Public stewardship of private for-profit healthcare providers in low- and middle-income countries (Review)

Wiysonge CS, Abdullahi LH, Ndze VN, Hussey GD
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Public stewardship of private for-profit healthcare providers in low- and middle-income countries

Charles S Wiysonge1,2, Leila H Abdullahi3, Valantine N Ndze1, Gregory D Hussey3

1Centre for Evidence-based Health Care, Faculty of Medicine and Health Sciences, Stellenbosch University, Cape Town, South Africa.
2Cochrane South Africa, South African Medical Research Council, Cape Town, South Africa.
3Vaccines for Africa Initiative, Institute of Infectious Disease and Molecular Medicine, University of Cape Town, Cape Town, South Africa

Contact address: Charles S Wiysonge, Centre for Evidence-based Health Care, Faculty of Medicine and Health Sciences, Stellenbosch University, PO Box 241, Cape Town, 8000, South Africa. charlesw@sun.ac.za, wiysonge@yahoo.com.

Editorial group: Cochrane Effective Practice and Organisation of Care Group.

Publication status and date: Edited (no change to conclusions), published in Issue 9, 2016.


ABSTRACT

Background

Governments use different approaches to ensure that private for-profit healthcare services meet certain quality standards. Such government guidance, referred to as public stewardship, encompasses government policies, regulatory mechanisms, and implementation strategies for ensuring accountability in the delivery of services. However, the effectiveness of these strategies in low- and middle-income countries (LMICs) have not been the subject of a systematic review.

Objectives

To assess the effects of public sector regulation, training, or co-ordination of the private for-profit health sector in low- and middle-income countries.

Search methods

For related systematic reviews, we searched the Cochrane Database of Systematic Reviews (CDSR) 2015, Issue 4; Database of Abstracts of Reviews of Effectiveness (DARE) 2015, Issue 1; Health Technology Assessment Database (HTA) 2015, Issue 1; all part of The Cochrane Library, and searched 28 April 2015. For primary studies, we searched MEDLINE, Epub Ahead of Print, In-Process & Other Non-Indexed Citations, MEDLINE Daily and MEDLINE 1946 to Present, OvidSP (searched 16 June 2016); Science Citation Index and Social Sciences Citation Index 1987 to present, and Emerging Sources Citation Index 2015 to present, ISI Web of Science (searched 3 May 2016 for papers citing included studies); Cochrane Central Register of Controlled Trials (CENTRAL), 2015, Issue 3, part of The Cochrane Library (including the Cochrane Effective Practice and Organisation of Care (EPOC) Group Specialised Register) (searched 28 April 2015); Embase 1980 to 2015 Week 17, OvidSP (searched 28 April 2015); Global Health 1973 to 2015 Week 16, OvidSP (searched 30 April 2015); WHOIS, WHO (searched 30 April 2015); Science Citation Index and Social Sciences Citation Index 1975 to present, ISI Web of Science (searched 30 April 2015); Health Management, ProQuest (searched 22 November 2013). In addition, in April 2016, we searched the reference lists of relevant articles, WHO International Clinical Trials Registry Platform, clinicaltrials.gov, and various electronic databases of grey literature.
Selection criteria
Randomised trials, non-randomised trials, interrupted time series studies, or controlled before-after studies.

Data collection and analysis
Two authors independently assessed study eligibility and extracted data, comparing their results and resolving discrepancies by consensus. We expressed study results as risk ratios (RR) or mean differences (MD) with 95% confidence intervals (CI), where appropriate, and assessed the certainty of the evidence using Grades of Recommendation, Assessment, Development and Evaluation (GRADE). We did not conduct meta-analysis because of heterogeneity of interventions and study designs.

Main results
We identified 20,177 records, 50 of them potentially eligible. We excluded 39 potentially eligible studies because they did not involve a rigorous evaluation of training, regulation, or co-ordination of private for-profit healthcare providers in LMICs; five studies identified after the review was submitted are awaiting assessment; and six studies met our inclusion criteria. Two included studies assessed training alone; one assessed regulation alone; three assessed a multifaceted intervention involving training and regulation; and none assessed co-ordination. All six included studies targeted private for-profit pharmacy workers in Africa and Asia.

Three studies found that training probably increases sale of oral rehydration solution (one trial in Kenya, 106 pharmacies: RR 3.04, 95% CI 1.37 to 6.75; and one trial in Indonesia, 87 pharmacies: RR 1.41, 95% CI 1.03 to 1.93) and dispensing of anti-malarial drugs (one trial in Kenya, 293 pharmacies: RR 8.76, 95% CI 0.94 to 81.81); moderate-certainty evidence.

One study conducted in the Lao People's Democratic Republic shows that regulation of the distribution and sale of registered pharmaceutical products may improve composite pharmacy indicators (one trial, 115 pharmacies: improvements in four of six pharmacy indicators; low-certainty evidence).

The outcome in three multifaceted intervention studies was the quality of pharmacy practice; including the ability to ask questions, give advice, and provide appropriate treatment. The trials applied regulation, training, and peer influence in sequence; and the study design does not permit separation of the effects of the different interventions. Two trials conducted among 136 pharmacies in Vietnam found that the multifaceted intervention may improve the quality of pharmacy practice; but the third study, involving 146 pharmacies in Vietnam and Thailand, found that the intervention may have little or no effects on the quality of pharmacy practice (low-certainty evidence).

Only two studies (both conducted in Vietnam) reported cost data, with no rigorous assessment of the economic implications of implementing the interventions in resource-constrained settings. No study reported data on equity, mortality, morbidity, adverse effects, satisfaction, or attitudes.

Authors' conclusions
Training probably improves quality of care (i.e. adherence to recommended practice), regulation may improve quality of care, and we are uncertain about the effects of co-ordination on quality of private for-profit healthcare services in LMICs. The likelihood that further research will find the effect of training to be substantially different from the results of this review is moderate; implying that monitoring of the impact is likely to be needed if training is implemented. The low certainty of the evidence for regulation implies that the likelihood of further research finding the effect of regulation to be substantially different from the results of this review is high. Therefore, an impact evaluation is warranted if government regulation of private for-profit providers is implemented in LMICs. Rigorous evaluations of these interventions should also assess other outcomes such as impacts on equity, cost implications, mortality, morbidity, and adverse effects.

**PLAIN LANGUAGE SUMMARY**

**Government regulation, training, or co-ordination of private for-profit health care in low- and middle-income countries**

**What is the aim of this review?**

The aim of this Cochrane review was to evaluate the effect of government regulation, training, or co-ordination of private for-profit health care in low- and middle-income countries.

We collected and analysed all relevant studies to answer this question and included six studies in the review.
Why do governments regulate, train or co-ordinate private healthcare providers?

In many low- and middle-income countries, the public sector is not able to provide high quality healthcare services to all citizens, and private healthcare providers therefore play a major role. However, there is concern that healthcare provided by the private sector is not always of high quality and that recommended practices and guidelines are not always followed. Governments therefore use different approaches to ensure that private for-profit healthcare services meet certain quality standards. This type of government guidance is referred to as 'public stewardship' and can for instance involve training and education for private for-profit healthcare providers; introduction of regulations where quality standards are set and enforced; and co-ordination between private for-profit and public sector healthcare providers, for instance, creating referral systems between the private for-profit and public sectors.

What happens when governments regulate, train or co-ordinate private, for-profit health care providers?

Training

In two studies in Kenya and Indonesia, the Ministry of Health offered private drug sellers short training sessions on prescribing and dispensing drugs. These sellers were compared to drug sellers who were not offered training. The studies suggested that training probably improves the quality of healthcare services.

Regulation

In one study in the Lao People's Democratic Republic, the Ministry of Health supervised private pharmacy services in certain districts over a three-month period, applied sanctions when rules were broken, and offered information about areas needing improvement. These districts were compared to districts without this enhanced supervision. The study suggested that this enhanced regulation may make little or no difference to quality of care.

Training and regulation

In three studies in Vietnam and Thailand, private pharmacies in some districts received educational visits as well as visits from pharmacy inspectors to enforce regulations. These districts were compared to districts that did not receive any visits. The studies suggested that these types of visits may improve quality of care.

Co-ordination

The review did not find any eligible study that assessed the effects of co-ordination on quality of care.

How up-to-date is this review?

The review authors searched for studies that had been published up to June 2016.
SUMMARY OF FINDINGS FOR THE MAIN COMPARISON

Training compared to no training for improving quality of care

Population: Private for-profit providers of healthcare services
Settings: Kenya and Indonesia (1 study) and Kenya (1 study)
Intervention: Training
Comparison: No training

<table>
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<tr>
<th>Outcomes</th>
<th>Impacts</th>
<th>No of Participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
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<tr>
<td>Quality of care</td>
<td>Both studies show that training probably improves the quality of healthcare services</td>
<td>486 pharmacies (2 studies)</td>
<td>⊗⊗⊗⊗ Moderate*</td>
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* We downgraded the certainty of evidence by 1 point, because of a moderate risk of selection bias in included studies

GRADE Working Group grades of evidence
High certainty: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate certainty: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low certainty: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low certainty: We are very uncertain about the estimate.

BACKGROUND

The public health sector in low- and middle-income countries is not always sufficiently well-equipped and financed to provide high quality health care that is accessible to all citizens (Basu 2012; Lagomarsino 2009). The consequence of this public sector failure has been a proliferation in private providers of healthcare services in most of the countries (Forsberg 2011; Levin 2011; Scott 2011). Governments have a responsibility to ensure the quality of healthcare services delivered by private providers, to expand the coverage of existing private providers, and to rationalise this coverage with that of public sector providers (Waters 2003). Such government guidance is referred to as public stewardship. However, there is a paucity of high quality research evidence on the effects of public stewardship on the quality and accessibility of private for-profit health care in low- and middle-income countries (Patouillard 2007; Waters 2003); thus the need for this review.

The private health sector is not homogeneous, but consists of not-for-profit and for-profit as well as formal and informal providers of healthcare services (Basu 2012; Sulzbach 2011). Private not-for-profit healthcare providers refer to healthcare organisations that use any surplus revenues to achieve their goals, rather than distributing them as dividends. On the other hand, the private for-profit sector refers to the part of the economy that is run by individuals and companies for profit and is not state-controlled. The consequence of the expansion in the private health sector in LMICs is that (poor) communities spend outsized amounts of money for private healthcare services; at times when cheaper public sector alternatives are available (Forsberg 2011; Patouillard 2007). However, the quality of the services provided by the private for-profit healthcare sector in LMICs is increasingly being questioned (Berendes 2011; Waters 2003).

Description of the intervention

The growing concern regarding the technical failures of health care provided by the private for-profit sector has led to the development of interventions aimed at addressing these limitations,
which simultaneously take advantage of the potential for involving the private for-profit sector to achieve public health goals. This review assessed the public stewardship of private for-profit healthcare providers in LMICs. Stewardship can be defined as a function of governments responsible for the welfare of their populations (Veillard 2011). It involves policy guidance to the whole health system, co-ordination between actors and regulation of different functions, levels and actors in the system, an optimal allocation of resources and accountability towards all stakeholders. Although many actors have an influence on stewardship, there is a central role for the government in ensuring equity, efficiency and sustainability of the health system (Van Olmen 2010). Therefore, stewardship entails oversight and guidance of the whole system; ensuring strategic policy frameworks exist and are combined with effective oversight, coalition-building, regulation, attention to system-design and accountability. The stewardship function involves the role of the government in health and its relation to other actors whose activities impact on health. Public stewardship encompasses government policies, regulatory mechanisms, and implementation strategies for ensuring guidance and accountability in which healthcare services are delivered; in order to protect the public interest (WHO 2007). While ultimately it is the responsibility of government, this does not mean all stewardship functions have to be carried out by central ministries of health (WHO 2009).

Various strategies have been proposed for improving the functioning of the private for-profit health sector in order to increase the quality, availability, and affordability of health care for poor people in LMICs (Lagomarsino 2009; Levin 2011; Patouillard 2007; Waters 2003). These strategies include regulation, contracting-out, social marketing, franchising, use of vouchers, training, pay for performance, accreditation, and co-ordination. The strategies use various markers of success which are analysed by their association with differences in performance of intermediate goals or outcomes (Travis 2002). We focused on three types of strategic interventions, namely, regulation, training, and co-ordination of private for-profit providers. In the context of this review, regulation refers to the setting and enforcing of standards for the private for-profit sector; training involves educating and supporting private for-profit service providers; and co-ordination entails organising and creating alliances between private for-profit and public sector healthcare providers. We excluded public stewardship interventions which are already covered by other Cochrane reviews; including social marketing and franchising (Koehlmoos 2009), contracting (Lagarde 2009), and pay for performance (Witter 2012).

**How the intervention might work**

Regulatory interventions take the form of rules, enforcement systems and sanction mechanisms, and can be applied at the levels of the healthcare provider, organisation, or facility. At the provider level, regulation may include requirements for pre-service training, continuing education, licensing, and certification. At the organisational or facility level, regulation may aim to control the location of facilities, their registration, prices, and minimum complement of staff or facilities. For example, pharmaceutical market regulation aims to limit the availability of harmful drugs and unregistered products, minimise drug misuse, control the sale of specific drugs through prescriptions, and control drug manufacture and importation. Training interventions may involve formal educational sessions (educational meetings and workshops), vendor-to-vendor education, distribution of guidelines, printed educational materials, educational outreach i.e. a personal visit by a trained government official to private for-profit healthcare providers in their own settings, or audit and feedback i.e. a summary of the performance of private for-profit providers over a specified period of time given in a verbal or written format; alone or in combination (Forsethund 2009; Jamtvedt 2006; O’Brien 2007; Patouillard 2007). A wide variety of private for-profit healthcare sector components could be targeted for training, including physicians, pharmacists, midwives, nurses, and traditional healers. Finally, government co-ordination of private for-profit health care ensures harmonised minimum standards for health service delivery across geographic areas and social groups (Waters 2003). For instance, the creation of referral systems between the private for-profit and public sector and ensuring that health professionals in different health sectors understand their roles in disease management. The ultimate aim of government regulation, training, and co-ordination of the private for-profit health sector is to promote equity, better health outcomes, and financial protection (Lagomarsino 2009).

**Why it is important to do this review**

A systematic review published in 2007 found “evidence that effective public-private partnerships can increase access, improve equity, and raise quality of health services” (Patouillard 2007). However, using the GRADE approach (Balshem 2011; Guyatt 2008), this evidence on the effectiveness of interventions for working with the private for-profit sector to improve the utilisation and quality of health services for the poor in low- and middle-income countries was found to be of low certainty (Wiysonge 2008). The implication of the low certainty of the evidence is that further research on this topic is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. It is possible that additional primary studies may have been conducted on this topic. Therefore, we reviewed the currently available evidence on public sector efforts to work with private for-profit health service providers to improve the quality of existing healthcare services as well as expand and rationalise their coverage (Waters 2003).
To assess the effects of public sector regulation, training, or co-ordination of the private for-profit health sector in low- and middle-income countries.

METHODS

Criteria for considering studies for this review

Types of studies
The studies eligible for inclusion in the review were:

- randomised trials, including individually-randomised and cluster-randomised trials;
- non-randomised controlled trials i.e. experimental studies in which people are allocated to different interventions using methods that are not random;
- interrupted time series studies with at least three measurements before and after introducing the intervention; and
- controlled before-after studies with at least two intervention groups and at least two comparable control groups, with simultaneous data collection (EPOC 2013).

Types of participants
Studies taking place in low- and middle-income countries as defined by the World Bank. All types of health services provided by for-profit providers were eligible for inclusion in this review.

Types of interventions
Regulation, training, and co-ordination of any intensity or duration, implemented by the public sector. The control group received no intervention or an alternative intervention.

Types of outcome measures
The outcomes of interest were as follows.

Primary outcomes
- Quality of care (defined as adherence to recommended practice or guidelines).

Secondary outcomes
- Equity
- Mortality or morbidity
- Adverse effects (e.g. undesirable impacts on existing public or private services, inappropriate use of services, and distortion in the provision of services)
- Satisfaction
- Attitudes
- Costs of implementing the interventions

Search methods for identification of studies
We developed a sensitive and previously validated search strategy for randomised trials, non-randomised trials, controlled before-after studies, and interrupted time series studies combined with relevant medical subject headings (MeSH) and free-text terms relating to health regulation, training and co-ordination literature for low- and middle-income countries. We placed no language or date restrictions on the search strategy. We translated the MEDLINE (Ovid) search strategy into the other databases using the appropriate controlled vocabulary.

Electronic searches
We searched the following databases for systematic reviews:

- Cochrane Database of Systematic Reviews (CDSR) 2015, Issue 4, part of The Cochrane Library. www.cochranelibrary.com (searched 28 April 2015)

We searched the following databases, with no language or date restrictions, for primary studies:

- MEDLINE, Epub Ahead of Print, In-Process & Other Non-Indexed Citations, MEDLINE Daily and MEDLINE 1946 to Present, OvidSP (searched 16 June 2016)
- Science Citation Index and Social Sciences Citation Index 1987 to present, and Emerging Sources Citation Index 2015 to present, ISI Web of Science (searched 3 May 2016 for papers citing included studies)
- Cochrane Central Register of Controlled Trials (CENTRAL), 2015, Issue 3, part of the Cochrane Library. www.cochranelibrary.com (including the Cochrane Effective Practice and Organisation of Care (EPOC) Group Specialised Register) (searched 28 April 2015)
- Embase 1980 to 2015 Week 17, OvidSP (searched 28 April 2015)
In April 2016 we searched the following databases and websites for eligible studies:

- OpenGrey (opengrey.eu)
- Grey Literature Report (greylit.org)
- World Bank e-Library (elibrary.worldbank.org)
- US National Institutes of Health (NIH) (nih.gov)
- United Nations Children's Fund (UNICEF) (unicef.org)
- Alliance for Health Policy and Systems Research (who.int/alliance-hpsr/en)
- United States Agency for International Development (USAID) (usaid.gov)
- Gavi, The Vaccine Alliance (gavi.org)
- Private Healthcare in Developing Countries (psi.org)
- Population Services International (PSI) (psi.org)
- Shops (shopsproject.org)
- United Kingdom Department for International Development (gov.uk/government/organisations/department-for-international-development)
- Center For Health Market Innovations (healthmarketinnovations.org)
- World Bank (worldbank.org)

We checked the reference lists of identified reviews (Basu 2012; Berendes 2011; Forsberg 2011; Forsedlund 2009; Levin 2011; Patouillard 2007; Sulzbach 2011; Waters 2003) as well as reference lists of full-text articles reviewed for inclusion in this review.

### Data collection and analysis

#### Selection of studies

Two authors (Leila Abdullahi and Valantine Ndze, Leila Abdullahi and Charles Wiysonge, or Valantine Ndze and Charles Wiysonge) screened the titles and abstracts of outputs from the searches using a pre-designed screening guide to identify potentially eligible studies. We retrieved the full text of all publications deemed potentially eligible by at least one of the two authors. The two authors then independently examined each of these for eligibility. Each author compiled a list of studies which he or she believed met the inclusion criteria. Both authors compared the lists and resolved discrepancies by discussion and consensus.

#### Searching other resources

In April 2016 we searched the following databases and websites for eligible studies:

- OpenGrey (opengrey.eu)
- Grey Literature Report (greylit.org)
- World Bank e-Library (elibrary.worldbank.org)
- US National Institutes of Health (NIH) (nih.gov)
- United Nations Children's Fund (UNICEF) (unicef.org)
- Alliance for Health Policy and Systems Research (who.int/alliance-hpsr/en)
- United States Agency for International Development (USAID) (usaid.gov)
- Gavi, The Vaccine Alliance (gavi.org)
- Private Healthcare in Developing Countries (psi.org)
- Population Services International (PSI) (psi.org)
- Shops (shopsproject.org)
- United Kingdom Department for International Development (gov.uk/government/organisations/department-for-international-development)
- Center For Health Market Innovations (healthmarketinnovations.org)
- World Bank (worldbank.org)

We also used three additional criteria specified by the Cochrane Effective Practice and Organisation of Care Group (EPOC) (EPOC 2015):

- Similar baseline characteristics
- Similar baseline outcome measures
- Reliable primary outcome measures and
- Adequate protection against contamination.

For each included study, two authors independently reported their assessment of the risk of bias for each domain (i.e. low, high, or unclear) together with a descriptive summary of the information that influenced their judgment. The two authors compared the results of their independent assessments of the risk of bias and resolved any discrepancies by discussion and consensus. Had the two authors failed to reach an agreement, a third author would have arbitrated.

#### Data extraction and management

The two authors independently extracted descriptive and outcome data from each included study using a pre-designed data collection form. Both authors compared extracted data, resolving any discrepancies by discussion and consensus, failing which a third author would have arbitrated. One of two authors (Leila Abdullahi and Charles Wiysonge) entered the data into Review Manager (RevMan) 5.3 (RevMan 2014) and the other author performed double checks to ensure that there were no errors in the data entered.

### Assessment of risk of bias in included studies

We assessed the risk of bias based on six standard domains:

- Sequence generation
- Concealment of allocation
- Blinded or objective assessment of primary outcome(s)
- Incomplete outcome data
- Selective outcome reporting; and
- Other sources of bias (Higgins 2011a).

We also used three additional criteria specified by the Cochrane Effective Practice and Organisation of Care Group (EPOC) (EPOC 2015):

- Similar baseline characteristics
- Similar baseline outcome measures
- Reliable primary outcome measures and
- Adequate protection against contamination.

For each included study, two authors independently reported their assessment of the risk of bias for each domain (i.e. low, high, or unclear) together with a descriptive summary of the information that influenced their judgment. The two authors compared the results of their independent assessments of the risk of bias and resolved any discrepancies by discussion and consensus. Had the two authors failed to reach an agreement, a third author would have arbitrated.

#### Measures of treatment effect

We grouped measures of treatment effect based on outcome variables and study designs. We recorded and used estimates of effect from the primary analysis reported by the investigators.

We anticipated that there would be important baseline differences between intervention and control groups and planned to base our
primary analyses for trials and controlled before-after studies on estimates of effect that were adjusted for baseline differences. For dichotomous outcomes we planned to calculate the adjusted risk difference as the difference in adherence after the intervention minus the difference before the intervention. A positive risk difference would indicate that compliance with the recommended practice improved more in the intervention group than in the control group (e.g. an adjusted risk difference of 0.11 would indicate an absolute improvement in compliance with targeted behaviours of 11%). For continuous outcomes we planned to calculate the adjusted change relative to the control group as the post-intervention difference in means minus the baseline difference in means divided by the baseline control group mean. As with the adjusted risk difference, a positive change would indicate that compliance improved more in the intervention group than in the control group. This is a relative effect rather than an absolute effect; the effect size reflects the baseline performance as well as the change in performance and it is not bound between -100% and +100%.

We planned to analyse interrupted time series studies using either a regression analysis with time trends before and after the intervention, which adjusts for auto-correlation and any periodic changes; or any other technique that adjusts for auto-correlation and periodic changes. We would present results for the outcomes as changes along two dimensions: change in level and change in slope. Change in level is the immediate effect of the policy and change in slope is the change in the trend from pre-to post-intervention. It reflects the long-term effect of the intervention. For all measures we planned to calculate 95% confidence intervals (CI).

Unit of analysis issues

We planned that if investigators reported cluster-randomised trial data as if the randomisation was performed on the individuals rather than the clusters, we would request the intra-cluster correlation coefficient from the study authors; failing which we would obtain external estimates of the intra-cluster correlation coefficient from similar studies or available resources. Once established, we would use the intra-cluster correlation coefficient to re-analyse the trial data to obtain approximate correct analyses; as described in the Cochrane Handbook for Systematic Reviews of Interventions (Deeks 2011). We planned to combine the effect estimates and their corrected standard errors from cluster-randomised trials with those from parallel group designs using the generic inverse variance method (Deeks 2011). If insufficient information was available to control for clustering in this way, we would enter data into RevMan using individuals as the unit of analysis. We would then perform sensitivity analyses to assess the potential bias that may have occurred as a result of the inadequately controlled cluster-randomised trials. We planned that we would also perform sensitivity analyses if the intra-cluster correlation coefficients were obtained from external sources to assess the potential biasing effects of inadequately controlled cluster-randomised trials.

Three included studies were cluster-randomised trials based on matched pairs of clusters (Chalker 2002; Chuc 2002; Stenson 2001). We did not re-analyse these data as matching cannot be taken into account in re-analyses in such studies unless the raw data are available. The studies, however, conducted appropriate analyses of the data, and we have provided the results as reported in the studies. We have re-analysed the data for the fourth cluster-randomised trial (Abuya 2009). We did not conduct a meta-analysis.

Dealing with missing data

We planned that where necessary, we would contact the corresponding authors of included studies to supply any unreported data. If the corresponding author did not respond within one week of our request, we planned to contact other authors (copying the corresponding author). If a study reported outcomes only for participants completing the trial or only for participants who followed the protocol, we planned to contact the authors and ask them to provide additional information to permit us to conduct meta-analyses by intention-to-treat. We would describe missing data and dropouts for each included study in the risk of bias table, and discuss the extent to which the missing data could alter our results. We planned to conduct sensitivity analyses to assess the effect of missing data on our primary meta-analyses. If we had at least 10 studies in a meta-analysis, we would have explored the impact of including trials with high levels of missing data in the overall assessment of intervention effects by using sensitivity analyses.

For the current version of the review, we did not contact the primary study authors for missing data. We identified levels of attrition for included trials and performed analyses for reported outcomes. All participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. We assumed that missing participants did have the outcome of interest, and did not conduct sensitivity analyses imputing values for the outcome status of missing participants.

Assessment of heterogeneity

Given the variation found across studies in relation to the interventions, study design and outcome measures, we have not conducted a meta-analysis of study results. A statistical assessment of heterogeneity of results was therefore not done.

If we found homogeneous studies of similar interventions that reported similar outcomes, we would have conducted a meta-analysis, examined statistical heterogeneity between study results using the Chi² test of homogeneity (with significance defined at the alpha-level of 10%) (Deeks 2011), and quantified any statistical heterogeneity between study results using the I² statistic (Higgins 2003).
Assessment of reporting biases
We employed strategies to search for and include relevant unpublished studies in order to reduce possible publication bias. These strategies included searching the grey literature and prospective trial registration databases to overcome time-lag bias.

Data synthesis
Due to important heterogeneity between studies, a pooled statistical analysis of the results was not possible. Therefore we did a qualitative analysis based on intervention and outcome measures. If we had identified two or more clinically homogenous studies with similar interventions and comparison groups that reported similar outcome measures, we would have used meta-analysis to estimate the overall effect across those studies. We would have calculated all overall effects, if applicable, using inverse variance methods.

We used the GRADE approach to summarise the certainty of the evidence for each outcome (Guyatt 2008). The GRADE approach results in an assessment of the certainty of a body of evidence as high, moderate, low, or very low. High certainty evidence implies that "further research is very unlikely to change our confidence in the estimate of effect". Moderate certainty evidence means that "further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate". Evidence is considered of low certainty if "further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate", and very low quality if "we have very little confidence in the effect estimate" (Balshem 2011).

Subgroup analysis and investigation of heterogeneity
We stratified analysis by type of intervention. We did not find any studies that were similar enough to combine in a meta-analysis and, therefore, we did not conduct any subgroup analyses.

Sensitivity analysis
If we had found 10 or more studies that were similar enough that it would be sensible to combine them in a meta-analysis, we would have conducted sensitivity analyses to investigate the robustness of the results to risk of bias (i.e. omitting any studies with high risk of bias) and method of meta-analysis (i.e. random-effects versus fixed-effect).

RESULTS

Description of studies

Results of the search
Our search yielded 20,177 titles and abstracts. After removing 1,419 duplicates, we screened 18,758 records; 18,708 of which were not relevant. We reviewed the 50 potential eligible articles for inclusion. Six of these studies met our inclusion criteria (Abuya 2009; Chalker 2002; Chalker 2005; Chuc 2002; Ross-Degnan 1996; Stenson 2001), and we excluded 39 for reasons given in the Characteristics of excluded studies. Five studies were identified after the review was submitted and are awaiting assessment (see Characteristics of studies awaiting classification). We present the search and selection of studies for this review in Figure 1.
Included studies

We included six randomised trials on regulation and training of private for-profit healthcare providers in low- and middle-income countries (Abuya 2009; Chalker 2002; Chalker 2005; Chuc 2002; Ross-Degnan 1996; Stenson 2001). One study (Ross-Degnan 1996) had two components: one being a randomised trial, and the other a non-randomised trial. Five studies assessed training (Abuya 2009; Chalker 2002; Chalker 2005; Chuc 2002; Ross-Degnan 1996), four studies assessed regulation (Chalker 2002; Chalker 2005; Chuc 2002; Stenson 2001), and no study assessed co-ordination.

Description of interventions

Two studies (Abuya 2009; Ross-Degnan 1996) assessed only training interventions (N = 486 pharmacies), one study (Stenson 2001) assessed regulation only (N = 115 pharmacies), and three studies (Chalker 2002; Chalker 2005; Chuc 2002) had a multifaceted intervention which combined training, regulation, and peer influence (N = 379 pharmacies). All six studies targeted private pharmacy workers or drug retailers.

Training

The intervention in the two ‘training-only’ studies consisted of short-duration training sessions of one or two days in Kenya (Abuya 2009; Ross-Degnan 1996) and Indonesia (Ross-Degnan 1996). In both studies drug sellers were trained on prescription and dispensing of drugs, and surrogate patients (i.e. simulated clients) were used to assess the effects of the intervention on the quality of care provided by the trained retailers. The training was provided by the Ministry of Health in each country.

Regulation

One study (Stenson 2001) assessed regulation only (N = 115 pharmacies). The regulatory intervention involved three-month intensive supervision of pharmacy services in the Lao People’s Democratic Republic, applying sanctions when rules were violated and providing up-to-date regulatory documents and information about particular areas needing improvements (Stenson 2001). The study compared districts with active regulation to districts with only “regular supervision”. The ‘regular supervision’ intervention package was implemented in the way and speed that would have
taken place in the absence of the study. The aim was to let the control districts follow their natural course. The intervention was provided by the Ministry of Health with assistance from the United Nations Children’s Fund (Stenson 2001).

Multifaceted intervention

Three studies (Chalker 2002; Chalker 2005; Chuc 2002) had a multifaceted intervention which combined training, regulation, and peer influence (N = 379 pharmacies). Each intervention lasted three months, with a gap of four months before the next intervention. The quality of practice after the intervention was assessed through simulated clients. Two studies (Chalker 2002; Chuc 2002) were performed in Hanoi (Vietnam) with the intervention delivered by the Hanoi Health Bureau and the Hanoi Pharmacy Association. One study (Chalker 2005) was performed in both Hanoi (Vietnam) and Bangkok (Thailand); with the intervention delivered by the Hanoi Health Bureau and the Hanoi Pharmacy Association in Vietnam and the Bangkok Health System Research Institute and the Community Pharmacy Association in Thailand. The studies compared pharmacies with the multifaceted intervention to pharmacies without any intervention. All pharmacists who received the multifaceted intervention received all three interventions as a set. Enforcement regulation was performed by pharmacy inspectors while the educational intervention consisted of educational visits by senior researchers. Peer influence involved a number of group leaders and representatives of the pharmacy associations, who attended seminars where the research group informed them about the peer influence strategy and reviewed management.

Co-ordination

We did not identify any study that assessed the effects of government co-ordination of private for-profit healthcare providers, such as the creation of referral systems between the private for-profit and public sectors.

Description of outcomes

All six included studies reported on change in quality of care. The latter was measured using different dimensions in the different studies. One study (Stenson 2001) that assessed only regulation measured quality of care through change in the quality of private pharmacy practices (using “pharmacy indicators”). The two studies (Abuya 2009; Ross-Degnan 1996) that assessed only training measured quality of care through correct management of childhood malaria or diarrhoea respectively. The three studies with multifaceted interventions (Chalker 2002; Chalker 2005; Chuc 2002) measured quality of care through change in the correct management of tracer conditions, antibiotic dispensing practices, and correct symptomatic treatment of sexually transmitted infections respectively. Two studies (Chuc 2002; Chalker 2002) reported the cost of implementing the interventions. No studies reported data on equity, mortality, morbidity, adverse effects, satisfaction, or attitudes.

Excluded studies


Risk of bias in included studies

We have summarised our judgements about the risk of bias in each included study in Figure 2 and Figure 3.
Figure 2. Risk of bias graph: review authors’ judgements about each risk of bias item presented as percentages across all included studies.
Figure 3. Risk of bias summary: review authors’ judgements about each risk of bias item for each included study.

<table>
<thead>
<tr>
<th>Study</th>
<th>Random sequence generation (selection bias)</th>
<th>Allocation concealment (selection bias)</th>
<th>Blinding of participants and personnel (performance bias)</th>
<th>Blinding of outcome assessment (detection bias)</th>
<th>Incomplete outcome data (attrition bias)</th>
<th>Selective reporting (reporting bias)</th>
<th>Other bias</th>
<th>Similar baseline characteristics</th>
<th>Similar baseline outcome measures</th>
<th>Reliable primary outcome measures</th>
<th>Adequate protection against contamination</th>
</tr>
</thead>
</table>
Allocation
The methods for generation of the randomisation sequence and allocation concealment were unclear in all six studies (Abuya 2009; Chalker 2002; Chalker 2005; Chuc 2002; Ross-Degnan 1996; Stenson 2001).

Blinding
Outcome assessors were blinded in two studies (Abuya 2009; Ross-Degnan 1996), but there was no description of blinding in the rest (Chalker 2002; Chalker 2005; Chuc 2002; Stenson 2001).

Incomplete outcome data
Loss to follow up was moderate to high in the six studies.

Selective reporting
Selective reporting was categorised as unclear since we had no access to the study protocols.

Other potential sources of bias
All studies reported similar baseline characteristics among the intervention and control groups. Two studies (Chalker 2002; Chalker 2005) reported small differences in the outcome measures at baseline while no description was provided on baseline outcome measures in the rest of the studies. In one cluster-randomised controlled trial there was some degree of contamination in a cluster that was meant to be a control cluster (Abuya 2009), but none of the other studies reported contamination of control clusters with the interventions assessed. We did not have any evidence that other biases were introduced into the remaining studies, over and above the ones reported above.

Effects of interventions
See: Summary of findings for the main comparison
Government training of private for-profit healthcare providers; Summary of findings 2 Government regulation of private for-profit healthcare providers; Summary of findings 3 Government training and regulation of private for-profit healthcare providers

Primary outcome
All six included studies reported effects on quality of care; although quality of care was measured using different indicators. Three studies focused on improving treatment of childhood illnesses such as acute respiratory infection, malaria, or diarrhoea (Abuya 2009; Chalker 2002; Ross-Degnan 1996); one assessed the quality of treatment of sexually transmitted infections (Chuc 2002); and two assessed antibiotic dispensing practices (Chalker 2005; Chuc 2002).

Training
Each of the two studies that assessed training alone (Abuya 2009; Ross-Degnan 1996) observed improvements in quality of care. The study conducted in Kenya and Indonesia (Ross-Degnan 1996) showed an overall improvement in the management of diarrhoea among counter attendants in the intervention pharmacies compared to the controls. The sale of oral rehydration solution in the intervention pharmacies increased by 204% in Kenya (1 trial, 106 pharmacies; RR 3.04, 95%CI 1.37 to 6.75; Analysis 1.1) and 41% in Indonesia (1 trial, 87 pharmacies; RR 1.41, 95%CI 1.03 to 1.93: Analysis 1.1); compared to control pharmacies. In Kenya (Abuya 2009), correct prescription and dispensing of anti-malarial drugs improved substantially (1 trial, 293 pharmacies; RR 8.76, 95% CI 0.94 to 81.81: Analysis 1.2). Using the GRADE approach (Balshem 2011) we judged the certainty of evidence on the effects of training on quality of care as moderate (Summary of findings for the main comparison). Although the findings were consistent across the studies, we downgraded the evidence because of a moderate risk of bias in the included studies (Figure 3).

Regulation
In the ‘regulation only’ study, conducted in the Lao People’s Democratic Republic, the distribution and selling of registered pharmaceutical products was regulated in order to protect consumers against unfair practices (Stenson 2001). The study observed an increase of 34% in the availability of essential materials for dispensing and an increase of 19% in mean orderliness (including the presence of advertisements, and storage of drugs in their original packaging away from sunlight) in the intervention pharmacies compared to the control pharmacies. "Information given to customers increased from 35% to 51% and the mixing of different drugs in the same package went down from 17% to 9%. The pharmacies in the active intervention districts showed greater improvements for four of the six pharmacy indicators” (Stenson 2001). Using the GRADE approach (Balshem 2011), we judged the certainty of the evidence on the effects of the regulatory interventions on quality of care as low (Summary of findings 2). Our main concern with the evidence was the imprecision of the effect estimate.

Multifaceted intervention
In the multi-faceted intervention studies (Chalker 2002; Chalker 2005; Chuc 2002), the interventions (regulation, training, and
peer influence) were applied in a sequence, and the study design does not permit separation of the effects of the different interventions. The three studies provided inconsistent results regarding the effect of the multiple interventions on quality of pharmacy practice; including the ability to ask questions, give advice, and provide appropriate treatment for four tracer conditions (acute respiratory conditions, malaria, diarrhoea, and sexually transmitted infections). In one study conducted in Vietnam (Chalker 2002), knowledge and reported practice among drug sellers improved for three of the four tracer conditions in intervention pharmacies compared to control pharmacies. The second study conducted in Vietnam, (Chuc 2002), found that the intervention pharmacies improved substantially in all tracer conditions compared to the control pharmacies. Chalker 2005 was conducted in both Vietnam and Thailand and had mixed results. Improvements were observed in Vietnam in the dispensers' behaviour for all tracer conditions, but in Thailand improvements occurred in only one of the tracer conditions. We judged the certainty of the evidence on the effects of the multifaceted intervention as low (Summary of findings 3), because of concerns regarding inconsistency of findings and high risk of bias in the included studies.

Secondary outcomes
Two multifaceted intervention studies reported the cost of the interventions (Chalker 2002; Chuc 2002). Chalker 2002 reported the cost incurred for the three interventions in 30 pharmacies to be USD 5700. The Chuc 2002 study reported that the costs of treating four tracer conditions increased for both intervention and control pharmacies.

No study reported data on equity, mortality, morbidity, adverse effects, satisfaction, or attitudes.
### Regulation compared to no regulation for improving quality of care

**Population:** Private for-profit providers of healthcare services  
**Settings:** Lao People's Democratic Republic  
**Intervention:** Regulation  
**Comparison:** No regulation

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Impacts</th>
<th>No of Participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of care</td>
<td>Regulation may improve quality of care. The study observed an increase of 34% in the availability of essential materials for dispensing and an increase of 19% in mean orderliness (including the presence of advertisements, and storage of drugs in their original packaging away from sunlight) in the intervention pharmacies compared to the control pharmacies</td>
<td>115 pharmacies (1 study)</td>
<td>⊕⊕⊕⊕ Low*</td>
</tr>
</tbody>
</table>

* We downgraded the certainty of the evidence by 2 points, because of a high risk of attrition bias and wide confidence intervals around the effect estimate, ranging from a large benefit to important harm.

**GRADE Working Group grades of evidence**

- **High certainty:** Further research is very unlikely to change our confidence in the estimate of effect.
- **Moderate certainty:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- **Low certainty:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
- **Very low certainty:** We are very uncertain about the estimate.

### Training and regulation compared to no intervention for improving quality of care

**Population:** Private for-profit providers of healthcare services  
**Settings:** Thailand and Vietnam  
**Intervention:** Training, regulation, and peer influence  
**Comparison:** No intervention

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Impact</th>
<th>No of Participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of care</td>
<td>Training and regulation may improve quality of care</td>
<td>379 pharmacies (3 studies)</td>
<td>⊕⊕⊕⊕ Low*</td>
</tr>
</tbody>
</table>
GRADE Working Group grades of evidence

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

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

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

**Very low certainty:** We are very uncertain about the estimate.

**DISCUSSION**

**Summary of main results**

Our comprehensive search of the literature identified 20,177 records, from which six randomised controlled trials fulfilled our inclusion criteria. In two studies in Kenya and Indonesia, the Ministry of Health offered private drug sellers short training sessions on prescribing and dispensing drugs. These sellers were compared to drug sellers who were not offered training. The studies suggest that training probably improves the quality of healthcare services. In one study in the Lao People's Democratic Republic, the Ministry of Health supervised private pharmacy services in certain districts over a three-month period, applied sanctions when rules were broken, and offered information about areas needing improvement. These districts were compared to districts without this enhanced supervision. The study suggests that this enhanced regulation may improve quality of care. In three studies in Vietnam and Thailand, private pharmacies in some districts received educational visits as well as visits from pharmacy inspectors to enforce regulations. These districts were compared to districts that did not receive any visits. The studies suggest that these types of visits may provide mixed results. The review did not find any eligible study that assessed the effects of co-ordination on quality of care.

**Overall completeness and applicability of evidence**

Despite the large number of records obtained in our literature search, only six studies with moderate to high risk of bias met our inclusion criteria. All studies were conducted in Africa and Asia; and the results may be applicable to low- and middle-income countries in other continents. Health worker availability in the public sector is a key barrier to strengthening health systems in LMICs. Effective government interventions to expand the coverage of private for-profit healthcare providers and rationalise access to their services with that of public sector providers could strengthen health systems in LMICs. However, countries considering the implementation of public stewardship interventions need to assess the human and financial resource capacity of the public sector to properly supervise private providers. All the studies covered only services of private for-profit pharmacists. The findings may not be directly transferable to other cadres of private healthcare providers. Therefore, there is a need for studies on other private sector components such as private hospitals, physicians, midwives, nurses, and traditional healers.

There were no studies that reported data on equity, mortality, morbidity, adverse effects, satisfaction, or attitudes. If training or regulatory interventions are directed at providers that serve disadvantaged populations they could help to decrease inequity. However, intervention effects could vary across settings, for example between rural and urban areas, because of the distribution of private providers in these different areas. Expanding the coverage of private for-profit providers could reduce inequity if, for example, access to the private sector is available where access to the public sector is limited. However, if private for-profit providers are unavailable in underserved areas, expanding access to private providers may increase inequity between urban and rural areas. There was no rigorous evaluation of the cost implications of implementing the interventions, thus this review does not provide evidence on investment in private for-profit providers on quality of care in low- and middle-income countries. The structure and specific tasks associated with a particular public stewardship function will determine the costs. Given these uncertainties, implementation of public sector regulation, training or co-ordination of private for-profit healthcare providers should be accompanied...
by a robust framework for monitoring the costs and impacts of the interventions.
Much of the currently available literature on training and regulation of private for-profit providers in low- and middle-income countries is descriptive rather than evaluative, detailing experiences that may have great potential without rigorously testing their effectiveness (Berendes 2011; Patouillard 2007; Waters 2003; Wiysonge 2008). Well-designed studies evaluating public stewardship functions are therefore needed before these are implemented on a large scale in low-income countries.

Certainty of the evidence
Using the GRADE approach, we judged the certainty of evidence on the effects of training interventions on quality of care as moderate; which implies that “further research is likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate”. We rated the certainty of evidence on regulation and the multifaceted intervention as low, which means that “further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate” (Balschom 2011). Our main concerns with the evidence were limitations of the included studies, wide confidence intervals around the effect estimates, and heterogeneity of intervention effects.

Potential biases in the review process
We minimised potential biases in the review process by adhering to Cochrane guidelines (Higgins 2011). We conducted comprehensive searches without limiting the searches to a specific language. Two authors independently assessed study eligibility, extracted data, and assessed the risk of bias in each included study.

Agreements and disagreements with other studies or reviews
Despite the widespread availability of private healthcare services in low- and middle-income countries, there is a shortage of systematic reviews that have assessed interventions showing how governments have worked with the private for-profit providers to achieve public health goals (Brugha 1998; Levin 2011; Patouillard 2007; Peters 2004; Waters 2003). To the best of our knowledge, our review is the most comprehensive and up-to-date assessment of the evidence on the effects of training, regulation, and co-ordination of private-for-profit health care in low- and middle-income countries.
In 2003 Hugh Waters and colleagues published a review that assessed the evidence available concerning public sector efforts to work with private health service providers and other components of the private sector, in order to both improve the quality of their services and to rationalise and expand their coverage (Waters 2003). The review focused on interventions aimed at regulating, contracting, financing, social marketing, training, co-ordinating, and informing private providers in low- and middle-income countries. The review authors searched Pubmed and Popline databases, and reference lists of included articles, for both published and unpublished literature from 1980 onwards. They included 42 studies including six ‘controlled’ trials comparing results in two or more groups; 10 studies with a pre-post evaluative component, but no comparison group; four cross-sectional studies; and 22 descriptive case studies. Waters 2003 found that although governments are gaining experience in using the tools of contracting, regulating, financial incentives, training, co-ordinating, and informing to influence the private sector, the evidence on the effectiveness of these interventions remains weak.
In 2007 Edith Patouillard and co-workers published a related review, which assessed the effectiveness of interventions on working with the private for-profit sector to improve utilisation of quality health services by the poor in low- and middle-income countries (Patouillard 2007). Interventions of interest to the review authors included social marketing, use of vouchers, pre-packaging of drugs, franchising, training, regulation, accreditation, and contracting-out. They conducted a comprehensive search of peer-reviewed and grey literature for eligible studies; focusing on studies which evaluated the impact of interventions on utilisation or quality of services, or both, and which provided information on the socioeconomic status of the beneficiary populations. The review authors identified 52 eligible studies; five provided data on the average socioeconomic status of recipient communities and five provided data on the distribution of benefits across socioeconomic groups. Patouillard 2007 concluded that it is not possible to prove from the available literature that private sector interventions benefit the poor and improve equity. However, they argue that the fact that many such interventions have operated successfully in relatively poor settings indicates that the interventions do benefit the poor. The authors went on to recommend that better evidence of the equity impact of interventions working with the private sector is needed for more robust conclusions to be drawn.
There are marked differences between these two previous reviews (Patouillard 2007; Waters 2003) and the current systematic review. Although the authors of the two previous reviews conducted literature searches that were relatively comprehensive, they do not explicitly say whether they undertook duplicate study selection and data extraction and do not report reliable criteria for assessing the risk of bias in included studies. They do not provide appropriate description of the characteristics of included studies and do not seem to synthesise data from included studies using reliable methods. In addition, much of the data reported in the reviews is descriptive rather than evaluative, detailing experiences that may have great potential without rigorously testing their effectiveness. Most of the studies included in the reviews were not set up as research projects (Patouillard 2007; Waters 2003). Furthermore, the two reviews included studies in which the stewardship functions
Implications for practice

This review provides different levels of strength for the currently available evidence on the effectiveness of the three public stewardship interventions. The finding that training probably improves quality of care implies that monitoring of the impact is likely to be needed and an impact evaluation may be warranted if government training of private for-profit providers is implemented in low- and middle-income countries. The low certainty of the evidence for regulation implies that an impact evaluation is warranted if government regulation of private for-profit providers is implemented in low- and middle-income countries. We found no studies on the effects of government co-ordination of private providers.

A C K N O W L E D G E M E N T S

We are grateful to the editorial base of the Norwegian Satellite of the Cochrane Effective Practice and Organisation of Care Group for assistance in the preparation of the review. In particular, we gratefully acknowledge Ms Marit Johansen for assistance in developing and implementing the search strategy, and Drs Andy Oxford, Susan Munabi-Babigumira and Gabriel Rada for advice and support at various stages of the preparation of the review.

We would also like to thank the following editors, peer referees and others who provided comments to improve the review: Cristian Herrera, John Chalker, Newton Opiyo, Jan Odgaard-Jensen; Claire Glenton for preparing the plain language summary, and Denise Mitchell for copy-editing the review.

We are very grateful to Dr Hassan Mahomed who contributed to the writing of the protocol of the review (Abdullahi 2012).

Charles S Wiyonge’s work is partly supported by Stellenbosch University, the South African Medical Research Council, the National Research Foundation of South Africa, and the Effective Health Care Research Consortium (EHCRC). The EHCRC is funded by UK aid from the UK Government for the benefit of developing countries (Grant: 5242). The views expressed in this publication do not necessarily reflect UK government policy.

The Norwegian Satellite of the Effective Practice and Organisation of Care (EPOC) Group receives funding from the Norwegian Agency for Development Cooperation (Norad), via the Norwegian Institute of Public Health to support review authors in the production of their reviews.

AUTHORS’ CONCLUSIONS

Implications for research

Rigorous evaluations of the interventions assessed in this review (as well as other public stewardship interventions) should assess cost implications, patient outcomes, and impacts on equity; in addition to quality of care. Given that there was no evidence on the impact of the interventions on equity, the challenge for the future is to design evaluations and report results in ways that can assess equity clearly, and indicate how equity can be enhanced.
References to studies included in this review

Abuya 2009 [published data only]

Chalker 2002 [published data only]

Chuc 2002 [published data only]

Ross-Degnan 1996 [published data only]

Stenson 2001 [published data only]

References to studies excluded from this review

Akol 2014 [published data only]

Akoria 2008 [published data only]

Ali 2011 [published data only]

Ali 2012 [published data only]

Andrianasolo 2012 [published data only]

Bhat 1996 [published data only]

Bin 2013 [published data only]

Bojalil 1999 [published data only]

Chakraborty 2000 [published data only]

Contiades 2007 [published data only]

Dholakia 2013 [published data only]

Farsi 1999 [published data only]

Fernandes 2009 [published data only]
Fernandes PS, Bernardo CD, Campos RMMB, Vasconcelos FAG. Evaluating the effect of nutritional education on the

**Goodman 2007** *(published data only)*


**Grundy 2010** *(published data only)*


**Guiscare 2001** *(published data only)*


**Harrison 2000** *(published data only)*


**Hongoro 2000** *(published data only)*


**Hulda 2015** *(published data only)*


**Kangwana 2011** *(published data only)*


**Khan 2006** *(published data only)*


**Kumaranayake 2000** *(published data only)*


**Maiga 2010** *(published data only)*


**Marsh 2004** *(published data only)*


**Minh 2013** *(published data only)*


**Morris 2013** *(published data only)*


**Murugesan 2009** *(published data only)*


**Nsamba 2007** *(published data only)*


**Obua 2004** *(published data only)*


**Okonofua 2003** *(published data only)*


**Osterholt 2009** *(published data only)*


**Rutta 2011** *(published data only)*


**Stenson 2001b** *(published data only)*

**Syhakhang 2001** *(published data only)*

**Tavrow 2003** *(published data only)*

**Tumwikirize 2004** *(published data only)*

**Ward 2013** *(published data only)*

**Willey 2014** *(published data only)*

**References to studies awaiting assessment**

**Anshah 2015** *(published data only)*

**El-Khouyr 2015** *(published data only)*

**Kaffe 2013** *(published data only)*

**Mbonye 2015** *(published data only)*

**Santa-Ana-Tellez 2016** *(published data only)*

**Additional references**

**Balshem 2011**

**Basu 2012**

**Berendes 2011**

**Brugha 1998**

**Deeks 2011**

**EPOC 2013**
Cochrane Effective Practice, Organization of Care (EPOC). What study designs should be included in an EPOC review?. EPOC Resources for review authors. Oslo: Norwegian Knowledge Centre for the Health Services; 2013. Available at: http://epoc.cochrane.org/epoc-specific-resources-review-authors.

**EPOC 2015**
Effective Practice, Organisation of Care (EPOC). Suggested risk of bias criteria for EPOC reviews. EPOC Resources for
Public stewardship of private for-profit healthcare providers in low- and middle-income countries (Review)

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Lagomarsino 2009

Levin 2011

O’Brien 2007

Patouillard 2007

Peters 2004

RevMan 2014 [Computer program]

Scott 2011

Sulzbach 2011

Travis 2002

Van Olmen 2010

Veillard 2011
Veillard JHM, Brown AD, Baris E, Permanand G, Klazinga NS. Health system stewardship of National Health

---

Higgins 2011

Higgins 2011a

Jamtvedt 2006

Koehlmoos 2009

Lagarde 2009
Lagarde M, Palmer N. The impact of contracting out on health outcomes and use of health services in low and middle-income countries. *Cochrane Database of Systematic Reviews* 2009, Issue 4. [DOI: 10.1002/14651858.CD008133]

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Forsberg 2011

Forsetlund 2009

Guyatt 2008

Higgins 2003

---

Jamtvedt 2008

**Waters 2003**


**WHO 2007**


**WHO 2009**


**Witter 2012**


**Wiysonge 2008**


References to other published versions of this review

**Abdullahi 2012**


* Indicates the major publication for the study
CHARACTERISTICS OF STUDIES

Characteristics of included studies  [ordered by study ID]

Abuya 2009

<table>
<thead>
<tr>
<th>Methods</th>
<th>Cluster-randomised trial conducted in 3 districts in Kenya from 2002-2005</th>
</tr>
</thead>
</table>
| Participants | Number enrolled: 10 clusters (sub-districts) with a total of 140 functional anti-malarial medicine 'shops'  
Study population: 10 divisions (clusters) in 3 rural districts in Kenya (i.e. Kwale, Makueni and Busia ) with divisions as unit of randomisation in Kenya  
Inclusion criteria: the main sellers in outlets stocking anti-malarial medicines. The eligible outlets had to be relatively stable (on the basis of local knowledge)  
Exclusion criteria: non-functional anti-malarial medicine outlets  
Withdrawals and exclusions: in Kwale district, 24% of trainees changed business or closed their outlets. In Makueni and Busia districts, 4% and 5% of trainees respectively closed their outlets within 6-8 months after training |
| Interventions | Intervention: 5 divisions (clusters) with 60 functional medicine outlets were allocated to the intervention group. In total, 122 private medical retailers were trained in Kwale, 79 in Busia, and 247 in Makueni districts  
Duration: the intervention consisted of 2-day training workshops at local venues  
Who delivered the intervention: Kenya’s Ministry of Health  
Description: the training covered signs of simple and severe malaria; malaria treatment and prevention; drug resistance; referral practices; storage and expiry of medicines; and communication skills  
Comparison: no training was conducted in 5 ’control’ divisions (clusters) with 80 outlets |
| Outcomes | Retailers’ knowledge on the treatment of childhood fevers; recommended amodiaquine adequately  
Surrogate clients were used to pose as patients and retail audits were used to collect information on the outlets and retailers |
| Notes | The study was approved by the Kenya National Scientific Steering and Ethical Research Committees and the WHO Secretariat Committee on Research Involving Human Subjects (SCRIHS)  
A cost-effectiveness study of the intervention in Kenya suggested that, although the initial cost of setting such programmes is high, the annual running costs could be contained within a typical district budget. In total, USD 5202.00 and USD 5882.00 were released to Kwale and Makueni districts respectively, for the implementation of the programmes in the setup year. The programme in Busia district was implemented with funds from UNICEF, with a total of USD5838 allocated |

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
</tbody>
</table>

Public stewardship of private for-profit healthcare providers in low- and middle-income countries (Review)

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## Abuya 2009

(Continued)

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<thead>
<tr>
<th>Allocation concealment (selection bias)</th>
<th>Unclear risk</th>
<th>No description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Low risk</td>
<td>Surrogate clients, fieldworkers posed as clients seeking care from a provider who was unaware of the clients’ identity</td>
</tr>
<tr>
<td>All outcomes</td>
<td>low risk</td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Surrogate clients, fieldworkers posed as clients seeking care from a provider who was unaware of their identity</td>
</tr>
<tr>
<td>All outcomes</td>
<td>low risk</td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>4% and 24% of trained outlets closed within 6-8 months of training</td>
</tr>
<tr>
<td>All outcomes</td>
<td>low risk</td>
<td></td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No evidence of other sources of bias</td>
</tr>
<tr>
<td>Similar baseline characteristics</td>
<td>Low risk</td>
<td>The District Health Management Team identified divisions they considered similar in characteristics</td>
</tr>
<tr>
<td>Similar baseline outcome measures</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Reliable primary outcome measures</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Adequate protection against contamination</td>
<td>High risk</td>
<td>It is possible that there was some degree of contamination in Busia district, a suggestion supported by the District Health Management Team report that the district had experienced almost complete coverage with PMR programmes at the time of the evaluation, leaving only one division as the control</td>
</tr>
</tbody>
</table>

## Chalker 2002

<table>
<thead>
<tr>
<th>Methods</th>
<th>Cluster-randomised trial conducted in Hanoi, Vietnam, conducted from May 1998-September 1999</th>
</tr>
</thead>
</table>
| Participants | Number enrolled: 34 paired pharmacies in urban Hanoi  
Study population: private pharmacies registered in the urban area of Hanoi  
Inclusion criteria: private registered pharmacies in urban Hanoi  
Exclusion criteria: pharmacies outside hospitals and not mainly wholesalers  
Withdrawal and exclusions: in the course of the study, 4 pharmacies closed and 1 refused to take part in the third intervention. No post-intervention interviews were taken from 4 intervention and 4 control pharmacies as they were closed early before the Vietnamese New Year holidays. These gave 22 matched pairs |
### Interventions

**Intervention:** regulatory enforcement, face-to-face education, and peer influence. The three interventions were implemented sequentially in 22 pharmacies.

**Duration:** each intervention lasted 3 months, with a gap of 4 months before the next intervention.

**Who delivered the intervention:** the Hanoi Health Bureau and the Hanoi Pharmacy Association.

**Description:**
- for the regulatory intervention, 4 inspectors of the Hanoi Health Bureau were trained to undertake the inspection. In pairs the inspectors visited the intervention pharmacies twice, a month apart.
- for the face-to-face education intervention, each intervention pharmacy was visited twice by 2 people who conducted face-to-face education sessions with all staff present. Each session lasted about 45 minutes and included both written and verbal information.
- For the peer influence intervention, a 1-day seminar was held with the 5 group leaders and representatives of the Hanoi Pharmacy Association.

**Comparison:** 22 pharmacies with no intervention.

### Outcomes

Knowledge and reported change in practice for correct management of tracer conditions.

### Notes

The cost for the 3 interventions was approximately USD 5700.00 for 30 pharmacies.

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>Failure to interview people from 4 intervention and 4 control pharmacies after the interventions may have caused a bias in results, but this is unlikely because of the</td>
</tr>
</tbody>
</table>
### Chalker 2002 (Continued)

<table>
<thead>
<tr>
<th>Equivalent Numbers Between Intervention and Control</th>
<th>Low risk</th>
<th>There was matching of pharmacies to ensure similar baseline characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Similar Baseline Characteristics</td>
<td>Low risk</td>
<td>There was a slight difference in the outcome measures at baseline level which was not statistically significant</td>
</tr>
<tr>
<td>Similar Baseline Outcome Measures</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Reliable Primary Outcome Measures</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Adequate Protection Against Contamination</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
</tbody>
</table>

### Chalker 2005

**Methods**

- Randomised trial conducted in Hanoi (Vietnam) and Bangkok (Thailand) from June 1998-September 1999

**Participants**

- Number enrolled: 68 pharmacies in Hanoi and 78 pharmacies in Bangkok
- Study population: private registered pharmacies in Hanoi and Bangkok
- Inclusion criteria: private pharmacies in Hanoi and Bangkok
- Withdrawals and exclusions: in Bangkok 1 intervention pharmacy and 2 control pharmacies closed down and 3 of each were missed in at least one of the simulated clients' round of visits. In Hanoi 1 intervention and 3 control pharmacies closed, 1 intervention pharmacy refused to continue, and 4 intervention and 4 control pharmacies had incomplete data for different rounds of client visits

**Interventions**

- Intervention: enforcement of regulations, education, and peer review in 34 pharmacies in Hanoi and 39 pharmacies in Bangkok
- Duration: each intervention lasted 3 months, with a gap of 4 months before the next intervention
- Who delivered the intervention: the Hanoi Provincial Health Bureau, Hanoi Pharmacy Association, Hanoi Medical University, and the Hanoi College of Pharmacy. In Bangkok, the interventions were delivered by the Health System Research Institute, Chulalongkorn University, and the Community Pharmacy Association
- Description
  - Regulation: in Hanoi, the intervention pharmacies were visited twice by 2 inspectors. A summary of the regulations on prescription-only medicine, a letter from the provincial health bureau, and an example of good labelling were handed out to each pharmacy. In Bangkok, the enforcement of regulation was performed by 6 inspectors. The inspectors checked the availability of steroids and steroid prescriptions (if the drug was found) and gave instructions to the seller on the respective regulations. A warning was given about the consequences of violation of the regulations.
  - Education: in Hanoi, each pharmacy received two 45-minute educational visits by a pair of senior researchers using both written and verbal information. In Bangkok, the educational intervention was performed in 3 groups. The pharmacy owners and the...
pharmacy assistants were invited to a 2-day seminar

- Peer review: the intervention pharmacies in Hanoi were divided into 5 area groups with 5-6 pharmacies in each. Each of the 5 area groups held 5 meetings averaging 1 every second week. In Bangkok, prospective peer facilitators were identified among the participants. The researchers initiated a group by visiting these 4-5 active drugstores in each district and introducing the concept of peer groups for drugstore staff

Comparison: no intervention on 34 control pharmacies in Hanoi and 39 control pharmacies in Bangkok

Outcomes

Change in the dispensing practices of antibiotics in Hanoi and Bangkok

Notes

The study had ethical approval from the Karolinska Institute as well as the Ministries of Health in Vietnam and Thailand

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) All outcomes</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>High risk</td>
<td>In Bangkok 1 intervention pharmacy and 2 control pharmacies closed down, and 3 of each were missed in at least one of the simulated clients’ visits. In Hanoi 1 intervention and 3 control pharmacies closed, 1 intervention pharmacy refused to continue and 4 intervention and 4 control pharmacies had incomplete data for different rounds of client visits</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The study appears to be free of other biases</td>
</tr>
<tr>
<td>Similar baseline characteristics</td>
<td>Low risk</td>
<td>Some basic characteristics (i.e. turnover, staff numbers and qualifications) were not possible to judge from the simulated clients’ visit. However, the random selection en-</td>
</tr>
</tbody>
</table>
### Chalker 2005 (Continued)

<table>
<thead>
<tr>
<th>Sured comparability between intervention and control pharmacies</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Similar baseline outcome measures</td>
<td>Low risk</td>
</tr>
<tr>
<td>Reliable primary outcome measures</td>
<td>Unclear risk</td>
</tr>
<tr>
<td>Adequate protection against contamination</td>
<td>Unclear risk</td>
</tr>
</tbody>
</table>

### Chuc 2002

<table>
<thead>
<tr>
<th>Methods</th>
<th>Cluster-randomised controlled trial conducted from October 1997-January 2000 in Hanoi, Vietnam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Number enrolled: 34 pairs of private pharmacies  Study population: 34 pairs of private pharmacies in Hanoi randomly selected according to the following matching criteria:  • turnover: high, medium, or low according to district inspectors;  • whether or not the pharmacist was the licence holder;  • whether or not the pharmacy was close to a hospital; and  • located in a different ward or more than 150 meters from all other pharmacies selected  Inclusion criteria: private pharmacies in the study area  Exclusion criteria: pharmacies located inside a hospital or that were mainly wholesalers were excluded  Withdrawals and exclusions: 4 pharmacies were excluded because of irregular opening hours. As a consequence, the other pharmacy in each pair was also excluded as the results were analysed in pairs</td>
</tr>
<tr>
<td>Interventions</td>
<td>Intervention: regulatory enforcement, educational intervention, and peer review  Duration: each intervention lasted 3 months, with a gap of 4 months before the next intervention  Who delivered the intervention: Hanoi Bureau Health and Hanoi Pharmacy Association  Description  • For regulation: 4 inspectors from the Hanoi Health Bureau were trained to cover these areas of inspection. In pairs they visited the intervention pharmacies twice with an interval of 1 month  • For education: 2 senior research team members and 2 clinicians conducted the intervention. Each intervention pharmacy received two 45-min face-to-face educational sessions  • Peer review: 5 group leaders conducted a 1-day seminar where the research group informed about the peer influence strategy and reviewed case management of the 4 tracer conditions. 3 meetings were held during 3 months where the participants presented and discussed their records</td>
</tr>
</tbody>
</table>
### Outcomes

Comparison: no intervention

Effect of multi-component intervention using tracer conditions i.e. correct symptomatic treatment of sexually transmitted disease

### Notes

The estimated total cost of the interventions was approximately USD 5700.00

### Risk of bias

<table>
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<tr>
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<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) All outcomes</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>High risk</td>
<td>4 pharmacies were excluded because of irregular opening hours. As a consequence, the other pharmacy in each pair was also excluded as the results were analysed in pairs</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The study appears to be free of other sources of bias</td>
</tr>
<tr>
<td>Similar baseline characteristics</td>
<td>Low risk</td>
<td>The pharmacies paired to ensure a similar composition for intervention and control groups</td>
</tr>
<tr>
<td>Similar baseline outcome measures</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Reliable primary outcome measures</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Adequate protection against contamination</td>
<td>Low risk</td>
<td>To prevent the client’s individual behaviour from affecting the pharmacy staff, all clients were trained to act in a reproducible way, and they were not informed about which pharmacies belonged to the intervention or control groups</td>
</tr>
</tbody>
</table>
**Ross-Degnan 1996**

| Methods | Non-randomised controlled trial conducted in Kenya  
Randomised controlled trial conducted in Indonesia Date not stated |
| --- | --- |
| Participants | Number enrolled: 112 pharmacies in Kenya and 87 pharmacies in Indonesia  
Study population  
• In Kenya, the study was done in Nairobi, Nakuru and Mombasa  
• In Indonesia, the pharmacies were selected from Jakarta and the neighbouring communities of Bogor, Tangerang, and Bekasi  
Inclusion criteria: private pharmacy in the study area  
Withdrawals and exclusions: Four pharmacies in Kenya and five pharmacies in Indonesia were excluded because the analyses were limited to the outcomes that were measured both before and after the intervention |
| Interventions | Intervention: training in 82 pharmacies in Kenya and 43 pharmacies in Indonesia  
Duration: 1 day in Kenya and 2 days in Indonesia  
Who delivered the intervention: Control of Diarrhoea Diseases (CDD) programmes in the Ministry of Health  
Description: in both countries, the intervention began with brief one-on-one meetings with pharmacists/pharmacy owners discussing key training messages and ways to deal with perceived barriers to practice recommendations, followed by training of all counter attendants in group sessions of 5-10 attendees organised close to their pharmacies. To measure changes in treatment practice, all pharmacies included in the study in both countries were visited by surrogate patients  
Comparison: the no-training control group consisted of 25 pharmacies in Kenya and 44 pharmacies in Indonesia |
| Outcomes | Proportion of cases who received oral rehydration salts (ORS) |
| Notes | |

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Low risk</td>
<td>Trainees and pharmacy owners were not informed that the sales practices in their pharmacies would be evaluated</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) All outcomes</td>
<td>Low risk</td>
<td>Outcomes were assessed by surrogate patients who were blind to the purpose of the study, and to the study or control status of the pharmacies</td>
</tr>
</tbody>
</table>
Ross-Degnan 1996  (Continued)

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear</td>
<td>No description</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear</td>
<td>No description</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low</td>
<td>The study appears to be free of other sources of.bias</td>
</tr>
<tr>
<td>Similar baseline characteristics</td>
<td>Low</td>
<td>There were similar baseline characteristics</td>
</tr>
<tr>
<td>Similar baseline outcome measures</td>
<td>Unclear</td>
<td>No description</td>
</tr>
<tr>
<td>Reliable primary outcome measures</td>
<td>Unclear</td>
<td>No description</td>
</tr>
<tr>
<td>Adequate protection against contamination</td>
<td>Unclear</td>
<td>No description</td>
</tr>
</tbody>
</table>

Stenson 2001

Methods
Randomised controlled trial conducted from June 1997 to March 1999 in the Lao People's Democratic Republic (Lao P.D.R.)

Participants
Number enrolled: 115 pharmacies
Study population: the study was based on licensed private pharmacies in Savannakhet province, Lao P.D.R. All pharmacies except 2 belonged to class 3, the lowest class of licensed pharmacies, where the licensee does not have to be a pharmacist or an assistant pharmacist. Most of them had a nursing background
Inclusion criteria: operating pharmacy within the province
Exclusion criteria: the pharmacies that were missed in the (post-intervention analysis) were excluded from the analysis
Withdrawals and exclusions: 14 pharmacies were missed during study and the reasons for missing pharmacies were mortality among drug sellers or that the pharmacy had moved or was closed for family reasons

Interventions
Intervention: active regulation in 46 pharmacies
Duration: One and half years
Who delivered the intervention: Ministry of Health with assistance from UNICEF
Description: the regulatory intervention involved three month's intensive supervision of the quality of pharmacy services, applying sanctions when rules were violated, and providing up-to-date regulatory documents and information about particular areas needing improvements. The study compared districts with active regulation to districts with regular care
Comparison: 92 control pharmacies received regular care

Outcomes
Change of the quality of private pharmacy practice (pharmacy indicators)

Notes
### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>It was not possible to make the study blinded with regard to the main intervention vehicle, the research assistant. It could not be established to what extent the drug sellers had any active knowledge of the study objectives</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>The district pharmacists who were active partners in the research team and participated in the sampling procedures and assessing the outcome were also aware of the scope of the intervention</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>14 pharmacies were missed during the study and the reasons for missing pharmacies were mortality among drug sellers or that the pharmacy had moved or was closed for family reasons</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The study appears to be free of other sources of bias</td>
</tr>
<tr>
<td>Similar baseline characteristics</td>
<td>Low risk</td>
<td>There were similar baseline characteristics i.e. income levels and literacy</td>
</tr>
<tr>
<td>Similar baseline outcome measures</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Reliable primary outcome measures</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
<tr>
<td>Adequate protection against contamination</td>
<td>Unclear risk</td>
<td>No description</td>
</tr>
</tbody>
</table>

UNICEF: The United Nations Children's Fund  
WHO: World Health Organization
### Characteristics of excluded studies [ordered by study ID]

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Akol 2014</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Akoria 2008</td>
<td>This was a controlled before-after study but the participants were not private-for-profit providers</td>
</tr>
<tr>
<td>Ali 2011</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Ali 2012</td>
<td>This was a cross-sectional survey</td>
</tr>
<tr>
<td>Andrianasolo 2012</td>
<td>This was a prospective descriptive study</td>
</tr>
<tr>
<td>Bhat 1996</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Bin 2013</td>
<td>A controlled before-after study with single unit for intervention and control arms</td>
</tr>
<tr>
<td>Bojalil 1999</td>
<td>This was a controlled before-after study and the participants were described as private providers, but it is not clear if these were for-profit or not-for-profit healthcare providers</td>
</tr>
<tr>
<td>Chakraborty 2000</td>
<td>This was an uncontrolled before-after study design</td>
</tr>
<tr>
<td>Contiades 2007</td>
<td>This was a descriptive study</td>
</tr>
<tr>
<td>Dholakia 2013</td>
<td>This was a descriptive study of an intervention administered through a non-governmental organisation</td>
</tr>
<tr>
<td>Farsi 1999</td>
<td>This was a randomised trial but its not clear who delivered the intervention</td>
</tr>
<tr>
<td>Fernandes 2009</td>
<td>This was a before-after study and the intervention was undertaken among school children and not healthcare providers</td>
</tr>
<tr>
<td>Goodman 2007</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Grundy 2010</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Guiscafre 2001</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Harrison 2000</td>
<td>This was a randomised trial; but the intervention was not implemented by the public sector, and participants were not private-for-profit providers</td>
</tr>
<tr>
<td>Hongoro 2000</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Hulda 2015</td>
<td>A controlled before-after study with single unit for intervention and control arms</td>
</tr>
<tr>
<td>Kangwana 2011</td>
<td>This was a randomised trial; but the intervention was not implemented by the public sector, and participants were not private-for-profit providers</td>
</tr>
<tr>
<td>Author</td>
<td>Study Design</td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Khan 2006</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Kumaranayake 2000</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Maiga 2010</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Marsh 2004</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Minh 2013</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Morris 2013</td>
<td>This was an uncontrolled before-after study</td>
</tr>
<tr>
<td>Murugesan 2009</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Nsimba 2007</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Obua 2004</td>
<td>This was a controlled before-after study, but it is not clear whether the participants were private not-for-profit or private for-profit providers</td>
</tr>
<tr>
<td>Okonofua 2003</td>
<td>This was a randomised trial, but the intervention was offered by the private sector rather than the public sector</td>
</tr>
<tr>
<td>Osterholt 2009</td>
<td>This was a time series study, with one measure before and two measures after introduction of the intervention. This does not meet our criteria for eligible interrupted time series studies i.e. at least three measurements before and after introducing the intervention</td>
</tr>
<tr>
<td>Rutta 2011</td>
<td>This was a descriptive pilot study</td>
</tr>
<tr>
<td>Rutta 2015</td>
<td>This was a prospective descriptive study</td>
</tr>
<tr>
<td>Stenson 2001b</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Syhakhang 2001</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Tavrow 2003</td>
<td>This was a cross-sectional study</td>
</tr>
<tr>
<td>Tumwikirize 2004</td>
<td>This was a non-randomised trial but it is not clear who offered the intervention</td>
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<td>Ward 2013</td>
<td>This was an uncontrolled before-after study</td>
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<tr>
<td>Willey 2014</td>
<td>The intervention was not administered on participants</td>
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### Characteristics of studies awaiting assessment  
**[ordered by study ID]**

#### Ansah 2015

<table>
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<tr>
<th>Methods</th>
<th>Cluster-randomised trial in Dangme West, a poor rural district of Ghana, from August 2011-January 2013</th>
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<tr>
<td>Participants</td>
<td>Drug sellers in registered chemical shops within 24 community clusters</td>
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<tr>
<td>Interventions</td>
<td>Intervention: training on malaria rapid diagnostic tests and appropriate malaria case management</td>
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<td>Change of practice in malaria diagnosis and antimalarial prescription</td>
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#### El-Khoury 2015

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<th>Methods</th>
<th>Randomised trial in two regions in Jordan, between January 2012 and January 2013</th>
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<tr>
<td>Participants</td>
<td>267 private doctors who provide family planning services in Amman and Zarqa regions in Jordan</td>
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<td>Interventions</td>
<td>Intervention: evidence-based medicine seminar on depot medroxy progesterone acetate and two educational visits to reinforce the messages from the seminar</td>
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<td></td>
<td>Comparison: invited to the seminar, but were not offered the educational visits</td>
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<tr>
<td>Outcomes</td>
<td>Providers’ knowledge, attitudes, practices regarding depot medroxy progesterone acetate</td>
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#### Kafle 2013

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<th>Methods</th>
<th>Randomised trial in three geographical regions of Nepal</th>
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<tr>
<td>Participants</td>
<td>342 drug sellers in private pharmacies in 12 districts in Nepal</td>
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<tr>
<td>Interventions</td>
<td>Intervention 1: mailed printed educational materials followed by mailed feedback</td>
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<td>Intervention 2: small group training followed by feedback</td>
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<td>Intervention 3: small group training only</td>
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<tr>
<td></td>
<td>Comparison group: no intervention</td>
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<tr>
<td>Outcomes</td>
<td>Quality of management of acute respiratory infections and diarrhoea in children, and anaemia in pregnancy</td>
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### Mbonye 2015

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<th>Cluster-randomised trial in Mukono district, central Uganda, from October 2010-July 2012</th>
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<tr>
<td>Participants</td>
<td>Drug sellers in 20 geographical clusters of registered drug shops</td>
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</tbody>
</table>
| Interventions | Intervention: training to perform malaria rapid diagnostic tests to inform malaria case management  
Comparison: current practice of presumptive clinical diagnosis and treatment of fever |
| Outcomes | Proportion of patients receiving appropriate treatment with artemisinin-based combination therapy |
| Notes | |

### Santa-Ana-Tellez 2016

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<td>Changes in the use of non-steroidal anti-inflammatory drugs, non-opioid analgesics, and cough and cold medicines and their relation with the use of antibiotics</td>
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### DATA AND ANALYSES

#### Comparison 1. Training

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<tr>
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<th>No. of participants</th>
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<td>Totals not selected</td>
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#### Analysis 1.1. Comparison 1 Training, Outcome 1 Quality of care.

- **Review**: Public stewardship of private for-profit healthcare providers in low- and middle-income countries
- **Comparison**: 1 Training
- **Outcome**: 1 Quality of care

<table>
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<tr>
<th>Study or subgroup</th>
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<th>No-training n/N</th>
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<td>2 Non RCT studies</td>
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<td>5/24</td>
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<td>Ross-Degnan 1996</td>
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Favours no-training Favours training
Analysis 1.2. Comparison 1 Training, Outcome 2 Quality of care.

Review: Public stewardship of private for-profit healthcare providers in low- and middle-income countries

Comparison: 1 Training

Outcome: 2 Quality of care

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0.01 0.1 1 10 100
Favours no-training  Favours training

APPENDICES

Appendix 1. Search strategies

CDSR and CENTRAL, Cochrane Library

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| #79 | (Romania or Rumania or Russia or Russian or Rwanda or Ruanda or "Saint Kitts" or "St Kitts" or Nevis or "Saint Lucia" or "St Lucia" or "Saint Vincent" or "St Vincent" or Grenadines or Samoa or "Samoa Islands" or "Navigator Island" or "Navigator Islands" or "Sao Tome" or "Saudi Arabia" or Senegal or Serbia or Montenegro or Seychelles or "Sierra Leone" or Slovenia or "Stri Lanka" or Ceylon or "Solomon Islands" or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria or Tajikistan or Tadzhikistan or Tadjikistan or Tadjik or Tanzania or Thailand or Togo or "Togolese Republic" or Tonga or Trinidad or Tobago or Tunisia or Turkey or Turkmenistan or Turkmen or Uganda or Ukraine or Uruguay or USSR or "Soviet Union" or "Union of Soviet Socialist Republics" or Uzbekistan or Uzbek or Vanuatu or "New Hebrides" or Venezuela or Vietnam or "Viet Nam" or "West Bank" or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia):ti,ab,kw | 7359 |

| #80 | (developing or less* next developed or "under developed" or underdeveloped or "middle income" or low* next income or underserved or "under served" or deprived or poor* ) next (countr* or nation* or population* or world):ti,ab,kw | 3266 |

| #81 | (developing or less* next developed or "under developed" or underdeveloped or "middle income" or low* next income) next (economy or economies):ti,ab,kw | 20 |

| #82 | low* next (gdp or gnp or "gross domestic" or "gross national") :ti,ab,kw | 31 |

| #83 | (low near/3 middle near/3 countr*):ti,ab,kw | 293 |

| #84 | (lmic or lmics or "third world" or "lami country" or "lami countries"):ti,ab,kw | 75 |

| #85 | ("transitional country" or "transitional countries"):ti,ab,kw | 2 |

| #86 | #75 or #76 or #77 or #78 or #79 or #80 or #81 or #82 or #83 or #84 or #85 | 38271 |
Continued

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#88  #7 and #33 and #86  190
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#92  #87 or #88 or #89 or #90 or #91 in Cochrane Reviews (Reviews and Protocols)  23
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DARE and HTA, Cochrane Library

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| 78  | (developing or less* developed or under developed or under-developed or middle income or low* income or underserved or under served or deprived or poor*) adj (countr* or nation? or population? or world?).ti,ab | 71001 |
| 79  | (developing or less* developed or under developed or under-developed or middle income or low* income) adj (economy or economies).ti,ab | 358 |
| 80  | (low* adj (gdp or gnp or gross domestic or gross national)).ti,ab | 187 |
| 81  | (low adj3 middle adj3 countr*).ti,ab. | 6548 |
82 (lmic or lmics or third world or lami countr*).ti,ab. 4266
83 transitional countr*,ti,ab. 127
84 or/75-83 3349766
85 randomized controlled trial.pt. 421325
86 controlled clinical trial.pt. 91035
87 pragmatic clinical trial.pt. 342
88 multicenter study.pt. 204840
89 non-randomized controlled trials as topic/ 66
90 interrupted time series analysis/ 163
91 controlled before-after studies/ 146
92 (randomis* or randomiz* or randomly or random allocat*).ti,ab 676468
93 groups.ab. 1601971
94 (trial or multicenter or multi center or multicentre or multiche).ti 184051
95 (intervention* or controlled or control group or compare or compared or (before adj5 after) or (pre adj5 post) or pretest or pre test or posttest or post test or quasiexperiment* or quasi experiment* or evaluat* or effect or impact or time series or time point? or repeated measur*).ti,ab 7859186
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**Science Citation Index; Social Sciences Citation Index, ISI Web of Knowledge**

TOPIC: ("public stewardship" or "public partnership") OR TOPIC: ((privat*) AND (stewardship* or governance or governing or policy or policies or politics or coordinat* or legislat* or regulat* or supervis* or monitor*) AND (health* or medical* or pharmac* or drug or drugs or doctor* or physician* or nurse or nurses or hospital*) AND ((developing or "less developed" or "lesser developed" or underdeveloped or "under developed" or "middle income" or "low income" or "lower income" or transitional) AND (count* or nation* or population* or world)) or (lmic or lmics)) AND (randomis* or randomiz* or impact or effect or evaluat* or control* or intervention* or "time series" or "time point" or "time points" or "repeated measure" or "repeated measures" or quasiexperiment* or "quasi experiment")) OR TOPIC: ((privat*) AND (public*) AND (partnership* or engagement* or collaborat*) AND (health* or medical* or pharmac* or drug or drugs or doctor* or physician* or nurse or nurses or hospital*) AND ((developing or "less developed" or "lesser developed" or underdeveloped or "under developed" or "middle income" or "low income" or "lower income" or transitional) AND (count* or nation* or population* or world)) or (lmic or lmics)) AND (randomis* or randomiz* or impact or effect or evaluat* or control* or intervention* or "time series" or "time point" or "time points" or "repeated measure" or "repeated measures" or quasiexperiment* or "quasi experiment"))

**Global Health, OvidSP**

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Public stewardship of private for-profit healthcare providers in low- and middle-income countries (Review)

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Public stewardship of private for-profit healthcare providers in low- and middle-income countries (Review)

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evaluate or effect or impact or "time series" or "time point" or "time points" or "repeated measure" or "repeated measures" or "repeated measurement" or "repeated measurements")

**OpenGrey**

((stewardship* OR partnership*) OR (privat* AND public*)) AND (05T Health services, health administration, community care services)

**The Grey Literature Report**

1. Keywords: public stewardship and tick off for Grey Literature under: Collection codes
2. Title: public stewardship and tick off for Grey Literature under: Collection codes
3. Keywords: private stewardship and tick off for Grey Literature under: Collection codes
4. Title: private stewardship and tick off for Grey Literature under: Collection codes
5. Keywords: public partnership and tick off for Grey Literature under: Collection codes
6. Title: public partnership and tick off for Grey Literature under: Collection codes
7. Keywords: private partnership and tick off for Grey Literature under: Collection codes
8. Title: private partnership and tick off for Grey Literature under: Collection codes

**World Bank e-Library**

[Title: stewardship* OR partnership* OR (privat* AND public*)] AND [Keyword: stewardship* OR partnership* OR (privat* AND public*)] AND [Abstract: stewardship* OR partnership* OR (privat* AND public*)]

**International Clinical Trials Registry Platform**

1. private AND public (in title) and set Recruitment status to ALL
2. private AND public (in intervention) and set Recruitment status to ALL
3. stewardship OR stewardships OR partnership OR partnerships (in title) and set Recruitment status to ALL
4. stewardship OR stewardships OR partnership OR partnerships (in intervention) and set Recruitment status to ALL

**ClinicalTrials.gov**

In Search Terms

(private OR public) AND (stewardship OR stewardships OR partnership OR partnerships)

**US National Institutes of Health**

In Search Terms

(private OR public) AND (stewardship OR stewardships OR partnership OR partnerships)

**United Nations Children's Fund**

In Search Terms

(private OR public) AND (stewardship OR stewardships OR partnership OR partnerships)

**Alliance for Health Policy and Systems Research**

In Search Terms

(private OR public) AND (stewardship OR stewardships OR partnership OR partnerships)

**United States Agency for International Development**

In Search Terms

(private OR public) AND (stewardship OR stewardships OR partnership OR partnerships)

**Gavi, The Vaccine Alliance**

In Search Terms

(private OR public) AND (stewardship OR stewardships OR partnership OR partnerships)

**Private Healthcare in Developing Countries**

In Search Terms

(private OR public) AND (stewardship OR stewardships OR partnership OR partnerships)

**Population Services International**

In Search Terms

(private OR public) AND (stewardship OR stewardships OR partnership OR partnerships)

**Shops**

In Search Terms

(private OR public) AND (stewardship OR stewardships OR partnership OR partnerships)

**Department for International Development**

In Search Terms

(private OR public) AND (stewardship OR stewardships OR partnership OR partnerships)

**Center For Health Market Innovations**

Public stewardship of private for-profit healthcare providers in low- and middle-income countries (Review)
Contributions of Authors

Charles Wiysonge and Leila Abdullahi conceived the review, were involved in all stages of the study, and share joint first authorship. All authors participated in the preparation and final approval of the review for publication.

Declarations of Interest

Charles S Wiysonge: none known
Leila H Abdullahi: none known
Valantine N Ndze: none known
Gregory D Hussey: none known

Sources of Support

Internal sources

- University of Cape Town, South Africa.

External sources

- Norwegian Knowledge Centre for the Health Sciences, Norway.
Leila Abdullahi received a travel grant to spend one week and finalise the review, at the Norwegian Knowledge Centre for the Health Sciences.

Differences between Protocol and Review

None

Index Terms
Medical Subject Headings (MeSH)

*Developing Countries; Government Regulation; Health Personnel [*education]; Health Services [legislation & jurisprudence; *standards]; Indonesia; Kenya; Laos; Pharmacies [legislation & jurisprudence; *standards]; Private Sector [legislation & jurisprudence; *standards]; Quality Improvement; Randomized Controlled Trials as Topic; Thailand; Vietnam

MeSH check words

Humans