Clinical guidelines and pharmacist intervention program for HIV-infected patients requiring granulocyte colony-stimulating factor therapy

Engles-Horton L L, Skowronski C, Mostashari F, Altice F L

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 use of clinical guidelines, as implemented by pharmacists, for the treatment of patients with human immunodeficiency virus (HIV) infection or acquired immunodeficiency syndrome (AIDS) who required granulocyte colony-stimulating factor (G-CSF) therapy. The guidelines provided criteria for when to begin G-CSF therapy and for determining the dose, frequency and duration of therapy.

Type of intervention
Treatment guidelines.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with HIV infection or AIDS, who required G-CSF therapy to manage the adverse effects of antiretroviral and anti-infective drugs. Further inclusion and exclusion criteria were not reported.

Setting
The setting was a teaching hospital. The economic study was carried out at the Yale-New Haven Hospital (CT), USA.

Dates to which data relate
The dates to which the effectiveness and resource use data related were reported. The price year was not given.

Source of effectiveness data
The effectiveness evidence came from a single study.

Link between effectiveness and cost data
The costing was performed retrospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations do not appear to have been conducted. The method used to select the sample was not reported, but the authors stated that a retrospective chart review was conducted to obtain information on the patients. A sample of 71 patients was identified in the 9-month pre-intervention phase (PIP). The mean age was 36.4 years and 66% were men. A group of 81 patients was selected in the 9-month intervention phase (IP). The mean age was 36.9 years and 74% were men.
Study design
This was a retrospective comparative study where the study groups were not evaluated concurrently but in two distinct (both retrospective) timeframes. The study was carried out in a single centre (the Yale-New Haven Hospital). The patients were allocated to the study groups according to the inclusion phase in the study (PIP or IP). The length of follow-up was not explicitly stated. However, it appears to have been reasonably short.

Analysis of effectiveness
All of the patients included in the initial study sample were taken into account when estimating the effectiveness. The health outcomes used in the analysis were:

the mean number of days of neutropenia after starting G-CSF,
the mean number of days with leukocytosis after starting G-CSF,
the mean number of days to G-CSF therapy after hospitalisation, and
the average length of hospital stay after starting G-CSF.

The two study groups were shown to be comparable at baseline for demographic and clinical conditions, although those in the IP group had a lower CD4 count.

Effectiveness results
The mean number of days of neutropenia after starting G-CSF was 1.1 in the PIP group and 1.0 in the IP group, (p>0.05).

The mean number of days with leukocytosis after starting G-CSF was 0.44 in the PIP group and 0.17 in the IP group, (p<0.01).

The mean number of days to G-CSF therapy after hospitalisation was 6.8 in the PIP group and 7.4 in the IP group, (p>0.05).

The average length of hospital stay after starting G-CSF was 13.8 days in the PIP group and 11.9 days in the IP group, (p>0.05).

Clinical conclusions
The effectiveness analysis showed that the new guidelines were effective in reducing the number of days with leukocytosis after starting G-CSF. The new guidelines did not increase the length of hospitalisation.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation. A cost-consequences analysis was therefore carried out.

Direct costs
Discounting was not relevant due to the short time horizon of the study and it appears not to have been conducted. The unit costs were not reported separately from the quantities of resources used. The health services included in the economic evaluation appear to have been only the G-CSF drugs used. The cost/resource boundary adopted in the study was not explicitly stated, but was likely to have been that of the hospital. Resource use was estimated using actual data coming from the same patients as those involved in the effectiveness study. The costs were estimated from the hospital billing database. No price year was reported.
Statistical analysis of costs
Standard statistical analyses were conducted to test the statistical significance of the differences in the observed costs.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not conducted.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The mean number of G-CSF doses per patient-day was 0.51 in the PIP group and 0.29 in the IP group, (p<0.0001).

The mean number of G-CSF doses per admission was 5.9 in the PIP group and 2.4 in the IP group, (p<0.0001).

The mean billing cost per patient-day was $200 in the PIP group and $112 in the IP group, (p<0.0001).

Synthesis of costs and benefits
The costs and benefits were not combined because a cost-consequences analysis was conducted.

Authors' conclusions
The new guidelines for the treatment of patients with human immunodeficiency virus (HIV) infection or acquired immunodeficiency syndrome (AIDS) decreased the hospital costs without affecting patient morbidity and level of care.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. The authors compared the new guidelines with the usual practice before implementation of the guidelines. You should decide whether it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness analysis used a comparative study, which was appropriate for the study question. However, the retrospective observational design is usually associated with some limitations, such as bias and confounding, which may have affected the results of the effectiveness study. It also has to be noted that time-related factors other than the study intervention may have affected the results of the analysis, although the authors stated that there were no differences in patient profile and use of other drugs over the entire study period. Further, the two study groups were comparable at baseline, although the patients in the intervention group had more advanced disease. Power calculations do not appear to have been performed and there was no evidence about the appropriateness of the sample size. The length of follow-up was not explicitly stated. These issues tend to limit the internal validity of the effectiveness study.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
The perspective adopted in the study was not stated. Only the costs strictly related to the use of G-CSF drugs were included in the analysis. The authors stated that other potential sources of cost-savings (such as decreased nursing time for drug administration and decreased pharmacist technician's time to label and distribute G-CSF to the hospital unit) were not included in the analysis, but could have been balanced by the costs of the programme. The unit costs were not analysed separately from the quantities of resources used. Sensitivity analyses were not performed and the cost estimates were specific to the study setting. Statistical analyses were conducted only to test the statistical significance of the total estimated costs. The price year was not reported, thus reflation exercises in other settings would be problematic.

Other issues
The authors compared their findings with those from other studies and similar results were obtained. However, the issue of the generalisability of the study results to other settings was not address. In addition, the external validity of the analysis was low due to the fact that no sensitivity analyses were conducted. The conclusions of the analysis were consistent with the initial study hypothesis. The study referred to patients with HIV infection or AIDS and this was reflected in the conclusions of the analysis.

Implications of the study
The authors noted that the results of their study should be confirmed in a prospective randomised trial.

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None stated.

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