Neonatal jaundice – scope consultation 19 December – 30 January 2008

Status	Organisation	Order no.	Section	Comment	Response
SH	Children's Liver Disease Foundation	1	2 a	Line 4 Suggest you add “neonatal” between “with” and “jaundice” – for clarity. This is so it is clear that you are not dealing with jaundice caused by liver disease	Thank you for your comments. The term ‘neonatal jaundice’ has been added.
SH	Children's Liver Disease Foundation	2	2f	There are other metabolic disorders which also need urgent recognition because they need nutritional treatment e.g. galactosaemia. It would be helpful to identify this.	Agreed. We will be covering the recognition and appropriate referral for metabolic disorders, but their management is outside the scope of this guideline.
SH	Children's Liver Disease Foundation	3	4.1.1a)	Suggest this should read “Newborn infants to 14 days “ (to ensure there is seamless management with the Yellow Alert campaign message) and dovetails with British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN) guidelines for the management of the infant with conjugated hyperbilirubinaemia. These are published on the website.	Agreed. The guideline will now cover infants from birth to first 28 days.
SH	Children's Liver Disease Foundation	4	4.1.2a)	Suggest this reads: The management of newborns with conjugated hyperbilirubinaemia	Agreed and changed.
SH	Children's Liver Disease Foundation	5	4.1.2c)	Whilst CLDF accepts that cut off points are needed to keep the scope manageable, this is an excellent opportunity to ensure that babies with liver disease do not slip through the net. I would delete c) if you include the suggested amend in comment number 4 above. It is vital that a clear call to action for babies with prolonged jaundice is given in the guidelines, that is: • Split bilirubin • Visual inspection of stool and urine colour • Referral to secondary or tertiary care for the management of conjugated hyperbilirubinaemia	We have changed 4.1.2a) as suggested, but would keep 4.1.2c) at the moment for clarity. We agree with action for babies with prolonged jaundice and will also consider the care pathway as suggested by you (including indications for referral to tertiary care).

Status	Organisation	Order no.	Section	Comment	Response
SH	Children's Liver Disease Foundation	6	4.3 b)	Whilst the clinical management is likely to alter during guidelines development, CLDF would advocate inclusion in the management in primary care: - Measurement of total serum and split bilirubin - Visual inspection of stool and urine	These tests will be considered under management in primary care (includes community care) which now reads as • Assessment in primary care • Estimation of hyperbilirubinaemia and it's management • Management at home, in the community and after discharge. • Indications for referral to secondary care Apart from reviewing evidence on the issue, we shall also seek guidance from primary care specialists.
SH	Children's Liver Disease Foundation	7	4.3 c)	Include measurement of INR so that injection with vitamin K can be given in sufficient time to avoid serious complications such as intercranial haemorrhage secondary to coagulopathy from malabsorption of vitamin K.	Agreed. This test will be covered under 'other relevant haematological and biochemical tests'.
SH	Children's Liver Disease Foundation	8	4.3 f)	Add - Clear (and simple) guidelines for referral / advice for the management of conjugated hyperbilirubinaemia **This is important. Ref:** Hussein M. Howard ER, Mieli-Vergani G et al (1991) Late referral for biliary atresia – missed opportunities for effective surgery. Lancet 1 (8635):421-3	The sentence cannot be added here as it is not an outcome, but we will ensure that this is adequately addressed in the full guideline. Thank you for giving us this important source of information.
SH	Department of Health	1	4.3 b	In our view, it would be helpful to expand the section on primary care, to include consideration of the remote recognition of jaundice (if a home visit is not performed by a midwife), and also the use of sunlight in primary care.	Thank you for your comments. The management in primary care has been expanded to include recognition and management at home and in the community. Although sunlight is probably not a practical option in different parts of the country all year around, we will review evidence on its effectiveness.

Status	Organisation	Order no.	Section	Comment	Response
SH	Department of Health	2	4.3 b or c	We feel that it would be helpful to include examination of any evidence around treatment, management and outcomes, in relation to the length of stay of the mother in hospital after delivery, or the number and timing of postnatal contacts with midwives; also, the incidence of re-admission, due to neonatal jaundice.	Thank you. We have included all these outcomes in the revised paragraph 4.3e.
SH	Det Norske Veritas - NHSLA Schemes	1	4.3 b)	Suggest that this section is re-titled to read 'Management out of hospital setting' so that it encompasses all settings where care of newborns may be managed eg at home, Sure-Start Clinics etc	Thank you for your comments. The section has been re-titled as 'management in primary care (includes community care)' to encompass all settings out of hospital.
SH	Det Norske Veritas - NHSLA Schemes	2	4.3.b)	Re estimating the extent of hyperbilirubinaemia – is this to include the methods used - Invasive or non-invasive technologies for diagnosis i.e. Capillary blood sampling; or transcutaneous bilirubinometer/flashgun/icterometer; or a combination of both?	Yes. The GDG will review published evidence on the effectiveness of both invasive and non-invasive methods of estimating neonatal hyperbilirubinaemia, before making any recommendation.
SH	Det Norske Veritas - NHSLA Schemes	3	4.3. b)	Re advice to parents – this should include in all appropriate languages/medium	Agreed. This is relevant for all advice given to parents and is not limited for neonatal jaundice only.
SH	Det Norske Veritas - NHSLA Schemes	4	4.3 b)	Re home care – would this include home phototherapy treatment which is available in some areas?	Yes, it would.
SH	Det Norske Veritas - NHSLA Schemes	5	4.3 c)	There is a good deal of overlap between the management in and out of hospital and would therefore suggest that these 2 sections are combined	Your point is well taken but we want to look at individual management options in primary and secondary care whilst stressing the need for communication and seamless transition.
SH	Det Norske Veritas - NHSLA Schemes	6	4.3 c)	Re timing of lab investigations – I feel there needs to be mention of point of care testing ie ward testing of SBR and its correlation with lab.results, including maintenance of equipment	These points will be addressed under the section 'timing of laboratory investigations'. It is outside our scope to comment on the maintenance of different equipments.
SH	Det Norske Veritas - NHSLA Schemes	7	4.3 d)	Re phototherapy this is a huge section and the following should be considered: type used; the spectrum of light used (blue/white/green/combination); distance of lights between baby and overhead light source; light	Although we agree that this is a very important area, we cannot address all the technical issues in this guideline. These lend itself very well to a Health Technology Assessment and maybe could be suggested

Status	Organisation	Order no.	Section	Comment	Response
				intensity of overhead light source and how measured and how often; how often phototherapy lights bulbs are replaced; what process in place for replacing when required; process for length of time lights are used, before replacing. All these factors have an effect on the efficacy of the phototherapy but which many units do not appear to recognise.	to the NICE topic selection committee. Nevertheless we will be covering the various modalities of phototherapy and their benefits and harm.
SH	Det Norske Veritas - NHSLA Schemes	8	4.3d)	Re interpretation of bilirubin levels and the use of normograms is a key area which the guideline without a doubt should address	Your concern is appreciated. The GDG is aware of the wide variation in practice across the country and intends to address this area on a priority basis.
SH	Det Norske Veritas - NHSLA Schemes	9	General	Support is given 100% to the guideline being applicable to all gestational age newborns	Thank you.
SH	Det Norske Veritas - NHSLA Schemes	10	General	I will be interrogating the NHSLA database for claims arising from hyperbilirubinaemia/kernicterus since 1995 and will advise you of the outcome if the data is useful and when available.	We appreciate your help and look forward to hearing back from you.
SH	Inspiration Healthcare	1	General	Blood takes are painful for newborns and should be avoided, especially for screening. If blood is taken, pain relief such as Sucrose should be used no matter where the baby is being seen. In hospitals there are leaflets such as 'your child's right to pain free procedures' yet in the community, blood takes are done with no pain relief yet it could cost as little as a few pennies per patient	Thank you for your comments. The GDG will endeavour to remind parents and caregivers about newborn pain control.
SH	Inspiration Healthcare	2	General	If a patient is suspected of having jaundice, a non-invasive method should be used until a full blood test is required prior to treatment to ensure that the patient is not subjected to unnecessary pain	The GDG will review published evidence on the effectiveness of both invasive and non-invasive methods of estimating neonatal hyperbilirubinaemia before making any recommendation.
SH	Inspiration Healthcare	3	General	Non-invasive methods allow 'instant results' are available from modern devices, thus allow community based testing reducing the need for parents to travel to hospital (environmentally friendly and less stressful)	Kindly see the response to your comment number 2.
SH	Inspiration Healthcare	4	General	Instant results allow faster turn around and therefore faster treatment, rather than waiting for staff to take blood back to the hospital sending to the lab, getting results back that may require an additional blood test etc	Kindly see the response to your comment number 2.

Status	Organisation	Order no.	Section	Comment	Response
SH	Inspiration Healthcare	5	General	If community based blood takes are acceptable, maybe community based phototherapy by simple LED panel wrap and under the supervision of the community midwife / local GP may mean that admissions to paediatric wards saving money and stress	Kindly see the response to your comment number 2.
SH	La Leche League GB	1	4.1.1	Birth to 14 days old would be a more useful group	Thank you for your comments. The guideline will now cover babies from birth to first 28 days.
SH	La Leche League GB	2	4.1.2	Provide relevant links eg Yellow alert for babies with jaundice that lasts longer than 14 days, etc.	Agreed. That will be done in the full guideline.
SH	La Leche League GB	3	4.3	Breastfeeding (usually one word) and the role of fluid supplementation -should have a '?' after it.	The relevant point has been changed to: Feeding – the role of breast milk insufficiency and dehydration.
SH	La Leche League GB	4	4.3	The importance of skin to skin contact for all babies- including this would give a powerful message.	This is a very valuable good practice point but it cannot be evaluated for the purposes of this guideline.
SH	Luton & Dunstable Hospital NHS Foundation Trust	1	General	Too much information in scope	Thank you for your comments.
SH	Luton & Dunstable Hospital NHS Foundation Trust	2	4.3c	Not many units will have transcutaneous bilirubinometer	It is outside our scope to comment on the service delivery or make recommendations regarding the availability of a service.
SH	Luton & Dunstable Hospital NHS Foundation Trust	3	4.3c	Which specific urine tests	It is not possible to define all the specific tests in the scope. The GDG will review published evidence on all the relevant urine and blood tests (their diagnostic value and effectiveness) before making any recommendation.
SH	Luton & Dunstable Hospital NHS Foundation Trust	4	4.3c	Is the bilirubin:albumin ratio really required for diagnosis	The evidence will have to be reviewed before commenting on this. Kindly see the above response also.
SH	Luton & Dunstable Hospital NHS Foundation Trust	5	4.3c	Not many units will have equipment to measure end tidal CO	Kindly see the response to your comment number 2.
SH	Luton & Dunstable Hospital NHS Foundation Trust	6	4.3d	Is tin-mesoporphyrin really evidence based treatment	The evidence has to be reviewed before drawing any conclusion on its effectiveness.
SH	Luton & Dunstable Hospital NHS Foundation Trust	7	4.3f	No mention of audiological assessment	Hearing loss would be considered as an outcome while reviewing evidence, but audiological assessment is outside the scope of this guideline.

Status	Organisation	Order no.	Section	Comment	Response
SH	National Childbirth Trust	1	3 (d)	Following the logic of this paragraph, and 3(a) above, it would be helpful if the scope and the guideline itself accepted that a degree of hyperbilirubinaemia is temporarily normal in comparison with adult levels.	Thank you for your comments. Agreed and the last sentence under paragraph 3 (d) has been revised.
SH	National Childbirth Trust	2	(e) and 4.3(a) and (b)	It is particularly important that the impression is not given in this guideline that breastfeeding is unusual. More than 70% of babies in the UK are breastfed at birth. Breastfeeding is listed as a risk factor, but it is actually inadequate or insufficient breastfeeding leading to dehydration, which has a role in the development of jaundice. There is a need to ensure that concerns about physiological jaundice do not undermine parents' confidence in breastfeeding. We have heard from many women who have been told that either their breastfeeding has caused jaundice or that they have to stop breastfeeding because the baby has jaundice and needs treating. Health professionals and carers need to be aware of the impact of their potentially negative statements about breastfeeding. Social and cultural factors mean some women have little confidence in their ability to breastfeed. If health professionals display no confidence in breastfeeding, women are more likely to stop before they wanted to and this can have a detrimental effect on their self-confidence and belief as a parent.	We agree wholeheartedly with your comment and do not want to undermine the importance of breastfeeding at any stage. In order to avoid misinterpretation of breastfeeding as a risk factor, we have reworded the relevant sentence as: 'Feeding – the role of breast milk insufficiency and dehydration'. Also added a sentence – 'the role of nutritional support and rehydration' under the treatment. .
SH	National Childbirth Trust	3	3(i)	The significance of the two phrases in the second sentence is not clear.	Agreed and appropriate changes made.
SH	National Childbirth Trust	4	3 (k)	We agree that lack of evidence based practice and consensus in this area is detrimental to babies and parents.	Thank you. We hope to address this as much as possible through this guideline.
SH	National Childbirth Trust	5	4.1.1 (a)	Will 10 days be sufficient to cover premature babies who may develop jaundice but do not come under 4.1.2 ?	The guideline will now cover babies from birth to first 28 days, and will include both term and preterm babies.
SH	National Childbirth Trust	6	4 General	Since detection and diagnosis seems to be an area of controversy, it would be helpful if it was that the guideline covered this aspect of care as	It is the intention of the GDG to provide clear evidence-based recommendations on all the controversial issues related to recognition,

Status	Organisation	Order no.	Section	Comment	Response
				well as appropriate management.	diagnosis and management of neonatal jaundice.
SH	National Childbirth Trust	7	4.3(a) and (b)	Parents 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.	Agreed. The correlation between adequacy of breast feeding/fluids and jaundice would be reviewed and parents advised accordingly. Kindly also see the response to your comment number 2 regarding breast feeding as a risk factor.
SH	National Childbirth Trust	8	4.3(e)	We welcome the inclusion of the effect on family bonding as a consideration in treating jaundice in babies. This is a time of immense anxiety for parents, although it may be a routine matter for staff. Separation of the baby from parents can have a long term effect and parents need to be welcome to stay with their baby.	Thank you.
SH	National Childbirth Trust	9	4.3 (g)	Opportunities to ask questions, however far fetched, and an understanding of parents' needs for information, support and reassurance when appropriate is vital.	We agree completely and recognise that this is vital to all encounters between clinicians and parents. This will be covered under section on information to parents in the guideline and we shall discuss with our public representation to clarify this.
SH	National Forum of LSA Midwifery Officers (UK)	1	4.3 (d) 5th bullet point	Is the "in" between tin-mesoporphyrin and treatment a typo?	Thank you for your comments. This was to reflect the use of tin mesoporphyrin in treatment rather than prevention but the sentence has now been changed to include all 'other treatment modalities'.
SH	National Forum of LSA Midwifery Officers (UK)	2	4.3 (e) 3rd bullet point	Suggest that the term nosocomial infections is changed to hospital acquired infections.	Agreed and changed. This section has now been combined with outcomes under section 4.3 e.
SH	National Forum of LSA Midwifery Officers (UK)	2	4.1.2	Should cover mixed conjugated and unconjugated jaundice	The guideline will cover identification of both unconjugated and conjugated hyperbilirubinaemia, but it will cover the management of unconjugated hyperbilirubinaemia only.
SH	National Forum of LSA Midwifery Officers (UK)	3	General	We welcome an evidence based guideline that will support the care of babies with jaundice.	Thank you.
SH	National Forum of LSA	3		Likely that 14 days is a better option than 10 – this	Agreed. The guideline will now cover babies

Status	Organisation	Order no.	Section	Comment	Response
	Midwifery Officers (UK)			could be a chance to re-establish yellow alert information within the mind set	from birth to first 28 days.
SH	National Forum of LSA Midwifery Officers (UK)	4	4.2	With 6 hr discharge, it is essential that this covers community and paediatric settings as well as NICUs, and post natal environments. Needs to include health and safety issues pertinent to the use of bilibeds in the home environment	This will be done, and "primary care" has been changed to include "primary care and community settings" to make this even clearer. Management in NICU is outside the scope of this guideline. The GDG will review evidence on the effectiveness of different modalities of phototherapy (including safety) before making a recommendation.
SH	National Forum of LSA Midwifery Officers (UK)	5	4.3 a	Polycythemia should be included on the risk factors	It has been added.
SH	National Forum of LSA Midwifery Officers (UK)	6	C	Blood group is missing.. Tools for assessment of bilirubin – screening and diagnostic Correct procedures for obtaining samples – for example non haemolysised, lights off, etc Time scales between sampling and analysis (more so in 4.3b)	Blood group is already mentioned under risk factors. The rest of the comments will be addressed under management in primary care (includes community care) which now reads as: • Assessment in primary care • Estimation of hyperbilirubinaemia and it's management • Management at home, in the community and after discharge. • Indications for referral to secondary care
SH	National Forum of LSA Midwifery Officers (UK)	7	d	Evidence to support any type of feeding during treatment, use of suppositories, phenobarbitone…?	The evidence for all these factors will be considered under 'Role of nutritional support and rehydration' and 'other treatment modalities'.
SH	National Forum of LSA Midwifery Officers (UK)	8	e	Transitional care management issues which may affect effectiveness of treatment interventions for example staffing ratios and staff training may also have to be covered.	It is beyond our domain to comment on the service delivery, staff training or staffing requirement.
SH	National Forum of LSA Midwifery Officers (UK)	9	general	A lot of the issues can be avoided by good communication processes and effective liaison between the different professional groups – i.e. midwives/ doctors (paediatrics / nicu)/ neonatal	Your concern is appreciated. The GDG will be multidisciplinary and we anticipate the recommendations will reflect the strong liaison required between health

Status	Organisation	Order no.	Section	Comment	Response
				nurses/paediatric staff nurses/ laboratory. Principally neonates should not be separated from parents for phototherapy unless additional interventions are required for example IV fluids etc. The problem is often that midwifery staffing levels on post natal wards do not allow for the additional care required by infants with additional needs – transitional care units are ideal but require appropriate staffing also.	professionals. For staffing levels, kindly see our response to your comment number 8.
SH	Royal College of Nursing	1	4.1.1	Needs to cover all neonates whatever the gestation	Thank you for your comment. The guideline will cover all neonates from birth to first 28 days irrespective of their gestational age.
SH	Royal College of Paediatrics and Child Health	1	General	The scope appears to have been clear, relevant and well constructed.	Thank you.
SH	Royal College of Paediatrics and Child Health	2	General	We are concerned that the guideline stops at 10 days. The majority of guidelines for the management of jaundice place their cut off for intervention predominantly at 14 days for term infants, and 21 days for preterm. We are also concerned that the scope may not indicate how to deal with conjugated hyperbilirubinaemia for primary and secondary care. The evidence is clear that early management of biliary atresia dramatically improves the outcome and reduces the need for liver transplant.	Agreed. The guideline will now cover infants from birth to first 28 days. We will also consider recognition and appropriate referral for the management of conjugated hyperbilirubinaemia at both the primary and secondary care settings. However management of biliary atresia is outside the scope of this guideline.
SH	Royal College of Paediatrics and Child Health	3	General	We wonder if there is any role for a single bilirubin check prior to discharge? This could then be plotted on a centile chart to predict likely problems post-discharge.	The GDG will review evidence on the predictive accuracy and effectiveness of all the tests including that of a single bilirubin testing before making any recommendation.
SH	Royal College of Paediatrics and Child Health	4	General	We would hope to see clear algorithms/nomograms included in order to keep the text as short as possible	This is indeed the aim of this guideline.
SH	Royal College of Paediatrics and Child Health	5	General	We have some concern about the exclusion of prolonged jaundice. Perhaps the guideline should include a statement about the need to refer newborns with prolonged jaundice. It would also be nice to see a separate guideline produced on prolonged jaundice, if this were to be the case this guideline should be called “Early Neonatal	Your concern is well appreciated. The age has been increased to first 28 days and we will be covering prolonged jaundice.

Status	Organisation	Order no.	Section	Comment	Response
				Jaundice". If two guidelines were to be produced there would need to be an introduction directing health care workers to either guideline appropriate to the clinical scenario.	
SH	Royal College of Paediatrics and Child Health	6	General	We feel a separate subheading of "Jaundice within 24 hours of birth" should be included as the aetiology and management (including urgency of treatment) will differ.	We agree with your comment but feel that scope is not the appropriate place for it. Separate sub-headings will be included in the main guideline.
SH	Royal College of Paediatrics and Child Health	7	General	The management for primary care workers, especially midwives, needs to be clearly defined	This will be covered under the management in primary care/community care section.
SH	Royal College of Paediatrics and Child Health	8	General	This document deals with unconjugated hyperbilirubinaemia alone and in isolation from conjugated hyperbilirubinaemia, but is entitled "Neonatal Jaundice". Liver disease, always implied by conjugated hyperbilirubinaemia, is one of the most serious causes of neonatal jaundice and unless this is addressed in this guideline alongside unconjugated hyperbilirubinaemia, the tendency to dismiss jaundice as physiological (and only serious if the bilirubin level is very high) will be perpetuated.	We disagree with your comment. There is a growing concern on the increasing number of kernicterus cases in the UK. Apart from delay in the recognition of such cases at an early stage, there is great variation in the management (diagnosis, treatment, referrals) of these cases. It is of paramount importance that evidence-based guidance is given to health care providers. Nevertheless we will be covering the diagnosis of conjugated hyperbilirubinaemia and the appropriate referral pathway to tertiary care centres.
SH	Royal College of Paediatrics and Child Health	9	1	The title as it stands requires clarification i.e. "recognition and treatment of neonatal jaundice within the first two weeks of life".	Agreed. The title has been changed to 'Neonatal jaundice'.
SH	Royal College of Paediatrics and Child Health	10	2 and 3	Are sections 2 and 3 part of the parent information leaflet as the information is rather superficial and in layman's terms rather than technical language?	This is not part of the parent leaflet at the moment, but the scope background needs to be readable by a large number of different groups including lay people.
SH	Royal College of Paediatrics and Child Health	11	3	We think this section would benefit from a paragraph outlining the positive physiological role of bilirubin as an antioxidant.	Evaluation of the role of bilirubin as an antioxidant is outside the scope.
SH	Royal College of Paediatrics and Child Health	12	3 i)	The age of the infant should be included as a variable in aetiology of encephalopathy.	It has been included.
SH	Royal College of Paediatrics and Child Health	13	3 (b)	We feel the comment 'yellow colouration' should be 'yellow discolouration'.	Agree with what you are trying to imply. However it could be equally described as a colouration as yellow is not necessarily a "dis" colouration.
SH	Royal College of Paediatrics	14	3.c	We are unsure as to whether using "direct" and	Agree with your comment that it may not be

Status	Organisation	Order no.	Section	Comment	Response
	and Child Health			"indirect" terminology for bilirubin is confusing or whether it is necessary?	necessary, but both the terms are widely used and probably need explaining or it could continue to cause confusion.
SH	Royal College of Paediatrics and Child Health	15	3e	Breast milk associated jaundice probably is harmless but its recognition is problematic. Campaigns by the children's liver disease foundation (Yellow Alert) for early diagnosis of liver disease, particularly biliary atresia, have presented a dilemma to GPs, health visitors, midwives and paediatric departments. This is because 10% of all breast fed infants will have prolonged jaundice yet only a tiny fraction of these have liver disease. Guideline 37 does not adequately tackle this. See *Acta Paed.* 1999; **88:** 969-74.	We are aware of this problem, and the need to plan sensibly for the few babies who need referral to tertiary centres because of conjugated hyperbilirubinaemia. The GDG will make sure that the guideline contains appropriate advice regarding interpretation of conjugated bilirubin results and early referral to specialist tertiary services.
SH	Royal College of Paediatrics and Child Health	16	3.f	The abbreviation of glucose-6-phosphate-dehydrogenase should be given in brackets after use of the full version as the abbreviated version is used in the next sentence without explanation.	Agreed and changed.
SH	Royal College of Paediatrics and Child Health	17	3 (g)	The sentence stating 'the exact level of bilirubin that will cause neurotoxicity in any individual baby cannot be predicted' we think would be better phrased 'the exact level of bilirubin that is likely to cause neurotoxicity in any individual baby depends on the interplay of multiple factors including acidosis, electrolyte disturbances, hypoalbuminaemia and infection, this can be anticipated by the use of bilirubin nomograms for different gestational ages'.	The sentence has been modified largely following this suggestion, apart from the last clause "this can be anticipated by the use of bilirubin nomograms for different gestational ages' which is not yet certain and which this guideline will address.
SH	Royal College of Paediatrics and Child Health	18	3(h)	We think 'acidosis' should be added to the list of factors influencing passage of bilirubin into the brain.	It has been added.
SH	Royal College of Paediatrics and Child Health	19	3.h & 3.i	We feel these two points essentially cover the same ground (relation of levels to encephalopathy). Could they be re-written into a single paragraph?	We considered combining them into one paragraph but on balance left them as two separate paragraphs as wanted to highlight the actual bilirubin levels associated with kernicterus (paragraph 3h) and the importance of nomograms (paragraph 3i).
SH	Royal College of Paediatrics and Child Health	20	3.j	"Phototherapy" is not defined – is this simply the "lamp" described previously? It will also be necessary to evaluate possible visual damage	The word "phototherapy" has now been added. All the side effects of phototherapy will be evaluated while reviewing evidence

Status	Organisation	Order no.	Section	Comment	Response
				relating to phototherapy, and precautions for minimising this.	on its effectiveness.
SH	Royal College of Paediatrics and Child Health	21	3.j	A definition of “exchange transfusion” may be useful.	It will be defined in the glossary in the full guideline.
SH	Royal College of Paediatrics and Child Health	22	3(k)	We feel the first sentence ‘There is uncertainty about when to treat…’ would be better phrased as ‘There is wide variation of practice between different units etc…’.	Thank you. The wording has been changed.
SH	Royal College of Paediatrics and Child Health	23	4.1.1a)	We would like to see inclusion of term and preterm infants.	Agreed. We have included both term and preterm babies.
SH	Royal College of Paediatrics and Child Health	24	4.1.1 a and 4.1.2 c	Jaundice does not always disappear completely by ten days and breast milk associated jaundice merges into the period of early jaundice. We therefore believe that it is illogical to focus on the first ten days and the guideline will be more useful if it addresses all the issues around jaundice in the newborn for a longer period. The areas that affect the interface and relationships between hospital staff and community staff should be particularly covered. Appropriate systems for spotting potentially serious jaundice in the first few days of life after discharge will be a crucial part of the guideline, but similar issues apply over the first 4-6 weeks of life with regard to identifying possible biliary atresia and other serious disorders, and how to ensure prompt referral and appropriate workup.	The guideline will now cover infants from birth to first 28 days. The GDG will be multidisciplinary and we anticipate the recommendations will reflect the strong liaison required between health professionals in the hospital and the community so that potentially serious cases of jaundice are not missed in the future. We appreciate your comments regarding conjugated hyperbilirubinaemia. We do plan to provide evidence-based guidance on its recognition and appropriate referral, but covering its management will be difficult within our timeframe and available resources.
SH	Royal College of Paediatrics and Child Health	25	4.1.2 c)	We expect the cut-off will be changed to 14 days as agreed at the stakeholder meeting.	It has now been changed to first 28 days.
SH	Royal College of Paediatrics and Child Health	26	4.3	On the whole this section has been written very thoroughly.	Thank you.
SH	Royal College of Paediatrics and Child Health	27	4.3a	Drugs which affect the binding of bilirubin to albumin are a risk factor for kernicterus and should also be noted.	Agreed. They have been added.
SH	Royal College of Paediatrics and Child Health	28	4.3(a)	Should ‘sex’ be included in maternal factors? Surely the sex will always be female?	Agreed, it has been deleted.
SH	Royal College of Paediatrics and Child Health	29	4.3(a)	The risk factors could be divided into maternal factors and infant related factors. Maternal factors could be further divided into family, labour and delivery. Alternatively the same proposed list could	The list of risk factors has been revised and divided into maternal and infant factors.

Status	Organisation	Order no.	Section	Comment	Response
				be used but arranged into alphabetical order. In the proposed list sepsis and infection are synonymous so one should be omitted.	Agreed regarding no need for both “sepsis” and “infection”. Appropriate change made.
SH	Royal College of Paediatrics and Child Health	30	4.3(a)	Perhaps this should be re-worded as prematurity is diagnosed by gestational age.	It has been done leaving only gestational age.
SH	Royal College of Paediatrics and Child Health	31	4.3 b	We think it would be wise to include the role of routine weighing around days 5-7 to detect abnormal weight loss.	This will be covered under management in primary/community care.
SH	Royal College of Paediatrics and Child Health	32	4.3.b	It would be helpful to consider the role of transcutaneous bilirubin estimate (whether by electronic device or even plastic colour strip) in assessing jaundice in primary care. One major problem in management is the early discharge of mothers before breast feeding is established, and then the lack of any easy system for midwives to accurately estimate bilirubin levels when babies develop jaundice at home. This often leads to serious delays in return to hospital.	The GDG will review all published evidence on the effectiveness of both invasive and non-invasive methods for estimating neonatal hyperbilirubinaemia, and its management in different settings before making any recommendation.
SH	Royal College of Paediatrics and Child Health	33	4.3b & c	The onset and duration of jaundice should be considered. i.e. Jaundice appearing in first 24 hours and after 2 weeks is more likely to be pathological.	It is not possible to provide all the details in the scope, but the full guideline will cover all these aspects and have a glossary with the relevant definitions.
SH	Royal College of Paediatrics and Child Health	34	4.3c	Under ‘Investigations’ we would like to see the sub-headings ‘Blood group for mother and infant’ and ‘Conjugated bilirubin more than 20% of total’ (this point should also include a note to say refer promptly for investigation of liver disease).	The section on investigation has been revised to encompass all the relevant tests without specifying these tests individually. It now reads as: Investigations including • Bilirubin – components and methods of estimation • Other relevant haematological and biochemical tests • Urine tests • Screening for metabolic disorders • End tidal Carbon Monoxide concentration Advice will be given regarding interpretation of tests; we are hoping the appropriate trigger level will be brought out in the systematic review.

Status	Organisation	Order no.	Section	Comment	Response
SH	Royal College of Paediatrics and Child Health	35	4.3 c	FBC and film , U & E (Na), 'urine tests'=microsc+C+S should also be included as points.	Kindly see the above response to comment number 34.
SH	Royal College of Paediatrics and Child Health	36	4.3(c)	If transcutaneous bilirubin is to be considered, its usefulness in primary care should also be investigated.	Kindly see the above response to comment number 31.
SH	Royal College of Paediatrics and Child Health	37	4.3 (c)	Blood group, blood gas (pH), film, clotting and platelet count should be included.	Kindly see the above response to comment number 34.
SH	Royal College of Paediatrics and Child Health	38	4.3 (c)	End tidal carbon dioxide levels should be compared to assessments of haemolysis.	End tidal CO is already included in the list of tests which will be evaluated.
SH	Royal College of Paediatrics and Child Health	39	4.3.c.	We think it may be worth including some advice (perhaps from the Medical Devices Agency?) on reliable ward-based bilirubin measures, without which babies will continue to slip through the net.	Near-patient testing will be evaluated as far as possible.
SH	Royal College of Paediatrics and Child Health	40	4.3(c)	In the investigations we would prefer to add full blood count and blood film, Liver enzymes, urine test should specify CMV and culture/sensitivity	Kindly see the above response to comment number 34.
SH	Royal College of Paediatrics and Child Health	41	4.3 d	Include 'rehydration and fluid balance' to treatment points.	Agreed and the words added.
SH	Royal College of Paediatrics and Child Health	42	4.3d	We think this section needs to have a clearer description that it is part of the scope to look at the clinical benefit of a mild degree of hyperbilirubinaemia versus its clinical risk and that of its treatment. Furthermore, whilst kernicterus must be avoided, we currently start phototherapy at bilirubin levels well below exchange levels. There may be room for some monitoring if, after some hrs of phototherapy, the bilirubin levels stay fairly constant albeit above the phototherapy threshold.	It could be very difficult to include an evaluation of any potential benefit of untreated mild hyperbilirubinaemia in this guideline. Reports show that some units do not start phototherapy until levels which are very, very close to the "exchange" level. There seems to be a lack of uniformity of approach in the UK at present. We are hoping that the systematic reviews will help us recommend on some of these issues.
SH	Royal College of Paediatrics and Child Health	43	4.3 (f)	Deafness should be particularly included here.	It has been added as auditory complication.
SH	Royal College of Paediatrics and Child Health	44	4.3f	See 4.3d. The guideline needs to look for any deterioration in physiological parameters as a result of phototherapy, in other words, 'side effects of treatment' would be a better expression than 'complications'.	All these side effects will be looked into while reviewing evidence on its effectiveness. The phrasing has been changed to 'benefits and harm of various treatments'.
SH	Royal College of Pathologists	1		The Royal College of Pathologists has no comments to submit at this stage of the consultation.	Thank you.

Status	Organisation	Order no.	Section	Comment	Response
SH	Royal Society of Medicine	1	Appendix	The Department of Health asked *NICE "to prepare a clinical guideline on the recognition and treatment of **babies** who are **jaundiced**".* Sensibly, the DoH does not limit the guideline to ***very young*** babies with ***unconjugated*** jaundice.	Thank you for your comments. Agreed. The guideline will now cover infants from birth to first 28 days of life. We appreciate your comments regarding conjugated hyperbilirubinaemia. We do plan to provide evidence-based guidance on its recognition and appropriate referral, but covering its management will be difficult within our timeframe and the available resources. Moreover the recognition and treatment of babies with conjugated jaundice is already covered in the Yellow Alert campaign run by the Children's Liver Disease Foundation and the recommendations of this guideline could be linked to that. For further information please visit their website: http://www.childliverdisease.org/education/yellowalert
SH	Royal Society of Medicine	2	4.1.1	*Groups that will be covered: Newborn infants from birth to 10 days old.* This is too restricted. The guideline should cover neonatal jaundice as a minimum – (i.e. birth to 28 days).	Agreed. The guideline will now cover infants from birth to first 28 days of life.
SH	Royal Society of Medicine	3	4.1.2	*Groups that will not be covered*. But these groups (babies with prolonged jaundice, and babies with conjugated hyperbilirubinaemia) **should** be covered. If they are not, NICE will have to produce separate guidelines about these problems. Biliary atresia in particular is *so* important (and easy to miss, and manage badly, with devastating health and financial consequences).	The guideline will be covering infants with prolonged unconjugated hyperbilirubinaemia. Kindly see the response to your comment number 1 for clarification regarding conjugated hyperbilirubinaemia.
SH	Royal Society of Medicine	4	4.3. a)	***Maternal factors including age, race, sex and diabetes*** Need to get rid of the word *sex* (all mothers are female)	Agreed and the word deleted.

Status	Organisation	Order no.	Section	Comment	Response
SH	Royal Society of Medicine	5	4.3. a)	*Serum albumin*. A low serum albumin is not a risk factor behind the development of jaundice. It is a risk factor for that jaundice causing kerbicterus.	Agreed. The term 'kernicterus' has been added in the subheading.
SH	Royal Society of Medicine	6	4.3. c)	*Investigations including: Glucose-6-phosphate dehydrogenase deficiency*. This is not an investigation, but a diagnosis. Omit the word "deficiency". (Just as one would not say "investigations such as hypothyroidism").	Agreed and done.
SH	Salford Royal Hospitals NHS Foundation Trust	1	4.1.1	The guidelines should address the approach to hyperbilirubinaemia in preterm infants as well as term infants.	Thank you for your comments. Agreed. Both term and preterm infants will be included in the guideline.
SH	Salford Royal Hospitals NHS Foundation Trust	2	4.1.2a	It is reasonable to exclude the detailed further management of conjugated hyperbilirubinaemia from these guidelines. However, the importance of its diagnosis and its initial investigation should be addressed (e.g. when to suspect, when to check conjugated bilirubin, initial blood tests etc.)	Thank you. We agree with your comment and this is the current plan.
SH	Salford Royal Hospitals NHS Foundation Trust	3	4.1.2c	Re: exclusion of "prolonged" jaundice. We suggest 14 days as the cut-off rather than 10 days (as discussed at the stakeholders meeting.) The work-up of conjugated hyperbilirubinaemia has been dealt with in other documents (e.g. "yellow alert"). However, the approach to prolonged unconjugated hyperbilirubinaemia has not been addressed and should be covered in these guidelines – e.g. when is it reasonable to assume that this jaundice is associated with breast milk/feeding, and when should further investigations for rarer causes (like CNJ 2) be done?	Agreed. The guideline will now cover infants from birth to first 28 days of life. We will also be covering the diagnosis and management of prolonged unconjugated hyperbilirubinaemia.
SH	Salford Royal Hospitals NHS Foundation Trust	4	4.2.a	The guideline should also cover management in tertiary care i.e. specialist neonatal units (extremely preterm infants, and older infants in need of exchange transfusions)	Considering the timeframe and available resources, it is not possible to cover management in specialist neonatal units.
SH	Salford Royal Hospitals NHS Foundation Trust	5	4.3.b	Recognition that in the era of early discharges the burden of detection of hyperbilirubinaemia falls primarily on the community midwife. Need for guidance on clinical assessment, point of care (transcutaneous) monitoring, blood testing and	We appreciate your concern. All these issues will be addressed under management in primary care (includes community care) which now reads as: • Assessment in primary care

Status	Organisation	Order no.	Section	Comment	Response
				suggested referral pathways.	• Estimation of hyperbilirubinaemia and it's management • Management at home and in the community. • Indications for referral to secondary care
SH	Salford Royal Hospitals NHS Foundation Trust	6	4.3.d & 4.3.e	Address the issue of the appropriate setting of treatment. 1. Is home phototherapy appropriate? If so, when? How will baby be monitored? 2. In the era of early discharges many babies are readmitted for phototherapy, often to paediatric wards where conditions and support for the otherwise well newborn and mother may be inappropriate. The guideline process should consider and recommend if and when babies should be readmitted to postnatal wards (or transitional care units?) for phototherapy. 3. Where should exchange transfusions be done?	Agreed. All these issues will be considered by the GDG while reviewing evidence on the various interventions used in different healthcare settings and before making any recommendation.
SH	Salford Royal Hospitals NHS Foundation Trust	7	General	The process should examine the technical aspects of phototherapy and the different modalities available (might involve an alongside technical review)	Although we agree that this is a very important area, we cannot address all the technical issues in this guideline. These lend itself very well to a Health Technology Assessment and maybe could be suggested to the NICE topic selection committee. Nevertheless we will be covering the various modalities of phototherapy and their benefits and harm.
SH	Salford Royal Hospitals NHS Foundation Trust	8	General	Exchange transfusions are now uncommon. Where should they be done and by whom? Should the guideline include an appendix on the technical procedure?	It is beyond our scope to comment on the service delivery. Kindly see the above response for answer to your second question.
SH	Southampton University Hospital NHS Trust	1	4.1.2	There is a need for this guideline to have some reference to obstructive and prolonged jaundice. While accepting that the management of these aspects of neonatal jaundice are perhaps more appropriately covered by other guidance and protocols it is important to take the opportunity to promote the detection of obstructive jaundice as early as possible.	Thank you for your comments. Agreed. The guideline will address both the issues – recognition of conjugated hyperbilirubinaemia with appropriate referral pathway, and the management of prolonged jaundice.

Status	Organisation	Order no.	Section	Comment	Response
				We would also advocate that this guidance covers the first 14 days rather than just the first 10 days, encouraging a responsibility on the part of health workers beyond the traditional juristiction of the midwife.	Agreed and the guideline will now cover infants from birth to first 28 days of life.
SH	Southampton University Hospital NHS Trust	2	4.3 a	It would be helpful if the guideline development led to a usable risk assessment tool helping to alert professionals to those infants more at risk of developing jaundice and thus worthy of closer monitoring, and / or delayed discharge from maternity units.	Thank you for this very valuable suggestion. We will be aiming to develop treatment algorithms and are aware of similar work being done in this area.
SH	Southampton University Hospital NHS Trust	3	4.3 d	It would be helpful to have a technical appraisal of phototherapy equipment and comments on maintenance. Should there be more widespread use of light meters to determine the effectiveness of phototherapy? Should we be using specific wave lengths? Are there optimal time periods for light exposure?	Although we agree that this is a very important area, we cannot address all the technical issues in this guideline. These lend itself very well to a Health Technology Assessment and maybe could be suggested to the NICE topic selection committee.
SH	Southampton University Hospital NHS Trust	4	4.3 g	I would suggest that information on recognition of jaundice should be available to all parents and there might be some cross reference to guidance on infant feeding with the objective of reducing the risk of developing significant jaundice.	Agreed and noted.
SH	Southampton University Hospital NHS Trust	5	4.3 d & 4.3 h	Recent Do H guidance does not recommend the use of immunoglobulin for haemolytic jaundice. I assume that if the guideline development group conclude that immunoglobulin may have a role in its management there would be a process of linkage to existing DoH guidance.	The GDG will have to review evidence on the effectiveness of immunoglobulins before recommending it or linking to DoH guidance.
SH	UNICEF Baby Friendly Initiative	1	General	We recognise the need for this guideline given the vast discrepancies between units in how babies with physiological jaundice are managed in particular with regard to use of phototherapy and breastfeeding advice.	Thank you for your comments and support.
SH	UNICEF Baby Friendly Initiative	2	3, e	Whilst it is acknowledged that breastfed babies are more likely to develop jaundice within the first week, the phrasing of the sentence infers that this is due to lower than normal intake. When breastfeeding is carried out frequently and effectively the volume of milk accessed by the	Agreed and the sentence has been deleted.

Status	Organisation	Order no.	Section	Comment	Response
				infant would be the physiological norm. It is suggested that the higher incidence of jaundice in breastfed infants is caused by the common (but not normal) impact of limited milk transfer caused by infrequent feeding or poor attachment.	
SH	UNICEF Baby Friendly Initiative	3	4.1.1 a	Birth to 14 days would be better in terms of timing of the scope of the guideline as this fits in better with current midwifery/health visitor hand over time and would not leave a potential 4 day gap with no guidance for care	Agreed. The guideline will now cover infants from birth to first 28 days of life.
SH	UNICEF Baby Friendly Initiative	4	4.1.1.c	As above	Agreed and changed.
SH	UNICEF Baby Friendly Initiative	5	4.3 a	It would be important to carefully word the section on risk factors and feeding in order to be clear that it is not generally normal breastfeeding which puts babies at risk of prolonged/marked physiological jaundice, but ineffective breastfeeding	We agree wholeheartedly with your comment and do not want to undermine the importance of breastfeeding at any stage. In order to avoid misinterpretation of breastfeeding as a risk factor, we have reworded the relevant sentence as: 'Feeding – the role of breast milk insufficiency and dehydration'.
SH	UNICEF Baby Friendly Initiative	6	4.3 b	It would be helpful in this section to offer guidance regarding how jaundice levels including screening of serum bilirubin can be assessed in community settings by midwives, routes of referral for babies requiring readmission, where that care then takes place and the skills needed by the carers should this be in a paediatric ward environment rather than maternity unit	All these issues will be addressed under management in primary care (includes community care) which now reads as: • Assessment in primary care • Estimation of hyperbilirubinaemia and it's management • Management at home and in the community. • Indications for referral to secondary care
SH	UNICEF Baby Friendly Initiative	7	4.3 d	Guidance on the importance of maintaining breastfeeding during treatment should be included; Time spent under phototherapy versus time spent breastfeeding and in contact with mother Any additional fluid requirements during phototherapy and how these may best be provided using EBM where possible	This issue will be covered under Treatment section 4.3 "Role of nutritional support and rehydration"
SH	UNICEF Baby Friendly Initiative	8	4.3 e	Guidance on optimising contact with the	We agree with your observation and shall

Status	Organisation	Order no.	Section	Comment	Response
				mother/family during phototherapy eg where phototherapy takes place and use of eye covering would be helpful	cover these under appropriate sections.
SH	University of York	1	3e	‘ thought to be caused by a lower intake of breastmilk…’ The meaning of this phrase in the scope is unclear - lower than what? It may be any or several of: lower than the baby needs, lower in breastfed babies who become jaundiced than in other breastfed babies, lower than it might be if breastfeeding were well supported, lower than it will be in subsequent weeks of breastfeeding, lower volume intake of breast milk by breastfed infants than volume intake of supplements/ formula by supplemented, mixed or formula fed babies, etc.	Thank you for your comments. Agreed. We have now amended this to “a relative insufficiency of breast milk”.
SH	University of York	2	3j	Levels of bilirubin can also be controlled by using a bilirubin blanket (‘biliblanket’). With the biliblanket, babies do not have to be nursed in an incubator and it is easier for their mothers to continue to be with them and care for them, especially in a transitional care setting. Evidence for this method of management should be included in the review.	The GDG will review published evidence on the effectiveness of all modalities of phototherapy (including biliblanket) in different health care settings before making recommendations.
SH	University of York	3	3j	Traditionally, advice on managing mild jaundice at home included exposing the baby’s skin to sunshine. The evidence base for this advice should be included in the review in relation to management in primary care.	Thank you. It will be done.
SH	University of York	4	General	Guidance on this topic is welcome. Distinguishing between jaundice that needs urgent treatment and jaundice that may never need treatment is an important clinical skill, and errors in either direction may have important consequences.	Thank you.