Cost-effectiveness analysis of enfuvirtide (ENF) added to an optimized therapy compared with an optimized therapy in patients with HIV/AIDS
Badia X, Lizán L, Magaz S, Alvarez Sanz C, Green J, Serrano D

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.

CRD summary
The study examined the cost-effectiveness of adding enfuvirtide (EFN) to an optimised antiretroviral therapy (OT) in patients with human immunodeficiency virus-1 in comparison with OT alone. The study demonstrated the cost-effectiveness of ENF plus OT from the perspective of the Spanish National Health System. On the whole, the study was satisfactorily carried out, but it was characterised by poor reporting of the sources used to populate the decision model. Thus, the authors’ conclusions should be considered with a degree of caution.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to examine the cost-effectiveness of adding enfuvirtide (EFN) to an optimised antiretroviral therapy (OT), compared with OT alone, in patients diagnosed with human immunodeficiency virus (HIV)-1.

Interventions
The study examined EFN (90 mg twice daily, b.i.d.) for 1 year added to OT in comparison with OT alone. OT consisted of a triple antiretroviral therapy composed of 3TC (lamivudine 150 mg b.i.d.), ddI (didanosine 200 mg b.i.d.) and lopinavir (400 or 100 mg b.i.d.).

Location/setting
Spain. Primary/secondary care.

Methods
Analytical approach:
This economic evaluation was based on a Markov model intended to simulate disease progression under the two strategies. The time horizon of the analysis was 10 years. The authors stated that the perspective of the Spanish National Health System was adopted in the study.

Effectiveness data:
The clinical estimates were derived from a selection of known, relevant studies. Key clinical data on treatment effectiveness came from randomised clinical trials (RCTs). These data were only available for a short timeframe (12 weeks). Long-term assumptions about disease progression were taken from published mathematical models and subsequently validated by a panel of experts. Few details of these sources were given. For example, the decline in CD4+ cell count was taken from the Multicenter AIDS Cohort Study and then projected through a published equation. The key clinical outcomes were the effects of treatment on CD4+ cell count and viral load.

Monetary benefit and utility valuations:
None.

Measure of benefit:
The summary benefit measure was the life-years (LYs). These were calculated using the decision model and were discounted at an annual rate of 3%.
Cost data:
The cost categories included in the study were medications, monitoring and follow-up of HIV patients (laboratory tests, emergency visits and other services), and the treatment of different events associated with acquired immune deficiency syndrome (AIDS). The costs and quantities were mainly derived from two studies carried out in the Spanish setting. The costs were defined as a function of the CD4+ cell count associated with each health state. The drug costs were taken from a standard Spanish price list. The price year was 2003. The costs were in euros (EUR). An annual discount rate of 3% was applied to costs accrued after the first year.

Analysis of uncertainty:
A deterministic sensitivity analysis was undertaken for each model input. The sources of the ranges of estimates used in the analysis were not reported. The results were presented using tornado diagrams.

Results
The expected costs over 10 years were EUR 160,728 with OT and EUR 200,859 with ENF plus OT.

Survival was 6.2 LYs with OT and 7.8 LYs with ENF plus OT.

The incremental cost per LY gained with ENF plus OT over OT alone was EUR 25,082.

The sensitivity analysis identified the most influential model inputs. These were the risk of AIDS-defining events (the lower the risk, the less efficient was ENF), baseline CD4+ cell count (a higher baseline count improved the cost-effectiveness of ENF), time horizon (ENF was more economically efficient in the short term) and time until immunological failure occurred (the longer the time, the greater the efficiency of ENF).

Authors' conclusions
The authors concluded that ENF added to OT was a cost-effective treatment for HIV-1-treated patients from the perspective of the Spanish National Health System.

CRD commentary
Interventions:
The selection of the comparators appears to have been appropriate in terms of reflecting the usual care versus the new strategy. These therapies are likely to reflect treatment patterns in other health care settings.

Effectiveness/benefits:
The approach used to identify the clinical sources of data was not reported. Thus, the sources may have been identified selectively. Short-term clinical estimates on treatment effect were derived from RCTs, which are usually considered to be a robust source of evidence given the strengths of the study design. However, the authors did not provide information on the sources used in terms of study populations and types of interventions, and the issue of potential heterogeneity among these sources was not addressed. Assumptions about long-term disease progression were based on published models and algorithms, which seems appropriate. The authors investigated the uncertainty surrounding some of these estimates in the sensitivity analysis. LYs are an appropriate benefit measure, and can be compared with the benefits of other health care interventions. The impact of the treatments on quality-of-life aspects was not investigated, although it would have been useful.

Costs:
The categories of costs included in the analysis were relevant to the perspective adopted in the study. The costs were presented as macro-categories and a detailed breakdown of the cost items was not provided. Some costs were related to the severity of disease. This approach is quite common in HIV studies, but reduces the transparency of the analysis. The sources of the costs and resource use data were only partially described. These issues tend to limit the study validity. Other aspects of the analysis, such as the price year and the use of discounting, were reported.

Analysis and results:
The synthesis of the costs and benefits was appropriate in its performance and presentation. The issue of uncertainty was addressed in the sensitivity analysis, which identified the most influential model inputs. Nevertheless, variability in
these inputs was tested individually. Thus, alternative scenarios with simultaneous variations in model estimates were not considered. This might affect the generalisability of the study findings to other settings. However, the authors compared their findings with those of other published economic evaluations on EFN and found very similar results.

Concluding remarks:
The study methodology would appear satisfactorily, but the analysis was characterised by a lack of detail in the reporting of the sources used to populate the decision model. Thus, the authors’ conclusions should be considered with a degree of caution.

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Bibliographic details

Other publications of related interest


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