## 8-year surveillance 2016 – Atopic eczema in under 12s: diagnosis and management (2007) NICE guideline CG57

## Appendix B: stakeholder consultation comments table

Consultation dates: 21/1/2016 - 03/02/2016

Do you agree with the proposal not to update the guideline?	Comments	NICE response
Agree	After reviewing the comments made by the topic experts we agree with their comments but feel that although there is some new evidence in specific areas these do not affect the Guidelines which remain current	Thank you for your comment.
Agree		Thank you for your answer.
Agree	The experts have not found any new evidence or research to warrant a new guidance.	Thank you for your comment.
Agree		Thank you for your answer.
Agree		Thank you for your answer.
Disagree	We know of significant published, about to be published and on-going trials. If the guideline is not updated at this time, then we feel that the number of ongoing large pragmatic NIHR-funded RCTs warrants a detailed review again in the near future	Thank you for your comments and for highlighting important new research in this area.  We found the SWET trial during this 8-year surveillance review and it is included under the review
	with the proposal not to update the guideline?  Agree  Agree  Agree  Agree	with the proposal not to update the guideline?  Agree

al PLoS Med 2011; 8: e1000395): A Randomised Controlled Trial of Ion-Exchange Water Softeners for the Treatment of Eczema in Children.

The value of water softeners in the treatment of eczema a question that is commonly asked by patients, and this large pragmatic trial gave a clear answer with narrow confidence intervals. This information would be helpful in allowing healthcare professionals to answer questions of importance to their patients.

CREAM (Children with Eczema Antibiotic Management, Francis et al, NIHR HTA 09/118/03, ISRCTN: 96705420) study.

Report currently with HTA, this is the largest RCT of its kind (113 participants), with an important message regarding the role of topical or oral antibiotics in addition to standard therapy for children (up to 7 years of age) with clinically infected eczema.

CLOTHES (Clothing for the Relief of Eczema Symptoms, Thomas et al, NIHR HTA 11/65/01, ISRCTN: 77261365) study:

RCT of 300 children aged 1 – 15 yrs with moderate to severe eczema to answer the research question "What is the effectiveness and cost-effectiveness of silk clothing for the management of eczema in children? Recruitment complete, due to report in June 2016. This topic was prioritised for research by NIHR HTA due to large cost implications of prescribing silk clothing for the management of eczema (their use is rising exponentially at the moment, with little good evidence for their efficacy).

question 28 - How effective and safe are other complementary therapies (for example, hypnotherapy) for managing atopic eczema in children? We concluded that this evidence shows no benefit of water softeners for atopic eczema because change in eczema severity was not significantly different between the water softener group and the usual care group. The 8-year surveillance noted that the guideline warns against the use of complementary therapies because the effectiveness and safety of these therapies have not yet been adequately assessed in clinical studies. On that basis, it was considered that this evidence is unlikely to impact on guideline recommendations.

The updated Cochrane systematic review by Ersser et al (2014) on psychological and educational interventions for atopic eczema in children was also identified through the 8-year surveillance review and is included under review question 30 - How effective are education programmes for children with atopic eczema and their families/carers?

BATHE (Bath Additives for the Treatment of childHood Eczema, Santer et al, NIHR HTA 11/153/01, ISRCTN: 84102309, DOI: 10.1136/bmjopen-2015-009575): multicentre, two arm RCT comparing the use of bath additives in addition to usual care for 405 children 1 to 12 years of age. Trial due to report in 2017.

The guideline states that "A complete emollient regimen produces optimum benefit." This is frequently interpreted in pharmaceutical advertising as suggesting that clinicians should prescribe a leave-on emollient, wash product plus bath emollient, although there is no evidence for the latter. Bath emollients cost £25m per year to the NHS in England so this evidence will be highly relevant to the guideline.

TREAT (TREatment of severe Atopic eczema in children Trial), Flohr et al. – NIHR EME funded 13/50/12, EudraCT Number: 2015-002013-29):

Trial comparing the treatment efficacy and safety as well as cost-effectiveness of methotrexate vs ciclosporin in children and young people with severe eczema, n=102, national trial with 14 centres, starting recruitment in spring 2016. Completion anticipated in 2019.

SPaCE (Support for Parents and Carers of Children with Eczema, Santer et al J Med Internet Res 2014 16: e70.):

Feasibility study (143 participants), providing important preliminary information on the value of an online educational intervention for carers of children with

We have added the SPaCE trial in the 8-year surveillance review decision matrix under review question 30 - How effective are education programmes for children with atopic eczema and their families/carers? Following an assessment of the abstract, we consider this trial to be supportive of the guidance recommendation 1.6.1.1 which covers education to children with atopic eczema and their parents or carers about atopic eczema and its treatment.

Many thanks for highlighting the following ongoing trials (CLOTHES, BATHE, and TREAT). The majority of these were identified through our surveillance review and have been added to our trial tracker so we can track their progress. This list is monitored continuously. Therefore, we will include these trials if they are published when the next surveillance review takes place. The CREAM trial has now published and this has been included under review question 22 - Which antimicrobial agents (including antiseptics) are effective and appropriate for treating

		eczema.	infected atopic eczema in children? The COMET trial has
		COMET (Choice of Moisturiser in Eczema Treatment, Ridd et al, NIHR RfPB PB-PG-0712-28056, ISRCTN: 21828118, doi: 10.1186/s13063-015-0830-y) study	published a paper and this has been included under review question 02 - What measures should be used to classify the
		Feasibility trial about to publish with novel head-to- head outcome data on the effectiveness of four commonly used emollients (Aveeno lotion, Diprobase cream, Doublebase gel, Hydromol ointment)	severity of atopic eczema in children in the setting of clinical management? The COMET trial has been kept in our trial tracker
		The below systematic review has been published and updated since the original guideline	because the main results have not been published.
		Ersser S.J, Latter S, Sibley A, Satherley P.A, Welbourne S. (2007) Psychological and educational interventions for atopic eczema in children. Cochrane Database of Systematic Reviews, Issue 3. Art. No.: CD004054. DOI: 10.1002/14651858.CD004054.pub2	Finally, the update of the Hoare et al. systematic review has been published (Nankervis et al. 2016) and the results have been included under review questions 08, 15-19, 22, 24-25, 27-28, and 30.
		Ersser. SJ, Cowdell, F, Latter.S, Gardiner.E, Flohr, C, Thompson. A.R, Jackson.K, Farasat.H, Ware.F, Drury.A. (2014) Psychological and educational interventions for atopic eczema in children Cochrane Database of Library of Systematic Reviews 2014, Issue 1. Article Number: CD004054. DOI: 10.1002/14651858.CD004054.pub3.	
		Finally, the 2001 systematic review of treatments for eczema (boy Hoare et al, http://dx.doi.org/10.3310/hta4370) has been updated by Hywel Williams and colleagues and is about to be published.	
TIPS LTD	Disagree	There appears to be no mention of the option to try a no-treatment approach whereby all products are	Thank you for your comments and for highlighting this evidence.

		excluded and a period of water-only skincare implemented. This gives the irritated or dry skin the chance to calm down and recover from minor damage caused by inappropriate use of personal care products. Moving straight into using emollilents can actually exacerbate the condition and label a child as an eczema sufferer when this may not be the case. A process of 'less-is-more' must be employed before any diagnosis is given and this is not clear within these guidelines at present. There is plenty of evidence to show that this approach works perfectly and could avoid a minor skin irritation to go on to become a chronic condition with all the associated costs involved with treatments that may do more harm than good. You can read the evidence here:  Trotter S (2010). Neonatal skincare. In: Care of the Newborn by Ten Teachers. Hodder Education, Health Sciences, Chapter 7.  Trotter S (2008). Neonatal skincare and cordcare — implications for practice. In: Examination of the newborn and neonatal health — a multidimentional approach. Churchill Livingstone, Elsevier Worldwide, Chapter14.	We have considered the evidence you have provided. However, the cited references do not meet the criteria for inclusion in this 8-year surveillance review which included systematic review and randomised controlled trials.  We have taken note of your comments in relation to this notreatment approach for consideration at the next surveillance review of the guideline.
Department of Health		I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.
British Society of Allergy and Clinical Immunology	Disagree	There is a consensus statement on early peanut introduction and the prevention of peanut allergy in high risk infants with severe eczema that was published in September 2015: Fleischer D.M. et al. Pediatrics: 2015; 136(3): 600-604. This is based on the LEAP study findings (reference 11 in surveillance document) and is endorsed by 11 national allergy	Thank you for your comments and for highlighting these studies.  We found this consensus statement during the surveillance review but it was not included because this publication does not meet the criteria for inclusion in

societies. The consensus statement recommends:

'Infants with early-onset atopic disease, such as severe eczema, or egg allergy in the first 4 to 6 months of life might benefit from evaluation by an allergist or physician trained in management of allergic diseases in this age group to diagnose any food allergy and assist in implementing these suggestions regarding the appropriateness of early peanut introduction. Evaluation of such patients might consist of performing peanut skin testing, in-office observed peanut ingestion, or both, as deemed appropriate after discussion with the family.'

This is useful information and would provide additional practical advice for the following questions:

CG57 – 09 What clinical tests should be used to identify relevant allergens and which children with atopic eczema would benefit from their use? (1.4.1.2-1.4.1.6)

CG57 – 10 How should food allergies in children with atopic eczema be identified and managed? (1.4.1.2, 1.4.1.5-1.4.1.10, 1.7.1.5)

There is a new guideline for the diagnosis and management of delayed cow's milk protein allergy (including its role in eczema) in primary care: Venter et al. Diagnosis and management of non-IgE-mediated cow's milk allergy in infancy - a UK primary care practical guide. 2013, 3 (23): 1-11.

This is useful and practical advice for general

this 8-year surveillance review which included systematic reviews and randomised controlled trials. However, the LEAP study was identified and included in the decision matrix as part of the 8-year surveillance review and we agree with your suggestion to add it under question 10. The surveillance review decision matrix has been amended to reflect this change.

The current guidance recommends that most children with mild atopic eczema do not need to have tests for allergies (recommendation 1.4.1.5). This consensus statement by Fleischer (2015) mentions an evaluation by an allergist/trained physician. This supports NICE quideline CG57 which recommends that children with moderate or severe atopic eczema and suspected food allergy should be referred for specialist investigation and management of the atopic eczema and allergy (1.7.1.5).

Finally, many thanks for highlighting the guideline on the diagnosis and management of delayed cow's milk protein allergy (including its role in eczema) in primary care. We did not consider this guideline to impact on NICE

		practitioners where cow's milk allergy is suspected of causing the eczema. It adds to the current NICE 2007 atopic eczema recommendations by including not just the recommendation: 'Healthcare professionals should offer a 6–8 week trial of an extensively hydrolysed protein formula or amino acid formula in place of cow's milk formula for bottle-fed infants aged under 6 months with moderate or severe atopic eczema that has not been controlled by optimal treatment with emollients and mild topical corticosteroids.' It provides an excellent algorithm for on-going management and also criteria for referral to secondary care.  This would be useful for the following question:  CG57 – 10 How should food allergies in children with atopic eczema be identified and managed? (1.4.1.2, 1.4.1.5-1.4.1.10, 1.7.1.5).	guideline CG57 as the atopic eczema in under 12s guideline already includes recommendations on the management of food allergies (recommendations 1.4.1.7 to 1.4.1.9) and referral to specialist investigation if food allergy is suspected (recommendation 1.7.1.5). NICE guideline CG116 Food allergy in under 19s: assessment and diagnosis includes primary care settings.
British Association of Dermatologists	Agree	No update required currently.	Thank you for your comment.
Stiefel Laboratories	Agree		Thank you for your answer.
Stakeholder	Do you agree the guideline should be added to the static list?	Comments	NICE response
Institute of Health Visiting	Yes		Thank you for your answer.
Royal College of Nursing	Agree		Thank you for your answer.
Royal College of	Agree		Thank you for your answer.

Pathologists			
Society for Academic Primary Care, Dermatology Research Specialist Interest Group	Disagree	For the reasons set out under question 1.	Thank you for your comment. In light of information provided through the consultation process, we propose not to transfer this topic to the static list, and the guideline will continue to undergo regular surveillance.
Department of Health		I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.
British Society of Allergy and Clinical Immunology	Agree		Thank you for your answer.
British Association of Dermatologists	Disagree	We disagree with putting the topic on the static list, due to new studies pending publication, and would recommend a review of the topic in 2 years' time.	Thank you for your comment. In light of information provided through the consultation process, we propose not transfer this topic to the static list, and the guideline will continue to undergo regular surveillance.
Stiefel Laboratories	Agree		Thank you for your answer.

Stakeholder	Comment on Equality Issues in Scope	NICE Response
National Health Service in	Could I ask you to confirm how you are planning to capture a child's experience of care within this work?	Thank you for your comment.
England	orma o experience of care within the work.	The current guideline recommends a holistic approach

	when assessing a child's atopic eczema at each consultation, taking into account the severity of the atopic eczema and the child's quality of life, including everyday activities and sleep, and psychosocial wellbeing (recommendations 1.2.1.1 to 1.2.1.6). No new evidence was identified through the 8-year surveillance review that would change the direction of these recommendations.
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