August 2008 – SUPPORT Summary of a systematic review

What are the impacts of policies regarding direct patient payments for drugs?

Policies in which consumers pay directly for their drugs when they fill a prescription include:

Caps – a maximum number of prescriptions or drugs that are reimbursed;

Fixed co-payments – people pay a fixed amount per prescription or drug;

Tier co-payments – people pay a fixed amount per prescription or drug which may depend, for example, on whether the prescription is for a brand (patented) drug or a generic;

Coinsurance – people pay a percent of the price of the drug;

Ceilings – people pay part of, or the full price, of the drug up to a set maximum amount over, for example, a year. Thereafter, people pay no, or less money, for their drugs.

Key messages

- **Cap, coinsurance with a ceiling, and co-payment polices can reduce drug use and save expenditures for drug policies or health plans.**
- **Reductions in drug use were found for life-sustaining drugs and drugs that are important in treating chronic conditions, as well as for other drugs.**
- **Although insufficient data on health outcomes were available, large decreases in the use of drugs that are important for peoples' health may have adverse effects. This could lead to the increased use of healthcare services and, therefore, to increases in overall spending.**
- **Policies in which people pay directly for their drugs are less likely to cause harm if only non-essential drugs are included in these policies, or if exemptions are built into the policies to ensure that people receive needed medical care.**

Who is this summary for?

People making decisions concerning pharmaceutical policies.

This summary includes:

- **Key findings** from research based on a systematic review
- **Considerations about the relevance of this research** for low and middle-income countries

Not included:

- Recommendations
- Additional evidence not included in the systematic review
- Detailed descriptions of interventions or their implementation

This summary is based on the following systematic review:

Austvoll-Dahlgren A, Aaserud M, Vist G, Ramsay C, Oxman AD, Sturm H, Kösters JP, Vernby , Å . Pharmaceutical policies: effects of cap and copayment on rational drug use. Cochrane Database Syst Rev 2008, Issue 1.

What is a systematic review?

A summary of studies addressing a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise the relevant research, and to collect and analyse data from the included studies.

SUPPORT – an international collaboration funded by the EU 6th Framework Programme to support the use of policy relevant reviews and trials to inform decisions about maternal and child health in low and middle-income countries.
www.support-collaboration.org

Glossary of terms used in this report:
www.support-collaboration.org/summaries/explanations.htm

Background references on this topic:
See back page

Background

Substantial and increasing healthcare funds are spent on drugs. Misuse, overuse and underuse of appropriate drugs can lead to wasted resources and health hazards. There is therefore pressure to ensure better use of drugs and to control drug costs, without decreasing health benefits. Policies regarding direct patient payments are an approach to this problem. These policies anticipate that patients respond to direct payments by:

1. decreasing drug use, either overall or for drugs of limited value;
2. shifting to cheaper drugs; or
3. paying more out of pocket, thus shifting costs from the insurer to patients.

Although drug use and costs can be reduced, an overly restrictive drug policy may have unintended consequences, particularly for low-income or other vulnerable populations. The discontinuation of necessary drugs may lead to a deterioration in health, and increase health care utilisation and expenditures for patients and insurers. This summary is based on a systematic review published in 2008, and focuses on the effects of direct patient payments for drugs on drug use, health care utilisation, health outcomes and costs. Drug groups are often categorised as "essential" (usually drugs that are life-sustaining or drugs that are important in treating chronic conditions) or "discretionary/less essential" (often referring to drugs that are symptom relieving, but also to drugs that are considered to be overprescribed or a less cost-effective alternative than other available treatments).

How this summary was prepared

After searching widely for systematic reviews that can help inform decisions about health systems, we have selected ones that provide information that is relevant to low and middle-income countries. The methods used to assess the quality of the review and to make judgements about its relevance are described here: http://www.support-collaboration.org/summaries/methods.htm

Knowing what's not known is important

A good quality review might not find any studies from low and middle-income countries or might not find any well-designed studies. Although that is disappointing, it is important to know what is not known as well as what is known.

About the systematic review underlying this summary

Review objective: To assess the effects of policies regarding direct patient payments for drugs on drug use, health care utilisation, health outcomes and costs (expenditures).

	What the review authors searched for	What the review authors found
Interventions	Randomised controlled trials (RCTs), non-randomised controlled trials (CCTs), repeated measures (RM) studies, interrupted time series (ITS) analyses, and controlled before after (CBA) studies of policies that regulate out-of-pocket payments for drugs by patients, including changes in the amount paid directly by patients or limits on the amount reimbursed, including caps, fixed copayments, coinsurance, maximum copayment ceilings and tier co-payments. Policies were defined as laws, rules or financial or administrative orders made by governments, non-government organisations or private insurers.	Overall 21 studies, reporting on 30 interventions, were included. For some of the interventions, the effects were measured using more than one design, i.e. different designs for different outcomes: RCT (4 interventions), RM (3), ITS (12), and CBA (14). Pharmaceutical policies included fixed co-payments (9 studies); coinsurance with ceiling policies (3); cap policies (4); fixed co-payment with ceiling policies (2); tier co-payments (2); ceiling policies (1); fixed co-payment and coinsurance with a ceiling policy (1); fixed co-payment with cap policy (1).
Participants	Healthcare consumers and providers within a regional, national or international jurisdiction or system of care, and organisations, such as multi-sited health maintenance organisations, serving a large population.	USA - Medicaid/Medicare (7), city level (1), HMO (1), Preferred Provider Organisation (1), commercial plans (1), health insurance (1); Sweden - Public health insurance (1); Canada - drug program (3), health insurance program (2); Australia - Pharmaceutical benefits scheme (2); Nepal, - Health posts (1).
Settings	Any	Studies from USA (13), Canada (5), Australia (1), Sweden (1), and Nepal (1).
Outcomes	Objectively measurement of at least one of the following outcomes: 1. Drug use 2. Health care utilisation 3. Health outcomes 4. Costs (drug expenditures and other healthcare and policy administration expenditures)	The studies provided data on drug use, i.e. the number of dispensed doses/prescriptions (19 studies); drug expenditures from a drug insurer's perspective (10); drug expenditures from the patient's perspective (3); health care expenditures (2); overall drug expenditures (4); health outcomes (1) and health care utilisation (5).

Date of most recent search: August 2007

Limitations: This is a good quality systematic review with only minor limitations.

Austvoll-Dahlgren A, Aaserud M, Vist G, Ramsay C, Oxman AD, Sturm H, Kösters JP, Vernby , Å . Pharmaceutical policies: effects of cap and copayment on rational drug use. Cochrane Database Syst Rev 2008, Issue 1.

Summary of findings

The review included 21 studies reporting on 30 interventions. Most studies were done in the USA (13) and Canada (5), and only one in a low or middle-income country (LMIC). In this summary we have focused on impacts on drug use and health care utlization. We have not included expenditures, which are a function of drug use and prices for drugs and for which there are limited data for health care utilisation.

1) Caps

Four interventions were evaluated. Restrictions ranged from a cap of three prescriptions per month (the most restrictive policy evaluated) to a 20 day minimum re-supply period cap for drugs with five or more repeats (the least restrictive policy evaluated). Restricting reimbursement using a cap reduced drug use and reduced drug plan expenditures. More restrictive policies resulted in larger reductions in drug use.

- **There is low quality evidence that caps can reduce both "limited efficacy" and "essential" drug use.**
- **There is low quality evidence that caps can increase hospitalisations in vulnerable subgroups.**

About quality of evidence (GRADE)

⊕⊕⊕⊕
High: Further research is very unlikely to change our confidence in the estimate of effect.

⊕⊕⊕◯
Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

⊕⊕◯◯
Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

⊕◯◯◯
Very low: We are very uncertain about the estimate.

For more information, see last page.

Caps compared to full drug coverage

Patients or population: Low-income public insurance program (Medicaid)
Settings: USA
Intervention: Restricting reimbursement to up to three prescriptions
Comparison: Full drug coverage

Outcomes*	Comparison	**Relative change (range)**† (p-vaue)	Number of studies	Quality of the evidence (GRADE)
"Limited efficacy" drug use	Three (versus all) prescriptions reimbursed	**-58%**‡ (p < 0.05)	1 study	⊕⊕◯◯ Low
"Essential" drug use	Three (versus all) prescriptions reimbursed	**-28%**‡ (p < 0.05)	1 study	⊕⊕◯◯ Low
Hospitalizations of vulnerable patients	One (versus all) prescriptions reimbursed	**+7.4% to +15.6%** § (p < 0.05)	1 study	⊕⊕◯◯ Low
	Three (versus all) prescriptions reimbursed	**+17.0%**** (p < 0.001)	1 study	

GRADE: GRADE Working Group grades of evidence (see above and last page)

* Not all comparisons and outcomes are included here. Decreases in overall prescription drug use ranged from -46% in vulneralbe patients for three (versus all) patients reimbursed to -5.9% for five (versus six) prescriptions reimbursed in vulnerable patients.
† Immediate or short-term effects. Estimated percentage increase or decrease relative to the predicted level without the cap.
‡ Monthly drug use (per 100 patients with indication for use of the drug).
§ For anti-ulcer prescriptions. Range by condition category: complicated, uncomplicated peptic and non-ulcer peptic disease. At 12 months the increase in hospitalisation rates ranged from 0.8% to 15.4% (and the differences were no longer statistically significant).
** For a cohort of schizophrenic patients. In a cohort of elderly patients (>65), the relative risk of admissions to nursing homes was RR 1.8 (95% CI 1.2 to 2.6). There were not statistically significant effects on hospitalizations in the other cohorts of patients that were studied.

2) Fixed co-payments

Eleven interventions evaluated in 10 studies were included. Introducing fixed co-payments reduced drug use across studies, even though the co-payments required by the patients were in most cases quite small. Substantial reductions in drug plan expenditures were found, whereas there were only modest reductions in overall drug expenditures, suggesting a shift of costs from drug plans to patients.

The only study included from a low or middle-income country (Nepal) had methodological limitations (Fryatt 1994).[1] The already existing "fee per prescription" scheme at primary care units serving the general Nepalese population was criticised for encouraging over-prescribing. A fee per drug included in a prescription was introduced to partly fund the "essential" drug supply needed at the health posts, and to encourage more rational prescribing. Patients attending the "fee per item" health posts had fewer items prescribed than the patients in the "fee per prescription" scheme. The investigators reported that there was a larger proportion of drugs that was either "low" or "empty" in stock in the fee per prescription scheme.

➔ **There is low quality evidence that fixed co-payments can reduce both "non-essential" and "essential" drug use.**

Fixed co-payments compared to full drug coverage

Patient or population: Low-income public insurance program (Medicaid)*
Settings: USA*
Intervention: Fixed co-payments
Comparison: Full drug coverage

Outcomes*	Comparison	**Relative change (range)**† (p-vaue)	Number of studies	Quality of the evidence (GRADE)
"Non-essential" drug use	US $1.50 to $3.00 or income-based fixed co-payments (versus none) per prescription in the **general population**	**-4%** (>0.05) to **-20%** (<0.001)‡	3 studies	⊕⊕◯◯ Low
"Essential" drug use	US $1.50 to $3.00 and income-based fixed co-payments (versus none) per prescription in the **general population**	**+2.6%** (>0.05) to **-13%** (<0.001)§	3 studies	⊕⊕◯◯ Low
Impacts on health or health care utilisation		None of the included evaluations reported effects on health or health care utilisation.	none	

GRADE: GRADE Working Group grades of evidence (see above and last page)

* Not all comparisons and outcomes are included here. Overall drug use was reduced between -10.6% (p< 0.001) and -22.5% (p-vaule not reported).
† Immediate or short-term effects. Estimated percentage increase or decrease relative to the predicted or comparison group level.
‡ A fixed co-payment of US $0.50 had similar effects on vulnerable patients (-0.3% to -11.1%, p-values not reported)
§ A fixed co-payment of US $0.50 had similar effects on vulnerable patients (-5.2% to -17%, p values not reported)
** For a cohort of schizophrenic patients. In a cohort of elderly patients (>65), the relative risk of admissions to nursing homes was RR 1.8 (95% CI 1.2 to 2.6). There were not statistically significant effects on hospitalizations in the other cohorts of patients that were studied.

[1] Fryatt RJ, Crowley SP, Gurung YB. Community financing of drug supplies in rural Nepal: Evaluating a "fee per item" drug scheme. Health Policy and Planning 1994; 9:193–203.

3) Fixed co-payments with a ceiling

Three interventions in two studies were evaluated.

➔ **There is low quality evidence that fixed co-payments with a ceiling can reduce both "non-essential" and "essential" drug use.**

Fixed co-payments with a ceiling compared to full drug coverage

Patient or population: Universal prescription drug plan (public)
Settings: Australia and Canada
Intervention: Fixed co-payments with ceiling
Comparison: Full drug coverage

Outcomes*	Comparison	**Relative change (range)**† (p-vaue)	Number of studies	Quality of the evidence (GRADE)
"Non-essential" drug use	CAN $2 per prescription with a $100 annual ceiling or an income-based fixed co-payment and ceiling (versus no co-payment) in the **general population**	**-1.3%** (p < 0.05) to **-27%** (p < 0.05)	2 studies	⊕⊕◯◯ Low
	CAN $2 per prescription with a $100 annual ceiling or AUS $2.50 per prescription with an annual ceiling‡ – **vulnerable patients**§	**-1.2%** (p < 0.05) to **-24%** (p < 0.05)	2 studies	
"Essential" drug use	CAN $2 per prescription with a $100 annual ceiling or an income-based fixed co-payment and ceiling (versus no co-payment) in the **general population**	**-3.7%** (p < 0.05) to **-22%** (p < 0.05)	2 studies	⊕⊕◯◯ Low
	CAN $2 per prescription with a $100 annual ceiling or AUS $2.50 per prescription with an annual ceiling‡ – **vulnerable patients**§	**-2.3%** (p < 0.05) to **-23%** (p < 0.05)	2 studies	
Impacts on health or health care utilisation		None of the included evaluations reported effects on health or health care utilisation.	none	

GRADE: GRADE Working Group grades of evidence (see above and last page)

* Not all comparisons and outcomes are included here. None of the included studies reported changes in overall drug use.
† Immediate or short-term effects. Estimated percentage increase or decrease relative to the predicted or comparison group level.
‡The level of the ceiling was not reported.
§ Low-income elderly patients.

4) Coinsurance with a ceiling

Six interventions in three studies were evaluated.

➔ **There is moderate quality evidence that coinsurance with a ceiling can reduce overall drug use.**

➔ **There is low quality evidence that coinsurance with a ceiling can reduce both "non-essential" and "essential" drug use.**

Coinsurance with a ceiling compared to full drug coverage

Patient or population: Universal (public) drug insurance and privately insured patients
Settings: Canada and USA
Intervention: Coinsurance with a ceiling
Comparison: Full drug coverage

Outcomes*	Comparison	**Relative change (range)**† (95% Confidence Interval)	Number of studies	Quality of the evidence (GRADE)
"Non-essential" drug use	25% coinsurance with an annual income based ceiling between CAN $200 and 750 in the **general population**	**-14%** (95% CI -13%, -15%)	1 study	⊕⊕◯◯ Low
	25% coinsurance with an annual income based ceiling between CAN $200 – **vulnerable patients**‡	**-19.4%** (95% CI -17.4%, -21.4%)	1 study	
"Essential" drug use	25% coinsurance with an annual income based ceiling between CAN $200 and 750 in the **general population**	**-6.9%** (95% CI -5.5%, -8.4%)	1 study	⊕⊕◯◯ Low
	25% coinsurance with an annual income based ceiling between CAN $200 – **vulnerable patients**‡	**-17.7%** (95% CI -14.8%, -20.5%)	1 study	
Impacts on health or health care utilisation		None of the included evaluations reported effects on health or health care utilisation.	none	

95% CI: 95% Confidence Interval; GRADE: GRADE Working Group grades of evidence (see above and last page)

* Not all comparisons and outcomes are included here. Overall drug use was reduced between -18.4% for 25% coinsurance and 33.6% for 95% coinsurance ($p < 0.05$) in a randomised trial in the USA with varying degrees of coinsurance (moderate quality evidence).
† Immediate or short-term effects. Estimated percentage increase or decrease relative to the predicted level.
‡ Welfare and low-income elderly patients.

5) Tier co-payments

Three interventions in two studies reported on the effects of tier co-payments. Increasing the number of tiers for co-payments together with a small increase in the co-payment for the lowest tier (generic drugs) reduced drug use across all tiers, including drugs used for treating chronic illnesses. Increasing the number of tiers saved expenditures for the insurer by increasing the consumers' financial responsibility for prescription drugs and inducing a shift of cost from the insurer to patients.

➔ **There is very low quality evidence that increasing the number of tiers for co-payments could reduce brand drug use.**

➔ **There is inconclusive evidence of the effects of tier co-payments on generic drug use and health care utilisation.**

Increase in tier co-payments for rational drug use

Patient or population: Privately insured
Settings: USA
Intervention: Tier co-payments (increasing the number of tiers)
Comparison: Tier co-payments (fewer tiers)

Outcomes*	Comparison	**Relative change (range)**† (p-value)	Number of studies	Quality of the evidence (GRADE)
Brand drug use	From 1 to 3-tier & tier-1 co-payment increased by US $1.00 versus 2 tiers	**-34%** (p < 0.001)	1 study	⊕◯◯◯ Very low
	From 2 to 3-tier & tier-1 co-payment increased by US $1.00 versus 2 tiers	**-3.8%** (p < 0.003) to **-21.8%** (p < 0.001)‡	1 study	
Generic drug use	From 2 to 3-tier & tier-1 co-payment increased by US $1.00 versus 2 tiers	**-2.2%** (p > 0.05)	1 study	⊕◯◯◯ Very low
Impacts on health or health care utilisation	From 2 to 3-tier & tier-1 co-payment increased by US $1.00 versus 2 tiers – **emergency room utilisation**	**+8.7%** (p > 0.05)	1 study	⊕◯◯◯ Very low
	From 2 to 3-tier & tier-1 co-payment increased by US $1.00 versus 2 tiers – **physician visits**	**+0.4%** (p > 0.05)	1 study	

GRADE: GRADE Working Group grades of evidence (see above and last page)

* Not all comparisons and outcomes are included here. Overall drug use across tiers was reduced between -2% (p 0 0.69) to 24% (p < 0.001).
† Immediate or short-term effects (after 1 year). Estimated percentage increase or decrease relative to the comparison group.
‡ For tier-2 (preferred brand drugs) and tier 3 (non-preferred brand drugs) respectively.

Relevance of the review for low and middle-income countries

➔ Findings	▷ Interpretation*
APPLICABILITY	
➔ **The studies reviewed were mostly form high-income countries (13 from USA and 5 studies from Canada), although some included low-income populations. Only 1 study was from a low or middle-income country.**	▷ *Factors that need to be considered in assessing whether the intervention effects are likely to be transferable to other settings where health subsidies are competitive to food and other essentials include:* *– The extent to which increased cost sharing for drugs may present a financial barrier to poor households or to patients with chronic conditions who need a high volume of pharmaceuticals;* *- The extent to which any deterioration of health in these vulnerable populations may result in increased use of healthcare services and increased overall healthcare expenditures.*
EQUITY	
➔ **Restricting reimbursement and higher ceilings reduced drug use and saved drug plan expenditures. It also had the unintended effect of reducing necessary drug use when applied to "essential" drugs, and placed extra strain on already vulnerable populations, such as the elderly and those on welfare.**	▷ *High proportions of vulnerable populations may exacerbate health inequities because:* *– Low-income populations may be particularly disadvantaged, depending on where the 'cut point' for direct payments is set.* *– Low-income populations may be particularly vulnerable if they are also more likely to be sick.* ▷ *Direct payments are less likely to cause harm if only non-essential drugs are included or if exemptions are built in to ensure that patients receive needed medical care.*
COST-EFFECTIVENESS	
➔ **The findings summarised here are largely based on observational studies from high-income countries. Few studies reported on the effects of direct patient payments for drugs on health and health care .**	▷ *It is difficult to extrapoate drug expenditures to low and middle-income countries because of differences in prices and conditions. Although direct patient payments can reduce drug use and drug plan expenditures, substantial reductions in the use of life-sustaining drugs or drugs that are important in treating chronic conditions may have adverse effects on health. This may result in increases in the use of healthcare services and in overall expenditures.*
MONITORING & EVALUATION	
➔ **Poor reporting of the intensity of interventions and differences in settings and populations make comparisons across studies difficult.**	▷ *The impact of changes in direct payments for drugs should be monitored, including impacts on health and health care utilisation. Information requirements to monitor some of the consequences of these policies, especially out of pocket payments by patients could be difficult. Consideration should be given to undertaking an impact evaluation prior to taking changes to scale or making them permanent, particularly when vulnerable populations may be affected. Randomised designs should be used when possible and interupted time series analyses, when a randomised impact evaluation is not feasible to assess effects on health, overall expenditure, and cost effectiveness.*

*Judgements made by the authors of this summary, not necessarily those of the review authors, based on the findings of the review and consultation with researchers and policymakers in low and middle-income countries. For additional details about how these judgements were made see: http://www.support-collaboration.org/summaries/methods.htm

Additional information

Related literature

Detailed information on the Expert Committee on the Selection and Use of Essential Medicines, Essential Medicines Lists and the WHO Model Formulary:
Selection and Rational Use of Medicines. World Health Organization.
http://www.who.int/medicines/areas/rational_use/en/index.html

A companion review that focuses on the effects of reference pricing and other pricing and purchasing policies:
Aaserud M, Dahlgren AT, Kösters JP, Oxman AD, Ramsay C, Sturm H. Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies. Cochrane Database of Systematic Reviews 2006, Issue 2.

The protocol for this series of reviews:
Aaserud M, Dahlgren AT, Sturm H, Kösters JP, Hill S, Furberg CD. Policies: effects on rational drug use, an overview of 13 reviews. (Protocol). Cochrane Database of Systematic Reviews 2006, Issue 2.

Another recent review of the impact of direct payments for drugs on efficiency and equity:
Gemmill MC, Thomson S, Mossialos E. What impact do prescription drug charges have on efficiency and equity? Evidence from high-income countries. International Journal for Equity in Health 2008, 7:12.
http://www.equityhealthj.com/content/7/1/12

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Conflict of interest

None declared. For details, see: http://www.support-collaboration.org/summaries/coi.htm

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About quality of evidence (GRADE)

The quality of the evidence is a judgement about the extent to which we can be confident that the estimates of effect are correct. These judgements are made using the GRADE system, and are provided for each outcome. The judgements are based on the type of study design (randomised trials versus observational studies), the risk of bias, the consistency of the results across studies, and the precision of the overall estimate across studies. For each outcome, the quality of the evidence is rated as high, moderate, low or very low using the definitions on page 3.

For more information about GRADE:
www.support-collaboration.org/summaries/grade.pdf

SUPPORT collaborators:

The Alliance for Health Policy and Systems Research (HPSR) is an international collaboration aiming to promote the generation and use of health policy and systems research as a means to improve the health systems of developing countries.
www.who.int/alliance-hpsr

The Cochrane Effective Practice and Organisation of Care Group (EPOC) is a Collaborative Review Group of the Cochrane Collaboration: an international organisation that aims to help people make well informed decisions about health care by preparing, maintaining and ensuring the accessibility of systematic reviews of the effects of health care interventions. www.epoc.cochrane.org

The Evidence-Informed Policy Netowrk (EVIPNet) is is an initiative to promote the use of health research in policymaking. Focusing on low and middle-income countries, EVIPNet promotes partnerships at the country level between policy-makers, researchers and civil society in order to facilitate both policy development and policy implementation through the use of the best scientific evidence available.
www.who.int/rpc/evipnet/en/

For more information, see:
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