Working Together for our Most Vulnerable: Neonatal Levels of Care

Eugene C. Toy, MD
DSHS Grand Rounds
Austin, Texas
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Disclosures

- No relevant financial relationships with commercial interests related to the content of this presentation.
Objectives

- Describe the scientific basis and evidence for designated neonatal levels of care
- Describe the basis of neonatal levels of care in Texas
- Apply the neonatal levels of care requirements to one’s own hospital setting to improve the quality of care
- Describe the state designation process in Texas
Part I: The Scientific Evidence for Neonatal Levels of Care
Neonatal Levels of Care

- Concept since 1970’s

- Well defined regional centers of neonatal ICU’s provide best outcomes
  - For very low birth weight (VLBW [ < 32 wks, <1500g])
  - Infants with complex problems
  - Place units in strategic locations to best serve the community (about 2-3% of births)
  - Concentrate expertise in these areas
## Causes of Infant Death in US 2011

<table>
<thead>
<tr>
<th>Causes (8 of top 10)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital malformations, deformations, chromosomal abnormalities</td>
<td>20.8</td>
</tr>
<tr>
<td>Disorders related to short gestation and low BW</td>
<td>17.2</td>
</tr>
<tr>
<td>Newborn affected by pregnancy complications</td>
<td>6.6</td>
</tr>
<tr>
<td>Newborn affected by complications of placenta, cord and membranes</td>
<td>4.1</td>
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<tr>
<td>Bacterial sepsis of newborn</td>
<td>2.2</td>
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<td>Respiratory distress of newborn</td>
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<tr>
<td>Diseases of the circulatory system</td>
<td>2.1</td>
</tr>
<tr>
<td>Neonatal hemorrhage</td>
<td>1.9</td>
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</tbody>
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Preliminary data

Hamilton BE. Pediatrics 2013 ePub Feb 11
Levels of Neonatal Care

- General principles – continued
  - Each newborn should be delivered and cared for in a facility most appropriate for his or her needs
  - Further definitions of facility level should include requirements for equipment, personnel, ancillary services, training, and organization (including transport)

AAP Committee on Fetus and Newborn. Levels of Neonatal Care 2004
**TIOP III: Regionalization Is Critical To Improved Perinatal Outcomes**

- Organizes a coordinated continuum of perinatal services within a geographic area
- Increases survival of high risk newborns
- Concentrates relatively rare cases at a few locations
- Centralizes expensive technologies
- Provides opportunities for clinical teams to develop expertise

Toward Improving the Outcome of Pregnancy III, March of Dimes 2010
Preterm Infant Mortality is Increased by Birth Outside of Level III Hospital

- Risk of death is greater for infants born outside of level III hospitals
  - VLBW ($\leq 1500$ g) infants (37 studies)(38 vs 23%)
    - OR 1.62, 95% CI 1.44-1.83
  - ELBW ($\leq 1000$ g) infants (4 studies)
    - OR 1.64 95% CI 1.14-2.36
  - Very Preterm ($\leq 32$ weeks) infants (4 studies)
    - OR 1.55, 95% CI 1.21, 1.98
- No changes over 30 year period

Lasswell S. JAMA 2010; 304:992
Extremely Low Birth Weight Mortality is Increased by Birth Outside Level III Hospital (59 vs 32%)

Lasswell S. JAMA 2010;304:992
Other Factors May Affect Outcome

- NICU volume - experience
- Obstetric characteristics – antenatal steroids
- Nursing staff
- Race or health insurance status
- Surveillance – how do we measure?
- Approach to aggressive resuscitation
- Congenital anomalies – typically not counted
- Practice issues
Risk of VLBW Mortality by NICU Level and Annual Volume

<table>
<thead>
<tr>
<th>NICU Level</th>
<th>Volume</th>
<th>Odds Ratio (95% CI)</th>
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<tr>
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48,237 infants 1991-2000, no anomalies  
Phibbs CS N Engl J Med 2007; 356:2165
Patient Volume Only Partly Explains NICU Quality

Mean standardized mortality ratio (observed/expected deaths)


Volume of admissions explained only 9% of variation in mortality rates, 7% other factors

Percent of VLBW Infants Delivered at Hospital with Level III NICU

< 50% in Texas

Source: MCHB, Title V Information System, 2009
National Observations

- Proliferation of NICU’s without consistent relationship to high risk infants delivered
- Proliferation of small NICUs in same region as large NICUs
- Failure of states to reach Health People 2010 goal of 90% of VLBW infants deliver in level III units

**BOTTOMLINE:** More money for lesser outcomes

**AAP Response:** Simplify to 4 levels and eliminate Level III subcategories
GUIDELINES FOR PERINATAL CARE, 7TH EDITION (2012)
Neonatal Levels of Care (2012)

- Level I – uncomplicated newborns, ≥ 35 weeks
- Level II – newborns > 32 weeks, 1500 g, need ventilatory support less 24 hours
- Level III- newborns all gestational ages, complicated problems, access to specialist consultation
- Level IV- most complex, surgery for complicated congenital conditions
Part II: Basis of Neonatal Levels of Care in Texas
NICU Council (2012-2013)

- HB 2636 (82 R) - Charge: Develop accreditation for NICU’s, best practices and cost containment

Implementation

- Transparency – meetings open
- Prioritizing patient quality
  - It’s about the babies & pregnant moms!!
- Evidence based
- Listening to each other,
- Open to input
- Developing consensus
- Credibility
Preterm Birth Rates

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

Low BW by Race (Texas)

Source: Texas DSHS 2011.
### Table 2. Births, VLBW numbers, and NICU beds from 2000 to 2010

<table>
<thead>
<tr>
<th>Category</th>
<th>2000</th>
<th>2010</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Births</td>
<td>363,300</td>
<td>385,700</td>
<td>6.2%</td>
</tr>
<tr>
<td>VLBW</td>
<td>4808</td>
<td>5400</td>
<td>12.3%</td>
</tr>
<tr>
<td>NICU (Level III)</td>
<td>1447</td>
<td>2520</td>
<td>74.2%</td>
</tr>
</tbody>
</table>

Figure 6

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

Source: Healthy Texas Babies Report, 2011
Figure 7  Very Low Birth Weight Births by County – Texas, 2010

Very Low Birth Weight Births ( < 1500g ) by County - Texas, 2010

Percent Very Low Birthweight (VLBW)
- Less Than 5 VLBW Births
- 0.8% - 1.1%
- 1.2% - 1.4% (Texas = 1.4%)
- 1.5% - 1.9%
- Greater than 1.9%
- Health Service Region

Source: Texas Vital Statistics Natality File, 2010, Texas Department of State Health Services
Prepared by: DSHS, Family and Community Health, Office of Program Decision Support, 04/23/2012
Figure 8  
Geographic Location of Hospitals by AAP-Based Level of Care

Geographic Location of Survey Responders by AAP-Based Newborn Level of Care

AAP-Based Newborn Level of Care
- Level I
- Level IIA
- Level IIB
- Level IIIA
- Level IIIB
- Level IIIC

Health Service Region

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 - 06/05/2012
Texas

- More than half of VLBW babies being delivered in non-level III/IV facility
- Texas much worse than national average
- Hospital “self designation” by state survey found to be inaccurate 30-40% of time

- Bottomline: “It’s about our babies”
Texas: It’s also about our moms!

- Beginning to recognize the increase in maternal mortality
- Understanding that to have a healthy baby, we need a healthy mom!
- Transfer of pregnant woman to the right facility at the right time
Maternal Mortality: ↑3x in 12 yrs

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

- Texas
- United States
Maternal Deaths in Texas, 2006-2014

Year
2006
2007
2008
2009
2010
2011
2012
2013
2014

Deaths
70
69
82
73
72
148
140
135

Obstet Gynecol 2016
Neonatal Intensive Care Unit Council
Annual Report

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

Health and Human Services Commission
January 2013
NICU Council Recommendations

1. Recommend a Perinatal Council to develop designation process for both maternal and neonatal levels of care
2. Work together with DSHS to develop these designation criteria
3. Levels of care should be based on national standards and evidence
4. Develop a regional coordination and collaboration (but not affect transfers)
Texas Perinatal Advisory Council

- HB 15 (83 R) authorized a state perinatal designation process for maternity and neonatal care
- Collaborative process of physicians, nurses, hospitals, and other stakeholders
Perinatal Council Philosophy

- Each hospital can strive for the level of care it desires (no certificate of need)
- Each hospital works out its own transfer agreements (but look out for patients!)
- Even playing field – big city hospitals or academic hospitals not to make rules to dominate, take unfair advantage
- Look out for rural areas
Taking Right Approach

- Decisions through consensus
  - Stakeholder input
  - Sounding board
  - Allowing for abundant discussion
  - Prioritization for patients
  - Expanded to maternity standards
  - Statewide designation
  - Broad support, expanded representation
**TimeLine**

- From NICU Council (2012-13) recommended
- To Perinatal Advisory Council (2014- )
- HB15 (83rd Legislative Session)
  - Specifies Neonatal Levels of Care Designation by Sept 1, 2017 for Medicaid payments *(to 2018)*
  - Specifies Maternity Levels of Care Designation by Sept 1, 2019 for Medicaid payments *(to 2020)*
  - Divide state into regions (Regional Advisory Councils)
  - Transfer agreements

HB3433 (84th Leg Session)
- Add 2 additional rural rep to Council
- Add 1 year to Neo and Mat deadline *(to 2018, and 2020)*
Perinatal Regions: same as current trauma regions
Perinatal Advisory Council
Report on Determinations and Recommendations

As Required By
H.B. 15, 83rd Legislature (Regular Session, 2013) and
H.B. 3433, 84th Legislature (Regular Session, 2015)

Health and Human Services Commission
September 2016
Neonatal Rules
Filed June 3, 2016:
Part III: Neonatal LOC to one’s own hospital to improve quality
Level I (Well Born Nursery)

- The Level I neonatal designated facility will throughout the continuum, provide care for mothers and their infants of $\geq 35$ weeks gestational age who have routine, transient perinatal problems; have skilled personnel with documented training, competencies and continuing education specific for the patient population served.
Level II (Special Care Nursery)

- Care for infants ≥32 wks GA and BW ≥1500 grams with physiologic immaturity or problems expected to resolve rapidly & not anticipated to require subspecialty services on urgent basis;
- May provide assisted ventilation on interim basis until infant’s condition soon improves or infant can be transferred to a higher-level facility; delivery of CPAP should be readily available by experienced personnel, and mech ventilation can be provided briefly (< 24 hours);
- Have skilled personnel with documented training, competencies and continuing education specific for the pt population served.
Level III

- Care for mothers and comprehensive care of their infants of all gestational ages with mild to critical illnesses or requiring sustained life support;
- Access for consultation to a full range of pediatric medical and surgical subspecialists, and the capability to perform major pediatric surgery onsite or at a closely related institution by prearranged consultative agreements, ideally in geographic proximity;
- Have skilled personnel with documented training, competencies and continuing education specific for the patient population served;
- Facilitate transport and provide outreach education.
Level IV (Advanced NICU)

- Provide comprehensive care for infants of all gest ages with mild to complex medical problems, or requiring sustained life support;
- Comprehensive range of pediatric medical and surgical subspecialists immediately available for consultation
- Capability to perform major pediatric surgery including the surgical repair of complex congenital or acquired conditions (eg, congenital cardiac malformations that require cardiopulmonary bypass with or without ECMO)
Level IV (Advanced NICU)-2

- Have skilled personnel with documented training, competencies and continuing education specific for pt population served; facilitates transports and provides outreach education to lower level designated facilities.
- Stand-alone childrens’ hospitals that do not provide obstetrical services are exempt from obstetrical requirements.
Examples: Level I Neonatal Quality Indicators

- Number of VLBW born in facilities
- Perinatal death rate

Other Ideas
- Transfers and outcomes
- Perinatal complications
- Readmissions
- % breast-fed
Examples: Level II Neonatal Quality Indicators

- Number of VLBW born in facilities
- Perinatal death rate
- Fraction/number admitted to level II nursery

Other Ideas
- Transfers and outcomes
- Perinatal complications
- Readmissions
- % breast-fed
- Developmental follow-up
Examples of Level III/IV Neonatal Quality Indicators

- Number of VLBW born in level III/IV facilities
- Perinatal death rate
- Transfers out and outcomes

Some other ideas:
- Chronic lung disease
- Intraventricular hemorrhage
- Nosocomial infection
- Hearing loss
- Severe Retinopathy of prematurity
MATERNAL MORTALITY IN TEXAS

Maternal Deaths in Texas, 2006-2014

- 2006: 70
- 2007: 69
- 2008: 82
- 2009: 73
- 2010: 72
- 2011: 148
- 2012: 140
- 2013: 135
- 2014: 135
Maternal Quality: Maternal Mortality & Serious Morbidity

• Each hospital and each region should review how monitor and improve its maternal complications
• Recall causes of maternal death in TX
  • #1: Cardiac
  • #2: Opioid overdose
• Work on guidelines for hypertension in pregnancy
• Guidelines for PP Hemorrhage
Part IV: Texas’ Neonatal Designation Process
How Does State Designation Work?

- Each hospital that provides neonatal and/or maternity care will need to undergo state designation process to receive Medicaid funds
  - Neo designation by Sept 1, 2018
  - Maternity designation by Sept 1, 2020
What is Involved in Designation?

- Hospitals will need to ensure they meet the requirements for the level of care they seek
- Submission to state: application, policies (QI, triage, transfer, etc), ID key personnel
- Site visit for levels 2, 3, 4
  - Level 1 = no site visit needed
- State will approve or not approve application (duration = 3 yrs)
Who Regulates Designation?

- The State Dept of Health Services (DSHS) Office of Trauma developing rules and process
  - Same place as trauma and stroke designation
- Health and Human Services Commission (HHSC) Perinatal Advisory Council
  - 19 member appointed committee (2 rural reps) makes recommendations to DSHS
  - Physicians, nurses, hospital administrators
Is Designation Optional?

- Yes, but hospital requirement for Medicaid funds
- Neonatal and maternity designation is governed by statute (HB 15 from 83R legislative session; and HB3433 from 84R)
- The designation will be housed in Title 25, Chapter 133 of Texas Administrative Code (Hospital Licensing)
How Will Designation Affect Me?

- All hospitals providing Neo or OB services will need state designation for Medicaid Funding
- QI process a strong part of designation process
Neonatal System Development

The purpose of the Neonatal Levels of Care Designation is to comply with House Bill 15, 83rd Legislature, Regular Session, 2013, which added Health and Safety Code, Subchapter H, Hospital Level of Care Designations for Neonatal and Maternal Care, Sections 241.181 - 241.187. House Bill 3433, 84th Legislature, Regular Session, 2015 amended Health and Safety Code, Chapter 241 requires the development of initial rules to create the neonatal/ maternal level of care designation by March 1, 2018. Currently only the neonatal level of care designation rule has been developed and is in the rule adoption process, expected to become effective on or about May 20, 2016. The designation for neonatal level of care is an eligibility requirement for Medicaid reimbursement beginning September 1, 2018.

Neonatal Designation Applications Now Available

Rule

The neonatal designation rule, effective June 9, 2016 is found at the Texas Administrative Code, Title 25, Chapter 133, Subchapter J

Related Programs

Survey Sites

American Academy of Pediatrics NICU Verification Program

TETAF NICU Services and Consultation

Resource Documents

Provider training webinars were held throughout the month of June for introduction and review of the new requirements. Recordings of the training are listed below. Each link will take you to a page where you must enter your name and email address to access the video.

Webinar recordings:
Level I Designation - June 13, 2016
Level II Designation - June 14, 2016
Level III and IV Designation - June 16, 2016
Level III and IV Designation - June 20, 2016
Level I Designation - June 21, 2016
Level II Designation - June 24, 2016
View System Requirements

PowerPoint presentations from webinars:
Level I PowerPoint presentation
Level II PowerPoint presentation
Level III PowerPoint presentation
Neonatal System Development

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Related Programs

Survey Sites

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TETAF NICU Services and Consultation
Bottom Line

- All Texas hospitals that provide neonatal care will need neonatal state designation (1-4) by Sept 1, 2018 to receive Medicaid Funding
- All Texas hospitals that provide maternity care will need maternity state designation (1-4) by Sept 1, 2020 to receive Medicaid Funding

**CAVEAT:** HB 3433 extended deadlines by 1 year (2018- neo, 2020 -maternal)
Bottom Line-2

- Children’s hospitals exempt from OB (maternity) requirements
- Hospitals may have different levels of between maternity and neonatal care
  - Example: Level II maternity and level III neonatal
Guestimate of # Hospitals

- 240 providing OB/Neo services & childrens’ hospitals in Texas
  - Level I (80)
  - Level II (80)
  - Level III (73)
  - Level IV (7)

- Written affadavit (no site visit)
- 160 hospitals (site visit)

If Level I exempt from site visit (submit application with data, documents), **160 hospitals need site visits**;
Neonatal Facility Designation Application
Levels II, III, and IV

INSTRUCTIONS AND HELPFUL INFORMATION

General Information

1. Where to call for information or guidance while completing the application:

   For technical assistance, call or email the Neonatal Program Specialist:
   • Jewell Potter - (512) 834-6743
   • Jewell_Potter@dshs.state.tx.us

   For process or rule clarification, please contact the following:
   Neonatal Designation Coordinator
   • Debbie Lightfoot, RN – (512) 834-6700 Ext. 2032
   • Debra_Lightfoot@dshs.state.tx.us

   Designation Program Manager
   • Elizabeth Stevenson, RN – (512) 834-6794
   • Elizabeth_Stevenson@dshs.state.tx.us

2. When should the application be submitted? Title 25 Texas Administrative Code (TAC) §133 Subchapter J, provides the guidelines for submission of designation application packets. According to TAC', a designation application packet shall be submitted to our office within 120 days of the facility’s survey date.

3. Need more information relating to the designation process? Call your assigned Designation Coordinator (above) or refer to the “Process for Neonatal Facility Designation Application” at the following Office of EMS/TS website:
   www.dshs.state.tx.us/emstraumasytems/neonatal.aspx

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TAC §133.184. Designation Process.

(a) Designation application packets. The applicant shall submit the packet, inclusive of the following documents to the Office of EMS/Trauma Systems Coordination (office) within 120 days of the facility’s survey date:

(1) an accurate and complete designation application form for the appropriate level of designation, including full payment of the designation fee as listed in subsection (d) of this section;

(2) any subsequent documents submitted by the date requested by the office;

(3) a completed neonatal attestation and self-survey report for Level 1 applicants or as a designation survey report, including patient care reviews if required by the office, for Level II, III and IV applicants;

(4) a plan of correction (POC), detailing how the facility will correct any deficiencies cited in the survey report, to include: the corrective action, the title of the person responsible for ensuring the correction(s) is implemented; how the corrective action will be monitored; and the date by which the POC will be completed and

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Site Visits

- SITE VISIT (levels II/III/IV)
  - After application is submitted
  - Need to also interview staff, physicians etc
  - View physical facility
  - Write up site visit report
  - Cost of site visit paid by hospital
DSHS Websites

- Applications for neonatal designation:

- Surveys: AAP and TETAF
AAP NICU Verification Program

NICU Verification Program
American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN

The mission of the AAP NICU Verification Program is to improve outcomes for high-risk newborns by supporting a system that ensures that every high risk newborn receives care in a facility with the personnel and resources appropriate for the infant's needs and condition.

About

The Committee on Fetus and Newborn 2012 policy statement, *Levels of Neonatal Care*, reaffirmed in 2015, and the *Guidelines for Perinatal Care*, published by the AAP and the American College of Obstetricians and Gynecologists, delineate the personnel and resources needed for four levels of Neonatal Intensive Care Units (NICUs) appropriate for newborns with increasingly complex needs. The AAP NICU Verification Program was created to achieve the best possible outcomes by ensuring that every high risk newborn is cared for in a facility with the personnel and resources appropriate for the infant's needs and condition. Program development was supported in part by a grant from the Centers for Disease Control and Prevention.
NICU Survey Request

Utilizing experienced neonatal medical directors and neonatal nurses that actively practice in Texas, TETAF will provide NICU survey services for Level I, II, III and IV Texas hospitals.

TETAF credentialed surveyors will provide the hospital with the required report for submission to the Texas Department of State Health Services, Office of EMS/Trauma for designation or re-designation. The TETAF survey experience offers an educational opportunity with experienced, knowledgeable neonatal medical staff and neonatal program management.

Once the request for survey application form is received, the TETAF NICU survey coordinator will contact the requesting hospital regarding potential survey dates.

Surveys will occur after January 1, 2017.
Maternity Levels of Care

- Published in Feb 2015 (Joint ACOG & SMFM)
- Perinatal Council is finalizing its maternity LOC

Maternity Levels 1 – 4

- Level 1 - uncomplicated
- Level 2 – moderately complicated
- Level 3 – complicated, high risk
- Level 4 – very complicated, critically ill
What Can You Do?

1. Visit the DSHS websites for Neo Designation application, site visit info, webinars

2. Get engaged with the state process (Perinatal Advisory Council + state Rule Making) – next mtg Nov 28, 2016 at 10:30am on Mon in Austin

3. Make sure your facility meets requirements for your level of care

4. Make sure your hospital has a QI process to look for key outcomes (get it ready for application process)
The Perinatal Advisory Council, created by House Bill 15 of the 83rd Texas Legislature (Regular Session), develops and recommends criteria for designating levels of neonatal and maternal care, including specifying the minimum requirements to qualify for each level designation and a process for the assignment of levels of care to a hospital, makes recommendations for dividing the state into neonatal and maternal care regions, examines utilization trends in neonatal and maternal care, and recommends ways to improve neonatal and maternal outcomes.

House Bill 3433 of the 84th Texas Legislature (Regular Session) amended House Bill 15 by adding two new members to the Perinatal Advisory Council and extended the date of its report.* The council must submit a report with its recommendations to the Health and Human Services Commission and the Department of State Health Services by September 1, 2016*.

**Members**

- Dr. Eugene Toy, Chair, Obstetrics-gynecology, Houston
- Dr. Emily Briggs, family medicine physician who provides obstetrical care in a rural community, New Braunfels
- Dr. Ely Xenakis, maternal fetal medicine, San Antonio
- Dr. Frank Cho, neonatologist in Level III or IV NICU, Austin
- Dr. Sanjay Patel, Rural Hospital Representative, Odessa
- Barbara Greer, RN, nurse with expertise in perinatal health, Benbrook
- Dr. Charleta Guillory, pediatrician, Houston
- Allen Harrison, representative from a hospital with Level II NICU, Austin
- Dr. John Harvey, neonatologist from rural area, Amarillo

**Events**

October 25, 2016

- Perinatal Advisory Council (webcasting available)
  Austin - 10:30 am
Resources

- NICU Council Report
- Perinatal Advisory Council Report
- Guidelines for Perinatal Care, 7th ed, 2012
- Laswell, Barfield, et al. JAMA 2010
Resources

- [https://hhs.texas.gov/about-hhs/leadership/advisory-committees/perinatal-advisory-council](https://hhs.texas.gov/about-hhs/leadership/advisory-committees/perinatal-advisory-council)
- [https://www.dshs.texas.gov/emstraumasytems/neonatal.aspx](https://www.dshs.texas.gov/emstraumasytems/neonatal.aspx)
- [www.aap.org](http://www.aap.org)
- [www.tetaf.org](http://www.tetaf.org)
For More Information

- Neo Designation (DSHS):
  - Debra.Lightfoot@dshs.state.tx.us
  - Elizabeth.Stevenson@dshs.state.tx.us

- HHSC Perinatal Advisory Council website
  - http://www.hhsc.state.tx.us/about_hhsc/AdvisoryCommittees/pac/

- Eugene Toy, Chair, Perinatal Advisory Council
  - eugene.c.toy@uth.tmc.edu

- David Williams
  - david.williams@hhsc.state.tx.us
  - Handles the administrative aspects of the Perinatal Advisory Council: