
Neonatal Intensive Care Unit Council Annual Report

**As Required by
H.B. 2636, 82nd Legislature,
Regular Session, 2011**

**Health and Human Services Commission
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Executive Summary

H.B. 2636, 82nd Legislature, Regular Session, established a Neonatal Intensive Care Unit (NICU) Council under the Texas Health and Human Services Commission (HHSC) to study and make recommendations regarding neonatal intensive care unit (NICU) operating standards and reimbursement payment through the Medicaid program for services provided to an infant admitted to a neonatal intensive care unit. The Council was to: (1) develop standards for operating an NICU in Texas; (2) develop an accreditation process for NICUs to receive payment for services provided through Medicaid; (3) study and make recommendations regarding best practices and protocols to lower NICU admissions.

The Council met in Austin six times in 2012 and reviewed a large number of documents and presentations. Three subcommittees (NICU Standards, Maternity Standards, and Best Practices) were formed and met regularly by telephonic conference.

Note: See Appendix 1 for supplemental information to the Executive Summary

Summary Recommendations

- 1) The standards for level of neonatal and maternal care will be further developed by the NICU Council. After the NICU Council's tenure ends in June 2013, a Perinatal Facility Designation Implementation Task Force (Task Force) should be convened to develop the process of designation and verification of hospital facilities in the state, and further provide operational definition of standards as necessary. The current NICU Council members should serve as members of the Task Force to provide continuity and expertise. An additional general hospital representative should also be appointed to the Task Force. Travel expenses for those who serve on this Task Force should be reimbursed.
- 2) HHSC, the NICU Council, and Task Force should work together with the Department of State Health Services (DSHS) to develop a process for the designation of maternal and neonatal levels of care for hospitals performing deliveries and/or caring for neonates. The same facility may have different levels of maternal and versus neonatal care. Only designated facilities should be eligible for the Medicaid payment for maternity or neonatal services.
- 3) The levels of neonatal care and maternal care should be based on the current American Academy of Pediatrics (AAP) standards and current Guidelines for Perinatal Care publication, and should be further defined for the geographic and varied needs of Texas by the NICU Council and Task Force as needed. The Task Force should develop a process for designation of level of care, make recommendations for the division of the state into regions, develop Regional Advisory Council (RAC) processes, and delineate reporting requirements.

I. Legislation

H.B 2636, 82nd Legislature, Regular Session, established a Neonatal Intensive Care Unit (NICU) Council (Council) under the HHSC. The Council is to make recommendations regarding NICU operating standards and payment through the Medicaid program for services provided to an infant admitted to an NICU. Specifically, the Council shall: (1) develop standards for operating an NICU in Texas; (2) develop an accreditation process for NICUs to receive payment for services provided through Medicaid; (3) study and make recommendations regarding best practices and protocols to lower admissions to NICUs. The bill specifies the composition of the Council, including sufficient diversity of medical specialty and geographic representation. A report is due to the HHSC Executive Commissioner, the Governor, the Lieutenant Governor, the Speaker of the House of Representatives and chairs of the appropriate legislative committees by January 1, 2013. The Council expires on June 1, 2013.

II. Formation of the Council and Council Makeup

H.B. 2636 required the Executive Commissioner to create and appoint the members to the Council and designate a chairperson. Per H.B. 2636, Council membership includes the following:

- Four neonatologists, at least two of whom must practice in a Level IIIC neonatal intensive care unit.
- One general pediatrician.
- Two general obstetrician-gynecologists
- Two maternal fetal medicine specialist
- One family practice physician who provides obstetrical care and practices in a rural community
- One representative from a children's hospital
- One representative from a hospital with a Level II neonatal intensive care unit
- One representative from a rural hospital.

The council includes health-care providers who serve pregnant women and newborns, with a focus on newborn needs in the NICU, including pediatricians, obstetrician-gynecologists, maternal fetal medicine specialists, neonatologists, children's hospital representatives, and rural providers.

Former Executive Commissioner Thomas M. Suehs appointed the following individuals to the NICU Council:

- Dr. Eugene Toy, Chair – Obstetrician /Gynecologist
- Dr. Brenda Morris, Vice Chair – Rural hospital representative, Neonatologist
- Dr. Emily Briggs – Family medicine physician delivering in a rural area
- Dr. Frank Cho – Neonatologist /Level IIIC NICU

- Dr. Byron Elliot – Maternal-Fetal Medicine
- Dr. Angelo Giardino – Pediatrician
- Dr. William “Brendle” Glomb- Pediatric Pulmonologist, ex officio
- Ms. Barbara Greer, RN, SMN, NE-BC – Children’s hospital representative
- Dr. Lisa Hollier – Maternal-Fetal Medicine
- Dr. Dynio Honrubia – Neonatologist
- Dr. Jonathan Nedrelow – Neonatologist
- Dr. Shelia Owens-Collins – Level II NICU representative
- Dr. Sanjay Patel – Neonatologist
- Dr. Joan Richardson – Neonatologist
- Dr. George Saade – Maternal Fetal Medicine
- Dr. Michael Speer – Neonatologist
- Dr. Michael Stanley – Pediatrician/Neonatologist
- Mr. Steve Woerner – Children’s hospital representative

III. Background

Note: See Appendix 2 for detailed background information on NICU issues in Texas, including definition of terms.

In deliberating over the complicated issues of neonatal standards of care and best practices, the NICU Council met six times in Austin in 2012, reviewed nearly a hundred publications and presentations, and formed three subcommittees which also met via telephone conference. Their work schedule was impacted by changes in perinatal national guidelines which occurred in the fall of 2012. The American Academy of Pediatrics (AAP) guidelines for neonatal levels of care were revised recently and released in September 2012, and the 7th edition of the publication “Guidelines for Perinatal Care”, a joint publication of the AAP and the American College of Obstetricians and Gynecologists (ACOG), was released October 2012. The release of these key publications led to a delay in developing Texas-specific neonatal and maternal levels of care. Currently, the Council is about 75 percent finished with the neonatal and maternal levels of care standards and anticipates completion by May 2013.

The Council has met in Austin a total of six times in the calendar year 2012: March 27, May 14, July 24, September 10, October 16 and November 12, 2012.

Note: Highlights of NICU Council Meetings (2012) can be found in Appendix 3

Based on the many documents reviewed, presentations heard, and numerous discussions, the following have been agreed by consensus of the Council:

Note: Specific document citations can be found in Appendix 4

- 1) The Council will use scientific evidence and a model of consensus to develop its standards and make decisions. The Council recommends a collaborative and transparent

process, with stakeholder input. Because Texas is a large and diverse state with different community needs, a careful implementation is required. Clear communication, a prioritization of patient care and outcomes, and awareness of the diverse community needs and resources are required.

- 2) Very Low Birth Weight (VLBW) infants (less than 1500g or less than 32 weeks gestation) seem to have improved outcomes when delivered at the appropriate (Level III, IV-highest level) facilities. Numerous studies nationwide as well as individual state investigations confirm this finding. Less than 50 percent of Texas VLBW babies are born at the highest level facility, which indicates an important non-compliance in a national quality measure, affecting neonatal outcomes. Whereas the percentage of VLBW births in Texas have remained relatively unchanged (1.3-1.4 percent), the number of NICU beds in Texas have increased 74 percent from 1447 beds to 2520 beds over the 10 year period from 2000 to 2010. A regionalized perinatal system with regional advisory councils would help to address this issue. (Laswell 2010 JAMA meta-analysis)
- 3) Currently there is no consistent and verifiable designation of neonatal levels of care for Texas hospitals. The Council believes that neonatal care standards are important to determine the quality of care provided as well as to help optimize resource utilization. Furthermore, the Council believes that the AAP statement on levels of neonatal care, and current “Guidelines for Perinatal Care” should be used as the basic template since the recommendations are derived from the best level of evidence. These guidelines are somewhat detailed, but still need further delineation and description which the NICU Standards Subcommittee has been developing with presentations to the full NICU Council.
- 4) The Council strongly believes that maternal levels of care also must be delineated to provide optimal care of both the neonate and the pregnant woman. Since decreases in NICU admissions are principally achieved by reducing preterm delivery, evidence-based, risk assessment of the pregnant patient is vitally important. The three-fold increase in maternal mortality in Texas likewise underscores the need for attention to care of the pregnant woman. Currently there are no established standards of maternal levels of care in Texas. It is important for the state to adopt consistent and defined standards of levels of care for patient outcomes, resource utilization, and coordination and collaboration. The Council is using the publication “Guidelines for Perinatal Care, 7th ed.” as the template for these standards. Data collection and process improvement are also important.
- 5) The Council will use the best available scientific evidence to make its recommendations, and use national standards as a template for development of Texas standards. The Council will take into account the diverse geographic and community needs of the state in making its recommendations. The Council believes that cost savings will take place primarily by institution of best practices to reduce the number of NICU admissions and reduce the NICU length of stay. Transferring the woman at high risk or impending risk for preterm delivery to the correct facility will lead to the best neonatal outcome. Back transfer of the infant to the lower level facility once the more critical conditions have resolved is an important principle for utilization of hospital beds and convenience for patients and their families.
- 6) The Council strongly believes that a “perinatal” system is critically important to reduce the incidence of preterm deliveries, and coordinate the care for the pregnant woman and

the premature or critically ill neonate. The Council advises a strong and consistent data reporting system for both maternal and neonatal outcomes to identify weaknesses, potential high and low performers, and to optimize perinatal healthcare.

- 7) Hospital Designation Process – Although H.B. 2636 calls for an accreditation process for hospitals providing neonatal ICU care, the Council has determined after hearing from Ms. Kathy Perkins, Director for DSHS Division for Regulatory Services, that neonatal and maternal levels of care would be a “state designation” rather than an accreditation. The designation may include a verification process that reviews the facility’s accreditations, certifications, or other methods to assess compliance with standards and possibly a site visit. To provide high quality care for all patients in Texas, the Council recommends that the designation be at the state level and be relevant to all patients rather than only Medicaid patients. The Council recommends that Medicaid payment for maternal or neonatal services only be made for those facilities that receive state designation.
- 8) Implementation – Because the Act authorizing the NICU Council will expire on June 1, 2013, the Council recommends the appointment of a Perinatal Designation Implementation Task Force to take over the role of developing a designation and verification process. The current NICU Council members are recommended to be on that Task Force working together with HHSC and the DSHS. The Council recommends that one additional hospital representative be appointed to the Task Force.

Best practices to reduce NICU admissions – The Best Practices Subcommittee had several recommendations, most notably based on decreasing preterm deliveries through the appropriate use of 17 Hydroxyprogesterone (17OHP). 17 Hydroxyprogesterone is a steroid hormone naturally produced by the adrenal glands. It has been shown to reduce pre-term labor in selected at-risk pregnant women with a history of pre-term labor when injected weekly starting between 16 and 21 weeks of gestation

- 9) There was discussion about the lack of use due in part to physician education and awareness, but mostly due to logistical barriers. HHSC staff noted 17OHP is covered by Medicaid, but noted issues such as payment for administering the injection and needing the patient to enter prenatal care early enough. Other best practice recommendations, to include better use of data, will be developed and implemented in the regionalized environment.

IV. Formal Council Recommendations

Based on the careful study of the various documents, input from key stakeholders, and reviewing the presentations from state officials, the Council has the following recommendations:

- 1) Best practices to reduce NICU admissions - The Best Practice Subcommittee had several recommendations, most notably based on decreasing preterm deliveries. There is strong clinical evidence that the use of 17 Hydroxyprogesterone (17OHP) initiated between 16 weeks, 0 days and OH Progesterone given by 20 weeks, 6 days gestation and continued every week until 36 weeks for patients with a history of spontaneous preterm birth in a prior pregnancy can reduce the risk of preterm birth by one-third. There was discussion about the lack of use due in part to physician education and awareness, but mostly due to logistical barriers. HHSC Staff noted that both compounded and Makena product of 17OHP are covered by Medicaid, but the logistical issues such as payment for administering the injection and needing the patient enter prenatal care early enough to begin this treatment are obstacles to successful implementation of this treatment. Other best practice recommendations will be developed and implemented in the regionalized environment. In a fully regionalized hospital system, those hospitals that are the highest level in the region should collaborate to act as the quality and educational leader for that area. The reporting of outcome data is important for continued quality improvement.

RECOMMENDATIONS

- a. Identification of strategies to enhance early access and enrollment into prenatal care.
 - b. Dissemination and implementation of evidence-based practice protocols (for example the use of progesterone by patients with prior spontaneous preterm birth)
 - c. Education of all health care providers about the need for early risk assessment and indications for 17OHP
 - d. Reducing barriers that prevent patients from receiving 17OHP (such as payment for the administration of the injection).
 - e. Provision of financial incentives for reaching quality metrics such as Joint Commission PC-03 (antenatal corticosteroids) and the percentage of eligible patients receiving 17OHP.
- 2) HHSC should work with the DSHS to develop a process for the designation of maternal and/or neonatal levels of care for hospitals. The same facility may have different levels of maternal and neonatal care.
 - 3) The standards for level of neonatal and maternal care will be further developed by the NICU Council. After the NICU Council's tenure ends in June 2013, a Perinatal Facility Designation Implementation Task Force (Task Force) should be convened to develop the process of designation and verification of hospitals in the state that deliver babies, and further provide operational definition of standards as necessary. The current NICU Council members should serve as members of the Task Force to provide continuity and expertise. An additional general hospital representative should also be appointed to the

Task Force. Travel expenses for those who serve on this Task Force should be reimbursed.

- 4) The levels of neonatal care will be based on the current AAP levels of care policy statement and current Guidelines for Perinatal Care publication, and further defined for the geographic and varied needs of Texas by the NICU Council and Task Force as needed. The Task Force should develop a process for the designation of the level of care, make recommendations for the division of the state into regions, develop Regional Advisory Council (RAC) processes, and delineate reporting requirements.
- 5) The levels of care for maternal care will be based on the current publication “Guidelines for Perinatal Care”, and further defined for the geographic and varied needs of Texas by the NICU Council and Perinatal Task Force as needed. The Task Force should develop a process for the designation of the level of care, make recommendations for the division the state into regions, develop Regional Advisory Council (RAC) processes, and delineate confidential reporting requirements.
- 6) Only hospitals that achieve state designation of maternal and neonatal levels of care should be eligible to receive Medicaid payments for obstetrical and/or neonatal services.
- 7) Neonatal Facility Levels of Care
 - a. Well Born Nursery Level of Care (Level I) – The facility meets the current AAP recommendations and current Guidelines for Perinatal Care publication, with definitions or modifications by the NICU Council or Perinatal Task Force, actively participates on the appropriate Regional Advisory Council (RAC), and regularly submits outcome and other data to the state as required and requested
 - b. Special Care Nursery Level of Care (Level II) – The facility meets the current AAP recommendations and current Guidelines for Perinatal Care publication, with definitions or modifications by the NICU Council or the Task Force, actively participates on the appropriate Regional Advisory Council (RAC), and regularly submits confidential outcome and other data to the state as required and requested
 - c. Neonatal ICU Level of Care (Level III) – The facility meets the current AAP recommendations and current Guidelines for Perinatal Care publication, with definitions or modifications by the NICU Council or the Task Force, actively participates on the appropriate RAC, and regularly submits confidential outcome and other data to the state as required and requested
 - d. Advanced Neonatal ICU (Level IV) – The facility meets the current recommendations and current Guidelines for Perinatal Care publication, with definitions or modifications by the NICU Council or the Task Force, actively participates on the appropriate RAC, and regularly submits confidential outcome and other data to the state as required and requested
- 8) Maternal Levels of Care
 - a. Basic Maternity Level of Care (Level I) – The facility meets the current AAP Guidelines for Perinatal Care publication, with definitions or modifications by the NICU Council or Perinatal Task Force, actively participates on the appropriate RAC, and regularly submits confidential outcome and other data to the state as required and requested
 - b. Specialty Maternity Care (Level II) – The facility meets the current AAP Guidelines for Perinatal Care publication, with definitions or modifications by the NICU Council or the Task Force, actively participates on the appropriate RAC,

and regularly submits confidential outcome and other data to the state as required and requested

- c. Sub-specialized Maternity Care (Level III) – The facility meets the current AAP Guidelines for Perinatal Care publication, with definitions or modifications by the NICU Council or the Task Force, actively participates on the appropriate RAC, and regularly submits confidential outcome and other data to the state as required and requested
- d. Advanced Subspecialty Maternity Care (Level IV) – The facility meets the current AAP Guidelines for Perinatal Care publication, with definitions or modifications by the NICU Council or the Task Force, actively participates on the appropriate RAC, and regularly submits confidential outcome and other data to the state as required and requested

V. Future Council Committee Activities

The Council is scheduled to meet three times in 2013 and will be available as a resource to HHSC to provide further details on recommendations provided. Currently, the Council is about 75 percent finished with the neonatal and maternal levels of care standards and anticipates completion by May 2013.

Appendix 1

Supplement to Executive Summary

Background: Very low birth weight infants (VLBW), defined as less than 32 weeks/⁷ gestation or 1500g birth weight, comprise less than 2% of US births, but account for 55% of infant deaths, and more than 1/3 of total neonatal hospital costs. VLBW Infants have significantly better outcomes when born at level III or level IV (highest level) facilities rather than being born in lower level facilities and transferred. Hospitals with higher volumes of VLBW care also seem to have better outcomes. (Sources: Laswell metaanalysis, JAMA 2010; Phibbs N Engl J Med 2007).

Over the 10 year period from 2000 to 2010, the Texas premature delivery rate consistently exceeded the national average (12.6% versus 11.6% in 2000; 13.2 versus 11.99% in 2010). In Texas, the rate of Low Birth Weight (LBW) births, defined as less than 2500g, increased from 7.4% (2000) to 8.4% (2010), whereas the VLBW births remained fairly constant at 1.3% (2000) and 1.4% (2010). The VLBW birthrate in black women is nearly twice that of other ethnicities (2.9% in 2010). **In 2010, only 48.9% of VLBW Texas infants were born in level III NICU facilities, resulting in Texas' ranking of this key quality measure in the bottom 5% of the country (national average 74.7%).** (Healthy Texas Babies 2011; US Health and Human Services 2011).

The number of Texas hospitals reporting having NICU (Level III) level III NICU beds increased from 70 hospitals in 2000, to 99 hospitals in 2010; hospitals reporting Neonatal Intermediate Care (level II) beds were unchanged at 61 hospitals (2000 to 2010). The number of NICU beds have increased 74.2% from 1447 (2000) to 2520 (2010). More than 55% of all births in Texas are paid by Medicaid. Costs related to infant care have grown almost 10% per year (2000 to 2008). NICU utilization has grown faster than expected, with over 50% of costs attributable to VLBW births (which are less than 2% of births). (Source: Healthy Texas Babies presentation Jan 2011).

Standards: The Council has concluded that both neonatal and maternal (perinatal) levels of care standards must be defined to provide care for neonates, and pregnant women, and to address cost effective use of the state's resources. **Defining neonatal standards without addressing pregnancy-related conditions would be ineffective in optimizing infant care and reducing costs.** Maternal and neonatal are optimized when women with high risk conditions including impending preterm birth, are cared for in facilities that can provide the appropriate acuity of care for both the mother and the fetus/newborn. The need for quality maternal care in Texas is emphasized by the markedly increased maternal mortality rate (almost 300% higher from 2000 to 2010). Defining maternal levels of care may result in improved outcomes for both pregnant women and neonates.

The Council recommends a regionalized perinatal system with local regional advisory councils; this would allow for an efficient and collaborative approach to meeting the state's health care needs. The neonatal and maternal levels of care should be based on national and evidence based standards. The Council has based its recommendations on the current AAP standards (published in the journal *Pediatrics* in Sept 2012 and the Guidelines for Perinatal Care, 7th edition, October 2012). Nevertheless, defining and applying those care standards to

the diverse regions of the state is a complex process. Unintended consequences such as excess morbidity or mortality or limiting access to care are some potential dangers that need to be recognized. Careful implementation is crucially important, with input from stakeholders such as hospitals, physicians and other providers, third party payers, specialty societies, and the public. Finally, one should be cognizant that the published standards are national, and based on retrospective data, and may not be uniformly applicable to the population and geographic regions of Texas. Careful monitoring during implementation would be prudent.

Designation vs. Accreditation: The Council has determined that the appropriate process for hospital perinatal levels of care is “state designation” of the hospital, with appropriate **verification**, which may include accreditation or certification. State designation (designation) of both neonatal and maternal levels of care and verification of meeting those standards, similar to the procedure for stroke and trauma hospital designation, would seem to offer the best overall system. Medicaid payment for maternity and neonatal services should only be provided to those hospitals receiving state designation. Requiring hospitals to regularly report outcome data to a confidential statewide database enables the assurance of high quality of care at the hospital, regional, and state levels.

The Council recommends that a state Perinatal Facility Designation Implementation Task Force (Task Force) continue the next step of hospital designation after the NICU Council ends its role on June 1, 2013. The Council believes that its current Council members serving on the Implementation Task Force would provide continuity, maintain the diversity of representation and expertise, and enhance the efficiency of the process. An additional hospital representative from a general hospital rather than a children’s hospital on the Task Force would give added perspective and expertise. Quality improvement, coordination of care, and cost-effective analysis can only be performed with consistent, timely, accurate and confidential submission of demographic, clinical, and outcome data. The Council recommends that the database is best housed in and administered by the state.

Best Practice and Cost Savings: Cost savings are projected with a carefully implemented regionalization system that would result in improved outcomes, institution of best practices, and prolonged gestation. For example, for infants born before 33 weeks’ gestation, prolonging the pregnancy by 2 weeks can result in a median cost savings of \$29,000-\$64,000 per infant. Decreasing the preterm delivery rate is the key to decreasing NICU costs. (Reference: Staebler, Adv Neo Prac 2011).

Timeline: After examining other states’ experiences with development of perinatal standards and regionalization, we estimate a 2 year timeline for full implementation after neonatal and maternal standards are completely defined in June 2013.

SUMMARY

- A. Standards for operating NICUs – The Council believes that neonatal levels of care delineations should be largely based on national standards, using the AAP Policy Statement on Levels of Care (published in Sept 2012) and the publication, “Guidelines for Perinatal Care, 7th ed” (released Oct 2012) as templates. Because the new standards were only recently published, the Council is formulating its recommendation and will have final proposed Texas standards by June 2013.

- B. Maternal Levels of Care** – The Council believes that to deliver the healthiest newborn and achieve cost savings, maternal levels of care need to be defined and implemented. The Council will use the publication “Guidelines for Perinatal Care, 7th edition” as the template. This publication was released in October 2012, and the Council will have its final maternal standards by June 2013.
- C. Hospital Designation Process** – Although H.B. 2636 calls for an accreditation process for hospitals providing neonatal ICU care, the Council is unsure whether accreditation is the best procedure, and proposes a more general option of verification of compliance with standards. The Council believes that the appropriate process for neonatal and maternal levels of care would be state designation with a verification procedure. The verification may include accreditation, certification, site visit, or other means. Consistent with H.B.2636, only designated facilities should be eligible for the Medicaid payment for maternal or neonatal services. To provide high quality of care for all patients in Texas, the Council recommends a state designation relevant to all patients rather than only Medicaid patients.
- D. Implementation-** Because the Act authorizing the NICU Council will expire on June 1, 2013, the Council recommends the appointment of a Perinatal Facility Designation Implementation Task Force to take over the role of developing a designation and verification process. The Council recommends that current NICU Council members serve on the Task Force working together with HHSC and the Texas Department of State Health Services. The Council proposes that one additional (non-children’s) hospital representative be appointed to the Task Force
- E. Best Practice and Cost-Effectiveness** – The Council has several consensus recommendations, the majority aimed at reducing the rate of preterm delivery and reducing the need for NICU admission. The Council believes that the principal method of cost savings will be achieved through prevention of early preterm labor and delivery, particularly births prior to 33 weeks’ gestation. Recommendations include 1) identification of strategies to enhance access to and early enrollment in prenatal care, and 2) dissemination and implementation of evidence-based practice protocols (for example, use of progesterone by patients with prior spontaneous birth). Further best practice recommendations will be efficiently communicated in the regionalized environment. In a fully regionalized system, those hospitals that are the highest level should collaborate to act as the quality and educational leader(s) for that geographical area. Additionally, in this example, each hospital should report specific outcome data will enable continued regarding the screening of women at risk for preterm labor, the use of progesterone, and preterm delivery rate to ensure continuous quality improvement.

Appendix 2

Background Information

DEFINITIONS

Premature (or Preterm) Delivery – delivery at less than 36 completed weeks.^{37 0/7} weeks' gestation. Prematurity is the leading cause of neonatal death.

Low Birth Weight (LBW) – birth weight less than 2500 g (5 lb 8 oz)

Very Low Birth Weight (VLBW) – birth weight less than 1500 g (3 lb 5 oz). The outcomes for VLBW babies are markedly improved when delivered at the highest level of neonatal care facility (level III pre-2012, level III or IV 2012 criteria).

Perinatal Mortality Rate – statistical rate of fetal and infant deaths including stillbirths up to 28 days of life, represented as deaths per 1000 total births.

Neonatal Mortality Rate – number of deaths in the first 28 completed days of life per 1000 live births

Regionalization – Perinatal regionalization is a system where infants are born or are transferred based on the amount of care they need at birth. It requires a system of facilities with coordinated and delineated levels of care designed to meet patient needs to promote optimal outcomes. This requires the development of consistent and specific definitions or standards of levels of care.

Neonates – infants that are less than 28 days old

Neonatal ICU – a hospital unit staffed and equipped to care for premature or seriously ill neonates.

Pre-2012 Neonatal Levels of Care – the American Academy of Pediatrics defined 3 levels of care: with level I lowest and level III highest.

- Level I = Basic Neonatal Care directed at infants 35 weeks and older;
- Level II = Intermediate Neonatal Care directed at infants 32 weeks and older;
- Level III = Neonatal ICU directed at all infants including less than 32 weeks gestational age

2012 Neonatal Levels of Care- In September 2012, The American Academy of Pediatrics revised its levels of care using 4 levels of care:

- Level I = Basic or well born care, directed at infants 35 weeks and older;
- Level II = Intermediate or special care, directed at infants 32 weeks and older;
- Level III = Neonatal ICU- directed at all infants including less than 32 weeks; and
- Level IV = Advanced Neonatal Services Center, with specialized services such as ability to care for complex congenital heart defects, or ECMO

Maternal Levels of Care- Stratification of hospitals based on the acuity of care that can be provided to the pregnant woman. Pregnant patients have different levels of severity of pregnancy complications or impending premature delivery with level I being uncomplicated, gestational age 35 weeks or greater, to level IV being most complex such as requiring to care for a critical maternal cardiac condition. Although a hospital does not necessarily need to have the identical neonatal and maternal levels, wide differences in maternity and neonatal levels of care in the same facility may not lead to the best overall care. For instance, a pregnant woman with complex medical problems who may be best served at a level III/IV maternity care facility would also more likely deliver prematurely or have fetal complications.

Accreditation – formal process by which a recognized body (usually a non-governmental entity) assesses and recognizes that a health care organization meets applicable pre-determined and published standards, typically a voluntary process, and typically a peer process. Accreditation for Breast Care through the American College of Surgeons would be an example.

Self-Designation – practice where a facility declares itself as meeting a level of care, generally without verification.

State Designation (designation) – formal process by which a governmental body recognizes a health care organization as meeting pre-determined and published standards. An example is state designated trauma center level, or stroke center level. The designation process best allows states to develop regionalization of its care. In this document, designation will be used interchangeably with “state designation.”

Certification – process by which an authorizing body, either a governmental or non-governmental organization, grants a time limited recognition to an individual or organization as meeting pre-determined requirements or criteria. A specialty board certification for physicians is an example.

Verification – a process in which a governmental or non-governmental body ensures that a health care organization meets pre-determined requirements or criteria by reviewing documentation and/or site visit. This can include different processes such as accreditation or certification or site visit checklists. The American College of Surgeons performing a verification site visit of a trauma hospital is an example.

HISTORY OF PERINATAL REGIONALIZATION

In 1977, the Committee on Perinatal Health, composed of members of the American Academy of Family Physicians, AAP, ACOG, American Medical Association (AMA), and the March of Dimes published “*Toward Improving the Outcome of Pregnancy*” (TIOP). This document describes the concept of regionalized perinatal care: “*Regionalization implies the development, within a geographic area, of a coordinated, cooperative system of maternal and perinatal health care in which, by mutual agreement between hospitals, and physicians, and based upon population needs, the degree of complexity of maternal and perinatal care each hospital is capable of providing is identified so as to accomplish the following objective: quality care for all pregnant women and newborns, maximal utilization of highly*

trained perinatal personnel and intensive care facilities, and assurance of reasonable cost effectiveness.” Three levels of perinatal care were defined. (Source: March of Dimes, Committee on Perinatal Health, TIOP 1976)

In the early 1980’s, regionalization was recognized nationally as a prudent direction for perinatal care, and many states developed formal regionalization plans. Perinatal regionalization was associated with decreased neonatal mortality. However, by the mid-1990’s and progressively over the past 15 years, there has been a shift away from a cooperative model of health care and instead to a competitive model, leading to an increase in hospitals having specialized care for infants (level II or III). There are concerns about the proliferation of NICU’s not matched to population needs and failure of states to reach the Healthy People 2010 goal that 90% of VLBW deliver at level III facilities. (Source: Committee on Fetus and Newborn, Pediatrics Sept 2012, Howell Am J Public Health 2002).

Currently, the national average of VLBW infants being delivered in a level III (highest level) NICU (Pre-2012 Standards) is 74%. Additionally, several retrospective studies have noted that neonatal outcome at those NICU level III centers with higher volumes are improved as compared to centers with lower volumes. (Source: Phibbs and colleagues, N Engl J Med 2007)

Meanwhile, preterm births have increased nationally 13% from 1990 to 2010 (from 10.6% to 12.0%), with the majority occurring in the late preterm gestational age (34-36 weeks). This increase can be attributed to a variety of factors including multiple births, advanced maternal age, complications of pregnancy, and elective early cesarean delivery. (Source: Committee on Fetus and Newborn, Pediatrics Sept 2012)

As per the original TIOP document, reiterated in TIOP II and III, and noted in the joint AAP and ACOG publication, “Guidelines of Perinatal Care”, the issue of premature delivery and pregnancy complications highlights the importance of not only delineating neonatal levels of care, but **also defining maternal levels of care**; this allows infants to be born in the appropriate facility, and for the pregnant woman with high risk or complicated maternal conditions to receive the best care. Nationally, the maternal mortality rate (MMR) has been increasing from a low of 6.6 deaths per 100,000 live births in 1987 to 12.7 deaths per 100,000 in 2007. Maternal mortality in non-Hispanic Black women was approximately 2.7 times the rate of non-Hispanic White women (28.4 versus 10.5 per 100,000), while the maternal mortality rate among Hispanic women was 8.9 deaths per 100,000 live births. This increase in the MMR is especially disheartening in light of the fact that maternal mortality rates have decreased each of the other regions of the world except North America. Texas MMR is even higher than the national average (see figure 1). Strategies to address the increasing MMR include state maternal morbidity and mortality review committees to elucidate the causes of “near misses”, severe morbidity and deaths, dissemination of best practices to physicians and health care providers, and engagement of the public. (Source: US Dept of Health and Human Services, 2011; Hogan MC, Lancet 2010;375:1609-23).

Figure 1 Maternal Mortality Ratio, United States and Texas, 1996-2010

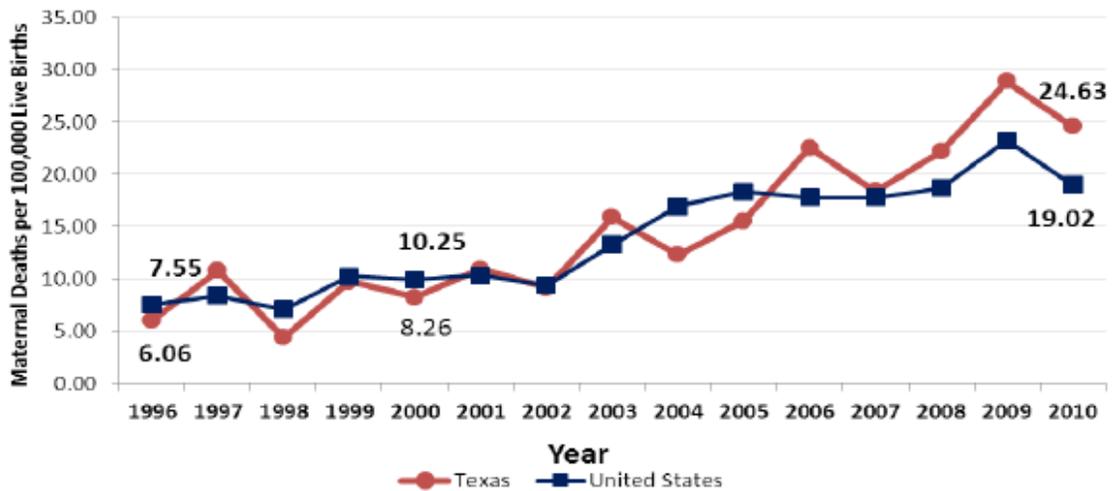


Figure 1: Source: Healthy Texas Babies Report 2011

There is paucity of data studying the effectiveness of perinatal regionalization. In a cost-benefit analysis using data from Rhode Island where regionalization was instituted in 1979 survival was given an economic value. The authors showed that neonatal mortality improved and unchanged neurodevelopmental morbidity, leading to a benefit surpassing cost of \$2M, when taking into account survival benefit. (Source: Walker et al, Pediatrics 1985).

Reducing the rate of preterm delivery would make a dramatic difference in cost expenditure. A California study on hospital costs associated with gestational age found that although infants born less than 32 weeks only comprised 1.9% of births, their costs accounted for 35.5% of all infants costs during the year 2000 (table 1) (Source: Schmitt, Pediatrics 2006):

Table 1. Hospital Costs per Infant versus Gestational Age in California, 2000

Gestational Age at Birth	% of All Births	Mean Hospital Cost per infant	Fraction of Total Annual Births Costs
< or = 32 weeks	1.9%	\$66,813	35.5%
33-36 Weeks	8.0%	\$7081	53.4%
>36 weeks	90.1%	\$1929	11.1%

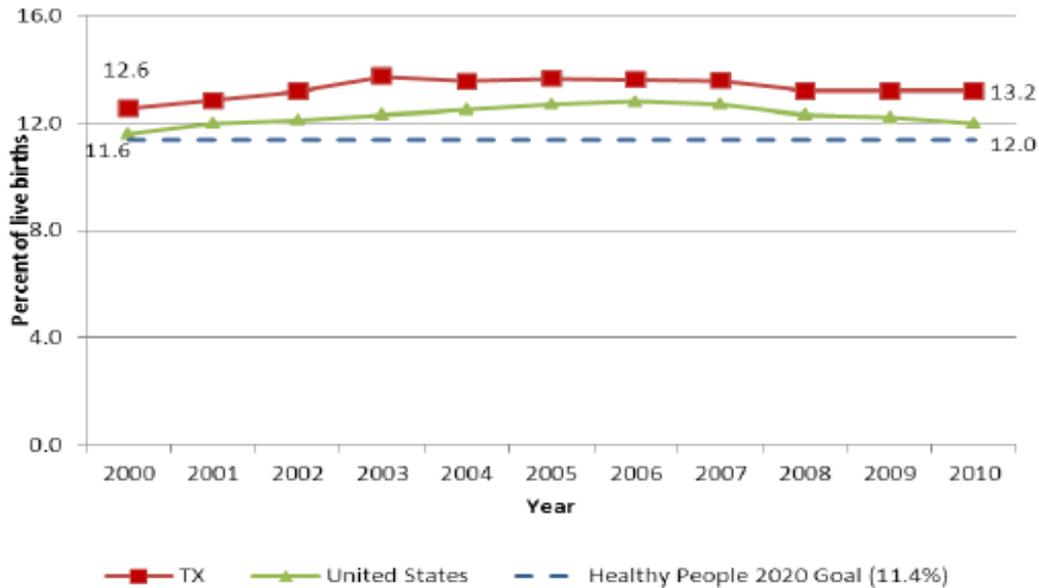
Source: Schmitt et al, Costs of Newborn Care in California: a population-based study, Pediatrics 2006;117:154

Cost savings are likely to be the result of a carefully implemented regionalization system, resulting in improved outcomes, institution of best practices, and prolonging gestation. It has been estimated that median cost savings of \$29,000-\$64,000 can be realized by extending the gestational age by 2 weeks of an infant born at less than 33 weeks gestation (Reference: Staebler, Adv Neo Prac 2011). When long term morbidities including neurodevelopmental outcomes are taken into account, there is likely an even more dramatic long term economic impact.

TEXAS SPECIFIC DATA

In 2010, there were 386,091 live births in Texas. Premature deliveries are defined as delivery at less than 37 weeks and 0 days gestation. In Texas, over the ten year period from 2000 to 2010, the number of premature deliveries has consistently exceeded the national average. In 2000, the premature delivery rate in Texas was 12.6 % of births, and the rate in 2010 was 13.2%. Both were higher than the national average of 12.0% Figure 2). (Source: Healthy Texas Babies Infant and Maternal Health Data 2010).

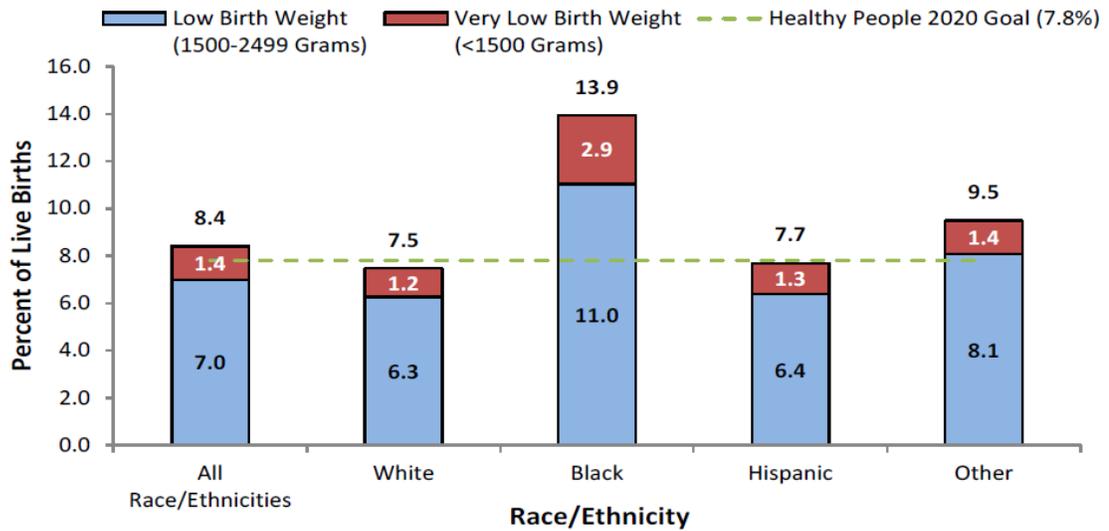
Figure 2 . Preterm Births for United States and Texas, 2000-2010



Source: Healthy Texas Babies Report, 2011.

The Low Birth Weight (LBW) rate in Texas has increased from 7.4% of births in 2000 to 8.4% in 2010, whereas the VLBW birth rates have remained fairly constant at 1.3% (2000) and 1.4% (2010). Births in Texas increased about 10% from 2000 to 2010, and the VLBW numbers increased proportionately by 12% over the same period (4808 to 5401). As reported nationally, the incidence of VLBW births in black women is nearly twice that of other ethnicities (2.9% in 2010). Some studies indicate that this racial discrepancy holds even after controlling for education and socioeconomic factors.

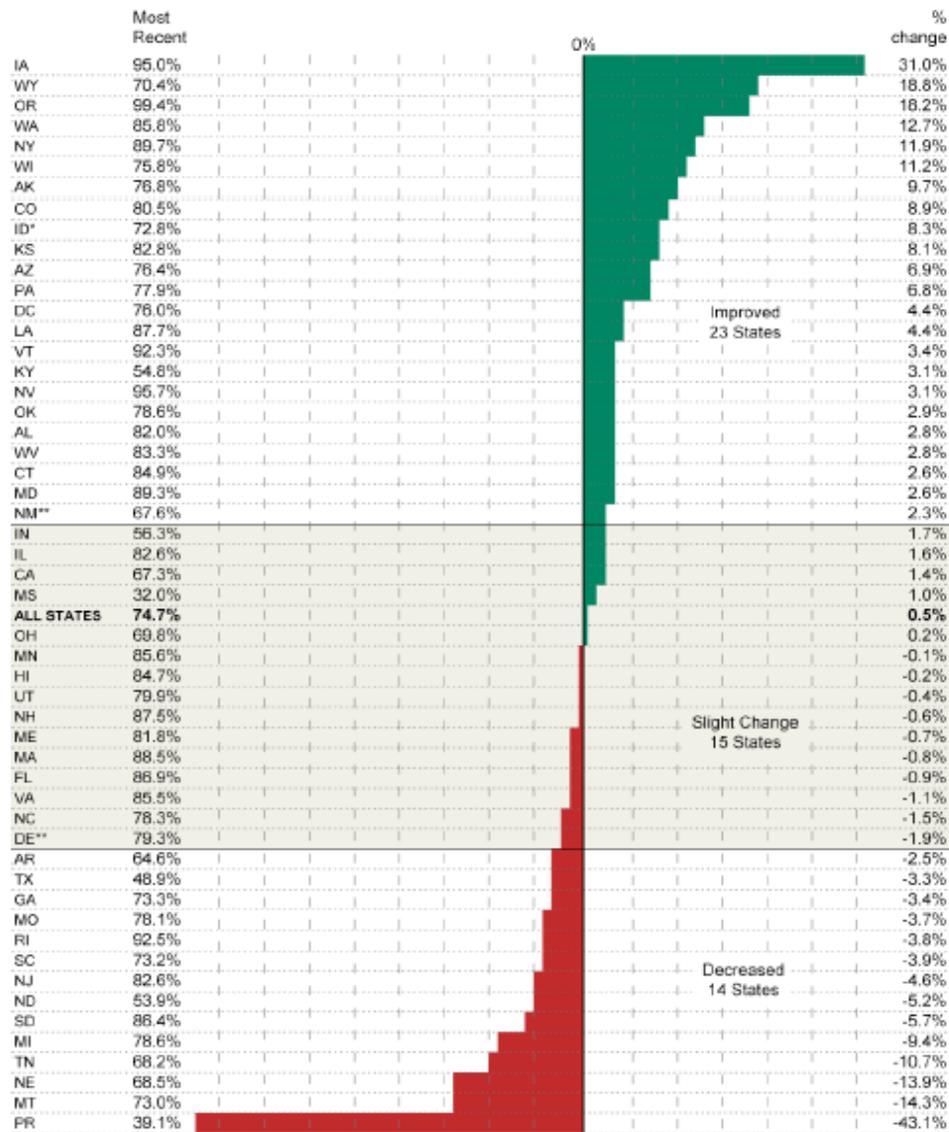
Figure 3 Low Birth Weight Births by Race/Ethnicity – Texas, 2010



Source: Texas DSHS 2011.

The very low birth weight infants (VLBW) comprise less than 2% of US births, but account for 55% of infant deaths. There is evidence in the medical literature that outcomes for VLBW infants are significantly better when those infants are born in a level III NICU as compared to VLBW babies delivered at hospitals with lower level nurseries and transferred to another hospital with a level III NICU. There is also evidence that a higher volume of VLBW admissions seems to correspond to better outcomes. **In 2010, only 48.9% of VLBW infants in Texas were born in level III NICUs, resulting in Texas being ranked in the bottom 5% of the country in this important quality measure. (Figure 4).** Fortunately, the neonatal mortality rate for Texas is lower than the national average; however, the rate in Black infants is significantly higher than other ethnicities (Figure 5) consistent with the national statistics.

Figure 4: Percent Absolute Change in NPM #17 in Order of Change (Positive to Negative)

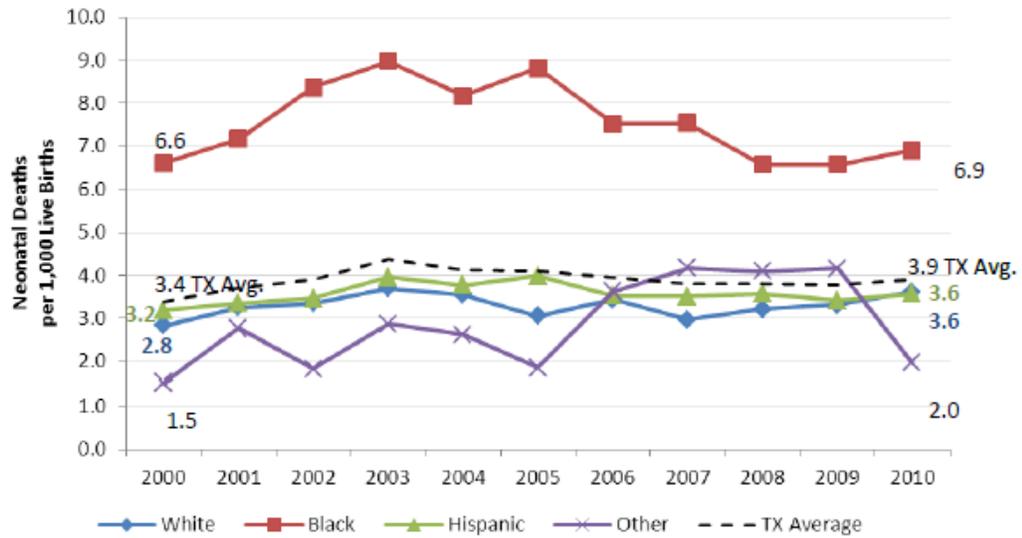


*2000-2003 only
 **2000-2006 only



Source: US Health and Human Services Report 2010

Figure 5 Neonatal Mortality Rate by Race/Ethnicity, Texas, 2000 – 2010



While neonatal mortality racial disparity has declined from the early years of the new millennium, there has been a consistent disproportionate burden of mortality among black

Source: Healthy Texas Babies Report 2011.

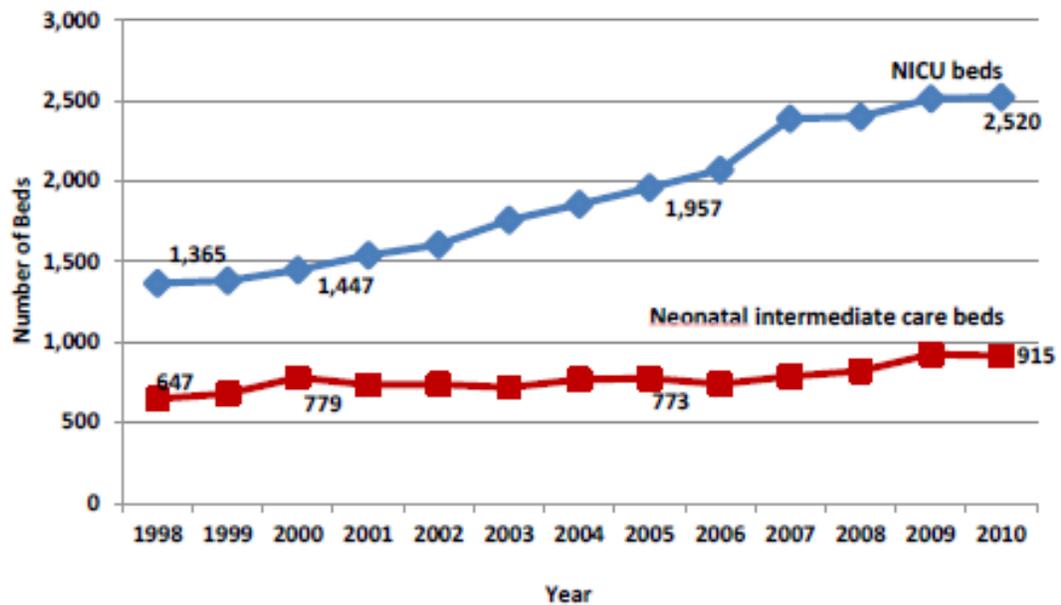
Based on self report, the number of hospitals that have reported NICU (Level III) beds have increased from 70 hospitals in 2000, to 99 hospitals in 2010, whereas the number of hospitals with Neonatal Intermediate Care (level II) beds have remained unchanged at 61 hospitals (2000 to 2010). Correspondingly, the number of NICU beds have increased from 1447 (2000) to 2520 (2010), which is a 74.2% increase in number of beds.(see table 2). The number of Intermediate care beds have increased less dramatically from 779 (2000) to 915 (2010), which is an increase of 17.5%.

Table 2. Births, VLBW numbers, and NICU beds from 2000 to 2010

Category	2000	2010	Percent change
Total Births	363,300	385,700	6.2%
VLBW	4808	5400	12.3%
NICU (Level III) Beds	1447	2520	74.2%

Source: Healthy Texas Babies Report, 2011; Dr. Rebecca Martin DSHS Report, 2012.

Figure 6 Number of Self-Reported NICU and Neonatal Intermediate Care Beds, Texas, 1998-2010



Source: Healthy Texas Babies Report, 2011

More than 55% of all births in Texas are paid by Medicaid. Costs related to infant care have grown almost 10% per year (2000 to 2008). NICU utilization is growing faster than expected, with over 50% of costs attributable to VLBW births (which are less than 2% of births). (Source: Healthy Texas Babies presentation Jan 2011).

The AAP has published its national guidelines on the various NICU standards. Currently in Texas, hospitals self report and self market their individual hospital's level of NICU care. In the past, HHSC has noted that it does not have the data collection capability to ensure consistent payment for like services across the state. Additionally, there is no current designation or assurance of hospitals meeting neonatal or maternal levels of care standards.

In the fall of 2011, the DSHS sent out the first neonatal and maternal level of care surveys to Texas hospitals that perform deliveries or care for children. Of the 247 hospitals that provide obstetrical/neonatal care in Texas, 71% sent in responses to the survey. There is a discrepancy between the self reported perception of level of care and actual level of care based on AAP criteria. Of the 40 hospitals that reported that it provided level I neonatal level of care, only 13 (32.5%) met AAP criteria; of 74 reporting having level II neonatal level of care, 21 (39%) met AAP criteria; of those reporting as having level III neonatal level of care, 17 (27%) met AAP criteria. It should be emphasized that these results have not been validated and there may be discrepancies and errors in a hospital's completion of the survey. Accurate data is paramount to ensure adequate healthcare resources to meet the perinatal needs of the state. Figure 7 depicts the percent of VLBW infants born in Texas, and figure 8 depicts the locations of facilities by AAP designated level of care facilities based on survey.

Figure 7 Very Low Birth Weight Births by County – Texas, 2010

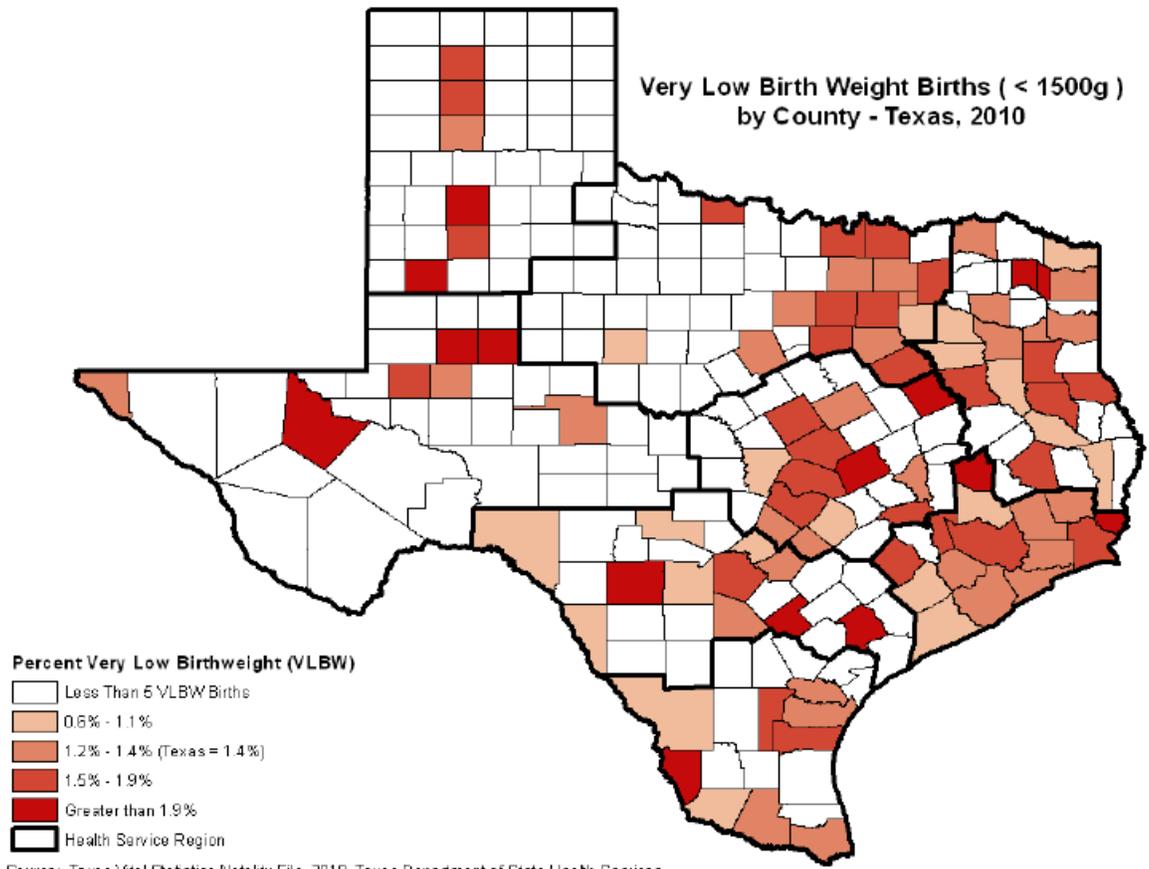
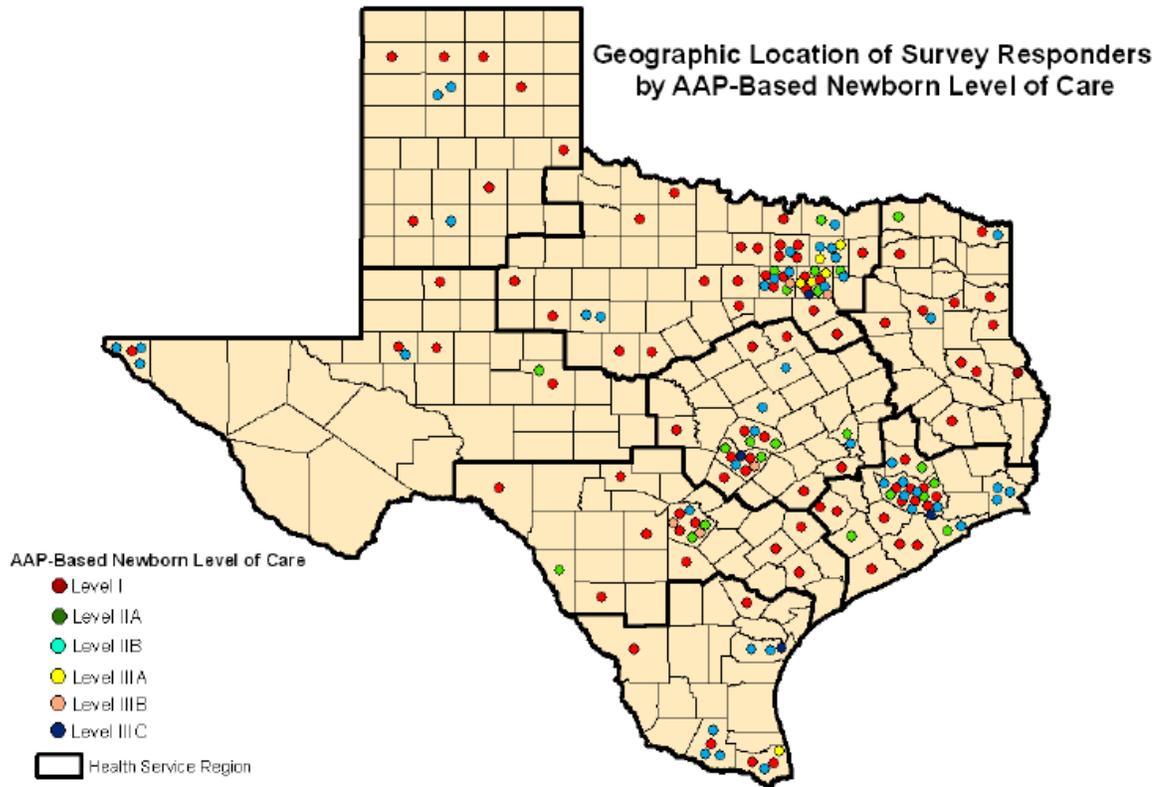


Figure 8 Geographic Location of Hospitals by AAP-Based Level of Care



Source: OPDS Newborn Level of Care Survey 2012
Prepared by: Texas Department of State Health Services, Family and Community Health - Office of Program Decision Support - 09/06/2012

Appendix 3

HIGHLIGHTS OF NICU Council Meetings (2012)

- **March 27, 2012** – H.B. 2636 reviewed, introduction of members, introduction of HHSC and DSHS staff. Thorough review of the Quality of Care surveys by Dr. Rebecca Martin demonstrated the lack of standardization of NICU definitions in the state, and also some missing information from some hospitals. There was general consensus that neonatal care for those infants of Very Low Birthweight (VLBW, i.e., < 1500 g) infants were best cared for in a level III (highest level) NICU. A NICU Standards subcommittee was established. There was discussion that the new NICU levels of care would be released in fall 2012. Dr. Toy appointed Dr. Brenda Morris, neonatologist from Tyler, TX as Vice Chair of Council.
- **May 14, 2012** – Dr. Rebecca Martin continued the review of the Hospital Quality of Care surveys and identified 16 hospitals that did not meet minimal standards for level 1 care as defined by the American Academy of Pediatrics (AAP). There was discussion regarding the need to investigate the reasons these hospitals did not meet minimal standards. There was agreement that the AAP standards should be used to assess levels of care in Texas. The NICU Subcommittee discussed their beginning to construct a template for levels of care, discussion about the phrase “continuously available” referring to neonatologists, and need to be aware of 2012 four levels of care to be released in fall 2012. There was general consensus that the Council would recommend standards based on evidence, on current national standards, and be based on the best interest for patients in Texas. The Council unanimously agreed that standards for NICU’s were necessary for patient care, reimbursement standardization, and quality of care. The Council also unanimously agreed that maternity levels of care should be established, since the appropriate maternal transfer leads to better neonatal outcomes compared to neonatal transfer. The Council reviewed the *New England Journal of Medicine* article (Phibbs et al, 2007) which reported that neonatal mortality was lowest when VLBW infants were born in Level III (highest) NICUs which also had high volume (>100 admissions per year). An Obstetrical Standards Subcommittee was established to develop the maternal levels of care criteria.

After the obstetrical and neonatal survey results were administered by the DSHS, in May 2012, there were 24 hospitals which were identified as not meeting even minimal standards (level I). Dr. Toy telephoned each facility and spoke to the Chief Nursing Officer or Chief Medical Officer at each hospital to clarify the issues. Of the 24 hospitals, 6 had erroneously filled out the survey. For instance, one level I facility stated: “Did not take care of infants > 2500 g”. Upon written correction of this error, the hospital was removed from the non-compliant list. Of the 18 remaining hospitals,

there were various issues such as not having neonatal or maternal transport protocols, not having the ability to consult an anesthesiologist for complicated or emergency situations, or not having nursery trained nurses. Each hospital was advised of the importance of these requirements, and each provided written verification of remedy, such that by July 2012, all hospitals met at least minimal standards for neonatal or maternity care. Uniformly, each hospital was grateful to have the opportunity to correct deficiencies and acknowledged that their level and quality of care had improved through the process. This example is the microcosm of the anticipated increased quality of care when the formal neonatal and maternity levels of care will be implemented.

- **July 24, 2012** – The Council reviewed the NICU Standards subcommittee report and entertained the possibility of telemedicine for subspecialty consultation in NICU's. The maternal levels of care subcommittee reviewed a template progressing from level I (lowest= basic care) to level IV (highest). The concept was level I = basic care encompassing deliveries of gestational ages >35 weeks, level II = gestational ages > 32 weeks gestational age, level III = all gestational ages and able to care for maternal critical illnesses, and level IV = Advanced NICU center that had special capabilities such as ECMO (Extra Corporeal Life Support) or caring for complex congenital heart disease. Level III or IV facilities may have the further responsibility of education and coordination of care of the region. The Council unanimously agreed that a standard for being able to start a cesarean for every maternity hospital is 30 minutes. There was discussion about the need for reporting of data that is uniform, and also that a Quality Improvement process be in place for every perinatal hospital. Dr. Toy noted that he called several of the hospitals identified as not meeting the minimal standards based on the Hospital Survey, and all of the hospitals corrected their deficiencies; these included hospital transfer protocols, availability of anesthesiologist consultation in case of problems, and nursery trained nurses. These findings have already elevated the standard of care for these hospitals. Ms. Jane Guerrero, Director of EMS/Trauma at DSHS explained their regionalization system and the process. A best practice subcommittee was established. The concept was discussed that the standards recommended by the Council could be used more universally than only relating to Medicaid patients.
- **September 10, 2012** – The new 2012 Neonatal Levels of Care policy statement published by the AAP was reviewed. There was ample discussion about the various definitions such as “continuously available”, availability of subspecialists, and question about whether advanced practice nurse practitioners could meet the definition of “continuously available”. There was acknowledgement that the article of NICU levels of care was a summary and would be expanded in the “Guidelines for Perinatal Guidelines, 7th edition” scheduled for release in Oct 2012. There was discussion that only 48.9% of Texas VLBW babies were born in a level III NICU,

which ranked Texas in the bottom 5% states in the country. There was consensus about maternal and infant transfer protocols that needed to be in place, coordination among children's hospitals, obstetrical hospitals and NICUs, and the need for back transfers from high levels of care back to home institution. Dr. Martin presented alarming statistics about the very high maternal mortality rates in Texas, which are 15 deaths/100,000 births, which is higher than the national average of 13/100,000. This rate is higher in African-American women and in urban centers. This racial difference is true for both maternal mortality and neonatal and infant mortality rates. The Council worked on defining terms within the AAP Guidelines. There was general agreement that as much as feasible the Council should use the AAP Guidelines, but since no national guidelines are "all encompassing", there may need to be some flexibility in application since Texas is large and diverse in its geographic and healthcare composition. There was discussion about the need for cooperation and collaboration among hospitals in transfer relationships, and reimbursement from third party payers for back transfers.

- **October 16, 2012:** March of Dimes information was reviewed, including 400,000 infants born in Texas annually of which 13% require higher level of care. Currently there are no NICU standards so there is no clarity for care and reimbursement. The Council agreed that the reporting of outcomes should be more regularly than annually. There was discussion regarding how to assure the correct requirements for each neonatal level of care and agreement that delivery volume, number of VLBW admissions, and average daily census may be used. The application of standards was discussed and it was agreed that for level III NICUs, an advanced neonatal nurse practitioner being in house with a neonatologist being readily available would be acceptable – provided that neonatologist is not "on call" for multiple institutions such that two simultaneous emergencies could not be sufficiently addressed. Discussions were held to develop processes allowing the use of telemedicine and prudent referrals so that there can be flexibility for smaller rural communities, but not allow abuse such as subpar "consultations" from remote locations that may satisfy the "rule" but not render quality care. There was agreement about the need for an in-house neonatologist in a level IV (highest level) facility. The importance of making induced hypothermia available in level III and IV NICUs with expertise was discussed, since there is good evidence that infants with ischemic brain injury have better outcomes with this treatment. Maternal levels of care were fine tuned and examples were given for each level of care. Best practice subcommittee continued to give examples of immunizations and therapeutic hypothermia as important. Ms. Kathy Perkins Director of Regulatory Services at DSHS gave a thorough presentation on the trauma and stroke designation and verification processes, and recommended that the NICU Council adopt this language. There are 22 regions for Trauma Care in Texas. Public comment was held. Various methods of verification were discussed with the recommendation being an outside reviewing body such Joint Commission for more

advanced levels of care, with the site visit paid by the hospital. The concept of a Regional Advisory Council (RAC) looking out for the well being of the community was discussed.

- **November 12, 2012 Meeting:** Dr. Morris gave a presentation with a summary of NICU standards including clarification of some terminology that she reviewed with Dr. Lu-Ann Papile, Chair of the AAP Committee on the Fetus and the Newborn. She also reviewed an article authored by Dr. Paul Wise entitled “Neonatal Healthcare policy: promise and perils of reform.” The Council then discussed ways of keeping with the national standards, but being somewhat flexible in the implementation of those standards. One example discussed was a level II nursery in a rural area that may serve the community with no other level II or higher hospital for hundreds of miles. If that rural hospital doesn’t have high enough volume, there may be ways of cross training, education, simulation, or other collaboration with other hospitals to maintain their skills. Meanwhile the outcomes would be monitored. Public comment revolved around clarification of next steps, recommendation to include hospitals in the implementation process, discussing that HHSC has already implemented decreased payment for NICU services by its new DRG payment system, and to consider flexibility in allowing family physicians to be medical co-directors of level II nurseries in rural areas. A timeline for implementation was described as 2 to 2 ½ years. A recommendation was made for the implementation and regionalization to be flexible enough to not disrupt existing referral patterns. A recommendation was made to reimburse for telemedicine since this technology would be essential in providing subspecialist care in rural areas. The regional advisory councils have not been formed yet and should be sufficiently small enough to understand and advocate for local and community needs. Each council member was also given the opportunity to describe his/her most pressing concern.

Appendix 4

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Listing of Presentations

Martin Rebecca. Obstetrical levels of care report and survey for Texas, 2012. Presented during NICU Council Meeting, July 2012.

Martin Rebecca. Neonatal levels of care report and survey for Texas, 2012. Presented during NICU Council Meeting, May 2012.

Kathy Perkins, Director of DSHS Division of Regulatory Services. Presentation on Designation of services for Trauma and Stroke levels of care, Texas, presented Oct 16, 2012.

Sam Cooper, Director of Title V and Family Health, DSHS. Healthy Texas Babies Report, March, 2012.

Jane Guerrero, Director of EMS/Trauma System, Texas DSHS. Texas process of regionalized Trauma Care, July 2012.

Brenda Morris, MD, Vice Chair, NICU Council. Review and summary of American Academy of Pediatrics Policy Statement on Levels of Care 2012.

Brenda Morris, MD, Vice Chair, NICU Council. Literature Review of neonatal outcomes and NICU utilization, Oct 2012.

Brenda Morris, MD, Vice Chair, NICU Council. Literature Review of neonatal outcomes and NICU utilization, Nov 2012.