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Title **Systematic Review and Economic Analysis of the Comparative Effectiveness of Different Inhaled Corticosteroids and Their Usage with Long Acting Beta2 Agonists for the Treatment of Chronic Asthma in Children under the Age of 12 Years**

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Aim

To assess the clinical and cost effectiveness of inhaled corticosteroids (ICS) alone, beclometasone dipropionate (BDP), budesonide (BUD), fluticasone propionate (FP), and ICS used in combination with a long-acting beta2 agonist (LABA), salmeterol (SAL), or formoterol fumarate (FF) in treating chronic asthma in children aged under 12 years.

Conclusions and results

Limited evidence indicates no consistent significant differences in effectiveness between the 3 ICS licensed for use in children at either low or high dose. BDP CFC-propelled products are often the cheapest ICS available at both low and high dose, and may remain so even when CFC-propelled products are excluded. Exclusion of CFC-propelled products increases the mean annual cost of all budesonide (BUD) and BDP, while the overall cost differences between the comparators diminish. Very limited evidence on the efficacy and safety of ICS and LABAs in children suggests no significant clinical differences in effects between using a combination inhaler versus the same drugs in separate inhalers. In the absence of any evidence concerning the effectiveness of ICS at higher dose with ICS and LABA, a cost-consequence analysis gives mixed results. Potentially, costs can be saved by using combination inhalers compared to separate inhalers. At present prices, the BUD/FF combination is more expensive than those containing FP/SAL, and no clinically significant differences are shown between them. A direct head-to-head trial comparing the two combination therapies of FP/SAL and BUD/FF is warranted. It is important to assess whether the addition of a LABA to a lower dose of ICS could potentially be as effective as an increased dose of ICS alone, but also be steroid sparing. Long-term adverse events associated with using ICS need to be systematically assessed. Future trials of treatment for chronic asthma in children should aim to standardize outcome measures. See Executive Summary link at www.hta.ac.uk/project/1524.asp.

Recommendations

See Executive Summary link at www.hta.ac.uk/project/1524.asp.

Methods

See Executive Summary link at www.hta.ac.uk/project/1524.asp.

Further research/reviews required

A scoping review is needed to assess the requirements for additional primary research on the clinical effectiveness of treatment for asthma in children aged under 5 years. Such a review could include all treatment options (pharmacological and nonpharmacological) for asthma. No trial evidence is currently available to inform the relative effectiveness of the two combination inhalers of FP/SAL and BUD/FF in a pediatric population. The current assessment found no significant differences in effectiveness of FP/SAL when the drugs were delivered via a single inhaler or concurrently in two separate inhalers. However, as ease of treatment regimen may affect concordance, a direct head-to-head trial comparing the two combination therapies of FP/SAL and BUD/FF is warranted.

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