Effects of restrictive formularies in the ambulatory care setting

Lexchin J

Authors' objectives
To determine the effects of restrictive formularies on four areas of ambulatory health care: overall drug expenditures, overall health care spending, physicians' prescribing habits, and health outcomes.

Searching
MEDLINE was searched for reports published in English or French from the start of 1977 to the end of 1999, using the search terms 'budgets', 'cost control', 'drug costs', 'drug utilization', 'formularies', 'health benefit plans' and prescription drugs'. In cases of duplicate publication, the more comprehensive report was chosen. Additional material was identified from the reference lists in reviews and original studies.

Study selection
Study designs of evaluations included in the review
Studies of any design, wherein the results were expressed quantitatively, were eligible for inclusion in the review. Included in the review were before-after, time series, cross-sectional and prospective studies. Most were uncontrolled.

Specific interventions included in the review
The use of restrictive measures in public drug programmes, i.e. the financial cover for a limited range of drugs or the need for a physician to obtain prior authorisation before prescribing certain drugs, in an attempt to control the costs in the out-patient sector. Studies on any form of formulary restriction in an ambulatory care setting were included. Studies that examined the effects of user fees or reference-based pricing were excluded.

Participants included in the review
The participants eligible for inclusion in the review were: recipients of public health care in the ambulatory care setting in countries belonging to the Organisation for Economic Cooperation and Development, e.g. USA. Included in the review were Medicaid recipients, Medicaid recipients in states with restrictive formularies, Irish low-income populations, General Medical Services patients (40% of the population), elderly (65 years and over) and non-elderly (0 to 64 years) patients in 6 Health Maintenance Organisations (HMOs), patients in a further 6 HMOs, and residents of Grampian (Scotland).

Outcomes assessed in the review
Four outcomes were assessed: overall drug expenditures, overall health care spending, physicians' prescribing habits, and health outcomes.

How were decisions on the relevance of primary studies made?
The author does not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
The author does not report a formal method for assessing validity, although the methodological limitations of the included studies were discussed briefly.

Data extraction
The author states that no attempt was made to blind the studies, and that the information in all studies was abstracted by the same reviewer.

Data were extracted on the time period of the study, geographic location and group of patients involved, outcome
measurement(s), intervention, study design and results.

**Methods of synthesis**

**How were the studies combined?**
The studies were combined narratively according to outcome, i.e. overall drug expenditures, overall health care spending, physicians' prescribing habits, and health outcomes. The data were not pooled statistically.

**How were differences between studies investigated?**
Heterogeneity was not tested.

**Results of the review**

Twenty-two studies were included in the review. Two were prospective, cross-sectional and after only; 2 were pooled, cross-sectional and post only; one was a pooled cross-sectional time series; one was a pooled cross-sectional time series, post only; 9 were time series with no control; and 7 were before-and-after designs with no control. The overall number of participants was not reported.

Poor methodologic quality made it difficult to draw definitive conclusions in most areas. The effect of formulary restrictions on overall drug expenditures from the view point of the payer (public-administered plans or HMOs) varied considerably. One pooled time series with post-test results only reported lower costs with a restrictive formulary; two other uncontrolled studies showed that a move from a restrictive to an open formulary resulted in higher drug costs. Three uncontrolled before-and-after studies reported that delisting both prescription and nonprescription drugs from formularies resulted in lower drug costs, although two others found that the costs actually increased. Three uncontrolled time series found that Medicaid drug costs decreased when prior authorisation was required. Other results from single studies were also presented in the review.

All studies on the effects of formulary restriction on other health care spending were performed with Medicaid recipients in the US, with the majority from single states; only one of these was controlled. Prior authorisation programmes and pharmacy-enforced treatment protocols did not lead to overall increases in health care spending. Open formularies usually led to higher out-patient costs and lower in-patient costs. Other results from single studies were also presented in the review.

Two studies examined the effects of formulary restriction on the physicians' prescribing pattern. In one of these, the physicians responded by substituting products that represented a probable improvement in therapy, or in other cases, by making inappropriate substitutions. Another study found that when over-the-counter products were delisted, the physicians did not respond by prescribing prescription-only products.

The studies that looked at the effect of formulary restrictions on health outcomes all showed a deleterious effect on health. The results from these studies were presented and discussed individually in the review.

**Cost information**

No formal costs were reported although the effects of formulary restrictions on overall drug expenditures, on spending in other health care sectors, on the physicians' prescribing behaviour, and on health outcomes were discussed.

**Authors' conclusions**

The author states that the quality of the literature on the effect of restrictive formularies on ambulatory health care is generally poor, and hence, it limits the ability to draw any definitive conclusions in most areas. There were no convincing data that restrictive formularies limit the drug costs, nor that open formularies increase the drug costs. The effects of delisting drugs from formularies was unclear. Prior authorisation plans seem to have had some success in slowing the cost increases for certain drug categories. Changes in prescribing patterns, ensuing from delisting drugs from formularies, can be either positive or negative. Many important areas of formulary management remain unexamined. The use of restrictive formularies in the ambulatory care setting requires more rigorous research. Before
changes are made in formularies, money needs to be set aside for research into the short- and long-term consequences of using restrictive formularies.

CRD commentary
The review question and the study selection criteria were clearly stated. The literature search was rather limited, searching MEDLINE only for articles in English and French, so relevant studies may have been missed. There were relatively few details on the methodology of the literature selection, validity and data extraction processes, although there was some discussion on the methodological limitations of the included studies. The decision not to pool the data in a statistical meta-analysis seems appropriate given the heterogeneity of these studies, although this is left to the inference of the reader, as the author does not state this reason for why a meta-analysis was not undertaken.

The author does not offer formal conclusions in the body of the text (only in the abstract), although these are readily understood from the 'Discussion' section. These conclusions seem appropriate in view of the data discussed and the methodological limitations of the studies reviewed.

Implications of the review for practice and research
Practice: The author states that before changes are made in formularies, money needs to be set aside for research into the short- and long-term consequences of using restrictive formularies. Physician and patient education must be included in future policy changes, in order to prevent changes in drug prescribing that could result in inappropriate treatment decisions or lead to undue economic hardship on beneficiaries of formularies. Currently existing formularies should be examined to determine whether there are cost-effective drugs that are not being covered. Policies such as prior approval and other restrictions on the use of listed drugs must be re-evaluated to ascertain that such drugs are appropriately restricted to patients with a true medical need, but on the other hand, to also ensure that patients are not denied necessary treatment.

Research: The author states that the use of restrictive formularies in the ambulatory care setting requires more rigorous research. This should address the following: the process by which drugs are selected and rejected for ambulatory care formularies; the impact of formulary restrictions that target clinically and economically important groups of drugs such as antipsychotic agents, oral hypoglycaemics and antidepressants; and the administrative cost burden to physicians and pharmacists as a result of restrictive formularies or a change in the status of drugs on formularies. Studies should focus on downstream effects and should specifically target vulnerable subsectors of the population served by the plans, such as the frail elderly and social welfare recipients receiving multiple chronic medications.

Research should examine not only the short-term effects but also the long-term consequences on quality of prescribing, spending in other areas of health care (e.g. physicians and hospitals), and administrative costs to both the payers and health care professionals (e.g. doctors and pharmacists).

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