

**HTB Provider Interventions Workgroup
Provider Subgroup #2 (Perinatal Regionalization)
Final Deliverable / Intervention Action Plan**

Healthy Texas Babies (HTB) Expert Panel (EP) Meeting Attendees: Please review the document below for content only. All HTB workgroup intervention deliverables will be consistently formatted following the July 30, 2011 EP meeting.

1.1 Detailed Intervention Description:

Goal: To improve the physical and neurodevelopmental outcome of premature babies born in Texas.

Outcome: Greater than 80% percent of very low birth weight (VLBW [< 1500 grams]) infants are delivered at facilities equipped (i.e., equipment and medical/nursing/ancillary personnel) for high-risk deliveries and neonates. Greater than 90% of extremely low birth weight (ELBW) infants are delivered in facilities with Level IIIB or Level IIIC NICU

Measurement of outcome: Measure through birth certificate data hospital specific gestational age and birth weight of the percent of the very low birth weight (VLBW) and extremely low birth weight (ELBW) infants delivered in facilities with Level IIIA, IIIB, and IIIC NICUs.

Intervention: Develop maternal transfer algorithms so that the delivery of VLBW & ELBW infants occur at facilities for high-risk deliveries and neonates

Activities:

1. Adopt definitions for Level IIA, IIB, IIIA, IIIB, and IIIC NICUs in Texas (<http://aappolicy.aappublications.org/cgi/reprint/pediatrics;114/5/1341.pdf>)
2. Ascertain the geographic location and specific hospitals in Texas where VLBW and ELBW infants are currently delivered.
3. Identify through self reporting all Level IIA, IIB, IIIA, IIIB, and IIIC NICUs in Texas.
4. Develop maternal transfer algorithms and develop criteria / levels of care for maternal acute care services.
5. Perform peer review of all ELBW deliveries that occur in facilities without IIIB, and IIIC NICUs.
6. Develop a certification process for the level of care of nurseries in Texas
7. Develop a method to identify and collect death certificate data appropriate to this intervention

1.2 Are there best practices associated with this intervention? If so, please highlight.

Neonatal morbidity and mortality are reduced when VLBW and ELBW infants are born in appropriate high risk perinatal hospitals. Evidence of promising practices should be found to inform the development of best practices.

1.3 Intervention -Desired Outcomes

Short-term (1-3 years):

- A. Build awareness of the HTB regionalization program among regional DSHS, March of Dimes®, physicians, and hospitals through development of coalitions.
- B. Clear and consistent messaging for HTB regionalization program.
- C. Increase the percentage of VLBW and ELBW delivered in an appropriate facility to 80% for VLBW and 90% for ELBW.

Long-term (5-7 years):

- A. Achieve greater than 80% of very low birth weight (VLBW [< 1500 grams]) infants delivered at facilities equipped (i.e., equipment and medical/nursing/ancillary personnel) for high-risk deliveries and neonates. Greater than 90% of extremely low birth weight (ELBW) infants delivered in facilities with Level IIIB or Level IIIC NICU.
- B. Greater media visibility leads to appropriate access to program populations. Greater knowledge of program benefits leads to potential for more appropriate resource utilization.

1.4 Data Elements to be Collected and Evaluated

Pre-Intervention:

- A. Ascertain the geographic location and identify of specific hospitals in Texas where VLBW and ELBW infants are delivered currently.
- B. Identify all self reported Level IIA, IIB, IIIA, IIIB, and IIIC NICUs in Texas and their geographical location.
- C. Identify the specific hospital of birth and its level of NICU service for all VLBW and ELBW babies born during a 30 day period in Texas.
- D. Receiving facility will determine and self report the percentage, the appropriateness and timeliness of any maternal or neonatal transfers received during a 30 day period to a body to be determined.

Monitoring:

- A. Perform peer review of all ELBW deliveries that occur in facilities without IIIB, or IIIC NICUs.
- B. Developmental follow-up of all ELBW infants born 6 months prior and 6 months after implementation of HTB regionalization program

C. Self-reporting of all new NICU facilities that open in the state using the identified criteria.

D. Peer review of all inter-facility transfers by team of peers from both facilities.

Post-Intervention:

A. Ascertain the geographic location and specific hospitals in Texas where VLBW and ELBW infants are delivered following implementation of regionalization intervention.

B. Identify through self reporting all Level IIA, IIB, IIIA, IIIB, and IIIC NICUs in Texas and their geographical location.

C. Determine the location (i.e., specific hospital of birth and its level of NICU service) for all VLBW and ELBW babies during a 30 days period

D. Receiving facility will determine and self report the percentage, the appropriateness and timeliness of any maternal or neonatal transfers received during a 30 day period to a body to be determined.

Process evaluation:

A. Workgroup Progress report at midpoint (June 2012)

1.5 Has the intervention been implemented in Texas? If yes, please provide specific details and contact information.

No.

1.6 Possible Partners (both public and private)

A. Federal

- Agency for Healthcare Research and Quality (AHRQ)
- Center for Medicaid, CHIP and Survey & Certifications (CMCS)
- Centers for Disease Control and Prevention
- Centers for Medicare and Medicaid Services (CMS)
- Health Resources and Services Administration (HRSA)

B. National

- America's Health Insurance Plans
- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Nurse Midwives
- American College of Obstetricians and Gynecologists (ACOG)
- American Hospital Association
- American Medical Association

- American Public Health Association
- Association of Women’s Health, Obstetric and Neonatal Nurses (AHWONN)
- Det Norske Veritas (DNV)
- Hospital Corporation of America (HCA)
- March of Dimes
- National Association of Children’s Hospitals and Related Institutions
- National Association of Neonatal Nurses
- National Committee for Quality Assurance
- National Initiative for Children’s Healthcare Quality
- National Institute of Child and Human Development (NICHD)
- National Medical Association
- National Perinatal Association
- National Quality Forum
- Neonatal Research Network
- Pediatrix/Obstetrix Medical Group
- Society for Maternal-Fetal Medicine
- The Joint Commission (Accreditation and Certification Operations)
- Vermont Oxford Network

C. State

- Children’s Hospital Association of Texas
- Department of State Health Services
- March of Dimes Texas
- Texas Association of Neonatal Nurse Practitioners
- Texas Association of Obstetricians and Gynecologists
- Texas Health and Human Services Commission
- Texas Hospital Association
- Texas Medicaid Program
- Texas Medical Association
- Texas Pediatric Society
- Texas Pediatrix/Obstetrix Medical Group
- Texas Perinatal Association

- Texas Schools of Public Health (Epidemiology Departments)
- Texas State Nurse Midwifery Board
- Vermont Oxford Network

D. Local and Regional

- Local health departments
- Local March of Dimes
- Local medical societies

1.7 Recommended appropriate assessment tools (e.g. Perinatal Periods of Risk (PPOR))

A. Toward Improving the Outcome of Pregnancy: Enhancing Perinatal Health Through Quality, Safety and Performance Initiatives (TIOP III)

- a. Recommends standardizing the regionalization of perinatal services to develop standard definitions and guidelines across Texas for levels of maternal and infant care that are consistently utilized, to help optimize the effective regionalization of maternal and newborn care.
- b. Strengthening the national/state vital statistics system by creating a highly reliable and valid collection of maternal and newborn vital statistics; maintain and promote electronic health records to enable measurement and improvements in perinatal care, use electronic health records and an electronic infrastructure to enhance communication across the integrated delivery systems or independent hospitals.
- c. Population based perinatal linked data system, such as vital statistics, disease registries and hospital discharge data are fundamental to identifying and monitoring perinatal outcomes. Enhanced data systems are needed to understand the association of regionalizing levels of care and its affect on infant and maternal health

B. To assess and evaluate the impact of regionalization, create a coordinating center to develop a statewide collaborative database such as the California Perinatal Quality Care Collaborative (CPQCC) or the Ohio Perinatal Quality Collaborative (OPQC) utilizing the Vermont Oxford Network (VON) Texas participating hospital data as a starting point to form a coalition. This multi-institutional system will provide their member NICU with useful benchmark on important system processes and outcomes of hospitals in the state.

1.8 Recommended Lead Agency for Intervention

A. A collaborative between the Texas Health and Human Services Commission (HHSC), the Texas Department of State Health Services (DSHS), and Texas licensing boards with support and leadership from statewide professional organizations and a statewide coalition.

1.9 Target Audience(s) – define for each specific activity included in the intervention

Intervention: Develop maternal transfer algorithms so that the delivery of VLBW & ELBW infants occur at facilities for high-risk deliveries and neonates

Activities:

- A. Develop definitions for Level IIA, IIB, IIIA, IIIB, and IIIC NICUs in Texas. (<http://aappolicy.aappublications.org/cgi/reprint/pediatrics;114/5/1341.pdf>; and future iterations Ascertain the geographic location and specific hospitals in Texas where VLBW and ELBW infants are delivered currently. (Target: Department of State Health Services, Children’s Hospital Association of Texas, proposed coordinating center utilizing Vermont Oxford Network member Texas hospitals, Texas Vital Statistics, private, payers to include private insurance, and Medicaid / CHIP)
- B. Ascertain the geographic location and specific hospitals in Texas where VLBW and ELBW infants are delivered currently.
- C. Identify through self reporting all Level IIA, IIB, IIIA, IIIB, and IIIC NICUs in Texas. Ask the Texas Pediatric Society (TPS) Committee on Fetus and Newborn to develop an electronic tool for self reporting. (Target: Neonatologists throughout the state, Children’s Hospital Association of Texas, Texas Hospital Association, Perinatal Section of AAP [United States and Canada Directory of NICUs and Neonatologists 2009]).
- D. Develop maternal transfer algorithms and guidelines / capabilities for hospitals for maternal acute care services. (Target: SMFM, Texas Hospital Association, Texas Association of Obstetricians and Gynecologists, ACOG, nurse midwives, obstetricians, maternal-fetal medicine specialists and family practice physicians throughout the state).
- E. Perform peer review of all ELBW deliveries that occur in facilities without IIIB, and IIIC NICUs. (Target: Texas Department of State Health Services, unbiased independent governing board selected by, Texas Medical Board.
- F. Develop an accreditation process to develop the levels of care for nurseries in Texas (Target: Texas Pediatrics Society, Health and Human Services Commission)
- G. Develop a method to identify and collect death certificate data appropriate to this intervention. (Target: Health and Human Services Commission)

1.10 Recommended Time Period for Implementation by Activity

| Item | Activity | Start Date | End Date |
|------|--|------------|----------|
| 1. | Develop definitions for level IIA,IIB,IIIA,IIIB, and IIIC NICU's in Texas <ul style="list-style-type: none"> Review states that have existing definitions and compare to AAP guidelines. Some states had definitions in effect prior to AAP publication and a review should be done to evaluate which if any are most applicable to Texas. | 7/1/2011 | TBD |
| 2. | Identify the geographic location and specific hospitals in Texas where VLBE and ELBW infants are born. Data obtained and scrubbed by birth certificate data. | 7/1/2011 | TBD |
| 3. | Identify through self reporting all Level IIA, IIB, IIIA, IIIB, and IIIC NICUs in Texas. <ul style="list-style-type: none"> After review of various states levels designation, define levels for Texas IF any modification to AAP guidelines warranted. | 7/1/2011 | TBD |
| 4. | Develop maternal transfer algorithms and guidelines / capabilities for hospitals for maternal acute care services. <ul style="list-style-type: none"> Work with TMA, SMFM, ACOG, TAOG, AAP and TSP to develop algorithms and guidelines. (Note: AAP Committee on Fetus and Newborn and ACOG Committee on Obstetric Practice are currently discussing the development of maternal transfer algorithms and guidelines.) | 7/1/2011 | TBD |
| 5. | Perform peer review of all ELBW deliveries based on maternal transport algorithms and regionalization criteria who are not born in a Level IIIB or IIIC NICU | 7/1/2011 | TBD |
| 6. | Develop an accreditation process to develop the levels of care for nurseries in Texas | 9/1/2011 | TBD |
| 7. | Develop a method to identify and collect death certificate data that has been obtained and scrubbed that is germane to this intervention. | 9/1/2011 | TBD |

1.11 Required Resources - (e.g. financial, human, in-kind, etc.)

- A. Estimated for roll-out only, does not include costs for sustained efforts
- B. Space for meetings.
- C. Realistic budget must be developed by DSHS including funding for provider and public awareness campaigns.
- D. Human investment of time by workgroup members to perform materials assessment, monitoring and evaluation, additional program support, etc.
 - a. Data analyst time to collect information on states' formal levels of care designation. Evaluate which are guidelines and which are regulatory. Collect information on reimbursement and outcomes as reported by various states. This could easily be 1.0 FTE for up to 4-6 months.
 - b. Expert review panel to regularly review information. Analyzing and creating definitions that apply to Texas. Review

- metrics, definitions, and algorithms as they are developed. Meet monthly for 12 months.
- c. Regional coordinators to roll out definitions and supply monitoring on an ongoing basis. The number of such ongoing FTE resources would be dependent on the products produced.

1.12 Possible Challenges to Implementation

- A. Financial- Costs of collection of needed information and expert participation during process of defining and creating algorithms. Ongoing cost of monitoring for compliance. While effective regionalization has been demonstrated to improve outcome, it could be more expensive in some instances as maternal transports build in geographical separation for families at times. Obtaining accurate data to support the decision making process for this intervention
- B. Political- Different regions with different historical levels and patterns of care could potentially need to make significant changes in practice styles or referral patterns. These historical patterns may have real barriers to implementation of new guidelines or regulations, and become a focus for political resistance to change at both local and state levels.
- C. Business practices - Neonatal care is a large business in Texas with hospitals and physicians as well as other providers all contributing to the rapid expansion of NICUs. These are a wide mix of governmental, not-for-profit, and for profit entities. To get these entities to align on a philosophical basis without very clear evidence will be contentious.

1.13 Communication Strategies – including who, what, when, where, how

Develop a comprehensive short and long-term communications plan to support the goal of implementing perinatal regionalization services in Texas. The communications plan must be strategic and must target perinatal health professionals, associations, and health facilities, key geographic areas of the state, and finally, the general public.

A. Short-term activities (focus on reaching partners in regionalization and key policy figures):

1. Decide if the HTB *perinatal regionalization project* should have a unique name/title for messaging. If needed, develop a project name and assure integration/coordination with other current HTB messages, logos, etc.
2. Develop and maintain a website on HTB with information on the HTB regionalization project - outlining the issue and with information for health professionals and health facilities. Website should:
 - i. Identify those currently involved in the project (get permission to use association logos if needed)
 - ii. Integrate information from other related topics (e.g. HB2636 & HB1983 implementation)
 - iii. Include relevant data on Texas and national perinatal outcomes and activities in other states
 - iv. Identify preliminary plans for use of new state funding for the project
 - v. Provide current best practices and other resources
 - vi. Allow visitors to the website to send in questions and comments on the project.
3. Form a communications workgroup to develop and implement short-term information and outreach plan with targeted messages for physicians, hospitals, and key public officials. Assure coordination with other HTB workgroup activities.

- i. Develop 2-3 clear messages for the outreach plan that highlight why HTB regionalization is important for Texas (e.g. improved health outcomes, cost efficiency and savings, local benefits); and encouraging use of social media especially by the panel members
 - ii. Write editorial piece for medical (e.g. Journal of the American Medical Association (JAMA) or nursing journal on the proposed intervention
 - iii. Clinician-to-clinician letter targeting OB/GYNs, medical directors, NICU managers to explain intervention and ask for their support
 - iv. Develop a packet of materials for media, community groups, professional associations, etc., using key messages and Texas data to describe the problem
 - v. Develop and distribute news releases to key markets and health reports; develop talking points; Q&A documents; targeted op ed articles, key contacts
 - vi. Identify others that should be included in the outreach plan: consult with the HTB expert panel and identify other state-level health and human services organizations with an interest in perinatal regionalization; consult with each DSHS region and identify local DSHS and HHSC staff, key community groups, facilities, and public officials that should be informed or brought into the process; identify any other state agency staff.
 - vii. Peer to peer communication (e.g., TNA or TMA leadership to professional colleagues)
4. Identify project spokespersons that will be available for meetings, conferences, media calls, local op ed pieces.

B. Long-term activities (increase communications to the public as HTB regionalization is further developed):

1. Communication workgroup develops a statewide public awareness campaign.
2. Work with hospitals to encourage accurate representation of NICU level and branding of that level for the public.
3. Plan on convening key partners in a conference or focus groups; include key legislative contacts. Consider regional level meetings if indicated.
4. Identify high interest stories or issues relevant for different regions of the state; identify any gaps in state information; respond to news stories that give incorrect information.
5. Work with professional associations (e.g. TMA, TPS, TAOG, THA, etc.) to identify ways to disseminate more in-depth communications as needed.
6. Develop maternal transfer algorithms and criteria / levels of care for maternal acute care services.

1.14 Detailed Implementation Steps (how this intervention should be operationalized)

- A. Develop, dissemination, collection, and analysis of survey data
- B. Disseminate the recommendations regarding the current and future NICU level of care criteria to all stakeholders (professional societies, governmental agencies, payers, and the general public).

- C. Achieve buy-in and endorsement by obstetrical care providers, professional societies, hospitals and payers.
- D. Develop systems that would identify a delivery falling outside accepted criteria for delivery of the less than 32 0/7th weeks' gestation infant or less than 1,500 grams. This would trigger a query to the provider as to why the mother was not delivered in an institution that provides the appropriate level of obstetric and neonatal care and generate an automatic peer-review.
- E. Develop patient education that would commence early in pregnancy, and be reinforced throughout pregnancy as to the importance of avoiding delivery of a baby less than 32 weeks' gestation or less than 1,500 grams in a hospital that does not have an appropriate level NICU.
- F. Track and publish deliveries that occur in inappropriate settings prior to 32 0/7th weeks gestation or less than 1,500 grams as determined by peer review (note that definitions for peer review, levels of care and provider classifications will need to be developed):
 - 1. Provider
 - 2. Practice group
 - 3. Hospital
 - 4. Hospital chain
- G. Add collection of this data to the State of Texas birth certificate and death certificate
- H. Consider the appointment of a small group to meet with The Joint Commission / DNV and Petition the Joint Commission to make this a priority for hospitals to monitor.
- I. Ask ACOG and AAP to consider issuing a document regarding the need to deliver babies of less than 32 0/7th or less than 1,500 grams in facilities that have both the obstetrical and neonatal expertise
- J. Evaluate the data we collect for suitability for peer-reviewed publication

1.15 Plan for sustainability

Once launched and following a run-in period of approximately 2 years the program will require the following if it is to be sustained:

- A. Acquisition of data specific to provider, practice group, hospital, and hospital chain that is collected and reported in an ongoing fashion.
- B. All outliers have mandated peer review.
- C. A mechanism of peer review is established for small practices / delivery services where true peer review would be difficult to achieve.
- D. The data is published or available to the public.
- E. The data is available to payers to potentially deny payment or drop providers from insurance plans.
- F. The criteria for maternal transport, once developed, should be reviewed at least every two years to ensure the guidelines / criteria still represents best practices / standards of care.
- G. To promote legislative support for this implementation in order to support sustainability.

1.16 Plan for scalability to acknowledge that resources available for implementation may vary

This plan could be launched as a demonstration project in specific urban and rural locations and compare pre and post implementation rates of deliveries less than 32 0/7th weeks' gestation and less than 1,500 grams. However, we submit that the project is ready for statewide implementation. The buy-in by DSHS, HHSC, and major payers will ensure its success. If the Joint Commission and DNV (Det Norske Veritas) would join and make this a priority for hospitals without appropriate obstetric and neonatal services (i.e., high risk obstetric and Level IIIA, IIIB, or IIIC NICUs) to monitor and reduce non-indicated deliveries prior to 32 0/7th weeks' gestation and 1,500 grams, it would assist us in accelerating both implementation and sustainability.

1.17 Relevant literature related to perinatal regionalization

| Source | Sample | Study Design Description | Objective | Results |
|---|---------------------------|---|---|--|
| <p>Gould JB, Marks AR, Chavez G. <i>Expansion of Community-Based Perinatal Care in California.</i> J Perinatol. 2002;22:630-40.</p> | <p>4,563,900 infants.</p> | <p>Secondary data analysis/ Retrospective cohort study.</p> <ul style="list-style-type: none"> • Born from 1990 to 1997 in California. • Infants were analyzed by levels of care. • Shifts in birth location and acuity were examined. • Neonatal mortality for singleton VLBW infants without congenital abnormalities was used to assess differences in level-specific survival. | <p>Investigate the effects of Community Neonatal Intensive Care Unit (NICUs) growth on level-specific distribution of births, acuity, and neonatal mortality in California.</p> | <ul style="list-style-type: none"> • Live births at hospitals with Community NICUs increased from 8.6% to 28.6%. • VLBW births increased from 11.7% to 37.4%. • Births and VLBW births at Regional NICUs decreased, whereas acuity was unchanged. • There were no differences in neonatal mortality of VLBW infants born at Community or Regional NICU hospitals. • Mortality for VLBW births at other levels of care was significantly higher. |

| Source | Sample | Study Design Description | Objective | Results |
|--|--|---|--|--|
| <p>Hall RW, Hall-Barrow J, Garcia-Rill E. <i>Neonatal Regionalization through Telemedicine using a Community-based Research and Education Core Facility. Ethn Dis.</i> 2010;20(1):136-40.</p> | <ul style="list-style-type: none"> 15 telemedicine units. 12,258 births. | <p>Survey/ Retrospective cohort study.</p> <ul style="list-style-type: none"> Data from all LBW infants born alive in Arkansas 2001-2004 with birth weights ≥ 500 g and ≤ 2499 g. Birth records from Arkansas Vital Statistics Data System used to identify all births 2001-2004 < 2400 g. | <ul style="list-style-type: none"> To assess the use of telemedicine to modify patterns of delivery in an established state network | <ul style="list-style-type: none"> Medicaid deliveries at the regional perinatal centers increased from 23.8% before the intervention to 33% in neonates between 500 and 999 grams ($P < .05$) Medicaid deliveries unchanged in neonates between 2001-2500 grams. <p>Additional Study Design Description</p> <ul style="list-style-type: none"> The Community Based Research and Education Core Facility of the Center for Translational Neuroscience established a network of 15 telemedicine units with real-time teleconferencing and diagnostic quality imaging, called Telenursery, placed in neonatal intensive care units, using T1 lines to link these units with a large academic neonatal practice. Weekly educational conferences were conducted to establish guidelines for obstetrical, neonatal and pediatric care in a program called PedsPLACE (Physician Learning and Collaborative Education). Patterns of delivery were assessed through a linked Medicaid database before and after the Telenursery initiative to determine if the most at-risk neonates were transferred to the academic prenatal center for delivery. Clinician satisfaction with the PedsPLACE educational conference was high as assessed through written survey instruments. |

| Source | Sample | Study Design Description | Objective | Results |
|--|-----------------|--|--|---|
| <p>Hein HA. <i>Regionalized perinatal care in North America.</i> Semin Neonatol. 2004;9:111-6.</p> | N/A | <p>Review article.</p> <ul style="list-style-type: none"> The Iowa model, utilizing some non-tertiary referral centers, is discussed in depth. | To familiarize the reader with the status of regionalized perinatal health care in North America, and specifically in the US, using the Iowa regionalization model. | <ul style="list-style-type: none"> Discussion over the impact of managed care systems on the overall role of regionalization. The future of regionalization is discussed in the face of deregionalization in populous areas. The need for the best possible care as close to the patients' homes as possible (regionalization) still seems apparent. |
| <p>Kamath BD, Box TL, Simpson M, and Hernandez JA. <i>Infants born at the threshold of viability in relation to neonatal mortality: Colorado, 1991 to 2003.</i> J Perinatol. 2008 Feb 14;28:354-60.</p> | 779,385 births. | <p>Retrospective cohort study.</p> <ul style="list-style-type: none"> All live births in Colorado from 1991 to 2003. Evaluated all live births in Colorado from 1991 to 2003 and compared the periods 1991 to 1996 versus 1997 to 2003. | To determine the contribution of infants born at the threshold of viability (defines as <750 g birth weight) and the role of regionalization of perinatal care on the neonatal mortality rate (NMR) in Colorado. | <ul style="list-style-type: none"> The overall unadjusted NMR of the two time periods was 4.3 and 4.4 per 1000 live births, respectively ($P=0.42$). The contribution of infants with birth weights <750 g to the overall NMR increased from 45.0 to 54.5% ($P<0.01$). The odds of death for infants <750 g increased between time periods (Odd ratio 1.3, 95% CI 1.11, 1.61). NMR decreased between time periods for all birth weight categories, until infants <600 g. Number of infants <750 g born in a level III care center increased slightly between the two time periods (69.9 vs. 73.3%; $P=0.04$) Adjusted analysis showed no difference in the practice of regionalization between time periods. Infants who weighted <750 g born in a level III center had 60% lower mortality risk when compared to <750 g infants born in a non-level III center ($P<0.01$; 95% CI 0.30, 0.52). |

| Source | Sample | Study Design Description | Objective | Results |
|--|-------------------------|--|---|---|
| <p>Lasswell SM, Barfield WD, Rochat RW, Blackmon L. Perinatal <i>Regionalization for Very Low-Birth-Weight and Very Preterm Infants: A Meta-analysis.</i> JAMA. 2010 Sept 1;304(9):992-1000.</p> | <p>41 publications.</p> | <p>Systematic literature review.</p> <ul style="list-style-type: none"> Systematic search of published literature (1976–May 2010) in MEDLINE, CINAHL, EMBASE, and PubMed databases and manual searches of reference lists. | <p>To evaluate published data on associations between hospital level at birth and neonatal or predischarge mortality for very low birth weight (VLBW) and very preterm (VPT) infants.</p> | <ul style="list-style-type: none"> Increased odds of death for VLBW infants (38% vs. 23%; adjusted OR, 1.62; 95% CI, 1.44-1.83) born outside level III hospitals. Increased odds of death for VPT infants (15% vs. 17%; adjusted OR, 1.55; 95% CI, 1.21-1.98) born outside of level III hospitals. Consistent results when restricted to higher-quality evidence: <ul style="list-style-type: none"> Mortality in VLBW infants (36% vs. 21%; adjusted OR, 1.60; 95% CI, 1.33-1.92) Mortality in VPT infants (7% vs. 12%; adjusted OR, 1.42; 95% CI, 1.06-1.88) Mortality in infants weighing less than 1000 g (59% vs. 32%; adjusted OR, 1.80; 95% CI, 1.31-2.46). No significant differences were found through subgroup analysis of study characteristics. Meta-regression by year of publication did not reveal a change over time (slope, 0.00; $P = .87$). <p>Other Study Design / Description</p> <ul style="list-style-type: none"> Met a priori inclusion criteria (randomized controlled trial, cohort, and case-control studies measuring neonatal or pre-discharge mortality among live-born infants ≤ 1500 g or ≤ 32 weeks' gestation delivered at a level III vs. lower-level facility.) Paired reviewers independently assessed publications for inclusion and extracted data using standardized forms. A third reviewer decided discrepancies. Publications were reviewed for quality by 3 authors based on 2 content areas: <ul style="list-style-type: none"> Adjustment for confounding Description of hospital levels. They calculated weighted, combined odds ratios (ORs) using a random-effects model and comparative unadjusted pooled mortality rates. |

| Source | Sample | Study Design Description | Objective | Results |
|---|--|--|--|---|
| <p>Mori R, Fujimura M, Shiraishi J, Evans B, Corkett M, Negishi H, Doyle P. <i>Duration of inter-facility neonatal transport and neonatal mortality: Systematic review and cohort study. Pediatr Int.</i> 2007;49:452-8.</p> | <ul style="list-style-type: none"> 32 publications. 16,429 neonates. | <p>Systematic literature review:</p> <ul style="list-style-type: none"> 6 major databases searched. Medline [1966 – 2004]; Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews; Database of Abstracts of Reviews of Effectiveness [2nd quarter 2004]; EMBASE [1980 – 2004]; Cumulative Index to Nursing and Allied Health Literature [CINAHL] [1982 – 2004]; and British Nurse Index [BN] [1985 – 2004]. | <p>Investigate the association between duration of inter-facility transport and perinatal mortality.</p> | <ul style="list-style-type: none"> Systematic review: <ul style="list-style-type: none"> Only one cross-sectional study in an urban area in India was identified. Showed that neonates with a long duration of transport had 79% higher odds of death than those transported for a short duration after adjusting for confounding effects. Cohort: <ul style="list-style-type: none"> Among 16,429 subjects, 4,966 resulted in full data collection. Strong evidence showed that those transported for >90 min had more than twice the rate of neonatal death (rate ratio [RR] 2.26, 95% CI: 1.26-4.04) Some evidence that those transported for between 60-89 min had an 80% higher rate of neonatal death (RR 1.81, 95% CI: 1.07-3.06) Both compared with those transported for between 30 and 59 min, after adjusting for confounding effects. Sensitivity analysis on missing values also supported results. <p>Other Study Design / Description</p> <ul style="list-style-type: none"> Comparative studies investigating association between duration of inter-facility neonatal transport and their outcomes. Studies were screened and reviewed by two independent researchers. <p>Cohort:</p> <ul style="list-style-type: none"> Every neonate transported to neonatal wards in Osaka, Japan between 1980 and 2000. Neonate information was collected from an existing surveillance called Neonatal Mutual Cooperative System. Neonates were followed up until 28 days of age, or discharged if earlier. Other variables considered as effect modifiers or confounders: calendar year, birth weight, gestational age, sex, maternal/paternal age, Apgar scores at 1 and 5 min, place of |

| Source | Sample | Study Design Description | Objective | Results |
|---|-------------------------|--|---|--|
| | | | | <p>birth, personnel accompanying the neonate during transport, body temperature before transport and on admission, severity of illness, and intraventricular hemorrhage grade.</p> <ul style="list-style-type: none"> Cox regression analyses were performed to obtain principal results, and sensitivity analysis performed to support the results. |
| <p>Mullen CV, Conway AE, Mounts K, Weber D, Browning CA. <i>Regionalization of perinatal care in Wisconsin: A changing health care environment.</i> Wisc Med J. 2004;103(5):35-8.</p> | <p>16 publications.</p> | <p>Literature review.</p> <ul style="list-style-type: none"> Observations of perinatal outcomes in Wisconsin and responses of Wisconsin Association for Perinatal Care (WAPC) from 1970s to 2003. Reviewed literature regarding neonatal mortality and NICU size. | <p>Investigate the current disconnect between Wisconsin's rapid increase in neonatal intensive care units (NICUs) (from 6 in 1970s to 18 in 2003) and the worsening of perinatal outcomes, noted especially in some racial/ethnic groups.</p> | <ul style="list-style-type: none"> Local policymakers should examine the factors that facilitate the development of small NICUs. Support recommendation that hospitals with no NICU or intermediate NICUs transfer high-risk mothers with fetal weight <2000g to a regional NICU. Birth at a hospital with a regional NICU is associated with a lower risk-adjusted mortality than birth at a hospital with no NICU, intermediate NICU of any size, or a small community NICU. Subsequent neonatal transfer to a regional NICU only marginally decreases the disadvantage of birth at these hospitals. The determination of the appropriate level of care to be provided by a given hospital should be guided by prevailing local health care regulations, national professional organization guidelines, and identified regional perinatal health care service needs. |

| Source | Sample | Study Design Description | Objective | Results |
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| <p>Nowakowski L, Barfield WD, Kroelinger CD, Lauver CB, Lawler MH, White VA, Ramos LR. <i>Assessment of State Measures of Risk-Appropriate Care for Very Low Birth Weight Infants and Recommendations for Enhancing Regionalized State Systems. Matern Child Health J.</i> 2010. Epub 22 Dec 2010.</p> | <p>7 states that presented at a 2009 Association of Maternal & Child Health Programs Perinatal Regionalization Meeting were included in the assessment.</p> | <p>Comparative study.</p> <ul style="list-style-type: none"> Comparative study of state perinatal regionalization models. Information was gathered from meeting presentations, presenters, state representatives, and state websites. The authors reviewed the seven state perinatal regionalization models and levels of care to compare varying definitions between states and assess mechanisms of measurement and areas for improvement. | <p>To examine state measurements and improvements in risk-appropriate care for very low birth weight (VLBW) infants.</p> | <ul style="list-style-type: none"> Comparison of state levels of care and forms of regulation were outlined. Review of state models revealed variability in the models themselves, as well as the various mechanisms for measuring and improving risk-appropriate care. Regulation of regionalization programs, data surveillance, review of adverse events, and consideration of geography and demographics were identified as mechanisms facilitating better measurement of risk-appropriate care. Variations in state regionalization models and measures arose from inconsistent definitions and models of perinatal regionalization and a void of explicit and updated national standards. |

| Source | Sample | Study Design Description | Objective | Results |
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| <p>Phibbs CS, Baker LC, Caughey AB, Danielsen B, Schmitt SK, Phibbs RH. <i>Level and Volume of Neonatal Intensive Care and Mortality in Very-Low-Birth-Weight Infants.</i> N Engl J Med. 2007 May;356:2165-75.</p> | 48,237 very-low-birth-weight infants | <p>Retrospective cohort study.</p> <ul style="list-style-type: none"> • Infants born in California hospitals between 1991 and 2000. • Linked birth certificates, hospital discharge abstracts (including inter-hospital transfers), and fetal and infant death certificates to assess neonatal mortality rates. | To examine differences in neonatal mortality among infants with very low birth weight (<1500g) among NICUs with various levels of care and different patient volumes of very-low-birth-weight infants. | <ul style="list-style-type: none"> • Mortality rates among VLBW infants varied according to both the volume of patients and the level of care at the delivery hospital. • The effect of volume also varied according to the level of care. • Lower levels of care and lower volumes (less than 100 per year) were associated with significantly higher odds ratios for death, ranging from 1.19 (95% CI, 1.04 to 1.37) to 2.72 (95% CI, 2.37 to 3.12). • Less than one quarter of VLBW deliveries occurred in facilities with NICUs that offered a high level of care and had a high volume; 92% of VLBW deliveries occurred in urban areas with more than 100 such deliveries. |
| <p>Serfaty A, Gold F, Benifla JL, Breart G. <i>From knowledge to planning considerations: a matrix to assess health needs for the perinatal network in eastern Paris.</i> Eur J Public Health. 2010. Epub 30 June 2010.</p> | N/A | <p>Health Needs Assessment.</p> <ul style="list-style-type: none"> • The matrix listed its columns as 'perinatal stages' from conception through the age of 6 years. • The rows covered components related to public health planning | To design a matrix to build a perinatal knowledge base for assessing health needs and facilitating a public health planning process for the perinatal network in eastern Paris. | <ul style="list-style-type: none"> • The matrix structured the cyclical process for building knowledge for action. • One of the most important services that the network must furnish is information about infertility treatments, contraceptions, prenatal care, delivery and postnatal care. • Information about perinatal health care facilities, in the area of the network, is essential to guide each woman and couple to a facility appropriate to their level of risk. • Distribution of information through a public campaign is the basic method of community education. • To assess perinatal health care facilities and equipment needs, a comparison of the services available and provided with the perinatal services needed must be done to plan an appropriate |

| Source | Sample | Study Design Description | Objective | Results |
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| | | <ul style="list-style-type: none"> For each situation, the matrix lists require information and potential data sources to measure health status and health services. | | <p>distribution of each level of care.</p> <ul style="list-style-type: none"> Eastern Paris has a population of 670,000. 9 maternity units distributed into 3 levels of care. Level-3 unit opened in June 2007. 16,400 deliveries occur annually; 2500 living in eastern area deliver outside the area. |
| <p>Shenai JP, Major CW, Gaylord MS, Blake WW, Simmons A, Oliver S, DeArmond D. <i>A successful decade of regionalized perinatal care in Tennessee: the neonatal experience.</i> J Perinatol. 1991 Jun;11(2):137-43.</p> | <p>479 neonates transported to NICUs.</p> | <p>Retrospective cohort study.</p> <ul style="list-style-type: none"> Two defined groups of neonates transported to regional perinatal centers in Tennessee: <ul style="list-style-type: none"> one group (n=218) from the 1st year of regionalization (1975) second group (n=261) from the 12th year (1986) Retrospective study of demographic characteristics and transport | <p>To test the hypothesis that successful implementation of regionalized perinatal care would:</p> <ol style="list-style-type: none"> result in early identification and antenatal referral of high-risk neonates, and improve stabilization before and during transport of those transferred postnatally | <ul style="list-style-type: none"> The percentage of outborn infants decreased, from 50% of all admissions in 1975 to 22% in 1986 (P = .005). The percentage of low-birth weight neonates transported after birth decreased, from 59% of all transports to 32% (P = .002). The frequency of stabilization measures performed before and during transport increased between study years (intravenous line placement: 12% to 58%, P = .0001; assisted ventilation: 10% to 33%, P = .001). The incidence of complications during transport decreased between study years (cyanosis: 25% to 8%, P = .0001; hypothermia: 30% to 3%, P = .0001; acidemia: 33% to 13%, P = .011). Both transport-related mortality and neonatal mortality decreased between study years (2.8% to 0.8%, P = .043; 17% to 7%, P = .0001, respectively). |

| Source | Sample | Study Design Description | Objective | Results |
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| | | outcome in two defined groups of neonates transported to regional perinatal centers in Tennessee | | |
| Stabler S. <i>Regionalized Systems of Perinatal Care: Health Policy Considerations. Adv Neonatal Care.</i> 2011;11(1):37-42. | N/A | Policy analysis. <ul style="list-style-type: none"> • Observation of perinatal and neonatal health care over the past 2 decades. • Analysis of perinatal and neonatal health care policy background, goals, objectives, options, and alternatives. | <ul style="list-style-type: none"> • Discuss the factors impacting implementation of a regionalized model at either the state or federal level. • Discuss the incorporation of perinatal regionalization as part of the national agenda of health care reform. | <ul style="list-style-type: none"> • Evidence demonstrates lower mortality risk for very low-birth-weight infants born in designated tertiary centers. • Regionalized systems of perinatal care are recommended to ensure that each mother and newborn achieve optimal outcomes. |

| Source | Sample | Study Design Description | Objective | Results |
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| <p>Vieux R, Fresson J, Hascoet JM, Blondel B, Truffert P, Roze JC, Matis J, Thiriez G, Arnaud C, Marpeau L, Kaminski M. <i>Improving Perinatal Regionalization by Predicting Neonatal Intensive Care Requirements of Preterm Infants: An EPIPAGE-Based Cohort Study.</i> Pediatrics. 2006 Jan 3;118(1):84-90.</p> | <p>1740 mother-infant pairs.</p> | <p>Retrospective cohort study.</p> <ul style="list-style-type: none"> Cohort of all preterm infants aged 22 to 32 weeks' gestation and a sample of preterm infants aged 33 to 34 weeks' gestation born in 1997 in nine French regions. | <p>To determine the antenatal factors that, in association with gestational age, predict the need for neonatal intensive care in preterm infants, to match the size of birth with the level of care required.</p> | <ul style="list-style-type: none"> The study focused on 1262 neonates aged 30, 31, and 32 weeks' gestation, where the need for intensive care was 42.8%, 33.2%, and 22.8%, respectively. Multivariate analysis showed that the risk factors for intensive care requirement with low gestational age were: <ul style="list-style-type: none"> twin pregnancies, maternal hypertension, antepartum hemorrhage, infection, and male gender. Antenatal steroid therapy and premature rupture of membranes were protective factors against intensive care requirement. <p>Additional Study Design / Description</p> <ul style="list-style-type: none"> Study population was defined as mother-infant pairs. The need for neonatal intensive care was defined as follows: <ol style="list-style-type: none"> The requirement for specialized management (mechanical ventilation for >48 hours, high frequency oscillation, or inhaled nitric oxide) or Poor outcome (transfer to a level III facility within the first 2 days of life or early neonatal death). Triplet pregnancies and pregnancies marked by fetal malformations or intensive care requirements for the mother before delivery were excluded. |

**Literature Review Summary Table
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