

Master of Public Health

Master International de Sante Publique

# A Cochrane systematic review:

# Which evidence on the impact of risk protection mechanisms in low and middle income countries?

Akpene FRED 2009-2010 Second year of MPH London School of Hygiene and Tropical Medicine Professional/Academic Advisor: Mylene Lagarde (LSTHM) **Acknowledgements:** I am grateful to my mentor Daisaku Ikeda for having believed in my potential and encouraging me with his writings. Thanks to all Soka fellow members from France and UK to supporting me through this long journey. Thanks to all ordinary people i could encourage with my inner steadily peaceful struggle. Thanks to my mother and my whole family and for you Zoe. Thanks to Florian my patient tender causal partner of Love. Thanks to the French and the British government. Thanks to Professor Czernichow, the EHESP and the London School of Hygiene.

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#### List of acronyms used:

DALYS	Disability Adjusted Life Years
LIC	Low Income Countries
MIC	Middle Income Countries
HIC	High Income Countries
СВНІ	Community based Health Insurance
PHI	private for profit health insurance
SHI	Social Health insurance
EPOC	Effective Practice and Organisation of Care Group
RCT	Randomized Controlled trial
C-RCT	Cluster Randomised controlled trial
СВА	Controlled Before and After Study
ITS	Interrupted Time series
Mesh	Medical subject headings
NGO	Non Governmental Organisation
ITT	Intention to treat Analysis
ATT	Average treatment effect on the treated
CACE	Complier average causal effect.
HH	households
CI	Confidence Interval
RR	Rate ratio
I	Intervention Group
C	Control Group
NS	(Statistically) Non Significant
NA	Not Available
ID	Identification
Nb	Number

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# **INTRODUCTION:**

Low Income and middle income countries (1) (2) are defined by the following characteristics with variation between countries and within countries: High population growth rates with poor standards of health and education housing, high percentage of rural population compared to urban population and high income inequalities across population. These countries are also characterized by high infant and maternal mortality rates with a high percentage of population living under less than \$2 a day. The population growth rate in Africa is one of the highest on the planet with 2.3% compared to 1.3% for Asia and 1.4% for Latina America. (3) The Infant mortality rate for children under five in 2008 is shared between 144 out of 1000 live births inSub-Saharian Africa compared to 76 in South Asia and 23 in Latina America and Caraibes.(4) On average the global burden of diseases represents 93% of DALYS lost in LIC/MIC while it represents 7% in HIC. (5)

Millennium Development Goals have been set up to be implemented in 2015(6). To achieve some of these goals, developing countries need to have a strong Health Care System supported by a sustainable health financing system.

Health financing is a complex system wide issue that involves several processes at different levels: Raising revenues through collection of money (that can be made in different ways through taxes or social contributions), pooling processes that enable the risk protection of the global population, purchasing services to deliver the appropriate care for those in needs.(7) "The choice of financing should mobilize resources for health care and provide financial protection"(8).

Health financing has always been a critical issue for health systems in low and middle income countries. Since the 1980s, the difficulty to raise national resources has been compounded by the consequences of structural adjustments. Many developing countries found it increasingly difficult to sustain sufficient financing for health care services. (8)

In low income countries health spending represent on average between 3-4% of the Growth domestic product. (9) In Middle income countries, health spending represent on average between 5-7 % of the Growth domestic product. (10) Funding for health care are shared between government, user fees and external assistance. There is an important reliance on donor funding with external assistance coming from Non Governmental Organisation and Charitable. Also important source of spending on health are private and comes from out of pocket payment. Public sources of revenue for health accounted for less than 25 percent of total health expenditures, while most of the remaining 75 percent from private sources is in the form of out-of-pocket payments.

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Health financing in Low and middle income countries is a mix of different financing strategies. (9) (10). "There is a need of evidence of what works and how governments can generate and manage finances in a sustainable and equitable way is vital." (11)

#### Description of different type of health financing mechanisms:

**Taxation** might be an important source of financing in LIC/MIC especially in Asia and Africa but its efficiency in its capacity to raising resources and its progressivity might be questionable.

#### **User Fees**

User fees means payment at the point of delivery when disease occur. There is limited evidence with user fees on a better access to care and more equity for the more in needs. User fees might lead to a fall in attendance to care. (12) (13) Some argued it should not be considered as the main source of financing in developing countries. (13)

Other alternatives to user fees such as risks protection mechanisms have been gradually promoted. These are Social Health insurance, CBHI, prepayment or PHI. Contrary to user fees, they involve regular prospective payments.

#### **Risk protection mechanisms**

Risk protection mechanism is described as any method management of risks that protect individuals from health and financial risks. Each individual that subscribes for a particular protection mechanism, pay in advance a predefined amount of money termed also as prospective payment, on a regular contribution calculated from the average cost of the risk when diseased.

The risk can be rather calculated through a pooling risk mechanism across subsidies (risk sharing mechanisms) or through an individual risk (prepayment scheme). Money collected in advance will serve at paying direct health care costs in case of disease.

**Social Health Insurance**: SHI is a form of compulsory insurance scheme, normally on a national scale. "Its ambition is to be universal: every household should be covered, and every citizen is required to make contributions. Governments may contribute on behalf of the poorest and the unemployed; employers also usually contribute for their employees".(16) It enables cross subsidies between members of the scheme, health to sick, younger to older, rich to poor: Money not used from healthy people in the scheme to pay for care will be redistributed to the sicker for access to care. One of the main characteristics is that it is

mainly based on Payroll taxes, so this is the formal sector that mostly contributes to raise revenues.

Social health insurance play a limited role in LIC particularly because of the small size of the formal sector, the weak institutional capacity and the instable economy while in MIC it might play an interesting role with an expanding formal sector, a growing economy and a better institutional capacity.

#### Community based Health Insurance:

"CBHI "movement" has proliferated at a high rate in recent years , now involving both national and local governments, civil societies, and international donor organizations and financers , with several tens of millions of dollars in turn over ". (8) Community based Health insurance is a voluntary not-for-profit insurance scheme involving some form of community participation in their management. It collects regular voluntary prospective payments that are pooled across beneficiaries of the scheme. Most CBHI try to target more people in the informal sector than in the formal sector as they are at lower risk to get access to a social insurance scheme.

**Prepayment scheme** also termed as "Medical Saving Account" is "a plan to encourage individuals or households to save money for investing on health. It includes rules about spending those savings only for costs of the owner or a limited number of family members". It is an "intertemporal transfer that could probably be used to buy a "health annuity" that would spread risks across members of the annuity group". Reimbursement of contribution is possible. There is no risk pooling, "the resources available to this limited group depend on steady and sufficient accumulated savings". (14)

**Private Health Insurance** meant by private health insurance for profit private voluntary health insurance scheme. We could consider community based health insurance as a non for profit private voluntary health insurance. It was assumed that this scheme will exclude a majority of the most vulnerable people.

Considering all those different financing schemes, can risk protection mechanisms such as CBHI, Social insurance or prepayment schemes protect vulnerable people from financial and health risks?

Vulnerable people means people more at risk of seeking care because of higher needs in health such as low income groups, elderly groups, female headed households and children. Protecting from health risks means have those vulnerable people access to care when

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disease occurs? Protecting from financial risks means if they can be protected from impoverishment or catastrophic expenditures when disease occurs?

Reviews concerning Risk Protection Mechanisms have been carried out (8) (15) (16). Two were systematic. (8) (16)

None of them searched simultaneously for evidence on the three following categories: Social Health Insurance, CBHI and Prepayment scheme. We performed a Cochrane systematic review on behalf of the group EPOC that differed in important aspects from existing reviews on community financing by assessing the impact on access to care rather than assessing the level of resources mobilized or the level of financial sustainability. (8) (15).

The Cochrane Collaboration is an international not-for-profit organisation providing up-todate information about the effects of health care. (18) The Cochrane Effective Practice and Organisation of Care Group (EPOC) is a Collaborative Review Group of the Cochrane Collaboration seeking to extend systematic reviews to a range of topics relevant to the organisation and delivery of care. It develops methods of synthesis for topics relevant to health systems. It has a special register databases and work with collaborative Cochrane centre satellite (one of them in Oslo). (19)

What is a Cochrane systematic review? "A review of a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies. A Cochrane Review is a systematic, up-to-date summary of reliable evidence of the benefits and risks of health care. Cochrane Reviews are intended to help people make practical decisions ". (17)

The following thesis presents an EPOC systematic literature review regarding evidence based policy on risk protection mechanisms in developing countries. The draft of the first review done in 2007 is currently available (22). But it needed to be updated as it has only identified one study that presented many limitations (16).

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**RESEARCH QUESTION**: Is there reliable evidence on the impact of risks protection mechanisms such as community based health insurance, social health insurance and prepayment scheme in increasing health service uptake, in particular for the poorest/vulnerable groups and when possible health outcomes ?

# **METHODS**

The review searched for studies in the literature that evaluated the impact of different insurance schemes in developing countries thanks to specific design evaluation.

"In Cochrane Reviews, to look at available evidence from the literature, the results of multiple primary investigations are synthesized by using strategies that limit bias and random error. These strategies include a comprehensive search of all potentially relevant articles and the use of explicit, reproducible criteria in the selection of studies for review. Primary research designs and study characteristics are appraised, data are synthesized, and results are interpreted". (20)

The following methodology matched the Structure of a Cochrane review (21) and the protocol defined by Mylene Lagarde and al. (22).

#### A) 1 Inclusion criteria for considering studies in the review:

#### Type of studies to be included:

Randomized Controlled Trials Controlled Before and after studies: Interrupted time-series analyses:

The review searched for studies that have a strong causal inference with limited biases. In evaluating insurance scheme, studies should be able to analyse that the outcomes observed are due to the intervention (insurance scheme). Therefore it was excluded all type of observational studies (policy review, descriptive case study, cross sectional study) prone to multiple biases.

#### RCT

Randomized trial can be a way to evaluate the effect of insurance scheme in specific setting. Randomization process is the best way to ensure that both known and unknown factors that may affect the outcomes of an intervention are likely to be distributed evenly between the randomized groups. Differences observed between groups can be more confidently assigned to the effect of the intervention (insurance scheme) rather than to other factors. Specific methods exist to ensure randomized attribution. We have included cluster randomised controlled trials. (C RCT)

In C-RCTs groups that are assigned the intervention, are not composed by individuals but Cluster. A Cluster is a group of people circumscribed by geographical, administrative boundaries or other predefined characteristics. C-RCTs develop both specifically sampling calculation and specific statistical analysis.

Clusters facilitate administrative and logistical convenience in the implementation of the intervention and may limit cross contaminations between control and intervention groups. C-RCTs help to look at the overall effect of the intervention at the population level.

Outcomes are measured at the level of a population dealing with aggregated data (example total number of consultations over a time period at a facility level or at a district level for a specified population ) rather than focusing on individual data( number of admissions for one individual over time).

#### СВА

A Controlled Before and After Study termed also as quasi experimental study is a trial in which two groups are chosen to participate the study (control and intervention group) other than by random process. Data is collected on the control and intervention groups before the intervention is introduced and then further data is collected after the intervention has been introduced. This study is prone to biases and need to be controlled for secular trend and seasonality. Two major criteria have been considered when including this design in the review:

-pre and post intervention periods for study and control are similar

-study and control sites are comparable with respect to dominant characteristics sites are the same.

#### ITS

An *Interrupted time series design* looks at a change in trend attributable to the intervention. Multiple data points are collected before and after the study. From this design it is possible to perform a curve from where a preslope and a post slope are calculated. Specific statistical tools should be applied to analyse the data measured.

Two major criteria have been considered when including this design.

- Intervention occurred at a clearly defined point in time.

- There are at least 5 or more data points before and after the intervention

<u>Type of participants</u> : Studies to be included should be carried out in developing countries following the World Bank definition of low and middle income countries.(1) (2)

Unit of study: they are populations who would potentially access health services.

<u>Units of allocation</u> may be facilities or districts. Studies that deal with all type of providers (private, governmental, NGOs) and all level of health care delivery or health services (primary /secondary level) are included in this review.

**Type of interventions**: Prepayment scheme, Community based Health insurance scheme and Social health insurance scheme. "It was decided not to include tax-funded systems. The potential absence of clear start in time would have been difficult to handle with the type of study designs to be included". (22)

#### Types of outcomes measured:

*Primary outcomes*: were changes in access to care or health care expenditures

- Access to care could be measured by objective measures related to the final consumption of health services. It could also be measured by changes in utilization patterns of health facilities or services (number of visits, rates of hospitalisation...) and/or equivalent information collected directly from the population through rigorous survey techniques. Information related to distance travelled or travel time was out of the scope of the review.
- Health care expenditures: we will look at direct costs (and indirect costs) borne by the patient or the family.

<u>Secondary outcomes</u>: were changes in equity access and changes in patient outcomes.

- Changes in equity of access means increased access for disadvantaged groups or a reduction in gaps in coverage. This requires a preliminary analysis and categorisation of the population of interest along a socio-economic scale. Any methodology (wealth/asset index) will be accepted provided it is rigorous and detailed.
- Changes in health outcomes, measured by morbidity and mortality rates (broken down by age group, sex.) can also be considered.

Considering all these outcomes, there should have been objective measures of utilization, performance or patient outcomes. Studies based only on measurements of attitudes, beliefs or perceptions were not included.

A) 2 Exclusion criteria: any study that would not follow the inclusion criteria described above.

#### B) Search Strategy:

The Health policy unit of the London School of Hygiene and Tropical Medicine worked with the Oslo EPOC satellite centre. It was in charge of defining and performing search strategies they applied to four databases covering the social sciences, economics and health literature. The search to identify studies to this review was initially done as part of a much wider review on health financing mechanisms references. (22) The broad review has been split into several sub –reviews, including the present one. Therefore the search methodology included terms that encompassed a broader scope that the one defined in this review. The research strategy has been refined to adapt what has been already retrieved to new published studies.

Electronic databases: The following electronic databases were searched without language or date restrictions: Dates of access are mentioned between parentheses. The search strategy used a combination of selected Mesh Terms and free text terms related to printed health financing literature for developing countries. Appendix 8

The search covered studies published between 1950 and 2010.

MEDLINE(R) 1950 to February Week 1 2010 (Ovid), (17.02.10) (refined search strategy)

MEDLINE(R) 1950 to April Week 4 2009 (Ovid), (05.05.09)

CENTRAL Cochrane Library Issue 2 2010, (04.03.10)

EMBASE 1980 to 2010 Week 08 (Ovid), (05.03.10) (refined search strategy)

ECONLIT (CSA Illumina) 1969 - present, (15.03.10)

In addition a hand search of references was carried out from the J-PAL website:

http://www.povertyactionlab.org/search/apachesolr\_search?filters=type:publication http://www.economics.harvard.edu/faculty/field/files/Nicaragua\_Ins\_Eval\_Nov12.pdf

#### C) Data collection and Analysis:

The following informations were extracted from included studies using a standardized data extraction form (See appendix 1 to 4): characteristics of included studies, context and intervention description, details on membership, outcomes measures. The MPH student performed the data collection and analysis under the supervision of the professional advisor.

#### D) Assessment of study limitations:

To appraise the quality of included papers, this review adapted the EPOC assessment criteria (see appendix 6). It assessed study designs in their ability to have a strong internal validity to infer a causal relationship between the intervention (risk protection mechanism) and the effects measured (a change in access to care). When a study presented more than two criteria scored as "not clear" or "not done", it was scored as being as "high risk of bias". When only one or two criteria scored as "not clear" or "not clear" or "not done", it was scored of being of "moderate risk of bias". When all elements were satisfied, the study was considered as being of "low risk of bias". Both professional advisor and MPH student performed independently the quality assessment of the included studies.

# RESULTS

#### A) Results of the search

The literature search generated 4878 references. The MPH student sifted trhrough the titles and abstracts of publications for retrieval. A number of articles were poorly indexed means that they had nonspecific Mesh terms that came up with papers not linked with the topics of interest. This EPOC systematic literature review tried to be a comprehensive literature review. It is possible that some non published articles were not accessible at the time of the literature search.

After screening the titles and abstracts of the 4878, the MPh student kept 41 documents for further investigation. Agreement with the supervisor was reached over whether they fulfilled the criteria for inclusion in the review. In case of disagreement full text was retrieved and examined. Three studies met our inclusion criteria. 38 studies were excluded because they were not designed as experimental or quasi experimental studies. See the appendix 7. Most excluded studies were observational studies such as cross sectional studies without control groups. We could not have access to five articles. The hand searching found one article we excluded.





A narrative approach to reporting the study has been adopted. A statistical Meta analysis could not be used because it will not make sense to synthesise data from studies dealing with different interventions and specific settings.

#### B) Description of included studies:

#### B1) Study designs: Appendix 1

The systematic review found 3 studies that met our inclusion criteria taking place in three countries: A Controlled Before After study (CBA) (Wang 2009) and two clusters controlled randomized trials (C-RCTs) (King 2009) and (Ansah 2009) (see references of included studies). We found no interrupted time series study. The Controlled Before After study took place in a North Western province in China (Wang 2009). One C RCT took place in Ghana, Dangme West district (Ansah 2009), and the other in South America, Mexico (King 2009).

The follow up period was 6 months in the study in Ghana (Ansah 2009), 10 months in the study in Mexico (King 2009) and three years in the study in China (Wang 2009) where households were surveyed twice in 2002 and in 2005.

#### <u>B2) Characteristics of setting and patients</u>: Appendix 2

All studies aimed at informing the implementation of policy reforms on voluntary health insurance. There was therefore the opportunity of evaluation to be planned systematically alongside implementation. In China in 2002 a modified governmental health policy called New Cooperative medical scheme was initiated to be implemented as a voluntary not for profit health insurance scheme in rural areas. In Mexico in 2003, the reform of the health care system led to the reform of the national health insurance (Seguro Popular) in extending the health coverage from the formal sector to the informal sector. In Ghana, in 2000 a voluntary national Community Health Insurance scheme has been implemented to remove user fees policy.

Settings were characterized by poor health care network organisation: Rural primary network in China had no referral system and was mainly organized around private "village doctors". Health care network in Mexico was unequally organized across states; poor remote areas were poorly provided on health facilities. In the study of Ansah (2009), the Dangme district had no hospital and patients had to be referred to surrounding district to get treated. Settings were also characterized by low supply side efficiency: In the study of Wang, a lack of regulation on provider payment, drug pricing and purchasing led to an over prescription of poor qualified services. In Mexico, the absence of trained medical staff, the stock out drug supply in remote area and the unequal distribution of services across states did not suit regional health priorities. In the study of Ansah, there was a lack of trained medical staff, diagnostic tools and appropriate treatment to tackle the malaria issue.

Participants were mostly vulnerable people: rural farmers with a high prevalence of delay in seeking care in the study of Wang. They were poor families defined as low assets income, female headed households and some families benefiting from the Opportunities antipoverty program in the study of King. They were rural poor households with children under five experiencing high mortality prevalence of malaria in 2004 in the study of Ansah.

All studies reported high levels of out of payment across population. In the study of Wang, it has increased among rural farmers on drugs consumption and access to basic health services. In the study of Ansah, user charges were a major barrier to accessing care for poor residents. In the study of King, it represented in Mexico more than half of total spending makes it difficult for 50 million uninsured Mexican people to access care.

#### B3) Characteristics of Intervention: Appendix 2 and 3

Interventions included local or national health insurance schemes ran by government or communities covering two types of risk protection mechanisms: national health insurance and voluntary not for profit health insurance. Ansah and Wang designed a "prepayment scheme": here the term is confusing but it did refer to a voluntary not for profit health insurance scheme.

King offered to 13 Mexican states to implement Seguro Popular one year before it should be launched. Ansah assessed the impact of the Dangme West insurance Scheme. Wang assessed the impact of the Mutual Rural Health Care Scheme.

In the study of King, the insurance scheme was piloted by the government with the particularity to decentralize its management (pooling funds, allocation of resources and purchasing services) to the regions. In the study of Wang, the scheme should be rolled out to several Chinese provinces and its management decentralized but no clear common regulation across regions and no specific rules for its management were enacted. Information is not available from the study of Ansah but it seems that each district scheme applied specific management to specific needs.

To tackle the issue of low supply side efficiency, all studies introduced simultaneously to the intervention, several supply side procedures to improve the quality of care: in the study of Ansah, malaria treatment was updated with better diagnostic tools to detect cases. Investigators made sure that no drug stock out occurred during the study period. In the study of King, as part of the reform, local government allocated funds in order to upgrade medical facilities with better drug supply and implemented accreditation system to health centre to provide benefit package. In the study of Wang, investigators contracted with qualified doctors, modified the provider payment and reorganize the referral system.

Enrolment to each scheme covered a period of three years (2002 to 2005) for Rural Mutual Health Care (China), one year (2005 to 2006) for Seguro Popular (Mexico) and one year for the Dangme west District (2004 to 2005).

Enrolment to each scheme was voluntary. To limit adverse selection, the Dangme West District implemented mandatory household registration. The enrolment scheme seemed to be at the individual level in the Rural Mutual Health Care. It is not clear if the entire family could benefit from the scheme.

The size of the scheme was large in each intervention group: the smallest size for Ansah (1227 HH) and the largest size for King 17950 HH covering 7 Mexican states. Wang included 1565 individuals across 1925HH.

Enrolment to the scheme was subsidized in all interventions to target people in the informal sector. In the Rural Mutual health Care insurance, the premium level to get enrolled into the prepayment scheme was subsidized with a supplementary contribution of the project. The study paid the fee premium for households to get ensured in the Dangme West District scheme. In the study of King, premium was subsidized by federal and governmental states to target poor families while there was a progressive contribution to the premium from high income households.

Benefit package consisted in all experiments in free access without copayment to primary care from the public sector (Wang, King, and Ansah) and with a limited access to secondary care.

In all studies, individuals in the control group had to pay user fees at the point of delivery.

#### B4) Outcomes: Appendix 4

One study reported outcomes on health expenditures (King 2009). Two studies reported outcomes on health services utilization (King 2009 and Ansah 2009). Two studies reported effect on health outcomes (Wang 2009 and Ansah 2009). Health expenditures and utilization measures were self reported: researchers used surveys at individuals or households levels to collect information through interviews (King 2009 and Ansah 2009). Objective measurement of health outcomes was performed only in one study (Ansah 2009) using standardized diagnostic tools to detect moderate and severe level of anaemia and parasitaemia among children. Wang measured self perceived health status using instrumental tools described as being a good prediction of the mortality and morbidity rate among the population interviewed.

In three studies (Ansah, King) health service utilization and health spending were measured by socio economic groups: these income groups were defined based on wealth index created with information about asset ownership. It was possible then to look at equity distribution in access to care in each scheme.

#### C) Quality assessment of included studies: Appendix 5

All studies were at high risk of biases.

The study included 2 C RCTs that might be considered as the gold standard evaluation design to attribute the effects observed to the intervention. Nevertheless studies found it difficult to guarantee comparability between groups and protection against contamination. King tried to limit it by setting up a pair matched cluster CRT but have a significant percentage of contamination while the study of Ansah is weakened by no clear comparability between groups. The quasi experimental study of Wang could not guarantee that the control site was comparable to the intervention group. It is reflected by a baseline measurement statistically different from the intervention group.

In the study of Ansah and Wang, the internal validity of the scheme is challenged by selection biases: Wang reported that the enrolees were older, female married, in worse health, with lower income and lower education level. King reported that 55% of enrolees were rich (high assets households). Ansah did not report major differences between enrolled and uninsured. Wang tried to compensate selection bias by using statistical methods such as propensity score matching: It tries to artificially build a statistical counterfactual group as similar as possible to the intervention group.

There is a high bias on the quality and reliability of data reported: Most are self reported such as self perceived utilisation of services (Ansah and King), health spending (King) and health status (Wang). This is prone to declaration biases. An other bias is that interviewing people may have changed their seeking behaviour (Hawthorne effect). In developing countries, self reported data might be the only alternative to report information due to the lack of reliable source on objective data (registration system, routine administrative data or surveillance system).One weakness of these studies is that survey techniques are not rigorously reported: we do not know how people were interviewed.

Protection against contamination bias was not respected in one study (King) .Information is not clear for Wang and not available for Ansah. Contamination means that participants in each group did not respect their assignment and the observed effect of the scheme might be over or underestimated depending on who and the percentage of participants that were not compliant. King reported that 7% of controls that should not receive treatment received it while only 44% of assigned to treatment were effectively ensured. King and Wang tried to take this into account by performing an intention to treat analysis that analysed the effect of the scheme by considering the loss to follow up and the contamination bias. They also performed an average treatment effect on the treated (ATT) to consider the effect of the scheme only on the compliant participants that adhere to their treatment assignment.

#### D) Synthesis of findings from included studies

<u>Health service utilization</u>: Two studies looked at the effect of insurance on uptake of health services and found mixed results: being subsidized to be insured and having free access to care does not necessarily increase uptake of health services.

#### Table 1 Outcomes on health services utilization

Study ID	Sample size(1) Nb of Interventi on/control intervwie d	Point estimates	Frequncy of data collection	% response at baseline/ follow up in cross sectional survey	Analysis stratified on confnders	Statistical Differenc between ensured and controls	Statistically significant?
Ansah 2009	2332 HH 1057i / 1094c	Incidence rate of uptake in formal/ informal health care services. (Number visit/person year)	Monthly collection over a 6 month period of follow up. (malaria transmissi on season)	92%/ 92% in the total sample per household	Yes , Distance of households distance from health facility, Household wealth, Age , Sex	RR= 1,25 If living less than 5 kms from Health facility.	Yes CI= (1,07- 1,48) p<0,01
King 2009	32515HH 16259 <mark>i</mark> / 16256c	ITT analysis and CACE to measure the statistical effect of the program on the uptake of health services.	Reported uptake of services in a 1 to 3 months recall period.	90%/ 89%	Yes , Low-asset, high asset and female headed households	Negative impact : drop in uptake of services in the ensured compared to control clusters on both ITT and CACE measure	Not reported by the study

Table adapted from Ansah (2009) and King (2009) Studies. (See the reference of included studies).

In the study of Ansah, removing user fees and providing free enrolment to the scheme has an immediate impact on access to care: there was an overall increase in the outpatient attendance by children under 5 during the study period while adult attendance remained stable (results not shown by the study). Children in households randomised to insurance attended primary care clinics more often and informal health care less often than children in control group. Informal care is defined as (home treatment made, chemical seller, and traditional healer). While in the study of King, ten months after enrolment to Seguro Popular, there was a decrease in uptake of services on inpatient, outpatient and preventative care among ensured households compared to control households (NS). Results are similar on both ITT analysis and CACE estimation: means that King did not find significant results when measuring the effect of the scheme on ensured that are both compliant and not compliant to the scheme (ITT analysis) or when measuring the effect of the scheme solely on ensured that are compliant means well informed about their social rights and really using care when needed(CACE).

Results are unexpected as observational studies (Gakidou 2006) (23) have found that "effective coverage rates for various medical services were higher for Seguro popular households than for uninsured".

<u>Health expenditures</u>: One study reported effect of the scheme on health expenditures and found positive impact.

Study ID	Sample size(2) Share of Intervention/control	Point estimates	Frequency of data collection	%response (baseline /follow up cross sectional survey)	Analysis stratified on confnders	Statistical Difference between groups(1)	Statistically significant?
King2009	32515 HH 16259 i / 16256 c	Effect of the program on catastrophic health expenditures and out of pocket payment measured by Intention to treat analysis and CACE.	Reported family health spending over a 1-3 months recall period.	90%/ 82.6%	socio economic status, sex,age,	Reduction of catastrophic expenditures when ensured compared to control. Reduction of OOP when ensured compared to not insured.	Yes p<0.05

#### Table 2 Outcomes on health expenditures.

Table adapted from King (2009) Study (See the reference of included studies).

King found that the effect of the scheme was effective in reducing catastrophic health expenditures of ensured households compared to control households. Among ensured households, the effect was more important among compliers for whom the effect is about double the intention to treat effect ": 52.5% decrease among compliers compared to 22.6% decrease in non compliers. Considering all type of health services, out of pocket expenditures were lower for ensured households compared to uninsured and the most

important decrease occurred for poor asset households compared to rich and female headed households. Among poor compliant households, the level of out of pocket payment was the lowest for outpatient and inpatient medical procedures but not for drug consumption. Results are unexpected as observational studies (Gakidou2006) (23) reported that affiliated families to the scheme spent about 14% less on drugs than uninsured families.

<u>Health outcomes</u>: All studies reported health outcomes and found mixed results. Ansah found no significant results of the effect of insurance on health enrolees. The percentage of children under five with moderate anaemia (hb<8g/dl) and severe anaemia (hb<6g/dl), the mean number of fever episode per person year and the children mortality rate were not statistically different between ensured and uninsured children. King did not report any significant difference in health self assessment between ensured and uninsured (results not shown). Wang reported from a regression analysis a 37% decrease from the baseline measurement as the proportion of enrolees that self reported a bad or fair health after three years of enrolment.

Equity outcomes: Studies indicated mixed results.

In the study of Ansah, wealthier ensured tend to use more formal services RR= 1,4CI (1, 18-1, 64) compared to poor ensured. Those living closer to health facilities attended more often to primary care clinics.

In the study of King, the scheme benefited more to poor households in decreasing health expenditures. He reported a reduction by 55% of the proportion of households incurring catastrophic health expenditures among compliant poor households while it represented 38% among rich compliant households and 40% among female headed households (results non significant for the two latest).

In the study of Wang, the effect of RMHC on health outcomes did not differ by income groups. Ill and middle aged groups experienced higher health improvements.

## **DISCUSSION:**

From this systematic review, the overall quality of available evidence is low. Despite the high enrolment rate (from 92% in Ghana to 44% of enrolled and compliant households to Seguro Popular in Mexico and 73% in China), the effort to improve the quality of care and to subsidize the poorest, it is not sure whether not for profit voluntary health schemes can increase uptake of health services in developing countries. The first systematic review found one study, a CBA in Rwanda about CBHI with high level of bias that found inconclusive evidence on access to care.

The study of King (2009) found a direct positive impact of not for profit voluntary health insurance in reducing catastrophic health expenditures and out of pocket payments mostly in outpatient and inpatient services.

This review found mixed evidence of such schemes in increasing the uptake of health services. King found a negative impact of the scheme on ensured compared to control.Results are surprising as catastrophic health expenditures and OOP in ensured households have decreased: access to care should have been more affordable then. Ansah found another result: being insured has a positive impact on access to care.

The study of Ansah did not translate the increase of health utilization into a change in health outcomes. The study of Wang found that being insured might improve the overall health status of the enrolees. Although one might be cautious with these outcomes as they are self reported and affected by declaration biases.

All schemes seemed to benefit more to the richest members than to the poorest.

The effects observed may not only be linked to the intervention but to problems associated with challenges in implementing the intervention and choice of outcomes measurements. King explained the negative impact on access to care for the following reasons. First, the benefit package was not effective in every accreditated health center. Second, the access to available drugs was hampered due to incomplete drug supply especially in remote areas. Finally the lack of awareness of some cluster treatment households automatically affiliated (1/3 of Opportunidades families) to the program underestimated the outcomes on health services utilisation.

The study of Ansah did not find any impact on health outcomes (the author used the level of anaemia to reflect untreated or under treated malaria). But many causes of anaemia other

than malaria may have influenced the average level of haemoglobin. It would therefore be worth looking at the number of children diagnosed and treated for malaria in insured and uninsured families to measure the impact of the scheme on health outcomes: The author found that 101 children were diagnosed for malaria but the distribution between insured and uninsured is not reported.

There is a high risk of biases from the studies that assessed voluntary health insurance. This systematic review questions whether EPOC criteria are relevant or not in assessing the quality of studies that evaluate the impact of financing health interventions at a large scale. Voluntary health insurance would be inevitably prone to selection and contamination biases. In the treated group, two types of people will enrol: those able to pay the premium (mostly the richer) and, when the scheme is subsidized, well informed people with specific needs and appropriate seeking behaviour (mostly the higher educated thus the better off). Contamination biases might be difficult to limit in a large scale design. De Allegri (24) proposed to limit it by selecting group of people linked by closed social ties in respect of cultural and ethnical backgrounds. Ansah limited it by allocating a unique pictorial ID card and defined a specific window enrolment. Protection against detection bias (double blinded assessment) is difficult because interviewers had to know individual's insurance status. Quality and reliability of data is also challenging in developing countries. Randomisation might be prone to ethical and organisational issue. Obtaining a sufficient sample size implies community agreement in participating to the evaluation and local authorities' cooperation.

It is difficult to attribute the observed outcomes only to the insurance and not to the supply side interventions because the intervention in treatment group was simultaneously on these two aspects. Every study measured the intervention as a whole and not each component separately (change in stewardship (King), quality of care (all studies), provider payment or insurance scheme).

Two studies are limited by a lack of external validity. In the study of Ansah and Wang, two specific types of population have been selected: district in a poor remote area with a bad health care delivery in Ghana, farmers in a rural remote province in China. The selected population might have specific and thus different seeking behaviours compared to the whole population. The results must not be generalized to other settings.

#### Policy issues:

Results show that not-for-profit voluntary health insurance schemes do not necessarily guarantee an improving access to care to vulnerable people in developing countries.

Removing financial barriers in access to care seems not to be sufficient. Other barriers to health care utilisation have to be considered, such as transportation and lodging costs or even parameters difficult to control such as opportunity costs, informal payments, bad risk perception, and mistrust towards insurance scheme or health facilities. Economic growth is another way to improve the health status of the population, by allowing larger amount of money in the healthcare system, and therefore increasing the level of hygiene and the coverage of the primary needs.

Policy makers should when implementing insurance scheme consider the issue of improving access to care as a holistic problem. Health insurance is one component that cannot be departed from other interventions. But studies suggested that their implementation (supply side interventions) might be challenged.

The scheme's enrolment rate was far higher (80%) than the one achieved usually in African countries (22) due to the important amount of public subsidies. Would it be financially sustainable in lower and middle income countries? This systematic review did not look at cost recovery impact: it would have been relevant as all schemes were subsidized. We did not include studies that assessed "the costs and benefits of implementing competing health insurance". Those two following information are crucial for policy makers when implementing such schemes to consider their financial sustainability and the possibility to "choose between different financing options for an optimal policy mix". (8)

This review questions whether subsidizing people to get enrolled and providing them care for free is appropriate? The scheme benefited more to the richest. How to encourage poor people to adhere in a voluntary scheme? Thornton (23) that assessed the impact of a voluntary scheme among poor self employed market vendors in Nicaragua tried to facilitate their enrolment by visiting participants at their work place in order to avoid time constraints to registration. Nevertheless enrolment did not exceed 20.3%. Ranson (25) that assessed the impact of a CBHI in Gujarat, India performed a management plan to inform villager's enrolees about their rights through home visits of commercial agents."Intervention was not sufficient to ensure that the poorest member were able to enjoy the greater share of the scheme benefits". King performed media campaigns of information but only 44% of treated participants were aware of their affiliation status mostly richer households. Some authors

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argued (De Allegri) (24) that before launching an insurance program it might be worth evaluating the risk perception mechanism of the population of interest to understand why they do enrol and not. It might also be worth performing willingness to pay analysis to adapt the premium level to the poorest. De Allegri did it when trying to assess the impact of a CBHI in Burkina Faso but enrolled less than 6% of people.

#### Research implications:

This review questions the relevance of using randomized controlled trials to assess the impact of voluntary scheme at a large scale. First RCTs tried to tackle the issue of compliance to the scheme by performing Intention to treat analysis. Most studies found the effect was low. On which indicators should policy makers based their decision then: ITT or ATT estimates? ITT effect would be more interesting to consider as it might be a good proxy to measure the real impact of a voluntary subsidizied insurance scheme in the total population.

Second RCTs are prone to biases due to their difficulties in implementing such schemes.

Third such studies should have a follow up period long enough to measure sufficient number of events. For example in the study of King, the effect of the scheme may occur after 10 months of assessment (Jet lag effect). Interrupted time series might have been useful. It would have taken into account changing contexts and informed about the dynamic effects of the scheme.

Fourth RCTs trials question organisational and ethical issue.

Ethical issues: It is not always clear whether random allocation has been made after participants agreed to participate (not clear for King and Wang).

Offering to one part of the population to get ensured while the other part will not be, is a critical issue in developing countries where access to care is crucial (in the study of Ansah there is a high children mortality prevalence due to non treated malaria cases, and delay in seeking treatment in the study of Wang or King). This could lead to a risk of social tensions.

This problem can be partially tackled if contact leader at the community level are involved into the randomisation process and informed about the fairness of the distribution (Ansah did it, information N/A for other studies) or if the control group will be enrolled at the following enrolment window. (Ansah and King did it, information N/A for Wang). King performed a step

wedge cluster trial were implementation occurs in a phased manner and areas act as controls before they receive the intervention.

All schemes targeted poor people with subsidies but what about the financial autonomy of their participants?

Organisational issue: There is a need of community participation in designing the evaluation of the scheme, as much as political interest means local authorities that accept study to be carried out: King did it by involving group of federal and states experts, Ansah did it by involving heads of households.

Then the question is how to design evaluations for voluntary insurance schemes?

Can RCTs only provide evidence? Eckman (8) performed another systematic review on community-based health insurance in LIC that included 36 studies. There were mostly descriptive cross sectional studies thus making it difficult to "draw conclusions as to the dynamic effects of schemes". He found "strong evidence that CBHI reduced significantly the level of OOP payment for care. But most schemes failed to cover the least well off". He found "moderately evidence that CBHI increase access to health care". He found that "effective population coverage was small and the renewal rate diminished for manyschemes".

Some have argued that other alternative to look at evidence of voluntary health insurance is to perform realist assessment (26): many financing interventions have complex causal pathways. Realist assessments try to understand why and how an intervention failed or succeeded in achieving outcomes. "This might be better answered by a series of case studies, which are argued to be good for understanding complex causal links between many variables". (11) Especially there is a need of multicentre case studies that look across countries why things do or do not work in specific settings.For example it would help understanding how the management of the scheme through the community participation is able to raise sufficient revenues to make the scheme sustainable. How the setting of the premium would make enrolment equitable and affordable to the poorest and how the negotiation of prices with providers will create efficient access to care for members.

# **CONCLUSION:**

This systematic review provided low evidence of not for profit voluntary health insurance on a better access to care for poor people in Low and Middle Income countries despite high level of coverage rate. Poor people are systematically excluded from the benefits of the scheme. This systematic review tried to be transparent and as a comprehensive as possible with less publication and language biases. It suffered from low reproducibility and also from a short period of time to perform it.

Further research is needed to look at reliable evidence on the impact of risks protection mechanisms in low and middle income countries. There is a need of sufficient resources for large scale assessment of financing schemes and a stronger support and demand from policy makers. Donors and international organizations should continue supporting research on providing reliable information in health financing for developing countries. They should improve the implementation of effective financing schemes by providing better data collection and defining appropriate indicators.

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## Summary

<u>Background</u>: There is a lack of available evidence in low and middle income countires on the impact of various risk protection mechanisms on a better access to care for the most vulnerable people.

<u>Methods</u>: We performed a cochrane systematic review to assess the impact of Social Health Insurance, Community Based health insurance and pre - payment schemes in Low Income and Middle income countries.We applied the EPOC criteria to the studies to be included and critically appraised from a comprehensive search strategy.

<u>Resuts</u>: We included out of 4878 references two cluster randomized trials and one controlled before after study that evaluate the impact of social health insurance in Mexico(Seguro Popular) and voluntary not for profit health insurance scheme in Ghana(Dangme west District).Studies included were at high risk of biases. There is conclusive evidence of Seguro Popular in decreasing out of pocket spending on ensured people especially for the poorest. There is mixed evidence on the effect of social health insurance and voluntary not for profit health insurance scheme in increasing utilization of care: access to care is unequal, richest group benefited more from the scheme.There is inconclusive evidence on an improvement of health status among enrollees.

<u>Conclusion</u>: This sytematic review is the first systematic review to look at the impact of voluntary health insurance on a new combination of outcomes.Further research is needed to provide higher quality of evidence based policy on the impact of voluntary health insurance. We think systematic review should be combined to realist assessment on risk protection mechanisms.Policy makers should carefully consider other barriers to care when implementing any type of voluntary health insurance in developping countries.

#### **Summary in French**

<u>Contexte</u>: Dans les pays à faible et moyen revenus, il persiste un manque de preuve fiable concernant l'impact des divers mécanismes de protection Santé pour un meilleur accès aux soins des personnes les plus vulnérables.

<u>Méthodes</u>; Nous avons effectué une revue systématique de la littérature en partenariat avec le centre référent Cochrane afin d'évaluer l'impact des assurances sociale de santé, mutuelles de santé communautaires et systèmes de prépaiement dans les pays en voie de developpement.Nous avons appliqué les critères du groupe EPOC dans l'inclusion et l'évaluation méthodologique des études sélectionnées à partir d'une large recherche de données.

<u>Resuts</u>: Sur 4878 références, nous avons inclus deux essais randomisés contrôlés et une étude avant après qui évaluaient l'impact d' une couverture universelle de santé au Mexique (Seguro Popular) et de deux mutuelles d' assurance santé respectivement au Ghana (Dangme West District Insurance) et en Chine (Rural Mutual health Care).

Les études incluses sont à risque élevé de biais. Il existe des effets concluants de la capacité de la couverture médicale universelle Seguro Popular à diminuer les dépenses directes de sante non remboursées des personnes assurées en particulier pour les plus pauvres. Il ya des éléments contradictoires sur la capacité de Seguro Popular et de mutuelle de santé communautaire telle que le Dangme West District Insurance à accroître l'utilisation des soins: l'accès au soin est inégal parmi les membres, les plus riches reçoient de meilleurs bénéfices. Il n' y a pas de preuves concluantes d'une amélioration de l'état de santé des assurés quelque soit le système assurantiel.

<u>Conclusion</u>: Cette revue systématique est la première revue à évaluer l'impact de différents systèmes assurantiels à partir d'une combinaison originale d'indicateurs.

D'autres recherches sont nécessaires pour fournir une meilleure qualité de preuve de l'impact d'un système assurantiel pour les plus pauvres. Nous pensons qu'une revue de ce type doit être combinée à une revue de type réaliste. Les decideurs de sante devraient avoir examiné attentivement l'ensemble des determinants a l acces aux soins dans la mise en place de systemes assurantiels dans les pays en voie de developpement. Liste of Appendix:

- Appendix 1: Characteristics of included studies
- Appendix 2: Context and intervention description
- Appendix 3: Details of memberships
- Appendix 4: Outcome measures
- Appendix 5: Results of Quality assessment
- Appendix 6: Criteria considering the assessment of study quality
- Appendix 7: Excluded studies
- Appendix 8: key words of search strategy.

#### Appendix 1: Characteristics of included studies

Study ID	Methods	Participants	Intervention	Outcomes
Wang 2009	Controlled Before and After Study	Population living in two townships of a rural province in China. A stratified random cluster sample (clustered at the village level) of 1,925 households led to a sample size of 3,062 individuals in the intervention site and 2,189 individuals in the control site. Note that only individuals aged more than 15 years old are included in the study survey, since outcome measures are self-reported health status.	Voluntary prepayment scheme (called Rural Mutual Health Care). Baseline survey in Dec 2002, Follow-up survey in Dec 2005.	Enrolees' health outcomes (information is collected through household and individual survey before and after the introduction of the scheme).
King, 2009	Clustered- Randomised Control Trial (step-wedge design, two arms)	Households living in 50 pairs of health clusters (65,072 households in total) half allocated to treatment. 32,515 households were interviewed at baseline (17,950 in intervention arm, 18,231 in control arm) and 29,897 were re-interviewed at follow up (14,949 in intervention arm, 14,948 in control arm). 55% of households in the sample fell into the high asset category.	Possibility to enrol in Seguro Popular (a voluntary Health insurance) and a set of supply-side interventions strengthening the quality and delivery of health services (funds to upgrade medical facilities, increase health personnel and improve drug supplies and medications). To increase enrolment into the scheme, media campaigns were also organised. In the control arm, there was no possibility to enrol in Seguro Popular and no extra supply-side intervention.	Health utilisation, health outcomes and health expenditures.
Ansah2009	RCT randomisation was performed at the household level (3 arms)	Households with at least one child aged 6 to 59 months who enrolled in a prepayment scheme for the year were eligible to participate in the trial. 2,332 (out of about 8,700) households were randomly selected from a district database to participate in the trial.	Free enrolment of households into a prepayment scheme in the South of Ghana (Dangme West District, greater Accra Region).	Health outcomes, health services utilisation.

#### Appendix 2: Context and intervention description

Study ID	Nature of intervention and control sites	Local contextual factors	Global/national contextual factors
Wang 2009	One township in a Chinese rural province was randomly selected to be the intervention site ; another township was then selected to match the intervention township on a number of variables for which official data were available (socio-economic conditions, availability of health facilities, distance to city centres).	In the intervention area, a series of measures were taken to address some of the issues of the health care delivery model. The scheme acted as purchaser and contracted with the best doctors, offering them a salary and outcome based performance fee. Several other measures relating to the drug procurement and purchasing were also taken to increase drug safety. Based on our own calculations, it seems that the enrolment rate in RMVH in the intervention arm was about 73% (1665 out of 2275). There was no health insurance or other new policy introduced in the control site during the study period.	A number of issues relating to the health care delivery model in rural China are highlighted: lack of regulation of drug pricing; doctors remunerated on a fee-for-service basis and on the profit from drug sales (these incentives leading to an over-consumption of drugs and escalating costs of drugs sold). The deterioration of the health care delivery model in rural China is said to have led to increasing financial burden on the patients, decreasing accessibility of health services and poorer quality of health care. These problems were still in place in the control site. The study aims to provide evidence to inform the design of a new financing health policy the Chinese government set out to introduce (the New cooperative medical Scheme).
King, 2009	One year prior to the official national launch of the Seguro Popular, 148 clusters (out of 12,284 nationally) were selected from 7 States (out of 32 States in Mexico) to join the experiment. Half were allocated to be a control arm. Following administrative constraints, the number of study clusters was reduced to 100 (50 paired clusters). Although the choice of study clusters could not be random due to implementation challenges, authors show good signs of external validity of their study sample based on the analysis of a number of indicators available at the national level.	Despite efforts to increase the enrolment of households in the scheme in intervention areas (media campaign, published list of benefits and rights, federal directives), only 44% of households enrolled in Seguro Popular in intervention areas (in high assets clusters the enrolment rate was 54% vs. 20% in low asset clusters). There was leakage of the intervention to control areas (in control clusters, 7% reported being affiliated).	Some of the poorest populations in study areas were existing beneficiaries of an anti poverty program (Opportunidades). This provides monthly cash transfers to individuals conditional on sending children to schools, attending health education workshops and regular health visits for children. Families already participating in the pre existing Opportunidades program were enrolled automatically in Seguro Popular. The Seguro Popular reform was one of several policies in the Mexican health care system that aimed to provide social protection to the population – prior to the introduction of SP, 50 million households were uninsured.
Ansah 2009	Households in the intervention arm were given free enrolment into a pre-payment scheme giving access to free primary care and limited free secondary care. Households in the control arm had to pay user fees to use the health services.	Households who were already members of the pre-existing scheme were included in a 3 <sup>rd</sup> arm of the trial. There was no drug stock-out during the study period.	Malaria is the main leading cause of mortality and morbidity among children under 5y in Ghana. Since the early 1980s, user fees have led to a drop in health services utilization and high proportion of people delaying the use of health services in Ghana. Although children under 5 should have access to free care since 1997, a survey revealed that only 6% accessed care for free. Indirect costs to accessing services and other indirect barriers (knowledge, distance to facility, perception) have been reported as factors affecting seeking behaviours in Ghana (as elsewhere).

#### Appendix 3: Details of memberships

Study ID	Benefit package	Limitations of membership	Premium level to enrol	Provider payment
Wang 2009	The benefit package includes outpatient services and hospital services with no co- payment at the point of delivery (Note: this feature differs from the NCMS whose benefit package is more limited). No specific details provided on	Voluntary enrolment. No limitation based on pre-existing conditions. The enrolment seems to be at the individual level (reference is made to "the farmer") but unclear whether the entire family then benefits from the scheme is made at the individual level. The authors refer to the scheme as a "prepayment scheme", but it is unclear whether the scheme is an individual pre- payment scheme or a voluntary health insurance scheme with pooling of risks across enrolees.	A farmer pays an annual premium of at least RMB10 (USD1.25), and there is a supplementary contribution of RMB20 funded by the project (to mimic the subsidy the government intends to introduce in their NCMS programme).	The scheme selected the best qualified doctors and then contracted them on a salary basis with outcome- based bonus (based on "selected health outcomes and performance measurements").
King, 2009	Beneficiary families have access to a broad package of services and drugs (312 medicines, 266 health interventions). States receive funding for improving health care delivery according to the number of beneficiary families.	Voluntary enrolment. It is unclear from the article whether the enrolment is at the household or individual level. Yet it is likely to be at the household level since health funding allocated to Mexican States depends on the number of affiliated families (Gakidou 2008, Knox 2008).	Not mentioned in the article. A former paper mentions that funding of Seguro Popular is based on contributions made by the federal government, the states, and beneficiary families (Frenk 2006). The amount of the family-level contribution is determined on a sliding scale: "Families in the lowest two income deciles do not contribute financially, but affiliation is conditional on participating in health-promotion activities. For the other income deciles, the family contribution is a fixed, equal proportion of disposable income, with an upper limit of 5%. One nominal contribution is defined for all of the income deciles three to nine, and two levels of contribution were established for the 10th decile owing to wide variation in the uppermost part of the income distribution." (Frenk 2006)	Not mentioned in the article, neither in other sources (Frenk 2006).The latter mentions that "services for Seguro Popular affiliates are contracted mostly, but not exclusively, from public providers".
Ansah 2009	The not-for-profit scheme provides access to free (unlimited) drugs and consultations in any of the 10 primary care clinics and (limited) free services when referred to a secondary care hospital	Normally the scheme is based on voluntary enrolment, with mandatory registration for the entire household (individual enrolment not possible). During the trial, the study offered to all households in the intervention arm the enrolment into the scheme (providing unique ID cards)	The study does not report the scheme fee. This is because fees to get enrolled in the scheme were paid by the study; therefore beneficiaries did not have to pay for the scheme.	The information was not available in the study, but for the public sector is it likely to follow the public health care system (salaried doctors receiving some top-ups from the user fees). It is unclear what sort of contract the scheme has with the health care providers to reimburse them for the costs of the drugs and visits.

#### Appendix 4: Outcomes measures

Study ID	Health expenditures	Health outcomes	Health utilization outcomes
Wang 2009	No	The study used two instruments relying on self-perceived measures of health status: 1/ a 5-point categorical rating scale (CRS) of self-perceived overall health status (poor/far/good/very good/excellent) 2/ the EuroQuol 5D (EQ-5D) instrument gathering self-reported perception of five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). For the analysis, the responses collected with both instruments were dichotomised to deal with the skewness of responses (towards no health problem) typically obtained in the general population as opposed to sick patients.	No
King 2009	Level of (out-of-pocket) expenditures for a range of health services (all, inpatient care, outpatient care, medicine and medical devices); proportion of households who incurred catastrophic expenditures (defined as more than 30% of income after having paid for food).	Health self-assessment (reportedly on 9 dimensions) – no more details on the instrument is given and specific results are not reported.	Health services utilization measured by a household survey: Number of outpatient visits and overnight hospital stays; coverage of preventative services (eye exam, flu vaccine, pap test, cervical screening, and mammogram).
Ansah 2009	No	Prevalence of moderate anaemia (supposed to reflect untreated and under-treated malaria) and severe anaemia; number of fever cases; number of deaths of children under five; mean haemoglobin concentration; level of parasaetemia.	Number of visits to a health facility per person per year (self-reported in household diaries collected monthly over a 6-month period).

# Appendix 5 : Results of Quality assessment

Randomised controlled trials

Study ID	Concealment of allocation	Protection against exclusion bias	Sampling	Appropriate Analysis (clustering)	Quality/ reliability of the data	Protection against detection bias	Baseline Measurement	Protection against contamination	Overall: Limitations
Ansah 2009	DONE	DONE	DONE	DONE	NOT CLEAR	NOT CLEAR	NOT DONE	DONE	High risk of bias
King 2009	NOT CLEAR	DONE	NOT CLEAR	NOT CLEAR	NOT DONE	NOT CLEAR	DONE	NOT DONE	High risk of bias

Controlled before and after (CBA) studies

Study ID	Baseline characteristics	Equivalent control site	Protection against exclusion or selection bias	Protection against contamination	Reliability of outcome measures	Appropriate analysis	Overall: Limitations
Wang 2009	NOT CLEAR	NOT DONE	NOT DONE	NOT CLEAR	NOT DONE	DONE	High risk of bias

# Ansah (2009): A randomized Controlled Trial in Ghana about the Dangme West Community Health insurance

Concealment of allocation	<b>DONE:</b> p50( random allocation of the
(protection against selection bias)	intervention to head of households : method of
	the rotating barrel)
Protection against exclusion bias	<b>DONE:</b> (p52) FOLLO UP in the intervention group
5	=91.6% and in the control group=92.2%.
Sampling	<b>DONE</b> : (p50)" the sample size would also be able
	to allow for the clustering effect of more than
(for Cluster Randomised Trials)	one eligible child in some households
	mean1.2,rho=0.4)", recruitment of 2.500.
Analysis	<b>DONE:</b> (p51) "the primary outcomes s analysis
	counted for cluster effect by household (using a
(for Cluster Randomised Trials)	population-averaged Generalized Estimation
	equation) and allow for clustering within
	households".
Quality/ reliability of data	NOT CLEAR: Use of laboratory methods for
(assessing the reliability and relevance of the data used)	investigating anaemia and their cause by two
	blinded biologists to the study group), but self
	reported documentary pictorial diaries by
	households to measure the utilisation of
	different health services.
Protection against detection bias	NOT CLEAR: (p49) "unblinded trial"
	Objective measures of health outcomes but not
	on health expenditures. Authors used self
	reported household survey.
Baseline measurement	<b>NOT DONE:</b> baseline measures are substantially
	different across study groups. (no statistical test
	have been performed between control and
	intervention group at baseline )p53 table1 but
	(p52) the author stated the contrary.
Protection against contamination	<b>DONE</b> : (p50)participants are not included if
	they would have to emigrate from the study
	area within the coming 2 years. There was a
	unique window enrolment. One randomised
	households could not change their group, every
	member of enrolled households had an
	individual picture ID card with a unique
	identification number .

# King (2009): A Cluster Randomized controlled trial in Mexico about the Seguro Popular Universal coverage.

Concealment of allocation	<b>NOT CLEAR:</b> p1448 "we randomly assigned one
(protection against selection bias)	cluster form each pair to be the treatment
	cluster". But don't know how the allocation has
	been proceeded.
Protection against exclusion bias	<b>DONE:</b> % of loss to follow up= 82.6% less than
	10%.
	NOT CLEAR: Authors did not explain which
Sampling	power calculation they have performed to take
(for Cluster Pandomicad Trials) cluster – present or	into account the cluster effect in the sampling
nlanned health clinic or hospital and the population in	frame? The study questions whether the sample
its catchment area.	was large enough to provide robust results =
	p14492 "expected to have up to about 380
	randomly chosen HH in each of the 100
	clusters." = total expected 38000 HH but at the
	baseline survey could only get 36181 hh.
	NOT CLEAR: if statistical analysis takes into
Analysis	account the cluster effects.
(for Cluster Randomised Trials)	
Quality/ reliability of data	<b>NOT DONE:</b> p1450 "annual self reported out of
(assessing the reliability and relevance of the data used)	pocket by the head of household during the
	previous three months".
Protection against detection bias	<b>NOT CLEAR:</b> first we don't know anything about
	the questionnaires, the questions head of
	households have to answer? How the analysis of
	the questionnaire has been done? And who
	analysed it and finally if it was blinded?
Baseline measurement	DONE : p1450 "there was a baseline survey to
	look at balance between treatment and control
	groups on the outcomes of interest at the time
	of the random assignment", there were
	differences only in one of the self reported
	health variable. "
Protection against contamination	<b>NOT DONE:</b> "it is likely that controlled received
	the interventionp1451 "In controls, 7% received
	the intervention.

Baseline characteristics (differences in outcome measures between control and intervention)	<b>NOT CLEAR</b> : Baseline measurement regarding only one outcome, (self reporting poor health), there are differences at the baseline level between control and intervention group (34 % of Enrolees in the preintervention group reported poor health compared to 19% in the control group) Results are statistically significant.
Equivalent control site (differences in 1/population 2/facilities 3/external influences)	NOT DONE : pS72 + table 2 "major differences in baseline characteristics (on observable socioeconomic and demographic variables) between control and intervention but no statistical test performed. Authors used Propensity score matching in order to reduce heterogeneity between groups. Table do not report results of matching between two groups on availability of health facilities and distance to city centres.
Protection against exclusion or selection	<b>NOT DONE</b> : The study reported they used
bias in the sample framing	representative sample of the population.p68 "
(population sample or facilities sample)	this study was conducted in the general
Adverse slection in intervention group =more	population rather than a population with
poor , ill , single(young).	illnesses" but targeted more rural farmers.
	No protection against exclusion bias = 20
	observations were excluded and no statistical
	analysis was performed on those excluded to
	look at a difference between excluded and
	groups in the study.28,3 % of loss to follow up in
	the total sample. (explain in the discussion but
	data not reported in a table).
Protection against contamination	NOT CLEAR if contamination between
	treatment and control group was likely to occur.
Quality/reliability of data	<b>NOT DONE</b> : Collection of the outcomes of
(assessing the reliability and relevance of the data used)	interest on longitudinal household and
	individual surveys, p 72 "we successfully
	interviewed" participants . Author mentioned
	the same survey instrument was used for both
	groups and both period of the study. Doubt
	regarding one criteria to report anxiety or
	depression.
Appropriate Analysis	<b>DONE</b> : ITT and ATT estimation method.

# Wang (2009) Control-before and after study in China on Rural Mutual Health Care

#### Appendix 6 : Criteria considering the assessment of study quality

We slightly adapted the standard criteria recommended by EPOC (EPOC 2002) to match the particularities of the studies found in the field of interest. For example criteria about following-up patients or doctors were not relevant as most of the studies used population survey data. Follow-up surveys, when carried out, would therefore not be done with the same population, but with a new random sample. In addition, we added some specific criteria to account for some of the limitations of studies found (e.g. no statistical analysis performed or failure to account for clustering effects). Appendix 2 presents the detailed list of all quality criteria used, and explain the amendments introduced to the original EPOC criteria for each type of design.

The criteria for RCTs and C-RCTs were:

- 1. Concealment of allocation
- 2. Protection against exclusion bias
- 3. Appropriate sampling strategy
- 4. Appropriate analysis
- 5. Reliable primary outcomes measures
- 6. Protection against detection bias
- 7. Baseline measurement of outcomes
- 8. Protection against contamination

The criteria for CBA studies were:

- 1. Baseline measurement of outcomes
- 2. Baseline characteristics of studies using second site as control
- 3. Protection against exclusion or selection bias
- 4. Protection against contamination
- 5. Reliable primary outcomes measures
- 6. Appropriate analysis of data

The criteria for ITS studies were:

- 1. protection against changes
- 2. appropriate analysis of the data (or re-analysis possible)
- 3. Protection against selection bias
- 4. Reliability of outcome data
- 5. Number of points specified
- 6. intervention effect specified
- 7. protection against detection bias

The quality of the selected studies was assessed independently by the two reviewers. Discrepancies in quality ratings were resolved by discussion

After assessment of all quality criteria, the studies were classified into three categories according to their risk of bias:

- low risk of bias = all criteria scored as 'done'
- moderate risk of bias = one or two criteria scored as 'not clear' or 'not done'
- high risk of bias = more than two criteria scored as 'not clear' or 'not done'

Appendix 2: quality criteria used for appraising quality of included studies

This appendix presents the detail of all of the criteria used in the appraisal of included studies.

CBA studies:

In the following list, criteria one, two and four are directly taken from the list of standard criteria of the EPOC Group.

Criteria three and five are adapted from the original criteria to make them more relevant to the specificities of the studies included in this review. Standards to judge the risk of exclusion or selection bias were rephrased to be more adapted to the types of population-based studies that might be included in the review. The criterion on quality and reliability of data was also adapted to reflect better the risks of bias relating to the type of outcomes that were the primary focus of the review.

Criteria six was added following preliminary findings which showed that statistical significance of studies was not systematically computed or available in the studies found.

Finally, we omitted a standard criterion of the Cochrane Collaboration textbook on the blinded assessment of primary outcomes. We judged that this was not relevant for the types of outcomes this review focused on.

- Baseline outcome characteristics: DONE if outcomes were measured prior to the intervention, and no substantial differences were present across study groups (e.g. where multiple pre intervention measures describe similar trends in intervention and control groups); NOT CLEAR if baseline measures are not reported, or if it is unclear whether baseline measures are substantially different across study groups; NOT DONE if there are differences at baseline in main outcome measures likely to undermine the post intervention differences (e.g. are differences between the groups before the intervention similar to those found post intervention?)
- 2. Equivalent control sites: DONE if characteristics of study and control sites are reported and similar (in terms of 1/population 2/facilities and 3/external influence characteristics); NOT CLEAR if it is not clear in the paper e.g. characteristics are mentioned in the text but no data are presented; NOT DONE if there is no report of characteristics either in the text or a table OR if baseline characteristics are reported and there are differences between study and control providers.
- 3. **Protection against exclusion or selection bias**: DONE if outcome measures obtained from the whole population or a representative sample of the population (and the control group) was studied; NOT CLEAR if not specified in the paper; NOT DONE if outcome measures were not obtained from a representative sample.
- 4. Protection against contamination: DONE if allocation was by community, institution, or practice and is unlikely that the control group received the intervention; NOT CLEAR if communication (i.e. individuals present in one control group cannot move and benefit from the interventions in experimental areas) between treatment and control group was likely to occur; NOT DONE if it is likely that the control group received the intervention (e.g. cross-over studies or if patients rather than providers were randomised).
- 5. **Quality/reliability of outcome measures**: scored DONE if the outcome is obtained from some automated system (e.g. length of hospital stay) or comes from another objective source; NOT CLEAR if reliability is not reported for outcome measures that are obtained by chart extraction or collected by an individual (will be treated as NOT DONE if information cannot be obtained from the authors); and NOT DONE if the primary data is reportedly of a poor guality.
- 6. Appropriate analysis: DONE if statistical significance of differences in outcomes was tested and/or statistical analysis was appropriate. NOT CLEAR if statistical significance of results is not specified in the paper or if the analysis chosen was not appropriate; NOT DONE if statistical significance of results was not tested.

#### Randomised Controlled Trials

All the following criteria are taken from the standard EPOC criteria (EPOC 2002), except for criteria three and four. Indeed, we judged important to add specific criteria for cluster-randomised for two reasons. Firstly because interventions of interest would be more likely to be implemented at community level, they would require such study designs. Secondly, issues regarding sampling and analysis have identified as particular concerns that might lead to biases when analysing cluster-randomised trials (Ukoumunne, Gulliford et al. 1999). We also omitted one criteria on exclusion bias concerning the follow-up of professionals. It was judged not relevant for the focus of our review (where studies are all focusing on populations).

1. Concealment of allocation: DONE if the unit of allocation was by institution, team or professional and any random process is described explicitly, e.g. the use of random number tables or coin flips; OR the unit of allocation was by patient or episode of care and there was some form of centralised randomisation scheme, an on-site computer system or sealed opaque envelopes were used. NOT CLEAR if the unit of allocation is not described explicitly OR the unit of allocation was by patient or episode of care and the authors report using a 'list' or 'table', 'envelopes' or 'sealed envelopes' for allocation. NOT DONE if the authors report using alternation such as reference to case record numbers, dates of birth, day of the week or any other such approach (as in CCTs) OR the unit of allocation was by patient or episode of care and the authors report using any allocation was altered (by investigators, professionals or patients).

- Protection against exclusion bias: DONE if outcome measures obtained for 80-100% of subjects randomised (or a biased sample) or for patients who entered the trial (do not assume 100% follow up unless stated explicitly); NOT CLEAR if not specified in the paper; NOT DONE if outcome measures obtained for less than 80% of subjects randomised (or a biased, non-representative sample).
- 3. **Sampling (for cluster-randomised trials)**: DONE if sampling took cluster effects/bias into account or if the sample is large enough to provide robust results; NOT CLEAR if not specified in the paper; NOT DONE if the sampling is too small to provide robust results.
- 4. **Appropriate Analysis (for cluster-randomised trials)**: DONE if the analysis accounted for cluster effects/bias; NOT CLEAR if not specified in the paper; NOT DONE if the analysis did not account for cluster effects/bias.
- 5. Quality/reliability of the data: scored DONE if the outcome is obtained from some automated system (e.g. length of hospital stay) or comes from another objective source; NOT CLEAR if reliability is not reported for outcome measures that are obtained by chart extraction or collected by an individual (will be treated as NOT DONE if information cannot be obtained from the authors); and NOT DONE if the primary data is reportedly of a poor quality.
- 6. **Protection against detection bias**: DONE if the authors state explicitly that the primary outcome variables were assessed blindly OR the outcome variables are objective, e.g. length of hospital stay, drug levels as assessed by a standardised test; NOT CLEAR if not specified in the paper; NOT DONE if the outcome(s) were not assessed blindly.
- 7. **Baseline Measurement**: DONE if performance or patient outcomes were measured prior to the intervention, and no substantial differences were present across study groups (e.g. where multiple pre intervention measures describe similar trends in intervention and control groups); NOT CLEAR if baseline measures are not reported, or if it is unclear whether baseline measures are substantially different across study groups; NOT DONE if there are differences at baseline in main outcome measures likely to undermine the post intervention differences (e.g. are differences between the groups before the intervention similar to those found post intervention?).
- 8. **Protection against contamination**: DONE if allocation was by community, institution or practice and it is unlikely that the control received the intervention; NOT CLEAR if professionals were allocated within a clinic or practice and it is possible that communication between experimental and group professionals could have occurred; NOT DONE if it is likely that the control group received the intervention (e.g. cross-over trials or if patients rather than professionals were randomised).

#### ITS analyses

We decided to slightly modify the criteria proposed by EPOC, and have provided some explanation on why we decided to do this. Basically, we argue that health service utilisation data (which are the longitudinal data used for the ITS included here) are subject to seasonal variation. In order to account for this potential bias, we decided to include studies that provided data where seasonal variation could be minimally accounted for (hence the requirement for example for 12 months before and after the intervention in the case of monthly data)

- 1. **Protection against changes**: DONE if the intervention occurred independently of other changes over time; NOT CLEAR if not specified (NOT DONE if information cannot be obtained from the authors); NOT DONE if reported that intervention was not independent of other changes in time.
- 2. **Appropriate analysis: DONE** if ARIMA (Auto-Regressive Integrated Moving Average) models were used OR time series regression models were used to analyse the data and serial correlation was adjusted/tested for OR if reanalysis performed; NOT CLEAR if not specified; NOT DONE if it is clear that neither of the conditions above not met.
- 3. **No selection bias in the sample framing**: DONE if outcome measures are obtained from the whole population or a representative sample of the population studied; NOT CLEAR if not specified (will be treated as NOT DONE if information cannot be obtained from the authors); NOT DONE if data set is not drawn from a representative sample.
- 4. Quality/reliability of outcome data: scored DONE if the outcome is obtained from some automated system (e.g. length of hospital stay) or comes from another objective source; NOT CLEAR if reliability is not reported for outcome measures that are obtained by chart extraction or collected by an individual (will be treated as NOT DONE if information cannot be obtained from the authors); and NOT DONE if the primary data is reportedly of a poor quality.
- 5. Number of points specified: DONE if monthly data for at least 12 months (or more) pre- and post-intervention were used (or an equivalent number allowing the analysis of seasonal variations), NOT CLEAR if less data points are given with a convincing argument that no seasonal variations occurred, NOT DONE if few data points are provided and seasonal variations are likely to have occurred.
- 6. **Intervention effect specified**: DONE if point of analysis was the point of intervention OR a rational explanation for the timing of intervention effect was given by the author(s).
- 7. **Detection bias**: DONE if it is reported that intervention itself was unlikely to affect data collection (for example, sources and methods of data collection were the same before and after the intervention).

# Appendix 7 : Excluded studies

Study ID/ year of publication	REASONS FOR EXCLUSION 1/2
Alevizos 2007	Study takes place in Greece
Asfaw 2004	Stated preference survey
Barros 2008	Study takes place in Portugal
Bogg 1996	Not clear when intervention started - use of longitudinal data, but no data before.
Chankova 2008	Cross-sectional survey, no control
Charry 2008	Retrospective study of breast cancer patients to look at the influence of SI status on
	cancer screening
Criel 1999	No control, cross-sectional data
Deiniger 2004	Cross sectional surveys, no control on user fees in Uganda.
Frenk 2009	Case study on the financial innovations needed for universal coverage in Mexico.
Giedon 2009	Literature review of three retrospective studies of cross sectional household survey
Kang 2009	Cross-sectional survey to assess the demand for screening services
Knaul 2005	Biannual time series of household survey on health care expenditures
Kozhimannil 2009	National policy - survey data before and after, no control
Limwattenanon 2007	National policy - survey data before and after, no control
Liu 2002	Pre-post-study design (evaluation of a pilot project) without control
Liu 2006	Pre- post- study design (evaluation of a pilot project) without control
Louvison 2008	Cross-sectional survey, econometric study of determinants of health services
Meuwissen2006	Patient studies follow up on the impact of voucher programmes in Nicaragua on reproductive care for younger.
Pagan 2007	econometric study of the determinants of the use of health services (incl. HI) using cross-sectional survey
Polonsky2009	No control, cross sectional survey
Ranson 2007	Intervention was trying to improve the insurance scheme among ensured people.(interv/control)

Study ID/ year of publication	REASONS FOR EXCLUSION 2/2
Ruiz 2007	Prospective cohort study and modelization to assess the impact of a social health
	insurance program in Colombia on health services and out of pocket expenditures
Soderlund 2000	Longitudinal data on insured groups in ZA ? South Africa, no intervention
Sosa Rubi 2009	Cross sectional studies
Sun 2009	Outcome not of interest (prescribing behaviour), very weak control
Tellez 2008	Pre-payment scheme offered over 5 years - X-sectional survey in the middle of the period
Trujillo 2005	Propensity score matching on household survey data to measure the impact of a
	subsidized health insurance program on medical care utilization in Colombia.
Victora 2009	Editorial of a policy analysis on Seguro Popular
Wagstaff lindelow 2009	Statistical modelization of Out of pocket payment and utilization patterns on cross sectional data
Wagstaff Moreno 2009	Regression analysis of Out of pocket payment and utilization patterns on cross sectional data
Witter 2009	Longitudinal data in Ghana, no clear timing of intervention
Xingyuan 1993	Cross sectional survey, no control compares different health financing mechanisms in China
Yip2009	Econometric analysis of the effect of MSA by using households' survey data in China.
Yip 2001	Logistic regression on cross sectional studies to measure the impact of a targeted
You2009	Literature review on evidence of the performance and impact of New scheme in China.
zhou 2009	Panel data analysis of the impact of insurance status on health service utilisation (no control)

# **Studies not retrieved**

Burge 2000	Article not found (Barriers to care for newly diabetes patient,
	N/A setting)
Jancloes 1979	Article not found (no full access) (Community auto financing
	program in Senegal)
Jones 1992	Article not found (malpractice insurance in South Africa)
Chiapa 2008	Thesis no access (Insurance and health effects in Mexico)
Delchva 2000	No access to bulgarian journal. (Impact of compulsory health
	insurance in Bulgaria)

References available on request.

#### **Appendix 8: Key Words of the Search strategy CENTRAL**

- #1 MeSH descriptor Fees and Charges, this term only
- #2 MeSH descriptor Fees, Dental, this term only
- #3 MeSH descriptor Fees, Medical, this term only
- #4 MeSH descriptor Fees, Pharmaceutical, this term only
- #5 MeSH descriptor Prescription Fees, this term only
- #6 MeSH descriptor Hospital Charges, this term only
- #7 MeSH descriptor Capitation Fee, this term only
- #8 MeSH descriptor Fee-for-Service Plans, this term only
- #9 MeSH descriptor Cost Sharing, this term only
- #10 MeSH descriptor Contract Services, this term only
- #11 MeSH descriptor Outsourced Services, this term only
- #12 MeSH descriptor Prepaid Health Plans, this term only
- #13 MeSH descriptor Prospective Payment System, this term only
- #14 MeSH descriptor Insurance, Health, this term only
- #15 (medical or dental or pharmac\* or dispensing or drug or drugs or medicament\* or medicine\* or prescript\* or consultation\* or treatment\* or registration\* or hospital\* or care) NEAR/3 (fee or fees or charge\*):ti,ab,kw
- #16 (user or users or patient\* or outpatient\* or inpatient\*) NEAR/3 (fee or fees or charge\* or pay\*):ti,ab,kw
- #17 ("fee for service" or "fee for services"):ti,ab,kw
- #18 capitation:ti,ab,kw
- #19 (pay\* or cash or money or monetary or economic or financial) NEAR/3 incenti ve\*:ti,ab,kw
- #20 (pay\* NEAR/3 performance):ti,ab,kw
- #21 p4p:ti,ab,kw
- #22 (result\* NEXT based or performance NEXT based):ti,ab,kw
- #23 (result\* or performance or output or "out put") NEAR/2 (financ\* or pay\* or incentive\* or initiative\* or bonus\*):ti,ab,kw
- #24 (cash or pay\*) NEAR/3 (condition\* or contingent or requirement\*):ti,ab,kw
- #25 (cash or pay\* or monetary ot money) NEAR/3 transfer\*:ti,ab,kw
- #26 "cost sharing":ti,ab,kw
- #27 cost NEXT recover\*:ti,ab,kw
- #28 price NEXT change\*:ti,ab,kw
- #29 (contract or contracts or contracting):ti,ab,kw

- #30 (outsourc\* or out NEXT sourc\*):ti,ab,kw
- #31 ("risk sharing" or shared NEXT risk\*):ti,ab,kw
- #32 prospective NEXT (pay\* or reimbursement\*):ti,ab,kw
- #33 (prepay\* or pre NEXT pay\* or prepaid or pre NEXT paid):ti,ab,kw
- #34 (health or medical) NEXT insurance\*:ti,ab,kw
- #35 (social or community) NEAR/3 (insurance\* or financ\*):ti,ab,kw
- #36 "demand side":ti,ab,kw
- #37 "supply side":ti,ab,kw
- #38 financ\* adj (strategy or strategies):ti,ab,kw
- #39 (Africa or Asia or Caribbean or "West Indies" or "South America" or "Latin America" or "Central America"):ti,ab,kw

#40 (Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Brazil or Bulgaria or "Burkina Faso" or "Burkina Fasso" or "Upper Volta" or Burundi or Urundi or Cambodia or "Khmer Republic" or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or "Cape Verde" or "Central African Republic" or Chad or Chile or China or Colombia or Comoros or "Comoro Islands" or Comores or Mayotte or Congo or Zaire or "Costa Rica" or "Cote d'Ivoire" or "Ivory Coast" or Croatia or Cuba or Cyprus or Czechoslovakia or "Czech Republic" or Slovakia or "Slovak Republic"):ti,ab,kw

#41 (Djibouti or "French Somaliland" or Dominica or "Dominican Republic" or "East Timor" or "East Timur" or "Timor Leste" or Ecuador or Egypt or "United Arab Republic" or "El Salvador" or Eritrea or Estonia or Ethiopia or Fiji or Gabon or "Gabonese Republic" or Gambia or Gaza or Georgia or Georgian or Ghana or "Gold Coast" or Greece or Grenada or Guatemala or Guinea or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or "Isle of Man" or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or "Kyrgyz Republic" or Kirghiz or Kirgizstan or "Lao PDR" or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania):ti,ab,kw

#42 (Macedonia or Madagascar or "Malagasy Republic" or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or "Marshall Islands" or Mauritania or Mauritius or "Agalega Islands" or Mexico or Micronesia or "Middle East" or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nepal or "Netherlands Antilles" or "New Caledonia" or Nicaragua or Niger or Nigeria or "Northern Mariana Islands" or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philippines or Philippines or Poland or Portugal or "Puerto Rico"):ti,ab,kw

#43 (Romania or Rumania or Russia or Russia 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 "Samoan 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 "Sri Lanka" or Ceylon or "Solomon Islands" or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria or Tajikistan or Tadzhikistan or Tadzhik 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 #44 (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

#45 (developing or less\* NEXT developed or "under developed" or underdeveloped or "middle income" or low\* NEXT income) NEXT (economy or economies):ti,ab,kw

#46 low\* NEXT (gdp or gnp or "gross domestic" or "gross national"):ti,ab,kw

- #47 (low NEAR/3 middle NEAR/3 countr\*):ti,ab,kw
- #48 (lmic or lmics or "third world" or "lami country" or "lami countries"):ti,ab,kw
- #49 ("transitional country" or "transitional countries"):ti,ab,kw

#50 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38)

#51 (#39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49)

#52 (#50 AND #51)

#### MEDLINE

- 1. "Fees and Charges"/
- 2. Fees, Dental/
- 3. Fees, Medical/
- 4. Fees, Pharmaceutical/
- 5. Prescription Fees/
- 6. Hospital Charges/
- 7. Capitation Fee/
- 8. Fee-for-Service Plans/
- 9. "Cost Sharing"/
- 10. Contract Services/
- 11. Outsourced Services/
- 12. Prepaid Health Plans/

13. Prospective Payment System/

14. Insurance, Health/

15. ((medical or dental or pharmac\$ or dispensing or drug or drugs or medicament? or medicine? or prescript\$ or consultation? or treatment? or registration? or hospital? or care) adj3 (fee? or charge?)).tw.

16. ((user? or patient? or outpatient?) adj3 (fee? or charge? or pay\$)).tw.

17. fee for service?.tw.

18. capitation.tw.

- 19. ((pay\$ or cash or money or monetary or economic or financial) adj3 incentive?).tw.
- 20. (pay\$ adj3 performance).tw.

21. p4p.tw.

- 22. ((result? or performance) adj based).tw.
- 23. ((result? or performance or output or out put) adj2 (financ\$ or pay\$ or incentive? or initiative? or bonus\$)).tw.
- 24. ((cash or pay\$) adj3 (condition\$ or contingent or requirement?)).tw.
- 25. ((cash or pay\$ or monetary ot money) adj3 transfer\$).tw.

26. cost sharing.tw.

- 27. cost recover\$.tw.
- 28. price change?.tw.
- 29. (contract or contracts or contracting).tw.
- 30. (outsourc\$ or out sourc\$).tw.
- 31. (risk sharing or shared risk?).tw.
- 32. (prospective adj (pay\$ or reimbursement?)).tw.
- 33. (prepay\$ or pre pay\$ or prepaid or pre paid).tw.
- 34. ((health or medical) adj insurance?).tw.
- 35. ((social or community) adj3 (insurance? or financ\$)).tw.
- 36. demand side.tw.
- 37. supply side.tw.
- 38. (financ\$ adj (strategy or strategies)).tw.

39. or/1-38

- 40. Developing Countries/
- 41. (Africa or Asia or Caribbean or West Indies or South America or Latin America or Central America).hw,kf,ti,ab,cp.
- 42. (Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or

Bahrain or Bangladesh or Barbados or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia

or Bosnia or Herzegovina or Botswana or Brazil or Bulgaria or Burkina Fasso or Upper Volta or Burundi or Urundi or Cambodia or Khmer Republic or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Mayotte or Congo or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or Croatia or Cuba or Cyprus or Czechoslovakia or Czech Republic or Slovakia or Slovak Republic or Djibouti or French Somaliland or Dominica or Dominican Republic or East Timor or East Timur or Timor Leste or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Estonia or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Gaza or Georgia Republic or Georgian Republic or Ghana or Gold Coast or Greece or Grenada or Guatemala or Guinea or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or Isle of Man or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or Kyrgyz Republic or Kirghiz or Kirgizstan or Lao PDR or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or Marshall Islands or Mauritania or Mauritius or Agalega Islands or Mexico or Micronesia or Middle East or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nepal or Netherlands Antilles or New Caledonia or Nicaragua or Niger or Nigeria or Northern Mariana Islands or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philippines or Philippines or Phillippines or Poland or Portugal or Puerto Rico or Romania or Rumania 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 Samoan 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 Sri 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 Tadzhik 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).hw.kf,ti,ab,cp.

43. ((developing or less\* developed or under developed or underdeveloped 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.

44. ((developing or less\* developed or under developed or underdeveloped or middle income or low\* income) adj (economy or economies)).ti,ab.

45. (low\* adj (gdp or gnp or gross domestic or gross national)).ti,ab.

46. (low adj3 middle adj3 countr\*).ti,ab.

47. (lmic or lmics or third world or lami countr\*).ti,ab.

48. transitional countr\*.ti,ab.

49. or/40-48

50. randomized controlled trial.pt.

51. random\$.tw.52. intervention\$.tw.53. control\$.tw.

- 54. evaluat\$.tw.
- 54. evalualş.tw
- 55. effect?.tw.
- 56. or/50-55
- 57. Animals/
- 58. Humans/
- 59. 57 not (57 and 58)
- 60. 56 not 59
- 61. 39 and 49 and 60

#### EMBASE

1. Fee/

- 2. Medical Fee/
- 3. Hospital Charge/
- 4. Hospital Billing/
- 5. Capitation Fee/
- 6. Prospective Payment/
- 7. Health Insurance/

8. ((medical or dental or pharmac\$ or dispensing or drug or drugs or medicament? or medicine? or prescript\$ or consultation? or treatment? or registration? or hospital? or care) adj3 (fee? or charge?)).tw.

9. ((user? or patient? or outpatient?) adj3 (fee? or charge? or pay\$)).tw.

10. fee for service?.tw.

11. capitation.tw.

12. ((pay\$ or cash or money or monetary or economic or financial) adj3 incentive?).tw.

13. (pay\$ adj3 performance).tw.

14. p4p.tw.

15. ((result? or performance) adj based).tw.

16. ((result? or performance or output or out put) adj2 (financ\$ or pay\$ or incentive? or initiative? or bonus\$)).tw.

17. ((cash or pay\$) adj3 (condition\$ or contingent or requirement?)).tw.

18. ((cash or pay\$ or monetary ot money) adj3 transfer\$).tw.

19. cost sharing.tw.

20. cost recover\$.tw.

- 21. price change?.tw.
- 22. (contract or contracts or contracting).tw.
- 23. (outsourc\$ or out sourc\$).tw.
- 24. (risk sharing or shared risk?).tw.
- 25. (prospective adj (pay\$ or reimbursement?)).tw.
- 26. (prepay\$ or pre pay\$ or prepaid or pre paid).tw.
- 27. ((health or medical) adj insurance?).tw.
- 28. ((social or community) adj3 (insurance? or financ\$)).tw.

29. demand side.tw.

- 30. supply side.tw.
- 31. (financ\$ adj (strategy or strategies)).tw.

32. or/1-31

33. Developing Country.sh.

34. (Africa or Asia or Caribbean or West Indies or South America or Latin America or Central America).hw,ti,ab,cp.

35. (Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Brazil or Bulgaria or Burkina Faso or Burkina Faso or Upper Volta or Burundi or Urundi or Cambodia or Khmer Republic or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Mayotte or Congo or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or Croatia or Cuba or Cyprus or Czechoslovakia or Czech Republic or Slovakia or Slovak Republic or Djibouti or French Somaliland or Dominica or Dominican Republic or East Timor or East Timur or Timor Leste or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Estonia or Ethiopia or Fiji or Gabon or Gabonese Republic or Gauna or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or Isle of Man or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or Kyrgyz Republic or Kirghiz or Kirgizstan or Lao PDR or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libuq or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or Marshall Islands or Mauritania or Mauritus or Agalega Islands or Mexico or Micronesia or Middle East or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nepal or Netherlands Antilles or New Caledonia or Nicaragua or Niger or Nigeria or Northern Mariana Islands or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philippines or Philippines or Poland or Portugal or Puerto Rico or Romania or Rumania or Roumania 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 Samoan 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 Sri Lanka or Ceylon or Solomon Islands or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria or Tajikistan or Tadzhikistan or Tadzhik or Tanzania or Thailand or Togo or Togolese Republic or Tonga or Trinidad or Tobago 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 Viet Nam or West Bank or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia).hw,ti,ab,cp.

36. ((developing or less\* developed or under developed or underdeveloped 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.

37. ((developing or less\* developed or under developed or underdeveloped or middle income or low\* income) adj (economy or economies)).ti,ab.

38. (low\* adj (gdp or gnp or gross domestic or gross national)).ti,ab.

39. (low adj3 middle adj3 countr\*).ti,ab.

40. (lmic or lmics or third world or lami countr\*).ti,ab.

41. transitional countr\*.ti,ab.

42. or/33-41

43. Randomized Controlled Trial/

44. Controlled Clinical Trial/

45. Time Series Analysis/

46. (randomis\* or randomiz\* or randomly).tw.

47. time series.tw.

48. intervention\*.tw.

49. control\*.tw.

50. evaluat\*.tw.

51. effect\*.tw.

- 52. impact?.tw.
- 53. or/43-52
- 54. Nonhuman/
- 55. 53 not 54
- 56. 32 and 42 and 55

#### EconLit

((DE=(Capitation or Outsource or Payment Method or Pay Performance or Financing or Compensation or Insurance or Compensation Packages, Payment Methods (J330) or Personnel Economics: Compensation and Compensation Methods and Their Effects ( M520)) and DE=(Healthcare or Health or Medical Care or Dentistry or Hospital)) or(KW=(payment system\* or payment incentive\* or payment method\* or payment strategy or payment strategies or monetary incentive\* or economic incentive\* or financial incentive\* or financial strategy or financial strategies or financing or fee or fees or charges or capitation or per capita or pay for performance or p4p or performance based or result based or results based or output based or out put based or bonus\* or cost sharing or cost recover\* or price chang\* or contract or contracts or contracting or outsourc\* or risk sharing or shared risk\* or prospective pay\* or prospective reimbursement\* or prepay \* or pre pay\* or prepaid or pre paid or demand side or supply side) and KW=(health or healthcare or medical or dental or pharmaceutical or drug or drugs or medicament\* or medicine\* or hospital or prescrip\* or prescrib \*)) or(KW=(cash or pay\*) and KW=(condition\* or contingent or requirement\*) and KW=(health or healthcare or medical or dental or pharmaceutical or drug or drugs or medicament\* or medicine\* or hospital or prescrip\* or prescrib \*)) or(KW=(cash or pay\* or monetary or money or finance\*) and KW=(transfer\*) and KW=(health or healthcare or medical or dental or pharmaceutical or drug or drugs or medicament\* or medicine\* or hospital or prescrip\* or prescrib\*)) or(KW=(health insurance or healthcare insurance or health care insurance or medical insurance or social insurance))) and((KW=(Africa or Asia or Caribbean or West Indies or South America or Latin America or Central America)) or(KW=(Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Herzegovina or Botswana or Brazil or Bulgaria or Burkina Faso or Burkina Fasso or Upper Volta or Burundi or Urundi or Cambodia or Khmer Republic or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Mayotte or Congo or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or Croatia or Cuba or Cyprus or Czechoslovakia or Czech Republic or Slovakia or Slovak Republic or Djibouti or French Somaliland or Dominica or Dominican Republic or East Timor or East Timur or Timor Leste or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Estonia or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Gaza or Georgia Republic or Georgian Republic or Ghana or Gold Coast or Greece or Grenada or Guatemala or Guinea or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or Isle of Man or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or Kyrgyz Republic or Kirghiz or Kirgizstan or Lao PDR or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or Marshall Islands or Mauritania or Mauritius or Agalega Islands or Mexico or Micronesia or Middle East or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanma or Myanma or Burma or Namibia or Nepal or Netherlands Antilles or New Caledonia or Nicaragua or Niger or Nigeria or Northern Mariana Islands or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philippines or Philippines or Poland or Portugal or Puerto Rico or Romania or Rumania or

Roumania 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 Samoan 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 Sri Lanka or Ceylon or Solomon Islands or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria or Tajikistan or Tadzhikistan or Tadzhik 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)) or(KW=(developing or less\* developed or under developed or underdeveloped or middle income or low\* income or underserved or under served or deprived or poor\*) and KW=(countr\* or nation or nations or population\* or world)) or(KW=(developing economy or less\* developed economy or under developed economies or underdeveloped economies or middle income economies or low\* income economies)) or(KW=(low\* gdp or low\* gnp or low\* gross domestic or low\* gross national or lmic or lmics or third world or lami countr\* or transitional countr\*)) or(KW=(low within 3 middle within 3 countr\*))) and(KW=(randomiz\* or randomis\* or randomly or intervention\* or control\* or effect\* or evaluat\* or impact\*))