Newborn Jaundice and the Prevention of Kernicterus

A Six-Sigma Approach

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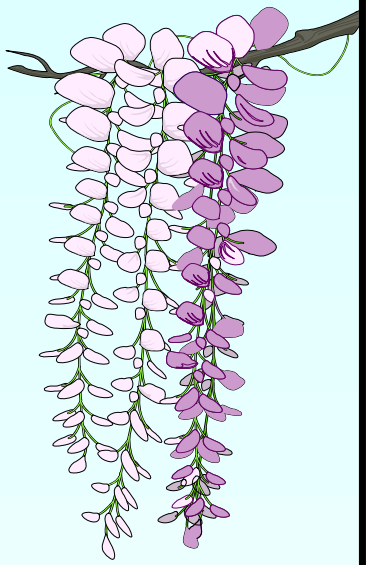


Newborn Jaundice and Kernicterus

- ★ **Condition:** Most newborn infants are at risk for jaundice during the first week after birth.
- ★ **Problem:** Usually benign; but, when unmonitored or untreated, it may progress to severe hyperbilirubinemia (often, the infant is at home).
- ★ **Intervention:** Severe neonatal hyperbilirubinemia is the most easily treatable and preventable cause of neonatal brain damage (kernicterus).

★ **Tragedy:** Kernicterus is the ultimate manifestation of neonatal brain damage. It is an untreatable and a lifelong disorder (also known as choreo-athetoid cerebral palsy).

CHARACTERIZATION

Review of a Kernicterus Case Reported to the Pilot Registry (Institute Of Medicine matrix)

Patient Centeredness	Safety	Effective Care	Timeliness
Lack of jaundice teaching	Lack of jaundice recognition for TSB or TcB	Lack of recognition for clinical risk factors	Lack of on-site lactation consultation
Lack of communication among professionals		Lack of recognition of jaundice as a vital sign	Lack of - documentation - response of laboratory staff
Lack of response to parent's report.	Lack of hospital based breastfeeding	Lack of TSB/TcB measure jaundice progression	Lack of consistent discharge plan.

Case # GWB (from a convenient sample of 125 cases (Kernicterus Registry)

IDENTIFICATION

System Failures	Major Root Causes for Reemergence of Kernicterus
Institutional	Early hospital discharge (before extent of jaundice is known and signs of impending brain damage have appeared).
	Structural limitations within the healthcare systems to deal with continuity of mother-infant care after birthing.
Providers	Lack of adequate concern for the risks of severe jaundice in healthy term and near term newborns
	Medical care cost constraints with early discharge and limited access to healthcare during the first week after birth.
Family and Societal	A lauded increase in breast feeding but unsupported by optimal lactation counseling to instruct, monitor and guide families.
	Paucity of educational materials to enable parents to participate in safeguarding their newborns.

OPTMIIZATION

Practice Guidelines and Family Education

AAP: Jay Berkelhammer (President): Wall Street Journal (Letter to the Editor)

CDC: website. www.cdc.gov/kernicterus

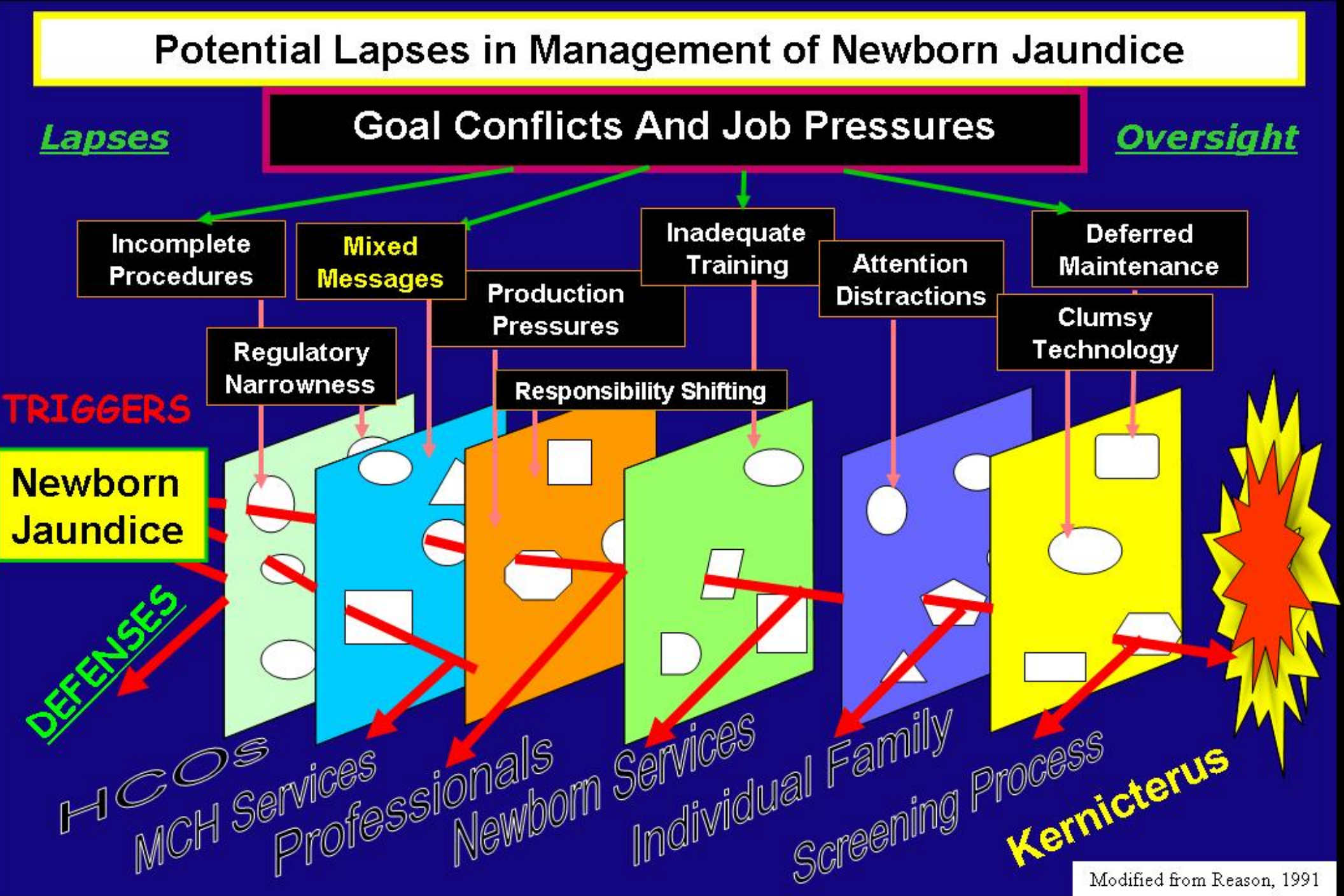
JCAHO: Sentinel Alert

www.jcaho.org/kernicterus

Clinical Practice: Quality Indicators

Available tool-kits.

Focus of messages to the community	
Reassurance	**Alarm**
Safer Management of Newborn Jaundice	Prevent Kernicterus
Mostly benign and usually resolves	Risk of brain damage
Pre-discharge risk assessment that also uses a pre-discharge bilirubin test	
Ensure follow-up within 48 hours	
Promote breast feeding	
Know the facts about jaundice	


Potential Lapses in Management of Newborn Jaundice
Lapses
Goal Conflicts And Job Pressures
Oversight
Incomplete Procedures
Mixed Messages
Inadequate Training
Attention Distractions
Deferred Maintenance
Production Pressures
Regulatory Narrowness
Clumsy Technology
Responsibility Shifting
TRIGGERS
Newborn Jaundice
DEFENSES
HCOs
MCH Services
Professionals
Newborn Services
Individual Family
Screening Process
Kernicterus
Modified from Reason, 1991

SURVEILLANCE

TSB ≥30 mg/dL (Sentinel Event)

Regions	Health practice	Study period	Frequency
UK	National review (home follow-up)	2003-2005	1 in 14,084
Canada	National survey	2002-2004	1 in 10,000
USA (HCA)	Health system review	2003	1 in 14,651
USA (CA)	HMO (retrospective)	1995-1998	1 in 10,000
USA (PA)	Hospital based systems program	1990-2003	zero
Brazil (SP)	Community-based systems program	2001-2005	zero

Goals: Apply Safety Performance Standards

Apply "world class" industry safety standards

Consider aviation safety standards for healthcare

A six-sigma approach

Systems-approach to Prevent Kernicterus: A Health-Societal Strategy

1 **Identification**

Cases of Kernicterus

2 **Characterization**

National AAP Guidelines

3 **Optimization**

Educational Tool-kits (eg: CDC/ AAP/CPQCC)

To Achieve Safety Standards

Systems-approach to Prevent Kernicterus: A Community-Based Approach

1 **Identification**

Cases of Kernicterus

2 **Characterization**

National AAP Guidelines

3 **Optimization**

Educational Tool-kits (eg: CPQCC)

To Achieve Safety Standards

4 **Implementation**

At Pediatrician's offices / clinics / and homes

5 **Outcomes**

- Exchange Tx
- Readmit rate

6 **Surveillance**

TSB ≥25 mg/dL

or, Sentinel event

? A Six-sigma Approach

Current Sigma level for Newborn Jaundice Management

- **TSB level >25 mg/dL ("close call")**
  - Incidence: 1 in 700 (1970s)
  - **Sigma level: 4.5**

  - Incidence: 1 in 600 (2000)
  - **Sigma level: 4.0**

- **Readmission for Jaundice Rates**
  - Rate: 27.7 per 1000 live-births
    - **Sigma level: 4.0 (1988-1988)**

Expectations: Sigma Level for Newborn Jaundice Management

- **TSB level >30 mg/dL** (Sentinel event)
  - Incidence: 142 to 3 in 1,000,000 births
  - Sigma level: 6.0

- **Readmission for Jaundice Rates**
  - Rate: 2,770 to 3 per 1,000,000 live births
  - Sigma level: 6.0 (1988-1988)

Can we apply Six Sigma to a newborn healthcare issue?

- Identify the issue: societal awareness of kernicterus (*CDC, PICK*)
- Characterize the problem: adverse outcome with high bilirubin levels (*CDC, AAP, JCAHO, AHRQ*)
- Optimal solution: pre-discharge screening and targeted follow-up in the first week (*AAP*)
- System-level change: family and nursing empowerment (*CDC, AAP, AWOHNN, PICK*)
- Measure impact on outcome: public health domain
- Maintain surveillance: A national strategy



American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Managing Newborn Jaundice

The American Academy of Pediatrics (AAP) has created recommendations for identifying and managing newborn jaundice. This common condition appears within a few days of birth and makes a baby's skin look yellow. Jaundice occurs when the chemical bilirubin, which is found in everyone's blood and removed by the liver, builds up. Most cases of jaundice are mild and resolve on their own. However, in rare cases excess bilirubin can lead to brain damage. The AAP recommendations have been put in place to ensure that newborns are screened for jaundice before they leave the hospital. The guidelines also suggests a follow-up visit when a baby is three to five days old, when bilirubin levels peak. Frequent breastfeeding in the first few days of life also is recommended. Frequent feedings help the baby's liver break down excess bilirubin and pass it through urine.

For more information on your child's health, visit www.aap.org.

Rev 12-1-2006

A Minute for Kids

IDENTIFICATION

FOR IMMEDIATE RELEASE

Thursday June 14, 2007

Universal screening and prompt follow-up essential to reducing debilitating jaundice among newborns

To reduce the occurrence of hyperbilirubinemia, the statement recommends that bilirubin concentrations be measured in all infants between 24 hours and 72 hours of life. If a mother and her new baby go home before 24 hours, they need an early follow-up visit to a health professional or a home visit by someone who can administer a bilirubin test, as well as look after any other potential health problems.

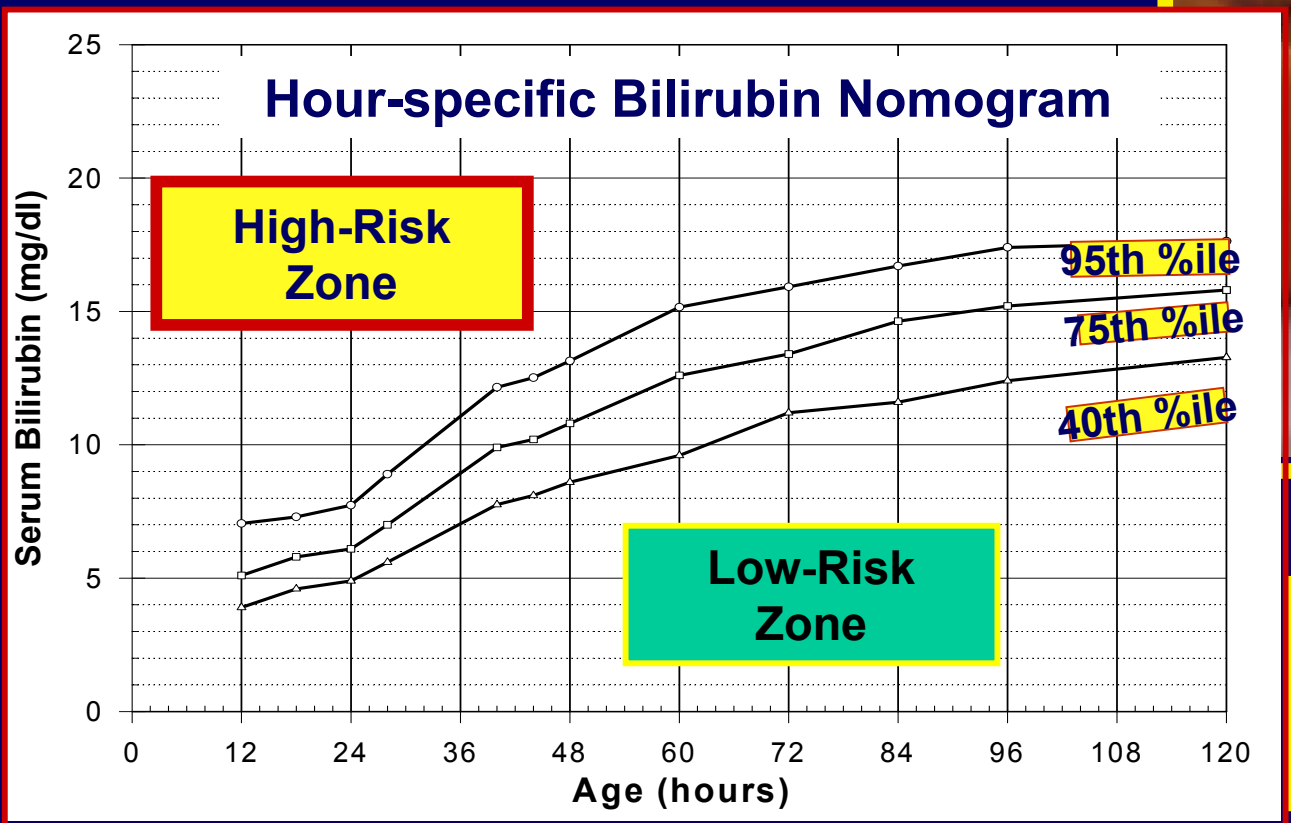
Five Key Areas That Need Attention

- Lack of lactation support
- Early hospital discharge (<age 72 hours)
- Infrastructure issues for follow-up within 48 hours
- Paucity of parent education to facilitate their role as partners in safeguarding their infant from BIND
- Loss of continuity and structural limitations to healthcare: multiple providers at multiple sites.

Systems-approach recommended by 2004 AAP Guidelines and local adaptations.

Measurement of Bilirubin

- TcB: BiliChek® / JM-103® devices
- TSB: at individual hospital laboratories
- Inter-and intra-institution calibration
  - Actual variance values: 2 to 3%.



* Bhutani et al: Pediatrics. 1999, 2000; Rubaltelli et al: Pediatrics. 2001 Maisels et al. Pediatrics 2005

Clinical Risk Factors for Severe Hyperbilirubinemia

Supposedly a baby who is not at (clinical or epidemiological) risk for hyperbilirubinemia is:

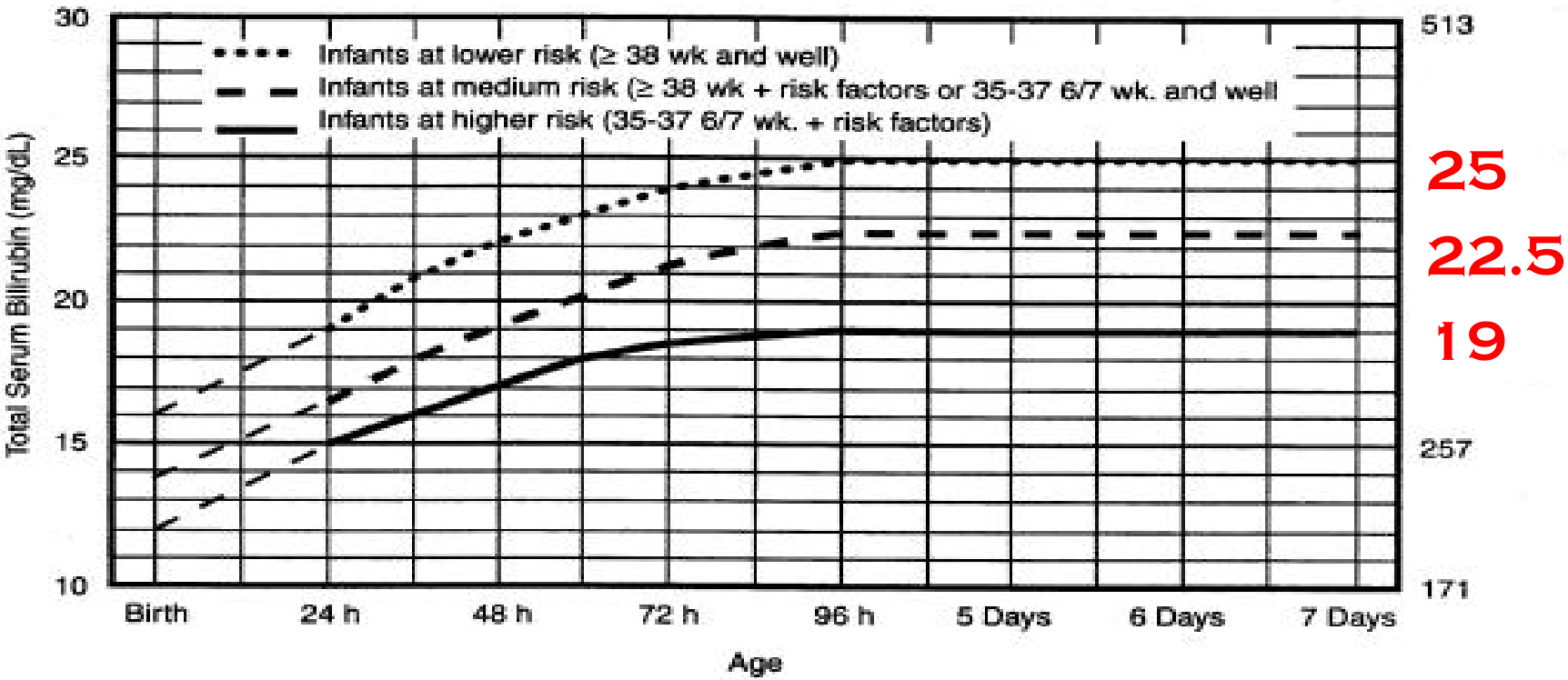
A white, anglo-saxon, female neonate, who is exclusively formula-fed, who has no bruising, does not have a sibling with jaundice and in whom there is no ABO / Rh, minor blood group incompatibility or other evidence of hemolysis.

Case report of Kernicterus in one such baby (Pilot Kernicterus Registry)

OPTIMIZATION

Guidelines for Exchange Transfusion in Infants ≥ 35 Weeks

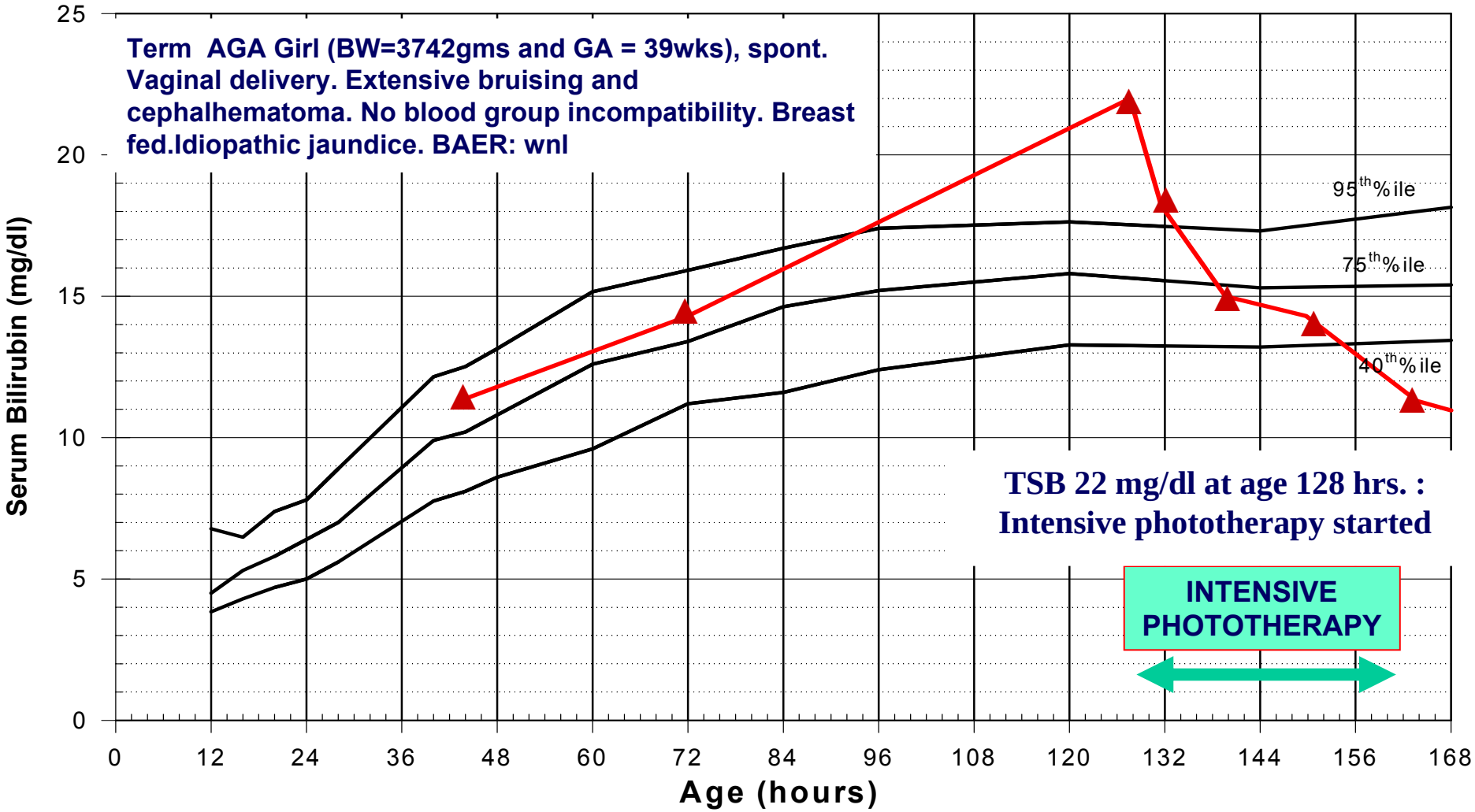
Note: These guidelines are based on limited evidence and the levels shown are approximations. During birth hospitalization exchange transfusion is recommended if TSB rises to these levels despite intensive phototherapy. For readmitted infants, if TSB is above exchange level, repeat TSB every 2-3hrs and consider exchange if TSB remains above levels indicated after intensive phototherapy for 6 hours.



- The dashed lines for the first 24 hours indicate uncertainty due to a wide range of clinical circumstances and a range of responses to phototherapy.
- Immediate exchange transfusion is recommended if infant shows signs of acute bilirubin encephalopathy (hypertonia, arching, retrocollis, opisthotonos, fever, high pitched cry) or if TSB is ≥5mg/dL (85µmol/L) above these lines.
- Risk factors - isoimmune hemolytic disease, G6PD deficiency, asphyxia, significant lethargy, temperature instability, sepsis, acidosis.
- Measure serum albumin and calculate B/A ratio (See legend)
- Use total bilirubin. Do not subtract direct reacting or conjugated bilirubin
- If infant is well and 35-37 6/7 wk (median risk) can individualize TSB levels for exchange based on actual gestational age.

OPTIMIZATION

Lesson Learned: CASE STUDY (1999)



5/98, VK Bhutani, LH Johnson, EM Sivieri, Section on Newborn Pediatrics, Pennsylvania Hospital, Phila., PA

IMPLEMENTATION

What is Newborn Jaundice?

Jaundice is caused by high levels of bilirubin, a natural substance that can build up in a baby's blood and skin.

- All babies are at risk for developing newborn jaundice
- 60% of newborn infants develop jaundice
- 1 in 10 newborns will need treatment. Most treatment is easy, low-cost, and painless
- If jaundice is not checked for and properly, high levels of bilirubin co brain damage resulting in a life-lo condition called kernicterus
- Although most babies with jaundi be fine, you should learn about ja and work with your doctor or nurs keep your baby safe and healthy
- Most importantly, ask your doct nurse about a jaundice bilirubin

How is my baby's jaundice treated

If your baby has high bilirubin levels, doctor or nurse might suggest increa feeding, or phototherapy treatment. phototherapy your baby will need to under special blue lights in the hosp or at home. Putting your baby in the is not a safe way to treat jaundice

Family education materials available on the CDC website: 8-page guide and interactive checklist

Your First Few Days at Home

Home Checklist
Is my baby having problems related to jaundice?

Check if it is true:

- ☐ Baby is having a hard time feeding (be sure to ask your doctor or nurse for help with breastfeeding)
- ☐ Baby is hard to wake up, even to feed
- ☐ Baby has fewer than four wet or dirty diapers within 24 hours
- ☐ Baby just can't be comforted
- ☐ Baby is arching back or neck
- ☐ Baby's cry sounds more shrill

Track number of wet or dirty diapers

Use the chart to the right to track the number of wet or dirty diapers each day. This will make it easy to tell if your baby is not getting enough milk. If there are fewer than four wet or dirty diapers in any 24-hour period, talk with your doctor or nurse right away.

Take Action
What should I do?

1) Talk with your baby's doctor or nurse about any of the boxes you've checked.
2) Be sure to go for your follow-up appointment within 48 hours of bringing your baby home from the hospital.

If you're worried about your baby, trust your instincts. Call or visit a doctor or nurse right away.

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
① ② ③ ④	① ② ③ ④	① ② ③ ④	① ② ③ ④	① ② ③ ④	① ② ③ ④	① ② ③ ④

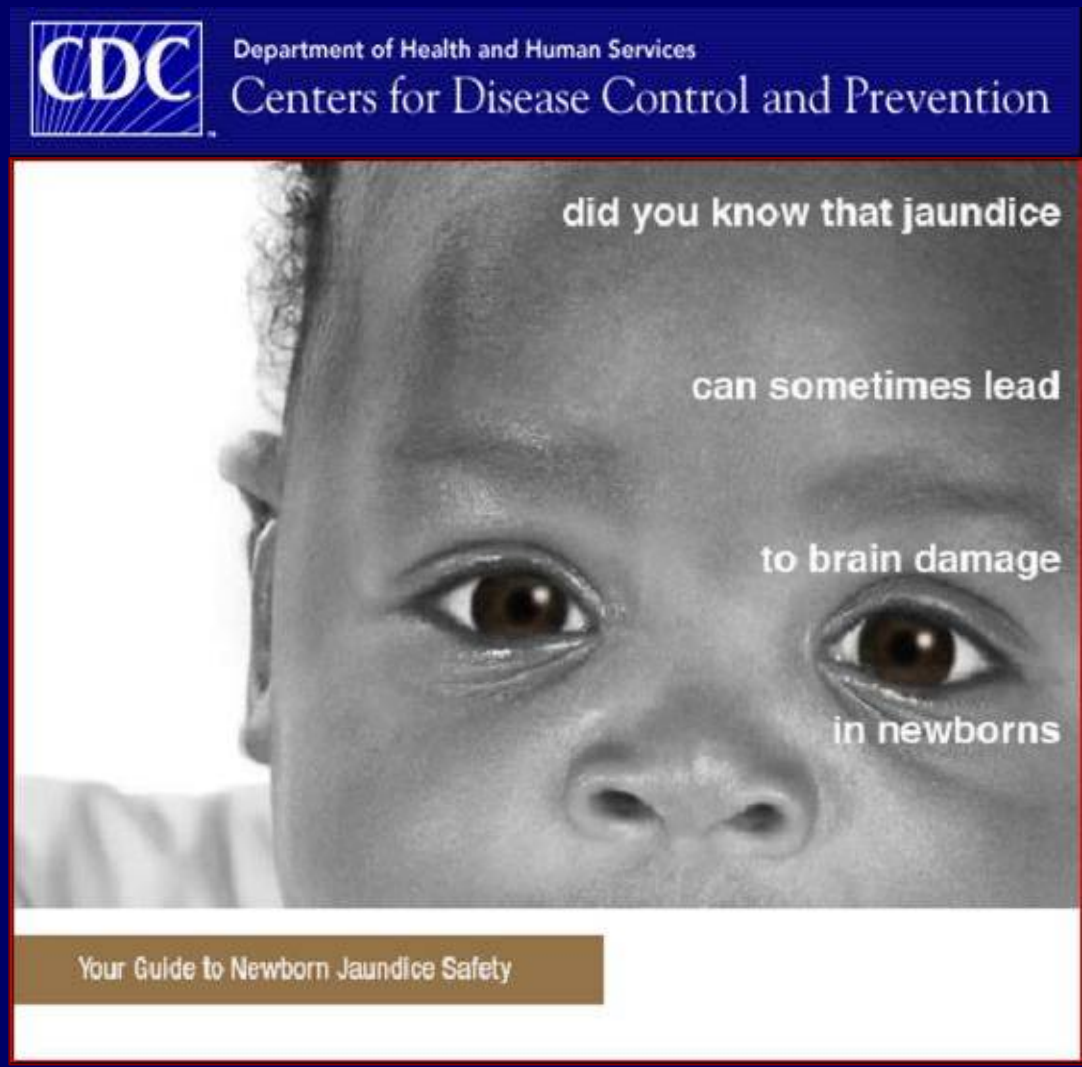
Know the facts about jaundice:

- Know if your baby is at risk
- Ask your doctor or nurse about a jaundice bilirubin test
- Make a follow-up appointment - and go

Office-based Management

IMPLEMENTATION

1. Familiarize “triage” staff with crash-cart approach
2. Assess for easy and rapid access to phototherapy
3. Review mechanisms of rapid transfer to neonatal intensive care units
4. Direct communication to NICU such that timely care is initiated.



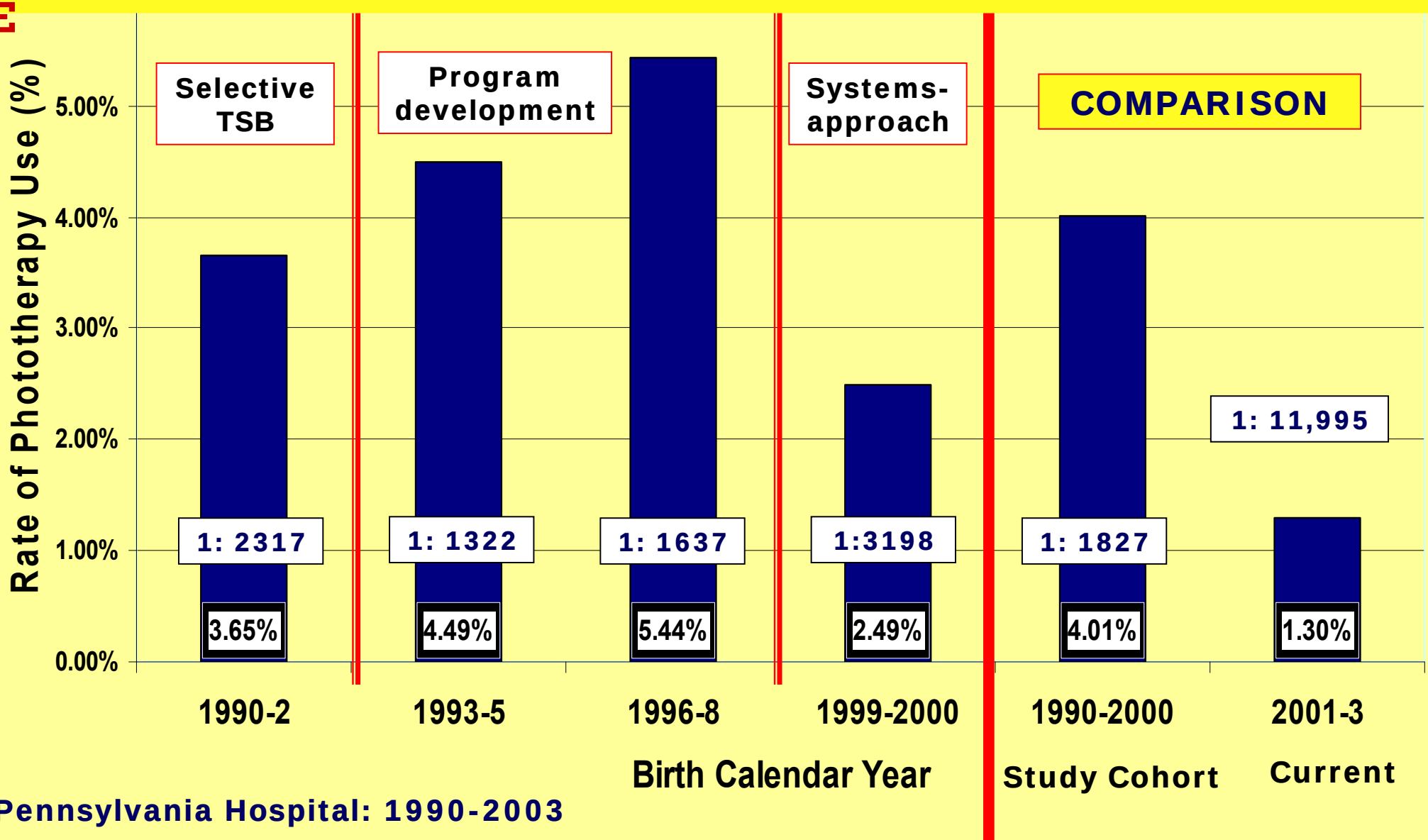
Download family education materials @ www.cdc.org

IMPLEMENTATION

Questions to ask parents of jaundiced infants?

- Can the baby be aroused from sleep?
- Has the baby feeding pattern deteriorated?
- Does the baby sleep with head in an extended posture?
- Are there any signs of arching?
- Is the baby unusually irritable or fussy?
- Has the cry pattern changed? Is it shriller?

Practice OUTCOME Evolution of Phototherapy and Exchange Transfusion Use with Systems-approach



Pennsylvania Hospital: 1990-2003

SURVEILLANCE

Frequency of TSB ≥25 mg/dL

Regions	Health practice	Years	Frequency
USA (CA)	HMO system data	1994-1998	1 in 700
USA (UT)	Health-system data	2002	1 in 1,522
USA (HCA)	Health system data	2003	1 in 1,878
Canada	National survey data	2002-2004	1 in 2,840
Denmark	National review	1994-2002	1 in 4,320
Brazil* (SP)	Community-based: systems program	2001-2005	I in 5,630
USA* (PA)	Hospital's System-based: program	1990-2003	1 in 15,000
Israel	Hospital - community-based program	2001-2002	1 in 18,079

Community SURVEILLANCE

Jerusalem's Hospital-community Initiative for Newborn Jaundice Management

1.	All parents are shown how to check for the appearance of jaundice.
2.	Parents are asked to return for a bilirubin test when baby becomes jaundiced.
3.	Daily outpatient follow-up by medical staff, until stabilization or decreased bilirubin values or hospitalization.
4.	Follow-up to well baby clinic or pediatrician office within 2 to 4 days of discharge.
5.	Mother-infant dyads may stay at postnatal convalescent homes for few days to 1 week with onsite access to bilirubin testing and pediatric supervision.
6.	Religious injunction against circumcision of a jaundiced infant on eighth day (checked by a mohel, a ritual circumciser).
7.	Unique and informal cultural and religious support for a wide-spread community awareness of jaundice.

Kaplan et al 2007. J of Peds

Key health-societal practices: Transformation

- **Lactation Support:** counselors, access, videos, aids.
- **Pre-discharge Data**
  - Jaundice screening and access to TSB/TcB screening
  - Pre-discharge risk assessment for hyperbilirubinemia
  - Explicit Parent education curriculum (interactive and video)
- **Follow-up Services**
  - Location of return visits (hospital supervised)
  - Timing of early and repeat, multi-disciplinary visits
  - **Critical Care Services**
    - Direct admission: bypass Emergency Room
    - "Crash-cart" approach for excessive TSB or ABE
- **Surveillance and Risk Management**
  - Outcome assessment of performance
  - Early intervention and follow-up for infants with TSB >25 mg/dL.

Incorporated in AAP 2004 Guidelines: Pediatrics 2004

SUMMARY

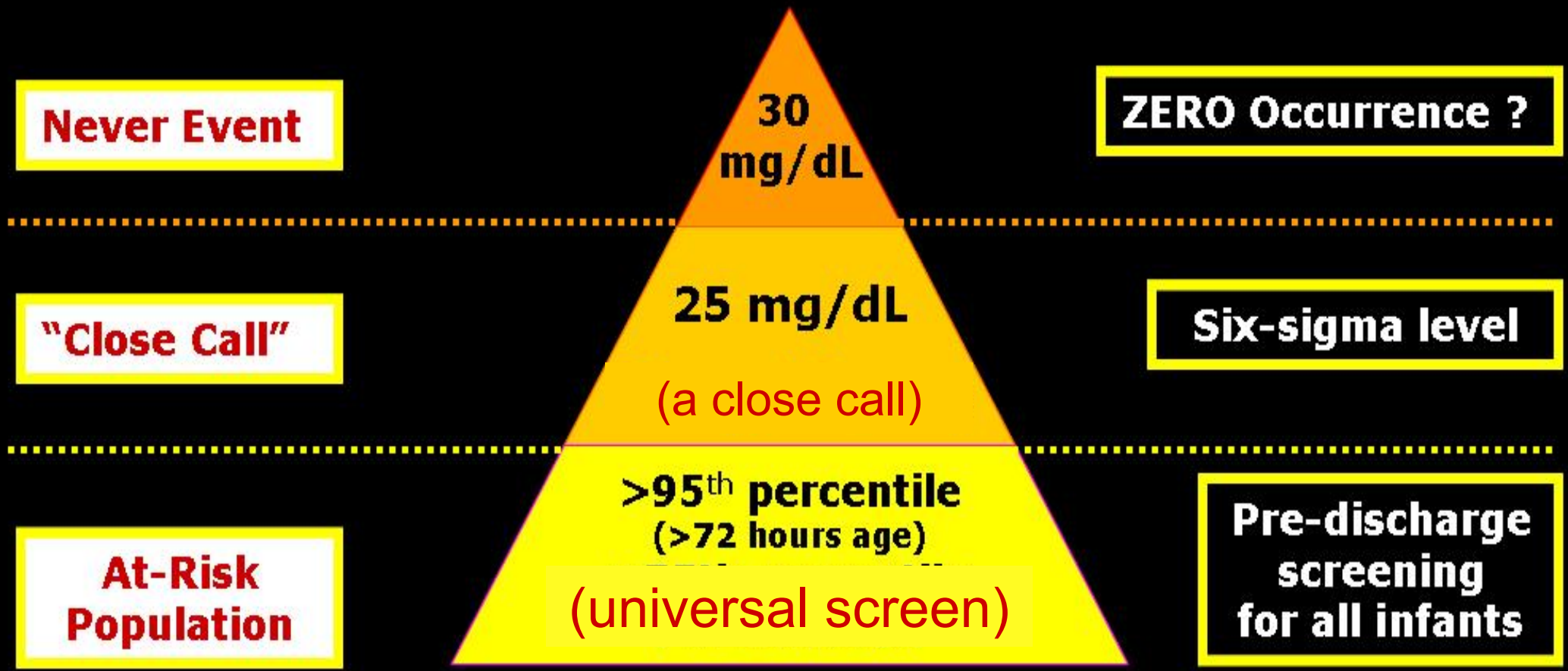
Management of Jaundice: A Matter of Patient Safety

Medical Interventions

- Decrease entero-hepatic circulation
  - Increase enteral milk intake
  - Promote breast feeding and milk transfer
  - Supplement enteral intake
- Phototherapy
- Exchange transfusion
- Chemoprevention

Preventive Strategies	Analogy	Incidence
Bilirubin test and lactation support	use of a safety belt	For all infants
Use of intensive phototherapy (hospital)	use of emergency procedures	Less than 1 in 50
Prepare for an exchange transfusion	a crash landing	A rare event

Outcome Assessment: Performance standards



Proposal: A Nation-wide strategy to Prevent Kernicterus in USA

Sentinel References

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