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Phototherapy Use in Jaundiced Newborns in a Large Managed Care Organization: Do Clinicians Adhere to the Guideline?

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ABSTRACT. ***Objective.*** **In 1994, the American Academy of Pediatrics (AAP) published a practice guideline with age-specific thresholds for phototherapy for healthy term newborns with hyperbilirubinemia. The purpose of this study was to examine adherence to the guideline in a large managed care organization.**

Methods. **We conducted a retrospective cross-sectional analysis of linked computerized databases from 11 Northern California Kaiser Permanente Medical Care Program hospitals. Newborn infants included were at least 37 weeks of gestation, had birth weights of at least 2500 g, and were born between January 1, 1995, and December 31, 1996. The primary outcome variable for the study was receipt of phototherapy according to the guideline. Total serum bilirubin (TSB) and infant age in hours at the time of bilirubin measurement were used to classify infants into 3 groups according to the AAP guideline: recommend phototherapy (R), consider phototherapy (C), and did not recommend phototherapy (N). Group R included infants with TSB levels of at least 15 mg/dL before 48 hours of age, at least 18 mg/dL before 72 hours, or at least 20 mg/dL after 72 hours. Group C included infants not in group R, with TSB levels of at least 12 mg/dL before 48 hours, 15 mg/dL before 72 hours, or at least 17 mg/dL after 72 hours. Group N included infants who were in neither group R nor group C and also did not have significant jaundice before 24 hours of age. Phototherapy codes from electronic databases were validated by chart review for a subset of 550 infants.**

Results. **Compared with chart review, phototherapy codes in the database were 94.4% sensitive (95% confidence interval [CI]: 89.1%–97.5%) and 100% specific (95% CI: 99.25%–100%). Among the 47 801 infants eligible, 2.3% received phototherapy. Phototherapy was administered to 54% of 1194 infants in group R (range across hospitals: 27%–77%), 16% of 2245 infants in group C (range: 5%–37%), and 0.2% of 44 362 infants in group N (range: 0.1%–0.6%). The predictors of phototherapy for group R, the group for whom phototherapy was recommended, determined by logistic regression were increasing TSB levels (odds ratio [OR]: 1.6/mg/dL; 95% CI: 1.4–1.7), reaching the AAP threshold at 24 to 47.9 hours of age compared with 48 hours or more (OR: 7.1; 95% CI: 4.3–11.9), gestational age of 37 weeks compared with 38 weeks or more (OR: 1.6; 95% CI: 1.1–2.3), age when phototherapy was first recommended (OR: 0.7/d; 95% CI: 0.6–0.8), and facility of birth (OR: 0.2–2.7). The facility of birth was a strong predictor of phototherapy use in all groups (R, C, and N).**

Conclusions. **Clinicians provided phototherapy to only 54% of term infants with hyperbilirubinemia for whom it was recommended by the AAP. There is marked interhospital variation in phototherapy use in this large managed care system. Improved adherence to the guideline would require only a slight increase in the total rate of phototherapy use if unnecessary use for infants with lower levels of TSB were simultaneously decreased.** ***Pediatrics*** **2003;111:e555–e561. URL: http://www.pediatrics.org/cgi/content/full/111/5/e555;** ***hyperbilirubinemia, clinical practice guideline, phototherapy.***

ABBREVIATIONS. AAP, American Academy of Pediatrics; KPMCP, Kaiser Permanente Medical Care Program; TSB, total serum bilirubin; RILIS, Region-wide Integrated Laboratory Information System; CI, confidence interval.

In 1994, the American Academy of Pediatrics (AAP) published a practice parameter that included age-specific thresholds for phototherapy for healthy term newborn infants with hyperbilirubinemia.[1] The guideline categorized infants by age (in hours) and provided ranges of total serum bilirubin at which phototherapy should be considered and at which phototherapy was recommended (Table 1). How closely have practicing clinicians actually been following this guideline?

Most previous studies of clinician management of jaundiced infants were conducted before the publication of the AAP practice parameter[2–5] with some[3,5] relying on response to questionnaires rather than observations of actual practice. Recently, Seidman et al[6] reported a dramatic decline in use of phototherapy and exchange transfusions in 2 hospitals in Israel after publication of the AAP practice parameter. However, no study has examined specific bilirubin levels at which clinicians actually initiate phototherapy to determine clinician adherence to the practice guideline. In the current study, we identified infants who were born in 11 hospitals of the Kaiser Permanente Medical Care Program (KPMCP) Northern California Region and whose age and bilirubin levels met the AAP criteria for treatment with phototherapy and determined the proportion that were treated as recommended.

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TABLE 1. Adapted AAP Guideline for Management of Hyperbilirubinemia in the Healthy Term Newborn Based on Age and TSB Levels

Age (Hours)	No Phototherapy	Consider Phototherapy	Recommend Phototherapy
<24	No recommendations	No recommendations	No recommendations
24–48	<12 mg/dL	≥12 mg/dL	≥15 mg/dL
49–72	<15 mg/dL	≥15 mg/dL	≥18 mg/dL
>72	<17 mg/dL	≥17 mg/dL	≥20 mg/dL

METHODS

Design

This study is a retrospective cross-sectional study analyzing linked computerized clinical databases. Infant demographic and phototherapy treatment variables were obtained from the KPMCP Admission-Discharge-Transfer database. Total serum bilirubin (TSB) levels were obtained from the Region-wide Integrated Laboratory Information System (RILIS).[7]

Subjects

Infants were included if they were born at any of 11 Northern California KPMCP hospitals between January 1, 1995, and December 31, 1996, and were at least 37 weeks of gestation and weighed 2500 g or more at birth. The time period was chosen because chart review data to validate phototherapy codes were available for this period and because home phototherapy was not yet in use in the KPMCP at that time. Infants who had been transferred to another hospital before discharge were assigned to their birth hospital.

Predictor Variables

The infants' birth weight, birth date and time, gestational age, treatment with phototherapy, and self-reported maternal race were obtained from the KPMCP administrative and research databases using methods previously described.[8] Gestational age was based on the estimated date of confinement from the obstetrician record. Race was based on maternal self-report. Bilirubin test results, with respective dates and times for infants <720 hours of age (30 days), were obtained from the RILIS, which tracks all laboratory data for the 11 Northern California KPMCP Hospitals.[9] The KPMCP databases used in this study have been previously described.[10–14] We used TSB levels and the infant age (in hours) and compared them with the AAP guideline to classify infants into 3 mutually exclusive groups: recommend phototherapy (group R), consider phototherapy (group C), and no phototherapy recommended (group N), as described below (Fig 1). Given the slight ambiguity in the AAP guideline regarding infants between 48 and 49 hours of age, we operationally defined 24, 48, and 72 hours as the minimum age (in hours) for each age interval. Thus, a 48- to 49-hour-old infant with a TSB of 16 mg/dL would be assigned to group C, not group R.

Group R, the recommend phototherapy group, consisted of infants whose TSB met the age-specific bilirubin level for recommend phototherapy as described in Table 1. Group C, the consider phototherapy group, were infants whose TSB met the age-specific bilirubin level for considering phototherapy and whose subsequent bilirubin did not qualify for group R. Group N, the no phototherapy recommendation group, consisted of infants whose TSB levels never qualified for either of the previous 2 groups and were not elevated at <24 hours of age (group X), as discussed below.

Infants with elevated bilirubin levels at <24 hours of age might appropriately receive phototherapy and thereby never have TSB that reach levels to qualify for group C or R. To avoid assigning

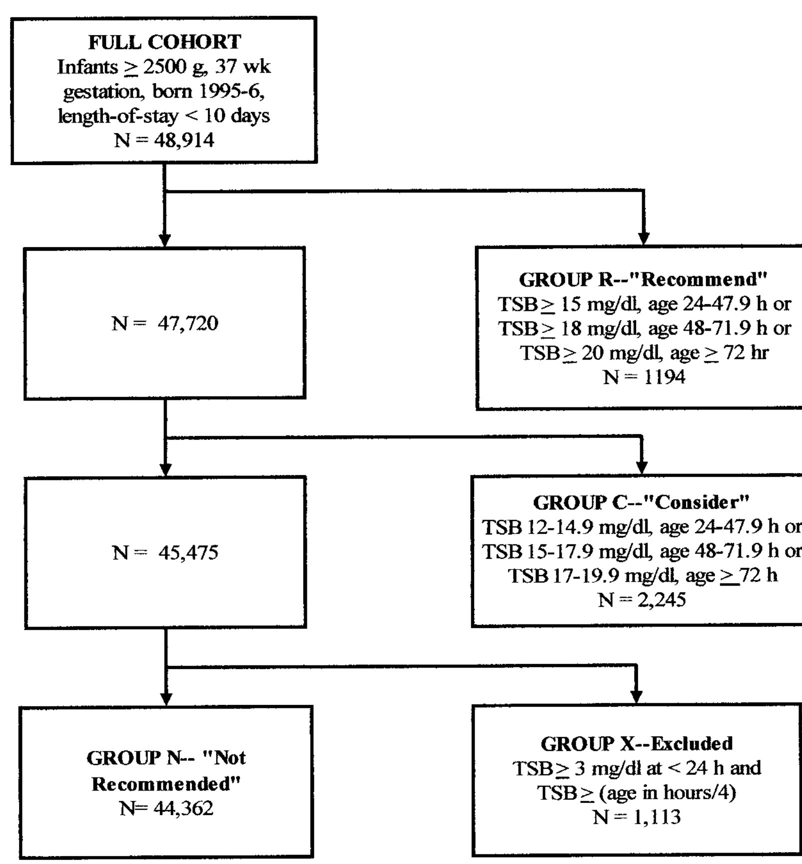

Fig 1. Distribution of study participants into groups defined by the AAP guideline.

these infants to group N, a group in whom phototherapy may have been overused, we excluded infants with TSB levels of at least 3 mg/dL and at least a quarter of the infants' age in hours. We used this liberal definition of when phototherapy might be reasonable on the first day because the guideline does not address infants <24 hours old. For example, we considered an infant with a TSB of 6 mg/dL at 20 hours of age to be a reasonable candidate for phototherapy, as the value 6 mg/dL is >3 mg/dL and greater than a quarter of the age in hours. Excluding such infants (group X) from our study provided greater assurance that infants who were left in group N and received phototherapy were treated at levels of TSB lower than recommended by the AAP.

Outcome Variable

The main outcome variable for this study was phototherapy use, a dichotomous variable (received phototherapy/did not receive phototherapy) for each infant. Phototherapy use was ascertained from the Admission-Discharge-Transfer database, using *International Classification of Diseases, Ninth Revision, Clinical Modification* codes 99.83 and 99.82, from the birth admission or rehospitalizations during the first 30 days after birth, supplemented by codes from the KPMCP Neonatal Minimum Data Set. The Neonatal Minimum Data Set is an internal KPMCP database with specific patient care data from chart review, which is entered by trained research assistants for all infants admitted to 1 of the 6 Northern California KPMCP neonatal intensive care units.[12] This information includes use of phototherapy noted in physician or nursing notes, including specific start and stop times of phototherapy use.

We assessed the sensitivity of the procedure codes using 141 infants from a previously reported case-control study[7] who were documented by chart review to have received phototherapy. We assessed the specificity of the code using the 409 randomly selected controls from that study who did not have indications of phototherapy in their charts. We supplemented this specificity estimate by determining the frequency of phototherapy codes among the 37 068 infants in the study population who never had a bilirubin level measured.

Data Analysis

We extracted data from RILIS and Northern California KPMCP databases using SAS (SAS Corp, Cary, NC). All analyses were performed using STATA 6.0 for Windows (Stata Corp, College Station, TX). Frequency of appropriate phototherapy use was obtained by comparing actual phototherapy use with that recommended by the 1994 AAP guidelines. Differences in categorical variables were assessed using the Pearson χ^2 test. We used a stepwise backward logistic model to identify predictors of receipt of phototherapy given that it was recommended by the AAP. Fit of logistic models was evaluated using the Hosmer-Lemeshow goodness-of-fit test.

RESULTS

The race and gestational age distributions and frequency of bilirubin testing and hyperbilirubinemia at the 11 birth hospitals for the 51 387 infants of at least 36 weeks' gestational age and with a birth weight of at least 2000 g in this cohort of infants have been previously described.[5] For the current study, we excluded 2302 infants with birth weight <2500 g or gestational age <37 weeks, 4 infants for missing gestational age data, 1 for indeterminate gender assignment, and 166 infants whose hospital stay was >10 days, suggesting poor health. The remaining 48 914 infants were classified into 4 groups on the basis of their serum bilirubin levels (Fig 1). Because the 1113 infants in group X were not addressed by the AAP guideline, they were excluded from additional analyses, leaving a study group of 47 801 infants.

Of the 47 801 total infants in groups R, C, and N combined, 1086 (2.3%) received phototherapy. Of these infants who received phototherapy, 59% were in group R, 32% were in group C, and 9% were in group N. Of the 1194 infants in group R (phototherapy recommended; 2.5% of the study population), 54% (643 infants) received phototherapy. The distribution of gender, race, gestational age, and birth weight for group R is shown in Table 2. In bivariate analyses, gender, race, birth weight, and maternal age did not predict phototherapy treatment within this group. Seventy-six percent of infants who were 24 to 47.9 hours old when their TSB first reached the AAP treatment threshold received phototherapy, compared with 49% of infants at 48 to 71.9 hours and 50% of infants at at least 72 hours of age ($P < .001$). Hospital of birth was a very strong predictor of phototherapy, with an interhospital range of 27% to 77% (Table 3).

Increasing TSB levels progressively increased the

TABLE 2. Demographic Characteristics of Infants and Use of Phototherapy in Group R (for Which the AAP Recommends Phototherapy)

	Total *N*	%	*N* in Group R	*N* Receiving Phototherapy	%
N	47 801		1194	643	54
Gender					
Male	24 646	52	709	377	53
Female	23 155	48	485	266	55
Race					$P = 0.6$
Asian	7455	16	348	195	56
Black	4208	9	61	30	49
Latino	8853	19	203	117	58
White	25 541	53	543	285	52
Other	1744	4	39	16	41
Gestational age					$P = 0.3$
37 wk	2688	6	186	112	60
38–39 wk	18 252	38	535	275	51
≥40 wk	26 861	56	473	256	54
Birth weight					$P = 0.1$
2.5–3 kg	6390	13	213	120	56
3–3.9 kg	34 298	72	820	439	54
≥4 kg	7113	15	161	84	52
					$P = 0.7$

TABLE 3. Use of Phototherapy by Hospital and AAP Guideline Group

Hospital	Total No. of Infants	Group R (%)	Group C (%)	Group N (%)	Total (%)
1	5368	40	15	0.41	2.8
2	3328	63	17	0.20	2.8
3	3053	63	19	0.24	2.3
4	4989	52	12	0.04	1.8
5	5273	66	14	0.10	1.9
6	4371	62	9	0.05	2.4
7	2619	63	17	0.12	2.0
8	3933	54	11	0.06	3.3
9	4408	27	5	0.10	0.9
10	4104	77	37	0.57	3.2
11	6355	56	21	0.35	2.0

See text and Fig 1 for definition of guideline groups.

odds of receiving phototherapy (Table 4). Gestational age of 37 weeks, reaching the AAP threshold at 24 to 47.9 hours of age, and younger age when first eligible for phototherapy recommendation were also significant independent predictors of receipt of phototherapy. Finally, when compared with the odds for hospital 11 (which had the most births), odds of phototherapy according to the AAP guideline for other hospitals ranged from 0.2 to 2.7 times as high. The fit of the logistic model was adequate (Hosmer-Lemeshow X^2 [10 groups] = 8.6; P = .37).

Among the 2245 infants in group C, for whom the AAP recommends that phototherapy be considered (4.7% of the study population), 16% (349 infants) received phototherapy. Infant birth weight, gestational age, and hospital of birth (Table 3) were significant predictors by bivariate analysis of phototherapy use for infants in this discretionary phototherapy group. Sixteen percent of infants with birth weight 2.5 to 2.9 kg, 14% of those 3 to 3.9 kg, and 21% of those ≥4 kg received phototherapy (P = .01). A higher proportion of infants born at 37 weeks of gestation received phototherapy (24%) compared with infants 38 to 40 weeks or greater (13–16%; $P <$ .001). Phototherapy use ranged from 5% to 37% of infants in group C across the 11 hospitals ($P <$ .001). The infant's gender and race and maternal age were not significant independent predictors of receipt of phototherapy in this group.

For group N, those for whom the AAP does not recommend phototherapy (93% of the study population), .2% received phototherapy. Gender, hospital of birth, birth weight, and gestational age were significant predictors of receipt of phototherapy. For gender, .3% of boys and .2% of girls received phototherapy (P = .04). Similar to previous results, birth weight was a significant predictor, with .4% of infants 2.5 to 2.9 kg, compared with .2% of 3 to 3.9 kg and .3% ≥4 kg, receiving phototherapy (P = .002). Gestational age was also a significant predictor, with 1.0% of infants born at 37 weeks compared with .2% born at ≥38 weeks receiving phototherapy ($P <$ .001). Hospital of birth was the strongest predictor of phototherapy, with a range of .1% to .6% of infants receiving phototherapy (Table 3). Race and maternal age did not predict receipt of phototherapy in group N.

When phototherapy treatment recorded in the KP-MCP electronic databases was compared with that recorded in the paper form of medical records, among the 141 patients who received phototherapy per medical record, 133 had a code for phototherapy in the computerized database (sensitivity: 94.4%; 95% confidence interval [CI]: 89.1%–97.5%). Among the 409 patients who had not received phototherapy according to medical records, 409 had no code for phototherapy in the database (specificity: 100%; 95% CI: 99.25%–100%). Of 37 068 infants who did not have a bilirubin value in the database, 3 had a phototherapy code. If these all are considered false-positive phototherapy codes (and not missing laboratory data or phototherapy treatment without a bilirubin value), then the specificity would be 99.99% (95% CI: 99.976%–99.999%).

TABLE 4. ORs for Predictor Variables of Phototherapy Use According to AAP Guidelines

Variable	OR	95% CI	P
Maximum TSB	1.6 mg/dL	1.4–1.7	<.001
Age when phototherapy was first recommended	0.7/d	0.6–0.8	<.001
Eligible for phototherapy at 24–47.9 h of age (vs 48–71.9 h and ≥72 h)	7.1	4.3–11.9	<.001
Hospital 11 (Reference)	1.0		
Hospital 9	0.2	0.1–0.3	<.001
Hospital 1	0.4	0.3–0.6	<.001
Hospital 4	0.5	0.4–0.8	.01
Hospital 10	2.7	1.3–5.5	.01
37 wk gestational age (vs 38–39 wk and >40 wk)	1.6	1.1–2.3	.01

OR indicates odds ratio.

DISCUSSION

In our study, just more than half of healthy term newborn infants for whom the AAP guideline recommends phototherapy received phototherapy in this large staff-model managed care organization. However, 16% of infants for whom phototherapy should be considered and .2% of those for whom phototherapy was not indicated received phototherapy. The single most important predictor of phototherapy use according to AAP guidelines was hospital of birth, with a range of 27% to 75% receiving phototherapy in group R.

There were a few limitations to our study. One such limitation was our reliance on electronic data, as specific data may be either missing or inaccurate. In addition, we were unable to assess the effect of other clinical factors on the use of phototherapy. The database used in our study did not include relevant clinical and laboratory data such as signs of illness (ie, presence of fever or temperature instability) and existence of ABO incompatibility or hemolysis. Absence of such data, however, would not explain the low phototherapy rates in the recommend phototherapy group because any such findings should have led to higher rates of phototherapy. The impact of missing or inaccurate data can also be directly determined. On the basis of our review of paper records, the electronic database captured 94.4% of those who received phototherapy. The proportion of infants in group R who received phototherapy is probably closer to 54%/.944 = 57%. If the sensitivity is at the lower limit of the 95% CI, then the rate could be as high as 54%/.89 = 61%. Thus, possible undercoding of phototherapy use also does not explain lack of adherence to the AAP guideline in group R.

Our conclusions must be more tentative regarding results for group N, who received phototherapy despite not having bilirubin levels high enough to need it according to the AAP. First, the practice guideline applies only to term newborns who are otherwise well. Some of the infants in group N may have had signs of illnesses (eg, temperature instability) or laboratory values consistent with hemolysis (eg, positive direct antiglobulin tests) that would have excluded them from the guideline or indicated phototherapy treatment at lower TSB levels. In addition, errors in gestational age in the database might have led to inclusion of some preterm infants in the current study. Although this type of error may be uncommon, such infants are appropriately treated at lower levels of TSB than term infants. However, lack of specificity of the data codes (ie, the possibility that the codes for phototherapy in group N were erroneous) is unlikely to explain the phototherapy codes in group N.

Why did many clinicians in our study not adhere to the AAP guideline? According to a systematic review of barriers to physician adherence to clinical practice guidelines conducted by Cabana et al,[15] there are 7 types of barriers: lack of awareness, lack of familiarity, lack of agreement, lack of self-efficacy, lack of outcome expectancy (that a particular outcome will occur if the guideline is not adhered to), inertia of previous practice (inability to change previous practice), and external barriers. Lack of awareness, lack of familiarity, and inertia are certainly possible, because the guideline was introduced in 1994 and the study covers the period 1995–1996. A survey of pediatricians' awareness and attitudes toward practice guidelines conducted in 1997 found that only 66% reported being aware of the AAP jaundice guideline.[16] Nonetheless, lack of awareness does not provide a good explanation for lack of phototherapy use in group R, because clinicians who were unaware of the guideline should have used phototherapy more often than recommended, because previous recommendations were for phototherapy use at lower bilirubin levels than those specified in the 1994 guideline. Our results are more consistent with the results of Seidman et al,[6] who noted a remarkable 63% decrease in the use of phototherapy in term newborns at 2 hospitals in Israel (from 7.9% to 2.9%) after publication of the AAP guideline. Thus, lack of awareness, lack of familiarity, and inertia all are better explanations for possibly excessive use of phototherapy in group N than for underuse of phototherapy in group R.

Lack of outcome expectancy and lack of agreement with the guideline are more likely reasons for the low rate of phototherapy in group R. As others have noted,[17–20] the incidence of kernicterus in the post-Rh disease era is low, and because most practicing pediatricians have not seen a case, their level of concern might have declined. If phototherapy treatment is not immediately initiated per AAP guideline, then clinicians may believe that either the bilirubin level will decline without medical treatment or infants can be followed clinically and phototherapy can be initiated later if the serum bilirubin rises to a higher level. Despite its apparent safety,[17] clinicians may also be concerned that phototherapy interrupts breastfeeding, disrupts mother-infant bonding, and leads to unnecessary hospitalization, particularly when home phototherapy is not available, as was the case in 1995–1996 in the KPMCP. These assessments of risk and benefits may account for the variability in treatment of term newborns with hyperbilirubinemia despite the AAP guidelines.

One of the strongest predictors of receipt of phototherapy in accordance with the AAP guideline was the hospital of birth. In the survey by Gartner et al,[3] neonatologists reported treating hyperbilirubinemia with phototherapy more often than did general pediatricians. However, interhospital variation in the current study is not explained by types of practitioners making phototherapy decisions, as there are neonatologists in 10 of the 11 Northern California KPMCP facilities included in this study. In hospital 10, an outlier with high phototherapy use, only general pediatricians make these decisions; at hospital 1, where the adherence rate was the second lowest in the study, there is a level 3 nursery and phototherapy decisions are more likely to be made by neonatologists. The interhospital variability in this study is remarkable, given that all infants were born in the same managed care organization in the same general region (Northern California). Hansen[5] found wide variation in reported bilirubin treatment practices in a survey of neonatal units in 22 countries on 4 continents. Our results suggest that the variation described in that study need not be based on geography but instead could be explained by variations in decision making by pediatricians at different institutions.

Increasing adherence to clinical practice guidelines is difficult. In 1986, the Canadian Medical Association published a guideline with recommendations on the use of phototherapy in newborns with hyperbilirubinemia.[13] Before publication of the Canadian Medical Association guideline, 10% of newborns received phototherapy in agreement with this guideline. After publication and educational component to increase knowledge of the guideline's recommendations, adherence increased to 17% and after an interview adherence increased only to 28% to 31%. These results illustrate the difficulty in increasing adherence to a guideline to high levels. One implication of the interhospital variability seen in this study is that interventions to increase adherence might be most efficiently targeted at hospitals rather than at individual clinicians. For example, an intervention for hospital 10, in which phototherapy use was 37% in group C and 0.6% in group N, might be different from one for hospital 9, in which phototherapy in group R was only 27%.

Increased adherence to any treatment modality relies on a proven favorable risk-to-benefit ratio. If the clinician does not agree with the risk-benefit profile on which the guideline is based or does not anticipate the occurrence of the adverse outcomes being addressed by the guideline, then there may be resistance to adhere to the guideline. Although some studies[21–25] have found associations between serum bilirubin and neurodevelopmental outcomes, none has shown any long-term beneficial effects of phototherapy.[26–28] Thus, the primary rationale for phototherapy must be to keep the bilirubin from rising to a level at which there is an increased risk of kernicterus. Because kernicterus remains rare, it may not be clear at exactly which bilirubin level the benefits of treatment exceed the risks and costs.

Clearly, additional studies to evaluate the neurodevelopmental outcomes of infants with various levels of hyperbilirubinemia and the effects of phototherapy and other interventions on bilirubin levels and neurodevelopmental outcome are needed. In the meantime, while acknowledging the shortcomings of available data,[2,5,28–30] it seems prudent to improve current adherence to the AAP phototherapy guidelines so that those who most need phototherapy are most likely to receive it.

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