Neonatal jaundice (SC update)
Consultation on draft guideline - Stakeholder comments table

29 July 2015 – 26 August 2015

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Royal College of Obstetricians and Gynaecologists	Addendum	General	General	We agree with the addendum.	Thank you.
British society of Paediatric Gastroenterology Hepatology and Nutrition	Addendum	6	3	significant hyperbilirubinaemia is an elevation to a level requring treatment should be changed to significant unconjugated hyperbilirubinaemia	Thank you for your comment. The committee highlighted that the distinction between conjugated/unconjugated bilirubin is not usually made within the first 10 days of life. Longer term care is outside the scope of this particular part of the update but is however covered in section 1.7 of the guideline (care of babies with prolonged jaundice) which includes checking for conjugated hyperbilirubinaemia in prolonged jaundice. This update was limited to the best mode and correct procedure of giving phototherapy (section 1.4 of the guideline).

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Natus Medical Inc	Addendum	12	23-26	There have been several studies comparing conventional phototherapy to LEDs. LED light sources have been proven to be effective. In addition to the articles listed below, the pure science of LEDs points to a narrow spectrum that can better target the peak absorption of bilirubin. Other studies we would like to see included are: • Vreman HJ, et al. Light-Emitting Diodes: A novel Light Source for Phototherapy. Pediatric Research 1998; 44:804-809. • Lund, et al. The Effect of Light-Emitting Diode Phototherapy on Transepidermal Water Loss (TEWL) in Premature and Term Infants. Journal of Perinatology 2004; 24: 579-580 (abstract • Maisels, et al. A Randomized Controlled Trial of Light Emitting Diode (LED) Phototherapy (PT) versus Special Blue Intensive Phototherapy. PAS poster, 2005.	Thank you for your comment. Based on the evidence included in this update, the Committee does not think there is sufficient evidence to suggest LED is superior to other types of phototherapy. Regarding the references you have provided, please see the Addendum appendix C, the review protocol. These 3 studies do not meet the inclusion criteria because: • Vreman et al. (1998) – this is an *in vitro* experiment. • Lund et al. (2004) – this is only a conference abstract, not a full peer-reviewed publication. • Maisels et al. (2005) – this is only a conference abstract, not a full peer-reviewed publication.
National Childbirth Trust	Addendum	13 27	23	We agree with NICE that "Parental experience/acceptability including access for bonding and breastfeeding" are critical outcomes; it is very disappointing that none of the studies included any reference to these outcomes or the perceived	Thank you for your comment. The committee agree with your suggestion for a research recommendation addressing parental and staff experience. Please refer to

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				experience of the baby. We would therefore suggest that research recommendations should include a recommendation to take parents experience and views into account in future research. None of the studies relate to phototherapy which enable parents to continue to cuddle babies skin-to-skin and feed their baby during the therapy. Given the greater awareness of the crucial importance to premature and term babies of close contact with their carers, we feel that therapy which enables this should be a priority and included in future research recommendations. Moore ER, Anderson GC, Bergman N, Dowswell T. Early skin-to-skin contact for mothers and their healthy newborn infants. Cochrane Database of Systematic Reviews 2012, Issue 5. Art. No.: CD003519. DOI: 10.1002/14651858.CD003519.pub3	section 1.3 of the addendum for further information on this.
Natus Medical Inc	Addendum	21	Table 2	The cost of the neoBLUE Phototherapy devices is inaccurate – correct LIST PRICE costings are: neoBLUE LED Phototherapy system – 2,300; neoBLUE cozy LED Phototherapy system 2,300; neoBLUE Blanket Phototherapy system 2,400; neoBLUE Mini Phototherapy system 1,450; neoBLUE Light panel replacement board 800. In addition, all neoBLUE phototherapy systems hold a 3 year warranty for International customers, adding to the cost effectiveness over lifespan. Finally, the LED panels in the neoBLUE systems are 40,000hours (excluding the	The prices you have provided now appear in the addendum. Detail regarding length of life has been moved to the linking evidence to recommendations table. The Linking Evidence to Recommendations table also contains the following sentence: Although the cost difference between modalities could not be established, topic experts advised the committee that LED devices cost less than

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				neoBLUE Blanket at 20,000hrs) as opposed to the 3000 hours stated in the guidelines. This demonstrates the most cost effective solution for phototherapy vs. conventional Fluorescent style lamps.	conventional phototherapy units based on their estimates of the cost of the initial purchase of devices, length of life, maintenance costs and electricity costs.
British Inherited Metabolic Disease Group	Addendum	24	4 (1.6-1.7)	We are concerned that 'routine metabolic screening' is non-specific and does not mention specific conditions or tests required. In particular we consider galactosaemia to be an important differential diagnosis of prolonged jaundice. Galactosaemia, although rare is an extremely treatable metabolic condition if diagnosed in a timely manner. Increasing awareness and diagnosis of this condition before it potentially results in liver failure or fatality may enable us to strengthen the case for newborn screening in the future. The gold standard investigation for galactosaemia is enzymology (GALIPUT level) which can be performed by specialist laboratories within 48 – 72 hours. We would also like to emphasize that although in general breastfeeding should be encouraged, if a metabolic disorder is suspected, milk feeds should be stopped and urgent advice sought from a specialist metabolic centre.	Thank you for your comment. We acknowledged the importance of diagnosis. However, this is outside the scope of this particular part of the update. This part of the update was limited to identifying the best mode and correct procedure of giving phototherapy (section 1.4 of the guideline)
Natus Medical Inc	Addendum	36	Section 2.2.3	In addition to the articles listed above, the pure science of LEDs points to a narrow spectrum that can better target the peak absorption of bilirubin than conventional phototherapy that does not have such a narrow band of	Thank you for your comment. Please see the Addendum appendix C, the review protocol. The purpose of the systematic review is to assess all

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				targeted light for peak absorption of bilirubin NICE have also neglected to include one of the most widely referenced, peer-reviewed publications on the subject, Subcommittee on Hyperbilirubinemia. American Academy of Pediatrics clinical practice guideline: Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. Pediatrics. 2004; 114(1):297-316. The guideline states: "All nurseries and services treating infants should have the necessary equipment to provide intensive phototherapy…" "Intensive phototherapy implies the use of high levels of irradiance in the 430–490 nm band (usually 30 μW/cm2/nm or higher) delivered to as much of the infant's surface area as possible." "The most effective light sources currently commercially available for phototherapy are those that use special blue fluorescent tubes or a specially designed light-emitting diode light (Natus Inc., San Carlos, CA)." "Blue-green spectrum is most effective. At these wavelengths, light penetrates skin well and	primary research RCT evidence on the effectiveness of phototherapy. The AAP guideline from America, which is mostly opinion-based, does not meet the inclusion criteria of this systematic review.

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				is absorbed maximally by bilirubin." 1 "When bilibrubin levels are extremely high and must be lowered as rapidly as possible, it is essential to expose as much of the infant's surface area to phototherapy as possible." We feel the NICE guidelines ignores this very important, peer-reviewed publication that states phototherapy should be used based on intensity, surface area and spectrum and we would like to see it included. The AAP Guideline also stated very clearly that LED phototherapy is The most effective light sources currently commercially available	
Natus Medical Inc	Addendum	37	13-14	We would ask you to consider adding in to this point that using an Intensive Light LED Blanket phototherapy during feeding will help to prevent interruption of intensive phototherapy for feeding/bonding purposes.	Thank you for your comment. However, the Committee cannot add this statement to the recommendation as it is not supported by evidence that meet the criteria of the review protocol. We have however added the point you raise about using an Intensive Light LED Blanket during feeding to prevent interruption of intensive phototherapy for feeding/bonding purposes to the linking evidence to recommendation

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					section of the guideline.
Royal College of Paediatrics and Child Health	Addendum	40		While we generally support the changes: Recommendation 1.4.10 and 1.4.11: We are concerned about the change in recommendation regarding the use of fibreoptic light for jaundice. Looking at the evidence presented in the forest plots at the end of the addendum we would still argue that the evidence still does not favour the use of fibreoptic light in term babies overall. Simply looking at the number of forest plots that show an average effect size that favours conventional phototherapy would support our concerns (let alone looking at term babies in isolation). If one then considers the value of some outcomes to be of greater importance, e.g. mean decrease in TSB or mean duration on PT, then it becomes very clear that fibreoptic PT bears a higher risk for prolonged treatment requirements, especially in term infants, potentially affecting length of stay. Finally the quality of the evidence is low - very low suggesting that any conclusions from this should be treated with caution. A change in national recommendation from my point of view sends out the	Thank you for your comment. From the evidence on conventional phototherapy compared to fiberoptic phototherapy for term babies (appendix I, forest plots), out of the 12 outcomes, 8 outcomes suggested no clinical or statistical significant difference between conventional phototherapy compared to fiberoptic phototherapy; 2 outcomes suggested conventional phototherapy was better (from one study [Sarici et al. 2001] with N=50), and 2 outcomes suggested on the other hand fiberoptic phototherapy was better (from one study [Pezzati et al. 2002] with N=21). With such inconsistent evidence on all the outcomes as a whole, with poor quality of the studies as well as small sample size of the studies, the Committee judged that there is insufficient evidence to specify which phototherapy is superior to the other.

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				wrong message providing false reassurance on weak grounds.	
Royal College of Surgeons of England	General	General	General	No comments	Thank you.
British society of Paediatric Gastroenterology Hepatology and Nutrition	General	General	General	The guidance pertains to Unconjugated hyperbilirubinaemia. Conjugated causes have not been discussed or listed in the table of causes of hyperbilirubinaemia We would suggest to change the title accordingly – conjugated causes should perhaps stay out and are beyond the scope of this article hence recommend to simply change the title	Thank you for your comment. The committee highlighted that the distinction between conjugated/unconjugated bilirubin is not usually made within the first 10 days of life. Longer term care is outside the scope of this particular part of the update but is however covered in section 1.7 of the guideline (care of babies with prolonged jaundice) which includes checking for conjugated hyperbilirubinaemia in prolonged jaundice. This update was limited to the best mode and correct procedure of giving phototherapy (section 1.4 of the guideline).
Department	general	general	gener	No comments	Thank you.

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of Health			al		
National Childbirth Trust	General	General	General	NCT appreciates the thoroughness of the review of the evidence.	Thank you.
National Childbirth Trust	General	10	20	I realise this may not be under current consideration but NCT remains concerned that references to breastfeeding – such as 'reassurance that breastfeeding can usually continue' is likely to reduce rather than enhance parents' confidence in breastfeeding. Since we live in a bottle feeding culture, both parents and health professionals have limited confidence in breastfeeding in general. We suggest that there is no need to mention jaundice in relation to breastfeeding antenatally and thereby avoid casting doubt in parents' minds. If parents themselves raise any questions about breastfeeding they can be reassured that breastfeeding can almost always continue.	Thank you for your comment. We acknowledged your concerns. Unfortunately, promoting breastfeeding and how to enhance confidence of parents are outside the scope of this particular update. This update was limited to identifying the best mode and correct procedure of giving phototherapy (section 1.4 of the guideline).
Royal College of Midwives	Short	20	General	Replaced with: 1.4.9 Use phototherapy to treat significant hyperbilirubinaemia (see the threshold table and the full guideline for treatment threshold graphs) in babies. **[new 2015]** We agree with the suggested changes to the recommendation here.	Thank you.
Royal	Short	20	Gener		Thank you.

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College of Midwives			al	Replaced with : 1.4.10 Consider intensified phototherapy to treat significant hyperbilirubinaemia in babies if any of the following apply **[new 2015]**: We agree with suggested changes to the recommendation here.	
Royal College of Midwives	Short	22	General	1.4.16 During phototherapy: • using clinical judgement, encourage short breaks (of up to 30 minutes) for breastfeeding, nappy changing and cuddles • continue lactation/feeding support • do not give additional fluids or feeds routinely. Maternal expressed milk is the additional feed of choice if available, and when additional feeds are indicated. **[2015]** We agree with the suggested changes to the wording here.	Thank you.
Natus Medical Inc	Short Version	11	16	We question why the use a transcutaneous bilirubin meter is recommended only in babies with a gestational age of 35 weeks or more and postnatal age of more than 24 hours. Please find attached an independent study utilising a new transcutaneous Bilirubin Meter	Thank you for your comment. The use of transcutaneous bilirubin meter is not the remit of the particular update. This update was limited to identifying the best mode and correct

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				(BiliCare™) in smaller gestational age infants. This device (and another device on the market) are both CE marked for infants as low as 24 weeks gestational age.	procedure of giving phototherapy (section 1.4 of the guideline).
Natus Medical Inc	Short Version	22	6	We would like you to consider adding in the fact that High Intensity LED Blanket Phototherapy could be used as an adjunct during feeding in the extremely jaundiced infant in order that treatment does not need to be stopped, in order to encourage oral hydration and nutrition and encourage the bonding process.	Thank you for your comment. However, the Committee cannot add this statement to the recommendation as it is not supported by evidence that meet the criteria of the review protocol.
Natus Medical Inc	Short Version	27	15	There is a 3rd Device available for Transcutaneous Bilirubin Monitoring in neonates in the UK. This device is BiliCare™. The comparative study of BiliCare vs TsB and JM103 is provided for you. We would ask to have this device included also on the guideline.	Thank you for your comment. The use of transcutaneous bilirubin meter is not the remit of the particular update. This update was limited to identifying the best mode and correct procedure of giving phototherapy (section 1.4 of the guideline).
Natus Medical Inc	Short Version	27	18	Comments as above – please also include BiliCare in this line.	Thank you for your comment. The use of transcutaneous bilirubin meter is not the remit of the particular update. This update was limited to identifying the best mode and correct procedure of giving phototherapy (section 1.4 of the guideline).