



2019 exceptional surveillance of atopic eczema in under 12s: diagnosis and management (NICE guideline CG57)

Surveillance report

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Surveillance decision

We will update the guideline on [atopic eczema in under 12s](#). This update will focus on emollient treatment.

Reason for the decision

Assessing the evidence

The purpose of this exceptional review was to examine any impact on NICE's guideline on atopic eczema in under 12s following the publication of a National Institute for Health Research (NIHR) funded trial on [Adding emollient bath additives to standard eczema management for children with eczema: the BATHE RCT](#).

Methods

The BATHE study is a randomised controlled trial assessing the clinical and cost-effectiveness of emollient bath additives in the management of childhood eczema. The trial was conducted in 96 general practices in England and Wales and included children aged between 12 months and 12 years providing they met the UK diagnostic criteria for mild to severe atopic eczema. Participants in the intervention group were prescribed bath additives for regular use over a 12 month period. The control group were asked not to use bath additives. Both groups continued with their standard eczema treatment when required including leave-on emollients and topical corticosteroids. The primary outcome was eczema severity, measured by parent/carer reported Patient Oriented Eczema Measure (POEM) score weekly over the first 16 weeks of the trial and then every 4 weeks, from 16 weeks to 12 months. Secondary outcomes included:

- Number of eczema exacerbations resulting in a primary healthcare consultation over 1 year, assessed by a review of participants' primary care records.
- Disease-specific and generic quality of life (QoL) at baseline, 16 weeks and 1 year, measured by the Dermatitis Family Impact Questionnaire (DFIQ) and the Child Health Utility-9 Dimensions (CHU-9D) respectively.

An economic evaluation was also conducted to determine the cost effectiveness of

emollient bath additives in addition to standard management for childhood eczema.

Results

The results of the BATHE study have been described in detail in an [NIHR signal](#) and a NICE medicines evidence commentary on [eczema in children](#). In summary, the new evidence suggests no added clinical benefit of using emollient bath additives:

- In the emollient bath additive group, the mean POEM score over the first 16 weeks of treatment was 7.5 points (SD 6.0) from a baseline score of 9.5.
- In the control group, the mean POEM score over the first 16 week period was 8.4 points (SD 6.0) from a baseline score of 10.1.

The results of the economic analysis indicated that the intervention was not cost effective. There was no difference between groups in secondary outcomes or in adverse effects such as redness, stinging or slipping.

Guideline development

NICE's guideline currently recommends emollients for all severities of eczema, to be used every day for moisturising, washing and bathing. A lack of evidence was identified evaluating the effectiveness of emollients in children with atopic eczema with available data consisting of isolated case series and case reports. Despite this, the guideline committee felt that emollients were the most important treatment option for atopic eczema because they believed that they restore the defective skin barrier. In particular, emollient bath additives and other emollient wash products were considered to provide an essential method to clean the skin without the damaging effect of soap and detergents. Adherence to emollient treatment was also cited as a key consideration in identifying a successful therapy option.

Due to the lack of good quality evidence of benefit for emollients, the committee made research recommendations in this area to generate evidence on:

- The most effective and cost-effective combinations of emollient products to use for the treatment of childhood atopic eczema.
- Whether the regular use of emollients reduce the severity and frequency of flares and the need for other topical agents in the treatment of atopic eczema in children.

While the BATHE study does not directly address the research recommendations identified in NICE's guideline, it does explore the benefit of emollient bath additives more generally.

Previous surveillance

Although evidence on emollients was identified in [previous surveillance](#) reviews of the NICE guideline, studies focused on leave-on emollients rather than emollient bath additives.

Research landscape

The NIHR has funded additional research in this area including [Best Emollient for Eczema \(BEE\): pragmatic, primary care, multi-centre, individually randomised superiority trial of four emollients in children with eczema, with internal pilot and nested qualitative study](#). This research remains ongoing and results are not expected until 2021 at the earliest. We will monitor the progress of this study and consider the impact of results on guideline recommendations when available.

Views of topic experts

In this exceptional review we engaged with topic experts who were either members of the guideline committee involved in the development of the NICE guideline or were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty. We received feedback from 3 topic experts.

Topic experts indicated that the BATHE trial had some important limitations:

- The study did not include children under the age of 1, when many babies are diagnosed with atopic eczema.
- It did not examine quiescent disease, or antimicrobial bath emollients.
- 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.

There was a view that GP prescriptions of emollient bath additives are now being limited in some areas in response to the BATHE trial. However, it's not entirely clear if this could be linked directly to the results of the BATHE study as [NHS England made recommendations](#)

in March 2018 for Clinical Commissioning Groups (CCGs) on the range of over the counter items (including emollients) that doctors could prescribe for certain conditions. The recommendations underwent extensive consultation with stakeholders including NHS staff, royal colleges, trusts, CCGs, patient groups and the pharmaceutical industry. This guidance advises CCGs that a prescription of emollients for treatment of contact dermatitis should not routinely be offered in primary care as the condition is appropriate for self-care. However, there are general exceptions to this guidance where patients should continue to have their treatments prescribed, for example treatment of long-term conditions or where a patient has not responded to treatment with an over the counter product. A NICE systematic review and update in this area will enable an expert committee to consider the full evidence base around emollient bath additives to inform recommendations for clinical practice.

Overall, topic experts supported an update to the guideline as they felt that the BATHE trial provides some evidence to support the view that in mild to severe atopic eczema, the addition of bath emollients to standard advice (including washing with emollients), offers little benefit. This differs from current guidance that recommends that healthcare professionals should offer children with atopic eczema a choice of unperfumed emollients to use every day for moisturising, washing and bathing.

Impact

The BATHE trial results are directly relevant to NICE's guideline and form the basis of this update decision.

NICE's guideline currently recommends that healthcare professionals should offer children with atopic eczema a choice of unperfumed emollients to use every day for moisturising, washing and bathing. However, the new evidence suggests no added clinical or economic benefit of using emollient bath additives in children with eczema.

Strengths of the BATHE trial are that it is a UK-based study directly relevant to NICE's guideline. A limitation is that the majority of children in the study had mild or moderate eczema at baseline so the effectiveness of emollient bath additives in children with more severe disease is unknown. Additionally, parents knew which group their child was randomised to which could have affected how they managed their child's eczema, for example the volume of soap substitute emollient used.

Following consideration of the results published in the BATHE trial, as well as topic expert

feedback, the new evidence may have an impact on the current recommendation to offer children with atopic eczema a choice of unperfumed emollients to use every day for moisturising, washing and bathing.

Other clinical areas

This exceptional surveillance review did not search for new evidence relating to other clinical areas in the guideline.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

See [how we made the decision](#) for further information.

How we made the decision

Exceptionally, significant new evidence may mean an update of a guideline is agreed before the next scheduled check of the need for an update. The evidence might be a single piece of evidence, an accumulation of evidence or other published NICE guidance.

For details of the process and update decisions that are available, see [ensuring that published guidelines are current and accurate](#) in developing NICE guidelines: the manual.

Evidence

This surveillance report provides an overview of one study published since the end of the search period for the guideline (March 2007). The results of this study were considered in detail to determine if there is an impact on guideline recommendations.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline.

Views of stakeholders

Because this was an exceptional surveillance review we did not consult on the decision.

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