Health worker roles in providing safe abortion care and post-abortion contraception

Web Supplement 1

Evidence to Decision (EtD) Frameworks

WHO/RHR/15.11a

Contents

This document is a supplement to the guideline which is available at: http://www.who.int/reproductivehealth/publications/unsafe_abortion/abortion-task-shifting/en/

Introduction to the framework structure

Each framework has the following sections:

- **Background information:**
  - This section contains information about the PICO (population, intervention, comparator, outcome), the context and general information about the task.
- **Benefits and harms:**
  - This section contains the Summary of Findings tables on safety, effectiveness and satisfaction, a narrative description of the included studies, and relevant additional contextual information.
- **Acceptability:**
  - The section contains the summary of key findings from qualitative studies regarding the extent to which a task-shifting intervention is considered to be reasonable among women potentially or actually receiving abortion care and among health workers potentially or actually delivering this care. Acceptability to women was prioritized in decision-making; health worker acceptability informed implementation considerations.
- **Feasibility:**
  - This section contains the summary of key findings from qualitative research and from country case studies regarding the extent to which a task-shifting intervention is capable of being accomplished or implemented. The focus was on the feasibility of the intervention from a health system perspective, as well as on broader social, legal and political factors.
- **Resources:**
  - This section contains a summary of all resource-related outcomes reported within the studies that were selected for the safety and effectiveness evidence, and a qualitative assessment of resource needs in terms of training, supplies, referrals, supervision and monitoring, time and health worker remuneration. A health systems perspective was used in considering resource use, but especially for self-assessment and self-management approaches, resource use by women was also considered.
  - No formal cost analysis was conducted as such analyses tend to be very context specific; nor was a systematic search and evaluation of resource use information undertaken.
- **Overall recommendations and decisions.**
- **Implementation considerations.**
- **Research needs.**

MVA1 and EVA1 – Vacuum aspiration for induced abortion

Should ASSOCIATE CLINICIANS, MIDWIVES, NURSES, AUXILIARY NURSES AND AUXILIARY NURSE MIDWIVES and DOCTORS OF COMPLEMENTARY SYSTEMS OF MEDICINE provide induced abortion to 12–14 weeks using manual vacuum aspiration (MVA)/electric vacuum aspiration (EVA)?

Background

Option: Provision of MVA/EVA for induced abortion in the first trimester by associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives and doctors of complementary systems of medicine. MVA/EVA provision includes component subtasks including determining gestational age, cervical preparation, performance of the procedure, verifying completion through visual inspection of products and pain management.
Comparison: Specialist or non-specialist doctors
Outcomes: Safety, effectiveness, satisfaction, acceptability, feasibility
Setting: Outpatient primary care facility
Subgroups: EVA and MVA
Note: The GDG decided that these tasks were within the scope of practice of specialist and non-specialist doctors and outside the scope of practice for pharmacists, pharmacy workers and lay health workers.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 15)* assessed the safety, effectiveness and satisfaction of MVA/EVA for induced abortion when provided by associate clinicians, midwives, nurses, auxiliary nurses, auxiliary nurse midwives and doctors of complementary systems of medicine, compared to doctors.

The review included:

- No studies that assessed the effects of MVA or EVA for induced abortion when performed by doctors of complementary systems of medicine or auxiliary nurses/auxiliary nurse midwives, compared to doctors.
- Four studies that assessed the effects of MVA or EVA for induced abortion when performed by associate clinicians, midwives or nurses, compared to doctors.

Study settings: India, South Africa, United States of America (USA) and Viet Nam. All done in dedicated reproductive health (RH)/abortion care NGO clinics.

Other information: Cadre disaggregated information was not available for Viet Nam and for one of the studies in the USA. The India study used nurses and doctors who were fresh graduates. In South Africa and Viet Nam the doctors were more experienced than the other providers. Both USA studies had a mix of EVA and MVA use among all types of providers.

Pregnancy duration: In the India study involving nurses, mean gestational age (GA) of women handled by nurses was 8.7 weeks; 17% of cases were > 10 weeks. In South Africa, mean GA handled by the midwife was 7.7 weeks, 12% of cases were > 10 weeks. In Viet Nam, less than 1% of cases were over 10 weeks and the mean gestation of cases done was 6.1 weeks. Approximately, 20% of cases handled by physician assistants in one study in the USA were > 10 weeks.

Summary of Findings: *Associate clinicians compared to doctors (the findings also contain data for midwives where disaggregation was not possible) (Web Supplement 2, Annex 1c)*

What happens?	Physicians providing surgical abortion	Associate clinicians[1] providing surgical abortion	Certainty of the evidence
Effectiveness: Complete abortion, RCTs There is probably little or no difference in the rate of complete abortions when associate clinicians provide surgical abortion.	994 per 1000	982 per 1000 (974 to 994 per 1000)*	⨁⨁⨁◯ Moderate
Effectiveness: Complete abortion, non-RCTs We are uncertain of the effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low
Safety: Serious adverse events[2] non-RCTs We are uncertain of the effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low
Safety: Any surgical abortion-related complication[3] RCTs There is probably little or no difference in the rate of any complications when associate clinicians provide surgical abortion.	1 per 1000	1 per 1000 (0 to 9 per 1000)*	⨁⨁⨁◯ Moderate
Safety: Any surgical abortion-related complication[3] non-RCTs We are uncertain of the effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low
Overall satisfaction with abortion services No direct evidence identified			
Overall satisfaction with provider No direct evidence identified			
Satisfaction with overall abortion experience There may be little or no difference in satisfaction with the overall abortion experience when associate clinicians provide surgical abortion.	720 per 1000	739 per 1000 (718 to 760 per 1000)*	⨁⨁◯◯ Low

* 95% confidence interval.
[1] A mix of associate clinicians and midwives, see the forest plots for detailed information about the cadre.
[2] Hospital admission, need for further surgery (excluding treatment for incomplete abortion or ongoing/ectopic pregnancy), blood transfusion, or death.
[3] Haematometra, bleeding/haemorrhage, infection, uterine perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death.

Summary of Findings: *Midwives compared to doctors (the findings also contain data for clinical associates where disaggregation not possible) (Web Supplement 2, Annex 1d)*

What happens?	Physicians providing surgical abortion	Associate clinicians[1] providing surgical abortion	Certainty of the evidence
Effectiveness: Complete abortion, RCTs There is probably little or no difference in the rate of complete abortions when midwives provide surgical abortion.	994 per 1000	982 per 1000 (974 to 994 per 1000)*	⨁⨁⨁◯ Moderate
Effectiveness: Complete abortion, non-RCTs We are uncertain of the effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low
Safety: Serious adverse events[2] non-RCTs We are uncertain of the effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low
Safety: Any surgical abortion-related complication[3] RCTs There is probably little or no difference in the rate of any complications when midwives provide surgical abortion.	1 per 1000	1 per 1000 (0 to 9 per 1000)*	⨁⨁⨁◯ Moderate
Safety: Any surgical abortion-related complication[3] non-RCTs We are uncertain of the effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low
Overall satisfaction with abortion services No direct evidence identified			
Overall satisfaction with provider No direct evidence identified			
Satisfaction with overall abortion experience There may be little or no difference in satisfaction with the overall abortion experience when midwives provide surgical abortion.	720 per 1000	739 per 1000 (718 to 760 per 1000)*	⨁⨁◯◯ Low

* 95% confidence interval.
[1] A mix of associate clinicians and midwives, see the forest plots for detailed information about the cadre.
[2] Hospital admission, need for further surgery (excluding treatment for incomplete abortion or ongoing/ectopic pregnancy), blood transfusion or death.
[3] Haematometra, bleeding/haemorrhage, infection, uterine perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death.

Summary of Findings: *Nurses compared to doctors (Web Supplement 2, Annex 1e)*

What happens?	Physicians providing surgical abortion	Nurses providing surgical abortion	Certainty of the evidence
Effectiveness: Complete abortion There may be little or no difference in the rate of complete abortions when nurses provide surgical abortion.	991 per 1000	991 per 1000 (971 to 1001 per 1000)*	⨁⨁◯◯ Low
Safety: Any surgical abortion-related complications[1] There may be little or no difference in the rates of any surgical abortion-related complications when nurses provide surgical abortion.	14 per 1000	18 per 1000 (7 to 53 per 1000)*	⨁⨁◯◯ Low
Overall satisfaction with abortion services There may be little or no difference in satisfaction with abortion service when nurses provide surgical abortion.	977 per 1000	977 per 1000 (967 to 996 per 1000)*	⨁⨁◯◯ Low
Overall satisfaction with provider (willing to have future abortions with same provider type) There may be little or no difference in satisfaction with the provider when nurses provide surgical abortion.	977 per 1000	996 per 1000 (987 to 1016 per 1000)*	⨁⨁◯◯ Low

* 95% confidence interval.
[1] Haematometra, bleeding/haemorrhage, infection, uterine perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death.

Indirect evidence

When *doctors of complementary systems of medicine* provide medical abortion (which includes assessment of gestational age with bimanual examination a skill also needed for MVA provision), compared to doctors there may be little or no difference in accuracy of eligibility assessment. Additionally there may be little or no difference in number of complete abortions (effectiveness) or in the rate of serious adverse events (safety). There may be little or no difference in women's satisfaction with abortion services or in their satisfaction with the provider).

(Web Supplement 2, Annex 6b)

Additional considerations

The *Safe abortion guidelines* (published by WHO in 2012): MVA and EVA are both safe and effective methods for termination to 12–14 weeks. Both can be done in outpatient settings. Procedure time is typically 3–10 minutes. General anaesthesia is not required. MVA is associated with less pain in pregnancies under 9 weeks of gestation and with more procedural difficulty in pregnancies over 9 weeks. Pregnancies > 12 weeks may require more experience and access to appropriate size cannulae. Skills needed to be able to be trained in MVA/EVA

include ability to perform a bimanual pelvic examination to diagnose and date a pregnancy, and to perform a transcervical procedure such as intrauterine device (IUD) insertion.

The *Optimize MNH* guidelines (also published by WHO in 2012) recommend IUD insertion and removal by auxiliary nurse midwives, nurses, midwives and associate clinicians but restricts this procedure to rigorous research contexts for auxiliary nurses. Advanced level clinicians (but not associate clinicians) were recommended to do vacuum extraction, midwives were conditionally recommended to do vacuum extraction. Advanced level clinicians were conditionally recommended to do caesarean section.

Judgements

Do the desirable anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of complementary systems of medicine	☒	☐	☐	☐	☐	☐	☐
Associate clinicians, midwives, nurses	☐	☐	☐	☐	☒	☐	☐
Auxiliary nurses/auxiliary nurse-midwives (ANMs)	☒	☐	☐	☐	☐	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours doctor*	*Similar results*	*Probably favours cadre*	*Favours the cadre*
Doctors of complementary systems of medicine	☒	☐	☐	☐	☐	☐	☐
Associate clinicians, midwives, nurses	☐	☐	☐	☐	☒	☐	☐
Auxiliary nurses/ANMs	☒	☐	☐	☐	☐	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Doctors of complementary systems of medicine	☒	☐	☐	☐	☐
Associate clinicians, midwives	☐	☐	☐	☒	☐
Nurses	☐	☐	☒	☐	☐
Auxiliary nurses/ANMs	☒	☐	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours doctor*	*Similar results*	*Probably favours cadre*	*Favours the cadre*
Doctors of complementary systems of medicine	☒	☐	☐	☐	☐	☐	☐
Associate clinicians, midwives, nurses, auxiliary nurses/ANMs	☐	☐	☐	☐	☒	☐	☐

Resources required

Research evidence

One study in the review found that in the initial stages a small minority of newly trained providers turned to a supervisor for support (refilling the cannula or dilating the cervix).

One study noted that there were no differences in provider types in terms of time taken for the procedure although in one setting doctors completed the procedure faster.

One study estimated that one additional complication might occur per 100 procedures performed by an associate clinician.

We did not systematically evaluate other cost and resource literature.

Additional considerations

Training: Competency-based training in MVA or EVA procedure, counselling, infection prevention etc.

Supplies: Supply chain of equipment and supplies needed for MVA/ EVA provision.

Change of location of service delivery: If a shift to using a particular cadre (e.g. ANMs) results in services moving to a lower level of care, initial investments in setting up services, equipment and supplies and a referral chain at that level of care may be needed. However, it could also allow for move from EVA to MVA (no electricity requirements).

Referrals: Referral link to a facility able to deal with complications (a marginally higher rate of complications is possible).

Supervision/monitoring: Increased supervisory time for support in doing the procedure in initial stages.

Remuneration: Financial or other incentives may be needed to sustain service provision and ensure retention in rural /underserved areas.

Judgements

How large are the resource requirements?

	Don't know	*Varies*	*Large costs*	*Moderate*	*Negligible or savings*	*Moderate savings*	*Large savings*
Doctors of complementary systems of medicine	☐	☒	☐	☐	☐	☐	☐
Associate clinicians, midwives, nurses, auxiliary nurses/ANMs	☐	☐	☐	☐	☒	☐	☐

Does the balance of resource use and effectiveness favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of complementary systems of medicine	☐	☐	☐	☐	☒	☐	☐
Associate clinicians, midwives, nurses, auxiliary nurses/ANMs	☐	☐	☐	☐	☐	☒	☐

(Note: The reasoning is that initial resource investments in training and monitoring and in setting up additional services may be offset by longer-term savings from increased access to safe services and decrease in need for post-abortion care services.)

Acceptability

Research evidence

Acceptability among women

We were not able to identify research addressing the acceptability specifically of this particular task.

One review (*Web Supplement 3, Annex 29)* identified the following acceptability issues among women regarding task shifting for abortion services in general:

- Abortion care service users had mixed experiences with abortion care, ranging from care that met their expectations to mistreatment and abuse. Some women preferred care from nurses or midwives rather than doctors, as the former were seen as more supportive, and some preferred female health workers as this was seen as more appropriate. Anonymity was an important concern for some women, and they therefore preferred to seek care at a facility where it was less likely that they would be recognized (very low to moderate confidence).

Acceptability among health-care providers

One review (*Web Supplement 3, Annex 29)* identified the following acceptability issues among *health-care providers*:

- Providers had different views regarding the effectiveness of MVA. While some providers supported its use, some others continued to believe that it was not effective as the older method they were used to, i.e. dilatation and curettage (D&C)[1] (low confidence).
- In one setting, auxiliary nurse midwives who provided medical abortion independently felt confident and requested training in MVA and in the management of abortion complications (very low confidence).

Additional information

International Council of Midwives (ICM): charter of competencies includes MVA to 12 weeks as a core midwife competency (competency #7).

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Doctors of complementary systems of medicine, associate clinicians	☐	☐	☐	☐	☒	☐
Midwives, nurses	☐	☐	☐	☐	☐	☒
Auxiliary nurses/ANMs	☐	☒	☐	☐	☐	☒

[1] Finding comes from an older study. WHO guidelines recommend that D&C needs to be replaced with safer and more effective methods like MVA and EVA.

Judgement

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☒	☐	☐	☐	☐

Feasibility

Research evidence

We were unable to identify research that explored the feasibility to provide *MVA/EVA specifically*.

Indirect evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers regarding task shifting of abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these findings was assessed as low to moderate.

Additional information

Examples of settings where MVA use (for abortion or for post-abortion care) is being practiced:

- Associate clinicians (assistant doctors/ assistant medical officers/clinical health officers): Bangladesh, Cambodia, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Nepal, Pakistan, Uganda, United Republic of Tanzania, USA (some states, may be called as nurse practitioners), Viet Nam, Zimbabwe.
- Midwives: Cambodia (secondary midwives), China, Ethiopia, Gambia, Ghana, Kenya, Malawi, Nigeria, Sierra Leone, South Africa, Uganda, United Republic of Tanzania, Viet Nam (secondary midwives).
- Nurses: Ethiopia, Kenya, Nepal, South Africa.
- ANMs: Bangladesh (family welfare visitors provide menstrual regulation (MR) without pregnancy confirmation, national programme in operation since 1979).

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Doctors of complementary systems of medicine	☐	☐	☐	☐	☒	☐
Associate clinicians, midwives, nurses, auxiliary nurses/ANMs	☐	☐	☐	☐	☐	☒

MVA1 and EVA1 RECOMMENDATIONS:

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
Doctors of complementary systems of medicine	☐	☒	☐	☐
Associate clinicians	☒	☐	☐	☐
Midwives	☒	☐	☐	☐
Nurses	☒	☐	☐	☐
Auxiliary nurses/ANMs	☐	☒	☐	☐

Recommendations and justifications

	Recommendation with specifications as needed	***Justification***
Associate clinicians	The panel recommends the option of associate clinicians providing induced abortion using manual vacuum aspiration (MVA)/electric vacuum aspiration (EVA**)**.	There is evidence on the safety and effectiveness (moderate certainty) and for women's satisfaction with the overall abortion experience (low certainty). This option is feasible in both high- and low-resource settings, and may decrease inequities by extending safe abortion care to underserved populations

Midwives	The panel recommends the option of midwives providing induced abortion using manual vacuum aspiration (MVA)/electric vacuum aspiration (EVA**)**.	There is evidence on the safety and effectiveness (moderate certainty) and for women's satisfaction with the overall abortion experience (low certainty). This task is recognized as a core competency in midwifery. Women often consider care received from midwives as more supportive (moderate confidence). The option has been shown to be feasible, including in low-resource settings.
Nurses	The panel recommends the use of nurses to provide induced abortion using manual vacuum aspiration (MVA)/electric vacuum aspiration (EVA).	There is evidence on the safety and effectiveness (low certainty) and for women's satisfaction with this option (low certainty). Women often consider care received from nurses as more supportive (moderate confidence). The option is feasible and may decrease inequities by extending safe abortion care to underserved populations.
Auxiliary nurses/ANMs	The panel recommends that ANMs can provide induced abortion using manual vacuum aspiration (MVA)/electric vacuum aspiration (EVA) in contexts where such cadres are already providing MVA as part of emergency obstetric care or post-abortion care.	Although there is insufficient direct research evidence on the effectiveness of this option, the benefits outweigh any possible harms. The option has also been shown to be feasible including at scale in low-resource settings, and has the potential to decrease inequities by extending safe abortion care to rural and underserved populations.
Doctors of complementary systems of medicine	The panel recommends the option of doctors of complementary systems of medicine providing **induced** abortion to using manual vacuum aspiration (MVA)/electric vacuum aspiration (EVA) in contexts with established health systems mechanisms for the participation of this cadre in other tasks related to maternal and reproductive health**.**	There is evidence for effectiveness of components of the task, e.g. assessing uterine size with bimanual examination as part of medical abortion (MA) provision (low certainty). These professionals perform transcervical procedures like IUD insertion in some settings. The benefits outweigh possible harms and the option has the potential to increase equitable access to safe abortion care in regions where these professionals constitute a significant proportion of the health workforce.

Subgroup considerations

There does not appear to be any reason to make separate recommendation for MVA and EVA. MVA is more commonly used and more likely at primary care settings but the recommendations would apply equally to EVA.

Implementation considerations

Whatever the cadre, greater experience may be required for pregnancies > 12 weeks when using MVA.

Note that this is a primary care level task.

Research needs

None specified.

MVA2 and EVA2 – Vacuum aspiration for incomplete abortion

Should ASSOCIATE CLINICIANS, MIDWIVES, NURSES, AUXILIARY NURSES AND AUXILIARY NURSE MIDWIVES and DOCTORS OF COMPLEMENTARY SYSTEMS OF MEDICINE manage uncomplicated incomplete abortion for uterine size < 13 weeks using manual vacuum aspiration (MVA)/electric vacuum aspiration (EVA)?

Background

Option: Management of uncomplicated incomplete abortion for uterine size < 13 weeks with MVA/EVA by associate clinicians, midwives, nurses, auxiliary nurses/auxiliary nurse midwives and doctors of complementary systems of medicine. This includes component subtasks including determining uterine size, performance of the procedure and pain management.
Comparison: Doctors
Setting: Outpatient primary care facility
Outcomes: safety, effectiveness, satisfaction, acceptability, feasibility
Subgroups: EVA and MVA
Note: The Guideline Development Group (GDG) decided that these tasks were within the scope of practice of specialist and non-specialist doctors and outside the scope of practice for pharmacists, pharmacy workers and lay health workers.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 15*) did not find any studies that assessed the management of incomplete abortion using MVA or EVA by associate clinicians, midwives, nurses, auxiliary nurses or auxiliary nurse midwives and doctors of complementary systems of medicine compared to doctors.

Indirect evidence

The assessment of effectiveness of induced abortion using MVA or EVA when performed by associate clinicians, midwives and nurses shows the following:

When associate clinicians perform induced abortion using MVA or EVA, compared to doctors:

- *Effectiveness*: There is probably little or no difference in the rate of complete abortions.
- *Safety*: There is probably little or no difference in the rate of any complications (haematometra, bleeding/haemorrhage, infection, uterine perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death).
- *Satisfaction*: There may be little or no difference in satisfaction with the overall abortion experience when associate clinicians provide surgical abortion.

(*Web Supplement 2, Annex 1c)*

When midwives perform induced abortion using MVA or EVA, compared to doctors:

- *Effectiveness*: There is probably little or no difference in the rate of complete abortions.
- *Safety*: There is probably little or no difference in the rate of any complications (haematometra, bleeding/haemorrhage, infection, uterine perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death).
- *Satisfaction*: There may be little or no difference in satisfaction with the overall abortion experience when midwives provide surgical abortion.

(*Web Supplement 2, Annex 1d)*

When nurses perform induced abortion using MVA or EVA, compared to doctors:

- *Effectiveness*: There may be little or no difference in the rate of complete abortions.
- *Safety*: There may be little or no difference in the rates of any surgical abortion-related complications when nurses provide surgical abortion.
- *Satisfaction*: There may be little or no difference in women's satisfaction with the abortion services (low certainty evidence). There may be little or no difference in satisfaction with the provider when nurses provide surgical abortion.

(Web Supplement 2, Annex 1e)

Additional considerations

The Safe abortion guidelines: Incomplete abortion with uterine size < 13 weeks can be managed by MVA or EVA. Both are effective, both can be done in an outpatient setting. General anaesthesia is not required.

Skills needed to be able to be trained in MVA/EVA include ability to perform a bimanual pelvic examination to determine uterine size, perform a transcervical procedure such as IUD insertion.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of complementary systems of medicine	☒	☐	☐	☐	☐	☐	☐
Associate clinicians, midwives, nurses	☐	☐	☐	☐	☒	☐	☐
Auxiliary nurses/ANMs	☒	☐	☐	☐	☐	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of complementary systems of medicine	☒	☐	☐	☐	☐	☐	☐
Associate clinicians, midwives, nurses	☐	☐	☐	☐	☒	☐	☐
Auxiliary nurses/ANMs	☒	☐	☐	☐	☐	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
All cadres	☒				

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of complementary systems of medicine	☒	☐	☐	☐	☐	☐	☐
Associate clinicians, midwives, nurses	☐	☐	☐	☐	☒	☐	
Auxiliary nurses/ANMs	☒	☐	☐	☐	☐	☐	☐

Resources required

Research evidence

We did not systematically evaluate evidence on resources and costs.

Additional considerations

Training: Competency-based training in procedure as well as counselling, infection prevention etc. Training can be integrated with EmOC training in many contexts.

Supplies: Supply chain of equipment and supplies needed for MVA (as per *Safe abortion guidelines)*

Change of location of service delivery: If a shift to using a particular cadre (e.g. ANMs) results in services being moved to a lower level of care, initial investments in setting up services, equipment and supplies and a referral chain at that level of care may be needed. It could also allow for moving from EVA to MVA (no electricity requirements).

Referrals: Referral link to a facility able to deal with complications (a marginally higher rate of complications is possible).

Supervision/monitoring: Increased supervisory time for support in doing the procedure in initial stages.

Remuneration: Financial or other incentives may be needed to sustain service provision and ensure retention in rural/underserved areas.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
All cadres	☐	☐	☐	☐	☒	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☐	☒	☐

Note: Initial resource investments in training and monitoring and in setting up additional services may be offset by longer-term savings from increased access to post-abortion care and the decrease in severe morbidity and mortality.

Acceptability

Research evidence

Acceptability among women

We were able to identify little or no research that assessed the acceptability of this particular task shifting intervention among *women.*

Indirect evidence

One review (*Web Supplement 3, Annex 29*) identified the following acceptability issues among *women* regarding task shifting for abortion services in general:

- Abortion care service users had mixed experiences with abortion care, ranging from care that met their expectations to mistreatment and abuse, Some women preferred care from nurses or midwives rather than doctors as the former were seen as more supportive and some preferring female health workers as this was seen as more

appropriate. Anonymity was an important concern for some women, and they therefore preferred to seek care at a facility where it was less likely that they would be recognized (very low to moderate confidence).

Acceptability among health-care providers

One review (*Web Supplement 3, Annex 29*) identified the following acceptability issues among *health-care providers* regarding this task-shifting intervention:

- Providers had different views regarding the effectiveness of MVA. While some providers supported its use, some others continued to believe that it was not effective as the older method they were used to, i.e. D&C[2] (low confidence).
- In one setting, auxiliary nurse midwives who provided medical abortion independently felt confident and requested training in MVA and in the management of abortion complications (very low confidence).
- Providers had different views regarding the provision of post-abortion care. While some were positive, saw it as necessary, others treated post-abortion patients as a low priority compared to other patients (low confidence).
- Attitudes to task sharing for post-abortion care, for instance to midwives, was positive and regarded as increasing efficiency (moderate confidence).

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Doctors of complementary systems of medicine	☐	☒	☐	☐	☐	☐
Associate clinicians	☒	☐	☐	☐	☐	☐
Midwives, nurses, auxiliary nurses/ANMs	☐	☐	☐	☐	☒	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☒	☐	☐	☐	☐

[2] Finding comes from an older study. WHO guidelines recommend that D&C needs to be replaced with safer and more effective methods like MVA and EVA.

Feasibility

Research evidence

We were unable to identify research that explored the feasibility of using non-doctor providers to provide *MVA/EVA for incomplete abortion specifically*.

Indirect evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for *different types of health-care providers* regarding task shifting abortion care in general, particularly in weaker health systems, including*:*

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these finding was assessed as low to moderate.

Additional information

Removal of retained products is one of the signal functions of basic emergency obstetric care (EmOC) and cadres trained in EmOC are supposed to be able to perform this intervention. In other settings, some cadres are allowed to do this as part of post-abortion care (PAC). Some *illustrative* examples are as follows:

- Associate clinicians (assistant doctors/ assistant medical officers/ clinical health officers): Bangladesh, Ghana, Kenya, Lao People's Democratic Republic, Malawi, Malaysia, Nepal, Pakistan, Uganda, Viet Nam.
- Midwives: Bhutan, Burkina Faso, Gambia, Ghana, Kenya, Malawi, Malaysia, Nigeria, Pakistan, Nepal (nurse midwives providing post-abortion care through national PAC programme since the late 1990s).
- Nurses: Bhutan, Burkina Faso, Guinea, Kenya, Malaysia, Nepal (since the late 1990s), Pakistan, Papua New Guinea, Philippines, Sierra Leone, Thailand, Turkey, Uganda, Zimbabwe.
- ANMs: Bangladesh (family welfare visitors), Nepal.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Doctors of complementary systems of medicine	☐	☐	☐	☐	☒	☐
Associate clinicians, midwives, nurses, auxiliary nurses/ANMs	☐	☐	☐	☐	☐	☒

MVA2/EVA2 RECOMMENDATIONS:

Type of recommendation/decision

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Doctors of complementary systems of medicine	☐	☒	☐	☐
Associate clinicians	☒	☐	☐	☐
Midwives	☒	☐	☐	☐
Nurses	☒	☐	☐	☐
Auxiliary nurses/ANMs	☐	☒	☐	☐

Recommendations and justifications

	Recommendation	*Justification*
Associate clinicians	The panel recommends the option of associate clinicians to manage incomplete abortion for uterine size < 13 weeks using manual vacuum aspiration (MVA)/electric vacuum aspiration (EVA).	There is evidence for the safety and effectiveness of provision of vacuum aspiration for induced abortion (moderate certainty) by these health workers. The skills required for the management of uncomplicated incomplete abortion with vacuum aspiration are similar.
Midwives	The panel recommends the option of midwives to manage incomplete abortion for uterine size < 13 weeks using manual vacuum aspiration (MVA)/electric vacuum aspiration (EVA).	There is evidence for the safety and effectiveness of provision of vacuum aspiration for induced abortion (moderate certainty) by these health workers. The skills required for the management of uncomplicated incomplete abortion with vacuum aspiration are similar. The option appears to be feasible, including in low-resource settings.

	Recommendation	*Justification*
Nurses	The panel recommends the use of nurses to manage incomplete abortion for uterine size < 13 weeks using manual vacuum aspiration (MVA)/electric vacuum aspiration (EVA).	There is evidence for the safety and effectiveness of provision of vacuum aspiration for induced abortion (low certainty) by these health workers. The skills required for the management of uncomplicated incomplete abortion with vacuum aspiration are similar. The option appears to be feasible, including in low-resource settings.
Auxiliary nurses/ANMs	We recommend this option be implemented in contexts where established health systems mechanisms to involve ANMs and ANs in provision of basic emergency obstetric care exist and where referral and monitoring systems are strong.	There is insufficient direct research evidence on the safety and effectiveness of this option. However, the option of this type of health worker delivering emergency obstetric care (which includes removal of retained products as a signal function) or post-abortion care using MVA has been shown to be feasible in programmes in several low-resource settings.
Doctors of complementary systems of medicine	We recommend this option be implemented in contexts with established health systems mechanisms for the participation of Doctors of complementary systems of medicine in other tasks related to maternal and reproductive health.	There is evidence for the effectiveness of components of the task, e.g. assessing uterine size with bimanual examination as part of MA provision (low certainty). These professionals perform transcervical procedures like IUD insertion in some settings This option has the potential to increase equitable access to safe abortion care in regions where these professionals constitute a significant proportion of the health workforce.

Subgroup considerations

- Appears to be no reason to separate out EVA and MVA in recommendations.

Implementation considerations

- Evacuation of retained products is also a signal function of basic emergency obstetric care (EmOC) and training and implementation can be integrated with EmOC services.
- Addressing provider attitudes towards service provision is a general implementation consideration.

Research priorities

- Implementation at scale.

MA1 and subtasks – Medical abortion in the first trimester

Should, ASSOCIATE CLINICIANS, MIDWIVES, NURSES, AUXILIARY NURSES AND AUXILIARY NURSE MIDWIVES and DOCTORS OF COMPLEMENTARY SYSTEMS OF MEDICINE provide medical abortion for pregnancies up to 12 weeks (i.e. first trimester) using mifepristone and misoprostol/misoprostol alone?

Background

Option: The provision of medical abortion for pregnancies in the first trimester (i.e. up to 12 weeks) using mifepristone and misoprostol/misoprostol alone by associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives and doctors of complementary systems of medicine (either fully or subcomponents of assessing eligibility, administering medications with instructions for their use, managing side-effects or assessing for completion).
Comparison: non-specialist or specialist doctors
Setting: Primary care facility; parts of the process may take place outside the facility
Outcomes: Safety, effectiveness, satisfaction, acceptability, feasibility
Subgroups: Mifepristone + misoprostol/misoprostol alone
Note: The GDG decided that these tasks were within the scope of practice of specialist and non-specialist doctors.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 16)* assessed the provision of medical abortion for pregnancies up to 12 weeks when provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives, compared to doctors. The review found:

- **no studies** that evaluated the provision of medical abortion by associate clinicians compared to doctors;
- **four studies** that evaluated the provision of medical abortion and its component tasks by doctors of complementary systems of medicine, midwives, nurses or auxiliary nurses/auxiliary nurse midwives, compared to doctors; and
- **one additional study** that evaluated the assessment of abortion completion by nurses.

Study settings: India, Mexico, Mozambique, Nepal, Sweden. Settings included public sector clinics as well as NGO or free-standing family planning clinics.

Other information: All cadres were new to the provision of MA in two studies and in one study the cadres did not have previous experience with bimanual exam or assessing gestational age. The nurse cadres in two studies had MVA training and considerably more years of professional experience than the doctors. Cadres were mixed (no disaggregated results available) in one study. All studies used mifepristone–misoprostol. While the four studies assessed overall medical abortion, they varied in the degree to which information was available on subtasks carried out by the study provider.

The one study that was looking only at assessing cadre ability to judge completion, included women who had had a misoprostol-only abortion.

Pregnancy duration: One study enrolled cases to 8 weeks, 2 studies enrolled cases to 9 weeks and one went up to 10 weeks.

Effectiveness, safety and satisfaction: Overall, the review shows that there may be little or no difference in effectiveness, safety or patient satisfaction when medical abortion is provided by these health-care providers compared to doctors.

Summary of Findings overview: *Doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives compared to doctors (Web Supplement 2, Annexes 6b–f; 6.1b–f; 6.2b–f; 6.3b–f; and 6.4b–f)*

	MA1: Provision of medical abortion	**MA1.1: Assessment of eligibility**	**MA1.2: Administration of medication + instructions for use**	**MA1.3: Management of common side-effects**	**MA1.4: Assessment of completion**
Doctors of complementary systems of medicine	*Effectiveness:* Little or no difference in number of complete abortions (low certainty)	Little or no difference (low certainty)			Little or no difference (low certainty)
	Safety: Little or no difference in the rate of serious adverse events (low certainty)				
	Satisfaction: Little or no difference in satisfaction with service (low certainty) Little or no difference in satisfaction with the provider (low certainty)				
Associate clinicians	No studies	No studies	No studies	No studies	No studies
Midwives	*Effectiveness:* Little or no difference in number of complete abortions (moderate certainty)				
	Safety: Little or no difference in number of serious adverse events (moderate certainty)				
	Satisfaction: More women are satisfied with the provider (moderate certainty)				
Nurses	*Effectiveness:* Little or no difference in the number of complete abortions. (moderate certainty)	Little or no difference (high certainty)	Little or no difference (high certainty)		Little or no difference (low certainty)

	MA1: Provision of medical abortion	MA1.1: Assessment of eligibility	MA1.2: Administration of medication + instructions for use	MA1.3: Management of common side-effects	MA1.4: Assessment of completion
	Safety: Little or no difference in the rate of serious adverse events (moderate certainty) *Satisfaction:* Little or no difference in overall satisfaction with abortion services (moderate certainty) Little or no difference in overall satisfaction with the abortion services (low certainty) Little or no difference in overall satisfaction with the allocated provider (moderate certainty)				
Auxiliary nurses/ auxiliary nurse midwives	*Effectiveness:* Little or no difference in number of complete abortions (moderate certainty) *Safety:* Little or no difference in the rates of serious adverse events (moderate certainty) *Satisfaction: Outcome not reported*	Little or no difference (moderate certainty)	Little or no difference (moderate certainty)	No evidence	No evidence

Indirect evidence on clinical associates

There is probably little or no difference in the rate of complete abortions when associate clinicians provide surgical abortion using MVA/EVA or in the rate of other complications.

(Web Supplement 2, Annex 1c)

Additional considerations

The *Safe abortion guidelines* indicate that mifepristone–misoprostol is the recommended regime – misoprostol alone can be used when mifepristone is not available. Routine follow-up visits are not mandatory if both mifepristone–misoprostol are used < 63 days.

Judgements for MA1 – medical abortion

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of complementary systems of medicine, nurses, auxiliary nurses/ANMs	☐	☐	☐	☐	☒	☐	☐
Associate clinicians	☒	☐	☐	☐	☐	☐	☐
Midwives	☐	☐	☐	☐	☐	☒	☐

Do the undesirable anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Doctors of complementary systems of medicine	☐	☐	☒	☐	☐
Associate clinicians	☒	☐	☐	☐	☐
Midwives, nurses, auxiliary nurses/ANMs	☐	☐	☐	☒	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of complementary systems of medicine, auxiliary nurses/ANMs	☐	☐	☐	☐	☒	☐	☐
Associate clinicians	☒	☐	☐	☐	☐	☐	☐
Midwives, nurses	☐	☐	☐	☐	☐	☒	☐

Resources required

Research evidence

We did not systematically search for and evaluate resource use information.

Within the studies included in the review: In the one study in a high resource setting, nurse midwives needed a second opinion significantly more often than physicians, but this decreased over time. The same study found that women needed a significantly less amount of time at the first visit at the clinic when the midwife was involved. Several studies noted that unscheduled visits and phone calls did not differ by the type of cadre providing care.

Additional information

Training:

- Competency-based training in all the steps involved in medical abortion; contraceptive counselling and values clarification. Duration of training could be from few hours to several days based on local requirements and on cadre's existing familiarity with other abortion-related interventions.

Supplies: supply chain of MA drugs; contraceptive availability

- Change of location of service delivery: If a shift to using a particular cadre (e.g. ANMs) results in services moving to a lower level of care, initial investments in setting up services, equipment and supplies and a referral chain at that level of care may be needed.

Referrals: Referral link to a provider/facility able to provide MVA if the cadre providing the medical abortion is not MVA trained (*Safe abortion guidelines* recommend access to MA back up). Link to higher level care for complication management.

Supervision/monitoring: Initial learning curve in involvement of a new cadre may mean increased time needed for the task, increased monitoring, increased supervision. This should decrease with time.

Remuneration: Financial or other incentives may be needed to sustain service provision and ensure retention in rural /underserved areas.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
All cadres	☐	☐	☐	☐	☐	☒	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of complementary systems of medicine, midwives, nurses, auxiliary nurses/ANMs	☐	☐	☐	☐	☐	☒	☐
Associate clinicians	☒	☐	☐	☐	☐	☐	☐

Acceptability

Research evidence

Acceptability for women

We were able to identify little or no research that assessed the acceptability of this specific task shifting intervention among women.

Indirect evidence: One review (*Web Supplement 3, Annex 29)* identified the following acceptability issues among *women* regarding task shifting *abortion care in general*. Abortion care service users had mixed experiences with abortion care ranging from care that met their expectations to mistreatment and abuse. Some women preferred care from nurses or midwives rather than doctors as the former were seen as more supportive, and some preferred female health workers as they were seen as more appropriate. Anonymity was an important concern for some women, and they therefore preferred to seek care at a facility where it was less likely that they would be recognized (very low to moderate confidence).

Acceptability for health-care providers

Two reviews (*Web Supplement 3, Annexes 28 and 29)* suggest that, for health-care providers, the acceptability of shifting the provision of medical abortion during the first trimester was mixed:

- Providers in a number of settings saw medical abortion as having a number of benefits for women. These included that it offered an additional method (to surgical abortion), that some women would find it less invasive and more acceptable, that it would give women more ability to control the process, and because medical abortion could be carried out by women themselves it could be used more discreetly and therefore with fewer potential legal consequences (moderate confidence).

- Some providers felt that medical abortion was only suitable for some women, and had informal criteria for assessing their suitability (moderate confidence).
- Some providers felt that medical abortion required more emotional care for women and that providers needed to be able to meet women's emotional and informational needs. This closer involvement in medical abortion was sometimes seen to have emotional impacts for mid-level providers. Midwives and nurses noted the importance of staying in contact with the woman during the procedure (low confidence).
- Some professionals had concerns about making drugs for medical abortion available to providers with lower levels of training than themselves (low confidence).

Indirect evidence

One review (*Web Supplement 3, Annexes 28 and 29*) suggests that, for different types of health-care providers, the acceptability of task shifting abortion care in general was mixed. The review shows that doctors, midwives and nurses varied in their willingness to become involved. Providers had a range of responses to involvement; Some were willing to be involved, others did not approve but agreed it was preferable to unsafe abortion, and still other providers refused any involvement at all (low to moderate confidence).

Additional information

The ICM charter of competencies for midwives includes medical abortion as a core competency (Competency #7): "prescribe, dispense, furnish or administer drugs (however authorized to do so in the jurisdiction of practice) in dosages appropriate to induce medication abortion".

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Doctors of complementary systems of medicine, associate clinicians, auxiliary nurses/ANMs	☐	☒	☐	☐	☐	☐
Midwives, nurses	☐	☐	☐	☐	☒	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☒	☐	☐	☐	☐

Feasibility

Research evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers regarding task shifting abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these findings was assessed as low to moderate.

Additional information

The provision of medical abortion by non-physician providers is already implemented in some country contexts – in some cases overall supervision by a doctor is needed. Gestational age limits are tied in to the approved limits for medical abortion in the countries.

- Associate clinicians: Ethiopia, Ghana, Kenya, Malawi, Mozambique, USA (some states), Zimbabwe.
- Midwives: Cambodia, China, Ethiopia, Ghana, Kenya, Mozambique, South Africa, Sweden, Tunisia, Viet Nam, USA (some states).
- Nurses: China, Ethiopia, Malawi, Mozambique, Nepal, South Africa, United Kingdom.
- ANMs: Nepal.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Doctors of complementary systems of medicine, associate clinicians, nurses, auxiliary nurses/ANMs	☐	☐	☐	☐	☒	☐
Midwives	☐	☐	☐	☐	☐	☒

MA1 and subtasks RECOMMENDATIONS:

Type of recommendation/decision

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Associate clinicians	☒	☐	☐	☐
Midwives	☒	☐	☐	☐
Nurses	☒	☐	☐	☐
Auxiliary nurses/ANMs	☒	☐	☐	☐
Doctors of complementary systems of medicine	☐	☒	☐	☐

Recommendations and justifications

	Recommendation	*Justification*
Associate clinicians	The panel recommends the option of associate clinicians providing medical abortion in the first trimester.	There is evidence for components of the task e.g. assessing gestation as part of MVA provision. There is also evidence that health worker types with similar or less comprehensive basic training (e.g. midwives, nurses, auxiliary nurse midwives) can provide medical abortion safely and effectively (moderate certainty). The option is feasible and the potential to expand access to underserved populations is high.
Midwives	The panel recommends the option of midwives providing medical abortion in the first trimester.	There is evidence on the safety and effectiveness (moderate certainty). More women are satisfied with the provider when midwives provide medical abortion (moderate certainty). The option appears feasible and is already being implemented in several country contexts.
Nurses	The panel recommends the option of nurses providing medical abortion in the first trimester.	There is evidence on safety and effectiveness, and women's satisfaction with abortion services with this option (moderate certainty).

	Recommendation	*Justification*
Auxiliary nurses/ANMs	The panel recommends the option of auxiliary nurses/ANMs providing medical abortion in the first trimester.	There is evidence on safety and effectiveness (moderate certainty). The option appears feasible and is already being implemented in some low-resource settings.
Doctors of complementary systems of medicine	The panel recommends the option of doctors of complementary systems of medicine providing medical abortion in the first trimester.	There is evidence on safety and effectiveness, and on women's satisfaction with the provider and services (low certainty). The benefits outweigh any possible harms and the potential to reduce inequities in access to safe abortion care in regions where such professionals form a significant proportion of the health workforce is high.

Subgroup considerations

None specified.

Implementation considerations

Ensure access to a facility/provider who can do vacuum aspiration if the provider doing the medical abortion is not trained in MVA provision.

Regulations related to prescribing authority to which various cadres are subject.

Research priorities

None specified**.**

MA1 and subtasks – Medical abortion in the first trimester by pharmacists and pharmacy workers

Should PHARMACISTS and PHARMACY WORKERS provide medical abortion in the first trimester using mifepristone and misoprostol/misoprostol alone?

Background

Option: Medical abortion in the first trimester using mifepristone and misoprostol/misoprostol alone (either fully or subcomponents of assessing eligibility, administering medications with instructions for their use, managing side-effects or assessing for completion) provided by pharmacists and pharmacy workers.
Comparison: Doctors or any other clinical cadre
Outcomes: Safety, effectiveness, satisfaction, acceptability, feasibility
Setting: Pharmacies
Subgroups: Mifepristone–misoprostol/misoprostol
Note: The GDG decided that these tasks were within the scope of practice of specialist and non-specialist doctors.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 19*) did not find any studies that assessed the management of the medical abortion process or its individual components when performed by pharmacists or pharmacy workers, compared to doctors or other clinical cadres.

Indirect evidence

A systematic review (*Web Supplement 2, Annex 18*) that assessed the effectiveness of using individual components of the medical abortion process, when provided by lay health workers, compared to doctors, shows the following:

- Fewer women may be assessed as eligible for medical abortion when lay health workers assess eligibility (low certainty evidence).
- The accuracy of the eligibility assessments cannot be estimated.
- The accuracy of the assessments of ectopic pregnancy cannot be estimated.
- There may be little or no difference in the number of complete abortion assessments when lay health workers assess medical abortion completeness (low certainty).
- The accuracy of the assessments of complete abortion cannot be estimated.

(*Web Supplement 2, Annexes 6.1i and 6.4i)*

A Cochrane systematic review (Nkansah et al., 2011; *Web Supplement 2, Annex 22*) examined the effect of outpatient pharmacists' non-dispensing roles on patient and health professional outcomes. The 36 included studies looked at pharmacist interventions that included monitoring of disease control and adverse drug reactions and compliance assessment. The review shows that:

- there was not enough quality evidence to make a conclusion about whether the delivery of patient-targeted services by pharmacists improve patient or health professional outcomes compares favourably to the delivery of the same services by a physician; and

- evidence supported the role of pharmacists in the delivery of patient-targeted services such as medication management and patient counselling to improve patient or health professional outcomes compared to the delivery of no comparable services.

Additional considerations

A systematic search looking at studies of knowledge and practices of pharmacy workers (*Web Supplement 3, Annex 36*) in low- and middle-income settings found that across both restrictive and liberal settings previously untrained pharmacy workers (studies did not distinguish between them) provide inaccurate information, may sell ineffective medication and provide incorrect information about its use, may not refer women to a health worker or provide her information on where to access one or may impose their moral judgements on women. Women do not necessarily interact with the pharmacist but with the pharmacy worker behind the counter.

Misoprostol is a prescription drug and dispensing misoprostol for management of incomplete abortion as per prescription of an authorized provider is expected within the scope of practice of pharmacists and pharmacy workers.

Judgements

Do the desirable anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the clinical cadres*	*Probably favours the clinical cadre*	*Does not favour either*	*Probably favours the pharmacists/ pharmacy workers*	*Favours the pharmacists/ pharmacy workers*
Pharmacists, Pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the clinical cadres*	*Probably favours the clinical cadres*	*Similar results*	*Probably favours the pharmacy worker*	*Favours the pharmacists/ pharmacy workers*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the clinical cadres*	*Probably favours the clinical cadres*	*Similar results*	*Probably favours the pharmacists/ pharmacy workers*	*Favours the pharmacists / pharmacy workers*
Pharmacist, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Resources required

Research evidence

We did not systematically search for and evaluate resource use information on pharmacist provision of medical abortion.

Additional information

Training:

- Competency-based training in all the steps involved in medical abortion; contraceptive counselling and values clarification.
- Training materials may be needed to be *de novo* for this cadre. Separate training programmes may be needed for pharmacists and for pharmacy workers even if they are at the same site.
- Given high turnover of pharmacy worker staff, repeated training sessions will be needed in order to sustain the intervention at a site.

Supplies: Supply chain of drugs; contraceptive availability.

Change of location of service delivery: Pharmacies that are not already delivering health-related interventions other than dispensing drugs may need to be set up with private space for counselling/interaction with women.

Referrals: Referral link to a provider /facility able to provide MVA. Link to higher level care for complication management

Supervision/monitoring: Systems will likely need to be set up *de novo*.

Remuneration: Financial incentives may be needed to sustain the referral linkages and meet reporting requirements; incentives or compensation for time may be needed for attending training sessions.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the clinical cadres*	*Probably favours clinical cadres*	*Similar results*	*Probably favours the pharmacists/ pharmacy workers*	*Favours the pharmacists/ pharmacy workers*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Acceptability

Research evidence

Acceptability among women

Three reviews (*Web Supplement 3, Annexes 27–29*) suggest that acceptability among *women* regarding task shifting for abortion care services (including medical abortion, counselling, or abortion-related family planning services) to pharmacies was mixed:

- Women sometimes preferred to go to pharmacies for information and for medical abortion because this was more convenient, private and cheaper than going to a health-care provider (low confidence). However, women as well as health providers sometimes distrusted pharmacists' ability to properly counsel and administer medical abortion. This distrust arose from a perception of pharmacists as businesspeople, as not holding adequate knowledge, and of being incapable or uninterested in providing follow-up in the case of complications. Distrust also stemmed from a sense that pharmacies and pharmacists were poorly regulated and controlled thus increasing the potential for unequal treatment options or prices for clients and counterfeit drugs (high confidence).
- In some settings men, female friends and others purchased drugs to induce abortion from pharmacies on behalf of women (low confidence). However, men's easy access to these drugs through pharmacies led to concern among health-care providers and others regarding the potential to coerce women. There was also some concern among health-care providers and older women that easy access through pharmacies would increase young women's ability to access medical abortion indiscriminately, potentially in substitution of birth control (low confidence).
- One study suggests that pharmacists' drug recommendations depended on the customer's ability to pay, with richer people being offered more expensive drugs; and whether or not the chemist knew the customer personally (low confidence).

Acceptability for health-care providers

We were able to identify little or no research that assessed the acceptability of this particular task shifting intervention among pharmacists and pharmacy workers.

Indirect evidence: Two reviews (*Web Supplement 3, Annexes 28 and 29*) suggest that the acceptability of shifting the provision of medical abortion to other health-care providers was mixed:

- Some providers felt that medical abortion was only suitable for some women, and had informal criteria for assessing their suitability (moderate confidence).
- Some providers felt that medical abortion required more emotional care for women and that providers needed to be able to meet women's emotional and informational needs. This closer involvement in medical abortion was sometimes seen to have emotional impacts for mid-level providers. Midwives and nurses noted the importance of staying in contact with the woman during the procedure (low confidence).
- Some professionals may have concerns about making drugs for medical abortion available to providers with lower levels of training than themselves (low confidence).

Additional information

Mifepristone and misoprostol are prescription drug and dispensing misoprostol for managing incomplete abortion as per prescription of an authorized provider is expected within the scope of practice for pharmacists and pharmacy workers.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, pharmacy workers	☐	☒	☐	☐	☐	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, pharmacy workers	☐	☒	☐	☐	☐	☐

Feasibility

Research evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified the following feasibility issues regarding task shifting *abortion care services* among pharmacists and pharmacy workers working both within and outside the formal health system:

- Some studies suggest that pharmacists and pharmacy workers often had incorrect knowledge about medical abortion (low confidence), although some pharmacists acknowledged this lack of knowledge and were keen to increase their skills (low confidence).

Indirect evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for *different types* of health-care providers regarding task shifting abortion care in general, particularly in weaker health systems, including*:*

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to policies of certain funding agencies. Our confidence in these finding was assessed as low to moderate.

Additional information: None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐

MA1 and subtasks RECOMMENDATIONS pharmacists and pharmacy workers:

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
Pharmacists	No recommendation made (see below**)**	☐	☐	☐
Pharmacy workers	☐	☐	☐	☒

Recommendations and justifications

	Recommendation	***Justification***
Pharmacists	No recommendation for the overall package; recommendations made for subtasks as below.	Before making a recommendation on full independent provision of medical abortion it will be important to demonstrate the effectiveness and feasibility of the subtasks.
Pharmacy workers	The panel does not recommend the option of pharmacy workers independently providing first trimester medical abortion.	There is no evidence on the safety, effectiveness, acceptability and feasibility of this approach. However it is important to note that, as with all other drugs and medications, pharmacy workers should dispense mifepristone and

misoprostol as indicated by prescription.

Subtasks of MA provision by pharmacists

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
a. *Assess eligibility*			***X***	
b. *Administration of medications with appropriate information*			***X***	
c. *Assessing completion of abortion process and need for clinic-based follow-up*			***X***	

Recommendations and justifications

	Recommendation	***Justification***
Assess eligibility	The panel recommends the option of pharmacists assessing eligibility for medical abortion within the context of rigorous research.	The approach has the potential to improve the triage of health care by screening and referral to appropriate health facilities. Rigorous research on this approach using simple tools and checklists is needed to address the uncertainties and to test the feasibility of the option in a programme setting.

	Recommendation	*Justification*
Administration of medications with appropriate information	The panel recommends the option of pharmacists administering medications for medical abortion with appropriate information within the context of rigorous research.	Dispensing medications on prescription is within the typical scope of practice of these health workers and should be continued. However, well-designed research is still needed on the effectiveness and feasibility in a programme setting of the approach of pharmacists independently making clinical judgements related to managing the process and its common side-effects. The approach has the potential to improve access as pharmacies are often women's first point of contact with the health system; however the feasibility of developing referral linkages with the health system also needs to be studied.
Assessing completion of abortion process and need for clinic-based follow-up	The panel recommends the option of pharmacists assessing completion of abortion process and the need for clinic-based follow-up for medical abortion within the context of rigorous research.	This option has the potential to improve the triage of health care by screening women in need of further care. Research on this approach using simple tools like urine pregnancy tests and checklists is needed, as is research to test the feasibility of the option in a programme setting.

Subgroup considerations

Mifepristone–misoprostol/misoprostol

Implementation considerations

Given that research into the best dosage and regimes for medical abortion for 63–84 days is also still evolving, the research into pharmacist ability to deliver subcomponents of medical abortion should be limited to pregnancy durations < 63 days.

Research priorities

Development of tools, feasibility of the approach.

MA1 – Medical abortion in the first trimester by lay health workers

Should LAY HEALTH WORKERS provide medical abortion in the first trimester using mifepristone and misoprostol/misoprostol alone?

Background

Option: Provision of medical abortion in the first trimester using mifepristone and misoprostol/misoprostol alone (either fully or subcomponents of assessing eligibility, administering medications with instructions for their use, managing side-effects or assessing for completion) provided by lay health workers.
Comparison: Doctors or other facility-based cadres
Outcomes: Safety, effectiveness, satisfaction, acceptability, feasibility
Setting: Community
Subgroups: Mifepristone and misoprostol/misoprostol alone
Note: The GDG decided that these tasks were within the scope of practice of specialist and non-specialist doctors.

Benefits and harms

Research evidence

- A systematic review (*Web Supplement 2, Annex 18)* assessed the provision of medical abortion < 12 weeks (in its entirety as well as subtasks) by lay health workers (LHWs) as compared to a doctor or other cadre of provider. The review found:
  - **no studies** that reported effectiveness, safety or satisfaction of medical abortion in the first trimester 12 weeks when provided by LHWs in its entirety compared with clinician providers; and
  - **two studies** that examined lay health workers' ability to assess eligibility for medical abortion and abortion completion compared to clinicians

  Study settings: India, Nepal, Ethiopia, South Africa

  Cadre specific information: LHWs in the studies (community health extension workers, ASHAs, female community health volunteers) included those working in within public sector health systems and NGO trained workers.

  Intervention-related information: Assessment of eligibility was performed using a checklist (one study) or a checklist and pregnancy test (one study). Determination of complete abortion was assessed using checklists in both studies (pregnancy test was not used).

Summary of Findings: *Lay health workers compared to clinicians, assessment of eligibility (Web Supplement 2, Annex 6.1i)*

What happens?	Physicians assessing eligibility	Lay health workers assessing eligibility	Certainty of the evidence
Eligibility assessment There may be fewer women assessed as eligible when lay health workers assess eligibility for medical abortion.	842 per 1000	706 per 1000 (675 to 731 per 1000)*	⨁⨁◯◯ Low
Accuracy of eligibility assessment (provider's assessment the same as the verifier's) We are uncertain of the effect of the intervention on this outcome as the direct group differences cannot be estimated.			
Inaccuracy of ectopic pregnancy assessment No direct evidence identified			

* 95% confidence interval.

Summary of Findings: *Lay health workers compared to clinicians, assessment of abortion completion (Web Supplement 2, Annex 6.4i)*

What happens?	Clinicians assessing completion of medical abortion	Lay health workers assessing completion of medical abortion	Certainty of the evidence
Effectiveness: Complete abortion assessment There may be little or no difference in the number of complete abortion assessments when lay health workers assess medical abortion completeness.	847 per 1000	839 per 1000 (813 to 873 per 1000)*	⨁⨁◯◯ Low
Effectiveness: Accuracy of complete abortion assessment We are uncertain of the effect of the intervention on this outcome as the direct group difference is not estimable.			

* 95% confidence interval.

Additional considerations

The Safe abortion guidelines: Mifepristone–misoprostol is the recommended regimen, misoprostol alone can be used when mifepristone is not available. The specific doses and regimes are different for < 63 days and between 63–84 days. Routine follow-up visits are not mandatory if both mifepristone–misoprostol are used though the guidelines indicate that approaches are being developed. The guidelines state that provision to stay in the facility until the abortion is complete is advised for > 63 days, though it acknowledges that research is ongoing on alternative strategies.

Optimize MNH recommended LHWs to:

- Use oxytocin to prevent or treat PPH (in context of rigorous research).
- Administer oral misoprostol to prevent PPH where a well functioning lay health worker programme already exists.
- Administer misoprostol to treat PPH (rigorous research).
- Manage puerperal sepsis with oral or IM antibiotics (rigorous research).
- Deliver injectable contraceptives (conditionally recommended).
- Insert and remove implants (rigorous research).

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours facility-based cadres*	*Probably favours facility-based cadres*	*Similar results*	*Probably favours LHW*	*Favours the LHW*
Lay health workers	X	☐	☐	☐	☐	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours facility-based cadres*	*Probably favours facility-based cadres*	*Similar results*	*Probably favours lay health workers*	*Favours lay health workers*
Lay health workers	☒	☐	☐	☐	☐	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Lay health workers	☐	☐	☒	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

Don't know	*Varies*	*Favours the facility-based cadre*	*Probably favours the facility-based cadre*	*Similar results*	*Probably favours the lay health worker*	*Favours the lay health worker*
☒	☐	☐	☐	☐	☐	☐

Resources required

Research evidence

We did not systematically collect research evidence on the additional resources that might be required for LHWs to provide this task.

Additional consideration

Training:

- Competency-based training in all the steps involved in medical abortion; contraceptive counselling, knowledge of legal conditions and values clarification. Duration of training could be from a few hours to several days based on local requirements and on cadre's existing familiarity with other abortion-related interventions.
- Early detection of pregnancy using urine pregnancy tests can be integrated with other aspects of MCH training as well since it has relevance whether pregnancy is wanted or unwanted.

Supplies: Supply chain of MA drugs; contraceptive availability. Availability of locally relevant checklists to assess eligibility and completion, availability and supply chains of urine pregnancy test both for pregnancy detection for eligibility and for determining ongoing pregnancy.

Change of location of service delivery: Moving care into community settings may result in cost savings associated with health-care facility provision, but initial investments in setting up services, equipment and supplies and a referral chain will be needed.

Referrals: Referral links needed to a primary care provider/facility able to provide further care for women screened by LHWs as being eligible for MA or those identified as needing further follow-up. Health-care facility backup for dealing with ongoing pregnancies.

Supervision/monitoring: Initial learning curve in involvement of a new cadre may mean increased time needed for the task, increased monitoring, increased supervision. This should decrease with time.

Remuneration: Financial or other incentives may be needed to sustain service provision especially as this cadre is often a volunteer cadre in many contexts.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
Lay health workers	☐	☒	☐	☐	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours facility-based cadre*	*Probably favours facility-based cadre*	*Similar results*	*Probably favours lay health worker*	*Favours lay health worker*
Lay health workers	☒	☐	☐	☐	☐	☐	☐

Acceptability

Research evidence

Acceptability among women

We were able to identify little or no research that assessed the acceptability of this specific task shifting intervention among women.

Indirect evidence: Four reviews (*Web Supplement 3, Annexes 28, 29, 32 and 33*) assessed the acceptability of task shifting to lay health workers for health services in general. These suggest the following:

- Recipients were generally very positive to lay health worker programmes (moderate confidence).
- Recipients appreciated the privacy afforded by lay health workers (low confidence).
- Recipients and other health workers found lay health worker drug delivery acceptable (low confidence).
- Women appreciated the provision of pregnancy tests through lay health workers, referring to the low cost, local availability, and privacy afforded by this group of health-care providers.

Acceptability among health-care providers

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified the following acceptability issues for lay health workers regarding task shifting medical abortion care:

- None of the reviews identified any data regarding the willingness of lay health workers to deliver abortion care services.
- The relationship between lay health workers and the formal health services impacted on lay health workers' willingness to accompany women to a facility (low confidence). Lay health workers' position in the community was sometimes undermined where specialist doctors refused to accept their referrals, or where complications occurred after an abortion for which they had referred a woman to the health services (low confidence).

Indirect evidence: Four reviews (*Web Supplement 3, Annexes 28, 29, 32 and 33)* assessed the acceptability of task shifting to lay health workers for health services in general:

- Where community-based lay health workers delivered different types of drugs, they were motivated by positive responses from the community and increased social respect (low confidence). These studies also suggest that recipients and other health workers found lay health worker drug delivery acceptable (low confidence). However, lay health workers were concerned over possible social or legal consequences if these interventions were perceived as unsuccessful or harmful (low confidence).
- Recipients were generally very positive to lay health worker programmes (moderate confidence).
- Recipients appreciated the privacy afforded by lay health workers (low confidence).

Additional information

None

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Lay health workers	☐	☐	☐	☐	☒	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Lay health workers	☐	☐	☐	☐	☒	☐

Feasibility

Research evidence

Two reviews (*Web Supplement 3, Annexes 28 and 33)* identified a number of feasibility issues specific to task shifting abortion care for lay health workers:

- Written systems of referral were difficult to use for lay health workers with low literacy levels (low confidence).
- Lay health workers sometimes found that the services for referring women were not there (low confidence).

Indirect evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers, including lay health workers, regarding task shifting abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services due to the policies of certain funding agencies. Our confidence in these findings was assessed as low to moderate.

Additional information

Country examples:

- Nepal: LHWs (female community health volunteers): early detection of pregnancy using urine pregnancy test and referral.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Lay health workers	☐	☒	☐	☐	☐	☐

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
Lay health workers	No recommendation made (see below**)**	☐	☐	☐

Recommendations and justifications

	Recommendation	***Justification***
Lay health workers	No recommendation for the overall package; recommendations made for subtasks as below	Before making a recommendation on full independent provision of MA < 84 days it will be important to demonstrate the safety and feasibility of the sub components (as below).

Subtasks of MA provision by lay health workers

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
a. Assess eligibility			**X**	
b. Administration of medications with appropriate information			**X**	
c. Assessing completion of abortion process and need for clinic-based follow-up			X	

Recommendations and justifications

	Recommendation	***Justification***
Assess eligibility	The panel recommends the option of lay health workers assessing eligibility for medical abortion within the context of rigorous research.	There may be fewer women assessed as eligible when lay health workers assess eligibility for medical abortion using simple checklists (low certainty). However, the option is promising and lay health workers are often involved, either formally or informally, in advising women who are seeking such care (moderate confidence). Well designed research is needed into refining the optimum tools and checklists needed and to test the feasibility in community settings.
Administering the medications, managing the process and common side-effects	The panel recommends the option of lay health workers administering medications with appropriate information for medical abortion within the context of rigorous research.	The option has the potential to expand access to safe care and well designed research has the potential to address any uncertainties around safety, effectiveness and feasibility.
Assessing completion of abortion process and need for clinic-based follow-up	The panel recommends the option of lay health workers assessing completion of abortion process and need for clinic-based follow-up within the context of rigorous research.	There is evidence that lay health workers can accurately assess abortion completeness using simple checklists (low certainty). Approaches using urine pregnancy test as part of the assessment toolkit could yield better results and require further research.

Subgroup considerations

The recommendation on LHW's role in assessing completion applies only to mifepristone–misoprostol abortions as the *Safe abortion guidelines* recommend clinic-based follow-up after a first trimester misoprostol alone abortion.

Implementation considerations

Referral mechanisms.

Research priorities

The development of tools, pregnancy tests, testing feasibility of the approach.

MA3 – Self management of components of early medical abortion

Should WOMEN self-manage components of the process of medical abortion in the first trimester?

Background

Option: Self-management of components of the process of medical abortion in the first trimester by women.
This assumes that this is taking place within the context of the woman having a source of appropriate and accurate information and that she has access to a health provider should she need or want it at any stage of the process.
Self-management tasks include determining eligibility, taking the medications unsupervised by a provider and outside of a facility, and self-assessing the successful completion of the abortion and determining the need for a follow-up visit.
Comparison: Doctor or other facility-based provider
Outcomes: safety, effectiveness, satisfaction, acceptability, feasibility
Setting: Community; home
Subgroups: Mifepristone and misoprostol/misoprostol alone

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 17*) evaluating the effectiveness, safety and satisfaction of medical abortion overall as well as with the management of various subtasks (eligibility assessment, appropriate administration of medications and determination of abortion completion) by women seeking medical abortion compared with doctors. The review found:

- **no studies** that assessed overall effectiveness, safety or acceptability of MA provision by women themselves compared to doctors;
- **one study** that reported women's ability to determine eligibility for MA using a checklist tool compared to a trained clinic-based provider using the same tool;
- **one study** that reported effectiveness, safety and acceptability of medical abortion when women self-administered mifepristone and misoprostol at home compared to use of mifepristone to initiate the MA process in a clinic supervised by a health professional. All received misoprostol for home use following mifepristone;
- **nine studies** that reported effectiveness, safety or acceptability of medical abortion when misoprostol was self-administered at home compared to in a clinic supervised by health professionals. All received mifepristone in clinic to initiate the MA process;
- **three studies** that reported on women's ability to actively self-assess abortion completion and/or determine need for additional follow-up; and
- **two studies** that reported effectiveness, safety or acceptability of medical abortion when women use an active approach to self-assessment of abortion completion.

Study settings: Albania, Austria, Finland, France, India, Nepal, Norway, Sweden, Tunisia, Turkey, Viet Nam, USA. Settings included public sector clinics as well as NGO or free standing family planning clinics.

More than half of the women in one study from India evaluating an active self-assessment approach to determining abortion completion were of low literacy.

Intervention specific information: All studies on self-administration of medications used the combined mifepristone and misoprostol regimens for MA. Eligibility was assessed with the aid of a gestational age dating wheel, a checklist of screening questions and/or a urine pregnancy test. Assessment of completion was done using a urine pregnancy test and/or a checklist of symptoms.

Pregnancy duration: No studies included women seeking medical abortion beyond 63 days' gestational age.

Summary of Findings MA 3.1 *(Web Supplement 2, Annex 8.1j)*

What happens?	Clinicians assessing eligibility	Women assessing eligibility	Certainty of the evidence
Eligibility assessment There may be fewer women assessed as eligible when women themselves assess eligibility for medical abortion.	840 per 1000	781 per 1000 (765 to 807 per 1000)*	⨁⨁◯◯ Low
Accuracy of eligibility assessment (the same as verifier's) Direct group differences not estimable			

* 95% confidence interval.

Summary of Findings MA3.2 *(Web Supplement 2, Annex 8.2j)*

What happens?	Administration of medication by clinicians/in clinical setting/offices	Administration of medication by women themselves/at home	Certainty of the evidence
Effectiveness: Complete abortion (determined by clinical assessment)[1] There may be little or no difference in the number of complete abortions when women themselves manage medication for medical abortion.	880 per 1000	871 per 1000 (844 to 906 per 1000)*	⨁⨁◯◯ Low
Safety: Serious adverse events[2] There may be little or no difference in the rate of serious adverse events when women themselves manage medication for medical abortion.	0 per 1666	0 per 213	⨁⨁◯◯ Low
Satisfaction with abortion service or method[3] There may be little or no difference in the number of women that are very or somewhat satisfied with the service or method when women themselves manage medication for medical abortion.	927 per 1000	908 per 1000 (871 to 955 per 1000)*	⨁⨁◯◯ Low

What happens?	Administration of medication by clinicians/in clinical setting/offices	Administration of medication by women themselves/at home	Certainty of the evidence
Satisfaction with abortion services or method[4] There may be more women that report the method to be acceptable when women themselves manage medication for medical abortion.	788 per 1000	938 per 1000 (788 to 1000 per 1000)*	⨁⨁◯◯ Low
Appropriate administration of mifepristone We are uncertain of effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low
Appropriate administration of misoprostol No direct evidence identified			
Appropriate self/home administration of misoprostol We are uncertain of the effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low

* 95% confidence interval. [1]In most of the studies, however, some studies do not report [2]Hospitalization, blood transfusion or death [3] Very or somewhat satisfied [4] Procedure is acceptable

Summary of Findings MA3.3 *(Web Supplement 2, Annex 8.3j)*

What happens?	Clinicians assessing complete medical abortion	Women assessing complete medical abortion	Certainty of the evidence
Effectiveness: abortion completion There is little or no difference in complete abortions when women themselves assess complete abortion.	939 per 1000	948 per 1000 (911 to 977 per 1000)*	⨁⨁⨁⨁ High
Safety: serious adverse events There is probably little or no difference in the number of serious adverse events when women themselves assess abortion completion.	3 per 1000	3 per 1000 (0 to 44 per 1000)*	⨁⨁⨁◯ Moderate
Complete abortion assessment There may be little or no difference in the number of complete abortions when women themselves assess completion of medical abortion.	846 per 1000	863 per 1000 (837 to 896)	⨁⨁◯◯ Low
Overall satisfaction with abortion services/provider No direct evidence identified			

* 95% confidence interval.

Additional considerations

The Safe abortion guidelines: Mifepristone–misoprostol is the recommended regime, misoprostol alone can be used when mifepristone is not available. The specific doses and regimes are different for < 63 days and between 63–84 days. Determination of eligibility includes determining pregnancy, gestational age, ruling out contraindications (previous allergic reaction to one of the drugs involved, inherited porphyria, chronic adrenal failure, known or suspected ectopic pregnancy). Though no clear recommendation (based on GRADE evidence assessment) was made on home use, guideline says that misoprostol use outside the facility (after mifepristone has been used) is an increasingly used option. Routine follow-up visit is not mandatory if both mifepristone–misoprostol are used. Guideline says that provision to stay in facility until abortion is complete is advised for > 63 days but that research is ongoing on alternative strategies.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the provider*	*Probably favours the provider*	*Does not favour either*	*Probably favours the woman*	*Favours the woman*
Self	☐	☐	☐	☐	☐	☒	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the provider*	*Probably favours the provider*	*Does not favour either*	*Probably favours the woman*	*Favours the woman*
Self-management	☐	☐	☐	☒	☐	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Self–management	☐	☐	☐	☒	☒

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the provider*	*Probably favours the provider*	*Does not favour either*	*Probably favours the woman*	*Favours the woman*
Self-management	☐	☐	☐	☐	☐	☒	☐

Resources required

Research evidence

Three of the reviewed studies, set in Nepal, Tunisia and Turkey, noted that a smaller percentage of women who self-administered their abortion medication made unscheduled visits or telephone calls to the hotline in comparison to those women who had their medication administered at the clinic. Two studies (both set in the USA) noted no difference between the two groups for unscheduled visits or telephone calls.

Additional information

Training: Accurate information about the medications, side-effects, knowing when to seek assistance from a provider and how to access contraception.

Supplies: Mifepristone and misoprostol with a mechanism to ensure that the drugs are not counterfeit.

Change of location of service delivery: Time and money saved for woman by reduction in visits to clinic, transport etc.

Referral: Link to a provider for information or in case of problems or for contraception.

Supervision/monitoring: Provider time freed up from having to deliver services. But additional time will be needed for providing information and counselling.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
Self-management	☐	☐	☐	☒	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the provider*	*Probably favours the provider*	*Does not favour either*	*Probably favours the woman*	*Favours the woman*
Self-management	☐	☐	☐	☐	☒	☐	☐

Acceptability

Research evidence

Acceptability among women

One review (*Web Supplement 3, Annex 27*) identified the following acceptability issues specific to self-administration of medical abortion:

- Women generally approved of the concept of self-administration and believed that it could be done feasibly, effectively and safely (high confidence).

- Women often reported some degree of anxiety at the beginning of the process but reported relief at the end of the process and a strong sense of satisfaction with the choice to self-administer (high confidence). Effective counselling by trained providers during the first step of the medical abortion that offered women a sense of confidence, being prepared, having a choice, and being in control were important in building the acceptability among women as was feeling like she had a choice in the decision to self-administer medical abortion (moderate confidence).

Acceptability among health-care providers

One review (*Web Supplement 3, Annex 27*) identified the following acceptability issues specific to self-administration of medical abortion:

- Providers generally approved of the concept of self-administration and believed that it could be done feasibly, effectively and safely (high confidence).
- Perceptions among providers about which kinds of health workers should be able to provide medical abortion drugs to women for self-administration depends on: perceptions of the strength of the drugs and hence the expertise in anatomy and physiology needed to explain their full effects; providers training in appropriate counselling for abortion; and providers knowledge of abortion-friendly emergency departments to refer women to in the case of complications; and clients experience, and therefore trust, of different health workers (moderate confidence).

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Self-management (to women, and providers)	☐	☐	☐	☐	☐	☒

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Self-management (to women, and providers)	☐	☐	☐	☐	☐	☒

Feasibility

Research evidence

One review (*Web Supplement 3, Annex 27*) identified the following feasibility issues specific to self-administration of medical abortion:

- Women were drawn to self-administration for a number of practical reasons including lower costs, ease of scheduling, reduced transport needs, ability to manage stigma, and quicker termination of pregnancy (high confidence). They also valued the sense of control over the abortion process and the ability to plan around work and caring duties and maximize comfort and support (moderate confidence).

- When women were counselled by trained providers in the use of misoprostol at home, providers trusted women's ability to comply with dosage and timing requirements, women felt confident and reported uncomplicated abortions for the most part, and women called hotlines or consulted providers when the abortion process did not proceed as expected (moderate confidence).
- Women sometimes confused self-administration of misoprostol for medical abortion with emergency contraception and oral contraceptives (low confidence). There are also reports of misunderstandings and inconsistencies regarding the prescription and use of pain killers as part of the counselling for home use (low confidence).

Additional information

None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Self-management	☐	☐	☐	☐	☒	☐

MA3 and subtasks RECOMMENDATION:

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
Self-management	No recommendation made (see below**)**	☐	☐	☐

Recommendations and justifications

	Recommendation	***Justification***
Self-management	No recommendation for the overall package; recommendations made for subtasks as below.	Individual components of the self-management of medical abortion have been tested; however there is as yet insufficient evidence on using all three components together.

Subtasks of MA self-management

Type of recommendation/decision

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
a. Assess eligibility			**X**	
b. Administration of medications with appropriate information		**X**		
c. Assessing completion of abortion process and need for clinic-based follow-up		**X**		

Recommendations and justifications

	Recommendation	*Justification*
Self-assessing eligibility	The panel recommends the option of women self-assessing eligibility for medical abortion in the context of rigorous research.	Women may be more conservative in assessing eligibility using simple checklists (low certainty). However, the approach is promising and further work on developing appropriate assessment tools is needed.
Managing the mifepristone and misoprostol medication without direct supervision of a health provider	The panel recommends the option of women managing mifepristone and misoprostol medication without direct supervision of a health provider in circumstances where women have a source of accurate information and access to a health provider should they need or want it at any stage of the process.	There is evidence that the option is safe and effective (low certainty evidence from numerous studies but using non-randomized designs given strong preferences of women for one or the other option). More women report the method to be satisfactory when it is self-managed (low certainty). Women find the option acceptable and feasible (high confidence) and providers also find the option feasible (high confidence).
Self-assessing completion of abortion process using pregnancy tests and checklists	The panel recommends the option of women self-assessing completion of abortion process using pregnancy tests and checklists in circumstances where both mifepristone and misoprostol are being used and when women have a source of accurate information and access to a health provider should they need or want it at any stage of the process.	There is evidence that the option is safe and effective including in low literacy, low-resource settings (moderate to high certainty).

Subgroup considerations

Mifepristone and misoprostol/misoprostol alone. All evidence is for mifepristone–misoprostol abortions, more caution needed for misoprostol alone.

Implementation considerations

Access to contraceptive counselling and services should be available to women.

Research priorities

None specified.

MA2 – Medical management, incomplete abortion

Should ASSOCIATE CLINICIANS, MIDWIVES, NURSES, AUXILIARY NURSES AND AUXILIARY NURSE MIDWIVES and DOCTORS OF COMPLEMENTARY SYSTEMS OF MEDICINE manage incomplete abortion for uterine size < 13 weeks using misoprostol?

Background

Option: Management of incomplete abortion for uterine size < 13 weeks with misoprostol by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives. This includes the component subtasks of diagnosing incomplete abortion, determining uterine size < 13 weeks, administering the misoprostol dose/s, verifying completion.
Comparison: Doctors
Outcomes: Safety, effectiveness, satisfaction, acceptability, feasibility
Setting: Outpatient primary care facility and higher
Subgroups: None

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 16*) assessed the management of incomplete abortion using misoprostol when provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses or auxiliary nurses/auxiliary nurse midwives, compared to doctors. The review identified:

- **no studies** of doctors of complementary systems of medicine, associate clinicians, nurses, auxiliary nurses/auxiliary nurse midwives; and
- **one study** of midwives.

Study settings: Uganda (rural and peri-urban primary health centres).

Cadre specific information: Government trained midwives. Midwives received study specific PAC training including in MVA provision. Adequate numbers of providers included in the study. Provider categories similar in terms of years of clinical experience.

Intervention-related information: Single dose of 600 mcg misoprostol orally. Assigned provider diagnosed incomplete abortion, administered the misoprostol, monitored the woman in the facility for four hours and provided contraceptive counselling.

Summary of Findings: *Midwives compared to doctors (Web Supplement 2, Annex 7d)*

What happens?	Physicians providing management of incomplete abortion	Midwives providing management of incomplete abortion	Certainty of the evidence
Effectiveness: Complete abortion (no need for surgical intervention) There is probably little or no difference in complete medical abortions when midwives provide management of incomplete abortions.	967 per 1000	957 per 1000 (938 to 986 per 1000)*	⨁⨁⨁◯ Moderate
Safety: Serious adverse events[1] There is probably little or no difference in the rate of serious adverse events when midwives provide management of incomplete abortion.	0 per 472	0 per 483	⨁⨁⨁◯ Moderate
Overall satisfaction with abortion services No direct evidence identified			
Overall satisfaction with provider (willing to have future abortion with similar provider type) There is probably little or no difference in overall satisfaction with the allocated provider when nurses provide medical abortion.	988 per 1000	988 per 1000 (968 to 997 per 1000)*	⨁⨁⨁◯ Moderate

* 95% confidence interval. [1]Hospitalization, blood transfusion or death

Indirect evidence

A systematic review (*Web Supplement 2, Annex 16*) assessed the effects of medical abortion and its individual components for induced abortion when provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses or auxiliary nurses/auxiliary nurse midwives, compared to doctors. This review shows that, overall, there is probably little or no difference in effectiveness or safety when medical abortion was provided by these health-care providers compared to doctors. This evidence was varyingly assessed as low, moderate or high certainty. Refer to EtD framework MA1 (see p. 25) for further details. The review also showed that there may be little to no difference in satisfaction with the abortion service when medical abortion is provided by these health-care providers compared to doctors, except in the case of midwives where more women are probably satisfied with provision by midwives. This evidence was also varyingly assessed as low, moderate or high certainty.

Additional considerations

The Safe abortion guidelines: Incomplete abortion with uterine size < 13 weeks can be managed by MVA/EVA or by misoprostol or by expectant management. All can be done at primary care in an outpatient setting. The use of medical methods of abortion requires the back-up of vacuum aspiration, either on-site or through referral to another health-care facility in case of failed or incomplete abortion.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Doctors of complementary systems of medicine, Associate clinicians, Nurses, auxiliary nurses/ANMs	☒	☐	☐	☐	☐
Midwives (indirect evidence from MA provision)	☐	☐	☐	☒	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

(based on indirect evidence for MA provision which is similar)

Resources required

Research evidence

The included study used a 5-day competency-based training for the nurses who were already trained in post-abortion care.

The study did not use routine ultrasound to determine incomplete abortion

We did not systematically collect other research evidence regarding the additional resources that might be required for this cadre to provide this task.

Additional considerations

Training:

- Competency-based training in all the steps involved in medical abortion; contraceptive counselling and values clarification. Duration of training could be from a few hours to several days based on local requirements and on the cadre's existing familiarity with other abortion-related interventions,

Supplies: supply chain of MA drugs; contraceptive availability

Change of location of service delivery: If a shift to using a particular cadre (e.g. ANMs) results in services moving to a lower level of care, initial investments in setting up services, equipment and supplies and a referral chain at that level of care may be needed.

Referrals: referral link to a provider/facility able to provide MVA if the cadre providing the medical abortion is not MVA trained (*Safe abortion guidelines* recommend access to MA back up). Link to higher level care for complication management.

Supervision/monitoring: Initial learning curve in involvement of a new cadre may mean increased time needed for the task, increased monitoring, increased supervision. This should decrease with time.

Remuneration: Financial or other incentives may be needed to sustain service provision and ensure retention in rural/underserved areas.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs*	*Moderate savings*	*Large savings*
Doctors of complementary systems of medicine, associate clinicians, midwives, nurses	☐	☐	☐	☒	☐	☐	☐
Auxiliary nurses/ANMs	☒	☐	☐	☐	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Does not favour either*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

Acceptability

Research evidence

Acceptability for women

We were able to identify little or no research that assessed the acceptability of this specific task shifting intervention among women.

Indirect evidence: One review (*Web Supplement 3, Annex 29*) suggests that, among women, the acceptability of task shifting abortion care in general was mixed. Abortion care service users had mixed experiences with abortion care, ranging from care that met their expectations to mistreatment and abuse, Some women preferred care from nurses or midwives rather than doctors, as the former were seen as more supportive and some preferring female health workers as this was seen as more appropriate. Anonymity was an important concern for some women, and they therefore preferred to seek care at a facility where it was less likely that they would be recognized (very low to moderate confidence).

Acceptability for health-care providers

Two reviews (*Web Supplement 3, Annexes 28 and 29*) suggest that, for different types of health-care providers, the acceptability of shifting the provision of medical treatment in connection with incomplete abortions was mixed:

- Some professionals had concerns about making drugs for medical abortion available to providers with lower levels of training than themselves (low confidence).
- Providers had different views regarding the provision of post-abortion care. While some were positive, saw it as necessary, and did not view it as resulting in blame or sin for the provider as she had not been involved in conducting the abortion, others treated post-abortion patients as a low priority compared to other patients (low confidence).
- Attitudes to task sharing for post-abortion care, for instance to midwives, was positive and regarded as increasing efficiency (moderate confidence).

Indirect evidence: One review (*Web Supplement 3, Annex 29)* suggests that, for different types of health-care providers, the acceptability of task shifting abortion care in general was mixed. The review shows that doctors, midwives and nurses varied in their willingness to become involved in abortion care (low to moderate confidence).

Additional information

None specified.

Judgement

Is the option acceptable to key stakeholders?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☐	☐	☐	☒	☐

(yes for women, but can vary among providers)

Feasibility

Research evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers regarding task shifting abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these findings was assessed as low to moderate.

Additional information

None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Doctors of complementary systems of medicine	☐	☐	☐	☐	☒	☐
Associate clinicians, midwives, nurses	☐	☐	☐	☐	☐	☒
Auxiliary nurses/ANMs	☐	☐	☐	☐	☒	☐

MA2 RECOMMENDATION:

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
Associate clinicians	☒	☐	☐	☐
Midwives	☒	☐	☐	☐
Nurses	☒	☐	☐	☐
Auxiliary nurses/ANMs	☒	☐	☐	☐
Doctors of complementary systems of medicine	☐	☒	☐	☐

Recommendations and justifications

	Recommendation	***Justification***
Associate clinicians	The panel recommends the option of associate clinicians providing management of uncomplicated incomplete abortion in the first trimester using misoprostol.	There is moderate certainty evidence on the safety and effectiveness of medical management of incomplete abortion by midwives and safety and moderate certainty effectiveness evidence for medical abortion by health worker types with similar or less comprehensive basic training. Additionally, there is direct evidence that these health workers can assess gestational age as part of MVA provision. The option is feasible and the potential to expand access to underserved populations is high.
Midwives	The panel recommends the option of midwives providing management of incomplete abortion in the first trimester using misoprostol.	There is evidence from a low-resource setting on the safety and effectiveness (moderate certainty) of this option and for women's overall satisfaction with the provider (moderate certainty) when midwives manage incomplete abortion. The option appears feasible and has the potential to reduce inequities in access to safe abortion.
Nurses	The panel recommends the option of nurses providing management of incomplete abortion in the first trimester using misoprostol.	There is evidence for the safety, effectiveness and satisfaction for provision of medical abortion (moderate certainty) and skills required for the management of incomplete abortion with misoprostol are similar. The option appears feasible and has the potential to reduce inequities in access to safe abortion.
Auxiliary nurses/ANMs	The panel recommends the option of ANMs providing management of incomplete abortion in the first trimester using misoprostol.	There is evidence for the safety and effectiveness of provision of medical abortion in the first trimester (moderate certainty) and skills required for management of incomplete abortion with misoprostol are similar.
Doctors of complementary systems of medicine	The panel recommends this option in contexts with established health systems mechanisms for the participation of doctors of complementary systems of medicine in other tasks related to maternal and reproductive health.	There is evidence for the safety and effectiveness of provision of medical abortion in the first trimester (low certainty) and skills required for management of incomplete abortion with misoprostol are similar.

Subgroup considerations

None. Recommendations would be same for incomplete abortion from induced or spontaneous.

Implementation considerations

Considerations for restrictions on prescribing authority for some cadres or other ways of allowing them to use medications within the health system.

Integrate training and implementation with basic emergency obstetric care (EmOC) services

Research priorities

None specified

MA2 – Medical management, incomplete abortion by pharmacists and pharmacy workers

Should PHARMACISTS and PHARMACY WORKERS manage incomplete abortion < 13 weeks using misoprostol?

Background

Option: Management of incomplete abortion at < 13 weeks by pharmacists and pharmacy workers. (This includes the component subtasks of diagnosing incomplete abortion, determining uterine size, administering the misoprostol dose/s, verifying completion).
Comparison: Management by doctors or other facility-based clinical providers
Outcomes: Safety, effectiveness, satisfaction, acceptability, feasibility
Setting: Pharmacies
Subgroups: None

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 19*) did not find any studies that assessed the provision of medical abortion by pharmacists or pharmacy workers, compared to doctors.

Indirect evidence

A Cochrane systematic review (*Web Supplement 2, Annex 22*) examined the effect of outpatient pharmacists' non-dispensing roles on patient and health professional outcomes. The 36 included studies looked at pharmacist interventions that included monitoring of disease control and adverse drug reactions and compliance assessment. The review shows that:

- there was not enough quality evidence to make a conclusion about whether the delivery of patient-targeted services by pharmacists improve patient or health professional outcomes compares favourably to the delivery of the same services by a physician; and
- evidence supported the role of pharmacists in the delivery of patient-targeted services such as medication management and patient counselling to improve patient or health professional outcomes compared to the delivery of no comparable services.

Additional considerations

Misoprostol is a prescription drug and dispensing misoprostol for management of incomplete abortion as per prescription of an authorized provider is expected within the scope of practice for pharmacists and pharmacy workers.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the pharmacist/ pharmacy worker*	*Favours the pharmacist/ pharmacy worker*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the pharmacist/ pharmacy worker*	*Favours the pharmacist/ pharmacy worker*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the pharmacist/ pharmacy worker*	*Favours the pharmacist/ pharmacy worker*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Resources required

Research evidence

We did not systematically collect and evaluate research evidence regarding the additional resources that might be required for pharmacy workers and pharmacists to provide this task.

Additional considerations

Training:

- Competency-based training in diagnosing an incomplete abortion, assessing uterine size of < 13 weeks, use of misoprostol, management of process, provision of contraceptive counselling and values clarification.
- Training materials may be needed to be *de novo* for this cadre. Separate training programmes may be needed for pharmacists and for pharmacy workers.
- Given the high turnover of pharmacy worker staff, repeated training sessions will be needed in order to sustain the intervention at a site

Supplies: Mifepristone–misoprostol supply chain; contraceptive availability.

Change of location of service delivery: Pharmacies that are not already delivering health-related interventions other than dispensing drugs may need to be set up with private space for counselling /interaction with women.

Referrals: Referral link to a provider/facility able to provide MVA. Link to higher-level care for complication management.

Supervision/monitoring: systems will need to be set up

Remuneration: Financial incentives may be needed to sustain the referral linkages and meet reporting requirements; incentives or compensation for time may be needed for attending training sessions.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
Pharmacists, Pharmacy workers	☐	☐	☐	☒	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the pharmacist/ pharmacy worker*	*Favours the pharmacist/ pharmacy worker*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Acceptability

Research evidence

Acceptability among women

Three reviews (*Web Supplement 3, Annexes 27–29*) suggest that acceptability among *women* regarding task shifting for *abortion care services* (including medical abortion, counselling, or abortion-related family planning services) to pharmacies was mixed:

- Women sometimes preferred to go to pharmacies for information and for medical abortion because this was more convenient, private and cheaper than going to a health-care provider (low confidence). However, women as well as health providers sometimes distrusted pharmacists' ability to properly counsel and administer medical abortion. This distrust arose from a perception of pharmacists as businesspeople, as not holding adequate knowledge, and of being incapable or uninterested in providing follow-up in case of complications. Distrust also stemmed from a sense that pharmacies and pharmacists were poorly regulated and controlled thus increasing the potential for unequal treatment options or prices for clients and counterfeit drugs (high confidence).
- In some settings, men, female friends and others purchased drugs to induce abortion from pharmacies on behalf of women (low confidence). However, men's easy access to these drugs through pharmacies led to concern among health-care providers and others regarding the potential to coerce women. There was also some concern among health-care providers and older women that easy access through pharmacies would increase young women's ability to access medical abortion indiscriminately, potentially in substitution of birth control (low confidence).
- One study suggests that pharmacists' drug recommendations depended on the customer's ability to pay, with richer people being offered more expensive drugs; and whether or not the chemist knew the customer personally (low confidence).

Acceptability for health-care providers

We were able to identify little or no research that assessed the acceptability of this particular task shifting intervention among pharmacists and pharmacy workers.

Additional information

A systematic search looking at studies of knowledge and practices of untrained pharmacy workers (*Web Supplement 3, Annex 36*) in low- and middle-income settings found that across both restrictive and liberal settings previously untrained pharmacy workers (studies do not provide a distinction) provide inaccurate information, may sell ineffective medication and may not refer women to a health worker or provide her information on where to access one or may impose their moral judgements on women. Women do not necessarily interact with the pharmacist but with the pharmacy worker behind the counter.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, Pharmacy workers	☐	☒	☐	☐	☐	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐

Feasibility

Research evidence

One review (*Web Supplement 3, Annex 29*) shows the following regarding the feasibility of providing abortion care services through pharmacists within and outside the formal health system:

- Some studies suggest that pharmacists and pharmacy workers often have incorrect knowledge about medical abortion (low confidence), although some pharmacists acknowledge this lack of knowledge and are keen to increase their skills (low confidence).

Indirect evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers regarding task shifting abortion care in general, particularly in weaker health systems, including*:*

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these finding was assessed as low to moderate.

Additional information

None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, pharmacy workers	☐	☒	☐	☐	☐	☐

MA2 RECOMMENDATION:

Type of recommendation/decision

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Pharmacists	☐	☐	☐	☒
Pharmacy workers	☐	☐	☐	☒

Recommendations and justifications

	Recommendation suggestions for discussion	*Justification*
Pharmacists	The panel recommends against the option of pharmacists independently managing incomplete abortions using misoprostol.	There is insufficient evidence of the safety and effectiveness of this option. It is also not within the scope of work for this cadre to conduct a full evaluation to diagnose incomplete abortion and determine uterine size.
Pharmacy workers	The panel recommends against the option of pharmacy workers independently managing incomplete abortions using misoprostol.	There is insufficient evidence of the safety and effectiveness of this option. It is also not within the scope of work for this cadre to conduct a full evaluation to diagnose incomplete abortion and determine uterine size.

Subgroup considerations: None specified.

Implementation considerations: None specified.

Research priorities: None specified.

MA2 – Medical management, incomplete abortion by lay health workers

Should LAY HEALTH WORKERS manage incomplete abortion < 13 weeks using misoprostol?

Background

Option: Management of incomplete abortion at < 13 weeks by lay health workers. This includes the component subtasks of determining eligibility, administering the misoprostol dose/s and verifying completion.
Comparison: Doctors or other facility-based providers
Setting: Community
Subgroups: None

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 18*) did not find any studies that assessed the provision of medical abortion for incomplete abortion by lay health workers, compared to doctors.

Indirect evidence

A systematic review (*Web Supplement 2, Annex 18*) that assessed the effectiveness of using individual components of the medical abortion process, when provided by lay health workers, compared to doctors, shows the following:

- Fewer women may be assessed as eligible for medical abortion when lay health workers assess eligibility (low certainty evidence).
- There may be little or no difference in the number of abortions assessed as completed (low certainty evidence).

(*Web Supplement 2, Annexes 6.1i and 6.4i)*

Additional considerations

Optimize MNH recommends LHWs to:

- use oxytocin to prevent or treat PPH (in context of rigorous research);
- administer oral misoprostol to prevent PPH where a well functioning lay health worker programme already exists;
- administer misoprostol to treat PPH (rigorous research);
- manage puerperal sepsis with oral or IM antibiotics (rigorous research);
- administer injectable contraceptives (conditionally recommended); and
- insert and remove implants (rigorous research).

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours LHW*	*Favours the LHW*
Lay health workers	☒	☐	☐	☐	☐	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Does not favour either*	*Probably favours the lay health worker*	*Favours the lay health worker*
Lay health workers	☒	☐	☐	☐	☐	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Lay health workers	☒	☐	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the LHW*	*Favours the LHW*
Lay health workers	☒	☐	☐	☐	☐	☐	☐

Resources required

Research evidence

We did not systematically collect research evidence regarding the additional resources that might be required for this cadre to provide this task.

Additional information

Training:

- Competency-based training in all the steps involved in medical abortion; contraceptive counselling, knowledge of legal conditions and values clarification. Duration of training could be from a few hours to several days based on local requirements and on cadre's existing familiarity with other abortion-related interventions.

- Early detection of pregnancy using urine pregnancy test can be integrated with other aspects of MCH training as well since it has relevance whether pregnancy is wanted or unwanted.

Supplies: Supply chain of MA drugs; contraceptive availability. Availability of locally relevant checklists to assess eligibility and completion, availability and supply chains of urine pregnancy test both for pregnancy detection for eligibility and for determining ongoing pregnancy.

Change of location of service delivery: Moving care into community settings may result in cost savings associated with health-care facility provision, but initial investments in setting up services, equipment and supplies and a referral chain will be needed.

Referrals: Referral link to a primary care provider/facility able to provide further care for women screened in by LHWs as being eligible for MA or those identified as needing further follow-up. Health-care facility backup for dealing with ongoing pregnancies.

Supervision/monitoring: Initial learning curve in involvement of a new cadre may mean increased time needed for the task, increased monitoring, increased supervision. This should decrease with time.

Remuneration: Financial or other incentives may be needed to sustain service provision especially as this cadre is often a volunteer cadre in many contexts.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
Lay health workers	☐	☐	☐	☒	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the lay health worker*	*Favours the lay health worker*
Lay health workers	☒	☐	☐	☐	☐	☐	☐

Acceptability

Research evidence

Acceptability among women

We were able to identify little or no research that assessed the acceptability of this specific task-shifting intervention among women.

Indirect evidence: Four reviews (*Web Supplement 3, Annexes 28, 29, 32 and 33*) assessed the acceptability of task shifting to lay health workers for health services in general. These suggest the following:

- Recipients were generally very positive to lay health worker programmes (moderate certainty evidence).
- Recipients appreciated the privacy afforded by lay health workers (low confidence).
- Recipients and other health workers found lay health worker drug delivery acceptable (low confidence).
- Women appreciated the provision of pregnancy tests through lay health workers, referring to the low cost, local availability, and privacy afforded by this group of health-care providers.

Acceptability among health-care providers

Two reviews (*Web Supplement 3, Annexes 28 and 29*) were unable to identify any data regarding the willingness of lay health workers to deliver abortion care services. The relationship between lay health workers and the formal health services impacted on lay health workers' willingness to accompany women to a facility (low confidence). Lay health workers' position in the community was sometimes undermined where specialist doctors refused to accept their referrals, or where complications occurred after an abortion for which they had referred a woman to the health services (low confidence).

Indirect evidence: Four reviews (*Web Supplement 3, Annexes 28, 29, 32 and 33*) assessed the acceptability of task shifting to *lay health workers* for *health services in general:*

- Where community-based lay health workers delivered different types of drugs, they were motivated by positive responses from the community and increased social respect (low certainty evidence). These studies also suggest that recipients and other health workers found lay health worker drug delivery acceptable (low certainty evidence). However, lay health workers were concerned over possible social or legal consequences if these interventions were perceived as unsuccessful or harmful (low certainty evidence).

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified the following acceptability issues for health-care providers other than lay health workers regarding task shifting medical abortion care. These reviews suggest that the acceptability to providers of such task shifting may be mixed:

- Some providers felt that continuity of abortion care was important, and that one provider should care for each woman through the abortion process (low confidence).
- Some professionals may have concerns about making drugs for medical abortion available to providers with lower levels of training than themselves (low confidence).

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Women and lay health workers	☐	☐	☐	☐	☒	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Women and lay health workers	☐	☐	☐	☐	☒	☐

Feasibility

Research evidence

Two reviews (*Web Supplement 3, Annexes 28 and 33*) identified a number of feasibility issues specific to *task shifting abortion care* for *lay health workers*:

- Written systems of referral were difficult to use for lay health workers with low literacy levels (low confidence).
- Lay health workers sometimes found that the services for referring women were not there (low confidence).

Indirect evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers, including lay health workers, regarding task shifting abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these findings was assessed as low to moderate.

Additional information

None specified.

Is the option feasible to implement?

Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
☒	☐	☐	☐	☐	☐

MA2 RECOMMENDATION:

Type of recommendation/decision

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Lay health workers	☐	☐	☒	☐

Recommendations and justifications

	Recommendation	*Justification*
Lay health workers	The panel recommends the option of lay health workers in managing incomplete abortions using misoprostol in the context of rigorous research.	There is no direct evidence on this task but some evidence that lay health workers can use simple tools and checklists to determine gestational age or abortion completeness (low certainty). Such health workers are often involved in advising women seeking such care (moderate confidence). In general LHW interventions are acceptable and have proved feasible in many contexts. Further development of tools and rigorous research can help address some of the uncertainties associated with this option.

Subgroup considerations

None specified.

Implementation considerations

None specified.

Research priorities

Research into lay health worker roles in this task require rigorous research on safety and effectiveness of their ability to recognize an uncomplicated incomplete abortion, administer the correct dose of misoprostol, ability to recognize and refer if other complications are present and the ability to recognize complications. Research into individual subcomponents is necessary before research on the full package. Strong referral linkage and backup care to emergency services must always be available.

D&E – Induced abortion using dilatation and evacuation at > 12 weeks

Should NON-SPECIALIST DOCTORS, ASSOCIATE CLINICIANS and DOCTORS OF COMPLEMENTARY SYSTEMS OF MEDICINE provide induced abortion at > 12 weeks using dilatation and evacuation (D&E)?

Background

Option: Provision of induced abortion > 12 weeks using dilatation and evacuation (D&E) by non-specialist doctors, doctors of complementary systems of medicine and associate clinicians.
Comparison: Specialist doctors
Setting: Referral hospitals
Subgroups: None
Outcomes: Safety, effectiveness, satisfaction, acceptability, feasibility
Note: The GDG decided that these tasks were outside the scope of practice for midwives, nurses, auxiliary nurses and auxiliary nurse midwives, pharmacists, pharmacy workers and lay health workers.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 15*) did not find any studies that assessed the provision of induced abortion with D&E by non-specialist doctors, doctors of complementary systems of medicine or associate clinicians, compared to specialist doctors.

Additional considerations

The Safe abortion guidelines: D&E is used for pregnancies > 12 weeks. Cervical priming prior to procedure is needed. Procedure can be done on outpatient basis with a paracervical block and non-steroidal anti-inflammatory analgesics or conscious sedation. General anaesthesia is not required and may increase risk. Use of ultrasound during the procedure may be helpful but not mandatory. Procedure takes about 30 minutes. Skills required are higher than similar procedures done using EVA/MVA for pregnancies < 12–14 weeks.

The *Optimize MNH* guidelines recommend most maternal health tasks including caesarean, vacuum extraction, tubal ligation considered as within scope of practice for non-specialist doctors and that advanced level clinicians can do vacuum extraction and conditionally recommended caesarean section for them. Both these tasks were not recommended for associate level clinicians.

Judgements

Do the desirable anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Non-specialist doctors	☐	☐	☐	☐	☒	☐	☐
Doctors of complementary systems of medicine, associate clinicians	☒	☐	☐	☐	☐	☐	☐

Do the undesirable anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Non-specialist doctors	☐	☐	☐	☐	☒	☐	☐
Doctors of complementary systems of medicine, associate clinicians	☒	☐	☐	☐	☐	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
All cadres	☒	☐	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Non-specialist doctors	☐	☐	☐	☐	☒	☐	☐
Doctors of complementary systems of medicine	☐	☐	☐	☒	☐	☐	☐
Associate clinicians	☒	☐	☐	☐	☐	☐	☐

Resources required

Research evidence

We did not systematically evaluate research evidence on resource needs specifically for doctors, associate clinicians and doctors of complementary systems of medicine in providing D&E.

Additional considerations

Training:

- Competency-based training in procedure and related aspects.
- Values clarification and careful pre-screening of trainees willing to perform second trimester procedures is needed.
- Trainers may not be locally or even nationally available,
- Training will need to be done at large facilities that see a high volume of second trimester cases

Supplies: Equipment and supplies for D&E (as per *Safe abortion guidelines* p. 70)

Referrals: Link to higher level care for complication management

Supervision/monitoring: Maintenance of D&E skills may require repeated training. Ongoing supportive supervision and mentoring mechanisms more crucial for second trimester abortion service provision

Remuneration: Financial and non-financial incentives and strategies to reduce burn out of providers and sustain service provision.

Judgements

How large are the resource requirements?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
All cadres	☐	☐	☒	☒	☐	☐	☐

Does the balance of resource use and effectiveness favor the option?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☒	☐	☐	☐	☐	☐	☐

Reasoning: Depends on local context, availability of trainers

Acceptability

Research evidence

Acceptability among women

We were able to identify little or no research that assessed the acceptability specifically of this particular task shifting intervention among women.

Indirect evidence

One review (*Web Supplement 3, Annex 29*) identified the following acceptability issues among *women* regarding task shifting for abortion services in general:

- Abortion care service users had mixed experiences with abortion care ranging from care that met their expectations to mistreatment and abuse. Some women preferred care from nurses or midwives rather than doctors as the former were seen as more supportive and some preferring female health workers as this was seen as more appropriate. Anonymity was an important concern for some women, and they therefore preferred to seek care at a facility where it was less likely that they would be recognized (very low to moderate confidence).

Acceptability among health-care providers

We were able to identify little or no research that assessed the acceptability specifically of this particular task shifting intervention among non-specialist doctors, doctors of complementary systems of medicine or associate clinicians. Two reviews (*Web Supplement 3, Annexes 28 and 29*) suggest that the acceptability of task shifting for abortion after first trimester among doctors, midwives and nurses was mixed based largely on their attitudes towards abortion care provision:

- These health-care providers' views on participating in abortions after first trimester varied. Some health-care providers, including doctors, midwives and nurses involved in either medical abortion or D&E in the second trimester, felt particularly uncomfortable because of the emotional burden of dealing with the fetus (low to moderate confidence). Some midwives developed strategies to cope with this, including not being present during the actual abortion procedure, while others saw second trimester abortions as part of their professional duty to women even though they found the work emotionally difficult (low confidence). Some midwives and nurses coped by attempting to distance themselves emotionally from patients and when dealing with the fetus (moderate confidence).

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☒	☐	☐	☐	☐

☐

Is the option acceptable to key health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☒	☐	☐	☐	☐

Feasibility

Research evidence

We were able to identify very little research that explored the feasibility of using *non-specialist doctors, doctors of complementary systems of medicine or associate clinicians* specifically to provide *D&E* or other methods of *abortion after second trimester abortion*.

Indirect evidence: Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers regarding task shifting abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these finding was assessed as low to moderate.

Additional information (country programmes)

National and sub-national programmes that incorporate D&E are few. Non-specialist doctors perform D&E in several settings, usually with specific requirements for additional training. Examples include China, Ethiopia, Ghana, Malawi, Malaysia, Nepal, South Africa, United Kingdom, USA (some states), Zimbabwe. Actual practice is unclear. NGO supported programmes exist in a few countries like Nepal.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Non-specialist doctors	☐	☐	☐	☐	☒	☐
Doctors of complementary systems of medicine, associate clinicians	☒	☐	☐	☐	☐	☐

D&E RECOMMENDATIONS:

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in context of rigorous research***	***Recommend against***
Non-specialist doctors	☒	☐	☐	☐
Associate clinicians	☐	☐	☒	☐
Doctors of complementary systems of medicine	☐	☐	☐	☒

Recommendations and justifications

	Recommendation	***Justification***
Non-specialist doctors	The panel recommends the option of non-specialist doctors providing induced abortion using D&E.	There was no direct evidence on the safety and effectiveness of this option as compared to specialist doctors. However, it appears to be feasible in both high and low-resource settings where D&E use is common. Such doctors also routinely perform other surgical procedures like caesarean section, vacuum extraction and tubal ligation. The potential benefits of this option outweigh the harms. A specialist provider may not always be available on site and this option may increase the ability of the health system to provide care for women needing it.
Associate clinicians	The panel recommends the option of associate clinicians providing induced abortion using D&E within the context of rigorous research.	There is no direct evidence on the safety and effectiveness, however the potential benefits outweigh the possible harms and the option has the potential to reduce inequities in access and increase the likelihood of facilities being able to provide care in the second trimester. Testing this option under research conditions is therefore important.
Doctors of complementary systems of medicine	The panel recommends against the option of doctors of complementary systems of medicine providing induced abortion using D&E.	There is no direct evidence on the safety, effectiveness and feasibility of this option. The procedure requires skills beyond what is required for vacuum aspiration in pregnancies up to 12 weeks and the procedure is usually performed at facilities where specialist or non-specialist doctors are available.

Subgroup considerations

None specified.

Implementation considerations

The procedure is facility-based but can be done on outpatient basis. There is a need for mentoring and support mechanisms for second trimester providers.

PRIME1 – Cervical priming with osmotic dilators

Should ASSOCIATE CLINICIANS, MIDWIVES, NURSES, AUXILIARY NURSES AND AUXILIARY NURSE MIDWIVES and DOCTORS OF COMPLEMENTARY SYSTEMS OF MEDICINE provide cervical priming with osmotic dilators?

Background

Option: Cervical priming with osmotic dilators or medications done by associate clinicians, midwives, nurses, auxiliary nurses, auxiliary nurse midwives and doctors of complementary systems of medicine. (This is a component of providing D&E and may be used prior to EVA/MVA too, but the task is separate from the main procedure and could be performed by a provider other than the one who does the main procedure).
Comparison: Doctors
Setting: Facility
Subgroups: None
Note: The GDG decided that these tasks were within the scope of practice of non-specialist doctors and outside the scope of pharmacists, pharmacy workers and lay health workers.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 15*) did not find any studies that specifically assessed the use of cervical priming using osmotic dilators by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses or auxiliary nurse midwives, compared to doctors.

Indirect evidence

The systematic review on MVA/EVA provision (*Web Supplement 2, Annex 15*) found that when associate clinicians were compared to doctors there was probably little or no difference in the rate of complete abortions (moderate certainty evidence). We were unable to assess the effect on number of serious adverse events (no evidence or very low certainty evidence). There may be little or no difference in the rate of overall abortion-related complications (low certainty evidence).

In one of the studies included in the above assessment, priming using laminaria was used by the assigned provider for procedures > 12 weeks (6.5% of all procedures). Outcomes specific to laminaria use were not reported.

Additional considerations

The *Safe abortion guidelines*: Cervical preparation with osmotic dilators or medications is recommended for all women undergoing a D&E. Priming (including with osmotic dilators) can be considered for women of any gestation and prior to vacuum aspiration as well. It is recommended they be placed intracervically 6–24 hours prior to the procedure.

The *Optimize MNH* guidelines:

- IUD insertion and removal: recommended for auxiliary nurse midwives, nurses, midwives and associate clinicians, but restricts to rigorous research context of auxiliary nurses. Alternate medicine doctors were not considered.

- Advanced level clinicians (but not associate clinicians) were recommended to do vacuum extraction; midwives were conditionally recommended to do vacuum extraction. Advanced level clinicians were conditionally recommended to do caesarean section.

Judgements

Do the desirable anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of complementary systems of medicine, midwives, nurses, auxiliary nurses/ANMs	☒	☐	☐	☐	☐	☐	☐
Associate clinicians	☐	☐	☐	☐	☒	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of complementary systems of medicine, midwives, nurses, auxiliary nurses/ANMs	☒	☐	☐	☐	☐	☐	☐
Associate clinicians	☐	☐	☐	☐	☒	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Doctors of complementary systems of medicine, midwives, nurses, auxiliary nurses/ANMs	☒	☐	☐	☐	☐
Associate clinicians	☐	☒	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of alternate medicine, midwives, nurses, auxiliary nurses/ANMs	☒	☐	☐	☐	☐	☐	☐
Associate clinicians	☐	☐	☐	☐	☒	☐	☐

Resources required

Research evidence

We did not systematically search for and evaluate resource use evidence for priming done with osmotic dilators by any of these cadres.

Additional considerations

Training:

- Competency-based training in laminaria insertion and removal and in related aspects of abortion care.

Supplies: Supply chain of osmotic dilators

Change of location of service delivery:

- Provision by nurses, midwives and ANMs could allow for initiation of the surgical process at primary care level and potential reduction in number of visits and time spent at a higher level facility.
- The shift to using a particular cadre may result in priming being offered at a lower level of care but if the D&E services are at a higher level of care this may increase costs for women and to the health services.

Referrals: Referral link to a provider/facility who will be providing the surgical abortion is needed. Link to higher level care needed for complication management.

Supervision/monitoring: Initial learning curve in involvement of a new cadre may mean increased time needed for the task, increased monitoring, increased supervision. This should decrease with time. The resources for this may be higher if the cadre providing the laminaria priming is not at the same facility where the surgical procedure will be performed.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
All cadres	☒	☐	☐	☐	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of complementary systems of medicine, midwives, nurses, auxiliary nurses/ANMs	☒	☐	☐	☐	☐	☐	☐
Associate clinicians	☐	☐	☐	☐	☒	☐	☐

Acceptability

Research evidence

Acceptability among women

We were able to identify little or no research that assessed the acceptability of this specific task-shifting intervention among women.

Indirect evidence: One review (*Web Supplement 3, Annex 29)* identified the following acceptability issues among women regarding task shifting for abortion services in general:

- Abortion care service users had mixed experiences with abortion care, ranging from care that met their expectations to mistreatment and abuse. Some women preferred care from nurses or midwives rather than doctors, as the former were seen as more supportive and some preferring female health workers as this was seen as more appropriate. Anonymity was an important concern for some women, and they therefore preferred to seek care at a facility where it was less likely that they would be recognized (very low to moderate confidence).

Acceptability among health-care providers

We were able to identify little or no research that assessed the acceptability of this particular task shifting intervention among health-care providers.

Indirect evidence: One review (*Web Supplement 3, Annex 29*) identified the following acceptability issues among health-care providers regarding task shifting for abortion services in general:

- The review shows that doctors, midwives and nurses varied in their willingness to become involved in abortion care. Providers had a range of responses to involvement; Some were willing to be involved, others did not approve but agreed it was preferable to unsafe abortion, and still other providers refused any involvement at all (low to moderate confidence.

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☒	☐	☐	☐	☐	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☒	☐	☐	☐	☐	☐

Feasibility

Research evidence

We were unable to identify research that explored the feasibility of using doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives to provide cervical priming specifically.

Indirect evidence: Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers regarding task shifting abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these findings was assessed as low to moderate.

Additional information

None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☒	☐	☐	☐	☐	☐

PRIME1 RECOMMENDATIONS:

Type of recommendation/decision

	Recommend	*Recommend in specific circumstances*	*Recommend in context of rigorous research*	*Recommend against*
Associate clinicians	☒	☐	☐	☐
Midwives	☐	☒	☐	☐
Nurses	☐	☒	☐	☐
Auxiliary nurses/ANMs	☐	☐	☐	☒
Doctors of complementary systems of medicine	☐	☐	☐	☒

Recommendations and justifications

	Recommendation	*Justification*
Associate clinicians	The panel recommends the option of associate clinicians providing cervical dilatation with osmotic dilators when required prior to a surgical abortion.	There is evidence for the safety and effectiveness of EVA/MVA provision (moderate certainty) which included cervical priming with osmotic dilators for select cases. This option may help optimize workflow within a facility and decrease waiting times for women.
Midwives	The panel recommends option of midwives initiating cervical dilatation with osmotic dilators in specific circumstances.	Although there is insufficient direct evidence on this option, midwives are recommended to do other transcervical procedures like inserting an IUD and there is evidence that provision of MVA by midwives is effective and safe (moderate certainty). This option may help optimize workflow within a facility and decrease waiting times for women.
Nurses	The panel recommends the option of nurses providing cervical priming with osmotic dilators in specific circumstances.	Although there is insufficient direct evidence on this option, nurses are recommended to do other transcervical procedures like inserting an IUD and there is evidence that provision of MVA by nurses is safe and effective (moderate certainty). This option may help optimize workflow within a facility and decrease waiting times for women.
Auxiliary nurses/ANMs	The panel recommends against the option of ANMs providing cervical priming with osmotic dilators.	There is insufficient direct evidence on the safety and effectiveness of this option. These health workers are not likely to be involved in second trimester abortion care.
Doctors of complementary systems of medicine	The panel recommends against the option of doctors of complementary systems of medicine providing cervical dilatation with osmotic dilators.	There is insufficient direct evidence on the safety and effectiveness of this option. These health workers are not likely to be involved in second trimester abortion care.

Subgroup considerations

None specified.

Implementation considerations

Osmatic dilators are placed 6 to 24 hours prior to the procedure. As such, placement can be performed by a health professional other than the provider conducting the D&E the placement can take place in a facility other than the facility in which the D&E will be performed.

Research priorities

None specified.

PRIME2 – Cervical priming with medications

Should DOCTORS OF COMPLEMENTARY SYSTEMS OF MEDICINE, ASSOCIATE CLINICIANS, MIDWIVES, NURSES, AUXILIARY NURSES AND AUXILIARY NURSE MIDWIVES provide cervical priming with medication?

Background

Option: Provision of cervical priming with medication by doctors of complementary systems of medicine, associate clinicians, midwives, auxiliary nurses, auxiliary nurse midwives. (Medication refers to using either oral mifepristone or sublingual or vaginal misoprostol). This is a component of providing D&E and may be used prior to EVA/MVA too, but the task is separate from the main procedure and could be performed by a provider other than the one who does the main procedure.
Comparison: Specialist doctors
Setting: No specific requirements
Subgroups: None
Note: The GDG decided that these tasks were within the scope of practice of specialist doctors and outside the scope of lay health workers.

Benefits and harms

Research evidence`

A systematic review (*Web Supplement 2, Annex 15*) did not find any studies that specifically assessed the use of cervical priming using medications by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses or auxiliary nurse midwives, compared to doctors.

Among the studies that included an overall assessment of MVA/EVA provision (*Web Supplement 2, Annex 15)* two studies noted the use of cervical priming pre procedure. In South Africa, sublingual misoprostol 400 mcg was used for all women but provision in both arms was by a non-study staff. In India, all women received IM prostaglandin 1–2 hours in advance of procedure, but it is unclear who provided it. Cadre-specific comparisons of priming are thus not possible. Overall, the review found that there is probably little or no difference in effectiveness of abortion when midwives are compared to doctors (moderate certainty) and there may be little or no difference in effectiveness when nurses are compared to doctors (low certainty).

Indirect evidence

A systematic review (*Web Supplement 2, Annex 16*) that assessed the provision of *medical abortion* by doctors of complementary systems of medicine, midwives, nurses and auxiliary nurse midwives shows that effectiveness may be similar when these cadres provide medical abortion (low to moderate certainty). The effect on serious adverse events was not estimable (full details in MA1 EtD framework).

Additional considerations

The Safe abortion guidelines: Cervical priming with osmotic dilators or misoprostol is recommended prior to D&E. Cervical priming is not routinely recommended at lower pregnancy duration but can be used for any woman and especially if woman is at risk of perforation/injury (i.e. case selection judgement is involved).

If mifepristone is used it is given orally 24–48 hours pre procedure, if misoprostol is being used it is given sublingually or vaginally 2–3 hours pre procedure. Both surgical and medical abortions > 12–14 weeks are facility-based procedures.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Does not favour either*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☒	☐	☐	☐	☐	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Does not favour either*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
All cadres	☒	☐	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

Resources required

We did not systematically search for and evaluate resource use evidence for priming done with medications by any of these cadres

Additional Considerations

Training: on safe abortion, legal issues, contraception

Supplies: misoprostol/mifepristone

Change of location of service delivery: decrease in hospital visit if priming is initiated outside of a health-care facility

Referrals: referral link to a provider /facility who will perform the surgical abortion

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
All cadres	☒	☐	☐	☐	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☒	☐	☐	☐	☐	☐	☐

Acceptability

Research evidence

Acceptability among women

We were able to identify little or no research that assessed the acceptability of this particular task shifting intervention among women.

Indirect evidence: One review (*Web Supplement 3, Annex 29*) suggests that, among *women*, the acceptability of task shifting *abortion care in general* was mixed. Abortion care service users had mixed experiences with abortion care, ranging from care that met their expectations to mistreatment and abuse. Some women preferred care from nurses or midwives rather than doctors, as the former were seen as more supportive and some preferring female health workers as this was seen as more appropriate. Anonymity was an important concern for some women, and they therefore preferred to seek care at a facility where it was less likely that they would be recognized (very low to moderate confidence).

Acceptability among health-care providers

We were able to identify little or no research that assessed the acceptability of this particular task shifting intervention among health-care providers.

Indirect evidence: One review (*Web Supplement 3, Annex 29*) identified the following acceptability issues among health-care providers regarding task shifting for abortion services in general:

- The review shows that doctors, midwives and nurses varied in their willingness to become involved in abortion care. Some providers refused any involvement; others did not approve but agreed it was preferable to unsafe abortion, while others were willing to be involved (low to moderate confidence).

Additional information

None specified.

Judgement

Is the option acceptable to key stakeholders?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☒	☐	☐	☐	☐	☐

Feasibility

Research evidence

We were unable to identify research that explored the acceptability of using doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives to provide cervical priming specifically.

Indirect evidence:

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers regarding task shifting abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these findings was assessed as low to moderate.

One review (*Web Supplement 3, Annexes 28 and 29*) identified the following feasibility issue for pharmacists and pharmacy workers working both within and outside the formal health system regarding task shifting for abortion care in general:

- Some studies suggest that pharmacists and pharmacy workers often had incorrect knowledge about medical abortion (low confidence), although some pharmacists acknowledged this lack of knowledge and were keen to increase their skills (low confidence).

Additional information

None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☒	☐	☐	☐	☐	☐

PRIME2 RECOMMENDATIONS:

Type of recommendation/decision

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Associate clinicians	☐	☒	☐	☐
Midwives	☐	☒	☐	☐
Nurses	☐	☒	☐	☐
Auxiliary nurses/ANMs	☐	☒	☐	☐
Doctors of complementary systems of medicine	☐	☒	☐	☐

Recommendations and justifications

	Recommendation	*Justification*
Associate clinicians	The panel recommends option of associate clinicians providing cervical priming with medication in specific circumstances.	There is evidence for health workers of similar or less comprehensive basic training e.g. midwives, nurses, ANMs using such medications to provide medical abortion (moderate certainty). Cervical priming is part of the training for MVA provision as well.
Midwives	The panel recommends option of midwives providing cervical priming with medication in specific circumstances.	There is evidence for safety and effectiveness of midwives being able to use these medications to provide medical abortion (moderate certainty). Cervical priming is part of the training for MVA provision as well.
Nurses	The panel recommends option of nurses providing cervical priming with medication in specific circumstances.	There is evidence for safety and effectiveness of nurses providing medical abortion using these medications (moderate certainty) and cervical priming is part of the training for MVA provision as well.
Auxiliary nurses/ANMs	The panel recommends option of auxiliary nurses/ANMs providing cervical priming with medication in specific circumstances.	There is evidence for safety and effectiveness of these health workers providing medical abortion using these medications (moderate certainty) and cervical priming is part of the training for MVA provision as well.
Doctors of complementary systems of medicine	The panel recommends option of doctors of complementary systems of medicine providing cervical priming with medication in specific circumstances.	There is evidence for safety and effectiveness of these health workers providing medical abortion using these medications (low certainty) and cervical priming is part of the training for MVA provision as well.

Subgroup considerations

None specified.

Implementation considerations

If mifepristone is used it is given orally 24–48 hours pre procedure; if misoprostol is being used it is given sublingually or vaginally 2–3 hours pre procedure.

Research priorities

None specified.

PRIME2 – Cervical priming with medications by pharmacists and pharmacy workers

Should PHARMACISTS AND PHARMACY WORKERS provide cervical priming with medication?

Background

Option: Provision of cervical priming with medication by pharmacists and pharmacy workers (medication refers to using either oral mifepristone or sublingual or vaginal misoprostol).
Comparison: Specialist doctors
Setting: Pharmacy
Subgroups: None
Note: The GDG decided that these tasks were within the scope of practice of specialist doctors and outside the scope of lay health workers.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 19*) did not find any studies that assessed the use of cervical priming using medications by pharmacists or pharmacy workers, compared to doctors.

Additional considerations

The Safe abortion guidelines: Cervical priming with osmotic dilators or misoprostol is recommended prior to D&E. Cervical priming is not routinely recommended at lower pregnancy duration but can be used for any woman and especially if woman is at risk of perforation/injury (i.e. case selection judgement is involved). If mifepristone is used it is given orally 24–48 hours pre procedure, if misoprostol is being used it is given sublingually or vaginally 2–3 hours pre procedure. Both surgical and medical abortions > 12–14 weeks are facility-based procedures.

A systematic search looking at studies of knowledge and practices of pharmacy workers (*Web Supplement 3, Annex 36*) in low- and middle-income settings found that across both restrictive and liberal settings previously untrained pharmacy workers (studies do not provide a distinction) provide inaccurate information, may sell ineffective medication and may not refer women to a health worker or provide her information on where to access one or may impose their moral judgements on women. Women do not necessarily interact with the pharmacist but with the pharmacy worker behind the counter.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Does not favour either*	*Probably favours the cadre*	*Favours the cadre*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Does not favour either*	*Probably favours the cadre*	*Favours the cadre*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Does not favour either*	*Probably favours the cadre*	*Favours the cadre*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Resources required

Research evidence

We did not systematically collect research evidence regarding the additional resources that might be required for this cadre to provide this task.

Additional information

Training:

- Unsafe abortion, legal aspects, safe providers, safe methods, contraception options etc. as well as values clarification.
- Separate training programs may be needed for pharmacists and for pharmacy workers as the background training of both groups is very different.
- Given high turnover of pharmacy worker staff, repeated training sessions will be needed in order to sustain the intervention at a site

Supplies: Information material, job aids

Change of location of service delivery: Pharmacies that are not already delivering health-related interventions other than dispensing drugs may need to be set up with private space for counselling/interaction with women.

Referrals: Referral link to a provider /facility able to provide safe abortion.

Supervision/monitoring: monitoring and accountability systems will need to be set up *de novo*.

Remuneration: Financial incentives may be needed to sustain the referral linkages and meet reporting requirements; incentives or compensation for time may be needed for attending training sessions.

Other: If effective, could reduce use of ineffective medications and products; could save time of providers in health facilities by better triaging (women reaching appropriate facility in first instance).

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Does not favour either*	*Probably favours the cadre*	*Favours the cadre*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Acceptability

Research evidence

Three reviews (*Web Supplement 3, Annexes 27–29*) suggest that the acceptability of task shifting abortion care services (including medical abortion, counselling, or abortion-related family planning services) among pharmacists and pharmacy workers working both within and outside the formal health system was mixed:

- The reviews identified very little data regarding the willingness of pharmacists or pharmacy workers to deliver abortion care services.
- Women sometimes preferred to go to pharmacies for information and for medical abortion because this was more convenient, private and cheaper than going to a health-care provider (low confidence). However, women as well as health providers sometimes distrusted pharmacists' ability to properly counsel and administer medical abortion. This distrust arose from a perception of pharmacists as businesspeople, as not holding adequate knowledge, and of being incapable or uninterested in providing follow-up in the case of complications. Distrust also stemmed from a sense that pharmacies and pharmacists were poorly regulated and controlled thus increasing the potential for unequal treatment options or prices for clients and counterfeit drugs (high confidence).
- In some settings, men, female friends and others purchased drugs to induce abortion from pharmacies on behalf of women (low confidence). However, men's easy access to these drugs through pharmacies led to concern among health-care providers and others regarding the potential to coerce women. There was also some concern among health-care providers and older women that easy access through pharmacies would increase

young women's ability to access medical abortion indiscriminately, potentially in substitution of birth control (low confidence).

- One study suggests that pharmacists' drug recommendations depended on the customer's ability to pay, with richer people being offered more expensive drugs; and whether or not the chemist knew the customer personally (low confidence).

Additional information

None specified.

Judgement

Is the option acceptable to key stakeholders?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐

Feasibility

Research evidence

One review (*Web Supplement 3, Annex 29*) identified the following issues regarding the feasibility of task shifting for abortion care services among pharmacists and pharmacy workers working both within and outside the formal health system:

- Some studies suggest that pharmacists and pharmacy workers often had incorrect knowledge about medical abortion (low confidence), although some pharmacists acknowledged this lack of knowledge and were keen to increase their skills (low confidence).

Indirect evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers regarding task shifting for abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these finding was assessed as low to moderate.

Additional information

None specified

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐

PRIME2 RECOMMENDATIONS:

Type of recommendation/decision

	Recommend	*Recommend in specific circumstances*	*Recommend only in the context of rigorous research*	*Recommend against*
Pharmacists	☐	☐	☐	☒
Pharmacy workers	☐	☐	☐	☒

Recommendations and justifications

	Recommendation	*Justification*
Pharmacists	The panel recommends against the option of pharmacists providing cervical priming with medications.	Although dispensing medications with a prescription is within the scope of practice for pharmacists, this procedure is for use in facility-based second trimester abortion.
Pharmacy workers	The panel recommends against the option of pharmacy workers providing cervical priming with medications.	This procedure is for use in conjunction with a facility-based second trimester abortion. Lay health workers are unlikely to be involved with second trimester abortion care.

Subgroup considerations: None specified.

Implementation considerations: None specified.

Research priorities: None specified.

MA4 – Medical abortion > 12 weeks

Should NON-SPECIALIST DOCTORS, ASSOCIATE CLINICIANS, MIDWIVES, NURSES, AUXILIARY NURSES AND AUXILIARY NURSE MIDWIVES and DOCTORS OF COMPLEMENTARY SYSTEMS OF MEDICINE provide medical abortion > 12 weeks using mifepristone and misoprostol/misoprostol alone?

Background

Option: Provision of medical abortion > 12 weeks using mifepristone and misoprostol/misoprostol alone by non-specialist doctors, associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives and doctors of complementary systems of medicine.
Comparison: Specialist doctors
Setting: Facilities with provision for inpatient stay
Subgroups: Mifepristone and misoprostol/misoprostol alone
Note: The GDG decided that these tasks were within the scope of practice of specialist doctors and outside the scope of pharmacists, pharmacy workers and lay health workers.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 16*) did not find any studies that assessed the provision of medical abortion > 12 weeks by non-specialist doctors, doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses or auxiliary nurse midwives, compared to specialist doctors.

Additional considerations

Safe abortion guidelines specify that it is done in a facility setting with women staying in the facility until abortion is complete, which can take 10–12 hours after misoprostol administration. More than one misoprostol dose may be needed. Needs for pain management are greater and oral/IM/IV opioids or epidural anaesthesia may be needed. Misoprostol alone is less effective than mifepristone–misoprostol used alone, and is associated with more side-effects.

Optimize MNH lists following tasks for these cadres:

- Non specialist doctors: Caesarean, tubal ligation, vacuum extraction within scope of practice.
- Associate clinicians: Caesarean section (recommended against for associate clinicians but conditionally recommended for advanced level clinicians); vacuum extraction delivery (recommended against for associate clinicians but recommended for advanced level clinicians); manual removal of placenta recommend conditionally for associate clinicians and recommended unconditionally for more advance level clinicians.
- Midwives: Vacuum extraction (conditional), initial management of PROM.
- Nurses: Vacuum extraction (conditional).

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Non-specialist doctors	☐	☐	☐	☐	☒	☐	☐
Associate clinicians, midwives, nurses, auxiliary nurses/ANMs, doctors of complementary systems of medicine	☒	☐	☐	☐	☐	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Non-specialist doctors	☐	☐	☐	☐	☒	☐	☐
Associate clinicians, midwives, nurses, auxiliary nurses/ANMs, doctors of complementary systems of medicine	☒	☐	☐	☐	☐	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
All cadres	☒	☐	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☒	☐	☐	☐	☐	☐	☐

Resources required

Research evidence

We did not systematically collect research evidence regarding the additional resources that might be required for this cadre to provide this task.

Additional considerations

Training:

- competency-based training in MA and related aspects;
- values clarification and careful pre-screening of trainees willing to be involved with second trimester abortion;
- training will need to be done at large facilities that see a high volume of second trimester cases.

Supplies: Supply of medical abortion drugs and related (as per *Safe abortion guidelines* for details).

Referrals: Link to higher-level care for complication management.

Supervision/monitoring: Ongoing supportive supervision and mentoring mechanisms more crucial for second trimester abortion service provision.

Remuneration: Financial and non-financial incentives and strategies to reduce burn out of providers and sustain service provision.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
All cadres	☒	☐	☐	☐	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the specialist*	*Probably favours the specialist*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☒	☐	☐	☐	☐	☐	☐

Acceptability

Research evidence

Acceptability for women

We were able to identify little or no research that assessed the acceptability of this specific task shifting intervention among women.

Indirect evidence: One review (*Web Supplement 3, Annex 29*) suggests that, among *women*, the acceptability of task shifting *abortion care in general* was mixed. Abortion care service users had mixed experiences with abortion care, ranging from care that met their expectations to mistreatment and abuse. Some women preferred care from nurses or midwives rather than doctors, as the former were seen as more supportive and some preferring female health workers as this was seen as more appropriate. Anonymity was an important concern for some women, and they therefore preferred to seek care at a facility where it was less likely that they would be recognized (very low to moderate confidence).

Acceptability for health-care providers

Two reviews (*Web Supplement 3, Annexes 28 and 29*) suggest that, for doctors, midwives and nurses, the acceptability of task shifting abortion services, including medical abortion and D&E, after the first trimester was mixed:

- Providers' views on participating in abortions after first trimester varied. Some health-care providers, including doctors, midwives and nurses involved in either medical abortion or D&E in the second trimester, felt particularly uncomfortable because of the emotional burden of dealing with the fetus (low to moderate confidence). Some midwives developed strategies to cope with this, including not being present during the actual abortion procedure, while others saw second trimester abortions as part of their professional duty to women, even though they found the work emotionally difficult (low confidence). Some midwives and nurses coped by attempting to distance themselves emotionally with patients and when dealing with the fetus (moderate confidence).

Indirect evidence: Two reviews (*Web Supplement 3, Annexes 28 and 29*) suggest that, *for different types of health-care providers,* the acceptability of shifting the provision of medical abortion *during the first trimester* may be mixed:

- Some providers felt that medical abortion was only suitable for some women, and had informal criteria for assessing their suitability (moderate confidence).
- Some providers felt that medical abortion required more emotional care for women and that providers needed to be able to meet women's emotional and informational needs. This closer involvement in medical abortion was sometimes seen to have emotional impacts for mid-level providers. Midwives and nurses noted the importance of staying in contact with the woman during the procedure (low confidence).
- Some professionals had concerns about making drugs for medical abortion available to providers with lower levels of training than themselves (low confidence)

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☒	☐	☐	☐	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*

All cadres	☐	☒	☐	☐	☐	☐

Feasibility

Research evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for *different types of health-care providers* regarding task shifting abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these findings was assessed as low to moderate.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Non-specialist doctors	☐	☐	☐	☐	☒	☐
Doctors of complementary systems of medicine, associate clinicians	☒	☐	☐	☐	☐	☐
Midwives, nurses	☐	☒	☐	☐	☐	☐
Auxiliary nurses/ANMs	☐	☐	☒	☐	☐	☐

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in context of rigorous research***	***Recommend against***
Non-specialist doctors	☒	☐	☐	☐
Associate clinicians	☐	☒	☐	☐
Midwives	☐	☒	☐	☐
Nurses	☐	☒	☐	☐
Auxiliary nurses/ANMs	☐	☐	☐	☒

Doctors of complementary systems of medicine	☐	☐	☐	☒

Recommendations and justifications

	Recommendation	***Justification***
Non-specialist doctors	The panel recommends the option of non-specialist doctors providing medical abortion > 84 days	There is insufficient direct evidence on this option; however, non-specialist doctors routinely carry out tasks of similar or great complexity (e.g. conducting deliveries, manual removal of placenta, vacuum extraction). The potential benefits of this option outweigh the harms and the intervention has proven feasible in several settings. A specialist provider may not always be available on site and this option may increase the ability of the health system to provide care for women needing it.
Associate clinicians	The panel recommends the option of associate clinicians assisting in the process of medical abortion > 84 days in specific circumstances.	There is insufficient direct evidence on this option; however such professionals are considered as options for tasks of similar complexity like vacuum extraction, and manual removal of placenta. They are often present at higher level facilities where second trimester care is provided. A trained specialist provider may not always be present at such a facility and the potential to sustain second trimester services is increased with more than one trained provider on site.
Midwives	The panel recommends the option of midwives performing the process of medical abortion > 84 days in specific circumstances.	Although there is insufficient direct evidence on the effectiveness of the intervention as a whole, midwives are often responsible for the monitoring and care of the woman from the time of misoprostol administration to completion of abortion and women often find care provided by midwives to be more acceptable (moderate confidence).
Nurses	The panel recommends the option of nurses assisting in the process of medical abortion > 84 days as part of a doctor led team in specific circumstances.	Although there is insufficient direct evidence on the effectiveness of the intervention as a whole, nurses are often responsible for the monitoring and care of the woman from the time of misoprostol administration to completion of abortion and women often find care provided by midwives to be more acceptable (moderate confidence).
Auxiliary nurses/ANMs	The panel recommends against the option of ANMs providing medical abortion > 84 days	There is no direct evidence on the effectiveness, safety and acceptability of this option. These health workers are unlikely to be present at the higher-level facilities where such care is provided or be involved in second trimester abortion care.

Doctors of complementary systems of medicine	The panel recommends against the option of doctors of complementary systems of medicine providing medical abortion > 84 days	There is no direct evidence on the effectiveness, safety and acceptability of this option. They are unlikely to be involved in second trimester abortion care and the procedure is performed at a higher level facility where specialist/non-specialist doctors are usually present.

Subgroup considerations

None specified.

Implementation considerations

Medical abortion at > 84 days needs to take place in a facility with provision for inpatient stay.

Research priorities

None specified.

COMP1 and COMP 2 – Managing non-life-threatening post-abortion infection and haemorrhage

Should, ASSOCIATE CLINICIANS, MIDWIVES, NURSES, AUXILIARY NURSES and AUXILIARY NURSE MIDWIVES and DOCTORS OF COMPLEMENTARY SYSTEMS OF MEDICINE manage non-life-threatening post-abortion infection and haemorrhage?

Background

Option: Management of non-life-threatening post-abortion complications (infection, bleeding) by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives.
Comparison: Doctors
Setting: Facility
Subgroups: None
Note: The GDG decided that these tasks were within the scope of practice of specialist and non-specialist doctors and outside the scope of pharmacists, pharmacy workers and lay health workers.

Benefits and harms

Research evidence

Two systematic reviews (*Web Supplement 2, Annexes 15 and 16*) did not find any studies that assessed the management of non-life-threatening post-abortion complications by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses or auxiliary nurse midwives, compared to doctors.

Additional considerations

Optimize MNH guidelines:

- Management of puerperal sepsis with IM antibiotics is within the scope of practice for associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives.
- Administering IV fluids as part of PPH management is recommended for auxiliary nurses and auxiliary nurse midwives and considered within the scope of practice for nurses, midwives and associate clinicians.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☐	☒	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
All cadres	☒	☐	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

Resources required

Research evidence

We did not systematically collect research evidence regarding the additional resources that might be required for this cadre to provide this task

Additional information:

None specified**.**

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
All cadres	☐	☐	☐	☐	☒	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☐	☒	☐

Acceptability

Research evidence

Acceptability among women

We were able to identify little or no research that assessed the acceptability of this specific task.

Indirect evidence:

One review (*Web Supplement 3, Annex 29*) suggests that, among women, the acceptability of task shifting abortion care in general for different types of health-care providers was mixed. Abortion care service users had mixed experiences, ranging from care that met their expectations to mistreatment and abuse, with some preferring care from nurses or midwives rather than doctors as the former were seen as more supportive, and some preferring female health workers as this was seen as more appropriate. Anonymity was an important concern for some women, who preferred to seek care at a facility where it was less likely that they would be recognized (very low to moderate confidence)

Two reviews (*Web Supplement 3, Annexes 29 and 30*) identified the following acceptability issues among women regarding the acceptability of task shifting to nurses and midwives:

- Recipients may regard nurses as more accessible and better at listening and caring than doctors (moderate confidence). However, some recipients may have concerns about nurses' competence and willingness to provide high quality care compared to doctors (low confidence).
- Mothers and midwives are more likely to accept task shifting initiatives if they increase the midwives' ability to provide more holistic and continuous care (moderate confidence).

Acceptability among health-care providers

One review (*Web Supplement 3, Annex 29*) identified the following acceptability issues regarding the use of midlevel providers to manage non-life-threatening complications*:*

- Attitudes to task sharing for post-abortion care were generally positive among health-care providers and it was felt that this increased efficiency. However, there were differing views among doctors regarding whether midwives should provide post-abortion care autonomously (low confidence).
- Providers' attitudes towards women seeking post-abortion care related in part to the reason for the abortion. Induced abortions were viewed negatively in some settings (moderate confidence).

Indirect evidence: One review (*Web Supplement 3, Annex 29)* suggests that the acceptability of task shifting abortion care in general for different types of health-care providers was mixed:

- The review shows that doctors, midwives and nurses varied in their willingness to become involved in abortion care. Providers had a range of responses to involvement; some were willing to be involved, others did not approve but agreed it was preferable to unsafe abortion, and still other providers refused any involvement at all (low to moderate confidence).

Two reviews (*Web Supplement 3, Annexes 29 and 30*) identified the following acceptability issues among midwives and nurses regarding the acceptability of task shifting in general:

- Nurses may be motivated to offer advanced care by increased recognition and job satisfaction (moderate confidence).

- Doctor acceptance of task shifting to nurses appears to be influenced by level of nurse experience (low confidence). Doctors may welcome the contribution of nurses where it reduces doctors' workloads (moderate confidence). However, an increase in nurse autonomy may negatively affect or produce negative reactions among other professions, including doctors and midwives, who for instance may be unwilling to relinquish final responsibility for patient care. A lack of clarity about nurse roles and responsibilities in relation to other health workers may also be a challenge (low confidence).
- Mothers and midwives are more likely to accept task shifting initiatives if they increase the midwives' ability to provide more holistic and continuous care (moderate confidence). Midwives may also be motivated by being "upskilled" as it can potentially lead to increased status, promotion opportunities and increased job satisfaction (moderate confidence). However, they may be concerned about the increased liability that may accompany new tasks (moderate confidence).
- A lack of clarity in roles and responsibilities between midwives and other health worker cadres, as well as status and power differences may also lead to poor working relationships and turf battles (moderate confidence).

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☒	☐	☐	☒	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☒	☐	☐	☐	☐

Feasibility

Research evidence

We were unable to identify research that explored the feasibility of using mid-level providers to manage non-life-threatening complications specifically.

Indirect evidence: Two reviews (*Web Supplement 3, Annex 28 and 29*) identified a number of feasibility issues for different types of health-care providers regarding task shifting abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; problems with poorly functioning referral systems; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of

certain funding agencies. Our confidence in these finding was assessed as low to moderate.

Additional information

None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☐	☐	☐	☒	☐

COMP1 RECOMMENDATION:

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
Associate clinicians	☒	☐	☐	☐
Midwives	☒	☐	☐	☐
Nurses	☒	☐	☐	☐
Auxiliary nurses/ANMs	☒	☐	☐	☐
Doctors of complementary systems of medicine	☐	☒	☐	☐

Recommendations and justifications

	Recommendation	***Justification***
Associate clinicians	The panel recommends the option of associate clinicians managing non-life-threatening post-abortion sepsis with antibiotics including IM antibiotics and administering IV fluids as part of initial management of PPH.	Although there was no direct evidence of management of post-abortion infection, management of puerperal sepsis with IM antibiotics which requires similar skills is recommended as being within the scope of practice for all of these health workers.
Midwives	The panel recommends the option of midwives managing non-life-threatening post-abortion sepsis with antibiotics including IM antibiotics and administering IV fluids as part of initial management of PPH.	Although there was no direct evidence of management of post-abortion infection, management of puerperal sepsis with IM antibiotics which requires similar skills is recommended as being within the scope of practice for all of these health workers.

Nurses	The panel recommends the option of nurses managing non-life-threatening post-abortion sepsis with antibiotics including IM antibiotics and administering IV fluids as part of initial management of PPH.	Although there was no direct evidence of management of post-abortion infection, management of puerperal sepsis with IM antibiotics, which requires similar skills, is recommended as being within the scope of practice for all these health workers.
Auxiliary nurses/ANMs	The panel recommends the option of ANMs managing non-life-threatening post-abortion sepsis with antibiotics including IM antibiotics and administering IV fluids as part of initial management of PPH in contexts where they have also been trained to provide basic EmOC.	Although there was no direct evidence of management of post-abortion infection, management of puerperal sepsis with IM antibiotics which requires similar skills is recommended as being within the scope of practice for all of these health workers.
Doctors of complementary systems of medicine	The panel recommends the option of doctors of complementary systems of medicine managing non-life-threatening post-abortion infection with antibiotics including l antibiotics (IV or IM) and administering IV fluids under specific circumstances.	There was no direct evidence on the management of post-abortion infection but the basic training of these professionals covers the skills required for this task.

Subgroup considerations: None specified.

Implementation considerations: None specified.

Research priorities: None specified.

COMP2 RECOMMENDATION:

Type of recommendation/decision

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Associate clinicians	☒	☐	☐	☐
Midwives	☒	☐	☐	☐
Nurses	☒	☐	☐	☐
Auxiliary nurses/ANMs	☒	☐	☐	☐
Doctors of complementary systems of medicine	☐	☒	☐	☐

Recommendations and justifications

	Recommendation	*Justification*
Associate clinicians	The panel recommends the option of associate clinicians managing non-life-threatening post-abortion sepsis with antibiotics including IM antibiotics and administering IV fluids as part of initial management of PPH.	Although there was no direct evidence of management of post-abortion haemorrhage, the management of postpartum haemorrhage with IV fluids which requires similar skills is considered as being within scope of practice.
Midwives	The panel recommends the option of midwives managing non-life-threatening post-abortion sepsis with antibiotics including IM antibiotics and administering IV fluids as part of initial management of PPH.	Although there was no direct evidence of management of post-abortion haemorrhage, management of postpartum haemorrhage with IV fluids which requires similar skills is considered as being within scope of practice.
Nurses	The panel recommends the option of nurses managing non-life-threatening post-abortion sepsis with antibiotics including IM antibiotics and administering IV fluids as part of initial management of PPH.	Although there was no direct evidence of management of post-abortion haemorrhage, management of postpartum haemorrhage with IV fluids which requires similar skills is considered as being within scope of practice.
Auxiliary nurses/ANMs	The panel recommends the option of ANMs managing non-life-threatening post-abortion sepsis with antibiotics including IM antibiotics and administering IV fluids as part of initial management of PPH in contexts where they	Although there was no direct evidence of management of post-abortion haemorrhage, initial management of postpartum haemorrhage with IV fluids, which requires similar skills is a recommended task.

	have also been trained to provide basic EmOC.	
Doctors of complementary systems of medicine	The panel recommends the option of doctors of complementary systems of medicine managing non-life-threatening post-abortion infection with antibiotics including I antibiotics (IV or IM) and administering IV fluids under specific circumstances.	There was no direct evidence for the management of post-abortion haemorrhage but the basic training of these professionals covers the skills required for this task.

Subgroup considerations: None specified.

Implementation considerations: None specified.

Research priorities: None specified.

MESSAGE1 AND MESSAGE2 – Information and counselling by pharmacists and pharmacy workers

Should PHARMACISTS AND PHARMACY WORKERS provide information on safe abortion care and should they provide pre- and post-abortion counselling?

Background

Option:
Information provision (message 1): Providing general information on safe abortion care encompasses information on how to prevent unintended pregnancy, including where and how to obtain contraceptive methods, where and how to obtain safe, legal abortion services and their cost, the details of legal limitations on the maximum gestational age when abortion can be obtained, the importance of early care seeking and information on how to recognize complications of miscarriage and unsafe abortion.
Counselling (message 2): The provision of information is an essential part of good-quality abortion services. Every pregnant woman who is contemplating abortion should receive medically accurate information in a form that she can understand and recall. Counselling however is more than information provision and refers to a focused, interactive process through which one voluntarily receives support, information and non-directive guidance from a trained person. It requires a much higher level of specific knowledge than providing general information about safe abortion. Counselling as per the *Safe abortion guidelines* is voluntary and non-directive and intended to facilitate informed decision-making.
Comparison: Usual care, which could include current pharmacy practices or information provided by any other type of health worker.
Setting: Pharmacies
Subgroups: None
Note: The GDG decided that provision of information on safe abortion was within the scope of practice of doctors, associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 20*) that assessed the effectiveness of using pharmacists or pharmacy workers to provide information on safe abortion care and pre- and post-abortion counselling. The review included:

- One controlled before-and-after study from Nepal. Pharmacy workers in this 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.

Summary of Findings: *Pharmacists or pharmacy workers compared to usual practice (Web Supplement 2, Annex 11h)*

What happens?	No information (usual practice)	Pharmacists or pharmacy workers providing information on safe abortion care	Certainty of the evidence
Correct knowledge of safe and appropriate abortion No effect estimate could be estimated	Not estimable	Not estimable	
Correct knowledge of safe post-abortion care No effect estimate could be estimated	Not estimable	Not estimable	

Indirect evidence:

One Cochrane review (*Web Supplement 2, Annex 23*) assessed the effectiveness of using pharmacists to provide education and counselling on chronic illnesses such as diabetes and asthma on patient outcomes. The review concluded that there were:

- small improvements in health outcomes such as blood pressure levels and glucose levels (low certainty evidence); and
- patients may use health services less (for instance fewer visits to the doctor, fewer stays in hospital) (low certainty evidence).

A limitation in generalizing this information is that very few pharmacists (four studies had only one) were actually delivering the intervention.

One Cochrane review (*Web Supplement 2, Annex 22)* assessed the effectiveness of outpatient pharmacists' non-dispensing roles on patient and health professional outcomes. The review included 36 studies that looked at pharmacist interventions targeted at patients. Interventions were performed by either practising pharmacists, pharmacy residents, or doctor of pharmacy students. The interventions included monitoring of disease control and adverse drug reactions and compliance assessment. One study evaluated home blood pressure monitoring with the pharmacist providing telephone follow-up to assess response to therapy. Only one included study compared pharmacists to another health cadre (physicians). The review concluded that:

- there was not enough quality evidence to make a conclusion about whether the delivery of patient-targeted services by pharmacists improve patient or health professional outcomes compares favourably to the delivery of the same services by a physician; and
- evidence supported the role of pharmacists in delivery of patient-targeted services such as medication management and patient counselling to improve patient or health professional outcomes compared to the delivery of no comparable services.

One Cochrane review (*Web Supplement 2, Annex 24*) assessed the effectiveness of using community pharmacy personnel (pharmacists or other pharmacy personnel) to assist clients to stop smoking. The review included two trials from the United Kingdom. The review concluded that:

- there was limited evidence that interventions in which pharmacists were trained to provide a counselling and record keeping support programme for smokers were associated with increased and more highly rated counselling and may have a positive effect on smoking cessation rates

Additional considerations

A systematic search for studies of knowledge and practices of untrained pharmacy workers (*Web Supplement 3, Annex 36*) in low- and middle-income settings found 16 studies. Settings of the studies included restrictive environments and less restrictive environments. Previously untrained pharmacy workers (none of the studies specifically differentiated pharmacy workers from pharmacists) provide inaccurate information, may sell ineffective medication and may not refer women to a health worker or provide her information on where to access one or may impose their moral judgements on women. Women do not necessarily interact with the pharmacist but with the pharmacy worker behind the counter.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours usual care*	*Probably favours usual care*	*Similar results*	*Probably favours pharmacy worker*	*Favours the pharmacy worker*
Pharma-cists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours usual care*	*Probably favours usual care*	*Similar results*	*Probably favours the inter-vention*	*Favours the inter-vention*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Pharmacists, pharmacy workers	☐	☒	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours usual care*	*Probably favours usual care*	*Similar results*	*Probably favours pharmacy worker*	*Favours the pharmacy worker*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Resources required

Research evidence

We did not systematically collect research evidence regarding the additional resources that might be required for this cadre to provide this task.

Additional considerations

Training:

- Unsafe abortion, legal aspects, safe providers, safe methods, contraception options, etc. as well as values clarification.
- Separate training programmes may be needed for pharmacists and pharmacy workers as the background training of both groups is very different.
- Given the high turnover of pharmacy worker staff, repeated training sessions will be needed in order to sustain the intervention at a site.

Supplies: information material, job aids

Change of location of service delivery: Pharmacies that are not already delivering health-related interventions other than dispensing drugs may need to be set up with private space for counselling/interaction with women

Referrals: Referral link to a provider /facility able to provide safe abortion.

Supervision/monitoring: Monitoring and accountability systems will need to be set up *de novo*.

Remuneration: Financial incentives may be needed to sustain the referral linkages and meet reporting requirements; incentives or compensation for time may be needed for attending training sessions.

Other: If effective, could reduce use of ineffective medications and products; could save time of providers in health facilities by better triaging (women reaching appropriate facility in the first instance).

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours usual care*	*Probably favours usual care*	*Similar results*	*Probably favours pharmacy worker*	*Favours the pharmacy worker*
Pharmacists, pharmacy workers	☐	☒	☐	☐	☐	☐	☐

Acceptability

Research evidence

Acceptability among women

Three reviews (*Web Supplement 3, Annexes 27–29*) suggest that acceptability among *women* regarding task shifting for *abortion care services* (including medical abortion, counselling, or abortion-related family planning services) to pharmacies was mixed:

- Women sometimes preferred to go to pharmacies for information and for medical abortion because this was more convenient, private and cheaper than going to a health-care provider (low confidence). However, women as well as health providers sometimes distrusted pharmacists' ability to properly counsel and administer medical abortions. This distrust arose from a perception of pharmacists as businesspeople, as not holding adequate knowledge, and of being incapable or uninterested in providing follow-up in the case of complications. Distrust also stemmed from a sense that pharmacies and pharmacists were poorly regulated and controlled thus increasing the potential for unequal treatment options or prices for clients and counterfeit drugs (high confidence).
- In some settings, men, female friends and others purchased drugs to induce abortion from pharmacies on behalf of women (low confidence). However, men's easy access to these drugs through pharmacies led to concern among health-care providers and others regarding the potential to coerce women. There was also some concern among health-care providers and older women that easy access through pharmacies would increase young women's ability to access medical abortion indiscriminately, potentially in substitution of birth control (low confidence).
- One study suggests that pharmacists' drug recommendations depended on the customer's ability to pay, with richer people being offered more expensive drugs; and whether or not the chemist knew the customer personally (low confidence).

Acceptability for health-care providers

We were able to identify little or no research that assessed the acceptability of this particular task shifting intervention among *pharmacists or pharmacy workers*.

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, pharmacy workers	☐	☒	☐	☐	☐	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, pharmacy workers	☐	☒	☐	☐	☐	☐

Feasibility

Research evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) show the following feasibility issues regarding of task shifting abortion care services through pharmacists and pharmacy workers within and outside the formal health system:

- Some studies suggest that pharmacists and pharmacy workers often had incorrect knowledge about medical abortion (low confidence), although some pharmacists acknowledged this lack of knowledge and were keen to increase their skills (low confidence).

Indirect evidence: Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers regarding task shifting abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; increased workloads; a need for incentives for providers undertaking these additional roles; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these findings was assessed as low to moderate.

Additional information

None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, pharmacy workers	☒	☐	☐	☐	☐	☐

MESSAGE1 AND MESSAGE2 RECOMMENDATIONS:

MESSAGE 1 Type of recommendation/decision

Information on safe abortion care

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Pharmacists	☒	☐	☐	☐
Pharmacy workers	☐	☒	☐	☐

MESSAGE2 Type of recommendation/decision

Pre- and post-abortion counselling

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Pharmacists	☐	☐	☐	☒
Pharmacy workers	☐	☐	☐	☒

MESSAGE1 Recommendations and justifications

Information on safe abortion care

	Recommendation	*Justification*
Pharmacists	The panel recommends the option of pharmacists providing information about safe abortion options *e.g.* where and how to obtain contraceptive methods, where and how to obtain safe, legal abortion services and their cost, specifics of local laws and the importance of early care seeking.	There is evidence on effectiveness of provision of education and counselling on chronic illnesses (low to moderate certainty). These professionals are often consulted by women seeking advice on how to deal with delayed menstruation (medium confidence). Pharmacists are qualified professionals and routinely provide information about medications.
Pharmacy workers	The panel recommends this option in contexts where it can be ensured that the pharmacy worker is under the direct supervision of a pharmacist and where access to a referral linkage with a formal health system exists.	There is insufficient direct evidence on the effectiveness, safety and acceptability of this option. However, in many contexts, such workers are often consulted by women seeking information on how to deal with delayed menstruation (moderate confidence). Even though the effectiveness of training interventions with such workers is uncertain, the potential benefits of such workers being able to provide basic information outweighs the potential harms of them not providing information or providing incorrect information.

Pre- and post-abortion counselling

	Recommendation	***Justification***
Pharmacists	The panel recommends against the option of pharmacists providing pre and post-abortion counselling to their clients.	Although pharmacists are qualified to provide information about the drugs they dispense and may effectively counsel patients on management of chronic conditions, their scope of practice does not include surgical options, thus they are not well placed to provide counselling on all safe abortion /contraception methods. Additionally, pharmacies may not be suitable places for the privacy required for providing pre and post-abortion counselling hence this option may not be feasible in most settings.
Pharmacy workers	The panel recommends against the option of pharmacy workers providing pre and post-abortion counselling to their clients.	There is no evidence for the safety, effectiveness or feasibility of this approach.

Subgroup considerations

None specified.

Implementation considerations

None specified.

Research priorities

Testing of interventions aimed at training pharmacy workers is a key area of research.

MESSAGE1 AND MESSAGE2 – Information and counselling by lay health workers

Should LAY HEALTH WORKERS provide (1) information on the availability of safe providers/care; and (2) pre- and post-abortion counselling?

Background

Option:
Information provision (message 1): Providing general information on safe abortion care encompasses information on how to prevent unintended pregnancy, including where and how to obtain contraceptive methods, where and how to obtain safe, legal abortion services and their cost, the details of legal limitations on the maximum gestational age when abortion can be obtained, the importance of early care seeking and information on how to recognize complications of miscarriage and unsafe abortion.
Counselling (message 2): The provision of information is an essential part of good-quality abortion services. Every pregnant woman who is contemplating abortion should receive medically accurate information in a form that she can understand and recall. Counselling, however, is more than information provision and refers to a focused, interactive process through which one voluntarily receives support, information and non-directive guidance from a trained person. It requires a much higher level of specific knowledge than providing general information about safe abortion. Counselling as per the *Safe abortion guidelines* is voluntary and non-directive and intended to facilitate informed decision-making.
Setting: Community
Subgroup: None

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 20*) did not find any studies that assessed the provision of abortion information or counselling by lay health workers, compared to doctors.

Indirect evidence

A systematic review (*Web Supplement 2, Annex 18*) assessed the effectiveness of using lay health workers to manage individual components of the medical abortion process, compared to doctors. The review shows that (*Web Supplement 2, Annexes 6.1i and 6.4i)*:

- Fewer women may be assessed as eligible when lay health workers assess eligibility (low certainty evidence).
- The accuracy of the eligibility assessments cannot be estimated.
- There may be little or no difference in the number of complete abortion assessments (low certainty evidence).
- The accuracy of the assessments of complete abortion cannot be estimated.

Additional considerations

Optimize MNH recommended the use of lay health workers to promote uptake of maternal- and newborn-related health-care behaviour and services.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours usual care*	*Probably favours usual care*	*Similar results*	*Probably favours the lay health worker*	*Favours the lay health worker*
Lay health workers	☐	☐	☐	☐	☐	☒	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours usual care*	*Probably favours usual care*	*Similar results*	*Probably favours the lay health worker*	*Favours the lay health worker*
Lay health workers	☐	☐	☐	☐	☐	☒	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Lay health workers	☒	☐	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours usual care*	*Probably favours usual care*	*Similar results*	*Probably favours the lay health worker*	*Favours the lay health worker*
Lay health workers	☐	☐	☐	☐	☐	☒	☐

Resources required

Research evidence

We did not systematically collect research evidence regarding the additional resources that might be required for this cadre to provide this task.

Additional information

Training: Training in safe abortion and post-abortion care, contraceptive counselling, knowledge of legal conditions and values clarification. Duration of training could be from a few hours to several days based on local requirements and on cadre's existing familiarity with other abortion-related interventions.

Supplies: Informational materials

Referrals: Referral link to a primary care provider/facility able to provide services or deal with complications.

Remuneration: Financial or other incentives may be needed to sustain service provision especially as this cadre is often a volunteer cadre in many contexts. Workload issues need to be addressed as this cadre is likely overburdened with numerous other health, nutrition and other related tasks.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
Lay health workers	☐	☐	☐	☒	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours usual care*	*Probably favours usual care*	*Similar results*	*Probably favours the lay health worker*	*Favours the lay health worker*
Lay health workers	☐	☐	☐	☐	☐	☒	☐

Acceptability

Research evidence

Acceptability among women

We were able to identify little or no research that assessed the acceptability of this specific task shifting intervention among women.

Indirect evidence: Four reviews (*Web Supplement 3, Annexes 28, 29, 32 and 33*) assessed the acceptability of task shifting to lay health workers for health services in general:

- Recipients were generally very positive to lay health worker programmes (moderate confidence).
- Recipients appreciated the privacy afforded by lay health workers (low confidence).

Acceptability among health-care providers

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified the following acceptability issues for lay health workers regarding task shifting for medical abortion care:

- None of the reviews identified any data regarding the willingness of lay health workers to deliver abortion care services.
- The relationship between lay health workers and the formal health services impacted on lay health workers' willingness to accompany women to a facility (low confidence). Lay health workers' position in the community was sometimes undermined where specialist doctors refused to accept their referrals, or where complications occurred after an abortion for which they had referred a woman to the health services (low confidence).

Indirect evidence: One review (*Web Supplement 3, Annex 29*) identified the following issues for different types of health-care providers regarding the acceptability of task shifting information about access to safe providers and dealing with complications:

- Some providers thought that more information on abortion care should be available to the public, but others expressed concern about this leading to the misuse of drugs for abortion (very low confidence).

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Lay health workers	☐	☐	☐	☐	☐	☒

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Lay health workers	☐	☐	☐	☒	☐	☐

Feasibility

Research evidence

Three reviews (*Web Supplement 3, Annexes 28, 29 and 33*) identified the following feasibility issues for task shifting to lay health workers and other health-care providers for health services in general or for abortion care specifically:

- Women did not always receive adequate information from providers, including on what constitutes normal and abnormal bleeding in the context of a medical abortion and about contraception (moderate confidence).
- Ongoing support, training and supervision were often insufficient in lay health workers programmes (moderate confidence). Counselling and communication were perceived by lay health workers as a complex task for which they sometimes felt unprepared and for which they requested specific training (moderate confidence). In addition, trainers were not necessarily competent to train them in these skills (low confidence).
- Task shifting often increased workloads (low confidence) and there was a need for incentives for providers undertaking these additional roles (moderate confidence).

When promoting the uptake of health services, obstacles to uptake and to referral included logistical factors, particularly lack of transport, but also lack of money to pay for transport; and a lack of health professionals (low to moderate confidence). Some lay health workers and their recipients also pointed to recipients' reluctance to be referred on due to bad experiences with health professionals and concerns over cost (moderate confidence)

Additional information

None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Lay health workers	☐	☐	☐	☐	☒	☐

MESSAGE1 and MESSAGE2 RECOMMENDATION:

MESSAGE 1: Type of recommendation/decision

Information on safe abortion care

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
Lay health workers	☒	☐	☐	☐

MESSAGE 2: Type of recommendation/decision

Pre- and post-abortion counselling

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
Lay health workers	☐	☒	☐	☐

MESSAGE 1: Recommendations and justifications

Information on safe abortion care

	Recommendation	***Justification***
Lay health workers	The panel recommends the option of lay health workers providing information about safe abortion options, e.g. where and how to obtain contraceptive methods, where and how to obtain safe, legal abortion services and their cost, specifics of local laws and the importance of early care seeking.	Lay health worker interventions in health promotion are generally well accepted and feasible in many contexts where there is a strong lay health worker programme. The potential to expand equitable access to information and safe abortion care is high.

As per the *Safe abortion guidelines* the information provision would encompass *medically accurate information about abortion in a form the woman can understand and recall, and non-directive counselling if requested by the woman to facilitate informed decision-making*.

Pre- and post-abortion counselling

	Recommendation	***Justification***
Lay health workers	The panel recommends the option of lay health workers providing pre- and post-safe-abortion counselling in contexts where the health-care provider managing the procedure is unavailable to provide counselling or the woman needs additional support.	There is insufficient direct evidence on the effectiveness, acceptability and feasibility of this option but lay health worker interventions are generally well accepted and feasible in many contexts and lay health workers are often intermediaries between the formal health systems and women seeking abortion-related care (moderate confidence). These workers could play a supportive role to the main provider/counsellor.

Subgroup considerations: None specified.

Implementation considerations: None specified.

Research priorities: None specified.

MESSAGE2 – Pre- and post-abortion counselling

Should DOCTORS OF COMPLEMENTARY SYSTEMS OF MEDICINE, ASSOCIATE CLINICIANS, MIDWIVES, NURSES, AUXILIARY NURSES AND AUXILIARY NURSE MIDWIVES provide pre- and post-abortion counselling?

Background

Option: Provision of pre- and post-abortion counselling and information by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives. The provision of information is an essential part of good-quality abortion services. Every pregnant woman who is contemplating abortion should receive medically accurate information in a form that she can understand and recall. Counselling however is more than information provision and refers to a focused, interactive process through which one voluntarily receives support, information and non-directive guidance from a trained person. It requires a much higher level of specific knowledge than providing general information about safe abortion. Counselling as per the *Safe abortion guidelines* is voluntary and non-directive and intended to facilitate informed decision-making.
Comparison: Doctor
Setting: Facility
Subgroups: None
Note: The GDG decided that these tasks were within the scope of practice of specials and non-specialist doctors.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 20*) assessed the effectiveness of pre- and post-abortion counselling when provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses and auxiliary nurses/auxiliary nurse midwives. The review included:

- **two studies** that assessed the effectiveness (in terms of contraceptive uptake) of using nurses and nurse-midwives to provide contraceptive counselling compared to doctors. However, we are uncertain of the effect of the intervention as the certainty of the evidence was assessed as very low.

Additional considerations

None specified.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Non-specialist doctors, doctors of complementary systems of medicine, associate clinicians, auxiliary nurses/ANMs	☒	☐	☐	☐	☐
Midwives, nurses	☐	☒	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☐	☐	☐	☐	☒	☐	☐

Resources required

Research evidence

We did not systematically collect research evidence regarding the additional resources that might be required for this cadre to provide this task.

Additional information

Training: Training in safe abortion and post-abortion care, contraceptive counselling, knowledge of legal conditions and values clarification. Duration of training could be from few hours to several days based on local requirements and on cadre's existing familiarity with other abortion-related interventions,

Supplies: Informational materials

Referrals: Referral link to a primary care provider/facility able to provide services or deal with complications

Remuneration: Financial or other incentives may be needed to sustain service provision especially as effective counselling takes a significant amount of time and may affect other potentially more remunerative tasks.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
All cadres	☐	☐	☐	☒	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
All cadres	☒	☐	☐	☐	☐	☐	☐

Acceptability

Research evidence

Acceptability among women

We were able to identify very little research that assessed the acceptability of this particular task shifting intervention among *women.*

Indirect evidence: One review (*Web Supplement 3, Annex 29*) suggests that the acceptability of task shifting abortion care in general among women was mixed. Service users had mixed experiences, ranging from care that met their expectations to mistreatment and abuse, with some preferring care from nurses or midwives rather than doctors, as the former were seen as more supportive and some preferring female health workers as this was seen as more appropriate. Anonymity was an important concern for some women, and they therefore preferred to seek care at a facility where it was less likely that they would be recognized (very low to moderate confidence).

Acceptability among health-care providers

We were able to identify very little research that explored the acceptability of this particular task shifting intervention among *health-care providers.*

Indirect evidence: One review (*Web Supplement 3, Annex 29*) suggests that doctors, midwives and nurses varied in their willingness to become involved in abortion care services. Providers had a range of responses to involvement; some were willing to be involved, others did not approve but agreed it was preferable to unsafe abortion, and still other providers any involvement at all (low to moderate confidence).

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☐	☐	☐	☒	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☒	☐	☐	☐	☐

Feasibility

Research evidence

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified the following feasibility issues regarding task shifting pre- and post-abortion counselling by mid-level providers:

- Health-care providers' knowledge about abortion legislation and the services that are available to women varied and was often lacking (low confidence).
- Abortion service providers lacked the time or training to provide adequate contraceptive counselling or other types of counselling and support to women (low confidence).
- Where there was a lack of clarify on who was responsible for post-abortion contraceptive counselling and provision, this was often inadequately done as each health-care provider assumes that the next person will do it (low confidence).
- Some programmes faced limits on incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies (low confidence).
- Providers complained of increased workloads (low confidence) and a need for additional incentives (moderate confidence).

Additional information

None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
All cadres	☐	☐	☐	☐	☒	☐

MESSAGE2 RECOMMENDATION:

Type of recommendation/decision

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Associate clinicians	☒	☐	☐	☐
Midwives	☒	☐	☐	☐
Nurses	☒	☐	☐	☐
Auxiliary nurses/ANMs	☒	☐	☐	☐
Doctors of alternative systems of medicine	☐	☒	☐	☐

Recommendations and justifications

	Recommendation	*Justification*
Associate clinicians	The panel recommends the option of associate clinicians providing pre- and post-abortion counselling.	This task is a core element of provision of abortion or post-abortion care.
Midwives	The panel recommends the option of midwives providing pre- and post-abortion counselling.	Counselling is a core competency for midwives and this task is a core element of provision of abortion or post-abortion care.
Nurses	The panel recommends the option of nurses providing pre- and post-abortion counselling.	This task is a core element of provision of abortion or post-abortion care.
Auxiliary nurses/ANMs	The panel recommends the option of auxiliary nurses/ANMs providing pre- and post-abortion counselling.	This task is a core element of provision of abortion or post-abortion care.
Doctors of alternative systems of medicine	The panel recommends the option of doctors of alternative systems of medicine providing pre- and post-abortion counselling.	This task is a core element of provision of abortion or post-abortion care.

CONTRA1 – IUDs/implants/injectables by doctors of complementary systems of medicine

Should DOCTORS OF COMPLEMENTARY SYSTEMS OF MEDICINE insert and remove IUDs; insert and remove implants and initiate and maintain injectable contraception?

Background

Option: The insertion and removal of IUDs, insertion and removal of implants and initiation/continuation of injectables by doctors of complementary systems of medicine.
Comparison: Doctor
Setting: Primary care or upwards
Subgroups: Implants, IUDs, injectables
Note: The GDG decided to extrapolate the *Optimize MNH* recommendations for all cadres that had been included in that guideline as the panel felt that recommendations for contraception provision in general would not be different from recommendations for post-abortion contraception provision. Doctors of complementary systems of medicine were not considered in *Optimize MNH*.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 21*) did not find any studies that assessed the provision of contraceptives by doctors of complementary systems of medicine, compared to doctors.

Additional considerations

The Safe abortion guidelines/Medical eligibility criteria for contraceptive use: Hormonal contraception may be started at the time of surgical abortion or as early as the time of administration of the first pill of medical abortion. An IUD may be inserted following medical abortion when it is reasonably certain that the woman is no longer pregnant.

IUD, injectables and implants are considered category 1 contraceptives following a first trimester abortion; IUDs are considered category 2 contraceptives following a second trimester abortion.

Optimize MNH recommended that:

- *IUD insertion and removal* be done by doctors, associate clinicians, midwives, nurses and ANMs. It was recommended only in a rigorous research context for auxiliary nurses and recommended against for LHWs.
- *Insertion and removal of implants* be done by doctors, associate clinicians, midwives, nurses and by auxiliary nurses and ANMs in the context of targeted monitoring and LHWs only in context of rigorous research.
- *Injectables* using standard syringe: All cadres. LHWs within context of targeted monitoring.
- *Implants* were recommended against for LHWs.

Recommendations on using a compact, prefilled auto-disable device (CPAD) were not made because these devices were not commercially available at the time and research was still ongoing.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	***Similar results***	***Probably favours the cadre***	***Favours the cadre***
Doctors of alternative systems of medicine	☐	☐	☐	☐	☒	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of alternative systems of medicine	☒	☐	☐	☐	☒	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Doctors of alternative systems of medicine	☒	☐	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of alternative systems of medicine	☐	☐	☐	☐	☒	☐	☐

Resources required

Research evidence

None

Additional considerations

Training: Competency-based training in provision including training in universal precautions, infection prevention, contraceptive counselling and values clarification. Training needs to be within the context of provision of contraception at any time the woman desires it, not just the post-abortion period.

Supplies: Supply chain of IUDs, antiseptic solutions, injectables, implants

Change of location of service delivery: If a shift to using this cadre results in services moving to a lower level of care, initial investments in setting up services, private space to provide service and counselling, equipment and supplies and a referral chain at that level of care may be needed.

Referrals: Referral linkages to a higher level of care may be needed for a small number of women if there are complications associated with removal of IUDs

Supervision/Monitoring: Initial learning curve in involvement of a new cadre may mean increased time needed for the task, increased monitoring, increased supervision. This should decrease with time

Remuneration: Financial or other Incentives may be needed to sustain service provision and ensure retention in rural /underserved areas

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
Doctors of alternative systems of medicine	☒	☐	☐	☐	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the doctor*	*Probably favours the doctor*	*Similar results*	*Probably favours the cadre*	*Favours the cadre*
Doctors of alternative systems of medicine	☒	☐	☐	☐	☐	☐	☐

Acceptability

Research evidence

Acceptability among women

We were unable to identify research that assessed the acceptability of this particular task shifting intervention among *women*.

Indirect evidence: A review of task shifting for family planning (*Web Supplement 3, Annex 31*), which mainly included lay health worker programmes, suggests that recipients appreciated the easy access that community-based provision of contraceptives provides and appreciated the use of female health workers in the delivery of contraceptives. However, the review also suggests that some health workers introduced their own criteria when determining who should receive contraceptives, including criteria tied to the recipient's marital status and age.

Acceptability among health-care providers

We were unable to identify research that explored the acceptability of this particular task shifting intervention among *health-care providers*.

Indirect evidence: Two reviews (*Web Supplement 3, Annexes 28 and 29*) show that some health-care providers were concerned that women used safe abortion as a form of contraception and emphasized the importance of family planning services (very low to low confidence).

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Doctors of complementary systems of medicine	☐	☐	☐	☒	☐	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Doctors of complementary systems of medicine	☒	☐	☐	☐	☐	☐

Feasibility

Research evidence

We were unable to identify research that explored the feasibility of using doctors of complementary systems of medicines to provide contraception or other abortion care services.

Indirect evidence:

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for *different types of health-care providers* regarding task shifting *abortion care in general*, particularly in weaker health systems, including*:*

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies. Our confidence in these findings was assessed as low to moderate.
- Where there was a lack of clarity on who was responsible for post-abortion contraceptive counselling and provision, this was often inadequately done (moderate confidence)

Additional information (country programs)

Doctors of complementary systems of medicine working within the public health care system are allowed to insert and remove IUDs in India (as of 2013).

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Doctors of complementary systems of medicine	☐	☐	☐	☐	☒	☐

*(if they are already involved in RH care**)***

CONTRA1 RECOMMENDATION:

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
IUD	☐	☒	☐	☐
Implants		**X**		
Injectables		**x**		

Recommendations and justifications – IUD

	Recommendation	*Justification*
Doctors of complementary systems of medicine	The panel recommends the use of doctors of complementary systems of medicine to insert and remove IUDs in contexts with established health systems mechanisms for the participation of Doctors of complementary systems of medicine in other tasks related to maternal and reproductive health.	The basic training generally covers the relevant skills needed for this task. This option is probably feasible and may promote continuity of care for women and increase access in regions where such professionals form a significant proportion of the health workforce.

Recommendations and justifications – Implant

	Recommendation	*Justification*
Doctors of complementary systems of medicine	The panel recommends the use of doctors of complementary systems of medicine to insert and remove provide implants in in contexts with established health systems mechanisms for the participation of Doctors of complementary systems of medicine in other tasks related to maternal and reproductive health and where training in implant removal is given along with training in insertion.	There is insufficient direct evidence on the effectiveness of this option. However the basic training of this cadre covers the relevant skills needed for this task. This option may promote continuity of care for women.

Recommendations and justifications – Injectable

	Recommendation	*Justification*
Doctors of complementary systems of medicine	The panel recommends the use of doctors of complementary systems of medicine to provide injectables in contexts with established health systems mechanisms for the participation of Doctors of complementary systems of medicine in other tasks related to maternal and reproductive health.	The basic training of this cadre covers the relevant skills needed for this task, hence additional training needs would be minimal. This option may promote continuity of care for women.

Subgroup considerations:

IUDs, injectables, implants: separate recommendations have been made for each.

Implementation considerations:

Specific consideration to implant removal, which is more difficult.

Research priorities:

None specified.

CONTRA1 – IUDs/implants/injectables by pharmacists and pharmacy workers

Should PHARMACISTS and PHARMACY WORKERS insert and remove IUDs, insert and remove implants and initiate and maintain injectable contraception?

Background

Option: Insertion and removal of IUDs, insertion and removal of implants and initiation/continuation of injectables by pharmacists and pharmacy workers.
Comparison: Doctors or other facility-based providers
Setting: Pharmacy
Subgroups: Injectables, implants, IUDs (intrauterine devices)
Note: The GDG decided to extrapolate the *Optimize MNH* recommendations for all cadres that had been included in that guideline as the panel felt that recommendations for contraception provision in general would not be different from recommendations for post-abortion contraception provision. Pharmacists and pharmacy workers were not considered in *Optimize MNH*.

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 21*) assessed the effectiveness of using pharmacists or pharmacy workers to administer insertion and removal of IUDs or implants and initiation and continuation of injectables as compared to a clinical provider. The review included:

- No studies that assessed the insertion or removal of IUDs or implants by pharmacists or pharmacy workers
- No studies that assessed contraceptive injectable provision by pharmacy workers
- One study that assessed the provision of injectable contraceptives by pharmacists

Study setting: USA,

Cadre-specific information: Three clinical pharmacists all of whom were certified to provide immunization /injections. Five clinical providers at a Planned Parenthood clinic.

Intervention-related information: Subcutaneous depo medroxyprogesterone acetate (DMPA-SC) for women who desired to initiate, continue or restart any form of DMPA. Initial injection by a clinic provider and two subsequent injections by the pharmacists at the pharmacy. The pharmacists also did blood pressure and urine testing to monitor side-effects. The two injections were given at an interval of every three months (12–14 weeks).

Other factors: number of events small (50 women) only three pharmacists.

Summary of Findings: *Pharmacists compared to clinicians (Web Supplement 2, Annex 13g)*

What happens?	Clinicians providing contraceptive injections	Pharmacists providing contraceptive injections	Certainty of the evidence
Effectiveness: Uptake of injectable contraceptive No direct evidence identified			
Effectiveness: continuation rates/re-injection We are uncertain of the effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low
Safety: Serious adverse events No direct evidence estimable	Not estimable	Not estimable	
Safety: Other complications No direct evidence identified			
Overall satisfaction with contraceptive service/ method No direct evidence estimable	Not estimable	Not estimable	
Overall satisfaction with provider No direct evidence estimable	Not estimable	Not estimable	

* 95% confidence interval.

Additional considerations

The Safe abortion guidelines/Medical eligibility criteria for contraceptive use: Hormonal contraception may be started at the time of surgical abortion or as early as the time of administration of first pill of medical abortion. An IUD may be inserted following medical abortion when it is reasonably certain that the woman is no longer pregnant.

IUD, injectables and implants are category 1 contraceptives following a first trimester abortion; IUDs are category 2 after second trimester abortion.

Optimize MNH recommended that:

- IUD insertion and removal be done by doctors, associate clinicians, midwives, nurses and ANMs. It was recommended only in a rigorous research context for auxiliary nurses and recommended against for LHWs.
- Insertion and removal of implants: be done by doctors, associate clinicians, midwives, nurses. By auxiliary nurses and ANMs in the context of targeted monitoring and LHWs only in context of rigorous research.
- Injectables using standard syringe: All cadres. LHWs within context of targeted monitoring.

Recommendations on using a compact, prefilled auto-disable device (CPAD) were not made because these devices were not commercially available at the time and research was still ongoing.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the facility-based providers*	*Probably favours the facility-based providers*	*Similar results*	*Probably favours the pharmacists/ pharmacy workers*	*Favours the pharmacists/ pharmacy workers*
Pharmacists, pharmacy workers	☐	☐	☐	☐	☒	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the facility-based providers*	*Probably favours the facility-based providers*	*Similar results*	*Probably favours the pharmacists/ pharmacy workers*	*Favours the pharmacists/ pharmacy workers*
Pharmacists, pharmacy workers	☐	☐	☐	☐	☒	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Pharmacists, pharmacy workers	☐	☒	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the facility-based providers*	*Probably favours the facility-based providers*	*Similar results*	*Probably favours the pharmacists/ pharmacy workers*	*Favours the pharmacists/ pharmacy workers*
Pharmacists, pharmacy workers	☐	☐	☐	☐	☒	☐	☐

Resources required

Research evidence

In the included study, time to train pharmacists was minimal (the enrolled pharmacists already met local regulatory requirements for providing injections) and involved reviewing protocols and forms, how the DMPA-SC syringe should be prepared for injection and demonstration in using and interpreting urine pregnancy test results. Included pharmacies had existing electronic record keeping systems.

Additional considerations:

Training:

- Competency-based training in provision including training in universal precautions, infection prevention, contraceptive counselling and values clarification.
- Training needs to be within the context of provision of contraception at any time the woman desires it, not just the post-abortion period.
- If pharmacists not already certified for injection provision training time and resources needed may be higher.
- Training material and curricula may need to be developed specifically for these cadres.

Supplies: Contraceptive supply chain

Change of location of service delivery: If the pharmacist/pharmacy is not already providing health-related care other than dispensing then costs of setting up the pharmacy to be a functional service delivery point need to be considered including:

- mechanisms for waste disposal (sharps, used injections)
- space for counselling, privacy, interaction with woman
- referral linkages to formal health systems
- record keeping.

Referrals: Referral linkages to a health-care facility/provider

Supervision/monitoring: Initial learning curve in involvement of a new cadre may mean increased time needed for the task, increased monitoring, increased supervision. This should decrease with time.

Remuneration: Financial or other incentives may be needed to sustain service provision.

Other: May result in cost savings for women by decreasing an additional clinic visit.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
Pharmacists, pharmacy workers	☐	☒	☐	☐	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the facility-based providers*	*Probably favours the facility-based providers*	*Similar results*	*Probably favours the pharmacists/ pharmacy workers*	*Favours the pharmacists/ pharmacy workers*
Pharmacists, pharmacy workers	☐	☐	☐	☐	☒	☐	☐

Acceptability

Research evidence

Acceptability among women

Three reviews (*Web Supplement 3, Annexes 27–29*) suggest that the acceptability of task shifting *abortion care services* (including medical abortion, counselling, or abortion-related family planning services) to *pharmacists and pharmacy workers,* working both within and outside of the formal health system, was mixed:

- Women sometimes preferred to go to pharmacies for information and for medical abortion because this was more convenient, private and cheaper than going to a health-care provider (low confidence). However, women as well as health providers sometimes distrusted pharmacists' ability to properly counsel and administer medical abortion. This distrust arose from a perception of pharmacists as businesspeople, as not holding adequate knowledge, and of being incapable or uninterested in providing follow-up in the case of complications. Distrust also stemmed from a sense that pharmacies and pharmacists were poorly regulated and controlled thus increasing the potential for unequal treatment options or prices for clients and counterfeit drugs (high confidence).
- One study suggests that pharmacists' drug recommendations depended on the customer's ability to pay, with richer people being offered more expensive drugs; and whether or not the chemist knew the customer personally (low confidence).

Acceptability among pharmacists and pharmacy workers

- The reviews identified very little data regarding the willingness of pharmacists or pharmacy workers to deliver abortion care services or to insert and remove IUDs and contraceptive implants and to initiate/continue injectable contraceptives.

(*Web Supplement 3, Annexes 27–29)*

Additional information

None specified.

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, Pharmacy workers	☐	☒	☐	☐	☐	☐

Is the option acceptable to health-care providers?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, Pharmacy workers	☒	☐	☐	☐	☐	☐

Feasibility

Research evidence

The reviews conducted for this guideline did not identify any research that explored the feasibility of using pharmacists or pharmacy workers to provide contraception.

Indirect evidence:

Two reviews (*Web Supplement 3, Annexes 28 and 29*) show the following feasibility issues regarding task shifting abortion care services to pharmacists and pharmacy workers within and outside the formal health system:

- some studies suggest that pharmacists and pharmacy workers often have incorrect knowledge about medical abortion (low confidence), although some pharmacists acknowledge this lack of knowledge and are keen to increase their skills (low confidence).

Two reviews (*Web Supplement 3, Annexes 28 and 29*) identified a number of feasibility issues for different types of health-care providers regarding task shifting abortion care in general, particularly in weaker health systems, including:

- a lack of knowledge among providers regarding abortion care; inadequate training; training not incorporated into medical or nursing school curricula; problems obtaining work release to attend in-service training; a lack of supervision and support; increased workloads; a need for incentives for providers undertaking these additional roles; problems with access to drugs and supplies; and in some settings, limits on using particular equipment for abortion care, or incorporating safe abortion messages into counselling services, due to the policies of certain funding agencies Our confidence in these findings was assessed as low to moderate.

Additional information

None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Pharmacists, pharmacy workers	☐	☐	☐	☐	☒	☐

CONTRA1 RECOMMENDATION:

Type of recommendation/decision

IUDs

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Pharmacists	☐	☐	☐	☒
Pharmacy workers	☐	☐	☐	☒

Implants

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Pharmacists	☐	☐	☐	☒
Pharmacy workers	☐	☐	☐	☒

Injectable contraceptives

	Recommend	*Recommend in specific circumstances*	*Recommend in the context of rigorous research*	*Recommend against*
Pharmacists	☒	☐	☐	☐
Pharmacy workers	☐	☒	☐	☐

Recommendations and justifications

	Recommendation	***Justification***
Pharmacists	The panel recommends against the option of IUD insertion and removal by pharmacists.	There is no direct evidence on the safety, effectiveness, acceptability or feasibility of this option.
	The panel recommends against the option of pharmacists inserting and removing implants.	There is no direct evidence on the safety, effectiveness, acceptability or feasibility of this option.
	The panel recommends the option of pharmacists managing the initiation and continuation of injectable contraceptives.	Although the available evidence for effectiveness is of very low certainty, administering injections is within the scope of work of pharmacists and the additional training needs for taking on this task would be minimal. This option has the potential to increase women's choices and to reduce inequities in the availability of contraception.
Pharmacy workers	The panel recommends against the option of IUD insertion and removal by pharmacy workers.	There is no direct evidence on the safety, effectiveness, acceptability or feasibility of this option.
	The panel recommends against the option of insertion and removal of implants by pharmacy workers.	There is no direct evidence on the safety, effectiveness, acceptability or feasibility of this option.
	The panel recommends the option of initiation and continuation of injectables by pharmacy workers only in contexts where the pharmacy worker is administering injectable contraceptives under direct supervision of a pharmacist.	There is no direct evidence on the effectiveness, acceptability or feasibility of this option. However, administering injections is within the scope of work for trained pharmacy workers, thus the additional training needs would be minimal. This option has the potential to increase women's choices and to reduce inequities in the availability of contraception.

Subgroup considerations

None specified.

Implementation considerations

Setting up adequate mechanisms for waste disposal of sharps and used injections is important and particularly relevant when involving pharmacists and pharmacy workers as pharmacies may not have such mechanisms in place.

Adequate arrangements for storage and for keeping sharps safely at home and training in and provision of mechanisms for waste disposal of used injectables (especially in settings with high HIV prevalence) and ensuring a way to procure injectables on a regular basis without needing to repeatedly visit a health-care facility are important considerations when making the self-injection option available.

For pharmacists not already certified to provide injections, investment in initial training may be higher.

Research priorities

None specified.

CONTRA1 – Self-administration of injectable contraception

Should WOMEN self-administer injectable contraceptives?

Background

Option: Women self-administering injectable contraceptives after information and instructions have been obtained from a trained provider.
Comparison: Injectable administered by a doctor or other facility-based provider (usual health provider)
Setting: Home
Subgroups: None

Benefits and harms

Research evidence

A systematic review (*Web Supplement 2, Annex 21*) found:

- three studies that assessed self-injection of contraception compared to administration by the usual health provider.

Study settings: Scotland; USA (two studies)

Cadre specific information: Two studies enrolled women who were existing DMPA users and one enrolled new users.

Intervention-related information: One study used an intramuscular formulation administered monthly and the other two studies used the subcutaneous form of DMPA that is administered every three months. In all three studies, the nurse or clinician administered the injection to the office group. One study was a crossover where the same group of woman performed self-administration in the first three months, then had the nurse administer the injection in the following three months. All three studies had the self-administration group undergo injection training and instruction, which included a supervised self-injection of the injectable contraceptive.

Other factors: The DMPA-SC injections were given to women as pre-filled syringes and needles. The kit that was given to the women to administer at home as described in one study included supplies for three self-injections, including medication, syringes, needles, alcohol swabs, a sharps box.

Summary of Findings: *Self-administration compared to provision by clinicians (Web Supplement 2, Annex 14j)*

What happens?	Clinicians providing contraceptive injections	Women self-administrating contraceptive injections	Certainty of the evidence
Effectiveness: Uptake of injectable contraceptive No direct evidence identified			
Effectiveness: Continuation rates/re-injection at 12 months (RCT) There may be little or no difference in continuation rates when women self-administer contraceptive injections/implants. However, the 95% CI shows that both fever and more events may occur.	304 per 1000	326 per 1000 (192 to 554 per 1000)*	⨁⨁◯◯ Low
Effectiveness: Continuation rates/re-injection at 12 months (non-RCT) We are uncertain of the effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low
Effectiveness: Continuation rates/re-injection at 3 months (non-RCT) we are uncertain of the effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low
Safety: Serious adverse events No direct evidence identified			
Safety: Other complications No direct evidence estimable	Not estimable	Not estimable	
Overall satisfaction with contraceptive service/method We are uncertain of the effect of the intervention on this outcome as the certainty of the evidence has been assessed as very low.			⨁◯◯◯ Very low

* 95% confidence interval.

Additional considerations

Medical eligibility criteria for contraceptive use: Initiation and/or continuation of contraceptive injectables (both combined injectables and progestogen-only injectables) are given a “1” for the

condition of post-abortion. (1= a condition for which there is no restriction for the use of the contraceptive method/use method in any circumstances).

Selected practice recommendations for contraceptive use: First injection of the combined injectable contraceptives (CIC) and progestogen-only injectables (POIs) can be given immediately post-abortion or within the seven days after the start of menses. First injection can also be given at any other time if it is reasonably certain that she is not pregnant.

Judgements

Do the <u>desirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the facility-based providers*	*Probably favours the facility-based providers*	***Similar results***	***Probably favours self***	***Favours self***
Self	☐	☐	☐	☐	☒	☐	☐

Do the <u>undesirable</u> anticipated effects favour the intervention or the comparison?

	Don't know	*Varies*	*Favours the facility-based providers*	*Probably favours the facility-based providers*	*Similar results*	*Probably favours the pharmacists/ pharmacy workers*	*Favours the pharmacists/ pharmacy workers*
Self	☐	☐	☐	☐	☒	☐	☐

What is the overall certainty of the evidence of effects?

	No included studies	*Very low*	*Low*	*Moderate*	*High*
Self	☐	☒	☐	☐	☐

Does the balance between desirable effects and undesirable effects favour the option or the comparison?

	Don't know	*Varies*	*Favours the provider*	*Probably favours the provider*	*Similar results*	*Probably favours the woman*	*Favours the woman*
Self	☐	☐	☐	☐	☒	☐	☐

Resources required

Research evidence

The three reviewed studies noted the cost saving aspect of self-administration of contraceptive injectables in terms of travel, time off work, childcare costs and savings for the health services. One of these studies compared the time and money spent on seeking/obtaining their DMPA injection (contraceptive behaviour) during the home phase versus office phase. All patients at

home spent less than 30 minutes on contraceptive behaviour while half of the subjects spent more than 30 minutes on contraceptive behaviour in the clinic. The same study also noted that the subjects spent US$ 10 more on contraceptive behaviour during the office than the home phase (due to travel costs, time away from work and childcare).

Additional considerations

Training:

- Competency-based training in self injecting, waste management etc.
- Training may need to be repeated and sustained as the frequency of injection provision is infrequent (1 month or 3 months) thus gaining competency and confidence may require longer time.

Supplies: Supply chain of injectables and a way to procure them on a regular basis without needing to repeatedly visit a health-care facility.

Change of location of service delivery:

- Although can be stored at room temperature, adequate arrangements for storage and for keeping sharps safely at home will need to be ensured.
- Training in and provision of mechanisms for waste disposal of used injectables will be needed. This may be particularly relevant in settings with high HIV prevalence.

Referral: Link to a provider for information or in case of problems.

Supervision/monitoring: Provider time freed up from having to deliver injections. But additional time will be needed for competency-based training of women to self-inject. Provider time may be increased at least initial stage in screening, training and monitoring the woman's self-use.

Remuneration: Financial or other Incentives may be needed to sustain service provision and ensure retention in rural /underserved areas.

Other: For woman: may reduce occupational costs (time off work), travel costs of an additional provider/clinic visit.

Judgements

How large are the resource requirements (costs)?

	Don't know	*Varies*	*Large costs*	*Moderate costs*	*Negligible costs or savings*	*Moderate savings*	*Large savings*
Self	☒	☐	☐	☐	☐	☐	☐

Does the cost effectiveness of the option favour the option or the comparison?

	Don't know	*Varies*	*Favours the provider*	*Probably favours the provider*	*Similar results*	*Probably favours the woman*	*Favours the woman*
Self	☒	☐	☐	☐	☐	☐	☐

Acceptability

Research evidence

Acceptability among women

We did not systematically collect research evidence regarding the acceptability of self-administering injectable contraceptives.

- In one existing review (*Web Supplement 3, Annex 35*), three studies in low- and middle-income countries addressed the hypothetical acceptability of home and self-injection of a long-acting contraceptive (DMPA – subcutaneous [SC]) using a compact, prefilled, auto-disable device (CPAD). Between one fifth and one half of women in two settings noted that they were moderately or very willing to try home or self-injection using this device after having been administered contraception using the device in a health-care facility. The appeal for women was the smaller needle in the CPAD device, compared to standard intramuscular injections, and the potential to save time and money by not having to travel to a clinic for their injections.
- In the same review, studies in high-income countries also explored the acceptability to women of this and similar devices for self-injection of DMPA-SC, and found acceptability to be good. In two studies, acceptability was linked to convenience and in one study also to cost and time savings. In one study in which two thirds of current users of intramuscular injections noted that they would prefer self-administration, the main reasons for rejecting self-administration were a fear of needles and lack of confidence in their ability to inject themselves properly. The numbers of participants in all of these studies were small.

Additional information

A systematic review (*Web Supplement 3, Annex 32*) of the acceptability of drug delivery by LHWs using a CPAD device suggests that LHWs find the CPAD device easy to use, carry, store and dispose of and are generally confident in their ability to use the device safely and correctly (low confidence). However, some LHWs voiced concerns about possible social or legal consequences if something went wrong. These concerns were at least partly addressed through support and supervision (low confidence).

Judgement

Is the option acceptable to women?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Self	☐	☐	☐	☐	☒	☐

(for some women, choice is important)

Feasibility

Research evidence

We did not systematically collect research evidence regarding the feasibility of self-administering injectable contraceptives:

- In one existing review (*Web Supplement 3, Annex 35*), two studies conducted in high-income countries using either the DMPA-SC CPAD or a similar subcutaneous DMPA injection had high continuation rates for administration of contraceptives at 12 months. In

one of these studies, participants had difficulty with 20% of injections, and this was usually attributed to plunger resistance. A third study in a high-income country of self-injected using DMPA-SC suggested that adolescents may be less proficient and confident in self-injecting. A study in a middle income country assessing user ability to self-administer a similar once-monthly contraceptive CPAD found that all 56 participants were able to self-administer this safely and easily and that over half of them would prefer to self-inject in the future. The numbers of participants in all of these studies were small.

Additional information

None specified.

Is the option feasible to implement?

	Don't know	*Varies*	*No*	*Probably no*	*Probably yes*	*Yes*
Self	☐	☒	☐	☐	☐	☐

CONTRA1 RECOMMENDATION:

Type of recommendation/decision

	Recommend	***Recommend in specific circumstances***	***Recommend in the context of rigorous research***	***Recommend against***
Self	☐	☒	☐	☐

Recommendations and justifications

	Recommendation	***Justification***
Self	The panel recommends this option in contexts where mechanisms to provide the women with appropriate information and training exist, referral linkages to a health-care provider are strong and where monitoring and follow-up can be ensured.	There is evidence from high resource settings that continuation rates for self-administered injectable contraceptives are similar to injectable contraceptives being provided by clinic-based providers (low certainty). The option may result in time and financial savings for women. There is evidence that some women prefer self-injection and the option may increase choice and autonomy in contraceptive use within a rights-based framework.

Subgroup considerations:

None specified.

Implementation considerations:

Adequate arrangements for storage and for keeping sharps safely at home and training in and provision of mechanisms for waste disposal of used injectables (especially in settings with high HIV prevalence) and ensuring a way to procure injectables on a regular basis without needing to repeatedly visit a health-care facility are important considerations when making the self-injection option available

Research priorities

Implementation in low-resource settings.