Effect of a prior-authorisation requirement on the use of nonsteroidal anti-inflammatory drugs by Medicaid patients

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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
Application of a prior-authorisation requirement for the prescription of non-generic non-steroidal anti-inflammatory drugs (NSAIDs) for Medicaid enrollees.

Type of intervention
Mandatory protocol.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of enrollees in the Tennessee Medicaid programme.

Setting
The practice setting was the hospital. The economic study was carried out in Nashville, Tennessee, USA.

Dates to which data relate
Effectiveness and resource use data were collected between 1st October 1988 and 30th September 1991. The price date was not stated.

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

Link between effectiveness and cost data
Costing was undertaken retrospectively on the same sample as in the effectiveness study.

Study sample
The study sample consisted of all enrollees in the Tennessee Medicaid programme during the study period. 44% of these were under 18 years of age, 63% were female, 38% were black, 5% lived in nursing homes and 64% lived in ‘Standard Metropolitan Statistical Areas.’ The analysis of all Medicaid enrollees included 495,821 individuals at the midyear point of the baseline year. This increased to 544,140 and 547,403 in years one and two respectively. A subgroup analysis was conducted on regular NSAID users, with an uninterrupted 36 months of enrolment in Medicaid during the study period. Enrollees had been prescribed a NSAID during the month prior to the introduction of the intervention policy and for at least 274 days during the baseline year. Patients who had been prescribed both non-generic and generic NSAIDs during this time were excluded from the analysis. There were 3,174 regular users of exclusively non-generic NSAIDs and
1,849 regular users of exclusively generic NSAIDs. Power calculations were not used to determine sample size.

**Study design**
The study was of a retrospective before-and-after design.

**Analysis of effectiveness**
The analysis of the study was based on a complete set of computerised Medicaid files. Intermediate health outcomes included days of NSAID drug use and number of non-study drug prescriptions. Primary health outcomes included inpatient admissions and outpatient and emergency room claims, made for diagnoses relating to musculoskeletal disorder. Medicaid enrollees before and after the intervention were shown to be comparable in demographic characteristics at the time of analysis, but the comparability of the two types of NSAID users in the subgroup was not demonstrated.

**Effectiveness results**
For all Medicaid enrollees, mean NSAID drug use fell from 19.04 (95% CI: 18.01 - 20.07) days in the baseline year to 15.37 (95% CI: 14.77 - 15.97) days in post-intervention period. Mean non-generic NSAID drug use fell from 10.72 to 3.16 days, whereas mean generic NSAID drug use rose from 8.32 days to 12.20 days. At the end of the post-intervention period, the number of non-study drug prescriptions had risen from 10.7 to 11.3 per person-year, outpatient claims had increased from their baseline value of 4.6 to 5.0 per person-year and inpatient admissions had fallen from 3.0 to 2.5 per person-year. The statistical significance of these results was not reported. For the subgroup of regular NSAID users, the number of days of NSAID use by non-generic users fell by 28% relative to generic users, following the introduction of the intervention. There was no change in the use of other drugs or in outpatient services in the non-generic group, relative to the generic group. There were too few monthly study inpatient admissions in the subgroup to permit a statistical analysis of this outcome.

**Clinical conclusions**
The prior-authorisation policy achieved an increase in the use of generic NSAIDs and a reduction in the use of non-generic NSAIDs. If changes in pain control or functional status occurred as a result of the prior-authorisation policy, they were not sufficient to increase the use of medical care.

**Measure of benefits used in the economic analysis**
Effectiveness estimates were not converted to a measure of health benefit.

**Direct costs**
Costs were calculated from Medicaid's perspective and included the cost of the prior-authorisation programme and Medicaid payments for NSAIDs, other analgesic or anti-inflammatory drugs and psychotropic drugs. For diagnoses relating to musculoskeletal disorder, inpatient admissions, outpatient and emergency room claims were assessed. Selective resource use quantities were reported separately from costs. Costs were not discounted and the date to which prices relate was not stated.

**Statistical analysis of costs**
The effects of policy change on all Medicaid enrollees were evaluated using an interrupted time-series analysis, to determine the immediate effects, and a weighted least squares, to determine the overall effects. The effects of policy change on the regular users of NSAIDs were evaluated using an interrupted time series analysis with a control analysis, comparing users of non-generic NSAIDs before the policy change with a control group of comparable users of generic drugs.
Indirect Costs
Indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
A sensitivity analysis was not performed.

Estimated benefits used in the economic analysis
Estimated benefits are proxied by the effectiveness estimates.

Cost results
Total per-patient costs were not reported. For all Medicaid enrollees, per-person NSAID prescription expenditure fell from $22.41 (95% CI: $21.19 - $23.62) in the baseline year to $10.62 (95% CI: $10.19 - $11.05) in the post-intervention period. This represented a 53% decrease in Medicaid expenditures for NSAIDs and led to an estimated reduction of $12.8 million in Medicaid expenditure. In the baseline year, the mean annualised expenditure on NSAIDs for regular users of non-generic NSAIDs was $554 compared with $162 for regular users of generic NSAIDs. Immediately after the policy change, NSAID expenditure for regular users of non-generic NSAIDs fell by 64%, relative to the generic users. Changes in NSAID expenditure were presented diagrammatically. No change in expenditure on other medical care was found to be statistically significant.

Synthesis of costs and benefits
A synthesis of costs and benefits was not performed.

Authors' conclusions
The prior-authorisation programme was cost-effective as it reduced the prescription expenditure on non-generic NSAID while increasing prescription expenditure on less costly, but similarly effective and safe, generic NSAIDs. The application of such a programme throughout the USA could potentially reduce NSAID prescription expenditure by over $1 billion. This finding may not, however, be reproducible for other classes of drug.

CRD COMMENTARY - Selection of comparators
The study was of a before-and-after design and without a formal control group and so the changes observed may not be entirely attributable to the intervention. In the subgroup analysis, the two cohorts compared were not demonstrated to be comparable in clinical or demographic characteristics. Although the results were statistically analysed and confidence intervals were reported, results should therefore be interpreted with caution. The interpretation of the results is further limited by their presentation, in terms of a change in one cohort, relative to the other.

Validity of estimate of measure of benefit
The health benefits of the prior-authorisation policy were not formally investigated in this study. Although the authors addressed this issue in a narrative fashion, and make reference to other studies to support their assumption that generic and non-generic NSAIDs are similar in their efficacy and safety, the authors did not demonstrate that no adverse health effect resulted from the intervention.

Validity of estimate of costs
In the subgroup analysis, the authors analysed expenditure on other anti-inflammatory and analgesic drugs. A one-
percent increase in expenditure was observed and results were presented diagrammatically. It would appear that this category of expenditure was still rising at the end of the study period. If new and expensive analgesics became available, these might be substituted for the non-generic NSAIDs, in the absence of a similar restriction.

Other issues
The cost savings reported in this study are related to the Medicaid study population, to baseline NSAIDs prescribing levels and to the mandatory nature of the policy restriction. These factors may not be representative of other settings, which limits the generalisability of the results.

Implications of the study
A randomised, controlled study, to investigate the health outcomes of changes in medication patterns for NSAIDs, would give a more reliable estimate of the cost-effectiveness of a prior-authorisation requirement.

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