

Working with non-state providers in post-conflict and fragile states in primary healthcare service delivery

Protocol written by Ekwaro Obuku, Ruth Stewart, Felix Achana, Rhona Mijumbi, Alison Kinengyere, Robert Basaza, Dickens Akena, Daniel Semakula, Richard Senono, Allen Nsangi, Boniface Mutatina, Hannington Muyenje, William Newbrander, Nelson Sewankambo

EPPI-Centre
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Institute of Education
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PROTOCOL

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1. Background

1.1 Aims and rationale for review

Home to at least a third of the world's poor with the worst health indicators, post-conflict and fragile states are lagging in their efforts to achieve the Millennium Development Goals (Alliance 2008). Health services are predominantly non-state in most low-income countries, including those that have relatively effective governance, and the poorest strata of the population are more likely to use non-state providers (Palmer 2006, OECD 2006). An important area of focus for the review is to identify the role of the national government in regulating, coordinating and information sharing among public and non-state providers, in settings where lack of regulation and organisation of health service provision are common characteristics of the health sector (Moran & Batley 2004).

One of the primary reasons for supporting health service delivery in fragile states is that it is an entry point for triggering broader governance reforms (Berry et al. 2004). As such, the effectiveness of different modes of engagement and the scope of the desired outcomes are important research questions. A central theme in the literature is the dynamics between the immediate need to reduce vulnerability and achieve specific health outcomes versus longer term objectives of building sustainable health systems that promote equitable access to health. There is thus a need for a review to address both the immediate and long term outcomes associated with health service delivery programs in fragile states (High Level Forum 2005).

Despite the wealth of challenges, from poor health to extreme poverty and destroyed infrastructure, early strategic investment in the health sector during transition and post-conflict periods can provide opportunities to re-align systems and introduce new service delivery models (High level Forum 2005). Effective government capacity-building to engage in essential tasks of leadership, planning, and oversight of a system based on primary care can lead to long-term returns in terms of the equity, efficiency, and effectiveness of the services provided (Macrae et al. 1996). It can also contribute to enhanced legitimacy of the state, known as the "peace dividend (Jones et al. 2006, Waldman 2006). While some researchers contend that there is too little empirical evidence of this effect to date (Rubenstein 2009), it is critical to thoroughly assess whether working with non-state actors has improved both health system capacity and health outcomes, and to examine where gaps in evidence remain.

1.2 Definitional and conceptual issues

In order to undertake this review, a variety of terms and definitions must be established including fragile state and post-conflict state, the non-state sector, and primary care.

1.2.1 *Fragile and Post-Conflict States*

Although there is not a single internationally-agreed definition of the term 'fragile states', or 'fragility'; most development agencies define a fragile state as one in which the state fails to perform functions necessary to meet citizens' basic needs and expectations (GSDRC 2010). In 2008 the Organisation for Economic Co-operation and Development (OECD) characterized fragile states as those countries 'unable to meet [their] population's expectations or manage changes in expectations and capacity through the political process' (OECD, 2008). DFID similarly defines fragile states as: 'those where the government cannot or will not deliver core functions to the majority of its people, including the poor' (DFID, 2005).

The International Development Association (IDA) defines post-conflict states as those meeting any of the three following conditions: (i) a country that has suffered from a severe and long-lasting conflict, which has led to inactivity of the borrower for an

extended period of, or at least a substantial decline in the level of external assistance, including from IDA; (ii) a country that has experienced a short, but highly intensive, conflict leading to a disruption of IDA involvement; and (iii) a newly sovereign state that has emerged through the violent break-up of a former sovereign entity (World Bank 2009). These countries generally fall into four typologies: prolonged crisis, post-conflict or political transition, gradual improvement or deteriorating government (Alliance 2008).

1.2.1.1 Included Countries

The initial list of fragile and post-conflict states for inclusion in this study was developed using two sources: i) the World Bank list of fragile states (also termed Lower Income Countries Under Stress of LICUS) available from 2003 to 2006 and ii) the Foreign Policy Failed States Index available from 2005 through 2009 (World Bank, 2009; Foreign Policy Group, 2010). A combined list was used because the approach is more inclusive, has broader and more diverse inclusion criteria, and because the sources were each found to have limitations when taken in the context of this review. The World Bank list is not available after 2006, is heavily concentrated on Africa and excluded countries such as Nepal, Sri Lanka, Iraq and Yemen that many people might consider as fragile states. The Foreign Policy Failed States Index on the other hand primarily focuses on social, economic, and political indicators and hence may not employ a methodology that is ideal for our purposes. It is also substantially longer than World Bank list which could broaden the scope of the review. However, given that the World Bank list of fragile states is only available up to 2006, combining the two may be the best way to objectively identify states which are or have become more unstable in recent years.

The combined list developed from these two sources includes all countries considered by the World Bank as fragile states, LICUS countries (core or severe designation; marginal countries were excluded because this designation primarily indicates a need for increased monitoring) and all countries categorized as failed states by the Foreign Policy Failed States Index which have a history of conflict. Through user engagement with DFID policy makers, we identified 11 additional countries of interest classified as fragile or conflict affected states. There are 55 countries of interest to DFID which list intersects with the initial selection of countries in the original protocol (Koehlmos et al. 2010). These include countries involved in the recent "Arab Spring" (Joffé, 2011).

The final list of 66 countries included in our review is presented in Table 1. Nearly half (48%) of the identified countries were in Africa. For each country included in our final list, reported conflict status was ascertained from the World Bank (fragile states list, 2003-2006); globalsecurity.org (2010); and Ploughshares Conflict Report (2009). The final determination of conflict status was made based on reported conflict status and text descriptions of the conflicts from these sources. There are 26 conflict-affected countries, 24 post-conflict countries, and 16 non-conflict affected countries that considered as fragile states.

Table 1: Updated list of included countries

Fragile States (non-conflict affected, n=16)	
Djibouti (1991-1999)	[§] Marshall Islands
[§] Bangladesh	Niger (1991-97)
[§] Burkina Faso	Papua New Guinea (1989-90)
Equatorial Guinea	Sao Tome and Principe
[§] Kenya	Togo (1986-91)
[§] Kiribati	Uzbekistan (1999-2000)
Lao PDR	Vanuatu
[§] Malawi	Zimbabwe
Post-Conflict (n=24)	
Angola (1975-2002)	Haiti (1989-2004)
Bhutan	Kosovo (1998-2006)
[§] Burma	Lebanon (2006-2007)
Bosnia & Herzegovina (1992-1995)	Liberia (2000-2003)
Cambodia (1978 - 1999)	[§] Mauritania
Comoros (1997)	Rep. of the Congo (1997 - 2000)
Eritrea (1993-2000)	Rwanda (1990-2001)
Ethiopia (1976-2002)	Sierra Leone (1991-2002)
Georgia (1991 - 2004; 2008)	Solomon Islands
Guatemala (1949-1995)	Tajikistan (1992-2000)
Guinea (2000-2002)	Timor-Leste (1975-2000)
Guinea-Bissau (1963-73; 1998-99)	[§] Tuvalu
Conflict affected (n=26)	
Afghanistan (1978 -)	[§] Micronesia
Burundi (1988-2009)	Myanmar (1988 -)
Chad (1966-)	[§] Nepal (1996 - 2008)
Central African Republic (1996-2006)	Nigeria (1990 -)
Colombia (1964 -)	North Korea (1953 -)
Cote d'Ivoire (2002 - 2007)	Pakistan (1992-)
Democratic Republic of Congo (1990 -)	Somalia (1988 -)
[§] Egypt (2011 -)	Sri Lanka (1983 - 2009)
Gaza & The West Bank (OPT) (1948 -)	Sudan (1983 -)
Iraq (2003-)	[§] South Sudan (2013 -)
[§] Libya (2011 -)	[§] Syria (2011 -)
[§] Madagascar	Uganda (1987 -)
[§] Mali	Yemen (2004 -)

*Abbreviations and symbols:

[§]Additional countries of interest to the DFID

* Dates in parentheses are years of conflict according to UCDP/PRIO Armed Conflict Database, Armed Conflicts Dataset v4 - 2009. Available at: <http://www.prio.no/CSCW/Datasets/Armed-Conflict/UCDP-PRIO/>

1.2.2 Non-state sector for health

In developing countries, the state is no longer seen as the sole provider of health care services. Recent years have seen an increased recognition of the significant number of non- state sector providers in developing countries, and at the same a real expansion in their numbers. This is primarily due to the rise of small, often informal, providers who are increasing in numbers, scope, scale and impact to fill the gap left by weak state capacity. However it is important to note that the blurring of the boundaries between state and

non- state may be extremely complex (Mills et al. 2002). This problem is compounded in fragile and post-conflict states.

Non-state providers comprise; formal, informal, for-profit, and not-for-profit actors who provide health promotion, preventive and curative services. Non-state providers are not employees of the public sector. They include commercial companies of varying sizes, professionals groups such as doctors, national and international NGOs, faith based organisations, community based organisations, village doctors, traditional birth attendants, and traditional healers such as herbalists and faith healers. A wide variety of services, including primary care, nursing and maternity clinics, hospitals, drug shops, and traditional approaches to care which vary by region are offered by non- state providers. There are numerous mechanisms through which governments and aid agencies can engage the non-state sector. These include; contracting out, social franchising, accreditation and training (Peters et al. 2004, Palmer 2006). The types of services they provide can be modern or traditional, preventative or curative and can include a range of specific services like diagnostics or deliveries (Walker et al. 2009).

1.2.3 Primary healthcare services

The ultimate goal of primary health care (PHC) is better health for the entire population. The concepts of primary health care are dictated most clearly in the Alma Ata Declaration of 1978 (Anonymous, 1978):

“Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community...It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process.”

Primary care can be more concretely defined as a set of activities that might include preventing, curing or managing common illnesses and disabilities; a level of care or setting that serves as an entry point into a system of secondary and tertiary care provided in community hospitals or medical centres or as ambulatory care versus inpatient care (Fry 1980); or a set of attributes marked as first contact, accessibility, longitudinality and comprehensiveness (Starfield 1992, IOM 1996).

35 years since the Alma Ata declaration, universal access to PHC remains an enormous challenge despite a clear demonstration that it expands the distribution of health care irrespective of country income status, and eventually improves health outcomes (Macinko et al. 2003; Starfield et al. 2005; Lewin et al. 2008). Indeed fragile, conflict and post-conflict states are more vulnerable and certainly have poorer performance with regard to MDGs, and access to PHC (Walker et al. 2009). The reduced availability of aid money (MDG 8) (United Nations, 2013), further compounds the problem since international NGOs (from the higher income countries) play a major role in PHC delivery in LMICs; making this systematic review even more relevant.

1.3 Policy and practice background

Fragile and post-conflict states are not an exception to the reality that in many low- and middle-income countries (LMIC) a substantial proportion of all health services are sought in the non-state sector (Mills et al. 2002, Bustreo et al. 2003, WHO and USAID 2007). There is growing acknowledgement that governments and donors must look beyond the traditional boundaries of public health service delivery and engage the private sector although it is not clear how best to do this and interventions to work with the private sector may have unintended effects (Bennet et al. 2005, Waters et al. 2003). Because of the ambitious health objectives established by the Millennium Development Goals with its rapidly approaching deadline, a sense of urgency is added to the necessity of non-state

sector engagement (Working with the Non-State Sector 2006, UN Millennium Development Project 2005). With barely two years to 2015, a significant majority of the Low and Middle Income Countries (LMICs) are yet to attain the Millennium Development Goals (MDGs) with, for example, moderate to very high maternal and child mortality in sub-Saharan Africa, Asia and parts of the Caucuses (United Nations, 2013). Many key decision makers in the health sector have looked toward reforms that can produce greater access, quality, efficiency and equity of health services (Liu et al. 2004). Further, the shift in health sector reform in low- and middle-income countries has been away from expanding direct government involvement in service delivery toward a greater role for government in health care funding or management and engaging the private sector via a variety of contracting mechanisms (USAID and PSP-One 2006, Mills 1997, Loevinsohn & Harding 2005).

1.4 Research background

A recent World Bank publication, *Improving Health Services in Developing Countries: From Evidence to Action*, includes three systematic reviews and one modified systematic review on health care delivery in low and middle-income countries (Peters et al. 2009). In addition, a search of the Cochrane Library identified four reviews on health service delivery in low -and middle-income countries (three of these were related to health service financing mechanisms). However, a preliminary literature search of the Cochrane Library and of PubMed revealed no systematic reviews that focus specifically on health service delivery on fragile and post-conflict settings.

Other non-systematic literature reviews and resource collections on health services in fragile states were predominantly in grey literature publications, and included 88 articles on health service delivery (Eldis), three articles on health and fragile states (Eldis), 13 publications recommended by the Health and Fragile States Network, and one review article on improving basic health service provision in fragile states commissioned by the AusAID Office of Development Effectiveness. Articles on fragile states and post-conflict contexts, including health as a bridge to peace and stability, and health sector governance and capacity building were common as was literature focusing on contracting, public-private partnerships, community health funds, and the informal sector.

Additionally, more than fifty country-specific journal articles on contracting mechanisms, insurance programs, franchising, and training to improve delivery of basic health services (primarily from Afghanistan, also from Cambodia, Democratic Republic of Congo, East Timor, Mozambique and Southern Sudan) were identified. Our review seeks to uncover this full body of literature, using standardized search strategies, systematic data abstraction, and framework analysis to glean information from studies of state and non-state providers across settings, populations and political situations. Examples of articles that are likely to be located through our more rigorous search and thus might be included in our study would include:

Doull L, Campbell F (2008) Human Resources for health in fragile states. *Lancet* 371(9613) 626-7.

Fenton, W. (2008). *Funding mechanisms in Southern Sudan; NGO perspectives*. Commissioned by the Juba NGO forum.

Health Systems Strengthening in Fragile Contexts: A Report on Good Practices & New Approaches (2009) Commissioned by the Health and Fragile States Network.

Jayasinghe S (2009) Contracts to devolve health services in fragile states and developing countries: do ethics matter? *J Med Ethics*. 35(9): 552-7.

Palmer N, Strong L, Wali A, Sondorp E (2006) Contracting out health services in fragile states. Lessons from Afghanistan, *BMJ*, 332: 718-721

Roberts B, Guy S, Sondorp, E, Lee-Jones L (2008) A Basic Package of Health Services for Post-Conflict Countries: Implications for Sexual and Reproductive Health Services Reproductive, *Health Matters* 16(31):57-64.

1.5 Objectives

The purpose of this review is to summarise the research literature about the types, effects and impact of non-state actors in the delivery of primary health care in fragile, conflict or post-conflict states. Specifically we seek to answer the following research questions: (1) How effective are different approaches and strategies in improving the delivery of primary care in fragile/post-conflict settings? (2) What is the impact of non-state actors' delivery of primary health care in fragile, conflict or post-conflict settings?

Primary objective: To describe the types and determine the effects of different approaches by non-state actors' delivery of primary health care in fragile, conflict or post-conflict settings.

Secondary objective: To assess the impact of non-state actors' delivery of primary health care in fragile, conflict or post-conflict settings.

2. Methods used in the review

2.1 User involvement

A recent review examining the use of different evidence types, highlighted timely access to good quality and relevant research evidence, collaborations with policymakers and relationship- and skills-building with policymakers as the most important factors in influencing the use of evidence (Oliver et al. 2014; Murthy et al. 2012). Further, for over three decades, the World Health Organisation has encouraged the involvement of individuals and communities in the planning and implementation of their health care (WHO 1978). To that end, review users at DFID have been consulted in the development of this protocol and will remain engaged throughout the production and dissemination of this review. Further, the team will seek to engage with members of the Health and Fragile States Network during the review process. We will consult with our advisory group of fragile states experts.

2.2 Identifying and describing studies

2.2.1 *Defining relevant studies: inclusion and exclusion criteria*

Types of studies

We will consider both published and grey literature for eligibility. Observational studies such as surveys, cohort studies, case- controlled studies and case studies (with or without economic or equity analyses) will be considered potentially suitable for assessing coverage, utilization, implementation, scalability and sustainability. Randomised controlled trials (RCTs) and non-randomised controlled trials (non-RCTs), controlled before and after studies, and interrupted time series will be considered potentially suitable for assessing effects and impacts of interventions. Studies on economic analyses will be used to capture costing and cost-effectiveness of specific interventions of primary health care by non-state actors. Systematic and non-systematic reviews will also be considered for inclusion as a guide to finding primary studies.

Publications describing and/or analysing theoretical frameworks, opinion pieces and policy documents will be excluded.

Types of participants and setting

Primary care providers (formal/informal) of non-state sector health care delivery in fragile and post-conflict states are eligible as described in section 1.2.2. All types of patients/consumers in the non-state sector in fragile and post-conflict states are eligible as defined in section 1.2.1.

We will exclude: Patients and providers in non-fragile/non-post conflict states, exclusively in the public sector and not engaged in primary care (e.g. secondary/tertiary care).

Types of interventions

Non-state sector interventions will be considered for inclusion in this review if they conduct or support the delivery of primary care in the non-state sector in fragile and post-conflict states. We will identify interventions covering the six health system pillars of the World Health Organization (WHO, 2004). These are arrangements for governance, financing, human resources, health services delivery, information systems and improving access the health technologies (WHO, 2004; Lavis, 2002). Governance arrangements would include mechanisms for engaging the non-state sector like contracting out, social franchising, and public-private partnerships. Financing arrangements will cover financial protection for example use of vouchers for antenatal care and maternal deliveries, user-fees, community health insurance, performance-based or results-based financing.

Arrangements for human resources will include training, mentorship, supportive supervision, task-shifting amongst others that we will identify by reviewing this literature.

We will exclude interventions focused on secondary or tertiary care.

Types of outcome and impact measures

Although our methodology is more conducive to inclusively exploring the literature, when provided we propose to collect information on this tentative list of outcomes organised according to a three part results framework:

- 1) Primary outcomes
 - (a) Health vital status outcomes i.e. changes in child, maternal and population general and disease specific mortality and morbidity rates.
- 2) Secondary outcomes or impacts
 - (a) Health sector capacity building i.e. governance mechanisms, training of human resources, information systems, procurement systems, infrastructure development.
 - (b) Adverse effects of non-state actors' interventions in primary health care i.e. undesirable impacts on existing public or private services, inappropriate use of services, distortions in the provision of services and mal-distribution of human resources.
- 3) Health service delivery process indicators or impacts
 - (a) Access to services i.e. affordability, utilization, client volume
 - (b) Coverage of health services i.e. health facility or health worker to patient or population ratios
 - (c) Quality of care i.e. compliance with nationally or W.H.O accredited standards
 - (d) Patient satisfaction i.e. utilization and intention to return for the service
 - (e) Cost-effectiveness of the non-state actors' primary health care interventions
 - (f) Cost of specific primary health care services i.e. maternal and child health care
 - (g) Catastrophic costs to primary health care user
 - (h) Out-of-pocket payments or user fees for health service

2.2.2 Identification of potential studies: Search strategy

We will search the following electronic databases for primary studies:

- Cochrane Effective Practice and Organisation of Care Group Specialised Register (and database of studies awaiting assessment). www.epoc.cochrane.org/epoc-register-studies
- Cochrane Central Register of Controlled Trials (*The Cochrane Library*, most current) www.cochrane.org/
- MEDLINE, PubMed (1990 to present) www.nlm.nih.gov
- Science Citation Index Expanded and Social Sciences Citation Index (1990-present).
- WHOLIS (1990 - present) www.who.int/library/databases/en
- EMBASE (1990 - present) www.elsevier.com/online-tools/embase

We will use the updated MEDLINE Ovid search strategy from 1990 to date as detailed in Appendix 2.2. It will be adapted for the other databases listed above using the appropriate controlled vocabulary. The full list of search strategies will appear in an appendix 2.2 when we complete the review.

In addition, the following sources will be searched to identify primary studies:

- a) Websites/Databases:
 - Eldis www.eldis.org/
 - Google Scholar www.scholar.google.com/
 - Health and Fragile States Network www.healthnettpo.org/en/1055/health-and-fragile-states-network.html
- b) Development Assistance Partners:
 - Active Learning Network for Accountability and Performance in Humanitarian Action (ALNAP) <http://www.alnap.org/>
 - African Medical Research Foundation (AMREF) www.amref.org/
 - Canadian International Development Agency (CIDA) www.acdi-cida.gc.ca/
 - Centre for Research on the Epidemiology of Disasters www.cred.be/
 - Department for International Development, UK (DFID) <https://www.gov.uk/.../department-for-international-development>
 - International Committee of the Red Cross (ICRC) www.icrc.org/
 - Management Sciences for Health (MSH) www.msh.org/
 - Marie Stopes International (MSI) www.mariestopes.org/
 - Medicines Sans Frontiers (MSF) www.msf.org/
 - Population Services International (PSI) www.psi.org/
 - ReliefWeb www.reliefweb.int
 - Research for Development www.r4d.dfid.gov.uk/
 - Reproductive Health Response in Crises Consortium www.rhrc.org/
 - United Nations High Commissioner for Refugees (UNHCR) www.unhcr.org
 - United Nations Populations Fund www.unfpa.org
 - United States Agency for International Development (USAID) www.usaid.gov/
 - The World Bank www.worldbank.org/en/topic/health
- c) Reference lists of all papers and the relevant reviews identified.
- d) Conference proceedings from subject matter specific meetings. For example, the Global Symposium on Health Systems Research <http://www.healthsystemsglobal.org/>
- e) Authors of relevant papers regarding any further published or unpublished work.
- f) Key informants including fragile-states experts, public relations or records personnel of agencies involved in health care delivery fragile states. Examples of key informants could come from the Health Care in Danger Network: www.healthcareindanger.ning.com

Search strategies for electronic databases were developed using the methodological component of the search strategy employed by the Cochrane Review Group for Effective Practice and Organisation of Care combined with selected MeSH terms and free text terms related to fragile states and the non-state sector. We will use the following PubMed search strategy from 1990 to date (<http://www.ncbi.nlm.nih.gov/pubmed/>). This search will be adapted for the other databases listed above.

The PubMed/Medline search strategy is listed below:

Line 1 - 6; terms related to fragile states

Line 7 - 14; terms related to non-state provider

Line 16; terms related to Primary health care service or other outcomes

1. Conflict[tw] OR "Post conflict"[tw] OR post-conflict[tw] OR failed[tw] OR collapsed[tw] OR vulnerable[tw] OR conflict-affected[tw] OR fragile[tw] OR War-torn[tw] OR demilitarised[tw] OR "military zones"[tw]) OR war[Mesh Terms]

2. (Remote[ti] OR hard-to-reach[ti])

3. (State*[tw] OR countr*[tw] OR region*[tw] OR area*[tw] OR territor*[tw] OR land[tw])

4. 1-2/or AND 3

5. Bangladesh OR Burkina Faso OR Burma OR Burundi OR Cameroon OR Djibouti OR “Equatorial Guinea” OR Togo OR Niger OR Vanuatu OR “Papua New Guinea” OR Angola OR Haiti OR Bhutan OR Kosovo OR “Bosnia & Herzegovina” OR Lebanon OR Cambodia OR Liberia OR Comoros OR Eritrea OR Rwanda OR Ethiopia OR Egypt OR Eritrea OR Malawi OR Nepal OR Sierra Leone OR Georgia OR “Solomon Islands” OR Guatemala OR Guinea OR “Timor-Leste” OR “East Timor” OR Guinea-Bissau OR Afghanistan OR Burundi OR Nigeria OR Occupied Palestinian Territories OR Chad OR “North Korea” OR “Central African Republic” OR Pakistan OR Colombia OR Somalia OR Syria OR “Cote d'Ivoire” OR “Ivory Coast” OR Sri Lanka OR “Democratic Republic of Congo” OR “Sao Tome and Principe” OR Sudan OR “Southern Sudan” OR Tuvalu OR

Kiribati OR Libya OR Marshall Is. OR Mauritania OR Micronesia FS OR OPTs OR Mali OR “Gaza & The West Bank” OR Tajikistan OR Uzbekistan OR Iraq OR Uganda OR Myanmar OR Yemen OR Zimbabwe

6. 4-5/or

7. (“Non-state sector” OR “Non state*” OR (formal OR “non formal” OR non-formal OR informal OR traditional OR “traditional practitioner*” OR “traditional healer*” OR licensed OR non-licensed OR “non licensed” OR unlicen* [MeSH Terms])

8. (NGO[ti] OR non-governmental organization*[tiab] OR Non-governmental organisation*[tiab] OR nongovernmental organizations[tiab] OR non-governmental organisations[tiab] OR not-for-profit organizations[tiab] OR not-for-profit organisations[tiab]) OR "Organizations, Nonprofit"[Majr:noexp] OR ("Organizations, Nonprofit/organization and administration"[Majr:noexp] OR "Organizations, Nonprofit/utilization"[Majr:noexp])

9. (“Private Sector”[tiab] OR “Private practice”[tiab] OR “Public private partnership”[tiab] OR “Public-private partnership”[tiab] OR “Public private partnership”[Majr:noexp])) OR “Public private cooperation”[tiab] OR “Public-private cooperation”[tiab])

10. (“Voluntary Health Agencies/manpower”[MeshTerms] OR “Voluntary Health Agencies/organization and administration”[MeshTerms] OR “Voluntary Health Agencies/supply and distribution”[MeshTerms] OR “Voluntary Health Agencies/utilization”[MeshTerms])

11. (“Contract Services”[tiab] OR outsourc*[tw] OR out-sourc*[tw])

12. (“Social franchising”[tw]) OR (franchis*[tw])

13. (faith-based [tw] OR “faith based”[tw] OR “social service”[tw] OR charit*[tw] OR religio*[tw] OR philanthrop*[tw] OR humanitarian*[tw]) AND (organization[tw] OR community[tw] OR society[tw] OR group[tw])

14. 7-13/or

15. 6 AND 14

16. “Primary Health Care” OR “Primary care” OR “Primary health Services” OR “Health Care Reform” OR “Health services” OR “Health Services Accessibility” OR “Delivery of health Care” OR Delivery of Health Care, Integrated OR (integrat* AND (care or service* or delivery or strategy* or program* or management)) OR “Continuity of Patient Care” OR “integrated programs” OR “Patient-Centered Care” OR “health service* delivery” OR “comprehensive health Care” OR “family medicine” OR “family practice” OR “Ambulatory Care” OR “Community Health Services” OR “Community Health Nursing” OR “Child Health Services” OR “Women’s Health Services” OR “Family Planning Services” OR

“Reproductive Health Services” OR “Maternal Health Services” OR “Postnatal Care” OR “Preconception Care” OR “Prenatal Care” OR “Preventive Health Services” OR “Diagnostic Services” OR “Adolescent Health Services” OR “Mental Health Services” OR “Community Mental Health Services” OR “Health Services for the Aged” OR “Health Services, Indigenous” OR “Ambulatory Care Facilities” OR “Mobile Health Units” OR “Rural Health Services” OR “Suburban Health Services” OR “Community Health Centers” OR “Substance Abuse Treatment Centers” OR “Community Mental Health Centers” OR “Child Guidance Clinics” OR “Maternal-Child Health Centers” OR “Outpatient Clinics, Hospital” OR “Outpatients” OR “Health Promotion” OR “Health Education” OR “Sex Education” OR “Patient Education” OR “Primary Prevention” OR “Immunization Programs” OR “Mass Immunization” OR Immunization OR Vaccination OR “disease control program”[tw] OR (primary AND (care or service* or clinic*)) [tw] OR “primary health care” OR (outpatient* AND (care or service* or clinic*)) [tw] OR “Referral and Consultation” OR “Interinstitutional Relations” OR “Community-Institutional Relations” OR integrat*[tw] OR (deliver* AND (with or within or together)) [tw] OR “bring together [tw] OR horizontal [tw] OR vertical [tw] OR coordinat*[tw] OR co-ordinat*[tw] OR link*[tw] OR (multi* AND team*) [tw] OR (multi* AND (care or service* or clinic*)) [tw] OR (multicare or multiservice* or multiclinic*) [tw] OR multiskill*[tw] OR multi skill*[tw] OR multitask*[tw] OR “multi task” [tw]

17. 15 AND 16

We will limit the search to humans and PubMed entry date from 1990/01/01 to date. The purpose of this time limitation is to provide a review of more recent literature and allowing for assessment of PHC interventions a decade after the 1978 Alma Ata declaration (Anonymous, 1978). However, in order to limit the effect of selection bias and expand applicability of these findings we propose to include French literature. To this end we will engage our collaborators in Francophone countries to provide expertise in assessing such studies. The updated list of included countries has 14 countries of Francophone Africa: (Burundi, Central African Republic, Chad, Cote d’Ivoire, Democratic Republic of the Congo (Congo Brazzaville), Equatorial Guinea, Guinea, Guinea Bissau, Mali, Madagascar, Mauritania, Republic of Congo, Rwanda and Togo).

2.2.3 Selection of the studies

EAO and RM will initiate independent and duplicate screening of all titles and abstracts (where available) of all articles obtained from the search, using EPPI-reviewer software to manage the information electronically (Thomas and Brunton, 2006).

The numbers of titles and abstracts (where available) from each search will appear in Appendix 2.2. EAO and RM will determine independently if studies meet the inclusion criteria, upon which we will estimate agreement using Cohen’s kappa (Edwards et al. 2002). We will resolve differences through consultation with RS or NKS.

AK and SR will have conducted duplicate and blinded electronic searches (at least for PubMed) before retrieving all included titles and/or abstracts. The full texts will undergo a round of double screening (FA, RBK, AD, AN, BM and DS) in order to determine which articles should be included in the review. Disagreement will be settled through consultation with RS or RBK or NKS. A list of potentially eligible but excluded full text primary studies will appear in an appendix in the review.

2.2.4 Characterizing included studies

A list of included studies will appear in the detailed tables created during the data extraction process described in section 2.3.2.

2.2.5 Identifying and describing studies: quality assurance process

Quality assurance will be maintained through the dual application of the inclusion and exclusion criteria and the coding will be conducted by pairs of the review team members working independently and then comparing their decisions and when disagreement continues through consulting RS or NKS.

2.3 Methods for synthesis

Studies will be stratified into two groups:

1. Quantitative descriptive studies about non-state provision (objective 1).
2. Quantitative studies measuring effectiveness of effort (objective 1 and 2).

In addition it is possible that quantitative papers measuring effectiveness may provide descriptive information about PHC delivery by non-state actors. Pairs of reviewers will assess the quality of all included studies, since this method has been shown to yield higher agreement (Edwards et al. 2002). The criteria for assessing quality of the studies are different for each of these groups as detailed below.

2.3.1 Assessing Risk of Bias of studies

- a) Studies describing types non-state providers and interventions for primary health care services (Objective 1): For these studies, we will explore the following Risk of Bias aspects for observational studies:

Sampling: It is important that the studies describe the sampling and representativeness of the subjects and measurements involved, including the types of providers, types of health services, and population served. Representative sampling will be given a higher weight than sample driven respondents, and both higher than convenience sampling.

Generalizability: Higher quality scores will be given to those studies that explain how their sample can be generalized to a larger population (e.g. the entire country or conflict-affected area).

Variable definition: These studies will also be assessed by the degree to which the study variables are carefully defined and assessed in reproducible ways.

- b) Quantitative studies addressing effectiveness and impact (Objective 1 & 2)

The quality of included studies will be assessed based on the design of the study according to the hierarchy of study designs as developed and first applied to the non-state sector literature by Peters and colleagues (2004), and outlined in Table 2. The hierarchy is based on guidelines for the quality of scientific studies and strength of the evidence in medicine and public health (Guyatt et al. 1995; Agency for Healthcare Research and Quality 2002; Centre for Evidence-Based Medicine 2001) and the scoring is based upon work by Grimshaw et al. (2004).

We will use the EPPI-Reviewer 4.0 software to manage this systematic review project (<http://epi.ioe.ac.uk/cms/Default.aspx?tabid=2967>). During data abstraction, each quantitative study will be assessed for relevance, outcome data, and quality of description, and classified according to the study design described in table 2. The quality of the studies will be reviewed largely on the following criteria: quality of study methods (assignment to treatment and control group, blinding, degree of potential confounding, classification of outcomes and follow up, and appropriate analysis), magnitude of effect, consistency, and generalizability of findings to other post conflict and fragile states. For research aim 2, this review will concentrate on the strongest study types (D1 and D2 study designs), placing greater weight on those studies that use

the following methods to improve comparisons and reduce potential bias:

- **Difference-in-difference analysis.** This method estimates effects by comparing the value of the indicator of interest between the recipients and non-recipients (first difference) before and after an intervention (second difference).
- **Propensity score matching.** This method calculates propensity scores (probability of participating in the intervention as a function of observed characteristics) for participants and non-participants. Participants are matched to non-participants on the basis of their scores.
- **Difference in means (after-only comparison).** This method estimates impacts by comparing the value of the indicator of interest for the recipients and the non- recipients.
- **Instrumental variables.** This method uses instrumental variables (that affect receipt of the intervention but not the outcomes of interest) to statistically control for selection bias.

Table 2: Categories of Quantitative Study designs

Study Type	Description	Study Design
D1: Randomized controlled trials	Studies that involve a random allocation of the intervention and comparison (such as “usual care”) to different study groups, including measurement of the outcome before and after the intervention is made. “Stepped Wedge” designs mean that the control group involves those who will later receive the intervention, so act as controls for initial comparisons, but are later part of the intervention group.	<u>Post-only randomized control design</u> R E X O1 R C -X O1 <u>Pre-Post randomized control design</u> R E O1 X O2 R C O1 -X O2
D2: Non-randomized controlled trials	Nonrandomized studies containing a before and after measurement that compare results in two or more groups. The comparison intervention may be “usual care” or another intervention.	<u>Pre-post or before-after with nonequivalent groups</u> NR E O1 X O2 NR C O1 -X O2
D3: Uncontrolled intervention: before-after trials and time-series studies	Nonrandomized studies containing a before and after measurement, but without any comparison group for the intervention (such as a cohort study). Time-series studies, where data on the cohort involves more than three data points prior to an intervention and more than three points after an intervention, provide stronger evidence than those with only one baseline point	<u>Group pre-post or before-after trials</u> NR E O1 X O2 <u>Time-series studies</u> NR E O1 O2 O3 X O4 O5 O6 (at least three data points before and after; single or multiple groups)
D4: Case-control studies (and cross-sectional studies with ≥ 2 comparison groups)	Case-control studies dividing groups based on different outcomes, and then assessing prior to “exposure” to an intervention. These studies are based on surveys conducted at one point in time. Nested case-control studies may be considered as having evidence comparable to D2 studies	<u>Post-only design with nonequivalent groups</u> NR E X O1 NR C -X O1
D5: Cross-sectional studies	Measurement is made at one point in time when an intervention has occurred without comparable control groups. Unless there are data to construct a time-series or case-control study, these studies are excluded from the systematic reviews.	<u>Group post-only design (exploratory studies)</u> NR E X O1
D6: Descriptive studies	Descriptive case studies and expert opinions, and reports lacking comparison groups or measurement of outcome variables. These studies are excluded from the systematic reviews.	No comparison and no measurements on outcomes
<p>Source: Author adaptation of Grimshaw et al. 2004</p> <p>R = randomized, NR = nonrandomized, E = experimental, C = control, O = observation, X “treatment” or implementation of strategy, -X = no “treatment” or usual care or existing strategy such as continued training.</p>		

2.3.2 Overall approach to synthesis of evidence

Framework analysis is the method of choice for synthesizing qualitative and quantitative research with the aim of learning about effecting change. Framework analysis allows the combination of issues important to policy makers, practitioners and service users; is sufficiently flexible to allow amendments to the analysis in light of the emerging literature; and leads to learning specifically linked to explicit principles driving activities and their contexts (Oliver et al. 2008).

Two pairs of reviewers (EAO, RM, FA, RBK, AD, DS, AN, BM) will extract the data from all included studies using the Effectiveness of Practice and Organization of Care data abstraction and risk of bias assessment tool, modified to suit this review's needs. Data relating to the following items will be extracted from included studies:

- 1) Administrative data: Author, year of publication and country where the study or project was carried out and type of actor as described in section 1.
- 2) Data describing the health care setting: rural, formal urban settlement, informal urban settlement (slum) and conflict/fragility status of country as described in section 1.
- 3) Data describing the types of interventions: Governance, Financing, Human resources, Health services delivery, information systems and access to health technologies as described in section 2.2.1.
- 4) Outcome and impact assessment data: primary, secondary and health services outcomes, impacts and indicators as described in section 2.2.1
- 5) Data to assess Risk of Bias: Depending on the study design including but not limited to sampling, sample size, control group, blinding, allocation concealment, outcome assessment, follow-up and reporting biases.
- 6) Data to assess equity in the delivery primary health care by non-state actors such as equitable access or utilization (distribution of access across socio-demographic characteristics poverty, rural-urban gap, race, gender, education levels), where available.

We will structure our analysis to answer the two overarching questions proposed in Section 1.5. In the first question is about the types and effects of non-state actors and types of PHC services they provide, we will conduct both structured narrative synthesis and statistical pooling of data as appropriate. Specifically for the studies of effects for the first question, we will apply quantitative synthesis methods in particular Random Effects Meta-analysis (REM), where appropriate. REM is more likely to be appropriate as the studies are expected to be variable because of differences in patient populations, design and intervention and outcome definitions. To the extent possible, if there are randomized controlled trials in the included literature we will visually explore any heterogeneity in results for the primary studies using forest plots (displaying appropriate measures of effect and uncertainty); and quantify this statistically using Higgins I^2 squared as well as significance using Cochran's Q as recommended in the Cochrane Handbook of systematic reviews (Cochrane Collaboration, 2011). If there are sufficient data, possible sources of the heterogeneity will be explored using subgroup analysis and random effects meta-regression.

To use a single statistic on which to compare the articles, the effect size will be calculated for each study together with the associated variance or standard error. Effect sizes will be expressed as odds ratios (OR) which is defined as the odds of a successful or desired outcome in the intervention group relative to the odds of a similar outcome in the control group (Durlak, 2009). The method used to calculate the odds ratio will depend on the type of outcome data reported by individual studies. For studies reporting dichotomous outcome data in the form of counts or proportions, the odds ratio and the associated variance will be calculated on the logarithmic scale using standard 2 x 2 table

formulae (Borenstein et al., 2009), Sutton et al., 2000). For example if the desirable outcome of interest is access to particular healthcare service, then the OR for a study in which 45% of the intervention group (n=100) and 30% of the control group (n=100) had access at end of follow-up will be given by:

$$OR = \frac{0.45 / (1 - 0.45)}{0.30 / (1 - 0.30)} = \frac{0.45 / 0.55}{0.30 / 0.70} = \frac{0.82}{0.45} = 1.91$$

Suggesting that, the intervention is associated with a 90% increased access compared to the control. If a study reports continuous rather than dichotomous data for the outcome (e.g. access to primary healthcare services), then the effect size will first be calculated as a Standardized Mean Difference (SMD) and then converted to OR using the following formula available from the Cochrane Handbook of systematic reviews that allows one effect measure to another and vice versa:

$$SMD = \frac{\sqrt{3}}{\pi} \log(OR)$$

The rationale for converting SMDs to ORs is that it desirable to express effect sizes for the same or related outcomes onto a common metric to facilitate pooling of data across studies. Effect sizes from Control-Before-After (CBA) studies which typically report outcome data at baseline and also at the end of follow-up will be adjusted to account for baseline rates before including them in the meta-analysis using methods described in Kendrick et al. (2012).

For qualitative results and for non-quantitative information included in the primary studies, we strongly suspect that we will employ a conceptual framework that will be constructed to accommodate the characteristics of the non-state sector in fragile and post-conflict states such as the four general typologies of a fragile state (Alliance 2008); the study designs appropriate for drawing conclusions about implementation, reach, maintenance and effects of non-state sector interventions in post-conflict and fragile states; and key issues raised by policy makers, practitioners or service users or emerging from the literature in the course of the review.

2.3.3 Assessing overall quality of evidence for quantitative outcomes

In order to assess the overall quality of evidence from quantitative studies, we will employ the GRADE framework for a select group of important outcomes (Atkins et al. 2004; Guyatt et al. 2008). We have chosen the GRADE approach since this reflects the extent to which we are confident that an estimate of effect is correct, and it is widely accepted and applied for systematic reviews of effects (Guyatt et al. 2008). We will categorize our outcomes into (a) Critical for decision making, (b) Important but not critical for decision making and (c) Low importance for decision making. Using GRADE Profiler software, we will consider the following GRADE criteria to make judgments about the overall quality of evidence: study design limitations (risk of bias), inconsistency or heterogeneity of effect estimates, imprecision, indirectness of the evidence, publication bias, and size of effect estimate, dose-response relationship and plausible confounding. In the final step, for each of the important outcomes we will summarize this degree of confidence into four categories: high, moderate, low and very low, (table 3). Noteworthy, using the GRADE framework randomized studies start at high quality of evidence and are downgrade-able; whilst all observational studies are set at low quality of evidence, with potential for upgrading (Balshem et al. 2011).

Table 3: GRADE categories of quality of evidence from quantitative studies

GRADE category	Explanation	Symbol
High	We are very confident that the true effect lies close to that of the estimate of the effect	⊕⊕⊕⊕
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different	⊕⊕⊕○
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect	⊕⊕○○
Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect	⊕○○○

Handling missing data

In the event of missing important information, we will attempt to contact corresponding authors to make available these data. A recent review found that 87% of trials had participants with missing data (Akl et al. 2012). Missing participant data increases the risk of bias, which may reduce the confidence in the estimates of effect (Akl et al. 2013). We anticipate that this missing information will include important but unreported outcomes, for example in quantitative studies of effectiveness, study level characteristics or patient demographics, mortality, morbidity, and other patient important outcomes or incomplete economic analyses. In certain instances if such data are reported, this is done in a manner that does not permit full assessment.

Where we are unable to access important information on outcomes, we will employ two possible approaches as deemed appropriate: (a) For excluded participants for whom data are available, we will add the total of the excluded participants to the denominator and the number of events to the numerator before conducting meta-analysis (Akl et al. 2013); (b) For missing participant data, we will report this as Not Reported (NR) and conduct a Complete Case Analysis (CCA) (Akl et al. 2013).

2.4 Deriving conclusions and implications

A series of tables will be prepared to describe the evaluative literature in terms of the characteristics of models to engage the non-state sector for primary care in fragile and post- conflict states and their context, and the focus of their evaluation (reach, implementation, maintenance or effects). The research evidence about working with the non-state sector for primary care will be described in terms of the populations served, the details of the interventions, the outcomes addressed and equity and economic analyses. We will reflect and synthesize based on themes that emerge such as level and type of provider included in the intervention, fragility typology of the setting, but always in response to our objectives so that we can present:

- 1) the types of state and non-state actors can be identified to offer different types of primary health services in fragile/post-conflict settings,
- 2) the effect of different approaches and strategies- financing, organizational, or oversight-in improving the delivery of primary care in fragile/post-conflict settings and
- 3) the impact of primary health service delivery as it contributes to better health outcomes.

The synthesis in each area will be presented as possible using our results framework of health service impacts, health outcomes and societal impacts.

We will reflect on our synthesized results through the wider literature for fragile states and for the non-state sector as appropriate. We will consult with experts in these fields as well as with our advisory group.

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Appendices

Appendix 1.1: Authorship of this protocol

Policymakers/Advisory Group/Technical Support:
Department for International Development (DFID):

1. Malcom McNeil
2. Chris Lewis
3. Laura Rivkin

EPPI-Centre, University of London (UoL):

1. Professor Sandy Oliver
2. Ms. Kelly Anderson
3. Dr. Claire Stansfield

Fragile States Experts:

1. Dr. William Newbrander, Management Sciences of Health (MSH), USA

Review Group membership:

Name	Institution
Ekwaro OBUKU	PhD Fellow and Project Officer, Makerere University College of Health Sciences, Kampala, UGANDA
Rhona MIJUMBI	PhD Fellow and Research Scientist, Makerere University College of Health Sciences, Kampala, UGANDA
Nelson SEWANKAMBO	Professor of Medicine and Principal, Makerere University College of Health Sciences, Kampala, UGANDA
Alison KINENGYERE	Information Science Specialist and Chief Librarian, Sir Albert Cook Library, Makerere University College of Health Sciences, Kampala, UGANDA
Ruth STEWART	University of Johannesburg, Johannesburg, RSA
Robert BASAZA	Research Scientist, Makerere University College of Health Sciences, Kampala, UGANDA
Felix ACHANA	PhD Fellow, University of Leicester, Leicester, UK
Richard SENONO	Librarian, Infectious Diseases Institute, Makerere University College of Health Sciences, Kampala, UGANDA
Boniface MUTATINA	PhD Fellow, Makerere University College of Health Sciences, Kampala, UGANDA
Allen NSANGI	PhD Fellow, Makerere University College of Health Sciences, Kampala, UGANDA
Daniel SEMAKULA	PhD Fellow, Makerere University College of Health Sciences, Kampala, UGANDA
Dickens AKENA	Psychiatrist, Department of Psychiatry, Makerere University College of Health Sciences, Kampala, UGANDA

Name	Institution
Hannington MUYENJE	Coordinator, Innovations and Knowledge Translation Office, Makerere University College of Health Sciences, Kampala, UGANDA

Fragile States Experts Advisory Panel

Name	Institution
William Newbrander	Senior Technical Advisor for Health Systems Strengthening African Strategies for Health Project Management Sciences for Health Cambridge, MA, USA

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Conflicts of interest

EAO, RM, AK, FA, DA, SR, RBK, AN, DS, RS, MH and NKS report no conflicts of interest.

Contact details

Ekwaro A. OBUKU,
Africa Centre for Systematic Reviews and Knowledge Translation,
Makerere University College of Health Sciences,
P.O Box 7072,
KAMPALA, UGANDA.

Tel: +256 (0) 414 530020/1 Cell: +256 (0) 752 375928

Fax: +256 (0) 414 532204

Email: eobuku@chs.mak.ac.uk

Website: <http://chs.mak.ac.ug/afcen/about-us>

Appendix 2.1: Inclusion and exclusion criteria

Types of studies

All types of studies will be included in this review, but sorted according to the type of research question they address. Observational studies such as surveys, cohort studies, case- controlled studies and case studies (with or without economic or equity analyses) will be considered potentially suitable for assessing coverage, utilization, implementation and maintenance issues (Objectives 1 and 3). Randomised and non-randomised trials, controlled before and after studies, and interrupted time series will be considered potentially suitable for assessing effects of interventions (Objective 2). Systematic and non-systematic reviews will also be considered for inclusion.

Publications describing and/or analyzing theoretical frameworks will also be reviewed to contribute to the goals of the study.

Opinion pieces and policy documents will be excluded.

Types of studies

Observational studies such as surveys, cohort studies, case- controlled studies and case studies (with or without economic or equity analyses) will be considered potentially suitable for assessing coverage, utilization, implementation, scalability and sustainability. Randomised controlled trials (RCTs) and non-randomised controlled trials (non-RCTs), controlled before and after studies, and interrupted time series will be considered potentially suitable for assessing effects and impacts of interventions. Studies on economic analyses will be used to capture costing and cost-effectiveness of specific interventions of primary health care by non-state actors. Systematic and non-systematic reviews will also be considered for inclusion as a guide to finding primary studies.

Publications describing and/or analysing theoretical frameworks, opinion pieces and policy documents will be excluded.

Types of participants and setting

Primary care providers (formal/informal) of non-state sector health care delivery in fragile and post-conflict states are eligible as described in section 1.2.2. All types of patients/consumers in the non-state sector in fragile and post-conflict states are eligible as defined in section 1.2.1.

We will exclude: Patients and providers in non-fragile/non-post conflict states, exclusively in the public sector and not engaged in primary care (e.g. secondary/tertiary care).

Types of interventions

Non-state sector interventions will be considered for inclusion in this review if they conduct or support the delivery of primary care in the non-state sector in fragile and post-conflict states. We will identify interventions covering the six health system pillars of the World Health Organization (WHO, 2004). These are arrangements for governance, financing, human resources, health services delivery, information systems and improving access the health technologies (WHO, 2004; Lavis, 2002). Governance arrangements would include mechanisms for engaging the non-state sector like contracting out, social franchising, and public-private partnerships. Financing arrangements will cover financial protection for example use of vouchers for antenatal care and maternal deliveries, user-fees, community health insurance, performance-based or results-based financing. Arrangements for human resources will include training, mentorship, supportive supervision, task-shifting amongst others that we will identify by reviewing this literature.

We will exclude interventions focused on secondary or tertiary care.

Types of outcome and impact measures

Although our methodology is more conducive to inclusively exploring the literature, when provided we propose to collect information on this tentative list of outcomes organised according to a three part results framework:

- 1) Primary Outcomes
 - (a) Health vital status outcomes i.e. changes in child, maternal and population general and disease specific mortality and morbidity rates.
- 2) Secondary Outcomes or Impacts
 - (a) Health sector capacity building i.e. governance mechanisms, training of human resources, information systems, procurement systems, infrastructure development.
 - (b) Adverse effects of non-state actors' interventions in primary health care i.e. undesirable impacts on existing public or private services, inappropriate use of services, distortions in the provision of services and mal-distribution of human resources.
- 3) Health service delivery process indicators or impacts
 - (a) Access to services i.e. affordability, utilization, client volume
 - (b) Coverage of health services i.e. health facility or health worker to patient or population ratios
 - (c) Quality of care i.e. compliance with nationally or W.H.O accredited standards
 - (d) Patient satisfaction i.e. utilization and intention to return for the service
 - (e) Cost-effectiveness of the non-state actors' primary health care interventions
 - (f) Cost of specific primary health care services i.e. maternal and child health care
 - (g) Catastrophic costs to primary health care user
 - (h) Out-of-pocket payments or user fees for health service

Appendix 2.2: Search strategy for electronic databases

Please see section 2.2.2 for the complete Medline search strategy. All search strategies will appear in this appendix in the full review.

Appendix 2.3: Draft coding guide

Data relating to the following items will be extracted from included studies:

- 1) Administrative data: Author, year of publication and country where the study or project was carried out and type of actor as described in section 1.
- 2) Data describing the health care setting: rural, formal urban settlement, informal urban settlement (slum) and conflict/fragility status of country as described in section 1.
- 3) Data describing the types of interventions: Governance, Financing, Human resources, Health services delivery, information systems and access to health technologies as described in section 2.2.1.
- 4) Outcome and impact assessment data: primary, secondary and health services outcomes, impacts and indicators as described in section 2.2.1
- 5) Data to assess Risk of Bias: Depending on the study design including but not limited to sampling, sample size, control group, blinding, allocation concealment, outcome assessment, follow-up and reporting biases.
- 6) Data to assess equity in the delivery primary health care by non-state actors such as equitable access or utilization (distribution of access across socio-demographic characteristics poverty, rural-urban gap, race, gender, education levels), where available.

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Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre)
Social Science Research Unit
Institute of Education, University of London
18 Woburn Square
London WC1H 0NR

Tel: +44 (0)20 7612 6397

<http://eppi.ioe.ac.uk/>

<http://www.ioe.ac.uk/ssru/>

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telephone: +44 (0)20 7947 9556 email: info@ioe.ac.uk