Pharmacy utilization and the Medicare Modernization Act


CRD summary
This review assessed the effects of pharmacy utilisation management (PUM) on the care of senior service users. The authors concluded that there was insufficient evidence to adequately assess the impact of PUM on seniors and that further research is required. The limited search and lack of reporting of review methods make it difficult to verify the authors' conclusions.

Authors' objectives
To assess the effects of pharmacy utilisation management (PUM) on the care of senior service users.

Searching
MEDLINE and CINAHL were searched from January 1995 to May 2003 for reports published in English; the search terms were reported. The reference lists of selected studies were checked for additional studies published after 1983.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) and quasi-experimental studies were eligible for inclusion.

Specific interventions included in the review
Studies of PUM measures that were included or might be included in the Medicare benefit plan were eligible for inclusion. These included mechanisms for cost-sharing and administration. Studies of reference pricing were excluded. The included studies examined the following policies: drug benefit caps; copayments, coinsurance and deductibles; prior authorisation; and formularies (closed, therapeutic substitution, generic substitution and incented formulary).

Participants included in the review
Studies of people aged 60 years or older were eligible for inclusion. Studies in which the participants had a mean age of at least 60 years were included if the results were reported separately for people older than 60.

Outcomes assessed in the review
To be eligible for inclusion, the studies had to assess: prescription drug utilisation and/or expenditure; the effects of using other health services; underuse of effective medications; clinical outcomes; or adverse events or the impact of patient behaviour.

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

Assessment of study quality
Validity was not formally assessed, but some aspects of validity were discussed in the text: study design, presence of a control group, comparability of the control group, sample size and account taken of confounders.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
The studies were grouped by type of PUM and combined in a narrative.

How were differences between studies investigated?
Differences between the studies were discussed in the text and were apparent from inspection of the tables.

Results of the review
Eighteen articles were included in the review (n greater than 1,196,869): 10 pre-test post-test studies with no comparison group (n=981,319), 5 pre-test post-test studies with a comparison group (n=140,161), 2 post-test studies with no comparison group (n=62,392) and 1 post-test study with a comparison group (n=12,997). The duration of the studies ranged from 6 months to 4 years and 5 months.

Methodological flaws included small sample sizes, the lack of comparable control groups, and short-term follow-up.

Drug benefit caps (5 studies).

The studies found that drug benefit cap measures were associated with a significant increase in the risk of disenrolling from health plans (2 studies); a reduction in the number of prescriptions, including a 28% decrease in 'essential' medications such as insulin and thiazides (1 study); a significant increase in the rates of admission to nursing homes (1 study); and that people with multiple chronic diseases were more likely to reduce their use of 'essential' medicines (1 study).

Copayments, coinsurance and deductibles (5 studies).

The studies found conflicting results. One controlled study found that a small copayment system reduced drug consumption and expenditure and led to a short-term decrease in eight of the ten drug groups examined (exceptions were analgesia and sedatives or hypnotics). Other studies showed that small changes in copayments had little effect on prescription medications for drugs for self-limiting or progressive chronic diseases. Larger changes were associated with the decreased use of essential medications (1 study). Studies examining a cost-sharing insurance plan in Canada found that the plan did not significantly affect the use of the drugs studied, or increase admission rates, visits to physicians or emergency departments, or mortality (2 studies), but it did reduce consumption of 'essential' and 'less essential' medications (1 study).

Prior authorisation (1 study).

Prior authorisation was associated with a shift from non-generic to generic non-steroidal anti-inflammatory drugs in this study.

Formularies.

Closed formulary significantly increased the number of prescriptions, office visits and hospitalisation in senior patients in comparison with younger patients (1 study).

Two studies of therapeutic substitution were identified. One study found that the mandatory switching of stable calcium-channel blocker therapies had no significant effect on the short-term control of blood-pressure or adverse effects. The other study found that a statin interchange programme maintained lipid-lowering efficacy.

Generic substitution of warfarin had little effect on treatment efficacy (2 studies). Studies evaluating incented formularies were conducted in younger patients and the findings may not, therefore, be applicable to seniors (5 studies).

Cost information
Drug caps (2 studies) and a statin interchange programme (1 study) reduced costs. Small changes in copayments had little effect on the costs of drugs for self-limiting or progressive chronic diseases (1 study). Prior authorisation was associated with reduced costs of non-steroidal anti-inflammatory drugs without apparently increasing the Medicaid
costs of other analgesics or in- or out-patient services (1 study). Closed formulary significantly increased drug costs in senior patients in comparison with younger patients (1 study). Incented formularies reduced overall drug expenditures (2 studies) without significantly increasing the use of other medical resources (3 studies).

Authors' conclusions
There was insufficient evidence to assess the impact of PUM on seniors. However, the evidence suggested that although drug caps may reduce pharmaceutical costs, they may also increase the use of other health service resources.

CRD commentary
The review question was clear in terms of the study design, intervention, participants and outcomes. Despite inclusion criteria stating that only people aged 60 years or older were to be included, studies of younger people were discussed in the results. Two databases were searched for English language publications only, thus increasing the potential for publication and language bias. Since the methods used to select the studies, assess validity and extract the data were not described, it is not known whether any efforts were made to reduce errors and bias. It was unclear if validity was formally assessed but some relevant aspects of validity were considered during the synthesis.

Adequate details of each included study were given, although the extent of overlap between the studies was not always clear. Given the heterogeneity among studies, a narrative synthesis was appropriate. Although the authors' conclusions appear appropriately cautious, the limitations of the evidence presented, the limited search and lack of reporting of review methodology make it difficult to verify the authors' conclusions.

Implications of the review for practice and research
Practice: The authors stated that formularies should avoid excessive restriction to minimise the risk of patients stopping treatment or adverse drug effects. They recommended that prior approval programmes be implemented so that quality of care is ensured and appropriate medications are available to seniors without undue delay.

Research: The authors stated that more research is required to examine the economic and clinical impact of PUM on senior beneficiaries. The monitoring of short- and long-term impacts of PUM policies on the consumption and costs of medication to beneficiaries and spending on other health care areas was also suggested.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.