



January 2017 – SUPPORT Summary of a systematic review

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

Policies in which consumers pay directly for their medicines when they fill a prescription include *caps* (a maximum number of prescriptions or medicines that are reimbursed, *fixed co-payments* (patients pay a fixed amount per prescription or medicine), *tier co-payments* (the amount paid depends on whether the prescription is for a brand (patented) medicine or a generic medicine), *co-insurance* (patients pay part of the price of the medicine), and *ceilings* (patients pay the full price or part of the cost up to a ceiling, after which medicines are free or are available at reduced cost).

Key messages

- **Restrictive caps** may decrease use of medicines for symptomatic conditions and overall use of medicines and insurers' expenditures on medicines; and have uncertain effects on health service utilisation.
- **A combination of a cap, co-insurance, and a ceiling** may increase the use of medicines overall and for symptomatic and asymptomatic conditions, and decrease the cost of medicines for both patients and insurers.
- **A combination of a cap and fixed co-payments** may increase the use of medicines for symptomatic conditions; and has uncertain effects on the insurer's cost of medicines.
- **Fixed co-payments** may decrease the use of medicines for symptomatic and asymptomatic conditions and the insurer's expenditures on medicines.
- **Fixed and tier co-payments** have uncertain effects on the use of medicines and the insurer's expenditures on medicines.
- **A combination of a ceiling and fixed co-payments** may slightly decrease the use of medicines and lead to little or no difference in health service utilisation.
- **A combination of a ceiling and co-insurance** probably slightly decreases the overall use of medicines, may decrease the use of medicines for symptomatic conditions, may slightly decrease the insurer's short-term expenditures on medicines, and may increase health service utilisation.
- None of the included studies were conducted in a low-income country or reported health outcomes.

Who is this summary for?

People making decisions regarding policies to improve rational use of medicines

! This summary includes:

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

X 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:

Luiza VL, Chaves LA, Silva RM, et al. Pharmaceutical policies: effects of cap and co-payment on rational use of medicines. *Cochrane Database Syst Rev* 2015; 5:CD007017.

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 was an international project to support the use of policy relevant reviews and trials to inform decisions about maternal and child health in low- and middle-income countries, funded by the European Commission (FP6) and the Canadian Institutes of Health Research.

Glossary of terms used in this report:
www.supportsummaries.org/glossary-of-terms

Background references on this topic:
See back page

Background

Substantial and increasing healthcare funds are spent on medicines, posing a challenge to decision makers. It is necessary to optimise the use of medicines and to control medicine costs, without decreasing health benefits. Potential aims of introducing or increasing direct patient payments for medicines can be for patients to:

- decrease unnecessary use of medicines
- shift to cheaper medicines
- pay more out of pocket, thus shifting costs from the insurer to patients

Although medicine use and costs can be reduced, an overly restrictive policy may have unintended consequences, particularly for low-income or other vulnerable populations, even when there are exemptions. The discontinuation of essential medicines (medicines that are life-sustaining or that are important for managing chronic conditions) or medicines for relieving symptoms may lead to a deterioration in health and increase health service utilisation and expenditures for patients and insurers. The extent to which prescribers and patients are informed about the price of medicines, medicine substitution possibilities, and the patient's ability to pay can affect the impact of direct payment policies.

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-income countries. The methods used to assess the reliability of the review and to make judgements about its relevance are described here:

www.supportsummaries.org/how-support-summaries-are-prepared/

Knowing what's not known is important

A reliable review might not find any studies from low-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.

A lack of evidence does not mean a lack of effects. It means the effects are uncertain. When there is a lack of evidence, consideration should be given to monitoring and evaluating the effects of the intervention, if it is used.

About the systematic review underlying this summary

Review objective: To determine the effects of cap and co-payment policies on rational use of medicines.

Types of	What the review authors searched for	What the review authors found
Study designs & Interventions	Randomised trials, non-randomised trials, repeated measures studies, interrupted time series studies, and controlled before-after studies of policies that regulate out-of-pocket payments for medicines by patients, including changes in the amount paid directly by patients or limits on the amount reimbursed, including caps, fixed co-payments, co-insurance, maximum co-payment ceilings and tier co-payments	32 studies reporting on 39 interventions, including: 1 randomised trial, 8 repeated measures studies, 21 interrupted time series studies, and 2 controlled before-after studies. Pharmaceutical policies included cap policies (5 studies); cap with co-insurance and a ceiling policy (6); fixed co-payments policies (6); tier co-payment with fixed co-payment policies (2); fixed co-payment with ceiling policies (10); and co-insurance with ceiling policies (10).
Participants	Healthcare consumers and providers within a regional, national or international jurisdiction or system of care, and organisations, such as multi-site health maintenance organisations, serving a large population	Australia: pharmaceutical benefits scheme (PBM) (4); Canada: British Columbia PharmaCare Program (4), Canada, Ontario/Quebec medicine/health insurance program (4), Vancouver Residents of British Columbia (1); Swedish population (2); USA: Medicare (6), Medicaid (7) a large PBM (1), six cities (1), three nationwide pharmacy chains (1)
Settings	Any	USA (18), Canada (9), Australia (4), and Sweden (2)
Outcomes	Objectively measured outcomes: 1. Medicine use 2. Health service utilisation 3. Health outcomes 4. Costs (medicine expenditures and other healthcare and policy administration expenditures)	The studies provided data on medicine use (19 studies), costs (17) and health service utilisation (6). The data on costs were reported as medicine expenditures from the insurer's perspective (10), medicine expenditures from the patient's perspective (6), healthcare expenditures (1 study), and intervention costs (1). None of the included studies reported health outcomes.

Date of most recent search: February 2013

Limitations: This is a well-conducted systematic review with only minor limitations.

Luiza VL, Chaves LA, Silva RM, et al. Pharmaceutical policies: effects of cap and co-payment on rational use of medicines. *Cochrane Database Syst Rev* 2015; 5:CD007017.

Summary of findings

The review included 32 studies reporting on 39 interventions. In this summary we present results on medicine use, costs and health service utilisation. None of the included studies reported health outcomes.

1) Restrictive cap

Four cap policies were evaluated in four studies.

→ Introducing a more restrictive cap

- may decrease use of medicines for symptomatic conditions and overall use of medicines. The certainty of this evidence is low.
- may decrease insurers' expenditures on medicines. The certainty of this evidence is low.
- has uncertain effects on emergency department use, hospitalisations or use of outpatient care. The certainty of this evidence is very low.

About the certainty of the evidence (GRADE) *

⊕⊕⊕⊕

High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕○

Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate.

⊕⊕○○

Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕○○○

Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

* This is sometimes referred to as 'quality of evidence' or 'confidence in the estimate'.

† Substantially different = a large enough difference that it might affect a decision

See last page for more information.

More restrictive caps versus no restrictions or less restrictive caps			
People	Vulnerable and general populations		
Settings	High-income countries (USA and Australia)		
Intervention	More restrictive caps in terms of time of coverage or number of prescriptions		
Comparison	No restrictions or less restrictive caps		
Outcomes	Impact	Certainty of the evidence (GRADE)	Comments
Overall use of medicines	Moderate decrease	⊕⊕○○ Low	
Use of medicines for symptomatic conditions	Moderate decrease	⊕⊕○○ Low	The impact on use of medicines for asymptomatic conditions was not reported.
Insurers' expenditures on medicines	Moderate decrease	⊕⊕○○ Low	Introduction of a cap policy reduced Medicaid expenditures for medicines for vulnerable populations in the USA. No studies reported patient expenditures.
Emergency department visits and hospitalisations	Small increase	⊕○○○ Very low	Introduction of a cap policy in vulnerable populations in the USA led to a small increase in emergency department visits and hospitals and a moderate increase in outpatient care.
Outpatient care	Moderate increase	⊕○○○ Very low	
GRADE: GRADE Working Group grades of evidence (see above and last page)			

(Use the top rows for dichotomous outcomes when there is a meta-analysis. Use the bottom row for other outcomes.)

2) Combination of a cap, co-insurance, and a ceiling

One intervention was evaluated in seven studies.

→ Introducing a combination of a cap, co-insurance, and a ceiling

- may increase the use of medicines overall and for symptomatic and asymptomatic conditions. The certainty of this evidence is low.
- may decrease the cost of medicines for both patients and insurers. The certainty of this evidence is low.

Cap, co-insurance, and a ceiling versus limited medicines coverage			
People	Vulnerable population: Senior 65 years old or more		
Settings	USA		
Intervention	Implementation of Medicare part D (a cap combined with co-insurance and a ceiling)		
Comparison	Heterogeneous but limited medicines coverage		
Outcomes	Impact	Certainty of the evidence (GRADE)	Comments
Overall use of medicines	Uncertain	⊕⊕○○ Low	The impact of the intervention varied according to the previous medicines coverage. When the pre-policy medicines coverage was more restrictive, the impact was larger.
Use of medicines for symptomatic conditions	Moderate increase	⊕⊕○○ Low	
Use of medicines for asymptomatic conditions	Small increase	⊕⊕○○ Low	
Patients' expenditures on medicines	Moderate decrease	⊕⊕○○ Low	Introduction of a cap policy reduced Medicaid expenditures for medicines for vulnerable populations in the USA. No studies reported patient expenditures.
Insurers' expenditures on medicines	Large decrease	⊕⊕○○ Low	Introduction of a cap policy reduced Medicaid expenditures for medicines for vulnerable populations in the USA. No studies reported patient expenditures.
Health service utilisation			No studies reported on health service utilisation.
GRADE: GRADE Working Group grades of evidence (see above and last page)			

3) Combination of a cap and fixed co-payments

Two interventions were evaluated in two studies.

→ Introducing a combination of a cap and fixed co-payments

- has uncertain effects on the overall use of medicines. The certainty of this evidence is very low.
- may decrease the use of medicines for symptomatic conditions. The certainty of this evidence is low.
- has uncertain effects on the cost of medicines for insurers. The certainty of this evidence is very low.

Cap and fixed co-payment versus a cap alone or a lower cap and fixed co-payment			
People	Swedish population		
Settings	Sweden		
Intervention	Implementation of fixed co-payment or its implementation in association with a cap		
Comparison	Cap alone or a lower cap and fixed co-payment		
Outcomes	Impact	Certainty of the evidence (GRADE)	Comments
Overall use of medicines	Small decrease	⊕○○○ Very low	
Use of medicines for symptomatic conditions	Decrease	⊕⊕○○ Low	The impact on use of medicines for asymptomatic conditions was not reported.
Insurers' expenditures on medicines	Small decrease	⊕○○○ Very low	No studies reported patient expenditures.
Health service utilisation	See comments	-	No studies reported on health service utilisation.
GRADE: GRADE Working Group grades of evidence (see above and last page)			

4) Tier with fixed co-payments

Two interventions were evaluated in two studies.

The implementation or increase of tier combined with fixed co-payments showed inconsistent or potentially biased results. However, all the studies found very small differences (either increases or decreases). No studies reported the effects of this intervention on the cost of medicines or health service utilisation.

→ **Tier with fixed co-payments has uncertain effects on the overall use of medicines, medicines for symptomatic and asymptomatic conditions, hospitalisation and outpatient care. The certainty of this evidence is very low.**

5) Fixed co-payments

Four interventions were evaluated in five studies.

→ **Introducing fixed co-payments**

- has uncertain effects on the overall use of medicines. The certainty of this evidence is very low.
- may decrease the use of medicines for symptomatic and asymptomatic conditions. The certainty of this evidence is low.
- may slightly decrease the insurer's expenditures on medicines. The certainty of this evidence is low.

Fixed co-payments versus lower fixed co-payments or full coverage			
People	Seniors and general population		
Settings	USA and Canada		
Intervention	Implementation or increase of fixed co-payments		
Comparison	Lower fixed co-payments or full coverage		
Outcomes	Impact	Certainty of the evidence (GRADE)	Comments
Overall use of medicines	Small decrease	⊕○○○ Very low	The decreased use of medicine was directly related to the increase of cost sharing for patients.
Use of medicines for symptomatic conditions	Small decrease	⊕⊕○○ Low	Only the use of oral hypoglycaemic medicines increased (by approximately 2%).
Use of medicines for asymptomatic conditions	Small decrease	⊕⊕○○ Low	
Insurers' expenditures on medicines	Small decrease	⊕⊕○○ Low	The decrease in the insurer's expenditures on medicines ranged from -16.9% to 0.1%. No studies reported patient expenditures.
Health service utilisation	See comments	-	No studies reported on health service utilisation.
GRADE: GRADE Working Group grades of evidence (see above and last page)			

6) A ceiling with fixed co-payments

Five interventions were evaluated in nine studies.

→ Introducing a combination of a ceiling with fixed co-payments

- may slightly decrease the overall use of medicines, medicines for symptomatic and asymptomatic conditions. The certainty of this evidence is low.
- has uncertain effects on insurer expenditure on medicines. The certainty of this evidence is very low.
- may lead to little or no difference in emergency department visits, hospitalisations and outpatient care. The certainty of this evidence is low.

Ceiling + Fixed co-payment vs. lower value of fixed co-payment or full medicines coverage			
People	Low income and general population		
Settings	Australia and Canada		
Intervention	Implementation or increase of a ceiling combined with fixed co-payments		
Comparison	Full medicines coverage or lower fixed co-payments		
Outcomes	Impact	Certainty of the evidence (GRADE)	Comments
Overall use of medicines	Small decrease	⊕⊕○○ Low	The effect varied according to pharmaceutical groups of medicines, ranging from no effect to a reduction of approximately 25%. The reduction in the use of medicines was higher for symptomatic conditions.
Use of medicines for symptomatic conditions	Small decrease	⊕⊕○○ Low	
Use of medicines for asymptomatic conditions	Small decrease	⊕⊕○○ Low	
Insurers' expenditures on medicines	Small decrease	⊕○○○ Very low	No studies reported patient expenditures.
Emergency department visits and hospitalisations	No increase	⊕⊕○○ Low	
Outpatient care	No increase	⊕⊕○○ Low	
GRADE: GRADE Working Group grades of evidence (see above and last page)			

7) A ceiling with co-insurance

Five interventions were evaluated in nine studies.

→ Introducing a combination of a ceiling with co-insurance

- probably slightly decreases the overall use of medicines. The certainty of this evidence is moderate.
- may decrease the use of medicines for symptomatic conditions. The certainty of this evidence is low.
- has uncertain effects on the use of medicines for asymptomatic conditions. The certainty of this evidence is very low.
- may slightly decrease the insurer's short-term expenditure on medicines. The certainty of this evidence is low.
- may lead to an increase in emergency department visits and hospitalisations. The certainty of this evidence is low.
- has uncertain effects on outpatient care. The certainty of this evidence is very low.

A ceiling with co-insurance versus lower fixed co-payments or full coverage			
People	General population		
Settings	Canada, USA and Sweden		
Intervention	Implementation or increase of a ceiling combined with fixed co-insurance		
Comparison	Full coverage or fixed co-payments and lower co-insurance		
Outcomes	Impact	Certainty of the evidence (GRADE)	Comments
Overall use of medicines	Small decrease	⊕⊕⊕○ Moderate	There was a larger reduction in the use of medicines for symptomatic conditions, with the exception of asthma inhalers, for which there was only a slight increase (around 3%).
Use of medicines for symptomatic conditions	Medium decrease	⊕⊕○○ Low	
Use of medicines for asymptomatic conditions	Small decrease	⊕○○○ Very low	
Insurers' expenditures on medicines	Small decrease	⊕⊕○○ Low	There was an initial small decrease in the insurer's expenditures on medicines, but at the end of the first year there was a small increase. No studies reported patient expenditures.
Emergency department and hospitalisation	Medium increase	⊕⊕○○ Low	
Outpatient care	Small increase	⊕○○○ Very low	
GRADE: GRADE Working Group grades of evidence (see above and last page)			

Relevance of the review for low-income countries

→ Findings	▷ Interpretation*
APPLICABILITY	
<p>→ All the included studies were conducted in high-income countries. Some were targeted at poor or vulnerable populations.</p>	<p>▷ 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:</p> <ul style="list-style-type: none">– The extent to which increased cost sharing for medicines 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	
<p>→ Introducing a restrictive cap, a fixed co-payment, or a combination of a ceiling with fixed co-payments or co-insurance may have the unintended effect of reducing the use of necessary medicines for symptomatic conditions. Moreover, a ceiling with fixed co-insurance may lead to an increase in emergency department visits and hospitalisations. These effects could place an extra strain on already vulnerable populations, such as the elderly and those on welfare.</p>	<p>▷ Policies that increase direct payments for medicines may increase health inequities because:</p> <ul style="list-style-type: none">– 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. <p>▷ Direct payments are less likely to cause harm if only non-necessary medicines are included or if exemptions are built in to ensure that patients receive needed medical care.</p>
ECONOMIC CONSIDERATIONS	
<p>→ The findings are largely based on observational studies from high-income countries. None of the included studies reported the effects of direct patient payments for medicines on health outcomes and few reported effects on health service utilisation.</p>	<p>▷ It is difficult to extrapolate findings for medicine expenditures from high to low-income countries because of differences in prices and conditions. Although direct patient payments can reduce medicine use and insurers’ expenditures, substantial reductions in the use of necessary medicines may have adverse effects on health. This may result in increases in the use of health services and in overall expenditures.</p>
MONITORING & EVALUATION	
<p>→ Poor reporting of the intensity of interventions and differences in the size of caps or co-payments, pharmaceutical groups of medicines included in the policy, incentives to comply with the policy, information provided to patients and providers, exemptions, settings and populations make comparisons across studies difficult.</p>	<p>▷ The impact of changes in direct payments for medicines should be monitored, including impacts on health and health service utilisation and the factors that might modify the effects of policies. Information requirements to monitor some of the consequences of these policies, especially out of pocket payments by patients could be difficult.</p> <p>▷ Other interventions, such as education or prior authorisation, might be better suited to address inappropriate use of medicines.</p> <p>▷ Impact evaluations should be undertaken 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 interrupted time series studies when a randomised impact evaluation is not feasible to assess effects on health, overall expenditures, and cost-effectiveness.</p>

*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-income countries. For additional details about how these judgements were made see: www.supportsummaries.org/methods

Additional information

Related literature

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This summary was prepared by

Agustín Ciapponi, Argentine Cochrane Centre IECS –Institute for Clinical Effectiveness and Health Policy– Iberoamerican Cochrane Network, Argentina

Conflict of interest

None declared. For details, see: www.supportsummaries.org/coi

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About certainty of the evidence (GRADE)

The “certainty of the evidence” is an assessment of how good an indication the research provides of the likely effect; i.e. the likelihood that the effect will be substantially different from what the research found. By “substantially different” we mean a large enough difference that it might affect a decision. These judgements are made using the GRADE system, and are provided for each outcome. The judgements are based on the study design (randomised trials versus observational studies), factors that reduce the certainty (risk of bias, inconsistency, indirectness, imprecision, and publication bias) and factors that increase the certainty (a large effect, a dose response relationship, and plausible confounding). For each outcome, the certainty of the evidence is rated as high, moderate, low or very low using the definitions on page 3.

For more information about GRADE: www.supportsummaries.org/grade

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The Evidence-Informed Policy Network (EVIPNet) is an initiative to promote the use of health research in policymaking in low- and middle-income countries. www.evipnet.org

The Alliance for Health Policy and Systems Research (HPSR) is an international collaboration that promotes the generation and use of health policy and systems research in low- and middle-income countries. www.who.int/alliance-hpsr

Norad, the Norwegian Agency for Development Cooperation, supports the Norwegian EPOC satellite and the production of SUPPORT Summaries. www.norad.no

The Effective Health service Research Consortium is an international partnership that prepares Cochrane reviews relevant to low-income countries. www.evidence4health.org

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