

Dr. Smith NICU (Nursery) Classification Committee Report (*Final Draft*)

Submitted By Dr. Jayant Deshpande, Committee Chair

4/3/2014

I Charge to the Committee:

- Study and recommend whether Arkansas shall adopt a classification system for Neonatal Intensive Care Units (NICU) [and nurseries] within the state.
 - If a classification was recommended for adoption:
 - Recommend appropriate designation levels and how they would be defined and regulated.
 - Although the primary focus was to be NICU Classification, it rapidly became apparent to the committee that expansion to include perinatal classification was necessary. This was approved by Dr. Halverson.
 - The first committee meeting was held 3/1/2012. It was anticipated the process would take 3-6 months.
 - All committee members felt it was important to adopt a perinatal classification system for Arkansas to help lower our state's high Infant Mortality Rate (IMR) and better coordinate regionalization of our resources.
 - Arkansas' IMR is one of the highest in the nation [**See Table # 1**]
1. Arkansas is one of only 3 states in the US with no designated NICU criteria [1. Blackmon LR et al. **Hospital neonatal services in the United States: variation in definitions, criteria, and regulatory status, 2008.** J Perinatol. (2009)].
- Getting the “right pregnant mother to the right hospital for delivery” has been, by peer reviewed studies in both the US and Arkansas, associated with IMR reductions of 50-66% for pregnancies less than 32 weeks. [2,3]
 - It has been calculated [ADH unpublished data] that Arkansas can reduce its current IMR, of almost one baby dying every day in Arkansas before reaching their 1st birthday, by 20 babies each year.
 - This process was delayed because of the anticipated announced release in the fall of 2012 of new national NICU and perinatal guidelines by the American Academy of Pediatrics (AAP); continuing to work on the process was felt to be important with the understanding that changing national standards may also necessitate changes in our committee's recommendations.
 - The committee's overall recommendations have been to adopt the AAP's 2012 recommendations [4] with slight modifications due to Arkansas being a rural state.

II Special Criteria:

- Classification Criteria
 - Please see the attachment of v. 6.0 [Final version; Attachment # 1] for specific and complete revisions of the AAP recommendations by the NICU Committee.
 - The entire committee recommended following national classification changes [5] of Level I and eliminating the split of Level II into A and B sub-categories and making previous Level III-C into Level IV.
 - This is opposite of the Trauma System levels where the lowest number is the highest specialized. Any hospital would be allowed to increase or decrease their level by showing that they were meeting or would be likely to meet the specified criteria for their desired level.
 - Level III recommendations were adopted by unanimous vote of the committee.
 - The committee retained the division of Level III A and B that had been eliminated by the most recent national AAP recommendations (2012). AAP had anticipated that some modifications of their recommendations by some states would be necessary.
 - Elimination of subdivisions of Level III by AAP recommendations would have left Arkansas without any Level III NICUs outside of Little Rock.
 - The committee recommended that a Level III-A be allowed to receive and maintain care for pregnant women as early as 26 weeks gestation or higher if qualified to care for the complications of both the mother and the fetus. The reduction in IMR can only be achieved by having the mother in premature labor, or needing early delivery, to be delivered in the Level NICU that maximizes infant survival.
 - It is anticipated that 3 facilities will request Level III status in the NWR; the NWR has enough volume for either one Level III-B and two Level III-A, or three Level III-A facilities using current statewide birth criteria.
 - Three facilities in the Central Region may request Level III status with 2 currently meeting III-B status.
 - One facility in the NER is anticipated to request Level III status in the near future.
 - The SER and SWR both lack volume and resources so it is uncertain if either region has a facility that will be requesting Level III status. Texarkana deliveries all occur in hospitals on the Texas side making planning more difficult. It is possible that, like the trauma system,

voluntary compliance with Arkansas standards can be accomplished with out of state hospitals.

- The committee felt that Evidence Based Medicine (EBM), or peer reviewed medical journals, showed that the yearly volume of the NICU facility played a part in the outcome (IMR) of NICUs. The national committee was unable to agree on the absolute number for cut offs and left that decision to the states.
 - After review of both national and Arkansas data the decision of the committee was to require a minimum of 25 yearly admissions of babies less than 32 weeks gestation to the NICU to be a Level III-A and 75 to be a Level III-B. Arkansas' 10 year average, evidence requested of ADH by Dr. Hall, showed that high volume NICUs (> 75/yr.) had a 50% lower mortality rate when compared to low volume NICUs (< 75/yr.) for babies delivered at their hospitals less than 27 weeks (1000 gm.).
- **Implementation Criteria:**
 - The unanimous recommendation of the committee was for the Arkansas Department of Health (ADH) to be responsible for the level designations and inspection of all Arkansas hospital nurseries and NICUs. ADH currently is responsible for inspection of all Arkansas hospitals. AAP only designates Level I and II as nurseries and reserves the term "NICU" for Levels III and IV.
 - These recommendations are to be developed and codified in conjunction with the Board of Health (BOH) and the Legislature.
 - It was also understood that recommendations from this or other committees may require changes in the future as the science necessitates change.
- **Time Line for Implementation:**
 - The committee recognizes that adoption of these criteria will require action by ADH, BOH, and the legislature.
 - This will require a minimum of 2 years lead time.
 - It is the recommendation of this committee that facilities be encouraged to try voluntary compliance with these standards while working toward their desired classification levels.
 - Many facilities have been voluntarily complying with national AAP standards for many years since Arkansas has yet to have adopted any standards or state designated levels.
 - Thirty percent (30%) of current Arkansas deliveries of babies less than 32 weeks are still being delivered in Level I and II equivalent facilities and then transporting the infant to the proper facility. Unfortunately this doubles or triples the baby's risk of dying. For

babies less than 1500 gms. But especially for those babies weighing less than 1,000 gms., the womb is recognized by most high risk doctors as the safest method of transport for these high risk infants.

- Physician and health facility education concerning the importance of these changes is paramount.

- **Entity Responsible for Designation and Regulation:**

- The unanimous recommendation of the committee was for the ADH to be responsible for the level designations and inspection of all Arkansas hospital nurseries and NICUs with input from the Perinatology Specialists (Maternal Fetal Medicine [MFM] and Neonatologists).

- **Payer Reimbursement (Medicaid and Private Insurance):**

- The committee recognizes the important part that Medicaid and private insurance play in compliance with these levels and conditions. Medicaid is currently making numerous changes in Arkansas to improve quality and decrease cost. Some of these changes could be aligned to achieve higher compliance with these recommendations.

- **III Committee Makeup and Recognition:**

- Drs. Nate Smith and Jayant Deshpande wish to recognize and applaud the many voluntary hours and time away from their jobs and families that members and guests have devoted to making this endeavor a success. We have accomplished what many other states are only beginning to deal with. Everyone on the committee has been allowed to present their point of view and express to the committee how these changes may save baby's lives and help or hurt their community. They also greatly appreciate the support of AHA and ADH.
- The current committee is composed of a diverse membership. The following is a list of committee members, guests, consultants and the groups they represent:
 - Chair
 - Dr. Jayant Deshpande, Chief of Medical Staff and Quality Improvement at Arkansas Children's Hospital
 - Neonatologists
 - Dr. Victor Coloso; St. Edward Mercy Medical Center, AHA hospitals > 100 beds
 - Dr. Whit Hall; UAMS, Arkansas Medical Society
 - Dr. Marla Lightburn; Washington Regional Medical Center
 - Dr. Bo Lin; Willow Creek Women's Hospital, Arkansas Medical Society
 - Dr. Kristine Palmer; UAMS, Arkansas Medical Society
 - Dr. Sameer Wagle; Willow Creek Women's Hospital, AHA hospitals < 100 beds

- Dr. Terry Zuerlein; Baptist Medical Center (Little Rock), Arkansas Medical Society
- Maternal Fetal Medicine (MFM)
 - Dr. Curtis Lowery; UAMS, ANGELS
 - Dr. James Meserow; Baptist Medical Center (Little Rock)
 - Dr. Ricardo Sotomora; Arkansas Medical Society
 - Dr. Stephen Chatelain; ACOG
- Obstetrics (ACOG)
 - Dr. Brian Burton; ACOG
 - Dr. David Grimes; ADH, ACPM
- Family Physician (AAFP)
 - Dr. Lonnie Robinson; Regional Family Medicine (Mountain Home)
 - Dr. Michael Moody; AFMC
- DHS
 - Dr. Bill Golden; Medicaid
- Hospital Representatives
 - Phillip Gilmore; CEO Ashley County Medical Center, Critical Access Hospitals
 - Margaret West; CEO Magnolia Regional Medical Center, AHA Hospitals < 100 beds
 - Cindy Slaydon; CNO Sparks Health System, Subcommittee Chair
- March of Dimes (MOD)
 - Janalyn Williams; State Director
 - Tina Long
- Family Representatives
 - Christina Stengel; MOD
 - Jeremy Goss; MOD
- Recording Secretary
 - Cindy Brown (ADH)
- Guests
 - Austin Gaines, St. Edward Mercy Medical Center
 - Dr. Richard Nugent; UAMS
 - Debbie Crandall; Administrative Director Willow Creek
 - Peggy Starling; AFMC
 - Stephanie Williams; ADH
 - Dr. Mike Riddell; ADH, ACOG
 - Brad Planey; ADH

- Jodiane Tritt; AHA
- Don Adams; AHA

- **IV Explanation for Modification of AAP (2012) National Recommendations**

- In addition to level of care, patient volume in the NICU influences outcome. In a recent unpublished review of 10 years of Arkansas data by ADH for all Level III equivalent facilities, it was found that comparing high volume (> 75/yr. of less than 32 week yearly nursery admissions) to low volume (< 75/yr.) facilities resulted in a statistically significant 50% reduction in mortality for babies less than 27 weeks (or 1,000 gm.) delivered in high volume facilities.
- The 3A and 3B classification system was maintained for 2 reasons:
 - Arkansas data demonstrates that deliveries of neonates between 1000 and 1500 grams is not associated with increased mortality when delivered in hospital nurseries to be classified as 3A
 - Arkansas is a rural state and transport of mothers with neonates >27 weeks or >1000 grams to facilities that will be classified as 3B causes unnecessary hardship for families who may live a great distance from those units
- Uniform national standards such as requirements for equipment, personnel, facilities, ancillary services, and training, and the organization of services (including transport) should be developed for the capabilities of each level of care
- Population-based data on patient outcomes, including mortality, specific morbidities, and long-term outcomes, should be obtained to provide level-specific standards for volume of patients requiring various categories of specialized care, including surgery.
- Infant morbidity and mortality for babies less than 32 weeks or 1500 gm. is significantly lower if the infant is delivered at a facility with a Level III or higher NICU. This has been confirmed by EBM national studies and confirmed by Arkansas studies. Outborn infants (delivered in Level I and II hospitals and then transferred to a Level III or IV facility) have 2-3 times the risk of dying or serious morbidity compared to moms with the same gestational age babies that are transferred while still pregnant and deliver in the Level III or IV NICU hospital. If delivery in a facility without the necessary capabilities cannot be avoided, the infant should be stabilized and transferred to a NICU with the appropriate capabilities to ensure optimal outcome but will still have the increased morbidity and mortality from delivery in a Level I or II facility.
- **Level I** (Low risk 35+ weeks gestation)
 - Basic neonatal care is the minimum requirement for any facility that provides inpatient maternity care to infants at low risk. The institution must have the personnel and equipment to perform neonatal resuscitation,

- evaluate healthy newborn infants and provide postnatal care, and stabilize ill newborn infants until transfer to a facility that provides intensive care can be obtained.
- Capability to perform neonatal resuscitation at every delivery and to evaluate and provide routine postnatal care of healthy newborn infants.
 - Stabilize and care for near-term infants (35–37 weeks gestation) who remain physiologically stable and can stabilize newborn infants who are less than 35 weeks gestation or ill until they can be transferred to a facility at which specialty neonatal care is provided.
 - Supervised by a Family Practice specialist or a Pediatrician.
- **Level II** (Level I plus--Medium risk; 32+ weeks gestation; mechanical ventilation less than 24 hours)
 - Provide care to infants who are moderately ill with problems that are expected to resolve rapidly or who are recovering from serious illness treated in a level III (subspecialty) NICU and returned when they are deemed to be stable for the receiving nursery (“back transport”).
 - Supervised by Pediatricians experienced in the management of 32+ week infants or in some cases by a Neonatologist.
 - **Level III** (Level II plus---)
 - **Level III-A**
 - Newborn infants with birth weight of more than 1000 g and gestational age of more than 26 weeks can be cared for in a level III-A NICUs.
 - Volume requirements are > 25/yr. admissions of less than 32 week babies.
 - Acceptance of all appropriate maternal and infant transfers from Levels I and II.
 - Neonatologist always available and ability to be in house within 30 minutes
 - Ability to provide life support including assisted ventilation for a prolonged period of time (>24 hours)
 - **Level III-B**
 - Newborn infants of any weight or gestational age. A level IIIB unit should have the capability to perform major surgery (including anesthesiologists with pediatric expertise) on site or at a closely related institution. A closely related institution would ideally be in geographic proximity and share coordinated care such as physician staff.

- Volume requirements are > 75/yr. admissions of less than 32 week babies.
 - Acceptance of maternal and infant transfers from all levels.
 - Personnel (neonatologists, neonatal nurses, respiratory therapists) and equipment to provide life support for as long as needed.
 - MFM specialist on staff and available in house within 30 minutes.
 - Neonatal Nurse Practitioners (NNP), Neonatology trained Pediatricians (as determined by hospital credentialing), Neonatology Fellows, or Neonatologists in house 24/7
 - Neonatologist available in house within 30 minutes.
- **Level IV (Level III plus--)** [Some Level IV Children's Hospitals may not have delivery capabilities but have associations with nearby Level III facilities that have maternal facilities.]
 - Level IVs should have immediate and on-site access to pediatric medical and surgical subspecialty consultants to be available in house within 30 minutes.
 - ECMO
 - They can provide surgical repair of serious congenital cardiac malformations that require cardiopulmonary bypass.

V Implementation Issues

- Regulations versus Guidelines
 - Some recommendations of the committee are meant to be guidelines that fit with most existing hospital policies (nursing ratios and staff training).
 - Others are meant to be codified into legislation or regulations of ADH and the BOH (ex. volume requirements and appropriate maternal transfers)
- Funding the Inspection and Certification Process
 - Funding has yet to be determined but typically comes from the state legislature or from licensure fees
 - Hospitals requesting certain levels will be granted certification of that level as long as they meet ADH standards for that level
 - Pending legislative action, expected to require at least 1 year, hospitals will be asked to voluntarily comply
- Compliance and Enforcement
 - Hospitals participating in this program will be inspected biannually for compliance with ADH standards as part of their routine inspection.
 - Some states that define NICU levels also require that hospitals adhere to those levels in order to qualify for reimbursement by Medicaid or by private insurance.

- States can impose financial penalties, or rescind a hospital's license, for failure to comply with rules.
- Changing Levels
 - A hospital wishing to receive certification or change certification in maternal or neonatal care will apply to the Arkansas Department of Health (ADH) and schedule an inspection.
 - A site visit will be scheduled within 6 months of application, with approval based on compliance with Arkansas Levels of Care.
 - Approval may be withheld based upon community outcome data or failure to comply with ADH standards.
 - Approval actions to be taken by the ADH include:
 - Approval if ADH standards are met
 - Conditional approval, not to exceed 6 months, if documentation is lacking or there are readily available solutions to comply with ADH standards.
 - Denial if conditions cannot be met

VI Next Steps

- The most important point of these recommendations is to have evidence based requirements for designating facilities for specific levels based on the resources of their physical facilities and professional staff. The only way to reduce unnecessary infant morbidity and mortality is to get “the right mom to the right hospital” for delivery. Babies less than 26 weeks gestation (< 750 gm.) need to have every possible effort made to deliver at a Level III-B facility. Babies less than 32 weeks (< 1,500 gm.) need to deliver at a Level III-A or higher. Babies less than 35 weeks gestation need to deliver at a Level II or higher facility. Transfer of babies more than 27 weeks (> 1,000 gm.) to the appropriate level after delivery does not seem to affect mortality but does affect morbidity, especially Intraventricular Hemorrhage (IVH) [See Graph #2]. These differences disappeared with prenatal steroid administration.
- Continue or modify this committee as a permanent advisory task force to the State Director of ADH. A new and expanded charge will be necessary to cover and regulate these recommendations. Many states use voluntary or paid specialists from within the state for recommending changes, investigating complaints, and routine inspections.
- Continuous Quality Improvement (CQI) can only occur when a hospital can compare their data to other similar state and national facilities. Detailed biennial inspections and complaint investigations by committee task force members from “competing” facilities will require confidential and legally protected QI committees not available to the press/public and HIPAA (The Health Insurance Portability and Accountability Act) compliant. The Vermont Oxford Network (VON) is an excellent source for some of this data, to which many NICUs are already members. Hospitals credentialed as Level III and higher should be required to generate VON data to be shared with the other members and

the state. If not VON then an equivalent set of information. Being able to share individual hospital mortality data within a protected CQI process is essential to the success of this process.

- Data collection and facility inspection with a CQI process will require a source of funding similar to the AR Trauma System or an increase in licensing fees for maternity hospitals. A system for protected peer review and discussion will require legal protection and HIPAA compliance.
- Back transport when the infant is stable or just needs “comfort care”, to a proper level as close to home as possible, was identified as very important. Understanding that when a premature baby is ready to go to a Level I facility it may also be ready to go directly home. Family choice to remain at a Level III or IV until discharge also needs to be considered.
- Knowing that we always try to keep babies and their parents as close to home as possible is an important concept for needed patient education. Patients understand that if your child needs brain surgery and your hospital or county does not have a neurosurgeon then the child needs to be transferred. It is more difficult for them to understand that not having a Neonatologist at their hospital is an important reason to transfer mom “away from family” for the delivery in order to greatly decrease the chance of their baby dying. For many consumers all hospitals that deliver babies are “equal” in their minds and babies always “do better” close to home.
- Development of family support facilities close to “referral centers” (like Ronald Macdonald Houses) will be important for families transferred large distances. Having a baby in a NICU far from home causes significant emotional and financial stress on families.
- EBM and consensus based recommendations will require ongoing updates. Even if mortality rates are similar between levels, significant increases in morbidity may necessitate revision of some levels for infant protection.

Ref.

2. Blackmon LR et al. **Hospital neonatal services in the United States: variation in definitions, criteria, and regulatory status**, 2008. *J Perinatol.* (2009)
3. Lasswell SM, Barfield WD, Rochat RW, Blackmon L. Perinatal regionalization for very low birth weight and very preterm infants: a meta-analysis. *JAMA.* 2010; 304:992–1000.
4. Nugent R, Golden WE, Hall W, Bronstein J, Grimes D, Lowery C. Locations and outcomes of premature births in Arkansas. *J Ark Med Soc.* 2011 May; 107(12):258-9.
5. Levels of Neonatal Care; COMMITTEE ON FETUS AND NEWBORN; *Pediatrics* 2012;130;587; originally published online August 27, 2012

TABLE #1

Table 1. Infant mortality rates, by race and Hispanic origin of mother: United States and each state, Puerto Rico, Virgin Islands, and Guam, 2006–2008 linked files

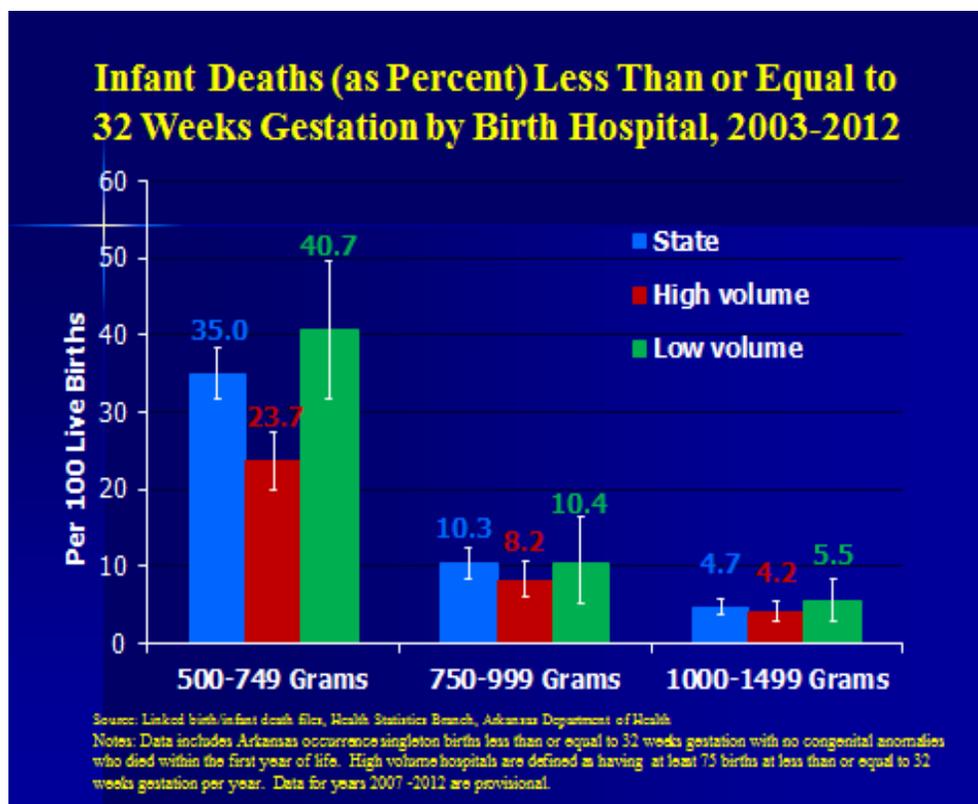
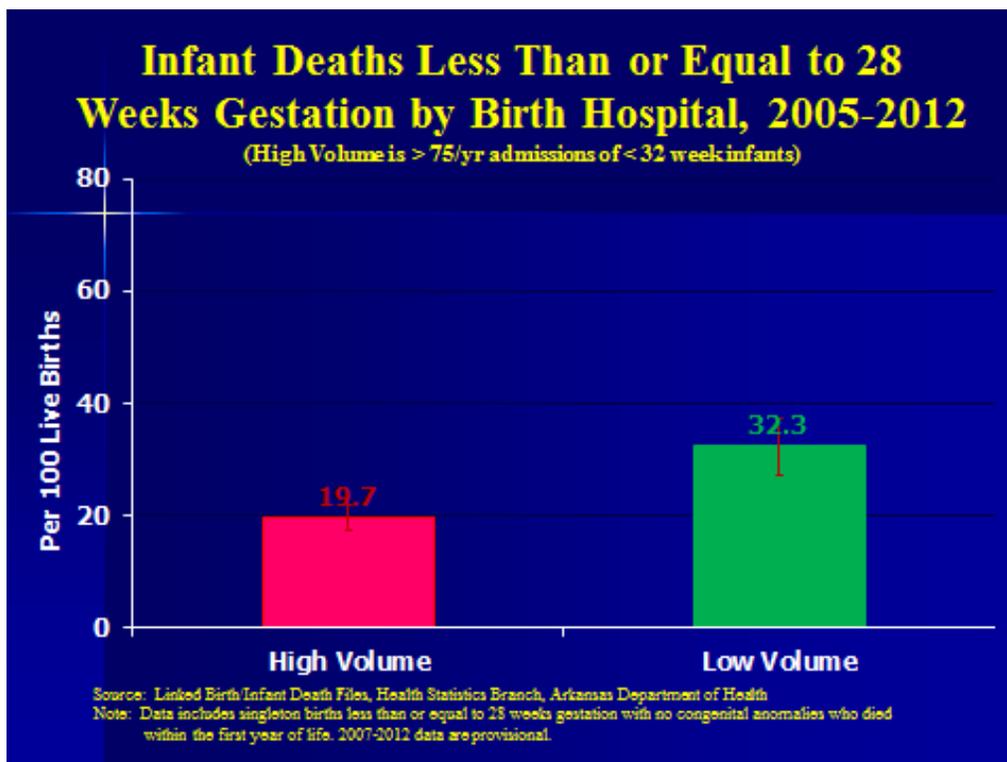
[By place of residence]

National Vital Statistics Reports, Vol. 60, No. 5, May 10, 2012 17

Infant mortality rates per 1,000 live births in specified group

	Overall	White	A/A	Hispanic			
United States ²	6.68	5.58	13.11	8.65	4.62	5.50	2.35
Alabama	9.47	7.67	13.73	*	*	7.50	1.79
Alaska	6.54	4.10	*	12.24	*	*	*
Arizona	6.54	6.04	14.85	7.57	6.54	6.13	2.46
Arkansas	7.89	6.70	13.53	*	*	5.71	2.02
California	5.12	4.51	10.72	7.05	4.30	4.88	2.38
Colorado	6.04	5.13	11.97	*	4.90	6.96	2.33
Connecticut	6.27	4.80	13.11	*	5.73	6.35	2.73
Delaware	8.03	5.89	13.46	*	*	7.10	2.29
District of Columbia	11.97	4.46	17.68	*	*	*	3.96
Florida	7.21	5.71	12.83	*	5.75	5.38	2.25
Georgia	8.02	5.87	12.70	*	4.37	5.06	2.16
Hawaii	6.04	4.58	18.54	*	6.27	4.98	4.05
Idaho	6.46	5.95	*	*	*	7.91	*
Illinois	7.10	5.70	13.45	*	5.31	5.91	2.36
Indiana	7.44	6.47	15.36	*	*	6.28	2.37
Iowa	5.43	5.06	11.10	*	*	6.61	2.19
Kansas	7.50	6.94	14.62	*	5.36	7.15	2.11
Kentucky	7.04	6.62	12.13	*	*	5.07	1.83
Louisiana	9.38	6.62	13.88	*	7.19	3.92	2.10
Maine	6.04	5.90	*	*	*	*	*
Maryland	7.98	5.50	12.98	*	5.33	5.33	2.36
Massachusetts	4.94	4.04	10.90	*	3.06	6.08	2.70
Michigan	7.56	5.87	14.70	*	4.89	7.09	2.50
Minnesota	5.55	4.77	11.33	10.25	5.65	4.64	2.38
Mississippi	10.16	7.07	13.82	*	*	6.64	1.95
Missouri	7.34	6.18	14.49	*	4.02	5.12	2.34
Montana	6.47	5.89	*	9.22	*	*	*
Nebraska	5.93	5.33	12.98	*	*	5.21	2.44
Nevada	6.10	5.29	12.54	*	4.96	5.69	2.37
New Hampshire	5.10	5.00	*	*	*	*	*
New Jersey	5.35	3.78	12.06	*	2.90	5.12	3.19
New Mexico	5.81	6.12	*	5.70	*	5.60	*
New York	5.57	4.29	11.29	*	3.35	5.01	2.63
North Carolina	8.29	6.17	14.62	15.37	5.62	6.32	2.37
North Dakota	6.44	5.63	*	12.27	*	*	*
Ohio	7.74	6.25	15.03	*	4.59	6.88	2.40
Oklahoma	7.85	7.52	13.91	8.36	5.64	5.09	1.85
Oregon	5.41	5.22	10.16	9.34	4.78	5.36	1.95
Pennsylvania	7.52	5.78	14.04	*	6.06	7.94	2.43
Rhode Island	6.47	4.28	10.56	*	*	7.77	2.47
South Carolina	8.30	6.04	12.97	*	5.32	5.87	2.15
South Dakota	7.15	5.59	*	13.00	*	*	*
Tennessee	8.37	6.54	15.36	*	5.78	6.47	2.35
Texas	6.22	5.48	11.69	7.47	4.16	5.61	2.13
Utah	4.94	4.73	*	*	7.10	5.03	*
Vermont	5.12	4.95	*	*	*	*	*
Virginia	7.24	5.48	13.40	*	4.74	5.97	2.45
Washington	5.01	4.33	7.66	9.15	4.26	5.28	1.77
West Virginia	7.38	7.11	14.93	*	*	*	2.10
Wisconsin	6.57	5.37	15.14	9.92	6.84	6.34	2.82
Wyoming	7.05	6.32	*	*	*	7.90	*
Puerto Rico	8.49	--	--	--	--	--	--
Virgin Islands	5.03	*	*	*	*	*	*

Graph #1 A and B



The Problem: Intraventricular Hemorrhage

- Severe IVH rate twice as high in out-born neonates transported after delivery versus in-born neonates



Percent Severe IVH (Grade 3 or 4)

