

# Impact of Universal Bilirubin Screening on Severe Hyperbilirubinemia and Phototherapy Use

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## KEY WORDS

bilirubin, jaundice, newborn, phototherapy, screening

## ABBREVIATIONS

TSB—total serum bilirubin

TcB—transcutaneous bilirubin

AAP—American Academy of Pediatrics

NC-KPMCP—Northern California Kaiser Permanente Medical Care Program

OR—odds ratio

CI—confidence interval

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**WHAT'S KNOWN ON THIS SUBJECT:** The 2004 AAP guideline on the management of hyperbilirubinemia recommends that every newborn be assessed for the risk of developing severe hyperbilirubinemia, through predischARGE TSB or TcB measurements and/or assessments of clinical risk factors.



**WHAT THIS STUDY ADDS:** Universal bilirubin screening can increase the identification of newborns needing phototherapy and significantly decrease the incidence of severe hyperbilirubinemia. There also may be an increase in the use of phototherapy at bilirubin levels lower than recommended by the AAP.

## abstract

**OBJECTIVE:** The goal was to assess the impact of universal bilirubin screening on severe hyperbilirubinemia and phototherapy use.

**METHODS:** In this retrospective cohort study of 358 086 infants of  $\geq 35$  weeks and  $\geq 2000$  g born between January 1, 1995, and June 30, 2007, we obtained demographic data, bilirubin levels, and codes for inpatient phototherapy from existing databases. We compared the incidence of high total serum bilirubin (TSB) levels and phototherapy before and after implementation of universal screening and examined risk factors for high TSB levels.

**RESULTS:** A total of 38 182 infants (10.6%) were born at facilities that had implemented universal bilirubin screening. Compared with infants born at facilities that were not screening, these infants had a 62% lower incidence of TSB levels exceeding the American Academy of Pediatrics exchange guideline (0.17% vs 0.45%;  $P < .001$ ), received twice the inpatient phototherapy (9.1% vs 4.2%;  $P < .001$ ), and had slightly longer birth hospitalization lengths of stay (50.9 vs 48.7 hours;  $P < .001$ ). Of those receiving phototherapy, 56% after initiation of universal screening had TSB levels at which phototherapy was recommended by the guideline, compared with 70% before screening. The adjusted odds ratio for developing TSB levels exceeding the guideline value was 0.28 (95% confidence interval: 0.20–0.40) for those born at a facility using TSB screening and 0.28 (95% confidence interval: 0.19–0.42) for those born at a facility using transcutaneous bilirubin screening.

**CONCLUSIONS:** Universal bilirubin screening was associated with a significantly lower incidence of severe hyperbilirubinemia but also with increased phototherapy use. *Pediatrics* 2009;124:1031–1039

The 2004 American Academy of Pediatrics (AAP) guideline on the management of hyperbilirubinemia recommends that every newborn be assessed for the risk of developing severe hyperbilirubinemia, by using pre-discharge total serum bilirubin (TSB) or transcutaneous bilirubin (TcB) measurements and/or assessment of clinical risk factors before discharge.<sup>1</sup> However, the effects of pre-discharge bilirubin screening on hyperbilirubinemia and phototherapy have not been studied adequately.<sup>2,3</sup> In an 18-hospital system, Eggert et al<sup>4</sup> showed that, after the initiation of a universal bilirubin screening program, the incidence of TSB levels of  $\geq 25$  mg/dL decreased from 1 in 1522 infants to 1 in 4037 infants. However, the authors did not provide information on how this result was achieved, such as increased use of phototherapy during the birth hospitalization, identification of more infants with hyperbilirubinemia, better follow-up monitoring, or improved lactation support.

In September 2005, the Northern California Kaiser Permanente Medical Care Program (NC-KPMCP) implemented the 2004 AAP guidelines by recommending that all newborns undergo TSB or TcB measurements before discharge. In addition, follow-up monitoring of these newborns, according to the risk group determined by plotting of their bilirubin measurements on the nomogram presented by Bhutani and colleagues<sup>2,5-7</sup> and the use of a clinical risk index,<sup>8</sup> was suggested.

The objective of this study was to determine the impact of universal bilirubin screening on the incidence of TSB levels above the 2004 AAP exchange level. In addition, we evaluated the mechanism for any differences in the incidence of severe hyperbiliru-

**TABLE 1** Modified Clinical Risk Index for Hyperbilirubinemia

Subtotal A		Subtotal B		Subtotal C	
Gestational Age	Score	Feeding	Score	Other	Score
35 wk	12	Breast milk only	6	Jaundice requiring phototherapy in parent or sibling	6
36 wk	10	Formula only	-6	Cephalhematoma or bruising	4
37 wk	7	Breast milk + formula	0	Asian	4
38 wk	4			Maternal age of $\geq 25$ y	3
39 wk	2			Male	1
40 wk	0				
41 wk	-2				
42 wk	-4				

Total score = subtotal A + subtotal B + subtotal C.

binemia by examining temporal trends in bilirubin testing and phototherapy use and comparing management with the AAP guidelines.

## METHODS

### Study Design

We used a historical cohort design to compare the incidence of severe hyperbilirubinemia and phototherapy use before and after implementation of universal bilirubin screening.

### Subjects and Settings

We included all live-born infants born in 11 NC-KPMCP hospitals between January 1, 1995, and June 30, 2007, if their gestational age was  $\geq 35$  weeks and their birth weight was  $\geq 2000$  g. The NC-KPMCP serves a population of 3.3 million members, which constitutes  $\sim 30\%$  of the insured population in Northern California. All NC-KPMCP facilities share the same common medical record numbers and database systems, which permits linkage of maternal and neonatal records to each other and to multiple information systems (eg, laboratory and hospitalization data). The NC-KPMCP institutional review board and the University of California, San Francisco, Committee on Human Research approved this project.

The NC-KPMCP implementation of the AAP guideline includes bilirubin screening before discharge, with ei-

ther TcB or TSB measurements. TcB measurements must be confirmed with TSB measurements if the TcB level is  $\geq 15$  mg/dL or if the TcB level plus 3 mg/dL is above the 2004 AAP phototherapy treatment line. Since 1998, as a result of reviews of internal analyses, 2 randomized trials,<sup>9,10</sup> and a case-control study,<sup>11</sup> all infants born at NC-KPMCP hospitals undergo a mandatory follow-up visit within 48 hours after discharge, with a pediatrician or nurse practitioner. In addition, a small number of infants receive home visits, at the discretion of the discharging physician. With the implementation of universal bilirubin screening, the suggested timing of follow-up visits was based on a modified clinical risk index<sup>8</sup> and the bilirubin values plotted on the nomogram described by Bhutani et al<sup>6</sup> (Tables 1 and 2).

Of the 11 hospitals in the NC-KPMCP, 4 adopted universal TcB screening policies, 5 adopted universal TSB screening policies, and 2 had not adopted either as of June 2007. For facilities reporting TcB screening, nursery directors reported initiation of universal screening in October 2005. For TSB screening, we considered the implementation date to be the month in which the facility achieved screening of  $\geq 95\%$  of all newborns, which ranged from September 2004 to February 2007.

**TABLE 2** Recommended Follow-up Period (days) on the Basis of Clinical Risk Index Score TSB and TcB Risk Group Measurements

Clinical Risk Index Score	TSB or TcB Risk Group			
	Low	Low-Intermediate	High-Intermediate	High
≥15	1–2	1	1	1
10–14	1–3	1–2	1	1
5–9	a	1–3	1–2	1
<5	a	a	1–3	1

TSB levels were recommended if TcB values were ≥15 mg/dL or within 3 mg/dL of the AAP phototherapy. Bilirubin values were plotted on the nomogram described by Bhutani et al<sup>6</sup> to determine risk group.

<sup>a</sup> Very low risk of significant jaundice, but follow-up evaluation for other reasons may be required.

### Outcome Variables

From existing KPMCP databases, we obtained all TSB values from an infant's first month of life, by using previously described methods.<sup>11–16</sup> We excluded any TSB measurements for which a corresponding conjugated or direct bilirubin measurement constituted ≥20% of the TSB level. We also obtained direct antiglobulin test results, if the test were performed. For all hospitalizations in the first month of life, we ascertained the use of phototherapy from International Classification of Diseases, Ninth Revision procedure codes. For each TSB value, we compared the value with the 2004 AAP treatment curves for phototherapy and exchange transfusions. Each infant's risk group was assigned on the basis of gestational age and direct antiglobulin test results (low risk: ≥38 weeks and negative or missing direct antiglobulin test results; medium risk: ≥38 weeks and positive direct antiglobulin test results or <38 weeks and negative or missing direct antiglobulin test results; high risk: <38 weeks and positive direct antiglobulin test results). We defined missed phototherapy as having a TSB level above the level at which the AAP recommends phototherapy, for a given time point and risk group, but not receiving phototherapy. In contrast, we defined sub-threshold phototherapy as receiving phototherapy but never having a TSB value over the threshold for phototherapy according to the AAP guideline. We

defined appropriate phototherapy as receiving phototherapy and having ≥1 TSB value over the threshold for phototherapy according to the AAP guideline.

### Statistical Methods

Characteristics of infants born before and after implementation of universal bilirubin screening were compared by using  $\chi^2$  and Student's *t* tests, as appropriate. We used  $\chi^2$  and Fisher's exact tests to compare the incidence of severe hyperbilirubinemia and phototherapy in these groups. To assess the odds of developing a TSB level of ≥25 mg/dL or above the 2004 AAP exchange transfusion threshold or receiving phototherapy, we used multivariate logistic regression models, including an indicator variable for being born at a facility after implementation of TSB or TcB screening. Covariables included were gender, gestational age, small-

for-gestational age status,<sup>17</sup> large-for-gestational age status,<sup>17</sup> race, facility, and AAP risk group. We performed all analyses with Stata 9.0 (Stata Corp, College Station, TX).

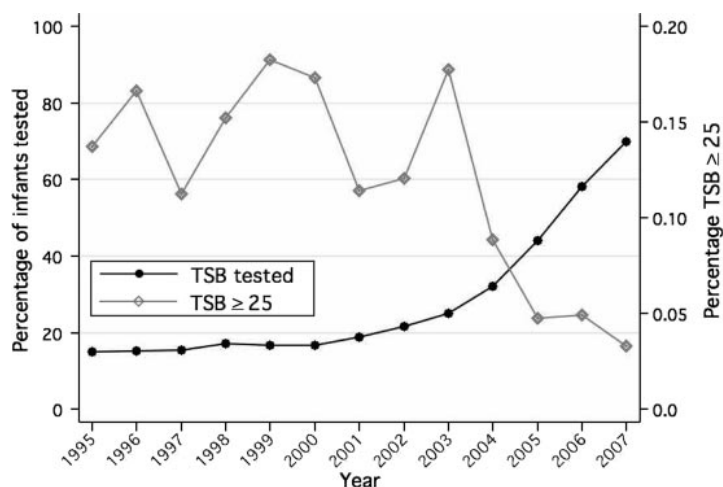
### RESULTS

A total of 319 904 infants were born at a facility before universal bilirubin screening and 38 182 infants after implementation of screening. The mean number of TSB tests per infant in the first month of life was  $0.8 \pm 1.7$  tests per infant (mean  $\pm$  SD) before implementation, compared with  $1.9 \pm 2.0$  tests per infant after implementation ( $P < .001$ ). The characteristics of the 2 groups were otherwise similar except that, after implementation of universal screening, the proportion of Asian infants was greater (22% vs 18%;  $P < .001$ ) and more infants were in the AAP medium-risk group (14.2% vs 12.4%;  $P < .001$ ) (Table 3). The mean length of birth hospitalization was 48.7 hours before universal screening and 50.9 hours after implementation, an increase of 2.2 hours (95% confidence interval [CI]: 1.4–2.9 hours). We also compared lengths of birth hospitalization with stratification according to phototherapy during the birth hospitalization. In the phototherapy group, the mean length of stay was 125.7 hours before universal screening and

**TABLE 3** Characteristics of Infants Born at Facilities With and Without Universal Bilirubin Screening

	No Universal Screening (N = 319 904)	Universal Screening (N = 38 182)	P
Gestational age, mean $\pm$ SD, wk	39.2 $\pm$ 1.4	39.0 $\pm$ 1.4	<.001
Birth weight, mean $\pm$ SD, g	3459 $\pm$ 505	3418 $\pm$ 499	<.001
Male, n (%)	163 406 (51)	19 706 (52)	.05
SGA, n (%)	3702 (1.2)	408 (1.1)	.1
LGA, n (%)	8571 (2.7)	975 (2.2)	.2
Black, n (%)	26 259 (8.2)	3048 (8.0)	.1
Asian, n (%)	56 248 (18)	9052 (22)	<.001
AAP risk group, n (%)			
Low risk	276 386 (87.3)	35 643 (85.5)	<.001
Medium risk	39 821 (12.5)	5437 (14.2)	
High risk	697 (0.2)	102 (0.3)	

SGA indicates small for gestational age; LGA, large for gestational age.



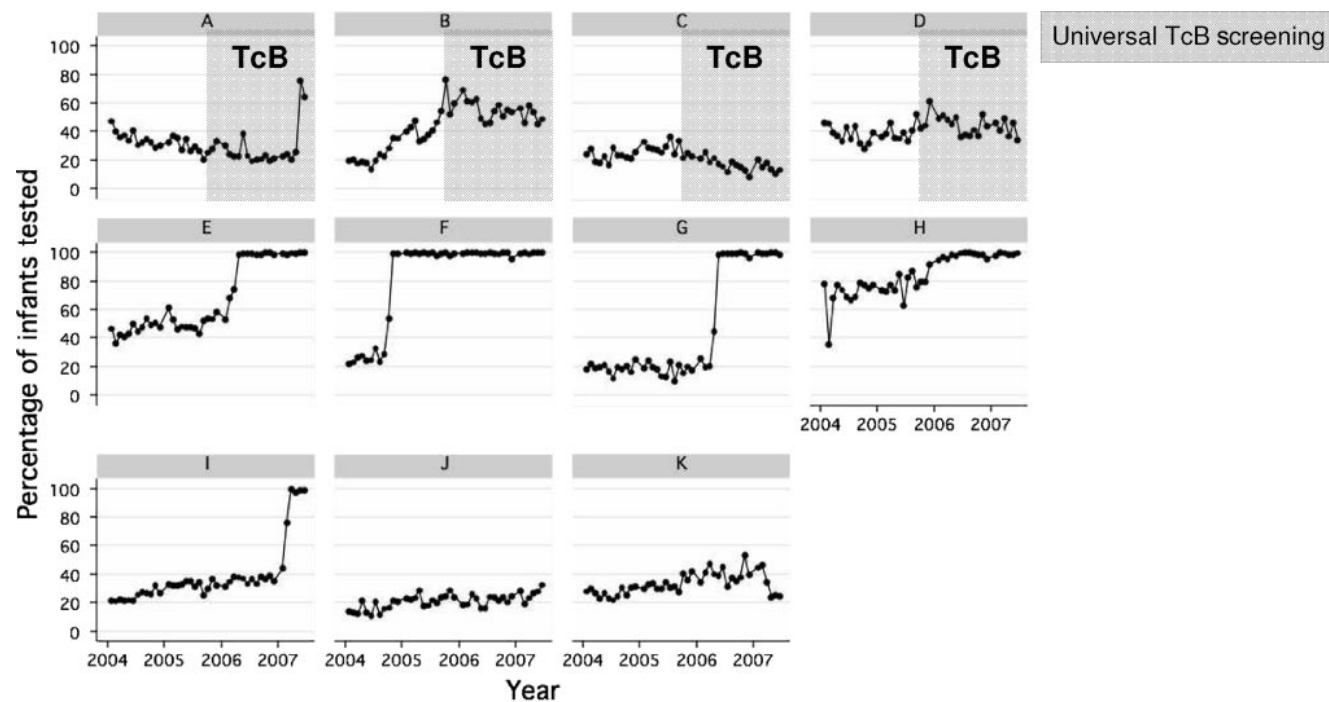
**FIGURE 1** Temporal trends (1995–2007) in TSB testing and TSB levels of  $\geq 25$  mg/dL. TcB testing not included in figure.

97.2 hours after implementation of screening, a decrease of 28.5 hours (95% CI: 23.5–33.4 hours). In the group not receiving phototherapy, the mean length of stay was 46.6 hours before universal screening and 47.6 hours after implementation of screening, an increase of 1.0 hour (95% CI: 0.3–1.7 hours).

Over the 12-year period between 1995 and 2007, as the proportion of infants who underwent TSB measurements during their birth hospitalization increased, the proportion of infants who had maximal TSB levels of  $\geq 25$  mg/dL decreased (Fig 1). The proportion of infants tested remained relatively constant until 2001, when it began to in-

crease, with more-significant increases beginning in 2003. In Fig 2, the monthly proportions of infants who underwent TSB screening at each facility between 2004 and 2007 are shown. Facilities A, B, C, and D initiated universal TcB screening in October 2005. Facilities J and K did not institute a screening program. The facilities that implemented universal TSB screening achieved compliance rates near 100%. In facilities that implemented universal TcB screening, TSB levels were measured only if TcB levels were high.

There was a 62% reduction in the incidence of maximum TSB levels above the exchange guideline, from 0.45% before universal screening to 0.17% after screening ( $P < .001$ ) (Table 4). Similarly, there was a 74% reduction in the incidence of maximum TSB levels of 25 to 29.9 mg/dL, from 0.12% before universal screening to 0.031% after screening ( $P < .001$ ). In contrast, there was a 56% increase in the incidence of maximum TSB levels of 15 to 19.9 mg/dL, from



**FIGURE 2** Temporal trends (2004–2007) in TSB testing according to facility.

**TABLE 4** Incidence of Hyperbilirubinemia

	Incidence, %		Change, %	P
	No Universal Screening	Universal Screening		
TSB level at or above AAP exchange level <sup>a</sup>	0.45	0.17	-62	<.001
TSB level of 15–19.9 mg/dL	9.59	14.94	+56	<.001
TSB level of 20–24.9 mg/dL	2.02	1.37	-32	<.001
TSB level of 25–29.9 mg/dL	0.12	0.031	-74	<.001
TSB level of $\geq 30$ mg/dL	0.012	0.0052	-57	.3

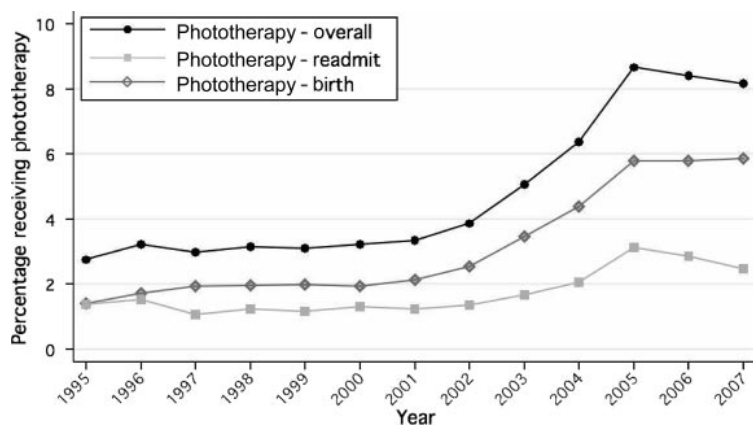
<sup>a</sup> From the 2004 AAP exchange transfusion guideline.<sup>1</sup>

9.59% before universal screening to 14.94% after screening ( $P < .001$ ).

Our multivariate logistic regression analysis showed that being born at a facility using universal bilirubin screening was protective. The adjusted odds ratio (OR) for developing a TSB level of  $\geq 25$  mg/dL was 0.22 (95% CI: 0.11–0.48) for those born at a facility using TSB screening and 0.25 (95% CI: 0.12–0.53) for those born at a facility using TcB screening, compared with facilities and years when universal screening was not being performed. Similarly, the adjusted OR for developing a TSB level over the 2004 AAP exchange threshold was 0.28 (95% CI: 0.20–0.40) for those born at a facility using TSB screening and 0.28 (95% CI: 0.19–0.42) for those born at a facility using TcB screening. The adjusted OR for phototherapy during the birth hospitalization was 3.03 (95% CI: 2.84–3.24) for those born at a facility using TSB screening and 2.43 (95% CI: 2.24–2.64)

for those born at a facility using TcB screening. The adjusted OR for readmission for phototherapy was 1.30 (95% CI: 1.17–1.45) for those born at a facility using TSB screening and 2.12 (95% CI: 1.93–2.34) for those born at a facility using TcB screening.

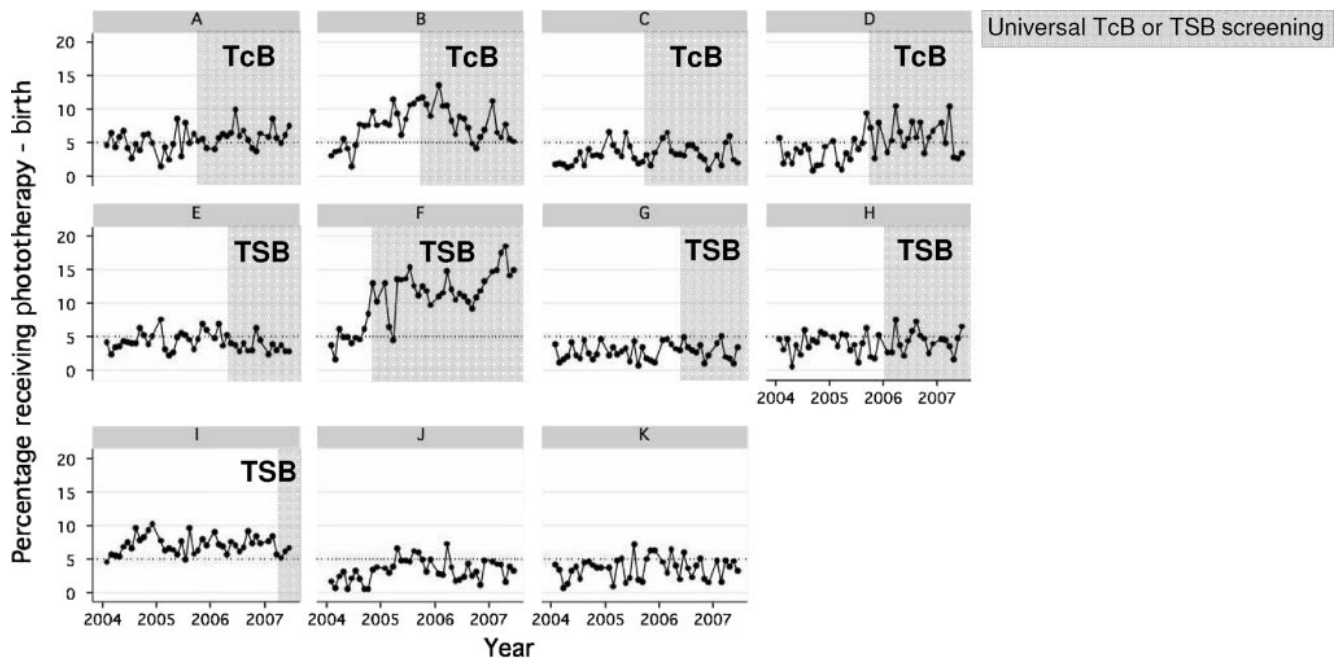
Phototherapy use began to increase after 2001 and increased dramatically between 2003 and 2005, before leveling off (Fig 3). Although there was an increase in readmissions for phototherapy after screening (2.7% vs 1.6%;  $P < .001$ ), the overall increase in phototherapy use was attributable mainly to a large increase in phototherapy during the birth hospitalization (2.7% vs 6.7%;  $P < .001$ ). There was marked interfacility variation in phototherapy use and in changes over time (Fig 4). Facilities B, D, and F had months after the implementation of universal screening when the proportion of infants receiving phototherapy exceeded 10%.

**FIGURE 3**

Temporal trends (1995–2007) in phototherapy (PT) use.

To assess the appropriateness of the phototherapy use, we compared all TSB values with the 2004 AAP guideline on the management of hyperbilirubinemia.<sup>1</sup> Among infants who received phototherapy during their birth hospitalization, the proportion of infants who had TSB measurements indicating the need for phototherapy decreased from 60% before screening to 43% after screening. Among infants who were readmitted for phototherapy, corresponding proportions were larger and less affected by screening (89% vs 84%). Figure 5 depicts the proportions of infants with subthreshold phototherapy, missed phototherapy, and appropriate phototherapy according to year. The proportion with subthreshold phototherapy began to increase in 2003 and plateaued in 2005. In contrast, the proportion with missed phototherapy was relatively constant and then decreased slightly in 2005–2007. The proportion of infants receiving appropriate phototherapy began to increase in 2003, with a more-significant increase beginning in 2005.

Examination of discharge diagnoses identified 5 infants with International Classification of Diseases, Ninth Revision codes for kernicterus. All of the infants were born before September 2005. For 2 of the infants, the diagnosis was clearly an error, because neither the clinical course nor the maximal TSB levels (5.6 and 16.0 mg/dL) were consistent with the diagnosis. A third infant had a maximal TSB level of 27.5 mg/dL, with equivocal MRI results; however, outpatient records at 4 years of age indicated that the condition of the child was completely normal, which suggests that the diagnosis was in error. Of the remaining cases, 1 infant was critically ill from birth with multiple-organ failure, had a maximal TSB level of 27.3 mg/dL, and died at 4 days of age, with kernicterus con-



**FIGURE 4** Temporal trends (2004–2007) in phototherapy use during the birth hospitalization according to facility.

firmed at autopsy; the second infant, who is still alive with significant sequelae, had a first TSB level of 48.0 mg/dL at 81 hours of age and positive blood culture results for *Enterococcus fecalis* and coagulase-negative *Staphylococcus*.

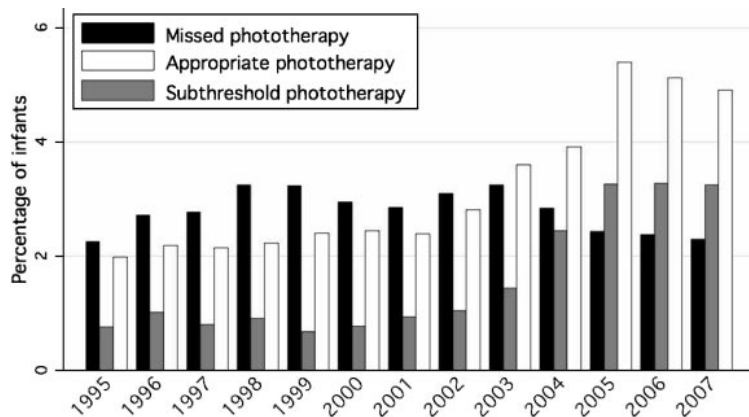
## DISCUSSION

We found a dramatic decrease in the incidence of TSB levels of  $\geq 25$  mg/dL as the proportion of infants who underwent bilirubin screening during

their birth hospitalization increased. We saw no difference in the impact of screening according to whether the facility performed TSB or TcB testing. These results are reassuring that screening with a noninvasive method worked as well as screening with a blood test. It is important to remember that TSB confirmation was recommended in conjunction with TcB screening if the values were within 3 mg/dL of the AAP phototherapy threshold or  $\geq 15$  mg/dL which might have

avoided any inaccuracy of TcB results at higher bilirubin levels. Our results are consistent with the findings of Eggert et al,<sup>4</sup> who also reported a decreased incidence of severe hyperbilirubinemia with universal bilirubin screening. With universal bilirubin screening, we seem to be identifying more infants who require phototherapy who might otherwise have been missed or identifying infants at earlier points in their courses. After implementation of universal screening, a larger proportion of infants received appropriate phototherapy. Furthermore, the incidence of TSB levels of 15 to 19.9 mg/dL increased while the incidence of more-severe hyperbilirubinemia decreased, which suggests that one mechanism for the decrease was earlier identification and treatment of hyperbilirubinemia.

Although the results of our study are encouraging with respect to the potential benefits of universal screening, we caution that other factors might have contributed to our findings. The reduction in the incidence of TSB levels of



**FIGURE 5** Comparison of phototherapy use with the 2004 AAP guideline.

$\geq 25$  mg/dL began before the implementation of universal screening and seemed to plateau with universal screening. This might be related to the increases in TSB testing that were observed in the years before universal screening or a general increase in the level of physician concern regarding hyperbilirubinemia.

The mechanism through which universal bilirubin screening reduces severe hyperbilirubinemia is likely multifactorial. The proportion of infants who received appropriate phototherapy increased with universal screening, and there was a small decrease in the proportion with missed phototherapy. The universal screening program was linked to follow-up recommendations. Other factors, such as better lactation support or earlier formula supplementation, also might have contributed to the reduction in hyperbilirubinemia. Because the trend toward fewer cases of severe hyperbilirubinemia began before universal screening was implemented, increased clinician concern about jaundice and kernicterus that predated screening might have led to management changes that contributed to the decrease.

Perhaps the more-important question is whether universal screening will reduce the incidence of kernicterus. This question is difficult to answer, given the infrequency of kernicterus. In our study, only 2 cases were identified among 358 086 infants, which made it difficult to draw any statistical conclusions. **If TSB levels of  $\geq 25$  mg/dL are considered a proxy or intermediate outcome for kernicterus, then universal bilirubin screening may be a potentially important intervention to reduce the incidence of kernicterus.** Kernicterus may occur despite universal screening, however, because TSB levels of  $\geq 25$  mg/dL occurred despite universal screening (0.036% in our population). This might be attributable to missed follow-up care, sepsis, glucose-6-phosphate dehydrogenase deficien-

cy,<sup>18</sup> failure of physicians to treat high bilirubin levels,<sup>19</sup> feeding difficulties, or other factors.

We also found that, with increased bilirubin testing, there were significant increases in phototherapy during the birth hospitalization and readmissions for phototherapy, often at TSB levels below those recommended by the AAP. This was in contrast to studies by Petersen et al<sup>5</sup> and Eggert et al<sup>4</sup> that found reductions in readmissions. In the study by Petersen et al,<sup>5</sup> however, there was a high baseline readmission rate (4.5%, compared with 1.6% in our study). In the study by Eggert et al,<sup>4</sup> the readmission rate was low at baseline (0.55%) and improved only slightly (to 0.43%). There was significant heterogeneity among the facilities in this study regarding the use of phototherapy, which indicates that universal screening by itself does not lead to significantly higher rates of phototherapy. We speculate that physician concern (anxiety) about hyperbilirubinemia, coupled with increased testing, could lead to subthreshold use of phototherapy.<sup>20,21</sup>

Neonatologists at some facilities reported starting phototherapy for infants with TSB levels lower than those recommended by the AAP in hopes of preventing readmissions for phototherapy. Some additional reasons for starting phototherapy at subthreshold TSB levels might include a high rate of increase in TSB levels, concern about the reliability of follow-up monitoring, or additional risk factors. Physician practices to initiate phototherapy also might have been influenced by payer factors such as the potential for parental copayments for hospital readmissions. The aim of the 2004 AAP guideline was to “reduce the frequency of severe neonatal hyperbilirubinemia and bilirubin encephalopathy and minimize the risk of unintended harm such as increased anxiety, decreased breastfeeding, or unnecessary treatment for the general popula-

tion and excessive cost and waste.”<sup>21</sup> Our data suggest that, although there has been some success regarding the first goal, it might have come at the cost of **sometimes-excessive treatment.** Somewhat reassuring were the findings that the mean length of birth hospitalization increased by only 2.2 hours with universal bilirubin screening and the length of stay for infants receiving phototherapy actually decreased by  $>1$  day. The decreased length of stay for infants receiving phototherapy might have been attributable to more-prompt initiation of phototherapy, which resulted in shorter stays, or to more infants receiving subthreshold phototherapy, which reduced the mean length of stay for all infants receiving phototherapy.

Our study has some limitations. Phototherapy use was derived from procedure codes and not chart review, which probably led to a slight ( $<10\%$ ) underestimation of phototherapy use.<sup>22</sup> We did not have information on how other interventions, including breastfeeding, formula supplementation, and lactation support, might have changed over the time period. We also did not have complete information on all risk factors (eg, sepsis and ill appearance) that might have influenced the decision to start phototherapy and altered our classification of subthreshold phototherapy. However, these factors are unlikely to have changed over time and would not explain the temporal changes in subthreshold phototherapy.

## CONCLUSIONS

**Universal bilirubin screening, with either TcB or TSB measurements, was associated with increased identification of newborns needing phototherapy and a significantly lower incidence of severe hyperbilirubinemia.** There also was a substantial increase in the use of phototherapy, often at bilirubin levels lower than those recommended

by the AAP. These results show the importance of monitoring the use of phototherapy as well as the frequency of bilirubin testing and hyperbilirubinemia after guideline implementa-

tion. With additional education, the reduction in serious hyperbilirubinemia with universal bilirubin screening may be achieved without excessive phototherapy use.

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