NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

Recommendation for Guidance Executive

Review of Clinical Guideline (CG37) – Postnatal care

Background information

Guideline issue date: 2006

3 year review: 2009 (No update required)

5 year review: 2011

National Collaborating Centre: Primary Care

Review recommendation

- The guideline should not be updated at this time.

Factors influencing the decision

Literature search

1. Through an assessment of abstracts from a high-level randomised controlled trial (RCT) search, new evidence was identified relating to the following clinical areas within the guideline:
    - Planning the content and delivery of care
    - Maintaining maternal health
    - Infant feeding
    - Maintaining infant health

    The findings of the identified studies mostly reinforce existing guideline recommendations and no new evidence was identified which would indicate a significant change in clinical practice or that would invalidate or change the direction of current guideline recommendations.

2. No evidence was identified which directly answered the research recommendations presented in the original guideline.

3. Several ongoing clinical trials were identified (publication dates unknown) focusing on:
    - improving health outcomes for new mothers and babies
    - the effect of postpartum pelvic floor muscle training in women with injured and non-injured pelvic floor muscles
    - assessing maternal post-partum pain with suppositories
    - lanolin for the treatment of nipple pain among breastfeeding women
    - the evaluation of lactobacilli (isolated from human milk) for the treatment of infectious mastitis.

Guideline Development Group perspective

4. A questionnaire was distributed to GDG members to consult them on the need for an update of the guideline. Three responses were received with respondents highlighting that although more literature has become available since the guideline was published, they were not aware of any new evidence that contradicts the recommendations.

5. One respondent stated that in their view, Baby Friendly Initiative (BFI) accreditation has become more cost-effective as more midwives, GPs and health visitors have been trained and university education is accredited.

6. Ongoing research was cited by GDG members including RCTs on breastfeeding peer support programmes and studies to improve the content and outcomes of routine postnatal care.

7. Changes to the organisation of care and issues relating to implementation of the guideline were also highlighted

8. Two respondents stated that overall the guideline remains a robust framework for post natal care and it is not necessary to update the recommendations at this time. One respondent stated that the

guideline needed updating on account of surveys on women's experience of maternity care that indicate the guideline recommendations are not being implemented.

Implementation and post publication feedback

9. In total 141 enquiries were received from post-publication feedback, most of which were routine. There was also a query on an inconsistency between the DH guidance 'The Green Book' (2006) and the postnatal care guideline recommendations which relates to the timing of MMR vaccination in women who also require the anti-D immunoglobulin injection. However, it was considered that this issue affects only a small group of women, for whom the guideline was conservative in its recommendations. There were no comments on this point during consultation.

10. The NICE implementation team identified two implementation studies from published literature relating to maternity care and services in England. One of these was the 2010 report of the Care Quality Commission (CQC) that was also mentioned by the GDG; the other was the report by the Healthcare Commission (2008) which showed that 71% to 91% of women reported receiving a postnatal check-up of their own health and wellbeing at six weeks and Trusts reported an average of 70% of mothers initiating breastfeeding.

11. Qualitative input from the field team highlighted that overall the guideline was considered to be useful, reliable and well written. However, there were concerns about the status of the 'Baby Friendly Initiative' and associated evidence base and resistance from Trusts commissioners to fund the complete examination of the baby within 72 hours of birth. There were also a few suggestions that recommendations on postnatal bladder care would be welcomed.

12. No new evidence was identified through post publication enquiries or implementation feedback that would indicate a need to update the guideline.

Relationship to other NICE guidance

13. NICE guidance related to CG37 can be viewed in Appendix 1.

Summary of Stakeholder Feedback

Review proposal put to consultees:

The guideline should not be updated at this time.

The guideline will be reviewed again according to current processes.

14. In total 10 stakeholders commented on the review proposal recommendation during the 2 week consultation period.
15. Two stakeholders agreed with the review proposal recommendation that the guideline should not be updated at this time and one stakeholder did not state a definitive decision.
16. Seven stakeholders disagreed with the review proposal with the following comments:
    - stakeholder commented that the recommendation in the guideline relating to skin care of babies in the neonatal period needs updating and provided a number of references. However, most of the references provided did not meet NICE's evidence threshold as they were narrative reviews of the literature or book chapters. The other references were deemed not to invalidate or change current guideline recommendations
    - stakeholder commented that there was need for proper examination of the palate, with no references provided. The guideline has already emphasised the importance of a thorough physical examination of the newborn (including the mouth and palate) within 72 hours after birth as recommended by the National Screening Committee

- stakeholder commented that there was a need for a clearer statement on the use of pacifiers. Current guideline already gives specific advice on the use of pacifiers.

17. During consultation stakeholders suggested new areas to consider in a future update of the guideline including. The suggested areas are:
    - debriefing session for mother about her experience of the delivery at 6-week postnatal visit
    - the use of email as part of secure referral systems to ensure follow up of any referrals is undertaken
    - referrals of obese women to local support groups for healthy living and weight loss services

Anti-discrimination and equalities considerations

18. No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The original scope is inclusive of women and their babies in the postnatal period, defined as 6–8 weeks after birth.

Conclusion

19. Through the process no areas were identified which would indicate a significant change in clinical practice; there are no factors described above which would invalidate or change the direction of current guideline recommendations
20. The Postnatal care guideline should not be considered for an update at this time

Relationship to quality standards

21. This topic has been referred to NICE as a quality standard.

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Centre for Clinical Practice
March 2012

Appendix 1

The following NICE guidance and quality standard are related to CG37:

Guidance	Review date
CG 110: A model for service provision for pregnant women with complex social factors September 2010	September 2013
CG104: The management of hypertensive disorders during pregnancy. August 2010	August 2013
PH 27: Dietary interventions and physical activity interventions for weight management before, during and after pregnancy. July 2010	To be confirmed
PH 26: How to stop smoking in pregnancy and following childbirth. June 2010	To be confirmed
CG93: Donor breast milk banks: the operation of donor breast milk bank services. February 2010	February 2013
CG62: Antenatal care: routine care for the healthy pregnant woman. March 2008	March 2014
PH 11: Guidance for midwives, health visitors, pharmacists and other primary care services to improve the nutrition of pregnant and breastfeeding mothers and children in low income households. March 2008.	July 2014
CG129: Multiple pregnancy: the management of twin and triplet pregnancies in the antenatal period.	No date given

September 2011	
Related NICE guidance in progress	
Diabetes in pregnancy (update of CG63) Intrapartum care (update of CG55) Antenatal and postnatal mental health (update of CG45)	To be confirmed To be confirmed To be confirmed
Related NICE quality standard	
Specialist neonatal care quality standard. October 2010	To be confirmed

Appendix 2

National Institute for Health and Clinical Excellence

Review of Clinical Guideline (CG37) – Postnatal care

Guideline Review Consultation Comments Table

4-17 January 2012

Stakeholder	Agree with proposal not to update?	Comments	Comments on areas excluded from original scope	Comments on equality issues	Response
Academic unit of Dermatology Research, The University of Sheffield And Sheffield Children's Hospital	**NO**	**'<u>Case for revision of the text regarding skin care in the NICE postnatal care guidelines</u>'** There is a major need to revise the current text regarding skincare in the NICE postnatal care guidance because it contains the following statement: *"The only cleansing agent suggested, where it is needed, is a mild, non-perfumed soap"* All of the available evidence suggests that this advice is likely to contribute to the development of atopic eczema in babies with a genetic predisposition to a defective skin barrier (reviewed in Cork *et al* 2009 and in Danby *&* Cork 2011*).*			Thank you for your comments and for supplying references We agree that atopic eczema may be a concern for skin care of new born babies. We consider that the statement that 'The only cleansing agent suggested, where it is needed, is a mild non-perfumed soap' does

Stakeholder	Agree with proposal not to update?	Comments	Comments on areas excluded from original scope	Comments on equality issues	Response
		There is, therefore, substantial evidence that the advice given in the current NICE guidance regarding the use of soap is likely to cause harm in a significant proportion of babies. The current prevalence in children is up to 25% (NICE guidance *CG57*). It is therefore essential that the skincare section of the NICE guidance on postnatal care is redrafted to include appropriate, evidence-based, guidance regarding skincare in babies. It will only be possible to do this if the guideline development group includes individuals with expertise in the care of infant skin. Over the past five years there has been a rapidly developing research area in prevention of development of atopic eczema in babies by changing the way we treat a baby's skin from birth. This includes all wash products, topical oils and emollients. My own Skin Barrier research group is collaborating with research groups led by Professor Tina Lavender in Manchester and professor Hywell Williams' department for Evidence-based dermatology in Nottingham in several related areas. Another problem with regard to providing parents/carers with the correct advice regarding the skincare of babies, to prevent atopic eczema, is that the NICE guidance on the treatment of atopic eczema in children (NICE guidance *CG57*)			not require to be revised. Of the references provided, Cork 2009 is a narrative review that reflects the authors' opinion rather than actual research while Danby & Cork 2011 is a textbook chapter. Hence these do not meet our inclusion criteria. The evidence statement for epidemiology in CG57 (full guideline, p. 56) states that It "is not possible to give a definitive prevalence of atopic eczema " as "there has been little consistency among epidemiological studies of atopic eczema in children with regard to the populations studied or the methods used,

Stakeholder	Agree with proposal not to update?	Comments	Comments on areas excluded from original scope	Comments on equality issues	Response
		did not contain advice regarding prevention. This means that the only advice regarding skincare of babies is the in the few lines in this NICE postnatal care guidance. The statement regarding the use of soap is not only incorrect (and based on no evidence) but also is very likely to cause harm in a significant proportion (up to 25%) of babies. With regard to comparisons between water and wash products formulated for use on baby skin; I declare an interest here, in that I was part of the research team led by Professor Tina Lavender, which conducted the two largest RCTs in this area (Lavender *et al* 2011). Professor Tina lavender will be submitting information regarding these trials to this postnatal guideline review separately. ***References*** 1) Cork MJ, Danby SG, Vasilopoulos Y, Hadgraft J, Lane ME, Moustafa M, Guy RH, Macgowan AL, Tazi-Ahnini R, and Ward SJ. Skin barrier dysfunction in atopic dermatitis. J Invest Dermatol. 2009 Aug; 129(8):1892-908 2) Simon G. Danby & Michael J. Cork. The Skin Barrier in Atopic Dermatitis. Ch 27 in Textbook of Pediatric Dermatology, 3rd edition. Edited by A. Irvine, P. Hoeger and A. Yan. © 2011 Blackwell Publishing Ltd. U.K.			leading to wide variations in the results reported in individual studies" In the light of this we do not consider it is appropriate to revise the guideline taking 25% as the prevalence rate Moreover, most of the data in CG57 relates to older children whereas the population in the postnatal care guideline is babies 6-8 weeks of age. The Lavender et al. 2011 study which you highlighted is included in the consultation document. The authors of this study hypothesised that an optimally formulated infant skin cleansing

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		3) S. Lewis-Jones, M. J. Cork, C. Clark, H. Cox et al 2007. A systematic review of the treatments for atopic eczema and guideline for its management: National institute for Clinical Excellence Dept. of Health. E-pub as 'Atopic eczema in children - Guideline consultation ref CG57' 4) Lavender T, Bedwell C, O'Brien E, Cork MJ, Turner M, Hart A. Infant skin-cleansing product versus water: A pilot randomized, assessor-blinded controlled trial. BMC Pediatr. 2011 May 13; 11:35.			product improves skin barrier function in newborn babies when compared with bathing with water and cotton wool. However, results showed similar rates of trans-epidermal water loss (TEWL) at 4 and 8 weeks after birth between the two groups, leading the authors to conclude that the superiority hypothesis was not plausible as there was no convincing trend for superiority for any measurements on any part of the body. As such a non-inferiority trial was recommended. Therefore as there is insufficient evidence of clinical effectives/cost-effectiveness of

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					cleansing agents over water, there is no compelling reason to revise the current text
Cleft Lip and Palate Association	No	It is important that guidelines stress the need to examine the palate by visualisation rather than finger sweep to avoid the risk of failing to diagnose a cleft palate.			Thank you for your comment. The guideline has emphasised the importance of a thorough physical examination of the newborn within 72 hours after delivery as recommended by the National Screening Committee, including the "examination of the exposed parts of the baby first: scalp, head (including fontanelles), face, nose, mouth including palate, ears, neck and general symmetry of head and facial features".

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					Finger sweeping of the palate is not mentioned anywhere in the guideline and it is our understanding that examination of the palate refers to visual examination (inspection) as well as palpation. The purpose of a clinical guideline is to serve as a guide for all professionals using it. It is therefore expected that when there are specific concerns, e.g. cleft lip/palate, a more detailed examination would be carried out to identify/rule out the problem
Cleft Lip and Palate Association	No	If a child is having difficulty feeding or food is coming down it's nose then these should be indicators that there may be a problem with the palate.			Thank you for your comment. The guideline states that the intention is to set out 'core care' and to

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					identify where additional support or care is required. Parents should be encouraged to seek advice from health professionals if concerned about their baby. Therefore if a child is having difficulty feeding or food is coming down its nose, these would usually be reported by parents. The guideline states that a newborn's examination "should incorporate a review of parental concerns and the baby's medical history should also be reviewed...."
Cleft Lip and Palate Association	No	mothers of children with cleft lip and palate who cannot breastfeed should be supported to express breastmilk and treated with respect - we are told by mothers that each new nurse on shift asks if they are breastfeeding and each time they have to explain why not despite that fact that in most			Thank you for your comment and anecdotal evidence. The guideline states that "women and their

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		cases they would prefer to breastfeed and are upset that they are unable to do so			families should be treated with kindness, respect and dignity at all times". It also says that "the views, beliefs and values of the woman, her partner and her family in relation to her care and that of her baby should be sought and respected at all times"
Department of Health	Yes	The review proposal on that basis of the literature search is that this guideline does not need updating. However, although the evidence does not invalidate the existing recommendations, it may identify new areas that should be included in the clinical guideline e.g. telephone support for ethnic minority women or telephone support to reduce post-natal depression. It would be helpful if you could consider whether the guideline should be updated to reflect these new areas.			Thank you for your comment. The robustness of new evidence is considered when deciding whether to update a clinical guideline. Only one small study conducted in Lebanon was identified on the use of telephone support for women in the postpartum period. This new evidence was

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					insufficient to warrant updating the guideline at this point. With regards to the issue of telephone support to reduce post-natal depression, the management of postnatal depression is not within the scope of this guideline but the subject of a separate NICE guideline (CG 45 - Antenatal and postnatal mental health)
Johnson & Johnson Consumer Services EAME Ltd	NO	The comments below relate specifically to paragraph 1.4.23 of the guideline, under the *Physical health and wellbeing* section, *Skin* subsection: *"*Parents should be advised that cleansing agents should not be added to a baby's bath water nor should lotions or medicated wipes be used. The only cleansing agent suggested, where it is			Thank you for your comments. Please see our responses to the individual comments below.

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		needed, is a mild non-perfumed soap." Johnson & Johnson Consumer Services EAME Ltd contends that this section of guideline CG37 should be updated based upon new clinical evidence that was not available at the time of the original guideline being written.			
Johnson & Johnson Consumer Services EAME Ltd	NO	**COMMENT 1:** **Skin cleansing is important not only for cosmetic purposes, but is essential for skin health and the wellbeing of the baby. There is a medical need for cleansing to remove impurities, which can otherwise cause inflammation to the skin.** SUPPORT FOR COMMENT 1: Keeping the skin clean is essential to the overall good health of an individual. This statement is even more relevant in the case of infants, since infant skin structure, function, and composition are still developing, underscoring the need for special care. *(Nikolovski J et al. "Barrier Function and Water-Holding and Transport Properties of Infant Stratum Corneum Are Different from Adult and*			Thank you for your comment and for supplying the reference by Nikolovski et al., 2011. This study does not meet our inclusion criteria as it is not a systematic review of primary research studies.

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		Continue to Develop through the First Year of Life" J Invest Dermatol 2008:128; 1728-1735). "Skin cleansing essentially means removing unwanted substances, including irritants from sources such as saliva, nasal secretions, urine, faeces, and dirt. These irritants include salts, lipolytic and proteolytic enzymes, infectious microbial species, as well as potential allergens. Keeping the diaper area clean helps prevent skin barrier breakdown and therefore rash (diaper dermatitis) and infection (candidiasis). Keeping hands clean, particularly in the case of babies with their hand-to-mouth behaviours, can help reduce or prevent oral transmission of microbial contaminants. Special attention should also be paid to the facial area, where vulnerable skin can be irritated by milk, saliva, and nasal mucosa, all of which have higher pH relative to skin which can be detrimental to skin barrier. Similarly skin folds and creases (prominent in infant skin) should be kept clean." (from: *Stamatas et al., "Keeping Infant Skin Healthy through Proper Cleansing"; chapter 1 in "Skin Care", edited by SM Hayes,*			Thank you for providing the reference by Stamatas et al., 2011. This publication does not meet our inclusion criteria as it is a book chapter.

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		Nova Publishers Inc., pp 1-29, 2011) In addition infant skin is frequently soiled with food that needs to be effectively cleansed as it has been shown that prolonged contact of foodstuff with the skin can be a potential root for skin sensitization and development of allergies (Lack G et al. “Factors associated with the development of peanut allergy in childhood” N Engl J Med 2003 Mar 13;348(11):977-85).			Thank you for supplying the reference by Lack et al., 2003. This study does not meet our inclusion criteria as it is not a systematic review of primary research studies.
Johnson & Johnson Consumer Services EAME Ltd	NO	**COMMENT 2:** **Water alone does not cleanse efficiently.** SUPPORT FOR COMMENT 2: “Washing the skin with water alone does not remove all of the impurities on the surface. This is because some of those substances are not water-soluble but fat-soluble, and therefore require the use of products capable of emulsifying them into fine droplets that can then be removed by water. These products, known as surfactants or detergents, act by suppressing the surface			Thank you for your comment and for supplying the reference by Gelmetti, 2001. This study does not meet our inclusion criteria as it is not a systematic review of primary research studies.

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		tension that allows fatty products to remain on the skin surface". (from: *Gelmetti, "Skin Cleansing in Children", JEADV 2001*). Thus, for example a) fat-soluble proteins from food stuff (potential skin sensitizers), b) fat-soluble proteases in faeces (sources of inflammation in diaper rash) and c) some fats themselves, such as oleic acid (a penetration enhancer and skin irritant), are not effectively removed from the skin surface with the use of water alone.			
Johnson & Johnson Consumer Services EAME Ltd	NO	**COMMENT 3:** **Bar soap can be damaging to infant skin.** SUPPORT FOR COMMENT 3: "These products, known as surfactants or detergents, act by suppressing the surface tension that allows fatty products to remain on the skin surface. The greater the suppression of surface tension, however, the greater is the risk of coincidental damage to the skin. The most commonly used detergents are soaps, which are products resulting from saponification, i.e. the action of an alkali on a fatty substance. The			Thank you for your comment and for supplying the reference by Gelmetti, 2001. This study does not meet our inclusion criteria as it is not a systematic review of primary research studies.

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		alkalinity induced by soaps can alter the ideal pH of the skin surface. This is however, transient." (from: *Gelmetti, "Skin Cleansing in Children", JEADV 2001*). Therefore, if possible, liquid detergents would be preferable to bar soap or soap-containing detergents (*RM Walters et al., "Designing Cleansers for the Unique Needs of Baby Skin", Cosmetics & Toiletries, 123(12), 53-60, 2008*).			Thank you for your comment and for supplying the reference by Walters et al., 2008. This study does not meet our inclusion criteria as it is not a systematic review.
Johnson & Johnson Consumer Services EAME Ltd	NO	**COMMENT 4:** **Mild and gentle cleansers which have been specifically formulated for infant skin, and robustly clinically tested, can be used safely on infant skin.** SUPPORT FOR COMMENT 4: An ideal cleanser for infants must provide appropriate cleansing action and yet be mild enough to avoid irritation of skin and eyes. In aqueous solutions surfactants exist both as individual monomers and as micelles			Thank you for your comments and for supplying the references by Kuehl et al., 2003 and Stamatas et al., 2011. However these studies do not meet our inclusion criteria as they are not systematic review of primary research studies.

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		(agglomerations of surfactant monomers). The larger and more stable the micelles the less the irritation potential for a surfactant system. While bar soaps are usually made up of surfactant systems that make up small micelles and therefore have higher irritation potential, liquid cleansers can be formulated to have large and stable micelles with low irritation potential. Non-ionic surfactants are the mildest, followed by amphoteric surfactants, while anionic detergents (commonly found in bar soaps) are at the other end of the spectrum (*Kuehl BL et al., "Cutaneous cleansers" Skin Therapy Lett. 2003;8(3):1-4; Stamatas et al., "Keeping Infant Skin Healthy through Proper Cleansing"; chapter 1 in "Skin Care", edited by SM Hayes, Nova Publishers Inc., pp 1-29, 2011*) In a randomized controlled study, Garcia et al showed that skin care regimens (bathing with water alone or with wash gel and/or creaming) did not harm physiologic neonatal skin barrier adaptation within the first 8 weeks of life (*Garcia et al, "Effect of Standardized Skin Care Regimens*			Thank you for your comment and for supplying the reference by Garcia et al. 2010 (Bartels et al., 2010) and Dizon et al. 2011. The authors of both RCTs concluded that

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		on Neonatal Skin Barrier Function in Different Body Areas" Ped Derm 27(1), 1-8, 2010). Dizon et al. report similar conclusions from a randomized controlled trials on 180 newborns: all the three studied interventions (water alone bathing or two commercial liquid washes) used as whole body cleansers were efficacious and well tolerated by infants (*MV Dizon et al., "Tolerance of Baby Cleansers in Infants: A Randomized Controlled Trial", Indian Pediatr 47(11), 959-63, 2010*). Further data from a large newborn cleansing RCT sponsored by Johnson & Johnson are available from Prof. Lavender *(Lavender T et al. Baby Skin Care Research Programme: a randomised, assessor-blinded controlled trial comparing an infant skin-cleansing product with water. http://www.controlled-trials.com/ISRCTN72285670. Submitted for publication*). Neonatal skin care guidelines from AWHONN			none of the regimes they tested demonstrated a beneficial effect over the others; therefore all three interventions were considered to be mild on the baby skin. Thank you for supplying the reference to the article by Lavender et al. However, as it has not yet been published we cannot include it in our review Thank you for supplying the reference by Blume-Peytavi et al., 2009. The article concluded that "further clinical research is now needed to investigate more fully the potential benefits of

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		(*Ref: http://www.awhonn.org/awhonn/store/productDetail.do?productCode=ENSC-2*) and roundtable recommendations on bathing newborns (*Ref: Blume-Peytavi et al., "Bathing and cleansing in newborns from day 1 to first year of life: recommendations from a European round table meeting", JEADV 2009, 23, 751–759*) have been produced in the past years and can be consulted. We also enclose a very recent literature review of the clinical evidence for best practices (*Ref. Blume-Peytavi et al, "Skin Care Practices for Newborns and Infants: Review of the Clinical Evidence for Best Practices", Pediatric Dermatology 1–13, 2011*)."			appropriate liquid cleansers in newborns." Thank you for for supplying the reference by Blume-Peytavi et al., 2011. The article concluded that "larger randomized clinical trials with age-defined cohorts of babies as well as more-defined parameters are required to identify optimal practices and products for skin cleansing of healthy infants."
Johnson & Johnson Consumer Services EAME Ltd	NO	**COMMENT 5:** **Wipes impregnated with lotions which are appropriately formulated and robustly clinically tested can be used safely on infant skin.** SUPPORT FOR COMMENT 5: Similarly to cleanser, certain wipes impregnated			Thank you for your comment and for supplying the reference by Visscher et al., 2009. The study was carried out on babies in the NICU, most of whom were premature and

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		with lotion formulations are appropriately designed for use on infant skin and have been clinically tested and proven safe even for use on newborns. In a RCT looking at the impact of two different wipes versus cotton wool and water, Visscher et al showed that both tested wipes are appropriate for use on medically stable NICU patients, including both full and preterm infants, and provide more normalized skin condition and barrier function versus the cotton wool and water standard. (*M Visscher et al., "Skin Care in the NICU Patient: Effects of Wipes versus Cloth and Water on Stratum Corneum Integrity", Neonatology, 96(4),226-234, 2009*). Results from a new RCT on newborn cleansing and wipes (sponsored by Johnson & Johnson) are available from Prof. Lavender (*Lavender T et al. Baby Skin Care Research Programme: Assessor-blinded randomised controlled trial comparing impregnated cleansing wipes with water in infants. http://www.controlled-trials.com/ISRCTN86207019. Submitted for*			most likely suffering from a pathology. This population of babies is different from that covered by the postnatal care guideline. Thank you for your comment and for supplying the reference to the article by Lavender et al. The study has not yet been published and therefore we cannot

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		publication.)			include it in our review
Johnson & Johnson Consumer Services EAME Ltd	NO	**COMMENT 6:** **Lotions which are appropriately formulated and robustly clinically tested can be used safely on infant skin.** SUPPORT FOR COMMENT 6: The role of emollients in the treatment of atopic dermatitis is well known and documented. Protection and care of healthy newborn skin through emollients is documented in one RCT, showing that, skin care regimens (including creaming) did not harm physiologic neonatal skin barrier adaptation within the first 8 weeks of life.(*Garcia et al, "Effect of Standardized Skin Care Regimens on Neonatal Skin Barrier Function in Different Body Areas" Ped Derm 27(1), 1-8, 201*0).			Thank you for your comment. As stated previously, this RCT did not conclude that any of the regimens tested demonstrated a beneficial effect over the others.
Johnson & Johnson Consumer Services EAME Ltd	NO	Supporting references for the above:			Thank you for providing the references. These are discussed above under the relevant sections.
Midwifeexpert.co	No	Visits need to reflect multi cultural / complex			Thank you for your

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m		needs of families – often p/n visits are those cut back			comment. The guideline already states “both care and information provided should be culturally appropriate and the cultural practices of women from ethnic minority groups should be incorporated into their individual postnatal care plans. Care and information should also be provided in a form accessible to women, their partners and families with additional needs, such as people with physical, cognitive or sensory disabilities, and people who do not speak or read English.” Moreover, it is one of the guideline ethos that “women’s views, beliefs and particular

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					circumstances are respected”
Midwifeexpert.com			Pn at 6 weeks should allow mother to debrief about delivery – especially if LSCS		Thank you for your comment. Debriefing was considered in the existing guideline and also in the review document, with no strong evidence emerging of its effectiveness
Midwifeexpert.com			Robust secure referral systems – via secure email to ensure follow up of any referrals is undertaken		Thank you for your comment. This point has been noted and will be taken into consideration in the next review
Midwifeexpert.com			Obese women should be referred to local support groups for healthy living and weight loss services		Thank you for your comment. The guideline does not aim to address the care/needs of particular subgroups of women.

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NHS Sickle Cell and Thalassaemia Screening Programme		**Clinical area 4: Maintaining infant health** **Question 6: What routine screening tests are appropriate in the first 8 weeks?** As described by the UK NSC this should include screening for sickle cell disease. Screening for thalassaemia is currently under review **Question 10: What information should parents receive?** **Question 11: What information or advice would enable women to support and monitor their babies' health and well-being?** The responses from the Screening programme are informed by three documents: 1. Kai et al[1] 2. Clinical standards[2] 3. Screening programme standards[3] Newborn Screening results should be reported in a timely manner and by knowledgable healthcare professionals. This includes • Screen negative results should be available fro reporting by six weeks of			Thank you for your comment. The guideline already includes screening for sickle cell disease and also cross-refers to the UK NSC programme

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		age, • Carrier results should be given to parents, ideally face to face by someone who is knowledgeable about the condition, • Screen positive results, along with supporting information should be given to parents by the time the baby is four weeks of age and the baby should attend local clinic by 3 months of age. GPs and HV to be informed of screen positive result by 4 weeks of age. To reduce parental anxiety it is recommended that antenatal and newborn screening results are linked (http://sct.screening.nhs.uk/linkage#fileid11146). If newborn screening identifies a baby as a carrier or affected by haemoglobinopathy consideration should be given to counselling the parents about future pregnancies. 1. Kai, J., et al., *Communication of carrier status information following universal newborn screening for sickle cell disorders and cystic fibrosis: qualitative*			

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		study of experience and practice. Health Technology Assessment, 2009. **13**(57): p. 1–82. 2. NHS Sickle Cell and Thalassaemia Screening Programme, *Sickle Cell Disease in Childhood: Standards and Guidelines for Clinical Care*. 2010. 3. NHS Sickle Cell and Thalassaemia Screening Programme, *Standards for the linked Antenatal and Newborn Screening Programme*. 2011.			
Royal College of Midwives	No	The RCM consider that the large body of new evidence emerging could suggest changes in the recommendations. This justifies an update of the guideline at this time, and the RCM strongly supports such an update. It is also useful for practitioners and the public, to have current evidence available and cited in the guideline, even if the recommendations are not changed.			Thank you for your comment. Through the review process we identified a number of studies related to the guideline, but concluded that there was no new evidence which would invalidate or change the direction of the current guideline recommendations.
Royal College of Midwives		It is important to do a more in depth literature review, to find the literature covering more than high level RCTs in order to access the views of	Frequency of postnatal visits.	It is particularly important to incorporate views	Thank you for your comment.

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		women and their families in this area.		of vulnerable women.	For the purpose of review, current process does not include conducting a full systematic review of the whole guideline. We use intelligence from the GDG questionnaire, post-publication enquiries, initial intelligence gathering and a high-level RCT search to determine clinical areas within the guideline where new evidence exists that may have an impact on current guideline recommendations in addition to taking consideration of any safety aspects and drug licensing. All this information is used to form the basis of more focused searches for evidence on key topic areas. All of which

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					informs the review proposal. With regards to frequency of visits, the guideline recommends that “postnatal services should be planned locally to achieve the most efficient and effective service for women and babies” With regards to views of vulnerable women, the guideline states that “the views, beliefs and values of the woman, her partner and her family in relation to her care and that of her baby should be sought and respected at all times”. Moreover, it is one of the guideline ethos that “women’s views, beliefs

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					and particular circumstances are respected.”
Royal College of Midwives		The methodology for this initial literature review is unclear, as despite the statement that it was a search of high-level RCTs, there are some surveys included in the findings. Presumably these came from GDG members. A more inclusive approach to finding these papers would be appropriate.			Thank you for your comment. For the purpose of review, current process does not include conducting a full systematic review of the whole guideline. We use intelligence from the GDG questionnaire, post-publication enquiries, initial intelligence gathering and a high-level RCT search to determine clinical areas within the guideline where new evidence exists that may have an impact on current guideline recommendations in addition to taking consideration of any safety aspects and drug

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					licensing. All this information is used to form the basis of more focused searches for evidence on key topic areas. All of which informs the review proposal.
Royal College of Midwives		The RCM is very concerned about the current standard of postnatal care when so many surveys identify that the care women are receiving is not adequate. It is important in this context to revisit the literature and practice recommendations in detail.			Thank you for your comment. Based on the available evidence identified by us, there was no new evidence that would invalidate or change current guideline recommendations. Implementation support is provided by NICE to facilitate implementation of the guideline.
Royal College of Midwives		We also know that many Local Authorities are considering postnatal care and breastfeeding – within the context of the health and well-being of women and children - as a key area for action within their borough's Joint Strategic Needs			Thank you for your comment. Based on the available evidence identified by

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		Assessments (JSNAs). The pan London approach to public health which is being replicated in other English cities, is an example of a local approach to improving health. It would it benefit women, midwifery/maternity services to review the evidence before the public health policies and systems are set so that it can inform and support the process			us, there was no new evidence that would invalidate or change current guideline recommendations.
Royal College of Nursing	No	The Royal College of Nursing consider that the guideline itself does not need to change, however, there are plethora of new evidence for example, around infant feeding, maternal support, pelvic floor therapy etc, that need to be acknowledged and included within the guidance document.			Thank you for your comment. Through the review process we identified a number of studies related to the guideline. However, we concluded that there was no new evidence which would change the direction of the current guideline recommendations.
Royal College of Nursing		Also - would it be appropriate to include the needs of women with disabilities, unless it is considered that this is a 'principles' document that applies to all women anyway so making special attention inappropriate. If so would it be considered elsewhere?			Thank you for your comment. The guideline already states that “care and information should also

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					be provided in a form accessible to women, their partners and families with additional needs, such as people with physical, cognitive or sensory disabilities."
Royal College of Obstetricians and Gynaecologists	Yes	We were not identified of this consultation when first released and so we had a very short period of time to respond. Could you please ensure that your database is updated with the correct contact details at the RCOG. Thank you.			Thank you for your comment. This information will be passed to the coordinators within the Centre for Clinical Practice at NICE who maintain the relevant contact database of stakeholders
Royal College of Paediatrics and Child Health	No	Looking at the current guideline and the presented updated evidence it is obvious that the use of pacifier does not affect the success of breastfeeding negatively. There is also evidence from Cochrane reviews suggesting that cup feeding does not confer any benefit to establishing successful breastfeeding.	None	None	Thank you for your comment for supplying the FSID document that contains advice on how to reduce the risk of cot death The postnatal care

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		This is in clear contrast to a widely accepted belief and practice that is particularly promoted by the BFI amongst healthcare workers. It is the cause of recurrent conflicts between different groups of professionals leading to confused and disturbed parents and ultimately affecting the relationship of all professionals to the parents. We noticed that the NICE guidance does not directly comment on these issues and only the full version provides two statements (number 60 and 61 on page 201) that are essentially contradictory. BFI bases their anti-teat/dummy statements on the WHO code from the 80's backed up with more recent weak evidence. Based on this we can only speculate why the NICE team decided to sit on the fence in this matter. A clearer statement about the use of dummy/pacifier/artificial teats (the different terms are just semantics), as is found in the attached FSID document, would possibly cause a major conflict with the BFI. Is it not about time that we base decisions on the best available evidence irrespective of what other potentially influential groups/campaigns might suggest?			guideline does not actually recommend the Baby Friendly Initiative but states that "all health care providers (hospitals and community) should implement an externally evaluated structured programme that encourages breastfeeding, using the Baby Friendly Initiative [BFI] as a minimum standard." The statements you refer to on page 201 of the full guideline (numbers 60 and 61) are not recommendations but evidence statements which merely state the findings of studies The FSID document states that "settling your baby to sleep with a

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					dummy, even for naps, can reduce the risk of cot death, even if the dummy falls out while your baby is asleep." This advice is essentially the same as the recommendation in the guideline that "if a baby has become accustomed to using a pacifier (dummy) while sleeping, it should not be stopped suddenly during the first 26 weeks." The findings in the review proposal on pacifier use - that it may be protective against cot death and does not affect breastfeeding rates or duration - appear to support the current guideline recommendations.

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					Moreover, the authors of the Cochrane review concluded that "evidence to assess the short-term breastfeeding difficulties faced by mothers and long-term effect of pacifiers on infants' health is lacking". Therefore, taking this into account and that this is a small area of the guideline, it was considered that this new evidence may not be significant enough to warrant updating the guideline at this point.
Royal College of Paediatrics and Child Health	No	1. Inadequate importance is attached to appropriate examination of the newborn / neonate's mouth and palate. Failure to do so is associated with delay in identifying cleft palate (CP) in the absence of cleft lip. The incidence of CP is 1 in 2000 births. Failure to detect during the first week of life occurs in 30-	1. Page 29 under the paragraph Examine ..'mouth and palate'. **Recommendati**	None	Thank you for your comment. The guideline has already emphasised the importance of a thorough physical

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		40%, and 12% after the first week into 2nd year of life. Delayed detection may result in unnecessary weight loss, possible delay in surgery, and anxiety for the carers. Syndromes are present in 50% with CP. Missing a CP in the newborn may delay identification of other underlying conditions. Loss of trust in local staff by parents is common, litigation sometimes results. Parents and cleft surgical teams see this as an unnecessary failure of midwives, paediatric and GP services. It is a training issue which needs endorsement from national bodies to ensure the correct skills are taught. 2. Tongue tie remains contentious	**on:** It is good practice to examine the mouth and palate by visual inspection as well as palpation (also when looking for local and structural reasons for failure to establish feeding, and excessive weight loss as in oral candida infection, cleft palate, neonatal teeth). *Reference: A Habel, N Elhadi, B Sommerlad, J Powell. Delayed detection of cleft palate: an audit of newborn examination.*		examination of the newborn within 72 hours after birth, as recommended by the National Screening Committee, including the "examination of the exposed parts of the baby first: scalp, head (including fontanelles), face, nose, mouth including palate, ears, neck and general symmetry of head and facial features" The purpose of a clinical guideline is to serve as a guide. It is therefore expected that when there are specific concerns, e.g. cleft lip/palate, a more detailed examination would be carried out to identify/rule out the problem

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			Arch Dis Child 2006;91:238-240. 2. Re: Question 20. Update evidence for tongue tie (TT), based on NICE IPG 149. TT is relatively frequently cited as a cause for feeding impairment. Present treatment recommendations appear subjective.		For babies suspected to have tongue tie, the guideline already recommends referral to NICE IPG 149: "Babies who appear to have ankyloglossia should be evaluated further (non-urgent action; refer to NICE Interventional Procedure on Tongue Tie (National Institute for Health & Clinical Excellence, 2005)"
Royal College of Paediatrics and Child Health					Thank you for providing this reference. It has been discussed above under the relevant section.

These organisations were approached but did not respond:

Action on Pre-Eclampsia
Bayer Schering
Bradford District Care Trust
British Association for Counselling and Psychotherapy
British Association of Behavioural and Cognitive Psychotherapies
British Medical Association
British Medical Journal
British National Formulary
British Pain Society
British Psychological Society
Cambridge University Hospitals NHS Foundation Trust
Camden Link
Care Quality Commission (CQC)
Chartered Physiotherapists Promoting Continence
Department of Health, Social Services and Public Safety - Northern Ireland
Dorset Primary Care Trust
Drinksense
Faculty of Sexual and Reproductive Healthcare
Ferring Pharmaceuticals
Health Quality Improvement Partnership
Healthcare Improvement Scotland
Infection Control Nurses Association
Innermost Secrets Ltd
Lancashire Care NHS Foundation Trust
Livability Icanho
Liverpool Primary Care Trust
Luton and Dunstable Hospital NHS Trust
Maternal Mental Health Alliance
Maternity Action

Medicines and Healthcare products Regulatory Agency
Ministry of Defence
Mumsnet
National Clinical Guideline Centre
National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Institute for Health Research Health Technology Assessment Programme
National Obesity Forum
National Patient Safety Agency
National Public Health Service for Wales
National Treatment Agency for Substance Misuse
NCC Women & Childrens Health
Netmums
NHS Confederation
NHS Connecting for Health
NHS Direct
NHS Plus
NHS Warwickshire Primary Care Trust
North Essex Mental Health Partnership Trust
North Tees and Hartlepool NHS Foundation Trust
North West London Perinatal Network
Nottingham City Hospital
Public Health Wales NHS Trust
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of General Practitioners in Wales
Royal College of Paediatrics and Child Health
Royal College of Paediatrics and Child Health , Gastroenetrology, Hepatology and Nutrition
Royal College of Pathologists
Royal College of Physicians

Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons of England
Royal Pharmaceutical Society
RSPH health visitor steering group
Sands, the stillbirth and neonatal death charity
Scottish Intercollegiate Guidelines Network
SNDRi
Social Care Institute for Excellence
The British In Vitro Diagnostics Association
The College of Social Work
UNICEF UK
University Hospital Birmingham NHS Foundation Trust
University Hospitals Bristol NHS Foundation Trust
Welsh Government
Welsh Scientific Advisory Committee
West Middlesex University Hospital NHS Trust
Wirral University Teaching Hospital NHS Foundation Trust
York Hospitals NHS Foundation Trust