Improving maternal, newborn and women’s reproductive health in crisis settings (Protocol)

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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEADER</td>
<td>1</td>
</tr>
<tr>
<td>ABSTRACT</td>
<td>1</td>
</tr>
<tr>
<td>BACKGROUND</td>
<td>1</td>
</tr>
<tr>
<td>Figure 1.</td>
<td>3</td>
</tr>
<tr>
<td>Figure 2.</td>
<td>4</td>
</tr>
<tr>
<td>OBJECTIVES</td>
<td>7</td>
</tr>
<tr>
<td>METHODS</td>
<td>7</td>
</tr>
<tr>
<td>ACKNOWLEDGEMENTS</td>
<td>12</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>13</td>
</tr>
<tr>
<td>ADDITIONAL TABLES</td>
<td>16</td>
</tr>
<tr>
<td>APPENDICES</td>
<td>18</td>
</tr>
<tr>
<td>CONTRIBUTIONS OF AUTHORS</td>
<td>25</td>
</tr>
<tr>
<td>DECLARATIONS OF INTEREST</td>
<td>25</td>
</tr>
<tr>
<td>SOURCES OF SUPPORT</td>
<td>26</td>
</tr>
</tbody>
</table>
Improving maternal, newborn and women’s reproductive health in crisis settings

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To identify, synthesise and evaluate the effects of health system and other interventions aimed at improving maternal, newborn and women's reproductive health in crisis settings.

BACKGROUND

Description of the condition

Reproductive, maternal and newborn health in humanitarian crises

Worldwide, humanitarian crises impact significantly on public health, health infrastructure and the delivery of health care (WHO 2012). A humanitarian crisis can be understood as ‘...a situation in which there is an exceptional and generalized threat to human life, health or subsistence. These crises usually appear within the context of an existing situation of a lack of protection where a series of pre-existent factors (poverty, inequality, lack of access to basic services) exacerbated by a natural disaster or armed conflict, multiply the destructive effects’ (Francesch 2010). Humanitarian crises are generally grouped into the following three categories:

- natural disasters (e.g. earthquakes, floods, storms and volcanic eruptions);
- man-made disasters (e.g. conflicts, plane and train crashes, fires and industrial accidents); and
• complex emergencies (Humanitarian Coalition).

The Inter-Agency Standing Committee (IASC) is an inter-agency forum of United Nations (UN) and non-UN humanitarian partners founded in 1992, to strengthen humanitarian assistance by improving the delivery of humanitarian assistance to affected populations. The IASC defines a complex emergency as ‘a humanitarian crisis in a country, region or society where there is total or considerable breakdown of authority resulting from internal or external conflict and which requires an international response that goes beyond the mandate or capacity of any single and/or ongoing UN country programme’ (OCHA 1999). The hallmarks of complex emergencies include: ‘extensive violence and loss of life; displacements of populations; widespread damage to societies and economies; the need for large-scale, multi-faceted humanitarian assistance; the hindrance or prevention of humanitarian assistance by political and military constraints; and significant security risks for humanitarian relief workers in some areas’ (OCHA 1999).

The past decades have seen an increase in the number of humanitarian crises (primarily disasters) and number of people affected globally. In 1990, the World Health Organization (WHO) collaborating Centre for Research on the Epidemiology of Disasters (CRED) reported a total of 278 disasters which affected about 80 million people (Guha-Sapir 2012). By 2011 this number had risen to 332 with 245 million people affected. In contrast, the number of armed conflicts reported over the same period has declined (Themnér 2013), although the overall number of displaced people in the form of internally displaced persons (IDPs) and refugees has failed to decline (UNHCR 2013). For the purpose of this review, we will use the terms ‘crises’ and ‘emergencies’ interchangeably. The International Conference on Population and Development (ICPD 1994) broadly defines reproductive health as follows: ‘Reproductive health is a state of complete physical, mental and social wellbeing and not merely the absence of disease and infirmity, in all matters relating to the reproductive system and to its functions and processes. Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so. Implicit in this last condition are the rights of men and women to be informed and to have access to safe, effective, affordable and acceptable methods of family planning of their choice, as well as other methods of their choice for regulation of fertility which are not against the law, and the right of access to appropriate health-care services that will enable women to go safely through pregnancy and childbirth and provide couples with the best chance of having a healthy infant.’ According to the WHO, the concept of maternal health is more focused and is defined as the health of women during pregnancy, childbirth and the postpartum period. Newborn health is largely understood as the health of the baby during the first 28 days of life. Maternal and newborn health is largely promoted through access to services such as antenatal care (ANC), skilled birth attendance, emergency obstetric and neonatal care, postnatal care and comprehensive maternal and newborn immunisation services among others. These services, in turn, reduce the risk of maternal and neonatal morbidity and mortality. The importance of maternal health for newborn health and survival cannot be overemphasised: early identification and management of maternal health complications leads to improved neonatal health outcomes. For example, a recent WHO multi-country survey on maternal and newborn health found that late fetal deaths and early neonatal deaths were substantially higher among women with complications such as placenta abruption, ruptured uterus, systemic infections/sepsis, pre-eclampsia and severe anaemia (Vogel 2014). Also, early age at pregnancy and short interpregnancy intervals have been shown to increase the risk of low birthweight and neonatal death (Ramakrishnan 2014).

Due to the wide range of issues encompassed by the concept of reproductive health, we have taken a pragmatic decision within this review to focus on women’s reproductive health and on maternal and newborn health. We will not, therefore, address sexual and reproductive health issues for men and adolescents.

According to the United Nations Population Fund (UNFPA), humanitarian crises put women and their babies at increased risk of poor health outcomes as a result of a sudden loss of medical support, exacerbated in many cases by reduced access to information and essential social services, massive population displacement, trauma, malnutrition or disease, and exposure to violence (UNFPA 2010, UNFPA 2012, Lam 2012). Due to such crises, maternal and neonatal deaths, and physical and sexual violence increase, coupled with limited or no access to reproductive health services such as family planning, prenatal care, assisted delivery, and emergency obstetric care. This leads to a surge in the prevalence of unintended pregnancies and unsafe abortions that further jeopardises the health of an already vulnerable population. The situation is further compounded by the fact that in any crisis setting, especially among refugees and IDPs, one in five women of childbearing age is likely to be pregnant (UNFPA 2012). More specifically, disasters have also been shown to negatively affect the reproductive health and pregnancy outcomes of women including, but not limited to, early pregnancy loss, birth defects, low birth weight and pre-term births (Zotti 2012).

A number of conceptual frameworks/models have been proposed to assess the causes of maternal and neonatal morbidity and mortality. One of the first models to focus specifically on causes of maternal deaths is the Three Delays Model (Figure 1) (Thaddeus 1994). This model identifies three major delays that lead to maternal mortality:
Figure 1. The Three Delays Model (Thaddeus 1994)

Factors Affecting Utilization and Outcome

Phases of Delay

Phase I:
Decision to Seek care

Socioeconomic/Cultural Factors

Phase II:
Identifying and Reaching Medical Facility

Accessibility of Facilities

Phase III:
Receipt of Adequate and Appropriate Treatment

Quality of Care
• delay in deciding when to seek care;
• delay in identifying and reaching a health facility; and
• delay in receiving appropriate care and treatment when in a health facility.

A more extensive model identifying the causes of maternal and newborn morbidity and mortality has been proposed by the United Nations Children’s Fund (UNICEF 2009) (Figure 2). This framework highlights that maternal and newborn health outcomes (morbidity and mortality) are largely determined by a number of interconnected causes, including basic causes operating at the societal level; underlying causes operating at the household, community and district levels; and direct/proximal causes operating at the individual level. Although these frameworks are not specifically developed for crisis settings, it can be inferred that the main ‘causes’ and ‘delays’ of maternal and neonatal morbidity and mortality are severely exacerbated during a crisis, potentially leading to increased morbidity and mortality. For example, it is well known that in emergency settings access to basic health care services (including access to emergency obstetric care and family planning), hygiene and sanitation is severely disrupted, and is coupled to poor access to nutritious foods. These inadequacies are directly or indirectly translated into increased obstetric risk, diseases and poor dietary intake at the individual level.

Figure 2. Conceptual framework for maternal and newborn mortality and morbidity (UNICEF 2009)
Impact of emergencies on reproductive, maternal and newborn health

Humanitarian emergencies affect maternal and neonatal health mainly through weakening the health system (Southall 2011). Other contributing factors may include the breakdown of local social support structures, food shortages, diversion of available resources into defence and uncontrolled population displacement (Al Gasseer 2004, O’Hare 2007). Good health services, a well-performing health workforce, equitable access to medical products, vaccines and technologies, a good health financing system, a well-functioning health information system, and effective leadership and governance characterise a normal functioning health system. However, during humanitarian emergencies the effectiveness of the health system is severely disrupted resulting in the following (Newbrander 2011):

- failure to provide health services to a large proportion of the population living in urban areas (while recognising that most rural areas are generally under-served even in normal times) and a lack of infrastructure (including facilities, human resources, equipment and supplies, and medicines) for delivering health services;
- poorly functional or absent referral systems for the critically ill;
- nonexistent or insufficient capacity-building mechanisms and systems, such as national clinical training programmes, to address the dearth of clinical and management capacity;
- poor co-ordination, oversight and monitoring of health services by the prevailing administrative authorities, who may not have the capability to manage;
- inequity in who receives the available health services, resulting in limited public health services for the poor and those in rural areas;
- absence of policy mechanisms for developing, establishing and implementing national health policies;
- absence of operational health information systems for planning, management and disease surveillance; and
- lack of adequate management capacity and systems (such as budgeting, accounting and human resource management systems) for controlling resources.

In addition, there is the potential for lack of appropriate leadership and co-ordination/communication among organisations and relief teams streaming into the crisis area to provide support and the local health authorities in the affected countries (JCAHO 2003, Sohani 2013). An influx of organisations with their own mandates and perspectives (Roberts 2008) may disrupt existing services and community and cultural practices, ignore or under-utilise these services, or set up parallel systems that further weaken health systems.

The potential impact of a humanitarian crisis on maternal health is large. A 2010 review (Hogan 2010) of maternal mortality between 1980 to 2008 in 181 countries revealed that 50% of all maternal deaths were in only six countries in 2008 (India, Nigeria, Pakistan, Afghanistan, Ethiopia, and the Democratic Republic of the Congo). All of these countries are largely conflict or post-conflict states or both. Furthermore, for over a decade, the 10 countries ranked lowest on Save the Children’s ‘State of the world’s mothers’ Index have largely been conflict or post-conflict countries or both (Save the Children 2011). Similarly, the 10 countries ranked lowest in the UN Human Development Index for the last decade are either in conflict or emerging from one.

Like many other crisis situations, armed conflicts may affect maternal and neonatal health through severing the availability of basic reproductive health services, including accessibility to family planning, and basic and emergency maternity care. Conditions might become unbearable for women due to the destruction of health infrastructure where care is normally provided, the killing or fleeing of senior health personnel, and through women being cut-off from other basic amenities (Carballo 1996). A 2011 report published by the International Committee of the Red Cross (ICRC) revealed that violent, lethal attacks on patients, healthcare workers and facilities, and on medical vehicles are widespread in many conflict settings and pose a serious threat to access to health care in such settings (ICRC 2011). Furthermore, a study among Afghan refugees in Pakistan revealed that 41% of deaths among reproductive-age women were pregnancy-related, due to the inaccessibility of emergency obstetric care (Bartlett 2002). Significant reductions in maternal deaths in some countries (e.g. China, Egypt, Iran, Jordan, Maldives, Mongolia, Morocco, Peru, and Turkey) have been associated with increased availability of and access to basic and emergency obstetric care. This includes, but is not limited to, skilled birth attendance and the availability of caesarean section, penicillin, blood transfusion and ANC (Prata 2010). Many of these services are largely unavailable or overwhelmed in crisis settings.

Although the impact of these humanitarian emergencies on health systems differs from one setting to another, the extent of the impact is generally associated with the following factors (Ivers 2006):

- type of disaster;
- pre-disaster status of the health system;
- public health situation and disease pattern of the area prior to the crisis;
- impact of the disaster on other sectors such as water, sanitation, and shelter;
- population displacement;
- effectiveness of the response to the disaster; and
- socioeconomic status of the area prior to the emergency.

Another factor affecting the impact of humanitarian emergencies is the level of preparedness of the country experiencing the disaster (Sohani 2013). For instance, the pre-existence of a functional disaster/emergency management system will potentially reduce the mortality, morbidity and disability associated with a crisis. For example, an earthquake of the same magnitude in the US or Japan may affect fewer people compared to countries like Pakistan, Haiti.
or Iran, with a relatively less effective crisis management system. Furthermore, the occurrence of a disaster in a conflict-affected area can only exacerbate the already precarious health situation in such settings.

**Description of the intervention**

To improve reproductive, maternal and newborn health (RMNH) in crisis settings, local health systems need to be better equipped to deal with the health challenges that come with such emergencies. The interventions should be capable of overcoming the challenges of access to, and quality of health care in crisis settings, for example bringing care to the affected populations rather than expecting the population to look for the providers. In crisis settings, the provision of health care is often challenged or disrupted. In order to effectively provide basic health care, other innovative approaches have to be sought. Potential interventions will therefore seek to:

- improve the demand for and supply of basic health services;
- improve security for health personnel and infrastructure;
- prevent sexual violence and provide appropriate assistance to survivors;
- reduce the transmission of HIV and other sexually transmitted infections (STIs); and
- prevent excess maternal and newborn death and disability.

A summary of possible categories of interventions to improve RMNH in crisis settings, and their possible mechanisms of action, is shown in Table 1. These interventions may include, but are not limited to:

- expanding the provision of health care from facility-based to non-facility-based systems in homes or the community, or rolling out mobile health care services through a mobile clinic van.
- task shifting (the rational re-distribution of tasks among health workforce teams, whereby specific tasks are moved, where appropriate, from highly qualified health workers to health workers who have fewer qualifications in order to make more efficient use of the available human resources for health) (WHO 2008) might be encouraged. For instance, nurses and midwives might be trained to undertake some types of surgery that were previously undertaken only by surgeons as currently done by the CAPA project in Sierra Leone (http://capacare.org/projects-2).
- non-directive refugee policies, where refugees and their associated health services are integrated with those of the host country communities, rather than re-settled in areas isolated from the communities and services of the host country (Van Damme 1998). Such policies may maximise limited human resources, improve access and quality of health services for both refugees and host communities and enhance cohesion between refugees and host communities (Van Damme 1998; Van Damme 1995).

These interventions could, among others, be in line with the Three Delays Model interventions (Thaddeus 1994) and the Minimum Initial Service Package (MISP) for Reproductive Health (MISP for RH) (IAWG 2009). The MISP for RH is a co-ordinated set of priority activities designed to:

- improve the co-ordination of humanitarian activities,
- prevent and manage the consequences of sexual violence,
- reduce HIV transmission,
- prevent excess maternal and newborn morbidity and mortality, and
- plan for comprehensive RH services (IAWG 2010).

Although this package of services has been implemented in many humanitarian settings globally, including Pakistan, Chad, Kenya, Haiti and Indonesia, its successful implementation has been challenged by lack of awareness of the MISP among some key humanitarian actors, lack of human resources, poor logistics and poor co-ordination (Onyango 2013). As such, identifying and knowing that an intervention or package of interventions work(s) is not enough. We also need to consider important contextual and cultural factors associated with the implementation and effectiveness of potential interventions. Additionally, we will consider the governance, financial and delivery arrangements, and implementation strategies utilised (Appendix 1).

The review will explore a broad range of women's reproductive health services including:

- family-planning counselling, information, education, communication and services;
- education and services for ANC, safe delivery and postnatal care, and infant and women's health care;
- prevention and appropriate treatment of infertility;
- prevention of abortion and the management of the consequences of abortion;
- treatment of reproductive tract infections, sexually transmitted diseases, including HIV/AIDS;
- prevention, early detection and treatment of breast cancer and cancers of the reproductive system, and other reproductive conditions; and
- discouragement of harmful traditional practices, such as female genital mutilation (ICPD 1994).

Regarding maternal and newborn health, the range of services will include ANC, postnatal care, skilled birth attendance, emergency obstetric and neonatal care, appropriate breast-feeding, appropriate complimentary feeding, prevention of mother-to-child transmission of HIV, adequate nutrition, iron/folate supplementation, prevention and care-seeking for acute respiratory infections, and appropriate immunisation among others (Geibel 2012).

**How the intervention might work**

Health systems in crisis settings such as armed conflicts, tsunamis or earthquakes are generally characterised by damaged infrastructure, limited human resources and weak government stewardship. Also important are poverty, lack of preparedness and, in some
cases, the proliferation of interventions by non-governmental organisations (Roberts 2008).

Interventions to improve RMNH may work through:

- improving the demand for basic health services;
- increasing the supply and quality of basic health services;
- ensuring the security of health personnel and protection of health facilities;
- reducing the risk for sexual violence and providing adequate support for survivors;
- reducing the risk of transmission of HIV and other STIs; and
- ensuring mothers and newborns have access to life-saving health services.

(Also see column 4 of Table 1)

Why it is important to do this review

The impact of emergencies on RMNH has been well established, as discussed above. For instance, no low-income fragile or conflict-affected country has yet achieved a single Millennium Development Goal (MDG) (World Bank 2011) and all are furthest away from achieving any of the MDGs (New Deal for Building Peaceful States 2012). The MDGs are eight international development goals that were established following the Millennium Summit of the United Nations in 2000, following the adoption of the United Nations Millennium Declaration. Furthermore, humanitarian crises are relatively common, and the number of affected people appears to be rising (CRED 2011, UNHCR 2013). Existing reviews on RMNH have not explicitly and comprehensively considered the effects of interventions in crisis settings. For example, a 2011 global review of key interventions to improve RMNH identified a range of key interventions (PMNCH 2011) but specific guidance on contextual application in crisis settings was not provided. In addition, comprehensive information on governance, financial and delivery arrangements for the specific intervention packages was absent. A recent survey of current practices and programmes for implementing maternal and neonatal survival interventions in crisis settings observed that implementation was hampered by funding shortages, gaps in personnel training, and staff shortages and turnover (Lam 2012).

While a wide range of interventions are available to improve RMNH in crisis settings, the impacts of these are uncertain. Moreover, some of these interventions require substantial investments of resources or may have adverse effects or both, including on the wider health system. It is therefore important to review systematically the effects of these interventions.

OBJECTIVES

To identify, synthesise and evaluate the effects of health system and other interventions aimed at improving maternal, newborn and women’s reproductive health in crisis settings.

METHODS

Criteria for considering studies for this review

Types of studies

We will include:

- Randomised controlled trials (RCTs)
- Non-randomised controlled trials (non-RCTs)
- Controlled before-after (CBA) studies. For CBA studies, the outcome(s) of interest must be measured in both intervention and control groups before the intervention is introduced and again after the intervention has been introduced
- Interrupted time series (ITS) studies, in which the intervention was implemented at a clearly defined time, with at least three data points before, and three data points after rolling out the intervention (EPOC 2015).

We will only include cluster RCTs, non-randomised cluster trials, and CBA studies with at least two intervention sites and two control sites.

The review will include studies conducted in any country as disasters and conflicts are not only limited to low- and middle-income countries (LMICs). Although high-income countries’ (HICs) response to RMNH following a crisis may vary from those in LMICs, documenting the nature of such a response may be valuable for LMICs in their efforts to mitigate the impact of these crises.

Types of participants

Women of reproductive age and newborns in crisis and post-crisis settings. Due to the already broad scope of this review, we will exclude interventions directed at men and adolescents to improve their sexual and reproductive health. These interventions would be better addressed in separate reviews.

Types of interventions

The review will identify and synthesise evidence of the effects of health system and population health interventions aimed at improving RMNH in crisis/emergency situations. Potential interventions will meet the following criteria: they should

- be implemented in a crisis/post-crisis (conflict or disaster or both) setting. This must be explicitly acknowledged in the design of the study;
- be developed to improve RMNH in such settings and may or may not be part of a bigger package of interventions;
• Include women of reproductive age or newborns or both as participants and exclude men and adolescents as main participants;
• Be aimed at health system support or health system strengthening or both and may involve the delivery of clinical or public health services or both;
• Be compared with an alternative intervention, the usual health care in the study area or no intervention.

For the purpose of the review, a crisis setting is defined as ‘situations of armed conflict or natural disaster, often involving the displacement of populations, sometimes as refugees, other times as IDPs’ (WHO 2007). We will focus on:
• crises that have the potential to cause mass population displacement;
• conflict-related crises (conflict and post-conflict settings, including civil and political violence); and
• disaster-related crises (specifically droughts, floods, earthquakes, volcanoes, landslides, tsunami, and cyclones/hurricanes).

We will not consider studies in crisis settings emanating from man-made disasters with limited impacts in terms of population displacement, and morbidity and mortality (such as chemical spills, plane crashes, terrorist attacks, industrial explosions, armouy blasts etc.), unless there is a strong and compelling reason for inclusion. In such situations, we will clearly state the reason for such a decision. While acknowledging the difficulties in classifying a situation as ‘in crisis’ or ‘post-crisis’, we will include all eligible studies undertaken in countries where the state is unable or unwilling to provide basic health care for all the population because of crises arising from armed conflict or disasters. For each crisis, the underlying cause must be linked to a conflict or disaster. RMNH will be defined as above.

The review will focus on health system interventions aimed at improving the effectiveness, efficiency and equity in the delivery of clinical and public health services (Lewin 2010) (See Table 1 and Appendix 1 for detailed description). The interventions must be specifically developed to improve women’s newborn, or reproductive health, or a combination of all three, in such settings, and may or may not be part of a bigger package of interventions. The clinical and public health services addressed by the health system intervention(s) could or should be for the purpose of prevention, treatment or rehabilitation, and aimed at improving maternal and newborn health as well as reproductive health of women in its broadest sense as defined by the 1994 International Conference on Population and Development (UNFPA 1995). These could include the delivery of service packages to reduce maternal and neonatal morbidity and mortality, and service packages that enhance/promote the sexual and reproductive wellness/wellbeing of women in crisis/emergency settings (e.g. access to basic reproductive health/family planning services such as contraceptives, ANC etc. prevention of all forms of sexual violence; prevention and treatment of reproductive tract infections and diseases etc.). We will not include clinical interventions specifically for post-traumatic stress disorders (PTSD), as they constitute a major concern for populations in emergency settings and would be best examined in a separate review. Also, a Cochrane systematic review, ‘Non-specialist health worker interventions for mental health care in low- and middle-income countries’ (van Ginneken 2013) has recently been completed and covers task-shifting for the delivery of mental health care interventions. We will, however, include health system interventions for PTSD linked to maternal and women’s reproductive health, such as interventions for preventing or managing the consequences of sexual violence against women. Furthermore, while acknowledging the broad scope of these issues, we will focus on women’s reproductive health, maternal health (health of the woman during pregnancy, childbirth and the postpartum period), and the health of the newborn during the first 28 days of life. These are some of the most serious concerns in crisis settings that if not promptly addressed may lead to mortality, morbidities and disabilities.

We will consider both health system support and health system strengthening interventions. While health system support ‘includes any activity that improves services, from upgrading facilities and equipment to distributing mosquito nets to promote healthy behaviour, improving the health system’s functionality primarily through increasing inputs, for a short term and with a narrow focus, health system strengthening is achieved by more comprehensive changes to policies and regulations, organizational structures, and relationships across the health system building blocks that motivate changes in behavior, and/or allow more effective use of resources to improve multiple health services’ (Chee 2012). Arguably, differentiating between those types of interventions in such contexts might be very difficult as both supporting and strengthening interventions might be packaged and delivered simultaneously. However, in a crisis setting, it is widely expected that initial efforts will be focused on immediate inputs to provide health services (perceived as supporting), while identifying priority areas for strengthening is a long term priority (Chee 2012).

We will include and describe studies that meet the inclusion criteria in the characteristics of included studies table, even if they do not report usable results (EPOC 2015).

Types of outcome measures

Primary outcomes
• Coverage of or access to health services (e.g. ANC coverage and access to skilled birth attendance)
• Utilisation of health services (e.g. attendance at ANC clinics)
• Adverse effects (e.g. health worker attrition and unanticipated increased workload)
Secondary outcomes

- Patient outcomes (e.g., maternal and newborn mortality and morbidity)
- Quality of care (e.g., adherence to recommended practice or guidelines)
- Resource use

We will consider differential effects across advantaged and disadvantaged populations for all of the outcomes listed above.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases:

- The Cochrane Central Register of Controlled Trials (CENTRAL, latest issue), part of The Cochrane Library (www.thecochranelibrary.com), including the Cochrane Effective Practice and Organisation of Care (EPOC) Group Specialised Register, and the Cochrane Pregnancy and Childbirth Group Specialised register
- MEDLINE, and MEDLINE In-Process and other non-indexed citations, OvidSP
- Embase, OvidSP
- CINAHL (EbscoHost)
- POPLINE
- Latin American and Caribbean Health Sciences database (LILACS)(VHL)
- Global Health (CAB Direct)

Please see Appendix 2 for the MEDLINE search strategy.

Searching other resources

Grey Literature

- MSF database: http://www.epicentre.msf.org/
- Evidence Aid Resources: http://www.evidenceaid.org/resources
- Reproductive health gateway: http://www.k4health.org/resources/rhgateway

Trial Registries

- International Clinical Trials Registry Platform (ICTRP), World Health Organization (WHO) http://www.who.int/ictrp/en/
- ClinicalTrials.gov, US National Institutes of Health (NIH) http://clinicaltrials.gov/

We will also

- Contact experts in the field to find out if they are aware of any relevant studies.
- Check the reference lists of included studies and core papers in the field.
- Search the Science Citation Index and Social Sciences Citation Index (ISI Web of Knowledge) for studies citing studies included in the review.

All searches of all resources will be applied without language restrictions.

The definition of some major concepts used throughout the review can be found at Appendix 3.

Data collection and analysis

Selection of studies

Three authors (CPC, DD and OUJ) will independently read the titles and abstracts of identified studies to eliminate obviously irrelevant studies. For studies identified by any of the review authors that potentially meet our inclusion criteria, the full texts will be retrieved and two review authors (CPC and DD) will assess their final eligibility against the review inclusion criteria. Disagreements will be resolved by discussion and recourse to a third author on the team or the full team if appropriate.

Data extraction and management

We will develop a data extraction form based on the data extraction template provided by the Cochrane EPOC Group. Two reviewers (CPC and OUJ) will independently extract the following details of the eligible studies:

- General study information: title, authors, publication status, journal, funder and date of publication.
- Study design: RCT, non-RCT, CBA, and ITS and whether the design was clustered or non-clustered.
- Characteristics of study setting: category of crisis (conflict/disaster), type of crisis (armed conflict, droughts, floods, earthquakes/volcanoes/landslides, tsunami, and cyclones/hurricanes etc), nature of onset of crisis (slow/rapid), stage of the crisis (if reported), setting (urban/rural), and country (high, middle or low-incomes).
- Characteristics of study population: participant type (women/newborns), displacement status (not displaced/displaced (IDPs/refugees), description of comparison group, availability of functional health facility within community (present/absent), distance of tertiary care facilities from study population, ratio of population to health personnel, ratio of population to tertiary healthcare facilities before and after the crisis.
- Category of intervention: improve the demand for basic health services; improve the supply of basic health services;
improve security for health personnel and infrastructure; prevent sexual violence and provide appropriate assistance to survivors; reduce the transmission of HIV and other STIs; prevent excess maternal and newborn death and disability; and others

• Description of intervention: type and description of intervention, governance, financial and delivery arrangements, implementation strategies, duration of implementation, characteristics of providers, ‘intervention’ in comparison group, cost effectiveness of intervention (if reported) etc.
• Main outcomes: listing of all primary and secondary outcome measures as reported by the study authors.
• Study findings: reporting of all study findings with respect to the study outcomes reported by the study authors, adjusted and unadjusted changes in each included outcome measure in each comparison group as reported by the study authors; measures of effect reported by the study authors and the analysis method used; measures of precision as reported by the study authors; whether and if so how adjustment was made for clustering in estimates of precision.

Assessment of risk of bias in included studies
We will assess the risk of bias for each included study. Three of the study authors (CPC, OUJ and DD) will independently undertake the ‘Risk of bias’ assessment by using a form with the standard criteria described by the Cochrane EPOC Group (EPOC 2015). We will use the EPOC nine point criteria for RCTs, non-RCTs, and CBA studies and seven point criteria for ITS studies to determine the certainty of all included studies.

EPOC criteria for RCTs, non-RCTs, CBA studies
1. Was the allocation sequence adequately generated?
2. Was the allocation adequately concealed?
3. Were baseline outcome measurements similar?
4. Were baseline characteristics similar?
5. Were incomplete outcome data adequately addressed?
6. Was knowledge of the allocated interventions adequately prevented during the study?
7. Was the study adequately protected against contamination?
8. Was the study free from selective outcome reporting?
9. Was the study free from other risks of bias?

EPOC criteria for ITS studies
1. Was the intervention independent of other changes?
2. Was the shape of the intervention effect pre-specified?
3. Was the intervention unlikely to affect data collection?
4. Was knowledge of the allocated interventions adequately prevented during the study?
5. Were incomplete outcome data adequately addressed?
6. Was the study free from selective outcome reporting?
7. Was the study free from other risks of bias?

We will grade each eligible study against each criterion into ‘Low risk’, ‘High risk’ or ‘Unclear risk’.
In situations where the information is not reported in the paper, we will contact the study authors for further information. These assessments will be presented in a ‘Risk of bias’ table.

Measures of treatment effect
For dichotomous outcomes we will use risk ratios (RR), while for continuous outcomes the mean difference (MD) and the standardised mean difference (SMD) will be used. The MD will be used when the outcomes of interest from the included studies are measured in the same manner while the SMD will be used when similar outcomes are measured or assessed using different methods. We will base our analysis on the change in scores before and after the intervention for RCTs and non-RCTs. Where these treatment effects are not directly presented in the papers, we will contact the study authors for these data and if we are unable to secure these we will not impute the missing data but will include the study in the review and address the potential impact of the missing data in the Assessment of risk of bias and Discussion sections of the review.
For ITS studies we will record the change in level and the change in trend before and after the intervention. A change in level is defined as the difference between the observed level at the first intervention time point and that predicted by the pre-intervention time trend, while a change in trend is defined as the difference between post- and pre-intervention slopes (Ramsay 2003). This is measured as the difference between the fitted value for the first post-intervention data point (one, two, three etc months after the intervention) minus the predicted outcome (one, two, three etc months after the intervention) based on the pre-intervention slope only (EPOC 2015). Our preferred method of obtaining these will be a statistical comparison of time trends before and after the intervention using autoregressive integrated moving average (ARIMA) models, depending on the characteristics of the data, the number of data points available and whether autocorrelation is present (EPOC 2013). An ARIMA model is a form of regression analysis that uses time series data to predict future trends. Additionally, ARIMA models take into account seasonality, cycles, errors and non-stationary aspects of a data set when making forecasts. However, where the use of ARIMA models is inappropriate but the data in the original paper are presented in tables or graphs, with at least three data points before and three data points after the intervention, along with a clearly defined intervention point, we will re-analyse using the segmented time series regression techniques as described in the EPOC guidelines (EPOC 2013). To address the possibility of overestimation or underestimation of the intervention effect in ITS studies, we will avoid solely comparing the means before and after an intervention, without taking into account any secular trends. A secular trend is the smooth long-term direction of a time series; the act of a variable that continues to move in a somewhat consistent way over a long period of time.
For CBA studies, the difference-in-difference approach will be used to measure the treatment effects. Here, the treatment effect will be obtained by subtracting the average gain score at baseline and endpoint in the control group from the average gain score at baseline and endpoint in the treatment group.

In the case of RCTs, non-RCTs and CBA studies where the pre-intervention or baseline data are not available, we will compare the post-intervention data for the treatment and control groups.

### Unit of analysis issues

For cluster RCTs, non-RCTs and CBA studies we will assess whether an appropriate analysis has been done that adjusts for clustering in calculating measures of precision. If unit-of-analysis errors are identified in the studies we will undertake a re-analysis using an estimate of the intra-cluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. Where this approach is not possible, we will use the inflated standard errors method to address any existing unit-of-analysis issues as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). In the case of ITS studies, analysis will be done using either a regression analysis with time trends and change in levels before and after the intervention or ARIMA analysis, depending on the characteristics of the data, the number of data points available and whether autocorrelation is present (EPOC 2015).

### Dealing with missing data

For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data (> 20% for primary outcome) in the overall assessment of treatment effect by using sensitivity analysis. In cases of missing data, we will make efforts to contact the authors concerned. When this is unsuccessful, we will report the data as missing and will not attempt to impute missing values. We will include such studies and undertake an available case analysis. The potential impact of the missing data will be explored in the Assessment of risk of bias and Discussion sections of the review.

For all outcomes, we will carry out available case analyses. The denominator for each outcome in each trial will be the number of women or newborns or both randomised minus any women or newborns or both whose outcomes are known to be missing. However, if we are able to secure all the missing data we will undertake the analyses on a full intention-to-treat basis, i.e. we will attempt to include all women or newborns or both randomised to each group in the analyses, and all women or newborns or both will be analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention.

### Assessment of heterogeneity

We will assess methodological and clinical heterogeneity. Methodologically, we will explore the effects of different study designs employed (e.g. randomised and non-randomised). We will assess clinical heterogeneity at the following levels as described in Gagnier 2012:

- patient (patient category (newborns, women), age, and baseline severity);
- intervention (income level of study setting, duration, timing, intensity, frequency and co-interventions); and
- outcome (event type, length of follow-up, outcome measure type, repeated outcome measurements, research setting).

We do not anticipate obtaining sufficient studies to allow meta-analysis. As such, we might not be able to undertake a statistical assessment of heterogeneity across the included studies. However, should we find many related studies and to the extent possible, we will use forest plots, the $I^2$ statistic and the Chi$^2$ test to assess heterogeneity (Higgins 2003). We will regard statistical heterogeneity as potentially substantial if $I^2$ is greater than 30% and either $T^2$ is greater than zero, or there is a low $P$ value (less than 0.10) in the Chi$^2$ test for heterogeneity. We will interpret the $I^2$ taking into consideration the magnitude and direction of the treatment effects and the strength of the evidence for heterogeneity.

### Assessment of reporting biases

We will undertake assessment of reporting bias according to the criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Sterne 2011). We will assess the risk of publication bias based on the direction of the findings/results of the included studies, coupled with information obtained from experts in the field of RMNH in crisis settings. For example, if the review identifies only a small number of studies with overwhelming positive results, this would highlight the possibility of publication bias. We will contact experts in the field for their impressions about the findings and also the possibility of unpublished studies with negative or non-significant findings. We will further assess the reporting bias by testing for asymmetry of funnel plots. Tests for funnel plot asymmetry will be done only when there are at least 10 studies included in the meta-analysis. We will interpret the results of tests for funnel plot asymmetry by visual inspection of the funnel plots. To test for funnel plot asymmetry we will use Egger 1997 for continuous outcomes with intervention effects measured as mean difference, and Harbord 2006 for dichotomous outcomes with intervention effects measured as odd ratios (ORs), as suggested in the *Cochrane Handbook for Systematic Reviews of Interventions* (Sterne 2011).

### Data synthesis

If possible, we will undertake a main analysis involving eligible studies reporting similar outcomes and undertaken in related settings. We will stratify this analysis by the type of crisis, and the
category of the intervention. We do not anticipate finding many studies recording similar outcomes in similar settings that will justify merging and calculating an overall effect size and undertaking a meta-analysis. However, if there are two or more studies that evaluate similar interventions and report similar outcomes, we will calculate pooled RRs, MDs or SMDs using a random-effects model. Otherwise, we will report the median and range of effects, if relevant, or measures of effect from individual studies when there are no other studies evaluating a similar intervention and reporting a similar outcome. In the event that we cannot synthesise the data across the studies, we will undertake a structured synthesis of the results. For ITS studies, we do not anticipate finding many identical studies that will necessitate data pooling. However should we find up to 10 identical studies (methodologically homogenous) we will pool the adjusted effect estimates for possible meta-analysis. We will use GRADE to assess the certainty of the evidence for each study outcome (Schunemann 2011a). We will grade the certainty of the evidence for each major study outcome as 'High', 'Moderate', 'Low', or 'Very Low'. We will present assessments of the certainty of evidence in a 'Summary of findings' table (Schunemann 2011b).

Subgroup analysis and investigation of heterogeneity

We expect that there may be variations in the findings of the different studies included in the review due to various explanatory factors. If we identify sufficient studies for the review, we will further investigate this heterogeneity within the following subgroups.

- Place of care (facility versus non-facility)
- Displacement status (IDPs versus refugees)
- Category of provider (skilled versus unskilled)
- Nature of care delivery (stationary versus mobile facility).
- Nature of the crisis (slow versus rapid onset)

We anticipate more favourable outcomes for facility-based care as the probability of having access to skilled care is much higher compared to other structures outside the health facility. Refugees tend to have better health outcomes compared to IDPs possibly due to better international support, as international support for IDPs has been a long-neglected and complex issue within the humanitarian community. Furthermore, we expect that populations receiving healthcare from skilled personnel should have better outcomes compared to when the care is provided by less skilled or unskilled individuals. Health care from a stationary health facility, including some specialised services that provided on a 24-hour basis should be more comprehensive than health care provided by mobile facilities, that may provide only a limited range of services within a specific period. Concerning the nature of the crisis, we expect that those with a slow onset should experience a better response compared to crisis with a rapid onset that will provide little room for an effective response. However, it is possible that crises with a rapid onset may receive better international publicity and support and hence inhabitants may receive better services, compared to inhabitants in areas where the crisis is more gradual in nature.

Sensitivity analysis

Provided there are sufficient included studies, we will conduct sensitivity analyses to assess how robust the synthesis is in relation to any assumptions that are made with respect to the risk of bias for included studies and how these studies should be grouped (EPOC 2015). Sensitivity analyses will done by excluding:

- studies with an overall high risk of bias (defined as any study assessed as being at risk of bias for any of the main assessment criteria listed in Assessment of risk of bias in included studies);
- studies with clustered designs;
- studies with an attrition rate of more than 20% for the primary outcome; and
- study results directly received from study authors that were not available in the published papers.

If appropriate, we will also undertake a sensitivity analysis of varying the ICC used for re-analysis of results from clustered designs.

Acknowledgements

We are grateful to the advisory group from the Canadian Red Cross who reviewed and commented on the draft protocol for the review. The team included: Salim Sohani, Rachel Meagher, Catherine Marquis, Mary Thompson, Reed Morrison, and Sharonya Sekhar. We also thank Marit Johansen for developing the search strategies and Simon Lewin for editorial comments. We also thank the following reviewers for their comments: Jan Ogaard-Jensen (EPOC Statistical editor), Newton Opiyo (EPOC Editor), Denise Mitchell (Copy editor) and Natasha Howard (External referee).
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Higgins 2011

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Improving maternal, newborn and women’s reproductive health in crisis settings (Protocol)

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Improving maternal, newborn and women’s reproductive health in crisis settings (Protocol)

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**van Ginneken 2013**


**Vogel 2014**


**WHO 2007**


**WHO 2008**


**WHO 2012**


**World Bank 2011**


**Zotti 2012**


*Indicates the major publication for the study*

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**ADDITIONAL TABLES**

Table 1. Table 1: Possible interventions to improve reproductive, maternal, and newborn health in crisis settings

<table>
<thead>
<tr>
<th>Types of interventions</th>
<th>Examples of interventions</th>
<th>Mechanisms</th>
</tr>
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</table>
| **1 Improve the demand for basic health services** | Policies and activities aimed at stimulating the demand for basic health services | Improving the demand for basic health services will improve the number of people visiting the health facility to seek care. For example in crisis settings:   - The physical presence of health personnel at health facilities will reassure potential clients of their physical safety and security while in the facility and hence encourage patients to seek services.   - The provision of health services through a mobile clinic system overcomes the security challenges that may exist for seeking health care at a fixed facility and therefore reach many vulnerable and critical patients who otherwise wouldn’t be able to make it to the facility.  |   - Removal of user-fees.  
|   - Provision of specialised services (e.g. surgery, advanced family planning services etc.).  
|   - Provision of birth notification documents to facilitate issuance of relevant ID document.  
|   - Introduction of a voucher system.  
|   - Subsidisation of health care provision.  
|   - Provision of a 24-hours health care service.  
|   - Improved transportation (free ambulance service, other transport facilities especially at night).  
|   - Infrastructural improvements (e.g. renovation of old infrastructure).  
|   - The availability of a free or subsidised and secured transport system will encourage many patients to seek |
| 2 | **Improve the supply of basic health services** | • Contracting with private providers to deliver a package of services.  
• Linking payment of provider salaries and other incentives to specific performance targets.  
• Task-shifting.  
• Involvement of lay or community health workers.  
• Training/retraining of local health personnel, traditional birth attendants etc. | Supply-side incentives will increase coverage and quality of health services provided. For example in a crisis setting, involving lay or community health workers and implementation of task-shifting in health-care delivery especially as the demand for health care may be exceptionally high, more clients/patients will be received in a shorter period of time, reducing the waiting time and possibly reducing the risk of complications due to delays in receiving care. Also, with more health care providers available and services quickly delivered, potential clients and patients will not have to travel to other places to seek care which might pose a security risk to the travellers etc. |
|---|---|---|---|
| 3 | **Improve security for health personnel and infrastructure** | • Reducing the number of non-essential staff at the facility during periods of insecurity.  
• Transporting health personnel to and from the health facility in official institutional vehicles.  
• Involving local communities in the construction, management and protection of health facilities.  
• Policy of non-acceptance of armed individuals into the health facility.  
• Evacuation of foreign staff during times of high insecurity.  
• Fencing the health facility.  
• Adopting a non-directive refugee policy. | With improved security for health personnel and infrastructure, personnel will be able to continue providing essential services and the population will be sure of receiving appropriate /competent care and treatment when they visit the health facility. Providing a safe means of transport for health personnel to and from health facilities, involving the community in the construction, management and protection of the facility, and providing a protective fence around the facility will enhance the morale and sense of security of health personnel, ensuring their availability and concentration to provide services |
| 4 | **Prevent sexual violence and provide appropriate assistance to survivors** | • Involvement and targeting of women in camp planning committees and for food distribution.  
• Regular distribution of firewood to women.  
• Provision of clinical and psychosocial care and legal support for survivors of rape. | Risks for sexual violence will be reduced and survivors will be adequately supported. When these basic amenities are provided, and lighting is improved within the camps, women and girls will be less exposed to situations of increased risk of sexual violence. In crisis settings, many women and girls tend to be raped or sex-
### Table 1: Possible interventions to improve reproductive, maternal, and newborn health in crisis settings

#### 5 Reduce the transmission of HIV and other STIs

**Policies and activities aimed at reducing the transmission of HIV and other STIs**

- Promoting and ensuring safe blood transfusion practices.
- Facilitating and enforcing observation of standard precautions.
- Making condoms freely available.

With safe blood transfusion practices and observance of standard guidelines, the quality of blood used for transfusion will be improved as the screening process will be more efficient. As such, the risk of mothers and newborns being transfused with HIV and other STIs infected blood will be reduced.

When free condoms are available among crisis-affected populations, coupled with appropriate health promotion messages, the demand and use will be enhanced, leading to improved safe sex practices and consequently reduced risk of transmission of HIV and other STIs.

#### 6 Prevent excess maternal and newborn death and disability

**Policies and activities aimed at reducing maternal and neonatal morbidity and mortality**

- Ensuring availability of emergency obstetric care and newborn care (EmONC) services.
- Provision of clean delivery kits to all pregnant women and birth attendants.
- Provision of midwife delivery kits to facilitate safe deliveries in health facilities.
- Installing a referral system to manage obstetric emergencies.
- Undertaking regular maternal and newborn death audits.
- Recruiting more health personnel, especially midwives and doctors.
- Community sensitisation (pregnancy danger signs, facility-based delivery, skilled birth attendance etc)

Mothers and newborns will readily get the care they need and cases of mortality and disability will be reduced. With most maternal and newborn deaths in crisis settings associated with the lack of or poor quality EmONC services, the availability of these services with the appropriate quality will reduce the risk of maternal and newborn deaths as the demand for these services tend to be higher in such settings.
APPENDICES

Appendix 1. Taxonomy of governance, financial, and delivery arrangements within health systems for primary health care (Lewin 2010)

Taxonomy of governance, financial, and delivery arrangements within health systems for primary health care (adapted from Lavis and colleagues)

**Governance arrangements**
What are the effects of changes in or interventions to improve
- Policy authority, eg, who makes policy decisions about what primary health care encompasses (such as whether such decisions are centralised or decentralised)
- Organisational authority, eg, who owns and manages primary health-care clinics (such as whether private for-profit clinics exist)
- Commercial authority, eg, who can sell and dispense antibiotics in primary health care and how they are regulated
- Professional authority, eg, who is licenced to deliver primary health-care services; how is their scope of practice determined; and how they are accredited
- Consumer and stakeholder involvement, who from outside government is invited to participate in primary health-care policy-making processes and how are their views taken into consideration

**Financial arrangements**
What are the effects of changes in or interventions to improve
- Financing, eg, how revenue is raised for core primary health-care programmes and services (such as through community-based insurance schemes)
- Funding, eg, how primary health-care clinics are paid for the programmes and services they provide (such as through global budgets)
- Remuneration, eg, how primary health-care providers are remunerated (such as via capitation)
- Financial incentives, eg, whether primary health-care patients are paid to adhere to care plans
- Resource allocation, eg, whether drug formularies are used to decide which medications primary health-care patients receive for free

**Delivery arrangements**
What are the effects of changes in or interventions to improve
- To whom care is provided and the efforts that are made to reach them (such as interventions to ensure culturally appropriate primary health care)
- By whom care is provided (such as primary health-care providers working autonomously versus as part of multidisciplinary teams)
- Where care is provided, eg, whether primary health care is delivered in the home or community health facilities
- With what information and communication technology is care provided, eg, whether primary health care record systems are conducive to providing continuity of care
- How the quality and safety of care is monitored, eg, whether primary health-care focused quality-monitoring systems are in place

Appendix 2. MEDLINE search strategy

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Appendix 3. Key Definitions

- **Skilled birth attendance**: The proportion of births attended by skilled health personnel is the proportion of total live births that are attended by a skilled birth attendant trained in providing life-saving obstetric care (Handbook for monitoring MDGs).

- **Maternal Mortality Ratio**: The maternal mortality ratio (MMR) is the annual number of maternal deaths from any cause related to or aggravated by pregnancy or its management (excluding accidental or incidental causes) during pregnancy and childbirth or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, per 100,000 live births, for a specified year (Handbook for monitoring MDGs).

- **Contraceptive Prevalence**: The contraceptive prevalence rate is the percentage of women of reproductive age who are currently using, or whose sexual partner is currently using, at least one contraceptive method, regardless of the method used. It is reported for women aged 15 to 49 who are married or in a union (Handbook for monitoring MDGs).

- **Antenatal care coverage**: Antenatal care (ANC) coverage (at least one visit) is the percentage of women aged 15-49 with a live birth in a given time period that received ANC provided by skilled health personnel at least once during their pregnancy (Handbook for monitoring MDGs).

- **Armed conflict**: An armed conflict is a contested incompatibility which concerns government or territory or both where the use of armed force between two organised parties, of which at least one is the government of a state, resulting in at least 25 battle-related deaths in any given year (Themnér 2014).

- **Crisis**: A crisis is a situation that is perceived as difficult. Its greatest value is that it implies the possibility of an insidious process that cannot be defined in time, and that even spatially can recognize different layers/levels of intensity. A crisis may not be evident, and it demands analysis to be recognised. Conceptually, it can cover both preparedness and response (“crisis management”). It can equally be defined as a time of danger or greater difficulty, decisive turning point (The Pocket Oxford Dictionary 1992).

- **Disaster**: A disaster is a sudden, calamitous event that seriously disrupts the functioning of a community or society and causes human, material, and economic or environmental losses that exceed the community’s or society’s ability to cope using its own resources. Though often caused by nature, disasters can have human origins (IFRC n.d.).

- **Failing state**: In political science, ‘failing state’ means a state which is not able to maintain internal security. In economic terms, a failing state is a low-income country in which economic policies, institutions and governance are so poor that growth is highly unlikely. The state is failing its citizens because even if there is peace they are stuck in poverty (Chauvet 2005).

- **Conflict-affected**: A set of conflict-affected states was derived for each of the years between 1999 and 2010 using the Uppsala Conflict Data Programme’s (UCDP) database (UCDP 2015) to determine the incidence of active conflict in a given year (both involving state actors and where no state actor is involved but where more than 25 battle deaths resulted) and where the presence of a multilateral peacekeeping mission (excluding purely civilian missions) and no recurrence of violence in that year indicates a country in post conflict. Where a multilateral peacekeeping mission has been present with no recurrence of violence for up to seven consecutive years, a country is deemed to be post-conflict (GHA n.d.).

- **Emergency obstetric and neonatal care (EmONC) services**: are life-saving services for women and babies during childbirth. They include: administration of parenteral antibiotics, parenteral oxytocic drugs, parenteral anticonvulsants for pre-eclampsia, manual removal of retained placentas, removal of retained products of conception, assisted vaginal delivery (vacuum extractions or forceps deliveries), neonatal resuscitation, caesarean section and blood transfusion (AMDD 2013).

**Contributions of Authors**

CPC wrote the first draft protocol and undertook the subsequent revisions of the protocol.

All review authors reviewed the draft protocol before submission to the review group.
DECLARATIONS OF INTEREST
The authors declare no conflict of interest.

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