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Government regulation of private health insurance

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

The objective of this review is to assess the effects of policies that regulate private health insurance.

BACKGROUND

Health services, like any other services (e.g. food, accommodation, entertainment), have to be paid for by individuals or by groups of people and can be financed through various channels.

- Out-of-pocket payment. This category of private health expenditure involves any direct outlay by households, including gratuities and in-kind payments, to health practitioners and suppliers of pharmaceuticals, therapeutic appliances and other goods and services, whose primary intent is to contribute to the restoration or enhancement of the health status of individuals or population groups.

- Public insurance programmes. Funds are raised by the state through various forms of taxation, or are raised by social insurance institutions. This is done largely or wholly outside the commercial marketplace, and compulsory levies are imposed on all or some of the population (Evans 2002).

- Private health insurance (PHI). In this case, financial resources are directly channeled into a risk-pooling institution with very little or no state involvement (Drechsler 2007).

Out-of-pocket spending by patients is the most frequent method of paying for health services around the world (Savedoff 2004; WHO 2010). This is especially true for low- and middle-income countries (LMICs), where it can lead to catastrophic health expenditures for households (WHO 2000; Xu 2003). Catastrophic expenditure can force households to reduce spending on other basic goods (e.g. food, water), to sell assets or to incur high levels of debt and ultimately to risk impoverishment (McIntyre 2007; WHO 2010). The World Health Organization (WHO) has proposed that health expenditure should be called 'catastrophic' when it is greater than or equal to 40% of capacity to pay (Kawabata 2002)- expenditure at such a high level as to force households to reduce spending on other basic goods (e.g. food, water), to sell

assets or to incur high levels of debt, and ultimately to risk impoverishment. Internationally and especially in LMICs, vulnerable groups that constitute a significant segment of the population are largely excluded from access to health care and health insurance. Their ability to pay for health care is greatly reduced compared with more affluent groups of people. Moving towards risk pooling in health systems financing is thus essential in achieving universal health coverage, as it promotes equity, improves access and protects households from incurring catastrophic health expenditures (WHO 2000; WHO 2010). Risk pooling is the sharing of risk across a group of people or across an entire population, so that unexpected healthcare expenditure does not fall solely on an individual or household, and so that individuals or households are protected from catastrophic expenditure (McIntyre 2007; WHO 2010). Risk pooling therefore enables health services to be provided according to people's need rather than their individual capacity to pay for health services (Carrin 2003).

Generally, health insurance can be financed through three broad channels: taxation; social security; and private health insurance (Sekhri 2005a). The three main PHI schemes are non-profit plans, for-profit plans and community health insurance (Cutler 2000). Unregulated or poorly designed PHI systems have been shown to exacerbate inequalities and provide coverage only for the young and healthy, leading to cost escalation, but when appropriately managed, they could play a positive role in improving access and equity (Sekhri 2005a).

Private health insurance (PHI) schemes usually seek to achieve three main overlapping functions (OECD 2004; Thomson 2009): The first is to serve as an alternative or substitute for health care financed by the state. In this case, PHI may be crucial for certain populations that are excluded from some or all aspects of state-provided coverage, or it may provide an option for populations that are allowed to choose between state and private coverage (e.g. higher-income households). Second, PHI can be complementary, in which case it serves as co-payment for healthcare services (such as dental care) that are partially covered by the state. Finally, PHI could be supplementary, providing coverage for those services not covered by state insurance and allowing patients the choice of service provider or faster access to services.

In the absence of regulatory interventions in a PHI market, insurers might tend to adopt practices that seek to minimise their risk to avoid losses, including denial of coverage for applicants who have preexisting health conditions (Kofman 2006). On the other hand, overregulation might exert enormous stress on insurers, resulting in strangulation of the market (a situation whereby insurance schemes are unable to function in a sustainable manner and therefore are forced to shut down) (Sekhri 2005b).

Description of the condition

The basic function of health insurance is to provide access to care with financial risk protection (Kutzin 2001). Private health insurance (PHI) is defined as insurance taken up voluntarily and paid for privately, either by individuals or by employers on behalf of individuals (Mossialos 2002). It may be sold by a wide range of entities, both public and private in nature, which may include statutory 'sickness funds,' non-profit mutual or provident associations and commercial for-profit insurance companies (Thomson 2009). For the purpose of this review, we shall define PHI schemes as those wholly or partially financed and managed by an entity (organisation/institution/company) that is not state-owned, irrespective of whether it is a for-profit or a not-for-profit entity.

Health insurance comprises three components (Sekhri 2005b): collection of funds, pooling of funds and purchasing of services. To achieve the objectives of PHI schemes, governments have to establish a number of interventions. Private health insurance in advanced market economies is regulated by a government agency that implements statutory requirements, which include establishing administrative rules and procedures (Harrington 2007). Most countries that have well-established PHI markets intervene in the market to protect consumers and to promote the public health objectives of equity, affordability and access to health services through policies, incentives and regulations that "conscript private insurance to serve the public goal of equitable access" (Jost 2001). For instance, in the United States of America (USA), every state has adopted certain basic standards for health insurance that apply to all types of health insurance products (Kofman 2006). All states require insurers to be financially solvent and capable of prompt payment of claims and to employ fair claims handling practices. Within the health insurance literature, PHI has been used interchangeably with 'private medical insurance' and 'voluntary health insurance.' For the purpose of this review, we will use the term 'private health insurance.'

Description of the intervention

To effectively implement interventions targeted at fulfilling the goals of PHI, states have to develop a number of oversight and enforcement tools (Kofman 2006). An approach that policy makers can use in developing a regulatory scheme for PHI has been proposed by Sekhri and consists of addressing five key questions on interactions between key actors in the health insurance market: the insurers, the consumers and the providers (Sekhri 2005b).

- **Who can sell insurance?** Governments have to ensure that only appropriate institutions get involved in the PHI sector. These institutions should have sufficient financial means and should possess adequate human and technical resources to provide optimal services to users. The policies of these institutions benefit both patients and firms, as they offer consumer protection and ensure a viable insurance market.
- **Who should be covered?** Regulation of who should be covered enables policy makers to guide the breadth and depth of

coverage. 'Breadth of coverage' refers to the proportion of the total population covered by health insurance; 'depth of coverage' refers to the composition of the health insurance benefit package - the more comprehensive the package, the greater the depth of coverage (McIntyre 2007). Regulating who should be covered involves adverse selection and risk selection. 'Adverse selection' is the likelihood that a person with high risk of illness and a greater need for frequent health care will be more likely to enrol in a health insurance scheme than a person with low risk of illness and less need for frequent use of health care (McIntyre 2007). If the proportion of high-risk individuals insured is too high, this will lead to high expenditures for PHI firms and collapse of the market. When insurers have limited information about an individual's health status, they try to protect themselves from this unknown risk by setting insurance premiums above what they otherwise might (Sekhri 2005b). Policy regulation thus has to address these issues to prevent adverse selection and to allow the PHI market to thrive. 'Risk selection' (also referred to as 'cream-skimming' or 'cherry-picking') is the practice whereby an insurance firm enrolls a disproportionate percentage of individuals (e.g. young people) who present a lower than average risk of ill health (McIntyre 2007). This occurs when insurers try to counter adverse selection or to maximise profit by discouraging sicker individuals from purchasing insurance, or by finding ways to insure only lower-risk individuals (Sekhri 2005b). Regulatory policies therefore have to ensure that individuals can be enrolled regardless of their health risk, so as to counter risk selection. One way in which governments can reduce risk selection is by implementing a risk adjustment mechanism. Risk adjustment or risk equalisation enables enrolment of high-risk and low-risk individuals in insurance schemes that charge the same average premium (Kauter 2014). This is done by setting up a fund to pay participating insurance schemes so that they set their premiums based on the benefits offered, not on the health status of the individual.

- **What should be covered?** In settings in which health is considered a merit good, provision of health care ought to be based on people's need, not on their capacity to pay. As a result, a minimum health package has to be covered by PHI institutions. This set of regulations defines the basic benefits that must be provided to those insured while addressing societal values on health. These requirements are intended to protect consumers from unreasonable exclusions and to address adverse selection and risk selection.

- **How can prices be set?** Regulating how private companies can price their products is a significant governmental intervention that can lead to unintended consequences because of competing objectives such as affordability, equity, viability and avoidance of adverse selection, risk selection and moral hazard. Moral hazard is the tendency toward entitlement to the benefits of health insurance to act as a strong incentive for people to consume more and "better" health care, and as a weak incentive

for them to maintain a healthy lifestyle (McIntyre 2007). This can increase both appropriate and inappropriate use of services, as well as the cost of coverage.

- **How should providers be paid?** Regulating provider payment methods can address the problems of supplier-induced demand (when fee-for-service payments are used). With unregulated fee-for-service payments, consumers may tend to demand increased healthcare services and providers may induce inappropriate use of healthcare services.

Addressing the above regulatory issues in private insurance markets involves different tasks and an appropriate mix of skilled people, functioning institutions and good governance. Sekhri et al (Sekhri 2005b) have proposed policy tools that can be grouped into four general categories: legislation and licencing, monitoring, auditing and intelligence.

- **Legislation and licencing** focuses on setting up the legal framework for health insurance and verifies that new insurers entering the market comply with regulatory requirements.

- **Monitoring** includes procedures that insurance firms use to report financial status, health services utilised by clients and grievances or conflicts. At a minimum, a regulatory entity will require financial information from insurers regarding their reserves, risk categories of their investments and cash flow. Information on utilisation patterns, enrolment, claims experience and administrative costs is also important and can be used to forecast whether an insurance company might be at risk for failure, so that early actions can be taken. Health services information is also required and includes provider lists, licences and accreditation certificates to ensure quality, as well as the locations of all providers to verify geographic access. Grievances and conflicts will arise and proper procedures must be established, such as arbitration boards, regulatory review or as a last resort legal actions. Grievance procedures should include some recourse for outside agencies such as the regulator or a separate medical body to ensure adequate consumer protection. All grievances should be acknowledged and reported on a standard basis, and this information should be made publicly available.

- **Auditing** is necessary because insurance markets are decentralised and the steward institutions must rely heavily on compliance with specified reporting requirements. The degree of compliance will vary among countries. One way to maintain or improve compliance is to ensure that non-compliance is detected and punished. Two complementary auditing processes may be used: automatic and randomised. The former focuses on cases that surpass established limits (e.g. requiring detailed audits of the largest insurers on a rotating basis or of particularly large financial transactions). The latter ensures that every insurer has some chance of being audited and facing potential consequences.

- **Intelligence** entails assimilating information obtained through monitoring and auditing activities of the insurance market and combining this 'internal' information with 'external'

data on the overall condition of financial markets, the degree of insurance market concentration, insurance coverage in the population and health outcomes. A specialised government institution with access to relevant data sources can be in charge of this role. Information gathered in this manner can be used to inform interventions that fall within the scope of legislation and licencing, monitoring and auditing.

How the intervention might work

Specific goals have to be set in assessing the impact of policies that regulate PHI. Three main policy goals have been identified by Sekhri, each having a number of objectives that can be attained using well-designed instruments: to protect consumers, to promote equity and to promote cost containment (Sekhri 2005b).

To protect consumers, five objectives are proposed.

- To ensure financial solvency of the insurers. This can be achieved by establishing sufficient minimum capital/reserve requirements and financial reporting requirements for greater transparency.
- To promote a competitive market to encourage affordability and consumer choice. This can be achieved by establishing reserve requirements that allow different types of insurers to enter the market and by putting in place rules against monopolistic pricing.
- To promote transparency and fairness in transactions between consumers and insurers. This is done by establishing disclosure requirements for policies and ensuring that their content is understandable to consumers, and by monitoring advertising and sales practices to ensure consumer protection and provision of independent mechanisms to resolve consumer grievances.
- To ensure that insurance packages provide adequate financial protection to those insured. This can be achieved by defining at least one standard benefit package that all insurers must offer, and by getting insurers to set premiums for this package in similar ways.
- To address issues related to health as a merit good. This can be done by directly providing or purchasing healthcare interventions that are defined as public goods through public funds, ensuring that minimum benefit packages comprise those items and providing public subsidies to insurers for public goods.

To promote equity, three objectives are proposed.

- To minimize adverse selection and encourage broader risk pooling. This can be achieved by making insurance mandatory for certain categories of households, encouraging group enrolment (through employer groups, associations, co-operatives and labour unions), by creating incentives for low-risk individuals to join the insurance pool (e.g. tax incentives, rebates, life-time rating methods), by permitting defined waiting

periods for preexisting conditions and by permitting insurers to make enrolees disclose their medical history.

- To minimise risk selection or cream skimming and to encourage broader risk pooling. This can be achieved by covering high-risk individuals through publicly funded programs, by providing mechanisms to protect insurers (such as high-risk pools, reinsurance and risk equalisation schemes), by requiring guaranteed issue and renewal along with pricing guidelines that do not make premiums unaffordable for sicker individuals and by limiting exclusions and waiting periods to the first time that an individual purchases continuous insurance coverage.
- To establish premium setting guidelines that promote cross-subsidies between healthy and sick and/or between income levels. This is achieved by requiring community rating to promote cross-subsidies between healthy and sick and by encouraging income-based contributions when feasible to promote cross-subsidies between high- and low-income individuals (most often done only in social insurance).

To promote cost containment, two objectives are proposed.

- To reduce supplier-induced demand. This can be achieved by encouraging provider payment mechanisms that share risks and rewards with providers such as case rates (a predefined amount covering a specific group of procedures), per-diems (predefined daily rates in case of hospitalisation, or number of days during which healthcare services are provided in case of outpatient visits) and capitation, which is a method of paying doctors a fixed fee per period per patient registered (sometimes differentiated according to age or sex of patients), regardless of the amount of service provided.
- To reduce consumer-induced demand (moral hazard). Consumer cost sharing can be promoted through deductibles and co-payments. Monitoring of cost-sharing practices should be done to ensure that they do not limit access to needed services, and that they provide adequate financial protection.

Why it is important to do this review

With a growing global population and increasing strain on public resources to meet the healthcare needs of populations through state-provided health insurance programmes, many governments have turned to PHI to ease the pressure on state budgets (OECD 2004). Reduction in direct payments for health care is a key indicator of progress towards universal coverage (WHO 2010). However, in a number of LMICs, the population remains largely dependent on state-provided health insurance or poorly regulated PHI. Many advanced economies have long recognised the difficulties associated with solely public financing and provision of health care and have liberalised the health insurance market, with the goal, amongst others, to improve access to health care, while reducing direct state financing and provision of health care.

To cover more people, countries would need to ensure that a portion of healthcare costs is covered by funds from pooling institutions (WHO 2010); increasing enrolment in pooling institutions, such as PHI firms, is another of the political options for ensuring universal healthcare coverage. With the goal of improving access to basic health care for citizens through PHI programmes, state regulation of the market has been strongly incorporated into existing schemes in some countries. Low- and middle-income countries now have the opportunity to learn from this experience to optimise PHI (Sekhri 2005b). If poorly regulated, PHI can hardly achieve an adequate quantity or quality of population coverage, as can be seen in the USA, where a third of adults younger than 65 years of age have no insurance, sporadic coverage or coverage that exposes them to high out-of-pocket healthcare costs.

This review seeks to gather evidence on the effects of government regulation of the PHI market. Governments have several options that they can consider when aiming for universal coverage; these include social health insurance and public, private and mixed insurance schemes (WHO 2005). This review will contribute to inform the choice of PHI or another alternative. We aim to inform elaboration of policies that result in achievement of desired objectives of PHI and implementation of the most effective regulatory mechanisms.

OBJECTIVES

The objective of this review is to assess the effects of policies that regulate private health insurance.

METHODS

Criteria for considering studies for this review

Types of studies

We will consider the following study designs: randomised controlled trials (RCTs), non-randomised controlled trials (non-RCTs), interrupted time series (ITS) designs and controlled before-and-after studies (CBAs), meeting the quality criteria put forth by the Cochrane Effective Practice and Organisation of Care (EPOC) Group (EPOC 2013a). We will include both individually randomised and cluster-randomised controlled trials (CRCTs). An RCT is a study that allocates participants to the intervention group or to the control group using a random method. A CRCT is an experimental study in which groups of people (clusters) are allocated to different interventions through random methods. The EPOC Group recommends that only studies with at least two intervention sites and two control sites are included, to minimise

confounding due to study site. An NRCT is a study that allocates units to intervention groups and control groups by using methods that are not random. A CBA study is one in which observations are made before and after implementation of an intervention, both in the group that received the intervention and in the control group, which did not. We will exclude CBA studies and non-RCTs that have only two study locations, in accordance with the Effective Practice and Organisation of Care (EPOC) criteria for inclusion of studies in systematic reviews of effects. In observance of EPOC Group criteria, we will include an ITS study only if outcomes are measured during at least three points before and three points after the intervention, and we will exclude simple pre/post designs.

Types of participants

In this review, we will include studies done in any population, undertaken in any country without restriction on the health benefits provided by PHI schemes.

Types of interventions

Interventions

- **Legislation and licencing** of new and existing PHI schemes.
 - Ensure that they meet the requirements for providing health insurance.
 - Determine who should be covered and the depth/breadth of coverage.
 - Define provider payment methods.
- **Monitoring** of PHI schemes on a continuous basis.:
 - Regulate prices.
 - Apply risk adjustment mechanisms.
- **Auditing** processes.
 - Perform automatic auditing.
 - Perform randomised auditing.
- **Intelligence.**
 - Employ a functioning government intelligence organisation that collects internal and external data in relation to PHI, and use this information to inform the above three interventions.

Comparison

- No regulation or comparison of different regulations.

Types of outcome measures

Primary outcomes

- Utilisation and coverage. Utilisation of and access to healthcare services (both the proportion of people who have insurance and the proportion of people who receive effective services).

- Quality of health care provided.
- Cost of health care provided.

Secondary outcomes

- User satisfaction.
- Healthcare provider satisfaction.
- Patient (health) outcomes: mortality, quality of life, health care-seeking behaviour.
 - Healthcare provider outcomes: movement or loss of healthcare workers, workload, work morale, stress and burnout of healthcare personnel.
 - Equity: fairness in health expenditures and access to healthcare services for disadvantaged groups: place of residence (rural vs urban), gender, ethnicity, advanced age, socio-economic status and disability.
 - Any unintended effect on health or health behaviours, utilisation, coverage, access, quality of care, resource use and equity.

Search methods for identification of studies

We will search for all studies that meet our inclusion criteria, regardless of publication status or language. If a foreign language article with an abstract in French or English is identified, we will read the abstract and request a French or English translation of the full article if required.

Electronic searches

We will search the following electronic bibliographic databases.

- The Cochrane Central Register of Controlled Trials (CENTRAL), part of *The Cochrane Library* (www.thecochranelibrary.com), which includes the Cochrane Effective Practice and Organisation of Care (EPOC) Group Specialised Register.
 - MEDLINE.
 - EMBASE.
 - GlobalHealth.
 - International Bibliography of the Social Sciences.
 - Sociological Abstracts.
 - Social Services Abstracts.
 - EconLit.

See [Appendix 1](#) for the MEDLINE strategy.

Searching other resources

Grey literature

We will conduct a grey literature search of the following resources to identify studies not indexed in the databases listed above.

- Open Grey (<http://www.opengrey.eu/>).
- Grey Literature Report (New York Academy of Medicine) (<http://www.nyam.org/library/online-resources/grey-literature-report/>).
- EU Cordis (<http://cordis.europa.eu/>).
- International Monetary Fund (MF) (<http://www.imf.org/external/>).
- World Bank (<http://www.worldbank.org/>).
- Institute of Development Studies (<http://www.ids.ac.uk/>).
- International Initiative for Impact Evaluation (3iE) (<http://www.3ieimpact.org/>).

Trial registries

- International Clinical Trials Registry Platform (ICTRP), World Health Organization (WHO) (<http://www.who.int/ictpr/en/>).
- ClinicalTrials.gov, US National Institutes of Health (NIH) (<http://clinicaltrials.gov/>).

We will also:

- review reference lists of all included studies and relevant systematic reviews/primary studies;
- contact authors of relevant studies/reviews to clarify reported published information and to seek unpublished results/data;
- contact researchers with expertise relevant to the review topic/EPOC interventions; and
- conduct cited reference searches for all included studies in the Institute for Scientific Information (ISI) Web of Knowledge.

Data collection and analysis

Two review authors will independently carry out data extraction. We will develop a form that is based on the Cochrane data collection form, including both quantitative and qualitative elements. The qualitative elements will inform any grouping or any categorisation of interventions. We will extract standard information about study methods, participants, interventions and outcomes.

Selection of studies

The first two review authors will independently screen records obtained through the search and will exclude those that obviously do not meet the inclusion criteria. Both review authors will review

full-text articles of studies that appear to fulfil the inclusion criteria, and those that meet the inclusion criteria will be included and described in the 'Characteristics of included studies' table, even if investigators do not report usable results. Studies that do not meet the inclusion criteria will be excluded and listed in the 'Characteristics of excluded studies table,' along with the reasons for exclusion. We will resolve disagreements through discussion, or, if required, we will consult the third review author. We will demonstrate the study selection process using a PRISMA flow chart.

Data extraction and management

We will design and test a data extraction form. For included studies, two review authors will independently extract data using the agreed upon form. We will resolve discrepancies through discussion and will consult a third review author if necessary. Data extracted will include information on study design and types of participants, interventions and outcome measures. We will enter data into Review Manager software (Revman 2014) and will check them for accuracy.

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias in eligible studies using the EPOC risk of bias criteria (EPOC 2013b), which have been adapted from the criteria of The Cochrane Collaboration for assessing risk of bias. Risk of bias criteria can be found in Appendix 2. We will resolve disagreements through discussion and by consulting a third review author.

We will carry out a summary assessment of the risk of bias for each outcome, including all entries relevant to that outcome. We will assess specific risk of outcome entries, for example, blinding, separately for objective and subjective outcomes.

Assessment of quality of evidence across studies for each outcome

We will assess the quality of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Guyatt 2008). We will define the quality of evidence for each outcome as the extent to which one can be confident that an estimate of effect or association is close to the quantity of specific interest (Higgins 2011). The quality rating across studies includes four levels: high, moderate, low and very low. Randomised controlled trials are categorised as of high quality, but this assessment can be downgraded; similarly, other types of controlled trials and observational studies are categorised as of low quality, but assessment can be upgraded. Factors that decrease the quality of evidence include limitations in design, indirectness of evidence, unexplained heterogeneity or inconsistency of results, imprecision of results and high probability of publication bias. Factors that can

increase the quality level of a body of evidence include magnitude of effect, whether plausible confounding would reduce a demonstrated effect and whether a dose-response gradient is noted.

Measures of treatment effect

We will present results for dichotomous outcomes as summary risk ratios with 95% confidence intervals.

For continuous outcomes, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome but use different methods or tools. For ITS studies, we will report the measure of effect used by the study authors. This could be the immediate change in effect post intervention, the change in trend or the difference between the value expected at a specific time point post intervention and the value actually observed at this time point post intervention.

Unit of analysis issues

To identify unit of analysis errors, we will critically assess the method of analysis in each included study, taking into account the study design used. If the cluster-randomised controlled trials that are included have sufficiently accounted for the cluster design, we will include effect estimates in the meta-analysis, but if clustering has been ignored, we will adjust the data (by inflating standard errors by multiplying them by the square root of the design effect) (Higgins 2011). We will then include the data in the meta-analysis.

Dealing with missing data

When information regarding any of the studies is unclear, we will attempt to contact authors of the original reports to request further details. If incorrect analyses are reported, and if it is not possible to obtain missing data, we will attempt to impute data.

For all outcomes, we will carry out analyses, as far as possible, on an intention-to-treat basis (i.e. we will attempt to include in the analyses all participants randomly assigned to each group, and we will analyse all participants in the group to which they were allocated, regardless of whether or not they received the allocated intervention). The denominator for each outcome in each trial will be the number randomly assigned minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We will start by exploring clinical or policy heterogeneity by clearly documenting in table format the characteristics of participants, components of the intervention related to design and delivery of the intervention and outcomes and measurement of outcomes. In addition, we will report the regulatory context (political and socio-economic context) in which the intervention was delivered. We

will explore methodological heterogeneity by clearly documenting different study designs, as well as risk of bias for each study. We will assess statistical heterogeneity in each meta-analysis using the T^2 , I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if I^2 is greater than 30% and either T^2 is greater than zero or the P value (less than 0.10) obtained by the Chi^2 test for heterogeneity is low. If statistical heterogeneity is substantial, we will perform a random-effects meta-analysis; otherwise, we will carry out a fixed-effect meta-analysis.

Assessment of reporting biases

If 10 or more studies are included in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually and will use formal tests for funnel plot asymmetry. For continuous outcomes, we will use the test proposed by Egger (Egger 1997), and for dichotomous outcomes, we will use the test proposed by Harbord (Harbord 2006). If asymmetry is detected in any of these tests or is suggested by visual assessment, we will perform exploratory analyses to investigate it. This will entail reviewing the included studies to see whether all small studies show beneficial or less beneficial intervention effects, and if an outlier (individual study with very different intervention effect estimate) is present (Higgins 2011).

Data synthesis

We will group included studies according to the type of regulation measured. We anticipate that included studies will be quite diverse, and we will prepare 'Summary of findings' tables for each category of regulation. We will carry out statistical analysis using Revman 5.2 software (Revman 2014). We will summarise the results (using random-effects or fixed-effect meta-analysis) to produce an overall summary if an average intervention effect across studies is considered meaningful, and we will discuss the implications of any differences in intervention effects across studies.

We will present the results of random-effects analyses as the average treatment effect with 95% confidence intervals, along with estimates of T^2 and I^2 . We will report separately the results for RCTs, cluster-RCTs, NRCTs, CBAs and ITS studies.

Subgroup analysis and investigation of heterogeneity

If we identify substantial heterogeneity among studies using similar comparisons and outcome measures, we will investigate this by performing subgroup analyses.

We intend to carry out the following subgroup analyses.

- Different types of PHI: community, not for-profit and for-profit PHI. When compared with the first two, for-profit PHI schemes are more likely to have high premiums leading to increased costs and inequalities in health care.
- Level of income of the countries in which the studies were carried out (low, middle or high income). High-income countries usually have less inequality in access to healthcare services. The impact of PHI on access to health care could therefore be more significant in low-income countries.

Sensitivity analysis

If relevant, for studies with similar comparisons and outcome measures, we will carry out sensitivity analyses to explore the effects of study design (RCT or non-randomised study) and overall risk of bias on the treatment effect. We will perform sensitivity analyses by excluding only studies with high overall risk of bias and studies using a particular study design.

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* Indicates the major publication for the study

APPENDICES**Appendix I. MEDLINE search strategy**

#	Searches	Results
1	Government Regulation/	18074
2	Social Control, Formal/	11776
3	exp Government/	121380
4	Government Programs/	3582
5	Legislation as Topic/	15782
6	Health Care Reform/	27719
7	Health Policy/	49944
8	(government* or state or health authorit* or governance or stewardship? or policy or policies or regulat* or deregulat* or reregulat* or unregulat* or supervis* or monitor* or audit* or legislat*).ti,ab	2600951
9	or/1-8	2755893
10	exp Insurance Health/	121646
11	Insurance Coverage/	8804

(Continued)

12	Universal Coverage/	2020
13	Insurance Carriers/	2338
14	((health* or medical) and insuranc*).ti.	9238
15	(health* insuranc* or health care insuranc* or medical insuranc*).ab	19077
16	or/10-15	140253
17	Private Sector/	7376
18	Public-Private Sector Partnerships/	1016
19	(privat* or voluntar* or volunteer*).ti,ab.	252656
20	or/17-19	256764
21	9 and 16 and 20	4477
22	randomized controlled trial.pt.	370469
23	controlled clinical trial.pt.	88141
24	multicenter study.pt.	169888
25	(randomis* or randomiz* or randomly).ti,ab.	551771
26	groups.ab.	1342705
27	(trial or multicenter or multi center or multicentre or multi centre).ti	146723
28	(intervention? or effect? or impact? or controlled or control group? or (before adj5 after) or (pre adj5 post) or ((pretest or pre test) and (posttest or post test)) or quasiexperiment* or quasi experiment* or evaluat* or time series or time point? or repeated measur*).ti,ab	6432418
29	or/22-28	7208102
30	exp Animals/	17275146
31	Humans/	13350271
32	30 not (30 and 31)	3924875

(Continued)

33	review.pt.	1862448
34	meta analysis.pt.	46909
35	news.pt.	160913
36	comment.pt.	578659
37	editorial.pt.	352208
38	cochrane database of systematic reviews.jn.	10672
39	comment on.cm.	578658
40	(systematic review or literature review).ti.	49087
41	or/32-40	6598140
42	29 not 41	4918265
43	21 and 42	1669

Appendix 2. Risk of bias assessment

For RCTs, NRCTs and CBAs

Was the allocation sequence adequately generated?

Score “Yes” if the random component in the sequence generation process is described. Score “No” when a non-random method is used. NRCTs and CBA studies should be scored “No.” Score “Unclear” if not specified in the paper.

Was the allocation adequately concealed?

Score “Yes” if the unit of allocation was by institution, team or professional, and if allocation was performed on all units at the start of the study; or if the unit of allocation was by patient or episode of care, and some form of centralised randomisation scheme, an on-site computer system or sealed opaque envelopes were used. CBA studies should be scored “No.” Score “Unclear” if not specified in the paper.

Were baseline outcome measurements similar?

Score “Yes” if performance or patient outcomes were measured before the intervention, and no important differences were present across study groups. For RCTs, score “Yes” if imbalanced but appropriate adjusted analysis was performed. Score “No” if important differences were present and were not adjusted for in the analysis. If RCTs have no baseline measure of outcome, score “Unclear.”

Were baseline characteristics similar?

Score “Yes” if baseline characteristics of the study and of control providers are reported and similar. Score “Unclear” if this is not clear in the paper. Score “No” if no report describes characteristics in text or in tables, or if differences between control and intervention providers are noted. Note that in some cases, imbalance in participant characteristics may be due to recruitment bias, whereby the provider was responsible for recruiting patients into the trial.

Were incomplete outcome data adequately addressed?

Score “Yes” if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the intervention and control groups, the proportion of missing data was less than the effect size, i.e. unlikely to overturn the study result).

Score “No” if missing outcome data were likely to bias the result. Score “Unclear” if not specified in the paper (do not assume 100% follow-up unless stated explicitly).

Was knowledge of the allocated interventions adequately prevented during the study?

Score “Yes” if study authors stated explicitly that the primary outcome variables were assessed blindly, or if the outcomes are objective (e.g. length of hospital stay). Primary outcomes are those variables that correspond to the primary hypothesis or question as defined by the study authors. Score “No” if the outcomes were not assessed blindly. Score “Unclear” if not specified in the paper.

Was the study adequately protected against contamination?

Score “Yes” if allocation was by community, institution or practice, and if it is unlikely that the control group received the intervention. Score “No” if it is likely that the control group received the intervention (e.g. if patients rather than professionals were randomly assigned). Score “Unclear” if professionals were allocated within a clinic or practice, and it is possible that communication between intervention and control professionals could have occurred (e.g. physicians within practices were allocated to intervention or control).

Was the study free from selective outcome reporting?

Score “Yes” if no evidence suggests that outcomes were selectively reported (e.g. all relevant outcomes in the methods section were reported in the results section). Score “No” if some important outcomes are subsequently omitted from the results. Score “Unclear” if not specified in the paper.

Was the study free from other risks of bias?

Score “Yes” if there is no evidence of other risks of bias.

For CRCTs

In addition to the above domains for RCTs, we will look at the following risk of bias issues.

Recruitment bias

We will describe whether participants were recruited before or after randomisation of clusters. We will regard studies as having low risk of recruitment bias if participants were recruited before randomisation of clusters; high risk of bias if they were recruited after randomisation; and unclear risk of bias if information about the timing of recruitment is unclear.

Baseline imbalance

We will describe any baseline imbalances between individuals and clusters.

Loss of clusters

We will describe the number of clusters lost, as well as reasons for attrition.

Incorrect analysis

We will describe whether analysis was adjusted for clustering.

For ITS studies

Was the intervention independent of other changes?

Low risk of bias if compelling arguments suggest that the intervention occurred independently of other changes over time, and the outcome was not influenced by other confounding variables/historic events during the study period. High risk of bias if authors reported that the intervention was not independent of other changes in time. Unclear risk of bias if it is unclear whether the intervention was independent of other changes in time.

Was the shape of the intervention effect prespecified?

Low risk of bias if the point of analysis is the point of intervention OR if a rational explanation for the shape of intervention effect was given by the study author(s). When appropriate, this will include an explanation if the point of analysis is NOT the point of intervention. High risk of bias if it is clear that the condition above is not met. Unclear risk of bias if it is unclear whether or not the condition above is met.

Was the intervention unlikely to affect data collection?

Low risk of bias if study authors reported that the intervention itself was unlikely to affect data collection (e.g. sources and methods of data collection were the same before and after the intervention). High risk of bias if the intervention itself was likely to affect data collection (e.g. any change in source or method of data collection reported). Unclear risk of bias if it is unclear whether the intervention affected data collection.

Was knowledge of the allocated interventions adequately prevented during the study?

Low risk of detection bias if all were blind to knowledge about which intervention participants received, or if outcomes were objective. High risk of bias if blinding was absent. Unclear risk if blinding was not specified in the paper.

Were incomplete outcome data adequately addressed?

Low risk of attrition bias if no data were missing or if missing data were balanced across groups. High risk of bias if data were missing or if missing data were more prevalent in one of the groups, and this was likely to bias the results. Unclear risk of bias if it is not specified in the paper. We will not assume a 100% follow-up rate, unless this is explicitly stated.

Was the study free from selective outcome reporting?

Low risk of reporting bias if it is evident that all prespecified outcomes have been reported (e.g. all relevant outcomes in the methods section are reported in the results section). High risk of bias if it is evident that some outcomes were omitted from the report. Unclear risk of bias if it is unclear whether all outcomes have been reported.

Was the study free from other risks of bias?

Low risk of bias if there is no evidence of other risk of bias. High risk of bias if evidence suggests other risks of bias (e.g. conflict of interest). Unclear risk of bias if it is not clear from the paper whether other biases are present.

CONTRIBUTIONS OF AUTHORS

Motaze NV wrote the first draft of the review

Chi P wrote the first draft of the review.

All review authors reviewed the draft before submission to the review group.

DECLARATIONS OF INTEREST

None known.