

The clinical effectiveness and cost-effectiveness of inhaler devices used in the routine management of chronic asthma in older children: a systematic review and economic evaluation

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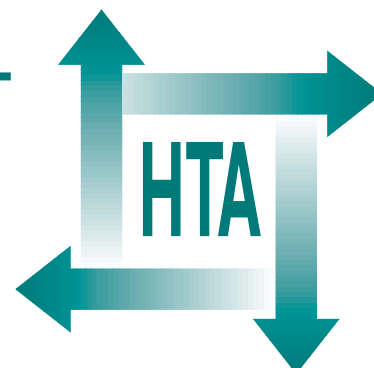
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Executive summary

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Executive summary

Background

This review examines the clinical effectiveness and cost-effectiveness of hand-held inhalers to deliver medication for the routine management of chronic asthma in children aged between 5 and 15 years.

Asthma is a common disease of the airways, with a prevalence of treated asthma in 5–15-year-olds of around 12% and an actual prevalence in the community as high as 23%. Treatment for the condition is predominantly by inhalation of medication. There are three main types of inhaler device, pressurised metered dose, breath actuated, and dry powder, with the option of the attachment of a spacer to the first two devices under some prescribed circumstances. Two recent reviews have examined the clinical and cost-effectiveness evidence on inhaler devices, but one was for children aged under 5 years and the comparison in the second was made between pressurised metered dose inhalers and other types only.

Objectives

This review examines the clinical effectiveness and cost-effectiveness of manual pressurised metered dose inhalers, breath-actuated metered dose inhalers, and breath-actuated dry powder inhalers, with and without spacers as appropriate, to deliver medication for the routine management of chronic asthma in children aged between 5 and 15 years.

Methods

Two previous HTA reviews have compared the effectiveness of inhaler devices, one focusing on asthma in children aged under 5 years and the other on asthma and chronic obstructive airways disease in all age groups. For the current review, a literature search was carried out to identify all evidence relating to the use of inhalers in older children with chronic asthma. A search of *in-vitro* studies undertaken for one of the previous reviews was also updated.

The data sources used were: 15 electronic bibliographic databases; the reference lists of one of the previous HTA reports and other relevant articles;

health services research-related internet resources; and all sponsor submissions.

Studies were selected according to strict inclusion and exclusion criteria, and relevant information concerning effectiveness and patient compliance and preference was extracted directly on to an extraction/evidence table. Quality assurance was monitored.

Economic evaluation was undertaken by reviewing existing cost-effective evidence. Further economic modelling was carried out, and tables constructed to determine device cost-minimisation and incremental quality-adjusted life-year (QALY) thresholds between devices.

Results

Number and quality of studies, and direction of evidence

Fourteen randomised controlled studies were identified relating to the clinical effectiveness of inhaler devices for delivering β_2 -agonists. A further five were on devices delivering corticosteroids and one concerned the delivery of cromoglicate. Overall, there were no differences in clinical efficacy between inhaler devices, but a pressurised metered dose inhaler with a spacer would appear to be more effective than one without. These findings endorse those of a previous HTA review but extend them to other inhaler devices.

Seven randomised controlled trials examined the impact on clinical effectiveness of using a non-chlorofluorocarbon (CFC) propellant in place of a CFC propellant in metered dose inhalers, both pressurised and breath activated, although only one study considered the latter type. No differences were found between inhalers containing either propellant.

A further 30 studies of varying quality, from 12 randomised controlled trials to non-controlled studies, were identified that concerned the impact of use by, and preference for, inhaler type, and treatment adherence in children. Differences between the studies, and limitations in comparative data between various inhaler device types, make it difficult to draw any firm conclusions from this evidence.

Summary of benefits

No obvious benefits for one inhaler device type over another for use in children aged 5–15 years were identified.

Costs and cost per quality-adjusted life-year

Two approaches have been taken: cost-minimisation and QALY threshold. In the QALY threshold approach, additional QALYs that each device must produce compared with a cheaper device to achieve an acceptable cost per QALY were calculated. Using the cheapest and most expensive devices for delivering 200 µg of beclometasone per day, assuming no cost offset for any device, and a threshold of £5000, the largest QALY needed was 0.00807. With such a small QALY increase, no intervention can be categorically rejected as not cost-effective.

Conclusions

Generalisability of findings

On the available evidence there are no obvious benefits for one inhaler device over another when used by children aged 5–15 years with chronic asthma. However, the evidence, in the majority of cases, was compiled on children with mild to moderate asthma and restricted

to a limited number of drugs. Therefore the findings may not be generalisable to those at the more severe end of the spectrum of the disease or to inhaler devices delivering some of the drugs used in the management of asthma.

Need for further research

Many of the previous studies are likely to have been underpowered. Further clinical trials with a robust methodology, sufficient power and qualitative components are needed to demonstrate any differences in clinical resource use and patients' asthma symptoms. Further studies should also include the behavioural aspects of patients towards their medication and its delivery mechanisms. It is acknowledged that sufficient power may prove impractical owing to the large numbers of patients required.

Publication

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The research reported in this monograph was commissioned by the HTA Programme on behalf of the National Institute for Clinical Excellence (NICE). Rapid reviews are completed in a limited time to inform the appraisal and guideline development processes managed by NICE. The review brings together evidence on key aspects of the use of the technology concerned. However, appraisals and guidelines produced by NICE are informed by a wide range of sources.

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