Do Social health insurance schemes in developing country settings improve health outcomes and reduce the impoverishing effect of healthcare payments for the poorest people?

Arnab Acharya[1], Sukumar Vellakkal[2], Soumik Kalita[2], Fiona Taylor[3], Ambika Satija[2], Margaret Burke[4], Edoardo Masset[5], Prathap Tharyan[6], Shah Ebrahim[3]

[1] Department of Public Health Policy, London School of Hygiene & Tropical Medicine, London, UK
[2]South Asia Network for Chronic Disease, Public Health Foundation of India, New Delhi, India
[3]Department of Epidemiology & Population Health, London School of Hygiene & Tropical Medicine, London, UK
[4]Department of Social Medicine, University of Bristol, Bristol, UK
[5]Institute of Development Studies, Sussex, UK
[6]South Asian Cochrane Network & Centre, Prof. BV Moses & ICMR Advanced Centre for Research & Training in Evidence Informed Health Care, Christian Medical College, Vellore, India

Citation example: Acharya A, Vellakkal S, Kalita S, Taylor F, Satija A, Burke M, Masset E, Tharyan P, Ebrahim S. Do Social health insurance schemes in developing country settings improve health outcomes and reduce the impoverishing effect of healthcare payments for the poorest people? [Protocol]. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Background

Health care financing and catastrophic expenditure

Health financing in many LMICs is characterized by high levels of out-of-pocket expenditure for serious illnesses leading to potentially catastrophic payment for health care among its citizens (WHO 2007). Financial constraint is one of the major barriers for access to healthcare in these countries for marginalized sections of society where health care expenditure is a major cause of impoverishment (Xu 2003; Peters 2002; Garg 2007; Pradhan 2002, Ranson 2002, Wagstaff 2003, Russell 2004). A study of 59 countries found lack of health insurance as one of the main factors engendering health expenditure at a level that can be thought of as catastrophic, up to nearly 40% of all household expenditure, and recommended the provision of some form of financial risk protection (Xu 2003). Such expenditure is likely to cause further impoverishments among households; for example, 3-5% of the Indian annual poverty rate can be attributed to high level of health expenditure relative to total household expenditure (Garg, 2007).

In the seminal empirical work, Robert Townsend (1994) showed that in rural India health crisis in a household induced significant declines both in total and non-health consumption, a drop more severe than that associated with any other type of crisis. Townsend examined a household's ability to 'consumption smooth', the maintaining of a level consumption over a

period of time. Health crises induce expenditure on health and may also induce declines in household income. The inability to consumption smooth over a time period due to health crisis has been confirmed elsewhere (Gertler 2002; Deaton,1997; Cohen 2003, Wyszewianski 1986) for other developing countries, defined here as low and middle-income countries (LMICs) by the World Bank classification system (World Bank 2008). Even a minor health shock can cause a major impact on poor persons' ability to work and curtail their earning capacity and given the strong link between health and income at low income levels, a health shock usually affects poor the most (Cohen 2003).

Catastrophic spending (for each individual/household) is usually defined as occurring when hospitalization spending for that person/household as a proportion of *ability to pay* (household consumption spending *less* combined survival income for all household members) exceeds a certain threshold (Xu 2003, Mahal 2010). The threshold value can range from 5 to 40% (Wyszewianski 1986, Berki SE 1986, Mahal 2010, Xu 2003, WHO 2000); thus there is not much agreement on how to measure this notion (Pradhan 2002, Ranson 2002, Wagstaff 2003, Russell 2004). The measure is considered theoretically unsound (Flores 2008); and the welfare implication of the measure is not clear especially when measured across income classes. It is most likely true that for the already impoverished a 40% drop in their usual consumption is likely to impact their wellbeing significantly. The need for large one time or even large life time health expenditure can be prevented if health insurance successfully spreads risk across time and people. Thus, social health insurance has the potential to prevent such impending impoverishment.

Description of the Condition

Social Health Insurance Schemes

Over the past decades many LMIC have found it increasingly difficult to sustain sufficient financing for health care particularly for the poor and as such international policy makers have been active in recommending a range of suitable measures including conditional cash transfers-cost sharing arrangements and a variety of health insurance schemes including social health insurance (Lagarde 2009, Ekman 2004). A focus on social health insurance schemes has been gaining strength. The WHO in 2005 passed a resolution that it would support a strategy to mobilize more resources for health, for risk pooling, increase access to health care for the poor and deliver quality health care (WHO 2005) in all its member states but especially low income countries. This is a strategy supported by the World Bank (Hsiao 2007).

Definition

Social health insurance schemes are generally understood as health insurance schemes provided by governments to its citizens, especially to low and middle income populations. Recently, apart from governments, several non-government organisations at the community level provide social health insurance in developing countries (Churchil 2006, Dror et al 2002). Social health insurance pools both the health risks of its members, on the one hand, and the contributions of enterprises, households and government, on the other, and is generally organized by national

governments (Carrin 2002, WHO 2004). Most social health insurance schemes combine different sources of funds, with government often contributing on behalf of people who cannot afford to pay themselves (WHO 2004). Social health insurance differs from 'tax based financing' which typically entitles all citizens (and sometimes residents) to services thereby giving universal coverage. However, social health insurance entitlement is linked to a contribution made by, or on behalf of, specific individuals in the population (WHO 2004).

Objectives
The prime objectives of social health insurance are:
a) to provide health care that avoids large out of pocket expenditure;
b) increase appropriate utilisation of health services;
c) improved health status. (International Labour Office 2008)

Social health insurance can bring about welfare improvement through improved health status and maintenance of non-health consumption goods through ensuring that health expenditures are smoothed over time and that there is no significant decline in household labour supply (Varian 1992, Townsend 1994).

Intervention

Development of schemes
Historically, social health insurance originated in developed countries as work related insurance programs and the coverage has been gradually expanded to the non-working parts of the population (Saltman 2004) (Table 1). In recent years, social health insurance is being introduced in parts of the developing world as an alternative to tax financing and out-of pocket payments (Vietnam 1993, Nigeria 1997, Tanzania 2001 and Ghana 2005). Discussions on implementation of schemes are underway in several countries (South Africa, Zimbabwe, Cambodia, Laos, Malaysia) and countries with social health insurance already in place are making vigorous efforts to extend coverage to the informal sector (i.e. self-and unemployed, retired people) (e.g. Colombia, Mexico, Philippines, and Vietnam) (Wagstaff 2007). There are examples of social health insurance schemes arising out of community-based health insurance organized through NGOs and often involving other elements such as micro-credit. These initiatives are generally weak in terms of efficiency and sustainability but have provided a means of development for government supported extensions to enable greater population coverage (Alkenbrack 2008).

Table 1. Introducing Social Health Insurance in Low- and Middle-Income Countries

Region	*Year introduced*	*Coverage*	*Per capita income (US $)*
Africa			
Key feature:	Gradual introduction for civil servants and formal sector		
Burundi	1984	10-15 %	150
Kenya	1960s	25 %	260
Namibia	1980s	10 %	2,030
Eastern Europe & FSU			
Key feature:	Transition from tax funded to social insurance		
Estonia	1992	94 %	2,820
Hungary	1992	High[a]	3,840
Russia	1991	High[a]	1,910
Slovenia	1993	High[a]	7,140
Asia			
Key feature (transitional):	Response to declining level of state funding		
Kazakhstan	1995	70-80%	1,110
Vietnam	1993	10 %	200
Key feature (other):	Expansion a response to the growth of the economy		
Indonesia	1968	13 %	790
Thailand	1990	13 %	2,210
South Korea	1977	94 %	8,220
Latin America & Caribbean			
Key feature:	Introduced from 1920s as part of wider package of pensions, unemployment and other benefits		
El Salvador	1960s	11 %	1,480
Argentina	1920s	90 %	8,060
Mexico	1930s	42 %	4,010
Bolivia	1930s	18 %	770
Paraguay	1930s	14 %	1,570

a. Introduced from a 100 percent universal tax funded base—coverage thought to be falling as nonworking lose effective entitlement.
Source: From Witter, et al. [41]

Impact of social health insurance

The effects of different social health insurance schemes LMICs have in recent years been evaluated (Hsiao 2007) including trials looking into specific effects of these schemes (Ranson 2007, King 2007, De Allegri 2008). Moreover, social health insurance does not provide complete insurance even if it covers the health care costs. (Wagstaff 2009) With incomplete social health

insurance there may also be a significant impact on household production through changes in labour supply, reshaping durable consumption or postponement of important life cycle events, drawing down of precautionary savings and borrowing (Gertler 2002, Russell 2004, Flores 2009, Wagstaff 2009). Management of risk within the household may well imply that even with the presence of social health insurance, a substantial amount of borrowing enhances the ability to smooth consumption over the period of major illnesses (Dercon 2007, Gertler 2002, GTZ 2005). Other barriers exist in accessing healthcare including distance to the nearest healthcare facility, lack of knowledge, skills and capabilities in filling forms and filing claims, lack of money to pay admission fees (in schemes that reimburse people), and indifferent attitudes of doctors (Sinha 2006). Furthermore, a more recent Mexican trial, in contrast with other published studies, did not find any effect of a social health insurance scheme (claimed to be universal) on health outcomes, utilization or spending on medications which challenges beliefs held by proponents of universal social health insurance schemes (King 2007). Despite this evidence, social health insurance schemes have been given priority in policies of several developing countries. (WHO 2007, World Bank 2009)

Potential limitations and considerations in conducting a review of evaluation studies

Theoretical framework: Following recommendations of a theory-based approach to evaluation we would expect studies to offer explanations that follow economic as well as social and psychological theory that may shape uptake of insurance and subsequent health seeking behaviour (White 2009, Mulainathan 2005). The welfare impact of social health insurance should be judged in terms of some measure of utilisation of health care for treatment, take up of preventive care, avoidance of large one time expenditure and improvement in health by facilitating access to care (Wagstaff 2010). In addition to ascertaining how well studies address the issue of household coping strategies it will be important to assess in this review both as part of study quality and in understanding pathways by which social health insurance schemes operate.

Selective outcome reporting: The social health insurance literature has reported multiple outcome measures including utilisation of health care, reduction in health care expenditure by income class, use of health care by income class (Ranson 2007, King 2007, De Allegri 2008, Wagstaff 2010, WHO 2005). Which outcome is reported may depend on what administrative data were collected or the surveys used to carry out a study. We will write to authors for complete data and if data are not available will undertake sensitivity analysis examining the effect of including and excluding studies with incomplete reporting of outcomes.

Appropriate utilisation of social health care insurance: Social health insurance allows health care to be accessed free or at low prices at the point of contact with the provider which may lead to an increase in inappropriate utilisation as the cost of receiving any service is small after one has paid the insurance premium; this is known as moral hazard of insurance. This type utilisation has no impact on health. Healthcare providers can offer guidance to patients to receive services that may also have no health effect, as patients may readily accept any particular care at a low or zero cost (Pauly 1968 and 1974, Zeckhauser 1970, Kotowitz 1987). Since people in developing countries are already ‘under utilising’ healthcare, an increase in uptake of

healthcare utilization should not necessarily be considered a moral hazard but could be a 'welfare gain' (Nyman 2003). This dilemma, whether over utilization of healthcare due to health insurance coverage is a moral hazard or not is a potential limitation for assessing the impact of health insurance on 'changes in utilization' if additional data on appropriateness of utilization are not available.

Enrolment: Studies indicate that the uptake of any type of insurance in developing countries is low; thus an important element of impact of insurance is its rate of enrolment (Gine 2007). However, the enrolment in voluntary health insurance schemes is subject to the problem of selection bias through adverse selection — the practice of more unhealthy people joining health insurance, and cream skimming — a practice by insurers enrolling only the healthy people and conveniently excluding the high risk population group consisting of aged, poor, and women from the insurance program (Gustafson 2009, Jack 1999; World Bank Development Report 1993).

Adverse selection arises when asymmetric information exists between insurers and consumers about individual health risk. People who insure themselves are those who are increasingly certain that they will need health insurance (high risk individuals) and hence they buy more insurance (World Bank Development Report 1993, Jack, 1999). Adverse selection introduces unobservable heterogeneity upon selection into the insurance between the insured and the non-insured in regards to factors that can affect important health outcome and utilisation measurements (Morris *et al.*2007, Wagstaff 2010). Thus it will affect enrolment and utilisation. Correction for this factor is an important element in proper analysis of insurance schemes. The majority of studies which measured the impact of health insurance in terms of utilisation did not distinguish whether changes in enrolment were subject to adverse selection (Allegri et al. 2008, Ranson et al. 2007, Wagstaff 2000, King et al 2009). Consequently, this bias will be one of the limitations in our review which we will attempt to address and discuss.

Cream skimming motivates bundled price and service offerings that would be attractive to healthier people. This can affect enrolment. As most of the insurance schemes offered to the poor are government or non-profit sponsored we do not expect cream skimming to play a major role, although insurance schemes will leave out provisions for many important needs. The outcomes of schemes may be dependent on the health care provision available making this an important covariate to be taken account of in our review.

Differences in social health insurance schemes: There may be heterogeneity in the organisation of social health insurance schemes across and within countries that may impact beneficiaries and result in making comparison of studies social health insurance schemes difficult. The anticipated variations would include:

1) insured amount and limitations on care that can be received,
2) premium (whether subsidised or not),
3) comprehensiveness of health insurance benefit packages: whether both outpatient care and in-patient care are covered and/or whether only curative care or preventive and promotive healthcare are included
4) use of private healthcare, public healthcare or both are covered in the schemes,

5) beneficiaries' co-payments and if yes, by how much.

We shall attempt to address these issues both statistically (where feasible) and by narrative review as described below.

Description of the target population for social health care insurance

We will only include studies conducted in LMIC as defined in 2008 (World Bank 2008). Along with mandated usually actuarially fair priced insurance for the well off and those employed in the formal sector, typically social health insurance schemes at a subsidised cost target the poorest section of society but we will include both low and middle income populations, especially those in the informal sector, as our study units (Wagstaff, 2009). Since the definition of low and middle income population varies across countries, we will use the official definition used by respective countries as well as the definitions adopted by the individual studies.

Description of the intervention

We will classify social health insurance into two groups: government based and community based and further classify on the basis of:

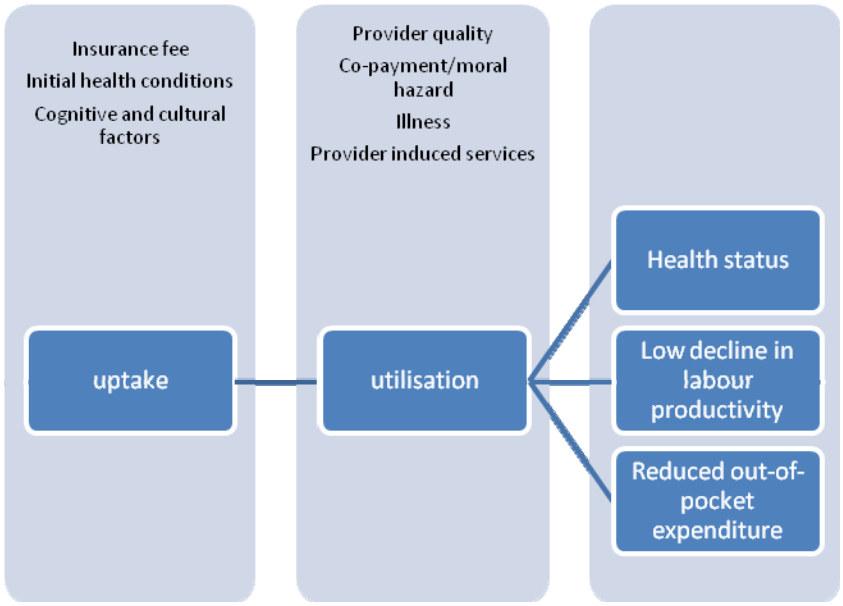
i. Sources of financing (premium subsidized or not)
ii. Nature of enrolment (compulsory or voluntary)
iii. Benefit packages covered (comprehensive or partial; total amount monetary amount of coverage) etc. For eg. Some SHI cover only hospitalization benefit while some other covers both hospitalization and non-hospitalization; some offer monetary cap.
iv. Cost-sharing where the beneficiaries have to pay certain portion of health expenditure

In our review, we define social health insurance as those health insurance schemes that target low and middle income people in developing countries and are organized by governments. In our definition, we also include those community based health insurance (CBHI) programs in developing countries that are receiving financial support from government or have large financial backing from donor funding and managed through non-governmental mechanisms. There may also be pilot randomized field level studies that examine how well insurance schemes can meet the health care needs of the poor and how such schemes can be analysed (Ranson 2007, Duflo 2007). As CBHI have been well studied, and in some cases the quality of evaluations of small programs can be high (Alkenbrack 2008, Lagarde 2009), we will include them to examine what lessons can be learned for scaling them up to government funded social health insurance schemes. We will be reliant of the authors' assessments of the potential for scaling up and possibly from prospective knowledge of whether or not scaling up was implemented from information provided by authors. For those for which we cannot assess scaling up potential we will note important lessons that may be relevant for the functionality of health insurance schemes in general.

How social health insurance works? Figure 1 summarises the pathways or 'a theory of change' as to how health insurance ultimately affects wellbeing; the figure summarises some of the

discussion above which uses standard theory of insurance applied to health care (Varian 1992, and Morris 2007). The primary purpose of insurance is to smooth out expenditure on a good for which the need arises unexpectedly; in the case of health insurance the good is health care over a life time. A further purpose is to provide subsidies across people as the particular need may not arise for some of the people who pay into a financial pool. Thus insurance provides risk pooling across time and people due to differentials in risk across time and people (Varian 1992). The uptake of insurance may depend on how one perceives one's own risk, understanding of the product and social factors such as trust in financial institutions as one pays into a fund where services are delivered if just in case some event occurs. The first column in Figure 1 depicts the offer of insurance and the consumer reaction. The second column depicts that the utilisation of health care may depend on the quality of service, fees charged at point of contact and guidance, which can be misleading, from the service provider. The third column indicates that proper health care delivered through insurance can improve health status, reduce out of pocket expenditure and lower decline in labour productivity or supply. The two non-health outcomes make up consumption smoothing.

Figure 1: A theory of change due to health insurance (constructed from economic theory of insurance and health insurance; Varian 1992; Morris 2007)



Why it is important to do this review

We located a number of related systematic reviews on the sources of financing of insurance schemes world-wide (Ekman 2004, Fowler 2010, Hanratty 2007) and an unpublished paper not yet released that focuses on the review of risk-sharing schemes for health care (Lagarde 2009) at the community level.

Fowler et al (2009), limited to the population in the United States, sought to determine whether differences in critical care access, delivery, and patient outcomes were associated with health insurance status. It did not examine the implication of the insurance status on the financial well being of the population or whether it protected individuals and households from catastrophic health expenditure. The results indicated that uninsured critically ill patients do not receive appropriate care and may experience worse clinical outcomes.

Hanratty et al (2007) focused on equity in use of curative health services in universal systems, was limited to developed countries and did not specifically examine the impacts of health insurance. The results indicated a pro-rich bias in use of specialist hospital services and a equitable access to primary health care by different socioeconomic groups.

Ekman (2004) focused on community-based health insurance in low-income populations in developing countries. He concluded that community-based health insurance provide some financial protection by reducing out-of-pocket spending. This review, however, did not consider whether these schemes protected households from catastrophic health expenditure, nor whether they protected households from falling below the poverty line. Moreover, the review was limited to community health insurance schemes and the search was only up to 2003. An update on the available literature would therefore be beneficial.

Despite support from international bodies, there has been no systematic review evaluating the impact of social health insurance schemes on health outcomes, access to healthcare and impoverishment due to health care expenditures in developing countries. The lack of a systematic or even a limited review may reflect lack of high quality evaluations of social health insurance schemes (WHO 2007), or that the diversity of schemes may not lead to coherent conclusions (Hsiao 2007). It may also reflect strong prior beliefs among policy makers (based on selective readings of the evidence) and/or limited alternative policy options. A systematic review would provide robust evidence to enable policy makers and other stake holders in developing countries to understand the impact and relevance of social health insurance schemes.

Objectives

To assess changes with the introduction of social health insurance in:

1. the health status of patients using the health services provided.

2. out of pocket expenditure per episode of illness relative to income and by income class (catastrophic health spending).

3. the utilisation of a health service use.

The systematic review will examine how well the impacts of insurance schemes are assessed.

Methods

Criteria for considering studies for this review

Types of studies

Social health insurance schemes that are organized or supported by governments and community organisation in developing countries, which targets the low and middle income population. Universal health insurance scheme covering all population will also be included but analysis will be limited to the impact low and middle income population.

1. Government based social health insurance schemes

2. Community based social health insurance schemes

Inclusion Criteria: Studies will have to have measured or reported on impact through a comparator either through a contemporaneous control or constructed control from data containing similar information collected in similar time period. Studies must clearly define temporal horizons where outcomes are measured before and after the introduction of a health insurance scheme.

The type of studies designs to be included will be:

1. Randomised Controlled (Field) Trials
2. Quasi-randomised controlled trials where methods of allocating are not random**,** but are intended to produce similar groupings of treatment and control, e.g methods include:
    i. Propensity score matching methods
    ii. Regression discontinuity design
3. Controlled before and after studies (CBA); If the pre and post intervention periods for study and control groups are the same and the choice of the control site is appropriate, e.g. similar socioeconomic characteristics and/or no major differences in the baseline. In the economics literature this is known as difference in difference (DiD) approach.
4. Regression studies where probability of selection into treatment is taken into account through instrumental variables.
5. Interrupted time series studies (ITS): If the point in time when the intervention/change occurred is clearly defined and there are at least 3 or more data points before and after the intervention.
6. Qualitative studies meeting the check list in Annex Table.

Exclusion Criteria: the following studies will be excluded:

- In which social health insurance is a component of a multiple intervention package.
- Those without any of the specified primary outcomes
- Where social health insurance scheme only cover government employees and their dependents.

- Those analysing private for-profit health insurance schemes that are funded by private source and employers.
- Those analysing small schemes that offer auxiliary schemes for the poor while providing for-profit schemes.
- Studies before 1990.

Types of participants

1. Studies taken place in low and middle income countries as defined by the World Bank.
2. Both low and middle income population from LMIC.

Types of interventions

Social health insurance schemes in developing countries including both:

1. Government based health insurance programs

2. Community based health insurance programs

Types of outcome measures

The welfare impact of social health insurance should be judged in terms of some measure of utilisation of health care for treatment, take up of preventive care, avoidance of large one time expenditure and improvement in health by being able to receive adequate care (Wagstaff 2010). More specifically, our primary and secondary outcomes are as follows:

Primary outcomes

1. Health outcomes, including incidence of mortality and morbidity
2. Consumption Smoothing
    i. Out-of-pocket expenditure per episode of illness or expenditure as a share of income (recognising to the extent they can be classified as catastrophic expenditure).
    ii. Household labour supply or maintenance of household income and assets (impoverishment)
3. Health care utilisation (Outpatient care visits and hospitalisation)
    i. Utilisation by severity (to the extent possible)
    ii. Appropriation Utilisation Rate (to the extent possible), as this may indicate the impact of the role of moral hazard plays on utilisation.

Intermediary Outcome

1. Enrolment rate

Secondary outcomes

1. Self perceived general health and/or quality of life
2. Patient satisfaction
3. Health Care expenditure

Search methods for identification of studies

We will attempt to identify all relevant studies regardless of language or publication status (published, unpublished, in press, and in progress).

Electronic searches

We will search the specialised register of the Cochrane Effective Practice and Organisation of Care Group (EPOCH), the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, ISI Citations Index, EconLit, IDEAS and ELDIS to identify studies published from 1990 when health insurance schemes were being introduced to LMIC.

Searching other resources

We will search the web sites of the RAND Corporation, the World Bank, the World Health Organization, USAID and other relevant sites identified during the search process.

Conference proceedings will be checked, including:

- GTZ-ILO-WHO-Consortium on Social Health Protection in Developing Countries, 2005,2006,2007 (Paris, Kigali)(http://www.socialhealthprotection.org/)
- Annual International Conference on Health Economics, Management & Policy, Athens, Greece; 2002-2010 (http://www.atiner.gr /docs/Health.htm)
- World Congress on Health Economics by International Health Economics Associations (IHEA): 1st to the 7th conference(http://www.healtheconomics.org/congress/)
- The Annual World Bank Conference on Development Economics(http://go.worldbank.org/6YVGDJNWM0)
- Malawi Conference on Micro Health Insurance in Africa (http://www.microfinancefocus.com/news/2009/09/10/malawi-conference-on-micro-health-insurance-in-africa/)
- Canadian Conference on Global Health (http://www.csih.org/en/conference/archives.asp)
- Asian Conference on Micro insurance (http://www.asiainsurancereview.com/pages/conference_details.asp?id=149)

The reference lists of identified papers will be examined. In addition, we will perform citation searches of key studies included in the review and will also contact the authors of key reports

and healthcare finance experts for information about other studies missed by us during the search process, including unpublished and ongoing studies.

Contacts with key investigators

We will contact authors that appear as prominent researchers in published and working papers. We will contact these authors to solicit what current work and unpublished work we should investigate.

Selection of studies

Two pairs of the authors (AS+SV, FT+EM) will independently screen all citations and abstracts identified by the search strategy to identify potentially eligible studies. These two pairs of authors will also screen all the potentially eligible studies that will be ascertained in paper form. Should any data be obscure or missing, we will aim to contact the authors of the studies for clarification to ensure eligibility. We will resolve any differences in opinion with the lead authors (AA, SE). A flow chart will be presented to provide information on the selection of studies (Moher 2009).

Data extraction and management

Data will be extracted independently by two reviewers (SK + SV) using a standardised form and according to the standard Cochrane EPOC checklist (http://epoc.cochrane.org/epoc-resources-review-authors). We will resolve any differences in opinion with the lead authors (AA+SE). Tables will be prepared for each type of social health insurance scheme, including the study ID, country and date of the intervention, characteristics of the scheme and the individual (facility/population level) and external/national level, health outcomes. Authors of reports will be approached (where necessary) for additional data and/or for clarification of methods or outcomes used in their studies.

As noted already, adverse selection may entail that for voluntary insurance schemes those with insurance will most likely differ from the control groups by unobservable factors that affect the outcomes of interest. Statistical identification problems may be severe in analysing the effects of social health insurance due to adverse selection and moral hazard (Wagstaff 2010). Identifying the outcome not only involves choosing the right indicators, we must take into account that control groups may not easily be comparable to the treatment group even when the study may have used a randomised design. Table 2 depicts outcome measures we are likely to find. The uptake of insurance is affected by initial health condition or expectation of one's ill health; thus in most naive evaluation methods health status of the insured would be compared to those uninsured who are likely to be less ill in general. Utilisation and other outcome measures may also be affected. All studies will be assessed on how well the identification problems are taken into account; the time-frame of the study should also be clear. Studies will be less able to correct

for moral hazard and provider induced utilisation of health care but any information on these issues will be recorded (Ekman 2004 and Wagstaff 2010).

Table 2: Quantitative Approach to Outcome Identification

Indicator	Metric	Comments and identification problems
Uptake	• Enrolment and drop-out rates	• Heterogeneity of adoption across social groups, gender, extreme poor, and initial health conditions (expectation of favourable outcomes)
Utilisation	• Use of health facilities during a year • Administration rates of selected procedures (example in-patient enrolment)	• Self-selection into the insurance because of: - Adverse selection (initial conditions) - Moral hazard (overuse of health services) Provider-induced services
Outcomes: • **Health status**	• Age specific mortality • Morbidity (example diabetic care, cardiovascular conditions)	• Conditioned by the time frame of studies and self-selection
• **Out-of-pocket expenditure**	• Out-of-pocket expenditure as a share of income • Expenditure per illness condition by income class	
• **Labour productivity**	• Working days lost • Household labour supply	

Assessment of risk of bias in included studies

Two authors (EM + FT) will independently assess the risk of bias in the included studies. Risk of bias will be explored following the guidelines set out in the Cochrane Handbook; for example publication bias will be assessed with funnel plot for the primary outcomes. (Higgins 2008)

For trials, we will assess the following components for each of the trials: sequence generation, allocation concealment, blinding, sampling strategy, reliability of outcomes measures, baseline measurement of outcomes, contamination, attrition, incomplete outcome data, selective outcome reporting, appropriateness of analysis and protection against other biases such as exclusion and detection bias. We will present our findings in a standard format as recommended by the Cochrane Collaboration. (Higgins 2008). We will assess as to how well the studies can recover

the average treatment effect on the treated or the 'local area treatment effect' (Angrist 1996) amid problems of selection into treatment due to heterogeneous impact expectation and contamination.

The CBA or DiD studies will be assessed for the following criteria: baseline measurement of outcomes, baseline characteristics of studies using second site as control, exclusion or selection bias, contamination, reliable primary outcomes measures, selective outcome reporting and appropriate analysis of data.

For those using matching methods without contemporaneous control we will assess the matching method and the comparability of the surveys used. For the use of instrumental approach to control for selection into the treatment we will assess the instruments used.

The criteria for ITS studies will be assessed for the following criteria: protection against secular changes, appropriate analysis of the data (or re-analysis possible), selection bias, reliability of outcome data, number of points specified, intervention effect specified, selective outcome reporting and detection bias.

For each of the components for the above studies, we will assign a judgment regarding the risk of bias as 'yes', 'no' or 'unclear'. (Higgins 2008) The studies will then be graded as 'A' if all criteria are marked 'yes', 'B' if one or more criteria are marked 'unclear', and 'C' if one or more criteria are marked 'no', with 'A' meaning low risk of bias, 'B' meaning moderate risk of bias, and 'C' meaning high risk of bias. We will contact the study authors for clarification if any of the components is unclear or is not stated in the report.

For studies with an ethnographic component, a critical appraisal tool devised by CASP 2002 will be used. (Campbell 2003) The main quality criteria include methodology used, sampling, rigour and appropriateness of data collection and analysis and justification of the interpretation. (Campbell et al 2003). For these studies we envision a checklist that appears in the Annex.

For all types of studies, other factors that will be taken into consideration while assessing quality include how well the studies have addressed the issue of household coping strategies, and whether they have reported on the appropriateness of healthcare service use if there has been an increase in the same due to the moral hazard effect

Data collection and analysis

Both impact evaluation and health insurance for the poor are new phenomena in LMICs, as such, we anticipate the literature will not be extensive. The evidence may indicate that insurance schemes are varied and as such no easy pooled estimates of the outcome of each type of insurance may be possible.

Methods of synthesis

A critical narrative summary of evaluation techniques used in the studies will be offered as a first step, under which we will summarise characteristics of the settings in which the studies were carried out and of the patients, characteristics of the interventions, outcome measures and methods (SK+SV).

Data will be pooled (where possible) following guidance by the Cochrane Collaboration Effective Practice and Organisation of Care (EPOC) group with whom the review will be registered formally which will facilitate future updating (Higgins 2008). We will carry out a formal meta-analysis of quantitative findings only if we are able to identify a sufficient number of studies and if these studies are sufficiently homogeneous regarding population studied, interventions used and comparisons made. We will perform data synthesis using Review Manager 5 (Higgins 2008). Risk of bias will be explored following the guidelines set out in the Cochrane Handbook. Where sufficient data are available we will perform subgroup analyses related to setting of social health insurance scheme and type of scheme. We will attempt to the extend meta-regression analysis of percentage of enrolment by types insurance and population characteristics. Dependent variables may use summary measure of determinants from the studies reviewed (Alston 2000).

If we do not find enough studies for a meta-analysis, we will report the review as a descriptive narrative. The details of each study (type of intervention and outcomes) will be presented in a tabular format, along with a summary of key contextual factors that might have affected study outcomes. We will attempt to judge how generalisable findings are by documenting contextual factors that can affect generalisability, and how consistent studies are in finding similar effects across different outcomes. We will then quantify the magnitude of effect for each outcome of each study, and an attempt will be made to standardize this measure, for instance by using percentage of change from baseline as a consistent indicator. These will then be categorized qualitatively as ‘high’, ‘medium’ and ‘low’ (Lagarde 2006). The findings for each outcome will then be summarized by commenting on the amount of evidence available, the quality of that evidence and the direction and magnitude of the findings. Qualitative reports from several studies will be synthesized using meta-ethnography methods (Barnett 2009).

Findings from qualitative and quantitative studies will be integrated using parallel synthesis methods (Spencer 2003).

Assessment of heterogeneity

If meta-analysis is possible, we will explore heterogeneity using the I^2 statistic and will produce forest plots which will assist us in exploring the underlying causes of heterogeneity between studies. Random effects models will be applied if heterogeneity is moderate and where it is high (>75%) no pooled estimates will be reported. The generated forest plots will assist us in interpreting the degree of heterogeneity between studies. (Egger 1997, Higgins 2002).

We will attempt to the extend meta-regression analysis of percentage of enrolment by types insurance and population characteristics. Dependent variables may use summary measure of determinants from the studies reviewed (Alston 2000). Specifically we will attempt to report the disaggregated measures on:

- The poorest quintile of the population or other vulnerable fraction of the targeted group
- Women, especially those not in child bearing age as maternal care is free in many countries

Sensitivity analysis

If sufficient data are available we will undertake sensitivity analysis to ensure robustness of the data by looking at quality of data and study design.

User Involvement

To ensure the work is widely circulated and discussed internationally the protocol and interim findings will be made available to health policy advisors not only in DfID but also in GTZ, World Bank, Rockefeller Foundation and other major organisations. We will seek the advice of our policy lead to identify the members of such organisations in India who would be willing to act as local policy advisors to the project. Through the help of our policy lead we will first present findings to the Indian Ministry of Labour and Ministry of Health and Family Welfare at the secretarial level. We will hold meetings with the health division at Department for International Development (DFID) to explain our findings. We will expand our user involvement through networking with authors of primary studies and will explore the possibility of organising a social health insurance website and e-discussion group. We will seek an audience with WHO, South-east Regional Office of WHO, Oxfam and the World Bank's Health Nutrition and Policy division. As part of our study intends to extend research on impact evaluation of social health insurance, we will aim organise a session on social health insurance in LMIC at the International Health Economics Biennial Congress in Toronto in 2011.

Deriving conclusions and implications

The conclusions of the review will be presented in the following ways:

- Visual tabular summaries of descriptions of insurance found will be made; categories would be defined by scheme, source of financing, package of care include, and target group (intended or already reached)
- Table(s) will present summary of type of study by evaluation methods, outcome reported, ranking of risk of bias or by classifying the statistical analysis of different biases

- Table(s) will present of summaries of findings according to outcome and number of studies reporting particular results and some distinct feature of the studies that would help interpret the results.

The final report will also discuss implications of the study for policy makers and future research. In particular, policy makers and academics will be advised regarding:

- The generalisability of the results observed: to what extent the aggregate programme outcomes found are representative of the expected outcomes in areas where programmes have not yet been implemented
- Evidence gaps: an assessment of the size and the quality of the evidence available
- Evaluation gaps: an assessment of methodological innovations to improve robustness of evaluation, health-related outcomes and collection of contextual data to aid interpretation of primary outcomes
- Theoretical gaps: an assessment of knowledge gaps in our understanding of programmes' effectiveness along the causal chain of the theory of change

Sources of support

Internal sources

- South Asia Network for Chronic Disease, Public Health Foundation of India, India
- South Asian Cochrane Network and Centre, India
- London School of Hygiene and Tropical Medicine, United Kingdom

External sources

- DFID: Grant for Systematic Reviews in International Development

Reviewers:

Billy Stewart – Policy Lead
Anne Mills – Internal Reviewer
Adam Wagstaff– External Reviewer

Blinded- Chosen by Policy Lead

References

Alkenbrack 2008

Alkenbrack S, Extending health insurance to the informal sector: A summary of approaches, London School of Hygiene and Tropical Medicine, Mimeo, 2008.

Angrist 1996

Angrist J, Imbens G and Rubin D, Identification of causal inference using instrumental variable, Review of Economics and Statistics, 1996, 91:434, 444-455.

Alston 2000

Alston J, Chan-Kang M, Marra P, Pardey N, Wyatt J. A Meta-analysis of rates of return to Agricultural R & D. International Food Policy Research Institute 2000

Barnett 2009

Barnett-Page E, Thomas J. Methods for the synthesis of qualitative research: a critical review. BMC Medical Research Methodology 2009; 9: 59

Berki 1986

Berki S. A look at catastrophic medical expenses and the poor. *Health Affairs* 1986; **5:** 139–45.

Carrin 2004

Carrin G and James C(2004). Reaching universal coverage via social health insurance: key design features in the transition period. Health Financing Policy Issue Paper, WHO.

Campbell 2003

Campbell R, Pound P, Pope C, Brotten N et al. Evaluating meta ethnography: a synthesis of qualitative research on experiences of diabetes and diabetes care. Social Science and Medicine 2003; 56: 671-684

Churchill 2006

Churchill, C. (2006). What is insurance for the poor? in C. Churchill (ed.), Protecting the

poor, A microinsurance compendium, International Labor Organisation, Geneva.

Cohen 2003

Cohen M, Sebstad J. Making Micro-insurance Work for Clients. Micro-insurance Center, Micro-insurance Center Briefing Note 2003 #3.

De Allegri 2008

De Allegri M, Pokhrel S, Becher H, Dong H, Mansmann, Kouyaté B, Kynast-Wolf G, Gbangou A, Sanon M, Bridges J, Sauerborn R.. Step-wedge cluster randomised community-based trials. An application to the study of the impact of community health insurance. BMC Health Research Policy and Systems 2008; 6(1):10.

Deaton 1997,

Deaton A. The Analysis of Household Surveys. Baltimore: Johns Hopkins University Press, 1997.

Dercon 2002

Dercon S. Income Risk, Coping Strategies and Safety Nets, World Bank Research Observer. 2002; 17:141-166.

Dror 2002

Dror DM, Preker AS (Editors): Social Reinsurance: A New Approach to Sustainable Community Health Financing, (Washington), World Bank & ILO, 2002, xvii+518 pp.

Duflo 2007

Duflo E, Banerjee A, Neelamraju K and Chen T. An Impact Evaluation of the Provision of Health Insurance Through Microfinance Networks in Rural India, Poverty Action Lab, 2007. http://www.povertyactionlab.org/sites/default/files/publications/59_CMF_Progress_Brief_Impact_Evaluation.pdf, Accessed 7 July 2010,

Egger 1997

Egger M, Davey Smith GD, Schneider M and Minder C. Bias in meta-analysis detected by simple graphical test.. BMJ 1997;315:629-34.

Ekman 2004

Eman B. Community based health insurance in low-income countries: a systematic review of the evidence. Helath Policy and Planning 2004; 19 (5): 249-70

Flores 2008

Flores G, Krishnakumar J, O'Donnell, O and van Doorslaer E, Coping with healthcare costs: Implication for measurement of catastrophic expenditure and poverty, Health Economics; 17: 1393-1412.

Fowler 2010

Fowler R, Noyahr L, Thornton J, Pinto R, Kahn J et al. An official Thoracic Society Systematic Review: the association between health insurance status and access, care delivery and outcomes for patients who are critically ill. Am J Crit CAer; 2010: 181: 1003-11

Garg 2009

Garg C, Karan A. Reducing out-of-pocket expenditures to reduce poverty: a disaggregated analysis at rural-urban and state level in India, Health Policy Plan. 2009 24: 116-128.

Gertler 2002

Gertler P, and Gruber J. Insuring Consumption against Illness. American Economic Review. 2002; 92(1):51-70.

Gine 2007

Gine X, and Yang D, 2007 Insurance, Credit, and Technology Adoption: Field Experimental Evidence from Malawi, *Policy Research Working Paper 4425* The World Bank, Washington DC. 2007.

GTZ 2005

GTZ, ILO and WHO. Recommendations for Action The International Conference on Social Health Insurance in Developing Countries. GTZ, ILO, and WHO,Geneva 2005.

Gustafsson 2009

Gustafsson-Wright E, Asfaw A, van der Gaag J. Willingness to pay for health insurance: An analysis of the potential market for new low-cost health insurance products in Namibia. Social Science and Medicine, 2009; 69:1351-9.

Hanratty 2007

Hanratty B, Zhang T, Whitehead M. How close have universal health systems come to achieving equity in use of curative services? A systematic review. Int J Health Serv 2007; 37 (1) 89-109

Higgins 2002

Higgins J, Thompson S. Quantifying heterogeneity in a meta analysis.. Statistics in Medicine 2002; 21:1539-58.

Higgins 2008

Higgins J, Green S, editor(s). Cochrane Handbook for Systematic Reviews of Interventions,. Version 5.0.1 (updated September 2008) edition. Available from www.cochrane-handbook.org. Accessed 23 March 2010: The Cochrane Collaboration, 2008.

Hsiao 2007

Hsiao W, Shaw RP. Social Health Insurance for Developing Nations. The World Bank Washington, D.C. 2007

International Labour Office 2008

International Labour Office (ILO). Social Health Protection: An ILO strategy towards universal access to health care 2008. International Labour Office. Social Security Department, Geneva

Jack 1999

William J. Principles of Health Economics in Developing Countries. World Bank Institute; Washington DC 1999.

King 2007

King G, Gakidou E, Ravishankar N, Moore R, Lakin J, Vargas M, et al. A "politically robust" experimental design for public policy evaluation, with application to the Mexican universal health insurance program.. J Policy Anal Manage 2007;26:479-506.

Kotowitz Y 1987

Kotowitz Y. Moral Hazard, The New Palgrave: A Dictionary of Economics. Eatwell J, ed. London: MacMillan Press, 1987.

Lagarde 2009

Largarde M, Palmer N. The impact of health financing strategies on access in low and middle income countries. The Cochrane Collaboration; 2009; Protocol Issue 4. Wiley Publishers. www.thecochranelibrary.com

Largarde M, Haines A, Palmer N. The impact of conditional cash transfers on health outcomes and use of health services use in low and middle income countries. The Cochrane Collaboration; 2009; Review Issue 4. Wiley Publishers. www.thecochranelibrary.com

Mahal 2010

Mahal A, Anup K and Engelgau M: The Economic Implications of Non-Communicable Disease for India, Health, Nutrition and Population (HNP) Discussion Paper 2010. The World Bank.

Mays 2005

Mays N, Pope C, Popay J. Systematically reviewing qualitative and quantitative evidence to inform management and policy- making in the health field. J Health Serv Res Pol 2005;10(Suppl 1):6-20.

Mohanan 2008

Mohanan M. Causal Effects of Health Shocks on Consumption and Debt: Evidence from Bus Accident Injuries. Unpublished Manuscript Harvard University 2008.

Moher 2009

Moher D, Liberati A and Tetzlaff J. The PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: The PRISMA Statement. PLoS Med. 2009; 6(6).

Morris, 2007

Morris A, Devlin N and Parkin D, Economic Analysis, Chichester, UK; John Wiley & Sons, 2007.

Mulainathan 2005

Mulainathan S. Development economics through the lens of psychology,. In: F. Bourguignon and B. Pleskovic, editor(s). Proceedings of the Annual Bank Conference on Development Economics : World Bank,. Washington DC, 2005.

Noyes 2008

Noyes J, Popay J, Pearson A, Hannes K, Booth A. Chapter 20: Qualitative research and Cochrane reviews. In: Higgins JPT, Green S, editor(s). Cochrane Handbook for Systematic Reviews of Interventions. Version 5.0.1 (updated September 2008) edition. Vol. Cochrane Handbook for Systematic Reviews of Interventions (editors). Available from www.cochrane-handbook.org. Accessed 23 March 2010: The Cochrane Collaboration

Nyman 2003

Nyman J. The Theory of Demand for Health Insurance. Stanford University Press 2003.

Pauly 1968 1974

Pauly M. The Economics of Moral Hazard: Comment. American Economic Review 1968; 58: 531-537.

Pauly M. Overinsurance and the public provision of insurance. Quarterly Journal of Economics 1974; 88; 44–45

Peters 2002

Peters D, Yazbeck A, Sharma R, Ramana G, Pritchett L, and Wagstaff A. Better health systems for Indias poor: findings, analysis, and options. Washington DC: World Bank, 2002.

Pradhan 2002

Pradhan M and Prescott N. Social Risk Management Options for Medical Care in Indonesia Health Economics 2002;11:431-46.

Ranson 2002 2007

Ranson M. Reduction of Catastrophic Health Care Expenditures by a Community based Health Insurance Scheme in Gujarat, India: Current Experiences and Challenges. Bulletin of the World Health Organization 2002; 80.(8):613-31.

Ranson M, Sinha T, Chatterjee M, Gandhi F, Jayswal R, Patel F, Morris SS, Mills AJ:. Equitable utilisation of Indian community based health insurance scheme among its rural membership: cluster randomised controlled trial. BMJ 2007; 334:1309.

Review Manager (RevMan) 2008

The Nordic Cochrane Centre. Version Version 5.0. Copenhagen. The Cochrane Collaboration, 2008.

Russell 2004

Russell S. The Economic Burden of Illness for Household in Developing Countries: A Review of Studies Focusing on Malaria, TB and HIV/AIDS. American Journal of Tropical Medicine and Hygiene 2004; 71(Supp 2):147-55.

Saltman 2004

Richard S, Busse R, Figuares J (eds): Social health insurance system in Western Europe, World Health organization, 2004

Sinha 2006

Sinha T, Ranson M, Chatterjee M, Acharya A, Mills A. Barriers faced by the poor in benefiting from community-based insurance services: lessons learnt from SEWA Insurance, Gujarat. Health Policy Plan 2006; 21:132-42.

Spencer 2003

Spencer L. Quality in Qualitative Evaluation. A Framework for Assessing Research Evidence. London (UK): Government Chief Social Researcher's Office, Cabinet Office. Available from www.gsr.gov.uk/downloads/evaluating_policy/a_quality_framework. Accessed 23 March 2010 2003.

Townsend 1994

Townsend R. Risk and Insurance in Village India. Econometrica 1994;62(3):539-91.

Varian 1994

Varian H, Microeconomic Analysis, New York: W.W. Norton and Co, 1994.

Wagstaff 2003 2009 and 2010

Wagstaff A and van Doorslaer E. Catastrophe and Impoverishment in Paying for Health Care: With Applications to Vietnam 1993-98. Health Economics 2003; 12: 921-34.

Wagstaff A, Social health insurance re-examined, Health Economics; 2009; 19: 503-517.

Wagstaff, A. Estimating health insurance under unobserved heterogeneity: The case of Vietnams Health Care Fund for the poor. Health Economics 2010;19:189-208.

White 2009

White H. Theory-based Impact Evaluation: Principles and Practice, Journal of Development Effectiveness, September 2009;1(3):271-84.

WHO 2000 2005 and 2007

WHO (World Health Organization) World Health Report 1999: Health Systems-Improving Performance. Geneva: WHO. Available from : http://www.who.int/whr/2000/en/whr00_en. Accessed 19 March 2010.

WHO. Sustainable Health Financing, Universal Coverage, and Social Health Insurance. In: 58th World Health Assembly. Agenda Item 13.16 Edition. Geneva, 2005.

WHO. Fact sheets on paying for healthcare services. Available from:http://www.who.int/mediacentre/factsheets/fs320. Accessed 17 March 2010.

Witter 2000

Witter S, Ensor T, Jowett M and Thompson R. (2000), Health economics for developing countries: a practical guide, Basingstoke: Macmillan.

World Bank 1993 2010

World Bank Development Report. Investing In Health. The World Bank 1993, Washington DC.

World Bank Statistics. Available from http://go.worldbank.org/K2CKM78CC0 Accessed 23 March 2010 2009.

World Bank. Country classifications. Available at http://data.worldbank.org/about/country-classifications [accessed 26 June 2010]

Wyszewianski 1986

Wyszewianski L. Financially catastrophic and high-cost cases: definitions, distinctions, and their implication for policy formulation. *Inquiry* 1986; **23:** 382–94.

Xu 2003

Xu K, Evans D, Kawabata K, Zeramdini R, Klavus J, Murray C. Household catastrophic health expenditure: a multi-country analysis.. The Lancet July 12, 2003;Vol 362.

Zeckhauser R 1970

Zeckhauser R. Medical Insurance: A Case Study of the Trade-off between Risk Spreading and Appropriate Incentives. Journal of Economic Theory 1970; 2: 10-26.

Annex:

Check list for screening and assessing qualitative studies

- Clear statement of the aims of research
- Statement of conceptual framework
- Presentation of theory of change
- Data source
- Conclusions supported by the data
- Representative sample explained as to why and how collected
- Analyses explained
- Observations triangulated
- Findings summarised, made explicit and easy to understand
- Conclusions supported by the evidence offered
- Transferability of findings to a larger audience