1. **Protocol Title:** Illinois Perinatal Quality Collaborative Data System (Version 1)
2. **Version Date:** March 11, 2014
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4. **Study Description:**

Background

The Illinois Perinatal Quality Collaborative (ILPQC) seeks to improve birth outcomes and reduce costs related to poor birth outcomes in the state of Illinois. The ILPQC will collaborate with IL perinatal stakeholders[1] to improve perinatal safety, efficiency, quality of care, and outcomes for women and infants. The ILPQC will initiate obstetric and neonatal quality improvement initiatives with participating hospitals. ILPQC will work with the hospitals to utilize quality improvement and implementation science methodologies to disseminate best practice approaches, collect process and outcome variables on these initiatives and, then, collectively work to design solutions to improve outcomes across the collaborative. ILPQC will develop a web-based, secure database for participating hospitals to regularly input their data. Each participating hospital will be able to review their own data in real time, as well as, generate monthly reports and compare their data to the other de-identified participating hospitals. All data will be linked only to a unique identifier number so that individual hospitals cannot be identified or linked to their data. Hospitals will know their unique identifier and will be able to compare their outcomes to the other de-identified hospitals. The ILPQC will use these data to engage perinatal stakeholders in process improvement and implementation of collectively developed best practices to increase the quality of perinatal care.

Overview

In 2010, 165,000 babies were born in the state of Illinois and 12.2% of these births were preterm (<37 weeks) (NCHS, 2010). The gestational age at the time of delivery for infants and their associated morbidity and mortality rate are indirectly proportional. Babies born with a low gestational age have an increased risk of morbidity and mortality.

The costs for IL preterm births are substantial and much of the costs are being covered by the IL Department of Healthcare and Family Services (HFS). In 2009, 166,211 babies were born in Illinois and (HFS) covered 89,621 (53.9%) of these births. Assuming the societal cost of each preterm birth is $51,600 (Institute of Medicine, 2006), the cost to care for the approximately 12% (N ~ 21,000) preterm infants in Illinois amounted to over $1.09 billion. The 40% of HFS-covered births that were non-normal accounted for 70 percent of the total birth costs (~$627,000,000). In addition, very low birth weight (VLBW) infants represent just over 1 percent of US births, but account for almost 59% of the average costs of births through first year of life.

The IL House Joint Resolution 111 mandated that "the Perinatal Advisory Committee shall, in a written report that is to be delivered to the General Assembly on or before November 1, 2012 make findings and recommendations concerning reducing preterm births in Illinois."

The report recommended the following actions to reduce preterm births in Illinois:

[1]Perinatal Stakeholders: Public and private providers and payers, public health professionals, patients/families, health advocates, and business groups

- Consolidate and link data systems in Illinois to better understand and prevent preterm births;
- Create a comprehensive dataset to capture data on infant outcomes and maternal health before, during and after pregnancy;
- Eliminate elective (non-medically indicated) deliveries <39 weeks gestational age;
- Monitor change process with continuous quality improvement (CQI); and
- Provide resources for perinatal quality collaborative to work in tandem with Illinois Regional Perinatal System (RPS) to engage in ongoing quality improvement initiatives.

The Illinois Perinatal Quality Collaborative (ILPQC) is a result of this report. ILPQC is collecting data for two quality improvement initiatives that aim to improve pregnancy outcomes in Illinois.

Neonatal Initiative

As compared with the intrauterine growth of normal term infants, the growth of prematurely born infants is typically delayed. Approximately 50% of VLBW infants fall in the category of extra-uterine growth restriction by 36 weeks post-conceptional age (Vermont Oxford State Report, 2012). Poor nutrition is a significant contributory factor and is associated with prolonged hospitalization and an increased risk for poor health outcomes.

To address this, ILPQC has launched the Neonatal QI Initiative:*Improving Neonatal Nutrition*. The goal of this initiative is to improve the nutritional status of premature infants, particularly VLBW, by instituting early enteral feeding and TPN (total parenteral nutrition) supplementation when indicated. By standardizing the method of early nutrition with increased use of breast milk, appropriate use of TPN together with closely monitoring the growth parameters (weight, length, head circumference) at each NICU, we will try to achieve improvement in the growth pattern, therefore diminishing the number of extra-uterine growth restricted infants in Illinois.

Obstetric Initiative

Early Elective Delivery (EED) before 39 weeks gestation may result in higher rates of adverse respiratory outcomes, mechanical ventilation, sepsis and hypoglycemia for the newborns (Tita et al., 2009). A study in the American Journal of Obstetrics and Gynecology estimated the cost of such deliveries to be nearly $1 billion dollars per year. The American College of Obstetrics and Gynecology (ACOG) recommends against non-medically indicated delivery prior to 39 weeks and recommends that all hospitals put in place a hard stop policy against this practice. The Illinois Department of Public Health (IDPH) also recommends implementation of a hard stop policy for all maternity hospitals in the state.

ILPQC has partnered with the Illinois Hospital Association, March of Dimes, IDPH and HFS to move forward the first ILPQC Obstetric QI Initiative: *Reducing Early Elective Delivery*. Many hospitals are already working on reduction of early elective delivery in Illinois. ILPQC is positioned to assist hospitals with data assessment at participating hospitals. IDPH has released provisional birth certificate data on early elective delivery to Illinois birthing hospitals. The birth certificate data, although not able to capture all indications for early elective delivery, allows for comparison across hospitals and across time using the same data elements captured from birth certificates across the state. ILPQC is working with hospitals to identify methods of improvement for birth certificate data collection and also to standardize the current data collected on early elective delivery so that accurate rates can be used to assist hospitals with quality improvement efforts across Illinois.

ILPQC is working to develop an Early Elective Delivery data form and data dictionary to provide hospitals a standard form that should match the Joint Commission Data that they are already collecting. ILPQC is creating a data system that will allow hospitals to submit Early Elective Delivery data and will provide monthly reports to hospitals so that hospitals can assess their progress over time and compare themselves to other hospitals. All hospital data will be held securely and hospital names / locations are never reported with the data. The data system is building capacity to pull data directly from EMR's and from other state data sources to reduce burden while adding value for hospitals.

Data System

ILPQC is collaborating with Northwestern University to create a data system to support the quality improvement initiatives. Data will be collected and managed using REDCap electronic data capture tools hosted at Northwestern University. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.[2]The ILPQC PI, State Project Director, and Database Management Team, including Site PI, Data Systems Project Lead, Data Analyst, and Software Developer, will be involved in database management. The REDCap database will be used for data collection, and the Data Analyst will prepare custom reports for participating hospitals and will share them securely via REDCap.

5. Site Information

Quality improvement data collected at participating hospitals will be submitted to ILPQC's REDCap data system, housed at Northwestern University. ILPQC is the data coordinating center for QI research. Hospitals participating on a voluntary basis and may join or withdraw at any time. Participating sites vary based on initiative. Since data collection for quality improvement does not require IRB approval, each participating hospital is responsible for determining the need for a Data Use Agreement and IRB application at its own site.

6. Inclusion/Exclusion Criteria:

Participating Sites:
Inclusion: Level II and Level III hospitals submitting data on infants considered pre-term (<37 week) or very low birth weight (VLBW) may voluntarily choose to participate in the Neonatal Initiative. All perinatal hospitals in Illinois may voluntarily choose to participate in the Obstetric Initiative. Participating hospitals submit identify their ILPQC Hospital Team. Each Hospital team includes at least one physician and one nurse and is responsible for data collection for the QI initiative, as well as acting as a liaison between their hospital and ILPQC. Hospital Team members will receive a Northwestern University username to access the REDCap database. They will also receive REDCap training from the Data System Team and will be instructed to view training videos available on the REDCap website. A data use agreement with ILPQC is optional, depending on individual hospital need. Each participating hospital is also responsible for determining whether IRB approval is required for its site.
Exclusion: Does not meet inclusion criteria.

[2] Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.

Subjects:

Data collected is for hospital-level quality improvement research. Sample sizes will vary by topic and based on the number and type of hospitals participating in the initiatives.
Neonatal Initiative: We expect between 1,000 and 5,000 neonates from participating hospitals.
Obstetric Initiative: In 2012, there were approximately 36,000 live births between 37 and 38 weeks GA, according to birth certificate data released by IDPH about Non-Medically Indicated Elective Delivery. We expect sample size to be in line with this, based on the number of hospitals participating.

*Inclusion:*Neonatal initiative: Neonates born <37 weeks
Obstetric initiative: Deliveries between 37 and 39 weeks
Exclusion: Does not meet inclusion criteria.

7. Data Collection Instruments:

Participating hospitals will submit quality improvement data to a secure, web-based REDCap database housed at Northwestern University in a FISMA compliant environment.

The Neonatal Initiative data collection form and data dictionary are attached. The only HIPAA identifiers that will be obtained are birth dates and hospital discharge dates. The date of birth and discharge date will be entered into the database and then coded into a variable for length of stay in the NICU. This non-identifiable variable will be used for analysis. The data collection will not include medical record number, patient's name, or contact information. Each patient will be assigned a unique identifier, based on the unique hospital ID number. There will be no record tying the patient back to his/her unique identifier.

Hospitals participating in the Neonatal Initiative will collect data as a retrospective chart review from January 1, 2014 up to date of IRB approval (estimated June 1, 2014) and a prospective chart review will begin upon IRB approval (estimated June 1, 2014).

8. Training:

Hospital team members will be assigned a REDCap user ID and given data entry and/or report review access rights in REDCap. They will be provided with a training manual that explains how to log in to the REDCap database and how to correctly enter data. There will also be live trainings (via Adobe Connect) available to REDCap users.

9. Data Safety Monitoring Plan:

a. **Data Transmission:** Data is collected through a secure REDCap interface, which stores and restricts access to any identifiable information to anyone outside the participating hospital/source. The data will be collected for the duration of the study and will be kept under the same security settings with a back-up. None of the investigators or data administrators would have access to identifiers at any point of time.

b. **Data Storage:** Quality improvement research is an ongoing process. The data will be retained in the secure REDCap database for continued analytics and improvement purposes. Only de-identified data will be available to anyone other than the participating hospital teams (who enter the data).

10. **Data Analysis:** Custom monthly reports of key outcome measures will be generated using this data and shared securely with participating hospitals using REDCap. Hospitals will be able to view aggregate data and will be able to compare their data to other similar participating hospitals. Each participating hospital will have a unique identification number known only to the Hospital Team and personnel on this project. Analysis will be done by the Data System Team, including the Data System Lead and the Data System Coordinator.

APPENDIX A

Nutrition Data Sheet

Version 05/22/14

Baby ID Number _____

Birth date _____ Birth gestational age _____

Was the infant an outborn? No☐ Yes☐ If Yes, transfer date _____

Gender Male☐ Female☐ Not known☐

Race White ☐ Black☐ Hispanic ☐ Other ☐

Birth Weight _____

HC _____

Length _____

DOL 7 Weight _____

HC _____

Length _____

DOL 28 Weight _____

HC _____

Length _____

36wks CA Weight _____

HC _____

Length _____

At Discharge Weight _____

HC _____

Length _____

Hour of life TPN Started _____

Hour of life Lipids Started _____

Day of Life First Feeding _____

Day of life > 120 ml/kg/day of feeding _____

Receiving Greater than 50% of feed as Breast Milk

- DOL 7 No☐ Yes☐
- DOL 28 No☐ Yes☐
- 36wks CA No☐ Yes☐
- At discharge No☐ Yes☐

Baby received Probiotics at any time No☐ Yes☐ Unknown ☐

Baby with NEC (VON Definition) No☐ Yes☐

Baby recorded the lowest weight on which date? _____ (the last date)

Disposition Discharge home☐ Transfer to other facility☐ Death☐

Disposition date _____

Nutrition Data Definitions

Version 05/22/14

1. Baby ID number – number assigned by each center to each individual infant (unique subject code)
2. Birth date – mm/dd/yyyy format
3. Birth gestational age – Determined by LMP or early ultrasound primarily. If not, use clinical estimate. Expressed in weeks (range 20-42) and days (range 0-6), for example 39w4d.
4. Was the infant outborn? – Delivered outside your center: yes or no
    a. If yes, include date transferred to your center.
5. Gender:male, female, or not known
6. Race – The race is determined following the VON data entry, e.g. the response for the maternal ethnicity/race should be obtained by personal interview with the mother or review of the birth certificate or medical record in that order of preference.
    a. Black: if the biological mother is a person having origins in any of original people in Africa
    b. White: if the biological mother is a person having origins in any of the people of Europe, the Middle East, North Africa (Arabic origins), or Western Russia (including Afghanistan and South Russia)
    c. Hispanic: if the biological mother is a person of Cuban, Mexican, Puerto Rican, South or Central American or other Spanish culture or origin, regardless of race
    d. Other: if none of the race categories above apply to the biological mother
7. Birth – day of birth
    a. Weight – enter in grams (range 250-6000 g) with 4 significant digits (i.e. 1235 g)
    b. HC – head circumference in cm to nearest tenth (range 15.0-50.0 cm)
    c. Length – in cm to nearest tenth (range 25.0-60.0 cm)
8. DOL 7 – Day of life 7(date of birth = day of life 1)
    a. Weight – enter in grams (range 250-6000 g) with 4 significant digits (i.e. 1235 g)
    b. HC – head circumference in cm to nearest tenth (range 15.0-50.0 cm)
    c. Length – in cm to nearest tenth (range 25.0-60.0 cm)
9. DOL 28 – Day of life 28 (date of birth = day of life 1)
    a. Weight – enter in grams (range 250-6000 g) with 4 significant digits (i.e. 1235 g)
    b. HC – head circumference in cm to nearest tenth (range 15.0-50.0 cm)
    c. Length – in cm to nearest tenth (range 25.0-60.0 cm)

10. 36 weeks CA – when infant reaches 36 weeks post-conceptual age (gestational age + birth age)
    a. Weight – enter in grams (range 250-6000 g) with 4 significant digits (i.e. 1235 g)
    b. HC – head circumference in cm to nearest tenth (range 15.0-50.0 cm)
    c. Length – in cm to nearest tenth (range 25.0-60.0 cm)
11. At Discharge– when infant leaves your center – home or transfer
    a. Weight – enter in grams (range 250-6000 g) with 4 significant digits (i.e. 1235 g)
    b. HC – head circumference in cm to nearest tenth (range 15.0-50.0 cm)
    c. Length – in cm to nearest tenth (range 25.0-60.0 cm)

Note: Percentiles based on Fenton growth charts

12. Hour of life TPN– birth = zero, to nearest hour (range 0-180)
    a. TPN – fluids containing glucose and protein
13. Hour of life lipids started – birth = zero, to nearest hour (range 0-180)
    a. Lipids- intravenous fat emulsion
14. Day of Life for First Feeding
    a. Date of birth = day of life 1
15. Day of life > 120 ml/kg/day of feeding
    a. Date of birth = day of life 1
16. Receiving Greater than 50% of feed as Breast Milk (breast milk: mothers or donor milk)
    a. DOL 7 – yes or no
    b. DOL 28 – yes or no
    c. 36 weeks CA – yes or no
    d. At discharge – yes or no
17. Baby received probiotics at any time (probiotics: any enteral bacterial supplement) – yes or no
18. Baby with NEC – yes or no
    a. Yes if the infant had Necrotizing Enterocolitis (NEC) diagnosed at surgery, at postmortem examination or clinically and radiographically using the following criteria:
        i. One or more of the following clinical signs present: billious gastric aspirate or emesis, abdominal distension, and/or occult or gross blood in stool in the absence of fissure AND

ii. One or more of the following radiographic findings present: pneumatosis intestinalis, hepato-biliary gas, pneumoperitoneum

b. No if the infant did not satisfy the above definition of NEC

19. The date of lowest postnatal weight– The date when the lowest body weight of the infant is recorded in the medical record expressed as mm/dd/yyyy format

20. Disposition: discharge home, transfer to another facility, or death

21. Disposition date – mm/dd/yyyy format

APPENDIX B

Coded Identifiers List

Unique subject code:

- 2 digit project number (01 for Neonatal Initiative, 02 for Obstetric Initiative)
- 3 digit hospital code (randomly assigned to participating hospitals, confidential)
- 4 digit patient code (assigned at participating hospitals, unique to each patient, cannot be tied back to patient)

Identifiers being collected:

- Date of birth

Coded identifiers:

- The data entered in REDCap, including DOB and discharge date, is secured and saved in a separate server with no access from any outside source.
- The project admin holds the rights to set up the permissions for all user level access.
- We will encrypt or encode the data before exporting it out of the REDCap for performing any kind of analytics.
- The decryption key will not be accessible by the same people who encrypt it and use it.
- This will ensure security of all PHI.