Gemcitabine: clinical and economic impact in inoperable non-small cell lung cancer

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
Impact of gemcitabine monotherapy, administered on an out-patient basis, on the management of inoperable stage III/IV non-small cell lung cancer in Germany. More details regarding administration and the comparator technology are given below in the estimates of effectiveness and key assumptions section.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population was patients with prostate, ovarian, non-small cell lung and other cancers.

Setting
The study setting was hospital. The economic study was carried out in Germany.

Dates to which data relate
Effectiveness and resource use data were collected from studies published between 1982 and 1995. Cost data were taken from sources published in 1991 and 1992. The price year was not reported.

Source of effectiveness data
Effectiveness data were derived from a literature review and expert opinion.

Outcomes assessed in the review
The review assessed tumour response rate, survival time, and side effects.

Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Methods used to judge relevance and validity, and for extracting data
Summary statistics from individual studies were used.

Number of primary studies included
At least six primary studies were included in the review.

Methods of combining primary studies
The narrative method was used to combine primary studies.

Investigation of differences between primary studies
Not stated.

Results of the review
The results of the review were as follows:

Response rates were 14-27% for ifosfamide/etoposide combination treatment and 22% for gemcitabine.

Median survival times were 8 months for ifosfamide/etoposide combination treatment and 9.4 months for gemcitabine.

Compared to ifosfamide/etoposide combination treatment, gemcitabine had a lower incidence of nausea and vomiting (65% versus 94%), and a lower incidence of alopecia (1% versus 99%).

Methods used to derive estimates of effectiveness
Assumptions regarding patient management were based on detailed interviews with practising German oncologists.

Estimates of effectiveness and key assumptions
Ifosfamide/etoposide combination treatment is given on an in-patient basis over 5 days per cycle. A physical examination is performed at hospital admission and discharge. A complete blood count, blood chemistry, and electrolytes are investigated on a daily basis, and repeated 10 days after discharge. A chest X-ray is performed every 4 weeks and an ECG every 8 weeks. Gemcitabine is administered on an out-patient basis. Three outpatient visits are needed. A physical examination, a complete blood count, blood chemistry, and electrolyte are carried out on each of the treatment days. A chest X-ray is performed every 4 weeks and an ECG every 8 weeks.

Measure of benefits used in the economic analysis
Efficacy was assumed to be equal for the two treatments and, hence, a cost-minimisation analysis was conducted. However, side effects were also considered in terms of health benefits for the patient (see results of the review).

Direct costs
Direct costs were, appropriately, not discounted (time horizon less than 1 year). Quantities and costs were not reported separately. Direct costs included costs of diagnosis and staging, investigations and procedures, delay of chemotherapy, management of leucocytopenia, thrombocytopenia, anaemia, and alopecia, pre-treatment and treatment of nausea and vomiting, treatment of flu-like symptoms, and hospital stay. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. Costs and quantities were obtained from published reimbursement rates. The price year was not reported.
Statistical analysis of costs
The cost data were not treated stochastically. The authors provided estimates of total costs.

Indirect Costs
Indirect costs were not included.

Currency
German marks (DM).

Sensitivity analysis
Sensitivity analyses were conducted on the duration and costs of hospital stay and other key assumptions (specific methods used were not stated but were probably one-way).

Estimated benefits used in the economic analysis
Efficacy was assumed to be equal for the two treatments and, hence, a cost-minimisation analysis was conducted. The side effect profile for the patient was superior for the gemcitabine regimen (see results of the review).

Cost results
Diagnostic and staging costs were similar for both treatments, but there were differences in the administration costs of chemotherapy. The hotel element of the in-patient stay accounted for 33% of total treatment costs with ifosfamide/etoposide combination treatment. The costs of managing toxicity represented less than 15% of the total. Total costs were DM11,151 for ifosfamide/etoposide combination treatment and DM5,798 for gemcitabine.

Synthesis of costs and benefits
Costs and benefits were not combined given that this was a cost minimisation/cost-consequences analysis.

Authors’ conclusions
Gemcitabine monotherapy could offer considerable cost savings while offering the potential for improved quality of palliative treatment compared to existing in-patient treatments, and it may have a place in shifting care from an in-patient to an out-patient setting in line with recent health care reforms.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used namely that it represented a current treatment alternative. The comparator was chosen as a representative sample of the dual therapy combinations currently employed in Germany and because of the availability of data. You, as a user of the database, should decide if these health technologies are relevant to your setting.

Validity of estimate of measure of effectiveness
The authors undertook a literature review to derive effectiveness estimates, which seemed appropriate, although they did not state that a systematic review of the literature had been undertaken. Additional effectiveness estimates were, appropriately, based on expert opinion. The validity of the results was enhanced by sensitivity analyses to account for variability in the estimates.

Validity of estimate of measure of benefit

The analysis of benefits was based upon therapeutic equivalence of treatment alternatives. The economic analysis therefore included only costs.

**Validity of estimate of costs**
A good feature of the cost analysis was that, with the exception of the cost of gemcitabine, all relevant direct cost categories were included. The validity of the cost results was enhanced by appropriate sensitivity analyses. However, quantities and costs were not reported separately, which limits the generalisability of the results; and the price year was not reported, which would make relflation exercises in other settings problematic. Moreover, charges were not converted into costs and, hence, true opportunity costs were not estimated.

**Other issues**
The authors did make appropriate comparisons of their findings with those from other studies but did not address the issue of generalisability to other settings. The authors did not present their results selectively. The study considered patients with prostate, ovarian, non-small cell lung and other cancers and this was reflected in the authors' conclusions. The authors noted that more meaningful data on symptom relief and patient quality of life would be desirable. They also noted that the cost savings were the result of an assumed shift from in-patient to out-patient care, which may not be achieved in practice. Policy changes in the German healthcare system (shifting from a per diem to a cost per case system of reimbursement) are forthcoming and will enable the economic benefits suggested in this study to be realised.

**Implications of the study**
Gemcitabine monotherapy could offer considerable cost savings while offering the potential for improved quality of palliative treatment compared to existing in-patient treatments, and it may have a place in shifting care from an in-patient to an out-patient setting in line with recent health care reforms.

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