breast, abdomen and genitals during pregnancy) that are not consistent with her explanation.

**-A**sk about abuse in a non-judgmental way. It is important to ask about current as well as past relationships, because past events could have an effect on current situation. Partner control is a key factor in violence and abuse. It is essential to ask questions in private, apart from the partner and apart from children, family and friends. The presence of a partner, who comes into the examining room with the patient and controls or dominates the interview, is overly solicitous and will not leave the patient alone with the provider, may be an indicator of abuse.

You may want to frame the questions about abuse by saying, "because violence is so common in many people's lives, I have begun to ask all my patients about it." Ask direct questions:

- "Are you in a relationship with a person who physically hurts or threatens you?"
- "Within the last year, have you been hit, slapped, kicked or otherwise physically hurt by someone?"
- "Since you've been pregnant, have you been hit slapped, kicked, or otherwise physically hurt by some one?"
- "Within the last year, has anyone forced you to do something sexually that you didn't want to do?"
- "Are you afraid of your partner or anyone else?"

It is important to document the woman's response, even when she says "no" and when you may suspect otherwise. When dealing with clear evidence of violence, even if denied, let a patient know that you and other staff are always available resources. Keep in mind that your questions about violence may help those who are experiencing violence move towards disclosure and help. Also a woman experiencing violence may be the best judge of her present situation and of her own and children's safety. Other reasons for non-disclosure may include lack of trust in others, economic dependence on partner, desire to keep family together and fear of retaliation by violent partner. When your patient confides that she is being abused, express support for her. Telling her

that the abuse is not her fault and that no one deserves to be treated this way is a powerful short intervention.

**-Documentation** of your findings is essential. Document your findings thoroughly in the patient's chart, using the patient's own words to describe the abuse. Use a body map to describe the locations of injuries. Ask her permission to take photographs of injuries. Documentation is one of the most important interventions for IPV. Medical records can be used by the woman to support charges of abuse if she chooses to do so.

**-Assess** the safety of the woman and her children. Questions should focus on whether the violence or threat of violence has escalated recently and whether there are weapons in the home. If guns are present, threats to kill have been made, or violence has intensified, this is an emergency that requires the formulation of a safety plan before the patient is discharged.

**-Review** options and provide referrals. This is the last step in the screening/intervention process. A team approach is helpful. Nurses are not, and don't have to be, experts in all fields. Care will be more efficient if referrals were made to experts in the field of IPV. Iowa's rural conditions can contribute to make IPV more difficult to escape. The distance to and the unavailability of services, provides challenges to abuse women and to healthcare providers. Victim advocates, mental health services, social workers, trained clergy and legal services can help the woman think about her options: whether to stay with the abuser and develop a safety plan, remove the abuser through arrest or protective orders, or leave the relationship temporarily or permanently. Remember the woman alone is in the best position to determine what she should do.

An indirect question during abuse assessment might be: "If a family member or friend was being hurt or threatened by a partner, do you know of resources that could help?" In our clinical settings, the staff should be provided with a list of local resources, shelters and hotlines. The National Domestic Violence hot line phone number is 1-800-799-SAFE (7233) Iowa State Hotline is 1-800-942-0333.

Given the large numbers of women who are exposed to abuse, there will be many healthcare providers who are survivors or who may still be in an abusive relationship. Responding to women effectively requires taking care of ourselves; we may need to seek support within or outside our community.

- 
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  3. Pluzzi and Houde-Quimby, “Domestic Violence. Implications for the American College of Nurse Midwives and its members. *Journal of Midwifery and Women’s Health* Vol. 41 No.6 Nov/Dec. 1996
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  5. Sharps et al., “ Healthcare Providers’ Missed Opportunities for Preventing Femicide.” *Preventive Medicine* Vol. 33 pp. 373-380, 2001

## Appendix 31. Guidelines for Newborn Screening for Critical Congenital Heart Disease

This guideline is intended for use by all individuals, including physicians, nurses, respiratory care practitioners, and clinical technicians involved in using pulse oximetry screening for critical congenital heart disease (CCHD) in newborns. The focus of this guideline is to provide guidance on the medical use of pulse oximetry devices for the sole intent of newborn screening for CCHD.

Senate File 452 from the 85<sup>th</sup> Iowa General Assembly was signed by the governor and went into effect July 1, 2013. Senate File 452 states:

### DIVISION VI NEWBORN CRITICAL CONGENITAL HEART DISEASE SCREENING

Sec. 91. NEW SECTION. 136A.5A Newborn critical congenital heart disease screening.

1. Each newborn born in this state shall receive a critical congenital heart disease screening by pulse oximetry or other means as determined by rule, in conjunction with the metabolic screening required pursuant to section 136A.5.
2. An attending health care provider shall ensure that every newborn under the provider's care receives the critical congenital heart disease screening.
3. This section does not apply if a parent objects to the screening. If a parent objects to the screening of a newborn, the attending health care provider shall document the refusal in the newborn's medical record and shall obtain a written refusal from the parent and report the refusal to the department.
4. Notwithstanding any provision to the contrary, the results of each newborn's critical congenital heart disease screening shall only be reported in a manner consistent with the reporting of the results of metabolic screenings pursuant to section 136A.5 if funding is available for implementation of the reporting requirement.

This section shall be administered in accordance with rules adopted pursuant to section 136A.8.

Sec. 92. NEWBORN CRITICAL CONGENITAL HEART DISEASE SCREENING.

Notwithstanding any provision to the contrary relating to the newborn screening policy pursuant to 641 IAC 4.3(1), critical congenital heart disease screening shall be included in the state's newborn screening panel as included in the recommended uniform screening panel as approved by the United States secretary of health and human services.

The center for congenital and inherited disorders advisory committee shall make recommendations regarding implementation of the screening and the center for congenital and inherited disorders shall adopt rules as necessary to implement the screening.

However, reporting of the results of each newborn's critical congenital heart disease screening shall not be required unless funding is available for implementation of the reporting requirement.

### Introduction

In September 2011, Department of Health and Human Services Secretary Kathleen Sebelius approved the addition of screening for critical congenital heart disease to each state's newborn

screening panel. Screening for CCHD is accomplished by using pulse oximetry to estimate levels of arterial oxygen saturation in the newborn's hand and foot.

Pulse oximetry is a noninvasive method of estimating the arterial oxygen saturation and pulse rate (PR) from pulsatile absorption signals derived from a sensor placed on the skin.

Pulse oximeters can be used for patients of all ages and are associated with minimal risk. Pulse oximetry should be performed by trained personnel who exercise sound judgment in selecting the site and sensor, interpreting the results, and formulating subsequent clinical decisions.

### **Definitions**

*Oxygen saturation:* the amount of oxyhemoglobin in blood expressed as a percent fraction of amount of hemoglobin able to bind oxygen (oxyhemoglobin plus deoxyhemoglobin).

*Pulse rate:* the pulse rate (PR) value is derived by a pulse oximeter and expressed in beats per minute (bpm).

*SaO<sub>2</sub>:* oxygen saturation of arterial blood

*SpO<sub>2</sub>:* in pulse oximetry, an estimate of the arterial oxygen saturation derived by measuring relative absorption of red and infrared light by pulsating arterial blood.

*Sensor:* the part of the pulse oximeter applied to the patient that contains the light source(s) and detector(s); NOTE: this term is used interchangeably with the term "probe."

### **Indication for Use**

The fundamental purpose of pulse oximetry is to noninvasively assess the level of blood oxygenation to aid in the detection of hypoxemia or hyperoxemia. The most thorough assessment of a subject's oxygenation status occurs via direct analysis of blood, which may include the measurement of arterial and mixed venous blood gases with laboratory oximetry.

Newborn screening for critical congenital heart disease in well-baby and intermediate-care nurseries uses pulse oximetry to detect low blood oxygen saturation.

Seven specific lesions are considered primary targets for screening: hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus. This subset of lesions excludes those not usually associated with hypoxia, such as aortic valve stenosis. Although the primary goal of screening is identification of these seven specific lesions, other hypoxic cardiac or non-cardiac associated conditions (e.g., persistent pulmonary hypertension) may be detected (secondary targets). Tracking rates of detection of such secondary targets could lead to modifications of the screening guidelines.

Pulse oximeters minimally display SpO<sub>2</sub> as a percentage, an estimate of the functional arterial oxygen saturation (SaO<sub>2</sub>), and PR in bpm. Pulse oximeters do not require operator calibration and are non-invasive, making it a preferred method for screening for CCHD.

**Environment of Use**

Pulse oximetry is prescribed by a physician or nurse practitioner, and its use should be medically supervised. The personnel directly responsible for its application should be trained and competent in the setup, short- and long-term use, the assessment of data reliability, and the limitations of the device. Perfusion and/or motion artifact can produce false-negative and false-positive results.

Newborn screening for CCHD will occur in well-baby and intermediate nurseries—those areas where newborns may appear healthy-looking and have shorter stays than an intensive care nursery.

**Instrument**

A pulse oximeter is composed of a sensor and a monitor, which may be combined in a single assembly. Most commonly, the photodetector is positioned opposite the light source. Pulse oximeters cannot be calibrated by the operator. The primary available method for determining the accuracy of an SpO<sub>2</sub> reading is to compare it with measurements of arterial blood using a laboratory oximeter.

The performance of a pulse oximeter can be adversely affected by the patient/sensor interface (i.e., the site selected and the type of sensor). It is essential to select a sensor that is appropriate for use on the newborn hand and foot, and that the sensor is correctly aligned and securely fitted to the patient. The site should also be well perfused and free of artifact sources (e.g., deep skin pigmentation, extraneous light, venous congestion, and motion).

Screening should be done with motion-tolerant pulse oximeters that report functional oxygen saturation, have been validated in low perfusion conditions, have been cleared by the FDA for use in newborns, and have a 2 percent root-mean-square accuracy. A new guidance document of the safety and effectiveness of pulse oximeters is being developed by the FDA, and when the guidance document is finalized, any pulse oximeter used for screening should meet FDA recommendations.

Pulse oximeters can be used with either disposable or reusable probes. Reusable probes can reduce the cost of screening, but must be appropriately cleaned between uses to minimize the risk of infection. Pulse oximeter probes may be a source of contamination.

Standard precautions—universal precautions and body substance isolation practices—should be used as it is impossible to know what isolates or specimens might be infectious.

The adhesives and materials used in the construction of disposable and reusable probes are generally latex-free but should be verified by the operator in conditions of known sensitivity.

As with any patient monitoring device that uses wire leads, there can be a risk of entanglement.

To prevent damage, soaking or immersing the pulse oximeter sensor in any liquid should be avoided. If the sensor is damaged in any way, it should be replaced immediately.

There is a need for ongoing assessment of the sensor site, type of sensor used, and device to limit the complications and optimize the performance of pulse oximetry.

### Site Selection and Preparation

- Application of the sensor for newborn screening for CCHD should be on the right hand and either foot. In cases of poor perfusion, local rewarming of sensor sites may restore adequate signal quality. Covering the site with a nonrestrictive bootie can correct poor perfusion.
- The site should be well perfused and completely cover the sensor's detector.
- The site should be cleaned of debris and dry before sensor placement.
- In newborns, the palm of the hand and lateral aspect of the foot are the preferred sites. See diagram below.



*Preferred pulse oximetry sites for newborn screening for CCHD*

- The extremity should be free of a blood pressure cuff or IV or intra-arterial catheters.
- In the presence of sources of bright light, covering the sensor site with an opaque material will minimize the potential for ambient light interference, which can cause inaccurate readings.
- Probes with close coupling to skin (i.e., taped rather than clamped), will provide better performance, however care must be taken to not damage fragile newborn skin. Adhesive sensors should not be wrapped too tightly.
- When applied to the selected area, the optical components must be properly aligned across a capillary bed.
- Do not hold the sensor in place, as that interferes with the signal.
- Anecdotal reports suggest that false positives are decreased if the infant is alert. In addition, timing the pulse oximetry screening around the time of the newborn hearing screening increases efficiency, assuming that the hearing screening is conducted at least 24 hours after birth or immediately prior to discharge.
- Use the same machine to test both the hand and foot to assure consistency of the readings.
- Take the reading on the foot first—baby may get fussy when opening up the hand to get a reading - doing the foot first while the baby is calm will help get a good reading in the foot.
- You may do the screen as the baby is nursing, just be sure the sensor is aligned properly.
- Pulse oximeters are validated only with the specific probes recommended by the manufacturer; therefore, to optimize valid screening, manufacturer-recommended pulse oximeter-probe combinations should be used. Third-party reprocessed sensors should not be used unless the original manufacturers of the sensors and instruments have approved the reprocessed sensors for the intended applications.

### Screening Criteria

- Screening should not occur until 24 hours of life, or as late as possible if earlier discharge is planned, and be completed by the second day of life. Earlier screening can lead to false positive results because of the transition from fetal to neonatal circulation and stabilization of systemic oxygen saturation levels. Later screening can miss an opportunity for intervention before closing of the ductus arteriosus.
- Screening is recommended in the right hand and either foot. See diagram for probe placement.



- The pulse oximetry measure is complete once the waveform on the oximeter's plethysmograph is stable or there is other indication that the device is appropriately tracking the baby's pulse rate.
- A screen would be considered positive when (1) any oxygen saturation measure is below 90%; (2) oxygen saturation is below 95% in both extremities on three measures each separated by one hour; or (3) there is a greater than 3% absolute difference in oxygen saturation between the right hand and the foot on three different measures each separated by one hour.
- Any screening that is higher than or equal to 95% in either extremity with less than or equal to 3% absolute difference in oxygen saturation between the hand and foot would be considered a pass and CCHD screening would end.

*The screening protocol is described below.*

### Follow up for the Positive Screen

The newborn's primary care physician (PCP) should be notified immediately of any abnormal screening results. The newborn should NOT be discharged. Support the newborn as per orders from the PCP.

After evaluation by the PCP, if there is not a respiratory reason for the positive screen, the PCP should obtain a consultation with a pediatric cardiologist and neonatologist from the provider list for the area.

If the birth facility has the capacity for pediatric echocardiography, prepare the infant for an echocardiogram, per physician orders. Transmit the results of the echocardiogram to the pediatric cardiologist, if they are off site.

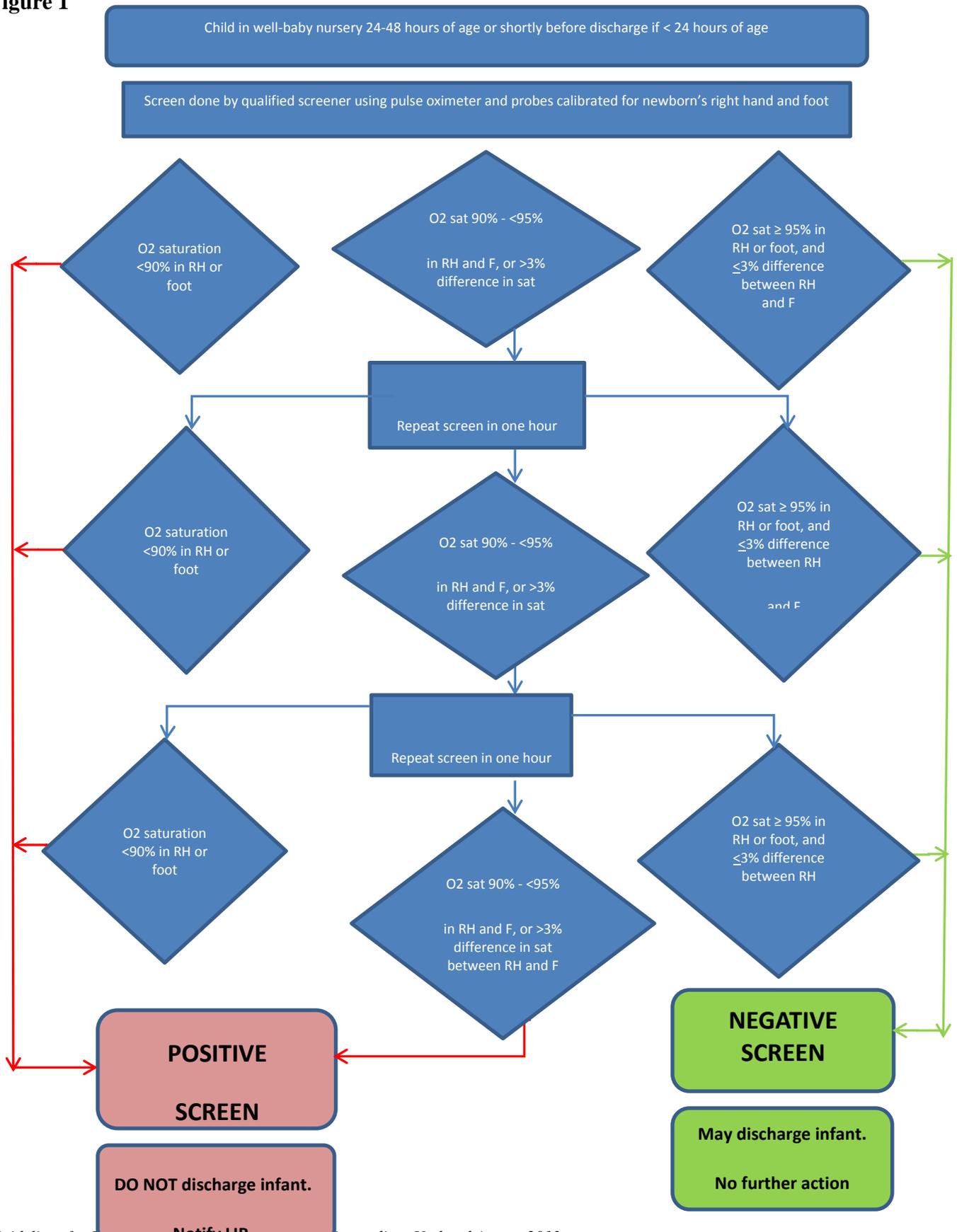
If the birth facility does not have the capacity to conduct a pediatric echocardiogram, arrange for transport to a perinatal center.

### Parent Education

Parents should be informed of the pulse oximetry screening prior to administration of the screen. Information may be provided at the same time the parents are informed of the other newborn screening procedures. A frequently asked question (FAQ) sheet is available from the Iowa Department of Public Health CCHD screening web page, available at [http://www.idph.state.ia.us/genetics/newborn\\_screening.asp](http://www.idph.state.ia.us/genetics/newborn_screening.asp), accessed June 26, 2013.

Parents should also receive communication and explanation of any abnormal screening results and the expected plan of care regarding the result. Parents may refuse the pulse oximetry screening. The health care provider should discuss this refusal with the parents to assure they understand the ramifications of a missed condition. The refusal should be documented in the baby's medical record, and any waiver forms should be completed according to hospital policy and procedures.

Figure 1



1. American Academy of Pediatrics. Kemper, Mahle et al. *Strategies for Implementing Screening for Critical Congenital Heart Disease*. Pediatrics 2011; 128:e1259; originally published online October 10, 2011. DOI: 10.1542/peds.2011-1317. Available at <http://pediatrics.aappublications.org/content/128/5/e1259.full.html>. Accessed June 26, 2013
2. *Pulse Oximetry; Approved Guideline—Second Edition*. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania, 19087. POCT11-A2; Vol.31 No.9; (replaces HS03-A Vol.25 No.5). Copyright. CLSI order #93607. Downloaded 5/31/2011.
3. *Evidence Review: Critical Congenital Cyanotic Heart Disease*. Prepared for the Maternal and Child Health Bureau. Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; Evidence-based Review Committee. Available at: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/nominatecondition/reviews/cyanoticheart.pdf>. Accessed June 26, 2013.
4. Centers for Disease Control and Prevention. *Newborn Screening for Critical Congenital Heart Disease*. Pediatric Genetics Homepage, available at: <http://www.cdc.gov/ncbddd/pediatricgenetics/cchdscreening.Html>. Accessed June 26, 2013.
5. *Baby's First Test*. Genetic Alliance, available at: <http://www.babysfirsttest.org/newborn-screening/conditions/critical-congenital-heart-disease-cchd>. Accessed June 26, 2013.
6. *Children's National Medical Center: Congenital Heart Disease Screening Program*. Videos about CCHD screening, including videos for parents and providers. Available at <http://www.childrensnational.org/PulseOx/>. Accessed June 26, 2013.
7. Iowa Department of Public Health, Center for Congenital and Inherited Disorders. <http://www.idph.state.ia.us/genetics/default.asp>. Accessed June 26, 2013.

## Appendix 32. Management of Late-Preterm Infants

Late-preterm refers to infants born at 34 0/7 through 36/6/7 weeks' gestation. They are often managed in Level I nurseries because their size and weight may be similar to that of term infants. However, these infants are both physiologically and developmentally immature. This puts them at higher risk for developing medical complications that can result in higher rates of morbidity and mortality during and after their birth hospitalization. During their birth hospitalization, late-preterm infants are at risk for respiratory distress, apnea, temperature instability, hypoglycemia, hyperbilirubinemia and poor feeding. During the first month after birth, they are more likely to be readmitted to the hospital for jaundice, feeding difficulties, dehydration and suspected sepsis.

When late-preterm birth is necessary due to fetal or maternal complications in pregnancy, collaborative counseling by obstetric and neonatal clinicians about fetal, neonatal and maternal outcomes is warranted. Information regarding gestational age-specific outcomes can help to prepare families for the infant's anticipated course in the nursery. Parents of late-preterm infants may also need additional guidance and education before discharge from the hospital. Infants who are first born or breastfed are particularly vulnerable to complications that may result in hospital readmission. It is important to educate first-time mothers on how to evaluate feeding success and recognize the signs of dehydration and jaundice. This education may necessitate a longer hospital stay. After discharge, late-preterm infants require closer follow-up with their medical care provider.

In 2007, the American Academy of Pediatrics (AAP) published a clinical report, "Late-Preterm Infants: A Population at Risk,"<sup>1</sup> available at: <http://pediatrics.aappublications.org/content/120/6/1390.full>, accessed June 26, 2013. The authors describe the characteristics of late-preterm infants that predispose them to a higher risk of morbidity and mortality than term infants and propose guidelines for the evaluation and management of these infants after birth. The AAP guideline includes minimum discharge criteria for late-preterm infants that are intended to reflect evidence of the following prior to discharge: physiologic maturity; feeding competency; thermoregulation; maternal education; assessment and planned interventions for medical, family, environmental, and social risk factors; and follow-up arrangements. Practitioners are encouraged to refer to these guidelines when caring for late-preterm infants and their mothers.

### Resources

- National Perinatal Association: "Multidisciplinary Guidelines for the Care of Late Preterm Infants" ©2007-2013 NPA; Available at: <http://www.nationalperinatal.org/>, accessed June 26, 2013.
- Association of Women's Health, Obstetric and Neonatal Nurses: "AWHONN Late Preterm Infant Assessment and Intervention Guide" ©2007

1. American Academy of Pediatrics. Clinical Report—"Late-preterm" infants: a population at risk. *Pediatrics*. 2007; 120(6):1390-1401. Available at: <http://pediatrics.aappublications.org/content/120/6/1390.full>. Accessed May 2, 2013.

## Appendix 33. Management of Newborns with Suspected Early-Onset Sepsis

The 2010 updated CDC guidelines provide guidance for the treatment of newborns and aim to reduce unnecessary evaluations.<sup>1</sup> The current guidelines are based on the child's clinical appearance and gestational age, as well as maternal factors such as chorioamnionitis, prolonged rupture of membranes, and adequacy of the IAP. The definition of adequate IAP has also been clarified; adequate IAP is defined as the administration of penicillin, ampicillin, or cefazolin for at least 4 hours prior to delivery. Any other agent or duration is considered inadequate.

In 2012, the American Academy of Pediatrics (AAP) published a clinical report, "Management of Neonates With Suspected or Proven Early-Onset Bacterial Sepsis."<sup>2</sup> The authors identify three challenges that clinicians face: 1) identifying neonates with a high likelihood of sepsis promptly and initiating antimicrobial treatment; 2) distinguishing "high-risk" healthy-appearing infants or infants with clinical signs who do not require treatment; and 3) discontinuing antimicrobial therapy once sepsis is deemed unlikely. They provide the following guidelines.

### Guidelines for the newborn WITH signs of sepsis:

- Newborns who have risk factors for infection should receive a full evaluation and broad-spectrum antibiotic therapy should be initiated after cultures are obtained.
- A full evaluation includes the following: a complete blood count (CBC) with differential and platelets; a blood culture; a chest radiograph if respiratory abnormalities are present; and a lumbar puncture if the infant can safely undergo the procedure; evaluation may include a C-reactive protein (CRP) obtained at birth and/or 6-12 hours of life. A follow-up CBC with differential and CRP at 24-48 hours of life may be indicated.
  - One milliliter of blood drawn before initiating antibiotic therapy is needed to adequately detect bacteremia when using a pediatric culture bottle.
  - Lumbar puncture is also indicated if the infant: 1) has a positive blood culture; 2) is likely to become bacteremic (on the basis of clinical status or laboratory data); and 3) does not respond to antimicrobial therapy in the expected manner.
  - Cultures of superficial body sites, gastric aspirates, and urine are of no value in the diagnosis of early-onset sepsis.
- Broad-spectrum antibiotic therapy should be directed toward the most common causes of neonatal sepsis, including ampicillin for GBS and coverage for other organisms (including *Escherichia coli* and other gram-negative pathogens). The optimal antimicrobial agents are ampicillin and an aminoglycoside, usually gentamicin.<sup>2</sup>
  - Once a pathogen is identified, antimicrobial therapy can be narrowed.
  - Antibiotic therapy should be discontinued at 48 hours in clinical situations where the probability of sepsis is low.
  - Third-generation cephalosporins: Studies have reported rapid development of resistance when cefotaxime was routinely used for the treatment of early-onset sepsis<sup>3</sup> and extensive/prolonged use of third-generation cephalosporins is a risk factor for invasive candidiasis.<sup>4</sup>
  - Empirical or therapeutic use of cefotaxime should be restricted for use in infants with meningitis attributable to Gram-negative organisms.<sup>2</sup>

- “More mature newborns” *without* risk factors for infection with relatively mild findings (tachypnea with or without an oxygen requirement) who clinically improve over the first 6 hours of life (eg, need for oxygen is decreasing and respiratory distress is resolving) may be observed without antibiotic therapy; any worsening of the infant’s condition should prompt a full evaluation and initiation of antibiotic therapy.<sup>2</sup>

### Guidelines for the newborn **WITHOUT** signs of sepsis:

- If intrapartum antibiotic prophylaxis (IAP) is indicated for the mother *without* chorioamnionitis and she receives adequate IAP: The asymptomatic newborn requires only observation for at least 48 hours.
  - If the infant remains asymptomatic, no additional diagnostic testing is necessary.
  - If signs of sepsis develop, a full diagnostic evaluation should be performed and antibiotic therapy should be initiated.
- If chorioamnionitis is diagnosed clinically: An infant born at **≥ 37 weeks’ gestation** should receive a limited evaluation and broad-spectrum antibiotic therapy should be initiated. A limited evaluation includes a blood culture at birth and a CBC with differential at birth and/or 6-12 hours of life; evaluation may include a C-reactive protein (CRP) obtained at birth and/or 6-12 hours of life. A follow-up CBC with differential and CRP at 24-48 hours of life may be indicated. Consultation with obstetric providers is important to determine the level of clinical suspicion for chorioamnionitis.
  - If the blood culture is negative and laboratory data remain normal and the infant remains well, antibiotic therapy can be discontinued by 48 hours and the infant can be discharged from the hospital.
  - If the laboratory data are abnormal and the blood culture is negative, continue antibiotic therapy if the mother received antibiotics during labor and delivery. Consultation with a referral center may be needed.
  - If the blood culture is positive, continue antibiotic therapy and perform a lumbar puncture if possible. Consultation with a referral center should be considered.
- If membranes are ruptured  $\geq 18$  hours *or* IAP is indicated but inadequate: An infant born at **≥ 37 weeks’ gestation** should receive a CBC with differential at 6-12 hours of life; evaluation may include a C-reactive protein (CRP) obtained at 6-12 hours of life. No antibiotics are needed; observation is required for at least 48 hours.
  - If the laboratory data are normal and the infant remains well, he can be discharged by 48 hours.
  - If the laboratory data are abnormal, a blood culture should be performed; if the blood culture is negative and the infant remains well, he can be discharged by 48 hours.
  - If the blood culture is positive, initiate antibiotic therapy and perform a lumbar puncture if possible. Consultation with a referral center should be considered.
- If membranes are ruptured  $< 18$  hours and IAP are indicated but inadequate (no chorioamnionitis): An infant born at **≥ 37 weeks’ gestation** requires only observation for at least 48 hours.
  - If the infant remains asymptomatic, no additional diagnostic testing is necessary.
  - Observation may occur at home after 24 hours if other discharge criteria have been met. Access to medical care must be readily available and a person who is able to comply fully with instructions for home observation should be present. If

any of these conditions are not met, the infant should be observed in the hospital for at least 48 hours and until discharge criteria are achieved.

- If chorioamnionitis is diagnosed clinically *or* membranes are ruptured  $\geq 18$  hours *or* IAP is indicated but inadequate (regardless of timing of rupture of membranes): An infant born at **<37 weeks' gestation** should receive a limited evaluation and broad-spectrum antibiotic therapy should be initiated. A limited evaluation includes a blood culture at birth and a CBC with differential at birth and/or 6-12 hours of life; evaluation may include a C-reactive protein (CRP) obtained at birth and/or 6-12 hours of life. A follow-up CBC with differential and CRP at 24-48 hours of life may be indicated. Consultation with obstetric providers is important to determine the level of clinical suspicion for chorioamnionitis.
  - If the blood culture is negative and laboratory data remain normal and the infant remains well, antibiotic therapy can be discontinued by 48 hours.
  - If the blood culture is negative and the infant remains well, but laboratory data are abnormal continue antibiotic therapy if the mother received antibiotics during labor and delivery. Consultation with a referral center may be needed.
  - If the blood culture is positive, continue antibiotic therapy and perform a lumbar puncture if possible. Consultation with a referral center should be considered.

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1. Prevention of Perinatal Group B Streptococcal Disease -- Revised Guidelines from CDC, 2010. *MMWR Recomm Rep*. Nov 19 2010; 59(RR-10):1-36.
  2. American Academy of Pediatrics. Clinical Report—Management of neonates with suspected or proven early-onset bacterial sepsis. *Pediatrics*. 2012; 129(5):1006-1015. Available at: <http://pediatrics.aappublications.org/content/129/5/1006>. Accessed June 4, 2013.
  3. Bryan CS, John JF, Jr, Pai MS, Austin TL. Gentamicin vs cefotaxime for therapy of neonatal sepsis. Relationship to drug resistance. *Am J Dis Child*. 1985;139(11):1086-1089.
  4. Manzoni P, Farina D, Leonessa M, et al. Risk factors for progression to invasive fungal infection in preterm neonates with fungal colonization. *Pediatrics*. 2006;118(6):2359-2364.

### Appendix 34. Neonatal Abstinence Syndrome

Neonatal abstinence syndrome (NAS) refers to the withdrawal symptoms a newborn experiences after birth when there has been intrauterine exposure to certain illicit or prescription drugs. NAS occurs in approximately 55-94% of drug-exposed infants and is most commonly seen with opioid exposure. However, exposure to sedatives, barbiturates, polysubstance abuse and occasionally alcohol exposure may cause NAS. The onset of withdrawal symptoms depends on the half-life of the drug, duration of the mother's addiction, and time of the last maternal dose prior to delivery (Table 2). On average, the observation period for withdrawal symptoms to appear is 3 days. Preterm infants may exhibit fewer signs of withdrawal than late preterm and term infants.

**Table 1: Clinical Signs of Withdrawal**

Neurological	Gastrointestinal	Autonomic
<ul style="list-style-type: none"> <li>• Irritability</li> <li>• Increased wakefulness</li> <li>• High-pitched cry</li> <li>• Tremor</li> <li>• Increased muscle tone</li> <li>• Hyperactive deep tendon reflexes</li> <li>• Frequent yawning</li> <li>• Sneezing</li> <li>• Seizures</li> </ul>	<ul style="list-style-type: none"> <li>• Vomiting</li> <li>• Diarrhea</li> <li>• Dehydration</li> <li>• Poor weight gain</li> <li>• Poor feeding</li> <li>• Uncoordinated and constant sucking</li> </ul>	<ul style="list-style-type: none"> <li>• Diaphoresis</li> <li>• Nasal stuffiness</li> <li>• Fever</li> <li>• Mottling</li> <li>• Temperature instability</li> <li>• Piloerection</li> <li>• Mild elevations in respiratory rate and blood pressure</li> </ul>

**Table 2: Onset of Withdrawal Symptoms**

Drug	Approximate time to onset of withdrawal symptoms
Barbiturates	4-7 days but can range from 1-14 days
Cocaine	Usually no withdrawal signs but sometimes neurobehavioral abnormalities (decreased arousal and physiologic stress) occur at 48-60 hours
Alcohol	3-12 hours
Heroin	Within 24 hours
Marijuana	Usually no clinical withdrawal signs
Methadone	3 days but up to 5-7 days; rate of severity of withdraw cannot be correlated to dose of maternal methadone
Methamphetamines	Usually no withdrawal signs but sometimes neurobehavioral abnormalities (decreased arousal, increased physiologic stress, and poor quality of movement) occur at 48-60 hours
Opioids	24-36 hours but can be up to 5-7 days
Sedatives	1-3 days
SSRIs	Several hours to several days—withdrawal linked with 3 <sup>rd</sup> trimester use

#### Finnegan Scoring

The Finnegan Scoring System is the tool most often used to quantify the severity of NAS symptoms (Fig 1).<sup>1</sup>

- Begin scoring within the first 2 hours of life.
- Continue scoring every 4 hours.
- Pharmacologic therapy is indicated when: **3 consecutive Finnegan scores are  $\geq 8$  or when the sum of 3 consecutive Finnegan scores is  $\geq 24$ .**

**Figure 1: Modified Finnegan Scoring System<sup>1</sup>**

System	Symptoms	Points	Score		
Central Nervous System	Excessive high pitched (or other) cry (< 5 min)	2			
	Continuous high pitched (or other) cry (> 5 min)	3			
	Sleep < 1 hour after feeding	3			
	Sleep < 2 hours after feeding	2			
	Sleep < 3 hours after feeding	1			
	Hyperactive Moro reflex	2			
	Moderately hyperactive Moro reflex	3			
	Mild tremors when disturbed	1			
	Moderate-severe tremors when disturbed	2			
	Mild tremors when undisturbed	3			
Moderate-severe tremors when undisturbed	4				
Increased muscle tone	1				
Excoriation (eg. Chin, knees, elbows, toes, nose)	1				
Myoclonic jerks (twitching/jerking of limbs)	3				
Generalized convulsions	5				
Metabolism Vasomotor Respiratory	Sweating	1			
	Hyperthermia (37.2 – 38.2°C)	1			
	Hyperthermia ( $\geq 38.4^\circ\text{C}$ )	2			
	Frequent yawning (>3-4/interval)	1			
	Molting	1			
	Nasal stuffiness	1			
	Frequent sneezing (> 3-4/interval)	1			
	Nasal flaring	2			
Respiratory rate > 60/min	1				
Respiratory rate > 60/min with retractions	2				
Gastro-intestinal	Excessive sucking	1			
	Poor feeding (infrequent/uncoordinated suck)	2			
	Regurgitation ( $\geq 2$ times during/past feed)	2			
	Projectile vomiting	3			
	Loose stool	2			
Watery stool	3				
	<b>TOTAL SCORE</b>				

### Treatment

The goals for treatment of NAS using both pharmacologic therapy and non-pharmacologic intervention are to stabilize the clinical manifestations of withdrawal and restore normal newborn activity. Infants with confirmed drug exposure who are unaffected or demonstrating minimal signs of withdrawal do not require pharmacologic therapy.<sup>2</sup> For these infants, non-pharmacologic interventions alone may be beneficial.

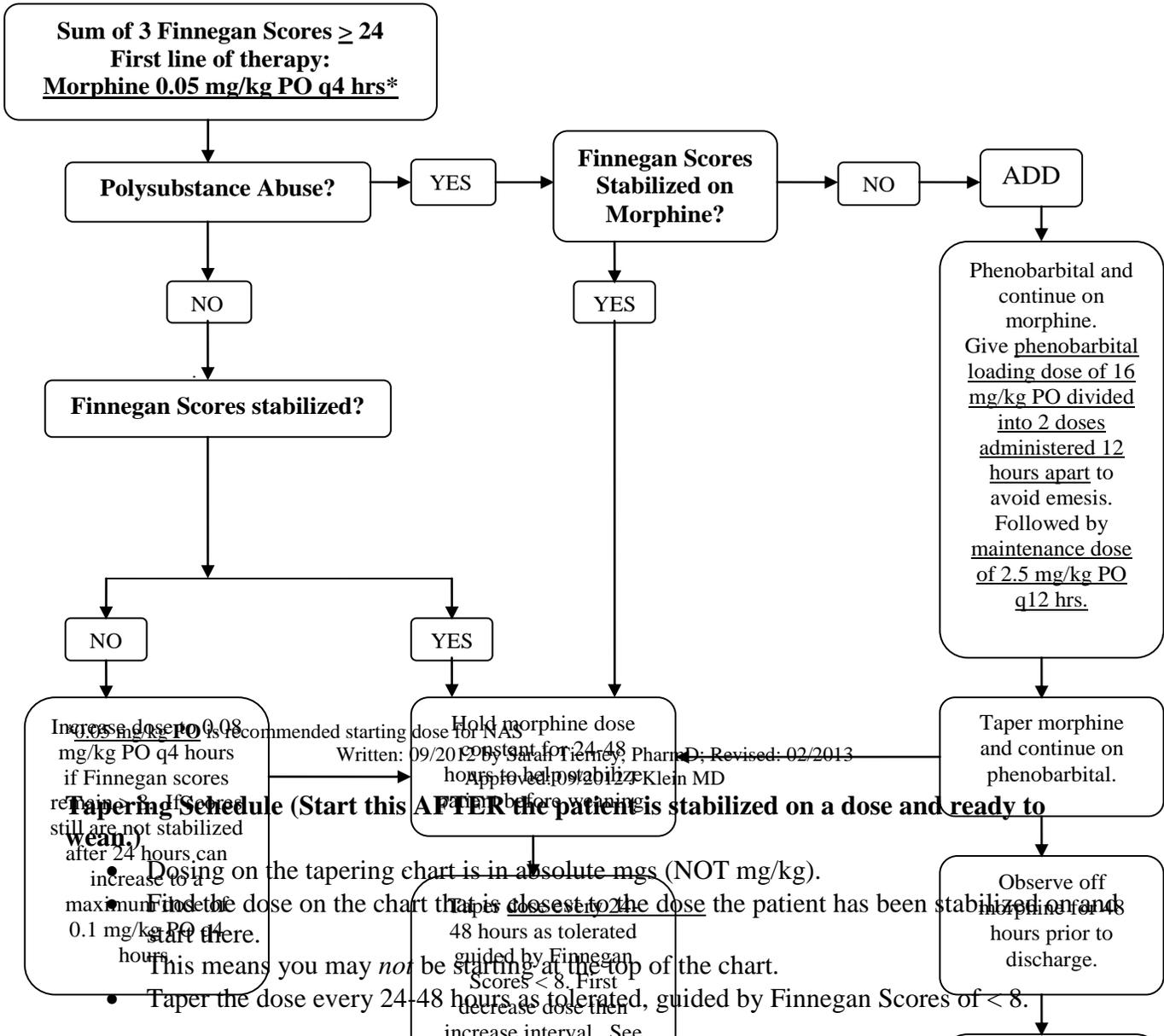
*Pharmacologic Therapy:*

Morphine is usually the first-line agent and mainstay of pharmacologic treatment. Phenobarbital is the first-line additional therapy for polysubstance exposure and may be used in combination with opioid therapy for NAS secondary to opiate withdrawal. Opioid dependency is likely seen after exposure to buprenorphine (Subutex), codeine, heroin, hydrocodone (Lortab, Vicodin), hydromorphone (Dilaudid), methadone, morphine, oxycodone (Percocet). Polysubstance-dependency is likely seen with the above drugs as well as barbiturates, sedatives and SSRIs. Specific treatment guidelines from the University of Iowa Children's Hospital are summarized in Figures 2 and 3.<sup>3</sup>

**Figure 2: Pharmacologic Management of Neonatal Abstinence Syndrome in the NICU<sup>3</sup>**

University of Iowa Children's Hospital

•STARTING



**Figure 3: Recommended Tapering Schedule**

Morphine TAPERING schedule (follow this side for infants > 3 kg)	Morphine TAPERING schedule (follow this side for infants ≤ 3 kg)	Notes
0.4 mg PO q 4 hrs	0.4 mg PO q 4 hrs	If possible, observe on morphine for 48 hours prior to discharge.
0.3 mg PO q 4 hrs	0.3 mg PO q 4 hrs	
0.2 mg PO q 4 hrs	0.2 mg PO q 4 hrs	Patient can go home on phenobarbital and be tapered off by weight gain OR the dose can be tapered by 20% every other day.
0.2 mg PO q 6 hrs	0.1 mg PO q 4 hrs	
0.2 mg PO q 8 hrs	0.1 mg PO q 6 hrs	
0.2 mg PO q 12 hrs	0.1 mg PO q 8 hrs	
0.2 mg PO q 24 hrs	0.1 mg PO q 12 hrs	
Discontinue	0.1 mg PO q 24 hrs	
	Discontinue	

*Alternative Pharmacologic Treatment:*

- 1) **Methadone** for opioid-dependency as an alternative to morphine. Dose 0.05 mg/kg PO every 12 hours. Increase by 0.05 mg/kg every 12 hours until NAS scores stabilize. Adverse effects include bradycardia and tachycardia and an ECG should be obtained to evaluate for QT-prolongation. Methadone has an extremely long half-life which can be up to 24 hours in a neonate. Methadone must be tapered by 10-20% per week over 4-6 weeks.
- 2) **Clonidine** as an alternative to phenobarbital. Clonidine is given in addition to morphine for polysubstance-dependency in term neonates with moderate to severe NAS uncontrolled by morphine alone. Dose 1 mcg/kg PO every 4 hours. Adverse effects include hypotension, rebound hypertension if clonidine is not tapered off over more than a week, AV-block, and bradycardia. MUST taper clonidine off over 10-14 days.

*Non-Pharmacologic Interventions:*

- Swaddling
- Rocking
- Minimal sensory or environmental stimulation
- Maintain temperature stability
- Feed (consider alternating bottle and pacifier during feed to compensate for excessive sucking and possibly prevent emesis)
- Breast milk feedings when appropriate can help reduce the need for pharmacological intervention

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