Clinical Intelligence

A Changing NICU Landscape

sg2
health care intelligence

Sg2 Staff

Project Director
Meghan Robb

Project Associates
Madeleine McDowell, MD
Kendahl Moser-Bleil

Editorial Review
Barbara Bennett, RN

A Changing NICU Landscape

Contents

A Changing NICU Landscape
Executive Summary

Demand for neonatal intensive care unit (NICU) services continues to rise as rates of preterm birth, low birthweight infants and multiples grow. Responding to demand and capitalizing on a profitable service, the number of NICUs grew substantially in the past 2 decades. Possible oversupply, particularly of midlevel services, has increased scrutiny on quality of care and future growth potential. Emerging clinical changes will reduce NICU growth potential in this decade, creating new market dynamics that proactive institutions must consider.

Institutions are acknowledging the significant impact design has on neonatology operations, clinical quality and consumer satisfaction. New designs are incorporating family-centered care principles, individual infant environmental control and workforce collaboration. Future NICUs must address new clinical demand and new service delivery expectations.

Key Facts

- The number of preterm infants, low birthweight infants and multiples has grown substantially. All use NICU services.
- NICU beds increased by 138% between 1980 and 1995.
- NICU services remain profitable and marketable.
- While population will increase demand, new technologies and care delivery strategies will retard long-term neonatology growth.

Prepare for a Changing NICU Landscape

- Understand recent NICU supply and demand trends.
- Prepare for clinical change.
- Consider the changing role of the laboratory, emerging technologies and innovative communication strategies to improve operations.
- Design facilities to address evolving standards of care, clinical quality improvement and patient/family experience.

A Changing NICU Landscape details current and emerging NICU trends and offers planning considerations for superior care delivery.

Today’s NICU Landscape

Demand for NICU Services Has Increased

- Escalating rates of preterm birth and low-birthweight infants
- Climbing cesarean delivery rate
- Rising number of multiples
- Growth of ART utilization
- Increasing maternal age and comorbidities
- Decreased infant mortality
- Exponential increase in number of NICU beds

©iStockphoto.com/Brent Deuel.

ART = assisted reproduction techniques; preterm = birth less than 37 weeks gestation.

Trends driving demand are varied.

- The preterm birth rate increased from 9% to 12% over the past 2 decades.
- Rising maternal comorbidities such as obesity, asthma and maternal hypertension have increased perinatal complications.
- Cesarean deliveries are at an all-time high.
  - In 2005 the cesarean delivery rate was 30%, an increase of 46% since 1996.
  - Infants delivered by cesarean are often preterm and may have excess amniotic fluid in their lungs; some may require low-level NICU care.

Various factors have influenced the supply of NICU services.

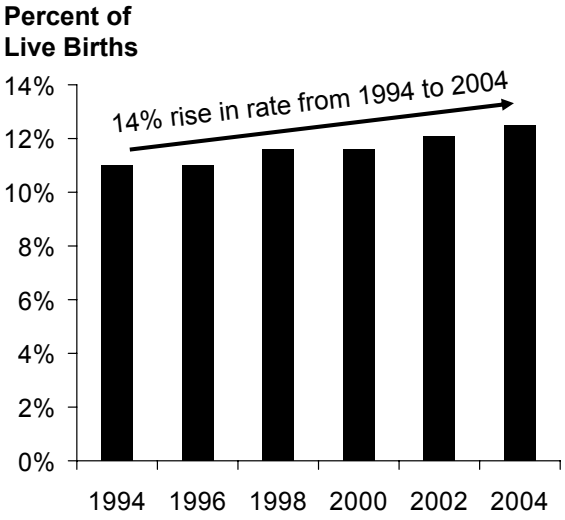
- Epidemiologic, technologic, sociocultural and financial factors have contributed to an increase in services.
- A proliferation of NICU beds has resulted from increasing demand for NICU services and increasing awareness of the profitability of such services.

Source: Hamilton BE et al. *Pediatrics* 2007;119:345–360.

Preterm Births Increased Nearly 14% Between 1994 and 2004

- Approximately 1 in 8 babies (12% of live births) is born preterm in the US.
- Preterm births are responsible for over half of all newborn neurological problems
  - Mental retardation, cerebral palsy, blindness, learning disabilities
- The IOM estimates the societal economic cost of preterm births in the US to be $51,600 per preterm infant.

Number of Preterm Births US, 1994–2004



IOM = Institute of Medicine.
Sources: National Center for Health Statistics, Final Natality Data. Retrieved January 12, 2007 from www.marchofdimes.com/peristats; American College of Obstetricians and Gynecologists.

Preterm birth poses significant clinical and operational challenges.

- Preterm delivery is the major determinant of infant mortality and is more common in the US than in other developed countries.
  - Attributed to one third of all US infant deaths in 2002
- Preventative treatment, including tocolytics (drugs designed to delay, not prevent preterm labor), antibiotics and bedrest have not reduced the rate of preterm birth.

Preterm birth costs are staggering due to intensive resource requirements.

- The IOM estimated that in 2005, the total societal cost of preterm birth in the US was $26 billion.
  - Two thirds of this estimated cost was for medical care, with 85% of services provided in early infancy.

Sources: Callaghan et al. *Pediatrics* 2006;118:1566–1573; Meis et al. *N Engl J Med* 2003;348:2379–2385; IOM. *Preterm Birth: Causes, Consequences, and Prevention*. July 2006.

Preterm Birth Risk Factors Vary

Sample Preterm Birth Risk Factors

Demographic	▪ Increasing maternal age ▪ In vitro fertilization (IVF) ▪ Low socioeconomic status
Behavioral	▪ Smoking ▪ Alcohol or drugs ▪ Stress ▪ Absent or delayed prenatal care
Genetic	▪ History of preterm birth ▪ DNA markers ▪ African-American descent
Medical	▪ Maternal infections ▪ Maternal hypertension ▪ Diabetes

Sources: National Center for Health Statistics, Final Natality Data. Retrieved January 12, 2007 from www.marchofdimes.com/peristats; American College of Obstetricians and Gynecologists.

Risk factors for preterm birth are varied.

- Factors span demographic, behavioral, genetic and medical characteristics.
- African-American women have a preterm birth rate of 18%, significantly higher than Pacific Islanders (10%) and Caucasians (11%).

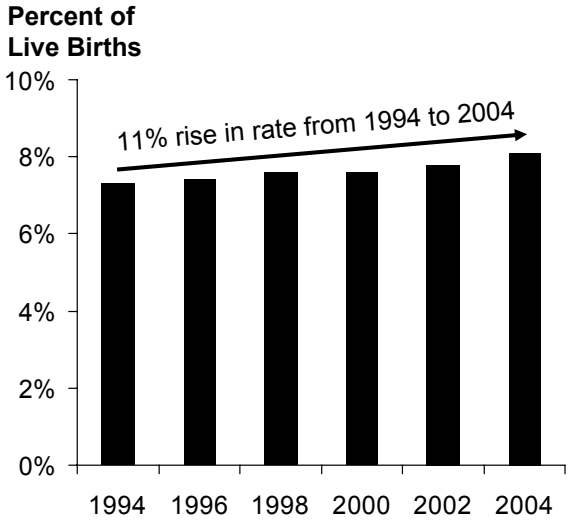
Understanding genetic predisposition for preterm birth has become a leading area of clinical research.

- Preterm birth is now believed to result from the interaction of multiple genes and environmental influences.
- Scientific evidence, thanks in part to the Human Genome Program, has shown evidence of genetic predisposition to preterm birth.
- Awareness of factors contributing to preterm birth, such as genetic predisposition, are critical for the development of prevention and early intervention strategies.
- Candidate genes now being studied as contributing factors to preterm birth include polymorphisms of cytokines involved in regulating the inflammation process, labor cascade genes and vasculopathic processes associated with preterm birth.

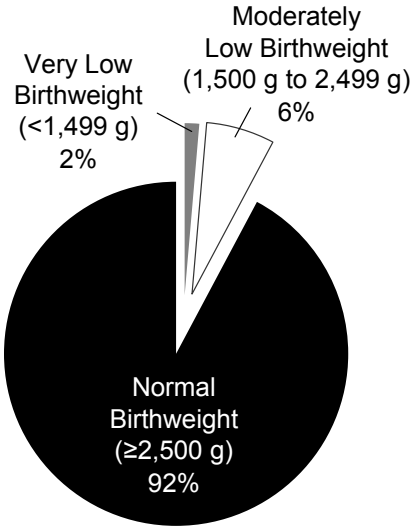
Sources: Callaghan et al. *Pediatrics* 2006;118:1566-1573; Meis et al. *N Engl J Med* 2003;348:2379–2385; Giarratano. *Am J Mat/Child Nursing* 2006;31:169–175.

Number of Low Birthweight Newborns Continues to Rise

Low Birthweight Infants*
US, 1994–2004



Live Births by Birthweight
US, 2004



*Low birthweight is defined as <2,500 g or <5.5 lbs.

Prematurity and low birthweight are highly correlated.

- Two thirds of low birthweight infants are born preterm.
- The rate of infant mortality due to low birthweight and preterm birth increased 15% between 1996 and 2002.

Low birthweight infants may require increased intervention, some life-long.

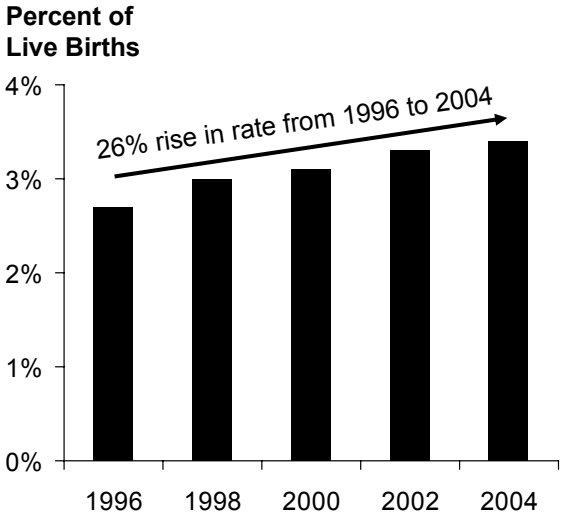
- Approximately 30% of preterm infants <1000 g at birth develop bronchopulmonary dysplasia (BPD) or chronic lung disease (CLD). These infants require supplemental oxygen and medications for months, sometimes years.
- 16% of extremely low birthweight (ELBW) infants had major neurosensory impairments (eg, cerebral palsy, deafness, blindness, feeding tube, wheelchair).
- 38% of ELBW infants receive ongoing special medical, education or therapy services for chronic conditions.

Sources: National Center for Health Statistics, Final Natality Data; Retrieved January 12, 2007, from www.marchofdimes.com/peristats; Jobe et al. *Am J Respir Crit Care Med* 2001;163:1723–1729.

Multiple Births Increased 26% Between 1996 and 2004

- Multiples represented 3% of all live births in 2004.
- The majority of multiple births are twins.
  - Higher order births represented only 0.2% of all live births in 2004.
- Almost two thirds of multiple births are delivered preterm (61% in 2004).

Number of Multiple Deliveries US, 1996–2004



Higher order birth = 3 or more children at one birth.

Advancing technologies have increased multiple births.

- IVF, ART and more women over age 30 having children has resulted in greater numbers of multiple births.
  - A survey of ART programs showed that 56% of pregnancies resulting from ART were multiples.
  - Women over 30 years old were responsible for 38% of live births between 2001 and 2003, and represent approximately one third of the increase in multiple births.

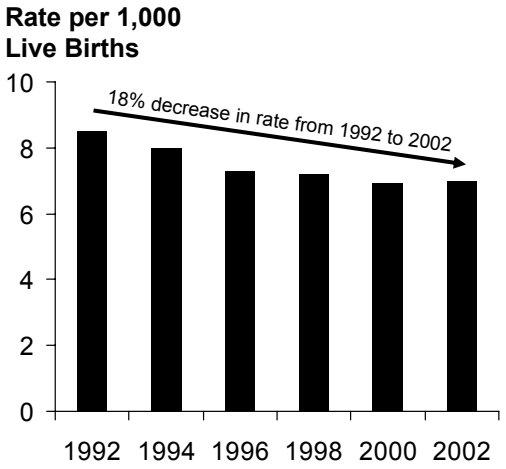
Multiples are frequent users of NICU services.

- In 2004, multiples were nearly 6 times more likely than singles to be born prematurely.
- A 2005 study found nearly 70% of twin neonates born between 34 and 37 weeks gestation were admitted to the NICU.

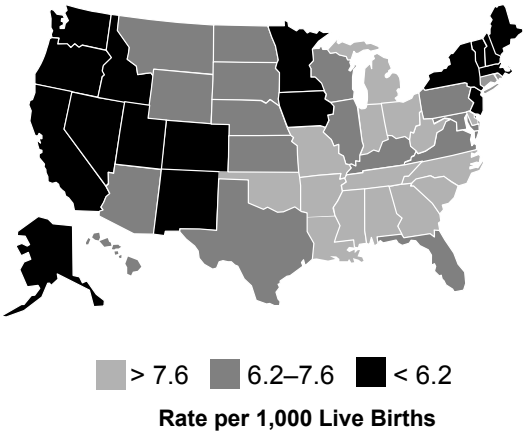
Sources: Elliott JP et al. *J Perinatol* 2005;25:4–7; National Center for Health Statistics, Final Natality Data; Retrieved January 12, 2007, from www.marchofdimes.com/peristat; March of Dimes.

Decreased Infant Mortality Has Altered NICU Patient Mix, Increasing Acuity

Infant Mortality Rates
US, 1992–2002



Infant Mortality Rate
US, 2002



Reductions in infant mortality have placed more pressure on NICUs.

- NICUs are treating more acutely ill infants with more intensive treatments for longer periods of time.
  - Several technologic innovations have significantly improved neonatal respiratory care and reduced mortality: surfactant, high frequency ventilation, extracorporeal membrane oxygenation (ECMO) and nitric oxide (NO).
  - These innovations have necessitated specialty capital, staffing and training modifications for select NICUs.

As neonatal acuity rises, so does the need for advanced levels of NICU care.

- Ranges in patient acuity have created a system that segments care based on available resources.
  - More acute patients demand more intense and expansive resources (eg, cardiac, neurological consults).

Source: National Center for Health Statistics, Final Natality Data; Retrieved January 12, 2007, from www.marchofdimes.com/peristats.

NICU Services Are Offered by Level of Care, Resource Availability

Nationally Recommended Neonatal Intensive Care Unit Definitions

		Age, Weight	Capabilities
Basic Nursery Care	**Level I**	Well-newborn	▪ Stabilizes ill infants and infants <35 weeks for transfer ▪ Neonatal resuscitation
Specialty Nursery Care	**Level IIa**	> 32 weeks > 1,500 g	▪ Prematurity apnea treatments ▪ Temperature instability treatments ▪ Orogastric tube feedings
	Level IIb (Level IIa Plus)	> 32 weeks > 1,500 g	▪ Mechanical ventilation for brief duration (<24 hours) ▪ Continuous positive airway pressure (CPAP)
Subspecialty Neonatal Intensive Care	**Level IIIa**	> 28 weeks > 1,000 g	▪ Mechanical ventilation ▪ Minor surgeries
	Level IIIb	< 28 weeks < 1,000 g	▪ Advanced respiratory support (hi-fi, NO) ▪ On-site access to full range of pediatric subspecialists ▪ Advanced imaging with interpretation on an urgent basis
	Level IIIc (Level IIIb Plus)	< 28 weeks < 1,000 g	▪ ECMO ▪ Surgical repair of complex congenital heart defects

Hi-fi = high frequency oscillation ventilation.

No national standards for NICU levels of care exist.

- In 2004, the American Academy of Pediatrics (AAP) recognized the need for a uniform system to allow for accurate comparisons between programs, education of consumers, and development of consistent standards of care.
- At the end of 2006, levels were still defined and regulated by the state.

Rising demand without uniform standards of care makes supply analyses difficult.

- Without national standards, true demand and the supply of NICU services is difficult to quantify.
  - Even within individual state regulations there is a lack of uniform definitions for basic requirements, such as “under the care of a neonatologist” or “hospitalist.”

Sources: AAP Policy Statement; *Pediatrics* 2004;114:1314–1323; Howell et al. *Am J Public Health* 2002;92:119–124.

Case Examples of NICU Care Intensity

Basic Nursery Care	▪ 39 weeks; 3,100 g; C-section ▪ LOS 3 days ▪ Diagnosis: Well-newborn
Specialty Nursery Care	▪ 33 weeks; 1,650 g; NVD ▪ LOS 21 days ▪ Diagnosis: premature infant ▪ Apnea of prematurity, sepsis evaluation ▪ Procedures: supplemental oxygen for 18 days
Subspecialty Neonatal Intensive Care	▪ 24 weeks; 690 g; NVD ▪ LOS 86 days ▪ Diagnosis: ELBW premature infant ▪ PDA, RDS, sepsis, hyperbilirubinemia, apnea of prematurity, anemia of prematurity ▪ Procedures: mechanical ventilation for 37 days, CPAP for 7 days, PDA ligation, supplemental oxygen for 21 days

LOS = length of stay; NVD = non vaginal delivery; PDA = patent ductus arteriosus; RDS = respiratory distress syndrome.

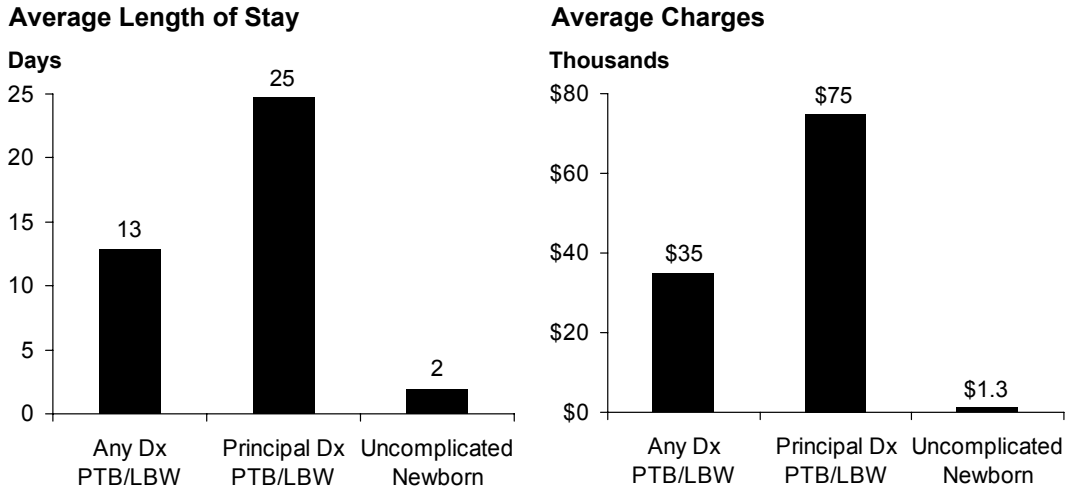
The need for advanced levels of NICU care rises as neonatal acuity rises.

- Growth in preterm births, maternal comorbidities, ART utilization, C-section rates and other factors have increased the intensity of NICU care.
- Increased care intensity, including more instances of complex procedures and ventilation, has driven demand for more resource intensive subspecialty NICU services.

Source: Sg2 Analysis, 2007.

NICUs Generate Significant Charges, Revenue

Comparison of Infant Stays Due to Prematurity/LBW and Uncomplicated Newborns
US Market, 2001



LBW = low birth weight; Dx = diagnosis; PTB = preterm birth.
Source: Agency for Healthcare Research and Quality, 2001 Nationwide Inpatient Sample, Prepared by March of Dimes Perinatal Data Center, 2003.

Longer stays and heightened resource intensity result in significant charges.

- While normal newborns account for 90% to 95% of all neonatal discharges, newborns with complications account for 60% of all newborn hospital days.
- In 2001, infant discharges related to prematurity accounted for only 8% of all infant discharges, but accounted for 46% of all infant charges.

Profitability makes NICU services and service expansion attractive.

- Long stays and high hospital charges for generally well-reimbursed services creates a significant revenue stream, often branding NICUs as “profit centers.”
  - Anecdotal accounts have indicated NICUs can produce “half the total yield of the entire academic medical center…a total gain of $10 million [annually].”

Sources: Owens PL et al. *Care of Children and Adolescents in U.S. Hospitals. Rockville* (MD): Agency for Healthcare Research and Quality, 2003; HCUP Fact Book No. 4; Silverman WA. *Pediatrics* 2004;113:402; *J Perinatol* 2005;25, 794–799.

Epidemiology, Clinical Innovation and Profitability Drove NICU Proliferation

- From 1980 to 1995, the number of hospitals providing NICU services grew by 99%.
- NICU beds increased by 138%.
- The number of neonatologists grew by 268%.
- Clinical outcomes data show a direct correlation between higher volumes and improved outcomes, raising concern over the proliferation of small, midlevel NICU facilities.

Printed with permission of Philips Medical Systems.

Sources: Howell et al. *Am J Public Health* 2002:92;119–124; Sg2 Interviews, 2006.

Growth in NICU care supply may have outpaced need in select markets.

- Basic clinical demand, technologic evolution and high profit margins have influenced NICU services expansion, at times in the absence of true market need.
  - In California, regional rates of very low birth weight (VLBW) (<1,500 g) infants remained relatively stable between 1990 and 1997, while the supply of community and regional NICUs increased from 37 to 82.

More NICUs may not translate to better quality care.

- The introduction of new midlevel* units in the US perinatal system resulted in a shift of births from high-level NICUs, which significantly diluted case volume.
- Births in hospitals with high-level (level III) NICUs averaging ≥15 patients per day have shown significantly lower adjusted mortality, compared to hospitals with lower volumes.

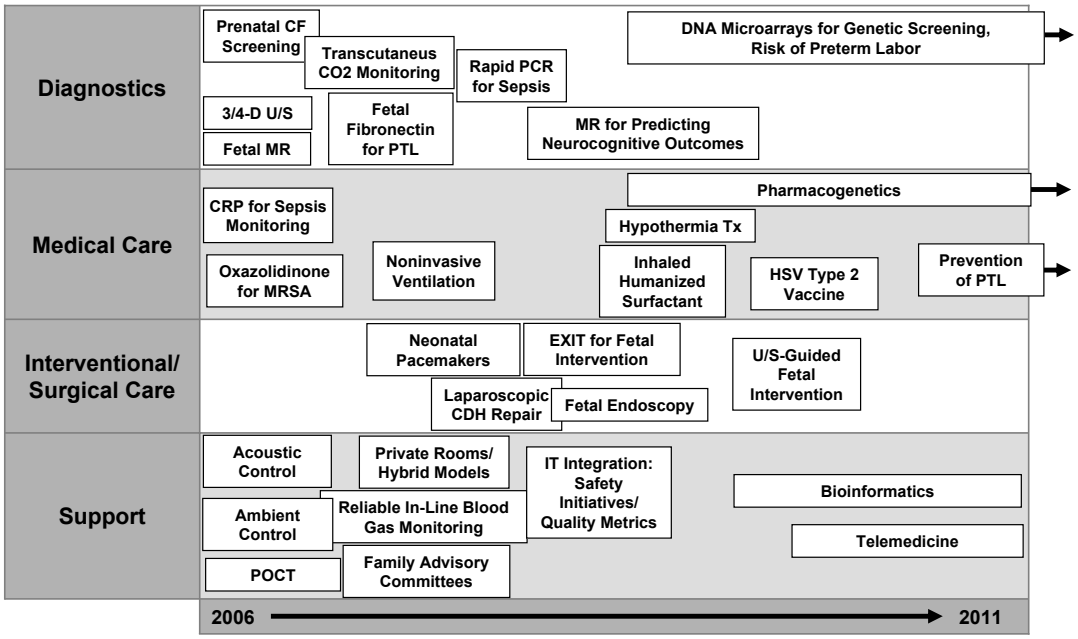
Future trends will negatively impact demand, requiring reevaluation of supply.

- Technology and care delivery evolution will reduce future NICU volume and average length of stay (ALOS), calling into question current care delivery organization.

*Midlevel = Level II and II+ facilities.
Sources: Haberland et al. *Pediatrics* 2006;118:e1667–e1679; Stahlman MT. *J Perinatol* 2005;25:794–799.

Emerging Clinical Change

Neonatology Will Change Significantly*



*This road map represents consensus adoption timing and NICU technologies across all levels of care.
See Sg2's *Smart Growth* Focus Report for more on technology adoption characteristics and implications.
Source: Sg2 Analysis, 2006.

Clinical technologies, care delivery methods will alter demand and outcomes.

- Methods to prevent many of the conditions complicating neonatal care today will begin to emerge in the next 10 years.
  - Advances in imaging techniques and molecular diagnostics will allow for earlier interventions and treatments.
  - Late effects of current treatments, such as RDS from mechanical ventilation, will decline as less invasive technologies continue to develop.
  - Bioinformatics and rapid, advanced diagnostics will accelerate the personalized medicine movement.
  - Strategies to reduce, and eventually prevent, preterm labor will begin to emerge.
  - Facility design will improve patient safety, quality and family engagement.
- Adoption of these innovations will vary with the NICU service level provided.

CF = cystic fibrosis, CO_2 = carbon dioxide; PCR = polymerase chain reaction; U/S = ultrasound;
MR = magnetic resonance; PTL = preterm labor; CRP = C-reactive protein; HSV = herpes simplex virus;
MRSA = methicillin-resistant *Staphylococcus aureus*; EXIT = ex utero intrapartum therapy;
CDH = congenital diaphragmatic hernia; POCT = point-of-care testing; Tx = treatment.

Advanced Respiratory Therapies Show Better Clinical Outcomes, Decreased LOS

Historic: Traditional Mechanical Ventilation

Positive pressure and a gas ventilator physically open and close patients' lungs, pumping air in and out to treat acute lung injury.

©Stockphoto.com/Matthew Hull.

Dangers/Side Effects:
▪ Concentrations of oxygen can be dangerously high. ▪ Tissues in the lungs can be damaged due to mechanically inflating the alveoli, causing CLD.

Emerging: New Uses for Old Technologies May Avoid Barotrauma

Bubble CPAP® System
The combined effect of CPAP and pressure oscillations from a bubble-delivery method is lung-protective, safe and effective for respiratory support.

Next-Generation Surfactant and Surfactant Delivery
Use of surfactant immediately after birth decreases the risk of acute pulmonary injury, mortality, CLD and RDS. Aerosolized delivery of synthetic surfactant will eliminate the need for invasive and damaging intubation.

Emerging techniques have improved oxygenation and reduced barotrauma.

- Bubble CPAP improves outcomes including: reduced delivery room intubations, fewer days on mechanical ventilation, reduced postnatal steroid use, decreased intubation time, improved success rates for newly extubated infants and increased postnatal weight gain.
- Inhaled NO therapy improves pulmonary outcomes for premature infants (7 to 21 days) at risk for BPD with no apparent short-term adverse effects.

Next-generation surfactants hold promise to improve outcomes.

- Lucinactant (synthetic surfactant containing a functional protein) reduced RDS-related mortality rates by 14 days when compared to animal-derived surfactants.
- Aerosolized delivery of synthetic surfactant is projected to eliminate the need for intubation and mechanical ventilation, reducing barotrauma and LOS.

Innovation has not been without setbacks.

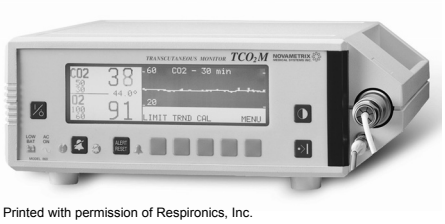
- Partial liquid ventilation proved to be nonsuperior to mechanical ventilation.
- Commercial release of lucinactant has been delayed due to regulatory process failures.

Sources: Ballard et al. *N Engl J Med* 355:343–353; Barrington et al. *Pediatrics* 2001;107:638–641; Narendran et al. *J Perinatol* 2003;23:195–199; Roemer et al. *Am J Respir Crit Care Med* 2006;173:882–889.

Noninvasive Continuous Monitoring Will Improve Patient Care

©iStockphoto.com/Paul Brian.

TCO_2M®



Printed with permission of Respironics, Inc.

Transcutaneous CO_2 Monitors

- Portable, noninvasive tool consisting of heating patches and electronic screens that test and monitor the amount of oxygen and carbon dioxide in a baby's blood
- Currently used in ambulances and other neonatal transport methods
- Will increasingly be used for continuous monitoring within NICU units

Sources: Radiometer; Novametrix; Bernet-Buettiker et al. *Pediatrics* 2005;115:e64–e68.

Advanced monitoring technology is critical for outcome improvements in complex care.

- Noninvasive transcutaneous monitoring of arterial oxygen (SaO_2) and arterial carbon dioxide ($PaCO_2$), the 2 most important parameters in neonate care, will provide continuous respiratory status estimates and reduce blood loss from repeated blood gas analyses.

New technologies will eliminate difficult monitor handling.

- Current models of transcutaneous measurement, used primarily in transport, are simple and noninvasive. However, sensor preparation, positioning, taping and repeated changes of sensor location complicate long-term use in the NICU.
- New sensor designs have combined assessment of pulse oximetry, SaO_2 and transcutaneous $PaCO_2$ in a reliable single-ear sensor.
  - Potential benefits include reduction in motion artifacts with less infant movement and use of a single cable. In addition, the sensor does not require removal for chest radiographs or for general nursing care.
  - The Ear Sensor (TOSCA monitor) is approved by the Food and Drug Administration (FDA).
    - Monitors cost approximately $9,600 to $13,000 each.

Rapid Testing Can Improve Clinical Safety and Quality

Case Example: MRSA Infection Rate Reduction With Rapid PCR

Leading Practice: Evanston Northwestern Healthcare
Critical Innovation: Rapid testing to identify and decolonize MRSA carriers

- Testing time was reduced from 1–5 days to 30 minutes–1 hour.
- NICU surveillance over 2 years prevented 15 infections, saving $1.2 million.
- MRSA transmission was prevented in 12 babies.
- Cost/benefit ratio was 1 to 1.5.

ENH Admission Screening Program

Reduced bloodstream infections	60%
Reduced respiratory infections	40%

Financial Impact on Average Hospital*

Screening costs: tests, labor, technology	$655,000
Estimated annual savings	>$900,000

*US hospital with overall infection rate of 5%, 20,000 annual discharges.
Sources: Davis KA et al. *CID* 2004;39:776–782; Graham PL III et al. *Ann Intern Med* 2006;144:318–325.
Sg2 expresses thanks to Dr Lance Peterson of Evanston Northwestern Healthcare for his generous assistance in the preparation of this case study.

Rapid testing allows for earlier diagnosis and appropriate treatment.

- Treatments can begin earlier, resulting in better quality care.
- Rapid tests will eliminate the need for precautionary treatments; treatments will only be given to those in need.

Rapid molecular diagnostic tests facilitate preadmission screening, reduced BSIs.

- Traditional bacterial cultures require 1 to 5 days to identify patients with MRSA, making widespread preadmission screening and isolation burdensome.
- Results from rapid molecular diagnostic tests are available within hours, minimizing resource drain.

System-wide screening can be feasible, based on reduced BSIs cost.

- Although BSIs account for only about 10% of nosocomial infections, they are among the most clinically severe and costly, increasing ALOS by 10 to 20 days.

BSI = bloodstream infection.

Innovative Interventions Expand Clinical Capabilities at Select Tertiary Hospitals

Ex Utero Intrapartum Treatment (EXIT) Procedure

Image courtesy of Deborah Levine, MD, Harvard Medical School.

- Used to deliver infants with airway compression
- Fetal head, neck and shoulders delivered surgically through uterine opening
- Allows assessment of airway while infant is still attached to placental circulation
- Other conditions benefiting from EXIT procedures:
  - Tracheal occlusion
  - Neck tumors
  - Congenital diaphragmatic hernia (CDH): EXIT to ECMO
  - Congenital cystic adenomatoid malformation (CCAM): EXIT lobectomy

Source: The Children's Hospital of Philadelphia, 2006.

EXIT improves outcomes for a select group of the most complex neonates.

- Fetuses with mass-obstructed airways previously had very poor outcomes.
- The EXIT procedure allows the fetal airway to be cleared while preserving feto-maternal circulation.
- Although the EXIT procedure has been performed in select tertiary care centers for over a decade, the technique has recently been perfected and expanded for treatment of other rare birth defects.

Advanced imaging supports EXIT procedures.

- The relationship between the fetal neck mass and airway structure can be defined prenatally with ultrasound and MR imaging.
- Infants with these rare conditions can be directed to delivery at institutions with advanced imaging equipment, EXIT experience and extensive intensive care resources after birth.

Refining Hypothermia Treatments for Improved Perinatal HIE Outcomes

Today: Anticonvulsant Treatments

©iStockphoto.com/Bonnie Jacobs.

- Although intravenous anticonvulsant medications are given to neonates who suffer from hypoxic ischemic encephalopathy (HIE) to stop seizures, it is not proven they cure or prevent injury.

Tomorrow: Hypothermia (Cooling) Treatments

Image courtesy of Natus Medical Incorporated.

- If cooling techniques are implemented after seizure, they can delay or minimize brain injury.
- Whole-body hypothermia was recently shown to decrease mortality and disability in neonates >36 weeks with encephalopathy.

Perinatal HIE is a small, niche market.

- Between 5,000 and 9,000 infants each year have moderate to severe HIE.
- HIE occurs in 1 to 2 infants per 1,000 full-term live births.
- Due to low volumes, treatments should be performed at larger, tertiary care centers.

Infants with HIE have an increased risk of death.

- A lack of oxygen leaves HIE infants with a damaged central nervous system.
- 10% will die; the mortality risk for severe HIE jumps to 60%. Those who survive are at risk for disability and have a high probability of being handicapped.

Current treatments do not prevent injury from HIE.

- Anticonvulsant treatments suppress rapidly firing neurons that start seizures. This reduces the seizure's spread, but it is not prevented.

Two hypothermia techniques have demonstrated improved outcomes for HIE.

- Brain hypothermia cooling targets the periphery of the brain via a cooling cap.
- Whole-body hypothermia cools the periphery and central brain structures via internal and external methods.
- Hypothermia treatments will potentially serve a small population of neonates at tertiary care centers.

Sources: Shankaran et al. *N Engl J Med* 2005;353:1574–1584; Gluckman et al. *Lancet* 2005;365.

Imaging Advances Will Push Innovative Fetal Interventions

Fetal intervention prevents further development of the most severe defects through fetal surgeries and procedures.

Ultrasound of 12-week fetus

Printed with permission of Philips Medical Systems.

Anatomic problems that are candidates for fetal intervention include:

- Neck tumors, cervical teratoma
- Hypoplastic left heart syndrome (HLHS)
- CDH
- CCAM
- Sacrococcygeal teratoma
- Myelomeningocele
- Twin-to-twin transfusion syndrome
- Amniotic bands
- Fetal blood sampling

Great strides in fetal imaging allow for advanced detection of fetal problems.

- Advancements in level 2 and 3 ultrasound, as well as fetal MR, have resulted in improved fetal imaging and prenatal diagnosis of congenital anomalies.
  - 1.5T MRs can effectively visualize congenital heart defects in fetuses, following negative ultrasound screens.

Fetal intervention is a growing, niche field following limited adoption.

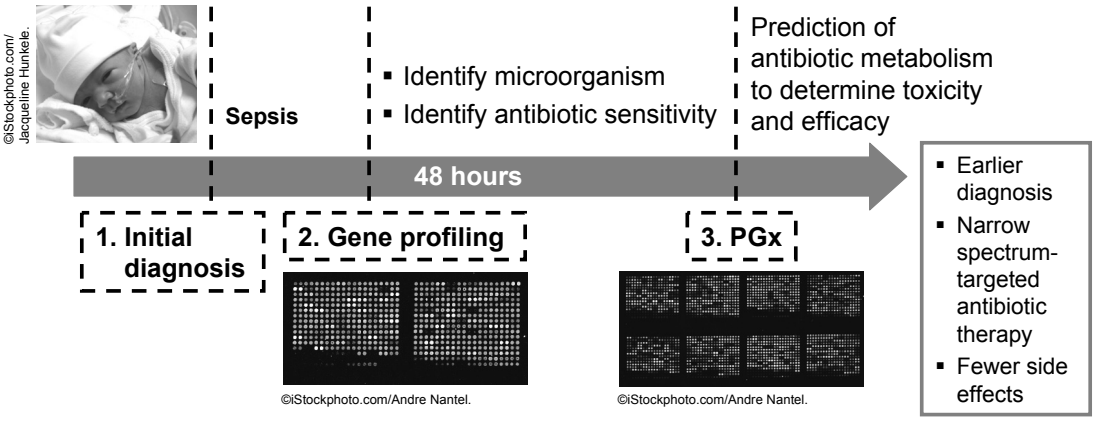
- The resources and clinical expertise needed for such niche procedures limits adoption to only a few, leading tertiary centers.
- At such centers, investigation of fetal intervention for HLHS is ongoing.
  - HLHS affects approximately 1 in 10,000 newborns in the US.
  - HLHS reduces blood flow to the left ventricle preventing normal growth, creating one of the most serious forms of congenital heart defects.
  - Catheter placement into the fetus' heart in utero to open narrow heart valves and increase blood flow to the left ventricle has shown signs of reversing HLHS development in limited applications.

Source: Soetenga et al. *Crit Care Nurse* 2004;24:46–62.

Pharmacogenetics and Molecular Profiling Will Personalize Medicine

Rapid PCR and pharmacogenetics will segment patients by disease subspecies, prognosis and optimal treatment path.

Case Example: Neonatal Sepsis



PGx = pharmacogenetics.

Improved subgrouping facilitates distinct care paths.

- Subgroupings will facilitate safer and more efficient treatment.
- In place of trial-and-error, molecular profiling and pharmacogenetics can create care paths for distinct population subgroups.

Gene profiling can identify specific disease subtype.

- In the case of neonatal sepsis, profiling can aid determination of prognosis and susceptibility to organ failure.

Pharmacogenetic tests segment patients by predicted drug response.

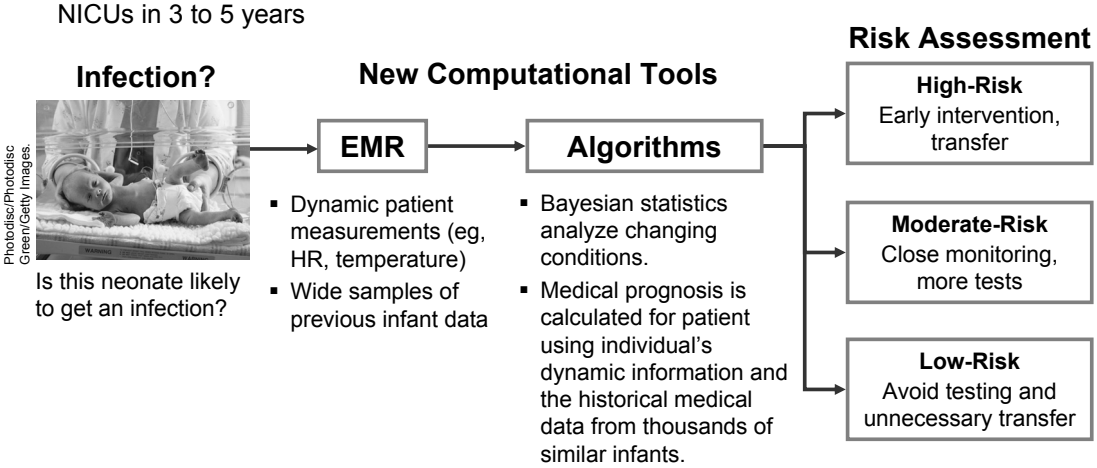
- Individualized genetic information will allow physicians to manage and fine-tune drug choice and dosage in a safer and more effective manner.
- PGx tests can analyze single or multiple genetic variations at a time in a microarray-type test, determining patient-specific prescribing and dosing detail.

Source: Vecchio et al. *Clin Perinatol* 2004;31:53–67.

Bioinformatics Will Accelerate Bench-to-Bedside Research Time

Case Example: Bioinformatics Used to Determine Infection Risk

- **Leading Practice:** Harvard University, UCSF, UC Santa Cruz, Kaiser Permanente Perinatal Research
- **Critical Innovation:** Prognostic strategies for potential risk of infection; expected to enter NICUs in 3 to 5 years



UCSF = University of California San Francisco; HR = heart rate.
Source: Woo M. New statistical approach could improve hospital care for sick newborns. *UC Santa Cruz Currents Online,* November 2006.

Bioinformatics utilizes a multidisciplinary team.

- To approach problems at the molecular level, bioinformatics utilizes mathematics, statistics, chemistry, biochemistry and computer science.

Future research will rely upon biomedical data.

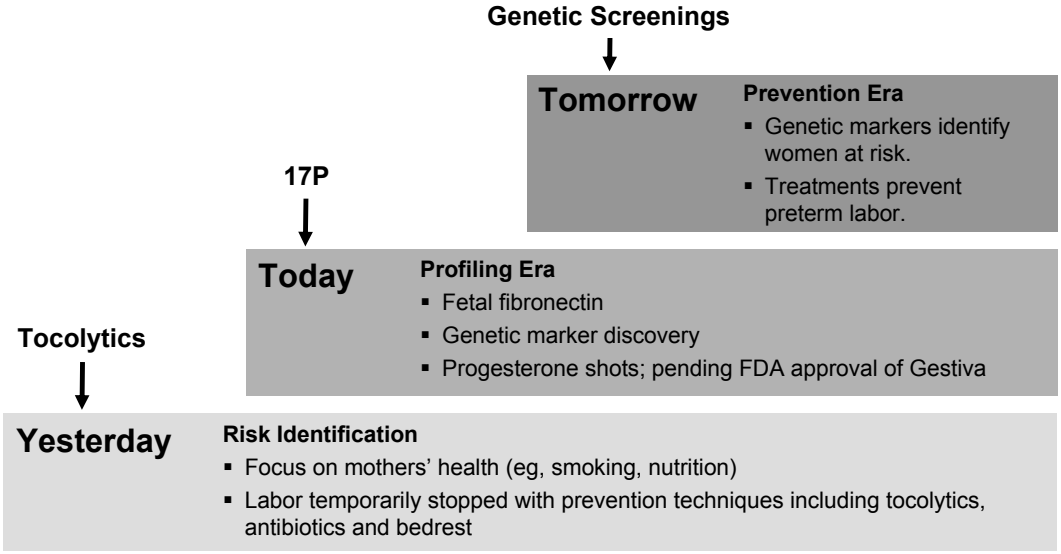
- Bioinformatics will allow for the acquisition, storage and analysis of large amounts of biomedical data.
- Investments in bioinformatics will allow for better managed data and may result in higher quality research, more discoveries and faster translations to clinical practice.
- The completion of the Human Genome Project will support future research.

Bioinformatics integration into clinical practice is expected in the next 5 years.

- Innovative children's hospitals are leading the way by establishing centers for computational medicine or bioinformatics that will accelerate bench-to-bedside research time.

Preterm Labor Will Enter the Prevention Era at the End of the Decade

Evolution of Preterm Labor Prevention



17P = 17 alpha-hydroxyprogesterone caproate.

Current treatments do not prevent preterm labor.

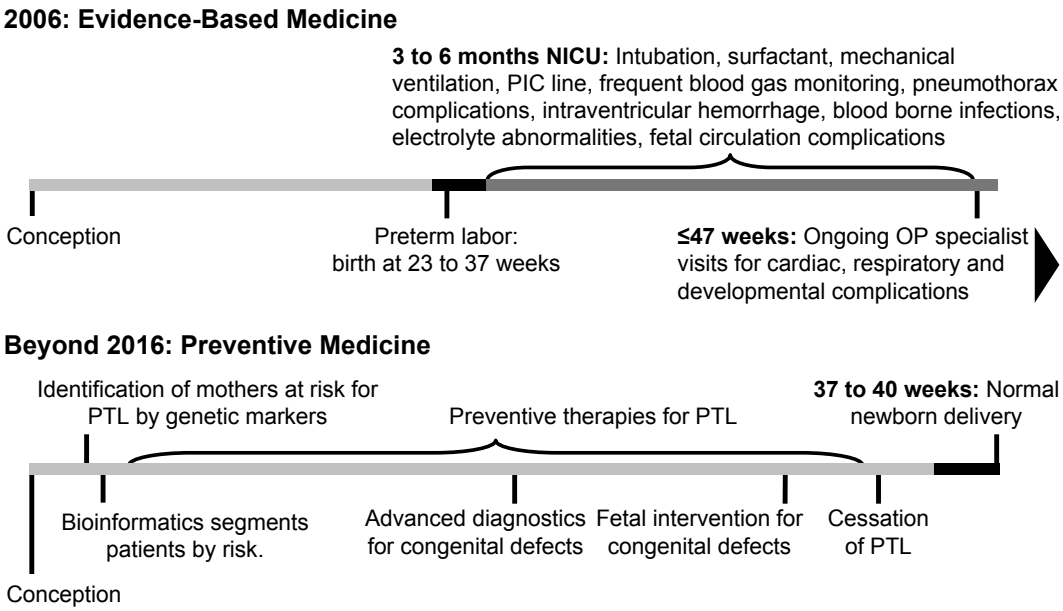
- Tocolytics briefly delay labor, allowing steroids to speed lung development.
- 17P has been prescribed off label to women with a history of preterm births by maternal-fetal-medicine specialists.
  - A 2003 National Institutes of Health (NIH) study showed an average pregnancy extension of 1 week and a 37% reduction in birth before 37 weeks in women with a history of preterm labor.
  - Gestiva (17P) is awaiting final FDA approval.
- The disintegration of fetal fibronectin (fFN), the biological glue joining the fetal sac and the uterine lining, can measure the likeliness of preterm labor.
  - Shown to be a significant diagnostic tool for negative predictive values only.

Research will lead to novel diagnostics techniques and preventative treatments.

- Researchers have identified genetic markers highly associated with preterm birth. This research is the beginning of improved identification of women at risk for preterm labor and better preventative treatments.
- New preventative strategies will necessitate a paradigm shift in the approaches of maternal-fetal medicine and neonatology; these shifts will be contingent not only on scientific discovery, but on new reimbursement models as well.

Source: Meis et al. *N Engl J Med* 2003;348:2379–2385.

Neonatal Medicine Will Evolve and Become Preventive



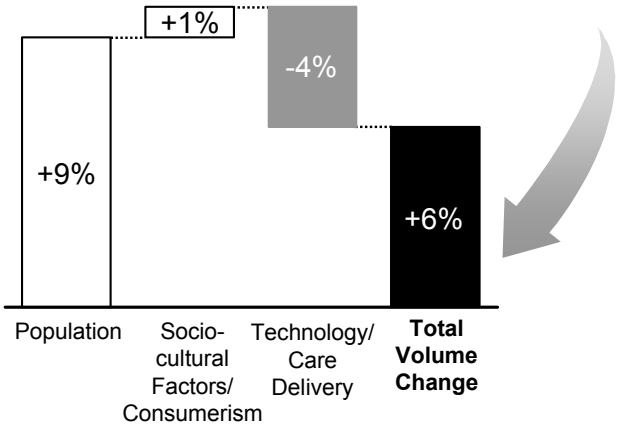
PIC = peripherally inserted central line; OP = outpatient.
Source: Sg2 Analysis, 2006.

Medicine is moving from evidence-based to preventive.

- New treatments aim to avoid late effects of preterm birth by challenging traditional delivery methods (eg, aerosolized surfactant).
- Technologic innovation will prevent anatomical development of some of the most severe conditions (eg, fetal intervention for HLHS).
- Widespread use of genetic subtyping, molecular diagnostics and bioinformatics will refine our understanding of an individual's disease and response to therapies.
- Strategies to prevent preterm labor will emerge at the end of the decade, decreasing the demand for NICU services.

Preventive Medicine Will Reduce Neonatal Intensive Care Demand

Components Contributing to Neonatal Forecast, (DRGs 385–390)* US Market, 2006–2016



Sample Factors Driving Change, DRGs 385–390

Increasing Age at First Pregnancy	+1%
Genetic Markers for Preterm Labor	–2%
Therapeutics for Preterm Labor	–1%
Rapid Group B Strep Testing	–1%

*DRGs 385–390 account for 98% of neonatal volumes nationally.
Note: These DRGs do not encompass rare congenital conditions such as HLHS.
Sources: NHDS, 2004; Sg2 Pediatric Impact of Change® Model v1.0; Sg2 Analysis, 2006.

Anticipate a slowing of intensive care demand by the end of the decade.

- Actively track adoption of clinical improvements related to advanced respiration techniques at your institution.
- Identify a clinical champion to track and lead implementation of rapid testing, bioinformatics and translational research in your institution.
- Watch for the adoption of prevention strategies and genetic risk stratification for preterm labor in your market.
- Focus on quality care delivery and improved outcomes for market share growth and improved payer negotiations.

Planning for
Superior Care Delivery

Care Delivery Must Evolve With Factors Driving NICU Demand & Clinical Change

- The physical plant of the NICU is evolving.
  - Design for refined quality and safety standards.
  - Recognize the increasing focus on family needs.
- Workforce redesign must be approached thoughtfully.
  - Changes to physical layout and clinical care will alter workflow and staff roles.
  - Simulation and collaborative workforce redesign are critical for optimizing efficiency, safety and staff satisfaction.
- New technologies and NICU equipment must be part of facility and workforce planning.
  - IT infrastructure and wireless remote monitoring are now necessities.
  - High-end diagnostics, innovative monitoring and niche interventional services will continue to delineate top-tier programs.

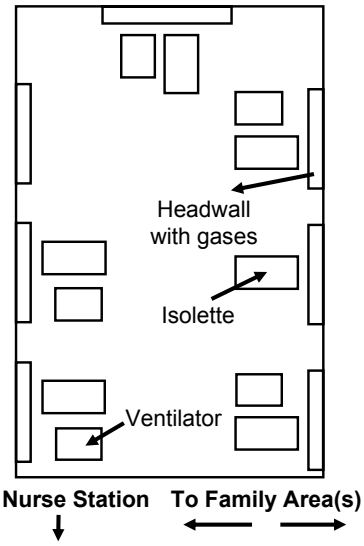
NICU operations must adapt.

- Case mix, spatial design, workforce roles and technology are evolving.
- Success necessitates construction of facility and workforce models that are aligned with future clinical need. Critical considerations include:
  - The rising role of niche technology in clinical care
  - The benefits of collective and collaborative approaches to workforce redesign
  - The growing focus on family-centered care
  - The projected tapering of NICU demand

NICU design must consider quality, safety and family.

- In an era of reduced mortality, clinical focus is expanding to rapid infection control, predictive medicine and personalized therapy.
- Physical design must compliment clinical innovation wherever possible.
- Increasing survival has meant extended, high-stress inpatient stays for the most critical NICU patients and their families.
- Facility and care delivery organizations that provide privacy, family amenities, consult space and coping/educational instruction are becoming standard of care.

Traditional NICU Design Has Followed the Open Pod Model



Note: 150 sq ft per infant recommended; requires extra parental sleeping spaces

Benefits
▪ Can view all patients simultaneously ▪ Requires less space ▪ Easy caregiver collaboration and support

Challenges
▪ Little dedicated family space; less family participation in care ▪ Additional space needed for family sleep rooms ▪ Limited personalized lighting and temperature control ▪ An inherently noisier environment ▪ Possible increased infection rates and LOS

Open pod models allow caregivers to work in close proximity.

- Caregivers are able to visualize all patients at once and often respond to infants by recognizing signs of distress before monitor alerts.
- Collaboration and multidisciplinary care is fostered.

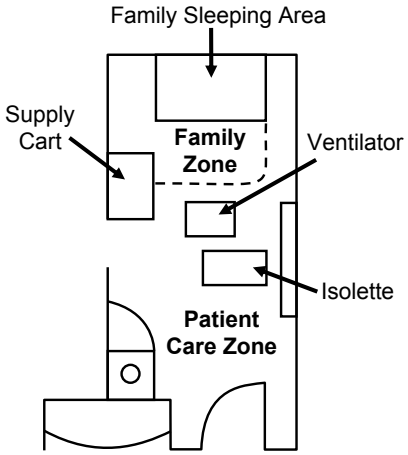
Multiple patients and families must share smaller spaces.

- Parents may feel crowded and may not actively participate in their infant's care.
- Acoustics, privacy and Health Insurance Portability and Accountability Act compliance are difficult to control.

Additional space is required for ancillary activities.

- Open pod models require less facility space, but parent sleeping rooms, consult rooms, showers spaces, etc, must be included to support family-centered care.

Private Room Design Better Controls the Environment, but Has Challenges



Benefits
▪ Personalized sound, light and temperature ▪ Dedicated family space, increased privacy ▪ Possible reduced infections and increased weight gain

Challenges
▪ May require reorganization of nursing stations and significant changes in workflow ▪ Represents a significant space expansion to most NICUs ▪ Requires large investment in wireless monitoring technology

Note: Typically requires >200 sq ft per infant. Most conversions require an expansion in overall NICU space.

Private rooms allow for increased environmental control and family space.

- Dedicated space increases family privacy and may increase family participation in care giving.
- Better environmental control may decrease nosocomial infections and ALOS.

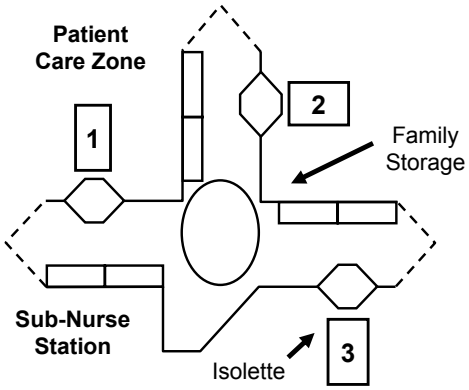
Private rooms demand new models for care delivery.

- Caregivers, patients and families may feel isolated.
  - Nursing turnover among open pod NICU staff forced to transition to private critical care rooms has been anecdotally reported as high as 30%.
- With reduced direct lines of sight between patients and caregivers, IT systems must include central monitoring and communication systems capable of providing patient data from remote locations.

The value of private critical care rooms requires more research.

- Although most argue the intuitive value of private NICU design, no clinical data yet exists that demonstrates improved quality of care, increased family satisfaction, reduced hospital cost or impact on workforce.

Hybrid Models May Offer Flexibility for Select Providers



Note: Multiple patient rooms can be traditionally organized or in a more controlled environment (eg, pinwheel).

Benefits
▪ Multiple and private rooms can be incorporated. ▪ Allows several patients to be monitored at once and permits collaborative care ▪ Increased environmental control compared with open pod models ▪ Increased dedicated family space and privacy, encouraging families to be more active in care

Challenges
▪ Possible increased rate of infection compared with all private rooms ▪ Potential change in care delivery ▪ Requires additional space, although not as much as all private rooms ▪ Requires additional ancillary space for families

Hybrid designs allow select benefits of the open pod and private room model.

- Mixed room hybrid arrangements allow for a separation of patients needing more focused care and those who are stable.
- Private rooms within mixed room arrangements allow for breastfeeding space, private consultations and parental training prior to discharge.
- Pinwheel configurations, the typical semi-shared layout in hybrid models, can be arranged in 4-patient or 3-patient configurations.
  - Four-patient configurations allow for only 94 to120 square feet per infant, potentially cramping highly complex care delivery and failing to meet the Standards for Newborn ICU Design recommendations of 120 square feet per infant minimum.

Sources: The Children's Hospital. *Caring for Our Future.* Denver, CO; Spring, 2006; *Recommended Standards for Newborn ICU Design: Report of the Sixth Census Conference on Newborn ICU Design;* Orlando, Florida, 25–27 January 2006. Available at: www.nd.edu/~nicudes.

Operations Focused on Environmental Control Are Critical

©iStockphoto.com/Matthew Hull.

Light
▪ Intense light can damage developing retinas and the visual cortex. ▪ Light should be adjustable for each infant based on developmental stage. ▪ Caregivers and parents may need natural light exposure.

Sound
▪ Noise is a noted infant stressor. ▪ It can prevent developmental benefits of sleep.

The act of providing NICU care can create undesired environmental stressors.

- Intense light is detrimental to visual and circadian rhythm development.
- High noise levels can lead to decreased oxygen saturation, elevation in blood pressure, increased heart and respiration rates and reduction in sleep.

Facility design and daily operations must balance.

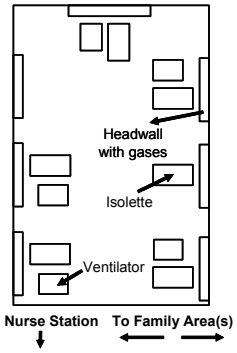
- Caregiver and family needs must be balanced with infant-friendly sights and sounds.
- Cycled light enhances infant circadian rhythm development.
- Facility modifications will reduce noise (eg, flashing light fire alarms, instant warm water faucets, and sound absorbing floors, walls and ceilings).
- Caregivers and families benefit from conditions favoring speech intelligibility and from natural light.

Source: *Recommended Standards for Newborn ICU Design: Report of the Sixth Census Conference on Newborn ICU Design;* Orlando, Florida, 25-27 January 2006. Available at: www.nd.edu/~nicudes.

Design Significantly Impacts Staff Organization and Operations

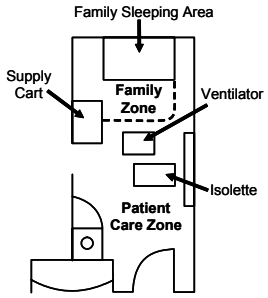
Open Pod

- Centralized nursing station
- Ability to visualize all patients at once
- Easy to share learning experiences and collaborate on care



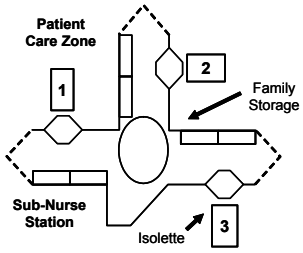
Private Rooms

- May require reorganization of nursing stations and significant changes in daily nursing care
- Relies on wireless remote monitoring technology
- Less intuitive opportunities to collaborate on care



Hybrid Model

- May require reorganization of nursing stations
- Potential change in daily nursing care
- Ability to monitor several patients at once
- Learning opportunities for caregivers, collaboration



The NICU is a unique critical care unit.

- Patients are unable to notify caregivers of changes in their condition.
- Constant observation is used to prevent problems (eg, apnea, bradycardia, labored breathing or need for suctioning) before monitors send out notification.

Private and hybrid models require tweaks to traditional nursing operations.

- Large central NICU nursing stations are eliminated and replaced with satellite stations located closer to patients.
  - Nurses are further from supporting colleagues, creating the potential for feeling isolated.
  - Satellite stations require the use of wireless monitoring technology.
  - A silent call system for nurses can be implemented to help nurses find each other quickly.
- Most facilities report total staff numbers similar to open pod models, although roles change.
  - Select private room and hybrid models have incorporated new roles, including clinical coordinators and “floating” resource nurses to eliminate isolation fears and better coordinate efficient, high-quality care.

Multidisciplinary Care Teams Require Innovative Communication Strategies

Information Transfer: Traditional wisdom is being challenged.

Virtual ICU Monitoring

Courtesy of Sentara Healthcare.

Telerounding

Printed with permission of InTouch Health.

Source: Sg2 Analysis, 2006.

Multidisciplinary teams increase the complexity of coordinating care.

- Physicians are relying on multidisciplinary teams to decipher the increasing complexity and amount of clinical information.
- Teams are not always at the same location.

New technologies allow for more timely information transfer.

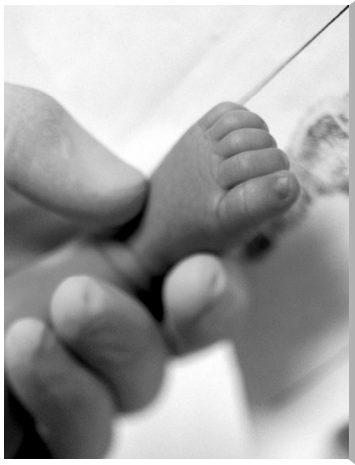
- Video monitoring, bar coding, radio frequency identification and virtual ICU monitoring will be added to traditional monitoring for enhanced safety and efficiency.

Technology advances open the door to pediatric telemedicine services.

- Telemedicine demand is heightened by the relative shortage of specialists and the increased resource needs of caring for children with chronic, complex diseases.
  - The Stanford University Network for Diagnosis of Retinopathy of Prematurity (SUNDROP) uses 5 telemedicine and digital image transfer units to serve 4 satellite hospitals, expanding the coverage of subspecialists trained to diagnose retinopathy of prematurity.
- Telemedicine is already receiving Medicaid reimbursement in approximately half of the states and will provide maximum outreach for limited pediatric specialists.

Source: Lucille Packard Children's Hospital at Stanford, 2006.

Operational Redesign Must Incorporate Increasing Roles of the Lab, IT



Advanced diagnostics and clinical information navigation will impact:

- **Speed:** Sensitivity, specificity and operational requirements of "rapid" infectious disease tests are improving.
- **Quality:** Bioinformatics will improve limited risk assessment techniques, better targeting interventions.
- **Safety:** CPOE, pharmacogenetics and drug delivery technologies are improving adverse event rates.
- **Treatment Alignment:** Personalization of therapies will ensure the right drug, at the right dose, to the right infant at the right time.

CPOE = computerized physician order entry.

Diagnostics will transform clinical decision making.

- Technologic advances are reducing advanced diagnostic turnaround times, providing more clinically relevant laboratory time frames.
  - Test results that took weeks and days, now take days and hours.
- These advances require consideration of location, staffing and communication systems between the laboratory and the NICU.
  - Satellite laboratories, POCT and electronic medical record design impact efficiency and outcomes.

It's not just diagnostics, it's clinical data navigation.

- The rise of molecular testing is increasing the data complexity provided by the lab.
  - Investments in new laboratory technologies will only be effective if physicians are able to access information that succinctly delineates a clinical decision point in an easy and timely manner.
- Electronic prescribing safeguards, IT-enhanced drug delivery schemes and pharmacogenetics will provide a more robust set of clinical information.
  - These advances will help to prevent the 13% of pediatric adverse drug events occurring in children under age 2, of which 41% result in death within the first month of age, improving outcomes and safety.

Source: Moore et al. *Pediatrics* 2002;110:e53.

Innovative Technologies Also Target NICU Pharmacy Operations

Leading Practice: Stanford pharmacy IT solution for nutrition support

Total Parenteral Nutrition (TPN)
Provides the essential nutrients, protein, carbohydrates, fats, vitamins, minerals and trace elements

Compounder mixes macronutrients; micronutrients added by hand

Old TPN Path

- 16 ingredients average, 9 of which can be lethal if given in overdose
- Time-consuming and error-prone process
- Contamination risk

System makes TPN with Baxa Exacta-Mix™ 2400 Compounder and Monterey Medical Solutions Software

Innovative TPN Path

- Reduced staff, increased production
- Reduced adverse drug reactions by over 70% in 24 months
- Reduced infections, errors
- JCAHO compliance for USP 797

Printed with permission of Baxa Corporation.

JCAHO = Joint Commission on Accreditation of Healthcare Organizations.

Multidisciplinary teams are using technologies to solve problems in new ways.

- A team of pharmacists and software experts devised a compounder with medical software designed specifically to produce TPN more safely and efficiently.
- The Baxa Exacta-Mix 2400 Compounder is a closed system that handles micro and macro ingredients.
- A TPN bag is mixed in 3 to 6 minutes.
  - Compounding staff can be reduced from 3 technicians to 1 technician making over 50% more solutions.

Source: Lucile Packard Children's Hospital (LPCH) at Stanford: New TPN process minimizes medical errors, while reducing man hours, case study.

Increased Focus on Family Needs Is Changing Care Delivery Standards

Family-centered care principles reflect the NICU mission.

- Parents are no longer "visitors," they are now partners in care.
- Parents have unrestricted access to the NICU.
- Family amenities, including sleeping space, toilet and shower areas and respite, must be provided.
- Family advisory committees are developed.
- Special programs reduce parental stress and result in decreased LOS.

Parental stress can be reduced with the integration of special programs.

- Early Intervention Programs for parents with preterm infants show parental stress can be reduced to levels comparable to their full-term peers.
  - The Creating Opportunities for Parent Empowerment (COPE) program employs audiotaped and written descriptions of premature infant development to outline specific ways to interact with premature infants.
    - Increased, positive parental interaction has shown ALOS reductions of 3.8 days, and higher cognitive development test scores at 6 months.
  - Baby CareLink allows families to view their infant and interact with caregivers using the Internet and telemedicine, increasing satisfaction and supporting parent education and emotional needs.
    - In a study of 26 VLBW Baby CareLink infants, hospital transfers were eliminated and ALOS was reduced.

Sources: Kaaresen et al. *Pediatrics* 2006;118:e9–e19; Melnyk et al. *Pediatrics* 2006;118:e1414–1427; Totzo et al. *Pediatrics* 2002.

Prepare for a Changing NICU Landscape

☑ Strategies
❑ **Understand recent NICU supply and demand trends.** ▪ Increasing rates of preterm birth, low birthweight infants and multiples have increased demand for NICU services. ▪ Neonatology remains profitable, resulting in a proliferation of services, raising quality-of-care issues. ▪ Next-generation preventative medicine will emerge late in the decade, ultimately reducing demand.
❑ **Prepare for clinical change.** ▪ Late effects of current treatments will decline as less invasive technologies are developed, affecting downstream service offerings. ▪ Strategies to reduce, and eventually prevent, preterm labor will emerge.
❑ **Consider the changing role of the laboratory, emerging technologies and innovative communication strategies to improve care delivery.** ▪ Diagnostics and therapy titration continue to advance with the integration of rapid PCR, gene profiling, pharmacogenetics and bioinformatics. ▪ Advanced imaging allows for earlier treatments (eg, EXIT, fetal intervention) for infants with serious defects. ▪ Access to high-end diagnostics, new monitoring, niche interventional services and novel staff and parent communication systems will continue to delineate top-tier programs. ▪ Multidisciplinary care teams require innovative communication strategies.
❑ **Design facilities to address evolving standards of care, clinical quality improvement and patient/family experience.** ▪ Design facilities for evolving safety and quality standards. ▪ Devise care delivery models that encourage caregiver collaboration and optimize efficiency. ▪ Ensure optimal organization and communication between the NICU and new laboratory and pharmacy innovations. ▪ Incorporate family-centered care principles into NICU culture.

Anticipate the Impact of Change

Sg2's analytics-based health care expertise helps hospitals and health systems integrate, prioritize and drive growth and performance across the continuum of care. Over 1,200 organizations around the world rely on Sg2's analytics, intelligence, consulting and educational services.

0207-CLN-205

5250 Old Orchard Road Skokie, Illinois 60077
847.779.5300 **Sg2.com**