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NOTES FOR REVIEW GROUPS

Structure for a protocol

Main title	Private vs. public strategies for health service provision for improving health in resource-limited settings
Sub title	What services, of what quality, are provided to the poor by private for-profit, private non-profit, and public sector providers; and what are the trade-offs between these sources of care?
Review group	Global Health Sciences, University of California, San Francisco
Section	PROCOTOL
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Conflicts of interest (if any)	Dr. Montagu is currently drafting a non-systematic review of interventions for working with the private sector in developing countries as part of a forthcoming series on the private sector, to be published in The Lancet.
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1. Background

1.1 Aims and rationale for review

Based on indirect evidence, private healthcare providers provide a significant proportion of healthcare services providing in low- and low-middle income countries (LLMICs). Some of the reasons for seeking care from private providers cited by patients include better and more flexible access to providers, shorter waiting times, greater sensitivity to patient needs, and greater confidentiality (Zwi, Brugha et al. 2001). Hanson et al., state that in many cases governments fail to create systems to remove or penalize staff offering low-quality services to patients (Hanson, Gilson et al. 2008). As a result patients seeking quality assurances may turn to private care.

In contrast to public healthcare, private healthcare involves a spectrum of "private" providers and services provided by these providers. These services vary in different countries and range from sophisticated care comparable to international standards, to individual doctors and nurses who are employed by public institutions but offer private care during their off hours, to unqualified quacks offering services that are not regulated or monitored (Hanson, Gilson et al. 2008). Though definitions vary, "private" providers are often described as health practitioners that are not directly controlled by the government and can either be individuals such as doctors, nurses, midwives, or groups of practitioners operating as for-profit entities or non-profit entities. Private providers may also offer healthcare facilities such as clinics and hospitals operated by private employers, religious based organizations and non-governmental organizations (NGOs). Available evidence indicates that across developing countries private healthcare is significant in both rural areas and urban areas, and for lower income groups as well as the wealthy (Hanson and Berman 1998).

According to estimates by Hanson and Berman based on a sample of low and middle-income countries (LMICs), nearly 40% of doctors practice privately and 24% of the total numbers of hospital beds available are private (includes for-profit and non-profit). In Asia private providers provide nearly 26% of all beds available, compared to 33% in Africa. In African countries, the NGOs provide a vast majority of all private services available (Hanson and Berman 1998). Though limited, evidence suggests that use of private health provision is increasing in LLMICs. Poorer patients are reportedly likely to spend a significant proportion of their incomes on private healthcare (Zwi, Brugha et al. 2001).

Though private providers offer an oft-used alternative to public providers, the evidence about services and quality of service provided by the private providers compared to public providers is scarce, and there is limited information regarding trade-offs between the two sectors.

1.2 Definitional and conceptual issues

Not applicable.

1.3 Policy and practice background

Not applicable.

1.4 Research background

While a number of systematic reviews have been conducted or are being conducted on specific areas of working with the private sector, these reviews have been primarily

intervention focused. Recently, Patoillard et al, conducted a systematic review of 52 studies on working with the private for-profit providers in LMICs; these studies focus on interventions (such as social marketing, pre-packaging drugs, provision of vouchers, contracting-out services, franchising, regulation and accreditation) to improve utilization of healthcare by poor. While some of the studies showed an increase in the utilization of services and improvement in the quality of care, impacts on equity could not be assessed because of data limitations. Because most of these interventions were not designed as research projects, the review was not able to explain what services are being utilized by the poor and who is providing these services (Patouillard, Goodman et al. 2007).

Currently, a moderately large body of literature documents the role of the private for-profit and not-for-profit sectors in the provision of health services and commodities for the poor in developing countries. Much of this documentation exists in the form of gray literature: program reviews, program evaluations, and summaries of experience from donor-supported interventions that support non-governmental organizations (NGOs) and/or private-sector delivery of health services. A much smaller collection of peer-reviewed articles exists documenting the scale of private for-profit and not-for-profit provision of healthcare to poor populations in developing countries, and, in rare cases, the quality or affordability of those services.

1.5 Objectives

The objective of this study is to determine what services, and of what quality, are provided to the poor by private for-profit, private non-profit, and public sector providers, and what are the trade-offs between private for-profit, private non-profit, and public sector sources of care for the poor.

2. Methods used in the review

2.2 User involvement

2.1.1 Approach and rationale

We will conduct this review using the Cochrane Effective Practice and Organization of Care (EPOC) Group's methodology to conduct Cochrane Reviews, following the guidance of the Cochrane Handbook for Systematic Reviews. This review will be of value to stakeholders both inside and outside the research community, helping public health practitioners, policy makers, donor agencies and Global Health Institutions in making evidence-based decisions on healthcare and healthcare policy.

2.2 Identifying and describing studies

2.2.1 Defining relevant studies: inclusion and exclusion criteria

We will include the following studies in our review:

- 1. Randomized controlled trials (RCTs)
- 2. Controlled clinical trials (CCTs)
- Controlled before-and-after studies (CBAs) with a minimum of two study and two control sites
- 4. Interrupted time series (ITS) with a minimum of three points both before and after the intervention.

Given the expected paucity of rigorous studies, we will also consider observational studies, to include cohort, cross sectional, and case control studies. We will examine grey literature, and will also take into account the limited number of specialized reviews that have been conducted for particular areas of health service or health service provision. Economic evaluations will be excluded.

In order to retrieve studies, we will use specialised search strategies of the EPOC Group, and will use search terms such as the following:

- 1. Public private; public vs. private; public/private; public- and private-; private and public; public-private interventions; PPP; Public Private Partnerships, Non State Actors; NSA, Non State Provider; nongovernment; NGO, nongovernmental organization; non-government; not-for-profit; non-profit; Informal Provider; Private Provider; Public Provider; Public Provider vs. Private Provider; government provider; private medical practitioner; private practitioner; private sector; private-sector; public sector; public-sector; private physician; public physician; private hospital; public hospital; government hospital; private clinic; private service; public service; private for profit; for-profit; private for-profit; private practice; private delivery; non-government; practicing privately; private doctor; public doctor; government doctor; private facilities; private facility; public facility; public facility; public facility; private ambulatory provider; private ambulatory health
- 2. Compared to; compare to; unlike; comparable; between; versus; than; more than; difference; ratio of; differential
- 3. Healthcare; health care; care; health planning; health services; utilization; client volume; coverage; attendance; affordability; cost; compliance; quality; case notification; diagnosis; fees; fee for service; morbidity; mortality; death; outcomes; expenditure; out of pocket; out-of-pocket; patient care; provision; consultation; examination; equity; integrity; clinical exam; drugs; dispense; injection; recommend; disease; disease category; efficacy; prescribe; inpatient; outpatient; fee-for-service; health policy; primary care

- 4. Developing countries; LMIC; LLMIC; low middle income; low low middle income; low income; middle income; resource constrained; resource limited; poor; lower middle; middle; low- and middle-income
- 5. Incidence, prevalence, risk ratio, odds ratio, relative risk, relative risk ratio, RR, OR, IR; mean; median

To be included the studies must report at least one of the following primary outcomes:

- Direct measures of improved health / health status / survival such as mortality or morbidity
- 2. Lifestyle factors where evidence indicates these have an effect on the above
- 3. Adverse effects (eg. Undesirable impacts on any of the above outcomes or on existing public or private services, distortions in provision of services, inappropriate use of services)

Upon meeting the primary inclusion criteria, we will include the following, if available:

- 1. Equitable access or utilization (distribution of access across socio-demographic characteristics)
- 2. Patient satisfaction (eg. Intent to return, level of service from a societal perspective or the perspective of the franchiser, franchisee or patients)
- 3. Measure access (eg. Affordability, utilization, client volume, attendance)
- 4. Quality of care (eg. Compliance with guidelines, case notification for specific diseases such as TB)

2.2.2 Identification of potential studies: Search strategy

A comprehensive search will be performed in order to avoid both selection bias of published articles and language bias of publications. Academic journals (peer-reviewed) and grey literature (non published/internal or non-reviewed papers, reports) will both be searched:

- Bibliographic databases: PubMED, EMBASE (Athens), Popline, CAB-Direct (Global Health), Healthcare Management Information Consortium (HMIC), World Health Organization Library Information System (WHOLIS), African Healthline (bibliographic databases on African health issues), International Bibliography in Social Sciences (Athens). The Cochrane Central Register of Controlled Trials (CENTRAL), the Database of Abstracts of Reviews of Effectiveness and the Cochrane EPOC Specialised Register (and database of studies awaiting assessment) will be reviewed.
- Development studies databases: ELDIS database database of development references developed by the Institute of Development studies (IDS); British Library of Development Studies (BLDS) - a database on economic and social issues in developing countries; IDS21 - database on international development research from the UK; The Antwerp Institute of Tropical Medicine database.
- Organizations and Websites: We will search websites of organizations likely to be active in the field including: the World Bank, United States Agency for International Development (USAID), Management Sciences for Health (MSH), PSP One, Centre for Global Development, World Health Organization (WHO), Swiss Tropical Institute, Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), KfW Entwicklungsbank, Department for International Development (DFID), The Global Alliance for Vaccines and Immunization (GAVI), The Global Fund to Fight AIDS, Tuberculosis and Malaria, Asian Development Bank, and Pan American Health Organization (PAHO), Partnerships for Health Reform, Save the Children, and Oxfam.

- Academic Institutions: We will also search websites of academic institutions active
 in this field, such as London School of Hygiene and Tropical Medicine, the Harvard
 School of Public Health, University of Cape Town, Institute of Policy Studies Sri
 Lanka (IPS), the Kenya Institute of Policy Analysis and Research (IPAR), the Institute
 of Tropical Medicine, Belgium. We will search ISI Web of Science for papers that
 cite studies included in the review. We will also use Google Scholar for studies
 meeting our criteria.
- Country websites: Databases and websites of the government of India, Brazil, Namibia, Uganda, and South Africa will also be searched.
- Reference lists of key authors/papers
- References on key web sites
- Personal contacts
- Direct requests to key informants

We will check references from included studies and related articles and documents to identify other relevant studies that meet the inclusion criteria.

A database system will be set up to code and keep track of studies found during the review. Titles and abstracts will be imported and entered manually into this database.

2.2.3 Screening studies: applying inclusion and exclusion criteria

Two authors will independently review abstracts to identify all studies that potentially meet the inclusion criteria and should be retrieved. The same two authors will independently assess each full text article that is retrieved to determine whether it meets all of the selection criteria. Any disagreements and uncertainties will be resolved by discussion, and / or the involvement of a third author.

2.2.4 Characterising included studies

The following elements will be extracted independently from each study by two review authors:

- 1. Study References:
 - a. Name of the first author and date of publication
 - b. Date of the study
 - c. Location of the study
- 2. Described intervention(s) and context:
 - a. Nature of intervention
 - b. Intervention (Exposure) group
 - c. Control group
 - d. Broader context/reforms in place if mentioned in the article
- 3. Study characteristics and inclusion criteria:
 - a. Type of study: ITS, BACS, or RCT (or Non-Randomized Study)
 - b. Assess risks (see below)
- 4. Results:
 - a. Main outcomes measured
 - b. Effect

2.2.5 Identifying and describing studies: quality assurance process

Please see section 2.2.3 and section 2.3.1 for details.

2.3 Methods for synthesis

2.3.1 Assessing quality of studies

Criteria recommended by EPOC will be used to assess the risk of bias for each main outcome in all studies that will be included in the review. An overall assessment of the risk of bias (high, moderate or low risk of bias) will be assigned to each main outcome in all included RCT studies using the approach suggested in Chapter 8 ("Assessing the Risk of Bias") of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green 2008). Risk of bias in observational studies will be assessed using the Newcastle-Ottawa Scale and other guidance outlined in the Cochrane Handbook's Chapter 13 ("Non-Randomised Studies").

If studies have missing data, we will contact the authors of studies to obtain missing data, including details of the intervention, the context, overall resource inputs, ancillary components and the results.

2.3.2 Overall approach to and process of synthesis

2.3.2.1 Selection of studies for synthesis (if not all studies that are included in the synthesis)

Studies that meet the inclusion criteria, and report the outcomes of interest, will be included for data synthesis.

Please review section 2.3.2.2. for detailed information.

2.3.2.2 Selection of outcome data for synthesis

For all studies we will record outcomes in each comparison or intervention group. Where possible we will record risk ratios (RRs) and odds ratios (ORs) for dichotomous outcomes and weighted mean differences (WMDs) for continuous outcomes. If adjusted analyses are reported (adjusting for potential confounders in non-randomized studies), we will record the estimates of effect together with the standard error. For a random effects meta-analysis, we will record the number of events and total number in each group (for risk ratio), or mean and standard deviation in each group (for weighted mean difference). All outcome effects will be shown with their associated 95% confidence intervals.

For ITS studies we will record changes in the level and in slope and their standard errors. Where analysis of ITS data is inappropriate we will try to re-analyze if possible.

2.3.2.3 Process used to combine/synthesise data

Selective outcome reporting will be assessed using the approach described in Chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green 2008). Publication bias will be assessed qualitatively based on the results and characteristics of the included studies, including the extent to which only small effects in favour of the intervention are reported, the extent to which funders or investigators have vested interest in the results, and the extent to which the authors' interpretations of the results are supported by the actual results.

A meta-analysis will only be carried out if we are able to identify a sufficient number of studies to provide an acceptable body of evidence to examine the intervention. If we do not find enough studies for a meta-analysis, the review will be reported as a descriptive narrative only. If we decide to conduct meta-analyses, we will assess the extent of heterogeneity in results across comparable studies using forest plots, the I2 statistic and the Chi² test.

For studies that are sufficiently homogeneous, a fixed-effect model will be used. Where there is evidence of heterogeneity, a random-effects model will be applied (a likely scenario in our case). Data synthesis will be performed using RevMan 5. We will provide an estimate and 95% confidence interval and generate a forest plot for each meta-analysis and will discuss the extent of evidence against homogeneity. If it is not possible to synthesize the data from included studies, we will describe the results in a narrative form.

For cluster-randomized trials we intend to ensure that an appropriate analysis has been done which adjusts for clustering in calculating confidence intervals. If this approach was not taken, we will attempt to extract the necessary data or obtain them from the corresponding authors. In cases were the unit of analysis is on a different scale in a study than in other studies, we will standardize our estimates.

Additionally, we will perform sensitivity analyses by excluding studies with a high risk of bias or by excluding studies, which add substantially to heterogeneity between studies for any outcome for which we find multiple comparable studies.

2.4 Deriving conclusions and implications

The health systems models used by the World Health Organization (WHO 2000) and the World Bank / International Finance Corporation (IFC forthcoming) provide a model for understanding the role of the private sector within the larger health system, and for analysing the best role for governmental stewardship of the private sector according to the size and scope of private healthcare provision. The application of these models to practical stewardship activities such as legislation, regulation, financing, or the provision or collection of information are hampered by a limited understanding of the relative benefits and drawbacks of private care provision in developing countries. The current systematic review will inform the scale and most applicable opportunities for effective stewardship, or highlight gaps in knowledge that merit further attention. The authors will build upon health systems models and the theoretical proposals for private sector engagement put forward by others (Bennett et al 2005; Zwi et al 2001; Patoillard et al. 2007), adding evidence to improve the conceptual discussions to date.

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Appendices

Appendix 1.1: Authorship of this report

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Appendix 2.1: Inclusion and exclusion criteria - See above

Appendix 2.2: Search strategy for electronic databases - See above

Appendix 2.3: Journals to be hand searched - N/A

Appendix 2.4: Draft coding tool - N/A