We Count What We Can Count and We Measure What We Can Measure: Are Traditional Perinatal Indicators Relevant in the 21st Century Context?

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Objectives

- To review the origins, use, and scientific utility of major clinical and public health indicators of perinatal outcomes
- To identify links between theory and practice in terms of clinical measures as public health indicators
- To illustrate a methodology for developing and evaluating new clinical indicators

“In theory, there is no difference between theory and practice. In practice there is.”

- Yogi Berra

Conflict of Interest Statement

- Dr. Kirby has grants and contracts from the Centers for Disease Control and Prevention, the Florida Department of Health, and the March of Dimes Foundation.
- Dr. Kirby serves as chair of the scientific advisory committee for the Nplate pregnancy exposure registry for Amgen Corp.
- Dr. Kirby is past president of the Society for Pediatric and Perinatal Epidemiologic Research and the Association of Teachers of Maternal and Child Health, serves on the executive committee of the National Birth Defects Prevention Network, and on the board of the Perinatal Foundation. He is also treasurer of the 37th Street Foundation, a family charitable foundation. He also leads the USF team in the annual March for Babies in support of the March of Dimes Foundation.
- Dr. Kirby is a bluegrass and roots music fanatic, has been known to travel long distances in search of the true article, and has considered placing the following bumper sticker on his car: "Caution: this car breaks for bluegrass".
- None of these relationships have any bearing on the content of this presentation.

As to potential versus actual conflicts of interest, the evidence is here for all to judge.

Birth defects and developmental disabilities epidemiologists have generated a new entity that must now be accorded its due:

Amniotic Band Syndrome

The Amniotic Band – Washington DC July 26, 2004

Where Will They Appear Next?

- Unconfirmed rumors suggest that the Amniotic Band may perform at the National Birth Defects Prevention Network, on the evening of February 26, 2013.

- Tickets are going fast, but its possible someone might post it on YouTube.

“We count what we can count, not what counts.”

- Dr. Brian McCarthy, CDC

Top Ten List of Beliefs Based on Perinatal Indicators and Outcomes (as presented by Dr. Kirby to the National Perinatal Association in 1998)

1. Adolescent mothers have poorer birth outcomes
2. Prenatal care prevents low birth weight and preterm birth
3. Cerebral palsy is caused by intrapartum events
4. Adequacy of prenatal care is associated with better perinatal outcomes
5. Cesarean section rates are too high due primarily to physician factors

Top Ten List of Beliefs Based on Perinatal Indicators and Outcomes (continued)

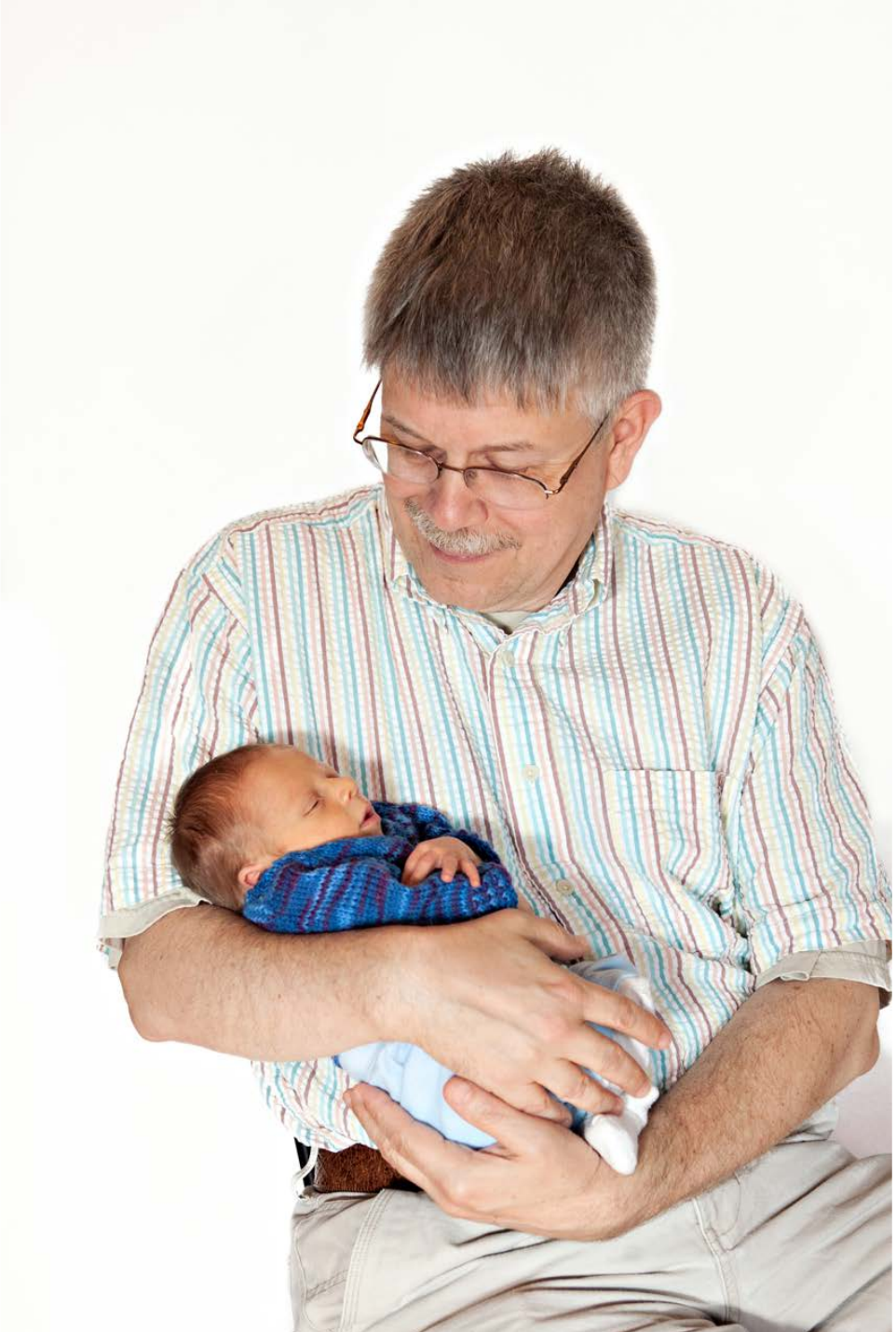
6. Now that every hospital is Level III, perinatal regionalization no longer matters
7. Infant mortality rates can be significantly reduced through social interventions (i.e. Healthy Start)
8. As survival of extremely low birth weight infants improves, rates of neurological/developmental disabilities are rising
9. Underlying causes of perinatal death accurately reflect clinically significant factors in mortality
10. If we keep track of indicators and outcomes, we are practicing clinical quality improvement

Why All the Fuss?

- Perinatal outcomes for the US have worsened during the past two decades.
  - Increases in low birth weight births
  - Large rise in rate of preterm delivery
  - Modest improvements in infant mortality rates, but declines in relative national standing
  - Small to no improvement in fetal mortality or stillbirth rates
  - Dramatic increase in rate of Cesarean section

Conventional Indicators in Perinatal Health

- Low Birth Weight
- Preterm Birth
- Neonatal Mortality Rate
- Adequacy of Prenatal Care
- And, time permitting, some others . . .



Low Birth Weight

- One of the most commonly used measures in perinatal care
- Measured as weight at birth of less than 2500g or 5lbs 8oz

Origins of the LBW Construct

- Low birth weight was originally conceived as a measure of the proportion of infants born at high risk.
- The use of the 2500g or 5lb 8 oz definition dates to a recommendation made by the World Health Organization in 1948, and was based on several early studies (Dunham 1936; Ylppo 1919).

Usage of the LBW Measure in the United States

- In early usage in American vital statistics, LBW was conceptualized as a synonym for prematurity.
- LBW was first incorporated into birth certificate reporting nationally in 1950.

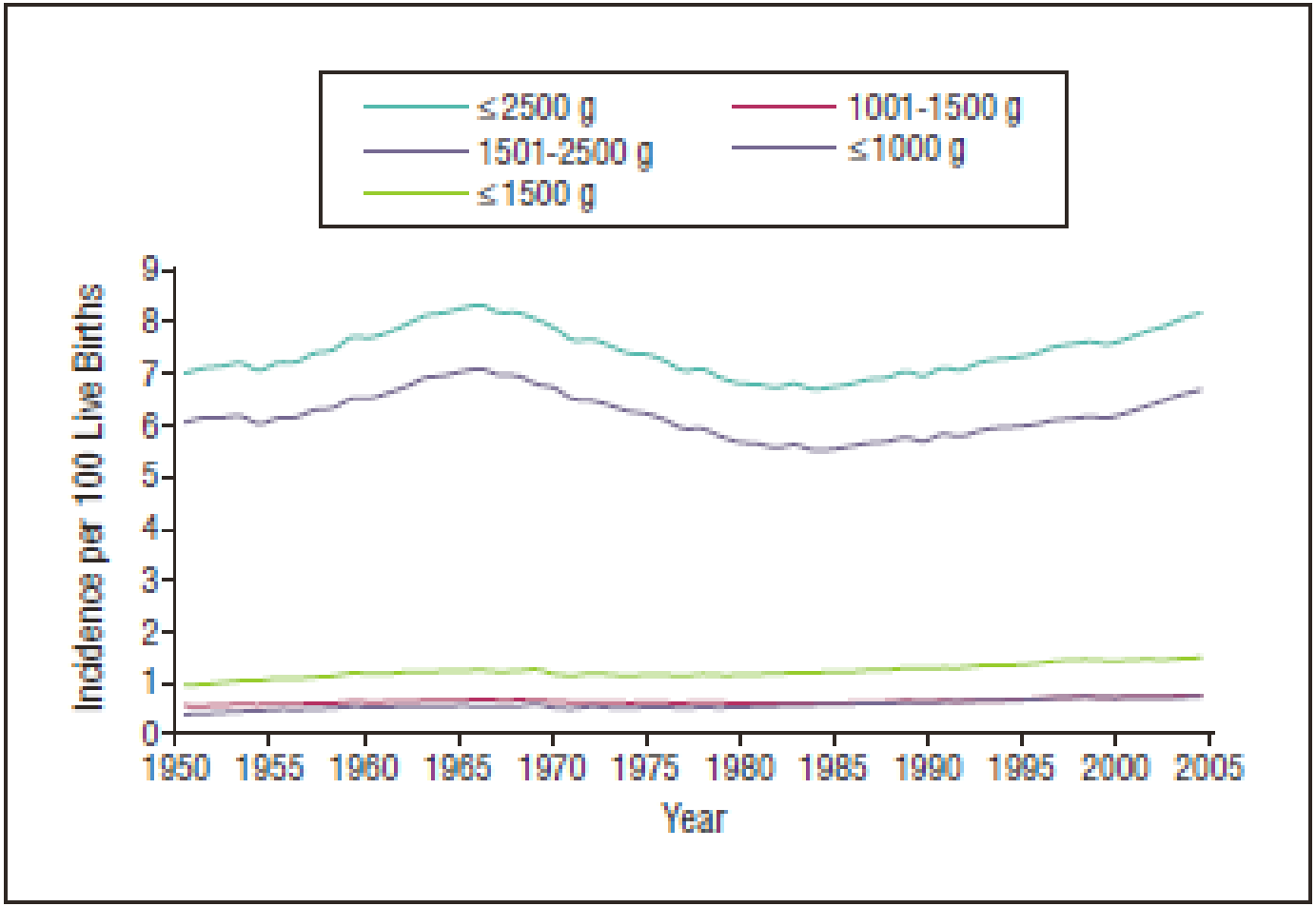


Figure. Incidence of low birth weight: 1950 to 2005.

Source: Brosco et al. Arch Pediatr Adolesc Med 2010;164:99-100

What's Happened Since the 1950s?

- Invention of neonatal intensive care
- Creation of regionalized systems of perinatal care
- Emergence of clinical sub-specialities in medicine, nursing, psychology, nutrition, social work
- Development of new therapies

LBW and Risk

- More than 80% of infants classed as LBW today are born at >2000g. The vast majority of LBW live births never spend a day in the NICU.
- There are differences also across race/ethnic groups. While the LBW rate for NHB infants is frequently twice that for NHW babies, by gender and birth weight strata their outcomes are generally better. Does using a single measure for birth weight across race/ethnic groups make sense?
- Also, as shown, LBW seems to be subject to secular variation.

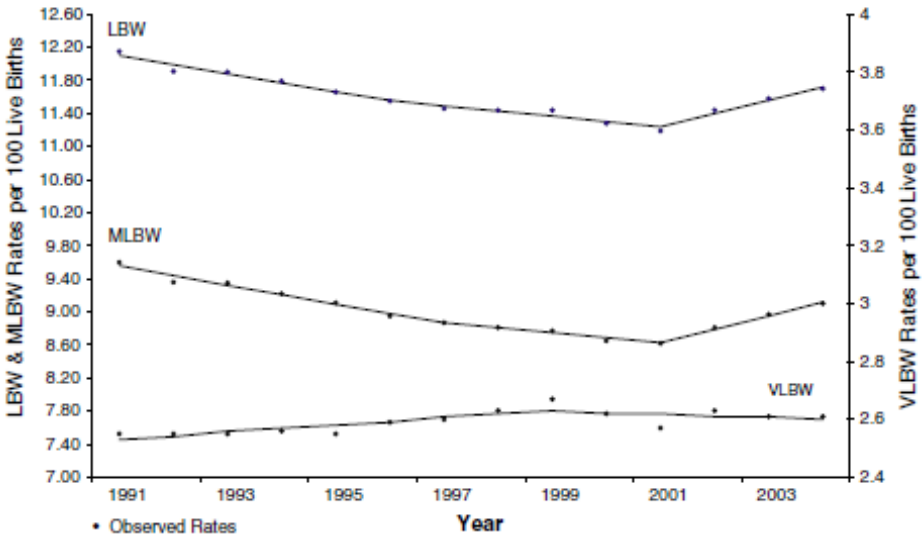


Fig. 1 Trends in birth weight outcomes, singleton births, US non-Hispanic black infants, all states, 1991–2004. *LBW* low birth weight (*left Y*-axis, %), *MLBW* moderately LBW (*left Y*-axis, %), *VLBW* very LBW (*right Y*-axis, %)

Alternative Measures

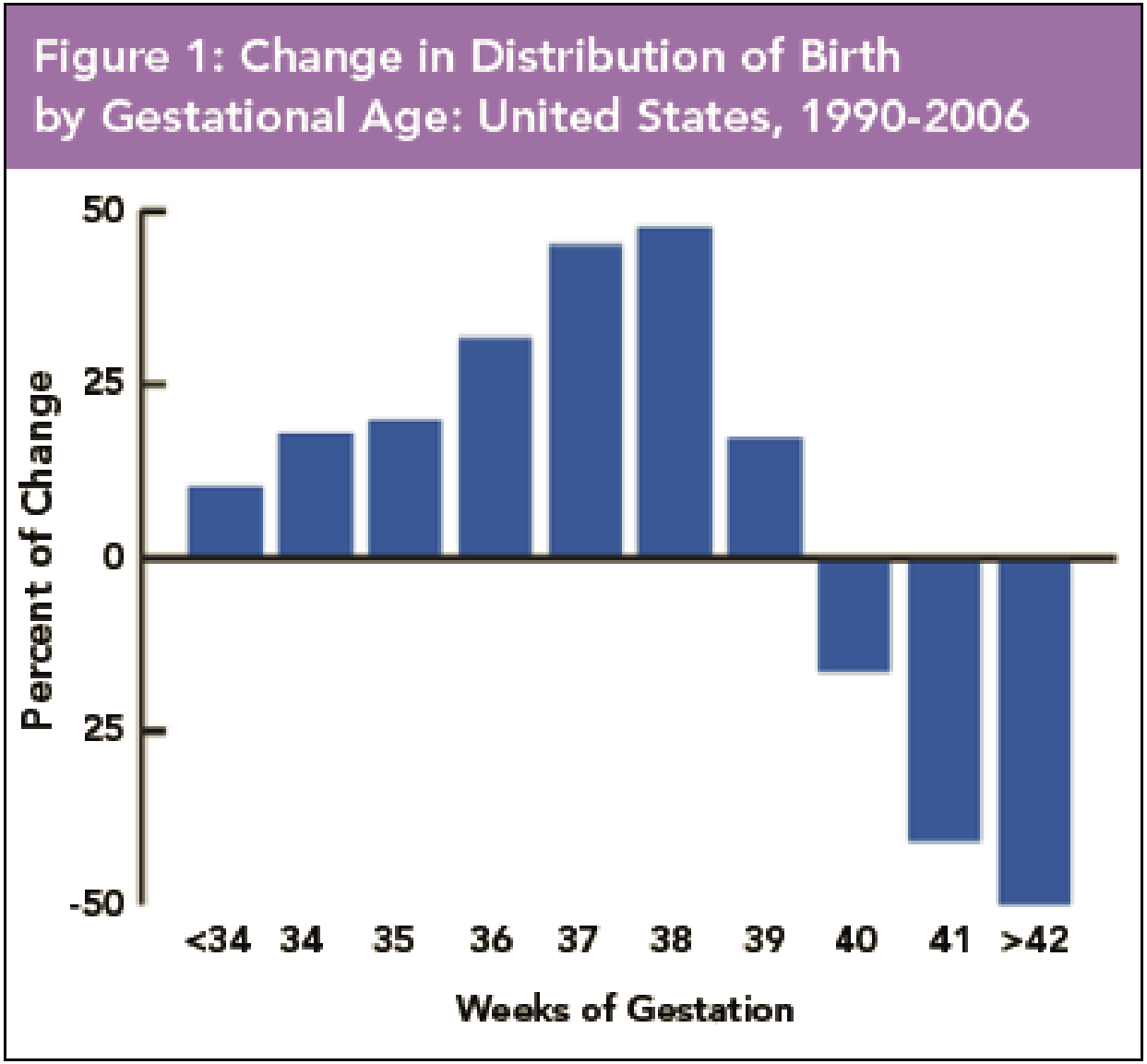
- Several alternative or related measures are already in use:
  - VLBW - <1500g and MLBW – 1500-2499g
  - XLBW – various definitions including <1000g, <750g, etc
- If our goal is to capture those infants that place a burden on our health and social systems, what about combination measures:
  - The small-for-gestational age low birth weight infant
  - Infants dying <24 hrs after birth plus those admitted to NICU for >24 hrs

Preterm Birth

- Preterm birth was proposed more recently as a measure of prematurity. It came into widespread use only in the 1980s, after gestational age dating began to be uniformly reported on birth certificates.
- Based on outcomes of NICU care at the time, it was decided that less than 37 weeks gestation would adequately capture the babies meeting the criterion of the theoretical construct of 'prematurity'.

Preterm Birth (continued)

- Mean gestation of a human pregnancy is thought to be approximately 280 days.
- Differences are routinely discerned in comparisons by race/ethnic groups, by maternal age, and other factors.
- Measurement has also changed – in the 1970s date of last menstrual period (LMP) was virtually the only option for calculating gestational age prior to birth, but now we take numerous ultrasounds and have developed several quantitative measures to make these estimates. Assessment of the physical characteristics of the infant/fetus at birth can also yield an estimate of gestational age.
- The distribution of live births by week of gestation has also been changing.



Source: CDC/NCHS, National Vital Statistics System.

Figure 4: Higher Ventilator Use Among Infants Delivered at 37 Weeks Gestation

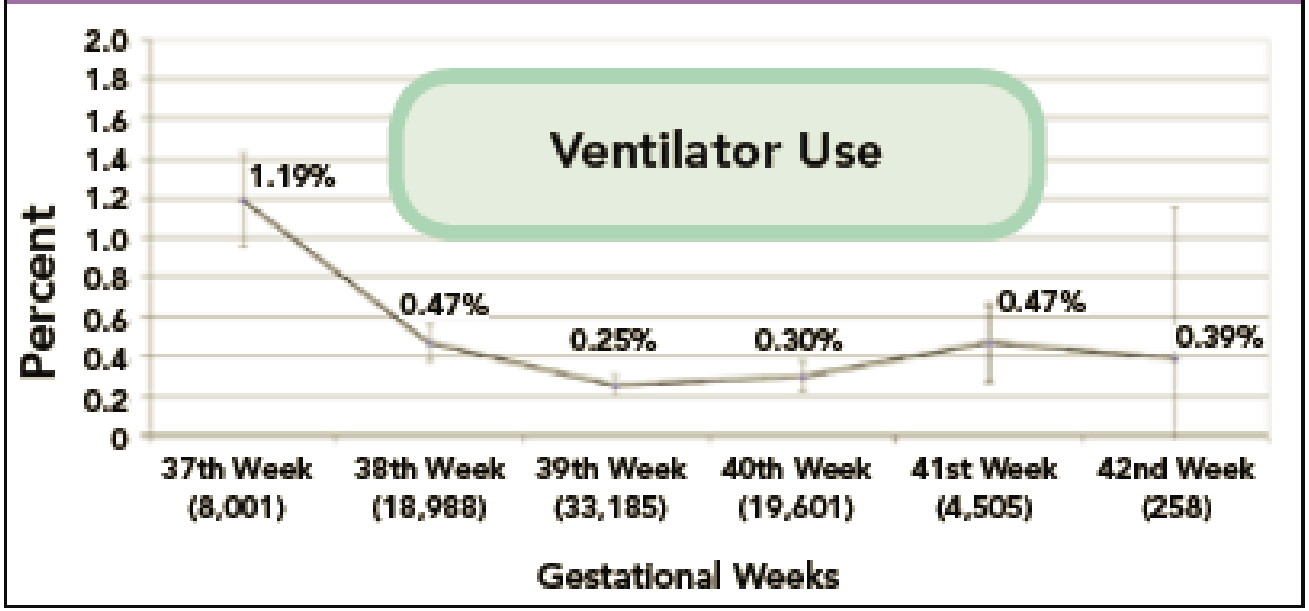
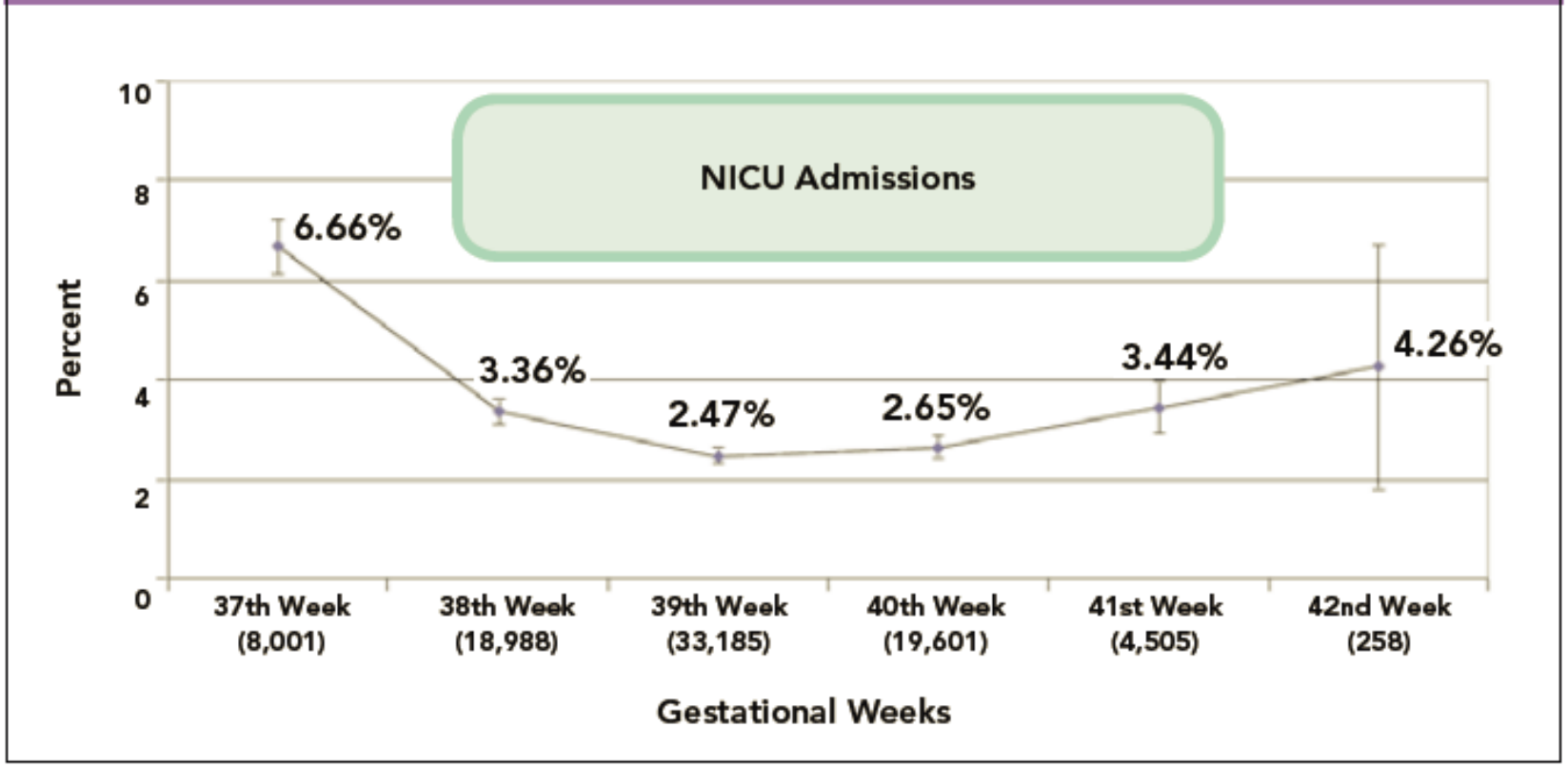


Figure 5: Increased NICU Admissions Among Infants Delivered at 37 Weeks Gestation



Figures 4 and 5: Oshiro, B. et al. Decreasing elective deliveries before 39 weeks of gestation in an integrated health care system. Obstet Gynecol, 2009. 113: p. 804-811. Permission to adapt and use granted.

Table 3: Risk of NICU Admissions for Elective Deliveries at 37-39 Weeks (HCA)			
	37+0 to 37+6 weeks	38+0 to 38+6 weeks	39+0 to 39+6 weeks
Elective inductions (N) NICU admission %	112 **15.2%**	678 **7.0%**	2004 **6.0%**
Elective cesarean births (N) NICU admission %	129 **20.1%**	793 **9.3%**	929 **8.0%**
TOTAL elective deliveries (N) NICU admission %	241 **17.8%** ($p<0.001$)	1471 **8.0%** ($p<0.001$)	2933 **4.6%**

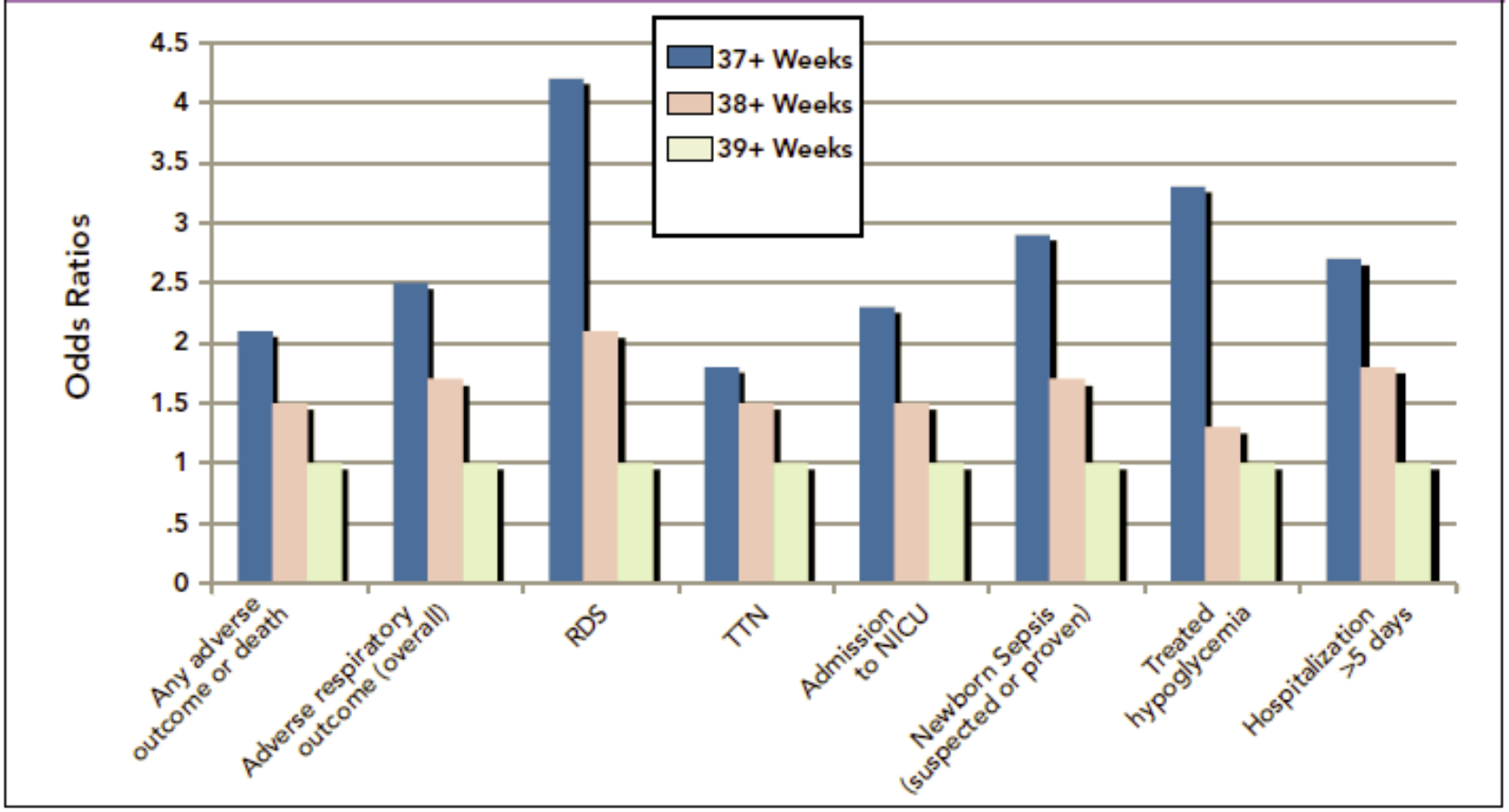
Adapted from: Clark, S.L. et al. Neonatal and maternal outcomes associated with elective term delivery. Am J Obstet Gynecol, 2009. 200(2): p. 156 e1-4. Permission to adapt and use granted

Table 4: Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes (MFM Network)

Outcome	37+0 to 37+6 weeks		38+0 to 38+6 weeks		39 Completed Weeks N=6512 (%) (Reference)
	N=834 %	Odds Ratio*	N=3909 %	Odds Ratio*	
Any adverse outcome or death	15.3%	2.1	11.0%	1.5	8.0%
Adverse respiratory outcome (overall)	8.2%	2.5	5.5%	1.7	3.4%
Respiratory Distress Syndrome (RDS)	3.7%	4.2	1.9%	2.1	0.9%
Transient Tachypnea of the Newborn (TTN)	4.8%	1.8	3.9%	1.5	2.7%
Admission to NICU	12.8%	2.3	8.1%	1.5	5.9%
Newborn sepsis (suspected or proven)	7.0%	2.9	4.0%	1.7	2.5%
Treated hypoglycemia	2.4%	3.3	0.9%	*1.3 (NS)	0.7%
CPR or ventilation in first 24 hours	1.9%	—	0.9%	—	0.4%
Hospitalization ≥5 days	9.1%	2.7	5.7%	1.8	3.6%

**All Odds Ratios are significant except "NS" (Not Significant).*
Adapted from: Tita, A. et al. Timing of elective cesarean delivery at term and neonatal outcomes. The New England Journal of Medicine, 2009. 360: p. 111-20.

Figure 7: Odds Ratios for Complications in Infants of Scheduled Repeat Cesarean Birth by Gestational Age (Weeks)



Figures 6 and 7 adapted from: Tita, A. et al. Timing of elective cesarean delivery at term and neonatal outcomes. The New England Journal of Medicine, 2009. 360: p. 111-20.

A baby's brain at 35 weeks weighs only two-thirds of what it will weigh at 39 to 40 weeks.

35 weeks

39 to 40 weeks

Comparison of Traditional Gestational Age-Specific Stillbirth Rate with Fetuses-At-Risk Approach

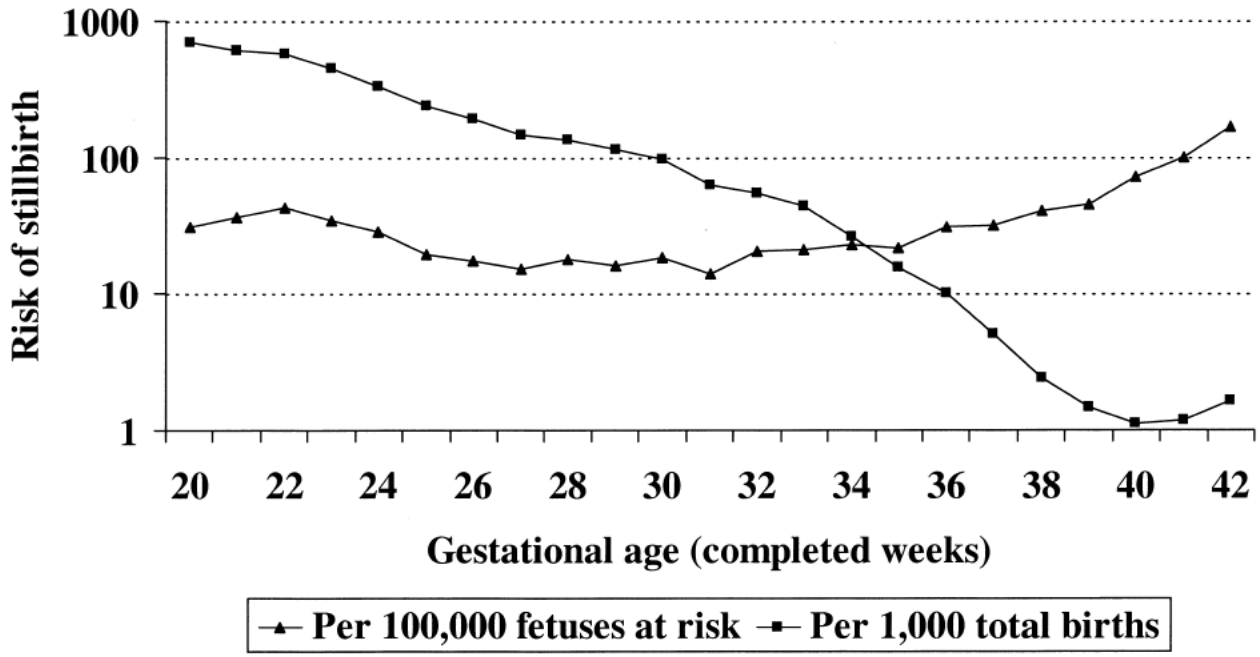


FIGURE 1. Hazard (per 100,000 fetuses at risk) versus proportion (per 1,000 total births) representations of stillbirth risk in Canada, 1991–1998.

Am J Epidemiol Vol. 156, No. 6, 2002

An Alternative Measure for Preterm Birth

- Rather than defining preterm birth as any delivery at <37 weeks gestation, why not bite the bullet and define it as a birth at <39 weeks gestation?
  - This is still less than 280 days
  - This would include all the infants in the so-called 'early term' period who clearly also have biologic risk associated with delivery prior to term
  - It would give us a lot of work to do . . .
  - Currently neither Peristats nor CDC Wonder can produce this statistic but if they could, close to half of all live births would be classed as preterm.

Neonatal and Postneonatal Mortality

- These terms are used to differential rates of infant death among live births between the first month and the balance of the first year of life.
- Historically, neonatal mortality was a proxy measure for infant deaths of *endogenous* causes (congenital or perinatal) while postneonatal mortality was used as a proxy for infant deaths of *exogeneous* causes (social or environmental).

Neonatal and Postneonatal Mortality (continued)

- While these proxy measures may have made sense in the 19th or early 20th centuries, they make little sense today.
- Yet, we continue to report and track both.
- Let's look at some empirical data to make this point more clear . . . The following are from Kirby RS, *J Perinatol* 1993.

Table 2

RELATIVE DIFFERENCE RATIOS FOR ENDOGENOUS-NEONATAL AND EXOGENOUS-POSTNEONATAL MORTALITY RATES BY BIRTH WEIGHT BASED ON UNDERLYING CAUSE OF DEATH, WISCONSIN, 1979 TO 1981 AND 1984 TO 1986

Birth Weight (gm)	Endogenous Mortality Rate	Neonatal Mortality Rate	Relative Difference Ratio*	Exogenous Mortality Rate	Postneonatal Mortality Rate	Relative Difference Ratio†
1979-1981						
<1500	442.66	412.25	0.93	6.91	33.16	4.80
1500-2499	26.59	21.88	0.82	2.66	7.36	2.77
≥2500	2.49	1.68	0.67	0.57	1.37	2.40
Total	8.05	6.81	0.84	0.74	1.99	2.69
1984-1986						
<1500	388.14	365.72	0.94	8.41	30.83	3.66
1500-2499	22.82	17.80	0.78	1.82	6.82	3.74
≥2500	2.22	1.45	0.65	0.51	1.31	2.57
Total	6.97	5.78	0.83	0.65	1.84	2.84

Endogenous, exogenous, neonatal, and postneonatal mortality rates are per 1000 live births.
*Neonatal mortality rate/endogenous mortality rate.
†Postneonatal mortality rate/exogenous mortality rate.

Kirby RS: J Perinatol 1993

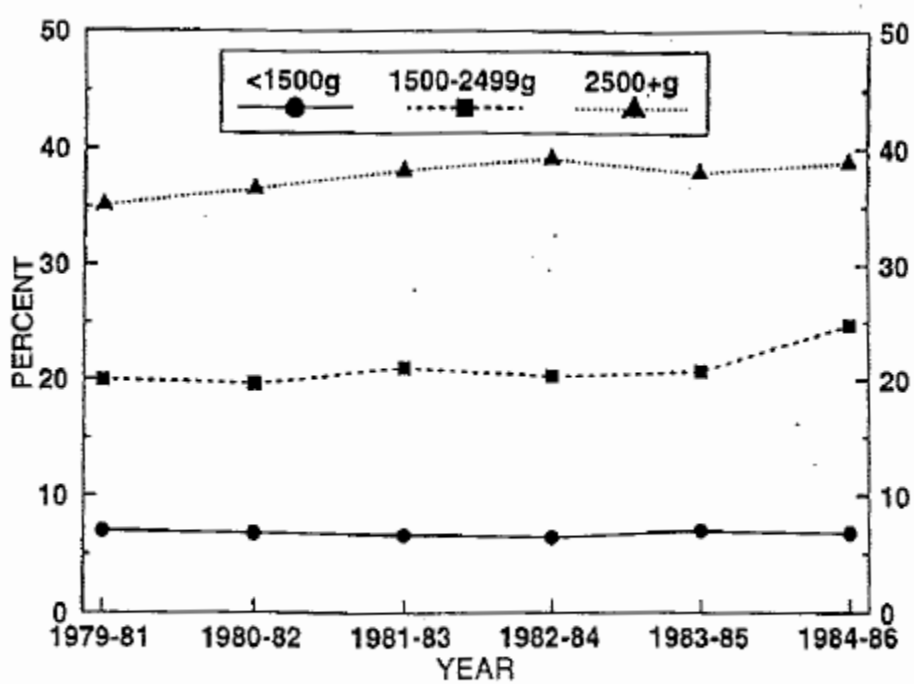


Figure 2 — Postneonatal deaths attributed to endogenous causes as percentage of all endogenous infant deaths by birth weight—Wisconsin, 1979 to 1986 (resident birth cohort data).

Kirby RS: J Perinatol 1993

Table 3

ENDOGENOUS AND EXOGENOUS NEONATAL MORTALITY RATES BY BIRTH WEIGHT, WISCONSIN, 1979 TO 1986 (RESIDENT BIRTH COHORT DATA)

Birth Weight (gm)	Yr	Total Live Births	Neonatal Deaths	Neonatal Mortality Rate	Endogenous Deaths	Endogenous Neonatal Mortality Rate	Exogenous Deaths	Exogenous Neonatal Mortality Rate
All Live Births	1979-1981	222,281	1,532	6.9	1,487	6.7	20	0.1
	1984-1986	218,926	1,283	5.9*	1,238	5.7*	19	0.1
< 1500	1979-1981	2,171	891	410.4	889	409.5	2	0.9
	1984-1986	2,141	777	362.9*	774	361.5*	1	0.5
1500-2499	1979-1981	9,779	218	22.3	209	21.4	5	0.5
	1984-1986	9,380	168	17.9†	163	17.4†	4	0.4
≥ 2500	1979-1981	210,256	374	1.8	341	1.6	12	0.1
	1984-1986	207,195	324	1.6	287	1.4†	14	0.1

*Significantly different from 1979 to 1981, $p < 0.001$.
†Significantly different from 1979 to 1981, $p < 0.05$.

Kirby RS: J Perinatol 1993

Table 4

ENDOGENOUS AND EXOGENOUS POSTNEONATAL MORTALITY RATES BY BIRTH WEIGHT, WISCONSIN, 1979 TO 1986 (RESIDENT BIRTH COHORT DATA)

Birth Weight (gm)	Yr	Total Neonatal Survivors	Postneonatal Deaths	Postneonatal Mortality Rate	Endogenous Deaths	Endogenous Postneonatal Mortality Rate	Exogenous Deaths	Exogenous Postneonatal Mortality Rate
All live births	1979-1981	220,749	755	3.4	312	1.4	129	0.6
	1984-1986	217,643	763	3.5	293	1.3	109	0.5
< 1500	1979-1981	1,280	79	61.7	67	52.3	5	3.9
	1984-1986	1,364	71	52.1	56	41.1	10	7.3
1500-2499	1979-1981	9,561	125	13.1	53	5.5	18	1.9
	1984-1986	9,212	108	11.7	53	5.8	11	1.2
≥ 2500	1979-1981	209,882	538	2.6	184	0.9	103	0.5
	1984-1986	206,871	581	2.8	182	0.9	88	0.4

Neonatal survivors are resident live births less neonatal deaths.

Kirby RS: J Perinatol 1993

Alternative Measures

1. Redefine neonatal and postneonatal mortality as density-based measures

   - Neonatal mortality would be calculated as all infant deaths occurring prior to initial newborn discharge, divided by the total number of days to initial newborn discharge among all liveborn infants

   - Postneonatal mortality would be calculated as all infant deaths occurring after initial discharge, divided by the total days from discharge to end of first year of life among all liveborn infants not dying prior to initial discharge

   This requires record linkage across hospital discharges serially linked across infants with birth and death certificates

Alternative Measures

2. Adjust the neonatal period for preterm infants to account for the number of preterm weeks. Calculate rates using conventional approach.

   - for example, a baby born at 34 weeks would have a neonatal period lasting till 10 weeks (6 preterm weeks plus the traditional four of the neonatal period) while a baby born at 41 weeks would have no adjustment.

   Experimentation would be necessary to determine whether adjustments should be made for early term infants.

Alternative Measures

3. Carefully delineate all factors and processes involved in the infant's demise.

Classify all infant deaths as endogenous or exogenous, and rather than operationalizing these measures as neonatal and postneonatal, measure them directly as the number of infant deaths due to endogenous causes, divided by all live births, and the number of infant deaths due to exogenous causes, divided by all live births.

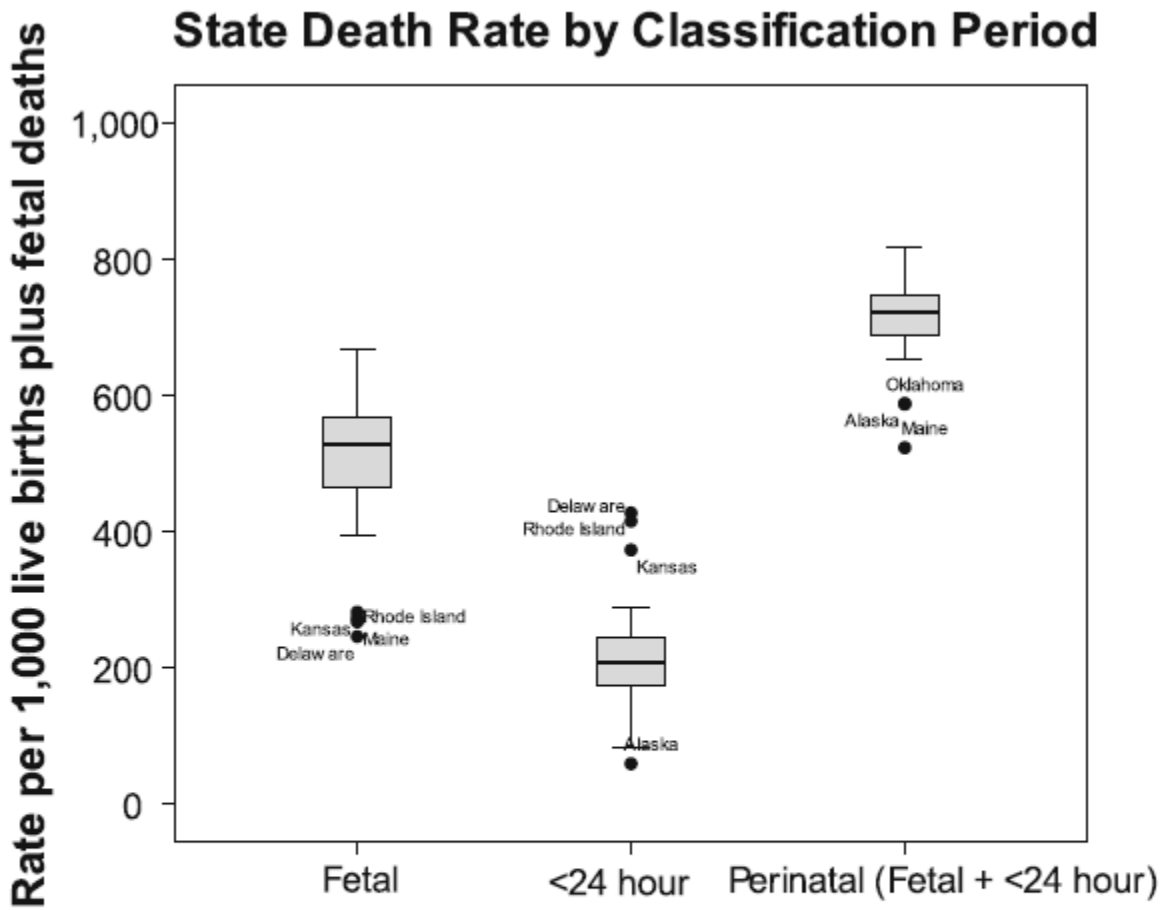
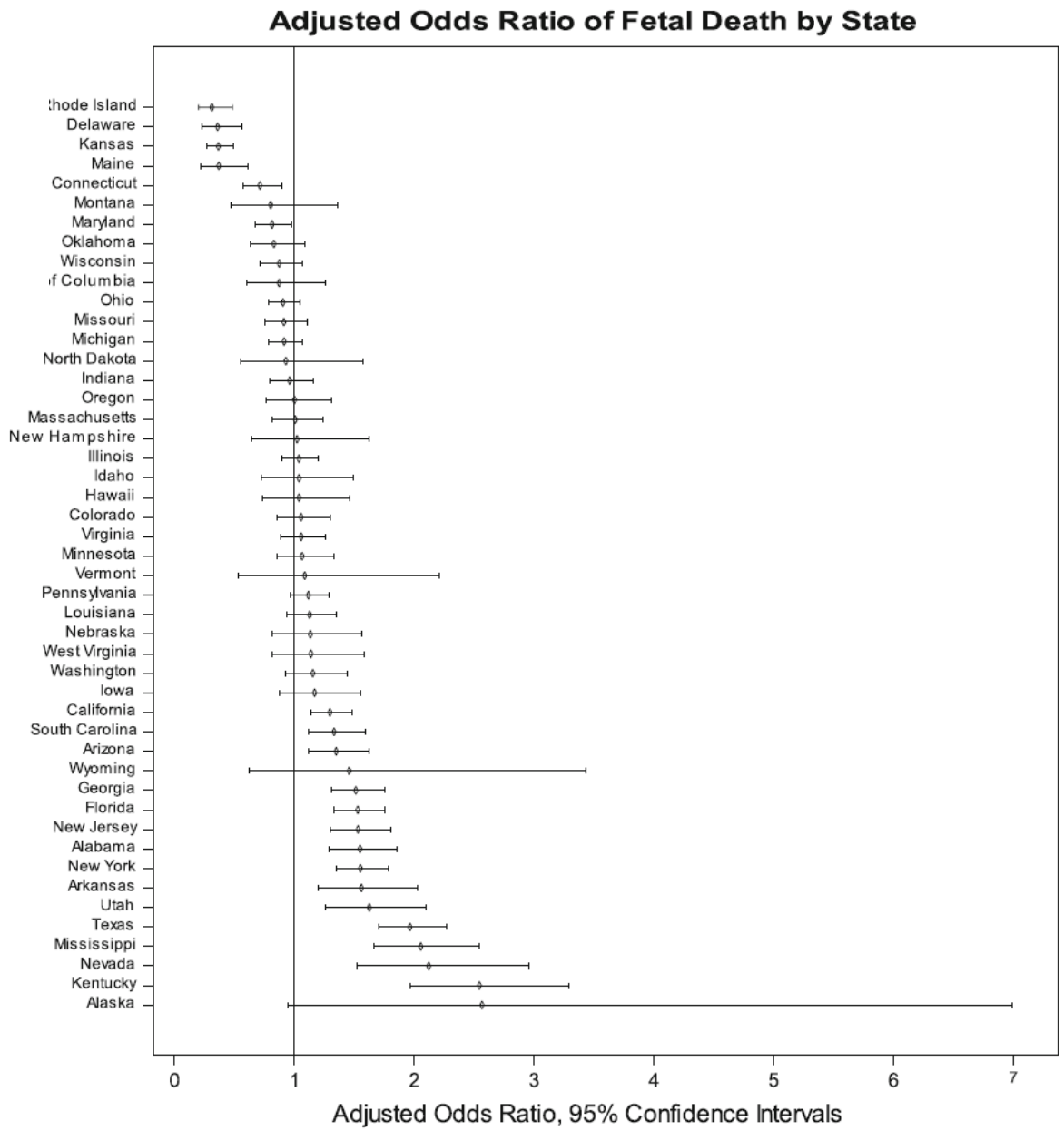


Fig. 1 State death rate by classification period. Death rates per 1,000 fetal deaths + live births under 500 g by state for the 48 states reporting fetal deaths in this birthweight category. States outside of the 1.5 inter-quartile range are identified as outliers (*filled circle*)

Source: Ehrenthal et al. MCH Journal 2011

Fig. 2 Adjusted odds ratio, with 95% confidence intervals, of fetal deaths among the cohort of fetal plus <24 h infant deaths for each state with North Carolina as the reference group



Source: Ehrenthal et al. MCH Journal 2011

Adequacy of Prenatal Care

- Presently, we collect data on when during the pregnancy prenatal care was initiated, and how many prenatal visits occurred during the pregnancy.
- In many states, we collect this information from the mother rather than from the clinical prenatal record.

Adequacy, continued

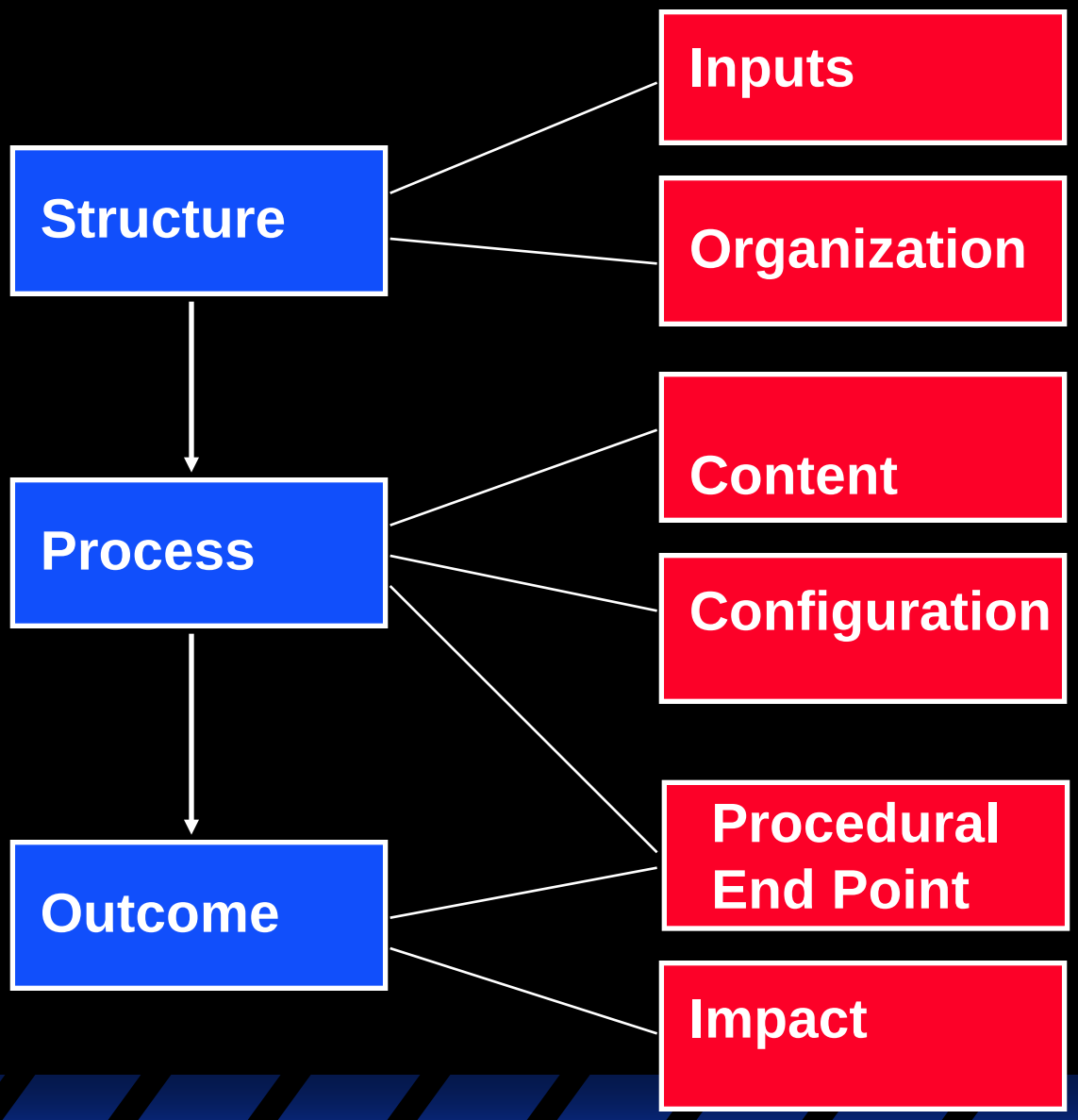
- Adequacy of prenatal care has been defined in terms of the relationship between the actual number of prenatal visits and the expected number according to ACOG or other clinical guidelines, adjusted for the duration of the pregnancy.
  - Kessner Index
  - Kotelchuck Index
  - Alexander's GINDEX

Adequacy, continued

- Each of the indices classifies prenatal care into adequate, intermediate, inadequate, in some cases further delineating an 'adequate plus' category for those women with considerably more than expected number of visits.
- Hundreds of scientific papers have been published using these indices, yet rarely do the researchers stop to think about the relationship of the measure to the theoretical construct, nor about the quality and integrity of the data elements used to compute the measures.

Adequacy, continued

- As long as we count only what we can count, this will be the basis for our discussions.
- But what is prenatal care really about?
  - A set of clinical services, tests and measures
  - Counseling, education, anticipatory guidance at critical points and continuing through the pregnancy
  - Continuity of care
  - Etc . . .
- Perhaps we should take a step back, and think about what we really want to know, then determine how we might effectively collect the data we really need.



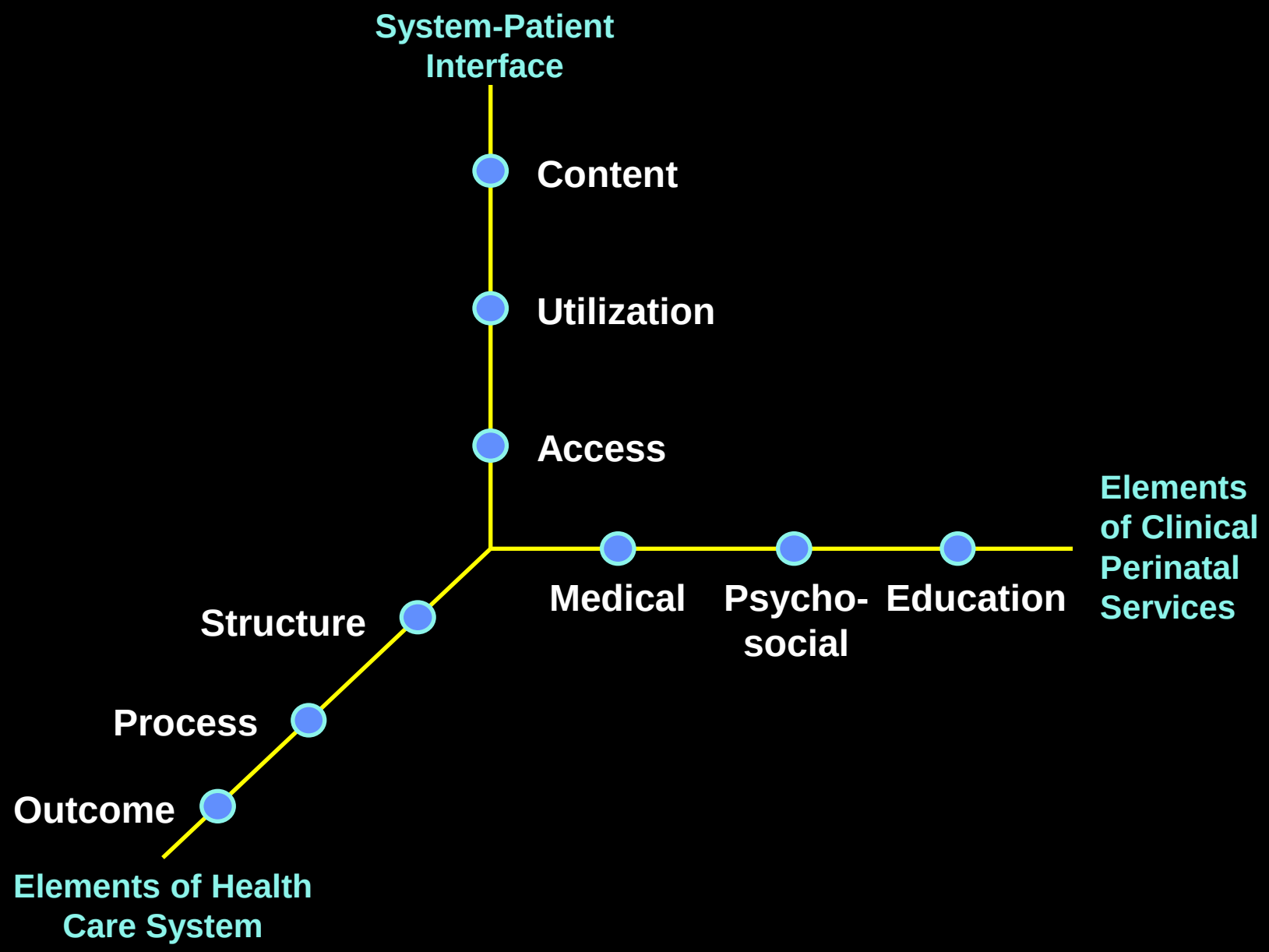
Source: Donabedian A: Explorations in Quality Assessment and Monitoring, Volume I. The Definition of Quality and Approaches to its Assessment. Ann Arbor: Health Administration Press, 1980; p. 90.

QUALITY INDICATORS IN RELATION TO APPROACHES TO ASSESSMENT IN HEALTH SERVICES RESEARCH

Maternal/Child Health Care Quality Indicators		Approaches to Assessment		
		Structure	Process	Outcome
System Attributes	Accessibility	X		
	Availability	X		
	Responsiveness	X		
	Adequacy	X	X	
Care Characteristics	Prevention		X	
	Minimization of Adverse Consequences		X	
	Maintenance of Health		X	
	Rehabilitation		X	
Effectiveness			X	X

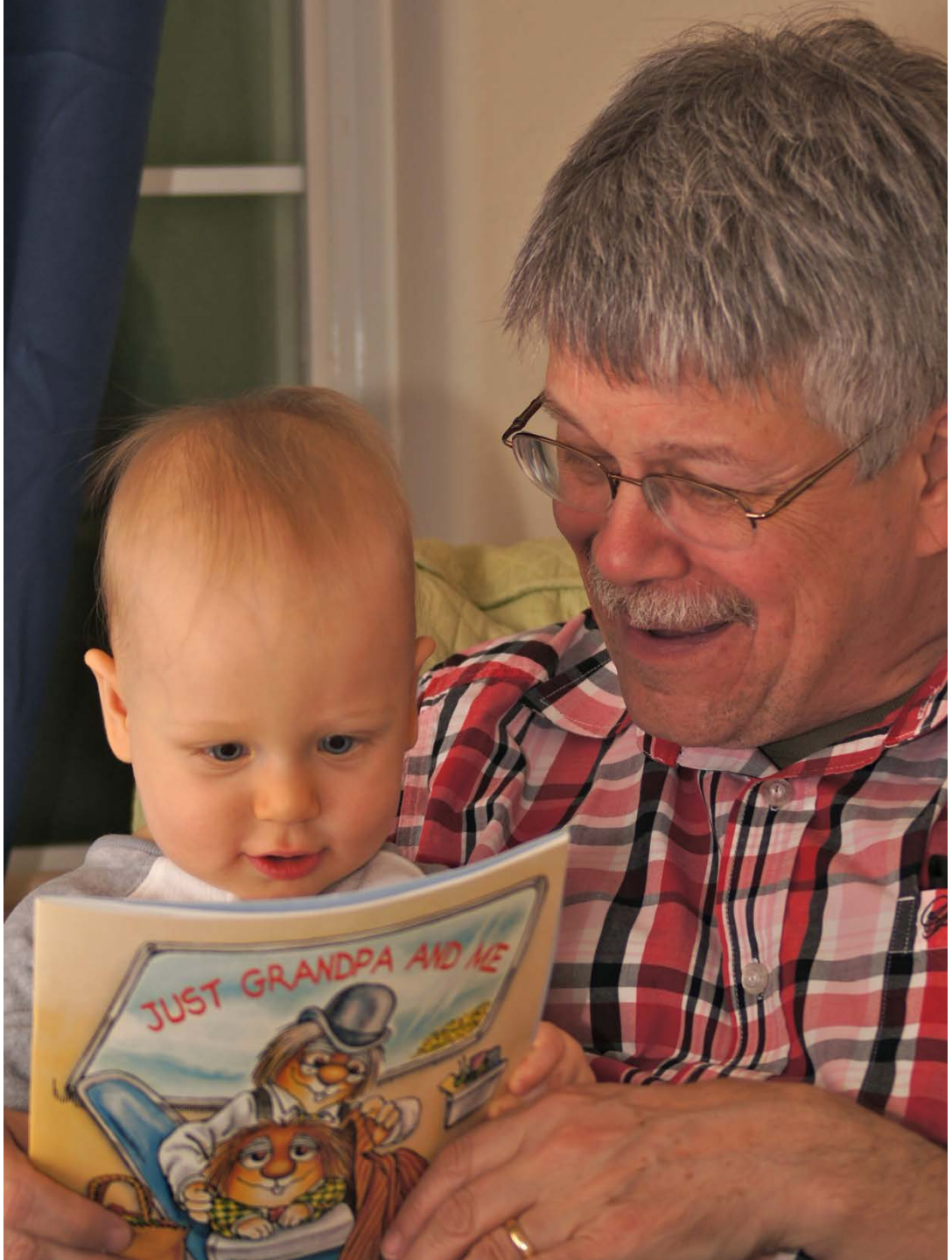
Source: modified from Donabedian A: Explorations in Quality Assessment and Monitoring, Volume I. The Definition of Quality and Approaches to its Assessment. Ann Arbor: Health Administration Press, 198

Contextual Model for Perinatal Care Services



Alternative Measures

- These are still in development.
- Perhaps clinicians who work in prenatal care settings or in settings where prenatal care is integrated with intra- and postpartum care might take the contextual model and define a set of objective data elements that could be quantified into a measure that truly reflects adequacy of care.


JUST GRANDPA AND ME

Apgar Score

- This is a score based on values from five ordinal scales, scored as 0, 1, or 2. It thus ranges from 0 – 10.
- Typically the Apgar score is measured at 1 and 5 minutes after birth, and also at 10 minutes for infants with low scores or for whom clinical urgency prevents an accurate measurement prior to 10 minutes after birth.

Use of the Apgar Score

- Dr. Virginia Apgar developed her score in the early 1950s to provide a quick assessment of the mortality risk of the newborn.
- The Apgar score has been collected on US birth certificates since 1968.
- It has been used in concert with other data to assess risk for cerebral palsy and other adverse neonatal sequelae, as well risk for neonatal and infant mortality.
- Some researchers have applied this measure to long-term outcomes, including likelihood of early intervention services and participation in special education at ages 6-8 or even to early adult outcomes. It won't be long before its associated with risk for autism spectrum disorder if this has not yet been studied.

Measurement Issues

- Who measures the Apgar score in the delivery room?
- Whose measurement is more valid and reliable?
- Whose measurement is reported on the birth certificate?

Alternative Measures

- Not much has been seriously considered for the birth certificate.
- Would it be interesting to conduct a SNAP assessment on all newborns – would that provide a better assessment of neonatal prognosis?
- Does it make sense to include measures like the Apgar score on the birth certificate?

Paternal Involvement

- The theoretical proposition is that pregnancies where the mother is involved with the father have better outcomes, and that infants raised with involvement with both mother and father have better outcomes.
- How is this measured on a population basis?
  - By the presence of information about the father on the birth certificate.

Induction of Labor

- We all know what this is – use of pharmacologic or surgical means to initiate labor.
- So why is it so hard to measure?
- One reason might be that historically we haven't asked the questions on the birth certificate using appropriate clinical terms (i.e. 'stimulation' rather than 'augmentation')
- But again, it all depends who's doing the reporting …

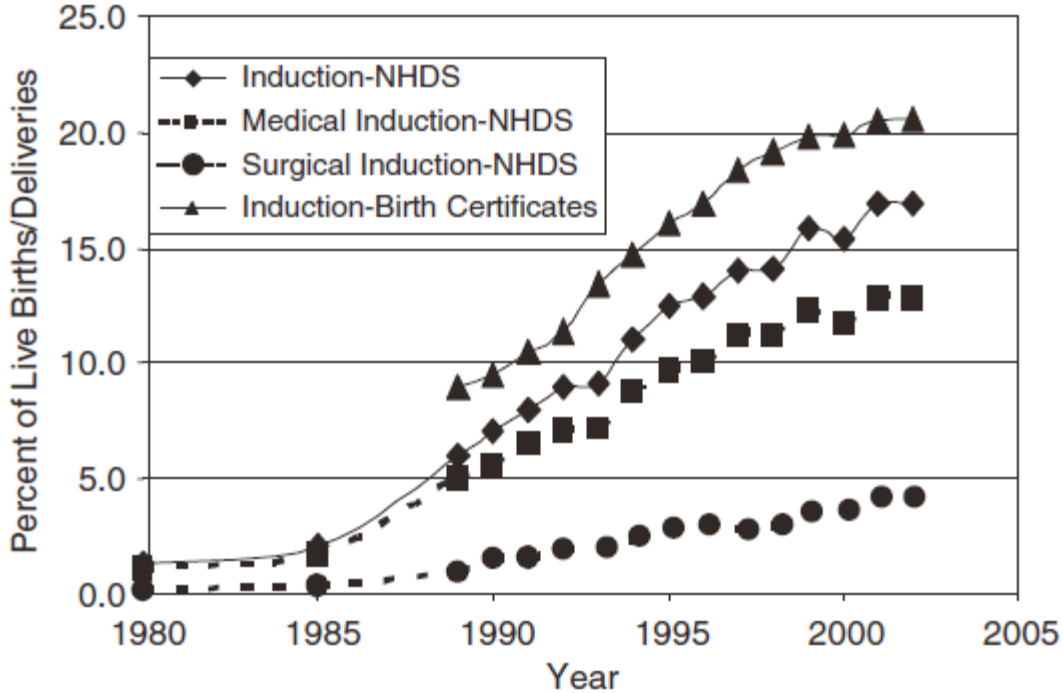
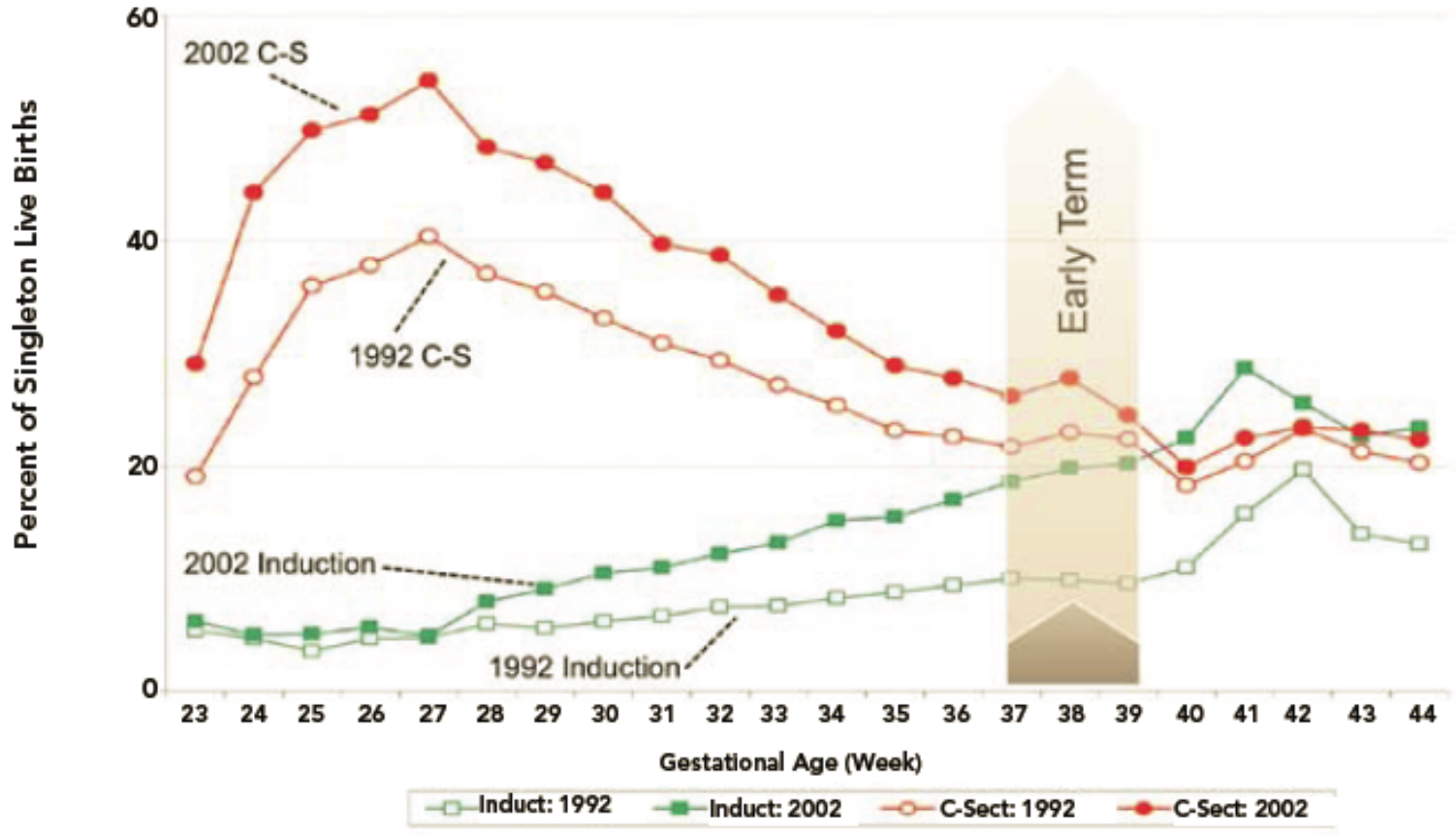


Fig. 1. Trends in labor induction in the United States, 1980–2002. (Source: National Center for Health Statistics; NHDS = National Hospital Discharge Survey.)

Kirby RS, Birth 2004;31:148-151

Figure 2: U.S. Cesarean Section and Labor Induction Rates Among Singleton Live Births by Week of Gestation, 1992 and 2002



Source: NCHS, final natality data. (Figure prepared by March of Dimes Perinatal Data Center, April 2006 and used with the permission of the March of Dimes)

Defining Indicators and Outcome Measures

- Identify
- Evaluate (literature review, evidence-based practice, assess feasibility)
- Implement
- Assessment
- Utilization in larger context

Indicators: Example

- **Problem: patients with pre-existing diabetes may not have their disease under control during preconception period**
- **Potential indicator: proportion of diabetic patients with HgA_1C levels within normal limits at first prenatal visit**
- **Rationale:**
  - **if no test was done, physician is not focused on the implications of diabetes for this pregnancy**
  - **if the test was done but yields an abnormal result, this is a marker for poor preconception care for this patient**
- **Assessment for informatics:**
  - **new systems of data gathering are necessary in order to implement this indicator**
- **Utilization: problematic due to lack of organizational commitment**

Indicators

- **There are no hard and fast rules in the development and implementation of indicators.**
- **Do NOT feel constrained by the current capabilities of the information services.**
- **Identify measures that are important for YOU, not those that others tell you to collect (Healthy People 2020, JCAHO, ACOG, etc.)**
- **Be prepared to critically evaluate the utility of each measure periodically, and make modifications as appropriate.**

Proportion of Live Birth Cohort Ready and Able to Learn at Entry into School

- Entry into kindergarten or 1st grade is a universal access point for assessing the health of the population.
- Most other western nations have comprehensive health and educational assessments at this point in the life cycle (and at exit from school).

Proportion of Live Birth Cohort Ready and Able to Learn at Entry into School (continued)

- How would this be operationalized?
  - All infant and child deaths prior to kindergarten would be debits against the goal of every child being ready and able to learn at school entry.
  - Children with education needs or chronic health conditions (birth defects, developmental disabilities, technology dependent chronic illnesses) that limit their ability to learn would also count against this goal.
  - Prior to beginning school, all children would receive a standardized growth and developmental assessment which includes a cognitive and behavior component.

Proportion of Live Birth Cohort Ready and Able to Learn at Entry into School (continued)

- How would this be operationalized (continued)?
  - The assessment would also collect data on socioeconomic status, household characteristics, access and utilization of pediatric well-child care and ER/hospital services.
  - On a population basis, analyses could adjust for the case-mix of live born infants for comparative purposes or to adjust for changes in perinatal outcomes over time.

Proportion of Live Birth Cohort Ready and Able to Learn at Entry into School (continued)

- Is this the radical idea of a utopian idealist from the progressive Midwest (remember, Florida is not really a Southern state), or an idea whose time has come?

“If you always do what you always did, you always get what you always got.”

- Anonymous

(quoted in J Epidemiol Commun Health, 2004;58:1034)

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- More top ten lists can be found at my USF website