

# **Protocol: Family and Community Interventions under Integrated Management of Childhood Illness Strategy for Reduction of Neonatal and Under-five Mortality among Children in Low-And-Middle-Income Countries: A Systematic Review**

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**THE CAMPBELL COLLABORATION**

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## Protocol

# Family and Community Interventions under Integrated Management of Childhood Illness Strategy for Reduction of Neonatal and Under-Fives Mortality among Children in Low-And-Middle-Income Countries: A Systematic Review

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## 1. BACKGROUND

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### 1.1 Description of the Problem

Millennium Development Goal 4, as defined by the United Nations in 2000, aims to reduce the 1990 under-five mortality rate (U5MR) by two thirds in the year 2015. A reduction of U5MR will reflect the impact of child survival interventions and global policies aimed at international development (Mosley, 2003). Nearly 98 per cent of the 7.6 million child deaths globally each year occur in Low-and-Middle-Income countries (LMICs) and 64 per cent of them are from preventable infectious causes namely sepsis, pneumonia, diarrhea and Malaria (Liu, 2012). About 40 per cent of the child deaths occur among neonates (0–28 days), from preventable causes such as preterm birth and intrapartum complications and sepsis (Liu, 2012; Lawn, 2012). Though U5MR has decreased from 9.6 million in 2000 (Black, 2003) to 7.6 million in 2010, reduction of U5MR could still improve in many developing countries where U5MR remains high (Liu, 2012). A slower decline of U5MR has been attributed to stagnant neonatal mortality rate (NMR) (Save the Children, 2013) and prevailing high childhood morbidity rates (Murray, 2007). Annual decline of NMR during 2000–2010 was slower than annual mortality decline among children 1–59 months when compared to 1990–2000 (Lawn, 2012). Hence, child survival strategies should focus on infectious and neonatal causes of mortality (Liu, 2012) and direct the resources towards vulnerable socio-economic groups for improved neonatal survival (Lawn, 2012).

Available evidence suggests that interventions such as exclusive breastfeeding, clean delivery and skilled attendance at delivery, tetanus toxoid immunization to pregnant mothers, newborn resuscitation, and appropriate management of infections can prevent most neonatal deaths (Darmstadt, 2005). In addition, prompt and appropriate management of acute diarrheal diseases (ADD), acute respiratory infections (ARI), and malaria and childhood under-nutrition can also prevent child mortality (Jones, 2003). Research has shown that comprehensive training of health care providers (HCPs) on management of childhood morbidities at health facilities and in outreach services, can prevent a significant proportion of childhood mortality (Gove, 1997). Studies have reported that available child health services are under-utilized; care-seeking

behavior during acute illnesses is neither prompt (timely) nor appropriate (Sreeramareddy, 2006a; Sreeramareddy, 2012) which could be a reason for a slower progress towards achieving MDG-4 in many LMICs. Stagnation in neonatal mortality rate has been attributed to unsafe delivery and newborn care practices particularly in underserved rural communities and urban slums (Osrin, 2002; Sreeramareddy, 2006b; Seward, 2012). Counseling the parents/caretakers about symptoms and danger signs of child illness may improve the care-seeking behavior during the episodes of childhood illness. Therefore, behavior change communication aimed at improving utilization of child health services, seeking prompt and appropriate treatment during illness, improving perinatal and childcare practices assume importance in LMICs where U5MR remains high.

## **1.2 Description of the interventions**

Previously child survival interventions were usually implemented as separate disease-specific programs for common causes of child mortality. Though interventions and others such as exclusive breastfeeding, vaccination and oral rehydration therapy (ORT), are effective, children attending primary care settings are often known to have multiple and overlapping morbidities which need an integrated approach to treat them adequately (Bryce, 2005b). The World Health Organization (WHO) and United Nations Children Fund (UNICEF), jointly with other technical partners, developed the Integrated Management of Childhood Illness (IMCI) strategy to reduce U5MR in 1997 (Tulloch, 1999). IMCI strategy aims to address the limitations encountered in disease specific child health programs by integrating treatment of common childhood morbidities that cause child mortality. Since its conception and after piloting the strategy in a few countries, more than 70 countries have fully implemented IMCI strategy (Lambrechts, 1999). Three components of the IMCI strategy are: 1) improving case management skills of healthcare providers (HCPs) particularly in the outpatient facilities (health worker interventions), 2) strengthening health systems (health system interventions) and 3) improving family and community health practices (WHO, 2003; WHO, 2005) (community interventions).

Health worker interventions are implemented by training healthcare providers about use of evidence-based, locally adapted guidelines for managing the leading causes of childhood illnesses. Training is provided in-service for duration of standard 11 days or shortened 5–10 days and a follow-up visit by the trainer after one month to reinforce the newly acquired skills for using IMCI guidelines and job-aids such as wall charts, diagnostic algorithms, and so forth. Health system interventions are mainly related to the key policies and management of health systems such as

- a) Ensuring availability of essential drugs and supplies (job aids),

- b) Organization of health facilities for rapid evaluation and management of sick children, and
- c) Establishing appropriate referral system, health information management system, monitoring and supervision of healthcare providers

Implementation of household and community interventions of IMCI is done in one or more of the following ways:

- 1) Counseling parents/caregivers at health facilities about care-seeking behavior, danger signs, and home management of childhood illness, compliance to treatment advice, child feeding and utilization of preventive services
- 2) Community-based peer educators providing information during in-home counseling sessions to parents/caregivers and family members of under-five children about nutrition and health practices and proper referral practices
- 3) Dissemination of IMCI practices through mass media (mainly television and radio), distribution of posters and brochures to educate the general public about child health issues
- 4) Community mobilization involves active and meaningful participation of the communities to establish a partnership between health workers and households with support from their communities. This is achieved by involving women's groups, community leaders, religious institutions and so forth, through meetings arranged by healthcare providers to sensitize and motivate them about IMCI interventions.

### **1.3 How the interventions might work**

The training component of Integrated Management of Childhood Illness (IMCI) is expected to improve case management skills of healthcare providers, thus reducing mortality from acute respiratory infections, acute diarrheal diseases and malaria. The health system interventions would improve the infrastructure of health facilities, that is, health staff, job aids, and treatment facilities (drugs) for treatment of childhood illnesses. While the health worker training and health system interventions together would improve the quality of care provided at health facilities, the family and community interventions may improve family's care seeking behavior and community childcare practices. Improved quality of care as a result of training and health system interventions together with community interventions may lead to increase in utilization of child health services. All the three IMCI interventions are expected to act synergistically

towards reducing child mortality (Ahmed et al., 2010; Lulseged, 2002). A causal chain (figure 1) shows various family and community interventions of IMCI strategy and ensuing programmatic pathways of intermediate and final health outcomes. Family and community interventions are expected to improve care-seeking behaviors of family members/caregivers for common childhood illnesses (choosing appropriate care and seeking prompt care (within 24 hours), community practices regarding perinatal and newborn care, and caregiver's compliance to HCP's treatment and advice. Family interventions are also expected to increase uptake of preventive services and improve child feeding practices. In addition to these expected changes, social mobilization through involvement of women's groups and community leaders will raise the general awareness and demand for improving household and community practices with regards to child health. All these improvements will increase the utilization of preventive and curative services and overall improvements in health and nutritional status of under-five children, thus decreasing child mortality (Bryce et al., 2005b).

#### **1.4 Why it is important to do this review**

Evidence about impact of Integrated Management of Childhood Illness (IMCI) is available from community trials, WHO multi-country evaluation report and a few systematic reviews. Primary studies which have assessed the impact of IMCI strategy on health care providers' performance have demonstrated that IMCI strategy can improve the quality of care at the health facilities (Amaral et al., 2004; Amaral et al., 2005; Amaral et al., 2008; Arifeen et al., 2005; Bryce et al., 2005a; Huicho et al., 2005). Primary studies which have assessed the impact of health care provider training alone as an intervention to strengthen IMCI programs have shown a variable effect on outcomes of childhood illness (Ahmed, Mitchell, & Hedt, 2010; Goga & Muhe, 2011; Lulseged, 2002). However, evidence from primary studies about the impact of one or more of IMCI interventions on child mortality is inconclusive (Amaral et al., 2005; Arifeen et al., 2009; Bhandari et al., 2012; Huicho et al., 2005). A report about Multi-Country Evaluation on Effectiveness of Integrated Management of Childhood Illness (IMCI), Cost and Impact (MCE-IMCI) suggested that IMCI delivery systems should be expanded to include other potential channels such as private health sector and adopt stronger community-based approaches rather than being just health facility-based (Bryce et al., 2005b). A mixed methods multi-country survey has highlighted financial shortages, logistic difficulties in follow-up after training in IMCI case management training and human resource shortages (in terms of number and/or skills) as challenges to IMCI scale-up (Goga et al., 2009; Goga and Muhe, 2011).

To date, we found three systematic reviews on this topic by searching in Index Medicus, Scopus and Cochrane library. A narrative review that focused on parents/caregiver's role in IMCI strategy has underscored that ICMI trained workers lacked communication skills about counseling the parents/caregivers about danger signs and homecare of the sick child (Paranhos



et al., 2011). A systematic review comparing the effect of standard 11-days training versus shortened 5–10 days training on quality of care has concluded that standard (11-days) IMCI training was marginally better and underscored the need for implementing other IMCI interventions irrespective of the training duration. This review also found that for a third of sick children, the HCPs did not adhere to IMCI guidelines (Rowe et al., 2012). A Cochrane systematic review protocol aims to synthesize the evidence on effect of integration of individual IMCI components as a healthcare package on both HCPs and its beneficiaries (Gera et al., 2012). However, a Cochrane review of both experimental and quasi-experimental studies has shown that there is very little evidence that integrating primary healthcare services at the point-of-delivery may improve the utilization and outputs of healthcare delivery (Dudley & Garner, 2011). However, among the published reviews, one review did not perform meta-analysis but only summarized the results on impact of IMCI interventions on mortality rates and utilization rates of child health care services (Rowe et al., 2012) while another review qualitatively synthesized the caregiver's (mothers and/or family members) child healthcare practices (Paranhos et al., 2011). A published Cochrane systematic review protocol aims to synthesize impact of various combinations of three IMCI interventions on mortality, quality of care and key IMCI indicators. Though family and community interventions of our review overlap with interventions to be included in a review by Gera et al. we aim to focus only on various components of family and community interventions (see section 3.1.2) and assess entire intermediate outcomes related to proximate determinants to childhood mortality. Moreover, none of the above reviews have focussed on the impact of IMCI interventions on community child healthcare practices as underscored by another review (Paranhos et al., 2011) or focussed the review on the impact of standalone community interventions on child mortality rates plus childcare practices of the family and community. Moreover, published reviews have not compared the impact of supply-side interventions (health worker and health system interventions) with demand-side interventions (community interventions). In addition, from the existing reviews evidence is lacking about the impact of family and community interventions on compliance to homecare of a sick child, care-seeking behavior and preventive practices (Thompson and Harutyunyan, 2009). Hence, synthesizing the evidence about impact of family and community interventions of IMCI strategy on its beneficiaries is timely and policy relevant. We aim to report the effect of household and community interventions inclusive of social mobilization on under-five mortality and other intermediate outcomes such as care seeking and community childcare practices. We also aim to compare the outcomes demand-side interventions (community) with outcome of supply-side interventions (health worker plus health system).

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## **2. OBJECTIVE OF THE REVIEW**

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### **2.3 Main objective**

1. To assess the effect of family and community interventions under Integrated Management of Childhood Illness (IMCI) strategy on childhood mortality rates, utilization of child health services and community child health practices in LMICs.
2. To compare the outcomes of health worker interventions combined with health system and/or community interventions with outcomes of family and community interventions only
3. To compare outcomes of health worker intervention together with health system and/or family and community interventions with outcomes of health worker interventions only.

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## **3. METHODS**

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### **3.1 Criteria For Considering Studies For The Review (PICOs)**

#### **3.1.1 Participants**

- Newborns (aged up to 28 days after birth) and children aged less than five years
- Parents/family members/caregivers of newborns and under-five children

If the studies/trials were randomized at the level of villages/wards (that is, cluster randomized trial) then all participants (as listed above) living in the clusters studied will be eligible. All the populations to be included will be residing in the low- and middle-income countries (LMICs) as defined by World Bank (The World Bank Group, 2011).

#### **3.1.2 Interventions**

We will include the family and community interventions, which is the third component of IMCI strategy listed in the IMCI document published by UNICEF (UNICEF, 1999). These interventions are:

- 1) Individual counseling provided by the HCPs to the caregivers either at health facilities or home
- 2) Peer-counseling provided to the caregivers and their family members at home
- 3) Behavior change communication about child health practices disseminated through posters, brochures and mass media
- 4) Social mobilization through involvement of women's groups, community leaders, and so forth

We will include all potential studies which have examined the effect of health worker training together with household and community interventions or family and community intervention only or health worker training only. We will also include the studies which have examined the effect of all the three IMCI interventions.

### **Comparison Groups**

Comparison groups in controlled study designs will be those individuals and clusters or communities where routine mother and child health services were ongoing without implementation of IMCI household and community interventions.

### **3.1.3 Study Types**

Studies which have adopted the following designs and are addressing the household and community interventions as described in UNICEF's IMCI document will be included:

#### **Experimental study designs:**

1. Individual Randomized Controlled Trials (iRCTs)
2. Cluster-Randomized Controlled Trials (cRCTs)
3. Quasi-Randomized Trials (qRCTs)
4. Non-Randomized Trials (NRTs)

#### **Quasi-experimental study designs:**

1. Controlled before-and-after (CBA) studies
2. Regression-discontinuity designs (RDD)

### 3. Interrupted time series (ITS) studies

We will include either individual or cluster RCTs where the unit of randomization is at individual or cluster (village or district) level and in each study, the comparison group will differ only in their exposure to the intervention—that is, baseline characteristics and potential confounding factors are adjusted for.

qRCT or NRT trials should have a concurrent comparison group (for example no IMCI intervention), and groups adjusted for baseline characteristic and investigator allocates into groups by non-random methods (in qRCT allocation into groups is done by pseudo-random sequence).

In CBA studies allocation into the different comparison groups are not made by the investigators and outcomes measurement is done in both intervention and control groups before the intervention is introduced and once again after the intervention has been introduced.

RDD studies are pretest-posttest design in which the investigators demonstrate interventions effects by assigning an intervention using a cut-off (that is, above or below a threshold).

In ITS studies, investigators obtain data on outcomes from the same population several times before and after intervention.

We will include cRCT, qRCT, NRT and CBA studies, if these studies have studied at least two intervention sites and two control sites.

We will include ITS studies, if the time point of intervention was clearly defined and data on outcomes is available from at least three time points before and after the intervention.

Considering that risk of bias and measures of effect to be different according to types of studies we will synthesize the results separately for RCTs and non-randomized trials (qRCT, NRT, CBA, RDD and ITS studies)

#### **3.1.4 Outcomes**

##### **3.1.3.1 Primary outcomes:**

1. Neonatal mortality rates (first 28 days of life)
2. Post-neonatal mortality rates (after 28 days up to, one year of age)
3. Infant mortality rates (first year of life)

#### 4. Under-five mortality rates (up to five years of age)

All mortality rates will be calculated as number of deaths per 1000 live births.

### **3.1.3.2 Secondary outcomes**

(Any of the outcome measures listed below and/or any other outcomes of interest that fit into the categories listed below if identified during the search for studies and/or data extraction will be included and be given an operational definition)

#### **Community child health practices**

##### ➤ **Newborn care practices such as (per cent of newborns)**

- Per cent of newborns for whom breast-feeding initiation was done within one hour after birth
- Per cent of newborns who were not given any pre-lacteal feeds
- Per cent of newborns who were exclusively breast-feeding at four weeks after birth
- Per cent of newborns who were given skin-to-skin care on the first day of life
- Per cent of newborns who were appropriately clothed on the first day of life
- Per cent of newborns for whom nothing was applied on the umbilical cord

##### ➤ **Child nutrition and feeding practices such as (% of children)**

- Per cent of children aged less than six months who were exclusively breastfed
- Per cent of children aged 6–9 months who received breast milk and complementary feeding

- Per cent of children aged 0–23 months who were stunted (defined as  $\leq 2$  weight-for-height  $Z$  score)
  - Per cent of children aged 24–59 months who were wasted (defined as  $\leq 2$  weight-for-height  $Z$  score)
- **Practices related to utilization of child health services and care during illness of child (for example, acute respiratory infections, diarrhea and Malaria) such as**
- Proportion of caretakers who sought appropriate care during the illness within last two weeks
  - Proportion of care takers who sought prompt (within 24 hours) care during illness in last two weeks
  - Proportion of care takers who continued feeding the child during illness
  - Proportion of care takers who adhered to the health care providers' advice on treatment
- **Practices related to utilization of preventive health care service**
- Improvement in utilization of public health facilities or private health facilities
  - Increase in immunization coverage according to expanded program of immunization (EPI)
  - Increase in the proportion of skilled attendance at birth
  - Increase in the proportion of childbirths at health facilities
- **Outcomes measuring the efficacy of community mobilization program**
- (Indicators that measure if IMCI strategy has been successful in educating community members/caregivers about childcare and healthcare seeking behavior)
- Proportion of care takers—that is, family members/parents who were counseled in the previous six months by a community health worker about child feeding, care-seeking etc

- Proportion of caretakers who had attended a session about community mobilization during last six months.
- Proportion of mothers/caretakers who have knowledge about Oral Rehydration Solution and/or home available fluids for management of diarrhea at home
- Proportion of mothers who have knowledge about at least two danger signs of a sick child

### **Other possible outcomes**

- Decrease in the incidence of acute respiratory infections and diarrhea (as a result of improved nutritional status)

## **3.2 Search methods for identification of studies**

### **3.2.1 Electronic searches**

We will perform a comprehensive electronic search for primary studies in both 'mainstream' databases and 'specialist databases'. To minimize the publication bias, we will search all available databases and the titles of the journals covering the fields of child health, public health, and global/international health. To avoid language bias and publication bias, we will perform the searches without any language and publication status restrictions.

The following 'mainstream' electronic databases will be searched for primary studies.

PubMed

EMBASE (Athens)

Popline

CINAHL (Cumulative Index to Nursing and Allied Health Literature)

Ovid

Index Copernicus

CAB-Direct (Global Health)

LILACS (Latin American and Caribbean health sciences)

Web of Science

SCOPUS

Science Citation Index Expanded

Social Sciences Citation Index

Sociological Abstracts

World Health Organization Library Information System (WHOLIS)

African Healthline (bibliographic databases on African health issues)

African Index Medicus

IndMed

Western Pacific Region Index Medicus

Index Medicus for South-East Asia Region

Australasian Medical Index

International Bibliography in Social Sciences (Athens)

The Campbell Library

The Cochrane Central Register of Controlled Trials

The database of Abstracts of reviews of Effectiveness

FRANCIS - bibliographic database in social sciences

BDSP (Banque de Donnees en Sante Publique) – French database on public health literature

MEDCARIB - Caribbean health sciences literature



JSTOR, Wiley Inter-science, Science Direct

HINARI (Health InterNetwork Access to Research Initiative)

We will develop the search strategy in MEDLINE as detailed in the annexure-5. The MEDLINE search strategy will be translated into other databases using appropriate vocabulary. Some suitable primary studies may have been published as monographs and reports or as research articles in journals that are not indexed in electronic databases listed above. So we will search the following 'specialist' electronic databases and non-governmental organizations' websites as further sources for primary studies.

WHO/CAH reports - World Health Organization's, Department of Child And Adolescent health ([www.who.int/child\\_adolescent\\_health/en/](http://www.who.int/child_adolescent_health/en/))

HCPP (Health Care Provider Performance) database

UNICEF (United Nations Children's Fund)

JOLIS Library Catalog - World Bank & IMF Libraries of the World Bank

British Library for Development Studies (BLDS) - a database about economic and social issues in developing countries at Institute for development studies

ID21 – a database reporting the UK-based international development research

Database on Prince Leopold Institute of Tropical Medicine, Antwerp, Belgium

WHO Regional Index Medicus for Eastern Mediterranean Region (EMRO)

PAHO - PAHO HQ Library Catalog

WHO Global Health Library

DFID (Department for International Development)

ELDIS (Electronic Development and Environment Information System)

OpenGrey

Partnership for Maternal, Newborn and Child Health

Global Strategy for Women's and Child Health

Healthy Newborn Network

Concern International

Hellen Keller International

World Vision International

Concern Worldwide

Save the Children

We will also use 'Google' and 'Google Scholar' search engines with one more of the following search terms; 'IMCI', 'care-givers' counseling', 'community mobilization', 'social mobilization', 'Millennium Development Goal 4', 'MDG-4', 'under-5 mortality', 'child mortality', 'infant mortality', and 'neonatal mortality'. In Google search we will use cited references feature to identify further studies.

### **3.2.2 Searching other resources**

We will hand search the journal titles and conference proceedings that have not been hand searched on behalf of the Campbell Collaboration. We will refer to Cochrane Collaboration's master list of journals and conference proceedings. The reference lists of retrieved studies will be searched to identify additional studies. Authors of the primary studies and investigators of IMCI evaluations will be contacted to identify any further published or unpublished studies. Experts in the field of health systems research or authors of any other relevant reviews will be contacted to know if they are aware of any relevant studies. For the ongoing trials, we will look into the registered trials at the following trial registries: a) International Clinical Trials Registry Platform (ICTRP), World Health Organization (WHO) <http://www.who.int/ictrp/en/> and b) ClinicalTrials.gov, US National Institutes of Health (NIH) <http://clinicaltrials.gov/>

### **List of journals for hand searching**

Lancet

Bulletin of World Health Organization

British Medical Journal

BMC Public Health, BMC Pediatrics, BMC International Health and Human Rights, BMC Health services Research

PLoS Medicine

PLoS One

Global Health Action

### **List of conference proceedings for hand searching**

International Conference of Pediatrics

World Congress of Public Health

World Congress of Epidemiology

## **3.3 Data collection and analysis**

### **3.3.1 Selection of studies**

The search results from various sources—that is, electronic databases, hand searching and other sources—will be merged into a reference manager file. Duplicate references will be deleted and a list of titles, abstracts and full text articles will be generated. Eligibility of the retrieved studies will be assessed by a two-stage process by two review authors (CTS and TNS). At first, two review authors, CTS and TNS will independently screen the lists of titles, abstracts and full text articles by applying pre-defined screening criteria (appendices 1 and 2). At this stage, if any titles/abstracts are deemed not eligible they will be excluded. If uncertain in the first stage, we will reassess by reading the full text at the second stage. If any disagreements have to arise during study selection, they will be resolved either by discussion or consulting a third review author (HNHK). If insufficient or ambiguous information is present in the studies, we will contact primary authors for further information or seeking clarification. All these processes will be guided and entered into a flow diagram provided in the Review Manager 5.1.

### **3.3.2 Data extraction and management**

At least two independent reviewers (among CTS, TNS, and HNHK) will extract the data using pre-designed data extraction form. Data extraction form will be piloted on a few studies and revised if necessary (see Appendix 1). Extracted data will be stored electronically in RevMan or Stata software. We will ensure inter-coder reliability by the following methods: 1) pilot testing the coding form, 2) creating a detailed codebook and 3) training about use of codebook and coding forms. The following information about details of the included studies will be recorded: 1) characteristics of the study, 2) participants, 3) comparison groups, 4) outcomes, 5) statistical analysis (measure of effect size reported) and 5) conclusions (for details see appendix 3). Data to be extracted for the possible meta-analysis includes the number of withdrawals, exclusions and loss to follow-up, and number included in the final analysis, baseline characteristics, types of statistical analysis used, specific measures of effect size reported (that is, both unadjusted and adjusted for overall sample and sub groups). We will also extract data about frequency of dichotomous outcomes, mean and standard deviation for the continuous outcomes. Data about relative risk as a measure of effect size for RCTs NRTs, and CBA studies.

If the same data has been published as more than one publication, the study with the most complete results will be included into meta-analysis. Disagreements will be resolved by consulting a third reviewer or an independent reviewer having expertise in content and methods. Any disagreements that cannot be resolved would be addressed by contacting the study authors. Finally, if all these attempts were unsuccessful, the disagreement would be reported in the review.

### **3.3.3 Assessment of risk of bias in included studies**

Two review authors (CTS and TNS) will independently assess the risk of bias for each included study. Disagreements will be resolved by a third reviewer who has methodological and statistical expertise (HNHK). Assessment of quality of the studies will be done by keeping Preferred Reporting Items for Systematic Reviews (Moher, 2009) guidelines as reference and using the risk of bias model in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins, 2008) for methodological quality of RCTs. For non-randomized studies, we will pay particularly attention to selection bias, such as baseline differences between the groups, and the potential for selective outcome reporting (Higgins, 2008).

The risk of bias assessment will be based on five dimensions (described below). The questions about assessment of risk of bias will be piloted and modified (appendix 3) and risk of bias will be rated as low risk, high risk, and uncertain risk of bias. Assessment of risk of bias will inform the

sensitivity analysis to be conducted (see 5.6.2 Sensitivity analysis). We will report the assessment of risk of bias for each included study.

## **Risk of Bias Dimensions:**

### **Selection bias**

Selection bias is systematic baseline differences between the groups (that is, observable factors that are not adequately accounted for) which may compromise comparability between the groups.

### **Performance bias**

Performance bias refers to systematic bias and confounding related to intervention fidelity and/or exposure to factors other than the interventions and comparisons of interest that may confound the outcome measured. Blinding of participants and intervention delivery is not applicable for IMCI strategy due to the nature of this intervention.

### **Detection bias**

Detection bias deals with systematic differences between groups in relation to how outcomes are determined, including blinding of outcome assessors. Participants who do not undergo IMCI family and community interventions before the end of the study should be censored from the outcome data and if not adequately accounted for may have the potential for introducing bias. Therefore, censoring of the participants is a potential source of detection and attrition bias (see below).

### **Attrition bias**

Attrition bias deals about completeness of the sample and follow-up data. This bias refers to systematic differences between the participants who did not complete the follow-up (drop-outs, migrated, and so forth) and those who completed the follow-up.

### **Reporting bias**

Reporting bias refers to both publication bias (see 5.5.3 assessment of publication bias) and selective reporting of outcomes data and results.

## **Other sources of bias**

We will examine for other potential sources of bias after extraction of data about study designs and the statistical analyses in the included studies. The focus will be to assess if the study authors have reported other potential sources of bias and if they have dealt with these biases adequately.

For individual randomized controlled trials, non-randomized controlled trials and CBA studies the following sources of bias will be included:

1. sequence generation (selection bias)
2. allocation sequence concealment (selection bias)
3. blinding of participants and personnel (performance bias)
4. blinding of outcome assessment (detection bias)
5. incomplete outcome data (attrition bias)
6. selective outcome reporting (reporting bias)
7. comparability of baseline outcomes and the characteristics and
8. protection from contamination

For cluster-randomized trials, specific attention will be paid to following types of biases:

1. recruitment bias
2. baseline imbalance
3. loss of clusters
4. incorrect analysis and
5. comparability with individually randomised trials (Higgins, 2011)

### **3.3.3 Measures of treatment effect**

Dichotomous outcomes will be analyzed using relative risk (RR) ratio and its 95 per cent confidence intervals (CIs). For continuous data, we will report mean and standard deviation for the outcome measures. If continuous data for the outcomes were measured on a same scale between trials, we will use mean difference (MD) with 95 per cent CIs otherwise we will calculate standardized mean difference (SMD) and its 95 per cent CIs. If the means, standard deviations, and/or effect sizes are not available, we will use chi-squared values and correlation coefficients. For rare outcome binary or continuous data (for example, prelacteal feeds, not seeking any healthcare), we will use Peto OR and Mann Whitney test. Hedges' 'g' will be used to correct for small sample size. For non-randomized studies, adjusted effect sizes will be calculated to account for the influence of confounding factors by propensity score matching. Exact criteria for selection of effect sizes will be a developed *ad hoc* during the coding phase

### **3.3.5 Unit of analysis issues**

The included studies are cRCTs or CBA studies, we will use the reported cluster adjusted risk ratios and their 95 per cent CIs. If unadjusted for clustering, we will use intraclass correlation coefficient (ICC), if available, or else we will impute ICC from any other included study. If multiple interventions groups are included in the trial, community interventions paired with training and health system intervention will be compared with the control group. If the included studies report variable and multiple time points of outcomes assessments, we will only focus on comparison of baseline and final endpoint even though it is known that effects of interventions may diminish over time.

### **3.3.6 Dealing with missing data**

We will attempt to contact the authors to obtain the missing data and any other information irrespective of whether it can assumed to be 'missing at random'. If it will not be possible to obtain the missing data, we will impute the missing values, and all the assumptions made for any imputation will be recorded. We will either use intention-to-treat analyses, if reported or contact the authors to carry out re-analyses. In the absence of intention-to-treat analyses and fair indications that data are not missing at random, we will consider missing data to constitute a risk of bias and report in risk of bias assessment.

Imputation made will be for missing aggregate data such as missing SD of for change-from-baseline, from SD for the same outcome from another study, or impute SD using recommended

methods (Abrams, 2005). If necessary, we will impute the missing data using appropriate statistical methods (White, 2009). In addition to this, we will report attrition rates of less than 50 per cent in any groups and explore its effect on the outcomes by doing a sensitivity analyses.

### **3.3.7 Assessment of heterogeneity**

We will measure heterogeneity using  $I^2$  statistic.  $I^2$  test measures the statistical heterogeneity across the studies.  $I^2$  statistic describes the percentage of total variation across studies due to heterogeneity rather than chance (Higgins, 2002).  $I^2$  can be readily calculated from basic results obtained from a typical meta-analysis.  $I^2$  is given by  $100 \% \times (Q - df) / Q$ , where  $Q$  is Cochran's heterogeneity statistic and  $df$  is the degrees of freedom (Higgins, 2002). Negative values of  $I^2$  are considered as zero so that  $I^2$  lies between 0% and 100%. (Higgins, 2002). We will also calculate Cochran's  $Q$ -test and  $\tau^2$  statistic.

### **3.3.8 Assessment of publication biases**

Publication bias will be evaluated using a quasi-statistical method of drawing a Funnel Plot. Funnel plots will be drawn to investigate relationships between effect size and study precision using the 'trim and fill method'. Meaningful Funnel plots will require an adequate number of studies with a diverse range of sample sizes (Hayashino, 2005). Hence, a funnel plot analysis will be drawn if there are at least ten studies with appropriate data. We will also conduct formal statistical tests for funnel plot asymmetry, using Begg's and Egger's methods (Egger, 1997).

## **3.4 Data synthesis**

Analysis will be conducted in RevMan 5 and/or Stata as appropriate. Meta-analysis will be done separately for RCTs and n-RCTs in accordance to current recommendations (Higgins, 2011). Due to diversity in interventions, participants and outcomes we anticipate the use of random effects models. If we find at least two studies that evaluated similar interventions and reported similar outcomes, we will calculate pooled risk ratios, mean differences or standardized mean differences using a random-effects model. Pooled estimates will be calculated by generic inverse variance method and will be generated as Forrest plots. If there are not enough (at least two) studies evaluating similar interventions and reporting a similar outcomes, we will report the median and range of effects, if relevant, or measures of effect from individual studies. We will do



separate meta-analysis for the following IMCI interventions or their combinations 1) community interventions only, 2) health worker interventions only, 3) health worker interventions combined with health system and/or community interventions. If meta-analyses is possible, we will compare the outcomes across combinations of IMCI interventions. If meta-analyses was not possible we will prepare a 'Summary of findings' table, including an assessment of the quality of evidence for each of the main outcomes or types of outcomes listed above. Quality of evidence will be assessed using the GRADE approach for each outcome and will be classified in four levels as 'high', 'moderate', 'low' and 'very low' (Guyatt, 2008).

### **3.4.1 Subgroup analysis and investigation of heterogeneity**

We will perform the following sub-group analysis, if data becomes available. The difference in outcome measures that may be explained by certain factors will be considered for sub-groups analysis. We will test the following sub-groups. If IMCI-family interventions were given as stand alone or along with training and/or health system component. We expect that the effects may be greater with addition of these IMCI components.

Country settings such as Low-Income Countries (LICs) or Middle-Income Countries (MICs) as defined by World Bank. The effects may be higher in LICs compared to MICs. Countries classified according to current U5MR as a benchmark. For example, we will classify countries with U5MR > 100 per 1000 live births and U5MR <100 per 1000 live births. The effects are expected to be greater in countries having high U5MR.

The uncertainty around heterogeneity will be explored with sub-group sensitivity analysis. Further, heterogeneity will be explored in meta-regression considering the potential covariates for comparison and as a possible explanation for heterogeneity. The coefficient for each covariate will be checked for statistical significance at conventional p-value of <0.05. This method has been considered as valid method for combining estimates from different types of study designs and to pool common estimate of interest (Harris, 2008).

### **3.4.2 Sensitivity analysis**

Sensitivity analysis will be used to examine the rigor of conclusions in relation to the quality of data and approaches to analysis. Sensitivity analysis will be used to investigate the possibility of study design influencing outcomes. We will perform sensitivity analysis encompassing all the probable studies included into meta-analysis. We will test our findings by modifying any assumptions we made about missing data within a plausible range of values and by removing those studies with high risk of bias, if there are studies with different levels of risk of bias. We

will report sensitivity analyses as a summary table. We will attempt to generate individual forest plots for some of the sensitivity analysis we will undertake.

### **3.4.5 Narrative analysis**

To capture the major studies and give a sense of research in IMCI family and community interventions as previously mentioned, we will include relevant studies. To make our analysis more transparent, we will report these studies in a separate narrative analysis that will focus on intervention characteristics and contextual factors. The narrative analysis will enhance our understanding of IMCI family and community interventions included in the review and inform the discussion section.

### **Acknowledgements**

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#### **Advisory group:**

1) Dr. Prathap Tharyan, (He is an Editor with the Cochrane Schizophrenia Group, Coordinator of the South Asian Cochrane Network) Expertise in systematic review methods

2) Anthony Costello ( Professor of International Child Health and Director of the UCL Institute for Global Health) His main scientific expertise is in the evaluation of community interventions to reduce maternal and newborn mortality

### **Contributions of authors**

**Chandrashekhara TS:** Formulated the idea and prepared protocol, will do searching for trials, quality assessment of trials, data extraction and writing up the final review.

**Sathyanarayana TN:** Prepared protocol development, will do searching for trials, quality assessment of trials, review development and writing up the final review

**Harsha Kumar HN:** Helped formulation of review topic, formulation of PICO questions and provided relevant literature for the protocol preparation, will do quality assessment of trials, data analysis, review development and writing up the final review

## Declarations of interest

None

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**APPENDIX-1**

**CRITERIA FOR SCREENING THE RELEVANT STUDIES (based on title and/or abstracts)**

Reference ID:.....

Reviewer authors name:.....

- 1) Is the study primary original research? Yes  No
- 2) Is the intervention studied related to IMCI? Yes  No
- 3) If related to IMCI which were the interventions applied in the study?
  - a) Training health workers (any duration) Yes  No
  - b) Health systems strengthening Yes  No
  - c) Family and community interventions Yes  No
- 4) Are the outcomes of key interest reported? Yes  No   
(Neonatal, infant and under-5 mortality rates, Newborn care practices, Child nutrition and feeding practices, Care during illness of child, Outcomes measuring the efficacy of community mobilization program)
- 5) Are the participants Newborns under-5 children and their parents/family members/caregivers and Community members/leaders? Yes  No
- 6) Are the participants and study conducted in a LMIC? Yes  No
- 7) Was the study conducted or publication date after 1995? Yes  No

Comments.....  
.....  
.....

Decision:

Exclude:

Include: Obtain full text for stage-2 screening



Uncertain: Obtain full text for stage-2 screening

Review author's initials:.....

### APPENDIX-2

#### CRITERIA FOR SCREENING THE RELEVANT STUDIES (based on full text articles)

- 1) Year in which the study was conducted:.....
- 2) Year in which the study was published:.....
- 3) Last name of the principal author:.....
- 4) Contact details of the principal author:.....
- 5) What is the study design? Tick the appropriate column

Design	Yes	No	Uncertain	Action
Individual Randomized Controlled Trial				
Cluster Randomized Controlled Trial				
Quasi-Randomized Trial				
Controlled Before-After Study				
Uncontrolled Before-After Study				
Interrupted Time Series Analysis				
Other Designs				EXCLUDE

- 1) Which are the interventions studied in this study? Please tick the appropriate column

Interventions	Yes	No	Uncertain	Action
Training health workers				
Health systems strengthening				
Family and community interventions				INCLUDE

- 2) Which are the outcomes reported by this study? Please tick the appropriate column

Outcomes	yes	No	uncertain	action
Neonatal, infant and under-5 mortality rates				
Newborn care practices,				
Child nutrition and feeding practices, care during illness of child				
Outcomes measuring the efficacy of community mobilization program				

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Comments.....  
.....  
.....

**APPENDIX-3**

**DATA EXTRACTION FORM FOR META-ANALYSIS**

**I. General details**

Reference ID:.....  
Review authors name:.....  
Year in which the study was conducted:.....  
Year in which the study was published:.....  
Country where study was conducted:.....  
Region/state within the country where study was conducted:.....  
World Bank classification of the country:.....  
(Low-income country, Middle-income country or High-income country)  
Last name of the principal author:.....  
Affiliation of the first author:.....  
Contact details of the first author:.....

**II. Type of publication (Tick the most appropriate)**

- Journal article (research)
- Conference proceedings
- Government or NGO report
- Master's or Doctoral thesis
- Unpublished report
- Other.....

Main objective/s of the study:

.....  
 .....  
 .....

**III. Type or types of interventions covered please appropriate one (could be more than one)**

<b>Interventions</b>	<b>Yes</b>
Training health workers	
Health systems strengthening	
Family and community interventions	
Any other:.....	

**IV. Types of family and community interventions covered (could be more than one)**

<b>Interventions</b>	<b>Yes</b>
Individual counseling by HCP to caregivers at health facilities or at home.	
Peer-counseling by HCP to caregivers, family members at home	
Behavior change communication about child health practices through posters, brochures and mass media etc	
Social mobilization through involvement of women’s groups, community leaders etc	
Other:..... .....	

**V. Study design:**

Design	
Individual Randomized Controlled Trial	
Cluster Randomized Controlled Trial	
Quasi-Randomized Trial	
Controlled Before-After Study	
Other Designs (specify)	

**VI. Data on PICO question (please tick the appropriate item in the first columns)**

<b>Participants</b>	<b>Main IMCI interventions</b>	<b>Family and community interventions</b>	<b>comparators</b>	<b>outcomes</b>
Newborns (age up to four weeks after birth) children aged less than five years Other:..... .....	Training health workers	Individual counseling by HCP to caregivers at health facilities or at home.	routine mother and child health services without any IMCI strategy	<b>Primary outcomes</b> 5. Neonatal mortality 6. Post-neonatal mortality 7. Infant mortality rate 8. Under-five mortality
Parents/family members/caregivers of newborns and under-five children Other:..... .....	Health systems strengthening	Peer-counseling by HCP to caregivers, family members at home		<b>Secondary outcomes: Newborn outcomes</b> 1. Breast-feeding initiation after birth 2. Not given pre-lacteal feeds 3. Exclusive breast-feeding 4. Skin-to-skin on first day 5. Appropriate clothing 6. Nothing applied to newborn
Community members/leaders women's groups, religious leaders Community Health Worker Traditional Birth Attendants Other:..... .....	Family and community interventions	Behavior change communication about child health practices through posters, brochures and mass media etc		<b>Secondary outcomes: Child health practices</b> 1. Child younger than 5 years not breastfed 2. Child aged 6–9 months not receiving appropriate complementary feeding 3. Wasting in children aged 6–9 months (defined as $\leq 2$ weight-for-height z-score) 4. Stunting in children aged 6–9 months (defined as $\leq 2$ weight-for-age z-score)
		Social mobilization through involvement of women's groups, community leaders etc		<b>Secondary outcomes: care-seeking</b> 1. Proportion of children receiving appropriate care during illness 2. Proportion of care-seeking within 24 hours of onset of illness 3. Proportion care taken from the child during illness 4. Proportion of care taken from care providers' advice

		Other:..... ..... ..... .....		<b>Secondary outcomes mean community mobilization</b> <ol style="list-style-type: none"> <li>1. Proportion of child members/parents previous 6 months worker on child fee</li> <li>2. Proportion of care session about comm last 6 months.</li> <li>3. Proportion of knowledge about C and/or home availa of diarrhea at home</li> <li>4. Proportion of moth least two danger sig</li> </ol>
				<b>Adverse and unintended</b> <ol style="list-style-type: none"> <li>1. Improved utilization or private health fac</li> <li>2. Increase in immun to expanded progra</li> <li>3. Increased proportio birth</li> <li>4. Increased proportio facilities</li> <li>5. Decreased incidenc and diarrhea by imp</li> </ol>
				Any other outcomes:.....

**APPENDIX-4**

**Check list for assessment of risk of Bias**

1. Did the authors make any policy recommendations?	[Yes/No/Unclear] If 'yes', please list them
2. Were there any unintended consequences?	[Yes/No/Unclear] If 'yes', please list them
<b>1. Enrolment:</b> (Did the study make adjustment for Adverse selection- a situation of more unhealthy people joining the SHI scheme which in turn can result in higher utilization of healthcare (more OP visit, more hospitalization) considered as a positive impact of SHI?)	
<b>2. Sample Size:</b> Power calculation considered?	[Yes/No/Unclear]
<b>3. Heterogeneity:</b> Are the following sub group effects considered? 1. Age group 2. Ethnicity 3. Women 4. Socio-economic status 5. Geographically remote areas 6. Other	[Yes/No/Unclear]
<b>6. Correction of statistical errors (if 'yes' please describe)</b>	
i) Did they correct for regional or subgroup in cluster data?	<i>Regional -</i> [Yes/No/Unclear] <i>Subgroup -</i> [Yes/No/Unclear]
ii) Did they take in to account serial autocorrelation in time series data?	[Yes/No/Unclear]
iii) Did they use robust standard errors such as Huber-White statistics?	[Yes/No/Unclear]
<b>A</b>	<b>SELECTION BIAS</b>
(Q1)	Are the individuals selected to participate in the study likely to be representative of the target population?  1. Very likely 2. Somewhat likely 3. Not likely 4. Can't tell
(Q2)	What percentage of selected individuals agreed to participate?  1. 80 – 100% agreement 2. 60 – 79% agreement 3. less than 60% agreement 4. Not applicable 5. Can't tell
<b>RATE THIS SECTION</b> See dictionary	<b>STRONG</b> <b>MODERATE</b> <b>WEAK</b> 1                      2                      3









<b>Incomplete data</b>	No + % of drop-outs for intervention group Reasons for drop out: No + % of drop-outs for control group Reasons for drop out: Incomplete outcome data addressed?	
<b>Data collection</b>	Were the data collected in a way that addressed the research question? Is it clear: a) where setting of the data collection was chosen b) why the setting was chosen c) that study objectives were explained to participants d) how data was collected e) how data was recorded f) who collected the data Were the methods modified during data collection	<i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i>
<b>Data analysis</b>	Was data analysis sufficiently rigorous? Is it clear a) How analysis was done b) How themes categories were derived from data c) Method of analysis explained d) That results were fed back to the participants e) Was triangulation used f) Was analysis repeated to ensure reliability by different researcher	<i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i>
<b>Research partnership relations</b>	Is it clear that researchers critically examined: a) their own role b) Potential influence Was relationship between researchers+participants considered?	<i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i>
<b>Findings</b>	a) Is it possible to summarize the findings? b) Where the findings made explicit? c) Were the findings easy to understand? d) Are key concepts presented? e) Is the interpretation clearly presented?	<i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i>
<b>Justification of the data interpretation</b>	a) Was all the data taken into account? b) Are quotes numbered or identified? c) Do authors explain how data was selected from original sample? d) Do authors indicate links between data presented and their own interpretation of data? e) Are negative, unusual or contradictory cases presented?	<i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i>

	f) Is there adequate discussion of the evidence both for and against authors own interpretation?	<i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i>
<b>Transferability</b>	a) Is there conceptual and theoretical congruence between this and other works? b) Are the findings transferable to another population?	<i>[Yes/No/Unclear]</i> <i>[Yes/No/Unclear]</i>
<b>Relevance and usefulness</b>	How important are the findings to practice?	

**APPENDIX-5**

**Search Strategy**

**Search Strategy for “family and community interventions under IMCI strategy for reduction of neonatal and under-fives mortality among children in Low-and-middle-income countries: a systematic review”**

<p><b>DATABASES</b></p>	<p>PubMed            EMBASE (Athens)            Popline            CINAHL            Ovid            Index Copernicus            CAB-Direct (Global Health)            LILACS (Latin American and Caribbean health sciences.)            Web of Science            SCOPUS            Science Citation Index Expanded            Social Sciences Citation Index            Sociological Abstracts            World Health Organization Library Information System (WHOLIS)            African Healthline (bibliographic databases on African health issues)            African Index Medicus            IndMed            Western Pacific Region Index Medicus            Index Medicus for South-East Asia Region            Australasian Medical Index            International Bibliography in Social Sciences (Athens)            The Campbell Library            The Cochrane Central Register of Controlled Trials            The database of Abstracts of reviews of Effectiveness            FRANCIS - bibliographic database in social sciences            BDSP (Banque de Donnees en Sante Publique) – French database on public health literature            MEDCARIB - Caribbean health sciences literature            JSTOR, Wiley Inter-science, Science Direct            HINARI</p>
<p><b>INTERVENTION</b>  <i>Family and community interventions under Integrated</i></p>	<p>Family intervention* [All Fields]            Community interventions *[All Fields]            Home based care [All Fields]</p>

<p><i>management of childhood illness (IMCI) strategy</i></p>	<p>Impact of counselling care-takers and family members on child health care  Impact of counselling care-takers and family members on community mobilisation  Home counseling visits by community health workers  Mother's groups meetings  Community mobilization through mini-theatre  "Care seeking behavior" [All Fields]  "Preventive primary care outreach interventions" [All Fields]  "Preventive care" [All Fields]</p>
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**OUTCOMES**

<ul style="list-style-type: none"> <li>• <i>Neonatal mortality</i></li> <li>• <i>Infant mortality</i></li> <li>• <i>Under five child mortality</i></li> <li>• <i>Newborn care practices</i></li> <li>• <i>Child nutrition and feeding practices</i></li> <li>• <i>Care during illness of child (Ex: acute respiratory infections, diarrhea and Malaria)</i></li> <li>• <i>Efficacy of community mobilization program</i></li> </ul>	<p>(A) infant mortality [All Fields]  infant morbidity [All fields]  neonatal mortality [All Fields]  neonatal morbidity [All fields]  infant mortality [MeSH Terms]  child mortality [MeSH Terms]  child mortality [All Fields]  child morbidity [All Fields]  under five child mortality [All Fields]  under five child morbidity [All Fields]  infant *mor rates [All Fields]  childhood *mor rates [All Fields]  neonatal *morb rates [All Fields]  Acute childhood *illness [All Fields]  Acute neonatal *illness [All Fields]  Acute infant *illness [All Fields]  infant nutrition disorders [MeSH Terms]  pneumonia or malaria or measles or malnutrition or fever or cough or diarrhea or acute respiratory infections in children less than (under) five years [All Fields]</p> <p>(B) Newborn care practices such as (% of newborns that were)</p> <ul style="list-style-type: none"> <li>• Breast-feeding initiation done within 1 hours after birth</li> <li>• Not given pre-lacteal feeds</li> <li>• Exclusive breast-feeding at 4 weeks</li> <li>• Skin-to-skin on first day of life</li> <li>• Appropriate clothing first day of life</li> <li>• Nothing applied to the umbilical cord</li> </ul>
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(C ) Child nutrition and feeding practices such as (% of children who are)

- Child younger than 6 months exclusively Breastfeeding
- Child aged 6–9 months receiving breast milk and complementary feeding
- Wasting in children aged 0–23 months (defined as  $\leq 2$  weight-for-height Z score)
- Stunting in children aged 24–59 months (defined as  $\leq 2$  weight-for-height Z score)

(D) Care during illness of child (Ex: acute respiratory infections, diarrhea and Malaria) such as

- Proportion of caretakers who sought appropriate care during illness in last 2 weeks
- Proportion of care takers who sought prompt (within 24 hours) care seeking during illness in the last 2 weeks
- Proportion care takers who continued feeding the child during illness
- Proportion of care takers who adhered to health care providers' advice on treatment

(E ) Outcomes measuring the efficacy of community mobilization program ( i.e. indicators measuring if IMCI strategy has been successful in educating community members/caregivers about childcare and healthcare seeking behavior)

- Proportion of child care takers i.e. family members/parents who were counseled in previous 6 months by a community health worker on child feeding, care-seeking etc
- Proportion of care takers who had attended a session about community mobilization during last 6 months.
- Proportion of mother/care takers with knowledge about Oral Rehydration Solution and/or home available fluids for management of diarrhea at home
- Proportion of mother with knowledge about at least two danger signs of a sick child

(F) Adverse and unintended effects, such as:

	<ul style="list-style-type: none"> <li>• Improved utilisation of public health facilities or private health facilities</li> <li>• Increase in immunisation coverage according to expanded program of immunisation</li> <li>• Increased proportion of skilled attendance at birth</li> <li>• Increased proportion of childbirths at health facilities</li> <li>• Decreased incidence of respiratory infections and diarrhoea by improved nutrition status</li> <li>• Appropriate care-seeking behavior,</li> <li>• Improved home case-management</li> <li>• Improved compliance to treatment</li> </ul>
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**Search strategy in Pubmed as on 07 Jan 2013**

Search	Add to builder	Query	Items found
#22	Add	Search (#14) AND #17	1123
#21	Add	Search (((((((((((children less than 5 years*) OR Caregivers for childrenless than 5 years) OR mothers with children less than 5 years) OR neonates) OR infants) OR toddlers)) AND (((((((Improved utilisation of public health facilities OR private health facilities)) OR Increased proportion of childbirths at health facilities) OR (Decreased incidence of respiratory infections and diarrhoea by improved nutrition status)) OR Appropriate care-seeking behavior) OR Improved home case-management) OR Improved compliance to treatment) OR Increased proportion of skilled attendance at birth) OR Increase in immunisation coverage according to expanded program of immunisation))) OR ((((((efficacy of community mobilization program) OR (educating community members/caregivers about childcare and healthcare seeking behavior)) OR Proportion of child care takers i.e. family members/parents who were counseled in previous 6 months by a community health worker on child feeding, care-seeking) OR care takers who had attended a session about community mobilization during last 6 months.) OR mother/care takers with knowledge about Oral Rehydration Solution and/ OR home available fluids for management of diarrhea at home) OR mother/caretakers with knowledge about at least two danger signs of a sick child)) OR (((((((Care during illness of child) OR caretakers who sought appropriate care during illness in last 2 weeks) OR care caretakers who sought prompt AND (within 24 hours) AND care seeking during illness in the last 2 weeks) OR care takers who continued feeding the child during illness) OR care takers who adhered to health care providers' advice on	2543

Search	Add to builder	Query	Items found
		<p>treatment) OR Care during acute respiratory infections in children less than 5 years) OR care during diarrhea in children less than 5 years) OR care during malaria in children less than 5 years) OR (((((((Child nutrition and feeding practices*)) OR (Child aged 6-9 months receiving breast milk and complementary feeding)) OR Wasting in children aged 0-23 months) OR Stunting in children aged 24-59 months) OR /2 weight-for-height Z score) OR Child younger than 6 months exclusively Breastfeeding)) OR (((((((Newborn care practices) OR Breast-feeding initiation done within 1 hours after birth) OR Exclusive breast-feeding at 4 weeks) OR Nothing applied to the umbilical cord) OR Appropriate clothing first day of life) OR Skin-to-skin on first day of life) OR given pre-lacteal feeds)) OR (((((((((((neonatal death) OR neonatal mortality) OR neonatal mortality rate) OR neonatal death rate)) OR (((infant mortality rate) OR infant mortality) OR infant death) OR infant death rate)) OR (((under five child mortality) OR under five child mortality rate) OR under five child death) OR under five child death rate)) OR (((child death[MeSH Terms]) OR neonatal death[MeSH Terms]) OR infant death[MeSH Terms])) OR (((((((("child mortality"[MeSH Terms]) OR "child nutrition disorders"[MeSH Terms]) OR acute childhood illness) OR acute childhood morbidity) OR acute childhood mortality) OR childhood illness) OR *child illness)) OR (((("infant/mortality"[MeSH Terms]) OR "infant care"[MeSH Terms]) OR "infant nutrition disorders"[MeSH Terms]) OR infant illness) OR infant morbidity)) OR (((("neonatal nursing"[MeSH Terms]) OR neonatal morbidity) OR neonatal illness) OR neonatal nutrition))) OR (((((((((((pneumonia in children) OR fever in children) OR malnutrition in children) OR diarrhoea in children) OR respiratory infection in children) OR measles in children) OR malaria in children) OR cough in children)) OR (((((((pneumonia in infants) OR malnutrition in infants) OR diarrhoea in infants) OR respiratory infection in infants) OR measles in infants) OR malaria in infants) OR cough in infants)) OR (((((((neonatal pneumonia) OR neonatal malnutrition) OR neonatal diarrhoea) OR neonatal respiratory infection) OR neonatal measles) OR neonatal malaria) OR neonatal cough)))))) AND (((((((((((integrated health care systems[MeSH Terms]) OR integrated management of childhood illness) OR integrated management of childhood illnesses) OR imci)) OR (((integrated management in child health) OR integrated management in infant health) OR integrated management in neonatal health)))) OR (((((((("home based care") OR "care seeking behavior") OR "preventive primary care outreach interventions") OR "preventive care")) OR (((compliance to home-based care,) OR compliance to care seeking behavior) OR compliance to preventive practices)) OR ((family intervention*) OR community interventions *)))) OR (Search Search AND ((((((((((((((((* AND Family and community interventions under Integrated management of childhood illness AND (IMCI) AND</p>	



Search	Add to builder	Query	Items found
		strategy)) OR Home based care) OR (Impact of counselling care-takers and family members on child health care)) OR (Impact of counselling care-takers and family members on community mobilisation)) OR Community mobilization through mini-theatre) OR Home counseling visits by community health workers Mother's groups meetings) OR Preventive care) OR Preventive primary care outreach interventions) OR Care seeking behavior) OR Community interventions *) OR Family intervention*) OR caregiver, family[MeSH Terms]) OR access to health care[MeSH Terms]) OR "home care services"[MeSH Terms]) AND actions, community[MeSH Terms]) OR community medicine[MeSH Terms]) OR aides, home care[MeSH Terms]) OR counseling[MeSH Terms]))	
#17	Add	Search (((((#11) OR #8) OR #7) OR #6) OR #3) OR #2	446897
#16	Add	Search (#15) OR #14	44983
#15	Add	Search ((((((((((integrated health care systems[MeSH Terms]) OR integrated management of childhood illness) OR integrated management of childhood illnesses) OR imci)) OR (((integrated management in child health) OR integrated management in infant health) OR integrated management in neonatal health)))) OR (((((((("home based care") OR "care seeking behavior") OR "preventive primary care outreach interventions") OR "preventive care")) OR (((compliance to home-based care,) OR compliance to care seeking behavior) OR compliance to preventive practices)) OR ((family intervention*) OR community interventions *))))	14672
#14	Add	Search SearchSearch ((((((((((((((((((((((• Family and community interventions under Integrated management of childhood Illness (IMCI)strategy)) OR Home based care) OR (Impact of counselling care-takers and family members on child health care)) OR (Impact of counselling care-takers and family members on community mobilisation)) OR Community mobilization through mini-theatre) OR Home counseling visits by community health workers Mother's groups meetings) OR Preventive care) OR Preventive primary care outreach interventions) OR Care seeking behavior) OR Community interventions *) OR Family intervention*) OR caregiver, family[MeSH Terms]) OR access to health care[MeSH Terms]) OR "home care services"[MeSH Terms]) AND actions, community[MeSH Terms]) OR community medicine[MeSH Terms]) OR aides, home care[MeSH Terms]) OR counseling[MeSH Terms]	30523
#11	Add	Search (#10) AND #9	1627
#10	Add	Search (((((children less than 5 years*) OR Caregivers for childrenless than 5 years) OR mothers with children less than 5 years) OR neonates) OR infants) OR toddlers	975750
#9	Add	Search ((((((((((Improved utilisation of public health facilities or private health facilities)) OR Increased proportion of childbirths at health facilities) OR	21232

Search	Add to builder	Query	Items found
		(Decreased incidence of respiratory infections and diarrhoea by improved nutrition status)) OR Appropriate care-seeking behavior) OR Improved home case-management) OR Improved compliance to treatment) OR Increased proportion of skilled attendance at birth) OR Increase in immunisation coverage according to expanded program of immunisation	
#8	Add	Search ((((((efficacy of community mobilization program) OR (educating community members/caregivers about childcare and healthcare seeking behavior)) OR Proportion of child care takers i.e. family members/parents who were counseled in previous 6 months by a community health worker on child feeding, care-seeking) OR care takers who had attended a session about community mobilization during last 6 months.) OR mother/care takers with knowledge about Oral Rehydration Solution and/or home available fluids for management of diarrhea at home) OR mother /caretakers with knowledge about at least two danger signs of a sick child	127
#7	Add	Search (((((((Care during illness of child) OR caretakers who sought appropriate care during illness in last 2 weeks) OR care caretakers who sought prompt (within 24 hours) care seeking during illness in the last 2 weeks) OR care takers who continued feeding the child during illness) OR care takers who adhered to health care providers' advice on treatment) OR Care during acute respiratory infections in childrengn less than 5 years) OR care during diarrhea in children less than 5 years) OR care during malaria in children less than 5 years	378
#6	Add	Search (((((((Child nutrition and feeding practices*)) OR (Child aged 6–9 months receiving breast milk and complementary feeding)) OR Wasting in children aged 0–23 months) OR Stunting in children aged 24–59 months) OR $\leq 2$ weight-for-height Z score) OR Child younger than 6 months exclusively Breastfeeding	1597
#3	Add	Search (((((((Newborn care practices) OR Breast-feeding initiation done within 1 hours after birth) OR Exclusive breast-feeding at 4 weeks) OR Nothing applied to the umbilical cord) OR Appropriate clothing first day of life) OR Skin-to-skin on first day of life) OR Not given pre-lacteal feeds	4176
#2	Add	Search (((((((((((neonatal death) OR neonatal mortality) OR neonatal mortality rate) OR neonatal death rate)) OR (((infant mortality rate) OR infant mortality) OR infant death) OR infant death rate)) OR (((under five child mortality) OR under five child mortality rate) OR under five child death) OR under five child death rate)) OR (((child death[MeSH Terms] OR neonatal death[MeSH Terms]) OR infant death[MeSH Terms])) OR (((((((("child mortality"[MeSH Terms]) OR "child nutrition disorders"[MeSH Terms]) OR acute childhood illness) OR acute childhood morbidity) OR acute childhood mortality) OR childhood illness) OR *child illness)) OR (((("infant/mortality"[MeSH Terms]) OR "infant care"[MeSH	443474

Search	Add to builder	Query	Items found
		Terms)) OR "infant nutrition disorders"[MeSH Terms]) OR infant illness) OR infant morbidity)) OR (((("neonatal nursing"[MeSH Terms]) OR neonatal morbidity) OR neonatal illness) OR neonatal nutrition))) OR (((((((((pneumonia in children) OR fever in children) OR malnutrition in children) OR diarrhoea in children) OR respiratory infection in children) OR measles in children) OR malaria in children) OR cough in children)) OR (((((((pneumonia in infants) OR malnutrition in infants) OR diarrhea in infants) OR respiratory infection in infants) OR measles in infants) OR malaria in infants) OR cough in infants)) OR (((((((neonatal pneumonia) OR neonatal malnutrition) OR neonatal diarrhea) OR neonatal respiratory infection) OR neonatal measles) OR neonatal malaria) OR neonatal cough))))))	

**APPENDIX-6**  
**Causal chain**

