Neonatal jaundice diagnosis
Consultation on draft guideline - Stakeholder comments table
7 January 2016 – 4 February 2016

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RCOG	Addendum	General	General	Thank you for asking the RCOG to comment and review this addendum. We feel these new and updated recommendations on diagnosis in this guideline are clearly presented and should be straight-forward to implement.	Thank you for your comment.
Royal College of Paediatrics and Child Health	Addendum	general	general	Can we suggest at least to look at this paper (*An early (sixth-hour) serum bilirubin measurement is useful in predicting the development of significant hyperbilirubinemia and severe ABO hemolytic disease in a selective high-risk population of newborns with ABO incompatibility - http://www.ncbi.nlm.nih.gov/pubmed/11927726*)? Was cited in "Evidence Based Medicine")? Suggests that a single sbr at 6hrs age can rule in /out if baby will develop sbr needing treatment (phototherapy etc), i.e. helps to facilitate safe early discharge	Thank you for your comment however this study does not compare a range of TSB thresholds for starting phototherapy as specified in the review protocol. The outcomes specified by the topic experts are also not reported hence why this study was not originally requested for review at the abstract sifting stage. It has now however been requested post-consultation to double check against your comment – the study does not meet the review protocol criteria and so has been added to the excluded studies list for clarity.
Royal College of Midwives	Addendum	general	general	The RCM agrees with the new and updated recommendations and the proposed deletions in the draft addendum.	Thank you for your comment.
NHS England	Addendum	General	General	Within the document it states that the baby is discharged from hospital to home. It is really important to note that majority of babies in the UK are being "transferred" to the care of the community midwife from hospital or birth centre care. After the midwife completes providing care to mother and baby in the post-natal period, the majority babies are then formally discharged to the care of the Primary Care	Thank you for your comment. Where the evidence permits we have extracted details relating to discharge and these are reported in the study tables.

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				Trust with the GP as the lead professional.	
NHS England	Addendum	General	General	Greater clarity when defining pathological jaundice in order to assist practitioners in their day to day care of the mother and baby. Practitioners need to understand that pathological jaundice is a term that applies to any baby less than 72 hours of age. In some areas, the time limit of 24 hours has been used and this has been viewed as a "cut off" meaning that babies developing jaundice after 24 hours are not recognised correctly as being at risk, requiring attention.	Thank you for your comment however pathological jaundice is covered in a separate section of the full guideline (chapter 4) which is outside of the scope of the current update. This update was limited to management and treatment of hyperbilirubinaemia (section 1.3 of the guideline).
NHS England	Addendum	General	General	Clearly state the link between poor feeding and severe jaundice and include the need to ensure adequate feeding and hydration in all newborn babies	Thank you for your comment. The committee noted the need to take the full clinical picture into account including checking records of maternal antibodies, ensuring that the baby is feeding adequately and has no signs of sepsis (see section 2.13 of addendum) however did not expand further on this area given it was outside of the scope of this particular update and addressed in chapter 6 of the full guideline. This update was limited to management and treatment of hyperbilirubinaemia (section 1.3 of the guideline)
NHS England	Addendum	General	General	Consider including that feeding should be assessed with a validated feeding tool	Thank you for your comment however this is outside the scope of this particular update which was limited to management and treatment of hyperbilirubinaemia (section 1.3 of the guideline).
NHS England	Addendum	General	General	How will the measurement of Parent Experience be included in this work?	Thank you for your comment. As stated in section 2.6 of the addendum, the

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					committee noted that measurement of parent experience could be a very useful surrogate outcome for assessing how distressed or comfortable babies are when they are under phototherapy. The distress to parents of their babies being removed from home and hospitalised for treatment and the impact of this on their bonding with babies can also be studied by the research recommendation your comment refers to.
NHS England	Addendum	General	General	How will the use of parent experience when captured be used to drive improvement in practice?	Thank you for your comment. As stated in section 2.6 of the addendum, the committee noted that measurement of parent experience could be a very useful surrogate outcome for assessing how distressed or comfortable babies are when they are under phototherapy. The distress to parents of their babies being removed from home and hospitalised for treatment and the impact of this on their bonding with babies can also be studied by the research recommendation your comment refers to.
RCOG	Addendum	General	21	Could you please amend the spelling of measure.	Thank you for spotting this error, it has now been corrected.
British Society of paediatric Gastroenter	Addendum	6	3	significant hyperbilirubinaemia is an elevation to a level requring treatment should be changed to significant unconjugated hyperbilirubinaemia	Thank you for your comment however this area is outside the scope of this particular update which was limited to management and treatment of

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ology, Hepatology and Nutrition					hyperbilirubinaemia (section 1.3 of the guideline). The committee however did discuss this same comment as part of the first consultation period where the phototherapy questions were reviewed (please refer to response to comment ID 13 in part 1 consultation document). The committee highlighted that the distinction between conjugated/unconjugated bilirubin is not usually made within the first 10 days of life. Longer term care is outside the scope of this particular part of the update but is however covered in section 1.7 of the guideline (care of babies with prolonged jaundice) which includes checking for conjugated hyperbilirubinaemia in prolonged jaundice. This update was limited to the accuracy of tests in recognising neonatal jaundice and optimal total serum bilirubin thresholds for starting phototherapy and exchange transfusion.
Royal College of Paediatrics and Child Health	Addendum	Page 11	Recommendation 8	This does not specify how old postnatally the baby is, so is potentially "mandating" repeat SBR measurement even in a 4 or 5 day old well term baby with a bili within 50 of threshold risks carrying out bilirubin measurements and starting phototherapy in babies with physiological jaundice. It is presumably judged that this	Thank you for your comment, however the postnatal age of 'more than 24 hours old' has been specified in this recommendation. The committee believes recommendation 8 does not mandate repeat SBR measurements but refers to the appropriateness of using

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				might prevent some cases of serious jaundice. I wonder whether it is worth considering a different approach in the first 3-4 days in well babies when it can reasonably be expected that jaundice levels will still be rising, and after this age?	TcB measurements. With regards to well babies the committee discussed in detail how best to protect normal newborns from over investigation whilst not missing the few babies that can become significantly jaundiced later than 72 hours. The committee believes that the current balance is appropriate in this regard and therefore does not think a different approach is needed in this group'.
NHS England	Addendum	Page 45		"Repeat measurements of bilirubin before phototherapy (in 6-12 hours) as recommended by the consensus-based thresholds table are too resource intensive to be implemented". While we accept the rationale for this, there is some concern that the move from 6-12 to 18 hours between screening, might leave some babies at risk. We would hope that by promoting the use of hand held bilirubinometers we could reduce the number of babies who had an 18 our window between measurements. **What would help users overcome any challenges:** strengthening the message that use of transcutaneous bilirubin meters are used in the community setting would help address some of the current resource issues.	Thank you for your comments and concerns being raised. The committee however felt that moving to testing within 18 hours would not leave babies at risk as the main purpose of treatment for hyperbilirubinemia is to prevent kernicterus (a serious bilirubin-induced brain dysfunction). However, kernicterus is very rare and extremely unlikely at levels below the treatment thresholds for phototherapy. The committee therefore believed that the new proposed timings for retesting which prioritise infants at high risk of hyperbilirubinemia balance the very low risk of kernicterus with practical considerations, and the harms of over-testing (such as finding clinically

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					irrelevant results causing unnecessary anxiety to the family as well as the uneccessary use of resources), while ensuring safe care.
Royal College of Paediatrics and Child Health	General	General	General	We are generally happy with all the proposed changes.	Thank you for your comment.
Department of Health	General	General	General	No comments	Thank you.
British Society of paediatric Gastroenterology, Hepatology and Nutrition	General			The guidance pertains to Unconjugated hyperbilirubinaemia. Conjugated causes have not been discussed or listed in the table of causes of hyperbilirubinaemia We would suggest to change the title accordingly – conjugated causes should perhaps stay out and are beyond the scope of this article hence recommend to simply change the title	Thank you for your comment. The committee highlighted that the distinction between conjugated/unconjugated bilirubin is not usually made within the first 10 days of life. Longer term care is outside the scope of this particular part of the update but is however covered in section 1.7 of the guideline (care of babies with prolonged jaundice) which includes checking for conjugated hyperbilirubinaemia in prolonged jaundice. This update was limited to the best mode and correct procedure of giving phototherapy (section 1.4 of the guideline).

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Royal College of General Practitioners	short	General	General	The RCGP welcomes this document and has no comments at this stage	Thank you for your comment.
Capnia UK	Short	General	General	This comment applies to all visual inspection references within the guidelines: Currently, there is no consistency in the evaluation of jaundice in neonates, even though 60-80% of all babies will have some level of jaundice around the time of birth. Visual inspection is commonly used as a method of screening in the UK but it is highly subjective and inaccurate particularly with ethnic minorities with different skin tones. In some cases, transcutaneous measurements of bilirubin are performed but those too are often inaccurate in babies with difference skin colours as well as in cases when bilirubin levels are high or when babies are receiving phototherapy. This drawback of jaundice evaluation exists for families, doctors as well as other health care providers who provide care to babies at home. There is a new CE Marked non-invasive monitoring device (CoSense) available that can accurately identify if a baby has a high bilirubin production rate as a result of haemolytic jaundice. This technology measures end-tidal carbon monoxide (ETCO) and can accurately identify babies, including those with darker skin tones, with high bilirubin production rates. Research shows that babies with an increased production rate (high rate of haemolysis) are at greater risk for adverse neurodevelopmental outcomes (Wong & Stevenson 2015, Bhutani & Johnson 2009, Bhutani & Wong 2013). All babies, especially darker skinned babies,	Thank you for your comment. We agree with your comment that visual inspection is highly subjective and inaccurate particularly in ethnic minorities with different skin tones and that this can also be the case with transcutaneous measurements in this group of babies. The committee tried to address this issue by specifying babies of different skin tones as a subgroup for analysis however no evidence was found by skin tone with regards to the diagnostic tests within the scope of this update. The accuracy of devices measuring end-tidal carbon monoxide levels (ETCO) is covered in a separate section of the full guideline (chapter 4) which was outside of the scope of this update. We will however pass on the information you have provided to the Medical Technologies Evaluation Programme (MTEP). This update was limited to management and treatment of hyperbilirubinaemia (section 1.3 of the full guideline). We will however share this information with our surveillance team

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				can be tested with this device to assess which babies would need further testing. If the ETCO levels are high (> 2ppm) then the baby can be further investigated for the cause of haemolysis (Christensen 2014). The technology was reviewed by the NIHR horizon scanning team: http://www.hsric.nihr.ac.uk/topics/cosense-end-tidal-carbon-monoxide-monitor-for-neonatal-haemolytic-disease/. Several peer reviewed publications have described its use in the setting of neonates and paediatric patients (Christensen 2015, Castillo Cuadrado 2015, Lal 2015, Christensen 2016, Bhutani 2016). Another device was evaluated several years ago for a similar purpose and had significant limitations. It led to a negative review by NICE and a comment in its guidelines that ETCO monitoring should not be used for the prediction of hyperbilirubinemia. CoSense overcomes all the limitations of the prior device and is not being recommended for the detection of jaundice- but to detect haemolysis which is a predictor of adverse outcomes in babies with jaundice. Capnia UK Ltd conducted research with Device Access UK Ltd to explore the rate of neonatal jaundice in NHS England using the HSCIC Hospital Episode Statistics Database. The analysis looked at the 155,698 babies readmitted from April 2013-October 2014, and examined the ethnicity data broken down by ICD-10 code. In addition, the length of stay data was examined to see the overall disruption to parents, their	who can consider the evidence presented when they review this section of the guideline for future updates.

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				babies, and NHS England. These results clearly showed a far greater rate of neonatal jaundice causing a readmission in NHS England within the following ethnic groups (D to S): White and Black Caribbean (Mixed), White and Black African (Mixed), White and Asian (Mixed), other Mixed background, Indian (Asian) or Asian British) Indian (Asian or Asian British) Pakistani (Asian or Asian British), Bangladeshi (Asian or Asian British), Any other Asian background Caribbean (Black or Black British) African (Black or Black British, Any other Black background Chinese (other ethnic group) & Any other ethnic group. One particular ethnic group (Chinese) had a very high 8.3% chance of readmission. These NHS data / information were offered to the committee at no cost. An economic analysis conducted with the above rates of readmission shows that there are substantial savings associated with the use of the CoSense device. In addition, the worst cases of adverse neurodevelopmental outcomes related to jaundice (called kernicterus) are typically associated with malpractice lawsuits worth several million pounds each. CoSense has the ability to identify cases of jaundice that may progress to kernicterus and potentially provide further savings to the NHS.	

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Capnia UK	Short	General	General	CoSense End-Tidal Carbon Monoxide Monitor has US FDA 510(k) clearance and has received a CE Mark for marketing in the EU. It is currently being evaluated by Medway Maritime Hospital – Kent, UK. CoSense is used to measure ETCO to detect haemolysis from the increased rate of production of bilirubin –not to predict subsequent levels of bilirubin. The current wording in the guidance, if not changed, will effectively prevent the use of this technology and will reduce the ability to detect haemolysis early in jaundiced patients. Early detection and treatment has been clearly shown to reduce permanent neurological damage. Current guidance has already made adoption difficult for hospitals to even evaluate this technology. The technology has been studied in major medical centres across the world and has been validated as the only test to accurately detect haemolysis (Castillo Cuadrado 2015).	Thank you for your comments however the accuracy of devices measuring end-tidal carbon monoxide levels (ETCO) is covered in a separate section of the full guideline (chapter 4) which was outside of the scope of this update. This update was limited to management and treatment of hyperbilirubinaemia (section 1.3 of the full guideline). We will however share this information you have provided with the Medical Technologies Evaluation Programme who can consider the evidence presented when they review this section of the guideline for future updates
Capnia UK	Short	General	General	Research shows that babies with an increased production rate (high rate of haemolysis) is a major cause of severe hyperbilirubinemia and are at greater risk for adverse neurodevelopmental outcomes (Wong & Stevenson, 2015). There is a new CE Marked device available that can quickly identify if a baby has a high rate of bilirubin production, by measuring ETCO.	Thank you for your comments however the accuracy of devices measuring end-tidal carbon monoxide levels (ETCO) is covered in a separate section of the full guideline (chapter 4) which was outside of the scope of this update. This update was limited to management and treatment of hyperbilirubinaemia (section 1.3 of the full guideline). We will however share this information with our surveillance team who can consider the evidence presented when they review

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					this section of the guideline for future updates
Royal College of Paediatrics and Child Health	Short	6	9-20 (section 1.2.16)	We think that one more line should be added – if a significant discrepancy in the bilirubin level is noted between transcutaneous bilirubinometer and laboratory measured bilirubin on a particular neonatal unit in previous samples, then the serum bilirubin should be measured to make all treatment decisions.	Thank you for your comment. We have discussed this with the committee and agreed not to add the third bullet as suggested. We consider that we have covered this issue adequately in the Linking evidence to recommendations table by highlighting existing concerns over the accuracy of TCB's in some scenarios such as babies with a darker skin tone, cases of severe hyperbilirubinaemia, babies undergoing phototherapy.
Capnia UK	Short	6	12-16	Currently, there is no consistency in the evaluation of jaundice in neonates, even though 60-80% of all babies will have some level of jaundice around the time of birth. Visual inspection is commonly used as a method of screening in the UK but it is highly subjective and inaccurate particularly with ethnic minorities with different skin tones. In some cases, transcutaneous measurements of bilirubin are performed but those too are often inaccurate in babies with difference skin colours as well as in cases when bilirubin levels are high or when babies are receiving phototherapy. This drawback of jaundice evaluation exists for families, doctors as well as other health care providers who provide care to babies at home. There is a new CE Marked non-invasive monitoring device (CoSense) available that can accurately identify if a baby has	Thank you for your comments and concerns being raised however the accuracy of devices measuring end-tidal carbon monoxide levels (ETCO) is covered in a separate section of the full guideline (chapter 4) which was outside of the scope of this update. This update was limited to management and treatment of hyperbilirubinaemia (section 1.3 of the full guideline). We will however share this information with the Medical Technologies Evaluation Programme (MTEP) who can consider the evidence presented when they review this section of the guideline for future updates

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				a high bilirubin production rate, as a result of haemolytic jaundice. This technology measures end-tidal carbon monoxide (ETCO) and can accurately identify babies, including those with darker skin tones, with high bilirubin production rates. Research shows that babies with an increased production rate (high rate of haemolysis) are at greater risk for adverse neurodevelopmental outcomes (Wong & Stevenson 2015, Bhutani & Johnson 2009, Bhutani & Wong 2013). All babies, especially darker skinned babies, can be tested with this device to assess which babies would need further testing. If the ETCO levels are high (> 2ppm) then the baby can be further investigated for the cause of haemolysis (Christensen 2014). The technology was reviewed by the NIHR horizon scanning team: http://www.hsric.nihr.ac.uk/topics/cosense-end-tidal-carbon-monoxide-monitor-for-neonatal-haemolytic-disease/. Several peer reviewed publications have described its use in the setting of neonates and paediatric patients (Christensen 2015, Castillo Cuadrado 2015, Lal 2015, Christensen 2016, Bhutani 2016). Another device was evaluated several years ago for a similar purpose but had significant limitations. It led to a negative review by NICE and a comment in its guidelines that ETCO monitoring should not be used for the prediction of hyperbilirubinemia. CoSense overcomes all the limitations of the prior device and is not being recommended for the detection of jaundice- but to detect haemolysis which is a	

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				predictor of adverse outcomes in babies with jaundice. Capnia UK Ltd conducted research with Device Access UK Ltd to explore the rate of neonatal jaundice in NHS England using the HSCIC Hospital Episode Statistics Database. The analysis looked at the 155,698 babies readmitted from April 2013-October 2014, and examined the ethnicity data broken down by ICD-10 code. In addition, the length of stay data was examined to see the overall disruption to parents, their babies, and NHS England. These results clearly showed a far greater rate of neonatal jaundice causing a readmission in NHS England within the following ethnic groups (D to S): White and Black Caribbean (Mixed), White and Black African (Mixed), White and Asian (Mixed), other Mixed background, Indian (Asian) or Asian British) Indian (Asian or Asian British) Pakistani (Asian or Asian British), Bangladeshi (Asian or Asian British), Any other Asian background Caribbean (Black or Black British) African (Black or Black British, Any other Black background Chinese (other ethnic group) & Any other ethnic group. One particular ethnic group (Chinese) had a very high 8.3% chance of readmission. These NHS data / information were offered to the committee at no cost. An economic analysis conducted with the above rates of	

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				readmission shows that there are substantial savings associated with the use of the CoSense device. In addition, the worst cases of adverse neurodevelopmental outcomes related to jaundice (called kernicterus) are typically associated with malpractice lawsuits worth several million pounds each. CoSense has the ability to identify cases of jaundice that may progress to kernicterus and potentially provide further savings to the NHS.	
Royal College of Paediatrics and Child Health	Short	10	1 -8 (section 1.4.1)	This recommendation can be a little bit challenging for nurses as well as doctors. We think that all babies whose bilirubin level is below the phototherapy threshold but within 50 micromoles/litre of the threshold should have their serum bilirubin repeated within 18 hours irrespective of the risk. We do not think a separate timetable for high risk (within18 hours) and for standard risk (within 24 hours) is necessary as it can be difficult to implement. The question might arise what we should do when the child is mostly on breast milk and a tiny amount of formula milk supplements. Moreover, the rate of rise of bilirubin in exclusively breastfed babies is not that high as to constitute high risk although total bilirubin can reach a high level if phototherapy is not instituted at the right time. Even if the serum bilirubin is repeated within 24 hours for all babies who had within 50 micromoles/litre of the phototherapy threshold,	Thank you for your comment. The committee noted that the main purpose of treatment for hyperbilirubinemia is to prevent kernicterus (a serious bilirubin-induced brain dysfunction). However, kernicterus is very rare and extremely unlikely at levels below the treatment thresholds for phototherapy. The committee therefore believed that the new proposed timings for retesting which prioritise infants at high risk of hyperbilirubinemia balance the very low risk of kernicterus with practical considerations, and the harms of over-testing (such as finding clinically irrelevant results causing unnecessary anxiety to the family as well as the unnecessary use of resources), while ensuring safe care. Please see section 2.25 (trade off between benefits and harms) of the linking evidence to recommendations table for further

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				evidence does not suggest that it would be a significant risk. But in my view 18 hours would be safest option for all babies in this situation.	details.
RCN	General	General	General	The Royal College of Nursing invited members who care for this group of children to review the draft document on its behalf. The comments below reflect the view of our members	Thank you.
RCN	Addendum	General	General	In general, our members believe that the recommendations being suggested are sensible and in line with the increased research evidence available. In particular the dropping of the threshold from 38 to 35 weeks for the use of TCB will be welcomed.	Thank you for your comment. Please however note that the threshold for the use of TcB has not been changed – it was recommended for those ≥35 weeks in both the original guideline and this update given the evidence identified.
RCN	Addendum	50	ii) 2nd bullet point	With reference to the comment: 'The committee acknowledged that midwives measuring bilirubin levels at 5pm in the evening for example are realistically only able to carry out a repeat measurement the following morning.'; Our members consider that this statement rather gives the impression that this is expedient for the system rather than acceptable for the clinical practice. They suggest that in line with 'person centred care initiatives' it might be helpful to rephrase the statement.	Thank you for your comment. We have rephrased this to read 'The committee acknowledged that it is clinically acceptable for midwives measuring bilirubin levels at 5pm in the evening for example to carry out a repeat measurement the following morning.'