



# Is honey a well-evidenced alternative to over-the-counter cough medicines?

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## DECLARATIONS

### Competing interests

None declared

### Funding

None

### Ethical approval

Not applicable

### Guarantor

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### Contributorship

All authors contributed equally

### Acknowledgements

None

The Medicines and Healthcare products Regulatory Agency (MHRA) recently banned use of the most commonly used over-the-counter (OTC) cough remedies in children under 6 years of age, responding to concerns about their lack of efficacy and adverse effects. Their report recommends, as an alternative, 'a warm drink of lemon and honey'.<sup>1</sup>

A sceptic might be prompted to ask whether this advice was:

- grounded more in folklore and accepted orthodoxy than empirical evidence;
- offered primarily to pacify not children but anxious parents who might feel disempowered and disconcerted by the MHRA's ruling?

A Cochrane systematic review<sup>2</sup> investigating the effect of honey and cough identified only one randomized controlled trial.<sup>3</sup> Undertaken in the United States by Ian Paul *et al.*, the study received widespread press coverage when it was published in December 2007, attracting such headlines as 'Honey beats cough medicine' in *The Guardian*.<sup>4</sup>

The trial recruited 105 children aged 2–18 years with cough as a feature of an upper respiratory tract infection. They were given either a syringe-full of honey or honey-flavoured dextromethorphan (DM, a common constituent of OTC cough remedies), while a third group received an empty syringe (to act as a control). The children's parents then reported via a telephone survey on their child's cough and sleep disturbance. These observations were compared with those taken the night prior to treatment. Each group showed much improved cough and sleep quality from the previous night and this was especially the case in the honey group. The researchers concluded that 'honey was

the most effective treatment for all of the outcomes related to cough, child sleep and parent sleep'.

The study was strongly criticized by experts, not least on the NHS website, Behind the Headlines.<sup>5</sup> The study was small-scale, short, subjectively reported, poorly controlled and supported financially by the US National Honey Board. In fact, pairwise comparison of the honey and DM group revealed no statistically significant differences for any outcome. The study's only statistically significant results – that honey reduced cough frequency and overall cough score more than an empty syringe – might easily be attributed to the placebo effect alone. *The Guardian* subsequently printed a correction recognizing that its article was misleading.

So why is the MHRA giving advice based on such substandard evidence? It could be argued that this is consistent with the agency's practice regarding other 'natural remedies', such as its provision of licences for homeopathic products sold in UK pharmacies. At least we can be quite sure that the latter are free from side-effects. Like all other evidence-based interventions, whatever benefit is to be conferred by honey must be balanced against its potential risks, including dental caries, anaphylaxis, insomnia and hyperactivity. It would be an unwelcome situation if patients and healthcare professionals were unable to trust the government's medicines regulator in this matter.

The MHRA may have hoped that promoting traditional home remedies would alleviate parental concerns about the ruling made about OTC cough medicines. Perhaps there is an argument to be made in favour of advising use of a placebo by patients who are seeking treatment for a problem for which medicine has little to offer, if only to

avoid the unwanted side-effects of 'real' medicines. However, this potential benefit compares badly with the risks of misleading patients and threatening to compromise the medical profession's core ethical values. We properly uphold the need for an honest and non-paternalistic approach to healthcare delivery, emphasizing informed and shared decision-making. This approach is equally applicable in treating young children as it is the *informed* decision of the parental guardian, not the healthcare professional, which determines the care that the child receives.

In the MHRA's documentation relating to its ruling on OTC cough remedies, it notes that 'coughs occur frequently in children but they are self-limiting and rarely harmful'.<sup>6</sup> However, each year '12 million packs [of such products] are sold with indications authorised for children less than six years of age'.<sup>7</sup> In the UK, the total population of children under six years old is approximately 3.6 million. The millions of pounds that were spent on these products is testimony to the scale of the problem as perceived by parents. It represents the most common presenting complaint in general practice,<sup>8</sup> results in millions of lost school and work days, and is a significant source of stress to both children and their carers alike.

We have then a noteworthy problem but the solution proposed by the MRHA lacks supporting evidence. This often happens when a potential solution is neither patentable nor particularly expensive. Since Paul's publication, research into honey as a treatment for cough has come to a standstill. As a consequence, we are left with the somewhat unsatisfactory conclusion that 'for those who choose to offer therapy to children with cough ... honey may be a reasonable option given its low cost, relatively low adverse effect profile, and potential benefit'.<sup>9</sup>

Without further credible evidence, healthcare professionals advocating honey as a treatment for

cough could be considered reckless. The Cochrane Collaboration recognizes the need for more substantial evidence regarding the effectiveness of honey in resolving acute cough in children. The 2nd International Cough Symposium concluded that there is a great need for effective new cough treatments.<sup>10</sup> What we need here is a well-designed, sufficiently powered, randomized controlled trial using a simple cough assessment tool to assess the effect of honey over a suitable period of time on children with cough as a feature of an upper respiratory tract infection. I suggest that many parents would ask us to make a beeline for this outcome as a matter of some urgency.

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