



Title	The Clinical and Cost Effectiveness of Inhaled Insulin in Diabetes Mellitus: A Systematic Review and Economic Evaluation
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Aim

To review the clinical effectiveness and cost effectiveness of a new technology, the inhaled insulin, Exubera®.

Conclusions and results

Nine trials of inhaled insulins were found, but only 7 used the Exubera form of inhaled insulin (five trials in type 1 and two in type 2 diabetes). Inhaled insulin is clinically effective. It is as good as short-acting soluble insulin in controlling blood glucose, plus it works slightly more quickly. Most patients in the trials were on combinations of short-acting, and either long- or intermediate-acting insulin, and in most trials, both were changed, making it difficult to assess the effects of only the change from soluble to inhaled insulin. Patient preference was the only significant difference between inhaled and soluble insulin in the trials. Most patients preferred inhaled to injected short-acting insulin. The control groups mostly used syringes and needles, rather than pens. As pens are more convenient, their use might have narrowed the patient satisfaction difference. There were no trials of inhaled insulin vs continuous subcutaneous insulin infusion (CSII). No serious adverse experiences of inhaled insulin in the lung have been observed, but it is too soon to judge long-term effects.

The manufacturer's model appears to be of high quality, although the results depend more on the assumptions fed into the model than on the model itself. Key assumptions are: the size of the gain in quality-of-life utility from inhaling rather than injecting insulin; the effect of having an inhaled option on the willingness to start insulin among people with poor diabetic control on oral drugs; and the effect on glycaemic control. We consider that the manufacturer's assumptions make the cost effectiveness appear better than it really would be. The manufacturer's submission assumed utility gains of 0.036 to 0.075 in patients with type 1 diabetes, and 0.027 to 0.067 in those with type 2 diabetes, based on an unpublished utility elicitation study sponsored by the manufacturer. These gains appeared optimistic.

However, patients having particular problems with injection sites might have more to gain, although they might also be a group with much to gain from CSII.

A key factor is the cost of inhaled insulin. Much more insulin has to be given by inhaler than by injection. Hence, the cost of inhaled insulin is much higher than injected. The extra cost depends on dosage, but ranges from around GBP 600 to over GBP 1000 per patient per year.

Recommendations

The inhaled insulin, Exubera, appears to be effective and, so far, safe. However, given the considerable incremental cost, it seems unlikely to the authors that it would be cost effective.

Methods

A systematic literature review was conducted and economic modeling carried out. Literature searches were done up to November 2005. The industry model, EAGLE, was used for modeling.

Further research/reviews required

Long-term research is recommended for safety purposes.