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PRACTICE POINTER

Treatments for cough and common cold in children

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What you need to know

- Upper respiratory tract infections are common, self-limiting illnesses that resolve without intervention in up to 10 days
- Treatments for the common cold do not shorten the length of illness but may relieve a child's discomfort by alleviating the effects of the most bothersome symptoms
- Antitussives, antihistamines, decongestants, expectorants, and aspirin are not recommended for use in children under the age of 6
- Safe treatments for bothersome symptoms include saline nasal irrigation, pasteurised honey for cough, and analgesics, but most symptoms require no interventions

Upper respiratory tract infections (URTIs) are common, self-limiting illnesses that are distressing for children and families.¹⁻³ Despite the large number of treatments marketed for relief of cough and common cold symptoms, the evidence for their efficacy is of poor quality with high risk of bias. Most studies find no evidence of benefit in reducing nasal symptoms and cough, and several treatments have serious risk of harm. Clinicians and healthcare practitioners can discuss with families how coughs and colds develop, can provide reassurance and safety netting advice, and discuss the pros and cons of treatments that are safe and may offer some symptomatic benefit. This practice pointer aims to describe commonly used cough and common cold therapies in children (aged 12 and under), including the data on their safety and effectiveness, and to

provide recommendations for practitioners and parents on how to manage bothersome symptoms and reduce the use of inappropriate treatments.

Cough and common cold therapies

What constitutes an over-the-counter cough and common cold therapy, and what requires a prescription, varies internationally. Despite limited data on effectiveness, revenue in the over-the-counter market in 2023 is estimated at \$41.27bn (£32.5bn; €37.7bn) and popularity of these medications continues to increase. Sales are estimated to grow 6% year on year into 2027, with most revenue growth concentrated in the US but also worldwide.⁴ In 2022, shortages of common medications, such as acetaminophen/paracetamol and ibuprofen, were reported in some countries,⁵ which coincided with reports of paediatric fatalities attributed to marketing of contaminated syrups used for treating cough and cold in children.⁶ Seventy deaths in Gambia and another 199 in Indonesia were linked to use of contaminated syrups.⁶

Tables 1 and 2 outline commonly used cough and cold therapies, including effectiveness and safety data, and quality of the associated evidence. The main groups or classes of medications, which are available individually or combined with other products, focus on symptom relief—namely rhinorrhoea (runny nose), nasal congestion, sore throat, and fever—treated with antihistamines, decongestants, and analgesics, and/or cough and chest congestion treated with antitussives, and expectorants.

Table 1 | Summary of evidence from systematic reviews examining the benefits and harms of cough and cold therapies in children

Study ID Year	Intervention	Number of studies	Main outcomes	Benefits	Harms	Quality of evidence*
<i>Oral (systemic) agents</i>						
De Sutter 2022 ⁷	Oral antihistamine decongestant analgesic combinations	9	<ul style="list-style-type: none"> Symptom relief Proportion of participants with treatment failure Adverse effects 	<ul style="list-style-type: none"> Effects are too small to be clinically relevant 	Sedation, dry mouth, drowsiness, lethargy, nausea, somnolence	Low to moderate
Smith 2014 ^{8†}	Antitussives, antihistamines, antihistamines-decongestant	4	<ul style="list-style-type: none"> Cough outcomes such as frequency, severity, amount of sputum, improvement in cough symptoms 	<ul style="list-style-type: none"> No more effective than placebo 	Higher frequency with preparations containing antihistamines and dextromethorphan	Low
Kim 2015 ^{9‡}	Non-steroidal anti-inflammatory drugs (NSAIDs)	9	<ul style="list-style-type: none"> Efficacy in improvement of common cold symptoms Decrease in number or duration of individual common cold symptoms 	<ul style="list-style-type: none"> No clear evidence that NSAIDs are effective in improving common cold symptoms 	Gastrointestinal upset	Moderate
Tan 2020 ^{10§}	Acetaminophen, ibuprofen	7	<ul style="list-style-type: none"> Reduced temperature within 4 hours and at 4-24 hours Reduced pain at 4-24 hours 	<ul style="list-style-type: none"> Compared with acetaminophen, ibuprofen resulted in reduced temperature at less than 4 hours, and at 4-24 hours Ibuprofen significantly reduced pain at 4-24 hours compared with acetaminophen 	Similar serious adverse event profiles	Moderate
Kuo 2022 ¹¹	Acetaminophen, ibuprofen	26	<ul style="list-style-type: none"> Resolution of fever 	<ul style="list-style-type: none"> No significant difference in fever resolution rates between acetaminophen and ibuprofen. In children <2 years, fever resolution rate was significantly lower with acetaminophen 	Acetaminophen had significantly lower adverse event rates compared with ibuprofen	Not reported. Low to moderate risk of bias
Trippella 2019 ^{12¶}	Combining or alternating acetaminophen and ibuprofen	9	<ul style="list-style-type: none"> Mean temperature Proportion afebrile at 1, 4, and 6 hours Child discomfort Number of doses given 	<ul style="list-style-type: none"> Combining resulted in higher proportion afebrile at 4 and 6 hours Alternating resulted in higher proportion afebrile at 6 hours, and reduced discomfort at day 1, 2, and 3 	Similar serious adverse event profiles	Low to moderate
Kenealy 2013 ¹³	Antibiotics	4	<ul style="list-style-type: none"> Persistence of symptoms: rhinitis, sore throat, and sneezing 	<ul style="list-style-type: none"> No evidence of benefit for the common cold or for persisting acute purulent rhinitis 	Risk of adverse events was not significantly increased	Not reported. Unclear risk of bias
<i>Intranasal agents</i>						
Cabailot 2020 ¹⁴	Saline nasal irrigation (eg, saline drops)	4	<ul style="list-style-type: none"> Improvement in nasal symptoms (obstruction, discharge, purulence, coughing and/or sneezing) Effects on respiration and health status and activity (eg, eating, drinking, sleeping, and playing) 	<ul style="list-style-type: none"> Significant benefit for clinical rhinological symptoms, but no significant effect on respiratory symptoms 	No serious adverse events	Not reported. Moderate to high risk of bias
Hayward 2015 ¹⁵	Intranasal corticosteroids (available as drops or sprays)	1	<ul style="list-style-type: none"> Proportion of participants with resolution or improvement of symptoms Time to resolution of symptoms 	<ul style="list-style-type: none"> Not effective for symptomatic relief of common cold 	Not reported	Not reported. High risk of bias

Table 1 | Summary of evidence from systematic reviews examining the benefits and harms of cough and cold therapies in children (Continued)

Study ID Year	Intervention	Number of studies	Main outcomes	Benefits	Harms	Quality of evidence*
AlBalawi 2013† ¹⁶	Intranasal ipratropium bromide (available as sprays)	7	<ul style="list-style-type: none"> • Rhinorrhoea • Nasal congestion 	<ul style="list-style-type: none"> • No studies included children under 12 years 	-	-
Deckx 2016 ¹⁷	Intranasal decongestants	1	<ul style="list-style-type: none"> • Nasal congestion • Overall patient wellbeing score 	<ul style="list-style-type: none"> • Effects are unclear 	Unclear	Low

* Based on the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) evaluation included in the systematic review. For systematic reviews that did not report the quality of the evidence, we have documented the overall risk of bias as reported by the authors.

† The review included 10 studies in total. However, we have excluded medications that were already reported in other reviews included in table 1 (oral antihistamine decongestant analgesic combinations) and table 2 (honey).

‡ Includes both children and adults.

§ Focused only on fever resolution outcome, did not report pain outcomes.

¶ May have included studies in which with fever was not attributed to cough and/or colds.

Table 2 | Summary of evidence from systematic reviews examining the benefits and harms of dietary and herbal therapies on cough and cold in children

Study ID Year	Intervention	No. of studies	Main outcomes	Benefits	Harms	Quality of evidence*
Oduwole 2018† ¹⁸	Honey	6	<ul style="list-style-type: none"> Cough frequency, duration, and severity Cough impact on parents' and children's sleep Adverse events 	<ul style="list-style-type: none"> Superior to usual care for the improvement of symptoms of cough frequency and severity 	No serious adverse events	Low to moderate risk of bias
Hemilä 2013 ¹⁹	Vitamin C	7	<ul style="list-style-type: none"> Mean number of days of illness of cold episodes Severity of cold symptoms Adverse events 	<ul style="list-style-type: none"> No consistent effect on the duration or severity of colds 	No serious adverse events were reported	Not reported. Low risk of bias
King 2014 ²⁰	Probiotics‡	10	<ul style="list-style-type: none"> Duration of illness episodes Number of days of illness Absenteeism (days away from day care/school/work) 	<ul style="list-style-type: none"> Significantly fewer numbers of days absent from day care/school compared to placebo 	Not reported	Not reported. Moderate risk of bias
Chen 2014 ²¹	Chinese patent (herbal) medicines	5	<ul style="list-style-type: none"> Fever duration Cure rate Time to resolution of individual symptoms (cough, nasal congestion, nasal drainage and sore throat) Adverse events 	<ul style="list-style-type: none"> Effects are unclear 	Uncertain	Low
Mao 2022 ²²	Tui Na	16	<ul style="list-style-type: none"> Cough related status (cough frequency, severity, and duration) Use of western medicines Quality of life Recurrence rate Adverse events 	<ul style="list-style-type: none"> Shortened cough duration and reduction in frequency of recurrence. 	Insufficient data	Low
Timmer 2013 ²³	<i>Pelargonium sidoides</i> extract	3	<ul style="list-style-type: none"> Resolution of all symptoms 	<ul style="list-style-type: none"> Significant improvement in symptoms of acute bronchitis with the liquid preparation 	Gastrointestinal symptoms	Low
Wang 2022 ²⁴	Herbal therapies containing <i>F. japonica</i>	3	<ul style="list-style-type: none"> Symptom improvement rate 	<ul style="list-style-type: none"> Significantly positive effect on symptom improvement rate compared to usual care Shortened the time with fever 	No significant effect on risk of adverse events	Low
Hu 2017 ²⁵	<i>Andrographis paniculata</i> (Chuān Xīn Lián)	1	<ul style="list-style-type: none"> Changes in symptom scores Symptom improvement 	<ul style="list-style-type: none"> Effects are unclear 	Unclear	Low

* Based on the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) evaluation included in the systematic review. For systematic reviews that did not report the quality of the evidence, we have documented the overall risk of bias as reported by the authors.

† Compared honey alone or honey in combination with antibiotics, versus no treatment, placebo, honey based cough syrup, or other over-the-counter cough medications

‡ Probiotics studied in the identified trials included *Lactobacillus rhamnosus*, *L. helveticus*, *L. bulgaricus*, *L. acidophilus*, *L. paracasei* subsp. *Casei*, *L. delbrueckii* subsp. *bulgaricus*, *Bifidobacterium infantis*, *B. bifidum*, *B. animalis*, and *Streptococcus thermophilus*.

Analgesics and antipyretics

Analgesics and antipyretics are recommended to relieve distress as part of a multimodal approach to managing pain and fever. Both acetaminophen/paracetamol and ibuprofen have been found to have a small effect on children's fever and are recommended by guidelines for children with a fever who appear distressed.^{26 27}

Combining or alternating acetaminophen/paracetamol and ibuprofen may be more effective in controlling fever than using either alone. A systematic review and meta-analysis found that their combined use, as opposed to a single analgesic-antipyretic, resulted in a higher proportion of children becoming afebrile within four hours (relative risk, RR, 0.18, 95% confidence interval, CI 0.06 to 0.53, n=3 studies, n=289 children) compared with alternating drugs, which resulted in a higher proportion of children afebrile at six

hours (RR 0.30, 95% CI 0.15 to 0.57, n=3 studies, n=580 children).¹² However, some guidelines recommend against combined use and advise alternating only if distress persists or recurs before the next dose is due, to reduce risk of dosing errors.²⁷

Parents and caregivers may perceive that fever in itself is potentially harmful, which can lead to medicating any fever in their child. No evidence suggests that using antipyretic agents reduces the incidence of febrile convulsions.²⁷ Also, thermometers can yield spurious results and are often used incorrectly in young children. More recent guidelines emphasise the effect on discomfort rather than fever, as fever is a physiological response to infection.²⁷

Saline nasal irrigation

Families are commonly advised to use saline nasal irrigation for relief of nasal secretions and nasal breathing, particularly in young children. A systematic review identified four randomised controlled trials (RCTs) including 569 children and found that saline irrigation has a small and short lived statistically significant benefit on rhinorrhoea and nasal congestion in children with URTIs.¹⁴ One trial also reported a reduction in use of decongestant medication in the group that used saline,²⁸ and several trials are ongoing. However, the studies were small, had a high risk of bias, and did not include standardised outcome measures. The main harms include patient discomfort from instillation of saline into the nares. Other intranasal agents, including corticosteroids, ipratropium bromide, and decongestants, have not been shown to be effective when considering the safety profile and quality of evidence.¹⁵⁻¹⁷

Antihistamines

Antihistamine medications reduce the release of histamine, thus decreasing secretion production and local congestion. Decongestants (eg, phenylephrine) are frequently combined with antihistamines and analgesics (eg, acetaminophen). One Cochrane review found no evidence of effectiveness for symptom relief of cough, nasal congestion, or sneezing in young children (6 months to 5 years) with oral antihistamine-decongestant and/or analgesic combinations. However, the same review indicated some potential benefit in older children (5-12 years).⁷ Antihistamines alone were also no more effective than placebo at relieving symptoms or improving sleep, and adverse events were more commonly reported.⁷

Antitussives

Antitussives, such as dextromethorphan or codeine, act by suppressing the cough reflex, either centrally or peripherally. A Cochrane review, which identified four RCTs including 327 children, found that antitussives were no more effective than placebo at improving cough symptoms in children, but had a high rate of adverse events.⁸ Expectorants, such as guaifenesin, lead to thinner mucus production, making secretions easier to clear by coughing. No trials have evaluated the effectiveness or safety of guaifenesin in children.

Antibiotics, corticosteroids, and humidified air

As most URTIs are viral in nature,²⁹ antibiotics have little role in symptom resolution,¹³ with a few notable exceptions such as streptococcal A tonsillitis.³⁰ No trials have evaluated the use of systemic corticosteroids. A Cochrane review did not identify any trials evaluating the effectiveness of heated, humidified air in children under 12.³¹

Dietary and herbal therapies

Several dietary and herbal therapies are marketed for symptom relief, of which the common agents are listed in [table 2](#). Honey has

the strongest evidence base in children over 1 year. A Cochrane review, which included six RCTs of 899 children, reported that honey reduces cough frequency, severity, and duration to a greater extent than no treatment, placebo, or diphenhydramine.¹⁸ A 2014 systematic review identified eight trials which reported a reduction in number of days absent from school or daycare in children who took probiotics compared with placebo (standardised mean difference, SMD -0.18, 98% CI -0.34 to -0.02), but the findings are limited by study quality and heterogeneity.²⁰ A systematic review of herbal therapies containing *Fatsia japonica* included three RCTs of 340 children and reported a positive effect on symptom improvement compared with usual care (RR 1.10, 95% CI 1.02 to 1.18).²⁴ However, the methodological quality of the trials was poor, and quality of evidence low. A single RCT of 138 children aged 2-11 using vapour rub identified a small improvement in sleep compared with placebo, no improvement in rhinorrhoea or cough, but a significant increase in adverse events including burning sensation of the skin in 28% of participants.³²

Limited and low quality evidence supports the use of Chinese patent (herbal) medicines, *Pelargonium sidoides* extract, and *Andrographis paniculata* (Chuān Xīn Lián) to relieve symptoms in children.

Safety concerns

Concerns about the safety of cough and common cold therapies in children have been reported for several decades. Most relate to adverse effects associated with use in therapeutic doses, effects associated with overdose (poisoning) and/or unintended exposure, and effects associated with contaminants.

At therapeutic doses, the risks of harms do not appear increased ([tables 1 and 2](#)). However, considering the lack of clear benefit, the low overall quality of evidence (except for honey and probiotics), and costs to families, the rationale for use of these therapies is highly debatable. Certain medications, however, should never be used in children with URTIs. Aspirin, when used as an analgesic or antipyretic, has been associated with Reye's syndrome, a rare but severe and potentially fatal illness characterised by abnormal liver function and encephalopathy, which is fatal in up to 40% of cases. Many natural health products also have potential risks in children, either related to use in certain populations (eg, pasteurised honey in infants under 12 months), or because of unknown data on safety in children because of a lack of regulation. Overuse of antibiotics is a serious global healthcare problem, and they have no role in children with URTIs.³³

Of greater concern is the risk of harm when children are unintentionally exposed to cough and common cold therapies in toxic doses. In a surveillance study involving 4756 children under 12 who were evaluated at a healthcare facility in the US after being exposed to cough and common cold therapies, unsupervised ingestions were the most common reason for encounter (69.5%).³⁴ In this study, the frequency of adverse events resulting in hospital admissions increased significantly from 32.4% in 2009 to 43.4% in 2016 ($P<0.01$). The hospital admissions were largely related to exposures to diphenhydramine (1305; 67.3%) and/or dextromethorphan (591; 30.5%). A subsequent analysis of unsupervised ingestions (n=3134)³⁵ of dextromethorphan and diphenhydramine, either alone or in combination with other products, accounted for 96% of ingestions.

A surveillance study of 180 paediatric deaths (<12 years) between 2008 and 2016³⁶ in the US found that 40 (22.2%) were attributed to 50 different cough and common cold therapies—the most frequently implicated agent being diphenhydramine (n=28; 70.0%). None of the fatalities occurred at therapeutic doses. Use of medicine to

intentionally sedate a child resulted in six deaths, while seven deaths resulted from intention to end a child's life. Most fatal events are reported in children under 2.

In response to paediatric fatalities attributed to contaminated over-the-counter syrups, the World Health Organization in 2022 issued a medical product alert related to four products implicated in the fatalities.^{6,37} These products were found to contain unacceptably high concentrations of diethylene glycol and ethylene glycol as contaminants. It is thought that the lack of robust drug regulation, especially in low and middle income countries, was responsible for the proliferation of these products.³⁷

Advice to practitioners

Deciding children's medications can be confusing and overwhelming for parents and caregivers. Practitioners can help by clarifying labels on products that promise symptom relief, explaining medication risk, and advising on when to seek additional medical care. They can provide evidence based information regarding symptom management at home, including pharmacological, psychological, and physical strategies, and red flags to be aware of (see infographic). This includes providing information about the course of URTIs (eg, cough lasts for 10 days in 50% of children and three weeks in 10%,^{3,38} and explaining that young children typically experience between six and eight infections per year²). Practitioners should individualise recommendations based on the child's age, weight, medical history, financial resources, and/or culture. Some parents may need help getting their child to take medication, such as strategies to teach pill swallowing.

Education into practice

- In children who present with an URTI, do you routinely ask what types of over-the-counter treatments their parents or caregivers are giving?

- What advice do you give parents to help them manage their child's bothersome symptoms?
- What safety netting advice do you provide to families?

How patients were involved in the creation of this article

Francine Buchanan, a parent adviser with no medical training, was a coauthor on this article. She consulted with other parents and together they highlighted the information parents deemed most important when seeking over-the-counter treatments for their child's cold symptoms. The parents' recommendations were considered when developing the content of the article, and how the information was organised and presented. As a member of the authorship group, the parent coauthor was involved in all group meetings, and their input, written contributions, and recommendations were considered on par with fellow coauthors.

How this article was made

We conducted electronic searches on PubMed via the Clinical queries filter, and using the following search terms: Over-the-counter, antitussives, antibiotics, corticosteroids, analgesics, herbal medicines, herbal remedies, probiotics, homeopathy, adverse events, safety and fatality. Each of the search terms was combined separately with cough (or cold) and children using the therapy/broad filter. The searches were conducted until February 2023. We used the following algorithm to narrow down the highest levels of evidence for each intervention: systematic review > randomised clinical trial > observational studies. We primarily included systematic reviews because they represent the highest levels of published evidence. If we identified two or more systematic reviews for a specific intervention, the most recent and comprehensive review was used to examine the evidence. We also checked the bibliographies of selected studies to identify other potentially relevant studies. Where identified reviews included both adults and children, we extracted only the data relevant for the paediatric population.

Treating a child with a cough or cold



Red flags

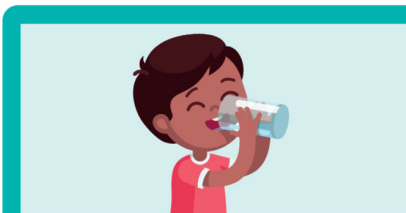
Requiring further medical attention

- Fever in an infant <3 months of age
- Prolonged fever for >3 days
- Dehydration, poor feeding, or fewer wet nappies/diapers (<50%)
- Increased work of breathing, or fast breathing
- Features of Kawasaki disease (eg, red eyes, red lips, rash, extremity changes)
- Petechial rash
- Seizures
- Limp, listless, or lethargic appearance
- Severe headache, confusion, and vomiting
- Parent/caregiver is distressed about the child's symptoms or feel this illness is different from previous illnesses



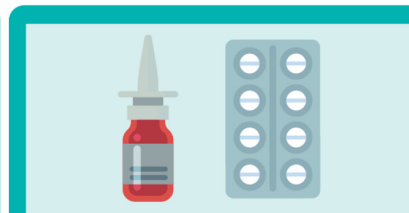
Rest is the best

Ensure the child rests; suggest relaxation and comfort positioning



Keep them hydrated

Ensure the child drinks adequate fluids and stays hydrated



Manage the discomfort

Manage the child's discomfort, with symptom support or treatments (eg., nasal drops).

Encourage pill swallowing techniques, distraction, and comfort measures

Symptom management

Nasal congestion/ runny nose



Saline nasal irrigation (saline drops/sprays)

- A low risk treatment option.
- Limited evidence it provides symptom relief over no intervention.

Cough/sore throat



Honey (pasteurised)

- A low risk treatment option that may reduce cough frequency and severity. Some children may experience nausea.
- Children <1 year should not be given honey

Fever



Acetaminophen/paracetamol/ ibuprofen

When used in safe doses, have been shown to alleviate discomfort due to fever, aches, and pains

DO NOT USE ASPIRIN

Over the counter cough and cold syrups are not recommended for children <6 years

Cough and common colds are self-limiting illnesses that resolve without intervention in up to 10 days. Most treatments will not shorten the length of illness but may relieve a child's discomfort by alleviating bothersome symptoms

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Contributorship and the guarantor: PJG conceptualised the article, conducted an initial literature review, developed the article outline, and led subsequent revisions. IJO conducted further reviews of the literature and revised subsequent drafts of the manuscript. IJO created the first draft of [tables 1 and 2](#), which were revised by PJG, FB, KB and AVdB. PJG, IJO, FB, KB, and AVdB reviewed and revised the manuscript. PJG is the guarantor.

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