Woman-Centered Outcomes for Medical and Surgical Abortion: A Systematic Review of Core Outcomes

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Part 0: Preamble

DECLARATION

I, Atara Jaffe, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Date: May 10, 2018

DEDICATION

I would like to dedicate this project to Christopher Colvin and Alison Swartz. Thank you for your guidance and support throughout my time as a postgraduate.

THESIS ABSTRACT

Background: The prevalence of global abortion rates coupled with the lack of systematic assessment tools for monitoring women's abortion experiences has necessitated the creation of a core outcome set (COS) outlining key outcomes of women's abortion experiences.

Objectives: Utilizing a woman-centered lens, this project attempts to establish this core outcome set through a qualitative systematic review of key abortion outcomes as espoused by women's perspectives across the globe.

Methods: A qualitative review was performed to determine outcomes that are meaningful to women experiencing abortion.

Findings: After analyzing the qualitative data produced by the 32 included studies, nine core outcomes were established. These outcomes include continuity of care, the capacity to cope effectively with the psychological dimensions of abortion, and the capacity for self-care/self-management during their abortion processes. Women also discussed the importance of feeling a sense of autonomy, choice and control during their abortion experiences as well as feeling that healthcare providers met their information needs. Feeling emotionally supported by healthcare providers as well as having felt treated respectfully by healthcare providers, the capacity to control/management of pain, side effects and complications and the social repercussions of abortion were identified as core outcomes.

Conclusion: Incorporating these findings into relevant surgical and medical abortion trials has the potential to increase the impact of women's perspectives and experiences on the study of abortion.

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TABLE OF CONTENTS

Part A: Protocol

STUDY PROTOCOL

Problem Question

What outcomes do women who experience abortion consider to be of the greatest significance to their abortion experience?

Objectives

The objective of this study is to develop a set of core outcomes for medical and surgical abortion experiences as discussed in Standardizing Abortion Research Outcomes (STAR) project for designing, distributing, and applying core outcome set for medical and surgical abortion experiences. This outcome set is intended for future use in medical and surgical abortion trials.

Abortion is one of most common procedures in women's healthcare worldwide (Stanley 1999, Whitehouse 2017). Despite this, no standardization for the selection or reporting outcomes in abortion clinical trials has been developed (Creinin 2016, Whitehouse 2017). The measurements by which abortion related clinical trial results are assessed varies between studies, undermining researchers' ability to compare, synthesize, and apply findings across studies (Khan 2014, Whitehouse 2017, Williamson 2012). This lack of homogeneity has necessitated the development and adoption of a set of core outcomes for assessing and measuring clinical trial results. Applying this core outcome set (COS) to abortion related clinical trials will assist researchers in coordinating studies, synthesizing findings, and designing guidelines and recommendations (Khan 2014, Whitehouse 2017, Williamson 2012, Young 2016). Development and implementation of standardized outcomes and outcome measures in abortion clinical trials will work to improve the applicability of results and better guide research on common women's health practices (Khan 2014, Whitehouse 2017, Williamson 2012).

The WHO Department of Reproductive Health and Research (RHR) is currently in the process of working on a project entitled the *Standardizing Abortion Research Outcomes* (STAR). The aim of this project is to develop, disseminate, and implement a core outcome set (COS) for medical and surgical abortion trials. The STAR project will be divided into three stages; the first stage will identify possible core outcomes, the second stage will finalize the list of core outcomes, and the third stage will define outcome measurements (i.e. definitions or instruments) for each selected outcome.

Part of stage 1 of the project involves assessing and incorporating woman-centered outcomes related to abortion care. An important, emerging component of COS methodology is the process of assessing and incorporating woman -centered outcomes. Woman-centered outcomes could include factors in decision-making, preferences, and experiences with providers. To ascertain these and other outcomes, we performed a rapid review of qualitative studies on the experiences of women and girls with medical and surgical abortion. From this review, we have produced a list of potential core outcomes to be used in the subsequent stages of the STAR project (Whitehouse 2017).

Methodology

COS Qualitative Review

Core Outcome Set (COS) methodology can be used as a highly effective tool for assessing and incorporating woman-centered outcomes (Khan 2014, Williamson 2012). Woman-centered outcomes were sought out as a means of incorporating women's decision-making, preferences, and experiences with providers. Outcomes were ascertained through a review of qualitative studies on experiences of women and girls with medical and surgical abortion.

Search Strategy

The development of a core outcome set was achieved by searching relevant qualitative studies in a number of databases. This list of databases included PubMed, SCOPUS, CINAHL,

Open Grey, Popline, Web of Science, and Google Scholar. I also conducted bibliographic back-referencing of the included studies. A search criteria was developed with a qualitatively skilled researcher. Qualitative studies exploring women's experiences with medical and surgical abortion were included. Studies on spontaneous abortion and fetal demise were excluded. Date and language restrictions were employed to those of the systematic review of clinical trials.

Full text reports of all selected studies were read, with data being extracted into a customized data extraction form and stored in a database. Key concepts and themes were then derived from the data extraction form while simultaneously being compared across all included studies throughout review process. Similarities and conflicts in concepts and themes across studies were identified and discussed amongst reviewers to arrive at a final list. The final themes and concepts were then considered as possible outcomes in COS for clinical trials on abortion.

Review Design

The core outcomes below were produced through a systematic review method to produce useful and well-founded summaries of the current state of evidence on a particular review question. A systematic review is a collection of all the findings of previously conducted studies pertaining to a given research question. It provides evidence on the treatments as a means of informing recommendations for future interventions (Higgins 2008). In this case, the key objective was to produce a descriptive list of core outcomes that were identified in the literature as important to women who have experienced medical or surgical abortion. An extensive qualitative systematic review synthesizes and deepens knowledge on these outcomes.

Inclusion and Exclusion Criteria

The focus of this review was on aspects of the medical and surgical abortion process that women report as important to their overall experience. These outcomes could include aspects of the experience both during and after the procedure.

Primary studies based on empirical research from around the world that were published in English or French from 2000 onwards that provided qualitative data produced with qualitative methods about women's experiences of medical and surgical abortion were included. Studies that did not offer women's perceptions of these outcomes, that described hypothetical or anticipated outcomes of abortion (rather than actual experiences of abortion) and studies on spontaneous abortion, fetal demise or post-abortion contraception were excluded.

Search Strategies and Inclusion Process

The following databases were searched for studies meeting the inclusion criteria: PubMed, Scopus, CINAHL, Open Grey, Popline, and Google Scholar. The search string incorporated a combination of terms for the *phenomenon of interest* (woman-centered outcomes), the *intervention of interest* (medical or surgical abortion), and the *study design* (qualitative). The generic search string was:

> (motiv* OR reason* OR experience* OR decision OR patient-centered OR outcome) AND (abortion OR termination of pregnancy OR pregnancy termination) AND (qualitative OR interviews OR focus groups)

This search string was tailored for each database and our other inclusion criteria (e.g. language and year). Only studies published from 2000 onwards were included in the search as the initial exploratory searches produced far fewer results before 2000.

Two reviewers reviewed the first 200 hits from PubMed, in the process, refining the inclusion and exclusion criteria. All results from the database searches were then reviewed for inclusion. A total of 2,939 abstracts were reviewed and 19 studies were eventually selected for inclusion. The studies came from a wide variety of settings (Africa, Europe, North America, Latin America) and populations. We also reviewed studies for inclusion that were part of a recent qualitative evidence synthesis (qualitative systematic review) on experiences of self-management of medical abortion that had very similar inclusion criteria (Wainwright 2016).

In addition to the 36 studies from that review that met this review's inclusion criteria, an addition 13 were included that were not found in the original search. The analysis explores findings from 32 studies with primary research conducted across 14 countries: 11 studies from 2 countries in Europe (7 of which came from Sweden and 4 of which took place in the U.K.), 8 in North America (all of which took place in the United States), 3 in Africa, 3 in Southeast Asia, 2 in Oceania, and 2 in Latin America. No studies from the Middle East or North Africa were found. Countries include Ghana, Gabon, Mozambique, Bangladesh, India (2), Sri Lanka, Cambodia, Malaysia, Peru, Brazil, US (8) UK (4), Sweden (7), Papua New Guinea, and Australia. The two reviewers then read the included studies and extracted findings about key outcomes of importance for women experiencing medical or surgical abortions. Rapid quality appraisals were conducted to ensure included studies met minimum criteria for being considered primary qualitative research.

Summary & Interpretation of Literature

32 studies were included in this systematic review, extracting key abortion outcomes identified by women as important and then synthesizing them into the broad outcomes. A majority of the studies reported negatively framed outcomes as well as positively framed ones. For ease and consistency of analysis, we have transformed all outcomes into positively framed outcomes (i.e. the outcomes that women sought/appreciated). In synthesizing the findings from the underlying studies, we have also had to make a judgment about how broadly or narrowly to construct these outcomes. We have aimed for a middle point where we had a manageable number of outcomes but were still working with variables that could be operationalized and assessed relatively easily. The outcomes also sometimes overlap or inter-related conceptually. This is unavoidable to some degree when trying to breakdown the holistic experience of the abortion process into discrete outcomes. We have tried to clarify what makes each outcome distinct. The systematic review includes further detail on these core outcomes, including internal variations within them (e.g. across different setting or groups).

Confidence in each qualitative review finding was determined the CERQual method (Lewin 2015). Each outcome was assessed using the CERQual method, a tool designed to measure the strength of qualitative evidence and the confidence that can therefore be placed in each finding. CERQual, or Confidence in the Evidence from Reviews of Qualitative Research, aims to assess findings reported in systematic reviews of qualitative evidence by stating the degree to which a review finding accurately represents a given finding (Lewin 2015). The four criteria of the CERQual assessment include methodological limitations of the individual studies, relevance to the review question, coherence, and adequacy of data. A graphic of the CERQual tool has been included in Appendix 2.2. In this study, each outcome was assessed as low, moderate, or high confidence based on these criteria (Lewin 2015).

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Part B: Structured Literature Review

LITERATURE REVIEW

Objectives

This thesis is part of a broader Standardizing Abortion Research Outcomes (STAR) project and guided by those objectives. The objective of the STAR project is to develop a set of core outcomes for medical and surgical abortion experiences as discussed in the protocol for the Standardizing Abortion Research Outcomes (STAR) project. This protocol outlines a means for designing, distributing, and applying a core outcome set for medical and surgical abortion experiences for future use in medical and surgical abortion trials (Whitehouse 2017). Developing this outcome set requires both qualitative and quantitative reviews, however, this review will focus on qualitative evidence about key woman-centered outcomes in abortion. For this literature review I began with some of the documentation for the project.

Research Justification

Abortion is one of most common procedures in women's healthcare worldwide (Whitehouse 2017). One in four pregnancies end in abortion, with 56 million abortions occurring worldwide every year (Whitehouse 2017). The global prevalence of abortion, coupled with the high risk of complications if performed unsafely has necessitated the development of sound guidelines and recommendations for abortion procedures (Whitehouse 2017).

Despite this, no standardization for the selection or reporting outcomes in abortion clinical trials has been developed (Whitehouse 2017). Variation in clinical trials has made it difficult to compare, contrast, and combine individual studies or draw meaningful conclusions across studies (Whitehouse 2017, Young 2016). This lack of homogeneity has necessitated the development and adoption of a core outcome set (COS) in abortion as a means of producing a standardized measure for assessing for the same condition across various studies (Young 2016).

Core Outcome Set (COS) methodology can be used as a highly effective tool for assessing and incorporating patient-centered outcomes. Woman-centered outcomes are sought out as a means of incorporating women's decision-making, preferences, and experiences into clinical research that is relevant to them. In this project, outcomes were ascertained through a review of qualitative studies on experiences of women and girls with medical and surgical abortion.

The STAR project will be the first core outcome set in abortion, contributing to the field by generating a robust list of peer-reviewed, standardized outcomes and outcome measures (Whitehouse 2017). This will serve to assist researchers in planning future trials, performing reviews, and the creation of guidelines and recommendations (Whitehouse 2017). Development and implementation of standardized outcomes and outcome measures in abortion clinical trials will work to improve the applicability of results and better guide research on common women's health practices (Whitehouse 2017).

Literature search strategy

Exploratory Search Strategy

The focus of this review is on aspects of the medical and surgical abortion process that women report as important to their overall experience. In order to understand the different kinds of outcomes that are currently being used in abortion research, I conducted a PubMed search which indicated a wide number of trials that focus on several key outcomes, few of which, however, addressed women's experiences.

Primary studies producing quantitative data were initially included as a means of exploring clinical outcomes regarding abortion. In a second search, primary studies that provided qualitative data produced with qualitative methods about women's experiences of medical and surgical abortion were then explored. In this second search, studies that did not offer women's perceptions of these outcomes,that described hypothetical or anticipated outcomes of abortion (rather than actual experiences of abortion) were excluded. In both searches, studies on spontaneous abortion, fetal demise or post-abortion contraception were excluded.

In order to understand the different kinds of outcomes that are currently being used in abortion research, I conducted two preliminary searches before delving into the main qualitative review. The following searches produced a large body of trials that focused on quantitative and clinical outcomes. Few of these results, however, focused on women's experiences. I reviewed the body of already existing literature focusing directly on quantitative studies of abortion. My findings revealed that studies assessing quantitative outcomes relating to success or completeness of medical abortion was a primary consideration produced in clinical trials (Dahiya 2011, Hamoda 2005, Montesinos 2011, Raghavan 2013, Seuc 2015). After conducting bibliographic back-referencing, 14 similar trials interrogating the efficacy and effectiveness of medical abortion methods and dosage regimens emerged, underscoring the abundance of this area of research (Akin 2009, Creinin, 2004, Faucher 2005, Fjerstad 2009, Hamoda 2005, Raghavan 2013, Saxena 2004, Schaff 1999, Spitz 1998, Tang 2002, Vimala 2004, von Hertzen 2003, Winikoff 2008, WHO 2000). The large body of clinical trials surrounding medical abortion methods and efficacy speaks to the salience of this area of study for abortion research.

Other significant considerations in clinical abortion trials measured quantitative outcomes such as levels of pain experienced during medical abortion, medical abortion follow-up, and post-abortion care following incomplete second trimester abortions (Fiala 2013, Mark 2015, Lynd 2013). The efficacy of antibiotic treatment of abortions that resulted in sepsis served as another quantitative outcome measured in clinical abortion trials (Udoh 2016). These considerations, while significant for understanding and improving the efficacy and manageability of women's abortion experiences, focus largely on quantifiable biological outcomes rather than women's personal reflections or considerations through their abortion experiences.

In light of these considerations I then created a final search string that focused specifically on women's personal accounts and reflections of their abortion experiences, with particular focus on patient-centered outcomes.

Search Strategies and Inclusion Process

After conducting the above searches as a framing mechanism for this preliminary literature review, I conducted searched for studies using the search string below:

(motiv* OR reason* OR experience* OR decision OR patient-centered OR outcome) AND (abortion OR termination of pregnancy OR pregnancy termination) AND (qualitative OR interviews OR focus groups)

The first 200 results from PubMed were reviewed, with studies pertaining to fetal anomaly and spontaneous abortion being excluded. This search strategy produced a number of studies relating to women's experiences of and decision-making strategies surrounding abortion, both medical and surgical (Altshuler 2017, Manríquez 2017, Sullivan 2017). Women's needs and preferences were largely discussed, with women's desire to self-manage their medical abortions appearing as a primary consideration for most of the studies (Altshuler 2017, Purcell 2017, Wainwright 2016). In a study on women's needs and preferences within the abortion experience, Altshuler et al. (2017) discuss several key outcomes derived from 20 semi-structured intensive interviews, most notably expressed through women's desire to be acknowledged as competent decision-makers throughout their abortion processes and women's desire to avoid stigma through discreetly administered care. Wainwright et al.'s study on self-management of medical abortion attests to the overall acceptability and satisfactoriness of self-administered pregnancy termination, synthesizing existing qualitative data from 36 studies (Wainwright 2016). While the overall reception of self-administered abortion medication was reported as positive amongst women surveyed, the relatively few studies eligible for inclusion point to a need for further research (Wainwright 2016). Maintaining autonomy in selecting a provider also appeared as a key consideration for some (Summit 2016). In a study by Summit et al., women preferred receiving abortion services in the care of their family physician rather than seeking care through an alternative provider or clinic (Summit 2016).

Receiving adequate health information prior to undergoing a termination of pregnancy emerged as a recurrent theme across several studies as well (Hedqvist 2016, Purcell 2017, Sullivan 2017). In a study on self-management of first trimester medical abortion in Scotland, qualitative data from 44 semi-structured interviews revealed that

women reportedly felt largely prepared and adequately informed to self-manage their at-home abortions (Purcell 2017). In this context, self-managed at home abortions are when a woman can "self-manage passing a pregnancy *after* misoprostol has been administered at an outpatient clinic" (Purcell 2017, p. 2001). In Hedqvist et al.'s study (2016) on early at-home medical abortion, feeling adequately informed about potential pain severity and the duration of bleeding prior to undergoing pregnancy termination and was discussed by women as particularly significant to their abortion experience (Hedqvist 2016). In this study, not having received adequate information regarding the possibility of an extended duration of bleeding was discussed as an area requiring particular attention, as some women bled for more than four weeks following the procedure reportedly felt unaware of the possibility of experiencing this outcome (Hedqvist 2016). Similarly, in a study on Cape Town women's abortion experiences, 16 women who had undergone abortion services were interviewed regarding their experiences, with a large proportion reporting a lack of necessary health information having been provided at the time (Sullivan 2017). These recurrent experiences demonstrate a lack of pertinent health information being provided to women undergoing termination of pregnancy services, ultimately reflecting a critical lapse in abortion care services.

In addition to the studies that met this review's inclusion criteria, two additional studies were included at the recommendation of an academic expert on abortion. A wide breadth of research on abortion has previously been conducted by the World Health Organization, which has produced global guidelines for safe abortion care and outlining women's roles in managing the medical abortion process (WHO 2015). Part of the WHO safe abortion guidelines describes what is considered essential information for women, including where and how to obtain safe, legal services, as well as information concerning potential complications (WHO 2012). Additionally, information regarding the legal limit of the gestational age of the fetus as well as complications arising with increasing gestational age are named as essential pieces of information for women seeking to undergo termination of pregnancy services (WHO 2012).

Women's roles in self-management of medical abortion are outlined as well, including self-assessing eligibility through rigorous research, self-managing medication with or without the assistance of healthcare professionals, and self-assessing completeness of

the medical abortion process (WHO 2015). Embedded in women's capacities to self-manage and self-administer medical abortions from the comfort of their own homes is the expectation that women receive adequate health information to enable their success in this undertaking (WHO 2015). While a large proportion of women have reported satisfaction and success in their self-administered medical abortion, it is recommended that women undertaking at-home medical abortions receive additional health information and access to a healthcare provider in order to manage expectations and ensure optimal results (WHO 2015). Women feeling in control of the process through self-management of the abortion is an important outcome, but it must be noted that self-manangement is just one model for abortion service provision.

Summary and Interpretation of Literature

Past systematic reviews regarding abortion have largely focused on quantitative studies and clinical trials as opposed to qualitative research and patient-centered outcomes. These studies have provided clinical findings related to the efficacy and effectiveness of various abortion methods, including comparisons between medical and surgical abortion treatment modalities, preoperative cervical preperation regimines, and reviews of adverse health outcomes arising from induced abortions such as rates of maternal moratlity and morbidity (Dastgiri 2017, Guo 2017). While these studies provide significant findings for women's health outcomes, many factors of the experiences that are important to women are not captured in these biomedical outcomes. These outcomes are significant but in many ways fail to take into account the reflections and experiences of the women who have undergone abortion.

After preliminarily exploring the existing literature surrounding women's needs, desires, and preferences within their abortion experiences, a number of key initial outcomes emerged as particularly pertinent to women's abortion experiences. A large body of research pointed to the context of self-administration. The desire to maintain autonomy over self-management and self-administration of their at-home medical abortions, coupled with service provider selection, and access to essential health information serve as some of the key outcomes women reported as essential to their abortion experience. These

outcomes, however, were also found in other models and contexts of care as well. The emergent emphasis on women's informational, psychological, and emotional needs rather than purely biomedical considerations attests to the significance of employing a more patient-centered approach when exploring women's abortion care needs and preferences. The existing body of work in this arena, while growing, requires more systematic exploration in order to provide a thorough and consistent means by which to measure and assess women's experiences. In doing so, researchers will enable healthcare providers to deliver for a more comprehensive, satisfactory level of care for women undergoing pregnancy terminations and, in doing so, create a more welcoming and accessible environment in which to meet women's reproductive needs. These initial findings from the preliminary literature review formed the basis for an initial conceptual framework for the systematic review data extraction.

Gaps in Literature

In the inclusion criteria, outcomes related to either during or after abortion were included, but no outcomes related to before abortion were included. While justifiable, the reason for the exclusion is that it was beyond the scope of the research being conducted under the STAR project. Some mention of pre-abortion counselling is included in two studies if readers are interested (Ganatra 2010 and Sri 2012).

The lack of abortion studies found from regions such as the Southeast Asia, Latin America, and sub-Saharan Africa point to an important gap in abortion research as precipitated by restrictive abortion laws in those regions (Udoh 2016). As stated by Atim Udoh in response to the lack of research in these highly impacted areas, "There is also a need to include institutions in low-resource settings, such as sub-Saharan Africa, Latin America and the Caribbean, and South Asia, with a high burden of abortion and health systems challenges," (Udoh 2016). The lack of diversity of contexts and settings in the evidence base is critical, as a COS that is largely based on the experiences of Northern women is limited in scope and application. The experiences of women in these regions requires further investigation, although the cultural barriers to care and the illicit nature of abortion services in these locales complicate such research efforts.

Table 8. Women's role in managing the process of medical abortion*

Woman's role	Recommendation	Justification
Managing the entire process of medical abortion up to 84 days	No recommendation for the overall package; recommendations made for subtasks as below.	Individual components of the self-management of medical abortion have been tested; however, there is as yet insufficient evidence on using all three components together.
Self-assessing eligibility for medical abortion	Recommended within the context of rigorous research 	Women may be more conservative in assessing eligibility using simple checklists (low certainty). However, the approach is promising and further work is needed on developing appropriate assessment tools.
Managing the mifepristone and misoprostol medication without direct supervision of a health-care provider	Recommended in specific circumstances  We recommend this option in circumstances where women have a source of accurate information and access to a health-care provider should they need or want it at any stage of the process.	There is evidence that the option is safe and effective (low-certainty evidence from numerous studies, but using non-randomized designs given the strong preferences of women for one or the other option). More women report the method to be satisfactory when it is self-managed (low certainty). Women find the option acceptable and feasible (high confidence) and providers also find the option feasible (high confidence).
Self-assessing completeness of the abortion process using pregnancy tests and checklists	Recommended in specific circumstances  We recommend this option in circumstances where both mifepristone and misoprostol are being used and where women have a source of accurate information and access to a health-care provider should they need or want it at any stage of the process.	There is evidence that the option is safe and effective including in low-literacy, low-resource settings (moderate to high certainty).

(WHO, 2015: 41)

BOX 4.2

Essential information for women

- Women have the right to decide freely and responsibly whether and when to have children without coercion, discrimination or violence.
- How pregnancy occurs, its signs and symptoms, and where to obtain a pregnancy test.
- How to prevent unintended pregnancy, including where and how to obtain contraceptive methods, including condoms.
- Where and how to obtain safe, legal abortion services and their cost.
- The details of legal limitations on the maximum gestational age when abortion can be obtained.
- That abortion is a very safe procedure but the risk of complications increases with increasing gestational age.
- How to recognize complications of miscarriage and unsafe abortion, the life-saving importance of seeking treatment immediately, and when and where to obtain services.

(WHO, 2012:97)

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Part C: Journal "Ready" Manuscript

Woman-Centered Outcomes for Medical and Surgical Abortion: A Systematic Review of Core Outcomes

Abstract:

The prevalence of global abortion rates coupled with the lack of systematic assessment tools for monitoring women's abortion experiences has necessitated the creation of a core outcome set (COS) outlining key outcomes of women's abortion experiences. Utilizing a patient-centered lens, this paper attempts to establish this core outcome set through a qualitative systematic review of key abortion outcomes as espoused by women's perspectives across the globe. In a separate study, a preliminary list of potential abortion outcomes was ascertained via systematic review of abortion. For this paper, a qualitative review was conducted to determine outcomes that are meaningful to women experiencing abortion. After analyzing the qualitative data produced by the 32 included studies, nine core outcomes were established. These outcomes include continuity of care, the capacity to cope effectively with the psychological dimensions of abortion, and the capacity for self-care/self-management during their abortion processes. Women also discussed the importance of feeling a sense of autonomy, choice and control during their abortion experiences as well as feeling that healthcare providers met their information needs. Feeling emotionally supported by healthcare providers as well as having felt treated respectfully by healthcare providers, the capacity to control/management of pain, side effects and complications and the social repercussions of abortion were

identified as core outcomes. Incorporating these findings into relevant surgical and medical abortion trials has the potential to increase the impact of women's perspectives and experiences on the study of abortion.

Background:

Abortion exists as one of most common procedures in women's healthcare worldwide [1] . One in four pregnancies end in abortion, with 56 million abortions occurring worldwide every year [2]. Some of these abortions are not performed safely and can result in complications. Complications from unsafe abortions include haemorrhage, infection, uterine perforation, and even death. The global prevalence of abortion [3,4], coupled with the high risk of complications if performed unsafely has necessitated the development of sound guidelines and recommendations for abortion procedures [2].

In spite of this, no standardization for the selection or reporting outcomes in abortion clinical trials has been developed [2]. Variation in clinical trials has made it difficult to compare, contrast, and combine individual studies or draw meaningful conclusions across studies [2, 5]. This lack of homogeneity has necessitated the development and adoption of a core outcome set (COS) in abortion as a means of producing a standardized measure for assessing for the same condition across various studies [5].

The Standardizing Abortion Research Outcomes (STAR) project will be the first core outcome set in abortion, contributing to the field by generating a robust list of peer-reviewed, standardized outcomes and outcome measures [2]. This will serve to assist researchers in planning future trials, performing reviews, and the creation of guidelines and recommendations [2]. Development and implementation of standardized outcomes and outcome measures in abortion clinical trials will work to improve the applicability of results and better guide research on common women's health practices [2].

The World Health Organization (WHO) is currently in the process of working on a project entitled the *Standardizing Abortion Research Outcomes (STAR)*. The aim of this project is to create, distribute, and implement a core outcome set (COS) for medical and surgical abortion trials. The STAR project will be divided into three stages; the first stage will identify possible core outcomes, the second stage will finalize the list of core outcomes, and the third stage will define outcome measurements (i.e. definitions or instruments) for each selected outcome. Part of stage 1 of the project involves assessing and incorporating woman-centered outcomes related to abortion care. The process of assessing and incorporating woman-centered outcomes is an important, emerging component of COS methodology. Woman-centered outcomes could include factors in decision-making, preferences, and experiences with providers. To ascertain these and other outcomes, we performed a rapid review of qualitative studies on the experiences of women and girls who underwent medical and surgical abortions. From this review, we have produced a list of potential core outcomes to be used in the subsequent stages of the STAR project.

Variation in clinical trial measurements complicates researchers' ability to compare individual studies or draw meaningful conclusions across studies [2]. In response to this problem, researchers utilize core outcome sets (COS) as a means of producing a standardized means of assessing for the same condition across studies. The STAR project will be the first core outcome set in abortion, contributing to the field by generating a robust list of peer-reviewed, standardized outcomes and outcome measures. The impact of the STAR project will be multifaceted, serving to guide the development of future clinical trials, advise trial reporting in collaborating peer-reviewed journals, improve the strength of literature reviews and subsequent guideline creations, and further advance and promote work in the field of core outcome set development. As abortion trials begin including components of the COS in their study design, researchers will be better able to draw meaningful conclusions from subsequent studies. Standardizing outcomes will improve the results of trials

and research on abortion issues. Guidelines and recommendations based on these studies will be more robust, and thus potentially more likely to be adopted. When trials include core outcomes that were chosen based on input from clinicians, researchers, and patients, resulting evidence may be more meaningful and applicable. Ultimately, we hope that the standardization in trial outcomes will lead to an improvement in the quality of evidence-based medicine that can be delivered by the service-provider to the woman.

Objective:

The objective of this study is to develop a set of core outcomes for medical and surgical abortion experiences as discussed in STAR project for developing, disseminating, and implementing core outcome set for medical and surgical abortion experiences [2]. This outcome set is intended for future use in medical and surgical abortion.

Methods:

A systematic review is a collection of all the findings of previously conducted studies pertaining to a given research question. It provides evidence on the treatments as a means of informing recommendations for future interventions [6]. In this case, the key objective was to produce a descriptive list of core outcomes that were identified in the literature as important to women who have experienced medical or surgical abortion. An extensive qualitative systematic review synthesizes and deepens knowledge on these outcomes. The core outcomes below were produced through a systematic review method to produce useful and well-founded summaries of the current state of evidence on a particular review question. The focus of this review was on aspects of the medical and surgical abortion process that women report as important to their overall experience. These outcomes could include aspects of the experience both during and after the procedure.

The development of a core outcome set was achieved by searching relevant qualitative studies in a number of databases. This list of databases included PubMed, SCOPUS, CINAHL, Open Grey, Popline, Web of Science, and Google Scholar. I also did a bibliographic back-reference of included studies. A search criteria was developed with a qualitatively skilled researcher. The search string incorporated a combination of terms for the *phenomenon of interest* (woman-centered outcomes), the *intervention of interest* (medical or surgical abortion), and the *study design* (qualitative). The generic search string was:

> (motiv* OR reason* OR experience* OR decision OR patient-centered OR outcome) AND (abortion OR termination of pregnancy OR pregnancy termination) AND (qualitative OR interviews OR focus groups)

This string was tailored for each database and our other inclusion criteria (e.g. language and year). Only studies published from 2000 onwards were included in the search as the initial exploratory searches produced far fewer results before 2000. No gray literature was included in the search. This search was conducted in 2017. Qualitative studies exploring women's experiences with medical and surgical abortion were included. Date and language restrictions were employed to those of the systematic review of clinical trials. Studies on spontaneous abortion and fetal demise were excluded. Primary studies based on empirical research from around the world that were published in English or French from 2000 onwards that provided qualitative data produced with qualitative methods about women's experiences of medical and surgical abortion were included. Studies that did not offer women's perceptions of these outcomes, that described hypothetical or anticipated outcomes of abortion (rather than actual experiences of abortion) and studies on spontaneous abortion, fetal demise or post-abortion contraception were excluded. It must be noted that the inclusion/exclusion criteria was aligned to the STAR project protocol.

Two reviewers reviewed the first 200 hits from PubMed, in the process, refining the inclusion and exclusion criteria. Qualitative research is an iterative process, and as the two researchers went through more papers, a saturation point was reached.

All results from the database searches were then reviewed for inclusion. Various stages of processing took place: Identification, Screening, Eligibility and Inclusion. *Identification* (see PRISMA Diagram, Appendix 2.1): A total of 2,939 records were identified through database searching. An additional 13 records were identified through other sources. Once duplicates were removed there was a total of 2941 records. *Screening*: (see PRISMA Diagram, Appendix 2.1): 2941 records were screened, and 2909 records were excluded as a result. *Eligibility:* 90 full-text articles were assessed for eligibility and 58 were excluded. *Included:* 32 studies were included in the qualitative synthesis and they were also included in the quantitative synthesis as part of meta-analysis. Overall, a total of 2,939 abstracted were reviewed and 19 studies were eventually selected for inclusion. The studies came from a wide variety of settings (Africa, Europe, North America, Latin America) and populations. We also reviewed studies for inclusion that were part of a recent qualitative evidence synthesis (qualitative systematic review) on experiences of self-management of medical abortion that had very similar inclusion criteria [7].

In addition to the 36 studies from that review that met this review's inclusion criteria, an addition 13 were included that were not found in the original search. The analysis explores findings from 32 studies with primary research conducted across 14 countries: 11 studies from 2 countries in Europe (7 of which came from Sweden and 4 of which took place in the U.K.), 8 in North America (all of which took place in the United States), 3 in Africa, 3 in Southeast Asia, 2 in Oceania, and 2 in Latin America. No studies from the Middle East or North Africa were found. Countries include Ghana, Gabon, Mozambique, Bangladesh, India (2), Sri Lanka, Cambodia, Malaysia, Peru, Brazil, US (8) UK (4), Sweden (7), Papua New Guinea, and Australia. The articles covered a wide geographical spread and abortion legality in their country representation. The two reviewers then read full text reports of all the

included studies and data linked to key outcomes of importance for women experiencing medical or surgical abortions was extracted into a customized data extraction form and stored in a database. When there was disagreement on whether to include a text, both referred back to the STAR protocol which clearly laid out on what should or shouldnt be included. Key concepts and themes were then derived from the data extraction form while simultaneously being compared across all included studies throughout review process. Similarities and conflicts in concepts and themes across studies were identified and discussed amongst reviewers to arrive at a final list. Rapid quality appraisals were conducted to ensure included studies met minimum criteria for being considered primary qualitative research. Minimum criteria in this instance is when the qualitative interviews which took place and data given were the participants' own words of their experiences as a patient or a health care provider to a patient. The process is captured in the PRISMA Diagram included in Appendix 2.1.

The final themes and concepts were then considered as possible outcomes in COS for clinical trials on abortion. Each outcome was assessed using CERQual, a tool designed to measure the strength of qualitative evidence and the confidence that can therefore be placed in each finding [8]. CERQual, or Confidence in the Evidence from Reviews of Qualitative Research, aims to assess findings reported in systematic reviews of qualitative evidence by stating the degree to which a review finding accurately represents a given finding [8]. The four criteria of the CERQual assessment include methodological limitations of the individual studies, relevance to the review question, coherence, and adequacy of data. A graphic of the CERQual tool has been included in Appendix 2.2. In this study, each outcome was assessed as low, moderate, or high confidence based on these criteria [8]. Inclusion in this study was not limited to high confidence.

Findings:

After analyzing the qualitative data produced by the 32 included studies, nine core outcomes were established. These outcomes include continuity of care, the capacity to cope effectively with the psychological dimensions of abortion, and the capacity for self-care/self-management during their abortion processes. Women also discussed the importance of feeling a sense of autonomy, choice and control during their abortion experiences as well as feeling that healthcare providers met their information needs. Feeling emotionally supported by healthcare providers as well as having felt treated respectfully by healthcare providers, the capacity to control/management of pain, side effects and complications and the social repercussions of abortion were identified as core outcomes.

Outcome 1: Convenience and continuity of care - Women expressed strong appreciation for abortion services that were convenient with respect to distance, language, opening hours, and cost, and that provided continuity of care (especially when they could access services within their existing primary care services).

Women's sense of convenience and continuity of care within the abortion experience was facilitated through a number of factors most notably that of medical at-home abortion and receiving care from a primary physician. In S. M. Harvey's [9] research on women's perceptions of medical abortion, many women who sought pregnancy terminations in rural or remote areas positively perceived medical abortion as it allowed them to access termination of pregnancy services that they would not have been able to otherwise. Sri et al.'s [10] research on rural South Indian women's experiences of medical abortion reflects this notion as well, with promptness, cost, and choice of service provider discussed as key factors in accessing services. Stephen L. Fielding et al. [11] reflects a similar appreciation for the convenience and continuity of care provided by the home abortion experience in study on women's experiences of mifepristone and home misoprostol abortions

[11]. In this study, women reported an appreciation for the sense of control they were granted by the at-home environment of medical abortion within the constraints of time, finances and emotional resources [11]. A majority of women reported the experience as one of convenience and relative comfort [11]. Women expressed appreciation for the convenience of receiving termination of pregnancy services in their usual primary care setting or from their general medical practitioner, citing the familiarity and continuity of the care as positive factors surrounding their experience [12]. This phenomenon is documented in a study by A. K. Summit [12], which explores women's experiences of abortion within their usual family medicine practice. Women reportedly experienced an increased sense of comfort and trust when receiving care from their usual provider within a familiar setting [12].

Several factors impeded upon women's sense of convenience and continuity of care, particularly logistical issues, long waiting times, and lack of follow-up services. This phenomenon is exemplified in S. Marie Harvey et al.'s study [9] on the means in which women's values and social context influences their perceptions of medical abortion. This study demonstrated the means in which having to return to the clinic after an initial consultation or to receive the second dosage or medication required for an at-home abortion frustrated women who were based in remote areas as the time, expense, and logistical considerations were challenging for many. Long waiting times were also cited as a crucial factor impacting women's abilities to conveniently access termination of pregnancy services [13]. This barrier is reflected in Pauline Slade et al.'s study [13] on patients' perceptions of care during and following their pregnancy terminations. In this study, once women have been deemed eligible to receive a termination of pregnancy, an extended waiting period between admittance and surgery obstructed women's ability and willingness to receive care. Women's concerns with a lack of continuity of care was reflected in Wen Ting Tong et al.'s study [14] on Malaysian women's abortion experiences, in which the majority of women reported dissatisfaction with the lack of continuity of care, citing post-abortion follow up and aftercare services, as well as pre and post-abortion counseling as services from which they would have benefited [14].

<u>Outcome 2</u>: Capacity to cope effectively with the psychological dimensions of abortion - Women described a wide range of emotional responses to the experience of abortion (often depending on setting, population group and other demographic factors) and were appreciative of abortion services and providers that supported and/or increased their capacity to cope with these psychological effects. The source of support and increased capacity came from a range of people and mechanisms, but the key outcome was that they felt able to personally cope with these effects during and after the process.

Most women felt that they were adequately equipped to cope with the psychological dimensions of abortion. Such was the case in Stephen L. Fielding et al.'s study [11] on women's experiences of mifepristone and home misoprostol abortions, in which some women reported experiencing the onset of enhanced emotional wellbeing following the procedure, expressing decreased psychological distress once the procedure had been completed [11]. Similarly, some women expressed positive psychological outcomes following their procedures including feelings of empowerment following their termination of pregnancy services. Such was the case for women in J. Andrews et al.'s study [15] on African American adolescents' experiences with abortion, in which empowerment was found as a common, unifying psychological outcome across women's post-abortion experience.

While most women felt that they were adequately equipped to cope with the psychological dimensions of abortion, others expressed having not received adequate resources to emotionally cope with the experience or feeling a combination of psychological outcomes throughout their abortion experience. For some women, undergoing a termination of pregnancy invokes a sense of uncertainty and existential anxiety [16]. Liljas Stålhandske et al. [16] document this phenomenon in their study on the experiences and strategies Swedish women discuss following their pregnancy terminations [16]. According to Stålhandske, many women lack access to the adequate resources to cope with such emerging emotional turmoil, necessitating an increase of employees trained in managing the psychological

dimensions of abortion [16].

In some cases, women discussed feeling a mix of psychological outcomes throughout their abortion experience, beginning with distress and settling into acceptance or vise versa. Such was the case in Alex et al.'s study [17] on women's experiences of induced abortions, in which women's positive perception of abortion in general was simultaneously expressed alongside their negative perceptions towards their own abortion. In this study, some women reflected feelings of ambivalence, expressing both an enhanced sense of maturity for having undergone the procedure while simultaneously struggling with negative emotions toward the experience [17]. Wen Ting Tong et al.'s study [14] on Malaysian women's experiences of abortion reflects this variability as well, highlighting the varied range of emotional responses across women. According to Tong et al. [14], this range of emotional responses post-abortion cut across feelings of relief, loss, sadness, and ambivalence, to having no notable feelings whatsoever [14]. For this reason, according to Tong et al., abortion patients require the services of health care professionals who have been trained in dealing with the diverse range of psychological needs and struggles, receiving pre and post abortion counseling [14].

The psychological responses to abortion also change over time within individual women. Women experience a wide range of emotional variability even within their own abortion experiences. This phenomenon was documented in Kathryn Dykes et al.'s study [18] on women's perspectives toward their previous abortions, as reflected upon during menopause. For some, emotional turmoil related to the experience surfaces later in life upon the advent of menopause, during which time regrets over failing to bear more children begin to emerge. This long-term follow-up study revealed emergent emotional responses that varied considerably from women's initial experiences, reflecting the variability in emotional response and experience of abortion even within the individual [18]. Phillippa Goodwin et al. [19] discuss a similar pattern of shifting perspectives in their research on women's changing emotional responses toward their abortions over time [19]. While women may initially perceive their experiences as positive, over time some women began to reflect on their abortion experiences as psychologically unsettling. Conversely, an

initial response of emotion distress may later be appraised by women as one that is not psychologically upsetting as women make peace with the experience over time [19]. These nonlinear appraisals of abortion experiences attest to the variability of women's psychological response and ability to cope with their abortions over time on the individual level [18, 19].

A number of personal and social factors impact women's abilities to cope with the psychological dimensions of abortion. In responding to these complex emotional needs, women draw upon both external support and internal perspectives. Social support from family members and partner relationships, as well as positive perspectives and adequate health information serve as key instruments aiding psychological coping. In their research on women's changing emotional responses toward their abortions over time, Goodwin et al. [19] discuss the impact of factors that improve women's abilities to cope with the psychological dimensions of abortion. According to Goodwin et al [19], some such factors include the woman's social support network, the woman's view of society's perception of abortion, as well as the woman's personal assessment of the fetus' humanness. Societal stigma and internal shame serve as meaningful barriers to positive psychological coping post-abortion. In a study on adolescent women's abortion experiences in Ghana, K. Esia-Donkoh et al. [20] reveal the impact of social stigma, poor partner relationships, and self- imposed stigma as critical factors limiting women's abilities to psychologically cope post-abortion. These studies reveal the significance of social support, particularly partner support, in psychological coping, and the means in which lacking such support and experiencing stigma limits psychological coping.

Managing women's perceptions and expectations of the abortion experience, sometimes through the provision of relevant health information, serve as other key factors which impact women's psychosocial coping post-abortion. Harvey et al. [9] and Slade et al. [13] discuss women's perceptions of their abortion experiences and the impact of those perceptions on psychological coping in their respective studies on the relationship between the patient experience and the contextual factors surrounding abortion**.** These respective studies both explore the importance of providing adequate health information as a means of managing expectations and

preparing women for negative emotional responses to potentially upsetting events such as seeing the fetus as critical means of enhancing women's abilities to cope emotionally [9, 13]. A. Kero, M. Wulff, and A. Lalos [21] also reflect the psychological benefits of receiving adequate health information prior to the abortion procedure in their study entitled *Home abortion implies radical changes for women*. According to Kero et al., arming women with adequate health information to perform the medical abortion procedure themselves was seen as an empowering experience that enhanced their capacities to emotionally cope post-abortion [21]. These studies collectively point to the value of providing women with adequate health information in order to manage expectations and facilitate psychological coping.

<u>Outcome 3</u>: Capacity for self-care/self-management during abortion process - In a similar vein, women described how it was important for them to feel that they could take care of themselves physically and to manage, to the degree possible, physical aspects of the abortion (especially during medical abortion).

Women's capacity for self-care and self-management during the abortion process was frequently cited as a central consideration for women undergoing abortion. Medical abortion was recurrently discussed as an important tool for preserving women's ability to self-manage and self-care as described through women's perception of the process as natural and non-invasive, the privacy permitted by the home environment of medical abortion, its bearable side effects, its limited need for additional medical intervention, and the overall empowering experience of the home abortion process [3]. In Makenzius et al.'s study [22] on women's experiences of home abortion, most women expressed an appreciation for being able to undergo medical abortions in the comfort and privacy of their own home, and felt adequately equipped with the necessary health information to carry out their at-home abortions without additional medical intervention [22]. Similarly, in Lohr et al.'s study [23] on women's opinions on home management and medical abortion in the U.K., the majority of respondents reported overall satisfaction with the experience, stating that they would prefer to undergo the procedure from the

privacy of their own homes rather than in a formal facility [23]. In B. Elul et al.'s study [3] on women's experiences of home-administrated misoprostol, women described the process of home-abortion as natural and non-invasive, with bearable side effects, especially when receiving support from a family member or partner at home. In their study on the impact of home abortion on women, Kero et al. also reflect women's experiences of medical abortion as contributing to feelings of self-care and self-management, particularly when receiving adequate health information prior to the abortion procedure [21]. According to Kero et al, being armed with adequate health information and being able to perform the procedure themselves was seen as an empowering experience and enhanced women's sense of privacy and self-sufficiency [21]. In E. Mitchell et al.'s study [24] on pregnancy termination methods in Urban Mozambique, while some found the process of vaginally inserting misoprostol challenging, overall the vast majority of women felt adequately prepared and comfortable with the procedure.

This outcome was not universal across all studies. While some studies describe medical abortion as a process that facilitated self-care and self-management, others revealed difficulties associated with medical abortion that could not be managed by women without additional medical intervention. Such was the case in Petitet et al.'s study [25] on medical abortion in Cambodia in which some women were unsuccessful in completing their abortions from home or faced excessive bleeding and discomfort during their home abortion experience. While home abortion facilitated self-management and self-care in many women, in these instances described by Petitet et al. it did not [25]. Women's concerns with their lack of ability to self-manage their medical abortions speaks to the importance of this outcome. According to Petitet et al., this experience points to the need for increased counseling regarding the possibility of medical abortion related complications as well as the appropriate protocol to follow in these instances [25].

<u>Outcome 4:</u> Feelings of autonomy, choice and control - Cutting across Outcomes 2 and 3, but also distinct from those outcomes, were feelings of autonomy, choice and control that many women reported as significant aspects of a positive abortion

experience. These feelings arose in different ways, in response to different aspects of the abortion process (counseling and decision-making, support during the process, managing complications, reflection on the experience post-abortion) but all shared an emphasis on the importance of feeling in control of the process and their experiences.

Women's sense of autonomy, choice, and control within and surrounding the abortion process frequently emerged as a core consideration within women's abortion experience. These outcomes were fulfilled by being presented with choice of treatment modality, choice of provider, control over clinic setting, the sense of autonomy over one's future, quality of life, and image, and control over associated financial, social, and future outcomes [15 11, 26, 22, 27, 28). Autonomy was defined as an important theme pertaining not only to the abortion proceedings themselves, but also in regards to being able to maintain control over important future life considerations such as finances, quality of life, and image [11, 28]. In their study on African American adolescents' experiences with abortion, J. Andrews et al. [15] discuss the means in which abortion for some women served as a symbol of taking control by being active decision makers in their own lives and preventing others from controlling their behaviors or decisions.

Presenting women with choice of provider and location of treatment setting was also found to be an important outcome in their abortion experiences. In their study on women's experiences of home abortion, Fielding et al. [11] reported that being able to exert control over the type of procedure being performed as well as maintaining autonomy over the course of her future served as important outcomes for many women undergoing abortion. In Weitz et al.'s study [28] on patients' opinions about obtaining abortions from general healthcare providers, being able to maintain control over choice of provider served as an important means of managing their image by preventing their general provider from passing judgment over their choice [28]. In Grindlay et al.'s study on medical abortion provided through telemedicine, women discuss the option of receiving care remotely via telemedicine as a welcome alternative, as many preferred the privacy and anonymity afforded by

the option [26]. Others, however, preferred meeting with their physician in person, highlighting the importance of presenting women with both options [26].

Home abortion was presented in a number of studies as an effective treatment modality promoting self-management and self-care. Makenzius et al.'s study [22] on women's experiences of home abortion discusses the means in which home abortion allowed many to maintain a sense of control over their environment during a difficult process and allowed them to involve their partners more in the procedure more intimately. Self-care was a major factor in undergoing an at home abortion, with partner support in both pain management and procedural considerations serving as a major advantage for many women [22]. Women and their partners also felt more at ease expressing and receiving emotional support within the privacy of their own homes [22]. In Wainer's study [27] on abortion in the 1970's, women reported that completing the home abortion process allowed them to experience an increased sense of autonomy as active decision makers in their own lives and felt more competent in managing the outcomes of their futures as a result.

While home abortion increases women's autonomy by enhancing their ability to self-care, it simultaneously requires additional instructions and information from health care professionals, a consideration which was in some ways found to increase reliance on others. This finding was discussed in Makenzius et al.'s study [22] on women's experiences of home abortion. While many women in this study felt adequately equipped with the necessary health information to carry out their at-home abortions without additional medical intervention, some expressed difficulties requiring additional medical intervention [22].

<u>Outcome 5</u>: Feeling that information needs were met by healthcare providers - An important part of feeling in control of the process often involved women having their informational needs adequately met by healthcare providers. We have separated this out as a separate outcome, however, given its importance to women, even when they did not feel in control in general of the abortion process themselves.

Being provided with the necessary health information to administer, cope with, and manage expectations toward the abortion process was regarded as a crucial form of support for most women [26, 29, 21, 30, 13, 10, 14]. In Grindlay et al.'s study on medical abortion provided through telemedicine, women valued being informed of their options in terms of treatment modalities and choice considerations in where and by whom the procedure could be administered [26]. In Kero, Wulff, and A. Lalos's study [21] on home abortion, those who opted to undergo at-home medical abortions felt generally comfortable and competent in administering the procedure and managing the side effects outside of a medical facility when equipped with the necessary health information. In Grossman et al.'s study [29] on self-induced abortion in America, when asked about the information provided to self-administer a medical abortion, most women reportedly felt that the information was useful, comprehendible, and delivered in a means in which women felt free to ask questions.

The most common information concerns surrounded possible side effects and negative outcomes of the procedure [13, 10, 14]. For some women, a lack of key health information regarding potential outcomes of medical abortion heightened a sense of emotional distress and served as a crucial obstacle in managing expectations when the procedure did not go as planned [13, 10, 14]. This experience was highlighted in Sri et. al.'s study [10] on medical abortion in rural South India. According to Sri et al. [10], while self-administered medical abortions were often completed with success, some women suffered incomplete abortions and were required to complete the process in a clinical setting, an outcome which for some was unexpected [10]. Women's gap in knowledge regarding such possible outcomes indicates a need for healthcare providers to offer women more information regarding emergency situations and other unfavorable outcomes such as persistent or excessive bleeding [10].

In addition to providing additional health information for managing distressing physical outcomes, women expressed a need for increased health information to manage expectations related to unforeseen emotional outcomes [13, 14]. In their study on women's perceptions of abortion care, Slade et al. discuss one

such emotionally charged and often unexpected outcome, the possibility of seeing the fetus, as many expressed a need for greater preparation to manage the emotional impact of such an event [13]. In Tong et al.'s study [14] on Malaysian women's abortion experiences, post-abortion counseling was frequently discussed as a crucial but lacking treatment modality which women felt could assist them in addressing emerging concerns and unforeseen information queries that had arisen post-procedure [14].

Outcome 6: Feeling emotionally supported by either healthcare providers ~~or others~~

Similarly, feeling emotionally supported during and after the abortion process, either by healthcare professionals, by auxiliary healthcare workers such as doulas, or by family members, partners, or friends, was identified as an important outcome by women. This outcome focuses more on the direct forms of emotional support offered or enabled whereas Outcome 2 focuses more on the woman's own ability to manage the short and longer-term psychological aspects of abortion.

Feeling emotionally supported by healthcare providers, family members, friends, religious leaders, and society at large was discussed as an important outcome for women who underwent abortion services (17, 31, 1, 18, 3, 4, 29, 32, 9, 21, 22, 30, 16, 10, 14, 28). In Mukkavaara et al.'s study [30] on women's experiences after an induced second trimester abortion, women expressed a desire to receive emotional support from partners, family members, healthcare providers, and friends throughout the abortion process. In Hess et al.'s study [33] on women's abortion experiences in Southern Gabon, women discussed calling upon the services of religious institutions to receive support and ease feelings of guilt and regret. Family support significantly impacted women's choices in selection of treatment modality while also largely shaping women's experiences of suffering, guilt, and regret [1, 4]. Partner support was also discussed as an important factor in selecting a treatment modality in both Harvey et al. [9] and Kero et al.'s studies on women's perceptions of medical abortion, with home abortion particularly fostering partner involvement [21]. In regards to decision making, a significant proportion of participants in Alex et

al.'s study [17] on women's experiences in connection with induced abortion reported experiencing the majority of their support from their friends and mother, while receiving much less from partners. In Tong et al.'s study [14] on Malaysian women's abortion experiences, some women sought their partner's approval before deciding to undergo the procedure. In Elul et al.'s study [3] on women's experiences of home administration of misoprostol, both family member and partner involvement were discussed as important for the abortion experience, with women reporting that having members of the household present to offer care and support was highly valued for home abortions.

Social sources of emotional support were found to be another important factor impacting women's abortion experience. In their study on women's reflections on past abortion experiences, Goodwin et al. [19] discuss the negative emotional impact of lacking social support throughout the abortion process, highlighting the means in which women who experienced a lack of social support suffered a greater sense of emotional distress than those who did not [19]. In Hallden et al.'s study [32] on women's abortion experiences in Sweden, participants discussed feeling emotionally supported and understood by community members as a crucial concern before, during, and after the abortion procedure. Women in Makenzius et al.'s study [22] on women's home abortion experiences mirrored this need for social support and understanding as a means of emotional wellbeing post-abortion.

Women across a number of studies discussed the need to feel emotionally supported by post-abortion aftercare services [18, 30, 14]. Long-term services, including pre-abortion counseling and post-abortion care, were perceived by women in a number of studies as a necessary and often lacking or absent treatment modality [18, 30, 14]. Dykes et al. [18] discuss the repercussions for this lack of follow-up services in their study on the emotional impact of abortion on older women reflecting upon a past termination of pregnancy. According to Dykes et al, [18] a need for lifelong follow up services was expressed by older women who had

undergone a pregnancy termination in their past, many of whom expressed an increase in negative views and feelings toward the termination when they reached menopause. Participants in Tong et al.'s study [14] on Malaysian women's abortion experiences echoed the need for an increase in after-care services, expressing a need to further explore unaddressed emotional issues. This outcome was reiterated in Mukkavaara et al.'s study [30] on women's experiences of second semester abortions, many of whom expressed a desire to receive increased follow-up services as a means of enhancing a sense of emotional wellbeing.

Women's perceptions and experiences of provider support played a key role in their pregnancy terminations (31, 29, 22, 10, 28]. In both Hallden et al.'s studyon Swedish women's abortion experiences and Makenzius et al.'s study on home abortion, being treated empathically and feeling understood by healthcare providers was discussed as a key consideration for women [32, 22]. In the secular settings discussed in Stålhandske et al.'s study [16] on women's abortion experiences in Sweden, abortion patients' existential anxieties surrounding their termination often remained unresolved, suggesting a need for greater provider support in these contexts [16]. In these ways, women's perceptions of their providers' abundance or lack of emotional support impacted the means in which women across a number of contexts experienced their abortions.

Providers' attitudes and beliefs both positively and negatively shaped service delivery, significantly impacting the level of support afforded to patients [31, 29, 10, 28]. A number of studies noted the means in which condemnatory provider attitudes and beliefs negatively impacted women's abortion experiences [31, 10, 28]. In some cases physicians' beliefs compelled them to deny women treatment, requiring women to justify their need for a pregnancy termination, or provide care only if women agreed to be sterilized afterward [10, 28]. In Arambepola et al.'s study [31] on unsafe abortion care in Sri Lanka, some women also faced verbal harassment by healthcare providers in regards to their abortion decisions. In contrast, women in Grossman et al.'s study [29] on self-induced abortion reported receiving high quality,

supportive care from clinic staff members, a phenomenon which positively impacted these women's abortion experience.

<u>Outcome 7</u>: Feelings of having been treated respectfully by healthcare providers - Women widely reported the importance of respectful treatment by healthcare providers (and often noted its absence in many services). This is related to, but distinct from the emotional support described in Outcome 6 since respectful treatment does not necessarily include direct emotional support.

Respectful treatment by health care providers was reported as an important outcome across a number of women's abortion experience [31, 22, 10, 12, 28]. An abundance of respectful treatment was found as a valued, encouraging outcome for women experiencing abortion across several studies [22, 12]. For the majority of women in Summit et al.'s [12] study on patients' experiences of abortion in family medicine, healthcare providers were discussed as having succeeded in creating a safe and trusting environment by treating patients with respect and care [12]. Similarly, women in Makenzius et al.'s study [22] on home abortion expressed an appreciation for being regarded respectfully and empathetically by healthcare providers, both in cases of surgical abortion as well as when dealing with issues of self-care information in the cases of medical abortion [22]. The respectful care experienced by women in these studies was discussed as an important outcome within their abortion experiences.

While women from the above studies expressed having received positive, respectful care from treatment providers, others, however, experienced disrespectful treatment at the hands of their providers [31, 10, 28]. In the field of maternal and child healthcare, disrespectful treatment (particularly related to the experience of childbirth) is discussed at length through the 2010 Bowser and Hill framework for disrespect and abuse in the context of maternal health [34]. This paper defines disrespectful treatment in the context of childbirth through physical abuse, non-consented care, non-confidential care, non-dignified care, discrimination, abandonment, and detention [34]. In Weitz et al.'s study [28] on women's

experiences of receiving abortion care from their general health care providers, some women avoided undergoing pregnancy terminations with their general provider out of concern that their physician would oppose their decision. This outcome reflects the category of disrespectful care discussed as abandonment of care, in which providers fail to intervene as needed, as well as the fear of non-dignified care as expressed through provider scolding, blaming, and negative perceptions of care [34]. A number of women in Arambepola et al.'s study [31] on unsafe abortion in Sri Lanka as well as participants in Sri et al.'s study [10] on women's abortion experiences in South India discussed experiencing similar disrespectful care through disparaging attitudes and remarks to degradation and verbal harassment. These experiences reflect the disrespectful care discussed by Bowser and Hill as non-dignified care, which is defined as care that is characterized by intentional humiliation, rough treatment, scolding, shouting, blaming, and negative perceptions of care [34]. In addition, some single women in Sri et al.'s study [10] on women's abortion experiences in South India were apprehensive to seek out services due to the perception of stigma amongst providers, claiming that as single women they would be barred from receiving services or would be offered services only under the conditions that they would be sterilized afterward [10]. This experience reflects the form of disrespectful care discussed as discriminatory care, in which patients are discriminated against based on personal attributes, here being marital status [34]. The threat of being sterilized post-abortion reflects a form of disrespectful care discussed as non-consented care, in which women are subject to forced procedures to which they did not consent [34].

<u>Outcome 8</u>: Effective control/management of pain, side effects and complications - Women also spoke about the importance of effective management and control of pain, other side effects and potential complications of the abortion process. This was the main clinically-related outcome that they reported as important.

Managing pain, side effects, and medical complications was frequently discussed as an important abortion outcome, particularly in the context of at home

medical abortion (35, 3, 20, 4, 23, 24, 10]. In Lohr et al.'s study [23] on women's opinions on the home management of medical abortion in the UK as well as in Elul et al.'s study [3] on women's experiences of home administration of misoprostol, the most common side effects include vaginal bleeding, abdominal pain, and psychological pain, with women largely feeling well equipped to manage these effects [20, 23]. In regards to bleeding, women in Alam et al.'s study [35] on Mifepristone-Misoprostol use in Bangladesh found the effects either matched or exceeded their expectations and sense of acceptability, reporting to have felt the overall side effects to be tolerable.

In Elul et al.'s study [3] on women's experiences of home administration of misoprostol, the comfort and flexibility of the at home environment played a critical role in women's management of side effects, with women expressing an appreciation for having family members, friends, or partners nearby for assistance. In Lohr et al.'s study [23] on women's opinions on the home management of medical abortion in the UK, being able to experience the procedure at home rather than in a formal clinic was discussed as a primary motivator for undergoing a medical abortion [23]. Women reported to have felt confident in their ability to access additional medical care if an issue had presented itself [23]. In Mitchell et al.'s study [24] on early pregnancy termination in urban Mozambique, many women found the process of vaginal insertion for medical abortion more difficult than expected, however overall, most felt prepared and competent to complete the process with the given information.

Compassionate, informative pre-abortion counseling was perceived as an important resource for managing fears and anxieties about the potential pain and side effects of the pregnancy termination [4, 10]. In Ganatra et al.'s study [4] on medical abortion in India, informative counseling was of critical significance to women undergoing at home medical abortions, particularly for those who required additional medical intervention to complete their abortion. In this study as well as in Sri et al.'s study [10] on women's abortion experiences in South India, some women felt unaware of the possibilities of having an incomplete or unsuccessful abortion, indicating a need for more comprehensive pre-abortion counseling [4, 10].

<u>Outcome 9</u>: Capacity to effectively manage possible social repercussions of abortion - Finally, women were appreciative of abortion services that were offered in a way that increased their capacity to manage the possible social repercussions of abortion. These potential repercussions included stigma within the family or community, threats to reputation or social capital they had built up, and even access to livelihoods). There were a range of mechanisms that supported this outcome, including effective counseling, integrated social support from family, friends and partners, and confidentiality.

Social stigma in the form shame, judgment, partner rejection, and abandonment were important considerations for women undergoing abortion [20, 19, 29, 32, 24, 10, 36, 28]. In Goodwin et al.'s study [19] on women's reflections of their past abortions, those who perceived society to be condemnatory of or misunderstanding toward the impact of abortion experienced a greater sense of emotional distress than those who did not. The desire to be trusted and understood in their decisions to undergo abortions was echoed in Hallden et al.'s study [32] on women's abortion experiences in Sweden in which a number of women expressed a concern with the impact of being criticized or misunderstood and the stigma that accompanies such judgment [32]. In Weitz et al.'s study [28] on women's experiences of receiving abortion care from their general health care providers, women were concerned not only with being judged by their families and partners but also by their primary physician, often opting to receive care from an outside provider as a result.

Women's perception of the stigma associated with abortion impacts their perception of what is considered a safe abortion. In Sri et al.'s study [10] on women's abortion experiences in South India, a safe abortion is discussed as one that is not only a procedure conducted by medical professionals, but also one that was socially safe. In Grossman et al.'s study [29] on self-induced abortion in America, being seen at a clinic known within the community for performing abortions posed a significant risk to many women, heightening the appeal of home abortions [29]. In

Mitchell et al.'s study [24] on early pregnancy termination in urban Mozambique, women prioritized abortion options that they perceived as the most a socially low-risk. In Vallely et al.'s study [36] on women's unsafe abortion experiences in Papua New Guinea, fears of transgressing social, cultural, and Christian norms drove them to secrecy. In these ways, confidentiality and privacy were a priority for many women seeking termination of pregnancy services in contexts in which abortion was highly stigmatized and therefore considered socially unsafe in some way.

Discussion

Women's values and preferences in relation to their abortion experiences serve as a key factor in the World Health Organization's guidelines for safe abortion [37, 40]. According to the WHO, a key determinant of care lies in the creation of an empowering environment for women with abortion in which women's abilities to make decisions are supported by the institutions guiding their procedures as well as the information provided to them throughout their abortion processes [37, 40]. While the preferences, reflections, and perspectives on abortion experiences vary tremendously both between and within individual women, a common thread amongst a range of abortion experiences lies in the benefit of providing choice wherever possible. The opportunity to provide choice lies in a number of aspects of the abortion experience, ranging from the method of abortion, location of abortion, type of provider, and postoperative service options, to name a few. Method and location of abortion includes surgical versus medical abortion, inpatient vs. outpatient procedures, and even self-management of all or parts of the medical abortion process via out-of-clinic administration of mifepristone and/or misoprostol. Allowing women to choose between their primary providers or an alternative provider was discussed as a means of reducing stigma and enhancing the overall abortion experience as well. Similarly, arming women with the capacity to determine the site of their procedure alleviates issues of stigma for some who would prefer not to be seen at a local clinic, or for others, allowing women to receive services at the closest proximity to home as a means of limiting logistical barriers. Providing the

option of aftercare services was important for some women but not for others. In many cases, such services were not offered, a reality which some women found troubling.

In outcome 6, many women expressed a need for aftercare services as a means of feeling emotionally supported by either healthcare providers or others [18, 30, 14]. Long-term services, including pre-abortion counseling and post-abortion care, were perceived by women in a number of studies as a necessary and often lacking or absent treatment modality [18, 30, 14]. Dykes et al. [18] discuss the repercussions for this lack of follow-up services in their study on the emotional impact of abortion on older women reflecting upon a past termination of pregnancy. According to Dykes et al, a need for lifelong follow up services was expressed by older women who had undergone a pregnancy termination in their past, many of whom expressed an increase in negative views and feelings toward the termination when they reached menopause [18]. Participants in Tong et al.'s study [14] on Malaysian women's abortion experiences echoed the need for an increase in after-care services, expressing a need to further explore unaddressed emotional issues. This outcome was reiterated in Mukkavaara et al.'s study [30] on women's experiences of second semester abortions, many of whom expressed a desire to receive increased follow-up services as a means of enhancing a sense of emotional wellbeing.

While post-abortion care is not always necessary, these experiences point to the need for increased counseling regarding the possibility of abortion related complications as well as the appropriate protocol to follow in these instances [37, 40]. In addition, abortion patients require the services of health care professionals who have been trained in dealing with the diverse range of psychological needs and struggles, receiving pre and post abortion counseling. Autonomy in decision-making reveals the unique variation in each woman's abortion needs as well as the importance of approaching abortion through a distinctly patient-centered lens. Incorporating these findings into relevant surgical and medical abortion trials has the potential to increase the impact of women's perspectives and experiences on the study of abortion.

These options reveal not only the underlying need for presenting women with their choice of preference but also the importance of presenting women with the adequate information necessary to make these choices. According to the WHO, essential information for women regarding abortion includes where and how to obtain safe, legal services, as well as information concerning potential complications [37, 40]. This need for adequate information is particularly important for decision-making in regards to selecting a medical abortion as opposed to a surgical one, as well as in relation to potential emotional outcomes, which some women reportedly felt unprepared to manage. These findings attest to a need for increased access to health information, which can be achieved through more rigorous attempts at health promotion both within the clinic setting as well as in local, district, and regional health education settings. Elaborating on Outcome 7, this COS defines respectful care as ensuring the mother feels dignified throughout the process, sure that the procdure will be kept confidential, safe, and free from stigma.

A critical gap identified in this research lies in the lack of focus on women's experiences of unsafe abortion, which occurs in ubiquity but often remains difficult to detect due to its clandestine nature as necessitated by its illicit and stigmatized status. According to the World Health Organization (WHO), unsafe abortion is defined as a procedure for terminating an unintended pregnancy, carried out either by persons lacking the necessary skills or in an environment that does not conform to minimal medical standards, or both [37, 40]. According to Singh et al., 6.9 million women were subject to unsafe abortion worldwide in 2012 [38]. Expanding the scope of this study to explore women's experiences of unsafe abortion has the potential to shed light on this covert and potentially hazardous practice, as well as the motivations behind the decision to seek such services. Similarly, the lack of abortion studies found from regions such as the Southeast Asia, Latin America, and sub-Saharan Africa point to an important gap in abortion research as precipitated by restrictive abortion laws in those regions [39]. As stated by Atim Udoh in response to the lack of research in these highly impacted areas, "There is also a need to include institutions in low-resource settings, such as sub-Saharan Africa, Latin America and the Caribbean, and South Asia, with a high burden of abortion and health systems

challenges," [39]. The experiences of women in these regions requires further investigation, although the cultural barriers to care and the illicit nature of abortion services in these locales complicate such research efforts.

Results of this review and the STAR project will serve to guide the development of future trials, advise trial reporting in collaborating journals, improve the strength of literature reviews and subsequent guidelines, and promote work in the field of COS development [2]. In order to best determine what to include in a core outcome set, the opinions, preferences, and perspectives of those who have experienced the condition first hand must be taken into consideration [5]. Implementing a patient-centered approach that incorporates women's experiences into abortion research by taking into account the espoused impact of social stigma, autonomy, and information access will improve the strength and efficacy of interventions designed to improve pregnancy termination care. Incorporating these perspectives into abortion care and research has the potential to uplift women's abortion experiences, promote mental and psychological wellbeing, and in short, transforming women's health across the globe.

The STAR project will be the first core outcome set in abortion, contributing to the field by generating a robust list of peer-reviewed, standardized outcomes and outcome measures. The impact of the STAR project will be multifaceted, serving to guide the development of future clinical trials, advise trial reporting in collaborating peer-reviewed journals, improve the strength of literature reviews and subsequent guideline creations, and further advance and promote work in the field of core outcome set development. As abortion trials begin including components of the COS in their study design, researchers will be better able to draw meaningful conclusions from subsequent studies. Standardization in the reporting of outcomes will improve the results of systematic reviews and meta-analyses on abortion issues. Guidelines and recommendations based on these studies will be more robust, and thus potentially more likely to be adopted. When trials include core outcomes that were chosen based on input from clinicians, researchers, and patients, resulting evidence may be more meaningful and applicable. Ultimately, we hope that the standardization in trial outcomes will lead to an improvement in the quality of

evidence-based medicine that can be delivered by the service-provider to the woman.

Policy Recommendations

Abortions need to be made more accessible, at all primary health care facilities and the option to conduct an at-home abortion should be offered to women who are in their first trimester and candidates for safe termination of pregnancy without the need for supervision. Sufficient guidance should be given to women who choose this option and guidelines should be disseminated to healthcare providers on how to handle patients who want to access these procedures with respect, care and consideration. This should include repercussions for turning away patients who do qualify for access to an abortion. Being turned away on a certain day may mean a woman may pass the window of time that she can access a safe, legal abortion due to lack of access to transport for example. Once the abortion has occurred, access to post abortion services should be easily accessible and encouraged. When offering access to at home abortions, health workers should be given a standard form of questions to go through to access if the living conditions the person resides in are sufficient to manage an at-home abortion hygienically and safely. Access to psycho-social pre and post abortion support needs to be rolled out at facilities where the procedure is made available. Lastly, there is a need to measure women's satisfaction with the service provided by the healthcare providers, establish the metrics for this measurement to ensure there is a standardised process used, and incorporate women's feedback in future healthcare work by the providers.

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Part D: Appendices

APPENDIX 1: INSTRUCTIONS FOR AUTHOR OF JOURNAL WHOSE FORMAT HAS BEEN USED

BMC Health Services Research

Quick points:

- Vancouver referencing style
- Include line and page numbering
- Use SI units: Please ensure that all special characters used are embedded in the text, otherwise they will be lost during conversion to PDF
- Do not use page breaks in your manuscript

File formats

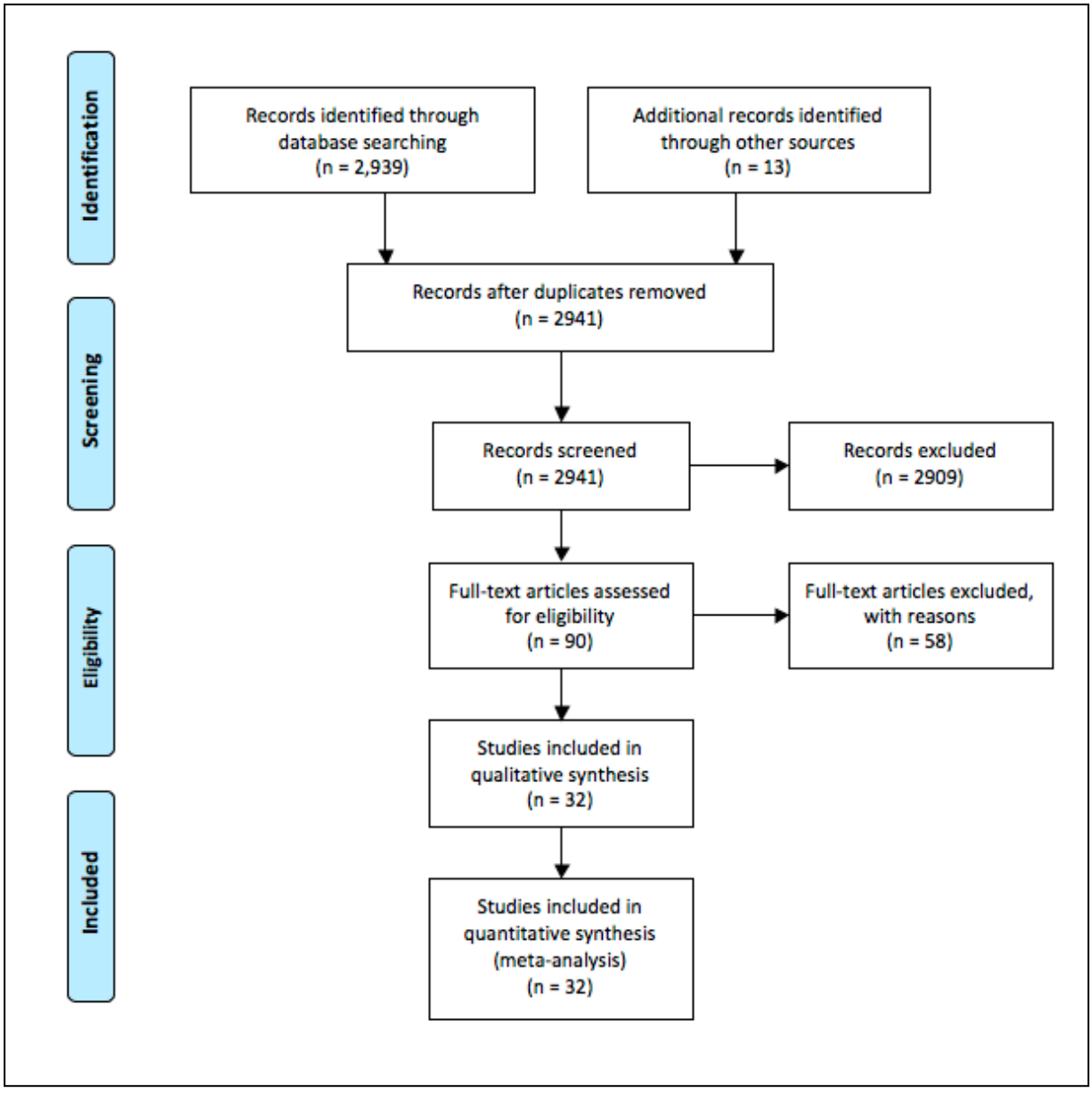
The following word processor file formats are acceptable for the main manuscript document:

- Microsoft word (DOC, DOCX)
- Rich text format (RTF)
- TeX/LaTeX (use BioMed Central's TeX template)

Please note: editable files are required for processing in production. If your manuscript contains any non-editable files (such as PDFs) you will be required to re-submit an editable file when you submit your revised manuscript, or after editorial acceptance in case no revision is necessary.

APPENDIX 2: SUPPLEMENTARY TABLES OR FIGURES OR TEXT

Appendix 2.1: PRISMA Diagram



Appendix 2.2: CERQual Assessment – Summary of Findings

Finding	CERQual Assessment	Explanation	Contributing Studies
Outcome 1: Convenience and continuity of care	Moderate confidence	While few concerns with methodology, relevance, coherence, and adequacy, there were also very few studies supporting this finding.	Harvey, Slade, Subha Sri, Summit, Tong
Outcome 2: Capacity to cope effectively with the psychological dimensions of abortion	Moderate confidence	Minor concerns over methodological limitations due to limited sampling populations.	Fielding, Alex, Dykes, Goodwin, Stålhandske, Harvey, Slade, Tong
Outcome 3: Capacity for self-care/self-management during abortion process	Moderate confidence	Minor concerns over relevance.	Fielding, Makenzius, Elul, Kero, Lohr, Mitchell, Petitet
Outcome 4: Feelings of autonomy, choice and control	Low confidence	Minor concerns over methodological limitations due to limited sampling population, few studies, and loss to follow up. Minor concerns over relevance.	Andrews, Elul, Fielding, Grindlay, Makenzius, Wainer, Weitz
Outcome 5: Feeling that information needs were met by healthcare providers	Moderate confidence	Minor concerns over methodological limitations due to limited sampling populations. Minor concerns over relevance.	Grindlay, Hallden, Hess, Mukkavaara, Slade, Tong, Ganatra, Grossman, Kero, Sri, Petitet
Outcome 6: Feeling emotionally supported by either healthcare providers or others	High confidence	Large volume of studies supporting this outcome. Minor concerns over methodological limitations due to limited sampling populations. Minor concerns over relevance.	Alex, Domingos, Dykes, Goodwin, Hallden, Hess, Makenzius, Mukkavaara, Stålhandske, Slade, Tong, Weitz, Elul, Ganatra, Grossman, Harvey, Kero, Arambepola, Sri
Outcome 7: Feelings of having been treated respectfully by healthcare providers	Moderate confidence	Minor concerns over relevance.	Arambepola, Makenzius, Summit, Weitz, Sri
Outcome 8: Effective control/management of pain, side effects and complications	Moderate confidence	Minor concerns over relevance of some study findings.	Esia, Alam, Elul, Ganatra, Lohr, Mitchell, Petitet, Vallely
Outcome 9: Capacity to effectively manage possible social repercussions of abortion	Moderate confidence	Minor concerns over methodological limitations due to recruitment bias. Minor concerns over relevance of some study findings.	Esia, Goodwin, Hallden, Mitchell, Ganatra, Grossman, Vallely, Wainer, Weitz