

Structure for a protocol

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Sub title	n/a
Review group	Health and the Non-State Sector
Section	PROCOTOL
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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). Another important area of focus for the review is identifying the role of the national government in regulation, coordination and information sharing among public and non-state providers, in settings where lack of regulation and organization 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. The dynamic between the immediate needs of vulnerability reduction and the achievement of specific health outcomes versus the longer term objectives of building sustainable health systems that promote equitable access as well as broader measures to strengthen civil society is central theme in the literature so that there is a need for a review to address both the immediate and long range outcomes of health service delivery programs in fragile states (High Level Forum 2005).

Despite the wealth of challenges, from poor health to extreme poverty to 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 where 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;' however, 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 Organization 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 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 general fall into four typologies: prolonged crisis, post-conflict or political transition, gradual improvement or deteriorating government (Alliance 2008).

Included Countries:

The list of fragile and post-conflict states for inclusion in this study was developed using two sources, the World Bank list of fragile states (also termed Lower Income Countries Under Stress of LICUS) which is available from 2003 to 2006 and the Foreign Policy Failed States Index, which is available from 2005 thru 2009. A combined list was used because the approach is more inclusive, has broader and more diverse inclusion criteria, and because lists from each of the sources were found to have limitations when taken in the context of this review. Limitations of the World Bank list were 1) it is not available after 2006; 2) it is heavily concentrated in Africa; and 3) some countries are missing from list that many people might consider fragile states (ex: Nepal, Sri Lanka, Iraq, Yemen). Limitations of The Foreign Policy Failed States Index include 1) it is focused on social, economic, and political indicators and may not employ a methodology that is ideal for our purposes; and 2) the list is substantially longer than that of World Bank which could broaden the scope of the review. However, given that the World Bank fragile states list is only available thru 2006, this may be the best way to objectively identify states which are have become more unstable in recent years. The combined list that was developed from these two sources includes all countries listed by the World Bank as fragile states or 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. The final list was comprised of 50 countries, and nearly half (48%) of the identified countries were in Africa. For each of the listed countries, 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 and included 20 conflict-affected countries; 21 post-conflict countries; and 11 non-conflict affected countries considered to be fragile states. The 21 countries identified as post-conflict and the 11 countries identified as fragile states were included as review countries; the 20 currently conflict-affected countries will also be considered for inclusion depending on the duration of the conflict and the scope of available literature.

Table 1. Included countries*

Fragile States (non-conflict affected)	
Djibouti (1991-1999)	Sao Tome and Principe
Equatorial Guinea	Togo (1986-91)
Lao PDR	Uzbekistan (1999-2000)
Niger (1991-97)	Vanautu
Papua New Guinea (1989-90)	Zimbabwe
Sao Tome and Principe	
Post-conflict	
Angola (1975-2002)	Haiti (1989-2004)
Bhutan	Kosovo (1998-2006)
Bosnia & Herzegovina (1992-1995)	Lebanon (2006-2007)
Cambodia (1978 - 1999)	Liberia (2000-2003)
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)	
Conflict-Affected	

Afghanistan (1978 -)	Nepal (1996-2008)
Burundi (1988-2009)	Nigeria (1990 -)
Chad (1966-)	North Korea (1953 -)
Central African Republic (1996-2006)	Pakistan (1992-)
Colombia (1964 -)	Somalia (1988 -)
Cote d'Ivoire (2002 - 2007)	Sri Lanka (1983 - 2009)
Democratic Republic of Congo (1990 -)	Sudan (1983 -)
Gaza & The West Bank (1948 -)	Tajikistan (1992-2000)
Iraq (2003-)	Uganda (1987 -)
Myanmar (1988 -)	Yemen (2004 -)

* 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 are comprised of formal, informal, for-profit, and not-for-profit actors whose aim is to treat illness or prevent disease. 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 organizations, 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 that 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 healthcare is better health for the entire population. The concepts of primary healthcare are dictated most clearly in the Alma Ata Declaration (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 a 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)

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). 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. Some of the 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 scoping review is to assess the size and nature of the literature addressing the research questions. It can be used to judge which areas of the fragile and post conflict states health service literature may be the focus of further, more detailed systematic reviews that appraise the quality of the studies and synthesize their findings as well as identify gaps in the literature and provide a basis for planning future research in the area of working with the non-state sector for primary care in fragile and post-conflict states.

It is not the intention to provide a comprehensive catalogue of all studies, particularly as many of them are published as standalone reports rather than in indexed journals readily identified in bibliographic databases. The objective is to illustrate the range of non-state models that have been evaluated and therefore may provide lessons about their applicability in different contexts, and specifically:

- To determine the scope of the literature addressing the availability and utilization of health services , implementation (adherence and integrity of interventions and strategies), maintenance (or sustainability) of efforts, and how well different models work for engaging non-state sector providers for primary care in fragile and post conflict states, and
- To use the literature to describe in detail models of non-state sector engagement for primary care in fragile and post-conflict states, their theoretical basis, and measures of effects on health systems and related social goals .

We ask the following specific research questions:

- 1) Which types of state and non-state actors can be identified to offer different types of primary health services in fragile/post-conflict settings?
- 2) How effective are different approaches and strategies- financing, organizational, or oversight-in improving the delivery of primary care in fragile/post-conflict settings? and
- 3) How does the strengthening of primary health service delivery contribute to better health outcomes while addressing different dimensions of fragility (e.g. capacity, legitimacy, social capital) and linking to other sectors to build trusted and accountable public institutions?

2. Methods used in the review

2.1 User involvement

For over three decades, the World Health Organization 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. Further we will consult with our advisory group. Further, we have accepted new advisory group members who have contacted us about the review and work in/are interested in fragile and post-conflict states.

2.2 Identifying and describing studies

2.2.1 Defining relevant studies: 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, but opinion pieces and policy documents will be excluded.

Types of participants

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. This would include mechanisms for engaging the non-state sector like contracting out, social franchising, and public-private partnerships.

We will exclude interventions focused on secondary or tertiary care.

Types of outcome 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 organized according to a three part results framework:

Health Service Impacts

- Access to services (e.g. affordability, utilization, client volume)
- Quality of care (e.g. compliance with standards)
- Patient satisfaction (e.g. intent to return)

- Cost/service (from a societal perspective or the perspective of the provider or patients)
- Catastrophic cost
- Out-of-pocket payment
- Equitable access or utilization (distribution of access across socio-demographic characteristics)
- Sustainability
- Scalability

Outcomes

- Health status outcomes (e.g. mortality, morbidity, malnutrition)

Societal Impacts

- Adverse effects (e.g. undesirable impacts on existing public or private services, inappropriate use of services, distortions in the provision of services)
- Health Sector Capacity Building (e.g., governance, training)

2.2.2 Identification of potential studies: Search strategy

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)
- Cochrane Central Register of Controlled Trials (*The Cochrane Library*, most current)
- MEDLINE, PubMed (1990 to present)
- Science Citation Index Expanded and Social Sciences Citation Index (1990-present)
- WHOLIS (1990 - present)

We will use the following MEDLINE Ovid search strategy from 1950 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.

We also plan to search the following databases, web sites and other sources for primary studies:

- Eldis
- Google Scholar
- World Bank
- Health and Fragile States Network
- Marie Stoppes International
- PSI
- USAID
- MSH
- Reference lists of all papers and relevant reviews identified.
- Conference proceedings from subject matter specific meetings.
- Authors of relevant papers regarding any further published or unpublished work.

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 used the following MEDLINE Ovid search strategy from 1990 to date. It will be adapted for the other databases listed above.

Line 1-9 terms related to fragile states

Line 11-20 terms related to non state provider

Line 24-30 terms related to Primary health care service or other outcomes

Medline Search Strategy:

1. (Conflict OR Post conflict OR post-conflict OR failure OR collapsed OR vulnerable OR conflict-affected)[tw]
2. (under Stress OR under-stress)[tw] OR (crisis OR failed) [tw]
3. Remote[tiab] OR 'hard to reach' [tiab]
4. (State* OR country* OR region* OR area* OR territory* OR land) [tw]
5. (#1 OR #2 OR #3) AND #4
6. ("Developing Countries"[MeSH]) OR (less developed countr*[tiab]) OR (third world countr*[tiab]) OR (under developed countr*[tiab]) OR (underdeveloped countr*[tiab]) OR (developing nation*[tiab]) OR (less developed nation*[tiab]) OR (third world nation*[tiab]) OR (under developed nation*[tiab]) OR (low income countr*[tiab]) OR (low income nation*[tiab])
7. ("djibouti"[MeSH Terms] OR "djibouti"[All Fields]) OR ("equatorial guinea"[MeSH Terms] OR ("equatorial"[All Fields] AND "guinea"[All Fields]) OR "equatorial guinea"[All Fields]) OR (peoples[All Fields] AND democratic[All Fields] AND republic[All Fields] AND ("laos"[MeSH Terms] OR "laos"[All Fields]) OR Lao Pdr[tiab]) OR("niger"[MeSH Terms] OR "niger"[All Fields]) OR "papua new guinea"[MeSH Terms] OR ("papua"[All Fields] AND "new"[All Fields] AND "guinea"[All Fields]) OR "papua new guinea"[All Fields] OR ("atlantic islands"[MeSH Terms] OR ("atlantic"[All Fields] AND "islands"[All Fields]) OR "atlantic islands"[All Fields] OR ("sao"[All Fields] AND "tome"[All Fields] AND "principe"[All Fields]) OR "sao tome and principe"[All Fields]) OR ("togo"[MeSH Terms] OR "togo"[All Fields]) OR ("uzbekistan"[MeSH Terms] OR "uzbekistan"[All Fields]) OR ("vanuatu"[MeSH Terms] OR "vanuatu"[All Fields]) OR ("zimbabwe"[MeSH Terms] OR "zimbabwe"[All Fields])
8. ("afghanistan"[MeSH Terms] OR "afghanistan"[All Fields]) OR ("angola"[MeSH Terms] OR "angola"[All Fields]) OR ("bosnia-herzegovina"[MeSH Terms] OR "bosnia-herzegovina"[All Fields] OR ("bosnia"[All Fields] AND "herzegovina"[All Fields]) OR "bosnia and herzegovina"[All Fields]) OR ("cambodia"[MeSH Terms] OR "cambodia"[All Fields]) OR("central african republic"[MeSH Terms] OR "central african republic"[All Fields]) OR ("comoros"[MeSH Terms] OR "comoros"[All Fields]) OR ("cote d'ivoire"[MeSH Terms] OR ("cote"[All Fields] AND "d'ivoire"[All Fields]) OR "cote d'ivoire"[All Fields] OR ("ivory"[All Fields] AND "coast"[All Fields]) OR "ivory coast"[All Fields]) OR ("eritrea"[MeSH Terms] OR "eritrea"[All Fields]) OR ("ethiopia"[MeSH Terms] OR "ethiopia"[All Fields]) OR ("georgia"[MeSH Terms] OR "georgia"[All Fields] OR "georgia (republic)"[MeSH Terms] OR ("georgia"[All Fields] AND "(republic)"[All Fields]) OR "georgia (republic)"[All Fields]) OR ("guatemala"[MeSH Terms] OR "guatemala"[All Fields]) OR ("guinea"[MeSH Terms] OR "guinea"[All Fields]) OR ("guinea-bissau"[MeSH Terms] OR "guinea-bissau"[All Fields] OR ("guinea"[All Fields] AND "bissau"[All Fields]) OR "guinea bissau"[All Fields]) OR ("haiti"[MeSH Terms] OR "haiti"[All Fields]) OR ("yugoslavia"[MeSH Terms] OR "yugoslavia"[All Fields] OR "kosovo"[All Fields]) OR ("lebanon"[MeSH Terms] OR "lebanon"[All Fields]) OR ("liberia"[MeSH Terms] OR "liberia"[All Fields]) OR Rep[All Fields] AND ("congo"[MeSH Terms] OR "congo"[All Fields]) OR ("rwanda"[MeSH Terms] OR "rwanda"[All Fields]) OR ("sierra leone"[MeSH Terms] OR "sierra leone"[All Fields]) OR ("melanesia"[MeSH Terms] OR "melanesia"[All Fields] OR ("solomon"[All Fields] AND "islands"[All Fields]) OR "solomon islands"[All Fields]) OR ("east timor"[MeSH Terms] OR "east timor"[All Fields]) OR ("timor"[All Fields] AND "leste"[All Fields]) OR "timor leste"[All Fields])

9. ("bhutan"[MeSH Terms] OR "bhutan"[All Fields]) OR ("burundi"[MeSH Terms] OR "burundi"[All Fields]) OR ("chad"[MeSH Terms] OR "chad"[All Fields]) OR ("colombia"[MeSH Terms] OR "colombia"[All Fields]) OR ("congo"[MeSH Terms] OR "congo"[All Fields]) AND Democratic[All Fields] AND republic[All Fields]) OR republic[All Fields] OR ("congo"[MeSH Terms] OR "congo"[All Fields]) AND Republic[All Fields]) OR ("congo"[MeSH Terms] OR "congo"[All Fields])OR Gaza[All Fields] AND ("middle east"[MeSH Terms] OR ("middle"[All Fields] AND "east"[All Fields]) OR "middle east"[All Fields] OR ("west"[All Fields] AND "bank"[All Fields]) OR "west bank"[All Fields]) OR ("iraq"[MeSH Terms] OR "iraq"[All Fields]) OR "myanmar"[MeSH Terms] OR "myanmar"[All Fields] OR "burma"[All Fields]) OR ("nepal"[MeSH Terms] OR "nepal"[All Fields]) OR ("nigeria"[MeSH Terms] OR "nigeria"[All Fields]) OR ("democratic people's republic of korea"[MeSH Terms] OR ("democratic"[All Fields] AND "people's"[All Fields] AND "republic"[All Fields] AND "korea"[All Fields]) OR "democratic people's republic of korea"[All Fields] OR ("north"[All Fields] AND "korea"[All Fields]) OR "north korea"[All Fields]) OR ("pakistan"[MeSH Terms] OR "pakistan"[All Fields]) OR ("somalia"[MeSH Terms] OR "somalia"[All Fields]) OR ("sri lanka"[MeSH Terms] OR "sri lanka"[All Fields]) OR ("sudan"[MeSH Terms] OR "sudan"[All Fields]) OR ("tajikistan"[MeSH Terms] OR "tajikistan"[All Fields]) OR ("uganda"[MeSH Terms] OR "uganda"[All Fields]) OR ("yemen"[MeSH Terms] OR "yemen"[All Fields]) OR Republic[All Fields] AND ("yemen"[MeSH Terms])
10. OR / 5 - 9
11. (Non state sector OR Non state*) OR (formal OR non formal OR informal OR traditional OR licensed OR non licensed OR unlicensed OR drug vendors OR medicine sellers)[tiab] OR General practitioners[MeSH]
12. (NGO [tiab] OR "Organizations, Nonprofit"[Majr:noexp] OR ("Organizations, Nonprofit/organization and administration"[Majr:noexp] OR "Organizations, Nonprofit/utilization"[Majr:noexp]))
13. ("Private Sector/classification"[Mesh] OR "Private Sector/economics"[Mesh] OR "Private Sector/organization and administration"[Mesh] OR "Private sector/standards"[Mesh] OR "Private Sector/utilization"[Mesh]) OR Private practices [MeSH]
14. (Public private sector partnership[Majr:noexp])) OR ((Public private cooperation[tw])) OR ((Public private partnership[TW]))
15. ("Voluntary Health Agencies/manpower"[Mesh] OR "Voluntary Health Agencies/organization and administration"[Mesh] OR "Voluntary Health Agencies/supply and distribution"[Mesh] OR "Voluntary Health Agencies/utilization"[Mesh])
16. (("Contract Services/manpower"[Majr:noexp] OR "Contract Services/methods"[Majr:noexp] OR "Contract Services/organization and administration"[Majr:noexp] OR "Contract Services/standards"[Majr:noexp] OR "Contract Services/utilization"[Majr:noexp])) OR ((Contract services[TW]))
17. ((profit*[tw] OR nonprofit*[tw]) AND (organisat*[tw] OR organizat*[tw])) OR (((not for profit"[tw]) AND (organiz*[tw] OR organis*[tw]))
18. social franchising[tiab] OR franchis* [tw]
19. (faith [tw] AND based [tw]) OR (social [tw] AND service [tw]) OR (charities[tw] OR religio*[tiab] OR philanthropi* OR humanitarian [tw] OR humanitari*)
20. (organization[tw] OR organiz* OR community[tw] OR society[tw] OR group[tw])
21. 19 AND 20
22. OR / 11 - 18
23. OR / 21 - 22

24. "Primary Health Care/economics"[Majr:noexp] OR "Primary Health Care/manpower"[Majr:noexp] OR "Primary Health Care/standards"[Majr:noexp] OR "Primary Health Care/utilization"[Majr:noexp]
25. Health Services [MeSH] OR ("Outsourced Services/economics"[Mesh] OR "Outsourced Services/ethics"[Mesh])) OR ("Privatization/economics"[Mesh] OR "Privatization/ethics"[Mesh])) OR ("Outcome and Process Assessment (Health Care)/economics"[Mesh] OR "Outcome and Process Assessment (Health Care)/ethics"[Mesh] OR "Outcome and Process Assessment (Health Care)/organization and administration"[Mesh] OR "Outcome and Process Assessment (Health Care)/utilization"[Mesh])) OR ("Health Services Needs and Demand/economics"[Mesh] OR "Health Services Needs and Demand/statistics and numerical data"[Mesh] OR "Health Services Needs and Demand/utilization"[Mesh])) OR ("Health Care Reform/economics"[Mesh] OR "Health Care Reform/organization and administration"[Mesh] OR "Health Care Reform/utilization"[Mesh]) OR ("Health Services Accessibility/economics"[Mesh] OR "Health Services Accessibility/statistics and numerical data"[Mesh] OR "Health Services Accessibility/utilization"[Mesh]) OR ("Delivery of Health Care/methods"[Majr:noexp] OR "Delivery of Health Care/organization and administration"[Majr:noexp] OR "Delivery of Health Care/standards"[Majr:noexp] OR "Delivery of Health Care/utilization"[Majr:noexp]) OR Health Services [MeSH]
26. (access OR equity OR quality OR efficiency OR performance OR coverage OR utilization OR patient satisfaction)[tw] OR Patients treated [tw] OR Health Services Accessibility [tw] OR Comprehensive Health Care [tw]
27. health care cost[tiab] OR Fees and Charges [Mesh] OR Health Expenditures [Mesh] OR Insurance, Health [Mesh] OR Catastrophic expenses [tw] OR Out of pocket payment [tw] OR Health expenditures [Mesh]
28. (Training OR capacity building OR human resources) [tw] OR Health Manpower [Mesh] OR Staff Development [Mesh] OR Health Personnel [Mesh] OR Health Policy [Mesh]
29. Patient Acceptance [tw] OR (Disease Management [Mesh] AND Quality [tw]) OR (Health care [tw] AND Access [tw])
30. local planning [tw] OR Credentialing [Mesh] OR Decentralization [tw] OR Health Care Reform [Mesh]
31. OR / 24 - 30
32. 10 AND 23 AND 31

Limits: Humans and English, Entry date from 1990/01/01 to date

2.2.3 Selection of the studies

Two reviewers (TK, RG, HT and MR) will screen 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. The reviewers will determine independently if studies meet the inclusion criteria. Differences will be resolved through consultation with DP.

We will retrieve all included titles and/or abstracts. The full texts will undergo a round of double screening in order to determine which articles should be included in the review. Disagreement will be settled through consultation with DP. A list of excluded full text primary studies will appear in an appendix in the review.

2.2.4 Characterising 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 RG members working independently and then comparing their decisions and when disagreement continues through consulting DP.

2.3 Methods for synthesis

Studies will be stratified into three groups: 1. Quantitative descriptive studies and qualitative studies that describe non-state provision (objective 1); 2. Quantitative papers measuring effectiveness of efforts (objective 2); 3. Qualitative studies to address how implementation worked and effects on institutions and fragility (objective 3). Mixed methods studies will be classified into more than one group as applicable. Each of the groups of papers would have a different abstraction form that is customized to the objective, and assessed according to the methodology. The criteria for assessing quality of the studies are different for each of these groups. Two reviewers will assess the quality of all included studies.

2.3.1 Assessing quality of studies

Quantitative and Qualitative Studies to Describe Non-State Providers and Primary Health Care Services (Objective 1)

For these studies, 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. 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). These studies will also be assessed by the degree to which the study variables are carefully defined and assessed in reproducible ways.

Quantitative Studies Addressing Effectiveness (Objective 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).

From strongest to weakest the designs are:

- (1) *Randomized controlled trials* (RCTs): Studies that involve a random allocation of the intervention and comparison (e.g. usual care) to different study groups, including measurement of the outcome before and after the intervention has been made.
- (2) *Non-randomized controlled interventions*: Non-randomized 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. Case-control studies, which divide groups based on different outcomes, and then assess prior 'exposure' to an intervention, could also be considered in this group (especially if the assessment of the involvement in an intervention is made in a nested, i.e. prospective, manner).

(3) *Uncontrolled interventions*: Non-randomized studies containing a before-and-after measurement, but without any comparison group for the intervention (a single cohort study).

(4) *Cross-sectional studies*: Studies based on surveys conducted at one point in time without comparison groups. (Peters et al. 2004)

During data abstraction, each quantitative study will be assessed for relevance, scientific strength, outcome data, and quality of description, and classified according to the study design described in table 1. 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), though will also examine D3 and D4 studies, 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 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

Source: Author adaptation of Grimshaw et al. 2004

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.

Qualitative Studies to Explain How Implementation Worked and Effects on Institutions and Fragility (Objective 3)

A recent study suggests that different structured approaches to reviewing qualitative research do not produce consistent results in assessing whether to include qualitative studies in a systematic review (Dixon-Woods et al., 2007). We will therefore apply a framework for appraising the study quality of quantitative studies, adapting the Critical Appraisal Skills Programs (CASP) and Quality in Qualitative Evaluation A Framework for Assessing Research Evidence (QF) to evaluate systematically how each qualitative research was conducted (Public Health Resource Unit, 2006; Spencer et al 2003). One major issue about appraising qualitative research is to determine the appropriateness of qualitative approach for each study. Qualitative studies are often conducted when researchers are interested in "understanding insiders' views", "identifying" variables for further quantitative study, or "to gain a deeper understanding of how things work" rather than "measuring" variables (Varkevisser et al 2003; Green & Thorogood 2004; Peters et al 2009).

We would review the quality of each qualitative paper using a systematic checklist that covers the following items:

- Fit of research design to research methods, including justification by the researcher
- Sampling strategy explained and appropriate for the research aims
- Clear description and justification for data collection methods used
- Clear explanation and interpretation of the relationship between the researcher and the study participants (reflexivity)
- Ethical conduct of human subject research
- Explanation and rigor of analysis methods
- Clear statement of findings
- Identified added value of research

2.3.2 Overall approach to and process of synthesis

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 reviewers will extract the data from all included studies using a standardized form. Data relating to the following items was extracted from all included studies:

- 1) Participants (health providers and service users). For health providers this included the number of providers and information on type of health care provider. For service users this included the number of users and the health problems/treatment received, age, and demographic details and their cultural background.
- 2) Health care setting (rural, formal urban settlement, informal urban settlement (slum)) and country as well as conflict/fragility status of country.
- 3) Study design and the key features of studies. To include but not limited to: Randomised and non-randomised trials, controlled before and after studies, and interrupted time series, surveys, cohort studies, case-controlled studies and case studies (with or without economic or equity analyses).
- 4) Intervention; description of model of working with the non-state sector: type of engagement (contracting out, franchising, public-private partnership, any others encountered in the literature). Where relevant we will include data on the comparison group intervention.
- 5) For outcome evaluations; outcomes including access (e.g. affordability, utilization, client volume, attendance); health outcomes; quality of care (e.g. compliance with guidelines, case notification for TB); cost/service (from a societal perspective or the perspective of the provider or patients to include catastrophic cost); patient satisfaction (e.g. intent to return); provider satisfaction; adverse effects (in addition to undesirable

impacts on any of the above outcomes, e.g. undesirable impacts on existing public or private services, inappropriate use of services, distortions in the provision of services); any other outcome described in the literature.

6) For all evaluations, measures of equity, such as equitable access or utilization (distribution of access across socio-demographic characteristics poverty, rural-urban gap, race, gender, education levels), where available.

7) For all evaluations, economic evaluation if measures available.

8) For all evaluation, scalability and sustainability, where available.

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 bubble plots or box plots (displaying medians, interquartile ranges and ranges). If there are sufficient data, we will explore heterogeneity in the findings for the primary outcomes using meta-regression.

Effect sizes will be assessed for each primary outcome for each study, which will equal the percentage point change in a performance indicator of an intervention group minus the change in the comparison group. When a study has more than one primary outcome, we will also calculate a median effect size as a summary measure of the study.

To use a single statistic on which to compare the articles, the effect size of each outcome will be calculated for each of the studies reviewed. The effect size will be calculated using four individual data points: post-intervention percentage for the intervention group; pre-intervention percentage for the intervention group; post-intervention percentage for the control group; and pre-intervention percentage for the control group using the following formula:

$$\text{Effect size} = (\%POST - \%PRE)_{\text{intervention}} - (\%POST - \%PRE)_{\text{control}}$$

When outcomes are determined as percentages, the effect size will be calculated as the net difference between percentage improvements in the intervention group and comparison group or the relative gain from the intervention (Ross-Degnan et al. 1997). If the outcome is not in the form of a percentage, then each value will be first converted to a percentage and then the effect size calculated. For example, if correct treatment rates in an intervention group increased from 25 percent to 55 percent (a 30 percentage point improvement), and correct treatment in the comparison group increased from 20 percent to 30 percent (a 10 percentage point improvement), the effect size for the strategy would be 20 percentage points (i.e., 30 minus 10 percentage points). For each study, one effect size was used to measure the study's effectiveness, and that was the effect size of the primary outcome (or a median effect size for studies where there was more than one outcome). We will then examine which variables are related to whether there was a positive effect, or the size of the effect, through cross-tabulations and regression analyses where sample size is sufficient.

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. Further, we will structure our analysis to answer the three overarching questions proposed in Section 1.5.

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 three 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 strengthening of primary health service delivery as it contributes to better health outcomes while addressing different dimensions of fragility.

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

Appendices should be numbered according to the chapter they relate to (i.e. Appendix 1.1 relates to Chapter 1, Appendices 2.1 and 2.2. relate to Chapter 2, etc.).

The numbering is only indicative but the appendices should normally include:

Appendix 1.1: Authorship of this report

Advisory Group membership

Professor Sandy Oliver, EPPI Centre, University of London
Dr. M. Kent Ranson, WHO, Alliance for Health Policy and Systems Research
Dr. Sara Bennett, Johns Hopkins School of Public Health
Mr. Juan Carlos Negrette, CP, Smiling Suns Franchise Programme
Professor Alejandro Cravioto, ICDDR,B
Professor Harun-ar-Rashid, Director, Bangladesh Medical Research Council
Dr. David Bishai, Johns Hopkins, Bloomberg School of Public Health
Dr. David Peters, Johns Hopkins, Bloomberg School of Public Health
Mr. Stefan Nachuk, Rockefeller Foundation
Dr. Dominic Montagu, University of California at San Francisco
Dr. Guy Stallworthy, Bill and Melinda Gates Foundation
Ms. Marit Johansen, Norwegian Knowledge Centre for the Health Services

We will add advisors with relevant Fragile States experience during the course of the review including:

Mr. Jack Eldon, Lead, Governance & Institutional Development, HLSP
Dr. James Campbell, Professor, Asia Pacific Centre for Security Studies

Review Group membership

Dr. Tracey Lynn Pérez Koehlmoos, ICDDR,B & BRAC University School of Public Health (coordinator)

Dr Shaikh A Shahed Hossain, ICDDR,B

Dr Rukhsana Gazi, ICDDR,B

Dr K Zaman, ICDDR,B

Ms. Tania Waheed, ICDDR,B

Ms. Nadia Ishrat Alamgir, ICDDR,B

Mr. Mohammad Enamul Hoque, ICDDR,B

Ms. Mashida Rashid, ICDDR,B

Dr. Damain G. Walker, Johns Hopkins & ICDDR,B

Professor David Peters, Johns Hopkins
Dr. Shannon Doocy, Johns Hopkins
Ms. Hannah Tapis, Johns Hopkins

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Conflicts of interest

TK, SH, HT, SD, DP, MR, and RG report no conflicts of interest.

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 participants

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. This would include mechanisms for engaging the non-state sector like contracting out, social franchising, public-private partnerships.

We will exclude interventions focused on secondary or tertiary care (such as contracting out hospitals for Emergency Obstetric Care).

Types of outcome measures

Include: Although our methodology is more conducive to inclusively exploring the literature, when provided we propose to collect information on this tentative list of outcomes:

Health Service Impacts

- Access to services (e.g. affordability, utilization, client volume)
- Quality of care (e.g. compliance with standards)

- Patient satisfaction (e.g. intent to return)
- Cost/service (from a societal perspective or the perspective of the provider or patients)
- Catastrophic cost
- Out-of-pocket payment
- Equitable access or utilization (distribution of access across socio-demographic characteristics)
- Sustainability
- Scalability

Outcomes

- Health status outcomes (e.g. mortality, morbidity, malnutrition)

Societal Impacts

- Adverse effects (e.g. undesirable impacts on existing public or private services, inappropriate use of services, distortions in the provision of services)
- Health Sector Capacity Building (e.g., governance, training)

Exclude: Primary studies or reviews that relate to secondary and tertiary care outcomes or behaviour change.

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 2.4: Draft coding tool

- 1) Participants (health providers and service users). For health providers this included the number of providers and information on type of health care provider. For service users this included the number of users and the health problems/treatment received, age, and demographic details and their cultural background.
- 2) Health care setting (rural, formal urban settlement, informal urban settlement (slum)) and country as well as status of country as fragile or post-conflict.
- 3) Study design and the key features of studies. To include but not limited to: Randomised and non-randomised trials, controlled before and after studies, and interrupted time series, surveys, cohort studies, case-controlled studies and case studies (with or without economic or equity analyses).
- 4) Intervention; description of model of working with the non-state sector: type of engagement (contracting out, franchising, public-private partnership, any others encountered in the literature)
- 5) For outcome evaluations; outcomes including access (e.g. affordability, utilization, client volume, attendance); health outcomes; quality of care (e.g. compliance with guidelines, case notification for TB); cost/service (from a societal perspective or the perspective of the provider or patients to include catastrophic cost); patient satisfaction (e.g. intent to return); provider satisfaction; adverse effects (in addition to undesirable impacts on any of the above outcomes, e.g. undesirable impacts on existing public or private services, inappropriate use of services, distortions in the provision of services); any other outcome described in the literature.

- 6) For all evaluations, measures of equity, such as equitable access or utilization (distribution of access across socio-demographic characteristics), where available.
- 7) For all evaluations, economic evaluation if measures available.