Clinical pathways for chronic cough in children (Review)

Bailey EJ, Morris PS, Kruske SG, Chang AB

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Clinical pathways for chronic cough in children (Review)

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Clinical pathways for chronic cough in children

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Editorial group: Cochrane Airways Group.

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Review content assessed as up-to-date: 9 July 2009.


ABSTRACT

Background

Chronic cough (a cough lasting longer than 4 weeks) is a common symptom presenting to primary care in Australia and internationally. Chronic cough costs the community, is distressing to parents, and ignoring cough may lead to delayed diagnosis and illness progression of serious underlying respiratory disease. Clinical guidelines have been shown to provide more efficient and effective patient care and can clarify clinical decision making. Cough guidelines have been designed to facilitate management of chronic cough, however treatment recommendations vary and specific clinical pathways for the treatment of chronic cough in children are important, as the cause and treatments for cough in a child vary significantly adults. Therefore, it would be beneficial to clinical practice to systematically evaluate the use of clinical pathways for the treatment of chronic cough in children.

Objectives

To evaluate the effectiveness of using a clinical pathway in the management of children with chronic cough.

Search methods

The Cochrane Register of controlled Trials (CENTRAL), the Cochrane Airways Group Specialised Register, MEDLINE, EMBASE, review articles and reference lists of relevant articles were searched. The search was carried out in June 2009.

Selection criteria

All randomised controlled trials with parallel group design comparing use vs non-use of a clinical pathway for treatment of chronic cough in children.

Data collection and analysis

Results of searches were reviewed against the pre-determined criteria for inclusion. Two reviewers independently selected the studies and it was planned that data extraction would have been done in duplicate.

Main results

The search identified 471 potentially relevant titles but no studies met criteria for inclusion in the review.
Authors’ conclusions

Without further available evidence, recommendations for the use of clinical pathways for the treatment of chronic cough in children cannot be made. Until further evidence is available, the decision for further investigation and treatment for the child presenting with chronic cough should be made on an individual basis (i.e. dependent on symptoms and signs) with consideration for existing data from other Cochrane reviews on specific treatments for cough. Trials are required to provide evidence on the effectiveness of clinical pathways for the treatment of chronic cough in children.

Plain Language Summary

Clinical pathways for chronic cough in children

Clinical pathways are used for various chronic diseases to facilitate diagnosis; aid decision making; and provide efficient care to patients. Chronic cough in children is a significant medical problem and in some situations, warrants thorough investigation. This review examined whether using clinical pathways for investigating and managing children with chronic cough were effective. No studies were found that used a clinical pathway for chronic cough in children. Therefore there is insufficient data to make recommendations regarding the use of clinical pathways for chronic cough in children.

Background

Cough is the most common symptom presenting to primary care in Australia and internationally (Irwin 2006; Britt 2002; Cherry 2003). In Australia, 5.8 of every 100 visits to general practitioners are for cough (Britt 2008). Chronic (prolonged) cough is also one of the most common presenting symptoms to respiratory physicians (Fitzgerald 2006). The burden of chronic cough (defined in children as a cough of >4 weeks duration (Marchant 2006; Chang 2006b)) is significant; both in terms of personal cost with impaired quality of life, and at a societal level where medication costs are substantial. Cough related illness costs the Australian community millions of dollars per year in Medicare rebates for GP visits. This does not include costs for visits to specialists.

Chronic cough in children causes a significant burden of distress to parents (Cornford 1993). Furthermore, while cough may be seen as a mere troublesome symptom without any serious consequences, ignoring cough that may be the sole presenting symptom of an underlying respiratory disease may lead to delayed diagnosis and progression of a serious illness or chronic respiratory morbidity (Karaloc 2002, Bart 2005). Thus in the management of chronic cough in children, it is important to define which patients will benefit from which intervention and treatment approaches (including ‘watchful waiting’ Gupta 2007).

Cough guidelines, first initiated by Irwin (Irwin 1990) were designed to facilitate the management of chronic cough. Subsequent cough guidelines have since been published by various societies. Currently, treatment recommendations vary between the published guidelines (Irwin 2006, Shields 2007, Kohno 2006) and of these, not all include the use of a clinical pathway or a pathway specific to children. We (Chang 2005, Marchant 2006; Chang 2006a) and others (Shields 2006) have argued that children with chronic cough should be evaluated and managed in accordance with guidelines specific to children, as both the etiologic factors and treatment in children have significant differences to those in adults (Chang 2006b).

The major aim of clinical pathways or guidelines is generally to improve diagnosis and/or management of the specific condition or symptom. Clinical guidelines have been shown to provide more efficient and effective patient care (Fessler 2005) and, if well designed, can clarify clinical decision making. This is turn should reduce variations in care delivery and delay in diagnosis or treatment (Kwan 2004). However, the use of guidelines is not universally popular in medical circles (Preiser 2004) and may arguably result in negative outcomes (e.g. from missed or delayed diagnosis). Clinical guidelines are regarded by some as ’cook-book medicine’, bothersome and negating critical thinking (Berg 1997). Examination through a systematic review of the effectiveness of using a clinical pathway in treating children with chronic cough would therefore be useful to guide clinical practice.

Objectives

To evaluate the effectiveness of using a clinical pathway in the management of children with chronic cough.
METHODS

Criteria for considering studies for this review

Types of studies
All randomised controlled trials with parallel group design comparing use vs non-use of a clinical pathway for treatment of chronic cough in children.

Types of participants
Children with chronic (>4 weeks) cough with an unknown aetiology for their cough.
Exclusion criteria: known pre-existing respiratory illness causing their cough.

Types of interventions
All randomised controlled comparisons of use of a clinical pathway. It was planned that trials that included the use of other medications or interventions would be included if all participants had equal access to such medications or interventions.

Types of outcome measures

Primary outcomes
a) proportions of participants who were not cured or not substantially improved at follow up (clinical failure).
Secondary outcomes:
b) proportions of participants who were not cured at follow up,
c) proportions of participants who were not substantially improved at follow up,
d) mean difference in cough indices (cough diary, cough frequency, cough scores),
e) proportions of participants experiencing adverse effects of the intervention (e.g. Cushing's syndrome from steroid overdose, etc)
f) proportions of participants experiencing complications e.g. acute hospitalisations or development of chronic lung disease from delayed diagnosis

Secondary outcomes
It was planned that the proportions of participants who failed to improve on treatment and the mean clinical improvement would be determined using the following hierarchy of assessment measures (i.e. where two or more assessment measures were reported in the same study, the outcome measure that is listed first in the hierarchy would be used):

i) Objective measurements of cough indices (cough frequency, cough receptor sensitivity).
ii) Symptomatic (Quality of life, Likert scale, visual analogue scale, level of interference of cough, cough diary) - assessed by the patient (adult or child)
iii) Symptomatic (Quality of life, Likert scale, visual analogue scale, level of interference of cough, cough diary) - assessed by the parents/carer
iv) Symptomatic (Likert scale, visual analogue scale, level of interference of cough, cough diary) - assessed by clinicians

Search methods for identification of studies
The following topic search strategy was used to identify relevant randomised controlled trials from the electronic databases:
"cough" OR "bronchitis", all as (textword) or (MeSH) AND "clinical guidelines" OR "guidelines" OR "clinical pathway" OR "pathway" (OR synonyms) AND "child" (OR synonyms); all as (textword) or (MeSH) AND "trial" (OR synonyms); all as (textword) or (MeSH).
See Table 1 for the full search strategies.
Trials were identified from the following sources:
1. The Cochrane Central Register of Controlled Trials (CENTRAL) Issue 2, 2009
2. The Cochrane Airways Group Specialised Register.
3. MEDLINE (1966 to May Wk 5, 2009). Topic search strategy combined with the RCT search filter as outlined in the Airways Group module.
4. OLDMEDLINE (1950 to 65). Topic search strategy combined with the RCT search filter as outlined in the Airways Group module.
5. EMBASE (1980 to Wk 23, 2009). Topic search strategy combined with the RCT search filter as outlined in the Airways Group module.
6. The list of references in relevant publications.
7. Written communication with the authors of trials included in the review.

Data collection and analysis

Selection of studies
Retrieval of studies: From the title, abstract, or descriptors, two reviewers (EJB, ABC) independently reviewed literature searches to identify potentially relevant trials for full review. Searches of bibliographies and texts were conducted to identify additional studies. From the full text using specific criteria, the same two reviewers independently assessed trials for inclusion. Disagreement was resolved by third party adjudication (PM).
Data extraction and management

It was planned that trials that satisfied the inclusion criteria would be reviewed and the following information recorded: study setting, year of study, source of funding, patient recruitment details (including number of eligible subjects), inclusion and exclusion criteria, other symptoms, randomisation and allocation concealment method, numbers of participants randomised, blinding (masking) of participants, care providers and outcome assessors, type of intervention, co-interventions, numbers of patients not followed up, reasons for withdrawals from study protocol (clinical, side-effects, refusal and other), details on side-effects of therapy, and whether intention-to-treat analyses were possible. Data were planned to be extracted on the outcomes described previously. Further information was requested from the authors where required.

Assessment of risk of bias in included studies

It was planned that studies included in the review would undergo quality assessment performed independently by 2 reviewers. Four components of quality would be assessed:

1. Allocation concealment. Trials would be scored as: Grade A: Adequate concealment, Grade B: Unclear, Grade C: Clearly inadequate concealment. (Grade A = high quality).
2. Blinding. Trials would be scored as: Grade A: Participant and care provider and outcome assessor blinded, Grade B: Outcome assessor blinded, Grade C: Unclear, Grade D: No blinding of outcome assessor (Grade A, B = high quality).
3. Reporting of participants by allocated group. Trials would be scored as: Grade A: The progress of all randomised children in each group described, Grade B: Unclear or no mention of withdrawals or dropouts, Grade C: The progress of all randomised children in each group clearly not described. (Grade A = high quality).
4. Follow-up. Trials would be scored as: Grade A: Outcomes measured in >90% (where withdrawals due to complications and side-effects are categorised as treatment failures), Grade B: Outcomes measured in 80-90%, Grade C: Unclear, Grade D: Outcomes measured in <80%. (Grade A = high quality).

While only the allocation concealment quality assessments would be displayed in the meta-analysis figures, all assessments would be included in the “Characteristics of included studies” table. Inter-reviewer reliability for the identification of high quality studies for each component would be measured by the Kappa statistic.

Measures of treatment effect

For the dichotomous outcome variables of each individual study, it was planned that odds ratios would be calculated using a modified intention-to-treat analysis. This analysis assumes that children not available for outcome assessment have not improved (and probably represents a conservative estimate of effect). Other indices would be assumed to be normally distributed continuous variables so the mean difference in outcomes could be estimated (weighted mean difference). If studies reported outcomes using different measurement scales, the standardised mean difference would be estimated.

Assessment of heterogeneity

Any heterogeneity between the study results would be described and tested to see if it reached statistical significance using the I² statistic (Higgins 2003). Heterogeneity is considered significant when the P value is < 0.10 (Higgins 2005).

Data synthesis

An initial qualitative comparison of all the individually analysed studies was planned to examine whether pooling of results (meta-analysis) was reasonable. This would have taken into account differences in study populations, inclusion/exclusion criteria, interventions, outcome assessment, and estimated effect size. The results from studies that met the inclusion criteria and reported any of the outcomes of interest would be included in the subsequent meta-analyses.

The summary weighted odds ratio and 95% confidence interval (fixed effects model) would be calculated (Cochrane statistical package, RevMan). Numbers needed to treat (NNT) would be calculated from the pooled OR and its 95% CI applied to a specified baseline risk using an online calculator (Cates 2003).

Subgroup analysis and investigation of heterogeneity

An a priori sub-group analysis was planned for children aged less than 7 years and 7 years and above.

Sensitivity analyses were planned to assess the impact of the potentially important factors on the overall outcomes:

a) analysis by type of clinical pathway (e.g. continent-specific)
b) analysis by settings whereby frequency of aetiology of chronic cough may be different (general practice vs specialists, affluent vs non-affluent countries, Indigenous vs mainstream communities, etc)
c) analysis using random effects model;
d) analysis by “treatment received”; and
e) analysis by “intention-to-treat”.

The 95% confidence interval estimated using a random effects model would be included whenever there are concerns about statistical heterogeneity.

RESULTS

Description of studies

See: Characteristics of excluded studies.
The searches identified 6 potential studies but none fulfilled the study eligibility criteria.

Risk of bias in included studies

Not applicable.

Effects of interventions

The Airways Group search identified 471 potentially relevant titles. After assessing the abstracts, 6 studies were considered for inclusion into the review but none fulfilled the study eligibility criteria. These are summarised in the ‘characteristics of excluded studies’ table.

DISCUSSION

No randomised controlled trials of clinical pathways for the management of chronic cough in children were identified. One RCT (Rutten 1991) was found examining changes in patient consulting behaviour for cough following an educational intervention. This trial was not included as specific data for children was not presented. We contacted the author regarding this, however separate data for children was not available. Also this study did not specifically trial a clinical pathway for the management of chronic cough, but rather examined the effect of an educational intervention aimed at modifying the consulting behaviour of the patient for subsequent presentations for cough. This study also did not limit participation to those with a chronic cough as opposed to an acute cough episode.

Several cohort studies describe the use of clinical pathways for the management of various respiratory conditions, including tuberculosis (English 2006) and acute respiratory infections (Flores-Hernandez 1999) (see excluded table). English 2006 et al showed that the use of a standardised clinical pathway for assessment and diagnosis of tuberculosis by a Nurse Practitioner was associated with a 68% increase in the rate of tuberculosis case detection. Flores-Hernandez 1999 et al found that a clinical pathway for acute respiratory infections, inappropriate prescribing of antibiotics and cough syrups was decreased.

AUTHORS’ CONCLUSIONS

Implications for practice

Without further available evidence, recommendations for the use of clinical pathways for the treatment of chronic cough in children cannot be made. Until further evidence is available, the decision for further investigation and treatment for the child presenting with chronic cough should be made on an individual basis (i.e. dependent on symptoms and signs) with consideration for existing data from other Cochrane reviews on specific treatments for cough.

Implications for research

Randomised controlled trials are needed for the evaluation of the use of clinical pathways for the management of chronic cough in children. In these trials, outcome measures should include cough resolution rates and Quality of Life outcomes in addition to clinical outcomes.

ACKNOWLEDGEMENTS

We thank Chris Cates and Toby Lasserson for their advice, supportive role and comments to the protocol and review. We also thank Susan Hansen for performing the search and for obtaining the relevant articles.

REFERENCES

References to studies excluded from this review


**Rutten 1991** *(published and unpublished data)*

**Spelman 1991** *(published data only)*

**Additional references**

**Barr 2005**

**Berg 1997**

**Britt 2002**

**Britt 2008**

**Cates 2003**

**Chang 2005**
Chang AB. Cough: are children really different to adults?. *Cough* 2005;1:7.

**Chang 2006a**

**Chang 2006b**

**Cherry 2003**

**Cornford 1993**

**Elbourne 2002**

**Fessler 2005**

**Fitzgerald 2006**

**Gupta 2007**

**Higgins 2003**

**Higgins 2005**

**Irwin 1990**

**Irwin 2006**

**Karakoc 2002**

**Kohno 2006**

**Kwan 2004**

**Marchant 2006**
Preiser 2004

Shields 2006

Shields 2007

* Indicates the major publication for the study
## Characteristics of excluded studies [ordered by study ID]

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<td>English 2006</td>
<td>Study excluded as not RCT and not examining use of a pathway for chronic cough. Study was a cross-sectional evaluation of the accuracy of guidelines for screening patients for tuberculosis. Study found that with the implementation of clinical guidelines for Nurse Practitioner screening of patients for suspected tuberculosis infection, there was a 68% increase in the rate of tuberculosis case detection</td>
</tr>
<tr>
<td>Flores-Hernandez 1999</td>
<td>Study excluded as not RCT and not examining the use of a clinical pathway for chronic cough in children. Before and after study of clinical guidelines for the management of acute respiratory infections, finding that after the implementation of management guidelines, inappropriate prescribing of antibiotics and cough syrups was decreased</td>
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<tr>
<td>Hover 2000</td>
<td>Study excluded as not RCT and not examining chronic cough in children. Study was an evaluation, via a pre- and post-analysis and randomised chart review, of the implementation of the American Academy of Pediatrics’ principles for the management of common office infections. Study did not utilise a clinical pathway and did not treat children with chronic cough</td>
</tr>
<tr>
<td>Norton 2007</td>
<td>A prospective cohort study examining the effectiveness of a clinical pathway at reducing hospitalisation for acute asthma episodes in children presenting to the Emergency Department of a children's hospital. Study showed that after implementation of the clinical pathway, hospital admissions in children with moderate to severe asthma were reduced by &gt;50% without an increase in re-presentations. Excluded as not RCT and pathway designed for acute asthma care, not chronic cough</td>
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<tr>
<td>Rutten 1991</td>
<td>RCT examining the use of an education program (patient handout) about cough and the effect on the consulting behaviour of patients after receiving the intervention. Study excluded as reported patient numbers did not specify numbers of children. We contacted the author to seek the numbers relevant for children the data was not available. Study also excluded as the intervention used was not a clinical pathway, and the intervention was used for patients presenting for acute cough episodes, not chronic cough</td>
</tr>
<tr>
<td>Spelman 1991</td>
<td>Prospective cohort study, examining the hypothesis that children with a chronic cough will develop asthma. 106 patients with a chronic cough, aged less than 10 years, from Irish General Practitioners, were treated according to an asthma protocol for 16 weeks. Follow up 2 years later showed that 71 children had been subsequently diagnosed with asthma. Study excluded as not RCT and the protocol used was not specific to the treatment of chronic cough in children</td>
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DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Search strategies

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<td>7 exp &quot;guideline [publication type]&quot;/</td>
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<td>or good clinical practice/ or nursing care plan/ or nursing protocol/</td>
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<td>8 or/5-7</td>
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<td>11 exp pediatrics/</td>
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<td>12 (child$ or paediat$ or pediat$ or adolesec$ or infant$ or toddler$ or bab$ or young$ or preschool$ or pre school$ or preschool$ or newborn$ or new born$ or new born$ or neo-nat$ or neonat$).mp.</td>
<td>or exp newborn/</td>
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WHAT'S NEW

Last assessed as up-to-date: 9 July 2009.

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<td>22 June 2009</td>
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HISTORY

Review first published: Issue 2, 2008

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CONTRIBUTIONS OF AUTHORS

Protocol was written by EJB and ABC, based on previous protocols for chronic cough in children. PSM reviewed protocol. EJB and ABC reviewed abstracts and articles and wrote review. PSM and SGK reviewed the manuscript.

DECLARATIONS OF INTEREST

EJB, ABC and PSM are involved in a multicentre RCT of a management protocol for the treatment of chronic cough in children.

SOURCES OF SUPPORT

Internal sources

- Royal Children's Hospital Foundation, Brisbane, Australia.
External sources

- National Health and Medical Research Council, Australia.

INDEX TERMS

Medical Subject Headings (MeSH)

*Critical Pathways; Chronic Disease; Cough [*therapy]

MeSH check words

Child; Humans