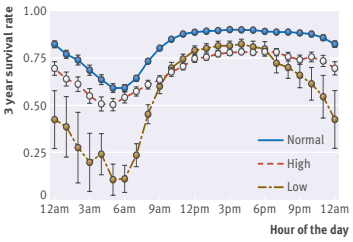
research

No benefit from emollient bath additives in addition to standard treatment for childhood eczema p 143

No evidence of risk averse practice or "gaming" of data with surgeon specific outcome reporting p 146



Presence of a laboratory test order, regardless of the result significantly associated with the odds of survival p 146

Bath emollients for children with eczema

ORIGINAL RESEARCH Pragmatic parallel group RCT of clinical and cost effectiveness

Emollient bath additives for the treatment of childhood eczema (BATHE)

Santer M, Ridd MJ, Francis NA, et al

Cite this as: *BMJ* 2018;361:k1332

Find this at: http://dx.doi.org/10.1136/bmj.k1332

Study question What is the clinical effectiveness of including emollient bath additives in the management of eczema in children?

Methods A randomised open label trial in 96 UK general practices. Children aged 1 to 11 years with eczema were randomised to advice to use regular emollient bath additives prescribed by their usual clinical team or no use of emollient bath additives, both for 12 months. The authors excluded children with very mild eczema or who bathed less than once weekly. Both groups continued with standard eczema management, including leave-on emollients and regular topical corticosteroids when required. 483 children were randomised; one was withdrawn, leaving 482 children in the trial. Eczema control was measured by the patient oriented eczema measure (POEM, range 0-28, with higher numbers representing greater symptom severity) weekly for 16 weeks.

Study answer and limitations No statistically significant difference was found in weekly POEM scores between groups over 16 weeks. The mean baseline POEM score was 9.5 (SD 5.7) in the bath additives group and 10.1 (SD 5.8) in the no bath additives group. The mean POEM score over the 16 week period was 7.5 (SD. 6.0) in the bath additives group and 8.4 (SD 6.0) in the no bath additives group. After controlling for baseline severity and confounders (ethnicity, topical corticosteroid use, soap substitute use) and allowing for clustering of participants within centres and responses within participants over time, POEM scores in the no bath additives group were 0.41 points higher than in the bath additives group (95% confidence interval −0.27 to 1.10), below the minimal clinically important difference of 3 points. Despite a relatively low response rate, participants were representative of children with eczema seen in primary care. Some contamination might have occurred between groups, but self reported adherence to treatment allocation was good.

What this study adds This trial found that emollient bath additives do not add any benefit over standard management of childhood eczema. Standard management includes soap avoidance, leave-on emollients, and topical corticosteroids when required. Further research is needed into regimens for leave-on emollient and soap substitutes.

Funding, competing interests, data sharing This study was funded by the National Institute for Health Research health technology assessment. The authors have no competing interests. No additional data are available.

Eczema is the commonest inflammatory skin condition in childhood, affecting around 20% of UK children and having a substantial impact on patients' and families' quality of life and National Health Service resources.[1] The regular application of leave-on emollients is a cornerstone of treatment,[2] based at least partly on evidence from intervention studies.

Little good evidence exists on the benefits of emollient bath additives,[3] although the National Institute for Health and Care Excellence recommends regular use of "emollient wash products" for children with eczema.[4] This is probably one of the reasons why emollient bath additives are commonly prescribed, costing the English NHS more than £17m a year in primary care alone.[5] But do emollient bath additives really reduce the severity of eczema and improve quality of life, in conjunction with standard care?

To answer these important questions, Santer and colleagues conducted a pragmatic randomised controlled trial comparing standard care with and without regular use of an emollient bath additive among children aged 1-11 years.[6] For one year, local general practitioners regularly prescribed one of three bath additives to children in the intervention group. In the control group, use of emollient bath additives was discouraged but all participants were instructed to use emollients as soap substitutes and to continue eczema care as usual.

Most participants had moderate eczema and all were followed up for 12 months. The primary outcome was change in disease severity during the first four months, measured using the patient oriented eczema measure (POEM) score. Disease severity at one year, disease specific quality of life, overall use of topical anti-inflammatory treatment, and resource utilisation were important secondary outcomes. In their main analyses the authors report no statistically significant difference between the groups for any outcome.

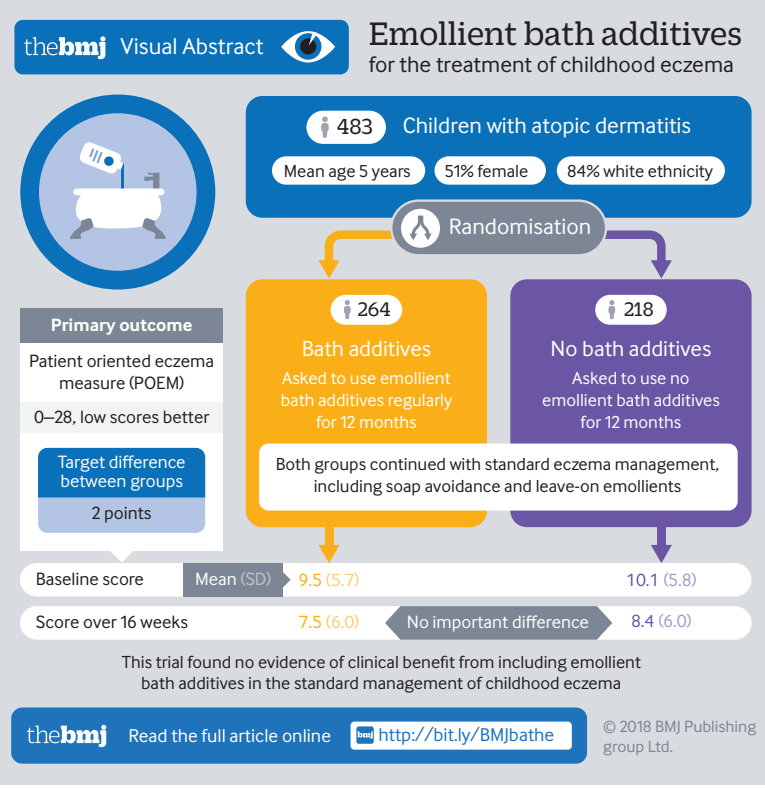
Emollient bath additives with antiseptic properties might still have a part to play in children with recurrent skin infections

Patient priorities

This trial answers an important question, included in the James Lind Alliance list of high priority research questions for eczema, to which both experts and patients contributed.[7] Patient presentation was also strong in the development of the study protocol and conduct of the trial. Rather than just using one specific product, general practitioners had a choice between the three most commonly prescribed emollient bath additives, more closely reflecting clinical practice. The trial team deserve particular credit for their one year follow-up period, which is unusually long and gave a full chance for the intervention to show any potential effects.

Interestingly, the prespecified subgroup analysis by age showed a significant improvement in children aged less than 5 years, with an adjusted mean POEM score difference of 1.29 (95% confidence interval 0.33 to 2.25). Although the upper limit of the confidence interval is below the minimal clinically important difference of the POEM (3 points), this leaves open the question of whether younger children might still benefit from bath emollients, especially infants who are often bathed daily but were excluded from this trial.

Only 36% of participants in the trial had five or more baths each week and 13% of the control group admitted using bath additives, at least occasionally. Both factors might have limited the trial's ability to detect any benefit associated with the intervention. Most importantly, the control group were encouraged to use emollient soap substitutes and standard leave-on emollients, potentially attenuating any small beneficial effect from emollient bath additives.



Carsten Flohr carsten.flohr@kcl.ac.uk
Amina Ahmed
See bmj.com for author details

Emollient bath additives cost the English NHS more than £17m a year in primary care alone

It was not feasible to produce a placebo, so the control group received standard care. If anything, the use of a placebo would have resulted in further reduction in the effect size. The same applies to the severity assessments conducted solely by the children or parents themselves, Ideally, the authors should have included an additional more objective outcome, measured by blinded assessors.[8]

The trial was not powered to compare the effectiveness of individual emollient products, but they all have a similar mode of action and would be expected to have largely similar effects. The trial did not assess the optimal regimen for leave-on treatments, soap substitutes, and frequency of bathing or washing in children with eczema.

Although there does not seem to be any additional benefit from standard emollient bath additives, those with antiseptic properties might still have a part to play in children with recurrent skin infections.

So there is still some room for further work, but it is heartening to see that at least one important evidence gap has been closed. Both the NHS and families of children with eczema can now better invest in more effective treatments for this common condition.

Cite this as: *BMJ* 2018;361:k1791

Find the full version with references at http://dx.doi.org/10.1136/bmj.k1791

AUTHOR'S PERSPECTIVE

Miriam Santer

Choice in emollients for eczema is crucial

Childhood eczema is very common and can have an enormous impact on families—lack of sleep for carers and child, time consuming care routines, additional cleaning and laundry, and worry about long term outlook.

Emollients form the mainstay of treatment, but there is little evidence about optimal emollient regimens. Current advice is to use emollient as a soap substitute and then use a leave-on emollient straight after having a bath. The BATHE research study set out to see if adding bath emollient to bath water, in addition to this best practice, has additional benefit.

Before designing the trial, we carried out a survey of bathing habits among families of children with eczema, distributed with the help of the National Eczema Society, the Centre of Evidence Based Dermatology, and others. This showed that most families were bathing their child at least three times a week. Importantly, it also showed that most families were using emollient bath additives as a soap substitute, so in order to ensure that both groups were washing in the same way, we advised everyone in the trial to use leave-on emollients as a soap substitute rather than emollient bath additives.

Many questions remain that BATHE doesn't answer

We found no additional benefit of pouring emollient additives into the bath. This suggests that, if a family is using leave-on emollients and avoiding soap, adding bath emollient to the bath water does not help. But many questions remain that BATHE doesn't answer: what is the optimal frequency of bathing; what is best to use as a soap substitute; are bath emollients easier to use as a soap substitute than leave-on emollients from a pump dispenser? Acceptability and ease-of-use are key when treating a long term childhood condition, as strategies to overcome a child's resistance are not always successful. Even though emollient bath additives may not add much to eczema care, it is crucial that these results are not extended to all emollients and that consideration is given to patient and carer choice in emollients for leave-on use and soap substitution.

Miriam Santer is a GP in Bournemouth and associate professor in primary care research at the University of Southampton. She is also a parent of children with mild eczema

ORIGINAL RESEARCH Population based cohort study

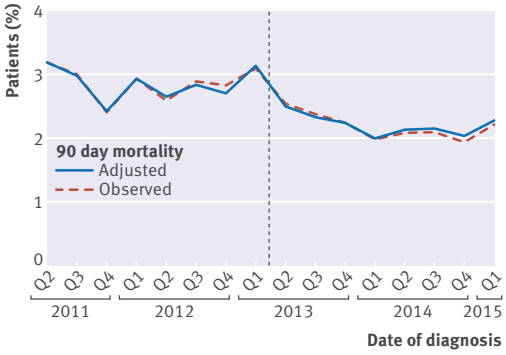
Effect of public reporting of surgeons' outcomes on patient selection, "gaming," and mortality in colorectal cancer surgery in England

Vallance AE, Fearnhead NS, Kuryba A, et al

Cite this as: *BMJ* 2018;361:k1581 Find this at: http://dx.doi.org/10.1136/bmj.k1581

Study question What was the effect of the introduction of surgeon specific 90 day mortality reporting in colorectal cancer surgery in June 2013 on risk averse clinical practice, "gaming" of clinical data, and 90 day postoperative mortality?

Methods This population based cohort study included 111 431 English NHS patients diagnosed as having colorectal cancer from 1 April 2011 to 31 March 2015 and included in the National Bowel Cancer Audit. The proportion of patients who had an elective major resection, the predicted 90 day mortality based on characteristics of patients and tumours, and the observed 90 day mortality adjusted for differences in these characteristics were compared between patients who had surgery before and after the introduction of the public reporting of surgeon specific outcomes.



Observed and adjusted mortality in patients undergoing elective or scheduled major resection according to date of surgery. Dotted line represents date of introduction of surgeon specific public outcome reporting

Study answer and limitations The proportion of patients with colorectal cancer undergoing major resection (39 792/62 854 (63.3%) before versus 30 706/48 577 (63.2%) after; P=0.8) and the proportion of these major resections categorised as elective or scheduled (33 638 (84.5%) before versus 25 905 (84.4%) after; P=0.5) did not change after the introduction of surgeon specific public outcome reporting. The predicted 90 day mortality remained the same (2.7% *v* 2.7%), but the observed 90 day mortality fell (952 (2.8%) *v* 552 (2.1%)), over and above the existing downward trend in mortality. The small differences in the characteristics of patients who had surgery before and after the introduction of public reporting were overcome through the use of a validated risk adjusted model.

What this study adds This study did not find evidence of risk averse clinical practice or "gaming" of data after the introduction of surgeon specific outcome reporting in elective colorectal cancer surgery in England. The introduction of surgeon specific outcome reporting coincided with a significant decrease in mortality.

Funding, competing interests, data sharing The National Bowel Cancer Audit is commissioned by the Healthcare Quality Improvement Partnership as part of the National Clinical Audit and Patient Outcomes Programme, and funded by NHS England and the Welsh government.

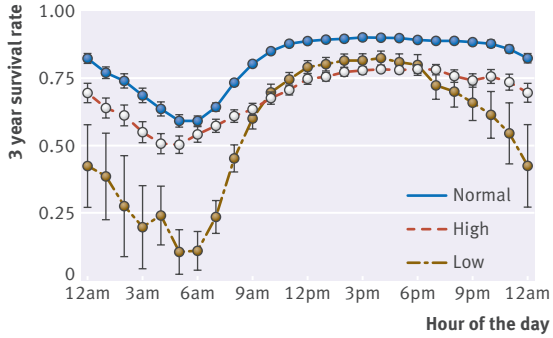
ORIGINAL RESEARCH Retrospective observational study

Biases in electronic health record data due to processes within the healthcare system

Agniel D, Kohane IS, Weber GM

Cite this as: *BMJ* 2018;361:k1479
Find this at: http://dx.doi.org/10.1136/bmj.k1479

Healthcare process dimensions of white blood cell count laboratory tests and survival



Study question What is the impact of healthcare processes on the predictive value of electronic health record data?

Methods A retrospective analysis of electronic health record data for all 669 452 patients treated over a one year period between 2005 and 2006 from two large hospitals in Boston, Massachusetts, was performed. The main outcome measure was the relative predictive accuracy of each laboratory test for three year survival, using the time of the day, day of the week, and ordering frequency of the test, compared with the value of the test result.

Study answer and limitations The presence of a laboratory test order, regardless of any other information about the test result, has a significant association (P<0.001) with the odds of survival in 233 of 272 tests (86%); and, data about the timing of when laboratory tests were ordered were more accurate than the test results in predicting survival in 118 of 174 tests (68%). The statistical models were intentionally simplistic to isolate the predictive value of individual variables and to demonstrate the biases that could result from ignoring the complexity of electronic health record data.

What this study adds Healthcare processes must be addressed and accounted for in analysis of observational health data.

Funding, competing interests, data sharing See bmj.com for funding. The authors have no competing interests. See bmj.com for data sharing.