



Being Born at the Right Place: Definitions and Data Collection on Neonatal Levels of Care

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Promotion, Centers for Disease Control and Prevention

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Acknowledgements

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Disclaimers:

Nothing to disclose

*The information presented does not necessarily reflect the official position of the Centers for
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Learning Objectives

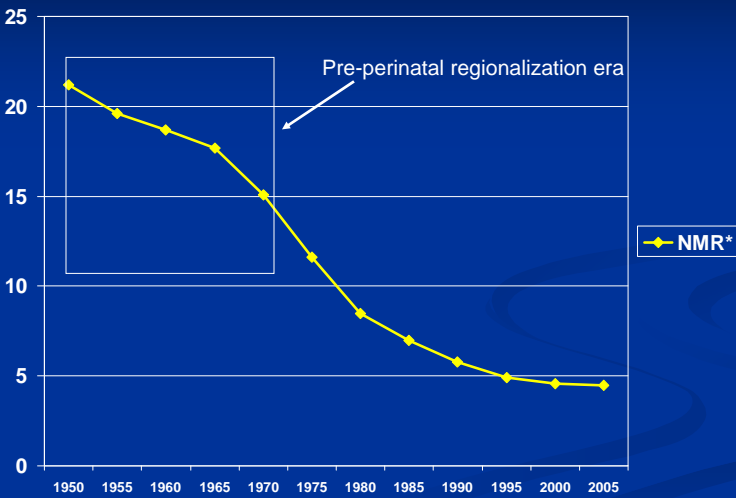
- Understand neonatal levels of care definitions
- Review evidence on the effectiveness of perinatal regionalized systems
- Learn about current data sources on perinatal regionalized systems
 - State definitions
 - 2003 revised birth certificate data
 - MCHB performance measures
- Identify ways to improve perinatal regionalized systems

History of Newborn Services Concepts and Standards

- AAP Committee on Fetus and Newborn
 - Hospital Care of Newborn Infants (1948 – 1977)
 - Level II Neonatal Units (1980)
 - Levels of Newborn Care (2004)
- Committee on Perinatal Health
 - Toward Improving the Outcome of Pregnancy I (1976)
 - Toward Improving the Outcome of Pregnancy II (1993)
- AAP/ACOG, CoFN/CoOP
 - Guidelines for Perinatal Care (1983-2007)



U.S. Trends in Neonatal Mortality: Advances in Intensive Care



*NMR=neonatal mortality rate: # deaths to infants <28 days/1,000 live births

Does Perinatal Regionalization Still Influence Outcomes?



VLBW Mortality is **Lower** for Infants Born in a Level 3 Center

- Shown in multiple studies since 2004 including
 - US
 - California, New York, Missouri, South Carolina, Missouri
 - Sweden – national registry
 - Finland – national registry
 - France - EPIPAGE

Morbidity is **Lower** for VLBW
 Infants Born in a Level 3 Center
 848 infants 500-1499 g in Cincinnati region

Risk adjusted	OR	95% CI
Death/major morbidity	2.64	1.70-4.17
Mortality	1.87	1.02-3.45
BPD or death	2.55	1.58-4.13
ICH or death	2.96	1.80-4.90
ROP or death	2.63	1.47-4.74

1995-97 births

Warner et al Pediatrics 2004; 113:35-41

VLBW Mortality is **Lower** at a
 Higher Level 3 Volume

Linked birth-death certificates, California VLBW infants,
 1991-2000, n = 66,838

Level and Volume	OR	95% CI
Level 3B or 3C		
≤ 25	1.51	1.17-1.95
26-50	1.30	1.12-1.50
Level 3B, 3C, or 3D		
51-100	1.19	1.04-1.37
>100	1.00	Ref

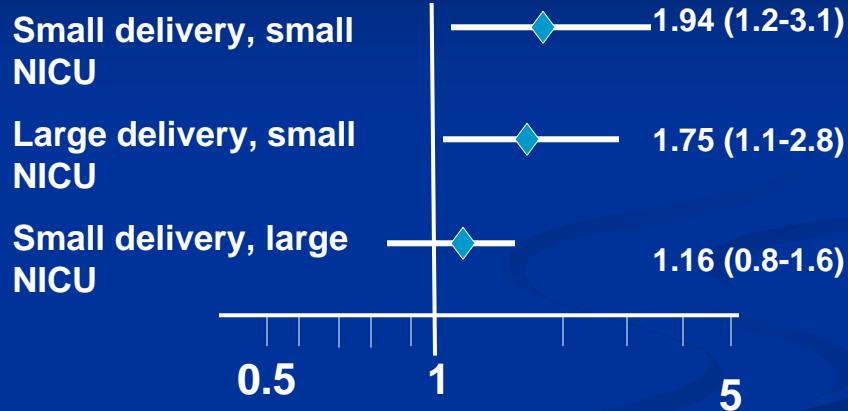
*Phibbs NEJM
 2007;356:2165

3B – vent; 3C + surgery; 3D + cardiac surgery and ECMO

* Risk of death greater with delivery at hospitals with lower volume
 (or level) NICUs compared to those treating at least 100 VLBWs/yr

VLBW Mortality is **Higher** in Small NICUs

Lower Saxony, Germany



-Small delivery service = < 1,000 births per year
-Small NICU = < 36 VLBW admissions per year
-Reference = large delivery, large NICU

Bartels DB Pediatrics 2006; 117:2206-14

VLBW Disparities in Level of Care

- Vital statistics records of VLBW infants in New York City, 1996-2001
- Risk adjusted neonatal mortality rates in 45 hospitals ranged from 9.6 to 27.2 per 1000 births
- Mortality lower in high-volume hospitals (>200 VLBW births/yr)
- Black VLBW infants more likely than white to be born in high mortality hospitals (21 vs. 11%) – explained about 1/3 of disparity

Howell EA Pediatrics 2008; 121:e407-415

AAP Committee on Fetus and Newborn Policy Statement: Levels of Newborn Care

- Objective: To develop nationally applicable uniform definitions of levels of neonatal care based on the capability of facilities to provide increasing complexity of quality care

• *Pediatrics* 2004; 114:1341-1347

General Principles

- Newborns have a gradation of risk based on gestational age and illness severity
- Definitions should be based on the capabilities needed by a unit to provide care appropriate for the level of risk
- Standards can be developed that specify the components needed for the capabilities of each level of care, such as equipment, personnel, facilities, ancillary services, etc

Level 1(Basic): Newborn Nursery

- Can perform neonatal resuscitation at every delivery
- Can evaluate healthy term newborns and provide postnatal care
- Can stabilize and provide care for infants 35 to 37 weeks gestation who remain physiologically stable
- Can stabilize newborns who are <35 weeks gestation or ill until transfer to a facility that provides specialty neonatal care

Level 2 (Specialty): Special Care Nursery

- Can care for infants with gestation >32 weeks and BW >1500 g who
 - have physiological immaturity, such as apnea, inability to maintain temperature, or inability to feed by mouth
 - are moderately ill with problems that are expected to resolve rapidly and are not expected to need subspecialty services on an urgent basis
 - are convalescing after intensive care
- Level 2a - No mechanical ventilation or CPAP
- Level 2b - Can provide mechanical ventilation for brief durations (<24 hr) or CPAP

Level 3 (Subspecialty): Newborn Intensive Care Unit

- A NICU organized with the personnel and equipment to provide continuous life support and comprehensive care for extremely high risk newborns and those with complex and critical illness
- Subdivided into three levels based on capability to provide advanced medical and surgical care



Level 3 NICU

- **Level 3a**
 - Infants with BW >1000 g and GA >28 weeks
 - Continuous life support (limited to conventional mechanical ventilation)
 - May perform minor surgical procedures
- **Level 3b (3a capabilities plus...)**
 - Comprehensive care for infants who are <1000 g or <28 weeks gestation
 - Can provide advanced respiratory support (HFOV, inhaled NO)
 - Prompt/on-site access to a full range of pediatric subspecialty consultants
 - Advanced imaging on an urgent basis (CT, MRI, and echocardiography)
 - Pediatric surgeons and pediatric anesthesia to perform major surgery
- **Level 3c (3b capabilities plus...)**
 - Can provide ECMO and surgical repair of complex congenital cardiac defects that require cardiopulmonary bypass

How do we currently measure perinatal systems of care?

- 3 studies
 - State definitions and criteria of neonatal health services
 - Vital records data (2003)
 - MCHB data (Performance Measure #17)

State Definitions and Criteria of Neonatal Services Study*

- States regulate health care services and facilities
 - License hospitals
 - Promulgate State Health Plans
 - Distribution of services
 - Allocation of resources
 - Approve facility expansion and construction
 - Implement Title V programs
 - Certification of specialty services
 - Reimburse for specialty care

*Blackmon, Barfield, Stark. *in press*

Methods

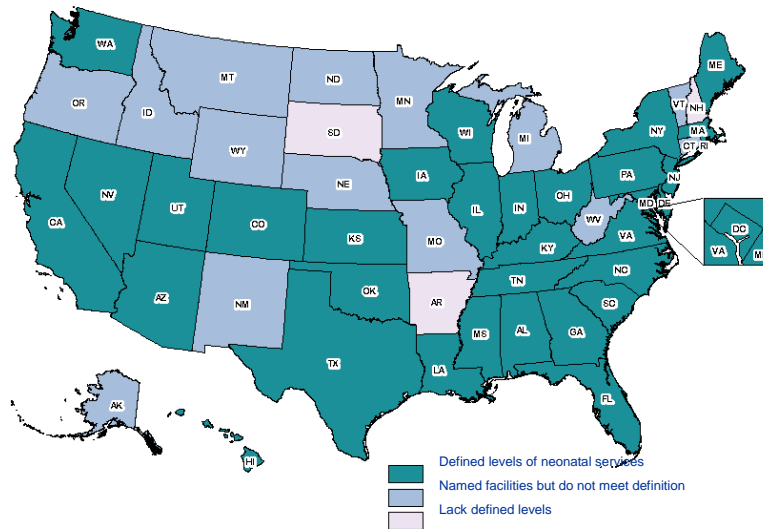
- Systematic search of websites for all 50 states and DC (2008)
 - Regulations for hospital licensure
 - Regulations for Certificate of Need
 - State health facility planning documents
 - State MCH funded patient services or programs
 - Publications by affiliated non-governmental state perinatal health entities

*Blackmon, Barfield, Stark. *in press*

Definition Criteria: Levels Designation

- Specific language to designate multiple patient care services (not physical facilities or units)
- Multiple care levels described
- Description of graduated requirements of complexity of care or capabilities of intensity of care

Results:



Results: Functional Criteria

- 25 states use one or a combination of:
 - Population characteristics such as BW or gestational age (most often < 1.5 kg or < 28 or < 32 weeks)
 - Respiratory care – supplemental O₂ concentration or duration; mode of ventilation or duration
 - Neonatal surgery, cardiac surgery, ECMO
- 8 states use non-specific terms (eg mild, moderate, severe) that limit objectivity

Results: Utilization Criteria

- 18 states have one or more requirement:
 - Capacity: Minimum number of bed type per unit or per population base
 - Volume: Deliveries or live births per year
 - Occupancy: average daily census or percent capacity
 - Case Mix:
 - VLBW admissions, VLBW patient days, ventilator days, or surgeries per year

Results: Utilization Criteria

<u>Utilization Criteria:</u>	<u>Capacity</u>	<u>Volume</u>	
	beds/unit	deliveries/yr	live births/yr
Number of States	10	6	5
Service Level			
Low – Advanced		600	
Mid – II, Intermediate Specialty, IIa	≥ 4-10 intermediate	Range: ≥ 500-2000	Range: 1000-2000
– CPC Intermediate	15 special care		
– Advanced, IIb		Range: 1000-≥1500	1000
High – Advanced, IIR, IIN	≥ 10		
– III, Subspecialty	9 – 15	Range: 1500-2500	1500
– RPC	4/1000 LB	Range: 8000-10000	8/1000 LB

red = region or district

Results: Compliance Criteria

Compliance	License Renewal	CON/SHP Approval	CERTIFICATION	SHD/Affiliated Program Measures:
Number of States	18, 10†		13, 4†	14, 9†
Renewal	1-5 yrs MF: annual		Application only	1-5 yrs
Mandated Reporting	11 states	7 states		2 regional centers only
On-site Inspections	11 states	2 states		7 states, 3 regional centers
	4 initial			
	7 episodic			
Self Designation	1 state		1 state	4 states

† Single source MF = Most Frequent

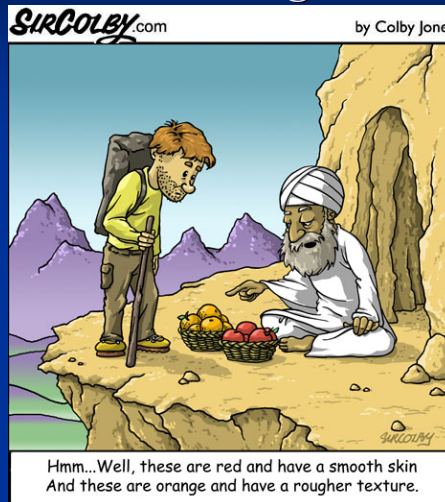
Results: Funding of Level 3 Care

- Funding Linkage for Level III/Subspecialty Care:
 - Total: 13 States
 - 7 with neonatal care levels definitions
 - 6 without neonatal care levels definitions
 - 4 specify funding for maternity care
- Funding source for patient care:
 - Medicaid, 11 states
 - MCH (Title V), 2 states
- Funding for regional program activities:
 - 3 states

Impact of AAP on State Regulations

- 22 states cite AAP documents as a source or incorporate by reference
- Guidelines for Perinatal Care – 17 states
- Neonatal Resuscitation Program – 4 states
- 2004 COFN Levels of Care Policy Statement
 - Resource for updates in 3 states and for VLBW outcome survey in 1 state

“States vary considerably in definitions, criteria, and monitoring of levels of care”



...comparing apples to oranges...

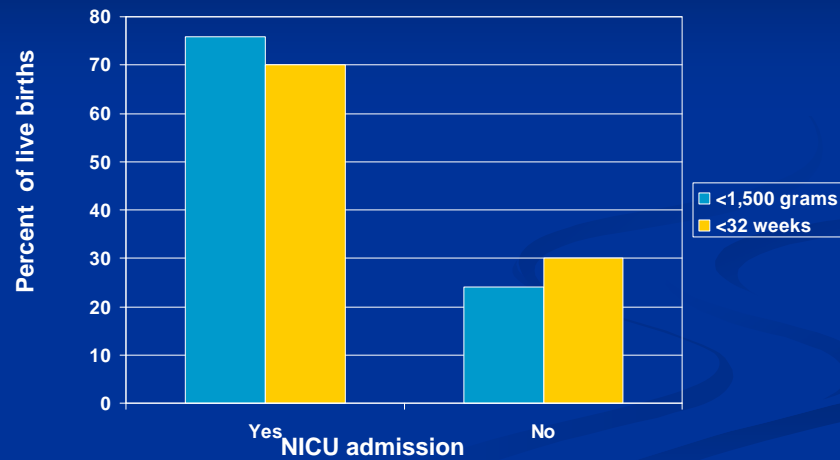
Birth Certificate Data

- Expanded birth certificate, 2003
- More data on mother – pregnancy, labor and delivery, antenatal steroids, maternal morbidity
- More data on newborn – including assisted ventilation, NICU admission, surfactant, antibiotics
- Implemented in 2005 in 12 states (FL, ID, KS, KY, NE, NH, NY, PA, SC, TN, TX, WA) with 16 states in 2006
- Goal: 24 hour electronic reporting
 - Strength: Drawn from documentation of the medical record

NCHS Definition

- CDC, National Center for Health Statistics (2000): NICU defined as “Hospital facility or unit staffed and equipped to provide continuous mechanical ventilatory support for a newborn for more than 24 hours.”

NICU Admissions by BW and GA*



Source: CDC/NCHS

*16 states

HRSA/MCHB

National Performance Measure #17

- Percent of VLBW (<1500 gram) infants delivered at facilities for high risk deliveries and neonates
 - Measurement:
$$\frac{\text{\# of <1,500 gram infants born at Level III facilities}}{\text{Total \# of <1,500 gram infants}} \times 100$$
- Healthy People 2010 Objective 16-8
 - Goal 90%

HRSA/MCHB

National Performance Measure #17

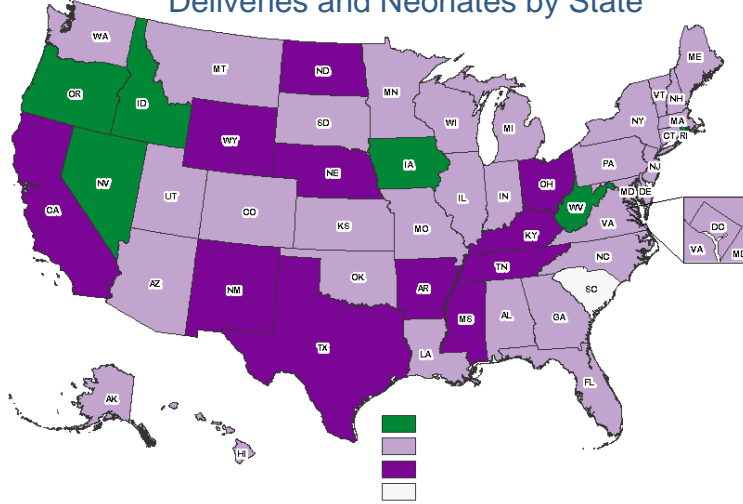
- State Data Source?... varies
 - Birth certificate data
 - Hospital records
 - Hospital surveys
 - National immunization survey (NIS)
 - Hospital self-report

HRSA/MCHB

National Performance Measure #17

- Numerator measure?... not uniform
 - Level 3 facilities only
 - Level 3 and Level 2 facilities
 - Level 3 vs. Level 2 facilities
 - Level 2s that function as Level 3 facilities
 - Perinatal Centers
 - All hospitals

HRSA/MCHB Performance Measure #17: Percent of VLBW Infants Delivered at Facilities for High Risk Deliveries and Neonates by State*



States and hospitals have not fully adopted 2004 AAP definitions of care”

Level of Enforcement of Policy

High intensity enforcement

Low intensity enforcement



Recommendation Strength
{Quality of evidence}

Discussion: Opportunities for a New Era

- How can we work together to improve the health of mothers and infants through improving access to appropriate levels of care?
- How can we better define capabilities with each neonatal level of care?
- How can we improve perinatal health systems beyond neonatal levels of care?

Discussion: Opportunities for a New Era (cont)

- State-based perinatal regulations
 - MA
 - WA
 - NY
- State/regional collaboratives
 - OH
 - NC
 - CA
- Quality benchmarks
 - VON
 - National Quality Forum/Joint Commission?
- Addressing issues of equity
 - Resources
 - Reimbursement

Summary

- Being born at the right place matters!
- States vary considerably in definitions, criteria, and monitoring of levels of care
- States and hospitals have not fully adopted 2004 AAP definitions of care
- Until standard measures are adopted, further improvements in perinatal outcomes may stall or worsen

“For VLBW infants, being born at the right place matters”

NOW...

THEN...



Figure 1-4. Front page of *The New York Times*, August 8, 1963. (Copyright © 1963 by *The New York Times Co.* Reprinted by permission.)





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