National Institute for Health and Care Excellence

Final

Abortion care

[G] Expulsion at home for early medical abortion

NICE guideline NG140

Evidence reviews

September 2019

Final

These evidence reviews were developed by the National Guideline Alliance hosted by the Royal College of Obstetricians and Gynaecologists

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

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Contents

Expulsion at home for early medical abortion

Review question

For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

Introduction

The aim of this review is to determine what gestational limit offers the best balance of benefits and harms for home expulsion of pregnancy.

At the time of development, the title of this guideline was 'Termination of pregnancy' and this term was used throughout the guideline. In response to comments from stakeholders, the title was changed to 'Abortion care' and abortion has been used throughout. Therefore, both terms appear in this evidence report.

Summary of the protocol

See Table 1 for a summary of the population, prognostic factor and outcome (PPO) characteristics of this review.

Table 1: Summary of the protocol (PPO table)

Population	Women who have requested a medical termination of pregnancy (using mifepristone + misoprostol) and expel their pregnancy at home (i.e., in a setting outside of a clinical facility)
Prognostic Factor	**Prognostic factor:** Gestational age • <63 days (9^{+0} weeks), • 64 to 70 days (9^{+1} to 10^{+0} weeks), • >71 days (10^{+1} weeks)
Outcome	**Critical outcomes:** • Need for emergency care/hospital admission • Haemorrhage requiring blood transfusion or > 500ml of blood loss • Patient satisfaction **Important outcomes:** • Complete abortion without the need for surgical intervention • Vomiting • Pain • Diarrhoea

For further details see the full review protocol in appendix A.

Clinical evidence

Included studies

One of the original inclusion criteria was to only include studies with ≥100 women per prognostic group. With the original inclusion criteria, no studies for prognostic group >71

days (10^{+1} weeks) were identified. However, the limit of number of women per prognostic group was lowered to 50 and this led to inclusion of 1 additional study (Gomperts 2014). Four cohort studies including 3 prospective cohort studies (Bracken 2014; Sanhueza 2015; Winikoff 2012) and 1 retrospective cohort study (Gomperts 2014) were included in this evidence review. The studies compared outcomes following home expulsion of pregnancies less than 9 weeks with those between 9 to 10 weeks or 9 to 12 weeks.

The included studies are summarised in Table 2.

See the literature search strategy in appendix B and study selection flow chart in appendix C

Excluded studies

Studies not included in this review with reasons for their exclusions are provided in appendix K.

Summary of clinical studies included in the evidence review

A summary of the studies that were included in this review are presented in Table 2.

Table 2: Summary of included studies

Study and setting	Population	Prognostic factor	Outcomes
Bracken 2014 Prospective cohort study Multi country (Georgia, India, Tunisia, Ukraine)	n=703 Women 18 years or older, in good health with pregnancies greater than 56 days and less than 71 days from LMP based on ultrasound and/or clinical exam and history	**Medical abortion regimen:** 200 mg oral mifepristone and 400 micrograms (mcg) sublingual misoprostol Gestational age: ≤ 9^{+0} weeks versus 9^{+1} to10^{+0} weeks	• Need for emergency care/hospital admission • Haemorrhage requiring blood transfusion or > 500ml of blood loss • Complete abortion without the need for surgical intervention • Vomiting • Pain • Diarrhoea
Gomperts 2014 Retrospective cohort study Brazil	n=307; out of which 278 had pregnancies less than or equal to 9 weeks, or 10-12 weeks and were included in the review Women from Brazil who contacted Women on Web from January to December 2011 and performed a medical abortion provided through	**Medical abortion regimen**: 200 mg mifepristone and 800 mcg sublingual misoprostol after 24 hours, followed by 400 mcg sublingual misoprostol after 4 hours. Gestational age: ≤ 9^{+0} weeks versus 9^{+1} to 12^{+0} weeks	• Complete abortion without the need for surgical intervention • Pain

Study and setting	Population	Prognostic factor	Outcomes
	Women on Web's telemedicine service.		
Sanhueza 2015 Prospective cohort study Mexico	n=960 Women with pregnancies up to 70 days LMP eligible for medical abortion	**Medical abortion regimen**: 200 mg mifepristone followed by 800 mcg misoprostol 24 to 48 hours later Gestational age: ≤ 9^{+0} weeks versus 9^{+1} to10^{+0} weeks	• Complete abortion without the need for surgical intervention • Vomiting • Pain • Diarrhoea
Winikoff 2012 Prospective cohort study United States	n=629 Women 18 years old and older with confirmed intrauterine pregnancy 57 through 70 days from LMP, based on routine ultrasound and able to speak and read English or Spanish.	**Medical abortion regimen:** 200 mg mifepristone and 800 mcg buccal misoprostol Gestational age: ≤ 9^{+0} weeks versus 9^{+1} to10^{+0} weeks	• Need for emergency care • Haemorrhage requiring blood transfusion or > 500ml of blood loss • Patient satisfaction (satisfied or very satisfied) • Complete abortion without the need for surgical intervention • Vomiting • Diarrhoea

LMP: Last menstrual period; mcg: micrograms

See the full evidence tables in appendix D and the forest plots in appendix E.

Quality assessment of clinical studies included in the evidence review

See the clinical evidence profiles in appendix F.

Economic evidence

Included studies

A systematic review of the economic literature was conducted but no economic studies were identified which were applicable to this review question.

A single economic search was undertaken for all topics included in the scope of this guideline. Please see supplementary material 2 for details.

Excluded studies

No full-text copies of articles were requested for this review and so there is no excluded studies list.

Economic model

No economic modelling was undertaken for this review because the committee agreed that other topics were higher priorities for economic evaluation.

Evidence statements

Critical outcomes

Need for emergency care/hospital admission

Evidence from cohort studies did not detect a clinically important difference in the need for emergency care/hospital admission rate following home expulsion after taking mifepristone and misoprostol for a medical abortion between ≤ 9^{+0} weeks and 9^{+1} to 10^{+0} weeks' gestational age (2 prospective cohort studies, n=1332; RR= 0.86 [95% CI 0.42-1.77]; very low quality); however, there was uncertainty around the estimate.

Haemorrhage requiring blood transfusion or > 500ml of blood loss

Evidence from cohort studies did not detect a clinically important difference in the haemorrhage requiring blood transfusion or > 500ml blood loss rate following home expulsion after taking mifepristone and misoprostol for a medical abortion between pregnancies ≤ 9^{+0} weeks and 9^{+1} to 10^{+0} weeks' gestational age (2 prospective cohort studies, n=1332; RR= 1.34 [95% CI 0.23, 7.94]; very low quality); however, there was uncertainty around the estimate.

Patient satisfaction (satisfied or very satisfied)

Evidence from a cohort study showed there was no clinically important difference in patient satisfaction (rated as satisfied or very satisfied) following home expulsion after taking mifepristone and misoprostol for a medical abortion between pregnancies ≤ 9^{+0} weeks and 9^{+1} to 10^{+0} weeks' gestational age (1 prospective cohort study, n=629; RR= 0.99 [95% CI 0.94, 1.05]; moderate quality).

Important outcomes

Complete abortion without the need for surgical intervention

Evidence from cohort studies did not detect a clinically important difference in the complete abortion without the need for surgical intervention rate following home expulsion after taking mifepristone and misoprostol for a medical abortion between pregnancies ≤ 9^{+0} weeks and 9^{+1} to 12^{+0} weeks' gestational age (1 retrospective and 3 prospective cohort studies, n=2570; RR= 1.02 [95% CI 0.99, 1.04]; very low quality); however there was uncertainty around the estimate.

≤ 9^{+0} weeks versus 9^{+1} to 10^{+0} weeks' gestation

Evidence from cohort studies did not detect a clinically important difference in the complete abortion without the need for surgical intervention rate following home expulsion after taking mifepristone and misoprostol for a medical abortion between pregnancies ≤ 9^{+0} weeks and 9^{+1} to 10^{+0} weeks' gestational age (3 prospective cohort studies, n=2292; RR= 1.02 [95% CI 1.00, 1.05]; low quality); however there was uncertainty around the estimate.

≤ 9^{+0} weeks versus 9^{+1} to 12^{+0} weeks' gestation

Evidence from a cohort study did not detect a clinically important difference in the complete abortion without the need for surgical intervention rate following home expulsion after taking mifepristone and misoprostol for a medical abortion between pregnancies ≤ 9^{+0} weeks and 9^{+1} to 12^{+0} weeks' gestational age (1 retrospective cohort study, n=278; RR= 0.95 [95% CI 0.83, 1.08); very low quality); however there was uncertainty around the estimate.

Vomiting

Evidence from cohort studies did not detect a clinically important difference in the vomiting rate following home expulsion after taking mifepristone and misoprostol for a medical abortion between pregnancies ≤ 9^{+0} weeks and 9^{+1} to 10^{+0} weeks' gestational age (3 prospective cohort studies, n=2271; RR= 0.80 [95% CI 0.69, 0.93]; low quality); however there was uncertainty around the estimate.

Pain

Evidence from cohort studies showed there was no clinically important difference in pain following home expulsion after taking mifepristone and misoprostol for a medical abortion between pregnancies ≤ 9^{+0} weeks and 9^{+1} to 12^{+0} weeks' gestational age (1 retrospective and 2 prospective cohort studies, n=1941; RR= 0.91 [95% CI 0.81, 1.03]; very low quality).

≤ 9^{+0} weeks versus 9^{+1} to 10^{+0} weeks' gestation

Evidence from cohort studies showed there was no clinically important difference in pain following home expulsion after taking mifepristone and misoprostol for a medical abortion between pregnancies ≤ 9^{+0} weeks and 9^{+1} to 10^{+0} weeks' gestational age (2 prospective cohort studies, n=1663; RR= 0.91 [95% CI 0.81, 1.02]; low quality).

≤ 9^{+0} weeks versus 9^{+1} to 12^{+0} weeks' gestation

Evidence from a cohort study did not detect a clinically important difference in pain following home expulsion after taking mifepristone and misoprostol for a medical abortion between pregnancies ≤ 9^{+0} weeks and 9^{+1} to 12^{+0} weeks' gestational age (1 retrospective cohort study, n=278; RR= 1.71 [95% CI 0.20, 14.43); very low quality); however there was uncertainty around the estimate.

Diarrhoea

Evidence from cohort studies did not detect a clinically important difference in diarrhoea following home expulsion after taking mifepristone and misoprostol for a medical abortion between pregnancies ≤ 9^{+0} weeks and 9^{+1} to 10^{+0} weeks' gestational age (3 prospective cohort studies, n=2272; RR= 0.85 [95% CI 0.73, 0.99)]; low quality); however there was uncertainty around the estimate.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee agreed that, although the need for emergency care/hospital admission is rare in women having home expulsion for medical abortion, this was a critical outcome for decision making given its seriousness and implications for the woman and the health care resources. Haemorrhage requiring transfusion or greater than 500ml of blood loss was also considered a critical outcome for decision making, because of the seriousness of the outcome. One of the main objectives of offering a choice for home expulsion is providing the convenience to stay at home and make the service more acceptable and improve satisfaction. Therefore patient satisfaction was also included as a critical outcome.

Complete abortion without the need for surgical intervention was selected as an important outcome as this may have implications for the woman in terms of having to undergo surgical intervention and also impact resources. Vomiting, pain and diarrhoea were included as important outcomes to allow for a balance of the benefits and harms as the likelihood of

these occurring increases with increasing gestational age and they are likely to impact patient satisfaction.

The quality of the evidence

A modification of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology was used to evaluate the quality of the evidence for, and confidence in, each outcome in the evidence review. The evidence for the need for emergency care/hospital admission was very low quality; the main reason evidence was downgraded was for imprecision due to wide confidence intervals caused by few events of interest. The evidence for haemorrhage requiring transfusion or > 500ml of blood loss was very low quality; as with need for emergency care/hospital admission, the main reason evidence was downgraded was imprecision due to wide confidence intervals caused by few events of interest. The evidence for patient satisfaction was moderate quality; the only reason to downgrade the evidence for this outcome was risk of bias in the included study due to lack of comparability and inadequate follow-up. The evidence for complete abortion without the need for surgical intervention was very low quality; the reasons for downgrading of evidence being risk of bias in studies reporting this outcome and imprecision. The evidence for pain, diarrhoea and vomiting was very low to low quality; with the evidence mainly downgraded for imprecision due to wide confidence intervals and risk of bias in the studies reporting this outcome.

Benefits and harms

Based on the evidence, it was unclear whether or not there was a clinically important difference in the rate of complete abortion without the need for surgical intervention between women undergoing home expulsion for medical abortion at gestational age ≤ 9^{+0} weeks and 9^{+1} to 12^{+0} weeks. The evidence showed no higher risk of serious complications (such as the need for emergency care/hospitalisation and haemorrhage requiring transfusion or > 500ml of blood loss) and adverse events like vomiting and diarrhoea between women with gestational age ≤ 9^{+0} and 9^{+1} to 10^{+0} weeks. There was no difference in the rate of women experiencing pain between those with gestational age ≤ 9^{+0} weeks or 9^{+1} to 12^{+0} weeks. The evidence also showed that home expulsion for medical abortion was equally effective in terms of patient satisfaction when performed at ≤ 9^{+0}or 9^{+1} to 10^{+0} weeks.

Based on this evidence, the committee agreed that the choice of medical abortion with expulsion at home can be safely offered up to and including 10^{+0} weeks' gestation. The committee noted that this recommendation is based on the evidence on the safety of home expulsion. Separate recommendations were made for women up to and including 9^{+6} weeks gestation and women at 10^{+0} weeks gestation due to the legal limit at which misoprostol can be taken at home, as specified in the Secretary of State's approval order of December 2018 (The Abortion Act 1967 – Approval of a Class of Places). The committee also noted that whilst there was some evidence about women undergoing home expulsion up to and including 12^{+0} weeks this was limited and very low quality. They therefore agreed this was not enough to support making a recommendation for clinical practice.

The committee noted that the evidence about women undergoing home expulsion up to and including 12^{+0} weeks was from a single, very low quality study from outside the UK. They agreed that further research on home expulsion up to and including 12^{+0} weeks in the United Kingdom setting would be beneficial to inform future practice and hence made a research recommendation (see Appendix L).

Cost effectiveness and resource use

A systematic review of the economic literature was conducted but no relevant studies were identified which were applicable to this review question and no economic analysis was conducted. The committee agreed that there was unlikely to be a significant resource impact from making these recommendations as expulsion at home after medical abortion is already

standard practice, just at varying gestational ages. The committee considered that there could be potential cost savings from these recommendations due to less women needing to be admitted for their medical abortion. Also that there might be a shift away from surgical abortions at this gestational age which are more costly than medical abortions.

Other considerations

The committee noted that at later gestational ages, the fetus becomes more visible during a medical abortion. Therefore the committee agreed that women who decide to have a medical abortion with expulsion at home at 10^{+0} weeks would need to be made aware of this as it can be distressing if the woman is not expecting it. This was not considered a part of this review question. However, the committee discussed that the recommendations on information needs of women undergoing an abortion cover this issue.

References

Bracken 2014

Bracken, H., Dabash, R., Tsertsvadze, G., Posohova, S., Shah, M., Hajri, S., Mundle, S., Chelli, H., Zeramdini, D., Tsereteli, T., Platais, I., Winikoff, B., A two-pill sublingual misoprostol outpatient regimen following mifepristone for medical abortion through 70 days' LMP: A prospective comparative open-label trial, Contraception, 89, 181-186, 2014

Gomperts 2014

Gomperts, R., Van Der Vleuten, K., Jelinska, K., Da Costa, C. V., Gemzell-Danielsson, K., Kleiverda, G., Provision of medical abortion using telemedicine in Brazil, Contraception, 89, 129-133, 2014

Sanhueza 2015

Sanhueza Smith, P., Pena, M., Dzuba, I. G., Martinez, M. L. G., Peraza, A. G. A., Bousieguez, M., Shochet, T., Winikoff, B., Safety, efficacy and acceptability of outpatient mifepristone-misoprostol medical abortion through 70 days since last menstrual period in public sector facilities in Mexico City, Reproductive health matters, Part S1. 22, 75-82, 2015

Winikoff 2012

Winikoff, B., Dzuba, I. G., Chong, E., Goldberg, A. B., Steve Lichtenberg, E., Ball, C., Dean, G., Sacks, D., Crowden, W. A., Swica, Y., Extending outpatient medical abortion services through 70 days of gestational age, Obstetrics and Gynecology, 120, 1070-1076, 2012

Appendices

Appendix A – Review protocols

Review protocol for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms??

Field (based on PRISMA-P	Content
Review question in SCOPE	For women who are having medical termination of pregnancy, what gestational limit for expulsion at home offers the best balance of benefits and harms?
Review question in guideline	For women who are having medical termination of pregnancy, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?
Type of review question	Prognostic review
Objective of the review	To determine what gestational limit offers the best balance of benefits and harms for home (i.e., setting outside of clinical facility) expulsion of pregnancy.
Eligibility criteria – population	Women who have requested a medical termination of pregnancy (using mifepristone + misoprostol) and expel their pregnancy at home (i.e., in a setting outside of a clinical facility) Exclusions: - Studies with indirect populations will not be considered
Eligibility criteria – prognostic factor(s)	Prognostic factor: Gestational age: - <63 days (9+0 weeks) - 64 to 70 days (9+1 to 10+0 weeks) - >71 days (10+1 weeks)
Confounding factors	Analysis should adjust for important confounding factors, as a minimum include: None applicable
Outcomes and prioritisation	**Critical outcomes:** • Need for emergency care/hospital admission • Haemorrhage requiring blood transfusion or > 500ml of blood loss • Patient satisfaction **Important outcomes:** • Complete abortion without the need for surgical intervention • Vomiting • Pain • Diarrhoea
Eligibility criteria – study design	- Systematic reviews of prospective and/or retrospective cohort studies

Field (based on PRISMA-P	Content
	- Prospective cohort studies n≥100 per gestational age group - Retrospective cohort studies n≥100 per gestational age group
Other inclusion exclusion criteria	Inclusion: - English-language - Studies conducted from 1995 (see below)
Proposed sensitivity/sub-group analysis, or meta-regression	Stratified analyses based on the following sub-groups of women, where possible: Medical conditions: - Complex pre-existing medical conditions - No complex pre-existing medical conditions Vulnerability of women: - Vulnerable (including adolescents) - Non-vulnerable Language of women: - English speaking - Non-English speaking
Selection process – duplicate screening/selection/analysis	Dual sifting will be undertaken for this question using NGA STAR software, with resolution of discrepancies in discussion with the senior reviewer if necessary. Sifting, data extraction, appraisal of methodological quality and GRADE assessment will be performed by the systematic reviewer. Quality control will be performed by the senior systematic reviewer. Dual data extraction will not be performed for this question.
Data management (software)	Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5). 'GRADEpro' will be used to assess the quality of evidence for each outcome. NGA STAR software will be used for study sifting, data extraction, recording quality assessment using checklists and generating bibliographies/citations,
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase Limits (e.g. date, study design): Apply standard animal/non-English language exclusion Dates: from 1995 Only studies conducted from 1995 onwards will be considered for this review question, as home expulsion for gestational ages above 63 days was not done in clinical practice before 1995.
Identify if an update	Not an update
Author contacts	For details please see the guideline in development web site.
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual
Search strategy – for one database	For details please see appendix B

Field (based on PRISMA-P	Content
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	Standard study checklists will be used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual The risk of bias across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual Meta-analyses will be conducted for this prognostic review only if the same covariates are included in the analyses (preferably only gestational age), the same analytical methods are, or can be, adopted, and the populations assessed are suitably similar. In all other cases, the results will reported separately.
Methods for analysis – combining studies and exploring (in)consistency	Where possible, univariate risk ratios will be calculated or reported, with their 95% confidence interval. However if risk ratios cannot be calculated or are not reported, odds ratios or hazard ratios will be reported (depending on what the included studies reported). The results will be plotted with their 95% confidence interval in forest plots in Review Manager, and if possible (see cell above), the results will be pooled. The forest plots will be used to visually see the studies alongside each other and to explore similarities and differences between them. Synthesis of data: Pairwise meta-analysis will be conducted where appropriate for all outcomes. When meta-analysing continuous data, change scores will be pooled in preference to final scores. For details regarding inconsistency, please see the methods chapter Minimally important differences: 'Need for emergency care/hospital admission' and 'haemorrhage requiring transfusion or > 500ml of blood loss': Statistical significance Complete abortion without the need for surgical intervention: 3% (with the upper end of the 95% CI ≤ 5%) For the remaining outcomes default values will be used: 0.8 and 1.25 for dichotomous outcomes; 0.5 times SD (for the control group) for continuous outcomes.

Field (based on PRISMA-P	Content
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual.
Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual
Rationale/context – Current management	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by The National Guideline Alliance and chaired by Profession Iain Cameron in line with section 3 of Developing NICE guidelines: the manual. Staff from The National Guideline Alliance will undertake systematic literature searches, appraise the evidence, conduct meta-analysis and cost-effectiveness analysis where appropriate, and draft the guideline in collaboration with the committee. For details please see the methods chapter.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists
Roles of sponsor	NICE funds The National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England
PROSPERO registration number	Not registered

GRADE: Grading of Recommendations Assessment, Development and Evaluation; NHS: National Health Service; NICE: National Institute for Health and Care Excellence; NGA: National Guideline Alliance; SD: standard deviation

Appendix B – Literature search strategies

Literature search strategy for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

The search for this topic was last run on 19th November 2018 during the re-runs for this guideline.

Database: Medline & Embase (Multifile)
Last searched on **Embase Classic+Embase** 1947 to 2018 November 16, **Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R)** 1946 to November 16, 2018
Date of last search: 19th November 2018

#	Searches
1	exp abortion/ use emczd
2	exp pregnancy termination/ use emczd
3	exp Abortion, Induced/ use ppez
4	Abortion Applicants/ use ppez
5	exp Abortion, Spontaneous/ use ppez
6	exp Abortion, Criminal/ use ppez
7	Aborted fetus/ use ppez
8	fetus death/ use emczd
9	abortion.mp.
10	(abort$ or postabort$ or preabort$).tw.
11	((f?etal$ or f?etus$ or gestat$ or midtrimester$ or pregnan$ or prenatal$ or pre natal$ or trimester$) and terminat$).tw.
12	((f?etal$ or f?etus$) adj loss$).tw.
13	((gestat$ or midtrimester$ or pregnan$ or prenatal$ or pre natal$ or trimester$) adj3 loss$).tw.
14	(((elective$ or threaten$ or voluntar$) adj3 interrupt$) and pregnan$).tw.
15	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16	*Outpatients/ use ppez
17	(*outpatient care/ or *outpatient/) use emczd
18	Ambulatory Care/ use ppez
19	ambulatory care/ use emczd
20	Self Administration/ use ppez
21	drug self administration/ use emczd
22	(exp home/ or home care/) use emczd
23	home monitoring/ use emczd
24	"at home".tw.
25	(home$ adj3 (base$ or phase$ or use$ or administrat$ or manage$ or abortion$ or termination$)).tw.
26	((misoprostol$ or mifepriston$) adj3 (self-administer$ or home$ or outpatient$)).tw.
27	16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26

#	Searches
28	15 and 27
29	Mifepristone/ use ppez
30	mifepristone/ use emczd
31	(mifepriston$ or mifeprex$ or mifegyn$ or ru-486$ or ru486$ or ru-38486$ or ru38486$).mp.
32	29 or 30 or 31
33	Misoprostol/ use ppez
34	misoprostol/ use emczd
35	(misoprostol$ or cytotec$ or arthrotec$ or oxaprost$ or cyprostol$ or mibetec$ or prostokos$ or misotrol$).mp.
36	33 or 34 or 35
37	Gestational Age/ use ppez
38	gestational age/ use emczd
39	gestation$.tw.
40	37 or 38 or 39
41	15 and 32 and 36 and 40
42	28 or 41
43	limit 42 to english language
44	limit 43 to yr="1995 -Current"
45	letter/
46	editorial/
47	news/
48	exp historical article/
49	Anecdotes as Topic/
50	comment/
51	case report/
52	(letter or comment*).ti.
53	45 or 46 or 47 or 48 or 49 or 50 or 51 or 52
54	randomized controlled trial/ or random*.ti,ab.
55	53 not 54
56	animals/ not humans/
57	exp Animals, Laboratory/
58	exp Animal Experimentation/
59	exp Models, Animal/
60	exp Rodentia/
61	(rat or rats or mouse or mice).ti.
62	55 or 56 or 57 or 58 or 59 or 60 or 61
63	letter.pt. or letter/
64	note.pt.
65	editorial.pt.
66	case report/ or case study/
67	(letter or comment*).ti.
68	63 or 64 or 65 or 66 or 67
69	randomized controlled trial/ or random*.ti,ab.

#	Searches
70	68 not 69
71	animal/ not human/
72	nonhuman/
73	exp Animal Experiment/
74	exp Experimental Animal/
75	animal model/
76	exp Rodent/
77	(rat or rats or mouse or mice).ti.
78	70 or 71 or 72 or 73 or 74 or 75 or 76 or 77
79	62 use ppez
80	78 use emczd
81	79 or 80
82	44 and 81
83	44 not 82
84	remove duplicates from 83

Database: Cochrane Library via Wiley Online
Date of last search: 19th November 2018

#	Searches
#1	MeSH descriptor: [Abortion, Induced] explode all trees
#2	MeSH descriptor: [Abortion Applicants] explode all trees
#3	MeSH descriptor: [Abortion, Spontaneous] explode all trees
#4	MeSH descriptor: [Abortion, Criminal] explode all trees
#5	MeSH descriptor: [Aborted Fetus] explode all trees
#6	"abortion":ti,ab,kw (Word variations have been searched)
#7	(abort* or postabort* or preabort*):ti,ab,kw (Word variations have been searched)
#8	((fetal* or fetus* or foetal* or foetus* or gestat* or midtrimester* or pregnan* or prenatal* or pre natal* or trimester*) and terminat*):ti,ab,kw (Word variations have been searched)
#9	((fetal* or fetus* or foetal* or foetus*) next loss*):ti,ab,kw (Word variations have been searched)
#10	((gestat* or midtrimester* or pregnan* or prenatal* or pre natal* or trimester*) near/3 loss*):ti,ab,kw (Word variations have been searched)
#11	(((elective* or threaten* or voluntar*) near/3 interrupt*) and pregnan*):ti,ab,kw (Word variations have been searched)
#12	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
#13	MeSH descriptor: [Outpatients] this term only
#14	MeSH descriptor: [Ambulatory Care] this term only
#15	MeSH descriptor: [Self Administration] this term only
#16	"at home":ti,ab,kw (Word variations have been searched)
#17	(home* near/3 (base* or phase* or use* or administrat* or manage* or abortion* or termination*)):ti,ab,kw (Word variations have been searched)
#18	((misoprostol* or mifepriston*) near/3 (self-administer* or home* or outpatient*)):ti,ab,kw (Word variations have been searched)
#19	#13 or #14 or #15 or #16 or #17 or #18

#	Searches
#20	#12 and #19
#21	MeSH descriptor: [Mifepristone] this term only
#22	(mifepriston* or mifeprex* or mifegyn* or ru-486* or ru486* or ru-38486* or ru38486*):ti,ab,kw (Word variations have been searched)
#23	MeSH descriptor: [Misoprostol] this term only
#24	(misoprostol* or cytotec* or arthrotec* or oxaprost* or cyprostol* or mibetec* or prostokos* or misotrol*):ti,ab,kw (Word variations have been searched)
#25	MeSH descriptor: [Gestational Age] this term only
#26	gestation*:ti,ab,kw (Word variations have been searched)
#27	((#21 or #22) and (#23 or #24) and (#25 or #26))
#28	#20 or #27

Database: Cinahl Plus
Date of last search: 19th November 2018

#	Searches
S24	S23 Limiters - Publication Year: 1995-2018; English Language
S23	S12 OR S22
S22	S4 AND S15 AND S18 AND S21
S21	S19 OR S20
S20	TI (gestation*) OR AB (gestation*)
S19	(MH "Gestational Age")
S18	S16 OR S17
S17	TI (misoprostol* or cytotec* or arthrotec* or oxaprost* or cyprostol* or mibetec* or prostokos* or misotrol*) OR AB (misoprostol* or cytotec* or arthrotec* or oxaprost* or cyprostol* or mibetec* or prostokos* or misotrol*)
S16	(MH "Misoprostol")
S15	S13 OR S14
S14	TI (mifepriston* or mifeprex* or mifegyn* or ru-486* or ru486* or ru-38486* or ru38486*) OR AB (mifepriston* or mifeprex* or mifegyn* or ru-486* or ru486* or ru-38486* or ru38486*)
S13	(MH "Mifepristone")
S12	S4 AND S11
S11	S5 OR S6 OR S7 OR S8 OR S9 OR S10
S10	TI ((misoprostol* or mifepriston*) N3 (self-administer* or home* or outpatient*)) OR AB ((misoprostol* or mifepriston*) N3 (self-administer* or home* or outpatient*))
S9	TI (home* N3 (base* or phase* or use* or administrat* or manage* or abortion* or termination*)) OR AB (home* N3 (base* or phase* or use* or administrat* or manage* or abortion* or termination*))
S8	TI ("at home") OR AB ("at home")
S7	(MH "Self Administration")
S6	(MH "Ambulatory Care")
S5	(MM "Outpatients")
S4	S1 OR S2 OR S3
S3	TI ((f?etal* or f?etus* or gestat* or midtrimester* or pregnan* or prenatal* or pre natal* or trimester*) and terminat*) OR AB ((f?etal* or f?etus* or gestat* or midtrimester* or pregnan* or prenatal* or pre natal* or trimester*) and terminat*)

#	Searches
S2	TI (abort* or postabort* or preabort*) OR AB (abort* or postabort* or preabort*)
S1	(MH "Abortion, Habitual") OR (MH "Abortion, Criminal") OR (MH "Abortion, Spontaneous") OR (MH "Abortion, Incomplete")

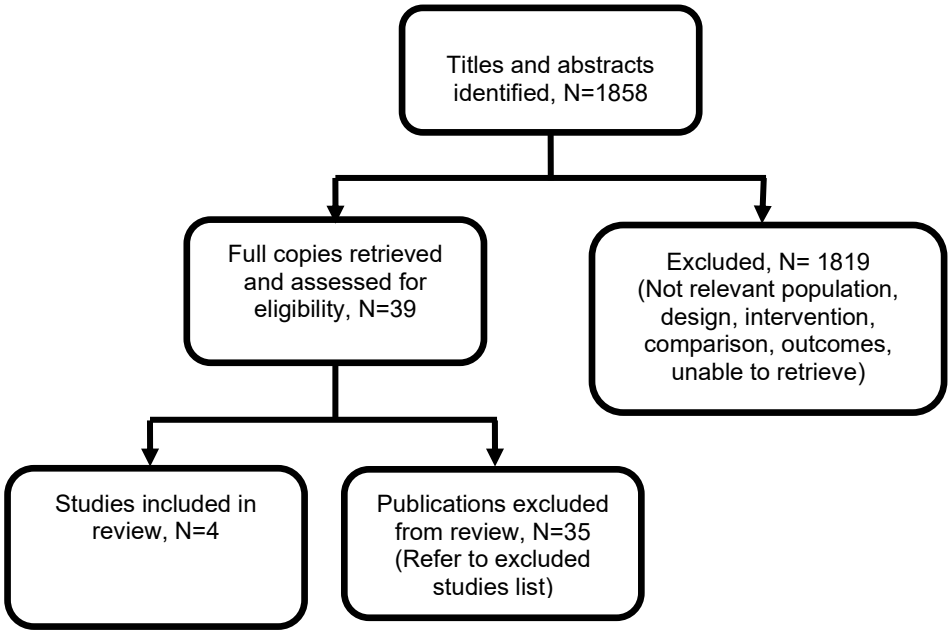
Database: Web of Science Core Collection
Timespan=1995-2018. Date of last search: 19th November 2018

#	Searches
# 14	#13 Refined by: [excluding] DOCUMENT TYPES: (NEWS ITEM OR EDITORIAL MATERIAL OR LETTER) Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 13	#12 OR #8 Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 12	#11 AND #10 AND #9 AND #3 Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 11	TS=(gestation*) Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 10	TS=(misoprostol* or cytotec* or arthrotec* or oxaprost* or cyprostol* or mibetec* or prostokos* or misotrol*) Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 9	TS=(mifepristone* or mifeprex* or mifegyn* or ru-486* or ru486* or ru-38486* or ru38486*) Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 8	#7 AND #3 Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 7	#4 OR #5 OR #6 Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 6	TS=("at home") Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 5	TS=((misoprostol* or mifepriston*) NEAR/3 (self-administer* or home* or outpatient*)) Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 4	TS=(home* NEAR/3 (base* or phase* or use* or administrat* or manage* or abortion* or termination*)) Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 3	#2 OR #1 Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 2	TS=((f?etal* or f?etus* or gestat* or midtrimester* or pregnan* or prenatal* or pre natal* or trimester*) and terminat*) Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018
# 1	TS=(abort* or postabort* or preabort*) Indexes=SCI-EXPANDED, SSCI Timespan=1995-2018

Appendix C – Clinical evidence study selection

Clinical evidence study selection for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

Figure 1: Study selection flow chart



Appendix D – Clinical evidence tables

Clinical evidence tables for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

Study details	Participants	Comparison groups	Outcomes and Results	Comments
Full citation Bracken, H., Dabash, R., Tsertsvadze, G., Posohova, S., Shah, M., Hajri, S., Mundle, S., Chelli, H., Zeramdini, D., Tsereteli, T., Platais, I., Winikoff, B., A two-pill sublingual misoprostol outpatient regimen following mifepristone for medical abortion through 70 days' LMP: A prospective comparative open-label trial, Contraception, 89, 181-186, 2014 **Ref Id** 802100 **Country/ies where the study was carried out** Multi country (Georgia, India, Tunisia, Ukraine) **Study type** Prospective cohort study **Aim of the study** To compare the effectiveness of an outpatient medical	**Sample size** N=703 **Characteristics** Age, mean (standard deviation): ≤9^{+0} weeks' gestation (n=382): 27.7 (5.7) years; 9^{+1} to 10^{+0} weeks gestation (n=321): 28.1 (6.4) years **Inclusion criteria** 1) Women 18 years or older, in good health 2) Pregnancy greater than 56 days and less than 71 days from LMP based on ultrasound and/or clinical examination and history 3) Willing and able to sign consent forms and agree to comply with the study	**Regimen:** Women received 200 mg oral mifepristone and the choice of administering 400 mcg sublingual misoprostol either in the clinic or at home 24 to 48 hours later. **Follow up:** Follow-up visits occurred at the clinic, 7 to 14 days after mifepristone administration. Outcomes were assessed by clinical assessment including ultrasonography and the data on side effects was self-reported. **Further management:** Surgical evacuation was offered to women with ongoing pregnancies. Women with nonviable pregnancies were given the options of expectant management, an additional dose of misoprostol or a surgical evacuation. **Comparison groups:** ≤9^{+0} weeks' gestation versus 9^{+1} to 10^{+0} weeks' gestation	**Outcome: Need for emergency care/hospital admission** ≤9^{+0} weeks' gestation: 2/382; 9^{+1} to 10^{+0} weeks' gestation: 1/321 **Outcome: Haemorrhage requiring blood transfusion or > 500ml of blood loss** ≤9^{+0} weeks' gestation: 1/382; 9^{+1} to 10^{+0} weeks' gestation: 1/321 **Outcome: Complete abortion without the need for surgical intervention** ≤9^{+0} weeks' gestation: 362/382**;** 9^{+1} to 10^{+0} weeks' gestation: 295/321 **Outcome: Vomiting**	**Limitations** Risk of bias assessed using Newcastle Ottawa Scale for Cohort Studies Selection Bias: 1) Representativeness of the exposed cohort a) Truly representative of the population of women having home expulsion for medical abortion (1 star) 2) Selection of the non-exposed cohort b) Comparison group drawn from the same population as the exposed cohort (1 star) 3) Ascertainment of exposure a) Ascertainment by medical records (1 star) 4) Demonstration that outcome of interest was not present at start of study a) Yes; primary outcome is need for emergency case/hospitalisation (1 star) Comparability:

Study details	Participants	Comparison groups	Outcomes and Results	Comments
termination of pregnancy protocol with 200 mg mifepristone and 400 mcg sublingual misoprostol at 64 to 70 days' last menstrual period (LMP) with 57 to 63 days' gestational age range **Study dates** July 2009 to March 2012 **Source of funding** Financial support for this study was provided by an anonymous charitable foundation.	procedures and visit schedule **Exclusion criteria** Those not willing to consent for the study		≤9^{+0} weeks' gestation: 54/380; 9^{+1} to 10^{+0} weeks' gestation: 56/313 **Outcome: Pain** Although pain is not reported, the need for nonsteroidal anti-inflammatory drugs for pain management is reported as an indirect outcome. ≤9^{+0} weeks' gestation:182/382; 9^{+1} to 10^{+0} weeks' gestation:172/321 **Outcome: Diarrhoea** ≤9^{+0} weeks' gestation: 35/380; 9^{+1} to 10^{+0} weeks' gestation: 39/314	1) Comparability of cohorts on the basis of the design or analysis controlled for confounders: No; no matching of the groups in the design and no adjustment in analysis Outcome: 1) Assessment of outcome b) For the outcomes, need for emergency care/hospital admission, haemorrhage requiring blood transfusion or > 500ml of blood loss and complete abortion without the need for surgical intervention, the outcome assessment was as per institutional protocol using ultrasound and clinical assessment (1 star). c) The outcomes vomiting, pain and diarrhoea were self-reported. 2) Was follow-up long enough for outcomes to occur a) Yes, the need for emergency care, haemorrhage, complete abortion rate, pain and gastrointestinal side effects are usually captured during the treatment. The 7 to 14 days follow-up window adequately captures this (1 star). 3) Adequacy of follow up of cohorts: c) No description of those lost to follow-up; 5 women in the ≤9^{+0} weeks' gestation group and 4 women in the 9^{+1} to 10^{+0} weeks'

Study details	Participants	Comparison groups	Outcomes and Results	Comments
				gestation group were lost to follow-up. The self-reported outcomes, vomiting and diarrhoea were not reported by 2 women in the ≤9^{+0} weeks' gestation group and 7 and 8 respectively in the 9^{+1} to 10^{+0} weeks' gestation group. Overall quality: Low; No stars in comparability and inadequate follow-up **Other information:** Indirectness due to outcome: Serious- The need for non-steroidal anti-inflammatory drugs for pain management is reported as an indirect outcome for pain.
Full citation Gomperts, R., Van Der Vleuten, K., Jelinska, K., Da Costa, C. V., Gemzell-Danielsson, K., Kleiverda, G., Provision of medical abortion using telemedicine in Brazil, Contraception, 89, 129-133, 2014 **Ref Id** 802114 **Country/ies where the study was carried out** Brazil **Study type**	**Sample size** N=307; out of which 278 had pregnancies less than or equal to 9 weeks, or 10 to 12 weeks and were included in the review **Characteristics** Age, mean (standard deviation): ≤9^{+0} weeks' gestation (n=207): 27.1 (6.8) years; 9^{+1} to 12^{+0} weeks' gestation (n=71): 25.6 (5.9) years	**Regimen:** 200 mg mifepristone, followed 24 hours later by sublingual application of 800 mcg misoprostol and a repeat dose of 400 mcg misoprostol sublingually 4 hours later. Online consultation was followed by delivery of the medicines and instructions on email. **Follow up:** Electronic follow-up was done at 5 weeks with self-reporting of the outcomes **Further management:** Women were given the information about the signs and symptoms that might indicate a complication and the need to seek medical care via email. They were also advised to do a pregnancy test after 3	**Outcome: Complete abortion without the need for surgical intervention** ≤9^{+0} weeks' gestation: 163/207; 9^{+1} to 12^{+0} weeks' gestation: 59/71 **Outcome: Pain** ≤9^{+0} weeks' gestation: 5/207; 9^{+1} to 12^{+0} weeks' gestation: 1/71	**Limitations** Risk of bias assessed using Newcastle Ottawa Scale for Cohort Studies Selection Bias: 1) Representativeness of the exposed cohort a) Somewhat representative of the population of the women having home expulsion for medical abortion as only the ones seeking telemedicine consultation were included (1 star). 2) Selection of the non-exposed cohort

Study details	Participants	Comparison groups	Outcomes and Results	Comments
Retrospective case review **Aim of the study** Evaluation of the need for and outcome of self-administered medical abortion with mifepristone and misoprostol in Brazil, provided through a global telemedicine abortion service. **Study dates** Jan-Dec 2011 **Source of funding** None	**Inclusion criteria** 1) Women from Brazil who contacted Women on Web from January to December 2011 2) Those who performed a medical abortion provided through Women on Web's telemedicine service. **Exclusion criteria** 1) Allergy to misoprostol or mifepristone 2) Chronic adrenal failure 3) Haemorrhagic disorder 4) Inherited porphyria 5) Not being able to get to a hospital within an hour	weeks or to have an ultrasound after 10 days to confirm the abortion. **Comparison groups:** $\leq 9^{+0}$ weeks' gestation versus 9^{+1} to 12^{+0} weeks' gestation		a) Comparison group drawn from the same population as exposed cohort (1 star). 3) Ascertainment of exposure: c) Self-reported period of gestation 4) Demonstration that outcome of interest was not present at start of study: a) Yes (1 star) Comparability: 1) Comparability of cohorts on the basis of the design or analysis: No; Study does not control for confounding factors or adjusts for it in analysis. Outcome: 1) Assessment of outcome: c) Self-reporting of outcomes 2) Was follow-up long enough for outcomes to occur: a) Yes; complete abortion rate and pain are usually captured during the treatment. The 5 weeks follow-up window adequately captures this (1 star). 3) Adequacy of follow up of cohorts c) follow up rate < 85% and no description of those lost to follow up Overall quality: Very low; No stars in comparability, self-reported period of gestation period and inadequate follow up **Other information**

Study details	Participants	Comparison groups	Outcomes and Results	Comments
				The gestation age was mentioned in terms of weeks and not days. Hence those in less than or equal to 9 weeks were included in the ≤9^{+0} weeks' gestation group, and those in 10, 11 and 12 weeks of gestation were included in the 9^{+1} to 12^{+0} weeks' gestation group.
Full citation Sanhueza Smith, P., Pena, M., Dzuba, I. G., Martinez, M. L. G., Peraza, A. G. A., Bousieguez, M., Shochet, T., Winikoff, B., Safety, efficacy and acceptability of outpatient mifepristone-misoprostol medical abortion through 70 days since last menstrual period in public sector facilities in Mexico City, Reproductive health matters, Part S1. 22, 75-82, 2015 **Ref Id** 816416 **Country/ies where the study was carried out** Mexico **Study type** Prospective cohort study **Aim of the study** To assess the safety, efficacy and acceptability of outpatient	**Sample size** N=960 **Characteristics** Age, median (range): 24 (13 to 45) years; Gravidity, median (range): 2 (1 to 8); Duration of pregnancy, median (range): 52 (25 to 73) days **Inclusion criteria** 1) Women eligible for medical abortion 2) Pregnancies up to 70 days LMP 3) Those agreeing for a surgical intervention (vacuum aspiration) if necessary 4) Those willing to provide contact details 5) Those having easy access to both a	**Regimen:** 200 mg mifepristone swallowed in the clinic followed by 800 mcg misoprostol administered buccally at home 24 to 48 hours later **Follow up:** Follow up visit at the clinic after 7 days; Lost to follow up (n=41) **Further management:** Vacuum aspiration was recommended to those with ongoing pregnancies. Those with non-viable pregnancies, including persistent gestational sac, retained products of conception or bleeding were offered the choice between an additional dose of 800 mcg buccal misoprostol, expectant management, or vacuum aspiration. Those opting for an additional dose of 800 mcg buccal misoprostol or expectant management were asked to return 1 week later for further follow-up. At that time women with a persistent non-viable pregnancy or substantial debris were offered vacuum aspiration. **Comparison groups:**	**Outcome: Complete abortion without the need for surgical intervention** ≤9^{+0} weeks' gestation: 761/812; 9^{+1} to 10^{+0} weeks' gestation: 135/148 **Outcome: Vomiting** ≤9^{+0} weeks' gestation: 182/812; 9^{+1} to 10^{+0} weeks' gestation: 39/148 **Outcome: Pain (more than expected)** ≤9^{+0} weeks' gestation: 341/812; 9^{+1} to 10^{+0} weeks' gestation: 66/148 **Outcome: Diarrhoea** ≤9^{+0} weeks' gestation: 350/812; 9^{+1} to 10^{+0} weeks' gestation: 78/148	**Limitations** Risk of bias assessed using Newcastle Ottawa Scale for Cohort Studies Selection Bias: 1) Representativeness of the exposed cohort a) Truly representative of the population of women having home expulsion for medical abortion (1 star) 2) Selection of the non-exposed cohort: a) Comparison group drawn from the same population as exposed cohort (1 star) 3) Ascertainment of exposure: a) Ascertainment by medical records (1 star) 4) Demonstration that outcome of interest was not present at start of study: a) Yes (1 star) Comparability: 1) Comparability of cohorts on the basis of the design or analysis:

Study details	Participants	Comparison groups	Outcomes and Results	Comments
mifepristone-misoprostol medical abortion up to 70 days since last menstrual period in public sector facilities in Mexico City **Study dates** January to March 2012 **Source of funding** Not reported	telephone and emergency transportation 6) Those willing to comply with the study protocol 7) Those ready to provide an informed consent **Exclusion criteria** Not reported	≤9^{+0} weeks' gestation versus 9^{+1} to 10^{+0} weeks' gestation	Data for ≤9^{+0} weeks' gestation group calculated by NGA team combining data for < 56 days and <63 days group	No; Study does not control for confounding factors or adjusts for it in analysis. Outcome: 1) Assessment of outcome: a) For the outcome, complete abortion without the need for surgical intervention, the outcome assessment was done by clinical assessment (1 star). c) The outcomes vomiting, pain and diarrhoea were self-reported. 2) Was follow-up long enough for outcomes to occur: a) Yes; complete abortion rate, vomiting, pain and diarrhoea are usually captured during the treatment. The 7 days follow-up window adequately captures this (1 star). 3) Adequacy of follow up of cohorts c) No description of those lost to follow-up Overall quality: Low; No stars in comparability and inadequate follow-up **Other information** None
Full citation Winikoff, B., Dzuba, I. G., Chong, E., Goldberg, A. B., Steve Lichtenberg, E., Ball, C., Dean, G., Sacks, D., Crowden,	**Sample size** N=629 **Characteristics**	**Regimen:** 200 mg mifepristone; followed by 800 mcg buccal misoprostol 24 to 48 hours later at home	**Outcome:** **Need for emergency care** ≤9^{+0} weeks' gestation: 12/325;	**Limitations** Risk of bias assessed using Newcastle Ottawa Scale for Cohort Studies

Study details	Participants	Comparison groups	Outcomes and Results	Comments
W. A., Swica, Y., Extending outpatient medical abortion services through 70 days of gestational age, Obstetrics and Gynecology, 120, 1070-1076, 2012 **Ref Id** 802045 **Country/ies where the study was carried out** United States **Study type** Prospective cohort study **Aim of the study** To compare the efficacy and acceptability of medical abortion at 64 to 70 days from last menstrual period (LMP) to 57 to 63 days from LMP gestational age range **Study dates** August 2009 to February 2011 **Source of funding** Not reported	Age, mean (range): 26 (18 to 42) years **Inclusion criteria** 1) Eligible for medical abortion 2) Age more than 18 years 3) Confirmed intrauterine pregnancy 57 through 70 days from LMP 4) Those willing and able to provide informed consent 5) Access to a telephone and emergency transportation 6) Able to speak and read English or Spanish, and agree to follow study protocols. **Exclusion criteria** Not qualifying the inclusion criteria	**Follow up:** Follow up assessment was done at 7 to14 days for clinical assessment including ultrasonography **Further management:** Women with ongoing pregnancies at follow-up were recommended uterine suction curettage. Those with non-viable pregnancies were offered the choice of a repeat misoprostol dose, expectant management or suction curettage. Further follow-up visit after 1 week was suggested to those opting for expectant management or repeat dose. Suction curettage was recommended for persistent non-viable pregnancies. **Comparison groups:** ≤9^{+0} weeks' gestation versus 9^{+1} to 10^{+0} weeks' gestation	9^{+1} to 10^{+0} weeks' gestation: 14/304 **Outcome: Haemorrhage requiring blood transfusion or > 500ml of blood loss** ≤9^{+0} weeks' gestation: 2/325; 9^{+1} to 10^{+0} weeks' gestation: 1/304 **Outcome: Patient satisfaction (satisfied or very satisfied)** ≤9^{+0} weeks' gestation: 284/325; 9^{+1} to 10^{+0} weeks' gestation: 268/304; **Outcome: Complete abortion without the need for surgical intervention** ≤9^{+0} weeks' gestation: 304/325; 9^{+1} to 10^{+0} weeks' gestation: 282/304 **Outcome: Vomiting** ≤9^{+0} weeks' gestation: 114/318; 9^{+1} to 10^{+0} weeks' gestation: 137/300	Selection Bias: 1) Representativeness of the exposed cohort a) Truly representative of the population of women having home expulsion for medical abortion (1 star) 2) Selection of the non-exposed cohort a) Comparison group drawn from the same population as exposed cohort (1 star) 3) Ascertainment of exposure a) Ascertainment by medical records (1 star) 4) Demonstration that outcome of interest was not present at start of study a) Yes (1 star) Comparability: 1) Comparability of cohorts on the basis of the design or analysis No; Study does not control for confounding factors or adjusts for it in analysis. Outcome: 1) Assessment of outcome a) For the outcomes, need for emergency care, complete abortion rate and haemorrhage, outcome assessment was done by clinical assessment (1 star).

Study details	Participants	Comparison groups	Outcomes and Results	Comments
			Outcome: Diarrhoea ≤9^{+0} weeks' gestation: 57/318; 9^{+1} to 10^{+0} weeks' gestation: 52/300	b) The outcomes vomiting, patient satisfaction and diarrhoea were self-reported. 2) Was follow-up long enough for outcomes to occur: a) Yes; need for emergency care, haemorrhage, complete abortion rate, vomiting, diarrhoea and patient satisfaction are usually captured during the treatment. The 7 to14 days follow-up window adequately captures this (1 star). 3) Adequacy of follow up of cohorts c) <90% follow up; No description of those lost to follow-up Overall quality: Low; No stars in comparability and inadequate follow-up **Other information** None

LMP: last menstrual period: mcg: micrograms; NA: not applicable; NGA: National Guideline Alliance

Appendix E – Forest plots

Forest plots for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

Figure 2: Need for emergency care/hospital admission following expulsion at home at ≤ 9^{+0} weeks compared to 9^{+1} to 10^{+0} weeks' gestation

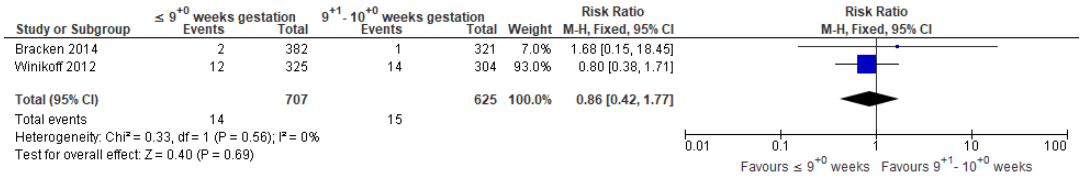


Figure 3: Haemorrhage >500ml/requiring blood transfusion following expulsion at home at ≤ 9^{+0} weeks compared to 9^{+1} to 10^{+0} weeks' gestation

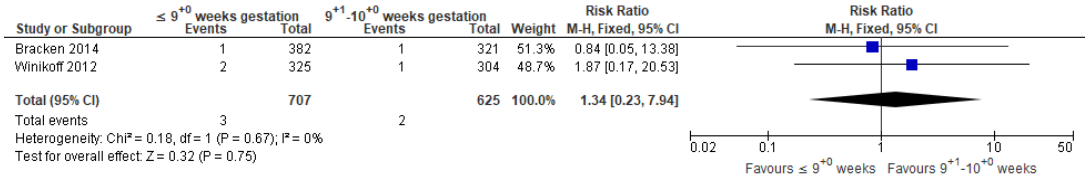


Figure 4: Complete abortion without the need for surgical intervention following expulsion at home at ≤ 9^{+0} weeks compared to 9^{+1} to 12^{+0} weeks' gestation

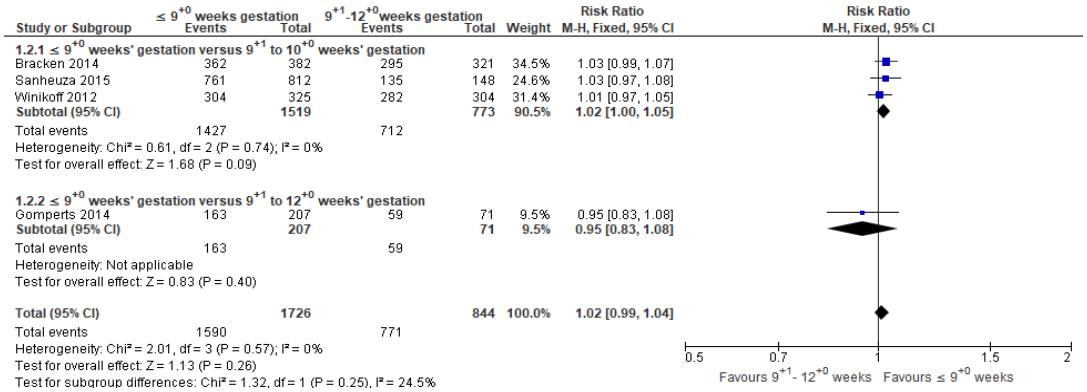


Figure 5: Vomiting following expulsion at home at ≤ 9^{+0} weeks compared to 9^{+1} to 10^{+0}weeks' gestation

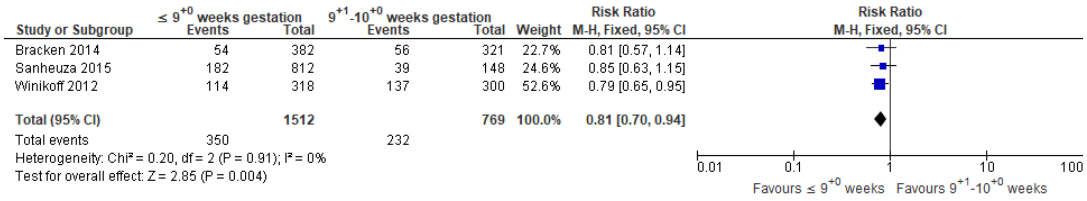


Figure 6: Pain following expulsion at home at ≤ 9^{+0} weeks compared to 9^{+1} to 12^{+0} weeks' gestation

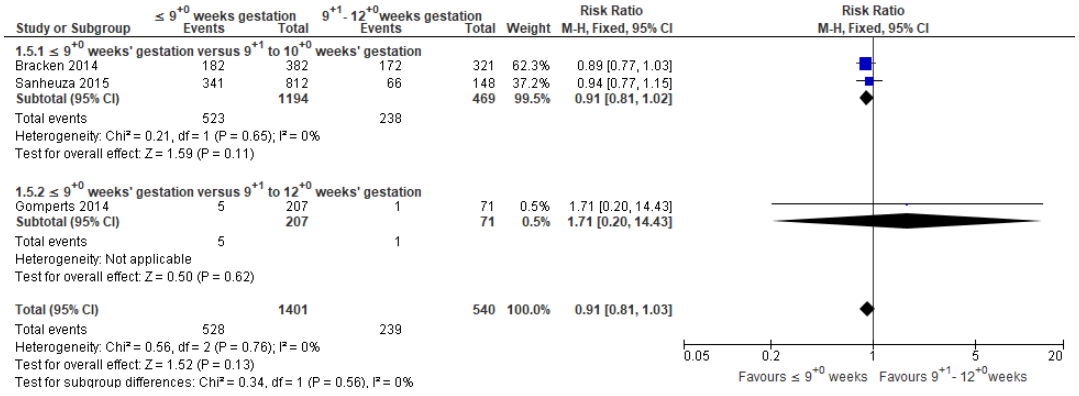
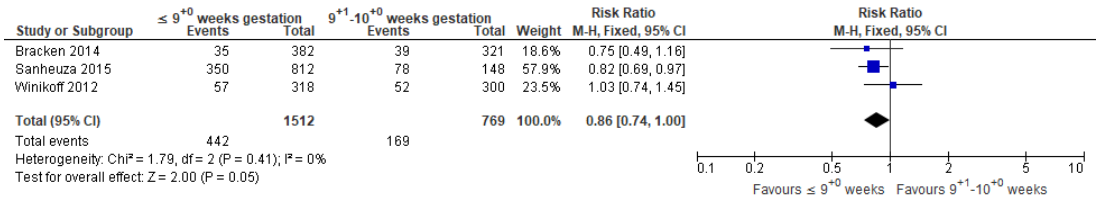


Figure 7: Diarrhoea following expulsion at home at ≤ 9^{+0} weeks compared to 9^{+1} to 10^{+0} weeks' gestation



Appendix F – GRADE tables

GRADE tables for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

Table 3: Clinical evidence profile

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	≤ 9 weeks	> 9 weeks	Relative (95% CI)	Absolute		
Need for emergency care/hospital admission												
2 (Bracken 2014; Winikoff 2012)	Cohort studies	Serious[1]	No serious inconsistency	No serious indirectness	Very serious[2]	None	14/707	15/625	RR 0.86 (0.42 to 1.77)	3 fewer per 1000 (from 14 fewer to 18 more)	VERY LOW	CRITICAL
Haemorrhage requiring transfusion or > 500ml of blood loss												
2 (Bracken 2014; Winikoff 2012)	Cohort studies	Serious[1]	No serious inconsistency	No serious indirectness	Very serious[2]	None	3/707	2/625	RR 1.34 (0.23 to 7.94)	1 more per 1000 (from 2 fewer to 22 more)	VERY LOW	CRITICAL
Patient satisfaction (satisfied or very satisfied)												
1 (Bracken 2014; Winikoff 2012; Sanhueza 2015)	Cohort studies	Serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	284/325	268/304	RR 0.99 (0.94 to 1.05)	9 fewer per 1000 (from 53 fewer to 44 more)	MODERATE	CRITICAL
Complete abortion without the need for surgical intervention (Pooled results: ≤ 9 weeks versus >9 weeks' gestation)												
4 (Bracken 2014; Winikoff 2012; Sanhueza 2015; Gomperts 2014)	Cohort studies	Very serious[4]	No serious inconsistency	No serious indirectness	Serious[5]	None	1590/1726	771/844	RR 1.02 (0.99 to 1.04)	18 more per 1000 (from 9 fewer to 37 more)	VERY LOW	IMPORTANT
Complete abortion without the need for surgical intervention (Subgroup: ≤ 9^{+0} weeks versus 9^{+1} to 10^{+0} weeks' gestation)												
3 (Bracken 2014; Winikoff	Cohort studies	Serious[1]	No serious inconsistency	No serious indirectness	Serious[5]	None	1427/1519	712/773	RR 1.02 (1.00 to 1.05)	18 more per 1000 (from 0	LOW	IMPORTANT

2012; Sanhueza 2015)										more to 46 more)		
Complete abortion without the need for surgical intervention (Subgroup: ≤ 9^{+0} weeks versus 9^{+1} to 12^{+0} weeks' gestation)												
1 (Gomperts 2014)	Cohort studies	Very serious[6]	No serious inconsistency	No serious indirectness	Very serious[5]	None	163/207	59/71	RR 0.95 (0.83 to 1.08)	42 fewer per 1000 (from 141 fewer to 66 more)	VERY LOW	IMPORTANT
Vomiting												
3 (Bracken 2014; Winikoff 2012; Sanhueza 2015)	Cohort studies	Serious[1]	No serious inconsistency	No serious indirectness	Serious[7]	None	350/1510	232/761	RR 0.8 (0.69 to 0.93)	61 fewer per 1000 (from 21 fewer to 95 fewer)	LOW	IMPORTANT
Pain (Pooled results: ≤ 9 weeks versus >9 weeks' gestation)												
3 (Bracken 2014; Sanhueza 2015; Gomperts 2014)	Cohort studies	Very serious[4]	No serious inconsistency	Serious[8]	No serious imprecision	None	528/1401	239/540	RR 0.91 (0.81 to 1.03)	40 fewer per 1000 (from 84 fewer to 13 more)	VERY LOW	IMPORTANT
Pain (Subgroup: ≤ 9^{+0} weeks versus 9^{+1} to 10^{+0} weeks' gestation)												
2 (Bracken 2014; Sanhueza 2015)	Cohort studies	Serious[1]	No serious inconsistency	Serious[8]	No serious imprecision	None	523/1194	238/469	RR 0.91 (0.81 to 1.02)	46 fewer per 1000 (from 96 fewer to 10 more)	LOW	IMPORTANT
Pain (Subgroup: ≤ 9^{+0} weeks versus 9^{+1} to 12^{+0} weeks' gestation)												
1 (Gomperts 2014)	Cohort studies	Very serious[6]	No serious inconsistency	No serious indirectness	Very serious[9]	None	5/207	1/71	RR 1.71 (0.20 to 14.43)	10 more per 1000 (from 11 fewer to 189 more)	VERY LOW	IMPORTANT
Diarrhoea												
3 (Bracken 2014; Winikoff 2012; Sanhueza 2015)	Cohort studies	Serious[1]	No serious inconsistency	No serious indirectness	Serious[7]	None	442/1510	169/762	RR 0.85 (0.73 to 0.99)	33 fewer per 1000 (from 2 fewer to 60 fewer)	LOW	IMPORTANT

CI: confidence interval; MID: minimally important difference; RR: risk ratio

[1]Downgraded by 1 level for serious risk of bias as some of the included studies were at high risk of bias as they did not control or adjust for confounding factors, and there was no description of those lost to follow-up

[2]The MID for this outcome is statistical significance, and the imprecision ratings were undertaken on that basis by using the optimum information size so that if the total event rate ≥300, then the quality was not downgraded, if the event rate = 150-299, then the quality was downgraded by 1 level and if the event rate <150, then the quality was downgraded by 2 levels

[3]Downgraded by 1 level for serious risk of bias as the included study was at high risk of bias as it did not control or adjust for confounding factors, and there was no description of those lost to follow-up
[4]Downgraded by 2 levels for very serious risk of bias as some of the included studies did not control or adjust for confounding factors, had self-reported period of gestation and provided no description of those lost to follow-up
[5]The MID for this outcome is 3%, and the imprecision ratings were undertaken on that basis by using the absolute effect estimates so that if the CI crosses 30 fewer (3% of 1000) or 30 more, then the quality was downgraded by 1 level. If the CI crosses both, then the quality was downgraded by 2 levels
[6]Downgraded by 2 levels for very serious risk of bias as the included study did not control or adjust for confounding factors, had self-reported period of gestation and provided no description of those lost to follow-up
[7]Downgraded by 1 level for serious imprecision as the 95% CI crosses 1 MID
[8]Downgraded by 1 level for serious indirectness as 1 of the included studies reports the need for nonsteroidal anti-inflammatory drugs for pain management instead of pain as an outcome
[9]Downgraded by 2 levels for serious imprecision as the 95% CI crosses 2 MIDs

Appendix G – Economic evidence study selection

Economic evidence for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

No economic evidence was identified which was applicable to this review question.

Appendix H – Economic evidence tables

Economic evidence tables for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

No economic evidence was identified which was applicable to this review question.

Appendix I – Economic evidence profiles

Economic evidence profiles for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

No economic evidence was identified which was applicable to this review question.

Appendix J – Economic analysis

Economic analysis for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

No economic analysis was conducted for this review question.

Appendix K – Excluded studies

Excluded studies for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

Clinical studies

Study	Reason for Exclusion
Abbas, D., Chong, E., Raymond, E. G., Outpatient medical abortion is safe and effective through 70 days gestation, Contraception, 92, 197-199, 2015	Review article
Aiken, A. R. A., Gomperts, R., Trussell, J., Experiences and characteristics of women seeking and completing at-home medical termination of pregnancy through online telemedicine in Ireland and Northern Ireland: a population-based analysis, BJOG: An International Journal of Obstetrics and Gynaecology, 124, 1208-1215, 2017	Only cases with gestation age less than 9 weeks were included
Akin, A., Blum, J., Ozalp, S., Onderoglu, L., Kirca, U., Bilgili, N., Kocoglu, G., Philip, N., Winikoff, B., Results and lessons learned from a small medical abortion clinical study in Turkey, Contraception, 70, 401-406, 2004	Only cases with gestation age less than 56 days were included
Ashok, P. W., Templeton, A., Wagaarachchi, P. T., Flett, G. M. M., Factors affecting the outcome of early medical abortion: A review of 4132 consecutive cases, BJOG: An International Journal of Obstetrics and Gynaecology, 109, 1281-1289, 2002	Only cases with gestational age less than 63 days were included
Aubeny,E., Chatellier,G., A randomized comparison of mifepristone and self-administered oral or vaginal misoprostol for early abortion, European Journal of Contraception and Reproductive Health Care, 5, 171-176, 2000	Only cases with gestation age less than 49 days were included
Bartz,D., Goldberg,A., Medication abortion, Clinical Obstetrics and Gynecology, 52, 140-150, 2009	Review article
Basu, R., Gundlach, T., Tasker, M., Mifepristone and misoprostol for medical termination of pregnancy: The effectiveness of a flexible regimen, Journal of Family Planning and Reproductive Health Care, 29, 139-141, 2003	Hospital based abortion
Bebbington, M. W., Kent, N., Lim, K., Gagnon, A., Delisle, M. R., Tessier, F., Wilson, R. A., Ngai, S. W., Vaginal misoprostol induced midtrimester termination of pregnancy more	Hospital based abortion

Study	Reason for Exclusion
quickly than oral misoprostol, Evidence-based Obstetrics and Gynecology, 5, 79-80, 2003	
Beckman, L. J., Harvey, S. M., Experience and acceptability of medical abortion with mifepristone and misoprostol among U.S. women, Womens Health Issues, 7, 253-62, 1997	Comparison of outcomes based on gestation age not available
Blum, J., Raghavan, S., Dabash, R., Ngoc, N. T. N., Chelli, H., Hajri, S., Conkling, K., Winikoff, B., Comparison of misoprostol-only and combined mifepristone-misoprostol regimens for home-based early medical abortion in Tunisia and Vietnam, International Journal of Gynecology and Obstetrics, 118, 166-171, 2012	Only cases with gestational age less than 63 days were included
Boersma, A. A., Meyboom-De Jong, B., Kleiverda, G., Mifepristone followed by home administration of buccal misoprostol for medical abortion up to 70 days of amenorrhoea in a general practice in Curacao, European Journal of Contraception and Reproductive Health Care, 16, 61-66, 2011	Less than 50 participants in each arm of comparison groups
Carbonell, J. L. L., Varela, L., Velazco, A., Fernandez, C., The use of misoprostol for termination of early pregnancy, Contraception, 55, 165-168, 1997	Does not include mifepristone and misoprostol regimen
Chen, M. J., Creinin, M. D., Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review, Obstet Gynecol, 126, 12-21, 2015	Relevant studies from this systematic review are included individually in the current review
Clark, W. H., Hassoun, D., Gemzell-Danielsson, K., Fiala, C., Winikoff, B., Home use of two doses of misoprostol after mifepristone for medical abortion: A pilot study in Sweden and France, European Journal of Contraception and Reproductive Health Care, 10, 184-191, 2005	Only cases with gestational age less than 49 days were included
Conkling, K., Karki, C., Tuladhar, H., Bracken, H., Winikoff, B., A prospective open-label study of home use of mifepristone for medical abortion in Nepal, International Journal of Gynecology and Obstetrics, 128, 220-223, 2015	Outcomes not reported separately for those more than 9 weeks' gestation
Dzuba, I., Chong, E., Adams, M. C., Ali, R., Rzayeva, G., Hannum, C., Lichtenberg, E. S., Nhu Ngoc, N. T., Patel, A., Sanhueza, P., Tsertsvadze, G., Winikoff, B., Outpatient mifepristone-misoprostol medical abortion through 77 days of gestation, European Journal of Contraception and Reproductive Health Care, 21, 62, 2016	Full text is an abstract. Further details about the study data is not available.
Esen, Umo Ita, Early medical abortion at home...Cameron S, Glasier A, Dewart H, et al. Women's experiences of the final stage of early	Letter to editor

Study	Reason for Exclusion
medical abortion at home: results of a pilot survey. J Fam Plann Reprod Health Care 2010;36:213-216, 37, 123-124, 2011	
Gallo, M. F., Cahill, S., Castleman, L., Mitchell, E. M. H., A systematic review of more than one dose of misoprostol after mifepristone for abortion up to 10 weeks of gestation, Contraception, 74, 36-41, 2006	All included studies in this systematic review have gestational period less than 9 weeks
Gomperts, R., Jelinska, K., Davies, S., Gemzell-Danielsson, K., Kleiverda, G., Using telemedicine for termination of pregnancy with mifepristone and misoprostol in settings where there is no access to safe services, International Journal of Gynecology and Obstetrics, 2), S230-S231, 2009	Full text is an abstract. Further details about the study data is not available.
Gomperts, R., Kleiverda, G., Gemzell, K., The effectiveness of home medical abortions provided through telemedicine, International Journal of Gynecology and Obstetrics, 5), E299-E300, 2015	Full text is an abstract. Further details about the study data is not available.
Guengant, J. P., Bangou, J., Elul, B., Ellertson, C., Mifepristone-misoprostol medical abortion: Home administration of misoprostol in Guadeloupe, Contraception, 60, 167-172, 1999	Only cases with gestational age less than 49 days were included
Hamoda, H., Ashok, P. W., Flett, G. M. M., Templeton, A., A randomised controlled trial of mifepristone in combination with misoprostol administered sublingually or vaginally for medical abortion up to 13 weeks of gestation, BJOG: An International Journal of Obstetrics and Gynaecology, 112, 1102-1108, 2005	Segregated data for gestation groups of interest was not available.
Jain, J. K., Dutton, C., Harwood, B., Meckstroth, K. R., Mishell Jr, D. R., A prospective randomized, double-blinded, placebo-controlled trial comparing mifepristone and vaginal misoprostol to vaginal misoprostol alone for elective termination of early pregnancy, Human Reproduction, 17, 1477-1482, 2002	Only cases with gestational age less than 56 days were included
Kawonga, M., Blanchard, K., Cooper, D., Cullingworth, L., Dickson, K., Harrison, T., Von Mollendorf, C., Winikoff, B., Integrating medical abortion into safe abortion services: Experience from three pilot sites in South Africa, Journal of Family Planning and Reproductive Health Care, 34, 159-164, 2008	Only cases with gestational age less than 56 days were included
Kiran, U., Amin, P., Penketh, R. J., Self-administration of misoprostol for termination of pregnancy: Safety and efficacy, Journal of obstetrics and gynaecology, 24, 155-156, 2004	Only 8 participants were in the more than 9 weeks' gestation period group
Kiran, U., Amin, P., Penketh, R. J., Self-administration of vaginal misoprostol after	Less than 50 participants in each comparison group

Study	Reason for Exclusion
mifepristone for termination of pregnancy: Patient acceptability, Journal of obstetrics and gynaecology, 26, 679-681, 2006	
Mention, J. E., Lanta, S., Drean, Y., Lalou, Y., Barbier, M., Early home abortion and immediate contraception with Evra (R) patch, Journal de Gynecologie Obstetrique et Biologie de la Reproduction, 40, 415-418, 2011	Full text in French
Patil, E., Edelman, A., Medical Abortion: Use of Mifepristone and Misoprostol in First and Second Trimesters of Pregnancy, Current Obstetrics and Gynecology Reports, 4, 69-78, 2015	Review article
Platais, I., Tsereteli, T., Grebennikova, G., Lotarevich, T., Winikoff, B., Prospective study of home use of mifepristone and misoprostol for medical abortion up to 10 weeks of pregnancy in Kazakhstan, International Journal of Gynecology and Obstetrics, 134, 268-271, 2016	Less than 50 participants in the comparison group > 9 weeks' gestation
Provansal, M., Mimari, R., Gregoire, B., Agostini, A., Thirion, X., Gamerre, M., Medical abortion at home and at hospital: A trial of efficacy and acceptability, Gynecologie Obstetrique & Fertilite, 37, 850-856, 2009	Full text in French
Raghavan, S., Maistruk, G., Shochet, T., Bannikov, V., Posohova, S., Zhuk, S., Lishchuk, V., Winikoff, B., Efficacy and acceptability of early mifepristone-misoprostol medical abortion in Ukraine: Results of two clinical trials, European Journal of Contraception and Reproductive Health Care, 18, 112-119, 2013	Only cases with gestational age less than 63 days were included
Schaff, E. A., Fielding, S. L., Westhoff, C., Ngai, S. W., For early medical abortion, 800 mug misoprostol was more efficacious as a single vaginal dose, than as two oral doses, Evidence-based Obstetrics and Gynecology, 4, 134-135, 2002	Only cases with gestational age less than 9 weeks were included
Schellekens, M., Gomperts, R., Kleiverda, G., Danielsson, K. G., The outcome of home medical abortions provided through telemedicine, European Journal of Contraception and Reproductive Health Care, 21, 63-64, 2016	Full text is an abstract. Further details about the study data is not available.
Shannon, C. S., Winikoff, B., Hausknecht, R., Schaff, E., Blumenthal, P. D., Oyer, D., Sankey, H., Wolff, J., Goldberg, R., Multicenter trial of a simplified mifepristone medical abortion regimen, Obstetrics and Gynecology, 105, 345-351, 2005	Only cases with gestational age less than 49 days were included
Tan, Y. L., Singh, K., Tan, K. H., Gosavi, A., Koh, D., Abbas, D., Winikoff, B., Acceptability	Less than 50 participants (n=11) in the >9 weeks' gestation comparison group

Study	Reason for Exclusion
and feasibility of outpatient medical abortion with mifepristone and misoprostol up to 70 days gestation in Singapore, European Journal of Obstetrics Gynecology and Reproductive Biology, 229, 144-147, 2018	

Economic studies

No economic evidence was identified for this review. See supplementary material 2 for further information.

Appendix L – Research recommendations

Research recommendations for review question: For women who are having medical abortion, what gestational limit for expulsion at home (i.e., setting outside of clinical facility) offers the best balance of benefits and harms?

For women who are having medical abortion between 10^{+1} and 12^{+0} weeks, what is the efficacy and acceptability of expulsion at home compared with expulsion in a clinical setting?

Why this is important?

Women after 10^{+0} weeks of pregnancy who choose a medical method of abortion have traditionally been admitted to a medical facility to pass the pregnancy. In contrast, women who are at the same gestation but with a non-viable pregnancy may choose to have medical management at home. The medical regimen used between 10^{+1} and 12^{+0} weeks' gestation is the same as that at less than 10 weeks except that additional dose of misoprostol may be required, and that bleeding/ pain may be greater and the acceptability of expulsion at home for women having a medical abortion at this gestation in the UK is not known.

There is some evidence from other countries where termination is restricted, that medical abortion at home up to 12 weeks is safe and acceptable. Considering the objective of the proposed research to compare the efficacy in two different settings, a randomised controlled trial design was considered to be suitable for address the research question.

Table 4: Research recommendation rationale

Research question	For women who are having medical abortion between 10^{+1} and 12^{+0} weeks, what is the efficacy and acceptability of expulsion at home compared to with expulsion in a clinical setting?
Importance to 'patients' or the population	May expand access to medical abortion for woman Home expulsion may increase acceptability for women Home expulsion may be associated with less pain/ discomfort / anxiety for women
Relevance to NICE guidance	Determine the gestational limit for expulsion at home that offers the best balance of benefits and harms
Relevance to the NHS	Expansion of access to medical abortion May liberate hospital / clinic resources for other procedures
National priorities	Better use of hospital / clinic resources
Current evidence base	Non UK settings where abortion is restricted
Equality	Home expulsion may facilitate access to medical abortion for women living far away from clinical settings/ hospitals

NHS: National Health Service; NICE: National Institute for Health and Care Excellence; UK: United Kingdom

Table 5: Research recommendation modified PICO table

Criterion	Explanation
Population	Women who are between 10^{+1} and 12^{+0} weeks pregnant seeking medical abortion
Intervention	Home expulsion

Criterion	Explanation
Comparator	Hospital/ clinic expulsion
Outcome	Success of medical abortion, complications, pain, patient acceptability with setting, cost effectiveness
Study design	RCT
Timeframe	18 months
Additional information	Permission from Department of Health needs to be sought to self-administer misoprostol at home for this study

RCT: randomized controlled trial