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Government regulation of private health insurance (Review)

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Government regulation of private health insurance

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A B S T R A C T

Background

The strain on public resources to meet the healthcare needs of populations through publicly-provided health insurance programmes is increasing and many governments turn to private health insurance (PHI) to ease the pressure on government budgets. With the goal of improving access to basic health care for citizens through PHI programmes, several high-income countries have developed strong regulations for PHI schemes. Low- and middle-income countries have the opportunity to learn from this experience to optimise PHI. 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.

Objectives

To assess the effects of policies that regulate private health insurance on utilisation, quality, and cost of health care provided.

Search methods

In November 2019 we searched CENTRAL; MEDLINE; Embase; Sociological Abstracts and Social Services Abstracts; ICTRP; ClinicalTrials.gov; and Web of Science Core Collection for papers that have cited the included studies. This complemented the search conducted in February 2017 in IBSS; EconLit; and Global Health. We also searched selected grey literature databases and web-sites.

Selection criteria

Randomised trials, non-randomised trials, interrupted time series (ITS) studies, and controlled before-after (CBA) studies conducted in any population or setting that assessed one or more of the following interventions that governments use to regulate private health insurance: legislation and licensing, monitoring, auditing, and intelligence.

Data collection and analysis

Two review authors independently assessed study eligibility, extracted data, and assessed risk of bias and certainty of the evidence resolving discrepancies by consensus. We planned to summarise the results (using random-effects or fixed-effect meta-analysis) to produce

an overall summary if an average intervention effect across studies was considered meaningful, and we would have discussed the implications of any differences in intervention effects across studies. However, due to the nature of the data obtained, we have provided a narrative synthesis of the findings.

Main results

We included seven CBA studies, conducted in the USA, and that directly assessed state laws on cancer screening. Only for-profit PHI schemes were addressed in the included studies and no study addressed other types of PHI (community and not for-profit). The seven studies were assessed as having 'unclear risk' of bias. All seven studies reported on utilisation of healthcare services, and one study reported on costs. None of the included studies reported on quality of health care and patient health outcomes. We assessed the certainty of evidence for patient health outcomes, and utilisation and costs of healthcare services as very low. Therefore, we are uncertain of the effects of government mandates on for-profit PHI schemes.

Authors' conclusions

Our review suggests that, from currently available evidence, it is uncertain whether policies that regulate private health insurance have an effect on utilisation of healthcare services, costs, quality of care, or patient health outcomes. The findings come from studies conducted in the USA and might therefore not be applicable to other countries; since the regulatory environment could be different.

Studies are required in countries at different income levels because the effects of government regulation of PHI are likely to differ across these income and health system settings. Further studies should assess the different types of regulation (including regulation and licensing, monitoring, auditing, and intelligence). While regulatory research on PHI remains relatively scanty, future research can draw on the rich body of research on the regulation of other health financing interventions such as user fees and results-based provider payments.

PLAIN LANGUAGE SUMMARY

Government regulation of private health insurance

What is the aim of this review?

The aim of this Cochrane Review was to assess the effects of government regulations of private health insurance. The review authors searched for all relevant studies to answer this question.

Key messages

We do not know what the effect of government regulations on private health insurance is as the evidence was of very low certainty. We need more studies from different settings, assessing different types of regulations, and different types of private health insurance.

What was studied in the review?

In many settings, people have to pay for their own health care. This means that people with small incomes are often not able to afford the health care they need. To solve this problem, some governments run public health insurance programmes. Governments usually pay for these programmes through taxes, but these programmes are complicated and expensive to run. Some governments therefore also rely on private health insurance companies to get people the health care they need.

Membership in a private health insurance scheme is paid for directly by the individuals themselves or by their employers. Private health insurance companies are sometimes run for profit and are sometimes non-profit. But most companies are likely to prefer members who are young and healthy as they need less health care. Governments therefore try to regulate these companies to make sure that anyone can join and that the health care on offer is of good quality. Governments do this by establishing laws that companies have to follow, by monitoring whether companies follow them and by punishing those who do not. Government regulations can increase people's access to health care and save the government money. But regulations can also lead insurance companies to shut down.

What are the main results of the review?

The review authors found seven relevant studies. All of the studies looked at the effect of state laws that aimed to regulate for-profit companies in the USA.

- The review authors assessed this evidence to be of very low certainty. We therefore do not know whether government regulation of private health insurance has any effect on people's use of healthcare services or on the cost of health care provided by private insurance companies

- None of the studies looked at the effect of government regulation on the quality of care provided by private insurance companies or on people's health.

How up-to-date is this review?

The review authors searched for studies that had been published up to November 2019.

SUMMARY OF FINDINGS

Summary of findings 1. Summary of findings

State mandate of private health insurance compared with no intervention for cancer screening

Patient or population: adults with private health insurance cover

Settings: USA

Intervention: regulation through state mandates requiring private health insurance companies to cover the costs of cancer screening tests

Comparison: states mandate with no mandate. In states with mandates, the comparison was the period of time prior to implementation of the mandate.

Outcomes	Impact	No of Participants (studies)	Certainty of the evidence (GRADE)
Utilisation of healthcare services – breast cancer screening	**We are uncertain of the impact of changes in government regulation of private insurers on the uptake of breast cancer screening as the certainty of the evidence was very low.** • Regulation allowing women direct access without referral to gynaecologists: may lead to little or no difference in the number of mammograms done (OR = 1.001 (95% CI 0.90 to 1.10)) (Baker 2007) • Supplemental screening mandate: rates of breast ultrasound following mammography may increase by 10.5 per 1000 mammographies (Busch 2019)	1,260,219 participants (2 CBAs)	⊕⊖⊖⊖ **Very low***
Utilisation of healthcare services – colorectal cancer screening	**We are uncertain of the impact of changes in government regulation of private insurers on the uptake of colorectal cancer screening as the certainty of the evidence was very low.** Impacts of mandates for screening coverage: Cokkinides 2011: use of colorectal cancer screening: OR = 1.10, 95% CI 1.02 to 1.20; Hamman 2016: use of colorectal cancer screening may increase by 0.8% among men and may decrease by 1.4% among women; Hamman 2015a: found racial differences in the use of colorectal cancer screening services; Xu 2016: may decrease screening for colorectal cancer by 0.1%	1,183,010 participants (4 CBAs)	⊕⊖⊖⊖ **Very low***
Utilisation of healthcare services – cervical cancer screening	**We are uncertain of the impact on the uptake of cervical cancer screening of changes in government regulation of private insurers as the certainty of the evidence was very low.** • Regulation allowing women direct access without referral to gynaecologists: may led to little or no difference in the number of PAP tests done (OR=1.011 (95% CI 0.91 to 1.11)) (Baker 2007) • Mandating PAP test coverage: may increase cervical cancer screening by 1.1% in the previous year, 1.3% in the previous two years, and 0.8% over a woman's life time (Bitler 2016) • Mandate on utilization of screening services: may increase cervical cancer screening by 0.56% (Xu 2016)	842,911 participants (3 CBAs)	⊕⊖⊖⊖ **Very low***

Utilisation of healthcare services – prostate cancer screening	**We are uncertain of the impact on the uptake of prostate cancer screening of changes in government regulation of private insurers as the certainty of the evidence was very low.** Mandate on utilization of screening services: may decrease prostate cancer screening by 0.2% (Xu 2016)	13,314 participants (1 CBA)	⊕⊖⊖⊖ **Very low***
Quality of health care provided	None of the included studies reported this outcome	---	---
Cost of health care provided	The increase in individual premiums due to the cancer screening mandates was estimated at 68.10 USD per year for colorectal cancer screening, 60.72 USD per year for cervical cancer screening, and 37.60 USD year for prostate cancer screening. Although the average net subsidy varied across various socio-demographic groups, it was zero for the total study population. (Xu 2016)	91,583 participants (1 CBA)	⊕⊖⊖⊖ **Very low***
Patient outcomes	None of the included studies reported this outcome.	---	---
Adverse effects	None of the included studies reported this outcome.	---	---

CI: Confidence interval; **OR**: Odds ratio; **CBA**: controlled before-after study; **USD**: United States Dollar.

GRADE Working Group grades of evidence
High certainty: this research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different** is low.
Moderate certainty: this research provides a good indication of the likely effect. The likelihood that the effect will be substantially different** is moderate.
Low certainty: this research provides some indication of the likely effect. However, the likelihood that it will be substantially different** is high.
Very low certainty: this research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different** is very high.

**Substantially different: a large enough difference that it might affect a decision

*All outcomes downgraded by two points for high risk of bias and by one point for imprecision

BACKGROUND

Health services have to be paid for by individuals or by groups of people (Wiysonge 2017) and can be financed through various channels.

- **Out-of-pocket payment:** this category of private health expenditure involves any direct outlay by individuals and 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 (Savedoff 2004).
- **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 (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). 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). 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 (Carrin 2003; McIntyre 2007; WHO 2010).

Generally, health insurance can be financed through three broad channels: taxation, social security, and PHI (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, PHI schemes could play a positive role in improving access and equity (Sekhri 2005a).

PHI schemes usually seek to achieve three main overlapping functions (OECD 2004; Thomson 2009). The first is to serve as a 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 avoid losses, including denial of coverage for applicants who have preexisting health conditions (Kofman 2006). On the other hand, over-regulation 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). 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 or institution or 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 often 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).

1. Who can sell insurance?
Governments should 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 should benefit both patients and firms, as they offer consumer protection and ensure a viable insurance market.

2. 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; and '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. 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 predominantly enrolls individuals who present a lower than average risk of ill health e.g. young people (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 (Kautter 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.

3. 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. Within this perspective, a minimum health package has to be covered by PHI institutions. Regulation regarding this minimum health package generally 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.

4. 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.

5. 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 and colleagues (Sekhri 2005b) have proposed policy tools that can be grouped into four general categories: legislation and licensing, monitoring, auditing and intelligence.

- **Legislation and licensing** 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 licensing, 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 and colleagues, 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.

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.

1. To minimise 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, and life-time rating methods), by permitting defined waiting periods for preexisting conditions and by permitting insurers to make enrollees disclose their medical history.
2. To minimise 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, re-insurance, 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.
3. 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.

1. 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.
2. 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.

Figure 1 shows the proposed logical framework for thinking through government regulation of private health insurance.

Figure 1.

Conceptual framework
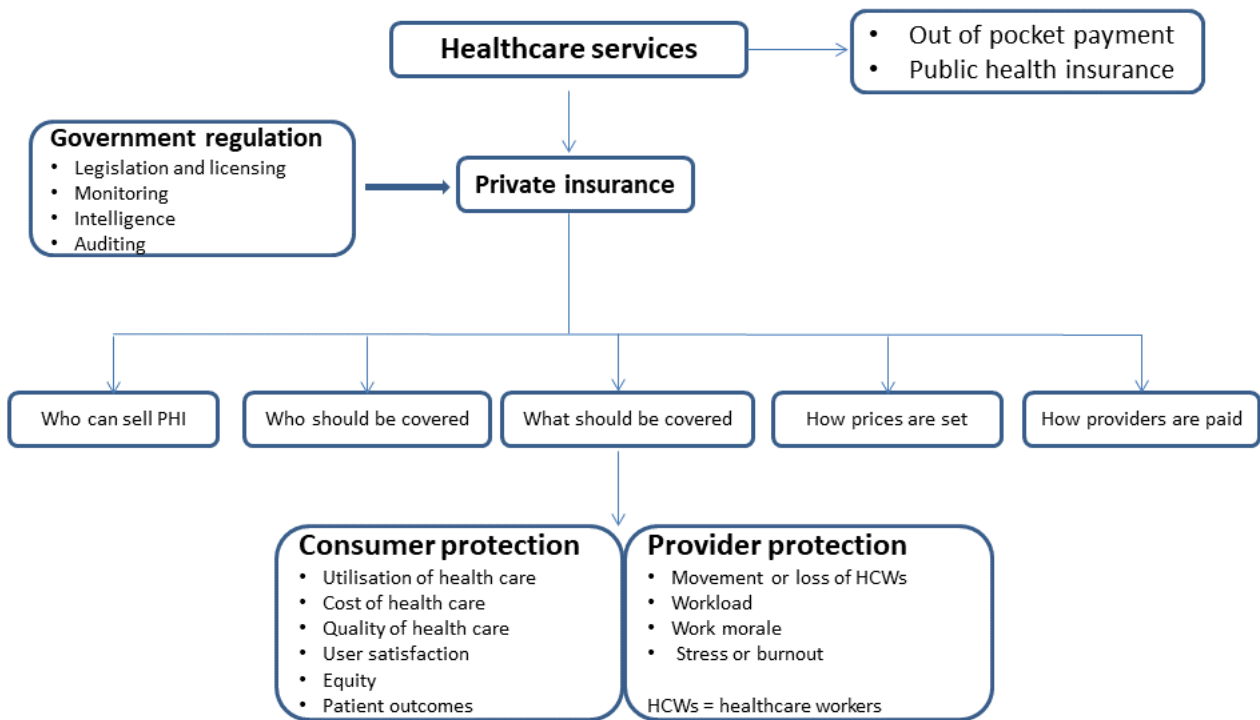
Why it is important to do this review

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.

O B J E C T I V E S

To assess the effects of policies that regulate private health insurance on utilisation, quality, and cost of health care provided.

METHODS

Criteria for considering studies for this review

Types of studies

We considered the following study designs suggested by the Cochrane Effective Practice and Organisation of Care (EPOC) Group (EPOC 2020a).

- Randomised trials, both individually-randomised and cluster-randomised
- Non-randomised trials
- Interrupted time series (ITS) studies
- Controlled before-after (CBA) studies

In accordance with the EPOC criteria for inclusion of studies in systematic reviews of effects, we excluded cluster-randomised trials, non-randomised cluster trials and CBA studies with only one intervention or control site. For ITS studies, we excluded those that did not have a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention. We also excluded simple pre/post designs.

Types of participants

In this review, we planned to 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 licensing of new and existing PHI schemes**
  - Ensure that PHI schemes 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 different forms of regulation

Types of outcome measures

Primary outcomes

- Utilisation and coverage i.e. use 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, healthcare-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 searched for studies that met our inclusion criteria, regardless of publication status or language. If a foreign language article with an abstract in French or English was identified, we read the abstract and requested a French or English translation of the full article if required.

Electronic searches

We searched the following electronic bibliographic databases.

- The Cochrane Central Register of Controlled Trials (CENTRAL), 2019, Issue 11, part of the Cochrane Library (www.cochranelibrary.com) (searched 18 November 2019)
- MEDLINE Epub Ahead of Print, In-Process & Other Non-Indexed Citations, MEDLINE Daily and MEDLINE 1946 to Present, Ovid (searched 18 November 2019)
- Embase 1974 to 2019 November 15, Ovid (searched 18 November 2019)
- Sociological Abstracts 1952 – current and Social Services Abstracts 1979 – current, ProQuest (searched 18 November 2019)
- International Bibliography of the Social Sciences (IBSS) 1951 – current, ProQuest (searched 27 February 2017)
- Global Health 1973 to 2017 Week 07, Ovid (searched 27 February 2017)
- EconLit 1969 – current, ProQuest (searched 27 February 2017)

IBBS, Global Health, and EconLit were not searched in 2019 as we no longer had access to these databases.

See Appendix 1 for strategies used.

Searching other resources

Grey literature

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

- Open Grey (http://www.opengrey.eu/) (searched 07 December 2019).
- Grey Literature Report (New York Academy of Medicine) (http://www.nyam.org/library/online-resources/grey-literature-report/) (searched 07 December 2019).

- EU Cordis (http://cordis.europa.eu/) (searched 07 December 2019).
- International Monetary Fund (MF) (http://www.imf.org/external/) (searched 07 December 2019).
- World Bank (http://www.worldbank.org/) (searched 07 December 2019).
- Institute of Development Studies (http://www.ids.ac.uk/) (searched 07 December 2019).
- International Initiative for Impact Evaluation (3iE) (http://www.3ieimpact.org/) (searched 07 December 2019).

Trial registries

- International Clinical Trials Registry Platform (ICTRP), World Health Organization (WHO) (http://www.who.int/ictrp/en/) (searched 18 November 2019).
- ClinicalTrials.gov, US National Institutes of Health (NIH) (http://clinicaltrials.gov/) (searched 18 November 2019).

We also:

- reviewed reference lists of all included studies and relevant systematic reviews/primary studies;
- contacted authors of relevant studies/reviews to clarify reported published information and to seek unpublished results/data;
- contacted researchers with expertise relevant to the review topic/EPOC interventions; and

- conducted cited reference searches for included studies using Web of Science Core Collection 1987-2019, Clarivate Analytics (searched 18 November 2019).

Data collection and analysis

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

Selection of studies

The first two review authors independently screened records obtained through the search and excluded those that obviously did not meet the inclusion criteria. Both review authors reviewed full-text articles of studies that appeared to fulfil the inclusion criteria. Those that met the inclusion criteria would have been included and described in the 'Characteristics of included studies' table, even if investigators did not report usable results. Studies that did not meet the inclusion criteria were excluded and listed in the 'Characteristics of excluded studies,' along with the reasons for exclusion. We resolved disagreements through discussion, or, if required, we consulted the third review author. We demonstrated the study selection process using a PRISMA flow chart (Figure 2).

Figure 2. **Study flow diagram.**


```
┌──────────────────┐   ┌──────────────────┐
│ 6448 records     │   │ Additional       │
│ identified       │   │ records          │
│ through          │   │ identified       │
│ database         │   │ through other    │
│ searching        │   │ sources = 0      │
└──────────────────┘   └──────────────────┘
           │                  │
           └────────┬─────────┘
                    ▼
        ┌──────────────────┐
        │ Number of        │
        │ records after    │
        │ duplicates       │
        │ removed = 6448   │
        └──────────────────┘
                    │
                    ▼
        ┌──────────────────┐       ┌──────────────────┐
        │ 6448 records     │──────▶│ 6419 records     │
        │ screened         │       │ excluded         │
        └──────────────────┘       └──────────────────┘
                    │
                    ▼
        ┌──────────────────┐       ┌──────────────────┐
        │ 29 full-text     │       │ 22 full-text     │
        │ articles         │──────▶│ articles         │
        │ assessed for     │       │ excluded, with   │
        │ eligibility      │       │ reasons          │
        └──────────────────┘       └──────────────────┘
                    │
                    ▼
        ┌──────────────────┐
        │ 7 studies        │
        │ included in the  │
        │ review           │
        └──────────────────┘
```
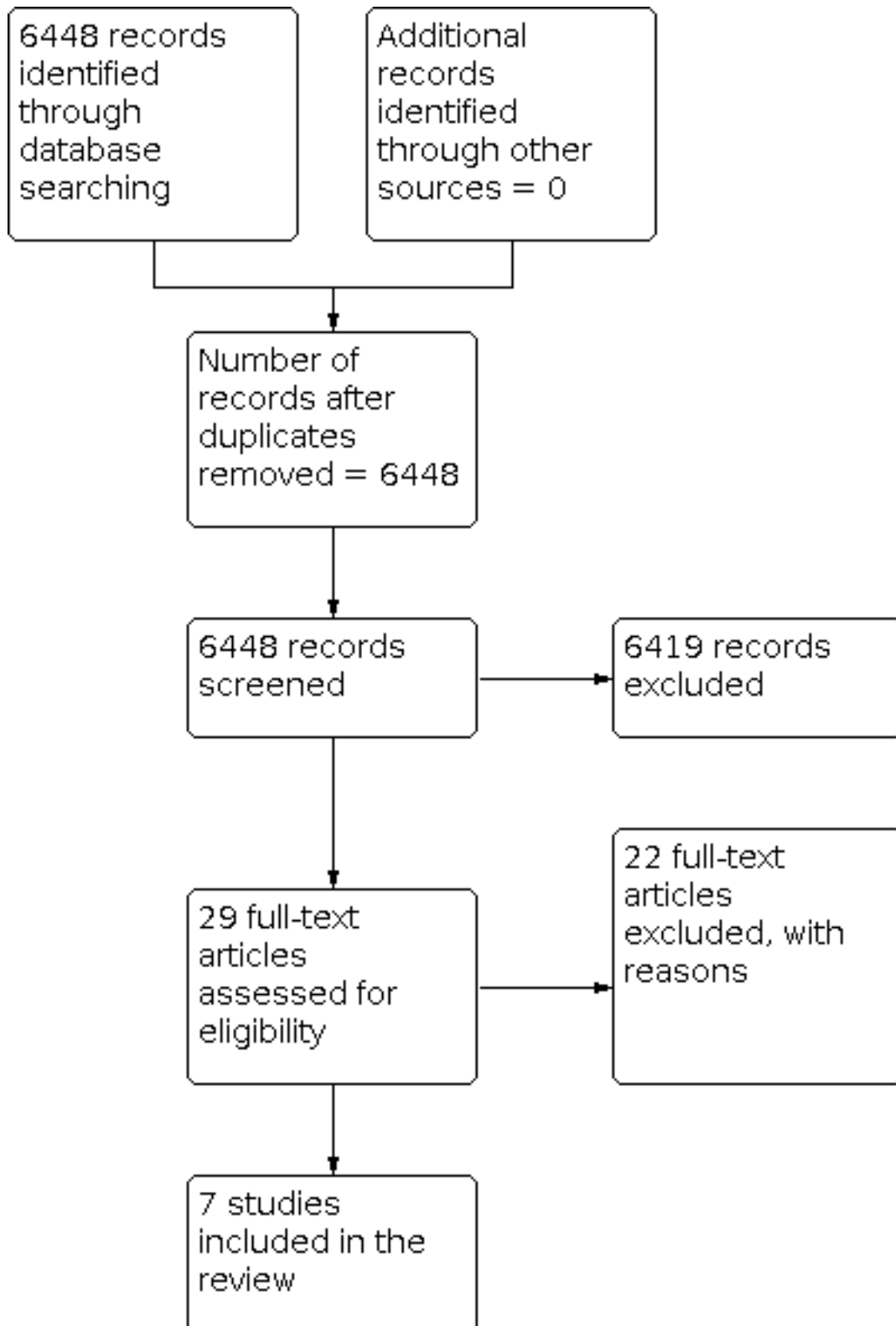
Data extraction and management

We designed and tested a data extraction form. For the included study, the first two review authors independently extracted data using the agreed upon form. We resolved discrepancies through discussion and consulted a third review author when necessary. Data extracted included information on study design and types of participants, interventions and outcome measures. We entered

data into Review Manager software (Revman 2014) and checked for accuracy.

Assessment of risk of bias in included studies

The first two review authors independently assessed the risk of bias in the included studies using the EPOC risk of bias criteria (EPOC 2020b), which were adapted from the criteria of Cochrane for assessing risk of bias. 'Risk of bias' criteria can be found in Appendix 2. We resolved disagreements through discussion and by consulting a third review author.

We carried out a summary assessment of the risk of bias for each outcome, including all entries relevant to that outcome. We had planned to assess specific risk of outcome entries, for example blinding, separately for objective and subjective outcomes. However, the included studies all reported only subjective outcomes.

Measures of treatment effect

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

For continuous outcomes, we intended to use the mean difference if outcomes were measured in the same way between trials. We planned to use the standardised mean difference to combine trials that measure the same outcome but use different methods or tools.

For ITS studies, we planned to 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. This was not possible due to the nature of the results.

There were six CBA studies included and we stated the results as reported by the study authors.

Unit of analysis issues

To identify unit of analysis errors, we critically assessed the method of analysis in the included study, taking into account the study design used. If cluster-randomised controlled trials were included and had sufficiently accounted for the cluster design, we would have included effect estimates in the meta-analysis, but if clustering was been ignored, we would have adjusted the data (proceeded to inflate standard errors by multiplying them by the square root of the design effect) (Higgins 2020). We would then have included the data in the meta-analysis. This was not done because we did not include any cluster-randomised controlled trials.

Dealing with missing data

When information regarding any of the studies was unclear, we attempted to contact authors of the original reports to request further details. If incorrect analyses were reported, and if it was not possible to obtain missing data, we had planned to attempt to impute data. This was not necessary since the included study had no missing information and the data analysis was correct.

We intended to carry out analyses, as far as possible, on an intention-to-treat basis (i.e. we planned to include in the analyses all participants randomly assigned to each group, and analyse all participants in the group to which they were allocated, regardless of whether or not they received the allocated intervention) for

all outcomes. The denominator for each outcome in each trial would have been the number randomly assigned minus any participants whose outcomes are known to be missing. There were no randomised controlled trials included so this was not possible.

Assessment of heterogeneity

We intended to explore clinical or policy heterogeneity by clearly documenting in table format; the characteristics of participants; components of the intervention related to design and delivery; outcomes and measurement of outcomes. In addition, we would have reported the regulatory context (political and socio-economic context) in which the intervention was delivered. We also planned to explore methodological heterogeneity by clearly documenting different study designs, as well as risk of bias for each study.

We would have assessed statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics, and regarded heterogeneity as substantial if an I^2 was greater than 30% and either the T^2 was greater than zero or the P value obtained from the Chi^2 test for heterogeneity was less than 0.10. If statistical heterogeneity was substantial, we planned to perform a random-effects meta-analysis; otherwise, a fixed-effect meta-analysis would have been done.

There was no assessment of heterogeneity in this review since meta-analysis was not done.

Assessment of reporting biases

If 10 or more studies were included in the meta-analysis, we would have investigated reporting biases (such as publication bias) using funnel plots. We would have assessed funnel plot asymmetry visually and using formal tests for funnel plot asymmetry. For continuous outcomes, we would have use the test proposed by Egger (Egger 1997), and for dichotomous outcomes, the test proposed by Harbord (Harbord 2006). If asymmetry was detected in any of these tests or was suggested by visual assessment, we would have performed exploratory analyses to investigate it. This would have entailed reviewing the included studies to see whether all small studies showed beneficial or less beneficial intervention effects, and if an outlier (individual study with very different intervention effect estimate) was present (Higgins 2020). Meta-analysis was not possible so this was not done.

Data synthesis

We planned to group included studies according to the type of regulation measured since we anticipated that included studies would have been quite diverse. We would have prepared 'Summary of findings' tables for each category of regulation and performed statistical analysis using Revman 5.2 software (Revman 2014). We planned to summarise the results (using random-effects or fixed-effect meta-analysis) to produce an overall summary if an average intervention effect across studies was considered meaningful, and we would have discussed the implications of any differences in intervention effects across studies.

We would have presented the results of random-effects analyses as the average treatment effect with 95% confidence intervals, along with estimates of T^2 and I^2. Results for randomised controlled trials (RCTs), cluster-RCTs, non randomised RCTs (NRCTs), CBAs and ITS studies would have been reported separately. Due to the nature of the data obtained, we provide a narrative report of the results.

Subgroup analysis and investigation of heterogeneity

If we had identified substantial heterogeneity among studies using similar comparisons and outcome measures, we would have investigated this by performing subgroup analyses.

We intended 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.

However, we did not perform any subgroup analysis because of the nature of the results.

Sensitivity analysis

For studies with similar comparisons and outcome measures, we had planned to 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 would have undertaken these sensitivity analyses by excluding only studies with high overall risk of bias and studies using a particular study design. The results of the search did not allow for sensitivity analysis.

Summary of findings and assessment of the certainty of the evidence

We prepared a 'Summary of findings' table for the main outcomes: utilisation, quality, and cost of healthcare services as well as patient health outcomes (Summary of findings 1). Two review authors (NVM and PCC) independently assessed the certainty of the evidence (high, moderate, low, and very low) using the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) (Guyatt 2008). We used methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of interventions* (Higgins 2020) and the EPOC worksheets (EPOC 2020c), using GRADEpro software (GRADEpro GDT). We resolved disagreements on certainty ratings by discussion and consulted a third review author (CSW) when disagreement persisted. Our decisions to downgrade are presented in footnotes in Summary of findings 1. We used plain language statements to report these findings in the review (Santesso 2020).

R E S U L T S

Description of studies

Results of the search

The search produced a total of 6448 records. After screening the titles and abstracts, 6419 records were excluded and 29 articles were retrieved for full-text assessment. Twenty-two articles were excluded and seven studies met the inclusion criteria. The study flow diagram (Figure 2) shows details of this process.

Included studies

Seven controlled before-after (CBA) studies, all carried out in the USA, were included in the review (Baker 2007; Busch 2019; Bitler 2016; Cokkinides 2011; Hamman 2015a;Hamman 2016; Xu 2016).

In all these studies the intervention consisted of a state law, which falls under the "legislation and licensing" category of regulations. The laws addressed the 'depth' (what healthcare services can be covered) of private health insurance (PHI) coverage (see Description of the intervention). The studies collected data on the effects of the interventions using validated surveys that were conducted on a regular basis, with each survey including different participants selected from all population groups in the USA. The Behavioral Risk Factor Surveillance System (BRFSS) was used in Baker 2007; Bitler 2016; Cokkinides 2011; Hamman 2015a and Hamman 2016 while the Medical Expenditure Panel Survey (MEPS) was used in Xu 2016. While Baker 2007 evaluated the effects of a law granting women direct access to obstetricians/gynaecologists (without specifically targeting cancer screening), the remaining included studies directly assessed state laws on cancer screening. The outcomes reported were measures of utilisation of health services and costs related to state mandates.

The detailed description of the studies is provided in the table of Characteristics of included studies.

Excluded studies

Twenty-two studies were excluded from this review; 18 because of ineligible study design (Andersen 2012; Ataguba 2012; Barry 2019; Bauhoff 2017; Dusetzina 2018; Ellis 2008; Grecu 2019; Gruber 1994; Hall 1991; Harvey 2019; Huckfeldt 2014; Mahal 2002; Marquis 2001; Moorin 2006a; Moorin 2006b; Shorten 2004; Soderlund 2000; Walker 2007); two because of ineligible study participants (Guthmuller 2014; Mobley 2014); and two were excluded because of ineligible study interventions (Hamman 2015b; Loehrer 2016) . Reasons for exclusion of individual studies are provided in the Characteristics of excluded studies table.

Risk of bias in included studies

Detailed assessment of the risk of bias in the included studies is presented in the 'Risk of bias' table under Characteristics of included studies and summaries in Figure 3 and Figure 4.

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Figure 3. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.
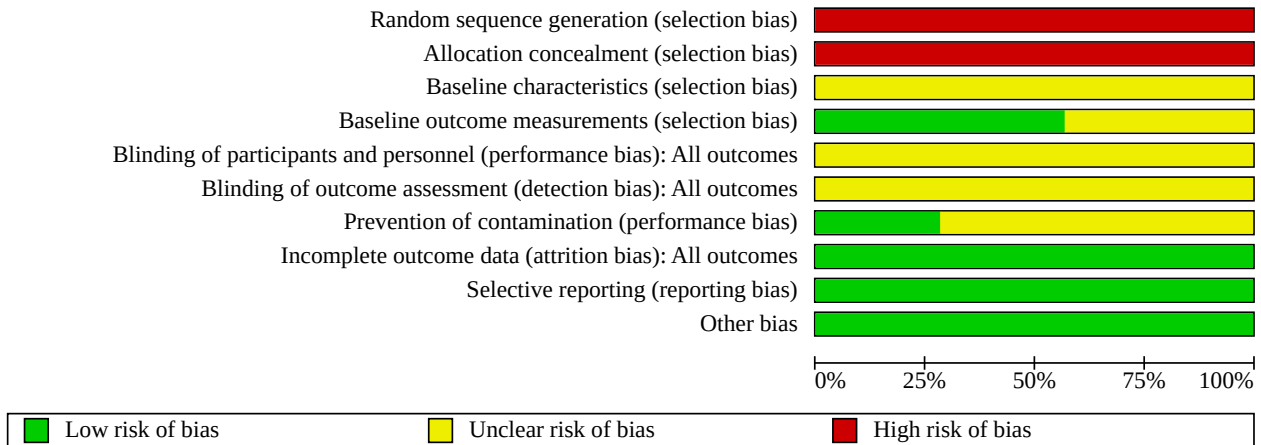
Figure 4. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.
"+" = low risk of bias; "?" = unclear risk of bias; and "-" = high risk of bias; Further information is available under
Characteristics of included studies

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All studies were assessed as having 'unclear risk' of bias for baseline participant characteristics because none of the studies presented baseline characteristics separately for intervention and control groups. Risk of bias for baseline outcome measurements was assessed as 'low risk' for Baker 2007, Bitler 2016 and Xu 2016, while it was assessed as 'unclear risk' for Cokkinides 2011, Hamman 2015a and Hamman 2016.

Allocation

Sequence generation and allocation concealment were assessed as 'high risk' for all included studies since there was neither random sequence generation nor allocation concealment in any of the CBA studies.

Blinding

Blinding was not possible in any of the studies due to the nature of the intervention (laws passed by states) and since all the outcomes were self-reported by the participants, all included studies were assessed as having 'unclear risk' of blinding.

Contamination was assessed as low risk in only two of the six studies (Hamman 2015a and Hamman 2016) because this was addressed in the analysis (by including a within state control group). This was not done in any of the other studies and they where assessed as having 'unclear risk' of contamination.

Incomplete outcome data

All the included studies were assessed as having 'low risk' of attrition bias because the response rate was acceptable during successive cross-sectional surveys.

Selective reporting

All six included studies were assessed as having 'low risk' of selective outcome reporting since they reported all relevant outcomes.

Other potential sources of bias

We have assessed all included studies as having a low risk of other potential sources of bias as we are not aware of other biases beyond the ones already listed above.

Effects of interventions

See: **Summary of findings 1** Summary of findings

Primary outcomes

Utilisation of healthcare services

All seven included controlled before-after (CBA) studies reported on utilisation of healthcare services. It is uncertain if laws to regulate private health insurance (PHI) – specifically access to cancer screening – improve utilisation of healthcare services because the certainty of this evidence is very low (Summary of findings table 1). These results are discussed in more detail below.

Utilisation of breast cancer screening

Two studies reported on screening for breast cancer (Baker 2007; Busch 2019).

Baker 2007 assessed the effects of a law that allowed direct access to specialist obstetrician / gynaecologists (without passing through a general practitioner) for privately insured women in the USA. The law was passed in 43 states while eight states did not have the law in place by the end of the study period. We are uncertain of the effect of this intervention on breast cancer screening (adjusted odds ratio (OR) 1.001, 95% confidence interval (CI) 0.90 to 1.10; 100,140 participants; very low-certainty evidence).

Busch 2019 assessed the association between two categories of state dense breast notification (DBN) laws and receipt of any supplemental ultrasound, magnetic resonance imaging (MRI), or breast biopsy, and cancer detection. The first category of mandate was a generic DBN law that did not require the patient to be informed about the possible benefits of supplemental screening. The second category mandated notification of the possible benefits of further screening tests. A total of 34 states were included in the analysis. At the end of the study, nine states had passed the law while 25 states had not. Analysis compared receipt of supplemental breast ultrasound, MRI, and biopsy within four months after index screening mammography. Breast cancer detection within nine months after the index screening mammography was also measured. Compared to no DBN law, we are uncertain of the effect of the DBN with mandatory notification of benefits on further screening (adjusted testing rate per 1000 screening mammograms = 10.5, 95% CI 2.95 to 17.60; very low-certainty evidence).

Utilisation of colorectal cancer screening

Four studies reported on screening for colorectal cancer (Cokkinides 2011; Hamman 2015a; Hamman 2016; Xu 2016).

Cokkinides 2011 assessed the effect of state colorectal cancer screening coverage mandates on self-reported utilisation of endoscopy during the previous year among insured adults aged 50 to 64 years. By the end of the study, 23 states had passed the screening mandate while 22 states had not. We are uncertain of the effect on colorectal cancer screening among participants in intervention states, compared to those in control states (adjusted OR 1.10, 95% CI 1.02 to1.20; very low-certainty evidence).

Hamman 2015a sought to identify correlates of racial disparities in colorectal cancer screening and changes in disparities under state-mandated insurance coverage using a triple-difference estimation strategy. The number of states that did or did not have the screening law by the end of the study period was not reported and any individual who had either a blood stool test within the past year or an endoscopic screening within the past five years was considered as being up-to-date. We are uncertain of the effect on racial disparities in screening (using non-Hispanic whites as the comparison group: Asians: 7.6% increase; Native Americans: 8.0% increase; Hispanics: 10% increase in screening for colorectal cancer; Blacks: 2.8% decrease in screening (very low-certainty evidence)).

The effect of state-mandated colorectal cancer screening coverage among privately insured adults aged 51 to 64 years was assessed in Hamman 2016, with 34 states having mandated screening and 17 states not having done so by the end of the study. We are uncertain of the effect on colorectal cancer screening using a blood stool test among men (0.8% increase) and among women (1.4% decrease) (very low certainty evidence). We are uncertain of the effect on

colorectal cancer screening using endoscopy among men (2.5% increase) and among women (0.7% increase) (very low-certainty evidence).

Xu 2016 investigated the effects of state mandates on utilisation of screening services for cancers of the colon and rectum (endoscopy). At the end of the study period, 28 states had passed screening laws for colorectal cancers. We are uncertain of the effect of this intervention on colorectal cancer screening (0.10% decrease; 27,605 participants; very low certainty evidence).

Utilisation of cervical cancer screening

Three studies reported on screening for cervical cancer (Baker 2007; Bitler 2016; Xu 2016).

Baker 2007 assessed the effects of a law that allowed direct access to specialist obstetrician/gynaecologists (without passing through a general practitioner) for privately insured women in the USA (see above). We are uncertain of the effect of this intervention on the number of PAP tests done (adjusted OR 1.011, 95% CI 0.91 to 1.11; 189,840 participants; very low-certainty evidence).

Bitler 2016 evaluated the effect of a state law requiring PHI companies to cover or offer PAP tests for privately insured women. By the end of the study period, 24 states had passed the law while 26 had not. The study compared within-state changes in the uptake of the PAP test in intervention versus control states. We are uncertain of the effect of this intervention on the likelihood of a woman having a PAP test (reported increase in likelihood of a woman having a pap test: 1.1% within the previous year, 1.3% within the previous two years, and 0.8% in her life time; very low-certainty evidence).

Xu 2016 investigated the effects of state mandates on utilisation of PAP tests to screen for cervical cancer. At the end of the study period, 28 states had passed screening laws for cervical cancer. We are uncertain of the effect of this intervention on cervical cancer screening (0.56% increase; 50,664 participants; very low-certainty evidence).

Utilisation of healthcare services – prostate cancer screening

Xu 2016 investigated the effects of state mandates on utilisation of prostate-specific antigen (PSA) testing to screen for prostate cancer. At the end of the study period, 33 states had passed screening laws for prostate cancer. We are uncertain of the effect of this intervention on prostate cancer screening (0.20% decrease; 13,314 participants; very low-certainty evidence).

Quality of health care provided

None of the included studies assessed this outcome.

Cost of health care provided

The certainty of the evidence was assessed as very low so it is uncertain if cancer screening laws reduce healthcare costs. One study, Xu 2016, calculated cross-subsidies and net subsidies associated with the cancer screening laws. Cross-subsidies refer to costs of a health service (in this case cancer screening) that are covered by non users through premiums paid by those enrolled (both users and non-users) in a PHI firm. With reference to the screening mandates, net subsidies refer to the difference between the expected change in cost of cancer screening and the fraction

of the premiums of enrolled individuals that cover the screening. Since mandating cancer screening is likely to result in increased utilisation of cancer screening services, PHI companies are likely to increase premiums. The increase in individual premiums due to the mandates was estimated at 68.10 USD per year for endoscopy, 60.72 USD per year for PAP test and 37.60 USD year for PSA test. Although the average net subsidy varied across various socio-demographic groups, it was zero for the total study population.

Secondary outcomes

None of the included studies assessed any of the secondary outcomes.

DISCUSSION

Summary of main results

Overall, we do not know what the effect of government regulations on private health insurance (PHI) is as the evidence was of very low certainty. Specifically, it is uncertain if laws to mandate access to cancer screening for people enrolled in PHI schemes impact on utilisation of cancer screening services and costs of health care.

Overall completeness and applicability of evidence

All the included studies in this review were conducted in the USA, which is a high-income country. The findings might therefore not be applicable to low-income or middle-income countries, or to other high-income countries since the aspects of the regulatory and health system environments could be different. Only for-profit PHI schemes were addressed in the included studies and no study addressed other types of PHI (community-based and not for-profit).

The type of intervention addressed in the included studies was a state mandate, through legislation, for PHI firms to cover screening tests for different types of cancers and most of the studies reported on utilisation of cancer screening services. The uptake of cancer screening is influenced by the individuals' perceived risk of cancer and the effects of the intervention could vary in other settings where the burden of disease due to the cancer studied is different. We did not identify studies regulating PHI in relation to care for other types of health issues. Regulation may also arise via the executive or the judiciary. These pathways for PHI scheme regulation will be explicit components of the conceptual framework and inclusion criteria in future iterations of this systematic review.

None of the included studies addressed other methods of government regulation such as monitoring, auditing and intelligence. Studies are therefore required to address these options in various settings and possibly combining two or more of these regulatory activities in an attempt to be more effective. Furthermore, future studies should report on outcomes not reported in the included studies. These include; quality of care provided; user satisfaction; healthcare provider satisfaction; patient (health) outcomes (mortality, quality of life, healthcare-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); and unintended effects on health or health behaviours.

Certainty of the evidence

The evidence was assessed as "very low" certainty, which means that we are uncertain about the effects of the interventions evaluated in the included studies. Our assessment of very low certainty was based, firstly, on the methodological limitations of the included studies leading to an assessment high risk of bias. Secondly, the findings were downgraded due to serious imprecision (see Summary of findings 1).

Potential biases in the review process

Potential biases in conducting the review were minimised by following the steps outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2020). We carried out the screening, study selection and data extraction in duplicate and a third review author provided input where there was disagreement or uncertainty about specific issues. A comprehensive search was carried out by the Information Scientist of the EPOC review group without limitations on language of publication and we performed a thorough search for ongoing and unpublished literature.

Agreements and disagreements with other studies or reviews

This review sought to assess the effects of government regulation of PHI in low-, middle- and high-income settings. Although PHI is a major option for healthcare financing in the majority of countries worldwide, there is a paucity of reviews that address interventions directed at PHI institutions. However, there are a few reviews looking at the relationship between healthcare utilisation and health insurance.

A systematic review looking at the effects of health insurance on utilisation of allied health services by people with chronic diseases (Skinner 2014) found an increase in utilisation of health services among individuals with health insurance. The authors of this review performed a search of studies published in English in five databases (MEDLINE, Embase, CINAHL, PsychINFO and the Cochrane Central Register of Controlled Trials) retrieved 158 records and included seven studies. Another review (Freeman 2008) assessed the causal effects of health insurance on healthcare utilisation and found increased healthcare utilisation among insured non-elderly adults. In this review, the authors performed a search of three databases (PubMed, JSTOR and Econlit), retrieved 9701 records and included 14 studies although the review was limited to studies conducted in the USA. The effect of health insurance on use of maternal health services in low- and middle-income countries was addressed in a recent systematic review (Comfort 2013). The authors conducted a search for studies irrespective of publication status, included 29 articles and found health insurance to be positively associated with use of maternal health services. These reviews did not directly evaluate the effects of regulation of PHI by governments. However, they do suggest that individuals are more likely to use health services for both acute and chronic care when these are covered by their insurance plans.

AUTHORS' CONCLUSIONS

Implications for practice

We are not able to draw definite conclusions regarding the effects of state laws or mandates to regulate private health insurance (PHI) on utilisation of screening services for breast, cervical, colorectal or prostate cancers. We are also not able to draw conclusions with respect to the impacts of these laws on utilisation of screening services for other types of cancers or utilisation of any healthcare services since these were not reported in the included studies. None of the included studies addressed other regulatory interventions that governments can implement in relation to PHI.

Implications for research

Further studies addressing government regulation of PHI institutions are required. These studies should assess all types of regulatory activities (including regulation and licensing, monitoring, auditing, and intelligence). Studies are required in countries at different income levels because the effects of government regulation of PHI are likely to differ across regulatory and health system settings. While regulatory research on PHI remains relatively scant, future research can draw on the rich body of research on the regulation of other health financing interventions; such as user fees and results-based provider payments (Wiysonge 2017). Given that randomised designs may not be feasible in this area, researchers should consider utilising non-randomised designs, such as well-conducted interrupted time series (ITS) studies, to evaluate the effects of policy interventions to regulate private health insurance. The framework provided in Figure 1 may be a useful guide for the development of future research studies.

ACKNOWLEDGEMENTS

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Baker 2007

Study characteristics	
Methods	Controlled before-after study (CBA).
Participants	Women aged 18–64 and living in the USA.
Interventions	The intervention was a new state law enabling women to have direct access to obstetricians and gynae-cologists without being referred by primary care providers. The comparison states had an existing law under which health plans required referrals by primary care providers before the plan would cover specialist care.
Outcomes	Had a mammogram, had a Pap smear.
Notes	Data collected from Behavioral Risk Factor Surveillance System (BRFSS).

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	There was no sequence generation, it was a CBA study.
Allocation concealment (selection bias)	High risk	There was no allocation concealment, it was a CBA study.
Baseline characteristics (selection bias)	Unclear risk	Baseline participant characteristics not presented separately for intervention and control groups.
Baseline outcome measurements (selection bias)	Low risk	Baseline outcome measurements were similar.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	There was no blinding of participants and personnel but it is not likely to affect the outcome.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was no information on blinding of outcome assessors but it is not likely to affect the outcome.

Baker 2007 *(Continued)*

Prevention of contamination (performance bias)	Unclear risk	There were no measures to prevent contamination and this was not adjusted for in the analysis.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Acceptable response rate at each data collection point.
Selective reporting (reporting bias)	Low risk	All relevant outcomes were reported.
Other bias	Low risk	We are not aware other biases beyond the ones already listed above.

Bitler 2016

Study characteristics

Methods	Controlled before-after study (CBA).
Participants	Women aged 19–64 and living in the USA.
Interventions	Intervention states implemented a law requiring PHI companies to cover Pap smears without cost-sharing. In control states, PHI companies did not cover Pap smears or imposed cost-sharing for patients who did a Pap smear.
Outcomes	Ever had a Pap smear, had a Pap smear in last two years, had a Pap smear in last 12 months.
Notes	The authors use the total number of women with a health plan as a proxy for the women with PHI. Data collected from Behavioral Risk Factor Surveillance System (BRFSS).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	There was no sequence generation, it was a CBA study.
Allocation concealment (selection bias)	High risk	There was no allocation concealment, it was a CBA study.
Baseline characteristics (selection bias)	Unclear risk	Baseline participant characteristics not presented separately for intervention and control groups.
Baseline outcome measurements (selection bias)	Low risk	Baseline outcome measurements were similar.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	There was no blinding of participants and personnel but it is not likely to affect the outcome.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was no information on blinding of outcome assessors but it is not likely to affect the outcome.

Bitler 2016 *(Continued)*

Prevention of contamination (performance bias)	Unclear risk	There were no measures to prevent contamination and this was not adjusted for in the analysis.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Acceptable response rate at each data collection point.
Selective reporting (reporting bias)	Low risk	All relevant outcomes were reported.
Other bias	Low risk	We are not aware of other biases beyond the ones already listed above.

Busch 2019

Study characteristics

Methods	Controlled before-after study
Participants	Privately insured women aged 40 to 59 years living in 9 states in the USA
Interventions	State dense breast notification law
Outcomes	Health care utilization of tests for breast cancer detection
Notes	Include

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	There was no sequence generation, it was a CBA study.
Allocation concealment (selection bias)	High risk	There was no allocation concealment, it was a CBA study.
Baseline characteristics (selection bias)	Unclear risk	Baseline characteristics not reported.
Baseline outcome measurements (selection bias)	Low risk	Baseline outcome measurements were similar between groups.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	There was no blinding of participants and personnel but it is not likely to affect the outcome.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was no blinding of outcome assessors but it is not likely to affect the outcome.
Prevention of contamination (performance bias)	Unclear risk	There were no measures to prevent contamination and this was not adjusted for in the analysis.

Busch 2019 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Acceptable response rate at each data collection point.
Selective reporting (reporting bias)	Low risk	All relevant outcomes were reported.
Other bias	Low risk	We are not aware other biases beyond the ones already listed above.

Cokkinides 2011

Study characteristics

Methods	Controlled before-after study (CBA).
Participants	Adults aged 50 to 64 years who indicated having any health insurance coverage and were residing in 44 states or D.C.
Interventions	Intervention states had a comprehensive legislation requiring private insurance plans to cover the full range of colorectal cancer screening tests, including endoscopy procedures, consistent with American Cancer Society guidelines on or before December 31, 2008. In control states, private insurance plans did not cover some of the screening tests or required patients to cover some of the cost of the screening test. Participants were considered as exposed if they had resided in a state with the law for 1 year or more prior to the date of their interview. Participants who at the time of interview had resided in states with mandates for less than 1 year or those in states with no mandates were considered as not exposed.
Outcomes	Receipt of an endoscopy (colorectal cancer screening test) in the past year.
Notes	Data collected from Behavioral Risk Factor Surveillance System (BRFSS).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	There was no sequence generation.
Allocation concealment (selection bias)	High risk	There was no allocation concealment.
Baseline characteristics (selection bias)	Unclear risk	Baseline participant characteristics not presented separately for intervention and control groups.
Baseline outcome measurements (selection bias)	Unclear risk	Baseline outcome measurements not presented for intervention and control groups.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not possible because the intervention (passing of a law) is made public. Outcome was participant reported, so subjective.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not possible because the intervention (passing of a law) is made public.

Cokkinides 2011 *(Continued)*

Prevention of contamination (performance bias)	Unclear risk	There were no measures to prevent contamination and this was not adjusted for in the analysis.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Acceptable response rate at each data collection point.
Selective reporting (reporting bias)	Low risk	All relevant outcomes were reported.
Other bias	Low risk	We are not aware of other biases beyond the ones already listed above.

Hamman 2015a

Study characteristics

Methods	Controlled before-after study (CBA).
Participants	Adults aged 51 to 75 years who indicated having any health insurance coverage from all 50 states in the USA and DC. Individuals aged 65 years were excluded.
Interventions	State laws requiring PHI companies to cover colorectal cancer screening. Uptake of colorectal cancer screening was compared by races and income levels.
Outcomes	Colorectal cancer screening up-to-date: defined as any individual who had either a BST within the past year or an endoscopic screening (flexible sigmoidoscopy and colonoscopy) within the past 5 years.
Notes	Data collected from Behavioral Risk Factor Surveillance System (BRFSS).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	There was no sequence generation.
Allocation concealment (selection bias)	High risk	There was no allocation concealment.
Baseline characteristics (selection bias)	Unclear risk	Participant characteristics not presented separately for intervention and control groups.
Baseline outcome measurements (selection bias)	Unclear risk	Baseline outcome measurements not presented for intervention and control groups.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not possible because the intervention (passing of a law) is made public. Outcome was participant reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not possible because the intervention (passing of a law) is made public.

Hamman 2015a *(Continued)*

Prevention of contamination (performance bias)	Low risk	There were no measures to prevent contamination. However, this was accounted for in the analysis.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Acceptable response rate at each data collection point.
Selective reporting (reporting bias)	Low risk	All relevant outcomes were reported.
Other bias	Low risk	We are not aware of other biases beyond the ones already listed above.

Hamman 2016

Study characteristics

Methods	Controlled before-after study (CBA)
Participants	Adults aged 51 to 75 years who indicated having any health insurance coverage from all 50 states in the USA and DC. Individuals aged 65 years were excluded.
Interventions	The intervention was a state law requiring PHI companies to cover colorectal cancer screening without cost-sharing for individuals aged 50 to 64 years. Screening rates after implementation of the state law were compared to screening rates before implementation of the state law.
Outcomes	Colorectal cancer screening up-to-date: defined as any individual who had either a BST or an endoscopic screening within the past year.
Notes	Data collected from Behavioral Risk Factor Surveillance System (BRFSS)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	There was no sequence generation.
Allocation concealment (selection bias)	High risk	There was no allocation concealment.
Baseline characteristics (selection bias)	Unclear risk	Participant characteristics not presented separately for intervention and control groups.
Baseline outcome measurements (selection bias)	Unclear risk	Baseline outcome measurements not presented for intervention and control groups.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not possible because the intervention (passing of a law) is made public. Outcome was participant reported so subjective.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not possible because the intervention (passing of a law) is made public.

Hamman 2016 *(Continued)*

Prevention of contamination (performance bias)	Low risk	There were no measures to prevent contamination. However, this was accounted for in the analysis.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Acceptable response rate at each data collection point.
Selective reporting (reporting bias)	Low risk	All relevant outcomes were reported.
Other bias	Low risk	We are not aware of other biases beyond the ones already listed above.

Xu 2016

Study characteristics

Methods	Controlled before-after study (CBA).
Participants	Privately insured adults under the age of 65 years. Individuals who are not privately insured and individuals with a prior diagnosis of cervical, prostate or colon cancer were excluded.
Interventions	State law mandating coverage of cervical, colon and prostate cancer screening for privately insured individuals under 65 years of age. Screening rates after implementation of the state law were compared to screening rates before implementation of the state law.
Outcomes	Receipt of: • annual Pap test for cervical cancer; • fecal occult blood test (FOBT), paired with a sigmoidoscopy every 5 years or colonoscopy every 10 years for colorectal cancer; • PSA test for prostate cancer.
Notes	Data collected using the Medical Expenditure Panel Survey (MEPS).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	There was no sequence generation.
Allocation concealment (selection bias)	High risk	There was no allocation concealment.
Baseline characteristics (selection bias)	Unclear risk	The participant characteristics not presented separately for intervention and control groups.
Baseline outcome measurements (selection bias)	Low risk	The outcome variable was similar for the intervention and control groups.
Blinding of participants and personnel (performance bias)	Unclear risk	Blinding not possible because the intervention (passing of a law) is made public. Outcome was participant reported so subjective.

Xu 2016 *(Continued)*
All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not possible because the intervention (passing of a law) is made public.
Prevention of contamination (performance bias)	Unclear risk	There were no measures to prevent contamination and this was not adjusted for in the analysis.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Acceptable response rate at each data collection point.
Selective reporting (reporting bias)	Low risk	All relevant outcomes were reported.
Other bias	Low risk	We are not aware of other biases beyond the ones already listed above.

BST: blood stool test; **PAP smear:** Papanicolaou test; **PHI:** private health insurance;**PSA:** prostate-specific antigen

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Andersen 2012	Ineligible study design
Ataguba 2012	Ineligible study design
Barry 2019	Ineligible study design
Bauhoff 2017	Ineligible study design
Dusetzina 2018	Ineligible study design
Ellis 2008	Ineligible study design
Grecu 2019	Ineligible study design
Gruber 1994	Ineligible study design
Guthmuller 2014	Ineligible study participants
Hall 1991	Ineligible study design
Hamman 2015b	Ineligible study intervention
Harvey 2019	Ineligible study design
Huckfeldt 2014	Ineligible study design
Loehrer 2016	Ineligible study intervention
Mahal 2002	Ineligible study design
Marquis 2001	Ineligible study design

Study	Reason for exclusion
Mobley 2014	Ineligible study participants
Moorin 2006a	Ineligible study design
Moorin 2006b	Ineligible study design
Shorten 2004	Ineligible study design
Soderlund 2000	Ineligible study design
Walker 2007	Ineligible study design

A P P E N D I C E S

Appendix 1. Search strategies

Cochrane Central Register of Controlled Trials (Central) Issue 11 2019, part of Cochrane Library (searched 18.11.2019)

ID	Search	Hits
#1	MeSH descriptor: [Insurance, Health] explode all trees and with qualifier(s): [legislation & jurisprudence - LJ]	15
#2	MeSH descriptor: [Government Regulation] this term only	17
#3	MeSH descriptor: [Social Control, Formal] this term only	30
#4	MeSH descriptor: [Government] explode all trees	926
#5	MeSH descriptor: [Government Programs] this term only	36
#6	MeSH descriptor: [Legislation as Topic] this term only	4
#7	MeSH descriptor: [Health Care Reform] this term only	23
#8	MeSH descriptor: [Health Policy] this term only	185
#9	#2 or #3 or #4 or #5 or #6 or #7 or #8	1203
#10	MeSH descriptor: [Insurance, Health] explode all trees	1084
#11	MeSH descriptor: [Insurance Coverage] this term only	65
#12	#10 or #11	1109
#13	#9 and #12	42
#14	(health* next insurance* or health next care next insurance* or health* next plan* or health next care next plan* or health next benefit next plan* or med-	4637

(Continued)

	ical next insurance* or insurance next coverage* or insurance next plan* or privat* next insur* or privat* next health next insur*):ti,ab,kw	
#15	(government* or health* next policy or "health care policy" or health* next policies or "health care policies" or regulat* or law or laws or legislat* or state next mandat* or state next insurance next mandat*):ti,ab,kw	44883
#16	#14 and #15	456
#17	#1 or #13 or #16	496
#18	#17 in Trials	482

MEDLINE and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to November 15, 2019, Ovid (searched 18.11.2019)

#	Searches	Results
1	Insurance, Health/lj [Legislation & Jurisprudence]	4578
2	Government Regulation/	20897
3	Social Control, Formal/	11706
4	exp Government/	144897
5	Government Programs/	5121
6	Legislation as Topic/	15849
7	Health Care Reform/	32197
8	Health Policy/	64378
9	or/2-8	263717
10	exp Insurance Health/	143399
11	Insurance Coverage/	12759
12	or/10-11	147570
13	Private Sector/	9021
14	Informal Sector/	53
15	privat*.ti,ab,kf.	88589
16	or/13-15	92397
17	9 and 12 and 16	1995
18	((health* insurance* or health care insurance* or health* plan? or health care plan? or health benefit plan? or medical insurance* or insurance coverage? or	556

(Continued)

	insurance plan?) and (government* or health* policy or health care policy or health* policies or health care policies or regulat* or law or laws or legislat* or state mandat* or state insurance mandat*)).ti.	
19	((privat* insur* or privat* health insur*) and (government* or health* policy or health care policy or health* policies or health care policies or regulat* or law or laws or legislat* or state mandat* or state insurance mandat*)).ti.	30
20	((health* insurance* or health care insurance* or health* plan? or health care plan? or health benefit plan? or medical insurance* or insurance coverage? or insurance plan?) adj3 (government* or health* policy or health care policy or health* policies or health care policies or regulat* or law or laws or legislat* or state mandat* or state insurance mandat*)).ab,kf.	1058
21	((privat* insur* or privat* health insur*) and (government* or health* policy or health care policy or health* policies or health care policies or regulat* or law or laws or legislat* or state mandat* or state insurance mandat*)).ab,kf.	1278
22	or/18-21	2718
23	1 or 17 or 22	8535
24	randomized controlled trial.pt.	494657
25	controlled clinical trial.pt.	93427
26	multicenter study.pt.	261242
27	pragmatic clinical trial.pt.	1223
28	non-randomized controlled trials as topic/	586
29	interrupted time series analysis/	711
30	controlled before-after studies/	451
31	(randomis* or randomiz* or randomly).ti,ab.	861547
32	groups.ab.	1977981
33	(trial or multicenter or multi center or multicentre or multi centre).ti.	247108
34	(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* or difference in difference*).ti,ab.	9268557
35	or/24-34	10331794
36	exp Animals/	22762834
37	Humans/	18118987
38	36 not (36 and 37)	4643847
39	review.pt.	2581178

(Continued)

40	meta analysis.pt.	107868
41	news.pt.	198370
42	comment.pt.	815397
43	editorial.pt.	509150
44	cochrane database of systematic reviews.jn.	15285
45	comment on.cm.	815343
46	(systematic review or literature review).ti,pt.	181776
47	or/38-46	8439264
48	35 not 47	7279060
49	23 and 48	1922

Embase 1974 to 2019 November 15, Ovid (searched 18.11.2019)

#	Searches	Results
1	health insurance/	118540
2	private health insurance/	4783
3	government regulation/	26111
4	(1 or 2) and 3	1325
5	((health* insurance* or health care insurance* or health* plan? or health care plan? or health benefit plan? or medical insurance* or insurance coverage? or insurance plan?) and (government* or health* policy or health care policy or health* policies or health care policies or regulat* or law or laws or legislat* or state mandat* or state insurance mandat*)).ti.	593
6	((privat* insur* or privat* health insur*) and (government* or health* policy or health care policy or health* policies or health care policies or regulat* or law or laws or legislat* or state mandat* or state insurance mandat*)).ti.	42
7	((health* insurance* or health care insurance* or health* plan? or health care plan? or health benefit plan? or medical insurance* or insurance coverage? or insurance plan?) adj3 (government* or health* policy or health care policy or health* policies or health care policies or regulat* or law or laws or legislat* or state mandat* or state insurance mandat*)).ab.	1472
8	((privat* insur* or privat* health insur*) and (government* or health* policy or health care policy or health* policies or health care policies or regulat* or law or laws or legislat* or state mandat* or state insurance mandat*)).ab.	1754
9	or/5-8	3586

(Continued)

10	4 or 9	4843
11	Randomized Controlled Trial/	580660
12	Controlled Clinical Trial/	462825
13	Quasi Experimental Study/	6205
14	Pretest Posttest Control Group Design/	426
15	Time Series Analysis/	24361
16	Experimental Design/	17667
17	Multicenter Study/	237103
18	(randomis* or randomiz* or randomly).ti,ab.	1211791
19	groups.ab.	2748585
20	(trial or multicentre or multicenter or multi centre or multi center).ti.	348318
21	(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* or difference in difference*).ti,ab.	11838046
22	or/11-21	13206404
23	exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/	26623089
24	human/ or normal human/ or human cell/	20353588
25	23 and 24	20292526
26	23 not 25	6330563
27	(systematic review or literature review).ti.	174188
28	"cochrane database of systematic reviews".jn.	13783
29	review.pt.	2506470
30	editorial.pt.	634141
31	or/26-30	9340299
32	22 not 31	9357534
33	10 and 32	1698
34	limit 33 to embase	806

Sociological Abstracts 1952-current and Social Services Abstracts 1979-current, ProQuest (searched 18.11.2019)

ALL(("health* insurance*" or "health care insurance*" or "health* plan*" or "health care plan*" or "health benefit plan*" or "medical insurance*" or "insurance coverage*" or "insurance plan*" or "privat* insur*" or "privat* health insur*") N/6 ("government*" or "health* policy" or "health care policy" or "health* policies" or "health care policies" or "regulat*" or "law" or "laws" or "legislat*" or "state mandat*" or "state insurance mandat*")) AND ALL("randomised" or "randomized" or "randomly" or "control*" or "before and after" or "pre and post" or (("pretest" or "pre test") and ("posttest" or "post test")) or "quasiexperiment*" or "quasi experiment" or "quasi experiments" or "quasi experimental" or "evaluat*" or "time series" or "time point" or "time points" or "repeated measure" or "repeated measures" or "repeated measurement" or "repeated measurements" or "multicentre" or "multicenter" or "multi centre" or "multi center" or "trial" or "intervention*" or "effect*" or "impact*" or "difference in difference*")

Web of Science Core Collection 1987-2019, Clarivate Analytics (searched 18.11.2019)

Citation search for: Baker 2007; Bitler 2016; Cokkinides 2011; Hamman 2015a; Hamman 2016; Xu 2016

EconLit 1969-current, ProQuest; International Bibliography of the Social Sciences (IBSS), ProQuest (searched 27.02.2017)

(ALL("health insurance" OR "medical insurance" OR "health plan" OR "health plans") OR ALL(("saving account" OR "savings account" OR "savings account" OR "savings accounts") AND (health* OR medical))) AND ALL(privat*) AND ALL(government* OR state OR 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* OR law OR laws OR act OR acts) AND ALL(randomised OR randomized OR randomly OR control* OR "before and after" OR "pre and post" OR ((pretest OR "pre test") AND (posttest OR "post test")) OR quasiexperiment* OR "quasi experiment" OR "quasi experiments" OR "quasi experimental" OR evaluat* OR "time series" OR "time point" OR "time points" OR "repeated measure" OR "repeated measures" OR "repeated measurement" OR "repeated measurements" OR multicentre OR multicenter OR "multi centre" OR "multi center" OR trial OR intervention* OR effect* OR impact*)

Global Health 1973 to 2017 Week 07, Ovid (searched 27.02.2017)

#	Searches	Results
1	exp health insurance/	5185
2	exp government/	2735
3	government policy/	855
4	regulation/	6458
5	legislation/	8308
6	or/2-5	17992
7	1 and 6	170
8	privat*.af.	29375
9	(insuranc* or health plan?).af.	14142
10	(government* or state or governance or policy or policies or regulat* or legislat* or law or laws).af.	453963
11	8 and 9 and 10	1087
12	7 or 11	1222
13	(randomis* or randomiz* or randomly or trial or multicenter or multi center or multicentre or multi centre or 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*).af.	1273663

(Continued)

14	12 and 13	536

Appendix 2. Risk of bias criteria

For randomised trials, non-randomised trials and controlled before-after studies

Was the allocation sequence adequately generated?

Score "Low risk" if the random component in the sequence generation process is described. Score "High Risk" when a non-random method is used. Non-randomised trials and controlled before-after studies should be scored "High risk"." Score "Unclear risk" if not specified in the paper.

Was the allocation adequately concealed?

Score "Low risk" 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. Controlled before-after studies should be scored "No." Score "Unclear risk" if not specified in the paper.

Were baseline outcome measurements similar?

Score "Low risk" if performance or patient outcomes were measured before the intervention, and no important differences were present across study groups. For randomised trials, score "Low risk" if imbalanced but appropriate adjusted analysis was performed. Score "High Risk" if important differences were present and were not adjusted for in the analysis. If randomised trials have no baseline measure of outcome, score "Unclear."

Were baseline characteristics similar?

Score "Low risk" if baseline characteristics of the study and of control providers are reported and similar. Score "Unclear risk" if this is not clear in the paper. Score "High Risk" 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 "Low risk" 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 "High Risk" if missing outcome data were likely to bias the result. Score "Unclear risk" 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 "Low risk" 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 "High Risk" if the outcomes were not assessed blindly. Score "Unclear risk" if not specified in the paper.

Was the study adequately protected against contamination?

Score "Low risk" if allocation was by community, institution or practice, and if it is unlikely that the control group received the intervention. Score "High Risk" if it is likely that the control group received the intervention (e.g. if patients rather than professionals were randomly assigned). Score "Unclear risk" 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 "Low risk" 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 "High Risk" if some important outcomes are subsequently omitted from the results. Score "Unclear risk" if not specified in the paper.

Was the study free from other risks of bias?

Score "Low risk" if there is no evidence of other risks of bias.

For cluster randomised trials

In addition to the above domains for randomised trials, 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 interrupted time series 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 pre-specified?
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 pre-specified 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.

H I S T O R Y

Protocol first published: Issue 4, 2015
Review first published: Issue 2, 2021

C O N T R I B U T I O N S   O F   A U T H O R S

Motaze NV, Chi P and Ndongo JS screened the search output. Motaze NV, Chi P, and Wiysonge CS assessed full text articles. Motaze NV and Chi P extracted the data and wrote the first draft of the review. All review authors reviewed successive drafts of the review and approved the versions submitted to the review group.

DECLARATIONS OF INTEREST

Nkengafac Villyen Motaze: none known.

Primus Che Chi: none known.

Pierre Ongolo-Zogo: none known.

Jean Serge Ndongo: none known.

Charles S Wiysonge: none known.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We have indicated in the Methods section when pre-specified procedures have not been implemented.

INDEX TERMS

Medical Subject Headings (MeSH)

Bias; Colorectal Neoplasms [diagnosis]; Controlled Before-After Studies [statistics & numerical data]; *Government Regulation; Health Care Costs; Health Services Needs and Demand [legislation & jurisprudence]; Insurance, Health [economics] [*legislation & jurisprudence]; Private Sector [economics] [*legislation & jurisprudence]; Prostatic Neoplasms [diagnosis]; *State Government; United States; Uterine Cervical Neoplasms [diagnosis]

MeSH check words

Female; Humans; Male