

What kind of family planning delivery mechanisms increase family planning acceptance in developing countries? A mixed methods Systematic Review.

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1. Background:

1.1. *Importance of a continued focus on family planning programmes*

In many developing countries (also termed low- and middle-income countries), official family planning programmes began during the 1960s with the aim of reducing high fertility¹ (Seltzer, 2002). However, in recent years, various Demographic and Health Surveys (DHS) report that women in developing countries have lower desired fertility than actual fertility, i.e. women are having more children than they want. This indicates that there is still an unmet need for family planning; there are a proportion of women of reproductive age who prefer to avoid or postpone childbearing but who are not using any method of contraception. In 2000, an estimated 17% of married women (105 million) had an unmet need for family planning in the developing world (USAID, 2005), and there is considerable variation across countries, for example, 5% in Vietnam and 40% in Haiti (Khan et al, 2007).

Indeed, despite official family planning programmes being in existence for more than 40 years, the contraceptive prevalence rate (CPR)² is still low in many countries. The optimum level for contraceptive prevalence is regarded as 80-85% as this level is quite consistent with replacement level fertility (approximately two children per women; Ross, no date) i.e. this level of CPR will ensure that sufficient numbers of children will be born and survive to maintain existing population levels. Although increased from the level seen in the 1960s (9%), according to the United Nations Population Division, the contraceptive prevalence for the developing world in 2007 was 61.7%, and there were huge variations in CPR within the developing countries; it was only 2.8% in Chad but 80% in Costa Rica, for example. There were also significant variations between regions- about 28% in Africa region and 74% in South America (United Nations, 2009).

An unmet need for family planning can have many undesired consequences in the areas of health, population growth and development. In developing countries, unintended pregnancies (either mistimed or unwanted at the time of conception) are one of the major consequences of an unmet need for contraception (Pallikadavath & Stones, 2006). This contributes towards accelerated population growth by unwanted fertility and closely spaced births. Further, unintended pregnancies often lead to closely spaced pregnancies and child births, early child bearing, and abortions, which in turn lead to high maternal and infant mortality (Sedgh et al, 2006). Moreover, the need for family planning is generally high in societies where poverty, illiteracy, and gender inequality are high (Nazar-Beutelspacher et al, 1999). In such societies, unintended and repeat pregnancies make it difficult for women to participate in economic development and self-development. This causes a cycle of ill health and poverty which, if

¹ High numbers of births per woman

² The proportion of women of reproductive age (or their partner) who are using a contraceptive method at a given point in time (World Health Organisation, 2010))

uninterrupted, could transfer to future generations. Thus, there is a strong health rationale for addressing the unmet need for family planning services in developing countries and thereby contributing to the achievement of the United Nation's Millennium Development Goals (MDGs); in particular goals 4 and 5:

MDG 4. To reduce child mortality:

- Target 1. Reduce by two-thirds, between 1990 and 2015, the under-five mortality rate.

MDG 5. To improve maternal health:

- Target 1. Reduce by three quarters the maternal mortality ratio.
- Target 2. Achieve universal access to reproductive health.

1.2. Delivery mechanisms of family planning services

One strategy towards the achievement of the MDGs is to increase access to high quality family planning services (USAID, 2005). In many developing countries family planning programmes are run by national governments often supported by international donor organisations/governments. The family planning services are delivered through: primary health care centres/sub centres where women could go and obtain the service; outreach health workers who visit potential family planning users at their homes to provide the service; through camps; mobile clinics; social marketing outlets; outlets managed by non-government organisations (NGOs); private outlets such as clinics/hospitals and pharmacies; and vending machines (Seltzer, 2002).

Although family planning programmes worldwide have been successful in increasing contraceptive prevalence, in some countries this has been the result of an intensive (and expensive) family planning programme. The domiciliary distribution of family planning in Bangladesh has been recognised as successful in increasing contraceptive prevalence in both urban and rural areas (Phillips, Hossain & Arends-Kuenning, 1996). However, as the number of women reaching reproductive age rapidly increased, and contributions from donor organisations decreased, the programme became unsustainable and the government needed to explore alternatives (Routh, Ashraf, Stoeckel & Khuda, 2001). The costs of different delivery mechanisms are therefore an issue for those developing family planning programmes. Hence, in developing family planning programmes, governments need to weigh up the cost of delivery mechanisms versus their effectiveness and the need to provide access to all (Barberis & Harvey, 1997).

1.3. Impact of delivery mechanisms of family planning on use of services

There are two key ways in which the delivery mechanism of family planning services may affect use of services: access to family planning services and the acceptability of such services to the women or men they are aimed at. Research suggests that distance alone does not explain use of family planning services. For example, although one study in Lesotho, Africa (Tuoane, Diamond & Madise, 2003) found that those women who lived in a community with a family planning facility accessed services more than did those who would have to travel to a facility, another study (using retrospective data) found that distance to family planning services did not explain contraceptive use in Malawi (Heard, Larsen & Hozumi, 2004). A similar study conducted in Guatemala also found that distance was not a major factor in use of services and that the quality of service was more important; some people were travelling beyond their nearest outlet to obtain family planning (Seiber & Bertrand, 2002). Moreover, research has shown that in Bangladesh the changes in the family planning programme away from domiciliary distribution (no travelling distance) towards clinic-based delivery (greater travelling distance) actually increased contraceptive prevalence (Routh, Ashraf, Stoeckel & Khuda, 2001).

Indeed, as Bertrand, Hardee, Magnani & Angle (1995) argue, access to services involves more than just the distance that individuals have to travel to reach their nearest family planning facility (geographical/physical accessibility) it can also include economic accessibility (whether the price of travel to nearest facility or of contraceptives is affordable), administrative accessibility (whether unnecessary rules inhibit use of services e.g. restrictive opening hours), cognitive accessibility (whether individuals know about the services) and psychosocial accessibility (whether clients are constrained by psychosocial factors, such as perceived stigma, in accessing services).

There is evidence to suggest that the type and quality of service provided is also an important determinant of use. A cross-sectional study in Tanzania found that subjective reports of the quality of family planning services were related to the use of such services (Mroz, Bollen, Speizer & Mancini, 1999). A different study in Lesotho, Africa (Tuoane, Diamond & Madise, 2003) found that the type of facility(ies) to which women had access (e.g. hospital, clinic, community-based and employment-based) was a significant predictor of current use of contraception. Use of contraception was higher where facilities did not combine family planning and maternal care services and qualitative data indicated that women felt such combined services prioritised maternal care over family planning, and this affected the acceptability of the service to them.

Qualitative studies support the argument that the mechanism by which family planning services are delivered is important. A focus group study with Iranian women (Mohammed-Alizadeh, Wahlstrom, Vahidi & Johansson, 2009) found that the women liked public services because they found them more accessible, more reliable and more responsive to women's needs than private outlets. However, they reported issues with regard to restricted opening hours and long waiting

times. They also disliked being given only a limited amount of contraceptives at a time (typically one month's provision), and this was, in some cases, cited as a reason for using private outlets. Some women worried about the competence of the staff in public outlets. However, they also highlighted issues with private outlets including high cost, lack of privacy and outdated information. A similar study conducted in Malawi reported that the attitude of the staff involved in the delivery of family planning services affected how women felt about using them "providers even shout at the women so most women go to paying hospital where there is better care, otherwise at our government hospitals all they do is shout and shout so the women just return (without a method)." (Lawrence, n.d., p.2).

The context in which family planning is provided is also likely to be an important factor influencing the success of different modes of delivery. For example, when domiciliary distribution of family planning in Bangladesh was introduced in the 1970s this was an important method of delivery in the context of a conservative social environment where women did not leave their homes (Routh, Arifeen, Jahan, Begum, Thwin & Baqui, 2001). Hence, it is important to evaluate the effectiveness of delivery mechanisms of family planning services in the context of different developing countries.

1.4 Conceptual framework

A conceptual framework to explain the relationship between both the context in which family planning is delivered and the properties of family planning programmes themselves, and unmet need for family planning, unintended pregnancy and fertility is presented below (Figure 1). As per the framework, family planning programmes and policies determine the number of contraceptive methods available for public use; the contraceptive choice mix. The range of contraceptives available to individuals may be more limited than those made available for public use; either affected by provider bias and/or an individual's access to and acceptability of the family planning services provided (as is the focus of this systematic review). The acceptability of the contraceptives to which individuals have access will affect both whether they will choose to use any of the available methods (initiation of contraceptive use) and whether they continue with their chosen method (continuation of contraceptive use). It may also affect whether or not an individual adheres to their chosen contraceptive method (adherence). The context (e.g. client characteristics, length of time since introduction of each method and properties of methods) may affect the expectations and requirements that an individual has of particular contraceptive methods and hence the acceptability of each method.

The acceptability of the contraceptives to which individuals have access will be reflected in the contraceptive prevalence and the method mix i.e. fewer people may use contraceptives if there is a lack of acceptable accessible methods and there may be a greater skew towards contraceptives

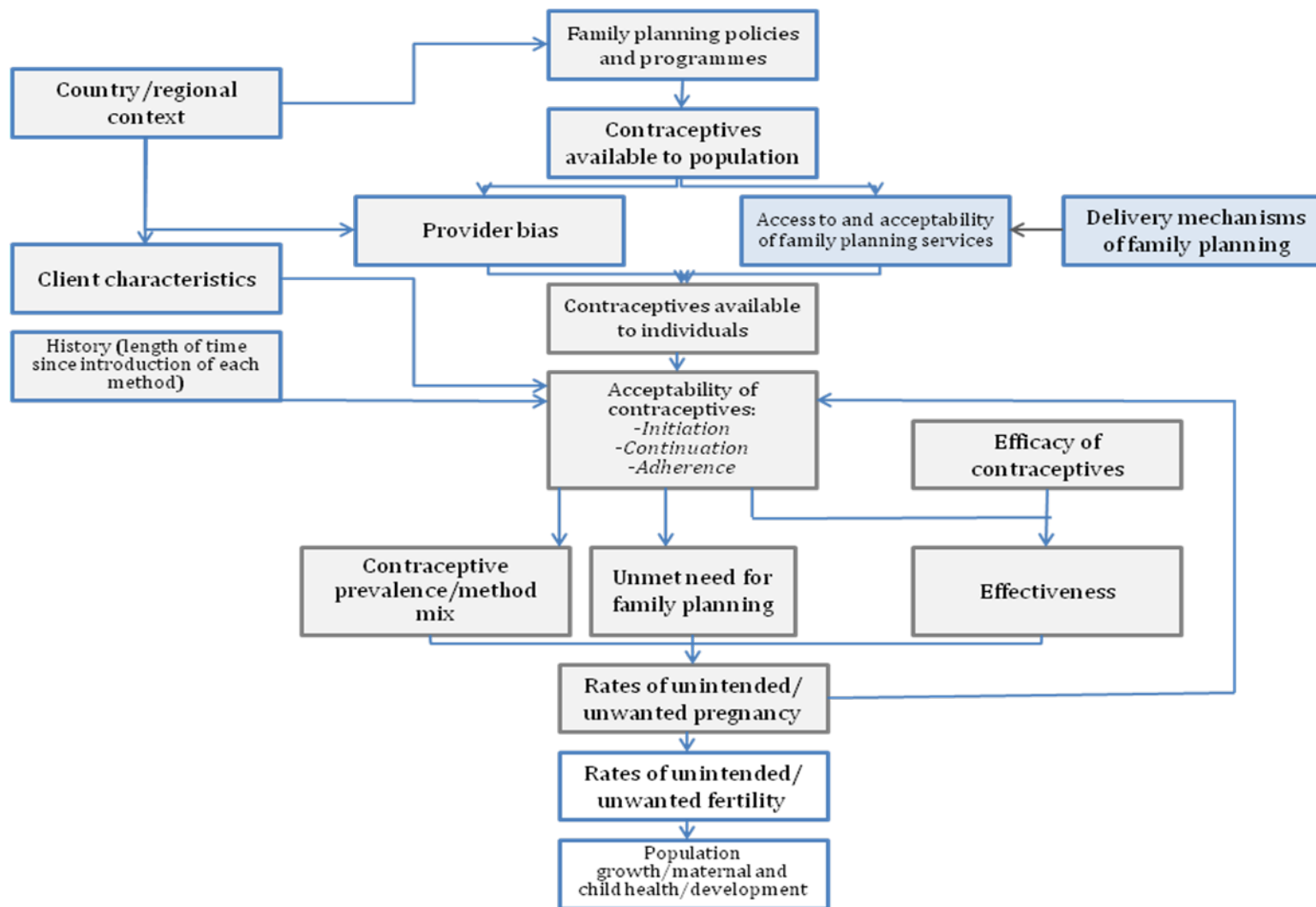


Figure 1. Conceptual framework of the factors influencing contraceptive prevalence, method mix, and unmet need for family planning (Light grey shaded boxes = contextual factors: Blue shaded boxes = focus of this systematic review: Unshaded boxes = consequences of unintended/unwanted pregnancies).

which are more acceptable (or more accessible). It will also be, more directly, reflected in the levels of unmet need for family planning i.e. where individuals lack access to acceptable contraceptives they will choose not to use the available method, even if they desire to space or limit their fertility. Further, the acceptability of the available contraceptives (individually and in combination) will combine with the known efficacy of the method to produce the effectiveness of both individual contraceptives and of the range of available contraceptives.

The effect of an unmet need for family planning and of the effectiveness of the available contraceptive methods (individually and in combination) is reflected in rates of unintended and unwanted pregnancies, and consequent rates of unintended/unwanted births (fertility). As discussed previously, unintended and unwanted pregnancies could have adverse health effects of mother and child this could also accelerate population growth and retard development by reinforcing poverty, illiteracy and gender inequality. Examination of rates of unintended and unwanted pregnancies may indicate where there is a greater need for acceptable spacing or terminal methods of contraception i.e. unintended pregnancies may indicate that more acceptable spacing methods are required and unwanted pregnancies may indicate that more acceptable terminal methods are required.

1.5. Summary: Focus of this review

Although it could be reasonably assumed that decreasing the distance women have to travel to access family planning services would increase use of such services research suggests that this is not the only important factor. Access to family planning services encompasses more than distance alone, including factors such as cost of services and travel, and knowledge about services. Moreover, the acceptability of services may be an important influence on whether women access particular services, for example, beliefs about the competence of staff in public versus private providers. The context in which family planning is delivered is also important. Hence, different mechanisms may be more or less successful dependent upon the context in which they are employed e.g. rural versus urban and conservative versus liberal areas. Therefore, where possible, there is a need to examine the impact of different delivery mechanisms of family planning on the acceptance of family planning in the context of each developing country and region.

To date, evidence on the effectiveness of different family planning delivery mechanisms has not been brought together and examined in a systematic manner. We will therefore conduct a systematic review (SR) to enable policy makers to identify those delivery mechanisms of family planning likely to be most successful in the context of a particular country or region. Given the complexities of conducting trials in this field, qualitative studies may contribute much needed understanding to help inform policy-makers; to further elaborate upon the contextual factors contributing to the success and failure of interventions, and possibly to aid decision-making in

the wake of inconclusive or tentative quantitative findings. Therefore, this SR will employ a mixed methods approach.

2. Objectives:

A Systematic Review (SR) will be conducted to meet the following objectives:

1. To assess the impact of various family planning delivery mechanisms on acceptance of family planning in developing countries.
2. To explore contextual factors contributing to the success or failure of family planning delivery mechanisms.

Objective 1: To assess the impact of various family planning delivery mechanisms on acceptance of family planning in developing countries.

3. Methods:

3.1. Criteria for considering studies for inclusion

3.1.1. *Types of studies:*

We will include (cluster) randomised and non-randomised trials, and observational studies, on family planning delivery mechanisms in developing countries. To be included, all studies should have:

- A clearly defined intervention/programme detailing the mechanism of family planning delivery (such that it could be replicated and implemented elsewhere).
- An identifiable point in time in which the intervention/programme was implemented.

Types of non-randomised trials include:

- Quasi-randomised controlled trial; for example, in which allocation to groups is via a non-random method such as alternation.
- Controlled before and after study (CBA); for example, one locality is matched to a second locality, and in one locality a new family planning delivery mechanism is implemented whilst the other locality stays the same, and both locations are measured concurrently before and after the intervention.
- Interrupted time series (ITS); for example, one locality is measured at series of points in time prior to, and again after, a new family planning delivery mechanism is implemented. A minimum of three time points before, and three time points after the intervention is

required in order to see a change in trend. This study type may or may not include a concurrent control arm.

- Simple “before and after” studies; for example, only one locality is measured, once before and once after an intervention, and there is no concurrent control arm. These studies will be included in this review however it is acknowledged that this type of study is subject to a lot of confounding.

Observational studies will additionally be included in this review. These studies may be opportunistic in that they measure the effects of an “exposure” (e.g. a planned change in service provision) as opposed to an intervention which has been specifically designed for the research study.

Observational studies will include:

- Cohort studies; for example a group of people who have been exposed to one type of family planning delivery mechanism are followed-up prospectively, and compared to a concurrent group of people who have been exposed to a different type of family planning delivery mechanism.
- Case-control studies; for example, a group of people with desirable outcomes are matched to a group of people with undesirable outcomes and a retrospective investigation takes place to examine the type of family planning delivery mechanisms they were exposed to.
- Longitudinal studies; for example, a study of a single service area which is followed up over a period in time before and after the implementation of a new service delivery mechanism (akin to ITS).

3.1.2. Types of participants:

We will include studies whose participants are sexually active women or men from countries classified as “developing”, “low income” or “middle income” countries by the author(s) of the study or those classified as low-and middle-income countries according to the World Bank classification of countries based on gross national income (GNI) (<http://data.worldbank.org/about/country-classifications>) at the time the study was conducted.

These inclusion criteria are broad in order to ensure that the SR includes all relevant studies. For example, although we acknowledge that Family Planning Services in developing countries are typically targeted at ‘currently married’ women aged 15-49 years, it is feasible that studies in the area may have taken a broader eligibility criterion, and we would seek to include these in the SR.

3.1.3. Types of interventions:

This part of the SR, we will include any family planning delivery mechanisms which are designed to facilitate contraceptive prevalence. Any of the following family planning delivery mechanisms will be included:

1. Clinic based delivery of family planning services (through government/NGO health facilities)
2. Community-based delivery of family planning services (CBD) (through government/NGO health workers)
3. Camps (Government/NGO)
4. Mobile clinics (Government/NGO)
5. Social marketing outlets (Government/NGO)
6. Private hospitals/clinics (Commercial sector)
7. Private/public Pharmacies
8. Private/public vending machines
9. HIV programmes/clinics (government/NGO)
10. Abortion clinics

3.1.4. Types of outcome measure:

This SR is interested in the following primary outcome measures:

- Utilisation of family planning services (*measured as the proportion of women of reproductive age (or their partner) who have accessed family planning services at a given point in time³*).
- Number of unwanted pregnancies (*unplanned pregnancies which are not desired by the woman: this could be measured either as number of unwanted pregnancies⁴ or as proportion of women who had an unwanted pregnancy³*).

If reported, the following secondary outcome measures will be included:

- Initiation of contraceptive use (*measured as the proportion of women (or their partners) initiating the use of contraceptives³*).
- Continuation of contraceptive use (*measured as either the proportion of women (or their partners) who have continued contraceptive use throughout the period of the study³ or as time-to-event⁵*).
- Adherence to contraception (*measured in a number of ways including number of missed pills, number of times had intercourse without contraception⁴*).

³ These outcome measures could be presented by studies as risk ratios, odds ratios, risk difference/absolute risk reductions or number needed to treat. We will seek to standardise these statistics to risk ratios.

⁴ These outcome measures may be presented by studies as a rate ratio, or as mean counts.

⁵ These outcome measures would be presented by systematic reviews as a hazard ratio and we will seek to standardise to a risk ratio.

- Time between pregnancies (*measured as time to event data – likely to be summarised as hazard ratios⁵*).
- Time between births (*measured as time to event data – likely to be summarised as hazard ratios⁵*).

3.2. Search methods for identification of studies

Searches will be conducted of a variety of electronic databases in the field of Healthcare and Geography. These databases will include the Cochrane Library, Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Bioline International, African Journals Online (AJOL), POPLINE[®] (POPulation information online), LILACS, Applied Social Sciences Index and Abstracts (ASSIA), Turning Research Into Practice (TRIP) database and Zetoc (The British Library's Electronic Table of Contents). Reference lists of relevant studies will be screened. We will contact relevant research groups in the field to ask if they are aware of any further studies. We will also contact international agencies (United Nations Population Fund) to find out if they know of any unpublished studies not identified by other strategies.

Searches will be tailored to the specific database and advice will be sought from an Information Specialist to ensure rigorous search strategies are employed. Search results will be managed using reference management software and duplicates will be removed prior to screening for relevance.

3.3. Data collection and analysis

3.3.1. Selection of studies

All abstracts and titles that are of potential relevance to this part of the SR will be independently screened by two review authors. These will be rated as either 'exclude' or 'potentially eligible'. Full reports of abstracts will also be obtained where they have been classified as potentially eligible, or where there is doubt about eligibility or disagreement between review authors. These will be assessed independently by two review authors to establish their eligibility for inclusion in this part of the SR. These will then be classified as either 'excluded' or 'included'. Disagreements will be resolved by discussion between the two review authors. Other authors will be brought in where disagreements cannot be resolved. Again, a resolution will be achieved by discussion amongst the review team.

3.3.2. Data extraction and management

Data will be extracted from included studies using a data extraction form designed for this review. In general, the data collection form will seek information on the following: general

information (e.g. authors, contact details), objectives, inclusion and exclusion criteria, participants, interventions, comparison interventions, length of interventions, length of follow-up, country(ies) in which study conducted, outcomes for which data were reported, comparisons performed, study limitations). Source page numbers will be included for ease of reference and, where information is missing or unclear, this will be marked as such on the form.

Data will be extracted independently by two authors and disagreements will be resolved by discussion. A third reviewer will be brought in where disagreements cannot be resolved by the two authors. Again, a resolution will be achieved by discussion. Study authors will be contacted to provide any missing data or to clarify uncertainties.

3.4. Assessment of methodological quality of included studies

3.4.1. Quality of included studies

The quality of included studies will be independently assessed by two review authors using a combination of the items from the Risk of Bias criteria outlined in The Cochrane Handbook of Systematic Reviews of Interventions, and the Effective Practice and Organisation of Care (EPOC) Cochrane Review Group criteria developed for non-randomised studies. For each item, a description will be given of the information upon which each judgement decision is based, and a judgement will be made of: high risk of bias, low risk of bias, unclear risk of bias.

The following items will be assessed for all studies:

1. Selection Bias:
 - a. Were participants recruited in an acceptable way? (e.g. was the participant group representative of a defined population)
 - b. Was the allocation sequence adequately generated?
 - c. Was the allocation sequence adequately concealed?
 - d. Were the groups similar at baseline?
2. Performance Bias:
 - a. Was there adequate protection against contamination (e.g. between study groups or against secular changes in ITS/longitudinal studies)?
 - b. Was knowledge of the allocated interventions/exposures adequately prevented during the study (participants)? (NB. Whilst we acknowledge that blinding of participants to the service they are receiving in this situation is impossible, as indeed is the blinding of healthcare professionals to the service they are providing, it may be feasible to conduct a study in which participants are unaware of the intervention components of interest).

- c. Was knowledge of the allocated interventions/exposures adequately prevented during the study (healthcare professionals)?
 - d. Was the intervention/exposure the only difference in care between groups?
3. Attrition Bias:
 - a. Were incomplete outcome data adequately addressed?
4. Detection Bias:
 - a. Was knowledge of the allocated interventions adequately prevented during the study (outcome assessors)?
 - b. Was the outcome measured in a reliable way?
 - c. Was the study appropriately sized? (e.g. for ITS a rationale for the number of time points is given, or a power calculation justifies the appropriateness of the study).
5. Reporting Bias:
 - a. Were all important outcomes that were assessed, fully reported?
 - b. Was the data analysed appropriately (e.g. for ITS using ARIMA models, or times series regression adjusting/testing for serial correlation; for other studies, taking into account cluster effects where applicable).

Whilst it is acknowledged that some of these items will always put particular study designs at high risk of bias (e.g. where randomisation is not possible), we feel that it is still important to assess each study by these criteria to acknowledge a potentially important inherent risk of bias.

Any disagreements will be resolved by discussion between the assessors and by bringing in a third review author. Where disagreements cannot be resolved through discussion amongst the review team, a two-thirds majority would inform the final decision. Where items are graded as 'Can't answer', the authors of the original study will be contacted for clarification.

3.4.2. *Quality of evidence in included studies*

The GRADE approach will be used to assess the overall quality of the evidence in the review (GRADE working group, 2004). This approach defines quality of evidence as “the extent to which one can be confident that an estimate of effect is correct”. The quality of evidence will be graded in the following stages according to the listed criteria:

- High = Randomised trials or double-upgraded observational studies
- Moderate = Downgraded randomised trials or upgraded observational studies
- Low = Double-downgraded randomised trials or observational studies
- Very low = Triple-downgraded randomised trials or downgraded observational studies or case studies/case reports

A study will be downgraded if:

1. Serious (-1) or very serious (-2) limitation to study quality
2. Important inconsistency (-1)
3. Some (-1) or major (-2) uncertainty about directness
4. Imprecise or sparse data (-1)
5. High probability of reporting bias (-1)

A study will be upgraded if:

1. Strong evidence of association – significant risk ratio of >2 (<0.5) based on consistent evidence from two or more observational studies, with no plausible confounders (+1)
2. Very strong evidence of association – significant risk ratio of >5 (<0.2) based on direct evidence with no major threats to validity (+2)
3. Evidence of a dose response gradient (+1)
4. All plausible confounders would have reduced the effect (+1)

3.5. Data synthesis

We will map the current evidence against the taxonomy of interventions detailed in the “Types of Interventions” section of this protocol. This mapping will additionally enable an assessment of areas in which there is a lack of evidence. Further, in synthesising the evidence, information will be sought on contextual factors and on intervention characteristics that may explain the extent to which the intervention or outcomes are sustained. For each country included in the final systematic review the following will be recorded:

- GDP (Gross Domestic Product), at the time of the study(s).
- A description of the current family planning programme as follows:
 - Family planning effort
 - Contraceptive methods available
 - Methods of delivery of family planning services (e.g. community based, home visits, incentives, social marketing)
- Method mix (the distribution of contraceptive methods used by a population)
- Contraceptive prevalence rate
- Total fertility rate (TFR)
- Average ideal number of children (AINC)

At the study level, for each outcome, and where possible (i.e. where description has been provided in the study or subsequently by authors), the following contextual factors will also be mapped: access to Family Planning Services will be examined including distance factors (e.g. distance to family planning services, lack of transportation), health-system factors (e.g. provider bias, staffing shortages, and lack of availability of preferred methods) and client/community factors (e.g. prohibitive cost of products/services, lack of client awareness, cultural factors).

Data synthesis will be largely narrative, using tables and text, and where feasible forest plots (with pooled statistics where appropriate). We will only perform meta-analyses, where appropriate, of RCTs which are judged to be suitably homogenous (having taken into account clinical, methodological, and statistical heterogeneity). All data will be presented taking into account the hierarchy of the evidence and risk of bias assessments. Data will be managed using RevMan 5.

Objective 2: To explore contextual factors contributing to the success or failure of family planning delivery mechanisms.

4. Methods

4.1. Criteria for considering studies for inclusion

4.1.1. Types of studies:

We will include studies that use qualitative methods. This will include both studies which have employed solely qualitative methods and those, such as trials, which have used qualitative methods to complement quantitative methods in order to elucidate their findings.

Eligible methods of data collection will include interview methods (eliciting open-ended responses), focus groups, observational studies (not generating numerical data), questionnaires (eliciting open-ended responses, where participants have adequate space to express their feelings/experiences/opinions) or any other method which seeks to explore participants' feelings, attitudes, experiences or opinions in an open manner. Descriptive papers, editorials or opinion papers will not be considered as qualitative studies.

4.1.2. Types of participants:

We will include studies whose participants are sexually active women or men from countries classified as “developing”, “low income” or “middle income” countries by the author(s) of the review or those classified as low-and middle-income countries according to the World Bank classification of countries based on gross national income (GNI) (<http://data.worldbank.org/about/country-classifications>) at the time the study was conducted. Studies which additionally include participants from “high income” or “developed” countries will be eligible, but we will only use the data from participants in “developing”, “low income” or “middle income” countries i.e. where the study has examined these separately. Where the study has combined data from developing/low income/middle income and developed/high income countries, and it is not possible to separate these, the study will be excluded.

These inclusion criteria are broad in order to ensure that the review includes all relevant studies, for the reasons described in the ‘Types of participants’ section of the methods presented for Objective 1 above.

4.1.3. Types of interventions:

This part of the review will include studies that consist of or include a qualitative evaluation of the implementation of a policy or programme to try and facilitate contraception uptake (to address appropriateness, acceptability and/or processes). Any of the following family planning delivery mechanisms will be included:

1. Clinic based delivery of family planning services (through government/NGO health facilities)
2. Community-based delivery of family planning services (CBD) (through government/NGO health workers)
3. Camps (Government/NGO)
4. Mobile clinics (Government/NGO)
5. Social marketing outlets (Government/NGO)
6. Private hospitals/clinics (Commercial sector)
7. Private/public Pharmacies
8. Private/public vending machines
9. HIV programmes/clinics (government/NGO)
10. Abortion clinics

4.2. Search methods for identification of studies

Some relevant qualitative studies may be identified as part of the searching for Objective 2. However, the search strategies have not been designed specifically to identify such literature. Hence, in addition, supplementary searches will be conducted of a variety of electronic databases (outlined above in section 3.2) in the field of Healthcare. A special effort will be made to search the grey literature through our network of contacts in low-to-middle income countries. We will also contact international agencies (United Nations Population Fund) to find out if they know of any unpublished studies not identified by other strategies.

The appropriate MeSH headings for qualitative research will be utilised in addition to free text searches tailored for the identification of qualitative research (example keywords include qualitative, and interviews). The reference lists of studies included in the systematic review will be inspected for mention of qualitative ‘sibling’ studies. In addition, we will examine ‘related articles’ and citation reports for these studies. Since qualitative research is often the subject of student work, collections of dissertations and theses will also be searched.

Searches will be tailored to the specific database and advice will be sought from an Information Specialist to ensure rigorous search strategies are employed. Search results will be managed using reference management software and duplicates will be removed prior to screening for relevance.

4.3. Data collection and analysis

4.3.1. Selection of studies

This will be conducted as described in section 3.3.1.

4.3.2. Data extraction and management

Data will be extracted using a data extraction form designed for this review. In general, the data collection form will seek information on the following: general information (e.g. authors, contact details), objectives, inclusion and exclusion criteria, participants, family planning delivery mechanisms to which participants had access/or were asked to discuss, country(ies) in which study conducted, type of analysis performed, themes reported, study limitations). Source page numbers will be included for ease of reference and, where information is missing or unclear, this will be marked as such on the form.

Data will be extracted independently by two authors and disagreements will be resolved by discussion. A third reviewer will be brought in where disagreements cannot be resolved by the two authors. Again, a resolution will be achieved by discussion. Study authors will be contacted to provide any missing data or to clarify uncertainties.

4.3.3. Assessment of methodological quality of included studies

There are no clear recommendations regarding the use of critical appraisal of qualitative research in systematic reviews (Noyes, Popay, Pearson, Hannes & Booth, 2008). Areas of debate include whether critical appraisal is appropriate for qualitative research, and, if so, whether formal checklists are appropriate for its assessment (and, even then, which of the plethora of available tools is most appropriate). Also debated is whether the use of critical appraisal should inform a decision with regard to the inclusion of a study in the review or whether it should be used to provide information about the range of quality of all the available studies (Noyes et al., 2008).

This part of the systematic review will follow the recommendations of The Joanna Briggs Institute (n.d.). Formal critical appraisal will ensure that each study is assessed on the same

aspects of quality and we will provide clear documentation of such appraisal. In line with the method of the Joanna Briggs Institute, critical appraisal will be used in the following way:

1. Filtering:

Studies will be appraised to inform their inclusion or exclusion in the review dependent upon whether the study describes: sampling strategy, data collection procedures, data analysis procedure.

2. Technical and theoretical appraisal:

Studies will be critically appraised to evaluate the methodological soundness of the study and whether the study has been conducted in line with the principles and practices of the chosen qualitative approach. The QARI Critical Appraisal Instrument (The Joanna Briggs Institute, n.d.) will be used to guide the critical appraisal (alongside the relevant guidance: The Joanna Briggs Institute, 2007). This instrument appraises studies on the following criteria (Responses are yes, no, unclear):

1. There is congruity between the stated philosophical perspective and the research methodology.
2. There is congruity between the research methodology and the research questions of objectives.
3. There is congruity between the research methodology and the methods used to collect data.
4. There is congruity between the research methodology and the representation and analysis of data.
5. There is congruity between the research methodology and the interpretation of results.
6. There is a statement locating the researcher culturally or theoretically.
7. The influence of the researcher on the research, and vice versa, is considered.
8. Participants, and their voices, are adequately represented.
9. The research is ethical according to current criteria or, for recent studies; there is evidence of ethical approval by an appropriate body.
10. Conclusions drawn in the research report do appear to flow from the analysis, or interpretation, of the data.

The outcome of the critical appraisal will be considered when drawing conclusions from the evidence, rather than providing grounds for exclusion. At present, evidence suggests that the exclusion of low quality qualitative studies does not affect the final outcome of the synthesis (Thomas et al., 2004; Noyes & Popay, 2007; Thomas & Harden, 2008).

Any disagreements will be resolved by discussion between the assessors and by bringing in a third review author. Where disagreements cannot be resolved through discussion amongst the review team, a two-thirds majority would inform the final decision. Where items are graded as 'Can't answer', the authors of the original study will be contacted for clarification.

4.4. Data synthesis

A thematic synthesis of the findings sections of the qualitative studies will be conducted using the method described by Thomas & Harden (2008). Synthesis of these studies will be conducted in three stages:

- (1) Coding text: The text will be coded line-by-line to express the meaning and content of each sentence. New codes that have been developed will be added to a bank of codes. These codes will be applied to remaining text as appropriate, and further codes developed as necessary. Once all text has been coded the coding will be reviewed for consistency of interpretation.
- (2) Developing descriptive themes: Similarities and differences between codes will be explored in order to group them into a hierarchical tree structure. These groups will be given a new code to express the meaning of the group.
- (3) Generating analytical themes: Taking into consideration the review question, the descriptive themes will be interrogated from the perspective of the barriers and facilitators of mechanisms of family planning in developing countries. From this analytical themes will be developed and reviewed against the descriptive themes. This will continue in a cyclical manner until the analytical themes are able to explain/describe all descriptive themes while also describing factors contributing to the acceptability of different mechanisms of family planning in developing countries.

This third stage will additionally entail mapping the themes against the contextualised findings of the quantitative evidence from Objective 1 to identify barriers and facilitators to successful intervention implementation.

5. Combining the results of the quantitative and qualitative evidence

The findings from quantitative evidence (Objective 1) to assess the impact of various family planning delivery mechanisms on acceptance of family planning in developing countries will be examined in light of the findings of the qualitative synthesis. This will likely be done using a

narrative approach, examining the findings of the quantitative evidence in light of the contextual factors which contribute to the success or failure of family planning delivery mechanisms.

6. User involvement

Consumer involvement in systematic reviews (SR) can help to ensure that reviews address topics and outcomes salient to a particular population. Due to time constraints it has not been possible to engage in a wide consultation with relevant stakeholders to inform the scope of the SR. In order to ensure the salience and scope of the SR we have established a multidisciplinary review team including Dr Saseendran Pallikadavath, who has experience of conducting global health research in India and Brazil, and Professor William Stones, who is the Puribai Kanji Professor and Chair, Department of Obstetrics and Gynaecology, Aga Khan University, Nairobi, Kenya. Further, we have sought peer review from the South African Cochrane Centre and the UK Cochrane Centre.

7. Dissemination

In addition to dissemination to the Department for International Development we plan to submit a paper on this SR to an international peer-reviewed journal in the area (e.g. *International Family Planning Perspectives*).

8. Contribution of authors

Develop and approve the protocol – HM, AD, SP, TD, WS

9. Declarations of interest

None of the authors have any past or present affiliations or other involvement with any organization or entity with an interest in the review which might lead to a conflict or interest (perceived or real).

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