

**MINUTES OF THE  
NICU ADVISORY SUBCOMMITTEE MEETING**

A meeting of the subcommittee of the Arkansas State Board of Health [Board] was held on Friday, February 21, 2014, in the Fifth Floor, Director's Conference Room at the Department of Health, 4815 West Markham, Little Rock, Arkansas.

**Committee Members Present:**

Dr. Clark Fincher, Subcommittee Chair  
Dr. Joe Thompson  
Dr. Terry Yamauchi  
Catherine Tapp, MPH  
Jim Lambert

**Committee Members Not Present:**

Dr. Anthony Hui

**Guests Present:**

Dr. R. Whit Hall, Arkansas Medical Society  
Austin Gaines, Mercy Health  
Derrick Smith, Mitchell Williams, (via telephone)  
Michelle Justus, Arkansas Center for Health Improvement

**Health Department Staff Present:**

Dr. David Grimes, Branch Chief, Family Health  
Bradley Planey, Associate Branch Chief, Family Health  
Stephanie Williams, Deputy Director for Public Health Programs  
Rick Hogan, General Counsel  
Elizabeth Pitman, Deputy General Counsel  
Leslie Lovett, Board of Health Liaison

## **Call to Order**

Dr. Clark Fincher, Subcommittee Chair, began the meeting at 2:00 p.m. He stated that the Subcommittee was tasked with reviewing both the majority and minority positions of the NICU Classification Advisory Committee, deciding whether or not to adopt the recommendations of the NICU Classification Advisory Committee, and ultimately assisting the Department of Health in drafting legislation regarding NICU classifications to benefit Arkansas newborn children. Dr. Fincher mentioned the importance of this subcommittee's recommendation, as it will ultimately be what is in the best interest of newborn babies at low birth rates and will save lives.

## **Scope of the Subcommittee Mission**

Rick Hogan, General Counsel for the Department of Health and the Board, was introduced. Mr. Hogan thanked the subcommittee members and guests present for participating in this very important public health issue. In giving a brief overview of the Committee's charge, he stated that the NICU Classification Advisory Committee was created and chaired by Dr. Jonathan Bates with Arkansas Children's Hospital.<sup>1</sup> After many meetings and almost two years, the NICU Classification Committee issued a final report dated September 5, 2013,<sup>2</sup> along with a letter from Dr. Bates dated September 19, 2013.<sup>3</sup>

Mr. Hogan stated that the Board was asked to look at this very important issue and to examine what was needed by the Department. At the last Board meeting it was decided to create this Subcommittee that would review all documentation and bring forth a recommendation. As seen from the NICU Advisory Committee's final report, there is a majority position and minority position. The different levels of Level III classification (Level III-A and Level III-B) are the main issue that divided the majority and minority positions. Because of the differing Reports, the Board's advice is needed. It is the charge of this Subcommittee to report, by April, to the full Board, (1) the adoption of the definitions for classifications, (2) the recommendation regarding moving forward on any statutory or regulatory authority, (3) encouragement with respect to voluntary compliance in the interim, and (4) a recommended approach with regard to financial incentives or a financial source to create or maintain such regulation.

Since the definitions in the NICU Classification Advisory Committee recommendations were not unanimous and significant opposition was expressed, the Minority created their own report to explain why they did not agree with the Majority Report. However, they were all in agreement that there is a need for system of NICU classification. Arkansas is only one of three states in the nation to not have any type of NICU classification system.

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<sup>1</sup> The NICU Classification Advisory Committee, initially composed of 21 members, was created by Dr. Halverson, on October 4, 2011, and was charged to report to the Director on/or before April 1, 2012. (See attached)

<sup>2</sup> NICU (Nursery) Classification Committee Report, Final Report. (See attached)

<sup>3</sup> Letter from Jonathan Bates, M.D. dated September 19, 2013. (See attached)

## **Introduction of NICU Classification Committee's Final Report**

Bradley Planey, Associate Branch Chief, Family Health, introduced the NICU Classification Advisory Committee's Final Report. He confirmed that the Majority and Minority Reports discussed many of the issues that this Subcommittee is charged with deciding. Mr. Planey stated that he believed they did an excellent job bringing together the recommendations in the Reports. Mr. Planey thanked everyone for participating and introduced Dr. Grimes.

### **Arkansas Perinatal Overview Presentation**

David Grimes, M.D. Branch Chief, Family Health, presented an Arkansas Perinatal Overview. Dr. Grimes explained that the proposed NICU system is the complete opposite of the Trauma System. Under the NICU system Level I would be the lowest qualified center. Every five (5) years, under the proposed NICU Advisory Committee, the American Academy of Pediatrics (AAP) makes recommendations for changes to NICU levels. After the NICU Advisory Committee received the updated national recommendations, it felt that it needed to modify the national recommendations to fit the situation here in Arkansas. These modifications resulted in the Majority Report.

Referring to the first slide,<sup>4</sup> Dr. Grimes explained the reason for starting this process by showing the most current statistics from 2012. In 2012, there were 37,993 babies born in the State of Arkansas. Of those, 247 died before their first birthday. Arkansas is unfortunately only one of three states in the whole U.S. that has never had regionalized state directives, NICU Systems, or NICU Levels.

It was mentioned that a researcher, SM Lasswell, and several others, did a meta-analysis<sup>5</sup> of all the literature on the subject. Looking across the United States, the Lasswell analysis found that, if you compare babies that delivered in Level III centers that were less than thirty-two (32) weeks, there was a significant difference in the number of deaths by almost fifty percent (50%). In other words, the odds of dying for a very low birth weight baby and any baby less than thirty-two (32) weeks or 1500 grams was thirty-eight percent (38%), if the mother delivered in a Level I or Level II hospital; however, it was only twenty-three percent (23%) if the mother delivered in a Level III hospital. Babies that are delivered in Level III centers have a significant survival benefit over babies that are not, even if those babies have a University transport team at the time of delivery. Babies that are above thirty-two (32) weeks do not have the same risks; therefore, there is not a reason to bring one hundred percent (100%) of all babies to Little Rock to deliver. It is important to bring lower gestation babies to Level III facilities and in some cases to high-volume Level III facilities.

Next, Dr. Grimes mentioned that Arkansas has consistently had a worse infant mortality than the rest of the nation. He explained that infant mortality is the number of infants that die before reaching one year of age for every thousand live births per year. Neonatal mortality, which used to be focused on much more, is defined as the number of babies that died before

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<sup>4</sup> Arkansas Perinatal Overview Presentation (See attached)

<sup>5</sup> Lasswell SM, Barfield WD, Rochat RW, Blackmon L2010; Perinatal regionalization for very low-birth-weight and very preterm infants. Journal of the American Medical Association, 305:992-1000

reaching twenty-eight (28) days of age. It is more important to look at the babies that don't make it to their first year. Dr. Grimes stated, after doing some calculations with Dr. Whit Hall and Dr. Robert West, (Formerly MCH Medical Director ADH) it was determined that infant mortality rate could be lowered at least .5 per thousand if you could get the babies that were less than twenty-eight (28) weeks to deliver in Level III NICU units. That calculation translates out to 15 or 25 babies' lives every year that can be saved in Arkansas if we can get high risk babies to Level III facilities.

Slide seven indicated that Arkansas has made more progress in reducing racial disparity than anywhere else in the Nation at this point. Looking at any state, no matter how good infant mortality rate is, the African-American infant mortality rate is always going to be higher. The biggest problem is people confuse disparity with the word discrimination. The understanding of this is very important. For example, African-Americans are going to have the majority of babies with sickle-cell. However, it is not due to discrimination, it is due to their genetic makeup. What we are seeing are things that are not correctable. In other words we know there are some things we cannot fix. It is known that African-American mothers go into premature labor more often, and at earlier stages, than any other group of racial ethnic distributions. That is the single biggest cause of the African-American disparity. Until the problem of premature delivery is solved we are not able to eliminate this disparity.

It was then asked, why according to the graph was there such a jump in 2011. Dr. Grimes stated that part of the reason is because the numbers are so small they are not stable. Therefore, to get around that you need to look at averages over several years or large numbers like national statistics.

Slide eight indicated neonatal deaths, before the baby is twenty-eight (28) weeks old, by birth hospital. Due to the Department not being allowed to share hospital specific data with anyone, you must de-identify the data. However, a hospital can share their data with the public. UAMS and Baptist have made their data public. In the high-volume hospitals and low-volume hospitals you will notice that the line through each year is what is called confidence levels. As long as those don't overlap then that means those are statistically significant. In 2010 the red line and the blue line overlap so you could argue that those really are not any different even though the numbers are different. As you can see over the majority of the years they were statistically significant. This data is very consistent with the U.S. data.

Slide nine indicates neonatal deaths less than or equal to thirty-two (32) weeks gestation by Level III hospitals. To be low-volume Level III-A, you have at least twenty-five (25) admissions to your nursery per year that are less than thirty-two (32) weeks. However, to be a Level III-B, what is called high-volume, you have to have at least seventy-five (75) admissions to your nursery per year that are less than thirty-two (32) weeks. It was mentioned that the babies did not have to be born at that hospital; however, they had to be admitted to the nursery. From the standpoint of mortality, Laswell's statistics and the statistics that were shown charged the death to the birth hospital.

It was asked of the 15 to 25 babies saved, are those children, as they are being brought up, at higher risk for pulmonary problems, to do poorly in school, etcetera. What is the risk for that kind of development and what is the financial cost. Dr. Hall replied we do not know that information for Arkansas. However, it is known per national data that babies that have moderate to severe adverse neurodevelopmental outcome, which is about thirty (30%) of babies under one-thousand (1000) grams, there is a poor correlation of those babies to what happens at age seven (7) and eight (8). So some of those babies will do somewhat better than thought from when Bayley exams<sup>6</sup> were done at eighteen (18) to twenty-two (22) months. That data comes from National Institute of Child Health and Development and includes thousands of babies. Yes, there are significant problems and we know that many of these babies, even though they do not do well at eighteen (18) to twenty-two (22) months of age; many do much better when they begin school. However, the special education needs, the incidents of attention problems are as high as fifty percent (50%) in very low birth weight babies.

Next they were asked to go back to the Importance of Maternal Transport slide. It was clarified that the P value was set at less than .01; and therefore, if the study were done one hundred times you would get the same result more than ninety-nine times.

Then skipping to the Neonatal Death Less than or Equal to 28 weeks Gestation by Birth Hospital slide it was noted this would be of importance for the Board, knowing whether the redline truly is different from the blue today. It clearly was from 2005 through 2010. The data for 2011 and 2012 was not presented at the meeting. Dr. Grimes was asked to have that information available at the next Subcommittee meeting.

Dr. Grimes stated that the AAP, in the past, before they changed in 2012 had Level I, Level II-A and II-B, and Level III-A, B and C, Children's Hospital was a Level III C. With the new recommendations Children's Hospital would be or the equivalent of a Level IV with all others being Level III, II and I. This would eliminate all the A and B levels; however, it was mentioned in the AAP Report that volume was an important consideration. It was added that the national recommendations did not address volume because they could not agree on where the line should be according to geographic locations, not because they didn't think geographic locations were important.

Next, it was discussed that if a mother is less than thirty-two (32) weeks and greater than twenty-eight (28) weeks she should deliver in a Level III-A. The difference is if she were less than twenty-eight (28) weeks. At that time she would deliver in Level III-B instead of what the Minority Report wants which is to be able to call everybody Level III. It was asked what the rationale of the majority was for the split classification when confronted with the minority report. It was stated that the rationale was strictly for decreasing infant mortality. There were no other questions. The NICU Subcommittee of the Arkansas State Board of Health agreed they would like to have someone from the Minority Report to comment at the next meeting.

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<sup>6</sup> Bayley Scales of Infant and Toddler Development, Third Edition (Bayley-III®)

**Chairman's Report**

Dr. Fincher closed the meeting by stating he was hopeful that after the next Subcommittee meeting they would have a recommendation to be brought forth to the full Board in April. The meeting closed at 3:45.

Respectfully submitted,

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Clark Fincher, Subcommittee Chair

DRAFT

**Advisory Committee on  
Neonatal Intensive Care Unit Classification**

**CHARGE:** To create a report to the Director of the Arkansas Department of Health, no later than April 1, 2012, detailing the results of the following activities:

To study and recommend whether Arkansas shall adopt a classification system for Neonatal Intensive Care Units (NICUs) within the state;

If yes, to recommend appropriate designations and regulations for NICUs operating in Arkansas to the Director of the Arkansas Department of Health.

**SPECIAL CONSIDERATIONS:**

- Classification criteria
- Implementation criteria
- Timeline for implementation
- Entity responsible for designation
- Payor reimbursement scheme

**COMPOSITION:**

The NICU Advisory Committee shall consist of 21 members, as follows:

- (1) One (1) member appointed by the Director of the Department of Human Services to represent Arkansas Medicaid
- (2) One (1) member appointed by the Arkansas Chapter of the American Academy of Pediatrics
- (3) Two (2) members appointed by the Arkansas Chapter of the American College of Obstetricians and Gynecologists
- (4) One (1) member appointed by the Arkansas Academy of Family Physicians
- (5) One (1) member appointed by Arkansas Children's Hospital
- (6) One (1) member appointed by the Arkansas Hospital Association to represent Critical Access Hospitals
- (7) Two (2) members appointed by the Arkansas Hospital Association to represent hospitals with less than 100 beds
- (8) Two (2) members appointed by the Arkansas Hospital Association to represent hospitals with more than 100 beds
- (9) Four (4) members appointed by the Arkansas Chapter of the March of Dimes of which at least two (2) of the four (4) members shall be family members of infants born that utilized NICU services.
- (10) One (1) member appointed to represent the ANGELS program
- (11) One (1) member appointed to represent the Arkansas Foundation for Medical Care
- (12) Four (4) members appointed by the Arkansas Medical Society of which three (3) shall be neonatologists and one (1) shall be a maternal fetal medicine specialist.



# Arkansas Department of Health

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4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000

**Governor Mike Beebe**

**Nathaniel Smith, MD, MPH, Director and State Health Officer**

September 19, 2013

Dear Dr. Smith:

On behalf of the members of the Neonatal Levels Committee, attached please find our final report recommending levels of neonatal care and providing specific guidelines whenever possible.

Because a more structured approach to neonatal care in Arkansas offers the hope of more healthy babies and mothers, this submission represents a major milestone and the members of the Committee thank you and Dr. Halverson for the opportunity to be part of this effort.

While a unanimous recommendation from the Committee would have been helpful, we were simply unable to reconcile on a few key points. The most contentious was whether the number of small infants was relevant to the qualifications distinguishing Levels III A and IIIB. Consequently you not only have the majority report but also a minority report which articulates the points of concern raised by a minority of the members.

Note that the recommendations pertain not only to the Neonatal Levels but also include recommendations regarding obstetric and other perinatal capabilities which go hand in glove with neonatal care.

With the submission of this report, the work originally framed by Dr. Halverson is complete. However several key considerations not directly related to levels of care remain and would be important to address.

First, we believe it would be important to spell out the process of credentialing neonatal and perinatal programs: for example, how would programs apply, how would they be reviewed, what circumstances would lead to programs qualifying for a higher level of credential at a later time, what circumstances would result in a program being downgraded to a lower level of credential and how might all this be enforced.

Second, we know that one of the primary opportunities for improved neonatal outcomes is to be sure that smaller infants (i.e. anticipated to weigh less than 1000 grams at birth) are born at hospitals credentialed to handle such infants. Nothing outlined in the definition of levels would drive this change, although depending on enforcement this goal could be achieved.

Third, one of the drivers for the behavior of hospitals and physicians is reimbursement. Our Committee does not have the authority to set reimbursement. The payors in Arkansas, particularly Medicaid, do set reimbursement and should be encouraged to structure incentives and disincentives in conjunction with the Levels.

Fourth, we learned that there is much about neonatal care compartmentalized to individual hospitals and therefore we could not answer many questions for lack of information. Basic information such as is now available statewide (but anonymous) could be linked with more detailed clinical information such as is gathered by hospitals participating in the Vermont Oxford Network (VON). If hospital-identifiable data of this sort were available in a confidential environment (much as has been done with the Trauma System) there would be great opportunity to enhance the quality of care and the efficiency of the overall system.

The Committee is prepared to tackle this agenda if it is your pleasure to have us continue. On the other hand, you may wish to disband our group and appoint new members to take on these and other such matters.

Finally it should be part of the record that the support from the Department has been tireless and instrumental and the entire Committee is grateful

Sincerely yours,



Jonathan Bates, M.D.  
Chairman, Neonatal Levels Committee

# NICU (Nursery) Classification Committee Report

Final Report

September 5, 2013

# Dr. Nate Smith NICU (Nursery) Classification Committee Report

*Submitted By Dr. Jonathan Bates, Committee Chair*

9/5/13

## **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 1<sup>st</sup> 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 majority vote of the committee but were not unanimous. A minority report will be attached to this report. (See attachment # 2)
    - 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 27 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 1 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 majority 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.).
  - See Minority Report for their comments.
- **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.
      - Fifty percent (50%) 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. Paul Halverson and Jonathan Bates 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. Jonathan Bates; CEO 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 27 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 2 years, 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 27 weeks gestation (< 1,000 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.

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## Attachment

1. Minority Report

**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]

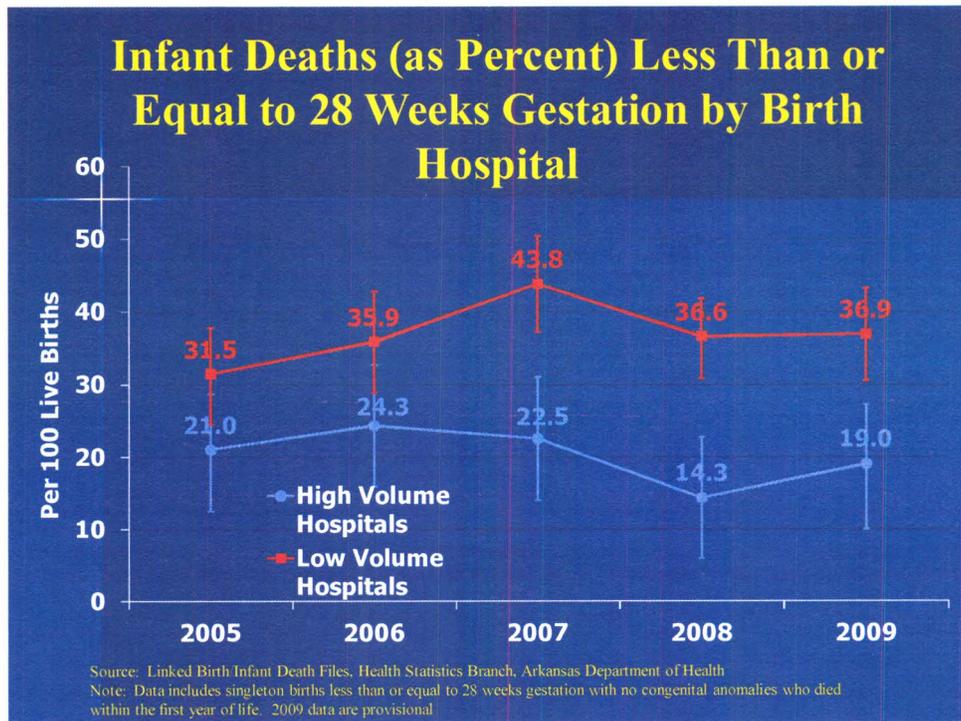
National Vital Statistics Reports, Vol. 60, No. 5, May 10, 2012 17

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

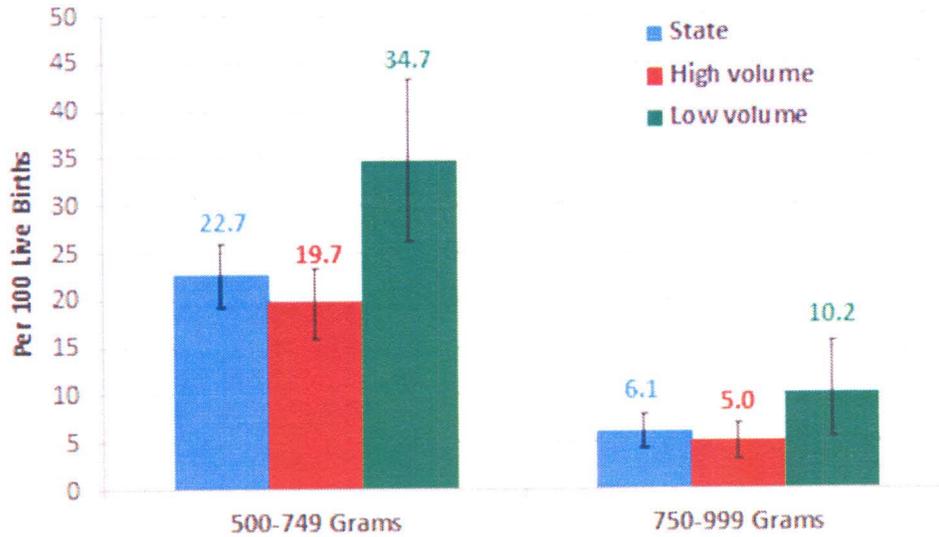
	<u>Overall</u>	<u>White</u>	<u>A/A</u>	<u>Hispanic</u>			
United States <sup>2</sup> .....	6.68	5.58	13.11	8.65	4.62	5.50	2.35
Alabama.....	9.47	7.67	13.73	*	*	7.50	1.79
Alaska .....	6.54	4.10	*	12.24	*	*	*
Arizona .....	6.54	6.04	14.85	7.57	6.54	6.13	2.46
Arkansas .....	7.89	6.70	13.53	*	*	5.71	2.02
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**



## Neonatal Deaths (as Percent) Less Than or Equal to 32 Weeks Gestation by Birth Hospital



Source: Linked birth-infant death files, Health Statistics Branch, Arkansas Department of Health. Data are limited to Arkansas occurrences, singleton births and infant deaths less than or equal to 32 weeks gestation with no reported congenital anomalies. High volume hospitals are defined as having greater than 75 births less than or equal to 32 weeks gestation per year. Neonatal deaths are defined as infant deaths that occur within the first 27 days of life.

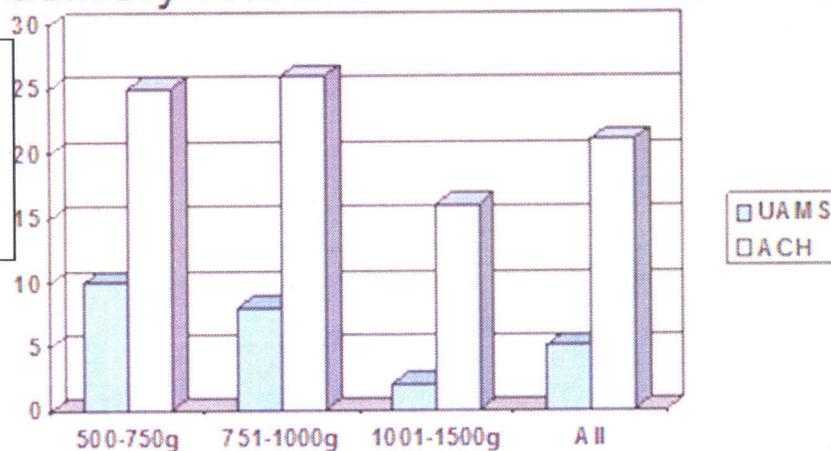
Graph #2

## 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)



Submitted by,

*Jim Bates*

Dr. Jonathan Bates

NICU (Nursery) Classification Committee Chair

September 5, 2013

# ARKANSAS PERINATAL LEVELS OF CARE REGULATIONS

## Dr. Halverson NICU (Nursery) Classification Committee Report

### Minority Report

April 2013

Bo Lin, MD; Sameer Wagle, MD  
Northwest Health System: Willow Creek Women's Hospital

Victor Coloso, MD,  
Sisters of Mercy Health System: Mercy Hospital Fort Smith

#### Minority Position – Physician Response

Dr. Halverson's NICU (Nursery) Classification Committee Report notes that the process of recommending an Arkansas classification system for Neonatal Intensive Care was delayed pending the release of the Guidelines for Perinatal Care, 7<sup>th</sup> Edition. However when the Guidelines for Perinatal Care, 7<sup>th</sup> Edition, was released, the Committee Report contained significant deviations from the 7<sup>th</sup> Edition. This minority report will focus on those significant deviations.

In general, the Committee Report proposes a public policy and regulatory framework that is restrictive, prescriptive and regressive. The Committee's recommendations disregard the flexibility that is the overarching theme in the Guidelines for Perinatal Care, 7<sup>th</sup> Edition. The most restrictive criteria in the Committee Report is the volume threshold proposed to qualify as a Level IIIA or Level IIIB NICU. Splitting Level III NICU into IIIA and IIIB is also a significant deviation from the Guidelines for Perinatal Care, 7<sup>th</sup> Edition.

#### Discussion

The neonatology literature has abundant and consistent evidence that very low birth weight (VLBW) infant delivery in higher volume, higher level NICUs leads to better survival and outcomes (1-4). These studies show that the effect of hospital volume of VLBW infants in isolation is greater than the impact of the hospital level of care. When adjusted for patient and hospital characteristics, the odds for mortality increase significantly with decreasing annual volume from above 100 to below 25 for even the highest Level IIIC and Level IV NICU-see Fig 1 (2).

Various approaches of risk adjusting for inherent biases in these observational studies, such as deductive logic theory for multivariate model construction (2), multilevel modeling (3) or instrumental variables' approach, (5) show even greater benefit of survival in a high volume (>100 VLBW per year) and a high level NICU.

However, in spite of the strong evidence in the literature, implementation of volume based criteria has proven difficult. Among western developed nations with single payor national health systems, only Portugal and Finland have been able to regionalize perinatal care based on volume (6). No state in the United States has successfully used volume requirements to defining levels of NICU care or to regionalize perinatal care to transfer high risk pregnant women to high volume centers preferentially. The Vermont Oxford Network (VON) prospective database has shown that the annual volume of VLBW infants only explained 9% of variation in mortality rates

between NICUs. For this reason, we propose that direct measures of patient outcomes be used for regionalization rather than volume criteria (7).

The recent analysis of VON has shown that quality based strategies are considerably more effective in improving VLBW outcome than volume based strategies (8, 9). The Guidelines for Perinatal Care, 7<sup>th</sup> Edition, has refrained from using volume as a requirement in defining levels of neonatal care. The 7<sup>th</sup> Edition recommends that the Guidelines should serve as a foundation to standardize nomenclature for public health departments, state health departments and national organizations to develop consistent standards of service. The 7<sup>th</sup> Edition emphasizes that a Level III NICU designation should be based on a region's consideration of geographic constraints, population size and personnel resources (10). The 7<sup>th</sup> Edition, in fact, advocates the same level of care and services for babies under 1500 gm birth weight (VLBW) as for babies under 1000 gm birth weight (Extremely low birth weight-ELBW) babies. This proposal is based on consistent evidence of better survival in a Level III NICU that emphasizes subspecialty support and round the clock Neonatology coverage. This consistent evidence of better survival in Level III NICU is a major reason for the new guidelines in the 7<sup>th</sup> Edition (10).

The best evidence of the effect of regionalization comes from the Greater Cincinnati region where all high risk deliveries were transferred to 2 regional subspecialty perinatal centers. While this regionalization effort achieved close to 90% of infants delivered in Level III NICUs (Healthy People 2010 objective), the infant mortality rate for VLBW infants, in fact, worsened for the region and went from 146.6 to 198 (11,12). This change in mortality was mostly related to worsening mortality in the small regional NICUs. The studies showing actual benefit of regionalized perinatal care delivery by time sequence analysis are lacking in the US, although the evidence supporting it is very consistent and strong (personal communication with CS Phibbs).

There is also strong evidence in the literature that the lack of availability of a NICU in underserved areas leads to increased mortality (13, 14, 15). There is consistent evidence that there is a significant physiologic instability and decline during transport of extremely preterm infants (16) that leads to more morbidity and mortality (17, 18). The transfer of preterm newborns should be minimized by promoting maternal transfers and by limiting transfers only to those newborns born in facilities incapable of caring for them, such as a VLBW infant born in a facility with a Level II NICU. Arkansas has many rural areas where access to NICU care is very limited, see Fig 2. (19).

As a result of this evidence from the literature, several authors have suggested that annual VLBW volume of 50 may be used as a threshold to regionalize the care for high risk infants in rural states such as Arkansas. See Fig 3 and 4 (20, 21). This threshold corresponds to an average daily census of about 15 patients or annual deliveries of about 2000 (22).

We (Doctors Lin, Wagle and Coloso) recommend that the levels of NICUs in Arkansas be based on resources and follow the Guidelines for Perinatal Care, 7<sup>th</sup> Edition. The Level III NICU should not be divided into IIIA and IIIB.

(Dr. Lin is Board Certified in Pediatrics, Neonatal-Perinatal Medicine)  
(Dr. Wagle is Board Certified in Pediatrics, Neonatal-Perinatal Medicine)  
(Dr. Coloso is Board Certified in Pediatrics, Neonatal-Perinatal Medicine)

### **Public Policy Implications – Health Systems Response**

Northwest Health System and Mercy believe that it is important for the state to adopt a perinatal classification system. We agree that the Arkansas Department of Health should implement and regulate a NICU classification system for the state of Arkansas. Northwest Health and Mercy concur in the recommendation that the state adopt the Guidelines for Perinatal Care, 7th Edition, published by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. The 7<sup>th</sup> Edition provides an up-to-date and flexible framework for state policy. However, the Committee has chosen to recommend a highly structured regulatory mandate with volume based criteria--recommendations that are not in harmony with the flexibility of the 7<sup>th</sup> Edition (the latest thinking of the AAP and ACOG) nor with the trends in surrounding states that have an established record of regulating levels of care. The Vermont Oxford Network has adapted the 7<sup>th</sup> Edition in data collection and comparisons (23).

In an unpublished survey of 15 states, Dr. Coloso found that volume based criteria was almost nonexistent, and that other states would be incorporating the guidelines of the 7<sup>th</sup> Edition into their regulatory programs on an “as soon as practical basis.” Specifically, the Texas NICU Council considered and rejected a volume criterion, choosing to adopt the 7<sup>th</sup> Edition as the best policy for their rural areas. New York and Arizona have criteria based on total deliveries, not VLBW. Massachusetts has removed the total delivery volume criteria.

Dr. Coloso consulted members of the AAP Committee on Fetus and Newborn. Dr. W. A. Carlo, (U of Alabama) indicated that a volume criterion was specifically not included in the 7<sup>th</sup> Edition and that the subdivision of Level III into A&B was not critically important. Dr. Lu-Ann Papile, Chairperson of the Committee, reviewed the Committee’s rationale with Dr. Coloso and confirmed that, after a significant study and review process, agreed that separation of Level III into A & B was unnecessary, the literature was not adequate on the effect of volume (the only published data is from CA) and the AAP seeks to provide guidelines that will be of value to states with rural areas and significant distances to overcome.

The 7th Edition deliberately does away with the subdivisions of Level III, stating that “Local circumstances must dictate the way in which these guidelines are best interpreted to meet the needs of a particular hospital, community or system” (24). Dynamic changes are occurring in the Arkansas health landscape led by the policy to expand Medicaid via the commercial health insurance plans and through changes in the health benefits’ payment model. The trends and factors that are relevant to the consideration of public health policy include:

- the rapid population and economic growth in Northwestern Arkansas
- the large capital investment in new tertiary hospital facilities in North East Arkansas
- the significant expansion of access to health benefits through the ‘private option’ for Medicaid
- the state initiative to stimulate the development of and access to the Patient Centered Medical Home model of care
- technology transformation reflected in the growth of electronic messaging between providers
- the use of the EMRs and telemedicine access to support and expand access to subspecialty consults

- and the episode of care and best practice focus emerging from the Arkansas Payment Improvement Initiative

Public policy that would institute inflexible criteria by codifying case volume limits for the delivery of service is not consistent with the flexibility intended by the authors of the 7th Edition and is not consistent with the delivery of NICU services that would best serve the people of Arkansas.

Neonatal intensive care is available in Fort Smith and Johnson. Both communities have placed a high value on the availability of local, high quality, family-centered new born care and have generously contributed to the expansion of neonatal services through fundraising and volunteerism. The development of the neonatal services at Mercy and Northwest Health System facilities began with requests from the community. Mercy and Northwest Health System, on behalf of the communities we serve and based on our extensive commitments to provide the highest quality of service, opposes creating a hierarchy of NICUs that would limit neonatal access and expansion in the already populous and rapidly growing western quarter of the state.

The Committee Report will include a document circulated among the members as *ATTACHMENT A: ARKANSAS PERINATAL LEVEL OF CARE REGULATIONS (Version 6 Final)*. Mercy and Northwest Health System contend that the components of the draft regulations should be subjected to a review process that contains representatives of nursing, hospital operations executives and perinatal service line managers. In line with the tenants of the 7<sup>th</sup> Edition, a broader base of nursing and operational expertise would add value to the Committee's strength in maternal-fetal medicine and neonatology.

Richard R. Nugent, MD MPH, has provided the Committee with an instructive and useful paper, *Planning for Perinatal Regions in Arkansas*. Rather than making the case for fixed criteria, Dr. Nugent establishes a flexible framework for policy discussions and provides a graphic platform for the presentation of Infant Mortality Rate and other data elements. The regional border concept based on a two-hour driving time from Little Rock is a picture of centralization, not regionalization. A viable alternative (and a realistic overlay) for consideration in policy development is a service area based on 90 minutes driving time each from Rogers-Johnson-Fayetteville, Fort Smith, Jonesboro, Texarkana, Pine Bluff and Hot Springs. These locations are the hubs of hospital services in Arkansas and rural communities turn to these facilities for tertiary care. Give the credible deliberation behind the 7<sup>th</sup> Edition and the rural landscape of our state; Mercy and Northwest Health System contend that the recommendation to establish two classes of Level III NICU care with codified volume criteria is not the most progressive policy to reduce IMR and to serve the socio economic character of Arkansas. While there is substantial agreement between the Committee's clinicians and hospitals on many elements of improving IMR, the volume criteria is an impasse issue threatens the consensus for rapid deployment of a collaborative system of perinatal and neonatal services.

In Summary:

The volume requirement in the proposed guideline for Level IIIA and IIIB are arbitrary and highly restrictive for less urbanized states like Arkansas. The Guidelines for Perinatal Care, 7<sup>th</sup> Edition,

has no such recommendation or requirements. The Committee chose references citing specific volume criteria. However, other references can also be cited that suggest no volume requirements or lower volume requirements.

Overly aggressive volume criteria will further limit access to the appropriate level of care for women and infants in Northwest Arkansas. Arkansas currently ranks low on access, and criteria that could further limit access is inconsistent with the goal of reduced infant mortality.

The proposed criteria have no specific quality metrics. Some limited hospital mortality has been reference and shared, but there is no consideration for morbidities or NICU specific outcome data. The mortality data does not correlate with the gestational age in the proposed criteria. (Mortality less than and equal to 28 weeks gestation vs. volume requirements that are based on less than 32 weeks gestation.)

According to the February 7, 2013 NICU CAC Minutes, the Committee Chair, Dr. Bates requested:

“Dr. Bates made a suggestion for consideration by the NICU CAC on the issue of Volume Requirements:

- Why have it either/or?
- Why not have a combined requirement that says you have to have certain proven results. For any Level III and above that participates in VONS - get the Committee together for review of information to include:
  - 1) minimum performance in terms of VONS and
  - 2) Set up a modest threshold for volume.
- As time goes on the thresholds can be increased accordingly. It would also help establish an entrance level threshold for future use.”

The CAC chose to disregard this request.

The criteria as proposed are overly restrictive, prescriptive and regressive. In its current form the criteria will limit access for the families in Northwest Arkansas where high quality NICU services are currently provided.

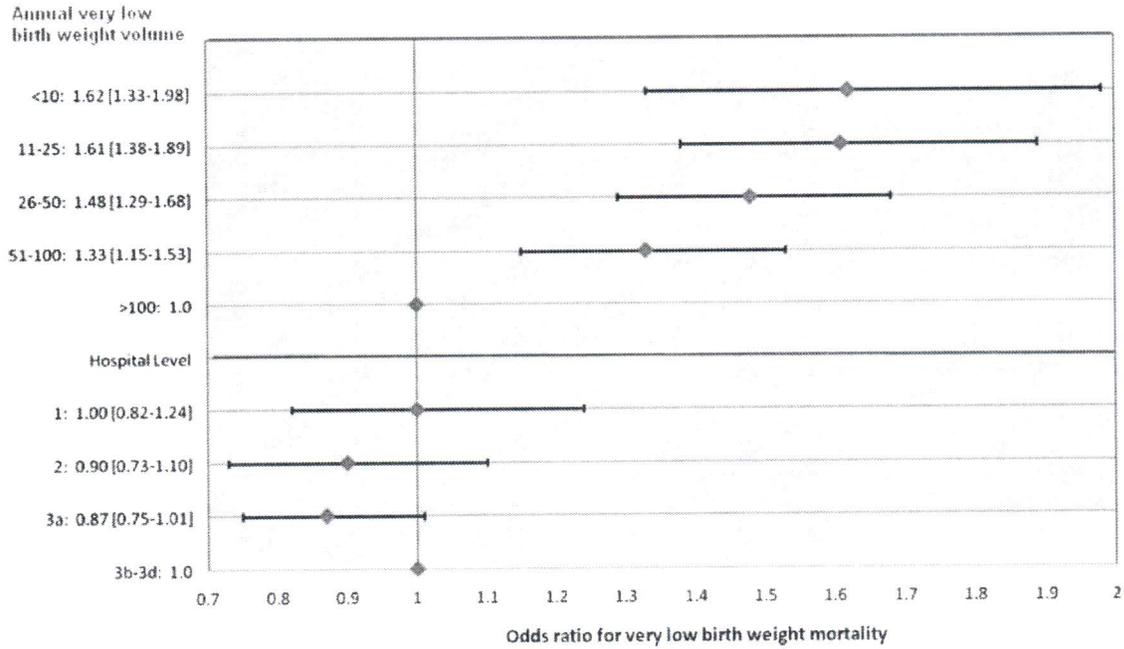
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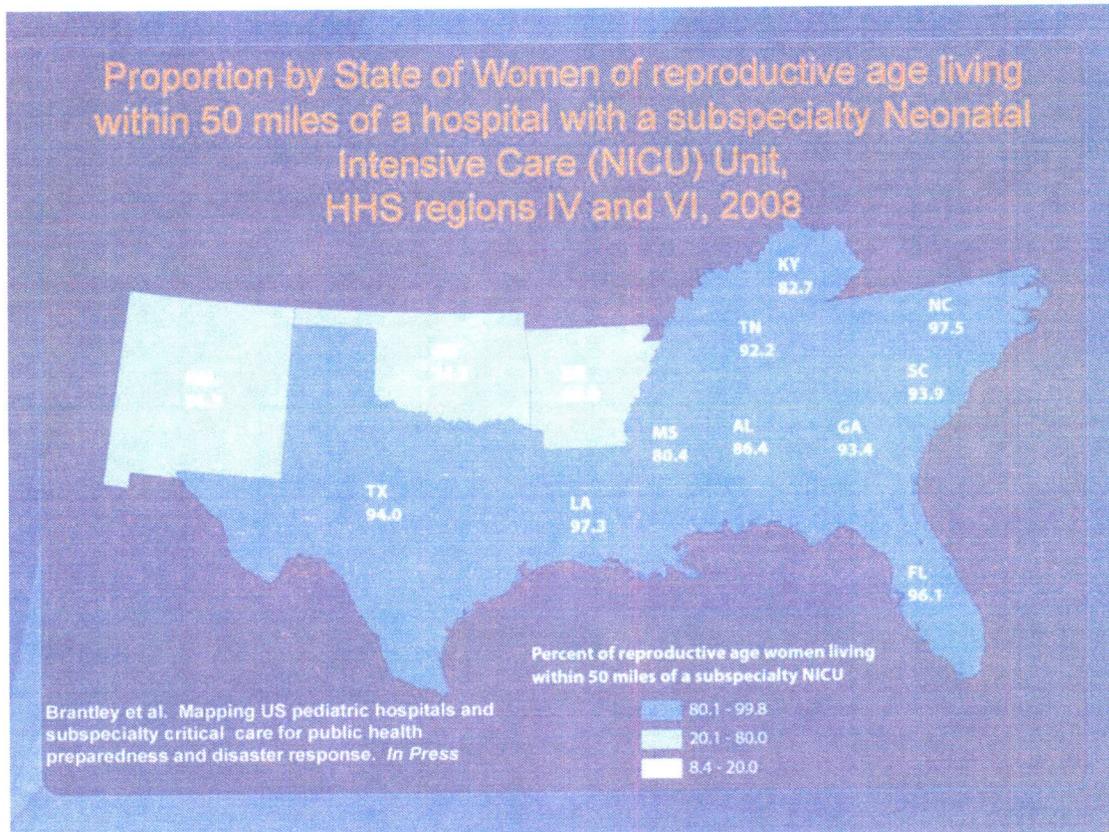
**FIGURE 1.**

Adjusted odds ratios (OR) and 95% confidence intervals (CI) of very low birth weight mortality for hospital-level and –volume categories, assessed independently, in California obstetrical hospitals (1997–2002). Very low birth weight mortality includes in-hospital fetal deaths, deaths within the first 28 days of life, and deaths within the first year of life among infants who were continually hospitalized from birth. Adjusted logistic regression model includes annual volume categories, level categories, demographic characteristics, maternal and fetal antenatal factors, delivery factors, and year of delivery (2).



**Figure 2.**

Barfield Wanda. Director, Division of Reproductive Health Region IV & Region VI Infant Mortality Summit January 12, 2012. Preventing Infant Mortality and Preterm Birth: Looking Beyond the Baby.



### Figure 3.

622 Holmstrom & Phibbs

in 1990 more than 80% of the smaller, lower-level NICUs were within 25 miles of an existing large tertiary facility, and this trend has only intensified over time.<sup>24</sup> This proliferation of NICUs also has meant that in many moderate-sized communities there are two or more smaller NICUs instead of a single large facility. In California in 2000 the authors found that 92% of VLBW deliveries occurred in geographic areas with at least 100 VLBW infants.<sup>25</sup> Although not everywhere is as urbanized as California, if treating 50 VLBW infants is considered as the threshold for a high-volume NICU, most VLBW deliveries (and other high-risk deliveries) occur in geographic areas where regionalization is feasible.

#### WHY HAS DEREGIONALIZATION OCCURRED?

### Figure 4.

and infant outcomes as well as reduction in overall health care costs. The other aspects of the plan would include cost-containment strategies with reimbursement restructuring, perinatal health prevention, community intervention strategies, mandated referral patterns, and plan enforcement regulations.<sup>2,16,20</sup> All of these items would be needed as part of the policy to ensure optimal patient outcomes as well as cost-effectiveness. Maximal cost reductions will be demonstrated as interventions to delay premature delivery are instituted at the regional centers. For each 2-week increase in gestational age, there is a median cost savings between \$28 870 and \$64 021 for infants born before 33 weeks.<sup>10</sup> Morbidities and long-term neurodevelopmental outcomes improve substantially for every 2-week increase in the gestational age<sup>26</sup> as well (Tables 2 and 3).

#### RECOMMENDED SOLUTION

Formal regionalized systems of care, as discussed in policy option 4, are recommended and supported by

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meet requirements as follows:  
Another barrier to be navigated involves compensation for obstetrical care. Currently, reimbursement for prenatal care is tied to delivery codes in most states. Obstetricians are understandably hesitant to transfer mothers to tertiary facilities where they cannot deliver the infant. This increases the number of VLBW infants delivered at small community hospitals.<sup>16,29</sup> Obstetrical providers should support public health efforts and perinatal health systems to ensure that all women have access to a strong system of risk-appropriate perinatal care.<sup>16</sup> All mothers/infants less than 31 weeks' gestation should be referred to a level III facility with the understanding that the best mode of transport for the infant is an intrauterine transport of mother.<sup>28</sup> The level of care available at the hospital of birth has much more impact on mortality risk than the level of care the infant eventually receives. Therefore, it is preferable that the level III facility designated as a regional or tertiary center have an average annual VLBW admission rate of at least 50<sup>24,31</sup> and at least 2000 total deliveries a year.<sup>30</sup>

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# 2012 Arkansas Infant Mortality Summary

- **37,993** babies were born to Arkansas residents.
- **247** babies died before their first birthday.
- **Only 0.8 % of babies delivered on or before 28 weeks but accounted for 29.1% of infant deaths in AR.**

Data source: Health Statistics Branch, Arkansas Department of Health.

2012 data are provisional.

# Regionalization

- Meta-analysis of 41 publications comparing level 3 centers with lower level units
- Odds of death of VLBW infants
  - 38% (Levels I and II) vs. 23% (Level III)  
(adjusted odds ratio [aOR], 1.62; 95% confidence interval [CI], 1.44–1.83).

## Odds of death of ELBW infants

- 59% (Levels I and II) vs. 32% (Level III)  
(aOR, 1.80; 95% CI, 1.31-2.46)

# Arkansas History

- Arkansas IMR has consistently been higher than the US average.
- Arkansas is one of only 3 states that have never had designated NICU levels.

# Brief Review

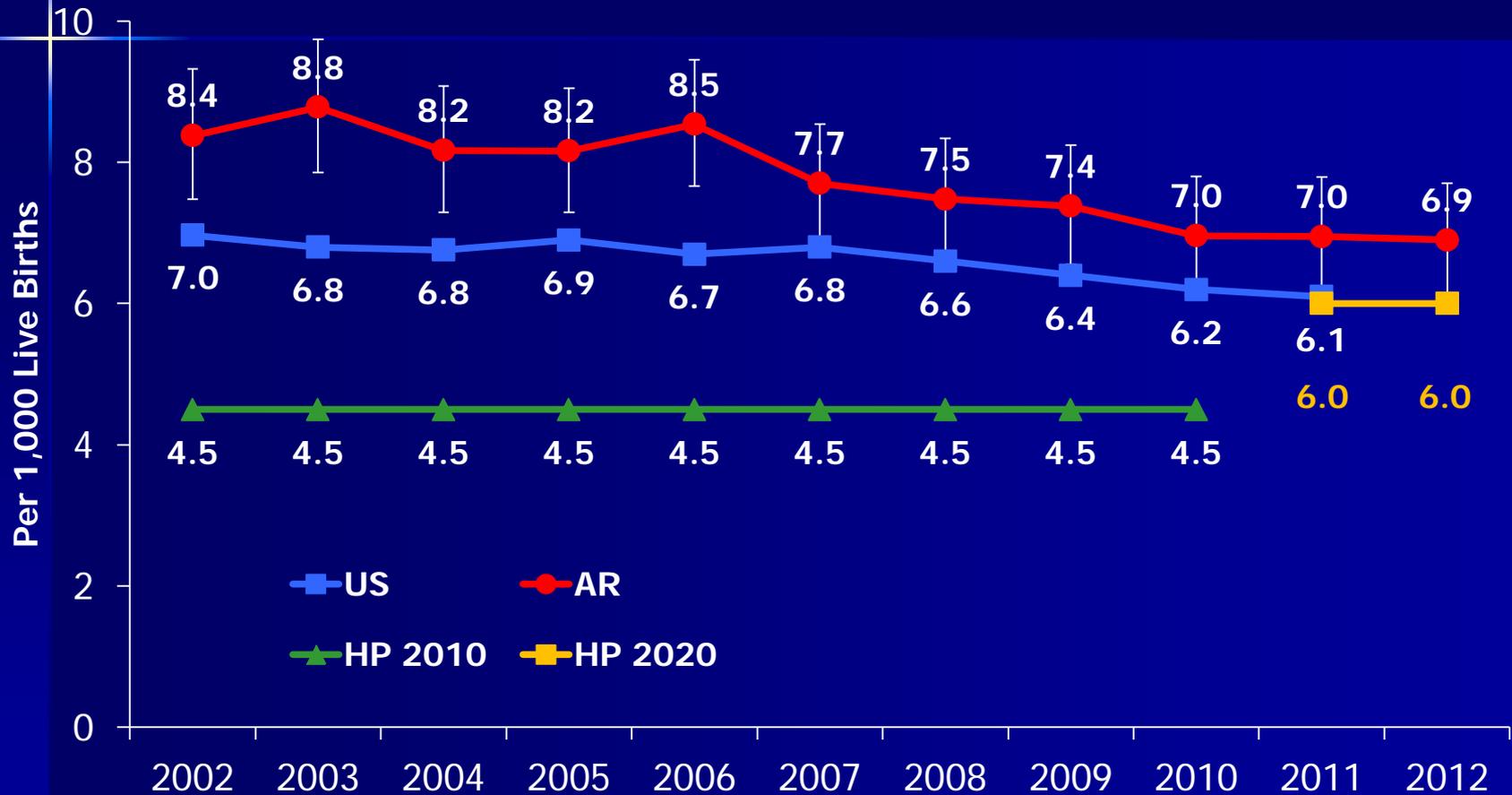
- Infant mortality rate is the number of infants dying before reaching one year of age, per 1,000 live births per year.
- Neonatal mortality rate is the number of infants dying before reaching 28 days old per 1,000 live births per year.

# Arkansas Mortality

- If 80-95% of all newborns less than 28 weeks were to deliver in a Level 3 NICU (vs. Levels I and II), IMR would be lowered by at least 0.5/1000. (Dr Whit Hall UAMS 2011)
- That means 15-25 babies could be prevented from dying each year. (Dr Bob West ADH 2011)

Data source: Health Statistics Branch, Arkansas Department of Health and National Center for Health Statistics (NCHS)

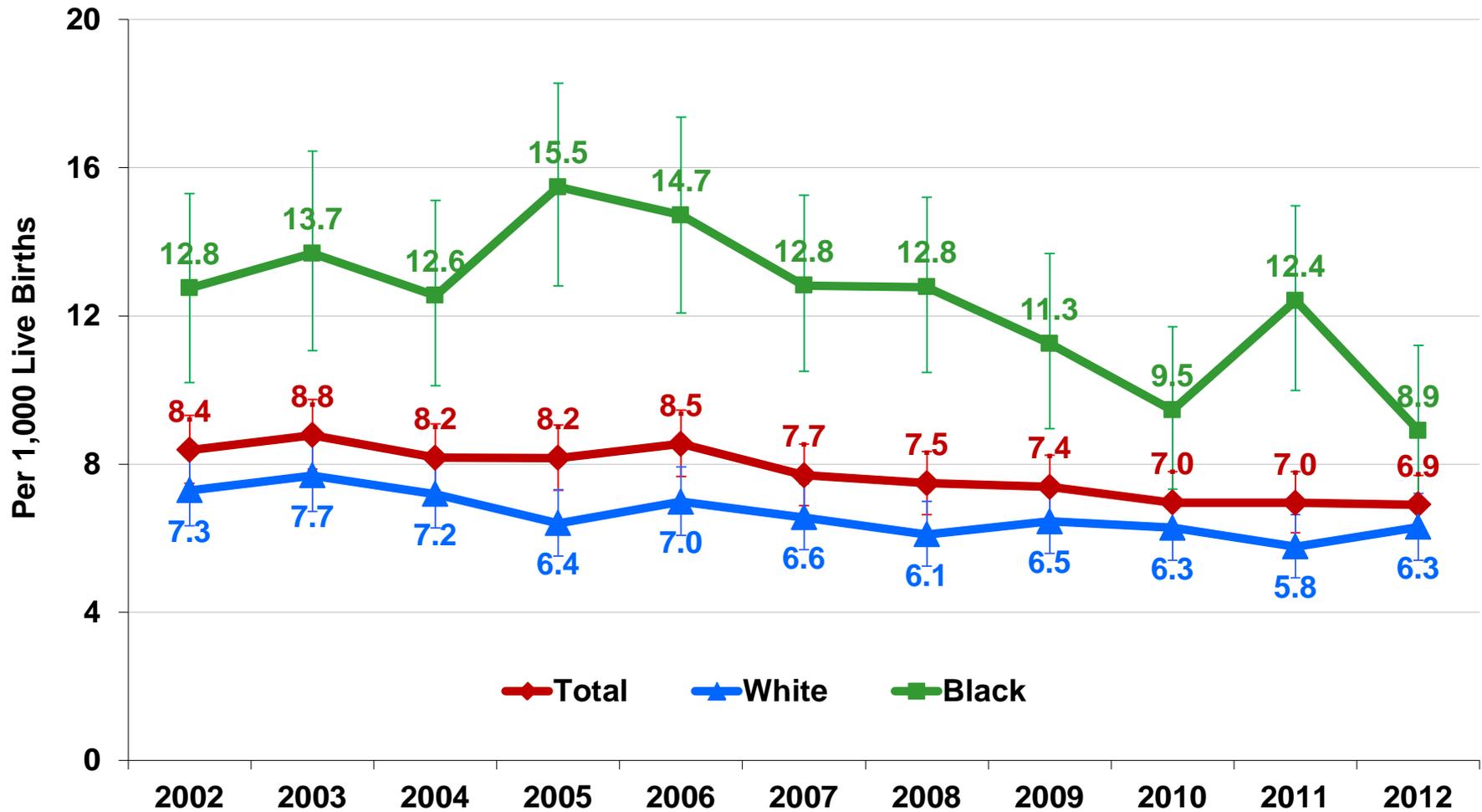
# Infant Mortality Rate



Data sources: Health Statistics Branch, Arkansas Department of Health and National Center for Health Statistics (NCHS)

Data for 2007-2012 are provisional.

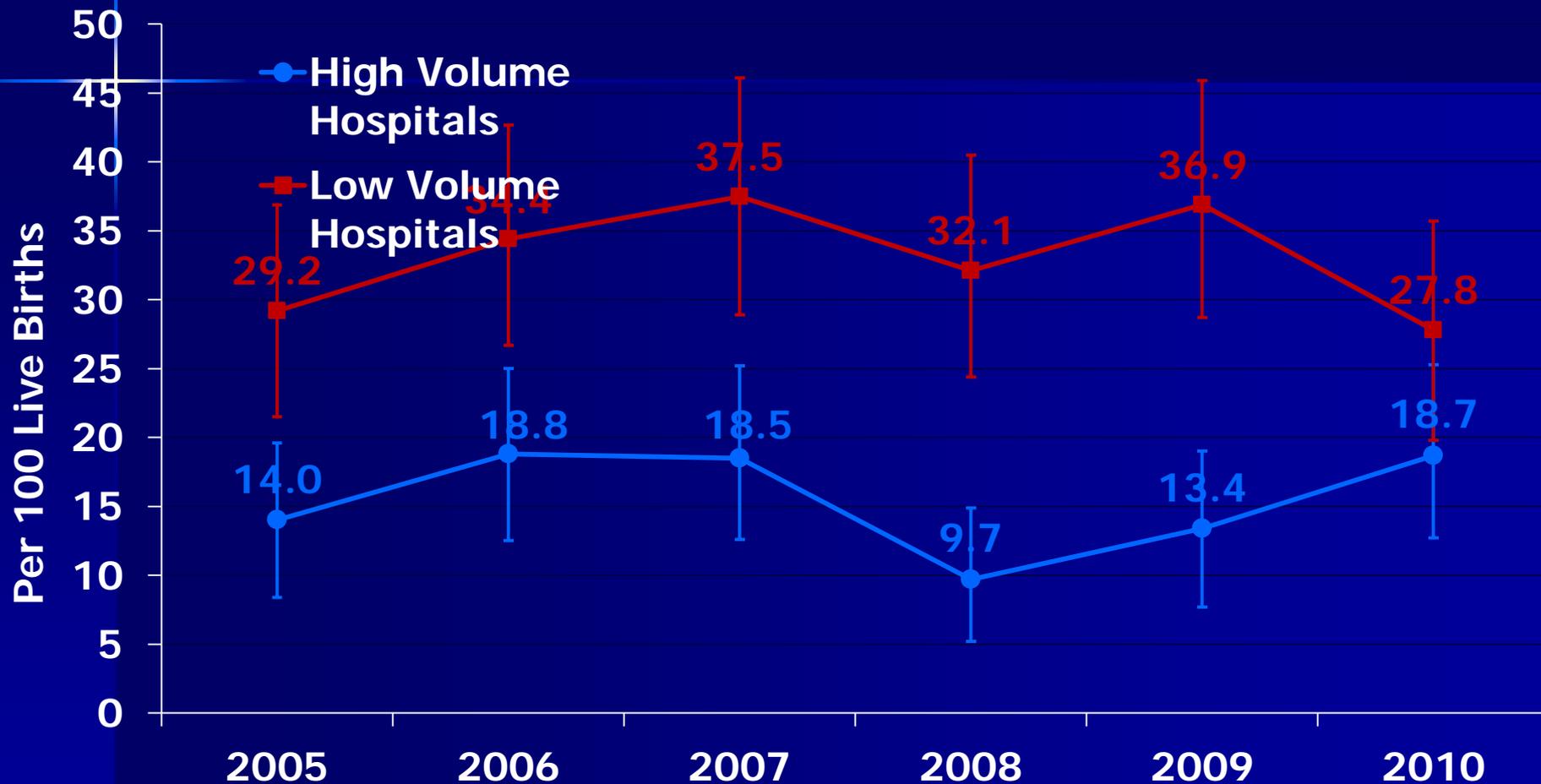
# Infant Mortality Rate by Maternal Race, Arkansas Resident Births



Source: Linked Birth/Infant Death Files, Health Statistics Branch, Arkansas Department of Health

2007-2012 data are provisional

# Neonatal Deaths Less Than or Equal to 28 Weeks Gestation by Birth Hospital



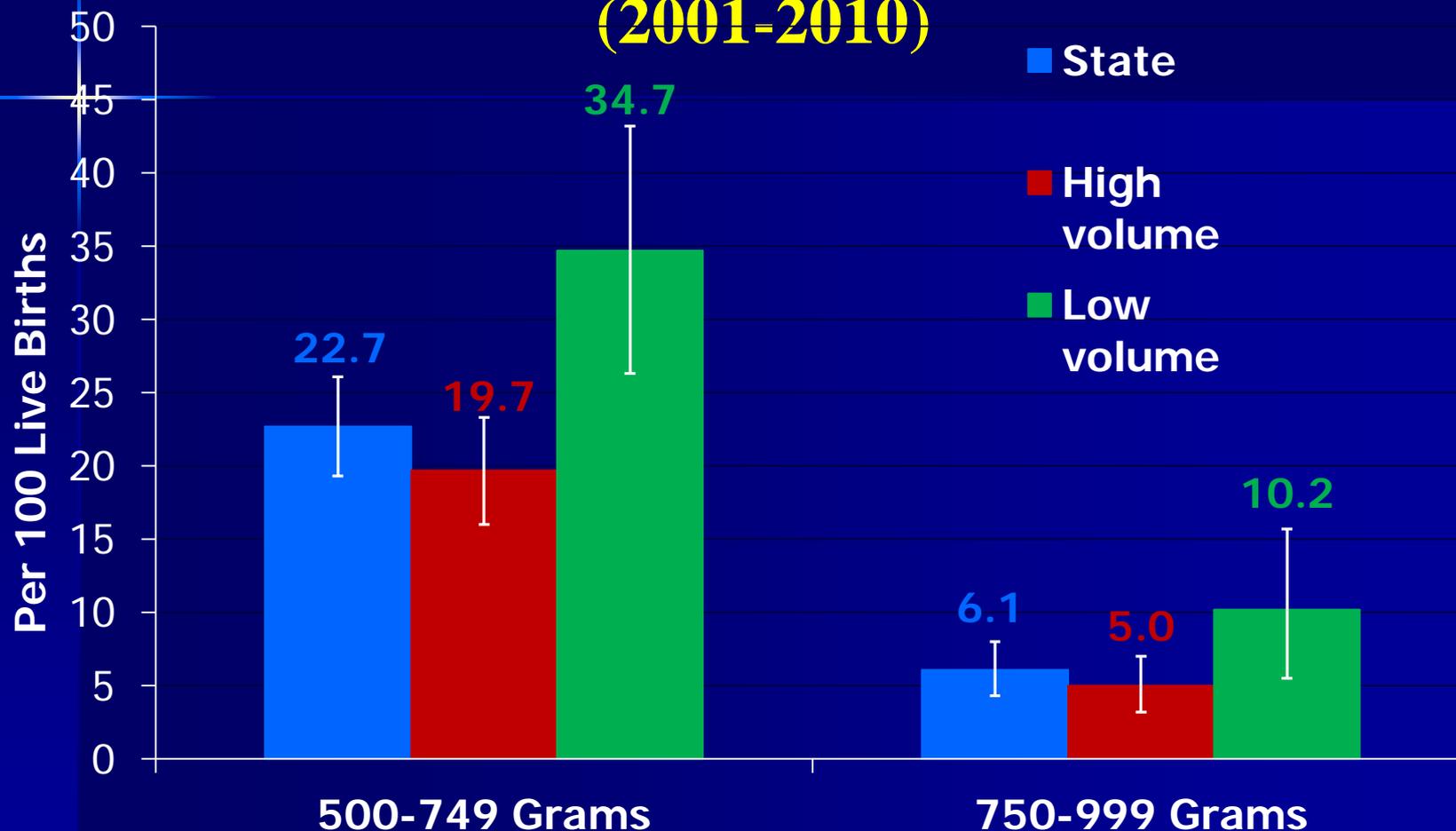
Source: Linked Birth/Infant Death Files, Health Statistics Branch, Arkansas Department of Health

Note: Data includes singleton births less than or equal to 28 weeks gestation with no congenital anomalies who died within the first 28 days of life.

High volume hospitals are defined as having >40 births at less than or equal to 28 weeks gestation per year.

2009 and 2010 data are provisional

# Neonatal Deaths (as Percent) Less Than or Equal to 32 Weeks Gestation by Level III Birth Hospitals (2001-2010)



Source: Linked birth/infant death files, Health Statistics Branch, Arkansas Department of Health

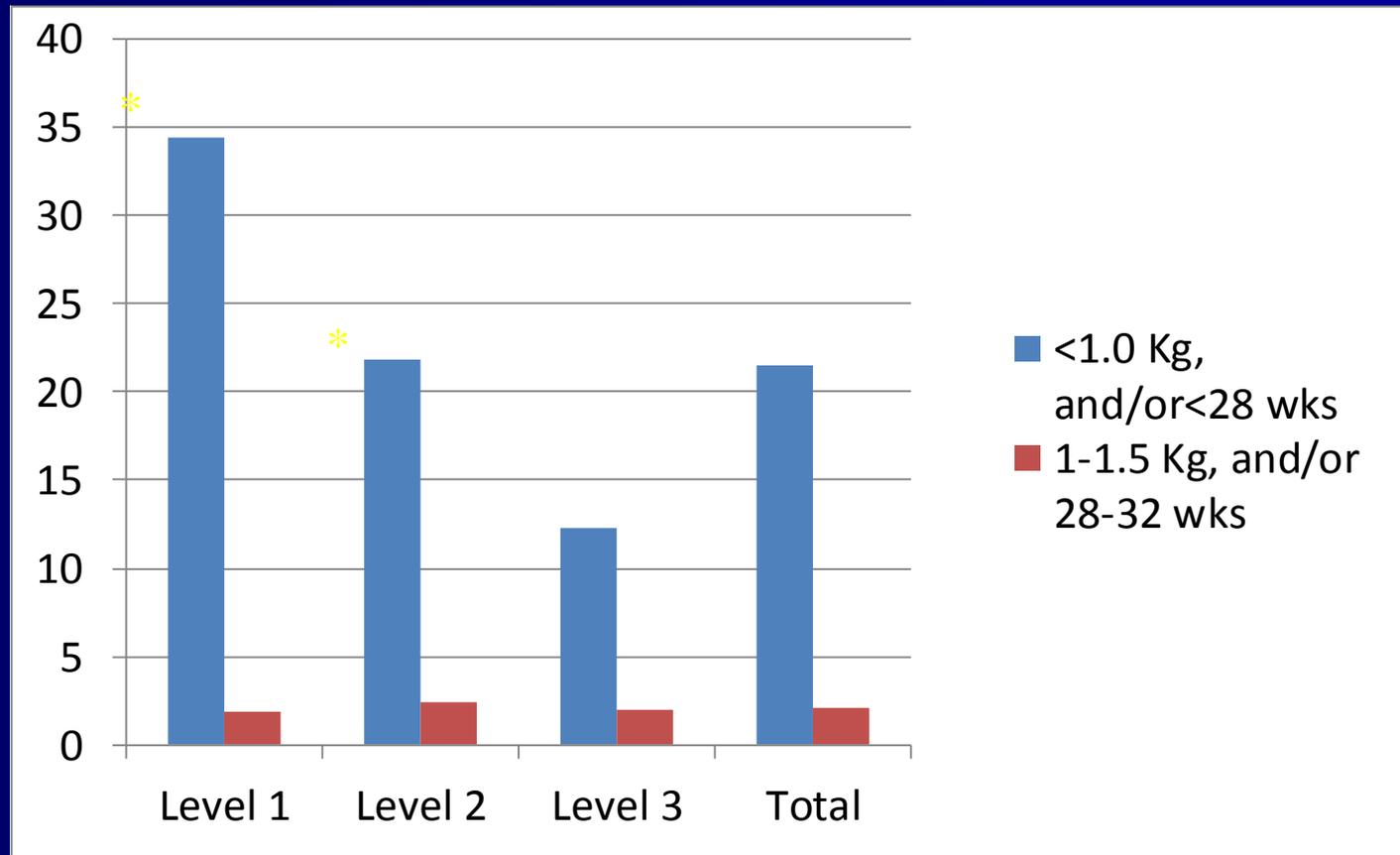
Data are limited to Arkansas occurrence singleton births and infant deaths less than or equal to 32 weeks gestation with no reported congenital anomalies.

High volume hospitals are defined as having greater than 75 births less than or equal to 32 weeks gestation per year.

Neonatal deaths are defined as infant deaths that occur within the first 27 days of life.

# The Arkansas Story

% Deaths



Nugent R, Golden WE, Hall R, Bronstein J, Grimes D, Lowery C. Locations and outcomes of premature births in Arkansas. JAMS. 2011;107(12):258-9.

# Importance of Maternal Transport For Reducing Infant Intraventricular Hemorrhage

(Palmer 2005 Journal of Perinatology)

Percent

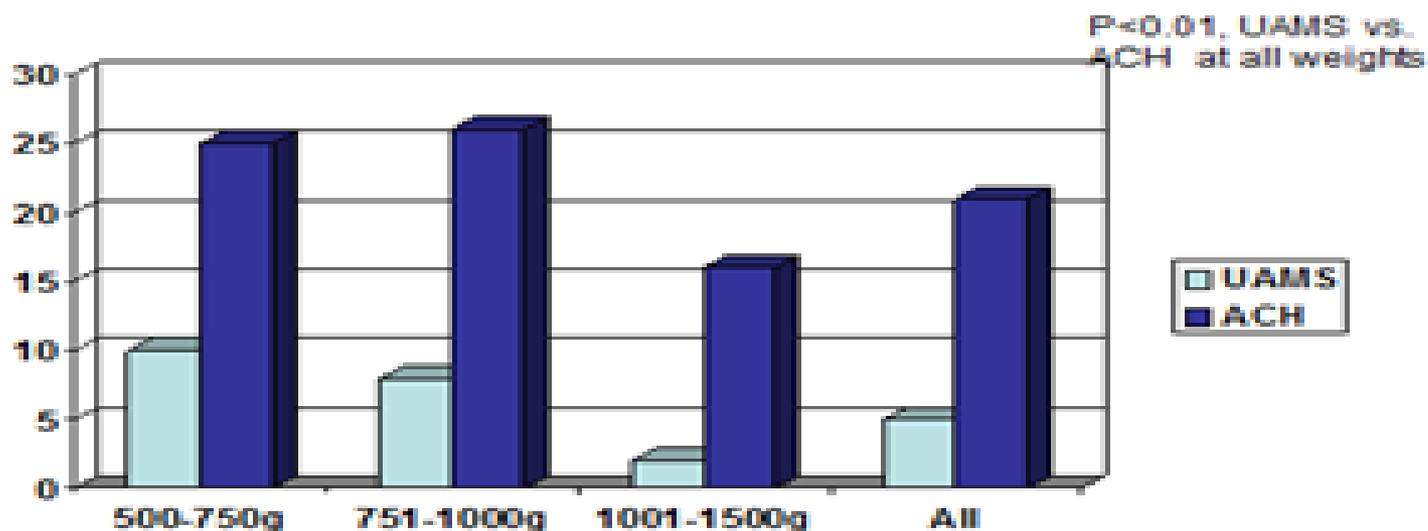


Figure 8. Comparison of grades 3 and 4 intraventricular hemorrhage for UAMS (inborn) vs ACH (outborn) neonates for 2001-2004

**THANKS!!**

**Your thoughts and  
questions??**