abstract

OBJECTIVE: To standardize the use of phototherapy consistent with the American Academy of Pediatrics clinical practice guideline for the management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation.

METHODS: Relevant literature was reviewed. Phototherapy devices currently marketed in the United States that incorporate fluorescent, halogen, fiber-optic, or blue light-emitting diode light sources were assessed in the laboratory.

RESULTS: The efficacy of phototherapy units varies widely because of differences in light source and configuration. The following characteristics of a device contribute to its effectiveness: (1) emission of light in the blue-to-green range that overlaps the in vivo plasma bilirubin absorption spectrum (~460–490 nm); (2) irradiance of at least 30 \( \mu \)W·cm\(^{-2}\)·nm\(^{-1}\) (confirmed with an appropriate irradiance meter calibrated over the appropriate wavelength range); (3) illumination of maximal body surface; and (4) demonstration of a decrease in total bilirubin concentrations during the first 4 to 6 hours of exposure.

RECOMMENDATIONS (SEE APPENDIX FOR GRADING DEFINITION): The intensity and spectral output of phototherapy devices is useful in predicting potential effectiveness in treating hyperbilirubinemia (group B recommendation). Clinical effectiveness should be evaluated before and monitored during use (group B recommendation). Blocking the light source or reducing exposed body surface should be avoided (group B recommendation). Standardization of irradiance meters, improvements in device design, and lower-upper limits of light intensity for phototherapy units merit further study. Comparing the in vivo performance of devices is not practical, in general, and alternative procedures need to be explored. Pediatrics 2011;128:e1046–e1052
Clinical practice guideline for the management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation.

Table 1: Phototherapy Devices Commonly Used in the United States and Their Performance Characteristics

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Distance to Patient (cm)</th>
<th>Footprint Area (Length × Width, cm²)</th>
<th>% Treatable</th>
<th>Spectrum, Total (nm)</th>
<th>Bandwidth* (nm)</th>
<th>Peak (nm)</th>
<th>Footprint Irradiance (µW/cm²/nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light Emitting Diodes (LED)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>neoBLUE</td>
<td>Natus Medical, San Carlos, CA</td>
<td>30</td>
<td>1152 (48 × 24)</td>
<td>100</td>
<td>420–540</td>
<td>20</td>
<td>462</td>
<td>12–37, 30 ± 7</td>
</tr>
<tr>
<td>PortaBed</td>
<td>Stanford University, Stanford, CA</td>
<td>≥3</td>
<td>1740 (30 × 58)</td>
<td>100</td>
<td>425–540</td>
<td>27</td>
<td>463</td>
<td>40–76, 67 ± 8</td>
</tr>
<tr>
<td>Fluorescent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BiliLite GW/BB</td>
<td>Olympic Medical, San Carlos, CA</td>
<td>45</td>
<td>2928 (48 × 61)</td>
<td>100</td>
<td>380–720</td>
<td>80</td>
<td>578</td>
<td>6–10, 8 ± 1</td>
</tr>
<tr>
<td>BiliLite BB</td>
<td>Olympic Medical, San Carlos, CA</td>
<td>45</td>
<td>2928 (48 × 61)</td>
<td>100</td>
<td>400–550</td>
<td>80</td>
<td>445</td>
<td>11–22, 17 ± 2</td>
</tr>
<tr>
<td>BiliLite TLS2</td>
<td>Olympic Medical, San Carlos, CA</td>
<td>45</td>
<td>2928 (48 × 61)</td>
<td>100</td>
<td>400–560</td>
<td>80</td>
<td>437</td>
<td>13–23, 19 ± 3</td>
</tr>
<tr>
<td>BiliBed</td>
<td>Medela, McHenry, IL</td>
<td>0</td>
<td>693 (21 × 35)</td>
<td>71</td>
<td>400–560</td>
<td>80</td>
<td>450</td>
<td>14–59, 38 ± 2</td>
</tr>
<tr>
<td>Halogen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MiniBiliLite</td>
<td>Olympic Medical, San Carlos, CA</td>
<td>45</td>
<td>490 (25 diam)</td>
<td>54</td>
<td>350–800</td>
<td>190</td>
<td>580</td>
<td>&lt;1–19, 7 ± 5</td>
</tr>
<tr>
<td>Phototherapy Lite</td>
<td>Philips Inc, Andover, MA</td>
<td>45</td>
<td>490 (25 diam)</td>
<td>54</td>
<td>370–800</td>
<td>200</td>
<td>590</td>
<td>&lt;1–17, 5 ± 5</td>
</tr>
<tr>
<td>Halogen fiber optic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BiliBlanket</td>
<td>Ohmeda, Fairfield, CT</td>
<td>0</td>
<td>150 (10 × 15)</td>
<td>24</td>
<td>390–600</td>
<td>70</td>
<td>533</td>
<td>9–31, 20 ± 8</td>
</tr>
<tr>
<td>Wallaby II Preterm</td>
<td>Philips, Inc, Andover, MA</td>
<td>0</td>
<td>117 (9 × 13)</td>
<td>19</td>
<td>400–560</td>
<td>45</td>
<td>513</td>
<td>8–30, 16 ± 6</td>
</tr>
<tr>
<td>Wallaby II Term</td>
<td>Philips, Inc, Andover, MA</td>
<td>0</td>
<td>280 (6 × 59)</td>
<td>53</td>
<td>400–560</td>
<td>45</td>
<td>513</td>
<td>6–11, 8 ± 1</td>
</tr>
<tr>
<td>SpotLight1000</td>
<td>Philips, Inc, Andover, MA</td>
<td>45</td>
<td>490 (25 diam)</td>
<td>54</td>
<td>400–560</td>
<td>45</td>
<td>513</td>
<td>1–11, 6 ± 3</td>
</tr>
<tr>
<td>PEP Model 2000</td>
<td>PEP, Fryebug, ME</td>
<td>23</td>
<td>1530 (30 × 51)</td>
<td>100</td>
<td>400–717</td>
<td>63</td>
<td>445</td>
<td>12–49, 28 ± 11</td>
</tr>
<tr>
<td>Bili Soft</td>
<td>GE Healthcare, Laurel, MD</td>
<td>0</td>
<td>825 (25 × 35)</td>
<td>71</td>
<td>400–670</td>
<td>40</td>
<td>453</td>
<td>1–52, 25 ± 16</td>
</tr>
</tbody>
</table>

Data in Table 1 are expanded and updated from that previously reported by Vreman et al. The definitions and standards for device assessment are explained below.

EMISSION SPECTRAL QUALITIES: Measured data of the light delivered by each of the light sources are presented as the minimum, maximum, and range. Light source emission spectra within the range of 300–700 nm were recorded after the device had reached stable light emission, using a miniature fiberoptic radiometer (RRAD2000, Ocean Optics, Inc, Dunedin, FL). For precision based device assessment, the spectral bandwidth (σ), which is defined as the width of the emission spectrum in nm at 50% of peak light intensity, is the preferred method to distinguish and compare instead of the total range emission spectrum (data usually provided by manufacturers). Emission peak values are also used to characterize the quality of light emitted by a given light source.

IRRADIANCE: Measured data are presented as a linear light (including spectral irradiance and radiant exposure). The spectral irradiance of blue light (400–500 nm) was measured accurately to ±10% by the National Institute of Standards and Technology (Gaithersburg, MD). Irradiance measurements were made using calibrated BiliBlanket Meters II and I (Ohmeda, GE Healthcare, Fairfield, CT), which were found to yield identical results with stable output phototherapy devices. This type of meter was used from the earlier to the newer phototherapy device manufacturers, which are commercially available, because it has a wider sensitivity range (400–700 nm) compared to the earlier phototherapy device measurements (350–700 nm) which overlap the bilirubin absorption spectrum and which renders it suitable for the evaluation of both narrow and broad wavelength band light sources. The devices have been found to measure exceptionally accurately in the range of 200–700 nm, which is where the vast majority of irradiance encountered with a device can be used as an indication of the uniformity of the emitted light. Measurements of irradiance were made using calibrated BiliBlanket Meters II and I. A device with a higher spectral irradiance footprint has greater dimensions than the emission surface, which is measured at the point where the light exists a phototherapy device. The minimum and maximum irradiance values are shown to indicate the range of irradiance encountered with a device and can be used as an indication of the uniformity of the emitted light. Phototherapy devices commonly used in the United States and their performance characteristics.

BILIRUBIN NEUROTOXICITY. In the United States, a complete discussion of the efficacy of phototherapy in reducing excessive unconjugated hyperbilirubinemia in the newborn infant 35 or more weeks of gestation.

Clinical practice guideline for the management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation.

A complete discussion of the efficacy of phototherapy in reducing excessive unconjugated hyperbilirubinemia in the newborn infant 35 or more weeks of gestation.

Clinical practice guideline for the management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation.
II. STANDARDS FOR PHOTOTHERAPY DEVICES

Methods for reporting and measuring phototherapy doses are not standardized. Comparisons of commercially available phototherapy devices that use in vitro photodegradation techniques may not accurately predict clinical efficacy. A recent report explored an approach to standardizing and quantifying the magnitude of phototherapy delivered by various devices. Table 1 lists technical data for some of the devices marketed in the United States. Factors to consider in prescribing and implementing phototherapy are (1) emission range of the light source, (2) the light intensity (irradiance), (3) the exposed (“treatable”) body surface area illuminated, and (4) the decrease in total bilirubin concentration. A measure of the effectiveness of phototherapy to rapidly configure the bilirubin molecule to less toxic photoproducts (predominantly isomers of bilirubin). Because of the photochemical properties of skin, the most effective light in vivo is probably in the blue-green region (460–490 nm). The first prototype phototherapy device to result in a clinically significant rate of bilirubin decrease used a blue (B) fluorescent-tube light source with 420- to 480-nm emission. More effective narrow-band special blue bulbs (F20T12/BB [General Electric, Westinghouse, Sylvania] or TL52/20W [Phillips]) were subsequently used. Most recently, commercial compact fluorescent-tube light sources and devices that use LEDs of narrow spectral bandwidth have been used. Unless specified otherwise, plastic covers or optical filters need to be used to remove potentially harmful ultraviolet light.

Clinical Context

Devices with maximum emission within the 460- to 490-nm (blue-green) region of the visible spectrum are probably the most effective for treating hyperbilirubinemia. Lights with broader emission also will work, although not as effectively. Special blue (BB) fluorescent lights are effective but should not be confused with white lights painted blue or covered with blue plastic sheaths, which should not be used. Devices that contain high-intensity gallium nitride LEDs with emission within the 460- to 490-nm regions are also effective and have a longer lifetime (>20,000 hours), lower heat output, low infrared emission, and no ultraviolet emission.

B. Measuring Light Irradiance

Light intensity or energy output is defined by irradiance and refers to the number of photons (spectral energy) that are delivered per unit area (cm²) of exposed skin. The dose of phototherapy is a measure of the irradiance delivered for a specific duration and adjusted to the exposed body surface area. Determination of an in vivo dose–response relationship is confounded by the optical properties of skin and the rates of bilirubin production and elimination. Irradiance is measured with a radiometer (W·cm⁻²) or spectroradiometer (µW·cm⁻²·nm⁻¹) over a given wavelength band. Table 2 compares the spectral irradiance of some of the devices in the US market, as measured with different brands of meters.
ters. Often, radiometers measure wavelengths that do not penetrate skin well or that are far from optimal for phototherapy and, therefore, may be of little value for predicting the clinical efficacy of phototherapy units. A direct relationship between irradiance and the rate of in vivo total bilirubin concentration decrease was described in the report of a study of term “healthy” infants with nonhemolytic hyperbilirubinemia (peak values: 15–18 mg/dL) using fluorescent Philips daylight (TL20W/54, TL20W/52) and special blue (TLAK 40W/03) lamps.\(^\text{15,16}\) The American Academy of Pediatrics has recommended that the irradiance for intensive phototherapy be at least 30 \(\mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}\) over the waveband interval 460 to 490 nm.\(^\text{1}\) Devices that emit lower irradiance may be supplemented with auxiliary devices. Much higher doses (\(\geq 65 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}\)) might have (as-yet-unidentified) adverse effects. Currently, no single method is in general use for measuring phototherapy dosages. In addition, the calibration methods, wavelength responses, and geometries of instruments are not standardized. Consequently, different radiometers may show different values for the same light source.\(^\text{2}\)

**Clinical Context**

For routine measurements, clinicians are limited by reliance on irradiance meters supplied or recommended by the manufacturer. Visual estimations of brightness and use of ordinary photometric or colorimetric light meters are inappropriate.\(^\text{1,2}\) Maximal irradiance can be achieved by bringing the light source close to the infant; however, this should not be done with halogen or tungsten lights, because the heat generated can cause a burn. Furthermore, with some fixtures, increasing the proximity may reduce the exposed body surface area. Irradiance distribution in the illuminated area (footprint) is rarely uniform; measurements at the center of the footprint may greatly exceed those at the periphery and are variable among phototherapy devices.\(^\text{1}\) Thus, irradiance should be measured at several sites on the infant’s body surface. The ideal distance and orientation of the light source should be maintained according to the manufacturer’s recommendations. The irradiance of all lamps decreases with use; manufacturers may provide useful-lifetime estimates, which should not be exceeded.

**C. Optimal Body Surface Area**

An infant’s total body surface area\(^\text{17}\) can be influenced by the disproportional head size, especially in the more preterm infant. Complete (100%) exposure of the total body surface to light is impractical and limited by use of eye masks and diapers. Circumferential illumination (total body surface exposure from multiple directions) achieves exposure of approximately 80% of the total body surface. In clinical practice, exposure is usually planar: ventral with overhead light sources and dorsal with lighted mattresses. Approximately 35% of the total body surface (ventral or dorsal) is exposed with either method. Changing the infant’s posture every 2 to 3 hours may maximize the area exposed to light. Exposed body surface area treated rather than the number of devices (double, triple, etc) used is clinically more important. Maximal skin surface illumination allows for a more intensive exposure and may require combined use of more than 1 phototherapy device.\(^\text{1}\)

**Clinical Context**

Physical obstruction of light by equipment, such as radiant warmers, head covers, large diapers, eye masks that enclose large areas of the scalp, tape, electrode patches, and insulating plastic covers, decrease the exposed skin surface area. Circumferential phototherapy maximizes the exposed area. Combining several devices, such as fluorescent tubes with fiber-optic pads or LED mattresses placed below the infant or bassinet, will increase the surface area exposed. If the infant is in an incubator, the light rays should be perpendicular to the surface of the incubator to minimize reflectance and loss of efficacy.\(^\text{1,2}\)

**D. Rate of Response Measured by Decrease in Serum Bilirubin Concentration**

The clinical impact of phototherapy should be evident within 4 to 6 hours of initiation with an anticipated decrease of more than 2 mg/dL (34 \(\mu\text{mol/L}\)) in serum bilirubin concentration.\(^\text{1}\) The clinical response depends on the rates of bilirubin production, enterohepatic circulation, and bilirubin elimination; the degree of tissue bilirubin deposition\(^\text{15,16,18}\); and the rates of the photochemical reactions of bilirubin. Aggressive implementation of phototherapy for excessive hyperbilirubinemia, sometimes referred to as the “crash-cart” approach,\(^\text{19,20}\) has been reported to reduce the need for exchange transfusion and possibly reduce the severity of bilirubin neurotoxicity.

**Clinical Context**

Serial measurements of bilirubin concentration are used to monitor the effectiveness of phototherapy, but the value of these measurements can be confounded by changes in bilirubin production or elimination and by a sudden increase in bilirubin concentration (rebound) if phototherapy is stopped. Periodicity of serial measurements is based on clinical judgment.

**III. EVIDENCE FOR EFFECTIVE PHOTOTHERAPY**

Light-emission characteristics of phototherapy devices help in predicting
their effectiveness (group B recommendation) (see Appendix). The clinical effectiveness of the device should be known before and monitored during clinical application (group B recommendation). Local guidelines (instructions) for routine clinical use should be available. Important factors that need to be considered are listed in Table 3. Obstructing the light source and reducing the exposed body surface area must be avoided (group B recommendation).

These recommendations are appropriate for clinical care in high-resource settings. In low-resource settings the use of improvised technologies and affordable phototherapy device choices need to meet minimum efficacy and safety standards.

IV. SAFETY AND PROTECTIVE MEASURES

A clinician skilled in newborn care should assess the neonate’s clinical status during phototherapy to ensure adequate hydration, nutrition, and temperature control. Clinical improvement or progression of jaundice should also be assessed, including signs suggestive of early bilirubin encephalopathy such as changes in sleeping pattern, deteriorating feeding pattern, or inability to be consoled while crying. Staff should be educated regarding the importance of safely minimizing the distance of the phototherapy device from the infant. They should be aware that the intensity of light decreases at the outer perimeter of the light footprint and recognize the effects of physical factors that could impede or obstruct light exposure. Staff should be aware that phototherapy does not use ultraviolet light and that exposure to the lights is mostly harmless. Four decades of neonatal phototherapy use has revealed no serious adverse clinical effects in newborn infants 35 or more weeks of gestation. For more preterm infants, who are usually treated with prophylactic rather than therapeutic phototherapy, this may not be true. Informed staff should educate parents regarding the care of their newborn infant undergoing phototherapy. Devices must comply with general safety standards listed by the International Electrotechnical Commission.21 Other clinical considerations include:

a. Interruption of phototherapy: After a documented decrease in bilirubin concentration, continuous exposure to the light source may be interrupted and the eye mask removed to allow for feeding and maternal-infant bonding.1

b. Use of eye masks: Eye masks to prevent retinal damage are used routinely, although there is no evidence to support this recommendation. Retinal damage has been documented in the unpatched eyes of newborn monkeys exposed to phototherapy, but there are no similar data available from human newborns, because eye patches have always been used.22–24 Purulent eye discharge and conjunctivitis in term infants have been reported with prolonged use of eye patches.25,26

c. Use of diapers: Concerns for the long-term effects of continuous phototherapy exposure of the reproductive system have been raised but not substantiated.27–29 Diapers may be used for hygiene but are not essential.

d. Other protective considerations: Devices used in environments with high humidity and oxygen must meet electrical and fire hazard safety standards.21 Phototherapy is contraindicated in infants with congenital porphyria or those treated with photosensitizing drugs.1 Prolonged phototherapy has been associated with increased oxidant stress and lipid peroxidation30 and riboflavin deficiency.31 Recent clinical reports of other adverse outcomes (eg, malignant melanoma, DNA damage, and skin changes) have yet to be validated.12,32,33 Phototherapy does not exacerbate hemolysis.34

TABLE 3 Practice Considerations for Optimal Administration of Phototherapy

<table>
<thead>
<tr>
<th>Checklist</th>
<th>Recommendation</th>
<th>Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light source (nm)</td>
<td>Wavelength spectrum in 460-490-nm blue-green light region</td>
<td>Know the spectral output of the light source</td>
</tr>
<tr>
<td>Light irradiance (μW·cm⁻²·nm⁻¹)</td>
<td>Use optimal irradiance: &gt;30 μW·cm⁻²·nm⁻¹ within the 460-to 490-nm waveband</td>
<td>Ensure uniformity over the light footprint area</td>
</tr>
<tr>
<td>Body surface area (cm²)</td>
<td>Expose maximal skin area</td>
<td>Reduce blocking of light</td>
</tr>
<tr>
<td>Timeliness of implementation</td>
<td>Urgent or “crash-cart” intervention for excessive hyperbilirubinemia</td>
<td>May conduct procedures while infant is on phototherapy</td>
</tr>
<tr>
<td>Continuity of therapy</td>
<td>Briefly interrupt for feeding, parental bonding, nursing care</td>
<td>After confirmation of adequate bilirubin concentration decrease</td>
</tr>
<tr>
<td>Efficacy of intervention</td>
<td>Periodically measure rate of response in bilirubin load reduction</td>
<td>Degree of total serum/plasma bilirubin concentration decrease</td>
</tr>
<tr>
<td>Duration of therapy</td>
<td>Discontinue at desired bilirubin threshold; be aware of possible rebound increase</td>
<td>Serial bilirubin measurements based on rate of decrease</td>
</tr>
</tbody>
</table>

V. RESEARCH NEEDS

Among the gaps in knowledge that remain regarding the use of phototherapy to prevent severe neonatal hyperbilirubinemia, the following are among the most important:

1. The ability to measure the actual wavelength and irradiance delivered by a phototherapy device is urgently needed to assess the efficiency of
phototherapy in reducing total serum bilirubin concentrations.
2. The safety and efficacy of home phototherapy remains a research priority.
3. Further delineation of the short- and long-term consequences of exposing infants with conjugated and unconjugated hyperbilirubinemia to phototherapy is needed.
4. Whether use of phototherapy reduces the risk of bilirubin neurotoxicity in a timely and effective manner needs further exploration.

**SUMMARY**

Clinicians and hospitals should ensure that the phototherapy devices they use fully illuminate the patient’s body surface area, have an irradiance level of ≥30 μW·cm⁻²·nm⁻¹ (confirmed with accuracy with an appropriate spectral radiometer) over the waveband of approximately 460 to 490 nm, and are implemented in a timely manner. Standard procedures should be documented for their safe deployment.

**LEAD AUTHOR**

Vinod K. Bhutani, MD

**COMMITTEE ON FETUS AND NEWBORN, 2010–2011**

Lu-Ann Papile, MD, Chairperson
Jill E. Bailey, MD
Vinod K. Bhutani, MD
Waldemar A. Carlo, MD
James J. Cummings, MD
Praveen Kumar, MD
Richard A. Polin, MD
Rosemarie C. Tan, MD, PhD
Kristi L. Watterberg, MD

**REFERENCES**


**LIAISONS**

CAPT Wanda Denise Barfield, MD, MPH – Centers for Disease Control and Prevention
William H. Barth Jr, MD – American College of Obstetricians and Gynecologists
Ann L. Jefferies, MD – Canadian Paediatric Society
Rosalie G. Mainous, PhD, RNC, NNP – National Association of Neonatal Nurses
Tonse N. K. Raju, MD, DCH – National Institutes of Health
Kasper S. Wang – AAP Section on Surgery

**CONSULTANTS**

M. Jeffrey Maisels, MBCh, DSc
Antony F. McDonagh, PhD
David K. Stevenson, MD
Hendrik J. Vreman, PhD

**STAFF**

Jim Couto, MA

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APPENDIX  Definition of Grades for Recommendation and Suggestion for Practice

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
<th>Suggestion for Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>This intervention is recommended. There is a high certainty that the net benefit is substantial</td>
<td>Offer and administer this intervention</td>
</tr>
<tr>
<td>B</td>
<td>This intervention is recommended. There is a moderate certainty that the net benefit is moderate to substantial</td>
<td>Offer and administer this intervention</td>
</tr>
<tr>
<td>C</td>
<td>This intervention is recommended. There may be considerations that support the use of this intervention in an individual patient. There is a moderate to high certainty that the net benefit is small</td>
<td>Offer and administer this intervention only if other considerations support this intervention in an individual patient Discourage use of this intervention</td>
</tr>
<tr>
<td>D</td>
<td>This intervention is not recommended. There is a moderate to high certainty that the intervention has no net benefit and that the harms outweigh the benefits</td>
<td>If this intervention is conducted, the patient should understand the uncertainty about the balance of benefits and harms</td>
</tr>
<tr>
<td>I</td>
<td>The current evidence is insufficient to assess the balance of benefits against and harms of this intervention. There is a moderate to high certainty that the intervention has no net benefit and that the harms outweigh the benefits. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined</td>
<td>If this intervention is conducted, the patient should understand the uncertainty about the balance of benefits and harms</td>
</tr>
</tbody>
</table>

Phototherapy to Prevent Severe Neonatal Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation

Vinod K. Bhutani and the Committee on Fetus and Newborn

Pediatrics 2011;128;e1046
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