A nurse-delivered advice intervention can reduce chronic non-steroidal anti-inflammatory drug use in general practice: a randomized controlled trial

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 nurse-delivered advice aimed at reducing non-steroidal anti-inflammatory drug (NSAID) usage. The intervention was reinforced with written information (a flow-chart tailored to the patient's current medication). Further patient-initiated telephone contacts were offered.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis; cost-utility analysis.

Study population
The study population comprised patients aged 18 years or older, using oral NSAID prescriptions covering at least 6 weeks of the last 12 months, and currently taking oral NSAIDs. Patients were excluded if they had a terminal disease, were unable to give valid informed consent, or defined inflammatory arthropathy or non-locomotor pain was the reason for NSAID use.

Setting
The setting was primary care. The economic study was conducted in five general practices covering urban and semirural populations in Nottinghamshire, UK.

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

Source of effectiveness data
The effectiveness evidence was derived from a single study.

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

Study sample
Power calculations were conducted in the preliminary phase of the study. These suggested that a sample of 260 patients would have been required to detect a 50% statistically significant reduction in NSAID use between the groups (95% power and 5% significance level), assuming a 50% acceptance rate for patients in the intervention group. From the GP lists of approximately 50,000 patients, 527 were identified and contacted. However, 59 did not respond, 90 were not
eligible, and 141 declined to participate. Thus, the final sample comprised 237 patients, 120 in the intervention group and 117 in the control group. In terms of age, the intervention group comprised 30.1% in the age class 22 - 53 years, 20.9% in the age class 54 - 64 years, 21.8% in the age class 64 - 73, and 26.4% in the age class 74 years or older. The control group comprised 21.4% in the age class 22 - 53 years, 27.7% in the age class 54 - 64 years, 28.6% in the age class 64 - 73, and 22.3% in the age class 74 years or older. The proportion of women was 60.9% in the intervention group and 57.1% in the control group. The demographics of patients who declined to participate were not available.

Study design
This was a prospective, randomised controlled trial, which was carried out in five general practices in the area of Nottinghamshire. Randomisation was based on computer-generated envelopes in permuted blocks (block size: 4) according to eight permutations of three criteria (age, gender and NSAID dose). The patients were followed for 6 months after randomisation, and the outcomes were assessed at baseline, 6 weeks and 6 months. Eight patients in the intervention group and 7 patients in the control group were lost to follow-up due to withdrawal. The patients were unaware of the study objectives, but the nurses were not blind to patient allocation. Thus, self-reported data were used to reduce potential assessment bias.

Analysis of effectiveness
The basis of the analysis of the clinical study is likely to have been intention to treat because the authors stated that data from withdrawn patients were included in the analysis whenever possible. The primary outcome measure used in the effectiveness study was the change in self-reported reduction in oral NSAID use after 6 months. The secondary outcome measures were changes in pain, physical functioning, utility, health status and quality-adjusted life-years (QALYs). These were estimated using the Short-Form 36, a visual analogue scale and EuroQol-5D. The authors stated that the two groups were comparable at baseline and the randomisation process was carried out successfully. A regression analysis was conducted to identify factors affecting the changes in the outcome measures.

Effectiveness results
NSAID use was:

stopped in 29% of the intervention patients and 11% of the control patients;

reduced by 50 to 99% in 9% (intervention) and 2% (control) of the patients, respectively;

reduced by 25 to 49% in 4% (intervention) and 6% (control) of the patients, respectively;

reduced by less than 25% or unchanged in 54% (intervention) and 79% (control) of the patients, respectively; and

increased in 4% (intervention) and 3% (control) of the patients.

The differences in the percentages between the groups were statistically significant.

Higher initial NSAID prescription costs, patients aged 69 - 79 years, and patients from practices associated with higher NSAID prescribing costs were factors associated with patients reducing their NSAID dose by more than 50%.

The changes in the remaining measures of health status, well-being and QALYs were generally not statistically different between the two groups. The exceptions were utility scores, which deteriorated significantly in the intervention group, and QALYs, which decreased in the intervention group while increasing in the control group. However, the regression analysis showed the lack of a relationship between this worse data and the lower use of NSAIDs.

Clinical conclusions
The effectiveness analysis showed that the nurse-delivered intervention was effective in reducing drug use in comparison with standard care, without significantly affecting the patients’ health and quality of life.
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 conducted.

Direct costs
Discounting was not relevant because the costs were incurred during less than two years. The unit costs were reported separately from the quantities of resources used. The health services included in the economic evaluation were prescriptions, GP visits, nurse educational package, patient travel expenses and patient expenses for pain relief. The cost/resource boundaries adopted in the study were those of the patient and of the GP. The costs related to telephone contacts were not included in the analysis because they were negligible. Patient and nurse resource use was recorded prospectively. The unit costs were estimated from wholesale prices and PSSRU. The source of the travel costs was not reported. No price year was reported.

Statistical analysis of costs
The costs estimated in the groups were compared using the Mann-Whitney U-test. The Wilcoxon matched pairs signed ranks test was also performed to assess the statistical significance of the change in the estimated costs between the baseline and post-intervention periods.

Indirect Costs
The indirect costs were not considered in the economic evaluation.

Currency
UK pounds sterling (€).

Sensitivity analysis
Sensitivity analyses were not conducted.

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

Cost results
At baseline, the median NSAID prescription costs in the 6 months before the study were 14.65 (interquartile range, IQR: 5.04 - 50.88) in the intervention group and 22.86 (IQR: 5.66 - 59.92) in the control, (p=0.004).

During the 6 months of the study, the costs were significantly reduced in the intervention group compared with baseline, (p=0.008), but did not change statistically in the control group.

The overall drug costs (including other medications) were comparable at 6 months, (p=0.25).

The cost of the intervention was 40.70 (IQR: 34.67 - 46.40).

The mean cost of patient travel expenses was 0.83 (IQR: 0 - 1.25).

At 6 months, the mean reduction per patient in NSAID costs for the intervention group versus the control group was 2.61 (IQR: -3.45 - 14.65).

Thus, from the GP perspective there was a small reduction in the costs of NSAID use, achieved at a cost of over 40 per patient.
From the perspective of the patients, drug costs were lowered at a small additional cost of 0.83 for travel expenses. However, it should be noted that other patient-related costs were not considered.

The analysis also showed that the median number of non-drug options tried per patient was 6 (range: 2 - 9).

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

**Authors’ conclusions**
The implementation of a nurse-delivered intervention was effective in reducing the use of non-steroidal anti-inflammatory drugs (NSAIDs) in primary care without affecting the patients’ health status. The intervention could lead to cost-savings from the perspective of patients who pay for the drugs themselves (e.g. over-the-counter medications). When the perspective of the general practitioner (GP) was adopted, the nurse-delivered advice demonstrated "overall affordability and reasonably good cost-effectiveness”.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. The study intervention was compared with the care provided routinely in the primary care setting. The characteristics of standard care were provided. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness used a prospective randomised trial, which was appropriate for the study question. The methods of sample selection and randomisation were reported. The authors performed statistical tests to take potential biases and confounding factors into account. However, a single-blind procedure was performed. Self-reported data were used to limit assessment bias, but this could have introduced other critical issues related to the use of such data (e.g. misreporting). Power calculations were performed but full recruitment was not achieved. Hence, the study was underpowered to detect statistically significant differences between the outcome measures. The authors also noted that some of the instruments used to value patients' health status were not very sensitive to small changes over time. A substantial number of eligible patients refused to participate, but their demographic and clinical characteristics were not eligible. Thus, it is not possible to exclude the possibility that those who remained in the study, who were volunteers, were more prone to modify their NSAID use. These issues may limit the internal validity of the analysis. The authors noted that some sub-groups of patients could benefit more from the study intervention than others.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis and a cost-consequences analysis was therefore conducted.

**Validity of estimate of costs**
The perspectives adopted in the study were clearly reported. It appears that all the relevant categories of costs have been included in the analysis. The unit costs and the quantities of resources used were reported separately, thus facilitating the replication of the study in other settings. The source of the cost data was reported. As in the analysis of effectiveness, resource use was estimated from self-reported data. The cost estimates were specific to the study setting. Statistical tests were conducted to compare the estimated costs.

**Other issues**
The authors compared their findings with those of other studies that evaluated the effectiveness of the nurse-delivered intervention in other health care fields. The issue of the generalisability of the study results to other settings was partially addressed, as the authors suggested a basic and easy way to implement training programme for nurses. However, sensitivity analyses were not conducted and the estimates were specific to the study setting. Thus, the external
validity of the analysis was low. The study results confirmed the hypothesis of the study. However, the authors drew conclusions about the cost-effectiveness of the intervention, which was not explicitly evaluated.

**Implications of the study**
The study results suggested that the nurse-delivered intervention for reducing NSAID usage has the potential to be cost-effective. Further work on the long-term implications of the intervention should be conducted.

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