

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Neonatal jaundice – recognition and treatment of neonatal jaundice

Guideline Consultation Comments Table  
27 August – 22 October 2009

Type

SH = Registered Stakeholders.

PR = Peer Reviewers or Experts

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Breastfeeding Network	25.01	Full	1.1	25	<p>Line 27: Risk factor exclusive – breastfeeding this is not a risk factor. It is the care of the mother that is exclusively breastfeeding that could be a risk factor.</p> <p>She needs support in ensuring her milk is transferred to the baby and an understanding of this concept.</p>	<p>Thank you for your comment. The GDG agreed with your point about breastfeeding support, although babies who are breast fed do have higher mean bilirubin levels than those who are not and were over-represented in kernicterus cases even when there was no weight loss i.e. that the jaundice was not attributable to lack of breast milk. However we have emphasised the need to provide support and encouragement to breastfeeding mothers.</p>
SH	Breastfeeding Network	25.02	Full	1.2	35	<p>Line 16: There is an apparent contradiction between stating encouraging breastfeeding mothers to feed their babies frequently and wake them if necessary and then saying later on "stop phototherapy for up to 30 minutes every 3 to 4 hours to allow feeds", which seems remarkably restricted in terms of normal newborn breastfeeding patterns.</p> <p>Is there sufficient evidence to justify not allowing more frequent feeds during phototherapy, especially as in another place it says to ensure the baby remains well hydrated during phototherapy?</p>	<p>Thank you for your comment. The GDG agrees that some flexibility is possible and an amendment has been made to reflect this. Although the GDG would stress there is a need to <b>continue</b> phototherapy for it to be effective. An amendment to "use clinical judgement" has been added to the recommendation concerning breaks in phototherapy although the GDG were satisfied that 30 minutes was a reasonable compromise between the baby's treatment needs and the need to encourage and facilitate bonding between the baby and its</p>

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							parents. The recommendation now reads: "Using clinical judgement encourage breaks of up to 30 minutes for breastfeeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated"
SH	British Nuclear Medicine Society	15.01	Full	general	general	This specifically excludes any discussion of babies with prolonged jaundice/conjugated hyperbilirubinaemia so as this is the patient group into whom we would have input ie perform a radionuclide study our procedures are not mentioned. The guideline states that 'management of babies with conjugated hyperbilirubinaemia' falls into 'Areas outside the scope of this guideline'. I think that this is a pity because some guidance on appropriate use of the relevant nuclear medicine investigation ie HIDA scanning would have been nice.	Thank you for your comment. While conjugated hyperbilirubinaemia is outside the scope of this guideline we have touched briefly on prolonged jaundice. .
SH	Children's Liver Disease Foundation	8.01	Full	General	General	Children's Liver Disease Foundation (CLDF) welcomes this guideline and acknowledges its scope does not include the management of the infant with conjugated hyperbilirubinaemia. We further acknowledge that it is essential that the incidence of kernicterus is prevented, as far as possible.  Overall, we are disappointed that the authors have not taken the opportunity to re-inforce and inform professionals of the importance of detecting conjugated	Thank you for your comments. While conjugated hyperbilirubinaemia is outside the scope of this guideline, the GDG has tried to take the opportunities it was offered to draw attention to liver disease.  The GDG have considered all the comments from the CLDF carefully and have made amendments in response.  The GDG was not responsible for defining the scope and had to work within it. They were aware of the need to consider this

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						<p>hyperbilirubinaemia which is always pathological. It is estimated that the incidence of neonatal liver disease is 1 in 2,500 live births [Suchy, Sokol, Balistreri – Liver Disease in Children, pg 179]. Anecdotally CLDF has been informed of an unpublished paper that indicates an incidence of 1 in 1,500 live births in the UK).</p> <p>It is important to identify liver disease early in the neonate and refer appropriately as left untreated, there is significant morbidity and mortality. At best, children require liver transplantation in early childhood. Early recognition of liver disease also avoids serious complications such as intercranial haemorrhage secondary to coagulopathy from malabsorption of vitamin K. Specialist liver centres have treated children whose liver disease has resolved but are left with cerebral palsy and other disabilities as a result of intercranial haemorrhage which was entirely avoidable.</p> <p>Late identification is common [<b>Hussein M, Howard ER, Mieli-Vergani G, Mowat AP (1991) Jaundice at 14 days: exclude biliary atresia. Arch Dis Child 66:1177-9.</b> In many cases, this is caused by a lack of awareness by health care professionals and parents of the significance of prolonged jaundice i.e. beyond 14 days of life [<b>Mieli-Vergani G, Howard ER, Portman B, Mowat AP (1989). Late referral for biliary</b></p>	<p>aspect of jaundice as one of the GDG members is the mother of a child with a liver transplant.</p>

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						<p><b>atresia – missed opportunities for effective surgery. Lancet i:421-3]</b></p> <p>A recent paper [<b>Impact of age at Kasai operation on its results in late childhood and adolescence: A rational basis for biliary atresia screening Serinet et al, Pediatrics 2009;123;1280-1286</b>] concludes that increased age at surgery had a progressive and sustained deleterious effect on the results of the kasai operation until adolescence and the authors believe that the findings indicate a rational basis for biliary atresia screening to reduce the need for liver transplantation I infancy and childhood.</p> <p>Whilst biliary atresia is a significant condition to be diagnosed in the first few weeks of life there are other liver conditions for which early diagnosis is equally important including metabolic conditions such as alpha 1 antitrypsin deficiency and galactosaemia.</p> <p>This guideline has the opportunity to inform healthcare professionals about how to detect conjugated hyperbilirubinaemia and ensure that this important diagnosis is not overlooked without compromising the scope. But, in the eagerness to prevent kernicterus (which we acknowledge is important and preventable) we believe that the draft guideline, as it stands currently,</p>	

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						<p>will be detrimental to the detection of conjugated bilirubin in the neonate. This would be an enormous pity and a retrograde step. The Department of Health has had the foresight to set up an exemplary service for the management of paediatric liver disease in England and the British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN) has developed an excellent model of shared care and managed clinical networks, which is providing an excellent service to families and patients.</p> <p>CLDF has had representation at the scoping and implementation meetings and recognises that the authors would not wish this to be an outcome of publication of this guideline. We ask them to consider carefully stakeholder comments in relation to the detection of conjugated hyperbilirubinaemia, which are intended to be constructive.</p>	
SH	Children's Liver Disease Foundation	8.02	Full	1.1	25	<p>Line 8 – 17: CLDF suggests that parents / carers should be informed of prolonged jaundice and the action that should be taken in the event of prolonged jaundice and that pale stools and yellow urine (and that a baby's urine should be colourless) should be reported to the midwife / health visitor and / or GP.</p> <p>CLDF has a parent / carer leaflet which explains physiological jaundice and the</p>	Thank you for your comment. The GDG discussed this matter in the context of the limits of this guideline's scope. The GDG amended the recommendation for clarity to include urine colour examination

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						action to be taken in the event of prolonged jaundice (which is also defined). This is on CLDF's website and is the area which has the highest number of hits on the site. Our experience is that if this is delivered in the antenatal period parents feel empowered and informed in the event of their baby having jaundice, whatever the cause.	
SH	Children's Liver Disease Foundation	8.03	Full	1.1	25	Line 19: For clarity we suggest that the word "serum" is inserted between "record" and "bilirubin"	Thank you for your comment. The suggested amendment has been made.
SH	Children's Liver Disease Foundation	8.04	Full	1.1	25	Line 30/31: Delete term "chalky" and after "stools", insert and/or yellow urine, whatever the age for further investigation.....	Thank you for your comment. The GDG discussed this matter in the context of the limits of this guideline's scope. The GDG amended the recommendation for clarity to include urine colour examination
SH	Children's Liver Disease Foundation	8.05	Full	1.1	27	Line 7: The list is starting to suggest a differential diagnosis. If serum bilirubin is to be measured, we believe that a split bilirubin would be appropriate to add to the list.  Consider adding IV injection of vitamin K to avoid serious complications such as intercranial haemorrhage secondary to coagulopathy from malabsorption of vitamin K?	Thank you for your comment. The GDG did not consider that a split bilirubin test was necessary for all babies requiring phototherapy. Moreover, there would be large resource implications associated with this investigation, to identify the very few babies with conjugated bilirubin results. Babies who have moderate levels (of conjugated bilirubin) and receive phototherapy will not have IV access for vitamin K injections.
SH	Children's Liver Disease Foundation	8.06	Full	1.1	27	Lines 21-25: Include <ul style="list-style-type: none"> <li>Examination of urine colour</li> </ul> CLDF believes that this should be done earlier and if pale stools and / or yellow urine are seen at whatever age that the	Thank you for your comment. The GDG discussed this matter in the context of the limits of this guideline's scope. The GDG amended the recommendation for clarity to include urine colour examination

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						infant should have a split bilirubin blood test.	
SH	Children's Liver Disease Foundation	8.07	Full	1.1	32	Lines 16/17: Delete term "chalky" and after "stools", insert and/or yellow urine, whatever the age for further investigation.....	Thank you for your comment. The GDG decided that the term "chalky" was appropriately used but the text was amended for clarity to include urine colour examination
SH	Children's Liver Disease Foundation	8.08	Full	1.1	32	Line 34: The list is starting to suggest a differential diagnosis. If serum bilirubin is to be measured, we believe that a split bilirubin would be appropriate to add to the list.  Consider adding IV injection of vitamin K to avoid serious complications such as intercranial haemorrhage secondary to coagulopathy from malabsorption of vitamin K?	Thank you for your comment. The GDG did not consider that that a split bilirubin test was necessary for all babies requiring phototherapy. Moreover, there would be large resource implications associated with this investigation, to identify the very few babies with conjugated bilirubin results. Babies who have moderate levels (of conjugated bilirubin) and receive phototherapy will not have IV access for more vitamin K. After discussion the GDG decided to leave the recommendation for a split bilirubin for the investigation of prolonged jaundice
SH	Children's Liver Disease Foundation	8.09	Full	1.1	33	Line 19: Add • Examination of urine colour	Thank you for your comment. The GDG decided to amend the recommendation for clarity and include urine colour examination
SH	Children's Liver Disease Foundation	8.10	Full	1.1	40	Line 11: CLDF suggests that parents / carers should be informed of prolonged jaundice and the action that should be taken in the event of prolonged jaundice and that pale stools and yellow urine (and that a baby's urine should be colourless) should be reported to the midwife / health visitor and / or GP.  CLDF has a parent / carer leaflet which	Thank you for your comment. The GDG made an amendment to the text for clarity to include urine colour examination see other comments on the same topic

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						<p>explains physiological jaundice and the action to be taken in the event of prolonged jaundice (which is also defined). This is on CLDF's website and is the area which has the highest number of hits on the site. Our experience is that if this is delivered in the antenatal period parents feel empowered and informed in the event of their baby having jaundice, whatever the cause.</p> <p>We are pleased to note literature should be used to back up verbal discussion, not a substitute.</p>	
SH	Children's Liver Disease Foundation	8.11	Full	2.1	42	<p>Lines 2-8: CLDF suggests that the sentence: However, there are pathological causes of jaundice in the newborn, which although rare, need to be detected. Such pathological jaundice may co-exist with physiological jaundice.</p>	Thank you for your comment, The text has been amended as suggested
SH	Children's Liver Disease Foundation	8.12	Full	2.1	43	<p>Line 13: Suggest reads Condition needs specialist investigation and early surgical treatment, preferably before 8 weeks of life.</p>	Thank you for your comment. The text has been amended as suggested
SH	Children's Liver Disease Foundation	8.13	Full	5		<p>Line 27: The authors raise an important point about the difficulty of recognition of jaundice. This also occurs in jaundice caused by liver disease.</p> <p>It would be helpful to include the following: In jaundice caused by liver disease the level of total bilirubin is variable and sometimes the baby may not be obviously jaundiced yet it might have a serious, lethal disease.</p>	Thank you for your comment The GDG considered your suggestion and although it is beyond the scope of this guideline, amendments were made to the text to clarify.

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						The degree of jaundice does not correlate to the severity of the liver disease.	
SH	Children's Liver Disease Foundation	8.14	Full	5	108	<p>Line 10/11: CLDF is concerned with this statement. It could be misleading.</p> <p>In jaundice caused by liver disease the level of total bilirubin is variable and sometimes the baby may not be obviously jaundiced yet it might have a serious, lethal disease. The degree of jaundice does not correlate to the severity of the liver disease.</p> <p>There is a need to encourage professionals to consider liver disease as a possible cause, albeit rare, as part of clinical assessment at every stage. A confusing factor is that often these babies seem entirely well and are feeding well, although if a feeding history is taken it can sometimes show that the baby is feeding excessively in order to compensate for its inability to absorb the nutrients from its food because of cholestasis (poor bile flow)</p>	Thank you for your comment The GDG considered your suggestion and although it is beyond the scope of this guideline, an amendment was made for clarity.
SH	Children's Liver Disease Foundation	8.15	Full	5	110	<p>Line 16: An abstract which has been submitted to RCPCH meeting in April 2010 provides useful information on the topic of stool colour (CLDF has been given permission to include this abstract in this submission):</p> <p><b>Can a widely used stool pigment chart be used to triage patients for investigation of neonatal jaundice?</b></p>	Thank you for your comment. The GDG discussed this matter in the context of the limits of this guideline's scope. Although the paper suggested is an abstract and not published work (and as such does not meet the inclusion criteria for studies in this guideline), the text was amended for clarity to include urine colour examination

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						<p>A Baker, G Serra-Feliu, M Akindolie, B Vadamalayan, C Arkley, M Samyn, A Sutcliffe.</p> <p>National liver centres receive many referrals of infants with neonatal jaundice. Those with more severe cholestasis are at greater risk of having biliary atresia, benefitting from early surgery. While information on stool pigmentation is sought at referral, our experience is that it is not always correct. Following first referral we therefore sent a covering letter with a stool pigment chart supplied by the Children's Liver Disease Foundation (CLDF) by first class post to the home or hospital where the child was resident and followed it up 1-2 days later by up to 4 telephone calls to record the colour of the stools assigned when they were compared to the chart. An admission date was assigned based on the referral information but if the stool colour proved to be pale on telephone inquiry a new date was assigned.</p> <p>123 infants who were referred had charts sent. At referral 30 were stated to have pale stools, 66 pigmented stools and in 27 pigment was unrecorded/unknown. Overall mean time from referral to admission was 10.1 days, range 0-25. Eighty-three parents and professionals (67.5%) who received the chart could be contacted. 24 graded the stools as pale by the CLDF chart and 59 as pigmented. In 8 cases (9.6%) stools graded</p>	

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						<p>pale at original referral were actually pigmented, while in 10 cases (12%) a 'normal' graded stool was reassessed as pale. These 10 proved to have non-specific neonatal hepatitis 4, (1 with intrahepatic calcifications), inspissated bile syndrome 2, Biliary atresia, alpha-1-antitrypsin deficiency, hypopituitarism, shock liver 1 each. As a result of re-assessment, in 8 patients the admission date was considered early enough or the patient was too sick to travel earlier, but 16 patients were brought in a mean of 6.1 days earlier (range 1-23) with the case of BA brought in 7 days earlier.</p> <p>Referrals stating stool colour had only 67% sensitivity for pale stools. Use of a posted stool colour chart followed up by telephone calls can allow prioritisation of patients with pale stools to optimise treatment timelines and allow effective use of resources.</p> <p>We are pleased that the GDG refer to stool colour but wish to give a note of caution and are concerned that the GDG over emphasise the importance of pale stools as an indicator of liver disease. Stool colour can be variable and over-emphasis may be misleading.</p> <p>The GDG only focus on pale stools and do not refer to yellow urine. A neonate is unable to concentrate urine and thus it should be colourless. Persistently yellow</p>	

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						urine which stains the nappy indicates the presence of bilirubin and thus liver disease which needs investigation.	
SH	Children's Liver Disease Foundation	8.16	Full	5	129	Line 22: Delete term "chalky" and after "stools", insert and/or yellow urine, whatever the age for further investigation.....	Thank you for your comment. The GDG decided that the term "chalky" was appropriately used but the recommendation was amended for clarity to include urine colour examination
SH	Children's Liver Disease Foundation	8.17	Full	6	141	<p>Lines 1-2: The list is starting to suggest a differential diagnosis. If serum bilirubin is to be measured, we believe that a split bilirubin would be appropriate to add to the list.</p> <p>Consider adding IV injection of vitamin K to avoid serious complications such as intercranial haemorrhage secondary to coagulopathy from malabsorption of vitamin K?</p>	Thank you for your comment. The GDG did not consider that that a split bilirubin test was necessary for all babies requiring phototherapy. Moreover, there would be large resource implications associated with this investigation, to identify the very few babies with conjugated bilirubin results. Babies who have moderate levels (of conjugated bilirubin) and receive phototherapy will not have IV access for more vitamin K. After discussion the GDG decided to leave the recommendation for a split bilirubin for the investigation of prolonged jaundice
SH	Children's Liver Disease Foundation	8.18	Full	6	146	Line 33: Include Examination of urine colour	Thank you for your comment. The recommendation has been amended for clarity to include urine colour examination
SH	Children's Liver Disease Foundation	8.19	Full	8	215	<p>Line 20: We entirely endorse this paragraph and would be pleased to update CLDF's baby jaundice literature in light of publication of this guideline.</p> <p>CLDF has considerable experience in providing information in various forms to parents about jaundice. Many report that they have not been informed about jaundice</p>	Thank you for your comment.

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						and are concerned. The popular misconception is that jaundice is an illness in itself. Our experience is that parents are reassured after being given an explanation and empowered to seek further investigation in the event of prolonged jaundice. Since the launch of CLDF's "Yellow Alert" programme in 1994 CLDF has only ever received one complaint from a member of the public about it "scaring parents" and this was from a grandparent. Our experience is contrary to the study in that parents are not distressed about their baby having a blood test once they are informed as to why it is needed.	
SH	Children's Liver Disease Foundation	8.20	Full	8	215	<p>Line 33: We apologise for repetition, but for completeness:</p> <p>CLDF suggests that parents / carers should be informed of prolonged jaundice and the action that should be taken in the event of prolonged jaundice and that pale stools and yellow urine (and that a baby's urine should be colourless) should be reported to the midwife / health visitor and / or GP.</p> <p>CLDF has a parent / carer leaflet which explains physiological jaundice and the action to be taken in the event of prolonged jaundice (which is also defined). This is on CLDF's website and is the area which has the highest number of hits on the site. Our experience is that if this is delivered in the antenatal period parents feel empowered</p>	Thank you for your comment. The GDG discussed this matter in the context of the limits of this guideline's scope. The GDG amended the recommendation for clarity to include urine colour examination

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						and informed in the event of their baby having jaundice, whatever the cause.	
SH	Countess of Chester Hospital NHS Foundation Trust	12.01	Full	Glossary	7	Opisthotonus and retrocollis -- definitions are interchanged	Thank you for your comment. This error has now been amended.
SH	Countess of Chester Hospital NHS Foundation Trust	12.02	Full	1.1	29	Line 9: "use phototherapy at lower levels" – what are these lower levels? Not mentioned what it means. Phototherapy thresholds for babies less than 72 hours should be defined.	Thank you for your comment. This information will be provided in graphs, in appendix F
SH	Countess of Chester Hospital NHS Foundation Trust	12.03	Full	1.1	28	It would be useful to have graphs in the guideline rather than just tables of age v thresholds for treatment.	Thank you for your comment. Graphs have been provided in an appendix F of the full guideline.
SH	Department of Health	21.01	NICE	General		Could you please consider the use of two separate flowcharts, so that it can be made clear which type of baby (and care) is being suggested.	Thank you for your comment. The algorithm from the QRG version of the guideline will be used in the full guideline.
SH	Department of Health	21.02	NICE	General		We feel that there is some inconsistency of language relating to 'urgent medical advice' and 'medical review' of jaundiced babies.  The reference to pre-term babies underneath table 1 (second bullet point) does not appear to define 'lower' bilirubin in pre-term babies.	Thank you for your comment. We have clarified to say 'urgent medical review' (with 2 hours) which is quite specific to babies with visible jaundice in the first 24 hours of life, and also "urgent medical review (as soon as possible and with 6 hours)" for babies older than 24 hours who have jaundice and in whom we need to exclude pathological causes.  The formula to generate this data is now reported in the text above the table and the data is represented on the graphs and in the MS Excel spreadsheets
SH	Department of Health	21.03	NICE	1.3.2		Could you please clarify whether this refers to a term or pre-term baby.	Thank you for your comment. An amendment has been added to the text to clarify.

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SH	Department of Health	21.04	NICE	1.3.4		You are no doubt aware that some babies are born at home, and so are not discharged from hospital.	Thank you for your comment An amendment has been made to reflect this.
SH	Department of Health	21.05	NICE	1.3.9		Could you please clarify the meaning of "pre-discharge". As previously stated, some babies are born at home.	Thank you for your comment. An amendment has been made to clarify this
SH	Department of Health	21.06	NICE	1.4.1		This states "assess all newborn babies especially in the first 72 hours at every opportunity". Could you please clarify who would be responsible for this.	Thank you for your comment. The recommendation has been amended to clarify that "parents, carers or health professionals can carry out assessment"
SH	Department of Health	21.07	NICE	1.4.2		Advising the use of bilirubinometers (in over 24 hours & bilirubin under 250) & to use serum bilirubin if bilirubinometers are not available. We are concerned at the implication that we should use bilirubinometers & blood is second best. However, at around \$5000 (plus consumables) the cost of this could be sizeable, unless bilirubinometers were to be restricted to in-patient units, which we feel would miss many jaundiced babies.	Thank you for this comment and your concern is reasonable. We are aware that this recommendation has a potentially high cost impact. An economic evaluation addressed the cost-effectiveness of this recommendation and gives thresholds when such a strategy might be cost-effective. Whilst the evidence of effectiveness of the recommendation is an unknown there are good clinical reasons to expect the recommendation to improve detection and thereby reduce cases of kernicterus. Furthermore, research to establish the effectiveness of the strategy would be difficult given the very small number of cases. Kernicterus itself carries high costs and some of the initial investment in bilirubinometers could be offset to some extent by a reduction in kernicterus cases. The model essentially concludes that the recommendation would not have to avert many cases of kernicterus cases to be considered cost-effective. However, it also acknowledges that cost-effectiveness will also be determined by the

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							number of bilirubinometers that are required to deliver this strategy
SH	Department of Health	21.08	NICE	1.4.5		With reference to 'discharge', could you please clarify whether this means 'discharged from the care of the maternity or neonatal service'.	Thank you for your comment. Service delivery is beyond the scope of this guideline.
SH	Department of Health	21.09	NICE	1.5.3		Could you please clarify whether this refers to all babies.	Thank you for your comment. An amendment has been made to clarify this
SH	Department of Health	21.10	NICE	1.6.1		(First bullet point): could you please consider replacing the word "alternatives" with "options".	Thank you for your comment. We have taken out this bullet point as not all parents would need information on treatment options only those whose babies need treatment
SH	Department of Health	21.11	NICE	1.6.2		Could you please confirm whether NICE intend to develop leaflets for parents.	Thank you for your comment. The GDG have developed a patient information leaflet that we anticipate will be incorporated into the Understanding Nice Guidelines version of the guideline.
SH	Department of Health	21.12	NICE	1.6.2		(Sixth bullet point): Could you please consider replacing the word "allowed" with "possible".	Thank you for your comment. The wording of this recommendation has been to changed to "reassurance that short breaks for feeding, nappy changing and cuddles will be supported as long as the bilirubin levels are not significantly elevated"
SH	Department of Health	21.13	NICE	1.6.2		(Seventh bullet point): Could you please consider replacing the word "should" with "might".	Thank you for your comment. An amendment has been made as suggested
SH	Department of Health	21.14	NICE	1.6.3, 1.6.4, 1.6.5, 1.6.6 & 1.6.7		Could you please clarify whether this also applies to pre-term babies.	Thank you for your comment. This has been clarified in the recommendations
SH	Department of Health	21.15	NICE	1.6.12		Could you please clarify why 'expressed'	Thank you for your comment. This is the only

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				& 1.6.13		breast milk is cited.	way of assessing fluid intake in breast fed babies when there is concern about dehydration – and the only way to give breast milk when baby is under continuous phototherapy
SH	Department of Health	21.16	NICE	1.6.19		Could you please clarify whether this applies to term or pre-term babies.	Thank you for your comment. This has been amended to clarify in the recommendation
SH	Department of Health	21.17	NICE	1.6.28		Could you please confirm whether there is any advice for clinicians, if the parents are Jehovah's witnesses.	Thank you for your comment. The GDG did not think it appropriate to make a recommendation for this situation as most hospitals have a local policy on this.
SH	Department of Health	21.18	NICE	4.2		(Prediction): regarding the reference to 'pre-discharge', you are no doubt aware that some babies are born at home.	Thank you for your comment. This has been removed from the recommendations
SH	Draeger Medical	20.01	Full	General	General	The JM-102 used in a number of the studies has now been discontinued, and replaced by the Draeger JM-103	Thank you for your comment. This has been noted in the guideline.
SH	Draeger Medical	20.02	Full	General	General	Will there be discussion as to whom and where transcutaneous measurements should be taken. In countries such as Canada, all babies are screen before discharge, and followed up by the community midwives. Should screening been done in the NICU, L&D, maternity ward or community. (Canadian article attached)	Thank you for your comment. It is beyond the remit of this guideline to specify the healthcare professional who would be responsible for this but we anticipate that it will be midwives and community health visitors. The GDG have extended the recommendation to include preterm babies
SH	Draeger Medical	20.03	Full	General	General	I have attached clinical papers on TC and ethnicity, TC in preterm babies. I also hope to have a clinical report on TC after Phototherapy, in the next few weeks which I will forward on	Thank you for your comment. These papers were examined but did not meet the inclusion criteria for the guideline.
SH	Imperial College Healthcare NHS Trust	23.01	Full	General	General	We support the recommendations that focus on the detection of jaundice within 24 hours of birth, the identification of risk	Thank you for your comment.

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						factors for hyperbilirubinaemia and the need for informed surveillance for jaundice in hospital and the community.	
SH	Imperial College Healthcare NHS Trust	23.02	Full	General	General	However the proposed bilirubin treatment threshold levels in the document and specifically in Table 1 (and Table 7.1) will result in significantly increased rates of intervention.	Thank you for your comment. The GDG accepts that there is variation of practice regarding thresholds and the impact of the recommendations on intervention rates is uncertain.
SH	Imperial College Healthcare NHS Trust	23.03	Full		28 Table 1 & 186 Table 7.1	<p>For well term babies with jaundice appearing after 24 hours of age, the treatment thresholds for phototherapy between 48 and 96 hours are below those used in current clinical practice in the UK. (Note page 174 line 1-3 and reference 167 and comment at order number 5).</p> <p>Using these thresholds would increase the rates of medical intervention (hospitalisation, length of stay, investigation and treatment costs) and could cause increased morbidity and family disruption.</p> <p>For jaundice that becomes apparent after 24 hours of age in well term babies we use a calculation to determine treatment threshold. (Gestational age X 10) – 100. This approximates to 300 micromol/l compared to 212 – 250 between 30 and 48 hours in Table 1 on page 28 (Table 7.1 page 186).</p> <p>Our treatment decisions are based on rate of rise of bilirubin at levels around the</p>	Thank you for your comment. The GDG discussed this point but made no amendment, They felt that the survey (Rennie JM, Seghal A, De A et al Range of UK practice regarding thresholds for phototherapy and exchange transfusion in neonatal hyperbilirubinaemia. <i>Archives of Disease in Childhood - Fetal and Neonatal Edition</i> 2009;94:F323-F327 shows most hospitals are using similar levels and to use a formula at 24 h does not fit with the Bhutani evidence that the levels are rising for 108 hours

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						threshold determined by the formula, risk factors for hyperbilirubinaemia, clinical condition or the presence of haemolysis.	
SH	Imperial College Healthcare NHS Trust	23.04	Full		28 Table 1 & 186 Table 7.1	The column heading for Exchange Transfusion in the table should read " <b>Consider</b> Exchange Transfusion" to be consistent with the recommendation on Page 30 Line 19.	Thank you for your comment. This was discussed extensively by the GDG and they decided that the current heading is an accurate reflection of the advice given in the guideline.
SH	Imperial College Healthcare NHS Trust	23.05	Full		174	Line 1-3: The current clinical practice in the UK is to initiate phototherapy in term babies at a bilirubin level of 340-350 mmol/l.  See Order Number 3	Thank you for your comment. The GDG agreed that this is the current median UK threshold for initiation of bilirubin
SH	Imperial College Healthcare NHS Trust	23.06	Full		182	Line 34: What treatment alternatives should be considered?	Thank you for your comment. This phrase has been removed.
SH	Imperial College Healthcare NHS Trust	23.07	Appendix B		4	Line 30: We do not agree that the GDG has set a relatively high bilirubin threshold as a basis for treatment.	Thank you for your comment. We accept that there is variation in practice and the text has been amended accordingly.
SH	Imperial College Healthcare NHS Trust	23.08	Appendix B		15	Line 30-33: We do not share the GDG's belief that improved monitoring will result in lower interventions because the thresholds recommended are lower than used in current practice in the UK.	Thank you for your comment. The recommended thresholds are largely in line with those currently used in the UK (Rennie JM, Seghal A, De A et al Range of UK practice regarding thresholds for phototherapy and exchange transfusion in neonatal hyperbilirubinaemia. <i>Archives of Disease in Childhood - Fetal and Neonatal Edition</i> 2009;94:F323-F327) However, we have amended the text to reflect that the effect of improved monitoring on intervention

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							rates is uncertain
SH	Imperial College Healthcare NHS Trust	23.09	Appendix B		16	Line 1-5: We do not agree that our current practice or that of other neonatologists in the UK is to use phototherapy indiscriminately without measuring bilirubin.  It follows therefore that no babies in our practice will avoid phototherapy by more intensive monitoring and the use of the suggested thresholds for intervention.	Thank you for your comment. We have amended the text to reflect variation in current practice and that the impact of more intensive monitoring on phototherapy is uncertain.
SH	Imperial College Healthcare NHS Trust	23.10	Full		28 Table 1 & 186 Table 7.1	Suggested alternative table. <b>(see attached file)</b>	Thank you for your comment. The GDG noted that levels in this table were broadly consistent with those presented in Table 1.
SH	Kings College Hospital NHS Foundation Trust	30.01	Full	6.8	145	Re: Investiagtion of prolonged jaundice, I would recommend adding in Ultrasound of the liver to all cases of prolonged conjugated hyperbilirubinaema to investigate structural causes. Referral to a specialist centre is then appropriate for consideration of liver biopsy and ERCP in cases of obstructive jaundice. HIDA scanning is useful as a follow up for surgically treated biliary atresia but may also be useful in differentiating biliary atresia from neonatal hepatitis in selected cases, although rarely necessary.	Thank you for your comment. The GDG discussed your suggestion but decided no amendment was necessary.
SH	La Leche League GB	13.01	Full	Acknowledgements	5	List of Stakeholders not present at time of consultation which has stopped collaboration between those with similar interests/areas of expertise	Thank you for your comment. The list of stakeholders has been added to the full guideline as suggested

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SH	La Leche League GB	13.02	Full	General		The numbering of the condensed form and the full guidelines is different which has made pulling together comments on both cumbersome and time consuming	Thank you for your comment which is noted.
SH	La Leche League GB	13.03	Full	General	7	The Glossary includes the term declaration of interest yet none is recorded anywhere in the guidelines. The inclusion of exclusive breastfeeding as a perceived risk factor for a serious disabling/fatal condition and calling for further research on this means that a declaration of any contributors' interest in the formula industry, namely having ever received any funding personally or by their department for education or research from that industry, is appropriate.	Thank you for your comment. The contributors' declarations of interest will be added to the full guideline as per the NICE Guidelines Manual 2009.
SH	La Leche League GB	13.04	Full	1.2	29	(unclear why also labelled as chapter 3 here ? typing error )  Ensuring adequate information and support is offered to all women especially those intending to breastfeed exclusively is an admirable intention. However, it needs to be supplemented with the phrase "accurate information" as the lack of this is what can lead to low milk yield and higher than physiologically normal bilirubin levels as it is not excreted quickly enough. La Leche League is delighted by the now almost universal appreciation of the many benefits of breastfeeding amongst the various health professions. However, the knowledge and skills needed to support and educate mothers in how to breastfeed exclusively are still in very short supply relative to the	Thank you for your comment. Recommendations regarding service provision are outside the scope of this guideline,

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						<p>need for them. Given current levels of knowledge about how to build up a full milk supply to flush out bilirubin coupled with the contraction of the midwifery and health visitor services , ie far fewer visits, this part of the guideline is unimplementable. Whilst visits that are provided can give some degree of emotional support the early discharge of mothers from hospital so that they immediately go back to caring for their families cooking cleaning and looking after other children far too soon gives very little prospect of establishing exclusive breastfeeding with an adequate milk supply. The physical support of home helps while the mother establishes her milk supply are the responsibility of social services and sadly outside the power of the NHS staff to whom these guidelines apply. With regards to the skills gap needing to be plugged to allow for NHS staff to support with accurate information, training can be provided by La Leche League, Unicef and members of the Lactation Consultant profession who are already frequently employed by NHS Trusts</p>	
SH	La Leche League GB	13.05	Full	1.2	32	<p>Repeat comment 4 above re skills gap Training is needed so that a mother can be given information about how to rouse a sleepy baby to feed more frequently including vigilance for REM, relying on cue rather than demand which may never come in a jaundiced or any sleepy baby eg after anaesthetic given in labour or on warm brightly lit wards. Training of ward staff to</p>	<p>Thank you for your comment. The GDG agreed wholly about breast feeding and have used every opportunity to mention it, however further recommendations are beyond the scope of this guideline .</p>

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						<p>encourage rather than discourage a baby who is sleeping too long between feeds to be fed whilst asleep or roused from sleeping is needed urgently to prevent non physiological starvation jaundice developing in exclusively breastfed babies.</p> <p>With regards to the baby who is diagnosed as jaundice and as the guidelines say, to be encouraged to feed frequently with waking however we recommend as follows-</p> <p>Since promotion of breastfeeding is such a high priority for the NHS there should be better protection and support for breastfeeding once treatment for jaundice is prescribed. This should be in the form of lactation support with as little separation as possible between mother and baby, using rooming in. Breast pumps and skilled help with and training together with information about expression technique should be provided as standard for the mother of a breastfed baby who is undergoing treatment for jaundice by the paediatric department providing the treatment because of the high risk of damage to her milk supply by the potential separation. This should be the clear responsibility of the paediatrician supervising the treatment who may chose to draw on the support of other health professionals for help with avoiding damage to lactation but as the physician responsible he/she needs to minimise the well established risks to damaging lactation, and therefore the babies' health overall, that</p>	

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						treatment for jaundice carries. This will reduce the risk of intervention with bottles and artificial milk substitutes.	
SH	La Leche League GB	13.06	Full	1.2	33	<p>(Chapter 7) Line 33 Treatment alternatives should be offered which are compatible with breastfeeding in a way that will allow a full milk supply to be established and continued rather than just a token reduced supply. The implications of the various treatment options and their likely impact on breastfeeding should be explained to encourage parents of breastfed babies to access treatment early enough to be treated effectively. Although La Leche League as a matter of policy encourages an open and honest relationship between parents and the health professionals responsible for their babies' health there is a general difficulty with suspicion of treatment of jaundice because of its notoriety for damaging breastfeeding. Thi appears to be largely avoidable given the existence of bili lights that can be placed over a mother and baby together and are sold all over the world where paediatricians recognise the value of keeping a mother and baby together during treatment. Pending the introduction of information regarding the importance of this to training of this profession in this country these lights do not seem to be in general use in the UK. However, their use would go a long way to improving take-up of phototherapy earlier by breastfeeding mothers and this is</p>	<p>We have reviewed the recommendations on the use of fiberoptic phototherapy and modified the recommendation for preterm babies. The recommendations now say:</p> <p>“Do not use fiberoptic phototherapy alone as first-line treatment for hyperbilirubinaemia in term babies.</p> <p>Use either fiberoptic phototherapy alone or conventional phototherapy as first-line treatment for hyperbilirubinaemia in preterm babies.”</p> <p>As stated in the translation to recommendations section, the GDG's experience is that fiberoptic devices <b>are</b> more acceptable to parents for reasons including that parents can hold the baby. For clarity we have amended the translation to say “hold and feed the baby”, but the GDG did not believe further stipulation of this patent benefit of fiberoptic technology was necessary in the recommendations.</p> <p>We agree that maternal-child bonding is important and the GDG have already stipulated that research into phototherapy devices includes "bonding" as one of its effect estimates. However, we are unclear as</p>

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						<p>particularly important given the need for self diagnosis of jaundice by parents given the reduction in the health visiting and midwifery services.</p>	<p>to which particular device for joint treatment you are referring; joint phototherapy is not used in this country and although this equipment is described as being “sold all over the world”, neither the research fellow nor the GDG chair could find any literature about a device of this kind.</p> <p>We believe the stakeholder may have been referring to a type of extra large “biliblanket” that would be wrapped around both mother and child. The GDG felt it would be unhelpful to support a research recommendation about such a device because of its impracticality in terms of expense and size, as well as the fact that it would both expose the mother to unnecessary risk from the lights (in terms of for example melanoma), whilst simultaneously reducing the baby’s exposure to light( contrary to the recommendation made to maximally expose the baby’s skin).</p> <p>The GDG have clearly prioritised jaundice prediction, recognition and registry development over phototherapy treatment research. Nevertheless the GDG believe that their existing research recommendations would address clinically relevant knowledge gaps in phototherapy – including the effects of a larger “biliblanket” for larger term babies and exploitation of the new blue light LED technology in phototherapy devices.</p>

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SH	La Leche League GB	13.07	Full	1.2	34	As per comment 6 Token breastfeeding and physical contact with the baby will not ensure a full milk supply just as one swallow will not make a summer. However, the acknowledgement that contact with a baby and breastfeeding can usually continue and that this is valuable enough to put into the guidelines is welcome.	Thank you for your comment
SH	La Leche League GB	13.08	Full	1.2	34	Given fibre optic phototherapy's traditional compatibility with breastfeeding some explanation of why its use alone is not recommended would be welcome here.	Thank you for your comment, There was no evidence of effectiveness in term babies, probably because the pads are too small. The GDG do say more research on larger pads is needed to examine effectiveness of the technology in larger, term babies. If this were demonstrated then the benefit of "traditional compatibility" with breastfeeding could be extended to these babies as well.
SH	La Leche League GB	13.09	Full	1.2	34	Not using sunlight to treat hyperbilirubinaemia will be difficult to implement given that it is widely used by keeping the post natal wards brightly lit as much as possible with a view to preventing jaundice. Although these guidelines do not cover prevention of jaundice this may presumably be changed in the final version after consultation. In post natal wards where a strong lead is taken towards creating favourable conditions for establishing breastfeeding curtains which dim the daylight seem to be provided. These stop the babies from becoming too sleepy from being in bright light to feed frequently enough to establish a full milk supply quickly.	Thank you for your comment, The GDG recognise that there is a conflict with the desire to be baby friendly, using Developmental Care which calls for low lighting. The suggestion that keeping wards brightly lit might help jaundice would mitigate wholly against the developmental care philosophy and we did not find any evidence on this topic .  It is not common practice in the UK to treat with sunlight due to low ambient levels of light in the winter months, It is practice in Africa but this guideline is limited to UK practice

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						It is ironic that the very public health treatment prescribed first in the 1930s for so many ailments, ie plenty of sunlight and adopted wholeheartedly for the avoidance of jaundice on hospital post natal wards has done so much to frustrate breastfeeding. And indeed now that the benefits of breastfeeding are so much better understood and appreciated, insistence on exclusive breastfeeding by mothers on wards which are so brightly lit that milk supplies are kept low is making jaundice such a common problem that it is almost expected in the exclusively breastfed baby. This is a complex problem and it will be interesting to see whether the guideline not to treat with sunlight will impact on it.	
SH	La Leche League GB	13.10	Full	1.2	35	<p>The phrase "usual clinical practice" needs clarification.</p> <p>Its inclusion will inhibit the use of and further development of lights that allow feeding to continue whilst under the lights and deter health professionals from allowing this. This is because it is not <b>usual clinical practice</b> for the baby to be positioned with access to the breast at present although the existence of lights on the market make this perfectly possible.</p>	<p>Thank you for your comment. The phrase "usual clinical practice" has been removed in accordance with your comment and those of several other stakeholders. The phrase "in the supine position" has been added in its place because this is clearly established current practice which the GDG believes should be implemented during conventional phototherapy.</p> <p>We have reviewed the recommendations on the use of fiberoptic phototherapy and modified the recommendation for preterm babies. The recommendations now say:</p> <p>Do not use fiberoptic phototherapy alone as first-line treatment for hyperbilirubinaemia in</p>

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							<p>term babies.</p> <p>Use either fibreoptic phototherapy alone or conventional phototherapy as first-line treatment for hyperbilirubinaemia in preterm babies.</p> <p>As stated in the translation to recommendations section, the GDG's experience is that fibreoptic devices are more acceptable to parents for reasons including that parents can hold the baby. For clarity we have amended the translation to say "hold and feed the baby", but the GDG did not believe further stipulation of this patent benefit of fibreoptic technology was necessary in the recommendations.</p> <p>We agree that maternal-child bonding is important and the GDG have already stipulated that research into phototherapy devices includes "bonding" as one of its effect estimates. However, we are unclear as to which particular device for joint treatment you are referring; joint phototherapy is not used in this country and although this equipment is described as being "sold all over the world", neither the research fellow nor the GDG chair could find any literature about a device of this kind.</p> <p>We believe the stakeholder may have been referring to a type of extra large "biliblanket" that would be wrapped around both mother</p>

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							<p>and child. The GDG felt it would be unhelpful to support a research recommendation about such a device because of its impracticality in terms of expense and size, as well as the fact that it would both expose the mother to unnecessary risk from the lights (in terms of for example melanoma), whilst simultaneously reducing the baby's exposure to light( contrary to the recommendation made to maximally expose the baby's skin).</p> <p>The GDG have clearly prioritised jaundice prediction, recognition and registry development over phototherapy treatment research. Nevertheless the GDG believe that their existing research recommendations would address clinically relevant knowledge gaps in phototherapy – including the effects of a larger “biliblanket” for larger term babies and exploitation of the new blue light LED technology in phototherapy devices.</p>
SH	La Leche League GB	13.11	Full	1.2	35	At line 16-20 the words during conventional phototherapy should be supplemented with the phrase “where older equipment is still in use that cannot be used simultaneously with feeding or the mother is not able or willing to feed at the same time as the phototherapy is given” as this makes clear that it is not always necessary for treatment to prevent access to the breast and indeed where it does it should be seen as outdated.	Thank you for your comment. The GDG agree that there is a need to <b>continue</b> phototherapy for it to be effective. An amendment to “use clinical judgement” has been added to the recommendation concerning breaks in phototherapy although the GDG were satisfied that 30 minutes was a reasonable compromise between the baby's treatment needs and the need to

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						<p>We would recommend that with regard to the recommendation that phototherapy stop every 3-4 hours for up to 30 minutes that this should not be set in stone and the individual paediatrician's discretion should be brought into play with the 3-4 hours being seen as a minimum for the otherwise healthy term baby. Where the baby wakens to feed more frequently then the option of feeding then should be considered by the individual paediatrician supervising. As jaundiced babies are usually too sleepy to wake frequently enough to feed well the need to watch for rapid eye movement and offer a feed should be considered. We strongly recommend the 3-4 hours should not be set in stone.</p> <p>Re continuing lactation/feeding support the comments made above are repeated. We very much applaud the enthusiasm for breastfeeding held by so many staff working with babies in this area. We hope that further specialist training with the skills and knowledge needed to treat lactation problems in the same way that any other health problems can be treated medically will allow that enthusiasm to be harnessed more effectively and used to follow these guidelines.</p> <p>With regards to maintaining lactation during a break during treatment it is very much regretted that the "remedy" of temporary weaning from the breast and substituting with artificial formula has not been dealt</p>	<p>encourage and facilitate bonding between the baby and its parents.</p> <p>The recommendation now reads:  "Using clinical judgement encourage breaks of up to 30 minutes for breastfeeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated"</p> <p>The GDG did not consider any evidence concerning the practice of treating hyperbilirubinaemia using remedy formula because the only study identified by the search strategy at review stage did not meet the terms of our inclusion criteria because it had the wrong comparison group. Therefore the GDG cannot make recommendations on remedy formula use either way.</p> <p>We agree that avoiding nipple confusion is an important point but regret that the details of feeding methods are beyond the scope of this guideline on Jaundice</p>

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						<p>with more fully here, albeit touched on later in the guidelines. Because of the ability of artificial formula to accelerate the expulsion of bilirubin from the babies' bodes at an artificially fast rate the use of formula is a commonly recommended remedy for jaundice in breastfed babies. This is a very common first line in the treatment of jaundice in neonatals and should be given far more attention in these guideline than just being hinted at here as a restarting of breastfeeding after treatment. The restarting of breastfeeding does need expert help and the way in which formula has been given if by an artificial nipple or by cup or tube which are less likely to interfere with breastfeeding has a big impact on the ease with which this may be accomplished. Because the remedy of a short spell on artificial formula will have various side effects these should be explained to the mother when the recommendation is given. These include, nipple confusion in the baby making feeding ineffective and painful, sensitisation to one or more of the many ingredients in the formula because of the lesions made in the gut wall by the formula ( any substance other than breast milk will cause these lesions if given before about 6 months) which set up the risk of allergies when food leaks through them, engorgement and mastitis in the mother and constipation in the baby.</p> <p>With regard to maternal expressed milk</p>	

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						being the additional feed of choice this should be followed by donor milk treated by a milk bank. Because of the risk of allergy from formula and the difficulty in establishing what its ingredients are, ie the food source from which they are taken, glucose water should be considered for use also where appropriate.	
SH	La Leche League GB	13.12	Full	1.2	36	Re Maintaining a thermo-neutral environment. A temperature range here would be helpful. This also overlaps with the next line on encouraging interaction with their baby. This could be clarified to include wherever possible that this be physical interaction with the baby, ie touching the baby so that skin to contact can take place. Newborns cannot regulate their heart beat, breathing or temperature when they do not have close contact with their mothers. This has led to the high temperatures on antenatal wards in an attempt to replicate the treatment of adults for hypothermia. However, the newborn, separated from his mother physically drops his temperature assuming himself abandoned to save precious energy ready for when he may be found again. Babies in conventional phototherapy who cannot have contact with their mothers are at risk not only of poor milk supply and distress to their mothers but also damage to their heart valves caused by the stress from unconsolated crying as well as later risk of depression and other mental health risks from permanent brain damage	<p>Thank you for your comment. A definition of thermo-neutral environment has been added but as guidance on the ambient temperature would vary according to body size, the GDG considered this too complex to give here. Tables of incubator temperatures, etc are available to inform standard nursing care.</p> <p>The GDG do not know of any evidence suggesting that babies can damage their heart valves, suffer from later depression, or are at greater risk of brain damage from inconsolable crying/ cortisol overdoses.</p>

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						from an overdose of cortisol, the stress hormone. As a breastfeeding organisation we are aware of these medical consequences to the health of a baby of separation of mother and baby because separation impacts on breastfeeding. This is why they are quoted here to support the guideline encouraging interaction and extending it if possible to physical interaction including skin to skin contact.	
SH	La Leche League GB	13.13	Full	1.2	38	Ensuring that babies are kept hydrated during phototherapy should be supplemented with an explanation of how that hydration should be achieved. How to assess for dehydration needs to be included as this is a skilled job. Hydration should be achieved, ie fluids given, without the use of artificial nipples where possible if the baby is breastfed.	Thank you for your comment. We agree that avoiding nipple confusion is an important point but regret that the details of feeding methods are beyond the scope of this guideline on jaundice.”
SH	La Leche League GB	13.14	Full	1.2	39	The list of treatments which should not be given for hyperbilirubinaemia should contain some reference to the practice of treating with the remedy of formula feeding temporary or otherwise. This is a common and ongoing practice and as mentioned above should be addressed by the guidelines.	The GDG did not consider any evidence concerning the practice of treating hyperbilirubinaemia using remedy formula because the only study identified by the search strategy at review stage did not meet the terms of our inclusion criteria because it had the wrong comparison group. Therefore the GDG cannot make recommendations on remedy formula use either way.
SH	La Leche League GB	13.15	Full	1.3	40	Re the recommendation that studies be carried out on factors underlying the association between breastfeeding and jaundice. There is already a clear association between breastfeeding and	Thank you for your comment, The GDG is satisfied with the research recommendations they have made for further studies to examine how breastfeeding is associated with jaundice cannot address issues about

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						<p>jaundice. The newborn becomes jaundiced for physiological reasons after birth and the artificially early rate at which bilirubin is cleared from a baby fed formula should not be considered normal or desirable as is it not a physiological process. What is needed is a consensus as to what is a normal level of jaundice in newborns and what is abnormally high .A level of jaundice above what is normal in an adult is the physiological norm in a newborn. As stated above the issue is confused by difficulty in obtaining information for parents and environments hostile to breastfeeding (warm and bright) which make normal physiological jaundice so often added to by starvation jaundice from inadequate milk supply.</p> <p>It is interesting to note that at the implementation planning meeting for these guidelines reference was made to exclusively breastfed babies who were presenting with kernicterus yet clearly were not suffering from poor milk supply because they were not underweight. Reference was made to pages of the guidelines with this(these) study(ies) at the meeting but the writer has not found clear reference within them to the "good weight" exclusively breastfed babies that had been identified. The inference from this was that the breast milk which they were feeding on had caused the jaundice and therefore the kernicterus. However, it is the case as set</p>	<p>drug or alcohol consumption in parents within this guideline.</p>

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						<p>out in the guidelines that the causes of kernicterus are not always known. Therefore it seems inappropriate to assume that because the baby who suffered from kernicterus was exclusively breastfed that the condition was caused by the breastmilk. The same inference has been drawn in other areas of medicine notably dentistry where avid feeding has been blamed for tooth decay rather than seen as the normal reaction of a child to any form of illness whether a bacteria (breast milk is antibacterial and analgesic) causing tooth decay or an underlying health problem leading to kernicterus.</p> <p>There is a further problem with the breastfed baby in that they may be at risk of later access to treatment which might have prevented kernicterus as those responsible for the care of the baby, both parents and health professionals may see the jaundice as expected in breastfed baby and/or have concerns mentioned above regarding the impact of treatment on breastfeeding.</p> <p>As is made quite clear in the guidelines a delay in treatment is very serious and urgent consideration needs to be given to whether the exclusively breastfed baby is at risk of such a delay in treatment.</p> <p>Again, at the implementation meeting reference was made to a recent increase in kernicterus which in the past had virtually disappeared.</p> <p>As a breastfeeding organisation La Leche</p>	

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						<p>League has some interest in anaesthetic used in labour because it will cross the placenta and can cause breastfeeding difficulties .It is a matter of common knowledge that alcohol consumption among women of childbearing age is now much higher as is the use of recreational drugs such as cannabis which are widely perceived as harmless by the users. It is also a matter of common knowledge that the liver is the organ responsible for processing alcohol, recreational drugs, anaesthetic and presumable the unregulated pseudo-herbal remedies which seem to be growing in favour amongst pregnant women. These should be the subject of research to establish whether they are causing strain on the liver in the womb and during birth with consequent risk of jaundice and kernicterus rather than assuming an increase in breastfeeding is causing an increase in kernicterus.</p> <p>A breastfed baby with a liver problem may often, the writer understands from brief consultation with another stakeholder, be feeding avidly ie far more frequently than would be normal to try to clear the disease/disability induced excess bilirubin from the body.</p> <p>A major advantage of the widespread increase in knowledge about breastfeeding amongst all health professionals (as recommended above to enable support to be given to mothers) would be that an ability</p>	

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						to recognise what is normal and what is abnormal in feeding patterns would allow for an invaluable extra diagnostic tool to be available to spot illness. For example, the exclusively breastfed baby which is feeding avidly, ie almost constantly, gaining weight and is still jaundiced could very quickly be identified as at high risk of a liver problem needing urgent investigation. At the implementation meeting reference was made by one stakeholder to the theory that breastfeeding was not a "medical" matter/factor. This went unchallenged or disputed by his many fellow neonatologists present and demonstrates the high potential for increasing knowledge in this area to the benefit of the all concerned.	
SH	La Leche League GB	13.16	Full	2.9	51	Because the recommendation that mothers rightly be given support to maintain lactation has so many other cost benefits to the NHS including lower tooth decay, less childhood obesity, leukaemia, breast/womb/ovarian cancers, asthma, eczema, gastroenteritis, allergies, osteoporosis, diabetes, postnatal depression, rheumatoid arthritis and infections generally the cost savings in all these areas should be considered.	Thank you for your comment. It is not within the scope of this guideline to examine the cost-effectiveness of support to maintain lactation.  However, the fact that we make this recommendation implicitly shows that we assume this to be cost-effective
SH	La Leche League GB	13.17	Full	2.9	52	It is disputed that genuine alternatives to current practice do not exist. Better training of staff including those at clinical director level, and improvement of environment have been achieved throughout the world in hospitals particularly through the UNICEF Baby Friendly Initiative. As a result,	Thank you for your comment. Recommendations regarding service provision (including staff training) are outwith the scope of this guideline,

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						exclusively breastfed babies are at much lower risk of poor milk supply which makes jaundice expected in breastfed babies in most UK hospitals. Products exist, potential for training is there and sources of good quality educational materials including La Leche League could be brought into play in the NHS. Consequently there would be an elimination of unnaturally high levels of newborn jaundice in exclusively breastfed babies and an end to the expected side effect of damage to breastfeeding during phototherapy.	
SH	La Leche League GB	13.18	Full	2.11	53	It is a matter of regret that the section on stakeholder involvement is missing as this would have been a useful point of reference for drawing up these comments.	Thank you for your comment. The list of stakeholders has been added as an appendix to the full guideline as suggested
SH	La Leche League GB	13.19	Full	3	53	With regard to babies who are breastfed having higher bilirubin levels than those who are formula fed this is like saying that dogs with undocked tails have longer tails than those with docked tails. It is the formula fed babies who have lower levels of bilirubin than the breastfed babies and the reason is that the bilirubin binds with the protein in the formula in the gut and clears it from the body so that the levels drop quickly to something closer to adult levels. It is not appropriate to assume that a baby needs to be cured of normal features of being a baby such as a bilirubin level higher than that of an adult nor to imply that the early expulsion of bilirubin is desirable. Breastfeeding has been severely damaged by pseudo-medical	Thank you for your comment. An amendment has been made.

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						attempts to "cure" the baby of the normal features of babyhood such as feeding in the night, feeding more frequently than an adult, becoming distressed at separation from the mother, etc and the artificially rapid lowering of bilirubin levels to adult levels is part of this general approach to babies both in society and medically. It is unhelpful for breastfeeding and the phrase should be rewritten as formula artificially accelerating the expulsion of bilirubin.	
SH	La Leche League GB	13.20	Full	3.1	62	The desire of the GDG to avoid undermining breastfeeding is applauded. The members were and clearly are in a very difficult position seeing jaundice, which is potentially an indicator for the risk of kernicterus, occurring in breastfed babies. It is hoped very much that the comments above help in resolving these difficulties by shedding much needed light provided by La Leche League's expertise in the subject of breastfeeding.	Thank you for your comments.
SH	La Leche League GB	13.21	Full	3.1	63	As above re support for breastfeeding women.	Thank you for your comment.
SH	La Leche League GB	13.22	Full	3.2	65	Re Feeding method during nursery stay-it is noted that a nursery stay was part of the experience of the babies in the study. This usually involves infrequent feeding which is clearly associated with slower clearing of bilirubin.	Thank you for your comment. There was no specific information on feed frequency available to the GDG.
SH	La Leche League GB	13.23	Full	3.2	67	It is noted that risk factors for kernicterus are notoriously difficult to identify and as such exclusive breastfeeding whilst a risk for jaundice is not a clear risk for	Thank you for your comment, Data on risk factors for kernicterus are scarce given its' rarity. Some babies with kernicterus have no other "risk factor" as evident in ref 19

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						kernicterus.	(Manning D, Todd P, Maxwell M et al. Prospective surveillance study of severe hyperbilirubinaemia in the newborn in the UK and Ireland. Archives of Disease in Childhood Fetal and Neonatal Edition 2007; 92:(5)F342-F346)
SH	La Leche League GB	13.24	Full	3.2	68	An association between jaundice and breastfeeding is clearly established and does not justify further research. However, as stated above, whether breastfed babies are at risk of late access to treatment and whether they are or are not at higher risk of kernicterus needs to be investigated thoroughly. The fact that the international registers are not reported in the guidelines as supporting any higher risk of kernicterus in exclusively breastfed babies would one hopes suggest that there is not such higher risk of kernicterus in exclusively breastfed babies for any reason that can be blamed on the fact that they are ingesting breastmilk.	Thank you for your comment. The GDG agree that an association is clearly established however, the mechanism for this association has not been found. The GDG noted the La Leche League's point about the artificial "forcing down" of bilirubin in formula fed babies – if this is the explanation then research will show this. The international kernicterus registry in the US does mention over-representation of breast fed babies.
SH	National Childbirth Trust	27.01	Full	General		Would be helpful to have a brief explanation of the complex reactions which mean that a degree of jaundice is physiologically normal- as in the scope. There is no definition of jaundice in the glossary and hyperbilirubinaemia is only 'too much' bilirubin. However parents' understanding of jaundice may be related to the jaundice associated with serious liver or other disorders. It is important to explain that there may be benefits associated with a slight degree of jaundice in newborns, but it	Thank you for your comment. We have amended the introduction and glossary as suggested to reflect your concern.

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						is difficult to tell which babies are at risk of high levels that could become dangerous. The information conveyed to parents by health professionals is so influential, it must be put across in a way that is tailored to needs and should not cause unnecessary anxiety.	
SH	National Childbirth Trust	27.02	Full	Glossary	16	Add multiple phototherapy	Thank you for your comment. Definitions of conventional, multiple, fiberoptic and LED have been added to the glossary
SH	National Childbirth Trust	27.03	Full	1.1 and		backed up by written information, Add "which does not unnecessarily increase parental anxiety"	Thank you for your comment. An amendment has been made as suggested.
SH	National Childbirth Trust	27.04	Full	1.1 and 1.2	25	<p>mother's intention exclusively to breastfeed. It is our understanding that good practice epitomised by the UNICEF Baby Friendly Initiative Standards, entails not asking mothers what their feeding intentions are in general, as this allows mothers who are undecided and those who are considering formula feeding an open option to start breastfeeding if that is how they feel once the baby is born. This also applies to continuation of breastfeeding once started. It is therefore more appropriate to include all babies who are breastfed. In some of the research studies included babies who were mixed fed were also at risk.</p> <p>Suggest at least including an asterisk here which reminds readers that it is important never to reduce confidence in breastfeeding and this</p>	Thank you for your comment. The mother's intention to exclusively breastfeed would be established on point of discharge rather than prior to the birth of their baby.

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						is possibly due to: Poor milk transfer in a breastfeeding dyad and Delayed lactogenesis Which can be generally prevented by adequate breastfeeding support	
SH	National Childbirth Trust	27.05	Full		26 /31	(31: Line 18) at every opportunity. If there are concerns about other conditions and babies are seen frequently in hospital for instance, it is surely not expected or reasonable to undress a baby who is asleep to assess jaundice at every opportunity. Could be at every home visit but no more often than once a day, or twice a day in hospital?	Thank you for your comment, Whilst the GDG agree that generally babies do not need to be undressed more than once during a home visit or twice a day in hospital, they did not amend the recommendation as they felt it was important to stress that the baby should be checked when undressed.
SH	National Childbirth Trust	27.06	Full		30 /31	Line 32/Line 4: risk assessment including assessment of milk transfer for breastfed babies	Thank you for your comment, This assessment is without the scope of this guideline
SH	National Childbirth Trust	27.07	Full		32	Line 20: wake the baby for feeds if necessary. Any evidence to indicate how often babies should be woken for feeds? (day and night ?) or depending on degree of jaundice, whether resolving etc.? This should include information about how long to continue this pattern.	Thank you for your comment. The GDG believed that this issue was beyond the scope of this guideline,
SH	National Childbirth Trust	27.08	Full		34	Line 11: the fact that interruptions will be <i>allowed</i> for feeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated  This sort of language again emphasises the assumptions of power relationships.	Thank you for your comment. The recommendations have been reviewed and wording amended to reflect the perspective of the parent/carer throughout the guideline. The recommendation quoted by the stakeholder now reads:

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						<p>Parents should not be disempowered by treatments.</p> <p>Suggest replace <i>allowed</i> with <i>arranged</i> or more positively: the fact that parents will be enabled/supported to continue to care, feed, cuddle and change their baby's nappy. Similarly the word allowed should be replaced in relation to parents in other sections of the guidance.</p>	<p>“Using clinical judgement encourage breaks of up to 30 minutes for breastfeeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated”</p> <p>The following recommendation in the treatment section has also been amended to improve the tone.</p> <p>“Reassurance that short breaks for feeding, nappy changing and cuddles will be supported as long as the bilirubin levels are not significantly elevated”</p>
SH	National Childbirth Trust	27.09	Full		34	(after line 15) add ‘potential impact on breastfeeding and how to minimise this.’	Thank you for your comment. The text has been amended to reflect this,
SH	National Childbirth Trust	27.10	Full		35	<p>Line 15: During conventional phototherapy stop phototherapy for up to 30 minutes every 3 to 4 hours to allow feeds continue lactation/feeding support</p> <p>This recommendation is in contrast to evidence and good practice in relation to breastfeeding, including the Baby Friendly standards. It seems both to hark back to scheduled feeds, which have been shown to lead to earlier cessation of breastfeeding and not to be responsive to babies’ needs. It may be that babies will sleep longer at some points and need more frequent feeds at other points. Surely more flexibility is appropriate to met the fluid and psychological needs of babies and to ensure mother’s milk supply is not</p>	<p>Thank you for your comment. The GDG agrees that some flexibility is possible and an amendment has been made to reflect this. Although the GDG would stress there is a need to <b>continue</b> phototherapy for it to be effective. An amendment to “use clinical judgement” has been added to the recommendation concerning breaks in phototherapy although the GDG were satisfied that 30 minutes was a reasonable compromise between the baby’s treatment needs and the need to encourage and facilitate bonding between the baby and its parents.</p> <p>The recommendation now reads: “Using clinical judgement encourage breaks</p>

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						compromised. Mothers can be encouraged to express if it is thought that the baby is not feeding frequently enough.	of up to 30 minutes for breastfeeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated"
SH	National Childbirth Trust	27.11	Full		35	Line 19: NCT supports this statement	Thank you for your comment
SH	National Childbirth Trust	27.12	Full		40	Line 18: Including the detection of jaundice which may be considered physiologically normal and the impact that diagnosis and treatment of jaundice have on families, (see page	Thank you for your comment. Research recommendations given for phototherapy stipulate that bonding should be examined as a treatment effect .
SH	National Childbirth Trust	27.13	Full		42	Approximately 60% of term and 80% of preterm babies develop jaundice in the first week of life' Are these UK figures? As the research studies accessed indicate more of these are breastfed babies, presumably the incidence varies across the country? As there is some indication that a degree of hyperbilirubinaemia is physiologically normal, what is the definition of the jaundice referred to here?	Thank you for your comment. The research refers to clinical jaundice of any degree. ( <a href="http://www.patient.co.uk/doctor/Neonatal-Jaundice.htm">http://www.patient.co.uk/doctor/Neonatal-Jaundice.htm</a> ) The definition is visible jaundice. Visible jaundice is usually detected around 100 micromol/l in a pale skinned baby.
SH	National Childbirth Trust	27.14	Full		42	In most babies with jaundice there is no underlying disease, and this early jaundice (termed 'physiological jaundice') is generally harmless. This is essential information to convey to parents both verbally and in written materials.	Thank you for your comment, The GDG feel that they have emphasized that, as you say, most jaundice is harmless
SH	National Childbirth Trust	27.15	Full		42	"Breastfed babies are more likely than bottle-fed babies to develop physiological jaundice within the first week of life" This and the information further down in the	Thank you for your comment. The GDG are strongly in favour of continuing breastfeeding if phototherapy is required, and we have made this clear at every opportunity. .

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						<p>introduction are again crucial to maintaining parents' confidence and reducing anxiety. Eg 'At present it is not possible to differentiate the natural, physiological jaundice and potentially pathological jaundice without further tests. '</p> <p>We have heard from mothers who have been told to stop breastfeeding, or lost confidence in breastfeeding because their baby had jaundice. However frequent it is, this situation, and any further reduction of confidence in breastfeeding among parents and health professionals should be avoided in the guidance itself and the process of implementation.</p>	
SH	National Childbirth Trust	27.16	Full		46	<p>Suggest add Guidance to improve the nutrition of pregnant and breastfeeding mothers and children in low-income households As the recommendations on breastfeeding support within the first 48h are very relevant</p>	Thank you for your comment. The GDG were not in a position to define "low income" households in this guideline – the evidence did not discriminate groups of newborns in this way.
SH	National Childbirth Trust	27.17	Full		62	<p>the GDG did not want to give the message that breast milk feeding should be replaced by formula milk if a baby was being treated for jaundice As discussed above it is more subtle than the replacement of breastfeeding by formula; it is confidence in breastfeeding as the norm and responsive feeding of babies in the early days as humane care.</p>	Thank you for your comment. The GDG have used every opportunity to recommend continuing breast feeding.
SH	National Childbirth Trust	27.18	Full		160	<p>Research recommendations Since there seem to be no studies on the effect on families or bonding this should be</p>	Thank you for your comments. The research recommendations made for phototherapy now stipulate "bonding" as an outcome to be

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						included in the recommendations for future studies. Specifically what effect does diagnosis of jaundice have on families and the effects of different types of phototherapy on relationships, adjustment, attachment and bonding with the baby or continuation of breastfeeding. (if some types of treatment enable more responsive care and holding or longer breastfeeding for instance, there may be an impact which outweighs slightly lower effectiveness.	examined. .
SH	National Childbirth Trust	27.19	Full		165	Line 26: Similarly there seem to be no quality studies looking at parents' experience, anxiety levels, family relationships, parent/infant bonding and attachment or continuation of breastfeeding according to the type of phototherapy and whether it was instigated early. This is an important omission and should be added to the research recommendations. Nor are these aspects discussed under the side effects section.	Thank you for your comments. A research recommendation has been added.
SH	National Childbirth Trust	27.20	Full		167	Effect of different coloured lights on staff are mentioned and they will be exposed more frequently, but the views of parents should also be considered.	Thank you for your comment. An amendment to the text has been made as suggested.
SH	National Childbirth Trust	27.21	Full		170	Line 13-15: Interrupting phototherapy at low bilirubin levels is safe. The GDG supports brief interruption of phototherapy treatment to facilitate breastfeeding and cuddles. This may help to reduce anxiety and stress <i>insert for both parents and babies</i> caused by phototherapy.	Thank you for your comment. We have made an amendment to the GDG translation in the full guideline as suggested.  The recommendation on conventional phototherapy has also been revised as follows: "Using clinical judgement encourage breaks

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						This is likely to be a very important recommendation and should be included in information provided to parents.	of up to 30 minutes for breastfeeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated.”
SH	National Childbirth Trust	27.22	Full		179	Line 21: Conventional phototherapy should be interrupted to facilitate breastfeeding, and mothers should be offered lactation support. Again this is very important and not yet current practice in most hospitals.	Thank you for your comment The recommendation on conventional phototherapy has also been revised to include both the following instructions:  "Using clinical judgement encourage breaks (of up to 30 minutes) for breastfeeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated."  • continue lactation/feeding support
SH	National Childbirth Trust	27.23	Full		183	the fact that interruptions will be allowed this is language which implies the baby belongs to the medical staff , rather than the parents. It is certainly not patients-focused.  Prefer: the fact that interruptions will be enabled/supported /possible	Thank you for your comment with which the GDG agreed. The recommendation on conventional phototherapy has also been revised as follows: "Using clinical judgement encourage breaks of up to 30 minutes for breastfeeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated."
SH	National Childbirth Trust	27.24	Full		184	Line 18: During conventional phototherapy stop phototherapy for up to 30 minutes every 3 to 4 hours to allow feeds This conflicts with good practice recommending demand feeding should continue. Surely phototherapy should be flexible to meet the individual needs of the	Thank you for your comment. The GDG agrees that some flexibility is possible and an amendment has been made to reflect this. Although the GDG would stress there is a need to <b>continue</b> phototherapy for it to be effective. An amendment to "use clinical

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						baby – much better to feed, cuddle wind if necessary a distressed baby than wait another three hours. They may then sleep for longer and allow the mother to relax.	judgement” has been added to the recommendation concerning breaks in phototherapy although the GDG were satisfied that 30 minutes was a reasonable compromise between the baby’s treatment needs and the need to encourage and facilitate bonding between the baby and its parents. The recommendation now reads: “Using clinical judgement encourage breaks of up to 30 minutes for breastfeeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated”
SH	National Childbirth Trust	27.25	Full		185	Line 9: add re facilities for parents to stay with baby  Both babies and parents need physical contact. Facilities to ensure that mothers can stay with the baby who is breastfed and either parent can stay with a baby who is formula fed are important.	Thank you for your comment. It is beyond the scope of this guideline to make recommendations about service delivery.
SH	National Childbirth Trust	27.26	Full		188	Line 28: continue lactation/feeding support so that breastfeeding can start again when treatment stops God point but needs to ensure that adequate information relayed to women who are expressing to ensure that they are aware that expressing at least every 3 hours is recommended to ensure their milk production is sufficiently stimulated at this crucial stage of lactation. Neither pumps nor hand expressing will be as effective as a	Thank you for your comment. Whilst the GDG agree that appropriate lactation/feeding support should be given, about the details of expressing milk and privacy etc further recommendations are beyond the scope of this guideline.

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						<p>baby feeding directly at the breast .</p> <p>Of course, equipment, facilities, information and privacy need to be provided to enable them express close to their baby.</p>	
SH	National Childbirth Trust	27.27	Full		210	Line 32: when parents or carers will be allowed see and hold the baby as above need more parent centred language	Thank you for your comment, We have replaced the term allowed and the recommendation now reads "when it will be possible for parents or carers to see and hold the baby "
SH	National Childbirth Trust	27.28	Full		213	Over 505% ?? of multiparous	Thank you for your comment. Amendments to the text have been made accordingly.
SH	National Childbirth Trust	27.29	Full		213	<p>Line 12-14: reference to most breastfeeding mothers whose babies had had jaundice believing that the quality and quantity of breastfeeding was pertinent to this. And guilt affecting 38% of the mothers most mothers saying they had not been given an explanation of jaundice [Again, this does not make sense. If uncertainty affected most of the respondents, this must be more than the 55% cited as the commonest theme].</p> <p>the comment inserted in square brackets does not seem helpful here. Better to present the results as the authors did, unless greater clarity is available from the study authors. It may be most mothers had not been given an explanation of jaundice, but only 23-25 were uncertain, which is still the majority.</p>	Thank you for your comment. The text has been amended for greater clarity as suggested
SH	National Childbirth	27.30	Full		215	Line 26: Offer parents or carers information	Thank you for your comment. Amendments

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	Trust					<p>about jaundice <i>ADD</i> which should be <i>tailored to their needs and expressed concerns</i> and include:</p> <p>Parents also need to know how to tell that their baby is receiving sufficient fluids, especially if the baby is breastfed, as 'insufficient milk' this is a reason many women give for stopping before they wanted to. Monitoring the babies output (wet and dirty nappies) can be useful if they are worried. This is relevant to risk factors and advice on management. Opportunities to ask questions, however far fetched, and an understanding of parents' needs for information, support and reassurance when appropriate is vital.</p>	to the recommendation have been made and in keeping with your suggestion
SH	National Childbirth Trust	27.31	NICE		5	<p>a degree of hyperbilirubinaemia is physiologically normal NCT supports the guidance on this page. Parents should be involved in drafting information so that it is appropriate to their needs.</p>	Thank you for your comment
SH	National Childbirth Trust	27.32	Neonatal Jaundice Care Pathway	General	General	<p>Considering discharge at less? This is not sufficiently clear</p> <p>Also feeding assessment should be carried out by a member of staff trained to do so.</p>	<p>Thank you for your comment. We have amended the text error that you have identified. The GDG assumes that trained health care professionals will offer advice and support as stipulated in the Post Natal Care Guideline see: <a href="http://www.nice.org.uk/nicemedia/pdf/CG037fullguideline.pdf">http://www.nice.org.uk/nicemedia/pdf/CG037fullguideline.pdf</a></p>

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SH	Natus Medical Inc.	14.01	Full	1.1 General	28	<p>Initiate Multiple Phototherapy : The move over the past few years has been away from the number of devices and more geared to the intensity delivered over the maximum surface area. One device such as a neoBLUE LED Phototherapy light delivers &gt;30 uW/cm<sup>2</sup>/nm over the entire body; whereas a halogen spotlight may only deliver 8 uW over an 8" diameter. Should be stated in terms of intensity and surface area.</p> <p>There was also a reference to the use of fiberoptic blankets for preemies. Depending on the bilirubin level of the premature infant, more intensive phototherapy over a greater surface area may be indicated.</p>	Thank you for your comments, As not all units will have access to the same devices, the recommendations cannot be device specific
SH	Natus Medical Inc.	14.02	Full	General	36, 184	Same as above	Thank you for your comment, however, we could not ascertain to what it referred.
SH	Natus Medical Inc.	14.03	Full	7	38	Hydration: According to a study done by Carolyn Lund at Oakland Childrens Hospital in California, neither fluorescent, not LED light sources contribute to insensible water loss. Halogen lights do. Therefore, this important statement should be accompanied by explanation of insensible water loss due to hot lights.	Thank you for your comment. The GDG made an amendment to the translation as suggested.
SH	Natus Medical Inc.	14.04	Full	7.11 General	159, 164	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	Thank you for your comment. One of the suggested papers has been included in the guideline (Seidman et al 2000– see bibliography reference 133). However, the remaining papers would be excluded for the following reasons :

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						<p>peak absorption of bilirubin. As far as cost effectiveness, the cost of replacing one panel every 4,000 hours is less than the cost of replacing 6-8 bulbs every 1,500 hours.</p> <ul style="list-style-type: none"> <li>• Vreman HJ, et al. Light-Emitting Diodes: A novel Light Source for Phototherapy. Pediatric Research 1998; 44:804-809.</li> <li>• Seidman DS, et al. A new blue light-emitting phototherapy device: A prospective randomized controlled study. J. Pediatrics 2000; 136:771-4.</li> <li>•</li> <li>• Seidman DS, et al. Blue LED phototherapy compared to halogen phototherapy. PAS abstract, 2002.</li> <li>•</li> <li>• 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).</li> <li>•</li> <li>• Maisels, et al. A Randomized Controlled Trial of Light Emitting</li> </ul>	<p>Vreman 2000 – is not a randomised controlled trial  Seidman 2002– is a conference abstract  Lund 2004 - is a conference abstract  Maisels 2005 – is a conference abstract</p>

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						Diode (LED) Phototherapy (PT) versus Special Blue Intensive Phototherapy. PAS poster, 2005.	
SH	Natus Medical Inc.	14.05	Full	General	General	By stating recommendations for treatment in terms of specifications (intensity, surface area, duration) rather than product (fiberoptic blanket, multiple), the guidance will not point to a specific manufacturer, but rather to good practices and the hospital will have a guideline from which to base a decision.	Thank you for your comment.
SH	Neonatal & Paediatric Pharmacists Group (NPPG)	5.01	Nice	1.2	10	We wonder if there should be a list of drugs which may be a risk factor in terms of aggravating hyperbilirubinaemia: eg. drugs which displace bilirubin eg co-trimoxazole	Thank you for your comment, The GDG did not examine the evidence for drugs as risk factors
SH	Neonatal & Paediatric Pharmacists Group (NPPG)	5.02	Nice	1.6.33	20	Barbiturates are mentioned – should this specifically say Phenobarbital?	Thank you for your comment. The GDG purposely used the term “barbiturates” as other drugs besides Phenobarbital were examined
SH	Neonatal & Paediatric Pharmacists Group (NPPG)	5.03	Nice	1.6.31	20	With regards to the IVIg. This is a blue indication in the national (DH) “immunoglobulin demand programme” for Haemolytic Disease of the Newborn. They also call it Isoimmune Haemolytic jaundice in neonates. We would suggest that the NICE guidance has the same definitions to ensure that the PCT's don't quibble over its use and indication. Essentially it is a blue indication in selected cases of haemolytic disease in the newborn with worsening hyperbilirubinaemia.	Thank you for your comment. The GDG were satisfied with their terminology but an amendment has been made to the glossary as follows: “Haemolytic disease of the newborn – Abnormal breakup of red blood cells in the fetus or newborn. This is usually due to antibodies made by the mother directed against the baby's red cells (also known as Isoimmune haemolytic disease)”
SH	Neonatal & Paediatric Pharmacists Group	5.04	Nice	1.5	14	For assessment in prolonged jaundice it would be worth checking for any maternal	Thank you for your comment. We agree this is an important issue but we are unable to

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	(NPPG)					medication which may have caused infant jaundice.	answer it from the evidence evaluated as part of this guideline.
SH	Neonatal & Paediatric Pharmacists Group (NPPG)	5.05	Nice	1.6.12	16	It states that additional fluids should not be given routinely. We agree with this point in as much as they should never be given routinely, but only on assessment of need. Most centres do use additional fluids and thus the wording may be better re-phrased. <i>"The babies hydration status should be closely monitored and additional fluids may need to be considered"</i>	Thank you for your comment. Amendments to "fluids and feeds" recommendations have been made for clarity 1.5.23 now reads ' During continuous multiple phototherapy: monitor hydration by daily weighing, and assessing wet nappies do not interrupt phototherapy for feeding but continue administering intravenous/oral feeds continue lactation/feeding support so that breastfeeding can start again when treatment stops. Maternal expressed milk is the additional feed of choice if available, and when additional feeds are indicated
SH	Neonatal & Paediatric Pharmacists Group (NPPG)	5.06	Nice	1.6.5	16	Fibreoptic phototherapy is sometimes used in term babies for convenience and to aid family/baby bonding. Thus we agree that it is perhaps not first line, but risk benefit should be considered.	Thank you for your comment. There was no evidence available to the GDG for the effectiveness of this intervention in term babies. Thus the GDG did not make a clinical recommendation on fibreoptic therapy. A research recommendation for investigation of the effectiveness of larger "biliblankets" for term babies has been included.
SH	NHS Direct	18.01	Full	General		Welcomed by NHS Direct. No comments to make on content	Thank you for your comment
SH	North Trent Neonatal Network	11.01	Full	General	general	The document is far too long	Thank you for your comment
SH	North Trent Neonatal Network	11.02	Full	General	general	There are too many comments on the American experience which is different from that of the UK because of the different health care organisations of both countries	Thank you for your comment. The GDG were aware of the differences between the two countries but as the majority of the evidence was sourced from the US - the GDG interpreted this for a UK guideline.

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SH	North Trent Neonatal Network	11.03	Full	General	General	Much is based on informing parents on recognising jaundiced baby. None on recognising other associated conditions i.e poor feeding, lethargy, sleepiness. Well babies who are feeding well and active and alert are unlikely to need treatment.	Thank you for your comment. The evidence did not support limiting treatment opportunities to babies who were not alert.
SH	North Trent Neonatal Network	11.04	Full	General	General	Emphasis needed on ensuring infants continue enteral feeding if able as this will increase gut motility etc and therefore assist with the excretion of bilirubin.	Thank you for your comment. The GDG have used every opportunity to reinforce continued breast feeding of infants if possible.
SH	North Trent Neonatal Network	11.05	appendices	General	general	A graph of serum bilirubin levels against the age of the baby with thresholds for phototherapy and exchange blood transfusion, for the preterm and term infants would be helpful.	Thank you for your comment. We have provided this graph as an appendix in the full guideline.
SH	North Trent Neonatal Network	11.06	Full	1.2	34	Line 28: need to clarify what is meant by multiple phototherapy 2 light 3 lights etc	Thank you for your comment. A definition of multiple phototherapy has been added to the glossary
SH	North Trent Neonatal Network	11.07	Full	1.2	38	Line 6-8: I know that this means that if the bili is at certain level on the transcutaneous monitor, but the baby does not require phototherapy you can carry on using the transcutaneous. But the sentence can also be taken to mean if a baby is being treated with phototherapy and the serum bili level falls low enough you can go back to using transcutaneous monitoring. Later in the document it says you should not do that, but if you just have this bit of the guideline you could misinterpret the sense easily. They need to choose words that do not have more than one meaning.	Thank you for your comment, An amendment has been made as suggested

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SH	North Trent Neonatal Network	11.08	Full	3.1	63	Line 9: implications of breastfeeding being down as a risk factor is not helpful - we have enough problems with breast feeding rates in this area, and this is more likely to be physiological jaundice.	Thank you for your comment. The GDG did not feel that they could leave out the implications of breastfeeding as a risk factor. Whilst many babies do have physiological jaundice it is a fact that breast fed babies are over represented in kernicterus registries. However, we appreciate your concern regarding the use of the word "risk "in relation to breastfeeding and potential mis-information that may result from this. We have therefore revised the recommendation to remove the word" risk".
SH	North Trent Neonatal Network	11.09	Full	4.8	101	<p>in the event of infants being discharged home within 72 hours (which is most cases) who is going to assess jaundice in 1st 72 hours. Midwives no longer do daily visits. Putting a lot of responsibility on parents.</p> <p>in the event of a preterm infant becoming jaundiced in 1st 72 hours the guidance is not specific regarding when to treat.</p>	<p>Thank you for your comment. If a baby is at high risk then the GDG do envisage a health care professional check, which may involve a midwife visit. The GDG believe that parents can recognise jaundice if given information. The recommendation now reads "When looking for jaundice in all babies (visual inspection)</p> <ul style="list-style-type: none"> <li>•check the naked baby in bright and preferably natural light.</li> <li>•Examination of the sclerae, gums and blanched skin is useful across all skin tones Parents, carers or healthcare professionals can carry out the visual inspection." . We hope this provides greater clarity</li> </ul> <p>A chart has been added to Appendix F to give guidance for preterm babies &lt;72 hours old.</p>
SH	North Trent Neonatal Network	11.10	Full	7.1.13	191	more guidance regarding what blood products to use in the event of an exchange transfusion. i.e to use recently bled only,	Thank you for your comment, Amendments have been made to recommend IVIG in Rh disease and ABO with rapidly rising bilirubin

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						<p>cmv negative etc.</p> <p>-in the event of the infant being in a DGH blood products and immunoglobulins are not always readily available and need to be transferred in from regional centre. In this event 1x dose of albumin sometimes bides a bit of time whilst we are able to receive the products, is this not acceptable?</p>	
SH	North Trent Neonatal Network	11.11	Full	7.3.14	211	<p>Line 1-3: While I agree that albumin is not a treatment for hyperbilirubinaemia. It is not uncommon for some babies to be dehydrated with this, due to poor feeding. Therefore it is reasonable to rehydrate them along with giving them intensive phototherapy. Usually around 10 to 20 mL/kg of fluid in this situation, usually while waiting for another bili to come back, or while waiting for the blood to be got ready for the exchange. What this seems to suggest that one cannot use albumin in this situation. This is not in keeping with the suggestion that the bill/albumin ratio may play a part in kernicterus risk. I think they need to amend the line to, "Do not solely use...."</p> <p>That brings me on to another question. While the guideline is very good at saying above 450 exchange. What happens if after some fluid, intensive phototherapy and waiting for the blood to arrive for the exchange, another bili result comes back at</p>	<p>Thank you for your comment. The GDG have added further advice in the section on fluids and feeds and have removed the phrase suggested. Graphs to clarify the treatment algorithm for a baby approaching the exchange level are now included</p>

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						less than the exchange level. Anecdotally this feels to be quite common. Would the recommendation be to perform the exchange anyway, because the great and the good do not recognize these as treatments for hyperbilirubinaemia?	
SH	Royal College of Midwives	26.01	All	General		The Royal College of Midwives welcomes the opportunity to comment on this guideline.	Thank you for your comment.
SH	Royal College of Midwives	26.02	Full version	General		The Royal College of Midwives is concerned about the focus on risk throughout this document. Despite a good discussion in the text about 'physiological jaundice' that is 'generally harmless' - this is not so evident in the bullet points and the algorithm. The lack of focus on normality could cause inappropriate anxiety.	Thank you for your comments. Appropriate amendments have been made to the bullet points.
SH	Royal College of Midwives	26.03	Full version	1.2.5		Are the GDG aware of the availability or not of transcutaneous bilirubinometers ?	Thank you for your comment. The GDG are aware of transcutaneous bilirubinometers being available in some but not all parts of the UK currently.
SH	Royal College of Midwives	26.04	NICE version	1.2		We consider that the statement 'mother's intention to exclusively breast feed' should not be with the other risk factors - this offers a very alarming and discouraging message about breastfeeding. It should be in a separate paragraph – alongside a discussion about the normality of 'breast milk jaundice' and the need for access to lactation support.	Thank you for your comment. We have revised the recommendation to remove the word 'risk', however, the GDG felt that it was not appropriate to separate breast feeding from other factors
SH	Royal College of Midwives	26.05	NICE version	1.3.2	7	The guideline appears to be saying that a visual assessment of the baby, including its feeding and other behaviour, is insufficient to assess whether the jaundice is likely to	Thank you for your comment. The evidence did show that visual assessment is unreliable. However, serum bilirubin testing is not necessary if transcutaneous bilirubinometry is

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						be problematic even in babies over 24 hours old. This could mean sending up to 60% of babies who are between 25 and 72 hours of age back to the hospital from the community for serum bilirubin testing This will promote anxiety in new parents, as well as putting newborns at risk of infection by bringing so many into hospital to wait in A&E.	used.
SH	Royal College of Midwives	26.06	Full version	1.2.7		It would be useful to include discussion of the evidence about the use of direct and indirect sunlight	Thank you for your comment. No evidence was found for sunlight as a treatment for hyperbilirubinaemia
SH	Royal College of Midwives	26.07	Full version	2.1		We are pleased to see the discussion in the text about the need for adequate breast feeding support and advice - but feel this should have a higher profile in the bullet points , as postnatal visits have been significantly cut back - and that contributes to the risk for breast fed babies. A recommendation of more visits for breastfeeding mothers would be helpful.	Thank you for your comment. Service delivery is beyond the scope of this guideline.
SH	Royal College of Midwives	26.08	Full version	2.1		The factors that increase the risk of severe neonatal jaundice ' dehydration, prematurity, respiratory distress etc ', would be useful in the bullet points	Thank you for your comment. However, we disagree as the evidence for dehydration, and respiratory distress as risk factors is weak and should not be in the bullet points. Prematurity is covered by the 'less than 8 weeks gestation' risk factor
SH	Royal College of Midwives	26.09	Full version	2.10		There is no description of 'the formal consensus methods' that were used.	Thank you for your comment. We agree, we have added ' using a nominal group technique' to this section of text and have added a definition to the glossary as follows  'Nominal Group technique = A decision making method for use among groups of

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							many sizes, who want to make their decision quickly, as by a vote, but want everyone's opinions taken into account'
SH	Royal College of Midwives	26.10	Full version	7.1.4		'position babies according to usual clinical practice' is not a clear recommendation	Thank you for your comment. Amendments have been made to the recommendation in line with the Cot Death recommendations and for clarity.
SH	Royal College of Midwives	26.11	Appendix B	General	General	We do not consider that the use of American data is appropriate for informing practice in the United Kingdom – where routine postnatal care by midwives provides careful monitoring of the baby's well being – this is not the case in America.	Thank you for your comments. This is presented as contextual evidence to suggest that there may be a relationship between monitoring in the postnatal period and kernicterus.  This data is not used in the economic model and is not used to support recommendations in this guideline
SH	Royal College of Nursing	19.01	General	General	General	The RCN welcomes proposals to develop this guideline.	Thank you for your comment
SH	Royal College of Nursing	19.02	NICE	General	7	<b>Transcutaneous bilirubin measurements have been used in many trusts.</b>  <b>For instance we are aware of a trust where they have used it for approximately eight years now. They are used on the Neonatal Unit, Maternity Unit and out in the community. Training for all users is not problematic although if staff do not use Bilicheck for a while then a couple of caps tend to get used for calibration due to failure because of user error.</b>	Thank you for your comment, This very helpful information has been considered by the Health Economics team.

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						<p><b>The cost of repair is also an issue. In that trust they found that repairing the unit is now more expensive – in the past they had been charged about ten percent of the purchase price for the repair, whereas now the last two repairs they have had, were nearly £1000 - which after eight years of a ten year programme, allowing for depreciation and replacement, makes them more expensive to repair. They are then often condemned /replaced as new ones only cost approximately £3,500.</b></p> <p><b>They recently trialed cap-less model by a different company.</b></p>	
SH	Royal College of Nursing	19.03	NICE	General	7	<p>Bilichex can be used in 'newborn patients <b>regardless of skin colour, gestational age, or postnatal age</b> (<i>Bilichex system non-invasive bilirubin analyzer user instruction manual, 2000: p4</i>).</p> <p>The NICE guideline advises that if a baby is visually jaundiced to use <b>serum bilirubin</b> to determine bilirubin in <b>pre-term</b> babies not transcutaneous.</p> <p>It is not clear what is this advice is based on and whether manufacturers support this use?</p> <p>For instance, in one trust, 35-37week pre-terms go to Maternity Unit and do not get</p>	Thank you for your comment. The GDG have included emerging published evidence, which supports the use in moderately preterm babies. Amendments have been made to the recommendations for Transcutaneous bilirubometers in light of this. .

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						<p>serum bilirubin if the TcB is below the threshold for treatment. They would not prick a baby's heel if visually jaundiced and &gt;24hrs old when non-invasive measurements are used, as per manufacturer's advice.</p> <p>Premature babies go home earlier with neonatal community nurse follow up and so may be premature in community to get screened by TcB as well as long as they had not received phototherapy and were below treatment threshold.</p>	
SH	Royal College of Nursing	19.04	NICE	1.3.4	11	Why is this <b>36</b> weeks particularly i.e. what about preterm are < 37weeks for example? It would be helpful to clarify this in this version.	Thank you for your comment. This definition has been amended to a term baby being 38 weeks or more
SH	Royal College of Nursing	19.05	NICE	1.4.5	13	<b>User manual of bilicheck states that if a small portion of skin is protected from the therapeutic effects of phototherapy lights, the relationship between the skin bilirubin in the protected skin site and bilirubin is likely to be maintained. However, in some practice in line with NICE do not use TcB after phototherapy until discharge. It is helpful to have a standardised guideline.</b>	Thank you for your comment. There is insufficient evidence at the present time for the GDG to recommend this
SH	Royal College of Nursing	19.06	NICE	1.6.3	15	<p>Conventional vs fibre optic phototherapy. It would be helpful to clarify what 'conventional' is?</p> <p>There is so much on the market now- bilipad, bilibed, overhead (needing to adjust</p>	Thank you for your comment. Amendments have been made for clarity. Definitions of conventional, multiple, fiberoptic and LED phototherapy have been added to the glossary

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						<p>for fluid loss and now not needing to account for fluid loss)!</p> <p>Even the fibre-optic bilipad has gone from a white cable to gray higher intensity levels (400-550 nanometer range).</p> <p>Bilibed is a fluorescent tube (? 425-475nm)</p> <p>Regarding the overhead type phototherapy units the more recent one does not need additional fluid like the traditional overhead lights do.</p> <p>Is the difference in conventional vs fibre-optic due to effects of water loss or due to strength of phototherapy delivered? A clarification would be helpful.</p>	
SH	Royal College of Nursing	19.07	NICE	1.6.19	17	Bili-wheel discussed would be a useful tool to deliver phototherapy/exchange level thresholds.	Thank you for your comment.
SH	Royal College of Nursing	19.08	NICE	1.6.23	19	<p>In babies who fall into repeat TcB category in Table 1 repeat TcB in 6-12hrs - this may have an impact on community.</p> <p>Would a repeat be done out of hours?</p> <p>Would the baby be referred back to hospital out of hours?</p>	Thank you for your comment. The GDG considered this very carefully and acknowledge that local arrangements would have to be put in place but were unable to be specific about where care is delivered as this is a service issue beyond our scope.
SH	Royal College of Obstetricians and Gynaecologists	17.01	full	General		Overall I found this very clear and easy to follow	Thank you for your comment
SH	Royal College of Obstetricians and	17.02	Full	3.1 Eviden	62	What is meant by increase in jaundice severity? Does this need to be clarified?	Thank you for your comment, An increase in jaundice severity means an increase in

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	Gynaecologists			ce summary			visible jaundice.
SH	Royal College of Obstetricians and Gynaecologists	17.03	Full	3.1 GDG translation	62	What is meant by adequate lactation support, can this be quantified or reference made to another guideline.	Thank you for your comment. The GDG have referenced the Postnatal care guideline and have made a number of amendments to the additional fluids and feeds section.
SH	Royal College of Obstetricians and Gynaecologists	17.04	full	3.1	63	Please specify what constitutes treatment in a sibling – should indicate at least phototherapy and exclude monitoring of SBR	Thank you for your comment. Amendments to the recommendation have been made for clarity ie specifying phototherapy as a treatment.
SH	Royal College of Obstetricians and Gynaecologists	17.05	Full	3.1	63	The point that breastfeeding should not be discouraged in women with risk factors needs further highlighting	Thank you for your comment. The GDG did not feel that they could leave out the implications of breastfeeding as a risk factor.. However, we appreciate your concern regarding the use of the word "risk" in relation to breastfeeding and potential misinformation that may result from this. We have therefore revised any recommendation to remove the word "risk". We have also recommended that information to be given to <b>all</b> women should include reassurance that breastfeeding can usually continue and that <b>all</b> women should receive breastfeeding support.
SH	Royal College of Obstetricians and Gynaecologists	17.06	Full	4.2 GDG translation	78	'requires urgent medical review'- should this specify that this needs to occur in hospital. How urgent is urgent- I assume this means that review needs to occur that day or can it be specified in hours?	Thank you for your comment. The recommendation has been amended for greater clarity to and now reads: Refer to ensure an urgent medical review (as soon as possible and within 6 hours) to exclude pathological causes of jaundice (see recommendations 1.4.1 and 1.4.2)  However, it is beyond the scope of this

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							guideline to recommend settings for service delivery
SH	Royal College of Obstetricians and Gynaecologists	17.07	Full	4.4 GDG translation	87	Should specific guidance be given on who should be responsible for giving this advice e.g. midwife responsible for discharge. Is jaundice discussed as a routine part of breastfeeding advice?	Thank you for your comment. As this is not a breastfeeding guideline, it would be inappropriate for further recommendations to be made here to further describe breastfeeding support. In accordance with NICE methods, the GDG have referred to the NICE postnatal care guideline (CG37). This guideline does not specify which healthcare professional provides advice.
SH	Royal College of Obstetricians and Gynaecologists	17.08	Full	4	100	There is no clear recommendation about who the baby should be referred to for "medical review". Should make clear that baby should be referred back to secondary care and not taken to GP	<p>Thank you for your comment. The recommendation has been amended for greater clarity to and now reads:</p> <p>Refer to ensure an urgent medical review (as soon as possible and within 6 hours) to exclude pathological causes of jaundice (see recommendations 1.4.1 and 1.4.2)</p> <p>However, it is beyond the scope of this guideline to recommend settings for service delivery</p>
SH	Royal College of Obstetricians and Gynaecologists	17.09	Full	4	100 and 101	Should 'check for jaundice' include how to do this	Thank you for your comment. A description of how to visually check for jaundice is given in the recommendations
SH	Royal College of	17.10	Full	5.1	109	'The experience of the GDG is that it is	Thank you for your comment. The text has

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	Obstetricians and Gynaecologists					important to examine the naked baby in good light, preferably natural light, and it is particularly important to look at the sclerae and gums, and an area of blanched skin'. - would it not be important to move this to the beginning of the paragraph rather than at the end	been amended as suggested.
SH	Royal College of Obstetricians and Gynaecologists	17.11	Full	5.4.1	116	This is interesting, but as the 'Minolta JM-102 is no longer available for purchase from the manufacturers' perhaps this statement should be included at the very beginning of this section.	Thank you for your comment, The GDG considered this but did not make the suggested amendment
SH	Royal College of Obstetricians and Gynaecologists	17.12	Full	5	128	if "jaundice develops in babies aged 24 hours and older, the intensity should be monitored and systematically recorded along with the baby's overall well-being with particular regard to hydration and alertness"- who should do this monitoring?	Thank you for your comment. This is a quoted recommendation from the NICE Postnatal care guideline. The GDG always considered that midwives, doctors and parents would monitor the baby.
SH	Royal College of Obstetricians and Gynaecologists	17.13	Full	5	129	Again there is no clarity as to who should measure the bilirubin. At present many midwives will perform test but not able to interpret results. Should make line of responsibility clear esp for those babies discharged home	Thank you for your comment. It is anticipated that an implementation tool to accompany this guideline "The Biliwheel" will allow interpretation of the result by whoever does the test, immediately. It will also include referral pathway details.
SH	Royal College of Obstetricians and Gynaecologists	17.14	Full	5	129	While inspection of baby is mentioned, there is no mention of behaviour. Is a sleepy baby, lack of tone etc significant in recognising jaundice or is this a much later sign??	Thank you for your comment. No evidence was available to assess whether a baby's behaviour would help discern jaundice.
SH	Royal College of Obstetricians and Gynaecologists	17.15	Full	5	129	Provide mothers with lactation and feeding support- can any specific advice be given on breastfeeding and jaundice levels or is this done on a case by case basis	Thank you for your comment, The GDG considered that lactation and feeding support would be on a case by case basis (as suggested) and that further advice was not appropriate to include in the

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							recommendations made,
SH	Royal College of Obstetricians and Gynaecologists	17.16	Full	7.1.3	167	Where does the evidence for green light being better on the eyes of staff come from? If there is none and this is anecdotal, then should green light be recommended as it is most effective in reducing serum bilirubin.	Thank you for your comment. Although green light may be more effective for reducing serum bilirubin, it is not tolerated well by staff ( one study found that staff complained of nausea and headaches)
SH	Royal College of Obstetricians and Gynaecologists	17.17	full	7	183	IS it necessary to make a distinction between a term normal weight baby and a term and low birthweight baby.? In the titles term and normal weight are grouped together as are preterm and low weight. However, this is not clear in the text.	Thank you for your comment. The GDG refers to preterm or term babies throughout the guideline. Although some literature used birth weight as a proxy for gestation, the GDG wanted to provide guidance based on gestation alone ; we do not suggest a lower level for a low birthweight baby at term, for example. There was no evidence available that IUGR is a risk factor for kernicterus,.
SH	Royal College of Obstetricians and Gynaecologists	17.18	full	7	184	Should the position of the baby not be specified as there are clear guidelines on this	Thank you for your comment. Amendments have been made to the text to recommend a supine sleeping position wherever possible
SH	Royal College of Obstetricians and Gynaecologists	17.19	full	7	187	“Ensure that babies are kept hydrated during conventional phototherapy” This statement is not helpful as stated elsewhere that additional fluids are not required and that feeding should continue as usual. Please clarify	Thank you for your comment. Amendments have been made to two recommendations to provide greater clarity.  The recommendation to guide fluid management during conventional phototherapy has also been amended to include the following points:  <ul style="list-style-type: none"> <li>• Using clinical judgement encourage breaks (of up to 30 minutes) for breastfeeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated.</li> <li>• continue lactation/feeding support</li> <li>• do not give additional fluids or feeds</li> </ul>

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							<p>routinely.</p> <p>Maternal expressed milk is the additional feed of choice if available, and when additional feeds are indicated.”</p> <p>The recommendation about monitoring hydration has been amended to say:</p> <p>“Monitor hydration by daily weighing and assessing wet nappies”</p>
SH	Royal College of Obstetricians and Gynaecologists	17.20	Full	7	190	“need for additional fluids ....made on individual basis”. Is it useful to add what factors would be relevant to this decision e.g duration of treatment, method of feeding??	Thank you for your comment. An amendment has been made to clarify that breast milk would be the preferred fluid, However, the method of feeding is outwith the scope of this guideline.
SH	Royal College of Obstetricians and Gynaecologists	17.21	full	8	215	The recommendations on information to be given are very helpful	Thank you for your comment
SH	Royal College of Paediatrics and Child Health	29.01	Full	General	General	<p>The College notes this is a superb piece of work. It is a hugely comprehensive trawl through the evidence base for the management of early onset jaundice. The evidence is adequately summarised and the recommendations are based on the findings. The GDG are to be congratulated on producing a balanced, informative and safe guideline for consultation.</p> <p>This is a valiant attempt at a Herculean task and the result is a very informative, helpful document on which to base local policies.</p>	Thank you for your comments

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SH	Royal College of Paediatrics and Child Health	29.02	Full	General	General	The College does think implementation will be very challenging (see more detailed comments below) with clinicians unable to agree on how to manage the individual baby; the lack of prescriptive guidance on many aspects of management is thus sensible. This is probably not a guideline to just cut and paste into local protocol files but rather one to be used to inform the local protocol writer.	Thank you for your comment. NICE develop tools to support the implementation of the guideline and we expect these to assist local uptake of the recommendations.
SH	Royal College of Paediatrics and Child Health	29.03	Full	General	General	The College recognises the lack of evidence base for the jaundice treatment chart; however, we strongly support the proposed chart, which would help to address the widespread variation in practise around the country at present.	Thank you for your comment. A chart will be added to Appendix F in the full guideline.
SH	Royal College of Paediatrics and Child Health	29.04	Full	General	General	The GDG have concentrated on preventing kernicterus cases, possibly partly influenced by the clinicians on the group being heavily involved as advisors in litigation work surrounding these patients. The College agrees with this as their priority but kernicterus is rare and we feel that the everyday issue of length of stay has not received a comparable amount of consideration in the guideline. We are pleased that the GDG are not recommending universal screening at this stage but even testing all babies with a tinge of jaundice on day 3 of life post Caesarean section on the postnatal ward is going to lead to those dyads staying in for a repeat test 6-12 hours later. It would not be practicable for a community midwife to visit	Thank you for your comment., The emphasis on kernicterus was due to the scope rather than the medico legal involvement of some of the GDG members. The GDG does not feel that hospital stays with be lengthened by this guideline

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						a baby at home on the day they are discharged from hospital. Even the following day may be impractical at a weekend given the current level of cover nationally.	
SH	Royal College of Paediatrics and Child Health	29.05	Full& NICE	General	General	<p>This document needs to clarify in the introduction that there are two types of neonatal jaundice – unconjugated hyperbilirubinaemia defined as conjugated bilirubin &lt; 20 micromols/L AND &lt; 20% of total bilirubin and conjugated hyperbilirubinaemia defined as conjugated bilirubin &gt;20 micromols/l AND &gt; 20 % of total bilirubin.</p> <p>The document is mainly concerned with unconjugated hyperbilirubinaemia. This can be physiological or pathological. In contrast, conjugated hyperbilirubinaemia is rarer but should always be considered as pathological and must be investigated immediately for the presence of liver disease because surgery for biliary atresia has a better outcome if it is performed before 60 days of age and because unrecognised neonatal liver disease can present as intracerebral haemorrhage due to malabsorption of vitamin K.</p>	<p>Thank you for your comment. Amendments have been made throughout for clarity.</p> <p>We have used a cut off of 25 micromol/L as a cutoff for conjugated hyperbilirubinaemia</p>
SH	Royal College of Paediatrics and Child Health	29.06	NICE	General	General	It is misleading to call this guideline "neonatal jaundice" and then only concentrate on unconjugated hyperbilirubinaemia without even clearly referring the reader to more information on conjugated hyperbilirubinaemia. As stated	Thank you for your comments. While conjugated hyperbilirubinaemia is outside the scope of this guideline, the GDG has tried to take the opportunities it was offered to draw attention to liver disease.

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						in the introduction most neonatal jaundice is physiological; however, jaundice is pathological, and needs to be investigated urgently in two groups of infants. These are: 1) those with very high levels of unconjugated bilirubin who are at risk of kernicterus (the theme of this guideline); and, 2) those with conjugated hyperbilirubinaemia who have liver disease. In order to identify infants with liver disease any baby who remains jaundiced beyond two weeks of age should have a total and conjugated bilirubin level measured and be referred for investigation if the conjugated bilirubin is >20% of the total, according to the guidelines posted on the BSPGHAN website, see <a href="http://www.bspghan.org.uk/working_groups/hepatology.shtml">http://www.bspghan.org.uk/working_groups/hepatology.shtml</a>	The GDG was not responsible for defining the scope and had to work within it. They were constantly aware of the need to consider this aspect of jaundice as one of the GDG members is the mother of a child with a liver transplant..
SH	Royal College of Paediatrics and Child Health	29.07	NICE	Introduction	3	The introduction states that there is some degree of jaundice in 60% of normal full term infants. This seems surprising, and we wonder if we have misunderstood.	Thank you for your comment. These are the data for visible jaundice of any degree.
SH	Royal College of Paediatrics and Child Health	29.08	NICE	Introduction	3	We recommend that the second paragraph be reworded so a non-medical reader does not confuse prolonged jaundice with physiological jaundice. In the last sentence of this paragraph, physiological jaundice is mentioned immediately after referring to what seems like breast milk jaundice: "10% of breast fed babies are still jaundiced at one month of age". This may create confusion, and needs clarification.	Thank you for your comment. An appropriate amendment has been made.
SH	Royal College of	29.09	NICE	Introdu	3	We note that the main cause of delay in	Thank you for your comment. The GDG has

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	Paediatrics and Child Health			ction		diagnosing neonatal liver disease is false reassurance that prolonged jaundice is benign. We are concerned that paragraph 3 of the introduction will perpetuate this. There needs to be an explanation (see above comment) and a statement in the introduction that prolonged jaundice requires excluding conjugated hyperbilirubinaemia by a split bilirubin test before reassurance can be given.	revised aspects of liver disease throughout the guideline in response to stakeholder comments.
SH	Royal College of Paediatrics and Child Health	29.10	NICE	Introduction	3	We feel that, though the numbers are small, "liver disease" should be added to the list of other causes of jaundice in paragraph 4 of the Introduction.	Thank you for your comment, An amendment has been made as suggested.
SH	Royal College of Paediatrics and Child Health	29.11	NICE	Key priorities for implement	6	This does not caution parents and carers about the importance of prolonged jaundice, which seems surprising.	Thank you for your comment. We disagree, we have made recommendations about prolonged jaundice although the GDG did not believe this to be one of the most important recommendations.
SH	Royal College of Paediatrics and Child Health	29.12	NICE	Key priorities	6	In the section, "Risk factors for hyperbilirubinaemia", the guideline includes jaundice in under 24 hours. We do not believe this is strictly accurate. If a baby is jaundiced, then this is not a risk factor but a given. We think the intention is to highlight those at special risk from hyperbilirubinaemia – in terms of cause or risk of severity – but it is not a risk factor. Perhaps this can be stated elsewhere?	Thank you for your comment. The point which is meant is that early onset jaundice increases the risk of later significant hyperbilirubinaemia. No amendment was made
SH	Royal College of Paediatrics and Child Health	29.13	NICE	Key priorities	7	We understand the recommendation for testing for jaundice correctly is that any infant with clinical jaundice must have a test within 6 hours. We are unsure whether this	Thank you for your comment. Service delivery is beyond the scope of this guideline.

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						is realistic. For example, does a health visitor seeing a patient at 4.00 pm on Friday do this? We do not think health visitors have ready access to bilirubinometers.	
SH	Royal College of Paediatrics and Child Health	29.14	NICE	Key priorities for implementation	7	Under the heading, "Formal assessment", we suggest that "establish maternal blood group' alongside baby's blood group and Coombs test" be added.	Thank you for your comment. An amendment has been made as suggested.
SH	Royal College of Paediatrics and Child Health	29.15	NICE	Key priorities for implementation	7	We think the guideline needs to explain how maternal anti-D during pregnancy can give a low grade false positive Coombs, as it is not currently clear in the text.	Thank you for your comment. A reference was added to the translation section of the full guideline and an amendment has been added to the recommendations which reads "When interpreting the result of a DAT (Coombs' test), take into account the strength of the reaction, and whether or not the mother received prophylactic anti-D immunoglobulin during pregnancy".
SH	Royal College of Paediatrics and Child Health	29.16	NICE	Key priorities for implementation	7	We suggest that a full blood count rather than just packed cell volume in isolation is carried out.	Thank you for your comment. The GDG considered that some units would choose to use the PCV from the "spun down" bilirubin sample.
SH	Royal College of Paediatrics and Child Health	29.17	NICE	Key priorities for implementation	7	We recommend rewording this sentence so that the investigation of jaundiced babies with pale chalky stools MUST (rather than should) include measurement of conjugated bilirubin. The total bilirubin may be quite low but if the percentage of conjugated bilirubin is > 20% this needs further investigation.	Thank you for your comment, The GDG were satisfied with their wording and no amendment was made.
SH	Royal College of Paediatrics and Child Health	29.18	NICE	Key priorities for implementation	9	We note that newborn screening is normally done around days 5-7. We believe new recommendations are due to suggest being done on day 1.	Thank you for your comment. We were unable to identify the guidance to which you refer.

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SH	Royal College of Paediatrics and Child Health	29.19	NICE	Key priorities for implement And 1.5.5	8 & 15	"Routine metabolic screening" is not the correct terminology and is misleading. The correct terminology is rather "newborn blood spot screening".	Thank you for your comment. An amendment has been made as suggested.
SH	Royal College of Paediatrics and Child Health	29.20	NICE	Key priorities and 1.2.1	7 & 10	These sections suggest that breast feeding is bad for babies. We suggest softening the tone for the exclusively breastfed to recognise we want mothers to undertake this.	Thank you for your comment. The have modified recommendations relating to breastfeeding throughout the guideline to improve the tone.
SH	Royal College of Paediatrics and Child Health	29.21	NICE	1.1	25	'Risk factors': the bullet point 'family history of neonatal jaundice' requires more precision, i.e. this should read 'neonatal jaundice requiring treatment in the baby's immediate siblings or parents.'	Thank you for your comment. The text has been amended to "history of a previous sibling with neonatal jaundice requiring phototherapy"
SH	Royal College of Paediatrics and Child Health	29.22	Full	1.1	26	Line 14: We disagree that inspection of gums is useful, and do not think this is practical.	Thank you for your comment. The GDG discussed this point but felt that the recommendation on gum inspection should remain as that was the evidence examined.
SH	Royal College of Paediatrics and Child Health	29.23	Full	1.1	27	Line 3: It is unclear why this heading, "Recommendations – Prolonged jaundice" is here.	Thank you for your comment. An amendment has been made to the text for clarity.
SH	Royal College of Paediatrics and Child Health	29.24	Full	1.1	27	Line 5: Routine metabolic screening needs to be defined.	Thank you for your comment, The GDG amended the recommendation wording to "blood spot"
SH	Royal College of Paediatrics and Child Health	29.25	Full	1.1	29	Line 8: The formula to calculate threshold for phototherapy for preterm is stated as "Gestational age (weeks) x 10 minus 100". If we take a 30 weeker and multiply by 90 it comes to 2600. The formula needs to be changed to "[gestational age (weeks) x 10]	Thank you for your comment. The text has been amended as suggested and the formula for an exchange has been added Gestational age (weeks) x 10.

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						– 100". We also recommend to include micromoles/L.	
SH	Royal College of Paediatrics and Child Health	29.26	Full	1.1	29	Line 9: Regarding phototherapy thresholds for preterm infants less than 72 hrs old: We realise that there is no evidence to support clear values, hence the statement "use phototherapy at lower bilirubin levels". Threshold values should be recommended through consensus. Threshold values for preterms should also be recommended through consensus. A national recommendation is required for phototherapy and exchange transfusion thresholds for preterm infants of all ages.	Thank you for your comment. Information for younger babies has been added in graphs, in appendix F and exchange levels have been made more clear. The formula for an exchange has been added Gestational age (weeks) x 10.
SH	Royal College of Paediatrics and Child Health	29.27	Full	1.2	30	Line 17: We disagree with the recommendation to repeat the serum bilirubin measurement between 6 and 12 hours, as this could lead to extremely high levels of bilirubin (and damage) before action is taken. We recommend that a repeat bilirubin level be taken within 1-2 hours of the first (as long as treatment is instituted).	Thank you for your comment. The GDG believed that a check 1-2 hours after the initial test would be too soon given the error of the measurement. Furthermore the GDG recognised that some babies would be distant from hospital and such a recommendation could be impracticable.
SH	Royal College of Paediatrics and Child Health	29.28	Full	1.2	30	Line 21: We disagree with the recommendation to conduct an urgent medical review within 6 hours. We instead recommend that the baby be reviewed by the paediatric team as soon as the first bilirubin level indicates that the baby is jaundiced, so that action can be taken by the medical team for an unwell baby as soon as possible. We note that this point does not tally with the NICE guideline on 'Postnatal care', which recommends that	Thank you for your comment, This recommendation has been amended in line with the Postnatal care guideline, as suggested, with an additional statement to allow for babies who are some distance from hospital for medical review The recommendation has now been amended to: Refer to ensure an urgent medical review (as soon as possible and within 6 hours) to exclude pathological causes of jaundice

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						"babies who develop jaundice within the first 24 hours after birth should be evaluated" as an emergency action.	
SH	Royal College of Paediatrics and Child Health	29.29	Full	1.2	30	Line 25: We recommend that this should state "Routine <i>daily</i> clinical examinations (by midwife)" to ensure clarity.	Thank you for your comment. No amendment was made. Service delivery is beyond the scope of this guideline.
SH	Royal College of Paediatrics and Child Health	29.30	Full	1.2	31	Line 11: We recommend that ETCOc is defined in the glossary.	Thank you for your comment. ETCOc has been added to the glossary, as suggested.
SH	Royal College of Paediatrics and Child Health	29.31	Full	1.2	34	We suggest the guideline emphasises that although the baby under phototherapy can be removed for feeding, these times must be minimal to ensure the length of time under phototherapy is maximised.	Thank you for your comment. The GDG agree that there is a need to <b>continue</b> phototherapy for it to be effective. An amendment to "use clinical judgement" has been added to the recommendation concerning breaks in phototherapy although the GDG were satisfied that 30 minutes was a reasonable compromise between the baby's treatment needs and the need to encourage and facilitate bonding between the baby and its parents. The recommendation now reads "Using clinical judgement encourage breaks of up to 30 minutes for breastfeeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated.
SH	Royal College of Paediatrics and Child Health	29.32	Full	1.2	34	Line 16: We suggest adding a statement that the nappy must be put on so that the maximum amount of skin is exposed to the phototherapy light. We note that midwives often have the nappy covering part of the baby's trunk, minimising the effect of phototherapy.	Thank you for your comment. The guideline does already specify that the maximum area of skin should be exposed

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SH	Royal College of Paediatrics and Child Health	29.33	Full	1.2	35	Line 18: We note it may be necessary to give additional fluids to breastfed babies who have clinical evidence of dehydration. We think it is better to give top-ups than to admit to NICU for IV fluids.	Thank you for your comment. The GDG agrees with this view and has clarified in the recommendations that IV fluids should be a last resort.
SH	Royal College of Paediatrics and Child Health	29.34	Full	1.2	36	Line 2: We note that the recommendation against using white curtains is counter to the AAP guidelines, which do recommend this. We note that white or reflective material can be placed around the sides of the cot without completely obscuring the baby.	Thank you for your comment. As there was very little available evidence in the area, the GDG consensus was that it would affect the ability to observe the baby,
SH	Royal College of Paediatrics and Child Health	29.35	Full	1.2	38	Line 3: We note that the difficulty in using number thresholds is that phototherapy may not be used for an excessive rate of rise of bilirubin early enough. A graphical representation in the form of a chart is more useful (see later comment on Table 1).	Thank you for your comment. A graph has been provided in appendix F of the full guideline.
SH	Royal College of Paediatrics and Child Health	29.36	Full	1.2	38	Line 21: We note that, from a practical point of view, a repeat bilirubin within 6 hours would be better; otherwise, mother and child will stay in hospital longer than absolutely necessary. This also has implications on postnatal bed availability.	Thank you for your comment. The GDG amended the "rebound" recommendation to try to reduce hospital stays. However, unless the baby was in a remote area, the GDG did not think that there was a need for them to remain in hospital
SH	Royal College of Paediatrics and Child Health	29.37	Full	1.2	33	Line 8: Anecdotal reports suggest that a haematologist maintains that measurement of G6PD in the neonatal period can be unreliable, or at least that a normal or high G6PD level may be misleading because of the relative abundance of reticulocytes and young erythrocytes in the newborn period (which have higher G6PD levels). Only a low level is diagnostically helpful; a normal or high level is unreliable in ruling out G6PD	Thank you for your comment. Our expert advice was as follows: 'I agree that levels of G6PD are higher in the newborn period. Results should therefore be interpreted as such and a repeat requested a few months later if there is still a need to rule out G6PD deficiency. This should not depend on the lab method used as it is a physiological effect'

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						as a cause of jaundice and should be repeated months later to reliably rule out G6PD. We wonder whether this is true or whether it depends on the precise laboratory test used? The GDG may need expert advice on this.	
SH	Royal College of Paediatrics and Child Health	29.38	Full version	1.2	33	Line 15: This seems like rather a limited number of investigations for 'prolonged jaundice'; the text books contain many more. Perhaps this needs to be explained.	Thank you for your comment. Amendments have been made to this list.
SH	Royal College of Paediatrics and Child Health	29.39	Full version	1.2	35	Line 30: It is not clear what is meant by "routine eye care".	Thank you for your comment This means basic hygiene for the eyes.
SH	Royal College of Paediatrics and Child Health	29.40	Full version	1.2	39	Line 1: We think that adult whole blood has a relatively low haemoglobin and PCV for neonatal use. We note that conventional practice has been to use 'plasma reduced blood' to overcome this. If this is a change in practice, then perhaps an explanation would be helpful.	Thank you for your comment. As the GDG did not review evidence on different blood products in exchange transfusion we have removed this specification from the recommendation. The GDG considered that local advice from a specialist haematologist would be appropriate and available. The recommendation now reads "Use a double-volume exchange transfusion to treat babies"
SH	Royal College of Paediatrics and Child Health	29.41	NICE	1.2.1	10	While we recognise the rationale for the use of the term "intention exclusively to be breastfed" as a risk factor, the College notes that this terminology might introduce confusion. We consider that "exclusive breastfeeding" is clearer and less prone to misinterpretation.	Thank you for your comment. An amendment was made ie "breastfeed exclusively".
SH	Royal College of Paediatrics and Child Health	29.42	NICE	1.3.5 and 1.3.6	12	The term "risk assessment" requires explanation, as it is not currently clear in the text.	Thank you for your comment. This term has now been removed from the recommendations

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SH	Royal College of Paediatrics and Child Health	29.43	NICE	1.4.2	13	The typo "with 6 hours" should be changed to "within 6 hours."	Thank you for your comment. An amendment has been made as suggested
SH	Royal College of Paediatrics and Child Health	29.44	NICE	1.5	14	We recommend specifying the at-risk ethnicities for G-6-PD at this point, as they are not stated elsewhere in the NICE guideline, although they are in the Full guideline in section 1.1.	In this guideline we did not conduct an evidence search addressing the clinical question "risk factors for G6P-D deficiency". Nevertheless we proposed including a list of countries with a high prevalence of the G6P-D deficiency as an appendix as requested, however, following discussion with NICE we have since decided that we cannot pursue this course of action because we have not reviewed the evidence. As such we have made not been able to make the suggested amendment to the guideline.
SH	Royal College of Paediatrics and Child Health	29.45	NICE	1.5	14	We recommend that any infant being investigated in hospital for jaundice have a conjugated bilirubin as part of the work up before instigating treatment. Phototherapy is not the appropriate treatment for an infant with jaundice due to liver disease.	Thank you for your comment. The GDG did not consider that that a split bilirubin test was necessary for all babies requiring phototherapy. Moreover, there would be large resource implications associated with this investigation, to identify the very few babies with conjugated bilirubin results. Babies who have moderate levels (of conjugated bilirubin) and receive phototherapy will not have IV access for more vitamin K. After discussion the GDG decided to leave the recommendation for a split bilirubin for the investigation of prolonged jaundice
SH	Royal College of Paediatrics and Child Health	29.46	NICE	1.5.1	14	We accept the reasons for a packed cell volume in all babies but not necessarily a complete full blood count. However, from a	Thank you for your comment. The GDG considered that some units would choose to use the PCV from the "spun down" bilirubin

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						pragmatic viewpoint, requesting a “packed cell volume” outwith the context of a “full blood count” is unlikely to occur in the vast majority of settings. Would it, therefore, be worth considering “full blood count including packed cell volume” in section 1.5.1 and “examination of blood film” in section 1.5.2?	sample.
SH	Royal College of Paediatrics and Child Health	29.47	NICE	1.5.1	14	We recommend that NICE add information about maternal blood group and full blood count to include packed cell volume and an explanation of the actual effect of maternal anti-D on the reliability of Coombs testing.	Thank you for your comment. We have added mother and baby blood groups and information an anti-D is included in recommendation
SH	Royal College of Paediatrics and Child Health	29.48	NICE	1.5.2	14	We recommend that reticulocyte count be added in the tests.	Thank you for your comment. This was considered but the suggested amendment was not made
SH	Royal College of Paediatrics and Child Health	29.49	NICE	1.5.4	14	We wonder whether urine culture should be added to the investigation list in this group of prolonged jaundiced neonates, as per NICE guideline, Urinary tract infection in children (CG54).	Thank you for your comment. “Urine culture has been added to the investigation list as suggested.
SH	Royal College of Paediatrics and Child Health	29.50	NICE	1.5.4	14	It should be made explicit that if conjugated hyperbilirubinaemia is found that urgent investigation or referral is indicated.	Thank you for your comment. Amendments have been made to make this more explicit
SH	Royal College of Paediatrics and Child Health	29.51	NICE	1.6.5	16	We recommend NIC explain ‘fibreoptic’ and ‘LED’ phototherapy, and give examples of commercially available kit, e.g. “Bilibed”.	Thank you for your comment. Definitions of conventional, multiple, fibreoptic and LED phototherapy have been added to the glossary
SH	Royal College of Paediatrics and Child Health	29.52	NICE	1.6.7	16	We think that term “multiple phototherapy” is unclear. Does the GDG mean double phototherapy or something else?	Thank you for your comment. Definitions of conventional, multiple, fibreoptic and LED phototherapy have been added to the glossary have amended glossary
SH	Royal College of Paediatrics and Child Health	29.53	NICE	1.6.11	16	We recommend the guideline specify supine positioning (“back to sleep”) rather than the unhelpfully vague “usual clinical	Thank you for your comment. This amendment has been made where relevant throughout the guideline.

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						practice”.	
SH	Royal College of Paediatrics and Child Health	29.54	NICE	1.6.8	16	We think that fibre optic phototherapy needs to be described in comparison to conventional phototherapy.	Thank you for your comment. Definitions of conventional, multiple, fiberoptic and LED phototherapy have been added to the glossary
SH	Royal College of Paediatrics and Child Health	29.55	NICE	1.6.13	17	We recommend NIC consider adding “nasogastric”, alongside intravenous/oral feeds.	Thank you for your comment, The GDG considered this addition but decided that recommendations on specific methods of alternative feeding could not be made as the evidence not covered but beyond the scope of this guideline.
SH	Royal College of Paediatrics and Child Health	29.56	NICE	1.6.13	17	We recommend this be rephrased; currently, the sentence implies that breastfeeding should cease during multiple phototherapy.	Thank you for your comment. The recommendation now reads “During continuous multiple phototherapy: <ul style="list-style-type: none"> <li>• monitor hydration by daily weighing, assessing wet nappies</li> <li>• do not interrupt phototherapy for feeding but continue administering intravenous/oral feeds</li> <li>• continue lactation/feeding support so that breastfeeding can start again when treatment stops.</li> </ul> Maternal expressed milk is the additional feed of choice if available, and when additional feeds are indicated.” We hope this is clear.
SH	Royal College of Paediatrics and Child Health	29.57	NICE	1.6.18	17	There should be stress to ensure that all measures are taken to prevent hypothermia during phototherapy.	Thank you for your comment. A definition of thermo-neutral environment has been added to the glossary but as guidance on ambient temperature would vary according to body size, the GDG considered this too complex to give here. Tables of incubator temperatures, etc are available to inform standard nursing

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							care. However, an amendment was made to the recommendation which now reads “During phototherapy: <ul style="list-style-type: none"> <li>monitor the baby’s temperature and ensure the baby is kept in an environment that will minimize energy expenditure (thermo-neutral environment</li> </ul>
SH	Royal College of Paediatrics and Child Health	29.58	NICE	1.6.19 (preterm)	18	In the treatment of preterm babies, the statement, “For babies younger than 72 hours: use phototherapy at lower bilirubin levels” is incredibly vague. We accept that there may not be a strong evidence base, but could this not be clarified – even as expert consensus?	Thank you for your comment., A chart has been added to Appendix F to give guidance for preterm babies <72 hours old.
SH	Royal College of Paediatrics and Child Health	29.59	NICE	1.6.23	19	If the transcutaneous bilirubin falls within the Phototherapy (or even Exchange Transfusion) range, should it be recommended that bilirubin is confirmed on serum testing at the start of phototherapy – while not delaying the start for the result? Although data is given in the full guideline, it is unclear whether the correlation in the individual patient between TCB and TSB is good enough for serial measurements, i.e. are we comparing like with like?	Thank you for your comment. Amendments have been made as suggested that bilirubin can be checked without treatment delays to treatment . Once phototherapy has started the GDG has recommended TSB
SH	Royal College of Paediatrics and Child Health	29.60	NICE	1.6.27	19	We recommend that this be changed to check for rebound serum bilirubin between six and 12 hours after stopping phototherapy (instead of between 12 and 18 hours).	Thank you for your comment which the GDG considered but decided they were satisfied with their initial statement. The recommendation reads: “Check for rebound of hyperbilirubinaemia with a repeat serum bilirubin measurement between 12 and 18 hours after stopping phototherapy – babies do not necessarily

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							have to remain in hospital for this to be done"
SH	Royal College of Paediatrics and Child Health	29.61	NICE	1.6.29	20	The term, "with or at risk of significant hyperbilirubinaemia" requires clarification.	We agree, we have taken 'significant hyperbilirubinaemia' to mean hyperbilirubinaemia levels at which an exchange transfusion is indicated  This definition has been added to the glossary
SH	Royal College of Paediatrics and Child Health	29.62	NICE	1.6.31	20	A dosage recommendation for IVIG would be very helpful here.	Thank you for your comment, The GDG has suggested a dose 500 mg over 2-4 hours in the text,
SH	Royal College of Paediatrics and Child Health	29.63	NICE	1.6.32		We are very concerned that IVIG is only briefly mentioned even though the NNT appears good. We note that exchange transfusions are risky and many neonatologists would probably use IVIG rather than undertake an exchange if time allowed them to do this.	Thank you for your comment. The GDG agreed with this and an amendment has been made in accordance with your concerns
SH	Royal College of Paediatrics and Child Health	29.64	Full	Table 1	37	The College notes that Table 1 would better be presented as a chart, not a table. A chart would be easier to use and it will be easier to see the rate of rise and improvement.  One paediatrician notes that plotting this in relation to the current local phototherapy chart, the AAP chart and Bhutani's nomogram gives exchange transfusion and phototherapy lines which are similar to those which would be expected and also to AAP guidelines.  The "consider phototherapy" in the first 24 hours of life should be considered for	Thank you for your comment. . A graph will be provided in a appendix F of the full guideline.  The GDG agree that the Bhutani prediction is a very useful piece of work , however, all babies with haemolysis were excluded from the chart. It cannot be known in a single baby that the bilirubin will not rise at, say, 8 micromol/l/h due to haemolysis and hence will "jump tracks" on the Bhutani nomogram. They only have a 0% change of moving up into the higher risk zone with the benefit of hindsight.

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						<p>rewording as the College cannot think of a situation where paediatricians would not start phototherapy at 6 hours of age with a serum bilirubin of 110micromol/L. Compared to current practice, this line becomes a bit cautious as it would be unlikely that a paediatrician would repeat a serum bilirubin of 250 at 72 hours of life in a well, feeding baby, let alone consider phototherapy. It correlates with the AAP less than full term phototherapy line though and we like the use of the term "consider" as it gives some leeway in devising local guidelines and referral pathways.</p> <p>The biggest concern is the "repeat TcB/SBR 6-12 hours later" category. Before 24 hours of age this gives an inexperienced clinician permission to leave a baby with a serum bilirubin of 100 at 6 hours of age for up to 12 hours before repeating it. Then from 36 hours of age the line correlates with Bhutani's 40<sup>th</sup> centile.</p> <p>The College has some concerns that it may not be feasible to repeat the TcB/TSB 6 – 12 hourly in babies who Bhutani found had a 0% risk of moving up to the high risk zone. This would apply to a huge number of babies and the majority would end up being sent into A&amp;E because it is not feasible for the community midwives to check bilirubins that frequently for that long.</p>	<p>The GDG discussed the time frame for a repeat test and believed that a check 1-2 hours after the initial test would be too soon given the error of the measurement. Furthermore the GDG recognised that some babies would be distant from hospital and such a recommendation could be impracticable.</p> <p>The GDG felt that 4 hourly repeat was too soon , and expert advice from the Royal Coll Path is that 6 hours is the minimum to be able to establish a reliable trend</p>

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						<p>We wonder how many of the kernicterus cases known to the panel developed it after they had had a reading of 100 or even 150micromol/L at 24 hours of age. Although we agree that we need to be better at picking jaundice up earlier, the College feels that the GDG's plans for our follow up regime after a first, relatively low, reading are so impractical and disruptive to baby, family and clinical staff that they need to be supported by better evidence before being imposed.</p> <p>We would suggest that NICE change column 1 to "Repeat serum bilirubin 4-6 hourly", have &gt;80 at 6 hours, &gt;100 at 12 hours, &gt;120 at 18 hours, &gt;137 at 24 hours and lose the rest of that column. Then change the second column's title to "Consider the need for phototherapy (check serum bilirubin 4-6 hourly in the first 24 hours of life)". We think these tweaks would make your table equally safe but more efficient.</p>	
SH	Royal College of Paediatrics and Child Health	29.65	NICE	Table 1	9 & 18	For reference purposes in clinical practice, this table is the most important part of the Guideline and the College has a few concerns regarding this. Firstly, use of >number in the boxes is potentially problematic. For example, a baby at 6 hours of age with a Bilirubin of 126 would fall into the >125 box, the >12 box and the >100 box leading to potential confusion regarding management. Whilst this may seem minor,	Thank you for your comment. We do not expect clinical staff to refer to this table to make clinical decisions as we have now proved graphs and MS Excel spreadsheets which will be used in clinical practice. We envisage that most babies $\geq$ 38 week will be in the community and the 'consider phototherapy' is to provide an indicator for community midwife, health visitor, GP etc to transfer the baby to a neonatal unit for

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						<p>we note that it is possible a busy clinician referring to the table might make mistakes. We would therefore prefer more defined ranges, e.g. 100-111, 112-124, 125-149 etc. Although this may make the Table “busier”, we do feel that it would be clearer.</p> <p>Our second concern is with the column “Consider Phototherapy”. While we assume that this is in place to allow clinicians scope to use their judgement, we do feel some guidance should be given as to what criteria to use in this consideration.</p>	phototherapy if required
SH	Royal College of Paediatrics and Child Health	29.66	NICE	Table 1	9 & 18	There needs to be an explanation of the distinction between “considering phototherapy” and the next column “phototherapy”.	Thank you for your comment. The GDG did not amend the wording as they did not want to preclude the option of a baby remaining at home if it was feeding well. If the bilirubin levels did not drop or stabilize there would be enough time to remain with safe limits before readmitting for phototherapy
SH	Royal College of Paediatrics and Child Health	29.67	NICE	Table 1	9	It is envisaged that a lot more babies than anecdotal reports of current practice suggest will undergo phototherapy between 36-72 hours if the Table 1 is strictly adhered to.	Thank you for your comment. The GDG acknowledged that there was variation in current practice and that the number of babies who would undergo phototherapy, according to this guidance, is uncertain. They believed that audits would be informative.
SH	Royal College of Paediatrics and Child Health	29.68	NICE	Table 1	9	The issue of whether to exchange is important and here the guideline is vague. Table 1, which is repeated twice in the document, has the same level at time 0 and more importantly does not mention IVIG use (although later suggests it can be used).	Thank you for your comments. The GDG believed they have stressed IVIG use where appropriate in the guideline.
SH	Royal College of	29.69	Full	Table 1	37	While we reiterate that this is an informative,	Thank you for your comment. The GDG

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	Paediatrics and Child Health					helpful document on which to base local policies, we think there needs to be a bit more emphasis on efficiency. In particular, Table 1 needs some significant amendments to make it sensible, safe and not a medico legal minefield for any clinician taking it upon themselves to say at 96 hours of life that a north European, bottle fed, well, full term baby whose mother is blood group A+, with a serum bilirubin reading of 252 does not need any further testing.	would argue that in fact such a baby does merit further testing. The advice in the guideline is to continue to reassess.
SH	Royal College of Paediatrics and Child Health	29.70	NICE	Table 1	9	We think that NICE should not miss this unique opportunity to produce a universal, nationally recognised graph/nomogram or set of graphs, derived from the numerical data in the table. We recommend that these are in three forms: a) a generic printable graph that could be displayed for reference on notice boards, etc. b) a patient specific graph with space for name, hospital number, bilirubin levels, etc. The clinician can plot the individual baby's values on to form part of the medical record. c) an electronic version of the graph (as part of a future electronic patient record) using a macro whereby age, bili level etc is entered and the result is plotted on the graph.	Thank you for your comment. Graphs have been provided in appendix F of the full guideline and your comment will be passed to the Implementation team at NICE.
SH	Royal College of Paediatrics and Child Health	29.71	NICE	Table 1 (preterm)	9	The treatment on preterm babies is also weak. We would like to see stronger guidance here as the risk in preterm babies may be far greater than in term. The statement about the need to consider exchange at lower levels, without indicating	Thank you for your comment. Amendments to the graph have been made to reflect your suggestion,

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						the level, for babies younger than 72 hours seems very weak.	
SH	Royal College of Paediatrics and Child Health	29.72	Full	3.1	62	We agree with the evidence and feel the way that it had been written is not discouraging women from breast feeding.	Thank you for your comment
SH	Royal College of Paediatrics and Child Health	29.73	Full version	4.1	75	Line 9: We think that this is an important conclusion, which, if correct, should be included in the short version together with an explanation. We are unsure whether the GDG is suggesting that cord blood bilirubin and haemoglobin should not be measured in babies identified as being at risk of rhesus haemolysis.	Thank you for your comment. The GDG has recommended that cord blood samples are taken in Rhesus disease which is a very specific indication and we have amended the translation to reflect this.
SH	Royal College of Paediatrics and Child Health	29.74	Full	4.1	100-101	The recommendations are practical whilst still be very clear and clinically relevant.	Thank you for your comment
SH	Royal College of Paediatrics and Child Health	29.75	Full	4.4	87	We think that Bhutani's nomogram is worthy of more emphasis. Although devised from one small urban population it is now in use across the USA as it forms part of the AAP guidelines on management of early onset jaundice. We do not think the exclusion of ABO incompatibility cases from his study detracts from its usefulness as a predictor of hyperbilirubinaemia as, by 12 hours, most ABO cases would be in one of the intermediate if not the high risk zones and warrant a timely repeat test. The strength of the nomogram lies in its negative predictive value and we have found use of it gives junior paediatricians the confidence to send babies home.	Thank you for your comment which is noted. We have discussed Bhutani's nomograms at length in translation throughout the guideline
SH	Royal College of Paediatrics and Child	29.76	Full	4.6	92	Thank you for endorsing transcutaneous bilirubinometry. One paediatrician reports	Thank you for your comments. The GDG agrees that 250 is a fairly high cut-off but

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	Health					<p>that she currently uses it before 24 hours of age. We note that the confidence interval is so wide around the mean differences between TcB and TSB, that we agree with your advice to use it after 24 hours of age on grounds of safety. Although the BiliChek performs well in different ethnic groups, anecdotal reports show that the Minolta JM-103 gives a consistently higher reading than TSB in babies with pigmented skin and consistently lower in white babies. However, the difference in the performance of the 2 devices was not sufficiently clinically significant to justify the extra expense of the BiliChek's disposable tips.</p> <p>Thank you also for choosing a cut off of 250 micromol/L on the transcutaneous devices before a TSB is required. This is a fairly high cut off but we note this will be safe after 24 hours of life and indeed those areas of the country with a high proportion of black babies may need to shift it even higher after local audits to avoid too many babies being over-investigated.</p> <p>We hope once your guideline is published that the NHS strikes a suitable deal with the manufacturers of these devices.</p>	hopes that you are correct that it proves safe and workable. Newer evidence is emerging on the use of TcB in preterm babies and we have amended the guideline regarding this too,
SH	Royal College of Paediatrics and Child Health	29.77	Full	6.8	145	The section on prolonged jaundice is not very clear and requires clarification. It reads that these babies only need a split bilirubin and their stools inspected though the evidence cited seems to suggest that they	Thank you for your comment, The text has been amended, as suggested, to reflect the need for first line investigations and a recommendation to address identification of conjugated bilirubin has been added.

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						would also still need the other first line investigations, e.g. FBC, Group and DCT etc.	
SH	Royal College of Paediatrics and Child Health	29.78	Full	7	152	The guideline should contain a recommendation to provide guidance as to how far away the phototherapy light is from the baby.	Thank you for your comment. The GDG referred to manufacturer's instructions for the purpose of this guideline
SH	Royal College of Paediatrics and Child Health	29.79	NICE	31	Appendix C	In the algorithm, "does the baby have risk factors?", it is unclear how many risk factors this applies to (i.e., whether this means that 1,2 or all 3 risk factors should be present)	Thank you for your comment, An amendment has been made to the algorithm to clarify if "the baby have <b>any</b> " risk factors?"
SH	Royal College of Paediatrics and Child Health	29.80	Full	7.1.2	165	Line 16: It seem inconsistent to justify the use of fibre optic phototherapy for preterm infants on the grounds of parental acceptability and yet to not apply this same argument for term infants.	Thank you for your comment. Whilst there was evidence available to support effectiveness of fibre optic phototherapy for preterm infants on the grounds of parental acceptability there was no evidence available for term babies. The recommendations reflect this.
SH	Royal College of Paediatrics and Child Health	29.81	Full	7.1.4	169	Line 2: We recommend that the GDG make a clear statement on positioning for phototherapy to recognise the importance of consistent advice and practice about supine sleeping/positioning as an important public health measure for reducing the risk of sudden infant death syndrome.	Thank you for your comment. Amendments have been made to the text to recommend a supine sleeping position wherever possible.
SH	Royal College of Paediatrics and Child Health	29.82	Full	7.1.11	178	Line 7-8: The sentence, "Babies with haemolysis, G-6-PD deficiency, fever, maternal use of narcotic analgesics during labour or ruptured membranes > 18 hours" appears not to be complete. Were these babies excluded from the study?	Thank you for your comment. An amendment to the text has been made as suggested.
SH	Royal College of Paediatrics and Child Health	29.83	Full version	7.1.12	183	Line 30: We recommend the GDG specify what the threshold value for this is, i.e. number of micromols within 6 hours of	Thank you for your comment. An amendment has been made as suggested. We have specified ceasing moving to multiple

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						starting conventional phototherapy.	phototherapy if bilirubin levels do not stabilise or fall
SH	Royal College of Paediatrics and Child Health	29.84	Full version	Table 7.1 And 7.1.12	186 & 187	(187: Line 6) The row for age 96+ hrs, we think that a transcutaneous bilirubin of >250 should be an indication for measuring serum bilirubin (rather than repeating transcutaneous value 6-12 hours later).	We have amended the table so that the repeat transcutaneous stops at 72 hours and if the baby reaches >250 the n the phototherapy charts will be used.
SH	Royal College of Paediatrics and Child Health	29.85	Full version	7.2	192	The guideline should mention the use of intravenous immunoglobulin here for rhesus but not ABO incompatibility.	Thank you for your comment, Amendments have been made to recommend IVIG in Rh disease and ABO with rapidly rising bilirubin. A research recommendation has also been made.
SH	Royal College of Paediatrics and Child Health	29.86	Care Pathway		General	This pathway is simple, informative and evidence based.	Thank you for your comment
SH	Royal College of Paediatrics and Child Health	29.87	Care pathway			<p>It is difficult to comment on as the diagram is not properly visible, and not all the writing is visible in the boxes.</p> <p>The immediate impression is that in areas of the country where exclusive breastfeeding numbers are high, the vast majority of babies will fall into the 'at risk group' and will need reviewing within 48 hours. We wonder whether that is feasible in the community. Testing every baby a community midwife or a family member thinks is slightly yellow is going to mean a huge increase in inconvenience and workload even if all community midwives have a transcutaneous bilirubinometer (TcB). We worry that many, many more well babies will be turning up to A&amp;E because the midwives</p>	Thank you for your comment. The evidence base shows that visual assessment is unreliable; hence it is clear that measurement is required; it is beyond the scope of this guideline to suggest service delivery strategies for obtaining these measurements

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						can not return 6 – 12 hours later to repeat a TcB even if the first one is not a “positive” reading.	
SH	Royal College of Paediatrics and Child Health	29.88	Care pathway			<p>The green top left hand box says “Consider discharge at less”, and we think this should be corrected to “Consider discharge less than 24 hours”.</p> <p>It looks as if all babies jaundiced at birth should have TSB measured, and all the rest should be reviewed daily and have TSB or TCB estimated if they become visibly jaundiced. This may result in a lot more interventions than is the case at present.</p>	Thank you for your comment; this has been amended as suggested. As babies are not jaundiced at birth and jaundice in the first 24 hours is a recognised emergency, the GDG considered that a TSB is required in this situation. Other babies are reviewed according to risk factors and need, and at “every available” opportunity. Whether or not this will result in more (or less) intervention is uncertain
SH	Royal College of Paediatrics and Child Health	29.89	Appendix B	Results	9	<p>There is an error in the first calculation (numbered 1). <math>690,000 \times 0.1 = 69,000</math> should actually be <math>690,000 \times 0.6 \times 0.1 = 41,400</math> as we currently test 10% of the 60% who are visibly jaundiced. The cost of current practice is therefore £1.01million rather than £1.68million. The modelling in the rest of this section is therefore also wrong though we are not certain that it makes a huge difference to the conclusions overall.</p> <p>There is no mention in the cost workings in Appendix 2 of the increased cost to the hospital of potential increased length of stay.</p>	<p>Thank you for your comment. We have amended the calculation error and the ensuing modelling .</p> <p>The GDG did not believe that length of hospital stay would increase as a consequence of the guideline recommendations</p>
SH	Royal College of Paediatrics and Child Health	29.90	Algorithm	General	General	We note that the algorithm is illegible if printed on an A4 sheet, which may be important for units using paper protocol folders.	Thank you for your comments. The lozenge algorithm has been removed. .

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						The algorithm suggests that phototherapy be started if serum bilirubin is >100 in the first 24 hours of life. This is at odds with Table 1 (page 28 in full guideline).	
SH	Royal College of Paediatrics and Child Health	29.91	NICE	Patient - centred care	5	The College recommends that treatment and care be done in the child's best interest, regardless of parents' views.	Thank you for your comment
SH	Royal College of Paediatrics and Child Health	29.92	NICE	Key priorities for implement	8	In the last bullet under Formal assessment, we would like clarification on whether this refers to prolonged jaundice only or all jaundice.	Thank you for your comment. An amendment has been made for clarity
SH	Royal College of Paediatrics and Child Health	29.93	NICE	1.5.6	15	We would like clarification on whether this includes babies with very high conjugated and low unconjugated bilirubin.	Thank you for your comment. Yes this would also include babies with very high or low conjugated bilirubin although the GDG recommend only looking for conjugated bilirubin in prolonged jaundice.
SH	Royal College of Paediatrics and Child Health	29.94	NICE	1.6.16	17	We note that we are unsure of the relevance of white curtains.	Thank you for your comment, This recommendation was made on the basis of GDG consensus as there is very little work in the area. The GDG believed that white curtains would affect the ability to observe the baby,
SH	Royal College of Pathologists	16.01	Full	General	General	Overall I found this a very clearly written and easy to read document, using non technical language where possible, especially in the recommendations section, and in the short version. There are a number of typos and spelling mistakes that I assume will be corrected at final proofreading. Eg all Tables in Section 2	Thank you for your comments. Amendments have been made to the text as suggested.

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						are referred to in the text as numbers 1.1, 1.2 etc instead of 2.1, 2.2 etc	
SH	Royal College of Pathologists	16.02	Full	2.1	42	Line 14: Suggest replace "partly" bound to albumin by "largely or mostly"	Thank you for your comment. The text has been amended as suggested
SH	Royal College of Pathologists	16.03	Full	4.4	82	I found the paragraph from lines 4 -14 difficult to follow. I assume 1 <sup>st</sup> percentile is a misprint and refers to a higher percentile or crossing centiles. There is inconsistent use of micromol/L and mg/dL within this and the following paragraph.	Thank you for your comment, This paragraph has been amended for clarity. The inconsistency was based on 1 study which used track 15 for over 15 mg/dl which did not translate well into micromol/L
SH	Royal College of Pathologists	16.04	Full	5.3	110	I had ask Google what an icterometer is or was. Is it still in production, and is it still used anywhere within the UK? Suggest at least add this term to the Glossary, along with transcutaneous bilirubinometer and clearly distinguish that the latter measures skin yellow colouration by reflectance measurement, while the former depends on an observer matching to blocks of colour.	Thank you for your comment. Definitions of both an icterometer and a bilirubinometer have been added to the glossary.
SH	Royal College of Pathologists	16.05	Full	5.3	111 -112	It would be helpful to indicate the dates and locations of the icterometer publications.	Thank you for your comment. The references have been amended as suggested. The text now reads 'The studies were carried out between 1974 and 1998 in the USA(2), Rhodesia, Tanzania and Turkey.'
SH	Royal College of Pathologists	16.06	Full	6.5	141	Bilirubin/albumin ratio is not recommended, which I fully agree with. The literature reviewed simply stated that albumin was by standard laboratory methods. It did not identify an important potential error in the calculated ratio ie that the most commonly used laboratory albumin methods	Thank you for your comment. An amendment has been made to the GDG translation to clarify this. ,

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						(bromocresol green & bromocresol purple) overestimate albumin compared to gold standard methods, especially at low albumin concentrations, such as are found in premature infants. The degree of overestimation depends on the reaction conditions and analyser used, as well as the dye selected. External Quality Assurance Data from Oct 09 ( <a href="http://www.birminghamquality.org.uk">http://www.birminghamquality.org.uk</a> ) demonstrates that the affected dye binding methods are used by virtually 100% of NHS laboratories. A key review is: The measurement of albumin in serum and plasma. Hill PG Ann Clin Biochem 1985; 22: 565-578. More recently: Measurement of serum albumin by capillary zone electrophoresis, bromocresol green, bromocresol purple and immunoassay methods. Duly EB, Grimason S, Grimason P, Barnes G, Trinick TR	
SH	Royal College of Pathologists	16.07	Full	6.6	142	Line 19: The heading is conjugated/unconjugated bilirubin, but the text refers to free bilirubin and unconjugated/indirect bilirubin. Suggest rename "Relationship between circulating free bilirubin and unconjugated bilirubin."	Thank you for your comment. The text has been amended as suggested.
SH	Royal College of Pathologists	16.08	Full	General		The term "serum bilirubin" is used throughout the document. Circulating bilirubin may be measured in whole blood by point of care testing analysers, in plasma from eg Lithium heparin tubes, or in serum.	Thank you for your comment. The GDG discussed this point and decided to retain the term "serum bilirubin" throughout the document but amended the glossary as suggested.

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						Suggest either: replace serum by circulating or: define serum bilirubin to include all of the above.	
SH	Royal College of Pathologists	16.09	Full	6.7	142	Line 31: Suggest expand title to "Medical co-morbidity identified by measuring conjugated bilirubin, routine haematology or urinalysis."	Thank you for your comment. The text has been amended as suggested.
SH	Royal College of Pathologists	16.10	Full	6.8 & 1.1 & algorithm	146 & 27	(146: line 20; 27: line 25) Does "routine metabolic screening" refer to population newborn screening, that in the UK would include testing for primary hypothyroidism? Suggest replace "routine metabolic screening" with "newborn bloodspot screening"	Thank you for your comment. An amendment has been made as suggested.
SH	Royal College of Pathologists	16.11	Full	7.1.8	174	Line 10-16: The methods for measuring bilirubin must be capable of accurately differentiating between sequential results to measure a true rate of increase. A threshold of 6 hourly testing will safely do this, and is a much clearer statement than the hourly increase rate, that might encourage bilirubin measurements too frequently to meet this standard. There is a UK guideline for laboratory performance of bilirubin measurement that the guideline group might like to consider. Access on <a href="http://www.birminghamquality.org.uk/">http://www.birminghamquality.org.uk/</a> >> education >> guidelines.	Thank you for your comment which has been accepted in principle, although the specific document was password protected and consequently not viewed. Stakeholders commented on this point although there was variation in their suggestions regarding frequency of measurement.
SH	Royal College of Pathologists	16.12	Full	Table 7.1 & 1.1 Table 1	186 & 29	(186: Line 32; 29: Line 9) Use phototherapy at lower bilirubin levels. Suggest replace by: Use phototherapy when bilirubin reaches the "consider phototherapy" level.	Thank you for your comment. The GDG did not amend the wording as they did not want to preclude the option of a baby remaining at home if it was feeding well.
SH	Royal College of	16.13	Jaundice	Genera	Gene	This large file takes in excess of 10 minutes	Thank you for your comments. This will be

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	Pathologists		Algorithm	I	ral	to download onto my NHS computer. If I print it I get a single page with the type too small to read, or an enlargement of only part of the diagram. Suggest it is re-formatted to use less memory (do grey background boxes really add any information?), and also so that the default print setting produces a hardcopy readable document, across several A4 pages if necessary.	passed on to the Editors at NICE
SH	Royal College of Physicians	22.01	Full	General	General	The Royal College of Physicians is grateful for the opportunity to comment on the guideline consultation. The proposed guidelines have been extensively researched and are based on the best available evidence. We are generally supportive of the guidelines.	Thank you for your comment
SH	Royal College of Physicians	22.02	Full	General	General	<p>There are particular sensitivities around the issue of exclusive breast feeding. The document states that the risk factors for hyperbilirubinaemia are:</p> <ul style="list-style-type: none"> <li>• gestational age under 38 weeks</li> <li>• history of a previous sibling with jaundice requiring treatment</li> <li>• mother's intention exclusively to breastfeed</li> <li>• visible jaundice in babies under 24 hours</li> </ul> <p>It is our opinion that it would be better to separate exclusive breast feeding from the other three 'medical' risk factors, and place</p>	Thank you for your comment. We have revised the recommendation to remove the word 'risk', however, the GDG felt that it was not appropriate to separate breast feeding from other factors.

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						it in a separate category. There is a risk that the guidelines as currently formulated will be interpreted by parents and midwives as a reason not to exclusively breast feed because it is a 'risk factor'.	
SH	Royal College of Physicians	22.03	Full	General	General	Our other major comment is that the proposed management of neonatal jaundice depends entirely on the nationwide availability of community midwifery staff who will be available on a 24 hour basis over the first days of life to examine, assess and refer newborns as necessary. However, there is good evidence that there are serious deficiencies in the availability of community midwives in many areas across the country. Hence the promotion of the guidelines must go hand in hand with practical initiatives to improve the recruitment retention and training of community midwives, especially in under-resourced areas.	Thank you for your comment. Recommendations regarding service provision are without the scope of this guideline.
SH	Royal Society of Medicine	1.01	Full	6.8	147	The tables that come after page 147 do not relate to prolonged jaundice	Thank you for your comment. These tables do not relate to prolonged jaundice, but rather support text earlier in the chapter.
SH	UNICEF Baby Friendly Initiative	10.01	Full	General		UNICEF UK recognises the need for this guideline and acknowledges the amount of work which has gone into it's development. We are grateful for the opportunity to comment.	Thank you for your comment.
SH	UNICEF Baby Friendly Initiative	10.02	Full Summary Care pathway	General	General	The drive to improve breastfeeding rates in the UK has gained momentum over the last few years and the importance of exclusive breastfeeding is clearly recognised and backed by both Government and NICE.	Thank you for your comment. We have revised the recommendation to remove the word 'risk', however, the GDG felt that it was not appropriate to separate breast feeding from other factors.

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						<p>However, increasing exclusive breastfeeding rates in the current culture both amongst families and within the NHS is still proving to be a major challenge. Avoidance of supplementation with infant formula unless this is clearly medically indicated is one of the greatest challenges. We acknowledge that greater number of breastfed babies show significant jaundice than amongst bottle fed babies and that this in great part due to ineffective breastfeeding. It is clear that this guideline in categorising "intention to exclusively breastfeed" as a risk factor is seeking to help prevent the ineffective breastfeeding which can lead to significant jaundice, however we feel very concerned that listing it in this way as a risk factor, together with the other clear risk factors and without qualification will result in staff believing that offering supplements of infant formula is acceptable practice in their attempts to avoid jaundice.</p> <p>Would it be possible to maintain the list of risk factors with the three other factors identified whilst separating out mothers intention to exclusively breastfeed. This could possibly be highlighted separately for example as a factor requiring effective or additional observation and support?</p>	
SH	UNICEF Baby Friendly Initiative	10.03	Full, Summary, care	General	General	In order for staff to be effectively empowered to discuss the risk factors as listed in the guideline with mothers without	Thank you for your comment, The GDG considered your comment and have added an additional point in the recommendations

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			pathway			causing undue anxiety or precipitating a mothers decision to offer infant formula significant training would be needed. At Baby Friendly assessments, assessors frequently encounter mothers who have offered formula at staffs suggestion due to concerns re jaundice even when this has not been severe or required treatment so this is currently an issue and it is of concern that the guideline may worsen this practice	on information that jaundice is not a reason to stop breastfeeding.
SH	UNICEF Baby Friendly Initiative	10.04	Full	3.1	62	Lines 25-31: It is recognised that in the full guideline the GDG expresses their aim that the contents do not reduce the number of mothers encouraged to breastfeed exclusively, however for the large numbers of staff who will not read this part of the document in detail, we feel that this will go unrecognised.	Thank you for your comment. We have included a recommendation in the information section of the guideline that parents/carers should be given reassurance that breastfeeding can usually continue. We have also revised recommendations that deal with breastfeeding in the treatment section to improve the tone in line with concerns. These amendment will ensure that our position is clear and consistent throughout all versions of the guideline
SH	UNICEF Baby Friendly Initiative	10.05	Full Summary	7.1.12	184	Line 19: The recommendation that phototherapy may be discontinued for 30 minutes every 3-4 hours has the potential to undermine breastfeeding if adhered to rigidly by staff. Most babies when demand fed would ask to feed more frequently than this. How should staff deal with babies who are unsettled and demand to be fed more frequently? In addition, restricting feed frequency could lead to insufficient milk supply and/or breast engorgement and	Thank you for your comment. The GDG agrees that some flexibility is possible and an amendment has been made to reflect this. Although the GDG would stress there is a need to <b>continue</b> phototherapy for it to be effective. An amendment to "use clinical judgement" has been added to the recommendation concerning breaks in phototherapy although the GDG were satisfied that 30 minutes was a reasonable compromise between the baby's treatment

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						subsequent suppression of lactation. 30 minutes may not be sufficient time to feed a sleepy baby and whilst the importance of not reducing the time under phototherapy excessively, setting a limit on time like this may result in the feed being cut short, reducing the milk volume ingested and the amount of high fat milk available to the baby. Use of the term "allow" for discontinuation of phototherapy for feeding sounds patronising.	needs and the need to encourage and facilitate bonding between the baby and its parents. The recommendation now reads: "Using clinical judgement encourage breaks of up to 30 minutes for breastfeeding, nappy changing and cuddles as long as the bilirubin levels are not significantly elevated"
SH	UNICEF Baby Friendly Initiative	10.06	Full	7.1.12	184	Line 22-23: Recommending the use of maternal expressed breastmilk should additional fluids be required is welcomed. It may be possible to further strengthen this statement and the likelihood of expressed milk being available by suggesting a proactive approach to expressing should phototherapy be commenced and additional fluids be likely to be required.	Thank you for your comment. An amendment has been made to the text to recommend expressing when phototherapy starts, as suggested
SH	UNICEF Baby Friendly Initiative	10.07	Full Summary	7.1.12	184	Line 26-27: In the full guideline it is suggested that during multiple phototherapy, do not interrupt phototherapy for feeding but continue administering IV/oral fluids, however the summary guideline refers to IV fluids only. Staff may query how they are expected to give oral fluids whilst phototherapy continues.	Thank you for your comment. The GDG have recommended that babies can have tube feeds during continuous phototherapy
SH	Welsh Assembly Government	7.01	NICE	Patient Centred Care	5	The text in the second sentence of the second paragraph reads:  <i>"If parents do not have the capacity to make decisions, healthcare professionals should</i>	Thank you for your comment, An amendment has been made as suggested.

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						<p><i>follow the Department of Health guidelines – ‘Reference guide to consent for examination or treatment’ (2001) (available from <a href="http://www.dh.gov.uk">www.dh.gov.uk</a>).”</i></p> <p>Could the following text be added to reflect that similar guidance has been issued in Wales:</p> <p><i>“In Wales, healthcare professionals should follow the guidance issued by the Welsh Assembly Government in 2008 – ‘Reference Guide for Consent to Examination and Treatment’ (available from <a href="http://www.wales.nhs.uk/consent">www.wales.nhs.uk/consent</a>)”</i></p>	
PR	Peer Reviewer 1 – Oakland University	28.01	Full	1.1	25	<p>Lines 22-28: in the listed risk factors for hyperbilirubinemia, I wonder why documented hemolytic disease (ABO, Rh or other isoimmune disease or G6PD) was not included as a risk factor.</p>	<p>Thank you for your comment. During our search of the evidence for risk factors we identified “history of a previous sibling with neonatal jaundice requiring phototherapy” as a factor that influences hyperbilirubinaemia, and this would take into account the two most likely causes of hyperbilirubinaemia (ABO incompatibility and G-6PD deficiency).”</p> <p>Maternal and child blood groups ( ABO and Rhesus) do not take account of other familial causes of hyperbilirubinaemia such as G6P-D deficiency, spherocytosis and minor blood group incompatibilities</p>
PR	Peer Reviewer 1 – Oakland University	28.02	Full	1.1	27	<p>Line 3: the heading reads "Recommendations - Prolonged Jaundice," but most of the subsequent text has nothing</p>	<p>Thank you for your comment. An amendment has been made to the text as suggested</p>

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						to do with prolonged jaundice. It is only addressed on L21 so that "prolonged jaundice" should be removed from the heading and reinserted on L20.	
PR	Peer Reviewer 1 – Oakland University	28.03	Full	1.1	27	Line 24: I don't understand the need for evaluating the stool color if you measure a total and conjugated bilirubin on an infant with prolonged jaundice. If the conjugated bilirubin is not elevated, there is no cholestasis and the stool color is irrelevant. Of course, stool color is an important screening tool and if pale requires the measurement of a total and direct or conjugated bilirubin. The advice to measure a conjugated bilirubin should read "the conjugated or direct reacting bilirubin." Many labs do not measure the conjugated bilirubin, which is only available if the Vitros technique is used. In all other labs that use a standard diazo technique, the measurement is of total and direct reacting bilirubin so that measurement of conjugated bilirubin should not be a requirement.	Thank you for your comment, The GDG recognised that some stakeholders would be concerned that some babies with serious liver disease do not have elevated bilirubin and would support the recommendation of examination of stool and urine
PR	Peer Reviewer 1 – Oakland University	28.04	Full	1.1	28	Table 1: Perhaps the guidelines for exchange transfusion should add the qualifier "if there is a failure to respond to multiple phototherapy." Is there no provision for a trial of phototherapy in an infant who has a bilirubin level of 205 µmol/L at age 12 hours? The overwhelming majority of such infants have ABO hemolytic disease and, in the vast majority of these infants, their subsequent bilirubin levels will either not increase dramatically or they will	Thank you for your comment, The GDG considered this but did not choose to make an amendment.

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						respond quite well to phototherapy. Thus, the recommendation to do an exchange transfusion at bilirubin levels at >200 µmol/L in a 12-hour-old infant will lead to many unnecessary exchanges.	
PR	Peer Reviewer 1 – Oakland University	28.05	Full	1.1	29	Line 8: If you apply the formula for phototherapy for preterm infants to a 25-week gestation infant who is 72 hours old, such an infant could have a bilirubin level of 230 µmol/L at age 72 hours but not qualify for phototherapy. This seems a little daring to me in view of the recent Morris et al study (New England Journal of Medicine 2008;359:1885-1896).	Thank you for your comment. The GDG have specified lower levels for younger babies, in graphs added in Appendix F but acknowledge that there is considerable variation in practice currently.
PR	Peer Reviewer 1 – Oakland University	28.06	Full	1.2	29	Line 14: You do not include any form of hemolytic disease with the risk factors. Surely ABO incompatibility with a positive Coombs' test should be included here as a risk factor as would Rh disease or G6PD deficiency etc.	Thank you for your comment. During our search of the evidence for risk factors we identified "history of a previous sibling with neonatal jaundice requiring phototherapy" as a factor that influences hyperbilirubinaemia, and this would take into account the two most likely causes of hyperbilirubinaemia (ABO incompatibility and G-6PD deficiency)." Maternal and child blood groups ( ABO and Rhesus) do not take account of other familial causes of hyperbilirubinaemia such as G6P-D deficiency, spherocytosis and minor blood group incompatibilities.
PR	Peer Reviewer 1 – Oakland University	28.07	Full	1.2	31	Line 12: It is not clear to me why you exclude Coombs' testing as a potential predictor of hyperbilirubinemia. It is true that, by itself, the DAT is not an excellent predictor but, in the presence of ABO	Thank you for your comment. The evidence was that DAT was not useful as a predictor but was useful in assessing cause.

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						incompatibility, the presence or absence of a positive DAT certainly changes the likelihood of the infant subsequently developing or not developing significant hyperbilirubinemia.	
PR	Peer Reviewer 1 – Oakland University	28.08	Full	1.2	36	Line 19: You recommend measuring the serum bilirubin or obtaining a transcutaneous bilirubin on all infants who are jaundiced, but you do not include that bilirubin level as a risk factor. Later on in the document you do not recommend universal measurement of bilirubin on all infants prior to discharge but, as you do recommend it for jaundiced babies, it is puzzling why you don't include this as a risk factor. On pages 80-87 you provide a detailed analysis of the value of a pre-discharge bilirubin level in helping to predict the likelihood of subsequent hyperbilirubinemia. If you are going to go to the trouble of measuring a bilirubin level on an infant, why ignore an important piece of evidence that can help to predict the risk, or lack of risk, of subsequent hyperbilirubinemia? It is true that the Bhutani nomogram might not be applicable to other populations, but it has been used in Israel and Turkey and in other parts of the USA and, notwithstanding its limitations, it seems to work.	Thank you for your comments, The GDG recommended measuring bilirubin for management purposes and have produced a table. Tools to aid interpreting the bilirubin levels will be produced. The evidence for pre-discharge bilirubin measurement was poor quality
PR	Peer Reviewer 1 – Oakland University	28.09	Full	1.2	38	Line 1: (Chapter 7: Treatment) - It is difficult to know how to interpret your advice that babies be "kept hydrated during conventional phototherapy." I am	Thank you for your comment, Amendments have been made to the text to provide more detail.

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						concerned that this might lead to the use of intravenous therapy in all of these infants, when it is clearly not necessary nor indicated in most. It might be better to say that supplemental feeding or intravenous therapy should be provided to infants who show evidence of dehydration.	
PR	Peer Reviewer 1 – Oakland University	28.10	Full	1.2	38	Line 21-22: I cannot agree with your recommendation that one should check for a rebound following phototherapy between 12 and 18 hours after stopping phototherapy. This will lead to many infants being kept in hospital much longer than is necessary, will interfere with breastfeeding and increase costs. The risk of significant rebound following phototherapy is really quite small, although it is larger in those infants who require phototherapy in the first couple of days following birth. Virtually all of these infants have some increase in the rate of bilirubin production (Pediatrics 2006;118:276-279), even if they don't have a documented hemolytic disease, but the vast majority of them do not have any kind of significant rebound. For such infants a bilirubin level 4-6 hours after stopping phototherapy is quite sufficient and they can then be discharged. If there is any concern about the magnitude of the rebound they can be seen the following day and a bilirubin obtained on an outpatient basis. I can't imagine any reason for keeping such an infant for 18 hours before obtaining a bilirubin level. In those who are discharged	Thank you for your comment. The GDG discussed your point and decided that there was a need to check for rebound in view of the recommendation to stop after 1 result below the line. However, unless the baby was in a remote area, there is no need for them to remain in hospital

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						and then readmitted for hyperbilirubinemia, the risk of significant rebound is much smaller. Most of these infants do not have hemolytic disease and their hyperbilirubinemia is usually the result of inadequate nursing combined with a minor degree of prematurity. They are usually 4-5 days old so that the bilirubin level has peaked and phototherapy just helps to get it down more quickly. Once the bilirubin level has come down to a reasonable range (e.g. 240 µmol/L) the lights should be turned off and the baby sent home. If there is any concern, the infant can be seen the next day and, if noticeably jaundiced, a bilirubin level can be obtained. Alternatively, a follow up bilirubin level could be obtained in all such infants the next day but they do not need to remain in the hospital once the phototherapy is discontinued.	
PR	Peer Reviewer 1 – Oakland University	28.11	Full		158	Line 5: "Conventional Phototherapy vs LED Phototherapy" - there is another randomized trial that could be quoted (Maisels et al. J Perinatal 2007;27:565-567).	Thank you for your comment, The suggested paper was identified and excluded (App C, p 34) as it compared two methods of delivering multiple phototherapy and was not a direct comparison between LED and conventional phototherapy
PR	Peer Reviewer 1 – Oakland University	28.12	Full		41	Line 1: In the October 2009 issue of Pediatrics (Kuzniewicz et al. Pediatrics 2009;124:1031-1039) the authors demonstrate that the introduction of universal bilirubin screening reduced the incidence of an infant exceeding the AAP exchange transfusion guidelines from .45% - .17%, a 62% reduction, although twice as	Thank you for your comment. The GDG are aware of this paper, however. universal screening is outwith the scope of this guideline

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						many inpatient newborns received phototherapy prior to discharge (9.1% vs 4.2%).	
PR	NETSCC, Health Technology Assessment (1)	2.01	Full	general	general	There are no specific recommendations re babies with darker skin	Thank you for your comment. The GDG did not feel that a recommendation was required for this.
PR	NETSCC, Health Technology Assessment (1)	2.02	Full	general	general	Nothing specific re tertiary referral	Thank you for your comment. It is beyond the scope of this guideline to make recommendations on service delivery
PR	NETSCC, Health Technology Assessment (1)	2.03	Full	2.6	47	Some elements of search strategy may cause concern (although I am not personally an expert in this area, I am highlighting in case these are issues): <ul style="list-style-type: none"> <li>a) Non- English publications not appraised</li> <li>b) Grey material not searched/included.</li> <li>c) No hand searching of non-indexed journals</li> <li>d) Some exclusions may be questionable eg. Kaplan et al, 2007 excluded because 'study restricted to African- American males babies' – Which seems strange since one of the scopes of the guidelines was to give special consideration to recognition and management in babies with darker skin.</li> </ul>	Thank you for your comment. The NCC-WCH develops its search strategies in accordance with the NICE Guidelines Manual and this notes there is no requirement to hand search journals. Non-English language studies are not routinely searched as the cost and time taken to translate this material could not be accommodated in the tight framework of guideline production. Similarly, grey literature is not included in the review due to the time lag in obtaining this material.  The Kaplan 2007 study was excluded as it restricted to male babies
PR	NETSCC, Health Technology Assessment (1)	2.04	Full	5	129	It is not clear how the last 2 recommendations (encourage frequent breastfeeding and provide lactation support) are arrived at from the available evidence.	Thank you for your comment, These recommendations are not derived from the available evidence but reflect the GDG's experience and concerns regarding breastfeeding support, and are consistent

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							with recommendations given in the NICE "Postnatal care" guideline (CG37).
PR	NETSCC, Health Technology Assessment (1)	2.05	Full	7.1.12	186	It is unclear how table 7.1 is arrived at.	Consensus, see text
PR	NETSCC, Health Technology Assessment (1)	2.06	Full	2.8	51	The statement that a correlation of 0.8 will be used as an arbitrary cut-off does not make sense. A cut-off for what? Why not calculate for each study if data available?	Thank you for your comment. 0.8 was used as an imputed value as this is an accepted threshold for strong and very strong correlation.
PR	NETSCC, Health Technology Assessment (1)	2.07	Full	2.8	51	The calculation for NNT appears wrong. For example, if 25/50 treated = 50% outcome present (and A=25, C=25) and 10/50 controls = 20% outcome present (and B=10, D=40), then the difference of 30% with the outcome equates to an NNT of 3.33; whereas the formula leads to a negative value.	Thank you for your comment. The error in the text has been amended as suggested
PR	NETSCC, Health Technology Assessment (1)	2.08	Full	3.1	62	Why is there no meta-analysis of the odds ratios?	Thank you for your comment. The GDG decided that a tabular presentation was best
PR	NETSCC, Health Technology Assessment (1)	2.09	Full	5	102	The 4th para states that the correlation coefficient "is largely dependent on the distribution of serum bilirubin values in the sample population and does not adjust for various biases" Please expand on this. In the subsequent section (5.1) studies are presented and correlations from these given. It seems surprising that estimates are made, fairly ad-hocly, on the actual serum bilirubin levels. – I would have expected it more likely that patients were classified as low, ok, not ok, v high or similar. Perhaps this is what is alluded to in the sentence	Thank you for your comment. Often serum bilirubin levels with be reported as risk zones according to Bhutani or according to local practices ie above or below a cut-off. We have tried to take account of this.

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						highlighted above. It does require clarification.	
PR	NETSCC, Health Technology Assessment (1)	2.10	Full	5.4.1	116	Figure 5.4.1.3 requires referencing in the text and description. (Similarly for figure 5.4.2.3 p119)	Thank you for your comment. An amendment has been made as suggested. The figures are now referenced in the text and a definition of ROC curve been added to the glossary as below  "Receiver Operating Characteristic Curve = A ROC curve can be used to evaluate the goodness of fit for a binary classifier. It is a plot of the true positive rate (rate of events that are correctly predicted as events) against the false positive rate (rate of nonevents predicted to be events) for the different possible cutpoints"
PR	NETSCC, Health Technology Assessment (1)	2.11	Full	1.1	26	The recommendations for identifying those at risk of kernicterus are in accordance with those presented in section 3.2 (page 68) but the fact that they are based on poor quality studies is lost in section 1.1. Since most readers may just utilize the first section, I wonder whether it would be better to have the research recommendation (page 68) in section 1.1	Thank you for your comment. This section is structured according to the NICE editing template and to introduce a research recommendation earlier would be inappropriate.
PR	NETSCC, Health Technology Assessment (1)	2.12	Full	general	general	Otherwise, recommendations seem fair.	Thank you for your comment
PR	NETSCC, Health Technology Assessment (1)	2.13	Full	general	general	Perhaps the questions re the review of the literature as cited in 2.1 above.	Not sure what this comment refers to
PR	NETSCC, Health Technology	2.14	Full	general	6	'RCO' should read 'ROC' (Abbrev)	Thank you for your comment. A correction has been made as suggested.

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	Assessment (1)						
PR	NETSCC, Health Technology Assessment (1)	2.15	Full	1.1	26	Refers to section 1.2.2 which does not exist	Thank you for your comment. The text has been amended as suggested
PR	NETSCC, Health Technology Assessment (1)	2.16	Full	2.5	45	'Table 1.1' should read 'Table 2.1'	Thank you for your comment. The text has been amended as suggested
PR	NETSCC, Health Technology Assessment (1)	2.17	Full	2.6	46	GDG not given in abbreviations (page 6)	Thank you for your comment. This term has now been added to the abbreviation list
PR	NETSCC, Health Technology Assessment (1)	2.18	Full	2.6	47	'Appendix C' should read 'Appendix A'	Thank you for your comment. The text has been amended as suggested
PR	NETSCC, Health Technology Assessment (1)	2.19	Full	2.7	47	I could not find Table 1.2 within the web-link given.	Thank you for your comment. This has now been correctly re-tagged as Table 2.2
PR	NETSCC, Health Technology Assessment (1)	2.20	Full	2.7	49 50	'Table 1.3' should read 'Table 2.3' 'Table 1.4' should read 'Table 2.4' 'Appendix E' should read 'Appendix C'	Thank you for your comment. The text has been amended as suggested
PR	NETSCC, Health Technology Assessment (1)	2.21	Full	3.1	61	The purpose of outlining the results from reference 17 at this point should be stated.	Thank you for your comment. Appropriate amendments have been made to the text in the translation
PR	NETSCC, Health Technology Assessment (1)	2.22	Full	3.1	63	The sentence "Ensure adequate and support is offered to all women especially those who intend to breastfeed exclusively." Needs the 'and' to be removed to make sense but is not a helpful statement anyway. How is this justified from the data? What is 'adequate support'?	Thank you for your comment. We have removed the additional "and" from the text as requested. As this is not a breastfeeding guideline, it would be inappropriate for further recommendations to be made here to further describe breastfeeding support. In accordance with NICE methods, the GDG have referred to the NICE postnatal care guideline. The recommendation now reads:  Ensure that adequate support is offered to all women who intend to breastfeed exclusively.

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							Refer to 'Routine postnatal care of women and their babies' (NICE clinical guideline 37) for information on breastfeeding support.  The GDG have made several amendments throughout the recommendation to strengthen their support of breastfeeding.
PR	NETSCC, Health Technology Assessment (1)	2.23	Full	3.2	63	1st sentence, 'the' should read 'that'.	Thank you for your comment. A correction has been made as suggested
PR	NETSCC, Health Technology Assessment (1)	2.24	Full	4	72-97	The reader is referred forward to pages 102-3 in several places and I think this should be 100-101	Thank you for your comment, This error has been amended and reference to page numbers deleted
PR	NETSCC, Health Technology Assessment (1)	2.25	Full	5.1-5.4	109-126	References to pages 131-2 should be referring to pages 128-130	Thank you for your comment. We have deleted these references
PR	NETSCC, Health Technology Assessment (1)	2.26	Full	6.1	135	Should read Figure 6.1 (similarly next figure reference – section 6.2- should be figure 6.2)	Thank you for your comment. The text has been amended as suggested.
PR	NETSCC, Health Technology Assessment (1)	2.27	Full	7	165-179	I think all references to pages 184-9 are meant to be 182-5	Thank you for your comment. Amendments to the text have been made as suggested.
PR	NETSCC, Health Technology Assessment (1)	2.28	Full	general	general	It may help to have recommendations also displayed in logical order ie. parental advice inserted at appropriate care-points. Sub-headings for primary, secondary and tertiary referral levels may also help.	Thank you for your comment. We agree that the order of some recommendations wasn't entirely logical so we have amended the relevant sections to rectify this issue. We have not, however, added the suggested sub headings.
PR	NETSCC, Health Technology Assessment (1)	2.29	Full	general	general	Overall a well written and comprehensive work. I think that most of my comments are relatively minor.	Thank you for your comments
PR	NETSCC, Health Technology	3.01	Full	general	general	General comment: The work has been done with accordance	Thank you for your comment

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	Assessment (2)					with the scope noted, and the NICE guideline. For specific comment, see comments on 2.2	
PR	NETSCC, Health Technology Assessment (2)	3.02	Full	general	general	General comment: The work has shown extensive and comprehensive review of literature or major issues (for example evidence of clinical effectiveness) to answer appropriate and relevant clinical questions.	Thank you for your comment
PR	NETSCC, Health Technology Assessment (2)	3.03	Full	general	general	Systematic review and analysis from the systematic review of the clinic evidence is not my expertise.	Thank you for your comment.
PR	NETSCC, Health Technology Assessment (2)	3.04	Full	general	general	Review of studies on costs effectiveness studies for alternative strategies to prevent neonatal jaundice should have been added. This would help to compare the results from the economic evaluation with other studies. See 2.2	Thank you for your comment. A review of the literature was undertaken and only one study identified for potential inclusion. This was not directly relevant to the decision facing the GDG for UK practice and so was not reported.  However, on reflection we agree that a discussion of this evidence would be useful and has been added to the text of the health economics appendix.
PR	NETSCC, Health Technology Assessment (2)	3.05	Full	2.9	51	General – The health economics section should include, as introduction of the section, some idea about the burden of hyperbilirubinaemia, or burden of kernicterus in terms of costs of treating the total number of cases in a year by NHS, loss of life or QALY loss etc.	Thank you for your comment. Hyperbilirubinaemia is not a disease but in term babies indicates neonatal jaundice, a normally harmless condition. An estimate of the number of kernicterus cases per year in England and Wales is given together with the model's assumptions regarding cost and QALYs.  Therefore, the GDG believed that this information is already presented in the

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							guideline. However, the NICE Guidelines Manual 2009 notes that cost of illness and burden of disease is not useful for decision making for clinical guidelines and therefore the GDG did not think it would be helpful to give this additional emphasis.
PR	NETSCC, Health Technology Assessment (2)	3.06	Full	2.9	51	I think there should have some arguments why the health economics section did not cover cost effectiveness of the recommended treatment/management of hyperbilirubinaemia for different groups. The remit suggests that this should be "guideline on the recognition and treatment ....."	Thank you for your comment. A paragraph added to the evidence statement discusses this in greater detail
PR	NETSCC, Health Technology Assessment (2)	3.07	Full	5	126	The section " Cost effectiveness" does not have number. Do you want to put it under "recognition" sub-heading? This is should put as separate sub-heading.	Thank you for your comment. The section sub-heading has been amended to "Cost-effectiveness of transcutaneous bilirubinometers" which the GDG believe will better describe the context of this evidence within the chapter
PR	NETSCC, Health Technology Assessment (2)	3.08	Full	5	126	The section "Cost-effectiveness evidence" does not provide any evidence from review of studies that has looked at alternative strategies to manage neo-natal jaundice and to prevent kernicterus.	Thank you for your comment. A literature search was undertaken which yielded a single included study. (Kuzniewicz M, Escobar G, and Newman T. The Impact of Universal Bilirubin Screening on Severe Hyperbilirubinemia and Phototherapy Use in a Managed Care Organization. Pediatrics . 2009) .A discussion of this paper was added but the screening approach in this article wasn't considered relevant to the UK context and the decisions facing the GDG.
PR	NETSCC, Health	3.09	Full	5	126	The search used, I suppose should have	Thank you for your comment. This paper was

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	Technology Assessment (2)					found the paper by Suresh, G.K. "Cos-effectiveness of Strategies That Are Intended to Prevent Kernicterus in Newborn Infants" published in Paediatrics Vol. 114 No.4 October 2004; p 917-924. Even though this is US based study, but this could be reported, and can used to have estimates for UK context. This study has used a decision model.	identified in the literature search and was included. An amendment has been made to include a discussion of it.
PR	NETSCC, Health Technology Assessment (2)	3.10	Full	5	126	There could be other studies which looked at the cost-effectiveness of different strategies.	Thank you for your comment. A description and discussion of our literature review has been added
PR	NETSCC, Health Technology Assessment (2)	3.11	Full	Appendix B	1	Line 14: The reference – should it not follow the same style of reference style as in the main text.	Thank you for your comment. This reference has been amended as suggested,
PR	NETSCC, Health Technology Assessment (2)	3.12	Full	Appendix B	1	Line 18: May need to add the reference, ref ID for the statement.	Thank you for your comment. A reference has been added to the text as suggested.
PR	NETSCC, Health Technology Assessment (2)	3.13	Full	Appendix B	1	Line 13/14: Reference – same style as text.	Thank you for your comment. This reference has been amended as suggested,
PR	NETSCC, Health Technology Assessment (2)	3.14	Full	Appendix B	1	Line 24: The word "important" may be deleted,	Thank you for this comment. The GDG accepted that there may be a degree of subjectivity in the term but given competing claims on NHS resources they thought that changes which have implications for NHS resources would generally be important
PR	NETSCC, Health Technology Assessment (2)	3.15	Full	Appendix B	2	(Background section) I think here again the section should include some information idea about the burden of hyperbilirubinaemia, or burden of kernicterus in terms of costs of treating the total number of cases treated in a year by	Thank you for your comment.  Hyperbilirubinaemia is not a disease but in term babies indicates neonatal jaundice, a normally harmless condition.

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						NHS, loss of life or QALY loss etc.	An estimate of the number of kernicterus cases per year in England and Wales is given (five to seven new cases per annum) together with the model's assumptions regarding cost and QALYs.  Therefore, the GDG believed that this information is already presented in the guideline. However, the NICE Guidelines Manual 2009 notes that cost of illness and burden of disease is not useful for decision making for clinical guidelines and therefore the GDG did not think it would be helpful to give this additional emphasis.
PR	NETSCC, Health Technology Assessment (2)	3.16	Full	Appendix B	2	Line 7/8: Evidence of this need to be referred even if this noted in other section.	Thank you for your comment, References to these studies are given at the end of this paragraph.
PR	NETSCC, Health Technology Assessment (2)	3.17	Full	Appendix B	2	Line 13/14: Reference – same style as text.	Thank you for your comment. The reference has been amended as suggested.
PR	NETSCC, Health Technology Assessment (2)	3.18	Full	Appendix B	2	Line 17: Evidence of this need to be referred even if this noted in other section.	Thank you for your comment, A reference has been added to the text, The reference is: Newman, T (2003) the power of statistics over stories, BMJ Vol 327 1424-1427
PR	NETSCC, Health Technology Assessment (2)	3.19	Full	Appendix B	2	Line 25: Evidence of this need to be referred even if this noted in other section.	Thank you for your comment, A reference to the relevant chapter in the full guideline which covers recognition of hyperbilirubinaemia has been added to the text on page 3.
PR	NETSCC, Health Technology Assessment (2)	3.20	Full	Appendix B	2	Line 31: I think it is possible to get an estimate of this figure. It would be useful to add information on how much does costs to NHS for treating diseases that are due to	Thank you for your comment. Hyperbilirubinaemia is not a disease but in term babies indicates neonatal jaundice, a normally harmless condition.

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						untreated cases of hyperbilirubinaemia and the costs to NHS to treat people with kernicterus.	An estimate of the cost of a kernicterus case is given in Table B.2. A discussion of this estimate and its limitations has been added (page 6) and an additional sensitivity analysis presented (page 15) to reflect the inherent uncertainty in this estimate.
PR	NETSCC, Health Technology Assessment (2)	3.21	Full	Appendix B	3	Line 13: "planned monitoring protocol" – which one is referred here?	Thank you for your comment. This has been amended to assessment and management
PR	NETSCC, Health Technology Assessment (2)	3.22	Full	Appendix B	2	Model Parameters and assumptions: The setting assumed for the economic evaluation is community level or primary level only – as suggested that nurses will do the test during home visits. This setting needs to be described clearly so the policy makers/ NHS authority can understand this with respect to the context.	Thank you for your comment. Amendments to the text have been made to clarify that the model is not intended to be for the community level or primary level.
PR	NETSCC, Health Technology Assessment (2)	3.23	Full	Appendix B	2	The scope of the guideline suggests that the guideline will cover management in primary and secondary care. The economic evaluation only considered the primary care setting. There should be some clear justification on why economic evaluation section did not include the secondary level of care.	Thank you for your comment. The economic evaluation does not make a distinction between settings and the recommendations also reflect this.
PR	NETSCC, Health Technology Assessment (2)	3.24	Full	Appendix B	general	The setting and assumptions does consider the costs in laboratory when TSB is done. Should it not be added	Thank you for your comment. Amendments have been made to clarify this point
PR	NETSCC, Health Technology Assessment (2)	3.25	Full	Appendix B	general	Model Parameters and assumptions: The model has not considered any sub-groups. For example, as noted and found from evidence, e.g. for dark skin babies, it	Thank you for your comment. Firstly, we could not identify the effectiveness of the strategies for different sub-groups.

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						would be difficult to identify the babies as visually jaundiced. For them testing all with TSB may be obvious choice. If you would like to exclude them from the model it needs to be mentioned.	Secondly, the guideline does not make different recommendations for visualisation of jaundice (which includes more than skin colour) based on skin colour
PR	NETSCC, Health Technology Assessment (2)	3.26	Full	Appendix B	5	In Table 1, the population for the model taken from total births. The community level intervention would not apply to all births; I suppose this will be for those who are discharge early. There will be some who be in the hospital due to other complication will be tested, and cannot be included in the model used. . Not all births	Thank you  We think the stakeholder has misunderstood in that the intervention is not only intended at a community level and so the population is not just those who discharge early. We have edited the appendix to make this more transparent (e.g. see last sentence in para 2 of "Model Parameters and assumptions")
PR	NETSCC, Health Technology Assessment (2)	3.27	Full	Appendix B	7	(Table 3) Venous blood test £ 7.00- Is this 2009 prices? The gloves are 2009 prices, the midwife pay at 2006 price. This prices need to be for one particular year- or to be adjusted for one particular year.	Thank you for your comment. Amendments have been made so that all costs/prices are for the same base year
PR	NETSCC, Health Technology Assessment (2)	3.28	Full	Appendix B	7	Similarly in Table 3 the unit costs should be for one particular year (need to be mentioned for all) or to be adjusted for particular year. Would not there be any cost involved to train the midwives to use the TCN meters?	Thank you for your comment. Amendments have been made so that all costs/prices are for the same base year.  Training seems to involve a demonstration and perhaps 3 return demonstrations by the trainee on an infant. The developers therefore considered that the costs of training midwives to use TCN would not be substantial especially in relation to the cost of the meters themselves . This view was also corroborated by a stakeholder comment and an Internet search ( <a href="http://www.respironics.com/UserGuides/UsageProtocolBiliChek.pdf">http://www.respironics.com/UserGuides/UsageProtocolBiliChek.pdf</a> ).

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							However, we suggest training is an area that the NICE costing analysis's may wish to pick up in their costing report
PR	NETSCC, Health Technology Assessment (2)	3.29	Full	Appendix B	12-13	Explanation of the results of sensitivity shown in Fig 3 and Fig. needs to be given	Thank you for your comment. An amendment has been made to the translation as suggested.
PR	NETSCC, Health Technology Assessment (2)	3.30	Full	Appendix B	15	It is useful to use the actual average number of postnatal visits made by midwives.	Thank you for your comments. The technical team tried to identify this data, however, it was unavailable at the time of the review's preparation. Our estimate of the 'typical' number of visits was derived from information from the GDG and midwives and is based on what we consider to be reasonable assumptions.  By 'typical' we mean average and the text has been amended to reflect this.
PR	NETSCC, Health Technology Assessment (2)	3.31	Full	Appendix B	general	The use of the results of economic model will largely depend on the service delivery relating the number of community midwives involved in home visits. As noted in the section – the implementation of the strategy (use of TCB) will depend on the local health authority, which may consider other issues. Besides, community level intervention may be more applicable in case of early discharge.	Thank you for your comment.
PR	NETSCC, Health Technology Assessment (2)	3.32	Full	Appendix B	general	Research recommendation: it can be recommended that – A cost effectiveness study of pre-discharge screening versus testing or screening level at the community (with different alternative strategies as used	Thank you for your comment. Screening is outwith the scope of the guideline.

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						here in this report), which may provide more economic evaluation information.	
PR	NETSCC, Health Technology Assessment (2)	3.33	Full	Appendix B	general	Research to determine the epidemiology and causes of kernicterus will provide useful information to work for decision model for economic evaluation	Thank you for your comment. The GDG agreed with your comment and this is reflected in the research recommendations
PR	NETSCC, Health Technology Assessment (2)	3.34	Full	general	general	Comments relates to Health economic only	Thank you for your comments
PR	NETSCC, Health Technology Assessment (2)	3.35	Full	general	general	Recommendations on economic evaluation are based on findings. They are quite justified following from the model used and are not overstated. The authors have noted the caveats and limitations. However, the economic evaluation could be improved if instead of cost minimization, costs effectiveness of alternative test at different settings (primary vs secondary – for early-discharge babies and others), and considering the relevant sub-groups could be done.	Thank you for your comment. Whilst we agree with the view expressed here, the effectiveness data for such analyses does not exist to our knowledge
PR	NETSCC, Health Technology Assessment (2)	3.36	Full	general	general	See comments in section 2.2.	Thank you for your comments
PR	NETSCC, Health Technology Assessment (2)	3.37	Full	general	general	General comment: Very comprehensive list of useful glossary, and the abbreviations are listed. GDD needs to be added in the list of abbreviation.	Thank you for your comment. This abbreviation has been added to the list.
PR	NETSCC, Health Technology Assessment (2)	3.38	Full	general	general	In glossary section some may need to be excluded – e.g. like “clinicians”- do you need to add that as well?	Thank you for your comment. The glossary used a standard terms for NICE guidelines with subject specific terms added.
PR	NETSCC, Health Technology Assessment (2)	3.39	Full	general	general	If some of these are not used in the text, that needs to be excluded as well.	Thank you for your comment. The glossary used a standard terms for NICE guidelines with subject specific terms added.

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PR	NETSCC, Health Technology Assessment (2)	3.40	Full	general	general	Since cost-effectiveness analysis and cost benefit analysis was added in the glossary, the term cost-minimization analysis (the type of economic evaluation that has been used) may be added to the glossary.	Thank you for your comment. This has been added to. The glossary as suggested CMA has been added to the glossary.
PR	NETSCC, Health Technology Assessment (2)	3.41	Full	1	25-41	This section is not well presented. Some parts are repeated.	Thank you for your comment which we have reflected in our copy editing.
PR	NETSCC, Health Technology Assessment (2)	3.42	Full	1	25-41	Not clear section 1.2 repeats a lot of the text mentioned at the beginning of the section 1. For example Table 1 on Page 28 is repeated in page 37. Sub-section "Risk factor" on Page 25 is repeated on page 29. Similarly, part of sub-section "Recognition", Formal Assessment, Treatment on Page 26, 27, 28 repeated on 31, 32, and 33. The whole section needs to be re-organised and re-written to make more readable and well presented.	Thank you for your comment which we have reflected in our copy editing.
PR	NETSCC, Health Technology Assessment (2)	3.43	Full	1	25-41	If this section summarise the findings, this should also have couple of lines from the findings from economic section.	Thank you for your comment. Pages 25-41 contain all the guideline recommendations (as would appear in the NICE version) and are not a summary of findings. There are no health economics recommendations for this guideline.
PR	NETSCC, Health Technology Assessment (2)	3.44	Full	2.8	51	Line 2, the word "standard" is repeated.	Thank you for your comment. The error in the text has been amended as suggested
PR	NETSCC, Health Technology Assessment (2)	3.45	Full	2.9	52	Line 13, Apart from referring to Annex B, it is useful to refer to the section on " Cost Effectiveness evidence" on Page 126	Thank you for your comment. An amendment has been made. accordingly to add a reference to this section
PR	NETSCC, Health Technology Assessment (2)	3.46	Full	4	72	In the box where the clinical questions is given- f) should it not be "Pre-discharge Risk Assessment" instead of "Risk	Thank you for your comment. We do not believe that an amendment is necessary as some babies are born at home and "pre-

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						assessment" only?	discharge" would not be appropriate term for them.
PR	NETSCC, Health Technology Assessment (2)	3.47	Full	general	general	My comments are mainly on the economic section- see comments on noted in 2.2	Thank you for your comments.
PR	Peer Reviewer 2 – University of Oslo	9.01	Full	Abbreviations	6	The use of UCB for umbilical cord bilirubin may be confusing. UCB in the bilirubin literature often means unconjugated bilirubin.	Thank you for your comment. Appropriate amendments have been made to the text for clarity (UCB has been changed to CB)
PR	Peer Reviewer 2 – University of Oslo	9.02	Full	Glossary	7	"ABO incompatibility describes an immune reaction that occurs [when?] mother and baby have different blood groups, typically maternal blood group O and baby blood group A or B." This wording may perhaps be misunderstood to suggest that ABO incompatibility occurs because an immune reaction is generated in the same way as in Rhesus incompatibility, i.e. because the mother forms ABO antibodies when her immune system is exposed to foreign red cells? As this is not the case, perhaps a different choice of words might avoid ambiguity?	Thank you for your comment. An amendment has been made for clarity. The definition now reads 'ABO incompatibility describes an antibody reaction that occurs when mother and baby have different blood groups, typically maternal blood group O and baby blood group A or B. Fetal red cells "leak" into the maternal circulation, and the immune system recognises them as foreign and makes antibodies against them, which can then pass back into the fetus and bind to fetal red cells.'
PR	Peer Reviewer 2 – University of Oslo	9.03	Full	Glossary	7	"Acute bilirubin encephalopathy is the clinical manifestation of bilirubin toxicity. The clinical course is hypotonia followed by hypertonia, opisthotonus (backward arching of the neck), or retrocollis (backward arching of the back) or both." I would suggest "manifestation of bilirubin brain toxicity". Opisthotonos (Greek word, note spelling) means backward arching of the back, while retrocollis means backward arching of the neck - i.e. the opposite of	Thank you for your comment. Appropriate amendments have been made to the text, as suggested.  The definition now reads 'Acute bilirubin encephalopathy is the clinical manifestation of bilirubin toxicity. The clinical course is hypotonia followed by hypertonia, retrocollis (backward arching of the neck), or opisthotonos (backward arching of the back) or both.'

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						what is stated in the original sentence.	
PR	Peer Reviewer 2 – University of Oslo	9.04	Full	Glossary	11	“Coombs’ test” is currently more commonly referred to as DAT - direct antiglobulin test	Thank you for your comment. The text has been amended to include both terms and a definition of DAT has been added to the glossary.
PR	Peer Reviewer 2 – University of Oslo	9.05	Full	Glossary	14	“Hyperbilirubinaemia” should be hyperbilirubinaemia	Thank you for your comment. The text has been amended as suggested.
PR	Peer Reviewer 2 – University of Oslo	9.06	Full	1.1	25	“• the importance of recognising jaundice” - recognising	Thank you for your comment. The suggested amendment has been made.
PR	Peer Reviewer 2 – University of Oslo	9.07	Full	1.1	27	“• blood packed cell volume.” - I presume this is the same as what is more commonly called hematocrit (or haematocrit in British spelling)?	Thank you for your comment. The “blood packed cell volume” is commonly referred to as the haematocrit. This has been added to the glossary
PR	Peer Reviewer 2 – University of Oslo	9.08	Full	1.1	27	“• glucose-6-phosphate levels (if the baby’s ethnic origin warrants a test)” - would it be more user friendly if the specific ethnic origins were listed?	In this guideline we did not conduct an evidence search addressing the clinical question “risk factors for G6P-D deficiency”. Nevertheless we proposed including a list of countries with a high prevalence of the G6P-D deficiency as an appendix as requested, however, following discussion with NICE we have since decided that we cannot pursue this course of action because we have not reviewed the evidence. As such we have made not been able to make the suggested amendment to the guideline.
PR	Peer Reviewer 2 – University of Oslo	9.09	Full	1.1	28	“7 • in cases of rhesus haemolytic disease initiate multiple phototherapy and prepare for an exchange transfusion.” I am not sure I would agree with this recommendation, although I guess it depends on what is meant by “prepare for”. In our practice we would definitely give intensive phototherapy	Thank you for your comment. We agree that IVIG should be given before an exchange transfusion and we have amended the order in which the recommendations appear to reflect the care pathway. The GDG felt that because blood can take a long time to obtain in the UK the recommendation to “prepare”

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						and IVIG before "preparing for" an exchange.	i.e. get the blood and insert IV lines was appropriate, given that the exchange can be called off if the bilirubin falls as a result of IVIG. The GDG have recommended use of IVIG in cases of rhesus haemolytic disease and ABO haemolytic disease, but did not have any evidence for IVIG use in other haemolytic diseases.
PR	Peer Reviewer 2 – University of Oslo	9.10	Full	1.1	28	Table of values which indicate treatment - this table and the following set of rules for how to calculate treatment levels for premature babies is, like all other such guidelines, based on the principle "let's think of a number". The evidence base for such tables and/or graphs is very weak, but that is unfortunately the current state of our knowledge. We have presented our national guidelines in the form of a graph rather than a table, and find this to be easier to access in clinical practice. But I guess this is primarily a question of preferences.	Thank you for your comment. A graph will be provided in the full guideline (appendix F), although the GDG accepted the lack of evidence base for the levels.
PR	Peer Reviewer 2 – University of Oslo	9.11	Full	1.2	31	The advice not to use DAT (Coombs test) to predict hyperbilirubinemia, in my mind, is not entirely correct. Thus, while a negative DAT does not rule out risk for significant hyperbilirubinemia, a positive DAT is associated with need for invasive treatment (Bakketeig E et al, Acta Paediatrica 2009 DOI:10.1111/j.1651-2227.2009.01478.x), and would certainly make me follow that infant very closely. I guess this comes down to whether "predict" is intended to mean "ruling in" or "ruling out"?	Thank you for your comment. The evidence was that DAT was not useful as a predictor but was useful in assessing cause. .
PR	Peer Reviewer 2 –	9.12	Full	1.2	33	In babies with prolonged jaundice (>14	Thank you for your comment. There was no

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	University of Oslo					days), an elevated gamma-GT is suggestive of cholestasis and may be worth including in the panel of tests.	evidence presented to the GDG on this matter and it has not been specifically included in the recommendations.
PR	Peer Reviewer 2 – University of Oslo	9.13	Full	1.2	34	It may be necessary to define what is meant by “conventional phototherapy”. Does it exclude photodiodes (e.g. NeoBlue)? If what one means is “do not use fiberoptic phototherapy” (which I suspect is the case), then this is what needs to be stated.	Thank you for your comments. Amendments have been made for clarity, as suggested and definitions of conventional, multiple, fibreoptic and LED phototherapy have been added to the glossary.
PR	Peer Reviewer 2 – University of Oslo	9.14	Full	1.2	34	“Multiple phototherapy” is a somewhat vague term, and a poor proxy for what really should be the aim, i.e. to give the baby phototherapy with high spectral power (irradiance x size of irradiated skin area). Whether “multiple phototherapy” is really helpful if a single modern phototherapy unit is used appropriately (lights close to the baby, baby completely disrobed, reflecting surfaces around baby) has, to be the best of my recollection, never been tested appropriately. Studies with “double/triple phototherapy” were performed with old phototherapy unit which had limited irradiance. In my mind the advice presented here is suboptimal and should be given in more precise terms.	Thank you for your comment. The GDG considered the available evidence when making its recommendations and evidence to support your point was not available although the GDG would tend to agree. The GDG therefore made a research recommendation for studies of phototherapy.
PR	Peer Reviewer 2 – University of Oslo	9.15	Full	1.2	35	What is the evidence in favor of preferring fiberoptic phototherapy for premature infants? As this is now worded, it gives the impression that fiberoptic phototherapy is superior in premature infants. I do not believe there is any evidence to show that.	Thank you for your comment, the recommendation has been amended to reflect that either fibreoptic or conventional phototherapy can be used as they are equally effective in pre-term babies.

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PR	Peer Reviewer 2 – University of Oslo	9.16	Full	1.2	35	I agree with the statement that fluid supplements should not be given routinely during phototherapy, but it might be wise to include a statement to the effects that fluid balance should be watched. On P38 the reader is enjoined to “ensure that babies are kept hydrated”, which I guess is pretty much what I am saying.	Thank you for your comment.
PR	Peer Reviewer 2 – University of Oslo	9.17	Full	1.2	35	The advice to use tinted head boxes our shields in lieu of eye protection is not sound. The head constitutes a significant proportion of the infant's skin surface, which should be available for phototherapy. Shielding that skin may be counterproductive, as indeed pointed out on P36 (“apply treatment to the maximum area of skin”).	Thank you for your comment, The recommendation has been amended to say that tinted headboxes should not be used in multiple phototherapy
PR	Peer Reviewer 2 – University of Oslo	9.18	Full	1.2	36	What is the basis for advising against the use of white curtains? I am unaware of any evidence that it should be harmful or counterproductive in any way. There is published evidence suggesting that it may indeed be helpful (Djokomuljanto S et al Arch Dis Child 91(6):F439-42, 2006).	Thank you for your comment. As there was very little available evidence in the area, the GDG consensus was that it would affect the ability to observe the baby
PR	Peer Reviewer 2 – University of Oslo	9.19	Full	1.2	36	As stated previously, in a baby with Rh disease I would, with few exceptions, give IVIG before I considered preparing for an exchange transfusion.	Thank you for your comment. The GDG has recommended this approach in the guideline after considering the evidence base
PR	Peer Reviewer 2 – University of Oslo	9.20	Full	1.2	38-39	I think the guideline is unclear as to whether exchange transfusion or IVIG is the preferred treatment. In my unit we have used IVIG as our first line of treatment for >10 years, and although we are a fairly large regional referral unit, we typically need	Thank you for your comment. Amendments have been made to the text to clarify that IVIG be given before exchange transfusion in rhesus and ABO haemolytic disease

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						to perform an exchange transfusion only 0-2 times a year. I really can see no reason why an exchange transfusion should be the preferred mode of treatment - it certainly is riskier than IVIG.	
PR	Peer Reviewer 2 – University of Oslo	9.21	Full	1.2	39	The advice against using barbiturates should be qualified. Phenobarbital may be useful in a few babies with prolonged jaundice, e.g. babies with possible Gilbert syndrome, and I think a clearly stated advice against its use is not warranted.	Thank you for your comment. The GDG did not consider the efficacy evidence to be strong enough to recommend barbiturates
PR	Peer Reviewer 2 – University of Oslo	9.22	Full	1.3	40-41	I would strongly support the proposal to establish a national registry. However, I believe the term “significant hyperbilirubinaemia” needs a definition. The other research proposals are also good and I shall be looking forward to the results of such studies.	Thank you for your comment. The GDG felt that a repeat UK survey is likely to use the same definitions as the first to facilitate comparisons
PR	Peer Reviewer 2 – University of Oslo	9.23	Full	2.1	43	See my suggestion previously to define groups at risk of G-6-PD.	Thank you for your comment. The GDG agreed with you and has expanded upon this issue by including an appendix
PR	Peer Reviewer 2 – University of Oslo	9.24	Full	3.1	62	I fully concur that breastfeeding should be encouraged. However, in exceptional cases admitted with extreme jaundice, and particularly in the presence of neurological symptoms suggestive of BIND, a breast milk substitute for a few hours may help to clear bilirubin from the gut, particularly if there is evidence of inadequate nutrition (“lack-of-breastmilk-jaundice” or “breastfeeding jaundice”).	Thank you for your comment. The GDG is satisfied that the recommendations made on breastfeeding are based on common sense and reflect stakeholders concerns.
PR	Peer Reviewer 2 –	9.25	Full	4.5	89	Re Coombs’ test. See my comments above	Thank you for your comment. The evidence

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	University of Oslo				-90	about the important distinction as far as DAT positivity ruling in vs DAT negativity ruling out risk of jaundice. Thus, while I would not rely on a negative DAT to rule out risk of jaundice, I would follow a DAT+ baby carefully.	was that DAT was not useful as a predictor but was useful in assessing cause. .
PR	Peer Reviewer 2 – University of Oslo	9.26	Full	7.1.1	159	See my critique of the use of the term “conventional phototherapy” as well as the review of “multiple phototherapy” above.	Thank you for your comment. Definitions of conventional, multiple, fiberoptic and LED have been added to the glossary
PR	Peer Reviewer 2 – University of Oslo	9.27	Full	7.1.7	173	See my comments on using white curtains above. Is there any evidence that the purportedly compromised ability to observe the baby who is receiving phototherapy behind curtains has had a negative impact on patient safety? I am not aware of any such evidence, thus that part of the CDG translation from evidence is based on opinion.	Thank you for your comment, This recommendation was made on the basis of GDG consensus as there is very little work in the area. The GDG believed that white curtains would affect the ability to observe the baby,
PR	Peer Reviewer 2 – University of Oslo	9.28	Full	7.1.12	183-185	See my comments above re the evidence for “multiple phototherapy” as well as the recommendation to use fiberoptic phototherapy as a first line for preterm infants. Similarly re tinted hoods and white curtains.	Thank you for your comment

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