One-year claims analysis comparing inhaled fluticasone propionate with zafirlukast for the treatment of asthma

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The health technology under investigation was the use of inhaled corticosteroids (ICSs), specifically fluticasone propionate (FP), in the treatment of asthma.

Type of intervention
Treatment and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised male and female patients starting a controller therapy for asthma. Patients had to have been continuously enrolled in their health plan for at least 9 months before and 12 months after the index event defined as a first prescription for FP or ZA. During the 9-month period before the index date, patients could not have been prescribed any ICS or leukotriene modifier. Patients taking salmeterol were also excluded from the analysis, to avoid possible confounding effects of this additional controller in the postindex period.

Setting
The setting was the community. The study was based on United Health Care-affiliated plans carried out in the USA.

Dates to which data relate
The effectiveness evidence, resources use data, and costs were obtained from administrative data from 13 United Health Care-affiliated plans, for the period October 1995 through December 1998.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costs were estimated using health care charges for the same sample.

Study sample
All patients from the database who met the inclusion criteria were included in the analysis. There were 725 patients who were FP users: 234 (32.3%) received 44 microg FP, 368 (50.6%) received 110 microg, and 123 (17.0%) received 220 microg. In addition, there were 309 patients who were identified and analysed as ZA users. Patient demographics, i.e. age and gender, were presented according to treatment and dose.
Study design
A retrospective study was performed, based on administrative data from 13 United Health Care-affiliated plans. The data for patients with full 21-month follow-up (9 months before and 12 months after the index event) were included in analysis.

Analysis of effectiveness
The primary effectiveness measures used in this retrospective database study were asthma-related ED visits and asthma-related hospitalisation rates.

The mean age of patients in the ZA group was 39.4 years; this was higher than that in the FP patients, 33.2 years. A higher proportion of the ZA patients had had a preindex event compared to FP: ED visits 8.7% and asthma hospitalisation 2.9% versus ED visits 6.1% and asthma hospitalisation 3.3%. The baseline rates for ED visits and hospitalisation were higher with increasing doses of FP.

The study estimates were adjusted for differences in baseline characteristics using the models described previously.

Effectiveness results
Compared with ZA, the adjusted OR for FP was 0.30 (95% confidence interval, CI: 0.11 - 0.85; P=0.0232) for hospitalisation, and 0.51 (95% CI: 0.26 - 1.01; P=0.0546) for ED visits.

The adjusted OR of either event was 0.49 (95% CI: 0.26 - 0.92; P=0.0262).

The ORs for ED visits consistently favoured the 44, 110 and 220 microg doses of FP, but only the 220 microg dose was statistically significant. (p=0.0289).

The ORs for hospitalisations also consistently favoured all three FP doses.

Clinical conclusions
Inhaled FP produces a significant reduction in the number of combined hospitalisations and ED visits than ZA, in the treatment of patients with a diagnosis of asthma who are beginning maintenance therapy.

Modelling
A logistic regression was used to adjust the odds ratios (ORs) of visits to emergency departments (ED) or hospitalisation events for FP users, compared with ZA users. The ORs were adjusted for age, gender, preindex health care costs, preindex co-morbidities (chronic obstructive airway disease), preindex concomitant asthma medications (beta-agonists and oral corticosteroids), and preindex ED visits or hospitalisation.

A linear regression was used to adjust the difference in monthly costs per treated patient between the postindex and preindex periods for FP users, compared with ZA users. The changes in costs were adjusted for age, gender, preindex health care costs, preindex co-morbidities, and preindex concomitant asthma medications.

Measure of benefits used in the economic analysis
The authors did not derive a measure of health benefit. The study was therefore categorised as a cost-consequences analysis.

Direct costs
The costs were incurred over a period less than 2 years and no discounting was necessary. The costs were analysed on the basis of patients’ charges. The costs included asthma pharmacy costs, total pharmacy costs, annual prescription...
claims for the index medications, total asthma and total health care costs. The resource quantities and unit costs were not reported separately.

**Statistical analysis of costs**
The costs were treated in a stochastic way, and CIs and p-values were reported.

**Indirect Costs**
No indirect costs were analysed.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The total asthma costs were lower for FP users than ZA users. The adjusted incremental total monthly asthma costs were negative, and this difference was consistent across different FP doses:

ZA versus FP, -$17.89 (p<0.001);

ZA versus 44 microg FP, -$18.51 (p<0.0004);

ZA versus 110 microg FP, -$16.02 (p<0.0015);

ZA versus 220 microg FP, -$16.97 (p<0.0219).

The adjusted incremental monthly health care costs were also consistently in favour of FP. The differences were not statistically significant:

ZA versus FP, -$44.20 (p<0.33);

ZA versus 44 microg FP, -$85.15 (p<0.17);

ZA versus 110 microg FP, -$35.14 (p<0.55);

ZA versus 220 microg FP, -$54.14 (p<0.5).

**Synthesis of costs and benefits**
Not applicable.

**Authors’ conclusions**
The authors concluded that the study demonstrated that inhaled FP produced significantly better outcomes than ZA in treatment of asthma patients starting maintenance therapy, as measured by the reduction in combined hospitalisations and ED visits. These results complement the position of the NIH Guidelines for the Diagnosis and Management of
Asthma that ICSs should be selected as first-line maintenance treatment for asthma.

**CRD COMMENTARY - Selection of comparators**
The selection of the comparator was justified as a possible first-line therapy for maintenance treatment for asthma, according to national and international guidelines.

**Validity of estimate of measure of effectiveness**
The study was based on a retrospective database of administrative data, a design that could not exclude possible selection biases. In addition, the study sample included only patients enrolled in United Health Care-affiliated plans for the whole study follow-up, and it was unclear how representative of the general population this was. The authors did, however, make adjustments for possible confounders through the use of regression models. Asthma-related admissions and ED visits represented only one measure of outcome. The appropriateness of this depends on consideration of other outcomes, in particular, individual preference or quality of life.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
All relevant direct costs seem to have been included in the analysis. The costs were estimated based on charges and this could have affected the generalisability of the cost results, especially given that costs were not reported separately from quantities and no sensitivity analysis was carried out. A statistical analysis of cost differences was performed.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies, but did not address the issue of generalisability to other settings. The authors do not appear to have presented their result selectively. They did, however, discuss the limitations due to the study design, and the possible impact of factors not included in the analysis.

**Implications of the study**
The authors support the use of ICSs as first-line maintenance treatment for asthma. The effectiveness evidence appeared to provide a useful contribution to knowledge, although generalisability of the results would have been enhanced had there been more information on the costs.

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