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Medical versus surgical methods of early abortion: protocol for a systematic review and environmental scan of patient decision aids

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ABSTRACT

Introduction: Currently, we lack understanding of the content, quality and impact of patient decision aids to support decision-making between medical and surgical methods of early abortion. We plan to undertake a systematic review of peer-reviewed literature to identify, appraise and describe the impact of early abortion method decision aids evaluated quantitatively (Part I), and an environmental scan to identify and appraise other early abortion method decision aids developed in the US (Part II).

Methods and analysis: For the systematic review, we will search PubMed, Cochrane Library, CINAHL, EMBASE and PsycINFO databases for articles describing experimental and observational studies evaluating the impact of an early abortion method decision aid on women's decision-making processes and outcomes. For the environmental scan, we will identify decision aids by supplementing the systematic review search with Internet-based searches and key informant consultation. The primary reviewer will assess all studies and decision aids for eligibility, and a second reviewer will also assess a subset of these. Both reviewers will independently assess risk of bias in the studies and abstract data using a piloted form. Finally, both reviewers will assess decision aid quality using the International Patient Decision Aid Standards criteria, ease of readability using Flesch/Flesch-Kincaid tests, and informational content using directed content analysis.

Ethics and dissemination: As this study does not involve human subjects, ethical approval will not be sought. We aim to disseminate the findings in a scientific journal, via academic and/or professional conferences and among the broader community to contribute knowledge about current early abortion method decision-making support.

Trial registration number: This protocol is registered in the International Prospective Register of Systematic Reviews (CRD42015016717).

BACKGROUND

In the USA, over 1 million women experience an induced abortion each year,[1] and a

Strengths and limitations of this study

- Uniquely, this study combines a standard systematic review with an environmental scan much broader in scope.
- Our methodology will enable a comprehensive understanding of the early abortion method decision aids available to women and their content, quality and impact.
- Although informed by the broader goals of this work, one weakness of the study is that the environmental scan is limited to a search of decision aids developed in the USA.

majority (64%) of these abortions occur during early pregnancy (ie, before 9 weeks' gestation).[2] Over a decade ago, mifepristone was approved by the US Food and Drug Administration for medical management of early abortion,[3] affording women a choice between medical and surgical procedures.[i] These methods have comparable success rates, but encompass quite different processes. Accordingly, women's preferences and circumstances are paramount in the choice between early abortion methods.[3] Some women favour medical abortion because they perceive it to be more natural, want to avoid surgery or value the privacy of the home environment.[4–7] Other women prefer surgical abortion because of the comfort and finality of the procedure being completed in a single clinic visit, their preference for anaesthesia or their desire not to see the fetus.[5 8 9]

Research has documented the significant value women place on having a choice between medical and surgical abortion,[7–11] and on receiving information to support their informed decision-making.[12–14] Despite

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[i]Although both methods are approved federally, differences in state-level regulations has made access to early abortion services more variable.[1]

women's articulated desire for trusted resources, scant research has evaluated the content or quality of information available to facilitate women's early abortion method decision-making. Evidence from the UK indicates that some information materials designed for this purpose are inadequate, unbalanced and difficult to read.[15] However, we are not aware of equivalent research in the USA or elsewhere. Such research is particularly important in the USA where abortion is simultaneously a highly prevalent and yet highly stigmatized[16] procedure, and where there remains widespread misinformation,[17] [18] poor access to services,[1] and broad variability in abortion counselling practices.

Counselling about abortion methods has the potential to overcome shortcomings in the quality and comprehensiveness of information materials. However, although women in the USA tend to report satisfaction with abortion counselling generally,[19] current information provision about available methods may limit informed, values-consistent decision-making. Indeed, there is evidence that some adolescent medicine providers have poor knowledge about the safety and effectiveness of medical abortion,[20] and that some front-line health workers and social service providers feel they lack the necessary skills and information to adequately support women when considering early abortion.[21] Studies have also found that healthcare providers have not disclosed information about available second trimester abortion[22] or ectopic pregnancy treatment options,[23] potentially delaying women's care or exposing them to unnecessary risk. It is unsurprising that in a recent qualitative study of 22 early medical abortion patients, women's beliefs about surgical abortion were often inaccurate.[4] Similarly, a recent survey of 67 women who had recently experienced early surgical abortion found that 78% overestimated the health risks of the procedure.[24]

On the basis of the evidence described above, several authors have called for the development of evidence-based educational interventions to enable women to make quality and unbiased choices about early abortion methods.[24] [25] One such intervention, the decision aid, is designed for this purpose. Specifically, decision aids are intended to help patients participate in making deliberative choices among healthcare options based on quality evidence and their preferences.[26] Decision aids have been shown to improve patients' knowledge of options, accurate expectations of possible benefits and harms and participation in decision-making as well as the alignment between patients' choices and their values.[26] Accordingly, implementation of a decision aid on early abortion methods has potential to address current deficiencies in information provision and counselling in the USA, particularly in areas with growing restrictions on abortion services.[1]

Three previous systematic reviews[26–28] consistently identified only one study evaluating a decision aid on early abortion methods. This study, which was conducted in the UK in 2002, evaluated a one-page paper decision aid that described surgical and medical methods of early abortion.[29] The study found that the 163 women randomised to use the decision aid had better knowledge and felt more informed than the 165 women randomised to receive usual care.[30] While this study speaks to the potential of a decision aid in this clinical context, this particular tool has limited suitability for the contemporary US context due to sociopolitical and cultural differences in the provision of early abortion care[31] [32] and developments in evidence over the past decade.[3] Whether other early abortion method decision aids—especially those relevant to the contemporary US context—have been developed and evaluated using non-randomised study designs, or have been developed but not evaluated quantitatively, remains unclear due to the scope of previous systematic reviews.

Ultimately, an inventory of available early abortion method decision aids, together with a summary of their quality and impact, would enhance our understanding of the decision support available to women choosing between medical and surgical early abortion. It would also elucidate necessary next steps for overcoming current limitations in information provision and counselling, and women's knowledge deficits, through implementation of a patient decision aid in the USA. The aim of this paper is to describe the protocol for a two-part study designed to identify existing decision aids and summarise evidence of their content, quality and impact.

OBJECTIVES AND RESEARCH QUESTIONS

This study will comprise a systematic review (SR) to identify, appraise and describe the impact of early abortion method decision aids that have been evaluated quantitatively and published in peer-reviewed outlets (part I) and an environmental scan (ES) of the grey literature to identify and appraise other early abortion method decision aids developed in the USA (part II). As this study does not involve human subjects, no ethical approval will be sought. This study will address several research questions (see table 1).

METHODS: SYSTEMATIC REVIEW (PART I)

This systematic review protocol was registered on 12 February 2015 with the International Prospective Register of Systematic Reviews (CRD42015016717) and adheres to PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-Analyses protocols).[33] Moreover, we intend to adhere to the PRISMA methodology when reporting on this systematic review.[30]

Eligibility criteria
Study design
Studies must be randomised controlled trials (ie, individual, crossover or cluster), non-randomised studies, cohort studies, case–control studies, before-and-after studies (ie, controlled or uncontrolled), interrupted-time-series studies or repeated measures studies.[34] We will exclude

Table 1 Study research questions

Research question	SR	ES
What early abortion method decision aids have been evaluated quantitatively and published in peer-reviewed outlets?	✓	
What other early abortion method decision aids have been developed for use in the USA?		✓
What is the impact of early abortion method decision aids on women's decision-making processes and outcomes?	✓	
What is the quality of early abortion method decision aids as measured by the International Patient Decision Aid Standards?	✓	✓
How does the content of early abortion method decision aids developed in the USA support quality decision-making?		✓

studies that do not have a comparison group (eg, case series, case reports).

Participants

Study participants must be women who are eligible for medical and surgical abortion (as defined by trialists) and who are facing a decision about method of early abortion. We will exclude studies involving women who are ineligible for medical and/or surgical abortion, who are making a hypothetical decision, or who are facing a decision about spontaneous abortion (ie, miscarriage).

Intervention

The intervention studied should have been a publicly available (ie, free) decision aid that compared medical and surgical abortion, and developed after 2000, when medical abortion became legal in the USA.[35] Decision aids that include a third 'no treatment' option (ie, continuing the pregnancy or adoption) will be included if they also compare the two methods of early abortion. We will adopt the Cochrane Collaboration definition of a decision aid (see box 1).[26]

For the purpose of this review, 'implicit methods to clarify values' are defined as methods that prompt deliberation about options or attributes of options,[36] such as a table enabling direct comparison of the features or outcomes associated with the options (eg, success rates, adverse effects) or a description of the options in "enough detail that clients can imagine what it is like to experience the physical, emotional, and social effects and/or guide clients to consider which benefits and harms are most important to them."[26] The decision aid may be designed for use before, during, or after a healthcare appointment or independent of any healthcare appointment, and may be in any format (eg,

pamphlets, booklets, videos, DVDs, interactive websites, static websites, electronic documents, smartphone mobile applications ('apps')).[37] The decision aid may be published in any language and could have been created for women in any country.

We will exclude studies of interventions that do not meet the above definition of decision aid, including standard health education materials. We will also exclude interventions that are not publicly available and those not designed primarily for women facing the decision (eg, clinical guidelines).

Comparison

The comparison studied may comprise usual care, no intervention (or baseline) or a non-decision aid intervention. We will exclude studies that either do not include a comparison group or, in the case of before-and-after studies, interrupted-time-series studies and repeated measures studies, that do not have a clearly defined intervention timeframe.

Outcomes

Studies must provide data on at least one outcome related to the decision-making process or decision-making outcome, whether reported by the woman, a provider and/or a third party (see table 2). Our primary outcome is decision quality, defined as the extent to which a decision is informed and based on personal values.[38]

Date of study

Based on the intervention inclusion criteria we will exclude studies published before 2000.

Data sources and search strategy

We will search the following electronic bibliographic database: PubMed (see box 2), The Cochrane Library, CINAHL, EMBASE and PsycINFO using, where appropriate, medical subject heading (MeSH) terms: "abortion, induced", "choice behavior", "patient education", "decision support techniques" and "decision making" and/or key words with Boolean operators (see online supplementary appendix 1). We will not apply any language limits. We will search for studies published since January 2000. We will also search the trial registry

Box 1 Decision aid definition (Reproduced from Stacey *et al*, p. 8[26])

"(I)nterventions designed to help people make specific and deliberative choices among options (including the status quo), by making the decision explicit and by providing (at the minimum) (a) information on the options and outcomes relevant to a person's health status and (b) implicit methods to clarify values."

Table 2 Potential outcomes and their definitions

Outcome	Definition
Decision quality	The extent to which a decision is informed and based on the patient's personal values[38 55 56]
Decision self-efficacy	A patient's degree of confidence or belief in one's ability to make decisions[57]
Decision aid utility	The extent to which a decision aid is considered useful for preparing a patient to communicate with his/her provider and to make a health decision[58]
Decisional conflict	A patient's degree of uncertainty about the right course of action to take (eg, due to to feeling uninformed, unclear about personal values and/or unsupported in decision-making)[59 60]
Decision-making role concordance	The alignment between a patient's preferred and assumed decision-making role[61 62]
Shared decision-making	The extent to which a healthcare decision is made collaboratively by patient and provider[63]

ClinicalTrials.gov and manually search the reference lists of all included articles for additional studies conducted or published since January 2000.

Additionally, any decision aid identified during the environmental scan (see below) that has been evaluated quantitatively and published in peer-reviewed outlets will be considered for inclusion in the systematic review.

Data screening

Search results will be downloaded and managed in Mendeley 1.13.1. After duplicate entries are removed, the primary reviewer (KD) will screen the titles and abstracts of all identified articles and classify each as potentially eligible or ineligible for inclusion. A second reviewer (RT) will independently screen random samples of 10% of the titles and abstracts in each classification. Inter-rater reliability will be measured using Cohen's κ.[39] If significant discrepancies are observed in either classification (ie, κ<0.7), the second reviewer will screen all titles and abstracts, and discrepant classifications will be resolved by discussion.

Full-text review

The primary reviewer will perform full-text review of all potentially eligible articles and classify each as eligible or ineligible for inclusion. The reason for ineligibility will be recorded. If a classification cannot be made based on full-text review, attempts will be made to contact the study authors for clarifying information. The second reviewer will independently review a random sample of 10% of the full-text articles and inter-rater reliability will be assessed. If major discrepancies in classification are identified (ie, κ<0.7), the second reviewer will perform a

full-text review of all articles and discrepant classifications will be resolved by discussion. Finally, the primary reviewer will contact the author of each included study to inquire about any related studies (eg, study protocols, companion studies).

Data abstraction

Both reviewers will use a piloted form (see online supplementary appendix 2) to abstract data (ie, study design, participant characteristics, decision aid format and administration, findings, etc) from all studies deemed eligible for inclusion. We will also abstract data on other relevant outcomes measured by these studies. All abstracted data will be compared and disagreements resolved by discussion. If multiple publications describe a single study, authors will consider these as a single study.

Study and evidence quality appraisal

Both reviewers will independently assess the methodological quality of included studies using the Cochrane Effective Practice and Organisation of Care Group's (EPOC) criteria for randomised, non-randomised studies, before-and-after, interrupted-time-series studies or repeated measures studies[40] and the Newcastle-Ottawa Scale for observational studies.[41] Using EPOC criteria, we will apply a judgment of 'unclear risk', 'low risk' or 'high risk' to nine categories for each randomised, non-randomised and before-and-after study, and for seven categories for each interrupted-time-series and repeated measures study.[40] Using the Newcastle-Ottawa Scale, we will award each study a maximum of nine points for items related to selection, comparability and outcome assessment bias.[41]

Both reviewers will also independently apply the Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria to rate the quality of evidence (high, moderate, low, very low) across studies for the primary outcome, decisional quality, using GRADEprofiler software (see online supplementary appendix 3).[42] We will assess key factors that can downgrade the quality of evidence (eg, methodological quality, directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias) and upgrade the quality of evidence (ie, magnitude of effect,

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Box 2 PubMed Search Strategy

Search Terms
("abortion, induced" [MeSH] OR "pregnancy termination" [tiab] OR "termination of pregnancy" [tiab] OR "abortion" [tiab]) AND ("choice behavior" [MeSH] OR "decision support techniques" [MeSH] OR "patient education" [MeSH] OR "decision making" [MeSH] OR "decision support" [tiab] OR "decision aid" [tiab] OR "decision aids" [tiab] OR "informed choice" [tiab])

dose–response gradient and ability of the study to limit bias and control for confounding).[43] The quality of evidence can be downgraded or upgraded by one level or two levels to eventually describe a 'high', 'moderate', 'low' or 'very low' assessment of our confidence in the estimate of effect. The methodological and evidence quality assessments made by the reviewers will be compared and disagreements resolved by discussion.

Decision aid quality appraisal

Both reviewers will independently assess the quality of decision aids evaluated in included studies using the International Patient Decision Aid Standards (IPDAS) checklist. This tool has 59 items which evaluate the domains of content, development process and effectiveness for decision aids not involving tests.[44] For each decision aid, we will assess each checklist item as 'yes' or 'no' or 'not applicable', with the final score ranging from 0 to 50 (Internet-based decision aids and those which integrate narratives have 6 and 3 additional items, respectively). Discrepant classifications will be resolved by discussion.

In addition, the primary reviewer will assess the readability and reading ease of text-based decision aids using the Flesch-Kincaid test.[45] [46] The Flesch-Kincaid Grade Level measures textual difficulty based on words per sentence and syllables per word, and presents a score as a US grade level. The Flesch Reading Ease Scale uses average sentence length and the average number of syllables per word to calculate a score on a scale of 0 (very hard to read) to 100 (very easy to read).

Analysis of decision aid impact

We will quantitatively synthesise the findings from included studies if they are sufficiently homogeneous. We will calculate weighted treatment effects with 95% CIs. We will calculate risk ratios for dichotomous data and mean differences for continuous data. We will pool the results across studies with comparable outcome measures using a random-effects meta-analysis. When necessary data are available, we will compute standardised outcome scores to have a mean of 50 with SD of 10 for ease of descriptive comparison. If effect sizes cannot be calculated for the key outcomes due to inadequate information, we will contact the study authors for additional data. For each outcome, data will be synthesised and analysed using the statistical software, RevMan 5.1, as indicated by the Cochrane Handbook of Systematic Reviews of Interventions.[47] Heterogeneity will be assessed and considered substantial if the I^2 statistic is >50% and the χ^2 test p value is <0.10.[48] If heterogeneity exists for a given outcome, we will seek to understand its source and conduct quantitative analysis on homogenous subgroups of studies. If relevant, the results of the methodological quality assessment will be used to perform sensitivity analyses to test the effect of omitting studies at high risk of bias. If meta-analysis is not possible, we will perform a narrative analysis and present

summary information on all study characteristics and the primary outcome in text and tabular form.

We will explore the potential for publication bias visually using funnel plots if 10 or more studies are included.[49] If study protocols have been published, we will also compare outcomes reported in the protocol and the published report to assess for selective outcome reporting.

METHODS: ENVIRONMENTAL SCAN (PART II)

Given the absence of quality standards for conducting environmental scan, our approach was informed by the methods of previous environmental scans about decision aids and/or shared decision-making.[50] [51]

Eligibility criteria
Intervention

The intervention must be a decision aid, as described above. For the environmental scan only, the decision aid must be written in English and have been created by a source in the USA for women residing in the USA.

Data sources and search strategy

The Internet will comprise the primary data source for identifying decision aids for inclusion in the environmental scan. The Internet will be used both to identify relevant web-based decision aids and to identify references to non-web-based decision aids. We will execute four searches using the Google Advanced Search 'all these words' function and the following key word strings: (1) *abortion decision aid*, (2) *abortion options*, (3) *pregnancy termination options* and (4) *medical or surgical abortion*. We will select 'USA' in the 'region' category to refine the search. Cookies will be disabled before the search to avoid inadvertent bias. Efforts will be made to obtain any relevant documents that elaborate on the development or use of the decision aids. This may involve searching other sections of a multipage website and/or contacting the developers of the tools directly to request further information. To identify smartphone apps, we will search the two most frequently used Internet-based app stores, the English-language, US-based Apple app store and Google Play.[52] We will use the key word *abortion* in the search field for both stores.

We will complement the Internet search by consulting organisations (eg, National Abortion Federation, Abortion Care Network, Reproductive Health Access Project, Planned Parenthood Federation of America, Provide and Society for Family Planning) and key informants (eg, women, researchers, clinicians, policymakers and/or advocates in the field). We will contact these organisations and individuals to solicit known examples of relevant decision aids (see online supplementary appendix 4) and will continue this consultation strategy until we determine that no new decision aids are likely to be identified.

Additionally, any decision aid identified during the systematic review will be considered for inclusion in the environmental scan.

Screening and full review

Owing to the dynamic nature of the Internet, the screening and full review of Internet pages identified in the Google searches will be conducted concurrently. The primary reviewer will perform the first search string, archive the list of the first 100 results (ie, web address, page title, brief description and date searched),[53] and classify each as potentially useful or not useful for identifying a decision aid. The reviewer will then open all pages considered potentially useful, archive each full page and if the page comprises or contains a decision aid, classify that tool as eligible or ineligible for inclusion. The reason for exclusion will be recorded. If the page contains only a reference to a decision aid, the primary reviewer will attempt to obtain a copy by contacting the source at a later time and, if successful, will then determine the eligibility of the decision aid for inclusion. Decision aids that cannot be obtained will be noted. This process will be replicated for each of the other three search strings.

For smartphone apps, the primary reviewer will archive and assess for eligibility the first 50 results on the general app description page of each Internet-based app store. The reviewer will then open, archive and assess the description of potentially eligible apps. The reviewer will download all apps considered potentially eligible to a smartphone and then classify each as eligible or ineligible for inclusion. At each stage, the reason for exclusion will be recorded.

The primary reviewer will use the same screening and review process to assess the eligibility of decision aids suggested by key informants.

Using the archives created by the primary reviewer, the second reviewer will independently open and assess random selections of 10% of the websites, apps and subsequently sourced decision aids classified by the primary reviewer as eligible and 10% of those classified as ineligible. The second reviewer will also archive the full page of each website opened for assessment (ie, included and excluded) in case the content has been modified since the primary reviewer undertook screening and full review. Inter-rater reliability will be measured using Cohen's κ.[39] If significant discrepancies are observed in either classification (ie, κ<0.7) that are not due to dynamic content, the second reviewer will complete screening and full review for all websites, apps and subsequently sourced decision aids, and the discrepant classifications will be resolved by discussion.

Data abstraction

Both reviewers will use a piloted form to abstract data from all decision aids (eg, characteristics, format and source) that meet inclusion criteria (see online supplementary appendix 5).

Decision aid quality appraisal

Both reviewers will independently evaluate the quality of the decision aids using the IPDAS checklist and the Flesch-Kincaid test, as described above.

Decision aid content analysis

We will analyse the content and presentation of information in included decision aids using methods from directed content analysis[54] with an emphasis on distinguishing similarities and differences across the body of included tools. We will focus on identifying patterns in content and presentation relevant to promoting quality decision-making such as inclusion or omission of particular method features, word choice, framing of language about women's decision-making role and values clarification approaches. Data collection and analysis will follow an iterative process, whereby the coding structure and emerging themes will continuously be expanded and refined as more data is collected and analysed. The primary reviewer will lead the qualitative data collection and analysis process, and intermittently consult with the secondary reviewer with respect to the coding structure and emergent themes.

CONCLUSION

This protocol describes a study that will provide evidence about the content, quality and impact of early abortion method decision aids, and produce an inventory of appraised tools relevant to the US context. We intend to publish the results in academic and non-academic outlets to contribute knowledge about current early abortion method decision-making support. In doing so, we hope to elucidate relevant next steps for attempting to overcome current limitations to counselling and women's knowledge deficits through implementation of a patient decision aid in the US.

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