PERINATAL CENTERS GUIDELINES

Perinatal Centers Task Force, September 2020

INDIANA PERINATAL QUALITY IMPROVEMENT COLLABORATIVE

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Overview

With the 2019 implementation of the Levels of Care rules, the need to provide guidance to those hospitals who identified their intent to become a Perinatal Center became necessary. Indiana Administrative Code 410 IAC 39-8 identifies the regulatory requirements of a perinatal center but does not address the implementation challenges that may occur. With the goal of improving outcomes for mothers and babies, the need to standardize expectations, support implementation efforts and reduce variability across the state was identified as an initial deliverable for the newly formed Perinatal Centers Task Force. This document incorporates guidance regarding the programmatic implementation of Administrative Code 410 IAC 39-8 and resources identified by task force participants that may be useful.

410 IAC 39-8-1 Qualifications for Perinatal Centers

As stated in the rule, *"The purpose of perinatal centers is to coordinate perinatal care throughout the state by affiliating with delivering facilities." To qualify as a center, the hospital must achieve ISDH designation status as a Level III or Level IV Obstetric facility and either a Level III or a Level IV Neonatal facility. In addition, the center must have the following capacity:*

1. *A maternal-fetal medicine (MFM) specialist readily available at all times for onsite consultation and management with full privileges.*
2. *Director of obstetric service is board certified in MFM or obstetrician-gynecologist (OB-GYN) with expertise in critical care obstetrics.*
3. *An advanced practice registered nurse shall be available to the staff for consultation, education, and support on nursing care issues.*

All delivering hospitals will be required to affiliate with one perinatal center. Centers are responsible for providing four basic functions to their affiliates:

1. Training;
2. Quality Assurance Review;
3. Transport Facilitation; and
4. Other Support Services, as necessary.

410 IAC 39-8-2 Perinatal Collaboration

Each perinatal center shall annually engage in a minimum of two (2) efforts sponsored by the department supporting improved outcomes for pregnant women and newborns. At least annually, perinatal centers and their affiliates shall review quality metrics recommended by the department and review and revise programs and activities to improve outcomes for pregnant women and newborns.

Perinatal centers may elect to collaborate with other centers to provide summits on hot topics within their region or utilize existing events (ex. Infant Mortality Summit, Perinatal Transport Conference, Perinatal Substance Use Conference, Breastfeeding Conference) to schedule networking conversations.

The intent when conference was referenced was to share timely regional mortality and morbidity statistics, identify best practices and/or challenges with time for solution discussion, evaluate regional FIMR and/or Maternal Mortality data, evaluate general transport data, and incorporate ISDH updates. It was never the intent for each perinatal center to organize and host an educational conference.

410 IAC 39-8-3 Training for Affiliate Hospitals

Perinatal centers shall provide clinical training to address affiliate needs that augment routine training as outlined by the department, including the following:

(1) *Obstetric training including fetal heart rate monitoring.*

(2) *Neonatal training including the following:*

- ***(A)*** *Neonatal Resuscitation Program (NRP).*
- ***(B)*** *Post-resuscitation and pre-transport stabilization care of sick infants.*

(3) *Universal training including the following:*

- ***(A)*** *Discharge planning.*
- ***(B)*** *Identification of high-risk patients and appropriate transfer.*
- ***(C)*** *Development of shared protocols with obstetrics and neonatology including the following:*
  - ***(i)*** *Perinatal hospice and bereavement.*
  - ***(ii)*** *Transport.*
  - ***(iii)*** *Safe sleep.*
  - ***(iv)*** *Car seat safety.*
  - ***(v)*** *Communication and patient safety.*
  - ***(vi)*** *Other topics that are jointly identified.*

Frequency

The perinatal center will work with the affiliate(s) leadership, providers, and staff to identify any new and ongoing educational needs. A plan will be developed that offers education to the affiliates that aligns with the affiliate(s) identified needs and the resources of the perinatal center. Education shall be offered a minimum of twice per year. The perinatal center will obtain yearly input from each affiliate to assure agreed upon training addresses identified quality outcome objectives.

Location

Perinatal centers will work with affiliates to determine the training location that best meets the identified needs. When possible, simulation training should be offered at each affiliate hospital for optimal learning. Some suggestions for perinatal centers providing education to affiliates include utilizing on-line meeting forums such as “go to meetings” or “Zoom”. They could also “train the trainer” to support affiliates training their own team members.

Documentation of Training Requirements

The training and education provided by perinatal centers will be assessed by the birthing hospital nurse surveyors during the re-designation visit. Documentation to verify education provided by the perinatal center may be demonstrated by, but not limited to, the following: education class calendars showing the number of seats offered and attendance rosters, which identify affiliate staff, attended education, training, drills, or simulations. Completion of education will also be assessed during the affiliate hospital’s re-designation visit and verified by staff education files and attendance rosters.

Perinatal centers should communicate both their own calendar of opportunities and external training opportunities to affiliates (ex. transport and PSU webinars, S.T.A.B.L.E. and OB safety courses) so they have a variety of options to meet their training needs.

Cost of Training

Each perinatal center is free to charge what they believe is necessary to provide education to affiliate hospitals. Affiliate hospitals are welcome to have a MOU with a perinatal center and seek training at another facility. The perinatal center’s responsibility is to offer training but is not required to provide training to 100% of the affiliate hospital team members.

Expenses such as books and/or course costs should be paid by affiliate hospitals, but instructor time should be paid by the perinatal center. The instructor expense could be minimized by hosting the training at the perinatal center and opening seats for the affiliate hospital staff to attend.

Opportunities to address unmet affiliate hospital needs could be brought to the Perinatal Center Task Force meetings for discussion. Opportunities for funding may be available by the ISDH based on historic funding and could include hospitals or perinatal centers matching grant funding. Centers should communicate and promote all education opportunities including those that are either low cost or free.

Affiliates could consider utilizing alternative fetal monitoring educational programs such as Relias OB or the ISDH fetal monitoring course.

Opportunities to address unmet affiliate hospital needs could be brought to the Perinatal Center Task Force meetings for discussion and potentially identify another hospital that has resources available (ex. obsolete equipment or NRP book sharing).

The ISDH could in turn identify funding as done historically utilizing Title V funding for S.T.A.B.L.E. courses and Safety PIN funding for the IHA safe sleep hospital education standardization. Future grant funding could address unmet needs such as purchasing NRP books for Level I and II hospitals.

Affiliate Participation in Training

The role of the perinatal center is to collaborate with its affiliates and support their needs to improve quality. If affiliates refuse training and are not in compliance with the level of care rules, the perinatal center can encourage and help guide them. The perinatal center can bring the concerns to the Perinatal Center Task Force meetings to discuss the barriers and concerns. If efforts are not successful and noncompliance continues, the perinatal center will report the issues to the ISDH who will address the noncompliance with the affiliate hospital.

Birth Centers

The perinatal center's goal is to decrease infant and maternal mortality and increase quality of care. Perinatal centers are not required to provide education to birthing centers or non-delivering hospitals but are encouraged to offer training that will support achieving the community and state goals. While perinatal center MOUs are not required, when transports occur between birth centers and hospitals, a transport review should occur as it would for transports between hospitals.

410 IAC 39-8-4 Quality Assurance

In addition to data collected on birth and death certificates, perinatal centers will review and analyze quality metrics recommended by the department with their affiliates for identification of quality improvement initiatives.

Because the ISDH perinatal data system is not in place at this time, data elements have been identified that are already being collected. The data measures and definitions are included in the following chart.

Data Element	Definition
Maternal Death	For reporting purposes, a pregnancy-related death is defined as the death of a woman while pregnant or within 1 year of pregnancy termination—regardless of the duration or site of the pregnancy—from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.
Elective Inductions	Elective deliveries without medical indications that are performed before 39 0/7 weeks.
Maternal Hemmorhage	Cumulative blood loss of greater than or equal to 1000 mL, or blood loss accompanied by signs or symptoms of hypovolemia within 24 hours after the birth process (includes intrapartum loss) regardless of the route of delivery
Eclampsia	Occurrence of one or more convulsions, not attributable to other cerebral conditions such as epilepsy or cerebral hemorrhage, in a patient with preeclampsia.
Unplanned trip to the OR	Maternal Morbidity: Unplanned operating room procedure following delivery (Any transfer of the mother back to a surgical area for an operative procedure that was not planned prior to the admission for delivery. Excludes postpartum tubal ligations.) Post discharge from birth, return to hospital for emergency surgery
Trip to the ICU	Maternal Morbidity: Admission to intensive care unit (any admission of the mother to a facility/unit designated as providing intensive care) Post discharge from birth, return to hospital, admission to ICU
C-section delivery for fetal status	Final Route and Method of Delivery: Cesarean (Extraction of the fetus, placenta, and membranes through an incision in the maternal abdominal and uterine walls)
Unplanned maternal readmit within 14 days of delivery	Readmission for SSI, pre-eclampsia needing magnesium and/or blood pressure management, seizure, or cardiac issues
Maternal Fetal Transport	Was the mother transferred to this facility for maternal medical or fetal indications for delivery? / Facility mother transferred from
Birth Weight	Birthweight in grams
NICU within 24 hours of birth	Abnormal conditions of the newborn: NICU admission (Admission into a facility or unit staffed and equipped to provide continuous mechanical ventilatory support for a newborn)
Gestational Age	Obstetric estimate of gestation at delivery (completed weeks)
Infant transport to another facility	Was infant transferred within 24 hours of delivery? / Facility child was transferred to?

410 IAC 39-8-5 Support Services

Delivering facilities serving as perinatal centers shall provide the following support to affiliate hospitals at all times:

(1) *Maternal-fetal medicine (MFM) specialist consultation by phone or telemedicine.*

(2) *Maternal-fetal transport including a reliable and comprehensive communication system to initiate transport.*

(3) *Communication with the discharging obstetrician-gynecologist (OB-GYN) or MFM specialist, and the referring OB-GYN or family medicine physician regarding the outcome of pregnancy, recommendations for postdelivery care or continued interpregnancy care, and management of the next pregnancy including, when appropriate, birth spacing.*

(4) *Neonatal consultation by phone or telemedicine.*

(5) *Neonatal transport, including a reliable and comprehensive communication system to initiate transport.*

(6) *Developmental follow-up program for high-risk newborns.*

As stated in the overview, the goal of the structure of Centers and Affiliates is to standardize expectations, support implementation efforts and reduce variability for perinatal services across the state. Level I and II delivering hospitals are critical to perinatal services statewide. Most deliveries happen in Indiana's Level I and II hospitals. The staffing and services available through the Centers are designed to provide specialized resources and supports to the affiliate hospitals. Those resources and supports include maternal-fetal and neonatal consultation by specialists, specialized transports that meet the perinatal transport standards, continuity of care post-delivery and transition from NICU and follow-up care of high-risk infants (detailed in 410 IAC 39-8-7).

410 IAC 39-8-6 Back Transport

Perinatal centers shall make every effort to transfer maternal-fetal or neonatal patients back to the affiliate hospital when risk appropriate and by mutual agreement with the affiliate hospital and family.

When medically appropriate and with the agreement of the affiliate hospital and family, the Center should make every effort to return maternal-fetal and neonatal patients back to their home hospital and community. Ease of access to family support and continuity of care can make a challenging situation easier for all involved.

410 IAC 39-8-7 Neonatal intensive care unit transition and developmental follow-up

Perinatal centers shall support the following services:

(1) Retinopathy of prematurity screening.

(2) Assistance to affiliate hospitals in accessing subspecialty care as needed.

(3) Work with affiliate hospitals and primary care providers to establish medical homes to coordinate ongoing well child care.

(4) Implementation of a developmental follow-up screening program, with the following requirements:

- *(A) Perinatal centers shall use a valid and reliable standardized screening tool.*
- *(B) The tool shall be administered at recommended intervals.*
- *(C) The developmental follow-up screening program shall serve high-risk infants including, but not limited to, those with the following conditions:*
  - ***(i)*** *Newborns weighing less than or equal to one thousand five hundred (1,500) grams at birth.*
  - ***(ii)*** *Hypoxic-ischemic encephalopathy (HIE).*
  - ***(iii)*** *Neonatal seizures.*
  - ***(iv)*** *Hypoxic cardiorespiratory failure.*
  - ***(v)*** *Complex, multiple congenital anomalies.*
  - ***(vi)*** *Neonatal abstinence syndrome (NAS).*
  - ***(vii)*** *All other high-risk infants with additional diagnoses at the discretion of the center.*

In 2015, the High Risk Newborn Subcommittee of the Indiana Perinatal Quality Improvement Collaborative (IPQIC) completed their recommendations regarding the requirement that Indiana Perinatal Centers provide for appropriate transition for newborns leaving the neonatal intensive care unit and follow-along supports for infants with high risk for developmental issues. The committee members began their work with a review of the existing literature. The most cited and definitive document was *Follow-Up Care of High-Risk Infants* published by the American Academy of Pediatrics. The paper was developed because of a 2002 workshop sponsored by the National Institute of Child Health and Human Development, National Institute of Neurologic Disorders and Stroke, and the Centers for Disease Control and Prevention. The paper concluded that "There are currently no standardized guidelines for the provision of follow-up services for high-risk infants in tertiary care centers despite the requirement for follow-up clinic experience in the 97 approved neonatal fellowship training programs in the United States and the increasing

number of centers participating in multicenter networks."[1] The paper identified the need to improve standardization, comparability and data collection within and among centers. There was general agreement that neurodevelopmental outcomes for the identified cohort of infants be systematically monitored. This paper addressed the benefits of neonatal follow-up, the population that should be followed, the periodicity of follow-up, tools to be used, finance issues and the role of the community physician. These components served as a road map for the activities of the subcommittee and their recommendations that were adopted by the IPQIC Governing Council.

In addition to providing the following supports to affiliate hospitals including Retinopathy of prematurity screening, assistance to affiliate hospitals in accessing subspecialty care as needed and work with affiliate hospitals and primary care providers to establish medical homes to coordinate ongoing well child care, there are two additional components related to the developmental follow-up requirement:

1. Population to be followed; and
2. Screening tools to be used.

Population to be followed

"Infants should receive follow-up assessments based on the severity of the perinatal problems, the interventions received in the NICU, the demographic risk factors of the infants' families, the outcome profile of the cohort in the individual NICU, and the NICU's resources. ... There is increased recognition of the potential disconnect between perinatal outcomes and long-term outcomes"[2]

Indiana Administrative Code 410 IAC 39-8-7 (4)(c) states

"The developmental follow-up screening program shall serve high-risk infants including, but not limited to, those with the following conditions:

i. Newborns weighing less than or equal to one thousand five hundred (1,500) grams at birth.
ii. Hypoxic-ischemic encephalopathy (HIE).
iii. Neonatal seizures.
iv. Hypoxic cardiorespiratory failure.
v. Complex, multiple congenital anomalies.

[1] Pediatrics Vol 114 No. 5 November 2004
[2] Ibid

vi. *Neonatal abstinence syndrome (NAS).*
vii. *All other high-risk infants with additional diagnoses at the discretion of the center."*

The administrative rules identify the population that must be served but does not limit any Center from adding additional diagnoses to the population to be followed.

Screening Tools

The regulations require that a valid and reliable standardized screening tool be used. In the original perinatal centers document, Ages and Stages was the recommended screening tool. The ASQ is an easy to administer questionnaire that can be completed by the family or could be administered by the medical home during routine visits. The ASQ has been in use for over 15 years and is considered highly reliable and valid. ASQ is a series of questionnaires designed to screen the developmental performance of young children in the areas of communication, gross motor skills, fine motor skills, problem-solving, personal-social skills, and overall development. The age appropriate scale is completed by the parent or caregiver. Each questionnaire looks at the strengths and challenges of the child and educates parents about their child's developmental milestones. The questionnaires take approximately 10-20 minutes to complete and are available in English, French, Korean and Spanish. The questionnaires can be administered in an online format or by paper and pencil. There is no minimum degree or license requirement to administer the scale. [3]

The recommendation was that the screenings occur at the established intervals of 4, 9, 12, 18 and 24 months, adjusted for prematurity. This is aligned with the national practice of ending these follow-along programs at 24 months adjusted age. An agreement with the medical home should be established upon discharge of the infant from the Perinatal Center NICU regarding the administration and reporting of the ASQ results.

While the regulations only require a screening tool be used with the identified population, Centers, at their discretion, may use a diagnostic evaluation tool.

Additional resources for screening tools are available at AAP's Screening Technical Assistance and Resource (STAR) Center: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Screening/Pages/default.aspx

When infants that meet the established criteria for follow-up are not discharged from the Perinatal Center but from an affiliate hospital, it is the responsibility of the discharging hospital

[3] http://www.cebc4cw.org/assessment-tool/ages-and-stages-questionnaire/

to ensure that the infant and family are referred to a community resource that can support the ongoing developmental screening. The affiliate hospital must log or document all referrals for follow up, monitor that the referral has been completed and share this log with their perinatal center. Linkage to the ongoing primary provider and community resource support services at the local level is optimal. If there are limited resources for that follow-up, hospital discharge staff can reach out to their Perinatal Center for assistance or contact:

- MOMS Helpline at https://www.in.gov/isdh/21047.htm, by phone at 1-844-MCH-MOMS (1-844-624-6667) or email MCHMOMSHelpline@isdh.in.gov. ; or
- Indiana 211: Indiana 211 is now part of the Indiana Family and Social Services Administration. Indiana 211 and FSSA will be able to aid Hoosiers in need more efficiently by providing a one-stop shop for community and state services. When they dial **2-1-1**, Hoosiers are connected to an experienced, responsive, and compassionate team of community navigators who are skilled at identifying needs and providing referrals that best meet those needs.

If an infant born in an affiliate hospital is transferred to a Center other than the Center with which they have an agreement, the discharging Center is responsible for follow-up and communication with the medical home.

In all cases, the arrangements for developmental follow-up must be clearly identified in the Memorandum of Understanding developed between Center and affiliate and evaluated on an annual basis.

Should the medical home be unable to participate in the administration of the ASQ, the perinatal center should facilitate the completion of the questionnaire. Results should be shared between the center and the PCP with any recommended interventions done at a local level.

410 IAC 39-8-8 Memorandum of understanding between perinatal center and affiliate hospitals

(a) Any facility not certified by the department as a perinatal center shall affiliate with a perinatal center. The department shall notify facilities when all initial perinatal centers have been certified. Facilities not certified by the department as perinatal centers will have twelve (12) months from notification to enter a memorandum of understanding with a certified perinatal center.

(b) Non-perinatal centers may affiliate with only one (1) perinatal center.

(c) Every perinatal center shall affiliate with at least one (1) hospital outside of its own network unless none are available.

(d) The department will assign unaffiliated hospitals to perinatal centers as needed.

(e) Each perinatal center and its affiliate hospitals shall enter into an agreement that defines the responsibilities of each partner as follows:

***(1)** Each perinatal center shall have the following responsibilities:*

***(A)** Training to affiliates as specified in section 1 of this rule.*

***(B)** Support services to affiliates as specified in section 1 of this rule.*

***(C)** Sponsor and coordinate visits to affiliate hospitals related to outcomes and quality assurance at least annually.*

***(D)** Support for transition of patients from perinatal specialty care to primary physician.*

***(2)** Each affiliate hospital shall have the following responsibilities:*

***(A)** Compliance with perinatal levels of care rules.*

***(B)** Collection of quality improvement data.*

***(C)** Attendance and participation in perinatal center and affiliate meetings.*

***(D)** Collaboration with the perinatal center and provision of data for annual visit to evaluate outcomes.*

***(E)** Collaboration with the perinatal center related to transition home and back transport of shared patients.*

The rules were adopted to identify the elements and responsibilities that both Centers and Affiliate hospitals have in the relationship. There was a deliberate decision that a template would not be developed as the legal and administrative personnel of each center would have specific language that would be required.

All delivering hospitals that are not designated as a Perinatal Center must affiliate with a single center. This section of the perinatal center rule makes clear that there are reciprocal responsibilities of both centers and affiliates. The MOU must clearly identify those responsibilities.

Appendix A: Developmental Follow-Up Algorithm

Developmental Follow-up Process for Perinatal Centers

PERINATAL CENTER OR DISCHARGING HOSPITAL

- Identify point person responsible for determining eligibility for follow-up as determined through the MOU governing the Center/ Affiliate
- Identification of infants that meet the state established criteria for follow-up
- Develop digital document for tracking of each infant that meets the criteria
- Establish dates for required screening intervals

OUTREACH TO PRIMARY CARE PROVIDER

- Identification of Primary Care Provider (PCP) for infant
- Discharge follow-up appointment is scheduled with PCP
- NICU discharge information sent to PCP along with information that identifies eligibility criteria, screening intervals and validated screening tools
- Provide resources for developmental testing and therapeutic services

DEVELOPMENTAL SCREENING

- Point person from Discharging Hospital contacts PCP to ensure screenings are occuring at the established intervals
- If screenings are occuring, establish whether development is age-appropriate
- If screening has identified a delay, referrals need to be made for formal evaluation and therapy provision
- If screenings have not occurred at regular intervals, Center point person must attempt to reach the family

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