

Abortion care guideline

Supplementary material 3: Evidence-to-Decision frameworks for the service delivery recommendations and best practice statements

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Supplementary material 3: Evidence-to-Decision frameworks for the service delivery recommendations and best practice statements

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Note: Details of all PICO (population, intervention, comparator, outcome) questions are provided in Annex 10 in the main guideline document: *Abortion care guideline* (2021).¹

¹ The main guideline is available at: <https://apps.who.int/iris/handle/10665/349316>.

Acronyms and abbreviations

ANM	auxiliary nurse midwife
CF	competency framework
CHW	community health worker
CI	confidence interval
DMPA	depot medroxyprogesterone acetate
DMPA-SC	subcutaneous DMPA
ERRG	Evidence and Recommendations Review Group
EtD	Evidence to Decision
FP	family planning
GRADE	Grading of Recommendations Assessment, Development and Evaluation
IUD	intrauterine device
MD	mean difference
PICO	population, intervention, comparator, outcome(s)
RCT	randomized controlled trial
RR	risk ratio
Rh	Rhesus
RTI	reproductive tract infection
SoF	Summary of Findings
SRH	sexual and reproductive health
STI	sexually transmitted infection
VA	vacuum aspiration

GRADE Working Group grades of certainty of evidence

(use as a reference for the SoF tables)

- **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect
- **Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
- **Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
- **Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

1. EtD framework for Information provision by pharmacy workers

Recommendation 4: Across the continuum of abortion care:

- a. **Recommend** provision of information on abortion care by community health workers, pharmacists, traditional and complementary medicine professionals, auxiliary nurses/auxiliary nurse midwives (ANMs), nurses, midwives, associate/advanced associate clinicians, generalist medical practitioners and specialist medical practitioners.
- b. **Suggest** provision of information on abortion care by pharmacy workers.

PICO 1: For a person seeking information about abortion care (before or after treatment/abortion), is information on the availability of safe providers for abortion care (abortion provision, care for complications of abortion, care for incomplete abortion) provided by a pharmacy worker a safe, effective and satisfactory/acceptable alternative to no provision of information (usual practice)? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A systematic review by Cochrane Response serves as the evidence base for this key question. No non-comparative studies reporting on pharmacy workers providing information on the availability of safe providers for abortion/care were identified by the search strategy.

Study settings: N/A

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

No studies were identified for this PICO question.

Desirable effects:

No studies were identified for this PICO question.

Undesirable effects:

No studies were identified for this PICO question.

Additional information

Pharmacy workers in one study included a mix of health worker cadres (pharmacy workers, health assistants, staff nurses, auxiliary nurse-midwives, and auxiliary health workers and community medical assistants). Changes in pharmacy worker knowledge and practice were reported but the effects were not estimable because of the study design.

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

		X	
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

				X		
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

					X	
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

Equity:

What would be the impact on health equity?

Judgement (draft)

					X	
Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased

Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

					X
Unable to determine	Varies	No	Probably No	Probably Yes	Yes

Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

					X
Unable to determine	Varies	No	Probably No	Probably Yes	Yes

Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to provide information on abortion care match the typical competencies of pharmacy workers

The BLUE highlighted boxes are the most relevant for the topic and cadre

DOMAIN	Competency	Pharmacy workers
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health (SRH) care (fundamental component of all competencies)	
Domain 3 General SRH competencies for health workers	<p>Competency 4: The primary health-care team member(s) provide high-quality health education related to SRH, and SRH services</p> <p>Tasks:</p> <ol style="list-style-type: none"> 1) Assess the local sociocultural, legal and gender concerns and issues related to programme implementation and service provision 2) Create an environment that is conducive to learning 3) Facilitate learning using a variety of techniques (discussion, demonstration, presentation) 4) Convey essential information related to specific SRH topics 5) Assess the transfer of learning <p>Competency 5: The primary health-care team member(s) provide high-quality counselling related to SRH, and SRH services</p> <p>Tasks:</p> <ol style="list-style-type: none"> 1) Plan a counselling session including the creation of a conducive counselling environment 2) Counsel effectively 3) Assess the effectiveness of counselling <p>Competency 6: The primary health-care team member(s) effectively assess the SRH needs of users of primary health care services for treatment and referral when necessary</p> <p>Tasks:</p> <ol style="list-style-type: none"> 1) Take an appropriate health history with a focus on factors related to SRH 2) Conduct a physical examination 3) Ensure faster and safe referral 4) Screen for male and female reproductive health preventable and/or treatable pathology 5) Obtain or refer for appropriate laboratory tests related to SRH 	

<p>Domain 4 Specific clinical competencies</p>	<p>Competency 10: The primary health care team member provides high-quality comprehensive abortion care</p> <p>Tasks as per Competencies 4–6 + the task to inform and counsel on spontaneous abortion, unwanted pregnancy and induced abortion</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • fertility return after abortion • symptoms and signs of abortion complications • risk factors for repeat spontaneous abortion • risks of unsafe abortion² • legal grounds for induced abortion • pregnancy options for women and couples, including those who are HIV positive • barriers to safe, legal abortion and how to address them • medical eligibility for abortion methods • emergency contraception and HIV post-exposure prophylaxis • how, when and where to refer women <p>Skills – ability to:</p> <ul style="list-style-type: none"> • provide complete and easy-to-understand information about abortion and recurrent abortions • refer the client to another provider in case of conscientious objection, or need for high-level care, or if abortion methods are not available • ability to refer for antenatal care (ANC) if the client decides to remain pregnant • ability to discuss SRH following abortion – i.e. contraception, STI screening 	<p>We suggest... (maintain)</p>
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² The items in bold are the most relevant competencies that were discussed with the Evidence and Recommendations Review Group (ERRG).

SUMMARY OF FINDINGS TABLE

No studies were identified for this PICO question.

References

Tamang A, Puri M, Lama K, Shrestha P. Pharmacy workers in Nepal can provide the correct information about using mifepristone and misoprostol to women seeking medication to induce abortion. *Reprod Health Matters*. 2014; 22(supp44): 104–15.

DRAFT

2. EtD framework for Pre- and post-abortion counselling

Recommendation 5: Across the continuum of abortion care:

- a. **Recommend** provision of counselling by community health workers, traditional and complementary medicine professionals, auxiliary nurses/ANMs, nurses, midwives, associate/advanced associate clinicians, generalist medical practitioners and specialist medical practitioners.
- b. **Suggest** provision of counselling by pharmacy workers and pharmacists.

PICO 2: For a pregnant person having an abortion, is pre- and post-abortion counselling provided by a traditional and complementary medicine professional, pharmacist, pharmacy worker or community health worker a safe, effective and satisfactory/acceptable alternative to counselling provided by in-clinic staff? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A systematic review by Cochrane Response serves as the evidence base for this key question. No comparative studies reporting on the provision of pre- and post-abortion counselling by traditional and complementary medicine professionals, pharmacists, pharmacy workers and community health workers (CHWs) were identified by the search strategy.

Study settings: N/A

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

No studies were identified for this PICO question.

Desirable effects:

No studies were identified for this PICO question.

Undesirable effects:

No studies were identified for this PICO question.

Additional information

One observational non-comparative study reporting a counselling intervention by CHW. They were trained to improve their knowledge of key aspects of contraceptive use and reproductive health care. Preliminary results from the pilot study revealed participants feeling comfortable speaking to their CHW about contraception and reproductive health care (*Chor et al. 2020*).

Reviews that informed the 2015 recommendation noted that recipients were generally very positive to community health worker programmes (moderate confidence) (*Glenton et al.*).

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

		X	
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

				X		
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

					X	
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

Equity:

What would be the impact on health equity?

Judgement (draft)

Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	X Probably increased	Increased
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Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

Unable to determine	Varies	No	Probably No	X Probably Yes	Yes
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Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	X Probably Yes	Yes
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Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to provide pre abortion and post abortion counselling match the typical competencies of the traditional and complementary medicine professionals, pharmacists, pharmacy workers and community health workers (CHWs)

The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	Traditional and complementary medicine professionals	Pharmacists	Pharmacy workers	Community health workers (CHWs)
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health care (fundamental component of all competencies)				
Domain 3 General SRH competencies for health workers	<i>See information in Section 1 (EtD 1) of this document</i>				
Domain 4 Specific clinical competencies	<p>Competency 10: The primary health care team member provides high-quality comprehensive abortion care</p> <p>Tasks as per Competencies 4–6 + the task to inform and counsel on spontaneous abortion, unwanted pregnancy and induced abortion</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • fertility return after abortion • symptoms and signs of abortion complications • risk factors for repeat spontaneous abortion • risks of unsafe abortion • legal grounds for induced abortion 	<p>Traditional and complementary medicine professionals</p> <p>We recommend (upgrade)</p>	<p>Pharmacists</p> <p>We suggest (upgrade)</p> <p>Condition: Balanced counselling is provided (to present both medical and surgical methods) and that there is linkage to health services should the client choose a surgical method</p>	<p>Pharmacy workers</p> <p>We suggest (upgrade)</p> <p>Condition: Balanced counselling is provided (to present both medical and surgical methods) and that there is linkage to health services should the client choose a surgical method</p>	<p>CHWs</p> <p>We recommend (upgrade)</p>

	<ul style="list-style-type: none"> • pregnancy options for women and couples, including those who are HIV positive • barriers to safe, legal abortion and how to address them • medical eligibility for abortion methods • emergency contraception and HIV post-exposure prophylaxis • how, when and where to refer women <p>Skills – ability to:</p> <ul style="list-style-type: none"> • provide complete and easy-to-understand information about abortion and recurrent abortions • refer the client to another provider in case of conscientious objection, or need for high-level care, or if abortion methods are not available • refer for antenatal care (ANC) if the client decides to remain pregnant • ability to discuss SRH following abortion – i.e. contraception, STI screening 				
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SUMMARY OF FINDINGS TABLE

No studies were identified for this PICO question.

References

- Chor J, Young D, Quinn MT, Gilliam M. A novel lay health worker training to help women engage in postabortion contraception and well-woman care. *Health Promot Pract.* 2020;21(2):172-4.
- Glenton C, Sorhaingo A, Ganatra B, Lewin S. Implementation considerations when expanding health worker roles to include safe abortion care: a five-country case study synthesis. *BMC Public Health* 2017;17. doi:10.1186/s12889-017-4764-z.

DRAFT

3. EtD framework for Cervical priming using medication and osmotic dilators

Recommendation 19. Cervical priming prior to surgical abortion using medication at any gestational age

Prior to surgical abortion at any gestational age:

- a. **Recommend** cervical priming with medication by traditional and complementary medicine professionals, auxiliary nurses/ANMs, nurses, midwives, associate/advanced associate clinicians, generalist medical practitioners and specialist medical practitioners.
- b. **Suggest** cervical priming with medication by community health workers, pharmacy workers and pharmacists.

PICO 3: For a pregnant person having an induced surgical abortion, is provision of cervical priming using osmotic dilators or medication by a traditional and complementary medicine professional, associate/advanced associate clinician, midwife, nurse or auxiliary nurse/auxiliary nurse midwife a safe, effective and satisfactory/acceptable alternative to provision of cervical priming by a physician? (Full details are available in Annex 10 in the main guideline)

BACKGROUND – Cervical priming using medication

Setting: Global

Perspective: Population

Literature review: A systematic review by Cochrane Response serves as the evidence base for this key question. No studies reporting on cervical priming using osmotic dilators by traditional and complementary medicine professionals, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers or community health workers were identified by the search strategy.

Study settings: N/A

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

No studies were identified for this PICO question.

Desirable effects:

No studies were identified for this PICO question.

Undesirable effects:

No studies were identified for this PICO question.

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

X			
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

X						
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

X						
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

Equity:

What would be the impact on health equity?

Judgement (draft)

X						
Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased

Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

Unable to determine	Varies	No	Probably No	X Probably Yes	Yes
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Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	X Probably Yes	Yes
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Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to match the typical competencies of the traditional and complementary medicine professionals, associate/advanced associate clinicians, midwives, nurses, auxiliary nurses/ANMs, pharmacists, pharmacy workers and community health workers

The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	Traditional and complementary medicine professionals	Associate/advanced associate clinicians	Midwives	Nurses	Auxiliary nurses/ANMs	Pharmacists	Pharmacy workers	Community health workers
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health care (fundamental component of all competencies)								
Domain 3 General SRH competencies for health workers	<i>See information in Section 1 (EtD 1) in this document</i>								
Domain 4 Specific clinical competencies	Competency 10: The primary health care team member provides high-quality comprehensive abortion care Tasks as per Competencies 4–6 + the task to provide for induced abortion Knowledge: • abortion law and its applicability (legal	Traditional and complementary medicine professionals We recommend	Associate/advanced associate clinicians We recommend	Midwives We recommend	Nurses We recommend	Auxiliary nurses/ANMs We recommend	Pharmacists We suggest With additional supporting text on the continuity of care (as this is part of a process)	Pharmacy workers We suggest With additional supporting text on the continuity of care (as this is part of a process)	Community health workers We suggest With additional supporting text on the continuity

	<p>protection available to women and providers)</p> <ul style="list-style-type: none"> • national norms, standards and guidelines for abortion care, including rules for conscientious objection to provision of induced abortion • confirmation of pregnancy and determination of gestational age • medical eligibility for all available abortion methods • pain management, including verbal reassurance • appropriate referral for abortion after 12 weeks since last menstrual period <p>Knowledge (Updated CF):</p> <ul style="list-style-type: none"> -Criteria for cervical preparation/priming -Protocols for use of laminaria or pharmacologic agents, indications, eligibility criteria, mode of action, route of administration, dosage and frequency -Infection prevention and waste management protocols 								<p>of care (as this is part of a process)</p> <p>*closer connection to the health system that allows for this to upgrade</p>
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	<p>-Complications and their management</p> <p>Skills – ability to:</p> <ul style="list-style-type: none"> • perform a bimanual uterine examination • perform vacuum aspiration (VA) and to provide medical abortion according to national standards, including appropriate pain management • manage abortion-related complications <p>Updated CF</p> <ul style="list-style-type: none"> -Confirm client eligibility and consent for procedure. -Explain cervical preparation method, administration and expected effects. -Check integrity of packaging and expiration dates of laminaria and pharmacologic agents used. -Insert or administer selected agent(s). -Provide pain management and anxiolytics as indicated. -Assess for adequacy of cervical response after 								
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	required time interval; repeat agent if indicated. -Assess amount of vaginal bleeding. -Check that all laminaria have been expelled or removed. -Maintain infection prevention and waste management standards. -Manage side-effects and complications								
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DRAFT

SUMMARY OF FINDINGS TABLE

No studies were identified for this PICO question.

BACKGROUND – Cervical priming using osmotic dilators

Setting: Global

Perspective: Population

Literature review: A systematic review by Cochrane Response serves as the evidence base for this key question. No studies reporting on cervical priming using osmotic dilators by traditional and complementary medicine professionals, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers or community health workers were identified by the search strategy.

Study settings: N/A

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

No studies were identified for this PICO question.

Desirable effects:

No studies were identified for this PICO question.

Undesirable effects:

No studies were identified for this PICO question.

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

X			
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

X						
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

					X	
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

Equity:

What would be the impact on health equity?

Judgement (draft)

				X		
Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased

Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

			X		
Unable to determine	Varies	No	Probably No	Probably Yes	Yes

Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	X Probably Yes	Yes
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DRAFT

Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to match the typical competencies of the traditional and complementary medicine professionals, associate/advanced associate clinicians, midwives, nurses and auxiliary nurses/ANMs.

The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	Traditional and complementary medicine professionals	Associate/advanced associate clinicians	Midwives	Nurses	Auxiliary nurses/ANMs
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health care (fundamental component of all competencies)					
Domain 3 General SRH competencies for health workers	<i>See information in Section 1 (EtD 1) of this document.</i>					
Domain 4 Specific clinical competencies	<p>Competency 10: The primary health-care team member provides high-quality comprehensive abortion care</p> <p>Tasks as per Competencies 4–6 + the task to provide for induced abortion</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • abortion law and its applicability (legal protection available to women and providers) • national norms, standards and guidelines for abortion care, including rules for conscientious 	<p>Traditional and complementary medicine professionals</p> <p>We suggest (upgrade)</p>	<p>Associate/advanced associate clinicians</p> <p>We recommend</p>	<p>Midwives</p> <p>We recommend</p>	<p>Nurses</p> <p>We recommend</p>	<p>Auxiliary nurses/ANMs</p> <p>We recommend</p>

	<p>objection to provision of induced abortion</p> <ul style="list-style-type: none"> • confirmation of pregnancy and determination of gestational age • medical eligibility for all available abortion methods • pain management, including verbal reassurance • appropriate referral for abortion after 12 weeks since last menstrual period <p>Knowledge (<i>Updated CF</i>):</p> <ul style="list-style-type: none"> -Criteria for cervical preparation/priming -Protocols for use of laminaria or pharmacologic agents, indications, eligibility criteria, mode of action, route of administration, dosage and frequency -Infection prevention and waste management protocols -Complications and their management <p>Skills – ability to:</p> <ul style="list-style-type: none"> • perform a bimanual uterine examination • perform VA and to provide medical abortion according to national standards, including appropriate pain management • manage abortion-related complications 					
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	<p>Updated CF</p> <ul style="list-style-type: none"> -Confirm client eligibility and consent for procedure. -Explain cervical preparation method, administration and expected effects. -Check integrity of packaging and expiration dates of laminaria and pharmacologic agents used. -Insert or administer selected agent(s). -Provide pain management and anxiolytics as indicated. -Assess for adequacy of cervical response after required time interval; repeat agent if indicated. -Assess amount of vaginal bleeding. -Check that all laminaria have been expelled or removed. -Maintain infection prevention and waste management standards. -Manage side-effects and complications 					
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SUMMARY OF FINDINGS TABLE

No studies were identified for this PICO question.

DRAFT

4. EtD framework for Vacuum aspiration for all indications < 14 weeks

Recommendation 24: Vacuum aspiration for surgical abortion at < 14 weeks:

- a. **Recommend** vacuum aspiration by traditional and complementary medicine professionals, nurses, midwives, associate/advanced associate clinicians, generalist medical practitioners and specialist medical practitioners.
- b. **Suggest** vacuum aspiration by auxiliary nurses/ANMs.

PICO 4: For a pregnant person seeking induced abortion or treatment for incomplete abortion or miscarriage (i.e. all indications for vacuum aspiration), is provision of vacuum aspiration by a traditional and complementary medicine professional, auxiliary nurse midwife or auxiliary nurse a safe, effective and satisfactory/acceptable alternative to provision of vacuum aspiration by a physician? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A Cochrane systematic review serves as the evidence base for this key question. Five studies (1 RCT, 4 cohort) were identified that compared vacuum aspiration by mid-level providers to physicians. The five studies assessed the following comparison:

- Vacuum aspiration by midwives compared to physicians
- Vacuum aspiration by physician assistants compared to physicians
- Vacuum aspiration by nurses compared to physicians
- Vacuum aspiration by advanced practice clinicians compared to physicians
- Vacuum aspiration by nurse practitioners, nurse midwives and physician assistants compared to physicians

Study settings: India, South Africa, Viet Nam, United States of America (USA)

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

There was no research evidence on these cadres performing vacuum aspiration (≤ 14 weeks) that allowed for pooled analysis and application of GRADE.

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

		X	
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

				X		
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

					X	
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

Equity:

What would be the impact on health equity?

Judgement (draft)

					X	
Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased

Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to match the typical competencies of the traditional and complementary medicine professionals and auxiliary nurses/ANMs.

The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	Traditional and complementary medicine professionals	Auxiliary nurses/ANMs
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health care (fundamental component of all competencies)		
Domain 3 General SRH competencies for health workers	<i>See information in Section 1 (EtD 1) in this document.</i>		
Domain 4 Specific clinical competencies	<p>Competency 10: The primary health care team member provide high-quality comprehensive abortion care</p> <p>Tasks as per Competencies 4–6 + the task to provide, or refer for, induced abortion</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • abortion law and its applicability (legal protection available to women and providers) • national norms, standards and guidelines for abortion care, including rules for conscientious objection to provision of induced abortion • confirmation of pregnancy and determination of gestational age • medical eligibility for all available abortion methods • pain management, including verbal reassurance • appropriate referral for abortion after 12 weeks since last menstrual period <p>Skills – ability to:</p>	<p>Doctors of complementary medicine:</p> <p>We recommend (upgrade)</p>	<p>Auxiliary nurses/ANMs</p> <p>We suggest (maintain)</p> <p>With the same condition from the 2015 recommendation</p>

	<ul style="list-style-type: none"> • perform a bimanual uterine examination • perform VA and to provide medical abortion according to national standards, including appropriate pain management • manage abortion-related complications 		
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Reference

Barnard S, Kim C, Park MH, Ngo TD. Doctors or mid-level providers for abortion. Cochrane Database Syst Rev. 2021 (unpublished).

5. EtD Framework for Dilatation and evacuation (D&E) for surgical abortion ≥ 14 weeks

Recommendation 26: D&E for surgical abortion at ≥ 14 weeks

For surgical abortion at ≥ 14 weeks:

- a. **Recommend** D&E by generalist medical practitioners and specialist medical practitioners.
- b. **Suggest** D&E by traditional and complementary medicine professionals, midwives and associate/advanced associate clinicians.

PICO 5: For a pregnant person having a surgical abortion (D&E), is provision by a traditional and complementary medicine professional, associate/advanced associate clinician, midwife a safe, effective or satisfactory/acceptable alternative to provision of care by a doctor? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A systematic review was undertaken to address the above question. There were no studies that met the inclusion criteria for D&E provision.

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

There was no research evidence on the cadres performing surgical or medical abortion beyond 12 weeks that allowed for pooled analysis and application of GRADE.

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

X			
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

X						
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

X						
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

Equity:

What would be the impact on health equity?

Judgement (draft)

X						
Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased

Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

X					
Unable to determine	Varies	No	Probably No	Probably Yes	Yes

Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	X Probably Yes	Yes
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DRAFT

Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to provide surgical abortion beyond 12 weeks match the typical competencies of the traditional and complementary medicine professionals associate/advanced associate clinicians, midwives

The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	Traditional and complementary medicine professionals	Associate/advanced associate clinicians	Midwives
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health care (fundamental component of all competencies)			
Domain 3 General SRH competencies for health workers	<i>See information in Section 1 (EtD 1) in this document</i>			
Domain 4 Specific clinical competencies	<p>Competency 10: The primary health care team member provides high-quality comprehensive abortion care</p> <p>Tasks as per Competencies 4-6 + the task to provide for induced abortion</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • abortion law and its applicability (legal protection available to women and providers) • national norms, standards and guidelines for abortion care, including rules for conscientious objection to provision of induced abortion • confirmation of pregnancy and determination of gestational age • medical eligibility for all available abortion methods • pain management, including verbal reassurance • appropriate referral for abortion after 12 weeks since last menstrual period <p>Knowledge (Updated CF):</p>	<p>Traditional and complementary medicine professionals</p> <p>We suggest</p>	<p>Associate/advanced associate clinicians</p> <p>We suggest</p>	<p>Midwives:</p> <p>We suggest</p>

	<ul style="list-style-type: none"> -Female anatomy and physiology -Comparative effectiveness, risks and benefits of abortion methods -Eligibility criteria and contraindications for method -Pain management protocols -Protocol for D&E method of abortion -Protocol for examination of fetal parts -Management of complications -Emergency referral protocols -Infection prevention and waste management protocols -Contraceptive methods appropriate post-D&E procedure -Self-care instructions <p>Skills – ability to:</p> <ul style="list-style-type: none"> • perform a bimanual uterine examination • perform VA and to provide medical abortion according to national standards, including appropriate pain management • manage abortion-related complications <p>Skills (Updated CF)</p> <ul style="list-style-type: none"> -Confirm clinical indication, gestational age, eligibility and consent for method, including consent for contraceptive method. -Review method effectiveness, benefits, risks, side-effects, complications and their management with individual. -Verbally inform individual of steps for method and what to expect. -Administer pre-medication (antibiotics, anxiolytics, analgesia) as per protocol. -Verify individual has emptied bladder immediately prior to procedure. -Prepare all supplies for procedure, checking integrity of packaging and expiration dates. -Monitor individual's vital signs, pain level and amount of vaginal bleeding as per protocol. -Provide pain management. 			
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	<ul style="list-style-type: none"> -Perform bimanual examination, determining uterine size, position, presence or absence of adnexal mass or tenderness. -Cleanse cervix and vagina with antiseptic. -Dilate cervix and perform aspiration using appropriately sized cannula. -Insert grasping forceps and extract fetal parts. -Perform vacuum aspiration to remove remaining tissue. -Examine tissue to confirm presence of all foetal parts. -Repeat aspiration or perform ultrasound examination if required. -Manage complications, including failed procedure. -Administer Rh-immunoglobulin if indicated. -Provide post-abortion contraception where desired. -Maintain infection prevention and waste management standards. 			
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DRAFT

6. EtD framework for Medical abortion < 12 weeks

Recommendation 28: Medical abortion at < 12 weeks in whole or in part (i.e. performing all or some of the subtasks)

For medical abortion at < 12 weeks:

Recommend medical management by self (see Recommendation 50, Supplementary material 2), community health workers, pharmacy workers, pharmacists, traditional and complementary medicine professionals, auxiliary nurses/ANMs, nurses, midwives, associate/advanced associate clinicians, generalist medical practitioners and specialist medical practitioners.

PICO 6: For a pregnant person seeking medical abortion at < 12 weeks, is provision of medical abortion (i.e. assessment of eligibility, administering quality assured medications, assessment of outcome/success) by a traditional and complementary medicine professional, pharmacist, pharmacy worker or community health worker, a safe, effective and satisfactory/acceptable alternative to provision of medical abortion by a physician?

PICO 6a: For a pregnant person seeking medical abortion, is assessment of eligibility for medical abortion by a traditional and complementary medicine professional, pharmacist, pharmacy worker or community health worker a safe, effective and satisfactory/acceptable alternative to – and as accurate as – assessment by a physician?

PICO 6b: For a pregnant person seeking medical abortion, is administration of medications for medical abortion (i.e. information provision, dispensing of quality assured medications, referral to a reputable source for medications) with instructions for their use by a traditional and complementary medicine professional, pharmacist, pharmacy worker or community health worker a safe, effective and satisfactory/acceptable alternative to administration by a physician?

PICO 6c: For a pregnant person seeking medical abortion, is assessment of the success of the medical abortion process by a traditional and complementary medicine professional, pharmacist, pharmacy worker or community health worker a safe, effective and satisfactory/acceptable alternative to – and as accurate as – assessment by a physician? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A Cochrane systematic review serves as the evidence base for this key question. Four studies (3 RCT, 1 cohort) were identified that compared medical abortion provision by mid-level providers to physicians. The four studies assessed the following comparison:

- nurse-midwives compared to physicians
- nurses compared to physicians
- ayurvedic physicians compared to physicians

Study settings: India, Mexico, Nepal, Sweden

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

Desirable effects:

- Women in both groups reported satisfaction with their provider type. This is based on low certainty of evidence.

Undesirable effects:

- Slightly more women in the intervention group (ayurvedic physicians) had a failed abortion than women in the comparison group (physician). This is based on very low certainty of evidence.

Balance of effects:

		X		
Favours the comparison	May favour the comparison	No difference between the intervention and the comparison	May favour the intervention	Favours the intervention

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

		X	
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

				X		
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

				X		
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

Equity:

What would be the impact on health equity?

Judgement (draft)

					X	
Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased

Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

					X
Unable to determine	Varies	No	Probably No	Probably Yes	Yes

Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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DRAFT

Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to provide medical abortion match the typical competencies of the traditional and complementary medicine professionals

The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	Traditional and complementary medicine professionals
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health care (fundamental component of all competencies)	
Domain 3 General SRH competencies for health workers	<i>See information in Section 1 (EtD 1) in this document</i>	
Domain 4 Specific clinical competencies	<p>Competency 10: The primary health care team member provide high-quality comprehensive abortion care</p> <p>Tasks as per Competencies 4-6 + the task to provide, or refer for, induced abortion</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • abortion law and its applicability (legal protection available to women and providers) • national norms, standards and guidelines for abortion care, including rules for conscientious objection to provision of induced abortion • confirmation of pregnancy and determination of gestational age • medical eligibility for all available abortion methods • pain management, including verbal reassurance • appropriate referral for abortion after 12 weeks since last menstrual period <p>Skills – ability to:</p> <ul style="list-style-type: none"> • perform a bimanual uterine examination • perform VA and to provide medical abortion according to national standards, including appropriate pain management 	<p>Doctors of complementary medicine:</p> <p>We recommend....</p>

	• manage abortion-related complications	
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References

Barnard S, Kim C, Park MH, Ngo TD. Doctors or mid-level providers for abortion. Cochrane Database Syst Rev. 2021 (unpublished).

Jejeebhoy SJ, Kalyanwala S, Mundle S, Tank J, Xavier AJ, Kumar R, et al. Feasibility of expanding the medication abortion provider base in India to include ayurvedic physicians and nurses. Int Perspect Sex Reprod Health. 2012;38(3):133-42. doi:10.1363/3813312.

DRAFT

SUMMARY OF FINDINGS TABLE

Question: Q1a. Mid-level providers compared to doctors for medical abortion

Bibliography: Barnard S, Kim C, Park MH, Ngo TD. Doctors or mid-level providers for abortion. Cochrane Database Syst Rev. 2021 (unpublished).

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Q1a. Mid-level providers	doctors	Relative (95% CI)	Absolute (95% CI)		

Failure/incomplete (follow-up: 30–42 days; assessed with: Provider assessment)

3	randomized trials ^{1,2,3}	serious ^a	not serious	not serious	serious ^b	none	35/1363 (2.6%)	35/1321 (2.6%)	RR 0.96 (0.60 to 1.52)	1 fewer per 1000 (from 11 fewer to 14 more)	⊕⊕○○ LOW	
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Failure/incomplete (follow-up: 15–21 days; assessed with: Verifier assessment)

1	observational studies ⁴	very serious ^c	not serious ^d	not serious	serious ^b	none	39/775 (5.0%)	18/389 (4.6%)	RR 1.09 (0.63 to 1.88)	4 more per 1000 (from 17 fewer to 41 more)	⊕○○○ VERY LOW	
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Complications (follow-up: 7–15 days; assessed with: SAEs recorded by providers)

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Q1a. Mid-level providers	doctors	Relative (95% CI)	Absolute (95% CI)		
1	randomized trials ²	not serious	not serious ^d	not serious	very serious ^e	none	0/386 (0.0%)	1/401 (0.2%)	OR 0.35 (0.01 to 8.50)	2 fewer per 1000 (from 2 fewer to 18 more)	⊕⊕○○ LOW	

Satisfaction "satisfied"/"very satisfied" (assessed with: Self-report)

2	randomized trials ^{2,5}	serious ^a	not serious	not serious	not serious	none	948/949 (99.9%)	960/966 (99.4%)	RR 1.01 (1.00 to 1.01)	10 more per 1000 (from 0 fewer to 10 more)	⊕⊕⊕○ MODERATE	
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Satisfaction

1	observational studies ⁴	very serious ^c	not serious ^d	not serious	not serious	none	762/775 (98.3%)	384/389 (98.7%)	RR 1.00 (0.98 to 1.01)	0 fewer per 1000 (from 20 fewer to 10 more)	⊕⊕○○ LOW	
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CI: confidence interval; RR: risk ratio; OR: odds ratio

Notes

- a. Downgraded 1 level due to risk of bias: unclear or high risk of detection bias
- b. Downgraded 1 level due to imprecision: wide confidence interval consistent with the possibility for benefit and the possibility for harm
- c. Downgraded 2 levels due to risk of bias: women were not randomized, confounders were not controlled or adjusted for. In addition, outcome assessors were not blinded.
- d. Single study, inconsistency cannot be assessed
- e. Downgraded 2 levels due to imprecision: few events and a wide confidence interval consistent with the possibility for benefit and the possibility for harm

References

1. Warriner IK, Wang D, My Huong NT, Thapa K, Tamang A, Shah I, et al. Can midlevel health-care providers administer early medical abortion as safely and effectively as doctors? A randomised controlled equivalence trial in Nepal. *Lancet*; 2011;377(9772):1155-61. doi:10.1016/S0140-6736(10)62229-5.
2. Olavarrieta C, Ganatra B, Sorhaindo A, Karver TS, Seuc A, Villalobos A, et al. Nurse versus physician-provision of early medical abortion in Mexico: a randomized controlled non-inferiority trial. *Bull World Health Organ*. 2015;93:249–58. doi:10.2471/BLT.14.143990.
3. Kopp Kallner H, Gomperts R, Salomonsson E, Johansson M, Marions L, Gemzell-Danielsson K. The efficacy, safety and acceptability of medical termination of pregnancy provided by standard care by doctors or by nurse midwives: a randomised controlled equivalence trial. *BJOG*; 2015. 122(4):510-7. doi:10.1111/1471-0528.12982.
4. Jejeebhoy SJ, Kalyanwala S, Mundle S, Tank J, Xavier AJ, Kumar R, et al. Feasibility of expanding the medication abortion provider base in India to include ayurvedic physicians and nurses. *Int Perspect Sex Reprod Health*; 2012;38(3):133-42. doi:10.1363/3813312.
5. Tamang A, Shah IH, Shrestha P, Warriner IK, Wang D, Thapa K, et al. Comparative satisfaction of receiving medical abortion service from nurses and auxiliary nurse-midwives or doctors in Nepal: results of a randomized trial. *Reprod Health*; 2017;14(1):176. doi:10.1186/s12978-017-0438-7.

7. EtD framework for Medical abortion ≥ 12 weeks

Recommendation 30: Medical abortion at ≥ 12 weeks

For medical abortion at ≥ 12 weeks:

- a. **Recommend** medical management by generalist medical practitioners and specialist medical practitioners.
- b. **Suggest** medical management by traditional and complementary medicine professionals, auxiliary nurses/ANMs, nurses, midwives and associate/advanced associate clinicians.

PICO 7: For a pregnant person seeking induced abortion, is medical or surgical abortion by a traditional and complementary medicine professional, associate clinician, midwife, nurse, auxiliary nurse, pharmacist, pharmacy worker or community health worker a safe, effective or satisfactory alternative to provision of abortion care by doctors? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Main outcomes: Effectiveness, safety and satisfaction

Setting: Global

Perspective: Population

Literature review: A systematic review was undertaken to address the above question. There were no studies that met the inclusion criteria.

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

There was no research evidence on the cadres performing surgical or medical abortion beyond 12 weeks that allowed for pooled analysis and application of GRADE.

Additional information

Indirect evidence from the Moseson study shows the role of CHWs in supporting the woman to self-manage their medical abortion beyond 12 weeks (Moseson et al. 2020)

Accompaniment model:

- 1) Screening conversation (eligibility):
 - confirms that the person is seeking abortion for themselves and is not being coerced
 - no known contraindications to medication abortion
 - assesses the gestational age of the pregnancy based on either the date of last menstrual period as reported by the caller, or an independently acquired ultrasound

- 2) After confirming eligibility for medication abortion,
 - provide step-by-step instructions for how to use medication to induce abortion based on current WHO protocols
 - provide information on obtaining the medications
 - highly detailed guidance on assessing abortion completion and potential warning signs of complications, as well as when formal health care may be needed.
 - Accompaniment group staff are in frequent contact with callers during the medication abortion process to answer questions and provide support to the person self-managing an abortion.

Between 2016 and 2018, 316 individuals received accompaniment support for 318 self-managed medication abortions between 13 and 24 weeks gestation. Individuals most commonly used mifepristone-misoprostol (n = 297, 93%), with sublingual misoprostol administration (n = 288, 88%).

Medication alone resulted in 241 complete abortions (76%); 37 (12%) individuals underwent manual vacuum aspiration or dilation and curettage within the formal health system, and 16 people (5%) required an additional medication abortion attempt at a later date, resulted in ongoing pregnancy, or were lost to follow-up. After accounting for additional interventions or monitoring at a health-care facility, 302 of 318 (95%) abortion attempts completed overall. We had complete information regarding complications only from Chile (n = 78); of these, 12 (15%) experienced potential complications, including delayed placental expulsion and/or heavy bleeding (n = 5, 6%), high fever (n = 3, 4%) and hypotension, panic attack, or vomiting.

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

		X	
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

				X		
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	X Probably favours the intervention	Favours the intervention
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Equity:

What would be the impact on health equity?

Judgement (draft)

Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	X Probably increased	Increased
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Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to provide medical abortion beyond 12 weeks match the typical competencies of the traditional and complementary medicine professionals, auxiliary nurses/ANMs, midwives, associate/advanced associate clinicians, nurses, pharmacists, pharmacy workers, CHWs
The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	Traditional and complementary medicine professionals	Associate/advanced associate clinicians	Midwives	Nurses	Auxiliary nurses/ANMs
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health care (fundamental component of all competencies)					
Domain 3 General SRH competencies for health workers	<i>See information in Section 1 (EtD 1) in this document</i>					
Domain 4 Specific clinical competencies	<p>Competency 10: The primary health care team member provides high-quality comprehensive abortion care</p> <p>Tasks as per Competencies 4–6 + the task to provide for induced abortion</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • abortion law and its applicability (legal protection available to women and providers) • national norms, standards and guidelines for abortion care, 	<p>Traditional and complementary medicine professionals</p> <p>We suggest (upgrade)</p>	<p>Associate/advanced associate clinicians</p> <p>We suggest (maintain)</p>	<p>Midwives</p> <p>We suggest (maintain)</p>	<p>Nurses</p> <p>We suggest (maintain)</p>	<p>Auxiliary nurses/ANMs</p> <p>We suggest (upgrade)</p>

	<p>including rules for conscientious objection to provision of induced abortion</p> <ul style="list-style-type: none"> • confirmation of pregnancy and determination of gestational age • medical eligibility for all available abortion methods • pain management, including verbal reassurance • appropriate referral for abortion after 12 weeks since last menstrual period <p>Knowledge (<i>Updated CF</i>):</p> <ul style="list-style-type: none"> -Female anatomy and physiology -Comparative effectiveness, risks and benefits of abortion methods -Eligibility criteria and contraindications for method -Pain management protocols -Protocol for medical management of abortion -Management of complications -Emergency referral protocols -Infection prevention and waste management protocols -Contraceptive methods appropriate for administration at time of medical abortion -Self-care instructions <p>Skills – ability to:</p> <ul style="list-style-type: none"> • perform a bimanual uterine examination • perform VA and to provide medical abortion according to 	<p>Pharmacists</p> <p>We recommend against (maintain)</p>	<p>Pharmacy workers</p> <p>We recommend against (maintain)</p>	<p>CHW</p> <p>We recommend against (maintain)</p>		
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	<p>national standards, including appropriate pain management</p> <ul style="list-style-type: none"> • manage abortion-related complications <p>Updated CF</p> <ul style="list-style-type: none"> -Confirm clinical indication, gestational age, eligibility and consent for method; including consent for contraceptive method (where desired). -Review method effectiveness, benefits, risks, side-effects, complications and their management. -Verbally inform individual of steps for method and what to expect. -Check integrity of packaging and expiration date of pharmacologic agents used or dispensed. -Provide pharmacologic agents in correct dosage, route and frequency regimen as per protocol. -Instruct individual on self-administration when method will be used at home. -Manage side-effects and complications. -Manage incomplete results of tissue inspection -Provide post-abortion contraception (where desired). 					
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	-Maintain infection prevention and waste management standards.					
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DRAFT

8. EtD framework for Medical management of intrauterine fetal demise

Recommendation 33: Medical management for IUFD at ≥ 14 to ≤ 28 weeks:

- a. **Recommend** medical management by generalist medical practitioners and specialist medical practitioners.
- b. **Suggest** medical management by traditional and complementary medicine professionals, auxiliary nurses/ANMs, nurses, midwives and associate/advanced associate clinicians.

PICO 8: For a pregnant person diagnosed with intrauterine fetal demise (IUFD), is medical management of IUFD (with mifepristone and misoprostol, or misoprostol alone) provided by a traditional and complementary medicine professional, associate/advanced associate clinician, midwife, nurse, auxiliary nurse/auxiliary nurse midwife, pharmacist, pharmacy worker or community health worker a safe, effective and satisfactory alternative to medical management by a physician? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A systematic review by Cochrane Response serves as the evidence base for this key question. No studies reporting on medical management for intrauterine foetal demise by traditional and complementary medicine professionals, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers or community health workers were identified by the search strategy.

Study settings: N/A

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

No studies were identified for this PICO question.

Desirable effects:

No studies were identified for this PICO question.

Undesirable effects:

No studies were identified for this PICO question.

Balance of effects: not able to complete

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

		X	
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

				X		
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

					X	
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

Equity:

What would be the impact on health equity?

Judgement (draft)

					X	
Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased

Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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Application of the competency framework: The GDG panel agreed that the knowledge /skills required for this task match that of medical abortion provision beyond 12 weeks. Therefore, the health worker recommendations for both tasks were discussed together.

Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to provide medical management of IUFD/medical abortion beyond 12 weeks match the typical competencies of the traditional and complementary medicine professionals, auxiliary nurses/ANMs, midwives, associate/advanced associate clinicians, nurses, pharmacists, pharmacy workers, CHWs

The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	Traditional and complementary medicine professionals	Associate/advanced associate clinicians	Midwives	Nurses	Auxiliary nurses/ANMs
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health care (fundamental component of all competencies)					
Domain 3 General SRH competencies for health workers	<i>See information in Section 1 (EtD 1) in this document</i>					
Domain 4 Specific clinical competencies	<p>Competency 10: The primary health care team member provides high-quality comprehensive abortion care</p> <p>Tasks as per Competencies 4–6 + the task to provide for induced abortion</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • abortion law and its applicability (legal protection available to women and providers) • national norms, standards and guidelines for abortion care, 	<p>Traditional and complementary medicine professionals</p> <p>We suggest (upgrade)</p>	<p>Associate/advanced associate clinicians</p> <p>We suggest (maintain)</p>	<p>Midwives</p> <p>We suggest (maintain)</p>	<p>Nurses</p> <p>We suggest (maintain)</p>	<p>Auxiliary nurses/ANMs</p> <p>We suggest (upgrade)</p>

	<p>including rules for conscientious objection</p> <ul style="list-style-type: none"> • to provision of induced abortion • confirmation of pregnancy and determination of gestational age • medical eligibility for all available abortion methods • pain management, including verbal reassurance • appropriate referral for abortion after 12 weeks since last menstrual period <p>Knowledge (<i>Updated CF</i>):</p> <ul style="list-style-type: none"> • Female anatomy and physiology • Comparative effectiveness, risks and benefits of abortion methods • Eligibility criteria and contraindications for method • Pain management protocols • Protocol for medical management of abortion • Management of complications • Emergency referral protocols • Infection prevention and waste management protocols • Contraceptive methods appropriate for administration at time of medical abortion • Self-care instructions <p>Skills – ability to:</p>	<p>Pharmacists</p> <p>We recommend against (maintain)</p>	<p>Pharmacy workers</p> <p>We recommend against (maintain)</p>	<p>CHW</p> <p>We recommend against (maintain)</p>		
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	<ul style="list-style-type: none"> • perform a bimanual uterine examination • perform VA and to provide medical abortion according to national standards, including appropriate pain management • manage abortion-related complications <p>Updated CF</p> <ul style="list-style-type: none"> • Confirm clinical indication, gestational age, eligibility and consent for method; including consent for contraceptive method (where desired). • Review method effectiveness, benefits, risks, side-effects, complications and their management. • Verbally inform individual of steps for method and what to expect. • Check integrity of packaging and expiration date of pharmacologic agents used or dispensed. • Provide pharmacologic agents in correct dosage, route and frequency regimen as per protocol. • Instruct individual on self-administration when method will be used at home. • Manage side-effects and complications. 					
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	<ul style="list-style-type: none"> • Manage incomplete results of tissue inspection • Provide post-abortion contraception (where desired). • Maintain infection prevention and waste management standards. 					
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SUMMARY OF FINDINGS TABLE

No studies were identified for this PICO question.

DRAFT

9. EtD framework for Medical management of incomplete abortion

Medical management with misoprostol for uncomplicated incomplete abortion at < 14 weeks:

Recommendation 37: Recommend medical management with misoprostol by community health workers, pharmacy workers, pharmacists, traditional and complementary medicine professionals, auxiliary nurses/ANMs, nurses, midwives, associate/advanced associate clinicians, generalist medical practitioners and specialist medical practitioners.

PICO 9: For a pregnant person with incomplete abortion, is management of incomplete abortion with misoprostol provided by a traditional and complementary medicine professional, pharmacist, pharmacy worker or community health worker a safe, effective and satisfactory/acceptable alternative to management with misoprostol provided by a physician? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A systematic review by Cochrane Response serves as the evidence base for this key question. Two studies reporting on medical management for incomplete abortion by traditional and complementary medicine professionals, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers or community health workers were identified by the search strategy. Both studies assessed the comparison: Medical management of incomplete abortion by midwives vs medical management of incomplete abortion by physicians

Study settings: Kenya, Uganda

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

Comparison of midwives vs physicians

Desirable effects:

There was little to no difference in the number of complete abortions in the intervention group (misoprostol administration by midwives) compared with the control group (misoprostol administration by doctors). The certainty of evidence is high.

There is likely to be little to no difference in pain intensity following treatment in the intervention group (misoprostol administration by midwives) compared with the control group (misoprostol administration by doctors). The certainty of evidence is moderate.

There may be little to no difference in the number of women reporting moderate to severe pain following treatment in the intervention group (misoprostol administration by midwives) compared with the control group (misoprostol administration by doctors). The certainty of evidence is low.

There is likely to be little to no difference in the number of days with vaginal bleeding following treatment in the intervention group (misoprostol administration by midwives) compared with the control group (misoprostol administration by doctors). The certainty of evidence is moderate.

There may be little to no difference in vaginal bleeding, defined as self-reported 'bleeding heavier than normal menstrual bleeding', following treatment in the intervention group (misoprostol administration by midwives) compared with the control group (misoprostol administration by doctors). The certainty of evidence is low.

Undesirable effects:

We do not know about the effect of the intervention (misoprostol administered by midwives) compared with the control (misoprostol administered by doctors) on unscheduled visits to health facilities. The certainty of the evidence is very low.

There may be little to no difference in adverse events following treatment in the intervention group (misoprostol administration by midwives) compared with the control group (misoprostol administration by doctors). The certainty of evidence is low.

No serious adverse events were reported by either study. The certainty of evidence is low.

Balance of effects:

		X		
Favours the comparison	May favour the comparison	No difference between the intervention and the comparison	May favour the intervention	Favours the intervention

Additional information

Indirect evidence from the Moseson study shows the role of CHWs in supporting the woman to self-manage their medical abortion beyond 12 weeks (Moseson et al. 2020). This includes supporting the woman to identify an incomplete abortion.

Reference

Moseson H, Bullard KA, Cisternas C, Grosso B, Vera V, Gerdtz C. Effectiveness of self-managed medication abortion between 13 and 24 weeks gestation: a retrospective review of case records from accompaniment groups in Argentina, Chile, and Ecuador. *Contraception*. 2020;102(2):91–8. doi:10.1016/j.contraception.2020.04.015.

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

		X	
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

				X		
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

					X	
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

Equity:

What would be the impact on health equity?

Judgement (draft)

					X	
Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased

Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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DRAFT

Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to provide medical management of uncomplicated incomplete abortion match the typical competencies of the traditional and complementary medicine professionals, pharmacists, pharmacy workers, CHWs

The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	DCSM	Pharmacists	Pharmacy workers	CHWs
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health care (fundamental component of all competencies)	fundamental	fundamental	fundamental	fundamental
Domain 3 General SRH competencies for health workers	<i>See information in Section 1 (EtD 1) in this document</i>				
Domain 4 Specific clinical competencies	<p>Competency 7: The primary health care team member provide high-quality family planning care</p> <p>Tasks as per Competencies 4–6 + the task to manage abortion complications:</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • signs and symptoms of pregnancy • gestational age and its calculation • signs, symptoms and management of spontaneous abortion, missed abortion, induced abortion and related complications • abortion management standards and guidelines • referral management for repeat spontaneous abortion and complications that are not treatable in loco <p>Skills – ability to:</p>	<p>DCSM:</p> <p>We recommend</p>	<p>Pharmacists:</p> <p>We recommend</p>	<p>Pharmacy workers:</p> <p>We recommend</p>	<p>CHWs</p> <p>We recommend</p>

	<ul style="list-style-type: none"> • perform abdominal and vaginal examination to assess gestational age • perform abortion care by appropriate VA or dilatation and curettage if VA is not available • recognize complications of abortion • treat abortion complications • refer when needed 				
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DRAFT

SUMMARY OF FINDINGS TABLE

Incomplete abortion – Misoprostol administered by midwives vs doctors

Patient or population: Women with signs of incomplete abortion and less than 12 weeks of gestation

Setting: Kenya and Uganda

Intervention: Misoprostol administered by midwives

Comparison: Misoprostol administered by doctors

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with misoprostol administered by doctors	Risk with misoprostol administered by midwives				
Complete abortion (not requiring further medical and/or surgical treatment) Assessed with: clinical assessment* Follow-up: up to 28 days	956 per 1000	956 per 1000 (937 to 975)	RR 1.00 (0.98 to 1.02)	1765 (2 RCTs)	⊕⊕⊕⊕ HIGH ^a	Misoprostol administered by midwives results in little to no difference in complete abortion compared with misoprostol administered by doctors. Risk difference: 0 per 1000 (from 29 fewer to 29 more per 1000)
Pain intensity Assessed with: VAS 0 to 10 before any use of analgesia, lower scores indicate less pain Follow-up: up to 28 days	The mean pain score following treatment was 3.5 points in the doctor group	The mean pain score following treatment was 3.6 points in the midwife group	MD 0.1 higher (0.12 lower to 0.32 higher)	950 (1 RCT)	⊕⊕⊕○ MODERATE ^b	Misoprostol administered by midwives likely results in little to no difference in pain intensity following treatment compared with misoprostol administered by doctors.

Severe to moderate pain intensity Assessed with: VAS 0 to 10 before any use of analgesia Follow-up: up to 10 days	303 per 1000	297 per 1000 (240 to 367)	RR 0.98 (0.79 to 1.21)	806 (1 RCT)	⊕⊕○○ LOW ^{b, c}	Misoprostol administered by midwives may result in little to no difference in severe to moderate pain following treatment compared with misoprostol administered by doctors.
Vaginal bleeding (days bleeding following treatment) Assessed with: self-report Follow-up: up to 28 days	The mean days of vaginal bleeding ranged from 4.08 to 5.0 in the doctor group	The mean days of vaginal bleeding ranged from 4.2 to 5.3 in the midwife group	MD 0.18 higher (0.03 lower to 0.39 higher)	1735 (2 RCTs)	⊕⊕⊕○ MODERATE ^b	Misoprostol administered by midwives likely results in little to no difference in the number of days bleeding compared with misoprostol administered by doctors.
Vaginal bleeding ("heavier than normal menstrual bleeding" following treatment) Assessed with: self-report in relation to normal menstrual bleeding Follow-up: up to 28 days	156 per 1000	150 per 1000 (120 to 188)	RR 0.96 (0.77 to 1.20)	1762 (2 RCTs)	⊕⊕○○ LOW ^{b, c}	Misoprostol administered by midwives may result in little to no difference in vaginal bleeding since treatment: heavier than normal menstrual bleeding compared with misoprostol administered by doctors.
Unscheduled visits to a health facility Assessed with: self-report questionnaire Follow-up: up to 28 days	50 per 1000	57 per 1000 (26 to 126)	RR 1.14 (0.51 to 2.52)	1755 (2 RCTs)	⊕○○○ VERY LOW ^{b, c, d}	The evidence is very uncertain about the effect of misoprostol administered by midwives on unscheduled visits to a health facility compared with misoprostol administered by doctors. Makenzius 2017: RR 0.76, 95% CI 0.43 to 1.33 Klingberg-Allvin 2015: RR 1.71, 95% CI 0.96 to 3.02

Adverse events (solicited side-effects of misoprostol) Assessed with: self-report Follow-up: up to 10 days	266 events in 401 women	297 events in 409 women	Not estimable	810 (1 RCT)	⊕⊕○○ LOW ^{b, e}	Reported side-effects such as abdominal pain, chills, nausea, diarrhoea, vomiting and foul smelling vaginal and/or cervical discharge were similar in both groups.
Follow-up: up to 28 days	495 events in 481 women	484 events in 472 women		953 (1 RCT)		
Serious adverse events Assessed with: self-report Follow-up: up to 28 days	0 per 1000	0 per 1000	Not estimable	1763 (2 RCTs)	⊕⊕○○ LOW ^{b, e}	No serious adverse events were reported in either group.
Acceptability Assessed with: self-report questionnaire Treatment perceived “as expected” or “easier than expected”	945 per 1000	945 per 1000 (927 to 964)	RR 1.00 (0.98 to 1.02)	1759 (2 RCTs)	⊕⊕⊕○ MODERATE ^b	Misoprostol administered by midwives likely results in little to no difference in acceptability compared with misoprostol administered by doctors.
Treatment “felt safe”	947 per 1000	957 per 1000 (928 to 985)	RR 1.01 (0.98 to 1.04)	799 (1 RCT)		
“Will recommend treatment to a friend”	970 per 1000	970 per 1000 (951 to 980)	RR 1.00 (0.98 to 1.01)	1753 (2 RCTs)		

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
CI: confidence interval; RR: risk ratio; RCT: randomized controlled trial; MD: mean difference.

Notes:

- Open label study. Evidence was not downgraded due to risk of bias as this is an objective outcome which is unlikely to be affected by outcome assessor judgement.
- Downgraded one level due to limitations in study design: open label study (i.e. no blinding of participants or care providers), assessment of this outcome could have been influenced by knowledge of the allocated intervention.
- Downgraded one level due to imprecision: few events.
- Downgraded one levels due to inconsistency: substantial unexplained heterogeneity ($I^2 = 74\%$).

e. Downgraded one level due to imprecision: insufficient data to calculate relative effect.

* The clinical assessments of this outcome are: (i) Physical examination (pulse, blood pressure and temperature); (ii) Pelvic examination that includes examination of size of the uterus (external genitalia, speculum examination, bimanual examination).

References

Included studies:

Klingberg-Allvin 2015 (Uganda)

Klingberg-Allvin M, Cleeve A, Atuhairwe S, Tumwesigye NM, Faxelid E, Byamugisha J, Gemzell-Danielsson K. Comparison of treatment of incomplete abortion with misoprostol by physicians and midwives at district level in Uganda: a randomised controlled equivalence trial. *Lancet*. 2015;385(9985):2392-8.

Cleeve A, Byamugisha J, Gemzell-Danielsson K, Mbona Tumwesigye N, Atuhairwe S, Faxelid E, Klingberg-Allvin M. Women's acceptability of misoprostol treatment for incomplete abortion by midwives and physicians-secondary outcome analysis from a randomized controlled equivalence trial at district level in Uganda. *PLoS One*. 2016;12;11(2):e0149172.

Makenzius 2017 (Kenya)

Makenzius M, Oguttu M, Klingberg-Allvin M, Gemzell-Danielsson K, Odero TM A, Faxelid E. Post-abortion care with misoprostol – equally effective, safe and accepted when administered by midwives compared to physicians: a randomised controlled equivalence trial in a low-resource setting in Kenya. *BMJ*. 2017;7(10):e016157.

Ongoing studies:

Atuhairwe 2019

Atuhairwe S, Byamugisha J, Klingberg-Allvin M, Cleeve A, Hanson C, Mbona Tumwesigye N, et al. Evaluating the safety, effectiveness and acceptability of treatment of incomplete second-trimester abortion using misoprostol provided by midwives compared with physicians: study protocol for a randomized controlled equivalence trial. *Trials*. 2019;20(1):376.

10. EtD framework for Vacuum aspiration for management of incomplete abortion

Recommendation 38: Vacuum aspiration for uncomplicated incomplete abortion at < 14 weeks:

- a. **Recommend** vacuum aspiration by traditional and complementary medicine professionals, nurses, midwives, associate/advanced associate clinicians, generalist medical practitioners and specialist medical practitioners.
- b. **Suggest** vacuum aspiration by auxiliary nurses/ANMs.

PICO 10: For a pregnant person seeking an induced abortion, is provision of vacuum aspiration for induced abortion/incomplete abortion/miscarriage (all indications) by traditional and complementary medicine professionals, auxiliary nurses or auxiliary nurse midwives a safe, effective or satisfactory option to provision of vacuum aspiration by physicians? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A Cochrane systematic review serves as the evidence base for this key question. Five studies (1 RCT, 4 cohort) were identified that compared vacuum aspiration by mid-level providers to physicians. The five studies assessed the following comparison:

- Vacuum aspiration by midwives compared to physicians
- Vacuum aspiration by physician assistants compared to physicians
- Vacuum aspiration by nurses compared to physicians
- Vacuum aspiration by advanced practice clinicians compared to physicians
- Vacuum aspiration by nurse practitioners, nurse midwives and physician assistants compared to physicians

All studies focused on induced abortion. There were no studies identified of vacuum aspiration for incomplete abortion by auxiliary nurses/nurse midwives or traditional and complementary medicine professionals.

ASSESSMENT OF RESEARCH EVIDENCE

There was no research evidence on these cadres performing vacuum aspiration (≤ 14 weeks) for incomplete abortion that allowed for pooled analysis and application of GRADE.

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

		X	
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

				X		
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

					X	
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

Equity:

What would be the impact on health equity?

Judgement (draft)

					X	
Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased

Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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DRAFT

Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to match the typical competencies of the traditional and complementary medicine professionals and auxiliary nurses/ANMs.

The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	Traditional and complementary medicine professionals	Auxiliary nurses/ANMs
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health (SRH) care (fundamental component of all competencies)		
Domain 3 General SRH competencies for health workers	<p>Competency 4: The primary health-care team member(s) provide high-quality health education related to SRH, and SRH services</p> <p>Tasks:</p> <ul style="list-style-type: none"> 6) Assess the local sociocultural, legal and gender concerns and issues related to programme implementation and service provision 7) Create an environment that is conducive to learning 8) Facilitate learning using a variety of techniques (discussion, demonstration, presentation) 9) Convey essential information related to specific SRH topics 10) Assess the transfer of learning <p>Competency 5: The primary health-care team member(s) provide high-quality counselling related to SRH, and SRH services</p> <p>Tasks:</p> <ul style="list-style-type: none"> 4) Plan a counselling session including the creation of a conducive counselling environment 5) Counsel effectively 6) Assess the effectiveness of counselling <p>Competency 6: The primary health-care team member(s) effectively assess the SRH needs of users of primary health care services for treatment and referral when necessary</p> <p>Tasks:</p>		

	6) Take an appropriate health history with a focus on factors related to SRH 7) Conduct a physical examination 8) Ensure faster and safe referral 9) Screen for male and female reproductive health preventable and/or treatable pathology 10) Obtain or refer for appropriate laboratory tests related to SRH		
Domain 4 Specific clinical competencies	<p>Competency 10: The primary health care team member provide high-quality comprehensive abortion care</p> <p>Tasks as per Competencies 4–6 + the task to provide, or refer for, induced abortion</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • abortion law and its applicability (legal protection available to women and providers) • national norms, standards and guidelines for abortion care, including rules for conscientious objection to provision of induced abortion • confirmation of pregnancy and determination of gestational age • medical eligibility for all available abortion methods • pain management, including verbal reassurance • appropriate referral for abortion after 12 weeks since last menstrual period <p>Skills – ability to:</p> <ul style="list-style-type: none"> • perform a bimanual uterine examination • perform VA and to provide medical abortion according to national standards, including appropriate pain management • manage abortion-related complications 	<p>Doctors of complementary medicine:</p> <p>We recommend (upgrade)</p>	<p>Auxiliary nurses/ANMs</p> <p>We suggest (maintain)</p> <p>With the same condition from the 2015 recommendation</p>

11. EtD framework for Diagnosis and management of abortion-related complications

Recommendation 39: For non-life-threatening post-abortion infection:

Recommend initial management by traditional and complementary medicine professionals, auxiliary nurses/ANMs, nurses, midwives, associate/advanced associate clinicians, generalist medical practitioners and specialist medical practitioners.

Recommendation 40: For non-life-threatening post-abortion haemorrhage:

Recommend initial management by traditional and complementary medicine professionals, auxiliary nurses/ANMs, nurses, midwives, associate/advanced associate clinicians, generalist medical practitioners and specialist medical practitioners.

PICO 11: For a person presenting with complication(s) of an induced abortion and in a stable condition, is diagnosis and management of abortion-related complications by a traditional and complementary medicine professional, pharmacist, pharmacy worker or community health worker a safe, effective and satisfactory/acceptable alternative to – and as accurate as – diagnosis and management by a physician? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A systematic review by Cochrane Response serves as the evidence base for this key question. No studies reporting on diagnosis and management of abortion-related complications performed by traditional and complementary medicine professionals, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers or community health workers were identified by the search strategy.

Study settings: N/A

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

No studies were identified for this PICO question.

Desirable effects:

No studies were identified for this PICO question.

Undesirable effects:

No studies were identified for this PICO question.

Draft judgement: Unable to determine

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

		X	
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

X						
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

					X	
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

Equity:

What would be the impact on health equity?

Judgement (draft)

Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	X Probably increased	Increased
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Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

Unable to determine	Varies	No	Probably No	X Probably Yes	Yes
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Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	X Probably Yes	Yes
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Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to provide initial management of non-life-threatening abortion complications match the typical competencies of the traditional and complementary medicine professionals, pharmacists, pharmacy workers, CHWs

The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	Traditional and complementary medicine professionals	Pharmacists	Pharmacy workers	Community health workers
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health care (fundamental component of all competencies)				
Domain 3 General SRH competencies for health workers	<i>See information in Section 1 (EtD 1) in this document</i>				
Domain 4 Specific clinical competencies	<p>Competency 10: The primary health care team member provides high-quality comprehensive abortion care</p> <p>Tasks as per Competencies 4–6 + the task to</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • signs and symptoms of pregnancy • gestational age and its calculation • signs, symptoms and management of spontaneous abortion, missed abortion, induced abortion and related complications • abortion management standards and guidelines • referral management for repeat spontaneous abortion and 	<p>Traditional and complementary medicine professionals</p> <p>We recommend (upgrade)</p>	<p>Pharmacists</p> <p>We recommend against (maintain) – specifically on the clinical delivery/skills</p> <p>Additional language to support the knowledge aspect (being able to recognize complications)</p>	<p>Pharmacy workers</p> <p>We recommend against (maintain) specifically on the clinical delivery/skills</p> <p>Additional language to support the knowledge aspect (being able to recognize complications)</p>	<p>CHW</p> <p>We recommend against (maintain) specifically on the clinical delivery/skills</p> <p>Additional language to support the knowledge aspect (being able to recognize complications)</p>

	<p>complications that are not treatable in loco</p> <p>Skills – ability to:</p> <ul style="list-style-type: none"> • perform abdominal and vaginal examination to assess gestational age • perform abortion care by appropriate VA or dilatation and curettage if VA is not available • recognize complications of abortion • treat abortion complications • refer when needed 				
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SUMMARY OF FINDINGS TABLE

No studies were identified for this PICO question.

12. EtD framework for Delivery of injectable contraceptives

Recommendation 46: For injectable contraceptives (initiation and continuation):

Recommend administration by self (see Recommendation 51 below), community health workers, pharmacy workers, pharmacists, traditional and complementary medicine professionals, auxiliary nurses/ANMs, nurses, midwives, associate/advanced associate clinicians, generalist medical practitioners and specialist medical practitioners.

PICO 12: For a person in the post-abortion period needing contraception, is provision of injectable contraceptives (initiation or continuation) by a traditional and complementary medicine professional, pharmacy worker or community health worker, a safe, effective and satisfactory/acceptable alternative to provision by a trained health worker? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A systematic review by Cochrane Response serves as the evidence base for this key question. One study reporting on delivery of injectable contraceptives by traditional and complementary medicine professionals, pharmacists/pharmacy workers and CHW was identified by the search strategy. The study assessed the comparison injectable contraception administered by a trained pharmacist versus usual family planning (FP) providers.

Study setting: USA

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

Comparison 1. Comparison of trained pharmacist versus usual family planning providers

Desirable effects

- Injectable contraception administered by a trained pharmacist may result in little or no difference to **continuation rates** at 3 months or at 6 months compared to administration by usual providers at FP clinics (very low-certainty evidence).
- Women in both groups reported satisfaction with DMPA-SC and with the location of delivery (very low-certainty evidence).
- Pharmacists and health-care professionals were satisfied with the new clinical arrangements with the pharmacy (very low-certainty evidence).

Undesirable effects

- No method failures were reported in either group (very low-certainty evidence).

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

X			
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

X						
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

X						
Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention	Probably favours the intervention	Favours the intervention

				or the comparison		
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Equity:

What would be the impact on health equity?

Judgement (draft)

Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	X Probably increased	Increased
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Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

Unable to determine	Varies	No	Probably No	X Probably Yes	Yes
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Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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Additional considerations (Competency framework)

Using the competency framework, we will focus on the cadre column: in this case, we will discuss if the required competencies to provide post abortion contraception (injectable contraceptives) match the typical competencies of the traditional and complementary medicine professionals, pharmacy workers and community health workers
The BLUE highlighted boxes are the most relevant for the topic and cadre.

DOMAIN	Competency	Traditional and complementary medicine professionals	Pharmacy workers	Community health workers
Domain 1 Attitudes	Attitudes for providing high-quality sexual and reproductive health care (fundamental component of all competencies)			
Domain 3 General SRH competencies for health workers	<i>See information in Section 1 (EtD 1) in this document</i>			
Domain 4 Specific clinical competencies	<p>Competency 10: The primary health care team member provide high-quality comprehensive abortion care</p> <p>Tasks as per Competencies 4–6 + the task to provide post-abortion contraception</p> <p>Knowledge:</p> <ul style="list-style-type: none"> • medical eligibility requirements for contraceptive methods • post-abortion FP methods • return to fertility post-abortion and safe time to get pregnant again • how and where to obtain contraceptives (preferably in the same place where they have had the abortion or post-abortion services) <p>Skills – ability to:</p> <ul style="list-style-type: none"> • provide contraceptive methods, including insertion of IUDs and implants, injectables and emergency 	<p>Doctors of complementary medicine:</p> <p>We recommend....</p>	<p>Pharmacy workers</p> <p>We recommend</p>	<p>Community health workers</p> <p>We recommend</p>

	<p>contraception immediately after abortion or post-abortion services have been performed</p> <ul style="list-style-type: none"> • also refer to Competency 8 (STIs) (collect an accurate history of past and present STI/RTI, detection and management of STIs/RTIs) 			
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DRAFT

SUMMARY OF FINDINGS TABLE

Comparison 1. Injectable contraception administered by trained pharmacists versus usual family planning providers

Q9. Injectable contraception administered by trained pharmacists compared to usual family planning providers for women with the intention of initiating, restarting or continuing DMPA, including after abortion

Patient or population: Women ≥ 18 years with the intention of initiating, restarting or continuing DMPA, including after abortion

Setting: USA

Intervention: Injectable contraception (DMPA-SC) delivered by trained pharmacists at pharmacy

Comparison: Injectable contraception (DMPA-SC) delivered by usual providers at family planning (FP) clinic

Outcomes	Anticipated absolute effects* (95% CI)			Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with DMPA-SC administered by usual FP providers	Risk DMPA-SC administered by pharmacist	Risk difference with DMPA-SC administered by pharmacist				
Continuation rates ^a Follow up: 3 months	600 per 1000	438 per 1000 (252 to 762)	162 fewer per 1000 (348 fewer to 162 more)	RR 0.73 (0.42 to 1.27)	50 (1 RCT)	⊕○○○ VERY LOW b,c,d	Injectable contraception administered by pharmacist may have little or no effect on continuation rates at 3 and 6

Outcomes	Anticipated absolute effects* (95% CI)			Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with DMPA-SC administered by usual FP providers	Risk DMPA-SC administered by pharmacist	Risk difference with DMPA-SC administered by pharmacist				
Continuation rates ^a Follow up: 6 months	480 per 1000	360 per 1000 (187 to 701)	120 fewer per 1000 (293 fewer to 221 more)	RR 0.75 (0.39 to 1.46)	50 (1 RCT)	⊕○○○ VERY LOW b,c,d	<p>months, though the evidence is very uncertain. The wide confidence intervals are consistent with the possibility for benefit and the possibility for harm.</p> <p>Reasons for discontinuation</p> <p>Pharmacy group: 3 received injection elsewhere, 1 changed method, 9 lost to follow-up</p> <p>Clinic group: 1 received injection elsewhere; 1 not eligible (elevated BP), 1 discontinued method, 13 lost to follow-up</p>
Method failure Assessed with: not reported Follow up: 6 months	No method failures were documented in either group			-	50 (1 RCT)	⊕○○○ VERY LOW c,e,f	We do not know about the effect of injectable contraception administered by pharmacist on method failure at 6 months because no events were reported.
Safety	Not reported						

Outcomes	Anticipated absolute effects* (95% CI)			Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with DMPA-SC administered by usual FP providers	Risk DMPA-SC administered by pharmacist	Risk difference with DMPA-SC administered by pharmacist				
Satisfaction Assessed with: self-report survey; range of scores: 1=lowest rating, 5=highest rating Follow up: 3 months	Median (range) score of pharmacy vs clinic group Satisfaction with DMPA: 5 (5–5) vs 5 (4–5); $P = 0.05$ Satisfaction with location: 5 (4–5) vs 5 (4–5); $P = 0.16$ Would recommend DMPA: 5 (3–5) vs 5 (4–5); $P = 0.72$ Would recommend location for DMPA: 5 (4–5) vs 5 (3–5); $P = 0.23$ Location convenience: 4 (1–5) vs 4 (1–5); $P = 0.89$			-	26 (1 RCT)	⊕○○○ VERY LOW e.g	Injectable contraception administered by pharmacist may have little or no effect on women's satisfaction at 3 and 6 months, both groups reported high satisfaction, though the evidence is very uncertain
Satisfaction Assessed with: self-report survey; range of scores: 1=lowest rating, 5=highest rating Follow up: 6 months	Median (range) score of pharmacy vs clinic group Satisfaction with DMPA: 5 (5–5) vs 5 (3–5); $P = 0.37$ Satisfaction with location: 5 (3–5) vs 5 (1–5); $P = 0.87$ Would recommend DMPA: 5 (4–5) vs 5 (4–5); $P = 0.38$ Would recommend location for DMPA: 5 (4–5) vs 5 (3–5); $P = 0.23$ Location convenience: 5 (3–5) vs 5 (3–5); $P = 0.87$			-	20 (1 RCT)	⊕○○○ VERY LOW e.g	

Outcomes	Anticipated absolute effects* (95% CI)			Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with DMPA-SC administered by usual FP providers	Risk DMPA-SC administered by pharmacist	Risk difference with DMPA-SC administered by pharmacist				
Health-care provider satisfaction Follow up: 6 months	Pharmacist All 3 pharmacists involved in DMPA-SC administration were very comfortable with their clinical role. They felt somewhat or very informed about DMPA-SC. They felt comfortable or somewhat comfortable administering the urine pregnancy tests, when applicable. They felt very comfortable checking blood pressures and administering the injections. All 3 pharmacists wanted to continue offering DMPA-SC injections in their pharmacy practice.			-	8 (1 RCT)	⊕○○○ VERY LOW g,h	Injectable contraception administered by pharmacist may have little or no effect on health-care provider's satisfaction at 6 months, both groups reported high satisfaction, though the evidence is very uncertain
	FP providers All 5 Planned Parenthood providers were positive overall about the clinical arrangement with the pharmacy. All were either somewhat or very comfortable knowing their patients were receiving their DMPA-SC by a clinical pharmacist. 1 provider felt it was very appropriate for pharmacists to administer DMPA-SC, while three felt it was somewhat appropriate. One felt neutral.						

*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
 CI: confidence interval; DMPA-SC: subcutaneous depot medroxyprogesterone acetate; RCT: randomized controlled trial; RR: risk ratio.

Notes:

- ITT analysis: only those women who returned on time and received their DMPA-SC injections at their assigned site were counted as a continuation.
- Downgraded 1 level due to risk of bias: unclear risk of random sequence generation and high risk of performance-bias due to lack of blinding.
- Downgraded 1 level due to indirectness: study includes women age 18 years and older with the intention of initiating, restarting or continuing DMPA, not just after abortion.
- Downgraded 2 levels due to imprecision: wide confidence interval consistent with the possibility for benefit and the possibility for harm and very low number of participants.

- e. Downgraded 2 levels due to risk of bias: unclear risk of random sequence generation, high risk of performance- and detection bias due to lack of blinding, and high risk of attrition bias due to high rate of missing outcome data.
- f. Downgraded 2 levels due to imprecision: no events in either group and very small sample size.
- g. Downgraded 2 levels due to imprecision: very small sample size.
- h. Downgraded 3 levels due to very serious risk of bias: pharmacists and clinicians were not randomized, and there was unclear risk of random sequence generation, high risk of performance- and detection bias due to lack of blinding.

References

Included studies

Picardo 2010 (USA)

Picardo C, Ferreri S. Pharmacist-administered subcutaneous depot medroxyprogesterone acetate: a pilot randomized controlled trial. *Contraception*. 2010;82(2):160–7.

13. EtD framework for Telemedicine

Recommendation 48:

Recommend the option of telemedicine as an alternative to in-person interactions with the health worker to deliver medical abortion services in whole or in part.

PICO 13: For a pregnant person seeking medical abortion, is medical abortion care provided through telemedicine (comprehensive care or individual components) a safe, effective and satisfactory/acceptable alternative to in-person medical abortion care? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A systematic review by Cochrane Response serves as the evidence base for this key question. Four RCTs and six observational comparative studies reporting on abortion care provided through telemedicine were identified by the search strategy. The studies assessed the comparison telemedicine versus in-person abortion care.

The following WHO definition of telemedicine was followed:

Client-to-Provider Telemedicine: Provision of health services at a distance; delivery of health services where clients/patients and health workers are separated by distance (synonyms: consultations between remote client/patient and health worker; clients/patients transmit medical data [e.g. images, notes and videos] to health worker)

Study setting: Bangladesh, Cambodia, Canada, Egypt, Indonesia, Peru, United Kingdom and USA

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

Comparison 1. Telemedicine versus in-person abortion care

Desirable effects:

Telemedicine compared with in-person abortion care:

- may result in little to no difference in complete abortion at up to 2 months follow-up (very low-certainty evidence)
- may result in little to no difference in ongoing pregnancies at up to 2 months follow-up (very low-certainty evidence)
- may result in a small reduction of receipt of or referral for surgical abortion at up to 2 months follow-up (very low-certainty evidence)
- may result in little to no difference on contraception uptake following abortion at up to 4 months follow-up (very low-certainty evidence)
- may result in little to no difference on patient satisfaction with the care received, willingness to use the same service again in the future and (very low-certainty evidence)
- may result in little to no difference on satisfaction with the services received and whether women would recommend the method to a friend (very low-certainty evidence)

Undesirable effects:

Telemedicine compared with in-person abortion care:

- may result in little to no difference on need for blood transfusions due to haemorrhage at up to 2 months follow-up (very low-certainty evidence)
- no hospitalizations or deaths were reported in either group at up to 2 months follow-up (very low-certainty evidence)

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

		X	
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

				X	
Unable to determine	Varies	Large costs	Moderate costs	Moderate savings	Large savings

				Negligible costs or savings		
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Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	X Favours the intervention
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Equity:

What would be the impact on health equity?

Judgement (draft)

Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	X Probably increased	Increased
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Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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SUMMARY OF FINDINGS TABLE

Comparison 1. Telemedicine versus in-person abortion care

Q12. Telemedicine compared to in-person abortion care for abortion

Patient or population: Women needing abortion and post-abortion care

Setting: Canada, United Kingdom and USA

Intervention: Telemedicine for abortion care

Comparison: In-person abortion care

Outcomes	Anticipated absolute effects* (95% CI)		Risk difference with telemedicine	Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with in-person abortion care	Risk with telemedicine					
Complete abortion follow up: up to 2 months	979 per 1000	989 per 1000 (989 to 989)	10 more per 1000 (10 more to 10 more)	RR 1.01 (1.01 to 1.01)	30813 (3 observational studies)	⊕○○○ VERY LOW ^a	Evidence from observational studies suggests that telemedicine results in little to no difference in complete abortion; however, the certainty is very low.
Ongoing pregnancies follow up: up to 2 months	5 per 1000	6 per 1000 (1 to 51)	1 more per 1000 (4 fewer to 46 more)	RR 1.24 (0.14 to 11.08)	34621 (3 observational studies)	⊕○○○ VERY LOW ^{a,b,c}	Evidence from observational studies suggests that telemedicine results in little to no difference in ongoing pregnancies; however, the certainty is very low.
Receipt of or referral for surgical abortion follow up: up to 2 months	26 per 1000	10 per 1000 (9 to 13)	16 fewer per 1000 (17 fewer to 13 fewer)	RR 0.40 (0.33 to 0.49)	34821 (3 observational studies)	⊕○○○ VERY LOW ^a	Evidence from observational studies suggests that telemedicine may result in fewer women been referred or having surgical abortion; however, the certainty is very low.

Outcomes	Anticipated absolute effects* (95% CI)		Risk difference with telemedicine	Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with in-person abortion care	Risk with telemedicine					
Contraception uptake following abortion follow up: up to 4 months	926 per 1000	898 per 1000 (806 to 991)	28 fewer per 1000 (120 fewer to 65 more)	RR 0.97 (0.87 to 1.07)	18 677 (2 observational studies)	⊕○○○ VERY LOW ^{d,e}	Evidence from observational studies suggests that telemedicine results in little to no difference in contraception uptake following abortion; however, the certainty is very low.
Haemorrhage requiring transfusion follow up: up to 2 months	1 per 1000	1 per 1000 (0 to 1)	0 fewer per 1000 (0 fewer to 1 more)	RR 0.94 (0.43 to 2.08)	55 555 (4 observational studies)	⊕○○○ VERY LOW ^{c,f}	Evidence from observational studies suggests that telemedicine results in little to no difference in haemorrhage requiring blood transfusion; however, the certainty is very low. A very small percentage of women (<0.1%) required transfusion.
Hospitalization follow up: up to 2 months	0 events	0 events	-	-	30 433 (2 observational studies)	⊕○○○ VERY LOW ^{a,g}	No events reported in either group.
Death follow up: up to 4 months	0 events	0 events	-	-	55 555 (4 observational studies)	⊕○○○ VERY LOW ^{f,g}	No events reported in either group.
Overall satisfaction: very or somewhat satisfied	977 per 1000	987 per 1000 (957 to 1000)	10 more per 1000 (20 fewer to 39 more)	RR 1.01 (0.98 to 1.04)	431 (1 observational study)	⊕○○○ VERY LOW ^{d,h,i}	Evidence from observational studies suggests that telemedicine may result in little to no difference in overall satisfaction; however, the certainty is very low.

Outcomes	Anticipated absolute effects* (95% CI)		Risk difference with telemedicine	Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with in-person abortion care	Risk with telemedicine					
Would recommend to a friend	829 per 1000	896 per 1000 (829 to 971)	66 more per 1000 (0 fewer to 141 more)	RR 1.08 (1.00 to 1.17)	431 (1 observational study)	⊕○○○ VERY LOW ^{d,h,i}	Evidence from observational studies suggests that telemedicine may result in little to no difference in participants recommending the service to a friend; however, the certainty of the evidence is very low.

*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
CI: confidence interval; RR: risk ratio

Notes:

- Downgraded 3 levels due to critical risk of bias: non-randomized studies. The largest study was rated at critical risk due to confounding and selection bias. Women in the analysed cohort were offered a preliminary consultation via phone or video call, during which an assessment of eligibility for treatment via telemedicine was made. No adjustment for confounders was made.
- Downgraded 1 level due to inconsistency: $I^2 = 68\%$
- Downgraded 1 level due to imprecision: few cases
- Downgraded 2 levels due to risk of bias: non-randomized; confounders were not controlled for
- Downgraded 1 level due to inconsistency: $I^2 = 85\%$
- Downgraded 3 levels due to critical risk of bias: non-randomized studies. The two largest studies were rated at critical risk due to confounding and selection bias. In one study, women in the analysed cohort were offered a preliminary consultation via phone or video call, during which an assessment of eligibility for treatment via telemedicine was made. No adjustment for confounders was made.
- Downgraded 1 level due to imprecision: no events
- Single study, inconsistency cannot be assessed
- Downgraded 1 level due to imprecision: small sample size

References

Included studies:

- Aiken A, Lohr PA, Lord J, Ghosh N, Starling J. Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study. BJOG. 2021.
- Grossman D, Grindlay K. Safety of medical abortion provided through telemedicine compared with in person. Obstet Gynecol 2017;130(4):778-82.

Grossman D, Grindlay K, Buchacker T, Lane K, Blanchard K. Effectiveness and acceptability of medical abortion provided through telemedicine. *Obstet Gynecol.* 2011;118(2):296-303.

Kohn JE, Snow JL, Simons HR, Seymour JW, Thompson Terri-Ann, Grossman D. Medication abortion provided through telemedicine in four U.S. states. *Obstet Gynecol.* 2019;134(2):343-50.

Lohr PA, Aiken ARA, Forsyth T, Trussell J. Telephone or integrated contraception counselling before abortion: impact on method choice and receipt. *BMJ Sex Reprod Health.* 2018;44(2):114-21.

Wiebe ER, Campbell M, Ramasamy H, Kelly M. Comparing telemedicine to in-clinic medication abortions induced with mifepristone and misoprostol. *Contraception.* 2020;2:100023.

14. EtD framework for Medical abortion provided in different settings

49. Best Practice Statement on service delivery

Part 1. There is no single recommended approach to providing abortion services. The choice of specific health worker(s) (from among the recommended options) or management by the individual themselves, and the location of service provision (from among recommended options) will depend on the values and preferences of the woman, girl or other pregnant person, available resources, and the national and local context. A plurality of service-delivery approaches can co-exist within any given context.

Part 2. Given that service-delivery approaches can be diverse, it is important to ensure that for the individual seeking care, the range of service-delivery options taken together will provide:

- access to scientifically accurate, understandable information at all stages
- access to quality medicines (including those for pain management)
- back-up referral support if desired or needed linkages to an appropriate choice of contraceptive services for those who want post-abortion contraception.

PICO 14: For a pregnant person seeking induced abortion, are community-based outreach models for provision of abortion care safe, effective and satisfactory/acceptable alternatives to provision of abortion care in a health-care facility by a trained health worker?

PICO 15: For a pregnant person seeking an induced abortion, is harm-reduction counselling on abortion care a safe, effective and satisfactory/acceptable alternative to routine in-clinic service delivery?

PICO 16: For a pregnant person seeking an induced abortion, can social marketing outreach provide improved access to safe, effective and satisfactory/acceptable induced abortion services compared with provision of abortion care in a health-care facility by a trained health worker?

PICO 17: For a pregnant person seeking induced abortion, is self-sourcing of medications through online sources a safe, effective and satisfactory/acceptable alternative to obtaining a prescription and/or medications from a trained health worker? (Full details are available in Annex 10 in the main guideline)

Evidence summaries

A series of systematic reviews were performed to assess the effectiveness, safety and acceptability of the above models. After discussion of each topic, the ERRG panel agreed that there was insufficient evidence to formulate a recommendation but that a good practice statement should be developed to address the range of counselling and support models that exist in the context of provision of medical abortion care.

Harm reduction counselling:

The systematic review of the question of whether harm reduction counselling is a safe, effective and satisfactory alternative to routine, in-clinic induced abortion services, found limited evidence. Four observational studies met the inclusion criteria (i.e. published studies where pregnant individuals were provided with information on safe use of abortifacient medications without being provided with the actual medication). They were set in three countries with a total of 4002 participants; none of the studies included a comparison group (Briozzo, 2006; Kahabuka, 2016; Labandera, 2016; Grossman, 2016). The interventions described in the reviewed studies could not always be strictly defined as “counselling” rather than provision of information.

Community-based outreach:

The systematic review on the use of outreach abortion care services (an extension of health facility-based primary care services used to reach the underserved) resulted in four observational studies for consideration. Of the four, two were comparative studies conducted in Nepal (Rocca 2018) and United Kingdom (Cameron 2015) involving a total of 1947 pregnant women who underwent a medical abortion at private pharmacies, outpatient SRH services and health facilities (including hospitals, primary health care centres and health posts). No differences are found in effectiveness, safety and satisfaction outcomes when comparing pharmacies with clinic-based settings. However, women tend to feel more satisfied with the pre-abortion care received and to call the community SHR service after medical abortion compared with hospitals.

Social marketing:

The systematic review on the question of whether social marketing outreach can provide access to safe, effective and satisfactory induced abortion services (compared with traditional, clinic-based abortion service provision, did not find any studies that met the inclusion criteria (i.e. RCTs, cohort studies, case-control studies, qualitative studies with or without comparisons, pre- and post-intervention studies). This means that there was no direct evidence on the impact of social marketing interventions on safe abortion services. Therefore, relevant articles were reviewed for indirect evidence (Sotheary, 2017; Gordon, 2006; Patouillard, 2007; Aya Pastrana, 2020; Olawepo, 2019; Wei, 2011; Gulzar, 2008; Agha, 2002; Aung, 2009). There was some indication that social marketing may increase access to different abortion method options, and may affect the cost/affordability of abortion. Unrelated to abortion, other studies indicated that social marketing could be a successful intervention for a range of health services/commodities (dietary intake, physical activity, substance misuse; Gordon, 2006; oral rehydration therapy (ORT), iron supplements, insecticide-treated bednets (ITNs), disease prevention; Aya Pastrana, 2020) in a range of settings (workplace, schools, family, community) and a range of subpopulations (youth, ethnic minorities; Patouillard, 2007).

15. EtD framework for Self-administration of injectable contraception

Recommendation 51: Injectable contraception (initiation and continuation)

Recommend the option of self-administration of injectable contraception in the post-abortion period.

PICO 18: For a person in the post-abortion period needing contraception, is **self-administration of injectable contraceptives (initiation or continuation)** a safe, effective and satisfactory/acceptable alternative to provision by a trained health worker? (Full details are available in Annex 10 in the main guideline)

BACKGROUND

Setting: Global

Perspective: Population

Literature review: A systematic review by Cochrane Response serves as the evidence base for this key question. Three RCTs and four observational comparative studies reporting on delivery of injectable contraceptives by women themselves were identified by the search strategy. The studies assessed the comparison self-administration versus health provider-administration of injectable contraception for women following abortion.

Study setting: Malawi, Senegal, Uganda, United Kingdom and USA.

ASSESSMENT OF RESEARCH EVIDENCE

For the analysis, research evidence was assessed for the following criteria:

- desirable effects
- undesirable effects
- certainty of evidence
- values
- balance of effects

The overall judgements on the above criteria are presented below to be considered by the ERRG in conjunction with information on values, resources, equity, acceptability or feasibility to arrive at recommendations.

Comparison 1. Self-administration versus health provider-administration of injectable contraception for women following abortion

Desirable effects:

Self-administration compared with health provider-administration of injectable contraception:

- may increase continuation rates at 3, 6 and 12 months (very low to low-certainty evidence)

- may have little or no effect on uninterrupted use of DMPA at 12 months (very low certainty evidence)
- may result in little or no effect on pregnancy rates (very low-certainty evidence)
- may result in little or no difference on satisfaction with the method and whether women would recommend the method to a friend (very low-to low-certainty evidence).
- may result in an increased willingness to continue with the same contraception method (very low to moderate-certainty evidence).

Undesirable effects:

Self-administration compared with health provider-administration of injectable contraception:

- may result in a slight reduction in any side-effects (very low to low-certainty evidence)
- may result in little or no effect on side-effects interfering with daily activities and injection site reactions were found (very low-certainty evidence)
- may result in little or no difference on adverse events and serious adverse events (low-certainty evidence). Overall, very few serious adverse events were reported.

Additional criteria

Values:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement (draft)

X			
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Resources required:

How large are the resource requirements (costs)?

Judgement (draft)

X						
Unable to determine	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Cost-effectiveness:

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement (draft)

X Unable to determine	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention
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Equity:

What would be the impact on health equity?

Judgement (draft)

Unable to determine	Varies	Reduced	Probably reduced	Probably no impact	X Probably increased	Increased
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Acceptability:

Is the intervention acceptable to key stakeholders?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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Feasibility:

Is the intervention feasible to implement?

Judgement (draft)

Unable to determine	Varies	No	Probably No	Probably Yes	X Yes
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SUMMARY OF FINDINGS TABLE

Comparison 1. Self-administration versus health provider-administration of injectable contraception for women following abortion

Q10. Self-administered injectable contraception compared to provider administered contraception for women of reproductive age, including post- abortion

Patient or population: Women needing/seeking injectable contraception, including post-abortion

Setting: Malawi, Senegal, Uganda, United Kingdom and USA

Intervention: Self-administration of injectable contraception

Comparison: Health-care provider administration of injectable contraception

Outcomes	Anticipated absolute effects* (95% CI)			Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Plain language summary
	Risk with provider administered injectable contraception	Risk with self-administered injectable contraception	Risk difference with self-administered injectable contraception				
Continuation rates	681 per 1000	865 per 1000 (797 to 933)	184 more per 1000 (116 more to 252 more)	RR 1.27 (1.17 to 1.37)	731 (1 RCT)	⊕⊕○○ LOW a,b,c	RCT evidence suggests that self-administered injectable contraception may increase continuation rates at 3 months, whereas one observational study suggests there is little to no difference.
Follow-up: 3 months	844 per 1000	928 per 1000 (818 to 1000)	84 more per 1000 (25 fewer to 211 more)	RR 1.10 (0.97 to 1.25)	122 (1 observational study)	⊕○○○ VERY LOW b,c,d,e	A cohort study with cross-over (N = 16) that could not be included in the analysis reported that 10 women completed both self-administration at home and clinic phases.
Continuation rates	550 per 1000	682 per 1000 (583 to 798)	132 more per 1000 (33 more to 248 more)	RR 1.24 (1.06 to 1.45)	401 (1 RCT)	⊕⊕○○ LOW a,b,c	RCT evidence suggests that self-administered injectable contraception may slightly increase continuation rates at 6 months, whereas one observational study suggests there is little to no difference.
Follow-up: 6 months	813 per 1000	894 per 1000 (772 to 1000)	81 more per 1000 (41 fewer to 228 more)	RR 1.10 (0.95 to 1.28)	122 (1 observational study)	⊕○○○ VERY LOW b,c,d,e	
Continuation rates	442 per 1000	597 per 1000 (473 to 756)	155 more per 1000 (31 more to 314 more)	RR 1.35 (1.07 to 1.71)	1264 (3 RCTs)	⊕○○○ VERY LOW a,c,f	RCT evidence suggests that self-administered injectable contraception may increase continuation rates at 12 months. Evidence from observational studies also

Outcomes	Anticipated absolute effects* (95% CI)			Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Plain language summary
	Risk with provider administered injectable contraception	Risk with self-administered injectable contraception	Risk difference with self-administered injectable contraception				
Follow-up: 12 months	703 per 1000	795 per 1000 (759 to 830)	91 more per 1000 (56 more to 127 more)	RR 1.13 (1.08 to 1.18)	2629 (3 observational studies)	⊕○○○ VERY LOW ^{c,d}	support this finding. However, the evidence is very uncertain. See reasons for discontinuation in Appendix 2.
Uninterrupted use of injectable contraception Follow-up: 12 months	483 per 1000	459 per 1000 (290 to 729)	24 fewer per 1000 (193 fewer to 246 more)	RR 0.95 (0.60 to 1.51)	90 (1 RCT)	⊕○○○ VERY LOW ^{b,c,g,h}	RCT evidence suggests that self-administered injectable contraception may have little to no effect on uninterrupted use of injectable contraception at 12 months, but the evidence is very uncertain.
Time between injections Follow-up: 12 months	median number of days between the fourth and fifth injection = 84 (95% CI 70 to 90)	median number of days between the fourth and fifth injection = 84 (95% CI 84 to 89)	-	p=0.38	90 (1 RCT)	⊕○○○ VERY LOW ^{b,c,g,i}	The time between injections was similar in both groups.
	-	35 days early to 14 days late	-	-	58 (1 observational study)	⊕○○○ VERY LOW ^{b,c,e,i}	The timing of self-administered injections ranged from 35 days early to 14 days late. None of injections were given with more than a 14-week interval between injections, but the evidence is very uncertain.
Pregnancy Follow-up: 12 months	16 per 1000	8 per 1000 (2 to 29)	8 fewer per 1000 (14 fewer to 14 more)	RR 0.49 (0.13 to 1.87)	928 (2 RCTs)	⊕○○○ VERY LOW ^{c,g,j}	The evidence is very uncertain about the effect of self-administered injectable contraception on pregnancy compared with injectable contraception administered by health workers.
	2 per 1000	3 per 1000 (1 to 13)	0 fewer per 1000 (2 fewer to 10 more)	RR 1.10 (0.23 to 5.25)	2459 (2 observational studies)	⊕○○○ VERY LOW ^{c,d,j}	

Outcomes	Anticipated absolute effects* (95% CI)			Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Plain language summary
	Risk with provider administered injectable contraception	Risk with self-administered injectable contraception	Risk difference with self-administered injectable contraception				
Side-effects Follow-up: 3 months	322 per 1000	257 per 1000 (203 to 325)	64 fewer per 1000 (119 fewer to 3 more)	RR 0.80 (0.63 to 1.01)	697 (1 RCT)	⊕⊕○○ LOW ^{b,g,k,l}	RCT evidence suggests self-administered injectable contraception may result in a small reduction in side-effects at 3 months, although there is a wide confidence interval consistent with the possibility for benefit and the possibility for no effect. Evidence from observational studies also supports this finding.
	347 per 1000	298 per 1000 (267 to 337)	49 fewer per 1000 (80 fewer to 10 fewer)	RR 0.86 (0.77 to 0.97)	2410 (2 observational studies)	⊕⊕○○ LOW ^{d,k}	
Side-effects Follow-up: 6 months	220 per 1000	170 per 1000 (121 to 238)	51 fewer per 1000 (99 fewer to 18 more)	RR 0.77 (0.55 to 1.08)	578 (1 RCT)	⊕⊕○○ LOW ^{b,g,k,l}	RCT evidence suggests self-administered injectable contraception may result in a small reduction in side-effects at 6 months, although there is a wide confidence interval consistent with the possibility for benefit and the possibility for no effect. Evidence from observational studies also supports this finding.
	267 per 1000	221 per 1000 (192 to 259)	45 fewer per 1000 (75 fewer to 8 fewer)	RR 0.83 (0.72 to 0.97)	2199 (2 observational studies)	⊕⊕○○ LOW ^{d,k}	
Side-effects Follow-up: 9 months	178 per 1000	134 per 1000 (89 to 202)	45 fewer per 1000 (89 fewer to 23 more)	RR 0.75 (0.50 to 1.13)	519 (1 RCT)	⊕⊕○○ LOW ^{b,g,k,l}	RCT evidence suggests self-administered injectable contraception may result in a small reduction in side-effects at 12 months, although there is a wide confidence interval consistent with the possibility for benefit and the possibility for no effect. Type of side-effects included: abdominal pain, nausea or vomiting; irregular or heavy bleeding; headaches; injection-site pain or irritation; amenorrhea; backaches; other aches or pains; decreased libido; and weight changes. Evidence from observational studies also supports this finding.
	225 per 1000	180 per 1000 (151 to 214)	45 fewer per 1000 (74 fewer to 11 fewer)	RR 0.80 (0.67 to 0.95)	2052 (2 observational studies)	⊕⊕○○ LOW ^{d,k}	

Outcomes	Anticipated absolute effects* (95% CI)			Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Plain language summary
	Risk with provider administered injectable contraception	Risk with self-administered injectable contraception	Risk difference with self-administered injectable contraception				
Side-effects interfering with daily activities: moderate/ very much	53 per 1000	54 per 1000 (28 to 100)	1 more per 1000 (24 fewer to 47 more)	RR 1.02 (0.54 to 1.90)	697 (1 RCT)	⊕○○○ VERY LOW b,g,k,m	The evidence is very uncertain about the effect of self-administered injectable contraception on side-effects interfering with daily activities. The wide confidence intervals at all three timepoints are consistent with the possibility for benefit and the possibility for harm.
• follow-up: 3 months							
• follow-up: 6 months	28 per 1000	18 per 1000 (6 to 54)	9 fewer per 1000 (21 fewer to 27 more)	RR 0.67 (0.23 to 1.97)	578 (1 RCT)	⊕○○○ VERY LOW b,g,h,k	
• follow-up: 9 months	23 per 1000	3 per 1000 (0 to 28)	20 fewer per 1000 (from 23 fewer to 4 more)	RR 0.14 (0.02 to 1.18)	519 (1 RCT)	⊕○○○ VERY LOW b,g,h,k	
Side-effects: injection site reactions	58 per 1000	137 per 1000 (44 to 428)	79 more per 1000 (14 fewer to 370 more)	RR 2.36 (0.76 to 7.36)	2410 (2 observational studies)	⊕○○○ VERY LOW d,k,n,o	Evidence from observational studies suggests that self-administered injectable contraception may result in an increase on injection site reaction, although the wide confidence intervals are consistent with the possibility for benefit and the possibility for harm. The evidence is very uncertain.
• injection 2							
• injection 3	58 per 1000	93 per 1000 (28 to 303)	35 more per 1000 (30 fewer to 245 more)	RR 1.60 (0.49 to 5.22)	2199 (2 observational studies)	⊕○○○ VERY LOW d,k,n,p	
• injection 4	35 per 1000	86 per 1000 (11 to 663)	51 more per 1000 (24 fewer to 628 more)	RR 2.43 (0.32 to 18.78)	2052 (2 observational studies)	⊕○○○ VERY LOW d,k,p,q	

Outcomes	Anticipated absolute effects* (95% CI)			Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Plain language summary
	Risk with provider administered injectable contraception	Risk with self-administered injectable contraception	Risk difference with self-administered injectable contraception				
Adverse events follow-up: 12 months	58 per 1000	53 per 1000 (31 to 94)	5 fewer per 1000 (27 fewer to 36 more)	RR 0.92 (0.53 to 1.62)	863 (2 RCTs)	⊕⊕○○ LOW _{g,k,r}	<p>RCT evidence suggests that self-administered injectable contraception may result in little to no difference in adverse events at 12 months.</p> <p>In one trial, 22 women in the self-administration group reported 50 adverse events (20 events were related or possibly related to the intervention), and 24 women in the provider-administration group reported 54 adverse events (28 events were related or possibly related to the intervention).</p> <p>The other trial reported zero adverse events in both groups.</p>
Serious adverse events	3 per 1000	4 per 1000 (0 to 25)	0 fewer per 1000 (3 fewer to 21 more)	OR 1.01 (0.14 to 7.20)	1179 (3 RCTs)	⊕⊕○○ LOW _{g,k,s}	Overall, very few serious adverse events were reported in the studies.

Outcomes	Anticipated absolute effects* (95% CI)			Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Plain language summary
	Risk with provider administered injectable contraception	Risk with self-administered injectable contraception	Risk difference with self-administered injectable contraception				
Follow-up: 12 months	Not estimable** 0/1249 (0%)	Not estimable** 1/1210 (0.1%)	Not estimable**	OR 3.21 (0.13 to 79.06)	2459 (2 observational studies)	⊕○○○ VERY LOW ^{d,k,s}	<p>RCT evidence suggests that self-administered injectable contraception may result in little to no effect on serious adverse events (SAE) at 12 months.</p> <p>Four women experienced serious adverse events in one trial. One woman in the provider group reported two events related to DMPA-SC (menorrhagia and anaemia requiring hospital admission). The other three events were deemed unrelated to DMPA-SC use (snakebite, death due to unrelated illness and menorrhagia due to miscarriage).</p> <p>The other two trials reported zero SAEs in both groups. Similarly, the evidence from observational studies suggests there is little no difference on serious adverse events between both groups, but the evidence is very uncertain.</p> <p>In one study, one serious adverse event occurred in a participant in the DMPA-SC group (death), which was determined to be unrelated to study participation. The other study reported zero events in both groups.</p>
Satisfaction: “somewhat to very satisfied” with injectable contraception end of intervention	918 per 1000	872 per 1000 (808 to 937)	46 fewer per 1000 (110 fewer to 18 more)	RR 0.95 (0.88 to 1.02)	316 (1 RCT)	⊕⊕○○ LOW ^{b,g,t,u}	<p>RCT evidence suggests that self-administered injectable contraception may result in little to no effect on satisfaction. Evidence from observational studies also supports this finding.</p>
	964 per 1000	915 per 1000 (838 to 1000)	48 fewer per 1000 (125 fewer to 39 more)	RR 0.95 (0.87 to 1.04)	116 (1 observational study)	⊕○○○ VERY LOW ^{d,t,u}	
Satisfaction: “wanting/ willingness to	784 per 1000	980 per 1000 (909 to 1000)	196 more per 1000 (125 more to 267 more)	RR 1.25 (1.16 to 1.34)	519 (1 RCT)	⊕⊕⊕○ MODERATE ^{b,g,t}	<p>RCT evidence suggests that self-administered injectable contraception probably increases willingness to continue with the same contraception method,</p>

Outcomes	Anticipated absolute effects* (95% CI)			Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Plain language summary
	Risk with provider administered injectable contraception	Risk with self-administered injectable contraception	Risk difference with self-administered injectable contraception				
continue with the same method” end of intervention	873 per 1000	881 per 1000 (777 to 1000)	9 more per 1000 (96 fewer to 140 more)	RR 1.01 (0.89 to 1.16)	116 (1 observational study)	⊕○○○ VERY LOW b,d,t,u	whereas evidence from observational studies suggests there is no difference. A cohort study with cross-over (N = 16) that could not be included in the analysis reported that all participants that completed the home phase (n = 10) preferred self- administered injection at home to nurse administration in the office.
Satisfaction: ‘Would recommend to a friend’ end of intervention	1000 per 1000	940 per 1000 (870 to 1000)	60 fewer per 1000 (130 fewer to 10 more)	RR 0.94 (0.87 to 1.01)	114 (1 observational study)	⊕○○○ VERY LOW b,d,t,u	RCT evidence suggests that self-administered injectable contraception may have little to no effect on the number of women who ‘would recommend to a friend’; however, the evidence is very uncertain. A cohort study with cross-over (N = 16) that could not be included in the analysis reported that all participants that completed the home phase (n = 10) would recommend self-administered injection at home to a friend.

*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** Assumed risk is not estimable because there were no events in the control group; the event rate is presented instead

CI: confidence interval; RCT: randomized controlled trial; RR: risk ratio; RD: risk difference; DMPA-SC: depot medroxyprogesterone acetate subcutaneous injections.

Notes:

- a. Downgraded 1 level due to risk of bias: high concerns regarding performance and detection bias (open label study)
- b. Single study, inconsistency cannot be assessed
- c. Downgraded 1 level due to indirectness: women of reproductive age who were already on injectable contraception or willing to initiate injectable contraception, regardless of prior history of abortion
- d. Downgraded 2 levels due to risk of bias: women were not randomized, confounders were not controlled or adjusted for, and all studies are open label
- e. Downgraded 1 level due to imprecision: small sample size and a wide confidence interval consistent with the for benefit and the possibility for no effect
- f. Downgraded 1 level due to inconsistency: $I^2 = 77\%$
- g. Downgraded 1 level due to risk of bias: high concerns regarding performance and detection bias (open label study) and high concerns regarding attrition bias
- h. Downgraded 2 levels due to imprecision: small sample size and a wide confidence interval consistent with the possibility for benefit and the possibility for harm
- i. Narrative outcome, imprecision cannot be assessed
- j. Downgraded 2 levels due to imprecision: few events and a wide confidence interval consistent with the possibility for benefit and the possibility for harm

- k. Although the study includes indirect population, we did not downgrade due to indirectness as we presume that side-effects and adverse events rates are similar in both populations
- l. Downgraded 1 level due to imprecision: wide confidence interval consistent with the for benefit and the possibility for no effect
- m. Downgraded 2 levels due to imprecision: wide confidence interval consistent with the possibility for benefit and the possibility for harm
- n. Downgraded 2 levels due to inconsistency: $I^2 = 87\%$
- o. Downgraded 1 level due to imprecision: wide confidence interval consistent with the possibility for large harm and the possibility for no effect
- p. Downgraded 2 levels due to imprecision: wide confidence interval consistent with the possibility for small benefit and the possibility for large harm
- q. Downgraded 2 levels due to inconsistency: $I^2 = 93\%$
- r. Downgraded 1 level due to imprecision: wide confidence interval consistent with the possibility of small benefit and the possibility for small harm
- s. Downgraded 1 level due to imprecision: very few events and a wide confidence interval consistent with the possibility for large harm and the possibility for no effect
- t. Although the study includes indirect population, we did not downgrade due to indirectness as we presume that satisfaction is similar in both populations
- u. Downgraded 1 level due to imprecision: small sample size

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