

BMJ Open How do financial (dis)incentives influence health behaviour and costs? Protocol for a systematic literature review of randomised controlled trials

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ABSTRACT

Introduction In this era of rising healthcare costs, there is a growing interest in understanding how funding policies can be used to improve health and healthcare efficiency. Financial incentives (eg, vouchers or access to health insurance) or disincentives (eg, fines or out-of-pocket costs) affect behaviours. To date, reviews have explored the effects of financial (dis)incentives on patient health and behaviour by focusing on specific behaviours or geographical areas. The objective of this systematic review is to provide a comprehensive overview on the use of financial (dis)incentives as a means of influencing health-related behaviour and costs in randomised trials.

Methods and analysis We will search electronic databases, clinical trial registries and websites of health economic organisations for randomised controlled trials. The initial searches, which were conducted on 13 January 2018, will be updated every 12 months until the completion of data analysis. The reference lists of included studies will be manually screened to identify additional eligible studies. Two researchers will independently review titles, abstracts and full texts to determine eligibility according to a set of predetermined inclusion criteria. Data will be extracted from included studies using a form developed and piloted by the research team. Discrepancies will be resolved through discussion with a third reviewer. Risk of bias will be assessed using the Cochrane Collaboration tool.

Ethics and dissemination Ethics approval is not required since this is a review of published data. Results will be disseminated through publication in peer-reviewed journals and presentations at relevant conferences.

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INTRODUCTION

In this era of rising healthcare costs,^{1,2} there is a growing interest in understanding how funding policies can be used to support effective, efficient, affordable and accessible care.³ Funding policies have the potential to influence the health-related behaviours and outcomes of individuals and costs.⁴⁻⁸ The costs borne by individuals may affect what services they will seek out or use, which have important implications not only on their

Strengths and limitations of this study

- This protocol presents a transparent methodology for conducting a systematic review of published evidence on health policy randomised controlled trials.
- Our mixed-method analysis will go beyond a summary of studies to frame them within the current context of research on health policy trials, thus bridging a crucial gap between research and policy making.
- Since there is no established vocabulary for this broad topic of research, the search strategy was designed to maximise sensitivity.
- We included only studies published in English.

health but also on the overall sustainability of the healthcare system.

There are two types of financial mechanisms that can be used in funding policies directed towards patients. Financial incentives, such as vouchers, cash transfers, free health services and increased health insurance benefits, are positive monetary benefits that encourage a behaviour.⁹ In contrast, financial disincentives, including fines, fees and out-of-pocket costs, are negative monetary penalties that discourage a behaviour.⁹ Both types of incentives can have an impact on direct measures of behaviour change (eg, patient behaviours) and indirect measures of behaviour change (eg, patient outcomes or healthcare resource use). For example, observational studies indicate that financial incentives, such as increased health insurance, are associated with a higher use of health services and better health outcomes.¹⁰⁻¹² Conversely, financial disincentives, such as out-of-pocket costs, have been shown to be associated with medication non-adherence.^{13,14}

Despite a wealth of evidence, critics argue that a causal relationship between financial (dis)incentives and an individual's behaviour within a given healthcare system

can only be established through a randomised experimental design (sometimes referred to as a health policy trial).¹⁵ A patient's access to financial incentives, such as health insurance, can be influenced by numerous demographic, social and environmental factors.¹⁶ Consider the impact of geographical location,^{17–19} level of education,²⁰ income^{21–23} and employment status²⁴ on behaviour. As a result, observational studies might not determine if any observed differences in behaviour or health outcomes are in fact caused by the financial (dis)incentives experienced by the patient.

Several reviews have explored the effects of financial incentives on patient-related health and behaviour. These reviews are restricted in scope, focusing on specific behaviours^{25–29} or geographical regions^{30–31} rather than on an individual's interaction with a healthcare system. In addition, some reviews include studies with an observational design,^{28–29} which makes it difficult to isolate the effect of financial (dis)incentives on patients' health and health-related behaviours.

A recent review published by Newhouse and Normand acknowledges how trials on financial incentives, such as the RAND Health Insurance Experiment³² and the Oregon Health Insurance Experiment,³³ have influenced health policy in the USA.³⁴ Despite their relevance to health policy decision-making, we do not have a comprehensive understanding of the research that has been conducted on patient-targeted financial (dis)incentives in a randomised experimental environment. The objective of this review is to describe the evidence landscape on the use of patient-targeted financial (dis)incentives as a means of influencing patient behaviour in randomised controlled trials (RCTs). The impact of these (dis)incentives will be assessed through both direct and indirect outcomes.

METHODS

Study design

This systematic review will be conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol guidelines.³⁵

Eligibility criteria

The research question guiding this review is: how do financial incentives and/or disincentives influence patient behaviour within the context of RCTs? Studies will be included if they meet the following criteria:

- ▶ The study includes human subjects.
- ▶ The language of publication is English.
- ▶ The study design is an RCT.
- ▶ The population consists of patients.
- ▶ The intervention is a patient-targeted financial incentive or disincentive provided within a healthcare system.

Given the broad scope of this review, no comparators or outcomes are specified a priori.

Reviews, editorials, books, abstracts and commentaries will be excluded. There are no restrictions in terms of date of publication.

Information sources

We will search the following electronic databases for eligible studies: MEDLINE (via Ovid), Embase (via Ovid), Econlit (via EbscoHost) and The Cochrane Library. Additionally, we will conduct a targeted search of various grey literature sources, including clinical trial registries and the websites of relevant health economic organisations and conferences. The reference lists of included studies will also be screened to identify additional eligible studies.

Search strategy

The search strategy was developed through a collaborative process that involved researchers with expertise in health economics and the methodology of systematic literature reviews, as well as an academic librarian. The strategy is based on concepts related to (1) financial (dis)incentives (eg, insurance coverage, out-of-pocket costs, cost sharing, fines or cash transfers) and (2) direct and indirect measures of behaviour (eg, patient behaviours, health outcomes and healthcare resource use). These concepts were operationalised using controlled vocabulary (Medical Subject Heading [MeSH] terms), keywords and synonyms. The initial strategy was designed in MEDLINE (via Ovid) and then adapted to the electronic databases. All search strategies are available in online supplementary appendix 1. The initial searches, conducted on 13 January 2018, will be updated every 12 months until the completion of data extraction and analysis.

Data management

All references will be imported into EndNote V.X8.2 (Clarivate Analytics, 2016) to remove duplicates. Data will be maintained in a Microsoft Excel workbook V.16.10 (Microsoft, 2017).

Selection process

Study eligibility will be assessed first at the title and abstract level followed by a full text review. Two reviewers will independently scan the titles and abstracts of all references identified in the literature search according to a screening form, which operationalises the study inclusion criteria. The same two reviewers will independently review the full text of all relevant studies. Any discrepancies in study eligibility will be resolved by discussion, with a third reviewer providing arbitration as necessary.

Data collection

A data extraction form was developed by the research team. Two reviewers, working independently and in duplicate, will extract data on the trial, patient and outcome characteristics. Further details are available in online supplementary appendix 2. Prior to commencing the full data extraction, two reviewers will pilot test the data extraction form to evaluate consistency, accuracy and

completeness.³⁶ If additional categories are identified during this process, the form will be amended accordingly and rationales for changes will be documented.

If information required to complete data extraction is missing or unclear, the study's corresponding author will be contacted by e-mail. At the end of the data extraction process, the two reviewers' data will be compared to ensure accuracy. Any discrepancies will be documented and resolved by discussion between the two reviewers.

Risk of bias

We will conduct a critical appraisal of eligible studies using the risk of bias tool developed by the Cochrane Collaboration.³⁷ All studies, regardless of their considered quality, will be included in this systematic review.

Data synthesis

Given the expected heterogeneity between health policy trials, we do not anticipate conducting a meta-analysis. Instead, we will take a convergent mixed-method approach to analyse the data from included studies (see figure 1 for details). The purpose of a convergent design is to obtain different but complementary data on the same topic.³⁸ First, we will conduct a quantitative analysis of the extracted data using descriptive statistics (eg, frequency counts and percentages) to describe general study (eg, country, population of interest and sample size) and intervention-specific characteristics (eg, type of intervention and magnitude of financial [dis]incentive). A qualitative content analysis of the full texts will follow. Content analysis entails the search for

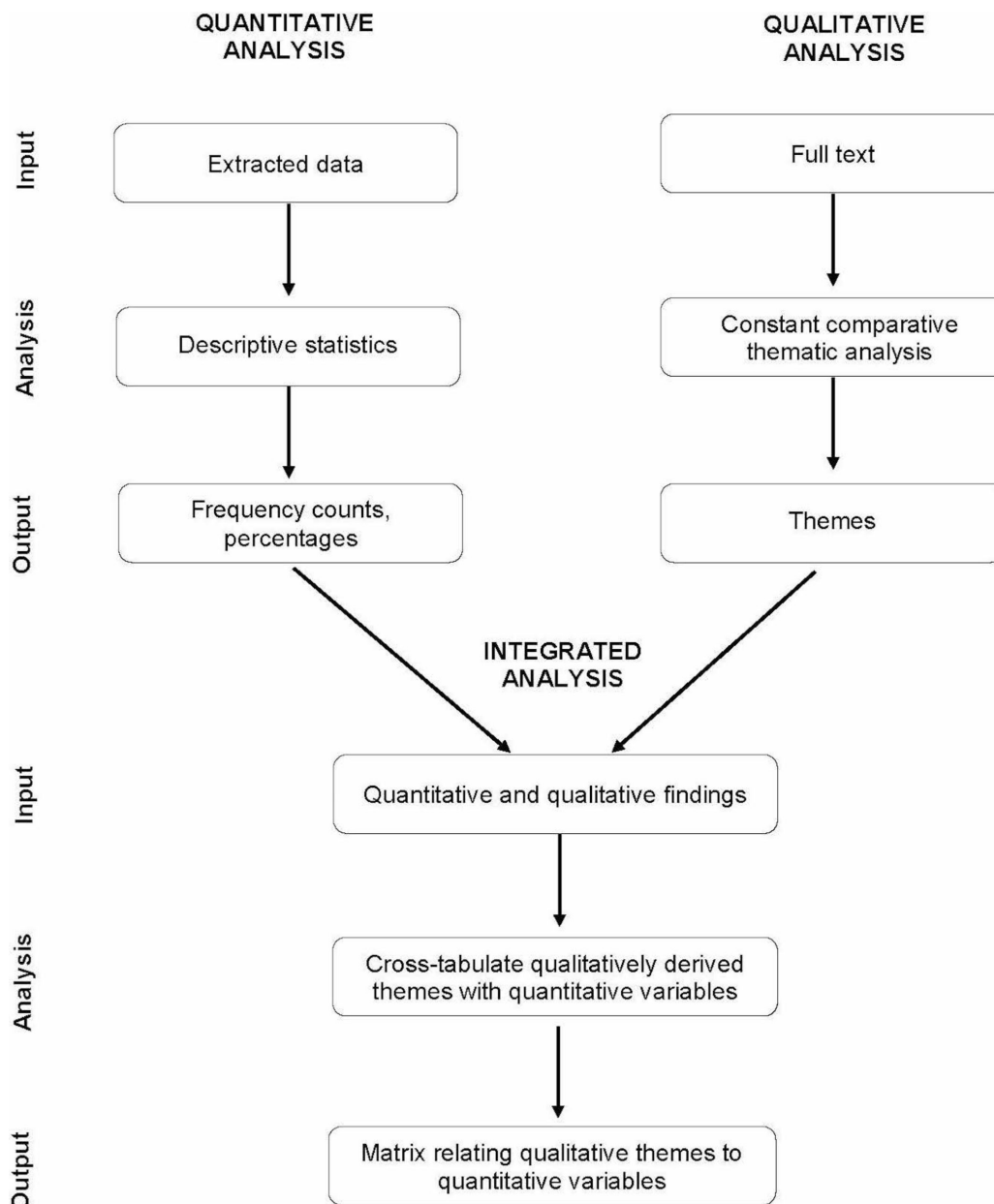


Figure 1 Concurrent mixed-method design.

and the identification of categories (or themes) across data.³⁹ This method is particularly suited for health policy trials⁴⁰ because the depth of the analysis allows for a more comprehensive understanding of complex social and context-dependent interventions. For this analysis, two reviewers will independently analyse a sample of the full texts of included studies, taking an inductive approach to identify emerging themes. Attention will be paid to language and content in order to identify common issues, controversies, and shared discourses from this body of literature on health policy trials. Passages will be coded as emerging themes are identified. The findings will be compared and discussed among the research team until consensus on a coding scheme is reached. The two reviewers will then code the remaining texts with the objective of highlighting similarities, differences, and outliers among included studies.⁴¹ Finally, the quantitative and qualitative data will be integrated using methods of triangulation. In this final analysis, two researchers will cross-tabulate the qualitatively derived themes with the quantitative variables to explore to what extent the results from both data sets relate to each other in order to obtain a better understanding of the evidence landscape. The intent is to link the quantitative findings to their context and the environment in which they were produced.

The number of studies identified and selected for inclusion in the systematic review will be recorded, and a flowchart will be used to illustrate the selection process. We will report the findings from the quantitative analysis using tables to summarise the general study and intervention-specific characteristics of included studies. A narrative summary will provide an overview of the qualitative component of the analysis, as well as the integration of qualitative and quantitative data.⁴²

Patient and public involvement

Patients and public partners were not involved in the design of the protocol for this systematic review.

DISCUSSION

When used as policy instruments, patient-targeted financial (dis)incentives have the potential to improve health outcomes and health care efficiency. However, in order to inform policy, it must first be understood what has been done in an experimental environment. This protocol presents a comprehensive, robust and transparent methodology for the conduct of a systematic review of published RCTs investigating the use of financial (dis)incentives as a means of influencing patient health-related behaviours, both directly or indirectly.

Limitations

We acknowledge that there are limitations. First, there is no established vocabulary for this broad topic of research. Studies on financial (dis)incentives could pertain to 'fines', 'vouchers', 'insurance', 'out-of-pocket costs' and so on. As a result, the search strategy was designed to

maximise sensitivity. This improves our ability to capture all relevant studies but reduces the overall precision of the search strategy, which may identify a large number of irrelevant references.

Second, we included only studies published in English. The decision was made in consideration of the time and costs required to translate articles published in other languages. It could result in language bias if the studies identified in our search strategy are not representative of existing evidence. However, a study on the use of English-language restrictions within the context of reviews failed to find evidence of a systematic bias from the use of language restrictions.⁴³

Third, we acknowledge that the scope of this review is limited to patient-targeted financial (dis)incentives that are a positive spur to behaviour change, such as vouchers or increased insurance benefits. However, given the complexity of healthcare systems, there are a multitude of mechanisms for change. For example, future work may more comprehensively evaluate financial mechanisms that remove barriers to patient behaviour change (eg, transport assistance or childcare) or that are directed towards different payers (eg, clinicians or government).

Implication of findings

Evidence-based policy making is becoming increasingly important, given the pressures faced by healthcare systems around the globe. There are a number of important policy issues that remain unresolved, including the debate over single versus multiple payer health insurance systems in the USA,^{44 45} the National Health Service financial crisis in the UK,⁴⁶ the implementation of Pharmacare in Canada⁴⁷ and the lack of access to healthcare in developing countries.^{48 49} The consequences of misinformed or uninformed policy decisions could be tremendous in terms of costs but also population health.

A comprehensive understanding of available experimental evidence is essential to support efficient and valid policy decision-making. There is a need to not only identify 'what works' but also understand why a given intervention is successful. Mixed-method approaches, which integrate quantitative and qualitative findings, are well suited for this purpose.⁵⁰⁻⁵² Our analysis will go beyond a summary of studies to frame them within the current context of research on health policy trials, thus bridging a crucial gap between research and policy making. Moving forward, there is the potential for embedding healthcare policy trials directly into existing healthcare systems. The established administrative structures of these otherwise routine processes are an ideal means by which we may enhance data collection and achieve long-term follow-up.⁵³

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Contributors BH contributed to the design of the systematic review, as well as the drafting of the protocol. AI and MZ contributed to the design of the systematic review and critically revised the protocol for important intellectual content. FX contributed to the conception and design of the systematic review and critically revised the protocol for important intellectual content. All authors gave final approval of the version submitted for publication and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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