

Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Allergy UK	Guideline	005	025	1.5.1.12 'emollient bath additives do not help with atopic eczema' have concerns that this statement may be detrimental to parents understanding and they may misconstrue this as emollient bath additives may be harmful. My concern is if this isn't explained properly to the parent or patient then they may take it that soap substitutes are not necessary and go back to using soap and detergent based products for bathing. I suggest softening this statement to 'emollient bath additives are not as useful/effective as leave on emollient and soap substitutes in the management of eczema'	Thank you for your comment. The committee decided to remove this recommendation following stakeholder consultation. The committee agreed that it was important that children with eczema receive appropriate information around using emollients for washing and bathing to ensure that they continue to apply leave-on emollients and wash with emollient products. The committee therefore decided to incorporate into the recommendations that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes to ensure that they do receive accurate information and advice that is tailored to the individual and their family. This would allow clinicians to provide solutions for patients who may benefit from having emollient added to the bath water.
Allergy UK	Guideline	005	009	1.5.1.8 - If their current emollient causes irritation or is not acceptable, offer a different way to apply it, or offer an alternative emollient. Is a good statement – will you be offering advice here? Eg different ways to apply?	Thank you for your comment. The committee agreed that it is important to make children with atopic eczema and their carers aware of the different ways that emollients can be used for washing and bathing, including the possibility of diluting some leave-on emollients in bath water. To address this, the committee decided to incorporate into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					emollients and emollient soap substitutes. This has also been addressed in the rationale and impact section, which highlights that leave-on emollients can be diluted in hot water and added to bath water.
Allergy UK	Guideline	007	001 - 008	<p>'Some children with sensory processing disorders are unable to tolerate leave on emollients that are applied directly to the skin....leave-on emollients can be diluted in hot water and added to bath water.'</p> <p>Will this advice be included in the guidance? This is important advice to give to a parent of a child with SPD and often these parents may be struggling financially so purchasing a bath emollient may not be affordable – could be included in 1.5.1.8 on page 5</p>	Thank you for your comment. The committee agreed that it is important to make children with atopic eczema and their carers aware of the different ways that emollients can be used for washing and bathing, including the possibility of diluting some leave-on emollients in bath water. To address this, the committee decided to incorporate into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. This has also been addressed in the rationale and impact section, which highlights that leave-on emollients can be diluted in hot water and added to bath water.
Association of Paediatric Emergency Medicine (APEM)	Guideline	General	General	<p>Many thanks for sending us the guideline update.</p> <p>We don't have any comments at this time.</p>	Thank you for your comment
Bournemouth University	Guideline	007	024	<p>We would add something about the environmental factors that also play a part in causing eczema e.g. "Atopic eczema often has a genetic component that leads to the breakdown of the skin barrier, environmental factors may also play a part". Blakeway H, Van-de-Veld V, Allen V, Kravvas G, Palla L, Page M, et al. What is the evidence for interactions between filaggrin null mutations</p>	Thank you for your comment. The context section does make reference to factors such as irritants and allergens, and so for brevity we have not added any further information.

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
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Bournemouth University	Guideline	007	029	We would replace asthma or allergic rhinitis to “asthma and/or allergic rhinitis and/or IgE-mediated food allergy” Hill DA, Spergel JM. The atopic march: Critical evidence and clinical relevance. <i>Ann Allergy Asthma Immunol.</i> 2018 Feb;120(2):131-137. doi: 10.1016/j.anai.2017.10.037. Erratum in: <i>Ann Allergy Asthma Immunol.</i> 2018 Mar 9	Thank you for your comment. Food allergy has been added to the guideline.
Bournemouth University	Guideline	008	003	We recommend adding more detail to the point that eczema has “significant negative impact on quality of life for children and their parents and carers”, we propose the following “significant negative impact on quality of life for children and their parents and carers particularly due to sleep disturbance and itching”. von Kobyletzki L, Beckman L, Smirnova J, Smeeth L, Williams H, McKee M, et al. Eczema and educational attainment: a systematic review. <i>British Journal of Dermatology</i> 2017;177(3):e47-e49.	Thank you for your comment. As multiple factors can lead to reduced quality of life in children with eczema, for brevity, the reasons for why quality of life was affected were not provided.
Bournemouth University	Guideline	008	004	We would add something about not being too shiny or greasy as emollients that are greasier than required impact quality of life for the child. We suggest “avoid treatments that give an oily appearance to the skin that children may find embarrassing.” Singleton H, Hodder A, Boyers D, Doney L, Almilaji O, Heaslip V, Thompson AR, Boyle RJ, Axon	Thank you for your comment. The scope of this guideline update was to review recommendations on emollient bath additives, and therefore this is outside the remit of this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.

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Bournemouth University	Guideline	008	006	We agree that these guidelines are suitable for age birth to 12 yrs, though the evidence provided was only from 5 months and over. It seems reasonable that the findings are also applicable to <5 months.	Thank you for your comment.
British Association of Dermatologists (BAD)	EHIA	007	001 – 008	The rationale not to recommend bath emollients for children with sensory perception disorders is discriminatory. While the committee has identified that children with sensory perception disorders may not tolerate the use of leave on emollients, the decision to not make an exception for this population may cause a negative impact on these children and their carers.	Thank you for your comment. The committee were aware that some children with sensory processing disorders may be unable to tolerate having leave-on emollients applied to their skin. However, they also discussed that no evidence was identified around the effectiveness of emollient bath additives in this population, or when emollient bath additives were used in the absence of leave-on emollients. The committee discussed that there are other ways that children who are unable to tolerate leave-on emollients may benefit from emollients, such as washing with them (recommendation 1.5.1.10). The committee also discussed that it is possible to dilute leave-on emollients and add them to bath water. The committee agreed on the importance of understanding the needs of individual children with atopic eczema and their families, and for clinicians to provide

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					personalised advice to patients and their carers based on this. Therefore, they decided to incorporate into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. The committee highlighted that this would be particularly relevant for children with sensory processing disorders.
British Association of Dermatologists (BAD)	Guideline	005	021	<p>Rec 1.5.1.11 – We are concerned that the recommendation “Do not offer” is too forceful for bath emollients, even though it is an intervention that has no proven benefit in eczema, as found in the BATHE study¹ but does not make eczema worse. We understand the need to standardise variations in prescribing across the UK and that this intervention was not found to be cost effective. We suggest that the guideline states that there is “insufficient evidence to recommend”, addressing the lack of evidence for significant benefit and therefore cost effectiveness. This may be useful for children with sensory perception disorders who may not be able to tolerate leave-on emollients but do tolerate bath emollients.</p> <p>References: Santer M, Ridd M J, Francis N A, Stuart B, Rumsby K, Chorozoglou M et al. Emollient bath additives for the treatment of childhood eczema (BATHE): multicentre pragmatic parallel group randomised controlled trial of</p>	<p>Thank you for your comment. NICE style provides actionable recommendations based on the evidence, and the evidence underpinning these recommendations is described in the rationale and impact section.</p> <p>The committee were aware that some children with sensory processing disorders may be unable to tolerate having leave-on emollients applied to their skin. However, they also discussed that no evidence was identified around the effectiveness of emollient bath additives in this population, or when emollient bath additives were used in the absence of leave-on emollients. The committee discussed that there are other ways that children who are unable to tolerate leave-on emollients may benefit from emollients, such as washing with them (recommendation 1.5.1.10). The committee also discussed that it is possible to dilute leave-on emollients and add them to bath water. The committee agreed on the importance of understanding the needs of</p>

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
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Dermal Laboratories Ltd	EHIA	003	Section 2	<p>We strongly recommend that the “Do not offer” statement is revised as this will disadvantage children who are currently using bath emollients and find them beneficial. It is unacceptable to advise that anyone wanting to use bath additives should be recommended to buy them over the counter. Atopic eczema is a chronic condition, most commonly affecting infants and young children who are the particular subgroup for whom bath emollients can be beneficial. This may be unaffordable for many parents on lower incomes, particularly as children have free prescriptions. In addition, it runs the risk of parents purchasing cosmetic bath additives that may make the condition worse.</p> <p>In the current financial climate, patients/parents/carers are struggling to pay prescription charges and may consider over the counter (OTC) medicines unaffordable. OTC presentations can be double the NHS cost owing to VAT and a pharmacy mark-up.</p>	Thank you for your comment. The committee considered the current financial climate, and that many families would find it difficult to pay for emollient bath additives over the counter. However, the committee agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care, which included applying leave-on emollients and washing with emollients. The committee discussed that they had not seen any evidence where emollient bath additives were used instead of leave-on emollients, and therefore did not have the evidence to make a recommendation for this. The committee did agree that applying leave-on emollients and washing with emollients is important, and they did not want patients to think they could use emollient bath additives as an alternative to this. The committee thought that it was important to educate and communicate this to patients and incorporated into recommendation 1.5.1.10 that patients and carers should be offered

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21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
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Dermal Laboratories Ltd	EHIA	002	4.1	<p>1)a There is an impact on children under 12 with the long-term condition of atopic eczema. Children receive free prescriptions for their treatments. Removing emollient bath additives from their prescription and asking parents/carers to purchase them over the counter provides an extra financial burden on these families.</p> <p>We disagree that the recommendation to purchase emollient bath additives over the counter is an appropriate alternative to them being prescribed, from an inequality point of view, for those families who cannot afford to purchase them. In the current financial climate, patients/parents/carers are struggling to pay prescription charges and may consider over the counter (OTC) medicines unaffordable. OTC presentations can be double the NHS cost owing to VAT and a pharmacy mark-up. This guideline is for children with a long-term condition, who do not pay for their prescriptions and parents may not be able to afford to purchase the bath emollients. This is a potential inequality affecting children and families on lower incomes.</p>	Thank you for your comment. The committee considered the current financial climate, and that many families would find it difficult to pay for emollient bath additives over the counter. However, the committee agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care, which included applying leave-on emollients and washing with emollients. The committee discussed that they had not seen any evidence where emollient bath additives were used instead of leave-on emollients, and therefore did not have the evidence to make a recommendation for this. The committee did agree that applying leave-on emollients and washing with emollients is important, and they did not want patients to think they could use emollient bath additives as an alternative to this. The committee thought that it was important to educate and communicate this to patients and incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice around washing with emollients and emollient soap substitutes. This would also provide a way for patients

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Consultation on draft guideline - Stakeholder comments table
21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
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Dermal Laboratories Ltd	Evidence Review	006	028	<p>In the PICOS table, we note that the inclusion criteria was “active eczema” and the exclusion criteria was “well-controlled eczema”. A definition is provided for “well-controlled eczema” as being children who have less than one week of flare per month. We are concerned that this implies that children must have at least 7 days of flare a month to be considered as having “active” eczema. Mild eczema is still “active eczema”. This level of eczema may still impact on quality of life for children and families. There is not necessarily a direct relationship between the severity of the atopic eczema and the impact of the atopic eczema on quality of life.</p> <p>In NICE guidance, it distinguishes between clear (normal skin, no evidence of atopic eczema), and mild (areas of dry skin, infrequent itching (with or without small areas of redness)).</p> <p>The BATHE study distinguished between ‘inactive’ and ‘very mild’ eczema within the exclusion criteria, defined as a score of 5 or</p>	<p>Thank you for your comment. The population for the evidence review excludes children with well-controlled eczema for the last 12 months, where well-controlled eczema is defined as:</p> <ul style="list-style-type: none"> • a history of eczema but no current evidence of inflammatory skin disease • less than 1 week of flare a month, or below 5 on the Nottingham Eczema Scale, or not needing any active treatment in the last month. <p>According to this definition, a study would still be included if they had less than 7 days of flare a month, but score 5 or above on the Nottingham Eczema Severity Scale OR needed any active treatment in the last month. The committee were asked to define inactive eczema to ensure that the most appropriate studies were used to answer the review question. They did this using their professional experience and referral criteria for atopic eczema defined in the NICE guideline. However, the impact of this definition on studies included in the review is minimal, as no studies were excluded on the</p>

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Dermal Laboratories Ltd	Evidence Review	023	023 – 027	<p>We do not agree that acquiring and using bath emollients is an extra burden on patients and carers. It is acknowledged in the guideline itself that <i>“Some children may also enjoy using bath additives generally.”</i> Using emollient bath additives is a convenient, effective and often enjoyable way of applying emollient to the whole body. This is a particularly useful option in the case of infants and young children, where it can form an appealing part of ‘fun time’ routine bathing. Treatment adherence can be a major problem with emollient therapy, and it is misleading to consider the merits of emollient bath additives only in the context of them being <u>added</u> to comprehensive “standard” therapy. For some patients, application via the bath is much more significant than leave on therapy. Children who enjoy bathing are more likely to be bathed regularly. In one of the BATHE group sub-group analyses “a small clinically meaningful benefit” of bath additives was shown in those children bathing more than 5 times a week (POEM score was 2.27 points higher in the ‘no bath additives’ group). Therefore, it has been shown that children bathing regularly benefit from emollient bath additives.</p>	<p>Thank you for your comment. The committee acknowledged that it may be less convenient to dilute leave-on emollients in bath water than to use emollient bath additives. However, the committee also agreed that the evidence showed that emollient bath additives are not effective, meaning that on a population level there is no clinical reason that children with atopic eczema should use them.</p> <p>The committee discussed the BATHE subgroup analysis of frequency of bathing and agreed that there is some evidence that emollient bath additives are effective in those who bathe 5 or more times a week. However, the evidence was judged to be of low quality according to GRADE, due to risk of bias and imprecision. The BATHE study report also cautioned the findings of the subgroup analysis as the study was not adequately powered to detect subgroup differences, and this is reflected in the judged imprecision, as the 95% CIs cross the line of minimally important difference. Because of this uncertainty in the evidence, the committee chose not to make an exception based on frequency of bathing. The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap</p>

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					Although the committee understood there may be individuals who feel they benefit from the intervention, they based their decision on the results of the BATHE study which demonstrated a lack of clinical and cost effectiveness at a population level. NICE bases its recommendations on an assessment of population benefits and value for money (NICE charter, Principle 7). Therefore, based on NICE methods, the committee concluded that funding bath emollients are unlikely to be a good use of NHS resources.
Dermal Laboratories Ltd	Evidence Review	023	028 – 043	The committee are asking healthcare professionals to explain to their patients and carers that emollient bath additives are not effective and that they won't be prescribed. Although some patients may be inclined to accept the rationale for this, the fact remains that the committees' categorical contention that " <i>emollient bath additives do not help</i> ", is not well supported by the reviewed evidence. Some patients will be upset and reluctant to accept this because they are convinced that their bath emollients are therapeutic. The committee agreed that it would be difficult to stop prescribing bath emollients for patients who find them beneficial. Indeed, it would be inappropriate to stop prescribing for these patients. We strongly recommend that the "Do not offer" statement is revised to allow for both plain as well as antimicrobial bath emollients to	Thank you for your comment. The consensus from the committee, including the lay members, was that patients and carers would accept not being prescribed bath emollients if the rationale was discussed with them. The committee incorporated into the recommendations that patients and carers should be offered personalised advice around washing with emollients and emollient soap substitutes, which would allow clinicians to have this discussion and to provide solutions effective solutions for patients. Antimicrobial bath emollients are outside the scope for this update, as they are covered in NICE's guideline on Secondary bacterial infection of eczema and other common skin conditions: antimicrobial prescribing [NG190] . The committee discussed that it is important for children to wash with emollients in the

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>continue to be prescribed for children with atopic eczema. There should be provision for prescribing bath emollients for young children with atopic eczema, and for those, in the prescriber's opinion, would benefit from frequent bathing.</p> <p>We disagree with the statement that <i>"the BATHE trial showed that bath emollients are not likely to be effective"</i> as the study actually demonstrated that there was no <u>additional</u> benefit of bath emollient additives when combined with a comprehensive "standard" treatment regime comprising the use of applied emollients, emollient soap substitutes and topical corticosteroids where appropriate. The BATHE study was not designed to show the benefit of bath emollients in their own right. Nevertheless, the committee recognised from the BATHE study results, that <i>"there will be individual patients who benefit from bath emollients"</i> as part of a comprehensive "standard" eczema treatment regime. Bath emollients can be a helpful and beneficial option in certain cases, such as children under 5 years and in those who bathe more than 5 times a week. This is supported by the BATHE study results, where one of the subgroup analyses showed "a small effect of bath additives" among children aged less than 5 years (POEM score was 1.29 points higher in the 'no bath additives' group) and</p>	<p>bath regardless of whether emollient bath additives are used, and that this is already recommended in 1.5.1.10. The committee discussed that washing with emollients in the bath would reflect current practice, and they agreed that it was valid for the intervention and control groups to continue to wash with emollients.</p> <p>The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap substitutes is well established, and that it is important that children with atopic eczema and their carers do not think that bath emollients can be used instead of applying leave-on emollients and using soap substitutes. The committee discussed that the BATHE trial gave important information on whether emollient bath additives would be of additional benefit to usual care.</p> <p>The committee discussed that age was not prespecified as a subgroup in the review protocol for the NICE evidence review. The BATHE study cautioned against findings of the subgroup analyses as the study was not adequately powered to detect subgroup differences. The committee discussed the possibility that the findings were due to multiple testing as they could not explain why emollient bath additives would be more effective in under 5s unless this was linked to bathing frequency. Due to the uncertainty</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>another sub-group analysis showed “a small clinically meaningful benefit” of bath additives in those bathing more than 5 times a week (POEM score was 2.27 points higher in the ‘no bath additives’ group). The BATHE study therefore showed that young children bathing regularly benefit from bath emollients. This is an age group more frequently affected by atopic eczema and provides a convenient way for parents to apply an emollient when the child is bathing.</p> <p>The findings of the BATHE study may not be so directly applicable to those with severe disease as few patients with severe disease were included in the study. These patients are more likely to be managed in secondary care. However, even if patients are prescribed or recommended bath emollients by their secondary care HCPs, the “Do not offer bath additives” recommendation would prevent them from being available as regular prescriptions in the community.</p> <p>Patients with severe eczema may benefit from an emollient bath additive with additional active ingredients, such as antimicrobial bath emollients. They have additional benefits over plain emollients, for example, our licensed medicine Dermol 600 Bath Emollient, has been formulated to contain emollient oils plus an antiseptic, benzalkonium chloride, in an emulsion</p>	<p>in this evidence, the committee decided not to make an exception based on age. The committee discussed the BATHE subgroup analysis of frequency of bathing and agreed that there is some evidence that emollient bath additives are effective in those who bathe 5 or more times a week. However, the evidence was judged to be of low quality according to GRADE, due to risk of bias and imprecision. The BATHE study report also cautioned the findings of the subgroup analysis as the study was not adequately powered to detect subgroup differences, and this is reflected in the judged imprecision, as the 95% CIs cross the line of minimally important difference. Because of this uncertainty in the evidence, the committee chose not to make an exception based on frequency of bathing. This committee acknowledged that the number of participants with severe eczema was lower than the number with mild or moderate eczema. However, the committee agreed that the proportion of patients with severe eczema reflects real world prevalence. The committee also highlighted that the BATHE study performed a subgroup analysis of baseline eczema severity, and that it was reported that emollient bath additives are also not effective in this population. Although the committee understood there may be individuals who feel they benefit</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>system specially designed to readily mix throughout the bath water. This evenly coats all submerged skin surfaces to reduce overgrowth of <i>Staphylococcus aureus</i> (<i>S. aureus</i>) in particular, which is known to exacerbate atopic eczema. This important antimicrobial action has also been shown to extend to antibiotic resistant strains of <i>S. aureus</i> such as meticillin-resistant <i>S. aureus</i> (MRSA) and fusidic-acid resistant <i>S. aureus</i> (FRSA.) mrsa_frsa.pdf (dermal.co.uk)</p> <p>Antiseptics are used to lower bacterial load Topical antibiotics and antiseptics Prescribing information Eczema - atopic CKS NICE and antimicrobial bath emollients can also assist in overcoming, or preventing, possible secondary infection.</p> <p>It is unacceptable to advise that anyone wanting to use emollient bath additives should be recommended to buy them over the counter. Atopic eczema is a chronic condition, most commonly affecting infants and young children who are the particular subgroup for whom bath emollients can be beneficial. This may be unaffordable for many parents on lower incomes, particularly as children have free prescriptions. In addition, it runs the risk of parents purchasing cosmetic bath additives that may make the condition worse.</p>	<p>from the intervention, they based their decision on the results of the BATHE study which demonstrated a lack of clinical and cost effectiveness at an individual and population level. NICE bases its recommendations on an assessment of population benefits and value for money (NICE charter, Principle 7). Therefore, based on NICE methods, the committee concluded that funding bath emollients are unlikely to be a good use of NHS resources.</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>In the current financial climate, patients/parents/carers are struggling to pay prescription charges and may consider over the counter (OTC) medicines unaffordable. OTC presentations can be double the NHS cost owing to VAT and a pharmacy mark-up. These financial obstacles are increasingly evident even in the prescription sector, as evidenced by a survey of 269 pharmacists by the Royal Pharmaceutical Society (RPS) towards the end of 2022. This showed that an increasing number of patients are contemplating discontinuing with some treatments because they cannot afford to pay the prescription charge. <i>The Pharmaceutical Journal</i>, PJ, February 2023, Vol 310, No 7970;310(7970)::DOI:10.1211/PJ.2023.1.174841 Half of pharmacists report increase in patients unable to afford prescription medicines, reveals survey - The Pharmaceutical Journal (pharmaceutical-journal.com)</p>	
Dermal Laboratories Ltd	Evidence Review	024	030 – 045	<p>Although “<i>the study concluded that there was no significant difference in quality of life between the bath additive and no bath additive arms</i>”, this is based on assessment of an additional effect of an emollient bath additive over comprehensive “standard” eczema therapy, i.e. applied emollients, emollient soap substitutes and topical steroid use, and the impact on quality of life within a controlled clinical trial where</p>	<p>Thank you for your comment. The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap substitutes is well established, and that it is important that children with atopic eczema and their carers do not think that bath emollients can be used instead of applying leave-on emollients and using soap substitutes. The committee discussed that the BATHE trial gave</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>adherence to treatment is likely to be higher than in the 'real world' scenario. The study also encouraged participants in both intervention and control arms to wash with emollients in the bath which may limit the impact of adding emollient bath additives.</p> <p>Bath emollients can be a helpful and beneficial option in certain cases, such as children under 5 years and in those who bathe more than 5 times a week. This is supported by the BATHE study results, where one of the sub-group analyses showed "a small effect of bath additives" among children aged less than 5 years (POEM score was 1.29 points higher in the 'no bath additives' group) and another sub-group analysis showed "a small clinically meaningful benefit" for bath additives in those bathing more than 5 times a week (POEM score was 2.27 points higher in the 'no bath additives' group). The BATHE study therefore showed that young children bathing regularly benefit from bath emollients. This is an age group more frequently affected by atopic eczema and provides a convenient way for parents to apply an emollient when the child is bathing.</p> <p>There was a difference in number of primary and secondary care consultations in the BATHE study with more consultations in the 'no bath additives' group. The mean number</p>	<p>important information on whether emollient bath additives would be of additional benefit to usual care.</p> <p>The committee discussed that it is important for children to wash with emollients in the bath regardless of whether emollient bath additives are used, and that this is already recommended in 1.5.1.10. The committee discussed that washing with emollients in the bath would reflect current practice, and they agreed that it was valid for the intervention and control groups to continue to wash with emollients.</p> <p>The committee discussed that age was not prespecified as a subgroup in the review protocol for the NICE evidence review. The BATHE study cautioned against findings of the subgroup analyses as the study was not adequately powered to detect subgroup differences. The committee discussed the possibility that the findings were due to multiple testing as they could not explain why emollient bath additives would be more effective in under 5s unless this was linked to bathing frequency. Due to the uncertainty in this evidence, the committee decided not to make an exception based on age.</p> <p>The committee discussed the BATHE subgroup analysis of frequency of bathing and agreed that there is some evidence that emollient bath additives are effective in</p>

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>of consultations at 16 weeks was 0.53 (SD 1.2) for the 'bath additives' group and 0.88 (SD 1.7) for the 'no bath additives' group, with a statistically significant difference of – 0.35 (95% CI –0.62 to –0.08), indicating that fewer consultations were reported within the bath additives group. Adding emollient bath additives to standard eczema management for children with eczema: the BATHE RCT (nih.ac.uk) Reducing the number of healthcare professional consultations is of benefit, particularly when there is a national shortage of GPs and limited number of appointments. If this reduction in consultation costs is extrapolated across the population the cost savings could be significant.</p> <p>If bath emollients are not prescribed, this may encourage bathing in plain water, which can sting and dry the skin. Even worse, it may encourage erroneous use of foaming and perfumed bath additives instead, which will dry and irritate atopic skin resulting in flares/worsening of the condition and consequential consulting and prescribing costs. In the BATHE study, the estimated mean costs to the NHS at 52 weeks were £180.50 in the bath additive arm and £166.12 in the no bath additive arm. This is a difference of just £14 between the two intervention groups over 1 year. In addition, the costs borne by families showed a higher</p>	<p>those who bathe 5 or more times a week. However, the evidence was judged to be of low quality according to GRADE, due to risk of bias and imprecision. The BATHE study report also cautioned the findings of the subgroup analysis as the study was not adequately powered to detect subgroup differences, and this is reflected in the judged imprecision, as the 95% CIs cross the line of minimally important difference. Because of this uncertainty in the evidence, the committee chose not to make an exception based on frequency of bathing.</p> <p>NICE methods require all NHS/PSS costs, therefore the committee decided the GP NR data from the study was more appropriate for decision making than the CSRI data as it includes intervention costs. The committee agreed the cost savings seen in reduced consultation costs for those in the bath emollient arm would be offset by the additional intervention costs.</p> <p>The committee agreed that certain products would be detrimental to children with eczema. The committee discussed how it is important to address this by educating children with atopic eczema and their carers not to use these products and to wash with leave-on emollients or emollient soap substitutes instead. Therefore, the committee incorporated into</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				annual spend in the no bath additives group of £51.37.	<p>recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes.</p> <p>The committee discussed that bathing in plain water may sting children with atopic eczema. However, the committee agreed that this can be alleviated by using emollient wash products in the bath. The committee agreed that it is important to communicate this to patients and incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap.</p> <p>The committee understood that the study showed a £14 difference per individual. If this cost difference was applied to the wider eligible patient population, the cost savings to the NHS would be substantially higher. NICE only consider NHS/PSS costs, therefore family borne costs were not considered as they lie outside of these costs.</p>
Dermal Laboratories Ltd	Evidence Review	025	008 – 017	We strongly recommend that the “Do not offer” recommendation is revised to allow for both plain as well as antimicrobial bath emollients to continue to be prescribed for children with atopic eczema. There should be provision for prescribing bath emollients for young children with atopic eczema, and for those, whom in the prescriber’s opinion, would benefit from frequent bathing. For	Thank you for your comment. The committee discussed that age was not prespecified as a subgroup in the review protocol for the NICE evidence review. The BATHE study cautioned against findings of the subgroup analyses as the study was not adequately powered to detect subgroup differences. The committee discussed the possibility that the findings were due to

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>example, regular bathers and those with sensory issues.</p> <p>With regard to the NHS England advice, this is guidance on items that should not routinely be prescribed in primary care but is not a negative "Do not offer". By using the statement "Do not offer" the guidance removes the clinical discretion of the prescriber in accordance with their professional duties, when faced with an individual patient who is benefiting from the use of a bath emollient. This discriminates against those patients/families on low incomes who are unable to afford to purchase the bath emollient.</p> <p>The recommendation not to offer a bespoke product designed to disperse in the bath water, but instead to try to disperse an emollient designed to leave on the skin is inconvenient and can lead to non-compliance with potential worsening of the skin condition especially if cosmetic bath emollients are used instead.</p> <p>We should also point out that the study only involved <u>plain</u> bath emollients. Antimicrobial bath emollients were excluded from the BATHE study. Antimicrobial bath emollients have additional benefits over plain emollients. For example, our licensed medicine Dermol 600 Bath Emollient, has</p>	<p>multiple testing as they could not explain why emollient bath additives would be more effective in under 5s unless this was linked to bathing frequency. Due to the uncertainty in this evidence, the committee decided not to make an exception based on age. The committee discussed the BATHE subgroup analysis of frequency of bathing and agreed that there is some evidence that emollient bath additives are effective in those who bathe 5 or more times a week. However, the evidence was judged to be of low quality according to GRADE, due to risk of bias and imprecision. The BATHE study report also cautioned the findings of the subgroup analysis as the study was not adequately powered to detect subgroup differences, and this is reflected in the judged imprecision, as the 95% CIs cross the line of minimally important difference. Because of this uncertainty in the evidence, the committee chose not to make an exception based on frequency of bathing. The committee were aware that some children with sensory processing disorders may be unable to tolerate having leave-on emollients applied to their skin. However, they also discussed that no evidence was identified around the effectiveness of emollient bath additives in this population, or when emollient bath additives were used in the absence of leave-on emollients. The committee discussed that there are other</p>

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>been formulated to contain emollient oils and an antiseptic, benzalkonium chloride, in an emulsion system specially designed to readily mix throughout the bath water. This evenly coats all submerged skin surfaces to reduce overgrowth of <i>Staphylococcus aureus</i> (<i>S. aureus</i>) in particular, which is known to exacerbate atopic eczema. This important antimicrobial action has also been shown to extend to antibiotic resistant strains of <i>S. aureus</i> such as methicillin-resistant <i>S. aureus</i> (MRSA) and fusidic-acid resistant <i>S. aureus</i> (FRSA.) mrsa_frsa.pdf (dermal.co.uk) Antiseptics are used to lower bacterial load Topical antibiotics and antiseptics Prescribing information Eczema – atopic CKS NICE and antimicrobial bath emollients can also assist in overcoming, or preventing, possible secondary infection.</p>	<p>ways that children who are unable to tolerate leave-on emollients may benefit from emollients, such as washing with them (recommendation 1.5.1.10). The committee also discussed that It is possible to dilute leave-on emollients and add them to bath water. The committee agreed on the importance of understanding the needs of individual children with atopic eczema and their families, and for clinicians to provide personalised advice to patients and their carers based on this. Therefore, they decided to incorporate into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. The committee highlighted that this would be particularly relevant for children with sensory processing disorders. NICE guidance allows clinicians to apply clinical judgment where appropriate for the patient and their family and carers. The document that went for consultation only included information specific to the update, however, at publication, the updated recommendations will be in the Atopic eczema in under 12s: diagnosis and management guideline, which contains the following statement: “The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners</p>

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Consultation on draft guideline - Stakeholder comments table
21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					<p>are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers." The committee also incorporated into the recommendations that patients and carers should be offered personalised advice around washing with emollients and emollient soap substitutes so that clinicians could advise and educate on how emollients can be added to bath water if this is appropriate for the patient and their family. The committee did agree that applying leave-on emollients and washing with emollients is important, and they did not want patients to think they could use emollient bath additives as an alternative to this. The committee thought that it was important to educate and communicate this to patients and incorporated into recommendation 1.5.1.12 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. This would also provide a way for patients and carers to get advice on alternative ways to bathe with emollients (such as diluting leave-on emollients in hot water and adding them to</p>

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Consultation on draft guideline - Stakeholder comments table
21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					<p>bath water) if applying leave-on emollients is not acceptable to the patient, or if the clinician feels that this would benefit the patient.</p> <p>The committee acknowledged that it may be less convenient to dilute leave-on emollients in bath water than to use emollient bath additives. However, the committee also noted that it is potentially inconvenient for patients and carers to have to acquire and use an additional product. The committee also agreed that the evidence showed that emollient bath additives are not effective, meaning that on a population level there is no clinical reason that children with atopic eczema should use them.</p> <p>Antimicrobial bath emollients are outside the scope for this update, as they are covered in NICE's guideline on Secondary bacterial infection of eczema and other common skin conditions: antimicrobial prescribing [NG190].</p>
Dermal Laboratories Ltd	Evidence Review	025	031 – 036	<p>It is acknowledged here that antimicrobial bath emollients are out of scope of the guideline but the "Do not offer bath emollients" recommendation applies to all bath emollients in this revised guidance. It is incorrect to include antimicrobial bath emollients in the recommendation that emollient bath additives do not help eczema when they were excluded from the evidence/BATHE study and efficacy was not assessed. In addition, it would appear that,</p>	<p>Thank you for your comment. Antimicrobial bath emollients are outside the scope for this update, as they are covered in NICE's guideline on Secondary bacterial infection of eczema and other common skin conditions: antimicrobial prescribing [NG190].</p> <p>In NG190 it is acknowledged that there is a lack of evidence on whether antiseptic bath emollients are more effective than standard bath emollients. This meant that the committee were unable to make any</p>

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>although antimicrobial bath emollients are considered effective, there is reluctance to include a recommendation to offer these bath emollients, as this may 'increase prescribing of antimicrobial bath emollients as a way of providing patients with bath emollients'. Surely, children with atopic eczema should have access to prescribed treatments that are considered effective, and they like to use, and not have access restricted as it is seen as a potential 'loop-hole' for all bath emollients to be prescribed.</p> <p>Antimicrobial bath emollients have additional benefits over plain emollients. For example, our licensed medicine Dermol 600 Bath Emollient, has been formulated to contain emollient oils plus an antiseptic, benzalkonium chloride, in an emulsion system specially designed to readily mix throughout the bath water. This evenly coats all submerged skin surfaces to reduce overgrowth of <i>Staphylococcus aureus</i> (<i>S. aureus</i>) in particular, which is known to exacerbate atopic eczema. This important antimicrobial action has also been shown to extend to antibiotic resistant strains of <i>S. aureus</i> such as meticillin-resistant <i>S. aureus</i> (MRSA) and fusidic-acid resistant <i>S. aureus</i> (FRSA.) mrsa_frsa.pdf (dermal.co.uk) Antiseptics are used to lower bacterial load Topical antibiotics and antiseptics Prescribing information Eczema— atopic </p>	<p>recommendations around antiseptic emollient bath additives, and the committee instead made a research recommendation to address the gap in the evidence.</p>

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				CKS NICE and antimicrobial bath emollients can also assist in overcoming, or preventing, possible secondary infection.	
Dermal Laboratories Ltd	Evidence Review	024 – 025	046 – 049 & 001 – 007	<p>Data from Openprescribing.net reflects all prescriptions for emollient bath additives and not those solely used for atopic eczema. There are other skin conditions such as ichthyosis where daily use of bath emollients is an essential treatment to help manage the condition Management of congenital ichthyoses: European guidelines of care, part one British Journal of Dermatology Oxford Academic (oup.com). Bath emollients have comparatively low acquisition costs and indeed the BATHE study found only a £14 difference per patient per year between the two arms of the study.</p> <p>Bath emollients can be a helpful and beneficial option in certain cases, such as children under 5 years and in those who bathe more than 5 times a week. This is supported by the BATHE study results, where one of the sub-group analyses showed “a small effect of bath additives” among children aged less than 5 years (POEM score was 1.29 points higher in the ‘no bath additives’ group) and another sub-group analysis showed “a small clinically meaningful benefit” for ‘bath additives’ in those bathing more than 5 times a week (POEM score was 2.27 points higher in the no bath additives group). The BATHE study</p>	<p>Thank you for your comment. The openprescribing.net data was used to give the committee an insight into spend and regional variation in prescribing of emollients. The committee understood this data was reflective of bath emollients in various conditions not just eczema. The BATHE study demonstrated a £14 additional cost in the use of bath emollients per individual, which would be greater if applied to the wider eligible patient population.</p> <p>The committee discussed that age was not prespecified as a subgroup in the review protocol for the NICE evidence review. The BATHE study cautioned against findings of the subgroup analyses as the study was not adequately powered to detect subgroup differences. The committee discussed the possibility that the findings were due to multiple testing as they could not explain why emollient bath additives would be more effective in under 5s unless this was linked to bathing frequency. Due to the uncertainty in this evidence, the committee decided not to make an exception based on age. The committee discussed the BATHE subgroup analysis of frequency of bathing and agreed that there is some evidence that emollient bath additives are effective in</p>

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>therefore showed that young children bathing regularly benefit from bath emollients. This is an age group more frequently affected by atopic eczema and provides a convenient way for parents to apply an emollient when the child is bathing.</p> <p>By using the statement "Do not offer" the guidance removes the clinical discretion of the prescriber in accordance with their professional duties, when faced with an individual patient who is benefiting from the use of a bath emollient. This discriminates against those patients/families on low incomes who are unable to afford to purchase the bath emollient.</p>	<p>those who bathe 5 or more times a week. However, the evidence was judged to be of low quality according to GRADE, due to risk of bias and imprecision. The BATHE study report also cautioned the findings of the subgroup analysis as the study was not adequately powered to detect subgroup differences, and this is reflected in the judged imprecision, as the 95% CIs cross the line of minimally important difference. Because of this uncertainty in the evidence, the committee chose not to make an exception based on frequency of bathing.</p> <p>NICE guidance allows clinicians to apply clinical judgement where appropriate for the patient and their family and carers. The document that went for consultation only included information specific to the update, however, at publication, the updated recommendations will be in the Atopic eczema in under 12s: diagnosis and management guideline, which contains the following statement: "The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations,</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					<p>and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers." The committee also incorporated into the recommendations that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes so that clinicians could advise and educate on how emollients can be added to bath water if this is appropriate for the patient and their family. The committee considered the current financial climate, and that many families would find it difficult to pay for emollient bath additives over the counter. However, the committee agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care, which included applying leave-on emollients and washing with emollients. The committee discussed that they had not seen any evidence where emollient bath additives were used instead of leave-on emollients, and therefore did not have the evidence to make a recommendation for this. The committee did agree that applying leave-on emollients and washing with emollients is important, and they did not want patients to think they could use emollient bath additives as an alternative to this. The committee thought that it was important to educate and communicate this to patients and</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					incorporated into recommendation 1.5.1.12 that patients and carers should be offered personalised advice on washing with emollients and emollient soap. This would also provide a way for patients and carers to get advice on alternative ways to bathe with emollients (such as diluting leave-on emollients in hot water and adding them to bath water) if applying leave-on emollients is not acceptable to the patient, or if the clinician feels that this would benefit the patient.
Dermal Laboratories Ltd	Guideline	004	005 – 007	We are concerned by the removal of the recommendation to use emollients <u>for bathing</u> , alongside moisturising and washing. Removal of bathing is based on a particular interpretation of the BATHE study results, to conclude that emollient bath emollients are not effective in atopic eczema. However, the study actually demonstrated that there was no <u>additional</u> benefit of bath emollient additives when combined with a comprehensive “standard” treatment regime comprising the use of applied emollients, emollient soap substitutes and topical corticosteroids where appropriate. Moreover, in the subgroup of patients aged under 5 years, and in the subgroup who used bath emollients frequently, there was nevertheless an added benefit of using emollient bath additives, although not deemed significant according to the BATHE study criteria.	<p>Thank you for your comment. The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap substitutes is well established, and that it is important that children with atopic eczema and their carers do not think that bath emollients can be used instead of applying leave-on emollients and using soap substitutes. The committee discussed that the BATHE trial gave important information on whether emollient bath additives would be of additional benefit to usual care.</p> <p>The committee discussed that age was not prespecified as a subgroup in the review protocol for the NICE evidence review. The BATHE study cautioned against findings of the subgroup analyses as the study was not adequately powered to detect subgroup differences. The committee discussed the</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>It is generally recognised that treatment outcomes tend to improve as a result of clinical trial participation, owing to the extra teaching/education received and greater attention to treatment concordance. This makes it more difficult to detect study treatment differences, especially when both “control” and “bath additives” groups involve active therapy. The children recruited to the BATHE study were already receiving existing treatments, so in this regard it is notable that their mean Patient Oriented Eczema Measure (POEM) scores improved in both study groups. For the “control” group on “standard” treatment without bath emollient additives, their POEM scores improved from a baseline of 10.1 to a score of 8.4 after 16 weeks, i.e., an improvement of 1.7 points. For the group using a bath additive in addition to “standard” care, their POEM scores improved from a baseline of 9.5 to a score of 7.5 after 16 weeks, i.e., an improvement of 2 points.</p> <p>Under normal conditions of use in the community, concordance can be the greatest obstacle to successful emollient treatment because these products have to be re-applied frequently, all over the body. Emollient bath additives can therefore provide a convenient and effective opportunity to apply an emollient, as part of</p>	<p>possibility that the findings were due to multiple testing as they could not explain why emollient bath additives would be more effective in under 5s unless this was linked to bathing frequency. Due to the uncertainty in this evidence, the committee decided not to make an exception based on age.</p> <p>The committee discussed the BATHE subgroup analysis of frequency of bathing and agreed that there is some evidence that emollient bath additives are effective in those who bathe 5 or more times a week. However, the evidence was judged to be of low quality according to GRADE, due to risk of bias and imprecision. The BATHE study report also cautioned the findings of the subgroup analysis as the study was not adequately powered to detect subgroup differences, and this is reflected in the judged imprecision, as the 95% CIs cross the line of minimally important difference. Because of this uncertainty in the evidence, the committee chose not to make an exception based on frequency of bathing.</p> <p>The committee discussed that in unblinded clinical trials, the effect of the intervention can be biased in favour of the intervention, especially when outcomes are patient reported. However, the committee noted that despite this, emollient bath additives were still found to be ineffective, which further</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>routine bathing. This is of particular benefit for parents coping with the added workload associated with caring for a child with atopic eczema.</p> <p>We strongly believe that the option of using emollient bath additives should be reinstated in this guideline. As stated by the NICE committee in relation to the BATHE study, <i>“there may be specific subgroups of children who may benefit from emollient bath additives. Some children may also enjoy using bath additives generally”</i> which helps with compliance in adding emollients to the skin. <i>“The evidence also suggested that emollient bath additives are unlikely to increase the risk of adverse events (such as slipping in the bath, stinging, redness, and refusal to bathe).”</i> We believe that bathing using emollients is an especially convenient and effective way of applying it to the whole body. As such, it is therefore particularly useful when treating babies and young children.</p> <p>When bathing, it is nevertheless important to avoid perfumed and foaming bubble baths because they dry and irritate the skin and make eczema worse. This is more likely to happen if emollient bath additives are no longer recommended/prescribed, and cosmetic bath additives are used instead. In addition, therapeutic bath emollients are</p>	<p>supports the conclusion that emollient bath additives are not effective. The committee agree that it is important that patients apply leave-on emollients and wash with emollients, and any improvement of eczema severity in the control group would support this.</p> <p>The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap substitutes is well established, and that it is important that children with atopic eczema and their carers do not think that bath emollients can be used instead of applying leave-on emollients and using soap substitutes.</p> <p>The evidence review reported that there was no significant difference between the bath emollients and no bath emollients groups for the adverse event of refusal to bathe. The evidence review does report that the adverse event of redness favours the bath emollients arm. As this is an adverse event, an increase in redness would strengthen a “do not offer” recommendation if the intervention was found to increase the adverse event, which was not the case here. Although evidence for the adverse event outcome of redness did favour bath emollients, the committee considered this outcome in the context of all the outcomes reported in the evidence review, which overall showed that emollient bath additives</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>specially formulated to readily emulsify/disperse within the entire volume of the bath water so that all submerged skin surfaces are treated. Although the NICE draft mentions that applied emollients can be mixed into bath water, this is difficult to achieve in practice, and is likely to leave clumps of undispersed emollient floating on the surface. Skin coverage is therefore compromised and the risk of slipping in the bath increases.</p> <p>Bathing in plain water can cause dryness and sting eczematous skin, making the condition worse - as commented by the NICE committee in the Evidence Review (page 23, lines 18-22), <i>“Although it is worth noting that treatment adherence data indicated that the numbers of participants bathing 5 or more times a week were similar in the intervention and comparator arm, and in the no bath additives group eczema severity was slightly more severe in the patients who bathed 5 or more times a week compared with patients who bathed 1 to 4 times per week (mean(SD) POEM score 8.75(6.12) vs 8.00(5.82) respectively).”</i></p>	<p>are not effective in reducing eczema severity. Additionally, the evidence for the adverse event outcome of redness was judged to be of low quality according to GRADE, which reduced the committee's certainty in the result.</p> <p>The committee acknowledged that it may be less convenient to dilute leave-on emollients in bath water than to use emollient bath additives. However, the committee also agreed that the evidence showed that emollient bath additives are not effective, meaning that on a population level there is no clinical reason that children with atopic eczema should use them.</p> <p>The committee agreed that certain products would be detrimental to children with eczema. The committee discussed how it is important to address this by educating children with atopic eczema and their carers not to use these products and to wash with leave-on emollients or emollient soap substitutes instead. Therefore, the committee incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes.</p> <p>The committee discussed that bathing in plain water may sting children with atopic eczema. However, the committee agreed that this can be alleviated by using emollient wash products in the bath. The committee</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					agreed that it is important to communicate this to patients and incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. Although the POEM score is slightly worse for those who bathe 5 or more times per week compared with 1 to 4 times per week in the no bath additive group, the mean difference (95% CI) was calculated and found to be not significant (-0.75 [-2.58 to 1.08]).
Dermal Laboratories Ltd	Guideline	005	021 – 022	<p>We do not agree with the recommendation “Do not offer emollient bath additives to children with atopic eczema” because it would be detrimental to children with atopic eczema. The recommendation stems from an unjustified extrapolation from the BATHE study results to state that bath emollients don't work in general.</p> <p>The BATHE study was designed to find out if bath emollients offer any 'additional' benefit to standard treatment, which, in the study, comprised a comprehensive regime of applied emollients, soap substitutes and use of topical steroids if needed. The study was not designed to show the benefit of bath emollients in their own right. Because children in both treatment groups were encouraged to use leave-on emollients, soap substitutes and topical steroids, and so were likely to show clinical improvement,</p>	<p>Thank you for your comment. The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap substitutes is well established, and that it is important that children with atopic eczema and their carers do not think that bath emollients can be used instead of applying leave-on emollients and using soap substitutes. The committee discussed that the BATHE trial gave important information on whether emollient bath additives would be of additional benefit to usual care.</p> <p>The committee discussed that age was not prespecified as a subgroup in the review protocol for the NICE evidence review. The BATHE study cautioned against findings of the subgroup analyses as the study was not adequately powered to detect subgroup differences. The committee discussed the</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>this made it difficult for the study to detect a significant 'additional' benefit (>3 POEM points) from also using emollient bath additives. For the "control" group on "standard" treatment without bath emollient, their POEM scores improved from a baseline of 10.1 to a score of 8.4 after 16 weeks, i.e., an improvement of 1.7 points. For the group using bath emollient in addition to "standard" care, their POEM scores improved from a baseline of 9.5 to a score of 7.5 after 16 weeks, i.e., an improvement of 2 points.</p> <p>Emollient bath additives can be a helpful and beneficial option in certain cases, such as children under 5 years and in those who bathe more than 5 times a week. This is supported by the BATHE study results, where one of the sub-group analyses showed "a small effect of bath additives" among children aged less than 5 years (POEM score was 1.29 points higher in the 'no bath additives' group) and another sub-group analysis showed "a small clinically meaningful benefit" of emollient bath additives in those bathing more than 5 times a week (POEM score was 2.27 points higher in the 'no bath additives' group). The BATHE study therefore showed that young children bathing regularly benefit from emollient bath additives. This is an age group more frequently affected by atopic eczema and</p>	<p>possibility that the findings were due to multiple testing as they could not explain why emollient bath additives would be more effective in under 5s unless this was linked to bathing frequency. Due to the uncertainty in this evidence, the committee decided not to make an exception based on age.</p> <p>The committee discussed the BATHE subgroup analysis of frequency of bathing and agreed that there is some evidence that emollient bath additives are effective in those who bathe 5 or more times a week. However, the evidence was judged to be of low quality according to GRADE, due to risk of bias and imprecision. The BATHE study report also cautioned the findings of the subgroup analysis as the study was not adequately powered to detect subgroup differences, and this is reflected in the judged imprecision, as the 95% CIs cross the line of minimally important difference. Because of this uncertainty in the evidence, the committee chose not to make an exception based on frequency of bathing.</p> <p>NICE guidance allows clinicians to apply clinical judgement where appropriate for the patient and their family and carers. The document that went for consultation only included information specific to the update, however, at publication, the updated recommendations will be in the Atopic</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>provides a convenient way for parents to apply an emollient when the child is bathing.</p> <p>The instruction "Do not offer ..." removes clinical discretion of the prescriber in accordance with their professional duties, when faced with a patient who, in their opinion, is likely to benefit from the use of a emollient bath additive. This also discriminates unfairly against those patients/families on low incomes who are unable to afford to purchase a bath emollient. It also increases the likelihood of inappropriate cosmetic bath additives being used instead. Using emollient bath additives is a convenient and effective way of applying emollient to the whole body. This is a particularly useful option in the case of infants and young children, where it can form an appealing part of 'fun-time' routine bathing. In addition, therapeutic emollient bath additives are specially formulated to readily emulsify/disperse within the entire volume of the bath water so that all submerged skin surfaces are treated. Although the NICE draft mentions that applied emollients can be mixed into bath water, this is difficult to achieve in practice, and is likely to leave clumps of undispersed emollient floating on the surface. Skin coverage is therefore compromised and the risk of slipping in the bath increases. If emollient bath additives are not prescribed,</p>	<p>eczema in under 12s: diagnosis and management guideline, which contains the following statement: "The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers."</p> <p>The committee also incorporated into the recommendations that patients and carers should be offered personalised advice on washing with emollients and emollient soap so that clinicians could advise and educate on how emollients can be added to bath water if this is appropriate for the patient and their family.</p> <p>The committee considered the current financial climate, and that many families would find it difficult to pay for emollient bath additives over the counter. However, the committee agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care,</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>this may encourage bathing in plain water, which can sting and dry the skin. Even worse, it may encourage erroneous use of foaming and perfumed bath additives instead, which will dry and irritate atopic skin resulting in flares/worsening of the condition and consequential consulting and prescribing costs. This will be an added risk if patients are advised to purchase bath additives for themselves.</p> <p>In the BATHE study, the estimated mean costs to the NHS at 52 weeks were £180.50 in the bath additive arm and £166.12 in the no bath additive arm. This is a difference of only £14 between the two intervention groups over 1 year. In addition, the costs borne by families showed a higher annual spend in the no bath additives group of £51.37. The CRSI estimated costs of consultations, which did not include the intervention costs, were higher in the 'no bath additive' arm at 52 weeks (£126.83 compared to £98.45 in the 'bath additive' arm), although this difference was not significant.</p> <p>Apart from our concerns that this objection to prescribe emollient bath additives stems from an unjustified extrapolation of the BATHE study results, we should also point out that the study only involved <u>plain</u> bath emollients. Antimicrobial bath emollients</p>	<p>which included applying leave-on emollients and washing with emollients. The committee discussed that they had not seen any evidence where emollient bath additives were used instead of leave-on emollients, and therefore did not have the evidence to make a recommendation for this. The committee did agree that applying leave-on emollients and washing with emollients is important, and they did not want patients to think they could use emollient bath additives as an alternative to this. The committee thought that it was important to educate and communicate this to patients and incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap. This would also provide a way for patients and carers to get advice on alternative ways to bathe with emollients (such as diluting leave-on emollients in hot water and adding them to bath water) if applying leave-on emollients is not acceptable to the patient, or if the clinician feels that this would benefit the patient.</p> <p>The committee acknowledged that it may be less convenient to dilute leave-on emollients in bath water than to use emollient bath additives. However, the committee also agreed that the evidence showed that emollient bath additives are not effective, meaning that on a population level there is</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>were excluded from the BATHE study. Antimicrobial bath emollients have additional benefits over plain emollients. For example, our licensed medicine Dermol 600 Bath Emollient, has been formulated to contain emollient oils plus an antiseptic, benzalkonium chloride, in an emulsion system specially designed to readily mix throughout the bath water. This evenly coats all submerged skin surfaces to reduce overgrowth of <i>Staphylococcus aureus</i> (<i>S. aureus</i>) in particular, which is known to exacerbate atopic eczema. This important antimicrobial action has also been shown to extend to antibiotic resistant strains of <i>S. aureus</i> such as meticillin-resistant <i>S. aureus</i> (MRSA) and fusidic-acid resistant <i>S. aureus</i> (FRSA.) mrsa_frsa.pdf (dermal.co.uk)</p> <p>Antiseptics are used to lower bacterial load Topical antibiotics and antiseptics Prescribing information Eczema - atopic CKS NICE and antimicrobial bath emollients can also assist in overcoming, or preventing, possible secondary infection.</p> <p>We strongly recommend that the “Do not offer” statement is revised to allow for both plain as well as antimicrobial bath emollients to continue to be prescribed for children with atopic eczema. There should be provision for prescribing bath emollients for young children with atopic eczema, and for those,</p>	<p>no clinical reason that children with atopic eczema should use them. The committee discussed that bathing in plain water may sting children with atopic eczema. However, the committee agreed that this can be alleviated by using emollient wash products in the bath. The committee agreed that it is important to communicate this to patients and incorporated this into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes.</p> <p>The committee understood that the study showed a £14 difference per individual. If this cost difference was applied to the wider eligible patient population, the cost savings to the NHS would be substantially higher. NICE only consider healthcare system costs, therefore family borne costs were not considered as these lie outside of health system costs. NICE methods require all health system costs to be considered, therefore the committee decided the GP NR data from the study was more appropriate for decision making than the CSRI data as it includes intervention costs. The committee agreed the cost savings seen in reduced consultation costs for those in the bath emollient arm would be offset by the additional intervention costs.</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				whom in the prescriber's opinion, would benefit from frequent bathing.	Antimicrobial bath emollients are outside the scope for this update, as they are covered in NICE's guideline on Secondary bacterial infection of eczema and other common skin conditions: antimicrobial prescribing [NG190] .
Dermal Laboratories Ltd	Guideline	005	023 – 028	<p>We disagree with the explanation in the first bullet point because it is an unjustified extrapolation from the results of the BATHE study to state that bath emollients do not help.</p> <p>The BATHE study was designed to find out if emollient bath additives offer any 'additional' benefit to standard treatment, which, in the study, comprised a comprehensive regime of applied emollients, soap substitutes and use of topical steroids if needed. The study was not designed to show the benefit of bath emollients in their own right. Because children in both treatment groups were encouraged to use leave-on emollients, soap substitutes and topical steroids, and so were likely to show clinical improvement, this made it difficult for the study to detect a significant 'additional' benefit (>3 POEM points) from also using emollient bath additives. For the "control" group on "standard" treatment without bath additive, their POEM scores improved from a baseline of 10.1 to a score of 8.4 after 16 weeks, i.e., an improvement of 1.7 points.</p>	<p>Thank you for your comment. The committee discussed that it is important for children to wash with emollients in the bath regardless of whether emollient bath additives are used, and that this is already recommended in 1.5.1.10. The committee discussed that washing with emollients in the bath would reflect current practice, and they agreed that it was valid for the intervention and control groups to continue to wash with emollients.</p> <p>The committee discussed that age was not prespecified as a subgroup in the review protocol for the NICE evidence review. The BATHE study cautioned against findings of the subgroup analyses as the study was not adequately powered to detect subgroup differences. The committee discussed the possibility that the findings were due to multiple testing as they could not explain why emollient bath additives would be more effective in under 5s unless this was linked to bathing frequency. Due to the uncertainty in this evidence, the committee decided not to make an exception based on age.</p>

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>For the group using bath emollient in addition to "standard" care, their POEM scores improved from a baseline of 9.5 to a score of 7.5 after 16 weeks, i.e., an improvement of 2 points.</p> <p>Bath emollients can be a helpful and beneficial option in certain cases, such as children under 5 years and in those who bathe more than 5 times a week. This is supported by the BATHE study results, where one of the sub-group analyses showed "a small effect of bath additives" among children aged less than 5 years (POEM score was 1.29 points higher in the 'no bath additives' group) and another sub-group analysis showed "a small clinically meaningful benefit" of emollient bath additives in those bathing more than 5 times a week (POEM score was 2.27 points higher in the 'no bath additives' group). The BATHE study therefore showed that young children bathing regularly benefit from bath emollients. This is an age group more frequently affected by atopic eczema and provides a convenient way for parents to apply an emollient when the child is bathing.</p> <p>It is also worth noting that, in the 'No bath additive' group at 16 weeks, there was a higher, although non-significant, increase in the use of soap substitutes and topical corticosteroids. Both of these interventions</p>	<p>The committee discussed the BATHE subgroup analysis of frequency of bathing and agreed that there is some evidence that emollient bath additives are effective in those who bathe 5 or more times a week. However, the evidence was judged to be of low quality according to GRADE, due to risk of bias and imprecision. The BATHE study report also cautioned the findings of the subgroup analysis as the study was not adequately powered to detect subgroup differences, and this is reflected in the judged imprecision, as the 95% CIs cross the line of minimally important difference. Because of this uncertainty in the evidence, the committee chose not to make an exception based on frequency of bathing. Subgroup analyses found that topical corticosteroid and soap substitute use did not impact the effectiveness of emollient bath additives. Although topical corticosteroid use was slightly higher in the control group, this is unlikely to have much of an impact if the difference is not significant.</p> <p>Antimicrobial bath emollients are outside the scope for this update, as they are covered in NICE's guideline on Secondary bacterial infection of eczema and other common skin conditions: antimicrobial prescribing [NG190].</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>could potentially improve the POEM scores, thereby differentially exaggerating the improvement seen in the 'No bath additive' group.</p> <p>Apart from our concerns that this objection to prescribe emollient bath additives stems from an unjustified extrapolation of the BATHE study results, we should also point out that the study only involved <u>plain</u> bath emollients. Antimicrobial bath emollients were excluded from the BATHE study. Antimicrobial bath emollients have additional benefits over plain emollients. For example, our licensed medicine, Dermol 600 Bath Emollient, has been formulated to contain emollient oils plus an antiseptic, benzalkonium chloride, in an emulsion system specially designed to readily mix throughout the bath water. This evenly coats all submerged skin surfaces to reduce overgrowth of <i>Staphylococcus aureus</i> (<i>S. aureus</i>) in particular, which is known to exacerbate atopic eczema. This important antimicrobial action has also been shown to extend to antibiotic resistant strains of <i>S. aureus</i> such as meticillin-resistant <i>S. aureus</i> (MRSA) and fusidic-acid resistant <i>S. aureus</i> (FRSA.) mrsa_frsa.pdf (dermal.co.uk) Antiseptics are used to lower bacterial load Topical antibiotics and antiseptics Prescribing information Eczema - atopic CKS NICE and antimicrobial bath</p>	<p>The committee discussed that bathing in plain water may sting children with atopic eczema. However, the committee agreed that this can be alleviated by using emollient wash products in the bath. The committee agreed that it is important to communicate this to patients and incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes.</p> <p>The committee agreed that certain products would be detrimental to children with eczema. The committee discussed how it is important to address this by educating children with atopic eczema and their carers not to use these products and to wash with leave-on emollients or emollient soap substitutes instead. Therefore, the committee incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes.</p> <p>The committee understood that the study showed a £14 difference per individual. If this cost difference was applied to the wider eligible patient population, the cost savings to the NHS would be substantially higher. NICE only considers NHS/PSS perspective</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>emollients can also assist in overcoming, or preventing, possible secondary infection.</p> <p>If emollient bath additives are not prescribed, this may encourage bathing in plain water, which can sting and dry the skin. Even worse, it may encourage erroneous use of foaming and perfumed bath additives instead, which will dry and irritate atopic skin resulting in flares/worsening of the condition and consequential consulting and prescribing costs. This will be an added risk if patients are advised to purchase bath additives for themselves. In the BATHE study, the estimated mean costs to the NHS at 52 weeks were £180.50 in the bath additive arm and £166.12 in the no bath additive arm. This is a difference of only £14 between the two intervention groups over 1 year. In addition, the costs borne by families showed a higher annual spend in the no bath additives group of £51.37. The CRSI-estimated costs of consultations, which did not include the intervention costs, were higher in the no bath additive arm at 52 weeks (£126.83 compared to £98.45 in the bath additive arm), although this difference was not significant.</p> <p>We strongly recommend that the “Do not offer” instruction is revised to allow for both plain as well as antimicrobial bath emollients</p>	<p>on costs, therefore family borne costs were not considered as these lie outside of NHS/PSS costs.</p> <p>The committee decided to remove this recommendation (1.5.1.12) following stakeholder consultation. The committee agreed that it was important that children with eczema receive appropriate information around using emollients for washing and bathing to ensure that they continue to apply leave-on emollients and wash with emollient products. The committee therefore decided to incorporate into the recommendations that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes to ensure that they do receive accurate information and advice that is tailored to the individual and their family. This would allow clinicians to provide solutions for patients who may benefit from having emollient added to the bath water.</p> <p>The evidence review reported that there was no significant difference between the bath emollients and no bath emollients groups for the adverse event of refusal to bathe. The adverse event of redness was worse in the no bath additives group, however, the evidence for this outcome was judged as low quality according to GRADE (see appendix F in the evidence review), which</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>to continue to be prescribed for children with atopic eczema. There should be provision for prescribing bath emollients for young children with atopic eczema, and for those, whom in the prescriber's opinion, would benefit from frequent bathing.</p> <p>We are concerned by the recommendation in the second bullet point, "<i>however, they [bath additives] do not make eczema worse, and they can be bought over the counter if the child and their parents or carers want to use them. [2023]</i>". For the reasons explained above, we are firmly of the opinion that emollient bath additives can, and do, help – particularly for infants and young children. Indeed, the BATHE study authors acknowledged that they don't make eczema worse but can help with some symptoms e.g. redness and refusal to bathe which were lower in the 'bath additive' group, and that this continued at 52 weeks.</p> <p>It is not an acceptable alternative to advise that anyone wanting to use emollient bath additives should be recommended to buy them over the counter. Atopic eczema is a chronic condition, most commonly affecting infants and young children who are the particular subgroup for whom emollient bath additives can be beneficial. This may be unaffordable for many parents on lower incomes, particularly as children have free</p>	<p>reduced the committee's certainty in the result. The committee also considered this outcome in the context of all the outcomes reported in the evidence review, which overall showed that emollient bath additives are not effective in reducing eczema severity when used in addition to usual care.</p> <p>The committee considered the current financial climate, and that many families would find it difficult to pay for emollient bath additives over the counter. However, the committee agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care, which included applying leave-on emollients and washing with emollients. The committee discussed that they had not seen any evidence where emollient bath additives were used instead of leave-on emollients, and therefore did not have the evidence to make a recommendation for this. The committee did agree that applying leave-on emollients and washing with emollients is important, and they did not want patients to think they could use emollient bath additives as an alternative to this. The committee thought that it was important to educate and communicate this to patients and incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes.</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>prescriptions. In addition, it runs the risk of parents purchasing cosmetic bath additives that may make the condition worse.</p> <p>In the current financial climate, patients/parents/carers are struggling to pay prescription charges and may consider over the counter (OTC) medicines unaffordable. OTC presentations can be double the NHS cost owing to VAT and a pharmacy mark-up. These financial obstacles are increasingly evident even in the prescription sector, as evidenced by a survey of 269 pharmacists by the Royal Pharmaceutical Society (RPS) towards the end of 2022. This showed that an increasing number of patients are contemplating discontinuing some treatments because they cannot afford to pay the prescription charge. <i>The Pharmaceutical Journal</i>, PJ, February 2023, Vol 310, No 7970;310(7970)::DOI:10.1211/PJ.2023.1.174841 Half of pharmacists report increase in patients unable to afford prescription medicines, reveals survey - The Pharmaceutical Journal (pharmaceutical-journal.com)</p>	<p>This would also provide a way for patients and carers to get advice on alternative ways to bathe with emollients (such as diluting leave-on emollients in hot water and adding them to bath water) if applying leave-on emollients is not acceptable to the patient, or if the clinician feels that this would benefit the patient.</p> <p>Although the committee understood there may be individuals who feel they benefit from the intervention, they based their decision on the results of the BATHE study which demonstrated a lack of clinical and cost effectiveness at a population level. NICE bases its recommendations on an assessment of population benefits and value for money (NICE charter, Principle 7). Therefore, based on NICE methods, the committee concluded that funding bath emollients are unlikely to be a good use of NHS resources.</p>
Dermal Laboratories Ltd	Guideline	006	014 – 022	<p>The committee recognises that “there may be specific subgroups of children who may benefit from emollient bath additives.” (lines 15-16). Specific subgroups of children may indeed benefit from using emollient bath additives, such as, children under 5 years</p>	<p>Thank you for your comment. The committee discussed that age was not prespecified as a subgroup in the review protocol for the NICE evidence review. The BATHE study cautioned against findings of the subgroup analyses as the study was not</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>and in those who bathe more than 5 times a week. This is evidenced, in the BATHE study, by the higher POEM improvement scores for these subgroups in the 'no bath additives' group. This acknowledgement is notable because the BATHE study was designed only to measure the <u>added</u> benefit of bath emollients and overlooked the wider therapeutic advantages of bath emollients in their own right. The committee also acknowledges that some children may enjoy using bath additives generally. The importance of this should not be underestimated either, because treatment adherence is often the biggest obstacle to successful emollient treatment. For patients who enjoy routine bathing, this can therefore be a very useful, and effective, means of administering an emollient to all submerged skin surfaces.</p> <p>Atopic eczema is a chronic condition most prevalent in young children. We therefore cannot understand why the draft guideline proposes to deny prescription access to this special subgroup – whom the committee acknowledges may benefit from using bath emollients. If 'informed decision making' for individual patients concludes that a bath emollient may be beneficial, then it should be made available on a free prescription. Instead, to steer such patients towards over the counter (OTC) purchasing is</p>	<p>adequately powered to detect subgroup differences. The committee discussed the possibility that the findings were due to multiple testing as they could not explain why emollient bath additives would be more effective in under 5s unless this was linked to bathing frequency. Due to the uncertainty in this evidence, the committee decided not to make an exception based on age.</p> <p>The committee discussed the BATHE subgroup analysis of frequency of bathing and agreed that there is some evidence that emollient bath additives are effective in those who bathe 5 or more times a week. However, the evidence was judged to be of low quality according to GRADE, due to risk of bias and imprecision. The BATHE study report also cautioned the findings of the subgroup analysis as the study was not adequately powered to detect subgroup differences, and this is reflected in the judged imprecision, as the 95% CIs cross the line of minimally important difference. Because of this uncertainty in the evidence, the committee chose not to make an exception based on frequency of bathing.</p> <p>The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap substitutes is well established, and that it is important that children with atopic eczema</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>inappropriate and leads to inequality. Quite apart from the question of affordability, this will either result in plain water baths which can sting and dry out the skin or introduces the added risk of an inappropriate cosmetic bath additive being used instead and worsening the condition. Furthermore, in current circumstances, where GP appointments can be so scarce, it is unlikely that children or their parents or carers will have the opportunity for the possible benefits of bath emollients being explained to them by a healthcare professional. Over time, this important and well-established role that bath emollients can play will be entirely neglected.</p> <p>Some patients are already having to 'ration' the numbers of prescriptions that they can afford to pay for, as evidenced by a recent survey performed by the RPS, The Pharmaceutical Journal, PJ, February 2023, Vol 310, No 7970;310(7970)::DOI:10.1211/PJ.2023.1.174841 Half of pharmacists report increase in patients unable to afford prescription medicines, reveals survey The Pharmaceutical Journal (pharmaceutical-journal.com). It is also worth noting that some OTC medicines can cost double their NHS counterparts, owing to VAT and pharmacy mark up. The notion that parents and carers, will first be given the opportunity</p>	<p>and their carers do not think that bath emollients can be used instead of applying leave-on emollients and using soap substitutes. The committee discussed that the BATHE trial gave important information on whether emollient bath additives would be of additional benefit to usual care.</p> <p>The committee acknowledged that it may be less convenient to dilute leave-on emollients in bath water than to use emollient bath additives. However, the committee also agreed that the evidence showed that emollient bath additives are not effective, meaning that on a population level there is no clinical reason that children with atopic eczema should use them.</p> <p>The committee agreed that it is important for children with atopic eczema and their parents to receive advice on bathing and showering and drafted a recommendation around offering personalised advice that is tailored to the needs of the child.</p> <p>The committee considered the current financial climate, and that many families would find it difficult to pay for emollient bath additives over the counter. However, the committee agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care, which included applying leave-on emollients</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				to make 'an informed decision', and will then proceed to buy a bath emollient for themselves, is therefore unrealistic.	and washing with emollients. The committee discussed that they had not seen any evidence where emollient bath additives were used instead of leave-on emollients, and therefore did not have the evidence to make a recommendation for this. The committee did agree that applying leave-on emollients and washing with emollients is important, and they did not want patients to think they could use emollient bath additives as an alternative to this. The committee thought that it was important to educate and communicate this to patients and incorporated into recommendation 1.5.1.12 that patients and carers should be offered personalised advice on washing with emollients and emollient soap. This would also provide a way for patients and carers to get advice on alternative ways to bathe with emollients (such as diluting leave-on emollients in hot water and adding them to bath water) if applying leave-on emollients is not acceptable to the patient, or if the clinician feels that this would benefit the patient.
Dermal Laboratories Ltd	Guideline	007	001 – 008	The absence of supporting evidence in this special group does not mean that emollient bath additives are not effective. If the committee accepts that some children with sensory processing disorders are unable to tolerate leave-on emollients, then application via their bath water is likely to be the most effective option. To deny such patients	Thank you for your comment. The committee were aware that some children with sensory processing disorders may be unable to tolerate having leave-on emollients applied to their skin. However, they also discussed that no evidence was identified around the effectiveness of emollient bath additives in this population, or

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>access to prescription bath emollients is therefore inappropriate and leads to inequality. Furthermore, the recommendation that leave on emollients are already an alternative option because they can be diluted in hot water and added to bath water, is impractical, and in most cases the oily phase of the emollient will not readily disperse throughout the body of the bath water. This leads to clumping, surface oil slicks and compromises effective coverage of all submerged skin surfaces. The risk of slippery bath surfaces also increases, and the whole bathing experience is unlikely to remain an enjoyable one. Emollient bath additives have been specially formulated, so they easily, and effectively disperse throughout the entire volume of the bath water. This is true even in tepid water, as patients with these skin conditions are advised to avoid bathing in hot water.</p> <p>Another important concern is that, in addition to an emollient action, some bath emollients have the added benefit of containing antiseptic ingredients. For example, our licensed medicine, Dermal 600 Bath Emollient, has been formulated to contain emollient oils plus an antiseptic, benzalkonium chloride, in an emulsion system specially designed to readily mix throughout the bath water. This evenly coats all submerged skin surfaces to reduce</p>	<p>when emollient bath additives were used in the absence of leave-on emollients. The committee discussed that there are other ways that children who are unable to tolerate leave-on emollients may benefit from emollients, such as washing with them (recommendation 1.5.1.10). The committee also discussed that it is possible to dilute leave-on emollients and add them to bath water. The committee agreed on the importance of understanding the needs of individual children with atopic eczema and their families, and for clinicians to provide personalised advice to patients and their carers based on this. Therefore, they decided to incorporate into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. The committee highlighted that this would be particularly relevant for children with sensory processing disorders.</p> <p>The committee noted that diluting leave-on emollients in the bath may cause bath surfaces to become slippery, however, emollient bath additives can also cause the bath surfaces to become slippery. This issue could be discussed with patients and their carers as part of the personalised bathing advice recommended in 1.5.1.10 to help them make an informed decision about whether they would like to dilute leave-on</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>overgrowth of <i>Staphylococcus aureus</i> (<i>S. aureus</i>) in particular, which is known to exacerbate atopic eczema. This important antimicrobial action has also been shown to extend to antibiotic resistant strains of <i>S. aureus</i> such as meticillin-resistant <i>S. aureus</i> (MRSA) and fusidic-acid resistant <i>S. aureus</i> (FRSA.) mrsa frsa.pdf (dermal.co.uk)</p> <p>Antiseptics are used to lower bacterial load Topical antibiotics and antiseptics Prescribing information Eczema - atopic CKS NICE and antimicrobial bath emollients can also assist in overcoming, or preventing, possible secondary infection.</p> <p>Using emollient bath additives, and antiseptic emollient bath additives, is a convenient and effective way of applying emollient, and antiseptic, to the whole body. This is a particularly useful option in the case of infants, young children and those with sensory processing disorders, where it can form an appealing part of 'fun time' routine bathing. If emollient bath additives are not prescribed, this may encourage bathing in plain water, which can sting and dry the skin. Even worse, it may encourage erroneous use of foaming and perfumed bath additives instead, which will dry and irritate atopic skin resulting in flares/worsening of the condition and consequential consulting and prescribing costs. This will be an added risk if patients</p>	<p>emollients in the bath in addition to standard care.</p> <p>The committee acknowledged that it may be less convenient to dilute leave-on emollients in bath water than to use emollient bath additives. However, the committee also agreed that the evidence showed that emollient bath additives are not effective, meaning that on a population level there is no clinical reason that children with atopic eczema should use them.</p> <p>Antimicrobial bath emollients are outside the scope for this update, as they are covered in NICE's guideline on Secondary bacterial infection of eczema and other common skin conditions: antimicrobial prescribing [NG190].</p> <p>The committee discussed that bathing in plain water may sting children with atopic eczema. However, the committee agreed that this can be alleviated by using emollient wash products in the bath. The committee agreed that it is important to communicate this to patients and incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes.</p> <p>The committee agreed that certain products would be detrimental to children with eczema. The committee discussed how it is important to address this by educating</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				are advised to purchase bath additives for themselves.	children with atopic eczema and their carers not to use these products and to wash with leave-on emollients or emollient soap substitutes instead. Therefore, the committee incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes.
Dermal Laboratories Ltd	Question	1		<p>1. Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives).</p> <p>The committee agreed that it would be difficult to stop prescribing bath emollients for patients who find emollients beneficial. We strongly recommend that the “Do not offer” instruction is revised to allow for both plain as well as antimicrobial bath emollients to continue to be prescribed for children with atopic eczema. There should be provision for prescribing bath emollients for young children with atopic eczema, and for those, whom in the prescriber’s opinion, would benefit from frequent bathing.</p> <p>The BATHE study was designed to find out if bath emollients offer any ‘additional’</p>	<p>Thank you for your comment. The committee discussed that age was not prespecified as a subgroup in the review protocol for the NICE evidence review. The BATHE study cautioned against findings of the subgroup analyses as the study was not adequately powered to detect subgroup differences. The committee discussed the possibility that the findings were due to multiple testing as they could not explain why emollient bath additives would be more effective in under 5s unless this was linked to bathing frequency. Due to the uncertainty in this evidence, the committee decided not to make an exception based on age.</p> <p>The committee discussed the BATHE subgroup analysis of frequency of bathing and agreed that there is some evidence that emollient bath additives are effective in those who bathe 5 or more times a week. However, the evidence was judged to be of low quality according to GRADE, due to risk of bias and imprecision. The BATHE study</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>benefit to standard treatment, which, in the study, comprised a comprehensive regime of applied emollients, soap substitutes and use of topical steroids if needed. The BATHE study did not show that emollient bath additives did not work and was not designed to show the benefit of bath emollients in their own right. Bath emollients can be a beneficial and helpful option in certain patients, for example, young children, those who bath frequently and those with sensory disorders. Therapeutic bath emollients should continue to be available on prescription, especially for young children (who have no ability to purchase the treatments for themselves) and who receive free prescriptions. Restricting access to relatively inexpensive treatments on the NHS, but costly to patients (who have free prescriptions) if they must purchase them over the counter, could be considered discriminatory to young children and those families on lower incomes. It also increases the likelihood of inappropriate cosmetic bath additives being used instead. Children, with a long-term condition such as atopic eczema, should have access to treatments they find beneficial on prescription.</p> <p>The instruction "Do not offer ..." removes clinical discretion of the prescriber in accordance with their professional duties,</p>	<p>report also cautioned the findings of the subgroup analysis as the study was not adequately powered to detect subgroup differences, and this is reflected in the judged imprecision, as the 95% CIs cross the line of minimally important difference. Because of this uncertainty in the evidence, the committee chose not to make an exception based on frequency of bathing.</p> <p>The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap substitutes is well established, and that it is important that children with atopic eczema and their carers do not think that bath emollients can be used instead of applying leave-on emollients and using soap substitutes. The committee discussed that the BATHE trial gave important information on whether emollient bath additives would be of additional benefit to usual care.</p> <p>NICE guidance allows clinicians to apply clinical judgment where appropriate for the patient and their family and carers. The document that went for consultation only included information specific to the update, however, at publication, the updated recommendations will be in the Atopic eczema in under 12s: diagnosis and management guideline, which contains the following statement: "The recommendations</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>when faced with a patient who in their opinion is currently benefiting or would likely benefit from the use of a bath emollient. Asking a healthcare professional to explain to a patient/parent that emollient bath additives do not work and will not be prescribed, when in fact they find them beneficial, causes an ethical dilemma and could compromise the patient-healthcare professional relationship.</p> <p>Furthermore, in current circumstances, where GP appointments can be so scarce, it is unlikely that children or their parents or carers will ever have the opportunity for the possible benefits of bath emollients being explained to them by a healthcare professional. Over time, this important and well-established role that bath emollients can play will be entirely neglected.</p>	<p>in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers.”</p> <p>The committee also incorporated into the guidance that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes so that clinicians could advise and educate on how emollients can be added to bath water if this is appropriate for the patient and their family.</p>
Dermal Laboratories Ltd	Questions	2		<p>2. Would implementation of any of the draft recommendations have significant cost implications?</p> <p>The recommendation to “not offer” emollient bath additives to children with atopic eczema was based on the BATHE study results. In the study, the estimated mean costs to the NHS at 52 weeks were £180.50 in the bath additive arm and £166.12 in the</p>	<p>Thank you for your comment. The committee understood that the study showed a £14 difference per individual. If this cost difference was applied to the wider eligible patient population, the cost savings to the NHS would be substantially higher. NICE only consider healthcare system costs, therefore family borne costs were not considered as these lie outside of health system costs.</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>no bath additive arm. This is a difference of just £14 between the two intervention groups over 1 year, which is a minimal potential saving. It is also worth noting that, in the 'No bath additive' group at 16 weeks, there was a higher, although non-significant, increase in the use of soap substitutes and topical corticosteroids. Therefore, hidden additional costs are likely due to the need for additional treatments. In addition, the costs borne by families showed a higher annual spend in the no bath additives group of £51.37, resulting on an additional financial burden for the families.</p> <p>If emollient bath additives are no longer used/recommended, as they are not prescribed or purchased, there is a risk it may encourage either bathing in plain water which can sting and dry the skin or erroneous use of foaming and perfumed bath additives instead, which will dry and irritate atopic skin resulting in flares/worsening of the condition and consequential consulting and prescribing costs. This will be an added risk if patients are advised to purchase bath additives for themselves. This could result in extra appointments with a healthcare professional and further prescriptions, all of which would be more costly than a prescription for a bath emollient.</p>	<p>The committee agreed that certain products would be detrimental to children with eczema. The committee discussed how it is important to address this by educating children with atopic eczema and their carers not to use these products and to wash with leave-on emollients or emollient soap substitutes instead. Therefore, the committee incorporated into recommendation 1.5.1.102 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes.</p> <p>The committee discussed that bathing in plain water may sting children with atopic eczema. However, the committee agreed that this can be alleviated by using emollient wash products in the bath. The committee agreed that it is important to communicate this to patients and incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes.</p> <p>As per NICE methods all health system costs are required to be considered, therefore GP NR data from the study is more appropriate for decision making than the CSRI data as it includes intervention costs. The committee agreed the cost</p>

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>In the BATHE study estimated costs of consultations (CRSI data), which did not include the intervention costs, were higher in the 'no bath additive' arm at 52 weeks (£126.83 compared to £98.45 in the 'bath additive' arm) although this difference was not significant. From this, the committee considered that bath additives may reduce the number of consultations required over 52 weeks. Reducing the number of healthcare professional consultations is of benefit, as shown in the 'no bath additive' group in the BATHE study, particularly when there is a national shortage of GPs and limited number of appointments. If this reduction in consultation costs is extrapolated across the population the cost savings could be significant.</p> <p>We disagree that the recommendation to purchase emollient bath additives over the counter is an appropriate alternative to them being prescribed, from an inequality point of view, for those families who cannot afford to purchase them. In the current financial climate, patients/parents/carers are struggling to pay prescription charges and may consider over the counter (OTC) medicines unaffordable. OTC presentations can be double the NHS cost owing to VAT and a pharmacy mark-up. This guideline is for children with a long-term condition, who do not pay for their prescriptions and</p>	<p>savings seen in reduced consultation costs for those in the bath emollient arm would be offset but the additional intervention costs. The committee were aware that there were some small, non-significant differences in primary care consultation costs at 52 weeks estimated by the GP NR but considered that these were offset by the significant differences in intervention costs.</p> <p>The committee considered the current financial climate, and that many families would find it difficult to pay for emollient bath additives over the counter. However, the committee agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care, which included applying leave-on emollients and washing with emollients. The committee discussed that they had not seen any evidence where emollient bath additives were used instead of leave-on emollients, and therefore did not have the evidence to make a recommendation for this. The committee did agree that applying leave-on emollients and washing with emollients is important, and they did not want patients to think they could use emollient bath additives as an alternative to this. The committee thought that it was important to educate and communicate this to patients and incorporated into recommendation 1.5.1.10 that patients and carers should be offered</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				parents may not be able to afford to purchase the bath emollients. This is a potential inequality affecting children and families on lower incomes.	personalised advice on washing with emollients and emollient soap substitutes. This would also provide a way for patients and carers to get advice on alternative ways to bathe with emollients (such as diluting leave-on emollients in hot water and adding them to bath water) if applying leave-on emollients is not acceptable to the patient, or if the clinician feels that this would benefit the patient.
Eczema Outreach Support	EHIA	002	4.1	4.1 1) b. <i>Disability</i> - More research is required to understand if children with sensory processing disorders can tolerate leave-on emollients diluted in the bath. Within our membership, a small number of children in this group exclusively use bath additives and do not use diluted leave-on emollients however, we do not know whether this is because they are not tolerated by the child or because the parent/carer does not know that they can use leave-on emollients for bathing.	Thank you for your comment. The committee were unable to make a research recommendation around the use of emollients in children with sensory processing disorders as the review focused only on emollient bath additives. The committee did consider the drafting a research recommendation on the use of emollient bath additives in children with sensory processing disorders. However, they noted that sensory processing disorders are complex. They discussed that not all children with sensory processing disorders are unable to tolerate leave-on emollients, and some children have additional needs that need to be considered. This underlines the importance of personalising treatment to the individual patient and their carer. To address this, the committee decided to incorporate into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					emollient soap substitutes. The committee agreed that it is important to make children with atopic eczema and their carers aware of the different ways that emollients can be used for washing and bathing, including the possibility of diluting some leave-on emollients in bath water. This has also been addressed in the rationale and impact section, which highlights that leave-on emollients can be diluted in hot water and added to bath water.
Eczema Outreach Support	EHIA	003	4.1	4.1 2) <i>Socioeconomic status and deprivation</i> - Many of our members are not aware that leave-on emollients can be diluted and used for bathing. For children living in deprivation, it will be essential that they are told they can use leave-on emollients as a suitable alternative to buying bath additives over the counter which are unaffordable for some, particularly during the current cost-of-living crisis.	Thank you for your comment. The committee agreed that it is important to make children with atopic eczema and their carers aware of the different ways that emollients can be used for washing and bathing, including the possibility of diluting some leave-on emollients in bath water. To address this, the committee incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. This has also been addressed in the rationale and impact section, which highlights that leave-on emollients can be diluted in hot water and added to bath water.
Eczema Outreach Support	Evidence Review	023	022 – 026	The experience of our membership on whether bath additives are a burden or not is mixed. For some families, including bath additives in a treatment regime is an added burden and worry if they cannot access an additive	Thank you for your comment. The committee agreed that it is important to make children with atopic eczema and their carers aware of the different ways that emollients can be used for washing and bathing, including the possibility of diluting

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				that is the same brand as the child's preferred emollient. However, some families find using a bath additive can reduce parental/carer anxiety at times when a child is refusing to use other treatments. The ease of being able to add an additive to the bath and not needing to administer it directly onto a child's skin is a significant benefit. In these cases, it will be important that children & their families understand they whilst they can dilute their leave-on emollients as an alternative to using specific bath additives.	some leave-on emollients in bath water. To address this, the committee incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. This has also been addressed in the rationale and impact section, which highlights that leave-on emollients can be diluted in hot water and added to bath water.
Eczema Outreach Support	Evidence Review	024	001 – 003	Further research into effective treatments for children with atopic eczema & sensory processing disorders is required. We have a small number of member children with sensory processing disorders who exclusively use a bath additive, which the research would suggest is an individual preference. However, some parent/carers & young people argue that they cannot tolerate any other treatment other than a bath additive and without them, their eczema would be left completely untreated. This consequently has a negative impact on the mental health of some parents/carers who feel hopelessness and despair at not being able to do anything to treat their child's eczema.	Thank you for your comment. The committee were unable to make a research recommendation around the use of emollients in children with sensory processing disorders as the review focused only on emollient bath additives. The committee did consider the drafting a research recommendation on the use of emollient bath additives in children with sensory processing disorders. However, they noted that sensory processing disorders are complex. They discussed that not all children with sensory processing disorders are unable to tolerate leave-on emollients, and some children have additional needs that need to be considered. This underlines the importance of personalising treatment to the individual patient and their carer. To address this, the committee decided to incorporate into recommendation 1.5.1.10 that patients and

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					<p>carers should be offered personalised advice on washing with emollients and emollient soap substitutes. The committee agreed that it is important to make children with atopic eczema and their carers aware of the different ways that emollients can be used for washing and bathing, including the possibility of diluting some leave-on emollients in bath water.</p> <p>NICE guidance allows clinicians to apply clinical judgement where appropriate for the patient and their family and carers. The document that went for consultation only included information specific to the update, however, at publication, the updated recommendations will be in the Atopic eczema in under 12s: diagnosis and management guideline, which contains the following statement: "The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers."</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Eczema Outreach Support	Guideline	General	General	Amongst our membership, soap substitutes are viewed as an essential part of eczema treatment and must remain on prescription.	Thank you for your comment. Recommendation 1.5.1.10 states that clinicians should explain to patients and carers to use leave-on emollients or emollient soap substitutes.
Eczema Outreach Support	Guideline	005	021	Rec 1.5.1.11- It may also be useful here to include a note that this includes children with sensory processing disorders to ensure complete clarity that this group is included in the "do not offer".	Thank you for your comment. Further clarification that children with sensory processing disorders are included in the 'do not offer' recommendation is provided in the rationale and impact section.
Eczema Outreach Support	Guideline	005	023 – 028	<p>Rec 1.5.1.12- Children currently accessing bath additives on prescription & their parents/carers will need consistent messages from clinicians about why the additives are no longer on prescription to support acceptance of their withdrawal. Signposting to a lay summary of the results of the BATHE Trial may also be helpful for families.</p> <p>In our experience, many families do not know they can dilute leave-on emollients in hot water until they speak to our team, so it must not be assumed that patients and their parents/carers will know that an alternative to bath additives is already available. This must be addressed.</p>	<p>Thank you for your comment. The main findings of the BATHE trial have been summarised in the rationale and impact section of the guideline, which provides patients and families for some context around why the recommendations were made.</p> <p>The committee agreed that it is important to make children with atopic eczema and their carers aware of the different ways that emollients can be used for washing and bathing, including the possibility of diluting some leave-on emollients in bath water. To address this, the committee decided to incorporate into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap. This has also been addressed in the rationale and impact section, which highlights that leave-on emollients can be diluted in hot water and added to bath water.</p>

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Eczema Outreach Support	Question	1		Would it be challenging to implement of any of the draft recommendations? In order to implement the draft recommendations effectively to children with atopic eczema & their parents/carers, consistent and clear messages on the rationale for withdrawing bath additives from prescription is essential. These messages must be consistent in the relevant literature and in the messages given by healthcare professionals.	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. The rationale for why emollient bath additives should no longer be offered has been stated in the rationale and impact section of the guideline and in the committee discussion section of the evidence review. This should provide clinicians with the rationale to inform patients and their carers.
Eczema Outreach Support	Question	2		Would implementation of any of the draft recommendations have significant cost implications? The option of using leave-on emollients diluted in the bath must be provided to all children and their parents/carers to avoid the unnecessary financial burden of purchasing bath additives over the counter. This is particularly important for families living in poverty and deprivation who may forego other essentials so they can buy bath additives, if they have been the only treatment their child has tolerated so far.	Thank you for your comment. The committee agreed that it is important to make children with atopic eczema and their carers aware of the different ways that emollients can be used for washing and bathing, including the possibility of diluting some leave-on emollients in bath water. To address this, the committee incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. This has also been addressed in the rationale and impact section, which highlights that leave-on emollients can be diluted in hot water and added to bath water.
National Eczema Society	EHIA	002	b. disability	We question whether the committee has taken sufficient consideration of the needs of children with sensory perception disorders, and is making recommendations based on the assumption that leave-on emollients used as a soap substitute are equivalent to	Thank you for your comment. The committee were aware that some children with sensory processing disorders may be unable to tolerate having leave-on emollients applied to their skin. However, they also discussed that no evidence was

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>bath emollients, in terms of efficacy and acceptability, as explained elsewhere in these comments.</p>	<p>identified around the effectiveness of emollient bath additives in this population, or when emollient bath additives were used in the absence of leave-on emollients. The committee discussed that there are other ways that children who are unable to tolerate leave-on emollients may benefit from emollients, such as washing with them (recommendation 1.5.1.10). The committee also discussed that it is possible to dilute leave-on emollients and add them to bath water. The committee agreed on the importance of understanding the needs of individual children with atopic eczema and their families, and for clinicians to provide personalised advice to patients and their carers based on this. Therefore, this was incorporated into recommendation 1.5.1.10. The committee highlighted that this would be particularly relevant for children with sensory processing disorders.</p> <p>The committee acknowledged that it may be less convenient to dilute leave-on emollients in bath water than to use emollient bath additives. However, as there was no evidence to suggest that emollient bath additives are effective in children with atopic eczema, the committee decided that it was more important to focus on understanding the needs of the patient and their family, and to tailor treatment to them (recommendation 1.5.1.10).</p>

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
National Eczema Society	EHIA	003	Section 2	We question whether the committee has taken appropriate account of the socioeconomic impact of these proposals, as explained elsewhere in these comments.	Thank you for your comment. The committee considered the current financial climate, and that many families would find it difficult to pay for emollient bath additives over the counter. However, the committee agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care, which included applying leave-on emollients and washing with emollients. The committee discussed that they had not seen any evidence where emollient bath additives were used instead of leave-on emollients, and therefore did not have the evidence to make a recommendation for this. The committee did agree that applying leave-on emollients and washing with emollients is important, and they did not want patients to think they could use emollient bath additives as an alternative to this. The committee thought that it was important to educate and communicate this to patients and incorporated this into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap. This would also provide a way for patients and carers to get advice on alternative ways to bathe with emollients (such as diluting leave-on emollients in hot water and adding them to bath water) if applying leave-on emollients is not acceptable to the patient, or if the

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					clinician feels that this would benefit the patient.
National Eczema Society	Evidence review	General	General	The NICE proposals rely almost entirely on the findings of just one research study, the BATHE (Emollient bath additives for the treatment of childhood eczema) trial. The White study, also cited, had only nine participants with four-week follow-up and is now nearly 30 years old. The evidence base in this area is very limited and as a result, there is a clear risk of over relying on the BATHE study findings. The quality of the BATHE trial evidence would be insufficient to justify the introduction of a new treatment, and it therefore seems perverse that it is seen as sufficiently robust to withdraw a treatment.	Thank you for your comment. The committee agreed that the evidence was limited in terms of the number of relevant studies. However, they considered that the BATHE trial was sufficiently rigorous to inform the update of the guideline. The BATHE trial found that there was moderate quality evidence (judged according to GRADE) that emollient bath additives do not improve eczema severity when used in addition to standard care.
National Eczema Society	Evidence review	General	General	We note that NICE has not sought to critically appraise the BATHE study design and review the findings in the light of the study's nuanced research question that does not sufficiently reflect real world practice. There is no robust evidence from clinical practice or patient experience to show that parents routinely use leave-on emollient as a soap substitute as well as bath emollient with their children for bathing. In this respect, it is a flawed research question.	Thank you for your comment. Evidence from the BATHE trial has undergone critical appraisal using GRADE in accordance with NICE's methods and processes . Risk of bias assessments were conducted using Cochrane RoB2, which found that there were concerns due to lack of blinding and use of subjective outcome measures. As well as risk of bias, the GRADE assessment also considered that the study was directly applicable to the PICO, and precision (whether the 95% CIs crossed the lines of minimally important difference). For the outcomes of eczema severity, the overall certainty in the evidence was moderate. Further information about the GRADE rating

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					<p>of other outcomes is provided in appendix F of the evidence review.</p> <p>The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap substitutes is well established, and that it is important that children with atopic eczema and their carers do not think that bath emollients can be used instead of applying leave-on emollients and using soap substitutes. The committee discussed that the BATHE trial gave important information on whether emollient bath additives would be of additional benefit to usual care.</p> <p>The committee discussed that it is important for children to wash with emollients in the bath regardless of whether emollient bath additives are used, and that this is already recommended in 1.5.1.10. The committee discussed that washing with emollients in the bath would reflect current practice, and they agreed that it was valid for the intervention and control groups to continue to wash with emollients.</p>
National Eczema Society	Evidence review	General	General	The BATHE study did not address the questions that would have been most insightful, such as 'what is the best soap substitute?' and 'are bath emollients more effective than leave-on emollients as soap substitutes?' Rather, the BATHE study focused on a nuanced research question that looked at the efficacy of bath emollients	<p>Thank you for your comment. The BATHE study was eligible for inclusion based on the population, intervention, comparator, and outcome described in the review protocol.</p> <p>The committee discussed that it is important for children to wash with emollients in the bath regardless of whether emollient bath additives are used, and that this is already</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>in a very specific set of theoretical circumstances, but these circumstances do not reflect real world patient experience or prescribing practice. It looked at outcomes when children used leave-on emollient during the day and leave-on emollient in the bath as a soap substitute, and bath emollient in the bath, compared to children who used only leave-on emollient and leave-on emollient in the bath as a soap substitute. Parents would typically use a bath emollient OR a leave-on emollient as a soap substitute when bathing their children, not both. The findings of the BATHE trial need to be critically appraised to take into account that the trial design does not sufficiently reflect real world practice.</p>	<p>recommended in 1.5.1.10. The committee discussed that washing with emollients in the bath would reflect current practice, and they agreed that it was valid for the intervention and control groups to continue to wash with emollients.</p> <p>The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap substitutes is well established, and that it is important that children with atopic eczema and their carers do not think that bath emollients can be used instead of applying leave-on emollients and using soap substitutes. The committee discussed that the BATHE trial gave important information on whether emollient bath additives would be of additional benefit to usual care. Evidence from the BATHE trial has undergone critical appraisal using GRADE in accordance with <u>NICE's methods and processes</u>.</p>
National Eczema Society	Evidence review	General	General	<p>The 'normal care' assumed in the BATHE trial included advice from healthcare professionals on how to use leave-on emollient, which is not routinely offered to parents, and is another example of how the BATHE trial did not sufficiently reflect real world practice.</p>	<p>Thank you for your comment. In the BATHE study, both intervention and comparator groups were given standardised written advice on how to wash. As both groups received this information, it would not have biased the results in favour of the control group. Recommendation 1.5.1.5 states that clinicians should explain to children with atopic eczema that they should use emollients on their whole body, both when their eczema is clear and when using other</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					treatments. Recommendation 1.5.1.6 states that clinicians should show children with atopic eczema and their parents or carers how to apply emollients, including how to smooth emollients onto the skin rather than rubbing them in. Therefore, patients and their carers should be receiving this information in practice.
National Eczema Society	Evidence review	General	General	For some parents, using bath emollient is more practical and more effective than using leave-on emollients in the bath with their children. Popping in a capful of bath emollient in the bath while the water is running is quicker, easier and more effective than trying to emulsify a leave-on emollient to serve the function of a bath emollient or using a leave-on emollient in the bath as a soap substitute. This can be important when busy parents have a number of children to care for and limited time. Caring for children with eczema can be exhausting and relentless for parents, as evidenced by the extensive literature on carer burden. Bath emollients are formulated to disperse evenly and well in bath water. This is not the case for leave-on emollients. As anyone knows who has tried to disperse leave-on emollient in water, it usually ends up with blobs of emollient in the bath water, rather than a uniform film that covers the child's skin more evenly and comfortably. This point is particularly relevant to children with sensory perception disorders, who can find it difficult	Thank you for your comment. The committee acknowledged that it may be less convenient to dilute leave-on emollients in bath water than to use emollient bath additives. However, the committee also noted that it is potentially inconvenient for patients and carers to have to acquire and use an additional product. The committee also agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care, meaning that on a population level there is no clinical reason that children with atopic eczema should use them.

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				to be touched or dislike the texture of leave-on emollients on their skin. Bath emollients can help restore the skin barrier without physical touch. The notion that using leave-on emollient as a soap substitute for washing children in the bath is equally or more effective than bath emollients with all children is not supported by the literature and is based on assumption.	
National Eczema Society	Evidence review	General	General	The BATHE study addresses likely population level impacts only and was not adequately powered to identify subgroup differences. As such, the BATHE study does not take into account sufficiently the heterogeneous nature of atopic dermatitis. It is a complex immune mediated disease and affects children differently. Treatments and treatment approaches that work for one child may not be effective for another. In particular, different or more intense treatments are often appropriate for children with more severe eczema. It is noted that the majority of participants in the BATHE study had mild or moderate eczema symptoms.	Thank you for your comment. The BATHE study had a good number of participants and reported that the sample size was sufficient to detect a mean difference in POEM score of 2.0 (SD 0.7) between the intervention and comparator group. Therefore, it appears that the study is adequate to determine the effectiveness of emollient bath additives, when used in addition to standard care, at a population level. This committee acknowledged that the number of participants with severe eczema was lower than the number with mild or moderate eczema. However, the committee agreed that the proportion of patients with severe eczema reflects real world prevalence. The committee also highlighted that the BATHE study performed a subgroup analysis of baseline eczema severity, and that it was reported that emollient bath additives are also not effective, when used in addition to standard care, in this population.

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
National Eczema Society	Evidence review	General	General	At National Eczema Society, we hear anecdotally from parents of children with eczema that they have been recommended and prescribed bath emollients for their children by their dermatologist, but these are not available on prescription in general practice. So dermatologists are either routinely wrong in their clinical knowledge and advice, or real world clinical experience would indicate that bath emollients can be clinically effective for children in some situations.	Thank you for your comment. The purpose of the evidence review is to collect, appraise, and synthesise the best available evidence from the literature to inform evidence-based recommendations. The aim of the update is to provide clarity to patients and practitioners around the use of emollient bath additives and to standardise treatment geographically.
National Eczema Society	Evidence review	General	General	The implicit inference that bath emollients are a 'nice to have' component of an effective skincare regimen for children with eczema is disingenuous. The committee acknowledges that some children will benefit clinically from bath emollients, but simply expects parents to pay for them. This is disrespectful and demeaning to many hard-pressed families who cannot afford to buy bath emollients and are already struggling to pay for food and energy amidst a cost of living crisis. The poorest families and the children with more severe eczema will be hit hardest by these proposals. It seems perverse that the NICE committee is choosing to penalise the poorest children and families in this way.	Thank you for your comment. The committee considered the current financial climate, and that many families would find it difficult to pay for emollient bath additives over the counter. However, the committee agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care, which included applying leave-on emollients and washing with emollients. The committee discussed that they had not seen any evidence where emollient bath additives were used instead of leave-on emollients, and therefore did not have the evidence to make a recommendation for this. The committee agreed that applying leave-on emollients and washing with emollients is important, and they did not want patients to think they could use emollient bath additives as an alternative to this. The committee thought that it was important to educate and

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					communicate this to patients and incorporated into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. This would also provide a way for patients and carers to get advice on alternative ways to bathe with emollients (such as diluting leave-on emollients in hot water and adding them to bath water) if applying leave-on emollients is not acceptable to the patient, or if the clinician feels that this would benefit the patient.
National Eczema Society	Evidence review	General	General	The BATHE study assumes that children and their parents have access to leave-on emollients on prescription, in sufficient quantities, that work effectively as a soap substitute. No evidence is provided that shows this is the case. The range of emollients available on prescription through local formularies is often very limited. Some products are more effective than others. Heavier types of emollients like ointments often do not work well as soap substitutes (explained elsewhere in the comments), unlike bath emollients that are formulated for this purpose.	Thank you for your comment. This will be considered by NICE where relevant support activity is being planned. The committee agreed that it is important that patients and their carers are educated about how different types of emollients can be used for washing and bathing. To address this, the committee recommended that patients and carers are offered personalised advice on using emollients and emollient soap substitutes for washing.
National Eczema Society	Evidence review	General	General	The NICE proposals will further limit healthcare professionals' ability to provide treatments that work for children with eczema. Patient confidence is already fragile. In the 2020 Eczema Unmasked survey of adults and parents of children with	Thank you for your comment. The committee considered that the BATHE trial was suitable in terms of rigour and applicability to inform this guideline update, and that moderate quality evidence (judged according to GRADE) from this trial showed

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>eczema, undertaken by National Eczema Society and LEO Pharma, 31% of parent respondents said they did not have confidence in the abilities of healthcare professionals to treat their child's eczema, and 40% of parent respondents said they felt their child has been let down by their healthcare professionals when it comes to their eczema. The Eczema Unmasked survey included 524 parents of children (aged 0-16) with eczema. Participants were screened using a proxy for EASI (Eczema Area and Severity Index) scores in order to ensure a representative range from the eczema population, including those with almost clear, mild, moderate, severe and very severe eczema. The Eczema Unmasked findings are reflected in the Global Patient Initiative to Improve Eczema Care, where UK respondents - both adults and parents of children - reported low or the lowest scores on the measures for long-term control of eczema symptoms, patient education and shared decision-making from among the eight participating countries.</p>	<p>that emollient bath additives do not improve eczema severity at a population level. NICE guidance allows clinicians to apply clinical judgement where appropriate for the patient and their family and carers. The document that went for consultation only included information specific to the update, however, at publication, the updated recommendations will be in the Atopic eczema in under 12s: diagnosis and management guideline, which contains the following statement: "The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers." The committee also added a recommendation around providing personalised advice around washing and bathing to children with atopic eczema and their carers so that clinicians could advise and educate on how emollients can be added to bath water if this is appropriate for the patient and their family.</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
National Eczema Society	Evidence review	General	General	The BATHE study was funded through the NIHR Health Technology Assessment (HTA) programme. A requirement for securing funding is that the intervention has the potential to save the NHS money. This bias needs to be considered when assessing the way the research question was constructed, the resulting findings and how these are being interpreted to influence policy and prescribing guidelines. Such critical consideration is important because the NICE proposals rely almost entirely on the BATHE study evidence.	Thank you for your comment. The NIHR HTA programme funds research that aims to establish the clinical and cost-effectiveness of an intervention for the NHS in comparison with the current best alternative (which in the treatment of eczema in under 12s would be application of leave-on emollients and washing with emollients or emollient soap substitutes). Although the studied interventions may be more or less expensive than the current best alternative, it is the cost-effectiveness of the intervention that is considered by NICE alongside the clinical effectiveness. The committee discussed that the BATHE trial gave important information on whether emollient bath additives would be of additional benefit to standard care, which involves the use of leave-on emollients and washing with emollients or emollient soap substitutes (also described in recommendations 1.5.1.4 and 1.5.1.10).
National Eczema Society	Evidence review	023	047 – 049	The committee acknowledges that the effectiveness of bath emollients is unclear when leave-on emollients are not used. This highlights the significant limitations of the BATHE study and assumptions underpinning the interpretation of the findings.	Thank you for your comment. The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap substitutes is well established, and that it is important that children with atopic eczema and their carers do not think that bath emollients can be used instead of applying leave-on emollients and using soap substitutes. Standard care that involves applying leave-on emollients and washing with either leave-on emollients

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					or emollient soap substitutes is also outlined in recommendations 1.5.1.4 and 1.5.1.10. The committee discussed that the BATHE trial gave important information on whether emollient bath additives would be of additional benefit to usual care.
National Eczema Society	Evidence review	024	009 – 013	We question the validity of relying on a multi-level regression model to estimate differences in costs and quality of life, as this does not provide the rigour and robustness of analytic models typically used in economic evaluation.	Thank you for your comment. The committee agreed the use of a multilevel regression model in the BATHE trial was acceptable as the BATHE study trial covers a short time period. Decision analytical models and multilevel models have no inherent differences in their rigour and robustness, with the appropriateness of each model dependant on different circumstances. The model was subject to applicable and limitation checklists, which found the study to be directly applicable with only minor limitations.
National Eczema Society	Evidence review	024	030 – 045	The cost analysis is based on an intervention that does not sufficiently reflect real world practice. The cost differential would have been considerably less and more meaningful if the BATHE study had investigated the efficacy of leave-on emollient as a soap substitute compared to bath emollients. We challenge the 'it's good enough' argument, when children with the highest need and from the poorest families will be affected most.	Thank you for your comment. The BATHE trial economic analysis was based on the interventions used in the BATHE trial; the study was found to have direct applicability and minor limitations. The committee expressed limited real-world practice of suggesting the use of regular emollients as a soap substitute. However, this can be done in replacement of bath emollients if patients wish to do so, which would not incur further costs.
National Eczema Society	Evidence review	024	030 – 045	The cost analysis relies heavily on numerous assumptions and estimates, and the committee is of the view that the	Thank you for your comment. The GP NR data source used to estimate resource use captured all eczema-related prescriptions; a

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				additional consulting costs in the no bath emollient arm were lower than the cost of the intervention. It was not clear whether costing assumptions took into account fewer prescriptions for leave-on emollient, as lower quantities would be needed if bath emollients were used instead of leave-on emollients as wash products. In general, children with poorly controlled eczema will go back to their GP more frequently, be prescribed more active treatments to manage eczema flare-ups and are more likely to be referred to secondary care. It is also noted the BATHE study participants were likely more motivated than typical children with eczema and their parents (being self-selecting volunteers for the trial), likely to be using leave-on emollients more effectively having had instruction as part of the trial, and likely had regular access to healthcare professionals as part of the trial, to support ongoing self-management. This does not reflect the real world experience of most children and their families and the data need to be assessed accordingly.	sentence has been added to the evidence review to make this clear. Whilst the study did find consultation costs were lower in the bath emollient arm, these savings are offset by the costs of the intervention.
National Eczema Society	Evidence review	023 – 024	049 and 001 – 003	While the committee may have discussed that it is possible to add leave-on emollients to the bath by diluting them in hot water, no evidence is offered to show this is effective for all leave-on emollients and/or provides comparable efficacy to bath emollients that are formulated specifically for this purpose.	Thank you for your comment. The committee acknowledged that it may be less convenient to dilute leave-on emollients in bath water than to use emollient bath additives. However, the committee also agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care,

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					meaning that on a population level there is no clinical reason that children with atopic eczema should use them.
National Eczema Society	Guideline	General	General	Children with atopic eczema (referred to hereafter as eczema) and their families will be disadvantaged and suffer as a result of these proposals and, on behalf of children affected by eczema and their families, we ask NICE to reconsider these proposals and continue to recommend the prescribing of bath emollients in clinical circumstances where it is appropriate to prescribe them.	Thank you for your comment. The committee considered the stakeholder feedback, and considered the evidence. The committee decided to recommend that emollient bath additives are not offered to children with atopic eczema and their carers. However, the committee have added that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. The committee agreed that the evidence showed that emollient bath additives are not effective when used in addition to standard care, which included applying leave-on emollients and washing with emollients. Although the committee acknowledged that there may be some patients who may benefit from using emollient bath additives, the committee felt that this could be addressed through personalised washing and bathing advice, where patients and their carers could be educated on alternative ways to use emollients for bathing, such as diluting leave-on emollients in hot water and adding them to the bath water.
National Eczema Society	Guideline	General	General	Following the earlier NHS England consultation and guidance on 'Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs', the Dermatology	Thank you for your comment. NICE guidance allows clinicians to apply clinical judgement where appropriate for the patient and their family and carers. The document that went for consultation only included

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>Council for England, British Association of Dermatologists and other stakeholders including National Eczema Society, sought clarification from NHS England & NHS Improvement. The Deputy Chief Pharmaceutical Officer at NHS England & NHS Improvement, Dr David Warner, in a letter to stakeholders dated December 2020 confirmed: "While there are no exceptions for prescribing bath and shower preparations on a routine or regular basis, there may be genuine clinical circumstances when it is appropriate to prescribe. These include where the prescribing clinician considers no other medicine or intervention to be clinically appropriate and available for the individual. The guidance does not inhibit the clinical discretion of the prescriber in accordance with their professional duties."</p>	<p>information specific to the update, however, at publication, the updated recommendations will be in the Atopic eczema in under 12s: diagnosis and management guideline, which contains the following statement: "The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers." The committee also added to the recommendations that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes so that clinicians could advise and educate on how emollients can be added to bath water if this is appropriate for the patient and their family.</p>
National Eczema Society	Guideline	General	General	<p>It is not clear if any parents of children with eczema were involved in the committee discussions, and it is also not clear how patient experience and views were taken into account in preparing the proposals, to reflect best practice in public and patient</p>	<p>Thank you for your comment. The committee included lay members, who have equal status with other members of the committee. Lay members are people using services, family members and carers, and members of the public and community or</p>

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				involvement. Seeking feedback at consultation stage does not feel like a genuine attempt to engage with patients, more a tokenistic box-ticking exercise at a point in the guideline setting process when it is considerably harder to influence the outcome. It is also noted that things that often matter most to patients, such as treatment adherence, patient satisfaction, and parent and carer satisfaction, were considered less important in the decision-making.	voluntary sector with relevant experience. Lay members champion the perspectives of people who use services, carers or the public as outlined in Developing NICE guidelines: the manual
National Eczema Society	Guideline	005	025	The statement 'emollient bath additives do not help with atopic eczema' is not universally true and is disingenuous. It is only valid in the context of the BATHE trial research question that does not reflect real world practice.	Thank you for your comment. The committee decided to remove this recommendation following stakeholder consultation. The committee agreed that it was important that children with eczema receive appropriate information around using emollients for washing and bathing to ensure that they continue to apply leave-on emollients and wash with emollient products. The committee therefore decided to incorporate into the recommendations that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes to ensure that they do receive accurate information and advice that is tailored to the individual and their family. This would allow clinicians to provide solutions for patients who may benefit from having emollient added to the bath water.

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
National Eczema Society	Guideline	005	022 – 025	The BATHE trial findings do not provide sufficient rationale, based on real world practice, for the proposal to stop recommending emollient bath additives for children with atopic eczema. On behalf of children affected by eczema and their families, we ask NICE to reconsider these proposals and continue to recommend the prescribing of bath emollients in clinical circumstances where it is appropriate to prescribe them, based on the rationale set out in these comments.	Thank you for your comment. The committee discussed that the effectiveness of applying leave-on emollients and washing with emollient soap substitutes is well established, and that it is important that children with atopic eczema and their carers do not think that bath emollients can be used instead of applying leave-on emollients and using soap substitutes. The committee discussed that the BATHE trial gave important information on whether emollient bath additives would be of additional benefit to usual care. The committee acknowledged that there may be some individuals who benefit from using emollient bath additives. However, the committee decided these patients could benefit from using emollients in alternative ways. The committee agreed that it is important to make children with atopic eczema and their carers aware of the different ways that emollients can be used for washing and bathing, including the possibility of diluting some leave-on emollients in bath water. To address this, the committee decided to incorporate into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. This has also been addressed in the rationale and impact section, which highlights that leave-on emollients can be diluted in hot water and added to bath water.

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Neonatal and Paediatric Pharmacy Group (NPPG)	Guideline	General	General	NPPG has no concerns regarding the proposed updates to the guideline.	Thank you for your comment
NHS England	Guideline	General	General	The advice to not prescribe bath additive but use emollients have be present for some time. This update should present no barriers or constraints to general practice and should not impact on patient care.	Thank you for your comment
North West Paediatric Allergy, Immunology and Infection Operational Delivery Network	Guideline	General	General	<p>As this is the first review of these NICE guidelines for 16 years, it is disappointing and disconcerting to see that the committee have only revised the recommendations for bath emollients/emollients, when the field has changed so much in the last decade – See Arkwright PD & Koplin JJ. Impact of a decade of research into atopic dermatitis. JACI Pract 2023;11:63-71. In this regard, this draft update is cursory and inadequate.</p> <p>We recommend that this draft requires a major revision, extending it to at least: (1) improving the readability of the 2007 guidelines by reducing the repetition within that document, (2) removing the promotion of pimecrolimus, which is no better and more expensive than 1% hydrocortisone, (3) not promoting the use of nonsedating antihistamines for eczema where there is no evidence, and (4) not promoting the use of phototherapy for eczema as this has been superseded by biologics.</p>	Thank you for your comment. The scope of this guideline update was to review recommendations on emollient bath additives, and therefore this is outside the remit of this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
North West Paediatric Allergy, Immunology and	Guideline	005	009 - 011	1.5.1.8 - Not all emollients are the same – some are known to disrupt skin barrier	Thank you for your comment. The scope of this guideline update was to review

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Infection Operational Delivery Network				function, as highlighted in a recent review, co-authored by one member of your review committee. See Van den Bogaard EH et al. Targeting skin barrier function in atopic dermatitis. JACI Pract Published online Feb 2023:17. This should be detailed in this section, with recommendations of which moisturisers HCPs should avoid and which are recommended.	recommendations on emollient bath additives, and therefore this is outside the remit of this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
North West Paediatric Allergy, Immunology and Infection Operational Delivery Network	Original guideline (2007)	General	General	This document is verbose and repetitive and could be significantly shortened. In this regard, the 2007 guidelines needs an overall revamp to improve readability.	Thank you for your comment. The scope of this guideline update was to review recommendations on emollient bath additives, and therefore this is outside the remit of this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
North West Paediatric Allergy, Immunology and Infection Operational Delivery Network	Original guideline (2007)	Tables		Stepped treatment options AND Table 2 Stepped treatment options - This is an example of duplication of information. Suggest removing "bandages" and "phototherapy" from this table. Phototherapy has been replaced by biologics particularly in children.	Thank you for your comment. The scope of this guideline update was to review recommendations on emollient bath additives, and therefore this is outside the remit of this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
North West Paediatric Allergy, Immunology and Infection Operational Delivery Network	Original guideline (2007)	1.5.1.24		Pimecrolimus is weaker and more expensive than 1% hydrocortisone and should not be promoted. Where 1% hydrocortisone is not effective or contraindicated, tacrolimus rather than pimecrolimus, should be considered.	Thank you for your comment. The scope of this guideline update was to review recommendations on emollient bath additives, and therefore this is outside the remit of this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.

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Atopic eczema in under 12s: diagnosis and management

Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
North West Paediatric Allergy, Immunology and Infection Operational 79elivered Network	Original guideline (2007)	1.5.1.36		Delete this section. Eczema is not mediated by histamine and non-sedating antihistamines will have no effect on the itch. The only exclusion is children who also have evidence of urticaria, where non-sedating antihistamines should be considered.	Thank you for your comment. The scope of this guideline update was to review recommendations on emollient bath additives, and therefore this is outside the remit of this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
North West Paediatric Allergy, Immunology and Infection Operational Delivery Network	Original guideline (2007)	1.5.1.50		Phototherapy should no longer be considered for treatment of severe eczema in children – biologics have now replaced this option in children.	Thank you for your comment. The scope of this guideline update was to review recommendations on emollient bath additives, and therefore this is outside the remit of this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
North West Paediatric Allergy, Immunology and Infection Operational Delivery Network	Original guideline (2007)	1.5.1.51		Phototherapy should no longer be considered for treatment of severe eczema in children – biologics have now replaced this option in children.	Thank you for your comment. The scope of this guideline update was to review recommendations on emollient bath additives, and therefore this is outside the remit of this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Primary Care Dermatology Society (PCDS)	Guideline	005	023	Re: 1.5.1.12 – we think the statement “ <i>emollient bath additives do not help with atopic eczema</i> ” should be removed, as the majority of patients report these do help their eczema. We feel the wording of this statement could be made clearer and also with an additional statement regarding children with sensory issues, for example:	Thank you for your comment. The committee decided to remove this recommendation following stakeholder consultation. The committee agreed that it was important that children with eczema receive appropriate information around using emollients for washing and bathing to ensure that they continue to apply leave-on emollients and wash with emollient products.

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Consultation on draft guideline - Stakeholder comments table 21/03/2023 - 04/04/2023

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p><i>Explain to children with atopic eczema and their parents or carers that:</i></p> <ul style="list-style-type: none"> <i>emollients should always be used for washing, instead of soap.</i> <i>whilst emollient bath additives should not be prescribed, for some they may be helpful and they can be bought over the counter if the child and their parents or carers wish to use them.</i> <p><i>children with sensory issues can use their usual emollient diluted in warm water and added to a bath, or parents/carers may prefer to purchase an emollient bath additive if that is more tolerable.</i></p>	<p>The committee therefore decided to incorporate into the recommendations that patients and carers should be offered personalised advice on washing with emollients and emollient soap to ensure that they do receive accurate information and advice that is tailored to the individual and their family. This would allow clinicians to provide solutions for patients who may benefit from having emollient added to the bath water. This has also been addressed in the rationale and impact section, which highlights that leave-on emollients can be diluted in hot water and added to bath water.</p>
Primary Care Dermatology Society (PCDS)	Question	1		<p>1. Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives.)</p> <p>No we do not believe this should be challenging to implement as it is simply making a clear recommendation that emollient bath additives should not be prescribed.</p>	<p>Thank you for your comment.</p>

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Primary Care Dermatology Society (PCDS)	Question	2		<p>2. Would implementation of any of the draft recommendations have significant cost implications?</p> <p>No – it will mean cost savings for the NHS.</p>	Thank you for your comment.
Royal College of General Practitioners (RCGP)	Guideline	General	General	The guideline for Atopic eczema in under 12s: diagnosis and management (update) has been reviewed by the RCGP and have no comments to add. It was felt this this was a good update to the guideline and there were no areas in which it was felt edits were required.	Thank you for your comment
Royal College of Nursing	Guideline	005	019	<p>1.5.1.10 “they can choose which product to apply first”.</p> <p>Useful there is clarity at last about order of application not being critical.</p>	Thank you for your comment.
Royal College of Nursing	Guideline	005	021	<p>1.5.1.11 “Do not offer emollient bath additives to children with atopic eczema”</p> <p>There is evidence that bath additives are not optimal BUT for a minority of children who are resistant to having emollient lotions, creams and ointments applied they may be the only option. Although there is advice that parents can buy these products not everyone can afford them. In these cases it is important to tell parents that they can dilute emollient products for use in the bath as an alternative.</p>	Thank you for your comment. The committee agreed that it is important to make children with atopic eczema and their carers aware of the different ways that emollients can be used for washing and bathing, including the possibility of diluting some leave-on emollients in bath water. To address this, the committee decided to incorporate into recommendation 1.5.1.10 that patients and carers should be offered personalised advice on washing with emollients and emollient soap substitutes. This has also been addressed in the rationale and impact section, which

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					highlights that leave-on emollients can be diluted in hot water and added to bath water.
University of the West of England (Centre for Appearance Research)	Guideline	005	015 – 020	<p>1.5.1.10 - There is evidence that using self-management care plans can help families feel more confident about managing childhood eczema and set out complex treatment regimens in clear understandable ways including explaining when do use treatments, how much, where on the body to apply it. Therefore, it could be beneficial to include a recommendation of completing a care plan such as the EWAP of Eczema Outreach support care plans with families to ensure they understand how and when to use treatment, increase adherence and confidence at managing their child's eczema.</p> <p>Powell, K., Le Roux, E., Banks, J. P., & Ridd, M. J. (2018). Developing a written action plan for children with eczema: a qualitative study. <i>British Journal of General Practice</i>, 68(667), e81-e89.</p> <p>Thandi, C. S., Constantinou, S., Vincent, R., & Ridd, M. J. (2023). Where and how have written action plans for atopic eczema/dermatitis been developed and evaluated? Systematic review. <i>Skin Health and Disease</i>, e213.</p>	Thank you for your comment. The scope of this guideline update was to review recommendations on emollient bath additives, and therefore this is outside the remit of this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Viatrix / Mylan UK	General	General	General	Whilst this is not within the scope of the consultation. Viatrix would like to highlight the change of Pimecrolimus' license, now extended to patients 3 months of age and older	Thank you for your comment. The scope of this guideline update was to review recommendations on emollient bath additives, and therefore this is outside the remit of this update. We will pass your

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				<p>Would now be an opportune time to update the following existing guidance?</p> <p>1.5.1.24 Pimecrolimus is recommended, within its licensed indications, as an option for the second-line treatment of moderate atopic eczema on the face and neck in children aged 2 years to 16 years that has not been controlled by topical corticosteroids (see recommendation 1.5.1.25), where there is a serious risk of important adverse effects from further topical corticosteroid use, particularly irreversible skin atrophy.</p> <p>Many thanks in advance for your consideration</p>	comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

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