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

Web Supplement 2

Annexes 1–26: Evidence base for benefits and harms

WHO/RHR/15.11b

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/

Annex 1: MVA1/EVA1

(MVA/EVA for induced abortion up to 12–14 weeks)

Annex 1b. MVA1/EVA1: Doctors of complementary systems of medicine

No direct evidence identified.

Annex 1c. MVA1/EVA1: Associate clinicians

Summary of Findings table (MVA1/EVA1: Associate clinicians)

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 is probably 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.

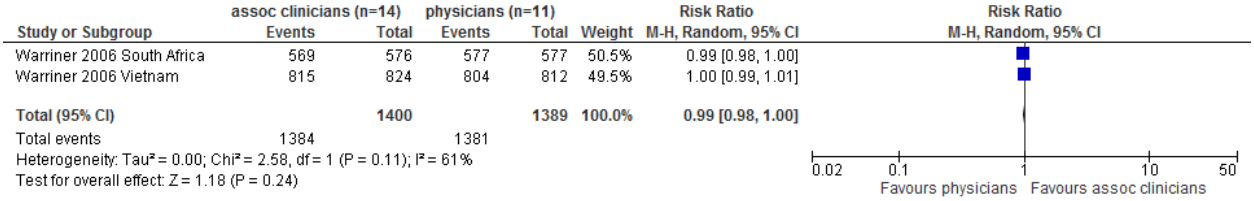
[1] A mix of associate clinicians and midwives; see the forest plots for detailed information about the cadre.

[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.

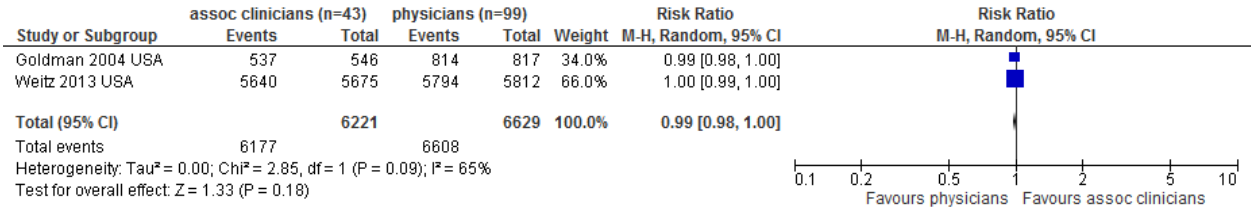
Forest plots (MVA1/EVA1: Associate clinicians)

Effectiveness: complete abortion (RCTs)



Note that there was 1 associate clinician and 13 midwives in this cadre. Disaggregated outcomes not reported.

Effectiveness: complete abortion (non-RCTs)

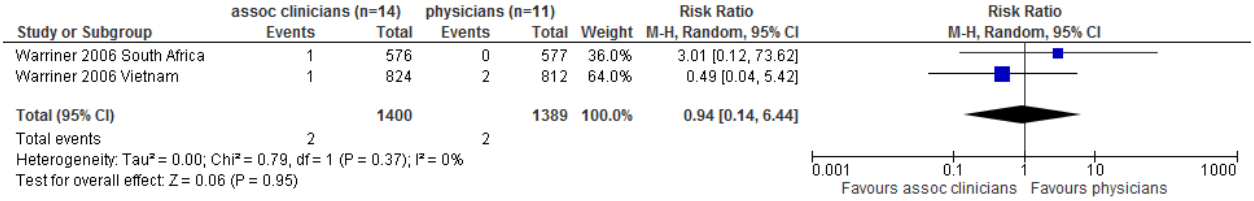


Note that there were 38 associate clinicians and 5 midwives in this cadre. Disaggregated outcomes not reported.

Safety: serious adverse events

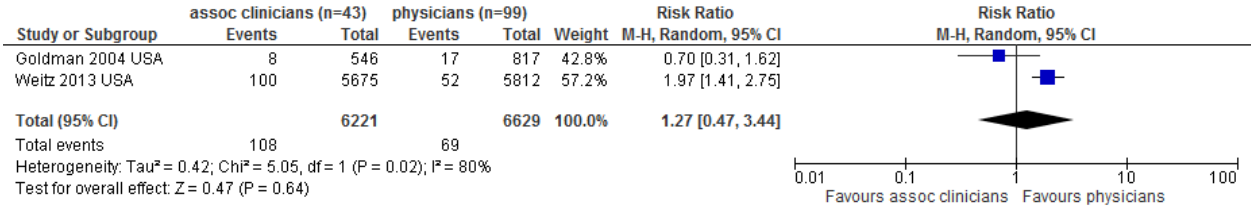
Note that there were 38 associate clinicians and 5 midwives in this cadre. Disaggregated outcomes not reported

Safety: any surgical abortion-related complication (RCTs)



Note that there was 1 associate clinician and 13 midwives in this cadre. Disaggregated outcomes not reported

Safety: any surgical abortion-related complication (non-RCTs)



Note that there were 38 associate clinicians and 5 midwives in this cadre. Disaggregated outcomes not reported

Satisfaction with abortion service

No direct evidence identified.

Satisfaction with abortion provider

No direct evidence identified.

Satisfaction with overall abortion experience

Data from one study (Taylor et al., 2013)[1] shows that 72% of all women receiving surgical management for induced abortion rated their overall abortion experience as excellent (10 points on a numeric rating scale from 0 to 10). Based on logistic regression analysis reported in the article, the absolute number of women rating their overall experience as excellent would be:

- 720 per 1000 by those having physicians as their provider (OR: 1.00); and
- 739 per 1000 (95% CI: 718–760) by those having associate clinicians or midwives as their provider (OR: 1.10, 95% CI: 0.99–1.23).

[1] Taylor D, Postlethwaite D, Desai S, Angel James E, Calhoun AW, Sheehan C, Weitz T. (2013). Multiple determinants of the abortion care experience. American Journal of Medical Quality. doi:10.1177/1062860613484295

Author(s): Fonhus MS and Fretheim A
Date: 26.09.2014
Question: Should MVA1/EVA1 associate clinicians vs doctors be used in surgical abortion provision (< 12–14 weeks)?
Settings: South Africa: 6 mid-level providers (most likely midwives, but information is not provided) (579 women) and 6 doctors/physicians (581 women). Viet Nam: 7 midwives and 1 doctor-assistant (874 women) and 5 doctors/physicians (860 women). USA: Goldman 2006 3 associate physicians (546 women) and 3 physicians (817 women). Weitz 2013 and Taylor 2013 40 mid-level providers: (28 nurse practitioners, 5 nurse midwives, 7 physician assistants) (5675 women) and 96 doctors (Ob/Gyn (5812 women)).
Bibliography (systematic reviews): Primary studies included: Warriner 2006 South Africa and Viet Nam, Weitz 2013 USA, Taylor 2013 USA and Goldman 2006 USA

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MVA1/EVA1 associate clinicians	MVA1/EVA1 physicians	Relative (95% CI)	Absolute (95% CI)		
Complete abortion RCT (one study, 2 arms)												
1	randomized trials	not serious	not serious	not serious	serious [1,2]	none	1384/1400 (98.9%)	1381/1389 (99.4%)	RR 0.99 (0.98 to 1.00)	10 fewer per 1000 (from 0 fewer to 20 fewer)	⊕⊕⊕◯ MODERATE	
Complete abortion non-RCTs												
2	observational studies	serious [3]	not serious	not serious	not serious	none	6177/6221 (99.3%)	6608/6629 (99.7%)	RR 1.00 (0.99 to 1.00)	0 fewer per 1000 (from 0 fewer to 10 fewer)	⊕◯◯◯ VERY LOW	
Serious adverse events non-RCTs (one study, 2 arms)												
1	observational study	serious [3]	not serious	not serious	not serious [4,5]	none	4/6221 (0.1%)	3/6629 (0.0%)	RR 1.38 (0.33 to 5.75)	0 fewer per 1000 (from 0 fewer to 2 more)	⊕◯◯◯ VERY LOW	
Any surgical abortion-related complication RCT (one study, 2 arms)												
1	randomized trials	not serious	not serious	not serious	very serious [1,2,4]	none	2/1400 (0.1%)	2/1389 (0.1%)	RR 0.94 (0.14 to 6.41)	0 fewer per 1000 (from 1 fewer to 8 more)	⊕⊕◯◯ LOW	
Any surgical abortion-related complication non-RCTs												
2	observational studies	serious [3]	not serious	not serious	not serious [4]	none	108/6221 (1.7%)	69/6629 (1.5%)	RR 1.27 (0.47 to 3.44)	3 more per 1000 (from 6 fewer to 25 more)	⊕◯◯◯ VERY LOW	
Satisfaction with abortion service												
0												
Satisfaction with abortion provider												
Satisfaction with overall abortion experience												
1	observational study	not serious	not serious	not serious	not serious	none	0/0		not pooled		⊕⊕◯◯ LOW	

MD: mean difference; RR: relative risk.
[1] One study only
[2] 95% CI crosses the line of no effect
[3] High risk of bias in one study
[4] Very few events, but not downgraded for this as few events are anticipated
[5] One study only, but not downgraded for this

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 1d. MVA1/EVA1: Midwives

Summary of Findings table (MVA1/EVA1: Midwives)

What happens?	Physicians providing surgical abortion	Midwives[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[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
Overall satisfaction with provider No direct evidence identified			
Overall satisfaction with abortion service No direct evidence identified			
Satisfaction with overall abortion experience There is probably 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.

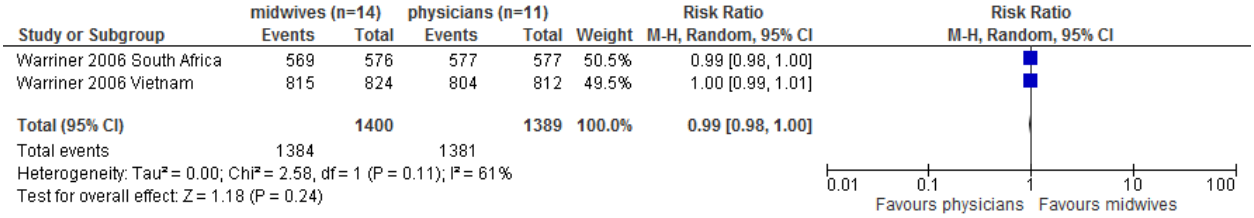
[1] A mix of associate clinicians and midwives, see the forest plots for detailed information about the cadre.

[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.

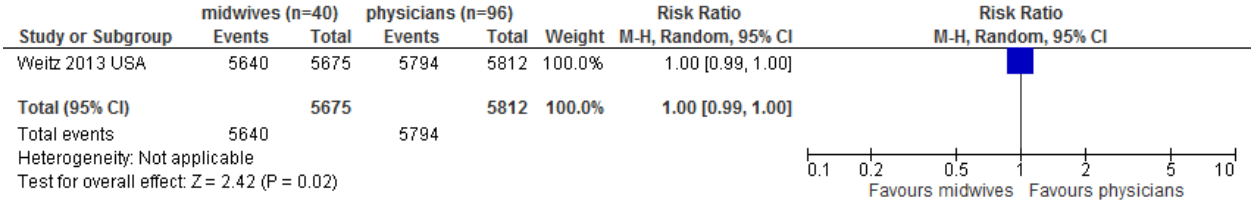
Forest plots (MVA1/EVA1: Midwives)

Effectiveness: complete abortion (RCTs)



Note that there was 1 associate clinician and 13 midwives in this cadre. Disaggregated outcomes not reported

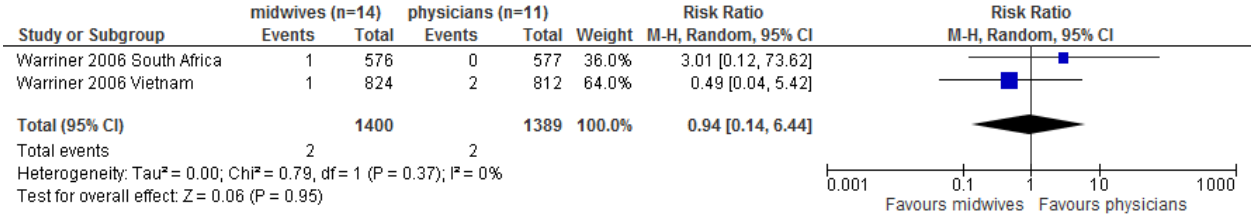
Effectiveness: complete abortion (non-RCTs)



Safety: serious adverse events (non-RCTs)

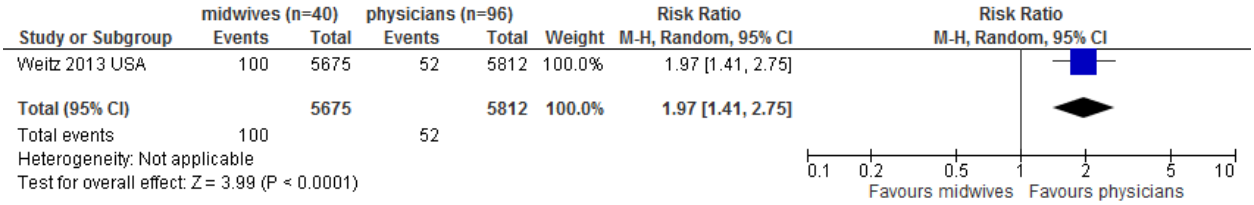
Note that there were 35 associate clinicians and 5 midwives in this cadre. Disaggregated outcomes not reported

Safety: any surgical abortion-related complication (RCTs)



Note that there was 1 associate clinician and 13 midwives in this cadre. Disaggregated outcomes not reported

Safety: any surgical abortion-related complication (non-RCTs)



Note that there were 35 associate clinicians and 5 midwives in this cadre. Disaggregated outcomes not reported

Satisfaction with abortion service

No direct evidence identified.

Satisfaction with abortion provider

No direct evidence identified.

Satisfaction with overall abortion experience

Data from one study (Taylor et al., 2013) shows that 72% of all women receiving surgical management for induced abortion rated their overall abortion experience as excellent (10 points on a numeric rating scale from 0 to 10). Based on logistic regression analysis reported in the article, the absolute number of women rating their overall experience as excellent would be: 720 per 1000 by those having physicians as their provider (OR: 1.00) and 739 (95% CI: 718–760) per 1000 by those having associate clinicians or midwives as their provider (OR: 1.10 95% CI: 0.99–1.23).

GRADE profile (MVA1/EVA1: Midwives)

Author(s): Fonhus MS and Fretheim A
Date: 26.09.2014
Question: Should MVA1/EVA1 midwives vs doctors be used for surgical abortion provision (< 12–14 weeks)?
Settings: South Africa: 6 mid-level providers (most likely midwives, but information is not provided) (579 women) and 6 doctors/physicians (581 women). Viet Nam: 7 midwives and 1 doctor-assistant (874 women) and 5 doctors/physicians (860 women). USA: Weitz 2013 and Taylor 2013 40 Mid-level providers: (28 nurse practitioners, 5 nurse midwives, 7 physician assistants) (5675 women) and 96 physicians: 96 Ob/Gyn (5812 women).
Bibliography (systematic reviews): Primary studies included: Warriner 2006 South Africa and Viet Nam, Weitz 2013 USA, Taylor 2013 USA

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MVA1/EVA1 midwives	MVA1/EVA1 doctors	Relative (95% CI)	Absolute (95% CI)		
Complete abortion RCT (one study, 2 arms)												
1	randomized trials	not serious	not serious	not serious	serious [1]	none	1384/1400 (98.9%)	1381/1389 (99.4%)	RR 0.99 (0.98 to 1.00)	10 fewer per 1000 (from 0 fewer to 20 fewer)	⨁⨁⨁◯ MODERATE	
Complete abortion non-RCTs												
1	observational study	serious [2]	not serious	not serious	not serious [3]	none	5640/5675 (99.4%)	5794/5812 (99.7%)	RR 1.00 (0.99 to 1.00)	0 fewer per 1000 (from 0 fewer to 10 fewer)	⨁◯◯◯ VERY LOW	
Serious adverse events non-RCTs												
1	observational study	serious [2]	not serious	not serious	not serious [3,4]	none	3/5675 (0.1%)	3/5812 (0.1%)	RR 1.02 (0.21 to 5.07)	0 fewer per 1000 (from 0 fewer to 2 more)	⨁◯◯◯ VERY LOW	
Any surgical abortion-related complication RCT												
1	randomized trial	not serious	not serious	not serious	very serious [1,4]	none	2/1400 (0.1%)	2/1389 (0.1%)	RR 0.94 (0.14 to 6.41)	0 fewer per 1000 (from 1 fewer to 8 more)	⨁⨁◯◯ LOW	
Any surgical abortion-related complication non-RCTs												
1	observational study	serious [2]	not serious	not serious	not serious [3,4]	none	100/5675 (1.8%)	52/5812 (0.9%)	RR 1.97 (1.41 to 2.75)	9 more per 1000 (from 4 more to 16 more)	⨁◯◯◯ VERY LOW	
Satisfaction with abortion service												
0												
Satisfaction with overall abortion experience												
1	observational study	not serious	not serious	not serious	not serious	none	0/0		not pooled		⨁⨁◯◯ LOW	

MD: mean difference; RR: relative risk.
[1] One study only
[2] High risk of bias in included study
[3] One study only, but not downgraded for this
[4] Very few events, but not downgraded for this as few events are anticipated

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 1e. MVA1/EVA1: Nurses

Summary of Findings table (MVA1/EVA1: Nurses)

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.

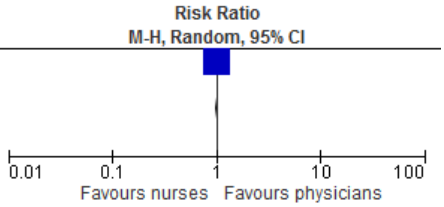
[1] Haematometra, bleeding/haemorrhage, infection, uterine perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death.

Forest plot (MVA1/EVA1: Nurses)

Effectiveness: complete abortion

Study or Subgroup	nurses (n=10) Events	Total	physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jejeebhoy 2011 india	428	433	428	432	100.0%	1.00 [0.98, 1.01]
Total (95% CI)		**433**		**432**	**100.0%**	**1.00 [0.98, 1.01]**
Total events	428		428			

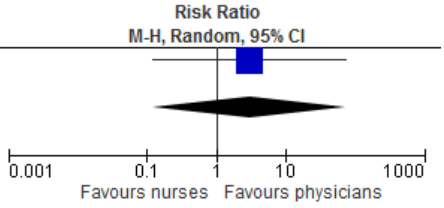
Heterogeneity: Not applicable
Test for overall effect: Z = 0.33 (P = 0.74)



Safety: any surgical abortion-related complication

Study or Subgroup	nurses (n=10) Events	Total	physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jejeebhoy 2011 india	1	433	0	432	100.0%	2.99 [0.12, 73.27]
Total (95% CI)		**433**		**432**	**100.0%**	**2.99 [0.12, 73.27]**
Total events	1		0			

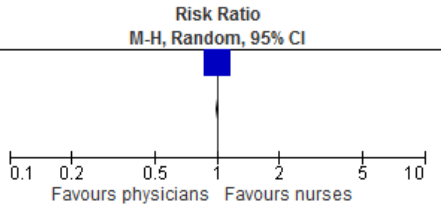
Heterogeneity: Not applicable
Test for overall effect: Z = 0.67 (P = 0.50)



Satisfaction with abortion service

Study or Subgroup	Nurses (n=10) Events	Total	Physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jejeebhoy 2011 india	425	433	422	432	100.0%	1.00 [0.99, 1.02]
Total (95% CI)		**433**		**432**	**100.0%**	**1.00 [0.99, 1.02]**
Total events	425		422			

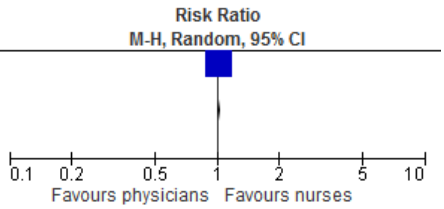
Heterogeneity: Not applicable
Test for overall effect: Z = 0.48 (P = 0.63)



Satisfaction with abortion provider

Study or Subgroup	Nurses (n=10) Events	Total	Physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jejeebhoy 2011 india	433	433	422	432	100.0%	1.02 [1.01, 1.04]
Total (95% CI)		**433**		**432**	**100.0%**	**1.02 [1.01, 1.04]**
Total events	433		422			

Heterogeneity: Not applicable
Test for overall effect: Z = 3.02 (P = 0.003)



GRADE profile (MVA1/EVA1: Nurses)

Author(s): Fonhus MS and Fretheim A
Date: 26.09.2014
Question: Should MVA1/EVA1 nurses vs doctors be used in surgical abortion provision (< 12–14 weeks)?
Settings: India 10 nurses (555 women) and 10 physicians (534 women)
Bibliography (systematic reviews): Primary studies included: Jejeebhoy 2011 India

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MVA1/EVA1 nurses	MVA1/EVA1 doctors	Relative (95% CI)	Absolute (95% CI)		
Completion abortion												
1	observational studies	not serious	not serious	not serious	not serious [1]	none	428/433 (98.8%)	428/432 (99.1%)	RR 1.00 (0.98 to 1.01)	0 fewer per 1000 (from 10 more to 20 fewer)	⊕⊕◯◯ LOW	
Any surgical abortion-related complication												
1	observational studies	not serious	not serious	not serious	not serious [1 2]	none	1/433 (0.2%)	0/432 (0.0%)	RR 2.99 (0.12 to 73.27)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⊕⊕◯◯ LOW	
Satisfaction with abortion service												
1	observational studies	not serious	not serious	not serious	not serious [1]	none	425/433 (98.2%)	422/432 (97.7%)	RR 1.00 (0.99 to 1.02)	0 fewer per 1000 (from 10 fewer to 20 more)	⊕⊕◯◯ LOW	
Satisfaction with abortion provider												
1	observational studies	not serious	not serious	not serious	not serious [1]	none	433/433 (100.0%)	422/432 (97.7%)	RR 1.02 (1.00 to 1.02)	20 more per 1000 (from 0 fewer to 20 more)	⊕⊕◯◯ LOW	

MD: mean difference; RR: relative risk.
[1] One study, but not downgraded for this
[2] Very few events not downgraded for this as few events are anticipated

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 1f. MVA1/EVA1: Auxiliary nurses/auxiliary nurse midwives

No direct evidence identified.

Characteristics of primary studies included for MVA1/EVA1

Goldman 2004 USA

Methods	Prospective cohort study
Participants	3 physician assistants treating 546 women and 3 physicians treating 817 women
Interventions	Surgical abortion: both manual (51.2%) and electric vacuum aspiration (48.8%) were performed by physician assistants; only EVA performed by physicians.
Outcomes	Complete abortion, any complication
Notes	All providers had a minimum of five years' professional experience with surgical abortion.

Jejeebhoy 2011 India

Methods	Prospective cohort study
Participants	10 nurses treating 555 women and 10 physicians treating 534 women
Interventions	Surgical abortion with manual vacuum aspiration provided by nurses or physicians
Outcomes	Complete abortion, any complication, satisfaction
Notes	No providers had prior professional training or experience in medical or surgical abortion provision, assessing gestational age or performing pelvic examinations. All providers underwent identical classroom and hands-on training that lasted 12 days followed by a 1-week field placement. All observed 10 procedures, assisted with 10 procedures and independently performed 5 procedures. All provider categories under overall supervision of a verifier (Ob/Gyn) who served as gold standard. Contact between providers and verifier kept to a minimum.

Warriner 2006 South Africa

Methods	Two sided RCT in South Africa and Viet Nam
Participants	6 non-physician providers (most likely midwives, but not clearly stated) treating 579 women; 6 physicians treating 581 women
Interventions	Surgical abortion with manual vacuum aspiration (< 12 weeks) provided by midwives or physicians
Outcomes	• Complete abortion, any complications
Notes	All non-physician providers completed standardized, government sponsored training to offer legal abortion. All providers (non-physicians and physicians) participated in refresher training in provision of cervical block, otherwise no additional abortion-related training was offered as part of the study. Professional experience performing abortions varied. Years of experience performing abortions: • Midwives Median (IQR): 4 (3–6); Mean (SD): 4 (2) • Physicians Median (IQR): 7(7–12); Mean (SD): 10 (8)

Warriner 2006 Viet Nam

Methods	Two sided RCT in South Africa and Viet Nam
Participants	7 midwives and 1 doctor assistant treating 874 women; 5 physicians treating 860 women
Interventions	Surgical abortion with manual vacuum aspiration (< 12–14 week) provided by non-physicians (midwives and doctor assistant) or physicians
Outcomes	• Complete abortion, any complications
Notes	All non-physician providers completed standardized, government sponsored training to offer legal abortion. All providers (non-physicians and physicians) participated in refresher training in provision of cervical block, otherwise no additional abortion-related training was offered as part of the study. Professional experience performing abortions varied. Years of experience performing abortions: • Non-physicians Median (IQR): 4 (3–6); Mean (SD): 4 (2) • Physicians Median (IQR): 7(7–12); Mean (SD): 10 (8)

Weitz 2013 and Taylor 2013 USA

Methods	Prospective cohort study
Participants	40 non-physician providers including 28 nurse practitioners, 5 nurse midwives, and 7 physician assistants treating a total of 5675 women; 96 general practice or Ob/Gyn physicians treating a total of 5812 women
Interventions	Provision of surgical abortion with aspiration (EVA more common after 9 weeks) by non-physicians or physicians.
Outcomes	Complete abortion, any complication, satisfaction with abortion service
Notes	Physicians with mean 14 years of professional experience providing abortion; non-physicians with mean 1.5 years. Nurse practitioners, certified nurse-midwives and physician assistants trained to competence in aspiration abortion (min. 40 procedures over 6 days assessed by authorized physician trainer); they also had to have a minimum of 12 months' clinical experience, including 3 months or more of experience providing medical abortion.

Annex 2: MVA2/EVA2

(MVA/EVA for management of incomplete abortion in the first trimester)

Annex 2b. MVA2/EVA2: Doctors of complementary systems of medicine

No direct evidence identified.

Annex 2c. MVA2/EVA2: Associate clinicians

No direct evidence identified.

Annex 2d. MVA2/EVA2: Midwives

No direct evidence identified.

Annex 2e. MVA2/EVA2: Nurses

No direct evidence identified.

Annex 2f. MVA2/EVA2: Auxiliary nurses/auxiliary nurse midwives

No direct evidence identified.

Annex 3: D&E

(Provision of dilation and evacuation)

Annex 3a. D&E: Non-specialist physicians

No direct evidence identified.

Annex 3b. D&E: Doctors of complementary systems of medicine

No direct evidence identified.

Annex 3c. D&E: Associate clinicians

No direct evidence identified.

Annex 4: PRIME1

(Cervical priming with osmotic dilators)

Annex 4b. PRIME1: Doctors of complementary systems of medicine

No direct evidence identified.

Annex 4c. PRIME1: Associate clinicians

No direct evidence identified.

Annex 4d. PRIME1: Midwives

No direct evidence identified.

Annex 4e. PRIME1: Nurses

No direct evidence identified.

Annex 4f. PRIME1: Auxiliary nurses/auxiliary nurse midwives

No direct evidence identified.

Annex 5: PRIME2
(Cervical priming with medication)

Annex 5b. PRIME2: Doctors of complementary systems of medicine
No direct evidence identified.

Annex 5c. PRIME2: Associate clinicians
No direct evidence identified.

Annex 5d. PRIME2: Midwives
No direct evidence identified.

Annex 5e. PRIME2: Nurses
No direct evidence identified.

Annex 5f. PRIME2: Auxiliary nurses/auxiliary nurse midwives
No direct evidence identified.

Annex 5g. PRIME2: Pharmacists
No direct evidence identified.

Annex 5h. PRIME2: Pharmacy workers
No direct evidence identified.

Annex 6: MA1

(Provision of medical abortion < 84 days)

Annex 6b. MA1: Doctors of complementary systems of medicine

Summary of Findings table (MA1: Doctors of complementary systems of medicine

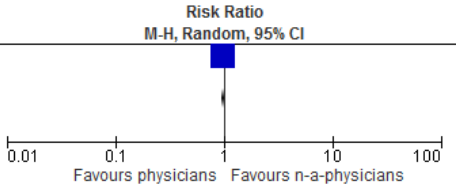
What happens?	Physicians providing medical abortion	Non-allopathic physicians providing medical abortion	Certainty of the evidence
Effectiveness: Complete abortion There may be little or no difference in complete abortions when non-allopathic physicians provide medical abortion.	954 per 1000	944 per 1000 (916 to 973 per 1000)*	⨁⨁◯◯ Low
Safety: Serious adverse events[1] There may be little or no difference in the rate of serious adverse events.	0 per 382	0 per 389	⨁⨁◯◯ Low
Overall satisfaction with abortion services There may be little or no difference in satisfaction with service when non-allopathic physicians provide medical abortion.	997 per 1000	977 per 1000 (958 to 997 per 1000)*	⨁⨁◯◯ Low
Overall satisfaction with provider[2] There may be little or no difference in satisfaction with the provider when non-allopathic physicians provide medical abortion.	1000 per 1000	1000 per 1000 (990 to 1000 per 1000)*	⨁⨁◯◯ Low

* 95% confidence interval.
[1] Blood transfusion, hospitalization or death.
[2] Willing to have future abortions with same provider type.

Forest plots MA1: Doctors of complementary systems of medicine

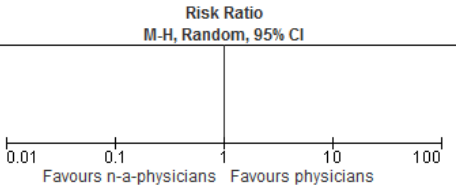
Effectiveness: complete abortion

Study or Subgroup	n-a-physicians (n=10) Events	Total	physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jeejebhoy 2012 India	361	382	371	389	100.0%	0.99 [0.96, 1.02]
Total (95% CI)		**382**		**389**	**100.0%**	**0.99 [0.96, 1.02]**
Total events	361		371			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.55 (P = 0.58)						



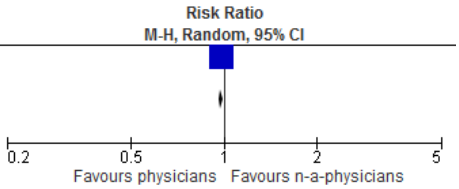
Safety: serious adverse events

Study or Subgroup	n-a-physicians (n=10) Events	Total	physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jeejebhoy 2012 India	0	382	0	389		Not estimable
Total (95% CI)		**382**		**389**		**Not estimable**
Total events	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						



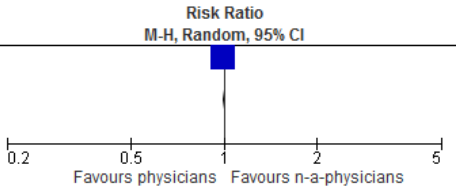
Satisfaction with abortion service

Study or Subgroup	N-a-physicians (n=10) Events	Total	Physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jeejebhoy 2012 India	373	382	388	389	100.0%	0.98 [0.96, 1.00]
Total (95% CI)		**382**		**389**	**100.0%**	**0.98 [0.96, 1.00]**
Total events	373		388			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.55 (P = 0.01)						



Satisfaction with abortion provider

Study or Subgroup	N-a-physicians (n=10) Events	Total	Physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jeejebhoy 2012 India	381	382	389	389	100.0%	1.00 [0.99, 1.00]
Total (95% CI)		**382**		**389**	**100.0%**	**1.00 [0.99, 1.00]**
Total events	381		389			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.72 (P = 0.47)						



GRADE profile MA1: Doctors of complementary systems of medicine

Author(s): Fonhus MS and Fretheim A
Date: 19.09.2014
Question: Should MA1 non-allopathic physicians vs physicians be used in medical abortion provision (< 84 days)?
Settings: India (10 Ayurvedic physicians (461 women) and 10 physicians (456 women))
Bibliography (systematic reviews): Primary studies included: Jejeebhoy 2011 India (non-RCT)

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1 Non-allopathic physicians	allopathic physicians	Relative (95% CI)	Absolute (95% CI)		
Complete abortion												
1	observational study	not serious	not serious	not serious	not serious [1]	none	361/382 (94.5%)	371/389 (95.4%)	RR 0.99 (0.96 to 1.02)	10 fewer per 1000 (from 19 more to 38 fewer)	⊕⊕◯◯ LOW	
Serious adverse events												
1	observational study	not serious	not serious	not serious	not serious [1]	none	0/382 (0.0%)	0/389 (0.0%)	not estimable		⊕⊕◯◯ LOW	
Overall satisfaction with abortion service												
1	observational study	not serious	not serious	not serious	not serious [1]	none	373/382 (97.6%)	388/389 (99.7%)	RR 0.98 (0.96 to 1)	20 fewer per 1000 (from 0 fewer to 40 fewer)	⊕⊕◯◯ LOW	
Overall satisfaction with provider (willing to have future abortions with same provider type)												
1	observational study	not serious	not serious	not serious	not serious [1]	none	381/382 (99.7%)	389/389 (100.0%)	RR 1 (0.99 to 1)	0 fewer per 1000 (from 0 fewer to 10 fewer)	⊕⊕◯◯ LOW	

MD: mean difference; RR: relative risk.
[1] One study only, but not downgraded for this because the outcome is already graded as low

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6c. MA1: Associate clinicians

No direct evidence identified.

Annex 6d. MA1: Midwives

Summary of Findings table (MA1: Midwives)

What happens?	Physicians providing medical abortion	Midwives providing medical abortion	Certainty of the evidence
Effectiveness: Complete abortion There is probably little or no difference in the number of complete abortions when midwives provide medical abortion.	974 per 1000	993 per 1000 (974 to 1003 per 1000)*	⊕⊕⊕◯ Moderate
Safety: Serious adverse events[1] There is probably little or no difference in the number of serious adverse events when midwives provide medical abortion.	0 per 473	0 per 443	⊕⊕⊕◯ Moderate
Overall satisfaction with abortion services No direct evidence identified			
Overall satisfaction with provider[2] More women are probably satisfied with the provider when midwives provide medical abortion.	23 per 1000	375 per 1000 (212 to 662 per 1000)*	⊕⊕⊕◯ Moderate

* 95% confidence interval.

[1] Blood transfusion, hospitalization or death.

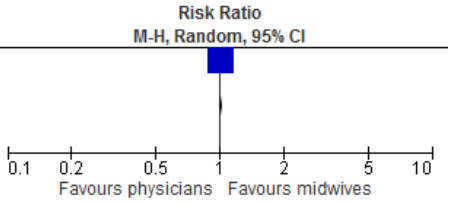
[2] Willing to have future abortions with same provider type.

Forest plots (MA1: Midwives)

Effectiveness: complete abortion

Study or Subgroup	midwives (n=2) Events	Total	physicians (n=34) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Kallner 2014 Sweden	476	481	445	457	100.0%	1.02 [1.00, 1.03]
Total (95% CI)		**481**		**457**	**100.0%**	**1.02 [1.00, 1.03]**
Total events	476		445			

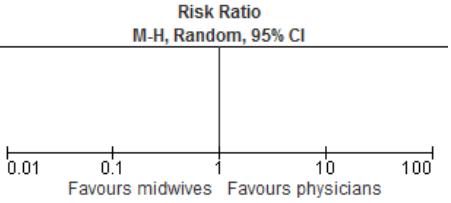
Heterogeneity: Not applicable
Test for overall effect: Z = 1.80 (P = 0.07)



Safety: serious adverse events

Study or Subgroup	midwives (n=2) Events	Total	physicians (n=34) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Kallner 2014 Sweden	0	473	0	443		Not estimable
Total (95% CI)		**473**		**443**		**Not estimable**
Total events	0		0			

Heterogeneity: Not applicable
Test for overall effect: Not applicable



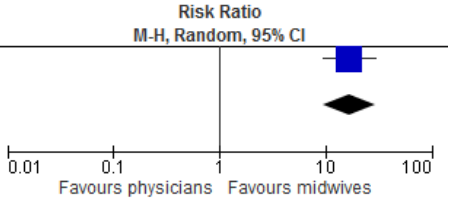
Satisfaction with abortion service

No direct evidence identified

Satisfaction with abortion provider

Study or Subgroup	midwives (n=2) Events	Total	physicians (n=34) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Kallner 2014 Sweden	200	534	12	533	100.0%	16.64 [9.41, 29.42]
Total (95% CI)		**534**		**533**	**100.0%**	**16.64 [9.41, 29.42]**
Total events	200		12			

Heterogeneity: Not applicable
Test for overall effect: Z = 9.67 (P < 0.00001)



GRADE profile (MA1: Midwives)

Author(s): Fonhus MS and Fretheim A
Date: 02.10.2014
Question: Should MA1 Midwives vs physicians be used in medical abortion provision (< 84 days)?
Settings: Sweden (2 nurse midwives (597 women) and 34 physicians (583 women)
Bibliography (systematic reviews): Primary studies included in review: Kallner 2014 Sweden.

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1 Midwives	Physicians	Relative (95% CI)	Absolute (95% CI)		
Complete abortion												
1	randomized trial	not serious	not serious	not serious	serious [1]	none	476/481 (99.0%)	445/457 (97.4%)	RR 1.02 (1 to 1.03)	19 more per 1000 (from 0 fewer to 29 more)	⊕⊕⊕◯ MODERATE	
Serious adverse events												
1	randomized trial	not serious	not serious	not serious	serious [1]	none	0/473 (0.0%)	0/443 (0.0%)	not estimable		⊕⊕⊕◯ MODERATE	
1	randomized trial	not serious	not serious	not serious	serious [1]	none	20/473 (4.2%)	29/443 (6.5%)	RR 0.65 (0.37, 1.12)	23 fewer per 1000 (from 8 more to 41 fewer)	⊕⊕⊕◯ MODERATE	
Overall satisfaction with abortion service												
0												
Overall satisfaction with provider (willing to have future abortions with same provider type)												
1	randomized trial	not serious	not serious	not serious	serious [1]	none	200/534 (37.5%)	12/533 (2.3%)	RR 16.64 (9.41 to 29.42)	352 more per 1000 (from 189 more to 640 more)	⊕⊕⊕◯ MODERATE	

MD: mean difference; RR: relative risk.
[1] One study only

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6e. MA1: Nurses

Summary of Findings table (MA1: Nurses)

What happens?	Physicians providing medical abortion	Nurses providing medical abortion	Certainty of the evidence
Effectiveness: Complete abortion RCTs There is probably little or no difference in the number of complete abortions when nurses provide medical abortion. However, the 95% CI includes differences that may be clinically important.	974 per 1000	945 per 1000 (867 to 1032 per 1000)*	⊕⊕⊕◯ Moderate
Effectiveness: Complete abortion non-RCTs There may be little or no difference in the number of complete abortions when nurses provide medical abortion.	954 per 1000	954 per 1000 (925 to 982 per 1000)*	⊕⊕◯◯ Low
Safety: Serious adverse events[1] There is probably little or no difference in the rate of serious adverse events when nurses provide medical abortion.	0 per 982	1 per 962	⊕⊕⊕◯ Moderate
Safety: Serious adverse events[1] non-RCTs There may be little or no difference in the rate of serious adverse events when nurses provide medical abortion.	0 per 393	0 per 389	⊕⊕◯◯ Low
Overall satisfaction with abortion service (RCTs) There is probably little or no difference in overall satisfaction with the abortion services when nurses provide medical abortion. However, the 95% CI shows both lower and higher satisfaction.	790 per 1000	759 per 1000 (703 to 814 per 1000)*	⊕⊕⊕◯ Moderate
Overall satisfaction with abortion service (non-RCTs) There may be little or no difference in overall satisfaction with the abortion services when nurses provide medical abortion.	997 per 1000	987 per 1000 (977 to 997 per 1000)*	⊕⊕◯◯ Low
Overall satisfaction with provider (felt comfortable with provider) (RCTs) There is probably little or no difference in overall satisfaction with the allocated provider when nurses provide medical abortion.	991 per 1000	991 per 1000 (981 to 1001 per 1000)*	⊕⊕⊕◯ Moderate
Overall satisfaction with abortion provider (willing to have future abortions with same provider type) (non-RCT) There may be little or no difference in overall satisfaction with the allocated provider when nurses provide medical abortion.	997 per 1000	997 per 1000 (987 to 1007 per 1000)*	⊕⊕◯◯ Low

* 95% confidence interval.

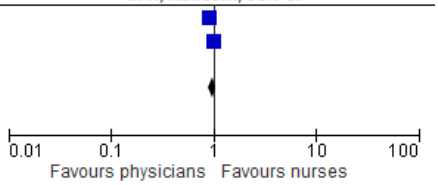
[1] Blood transfusion, hospitalization or death.

Forest plots (MA1: Nurses)

Effectiveness: complete abortion (RCTs)

Study or Subgroup	Nurses (n=18) Events	Total	Physicians (n=22) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Olavarietta 2014 Mexico	425	464	443	448	49.4%	0.93 [0.90, 0.95]
Warriner 2011 Nepal	504	518	494	514	50.6%	1.01 [0.99, 1.04]
Total (95% CI)		**982**		**962**	**100.0%**	**0.97 [0.89, 1.06]**
Total events	929		937			

Heterogeneity: Tau² = 0.00; Chi² = 23.03, df = 1 (P < 0.00001); I² = 96%
Test for overall effect: Z = 0.70 (P = 0.48)

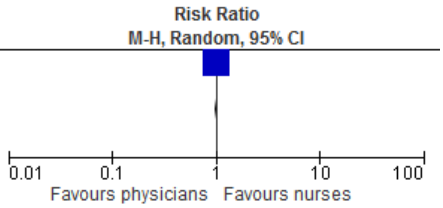


Note that there were 3 auxiliary nurse midwives and 15 nurses in this cadre. Disaggregated outcomes not reported in Warriner 2001.

Effectiveness: complete abortion (non-RCTs)

Study or Subgroup	Nurses (n=10) Events	Total	Physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jeejebhoy 2012 India	375	393	371	389	100.0%	1.00 [0.97, 1.03]
Total (95% CI)		**393**		**389**	**100.0%**	**1.00 [0.97, 1.03]**
Total events	375		371			

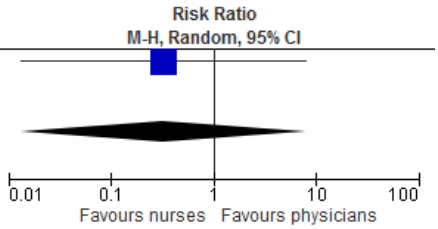
Heterogeneity: Not applicable
Test for overall effect: Z = 0.03 (P = 0.97)



Safety: serious adverse events (RCTs)

Study or Subgroup	nurses (n=18) Events	Total	physicians (n=22) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Olavarietta 2014 Mexico	0	464	1	448	100.0%	0.32 [0.01, 7.88]
Warriner 2011 Nepal	0	518	0	514		Not estimable
Total (95% CI)		**982**		**962**	**100.0%**	**0.32 [0.01, 7.88]**
Total events	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.69 (P = 0.49)

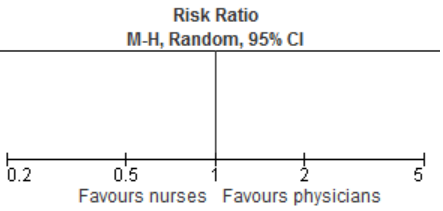


Note that there were 3 auxiliary nurse midwives and 15 nurses in this cadre. Disaggregated outcomes not reported in Warriner 2001.

Safety: serious adverse events (non-RCTs)

Study or Subgroup	nurses (n=10) Events	Total	physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jeejebhoy 2012 India	0	393	0	389		Not estimable
Total (95% CI)		**393**		**389**		**Not estimable**
Total events	0		0			

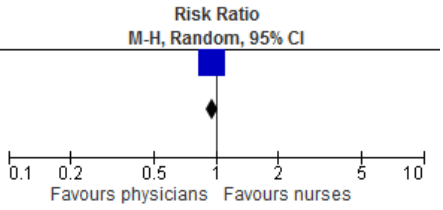
Heterogeneity: Not applicable
Test for overall effect: Not applicable



Satisfaction with abortion service (RCTs)

Study or Subgroup	Nurses (n=7) Events	Total	Physicians (n=8) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Olavarietta 2014 Mexico	340	448	343	434	100.0%	0.96 [0.89, 1.03]
Total (95% CI)		**448**		**434**	**100.0%**	**0.96 [0.89, 1.03]**
Total events	340		343			

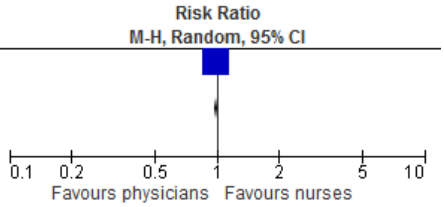
Heterogeneity: Not applicable
Test for overall effect: Z = 1.12 (P = 0.26)



Satisfaction with abortion service (non-RCTs)

Study or Subgroup	Nurses (n=10) Events	Total	Physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jeejebhoy 2012 India	389	393	388	389	100.0%	0.99 [0.98, 1.00]
Total (95% CI)		**393**		**389**	**100.0%**	**0.99 [0.98, 1.00]**
Total events	389		388			

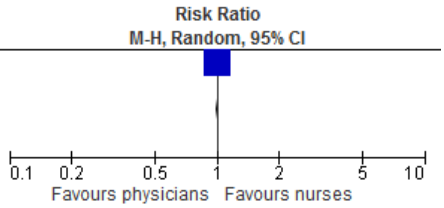
Heterogeneity: Not applicable
Test for overall effect: Z = 1.34 (P = 0.18)



Satisfaction with abortion provider (RCTs)

Study or Subgroup	Nurses (n=7) Events	Total	Physicians (n=8) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Olavarietta 2014 Mexico	444	448	430	434	100.0%	1.00 [0.99, 1.01]
Total (95% CI)		**448**		**434**	**100.0%**	**1.00 [0.99, 1.01]**
Total events	444		430			

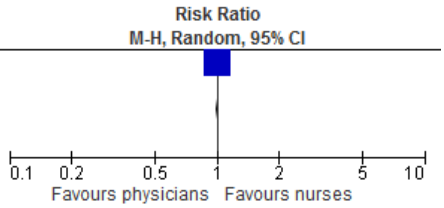
Heterogeneity: Not applicable
Test for overall effect: Z = 0.05 (P = 0.96)



Satisfaction with abortion provider (RCTs)

Study or Subgroup	Nurses (n=10) Events	Total	Physicians (n=10) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jeejebhoy 2012 India	392	393	388	389	100.0%	1.00 [0.99, 1.01]
Total (95% CI)		**393**		**389**	**100.0%**	**1.00 [0.99, 1.01]**
Total events	392		388			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.01 (P = 0.99)



GRADE profile (MA1: Nurses)

Author(s): Fonhus MS and Fretheim A
Date: 19.09.2014
Question: Should MA1 nurses vs physicians be used in medical abortion provision (< 84 days)?
Settings: India (10 nurses (497 women) and 10 physicians (456 women)), Mexico (7 nurses (503 women) and 8 physicians (514 women) and Nepal (8 nurses and 3 auxiliary nurse midwives (ANMs) (552 women) and physicians (6 Ob/Gyn, 3 GPs and 5 doctors (BM or BS degree)) (552 women)
Bibliography (systematic reviews): Primary studies included in review: Jejeebhoy 2011 India (non-RCT), Olavarrieta 2014 Mexico (RCT) and Warriner 2011 Nepal (RCT).

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1 Nurses	Physicians	Relative (95% CI)	Absolute (95% CI)		
Complete abortion (RCTs)												
2	randomized trials	not serious	serious [1]	not serious	not serious	none	929/982 (94.6%)	937/962 (97.4%)	RR 0.97 (0.89 to 1.06)	29 fewer per 1000 (from 58 more to 107 fewer)	⊕⊕⊕◯ MODERATE	
Complete abortion (non-RCT)												
1	observational study	not serious	not serious	not serious	not serious [2]	none	375/393 (95.4%)	371/389 (95.4%)	RR 1 (0.97 to 1.03)	0 fewer per 1000 (from 29 more to 29 fewer)	⊕⊕◯◯ LOW	
Serious adverse events (RCTs)												
2	randomized trials	not serious	not serious	not serious	serious [3]	none	0/982 (0.0%)	1/962 (0.1%)	RR 0.32 (0.01 to 7.88)		⊕⊕⊕◯ MODERATE	
Serious adverse events (non-RCT)												
1	observational study	not serious	not serious	not serious	not serious [2]	none	0/393 (0.0%)	0/389 (0.0%)	not estimable		⊕⊕◯◯ LOW	
Overall satisfaction with abortion service (RCT)												
1	randomized trial	not serious	not serious	not serious	serious [3]	none	340/448 (75.9%)	343/434 (79.0%)	RR 0.96 (0.89 to 1.03)	32 fewer per 1000 (from 24 more to 87 fewer)	⊕⊕⊕◯ MODERATE	
Overall satisfaction with abortion service (non-RCT)												
1	observational study	not serious	not serious	not serious	not serious [2]	none	389/393 (99.0%)	388/389 (99.7%)	RR 1 (0.99 to 1.01)	0 fewer per 1000 (from 10 fewer to 10 more)	⊕⊕◯◯ LOW	
Overall satisfaction with provider (RCT) (felt comfortable with allocated provider)												
1	randomized trial	not serious	not serious	not serious	serious [3]	none	444/448 (99.1%)	430/434 (99.1%)	RR 1 (0.99 to 1.01)	0 fewer per 1000 (from 10 fewer to 10 more)	⊕⊕⊕◯ MODERATE	
Overall satisfaction with abortion provider (non-RCT) (willing to have future abortions with same provider type)												
1	observational study	not serious	not serious	not serious	not serious [2]	none	392/393 (99.7%)	388/389 (99.7%)	RR 1 (0.99 to 1.01)	0 fewer per 1000 (from 10 fewer to 10 more)	⊕⊕◯◯ LOW	

MD: mean difference; RR: relative risk.
[1] Very high heterogeneity
[2] One study only, but not downgraded for this because the outcome is already graded as low
[3] One study only

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6f. MA1: Auxiliary nurses/auxiliary nurse midwives

Summary of Findings table (MA1: Auxiliary nurses/auxiliary nurse midwives)

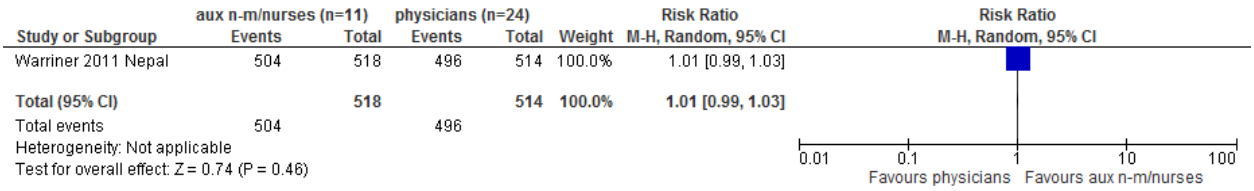
What happens?	Physicians providing medical abortion	Auxiliary nurse midwives/nurses providing medical abortion	Certainty of the evidence
Effectiveness: Complete abortion There is probably little or no difference in the number of complete abortions when auxiliary nurses/midwives provide medical abortion.	965 per 1000	975 per 1000 (955 to 994 per 1000)*	⊕⊕⊕◯ Moderate
Safety: Serious adverse events[1] There is probably little or no difference in the rates of serious adverse events when auxiliary nurses/midwives provide medical abortion.	0 per 518	0 per 514	⊕⊕⊕◯ Moderate
Overall satisfaction with abortion services No direct evidence identified			
Overall satisfaction with provider No direct evidence identified			

* 95% confidence interval.

[1] Blood transfusion, hospitalization or death.

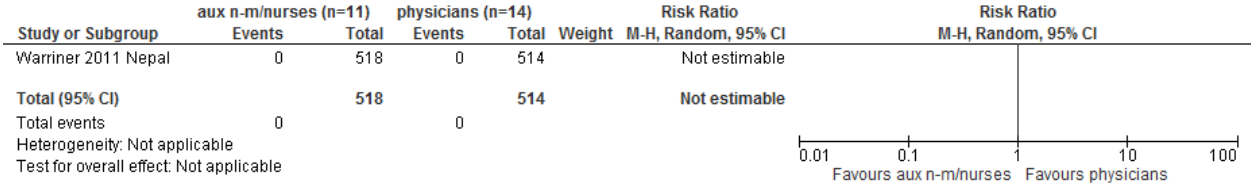
Forest plots (MA1: Auxiliary nurses/auxiliary nurse midwives)

Effectiveness: complete abortion



Note that there were 3 auxiliary nurse midwives and 8 nurses in this cadre. Disaggregated outcomes not reported.

Safety: serious adverse events



Note that there were 3 auxiliary nurse midwives and 8 nurses in this cadre. Disaggregated outcomes not reported.

Satisfaction with abortion service

No direct evidence identified.

Satisfaction with abortion provider

No direct evidence identified.

GRADE Profile (MA1: Auxiliary nurses/auxiliary nurse midwives)

Author(s): Fonhus MS and Fretheim A
Date: 19.09.2014
Question: Should MA1 auxiliary nurse midwives vs physicians be used in medical abortion provision (< 84 days)?
Settings: Nepal (mid-level providers: nurses (n=8) and aux. nurse midwives (n=3) ((552 women). Physicians. (Ob/Gyn (n=6), GPs (n=3), doctors (Bachelor of Medicine or Bachelor of Surgery degree (552 women))
Bibliography (systematic reviews): Primary studies included in review: Warriner 2011 Nepal.

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1 auxiliary nurse midwives	Physicians	Relative (95% CI)	Absolute (95% CI)		
Complete abortion												
1	randomized trial	not serious	not serious	not serious	serious [1]	none	504/518 (97.3%)	496/514 (96.5%)	RR 1.01 (0.99 to 1.03)	10 more per 1000 (from 10 fewer to 29 more)	⊕⊕⊕◯ MODERATE	
Serious adverse events												
1	randomized trial	not serious	not serious	not serious	serious [1]	none	0/518 (0.0%)	0/514 (0.0%)	not estimable		⊕⊕⊕◯ MODERATE	
Overall satisfaction with abortion service												
0												
Overall satisfaction with provider												
0												

MD: mean difference; RR: relative risk.
[1] One study only

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6g. MA1: Pharmacists

No direct evidence identified.

Annex 6h. MA1: Pharmacy workers

No direct evidence identified.

Annex 6i. MA1: Lay health workers

No direct evidence identified.

Annex 6.1: MA1.1

(Assessment of eligibility for medical abortion)

Annex 6.1b MA1.1: Doctors of complementary systems of medicine

Summary of Findings table MA1.1: Doctors of complementary systems of medicine

What happens?	Physicians assessing eligibility	Non-allopathic physicians assessing eligibility	Certainty of the evidence
Eligibility assessment No direct evidence identified			
Accuracy of eligibility assessment There may be little or no difference in accuracy of eligibility assessment when non-allopathic physicians assess eligibility for medical abortion.	961 per 1000	970 per 1000 (941 to 989 per 1000)*	⨁⨁◯◯ Low
Accuracy of ectopic pregnancy assessment No direct evidence identified			

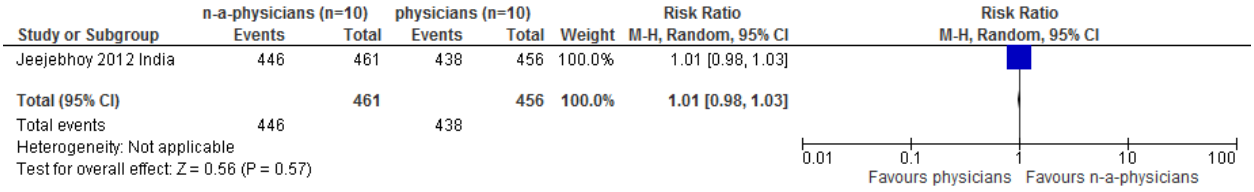
* 95% confidence interval.

Forest plots MA1.1: Doctors of complementary systems of medicine

Eligibility: assessment of eligibility

No direct evidence identified.

Eligibility: accuracy of eligibility assessment (providers assessment same as verifier)



Eligibility: accuracy of ectopic pregnancy assessment

No direct evidence identified.

GRADE MA1.1: Doctors of complementary systems of medicine

Author(s): Fonhus MS and Fretheim A
Date:02.10.2014
Question: Should MA1.1 non-allopathic physicians vs physicians assess eligibility for medical abortion (< 84 days)?
Settings: India (10 Ayurvedic physicians (461 women) and 10 physicians (456 women))
Bibliography (systematic reviews): Primary studies: Jejeebhoy 2011 India (non-RCT)

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1 non-allopathic physicians	Allopathic physicians	Relative (95% CI)	Absolute (95% CI)		
Eligibility assessment for medical abortion												
0												
Accuracy of eligibility assessment for medical abortion (provider's assessment the same as verifier's)												
1	observational study	not serious	not serious	not serious	not serious [1]	none	446/461 (96.7%)	438/456 (96.1%)	RR 1.01 (0.98 to 1.03)	10 more per 1000 (from 19 fewer to 29 more)	⊕⊕◯◯ LOW	
Accuracy of ectopic pregnancy assessment for medical abortion												
0												

MD: mean difference; RR: relative risk.
[1] One study only, but not downgraded for this because the outcome is already graded as low

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6.1c MA1.1: Associate physicians

No direct evidence identified.

Annex 6.1d MA1.1: Midwives

No direct evidence identified.

Annex 6.1e MA1.1: Nurses

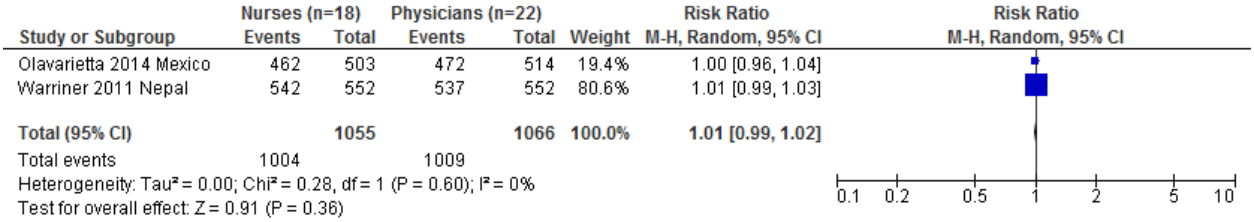
Summary of Findings table (MA1.1: Nurses)

What happens?	Physicians assessing eligibility	Nurses assessing eligibility	Certainty of the evidence
Eligibility assessment There is little or no difference in the number of women assessed as being eligible when nurses assess eligibility for medical abortion.	947 per 1000	956 per 1000 (937 to 965 per 1000)*	⨁⨁⨁⨁ High
Accuracy of eligibility assessment (provider's assessment the same as verifier's) There may be little or no difference in accuracy of eligibility assessment when nurses assess eligibility for medical abortion.	961 per 1000	961 per 1000 (932 to 989 per 1000)*	⨁⨁◯◯ Low
Accuracy of ectopic pregnancy assessment No direct evidence identified			

* 95% confidence interval.

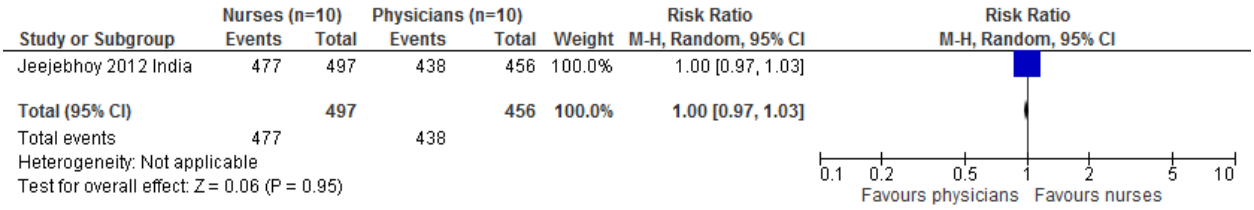
Forest plot (MA1.1: Nurses)

Eligibility: assessment of eligibility



Note that there were 3 auxiliary nurse midwives and 15 nurses in this cadre. Disaggregated outcomes not reported in Warriner 2011

Eligibility: accuracy of eligibility assessment



Eligibility: accuracy of ectopic pregnancy assessment

No direct evidence identified.

GRADE (MA1.1: Nurses)

Author(s): Fonhus MS and Fretheim A
Date: 19.09.2014
Question: Should MA1.1 nurses vs physicians be used in medical abortion provision (< 84 days)?
Settings: India (10 nurses (497 women) and 10 physicians (456 women)), Mexico (7 nurses (503 women) and 8 physicians (514 women)) and Nepal (8 nurses and 3 ANMs (552 women) and physicians (6 Ob/Gyn, 3 GPs and 5 doctors (BM or BS degree)) (552 women))
Bibliography (systematic reviews): Primary studies included in review: Jejeebhoy 2011 India (non-RCT) Olavarrieta 2014 Mexico (RCT) and Warriner 2011 Nepal (RCT)

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1 nurses	Physicians	Relative (95% CI)	Absolute (95% CI)		
Eligibility assessment for medical abortion												
2	randomized trials	not serious	not serious	not serious	not serious	none	1004/1055 (95.2%)	1009/1066 (94.7%)	RR 1.01 (0.99 to 1.02)	9 more per 1000 (from 9 fewer to 19 more)	⊕⊕⊕⊕ HIGH	
Accuracy of eligibility assessment for medical abortion (provider's assessment the same as verifier's)												
1	observational study	not serious	not serious	not serious	not serious[1]	none	477/497 (96.0%)	438/456 (96.1%)	RR 1 (0.97 to 1.03)	0 fewer per 1000 (from 29 more to 29 fewer)	⊕⊕◯◯ LOW	
Accuracy of ectopic pregnancy assessment for medical abortion												
0												

MD: mean difference; RR: relative risk
[1] One study only, but not downgraded for this because the outcome is already graded as low

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6.1f MA1.1: Auxiliary nurses/auxiliary nurse midwives

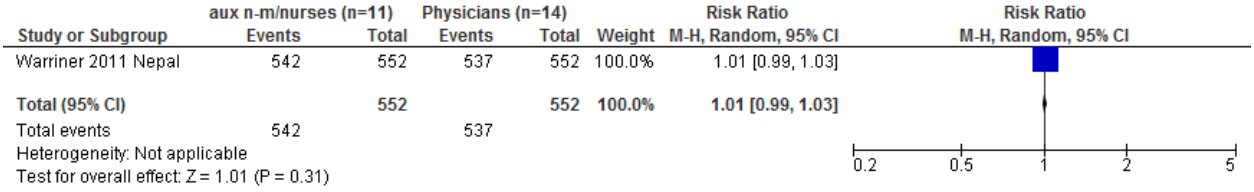
Summary of Findings table (MA1.1: Auxiliary nurses/auxiliary nurse midwives)

What happens?	Physicians assessing eligibility	Auxiliary nurse midwives/nurses assessing eligibility	Certainty of the evidence
Eligibility assessment There is probably little or no difference in the number of women assessed as being eligible when auxiliary nurse midwives/nurses assess eligibility for medical abortion.	973 per 1000	983 per 1000 (963 to 1002 per 1000)*	⊕⊕⊕◯ Moderate
Accuracy of eligibility assessment No direct evidence identified			
Accuracy of ectopic pregnancy assessment No direct evidence identified			

* 95% confidence interval.

Forest plots (MA1.1: Auxiliary nurses/auxiliary nurse midwives)

Eligibility: assessment of eligibility



Note that there were 3 auxiliary nurse midwives and 8 nurses in this cadre. Disaggregated outcomes not reported

Eligibility: accuracy of eligibility assessment

No direct evidence identified.

Eligibility: accuracy of ectopic pregnancy assessment

No direct evidence identified.

GRADE (MA1.1: Auxiliary nurses/auxiliary nurse midwives)

Author(s): Fonhus MS and Fretheim A
Date: 19.09.2014
Question: Should MA1.1 auxiliary nurse midwives vs physicians assess eligibility for medical abortion (< 84 days)?
Settings: Nepal (Mid-level providers: nurses (n=8) and aux. nurse midwives (n=3) (552 women). Physicians (Ob/Gyn (n=6), GPs (n=3), doctors (Bachelor of Medicine or Bachelor of Surgery degree (552 women))
Bibliography (systematic reviews): Primary studies included in review: Warriner 2011 Nepal

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1 auxiliary nurse midwives	Physicians	Relative (95% CI)	Absolute (95% CI)		
Eligibility assessment for medical abortion												
1	randomized trial	not serious	not serious	not serious	serious [1]	none	542/552 (98.2%)	537/552 (97.3%)	RR 1.01 (0.99 to 1.03)	10 more per 1000 (from 10 fewer to 29 more)	⨁⨁⨁◯ MODERATE	
Accuracy of eligibility assessment for medical abortion												
0												
Accuracy of ectopic pregnancy assessment for medical abortion												
0												

MD: mean difference; RR: relative risk.
[1] One study only

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6.1.g MA1.1: Pharmacists or pharmacy workers

No direct evidence identified.

Annex 6.1.h MA1.1: Pharmacy workers

No direct evidence identified.

Annex 6.1.i MA1.1: Lay health workers

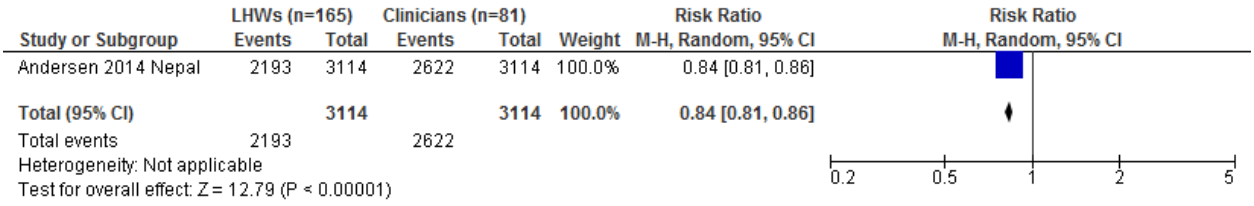
Summary of Findings table (MA1.1: Lay health workers)

What happens?	Physicians assessing eligibility	Lay health workers assessing eligibility	Certainty of the evidence
Eligibility assessment There may be fever women assessed 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.			
Accuracy of ectopic pregnancy assessment No direct evidence identified			

* 95% confidence interval.

Forest plots (MA1.1: Lay health workers)

Eligibility: assessment of eligibility



Note that there was a mix of both nurses and physicians in the clinician cadre. Disaggregated outcomes not reported.

Eligibility: accuracy of eligibility assessment

Andersen 2014:

	Provider Assessment			
	Eligible		Ineligible	
FCHV's Assessment	n	(%)	n	(%)
Eligible	2021	(65)	170	(6)
Ineligible	601	(19)	322	(10)
Total	**2622**	**(84)**	**492**	**(16)**

Note that there was a mix of both nurses and physicians in the clinician cadre. Disaggregated outcomes not reported.

Johnston 2014:

	Clinician tool validity (Clinician use of checklist tool vs clinician physical exam)						CHW tool validity (CHW use of checklist tool vs clinician physical exam)					
	India		Ethiopia		South Africa		India		Ethiopia		South Africa	
Diagnostics Test statistic	n_{CT}/N_{CE}		n_{CT}/N_{CE}		n_{CT}/N_{CE}		n_{CHW}/N_{CE}		n_{CHW}/N_{CE}		n_{CHW}/N_{CE}	
Accuracy (% of all cases correctly identified)	240/249	96.4%	189/201	93.6%	204/226	90.3%	199/250	79.6%	179/195	91.8%	173/225	76.9%
Sensitivity (95% CI)	197/197	100.0 (98.1, 100.0)	158/162	97.5 (93.8, 99.3)	140/151	92.7 (87.3, 96.3)	168/196	85.7 (80.0, 90.3)	147/157	93.6 (88.6, 96.9)	128/146	87.7 (81.2, 92.5)
Specificity (95% CI)	43/52	82.7 (69.7, 91.8)	31/40	77.5** (61.6, 89.2)	64/75	85.3 (75.3, 92.4)	31/54	57.4 (43.2, 70.8)	32/38	84.2** (68.8, 94.0)	45/79	57.0 (45.3, 68.1)
Predictive Value (+)	197/206	95.6 (91.9, 98.0)	158/167	94.6 (90.2, 97.5)	140/151	92.7 (87.3, 96.3)	168/191	88.0 (82.5, 92.2)	147/153	96.1 (91.7, 98.6)	128/162	79.0 (71.9, 85.0)
Predictive Value (-)	43/43	100.0 (91.8, 100.0)	31/35	88.6** (73.3, 96.8)	64/75	85.3 (75.3, 92.4)	31/59	52.5 (39.1, 65.7)	32/42	76.2** (60.6, 88.0)	45/63	71.4 (58.7, 82.1)
Likelihood ratio (+)	-	5.8	-	4.3	-	6.3	-	2.0	-	5.9	-	2.0
Likelihood ratio (-)	-	0.0	-	0.03	-	0.09	-	0.25	-	0.08	-	0.22

** Statistic underestimated due to missing reference standard observations
n_{CT} = cases identified by clinician using checklist, N_{CE} = cases identified by clinician physical exam (reference standard)
n_{CHW} = cases identified by CHW using checklist, N_{CT} = cases identified by clinician using checklist (non-reference standard)
n_{CHW} = cases identified by CHW using checklist, N_{CE} = cases identified by clinician physical exam (reference standard)

Note that there was a mix of both nurses (n=18 nurses/health officers) and physicians (n=7 Ob/Gyn) in the clinician cadre from this study.

Eligibility: accuracy of eligibility assessment

No direct evidence identified.

GRADE (MA1.1: Lay health workers)

Author(s): Fonhus MS and Fretheim A
Date: 01.10.2014
Question: Should MA1.1 lay health workers vs clinicians be used in assessing eligibility for medical abortions (< 84 days)?
Settings: Nepal (165 female community health volunteers and 81 comprehensive abortion care (CAC) providers (mix of physicians and nurses) assessing the same women (3131 women enrolled in study)) Ethiopia (n=9 health extension workers vs nurses n=6, 217 women assessed) India (ASHA n=7 village health workers n=5 vs Ob/Gyn n=7, 258 women assessed) South Africa (community-based educators n=7 vs nurses n=8, 236 women assessed)
Bibliography (systematic reviews): Primary studies included: Andersen 2014 Nepal and Johnston 2014 Ethiopia, India and South Africa

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1.1 lay health workers	Clinicians	Relative (95% CI)	Absolute (95% CI)		
Eligibility assessment for medical abortion												
1	observational study	not serious	not serious	not serious	not serious [1]	none	2193/3114 (70.4%)	2622/3114 (84.2%)	RR 0.484 (0.81 to 0.86)	138 fewer per 1000 (from 111 fewer to 167 fewer)	⊕⊕◯◯ LOW	
Accuracy of eligibility assessment for medical abortion												
2										not estimable		
Accuracy of ectopic pregnancy assessment												

MD: mean difference; RR: relative risk.
[1] One study only, but not downgraded for this because the outcome is already graded as low
High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6.2: MA1.2

(Administration of medication for medical abortion and instructions for use)

Annex 6.2b MA1.2: Doctors of complementary systems of medicine

No direct evidence identified.

Annex 6.2c MA1.2: Associate clinicians

No direct evidence identified.

Annex 6.2d MA1.2: Midwives

No direct evidence identified.

Annex 6.2e MA1.2: Nurses

Summary of Findings table (MA1.2: Nurses)

What happens?	Physicians informing/instructing use	Nurses informing/ instructing use	Certainty of the evidence
Effectiveness: Appropriate administration of medication for medical abortion (adherence to protocol for medication administration) There is little or no difference in the rate of appropriate medication administration when nurses inform or instruct use.	965 per 1000	965 per 1000 (946 to 985 per 1000)*	⊕⊕⊕⊕ High

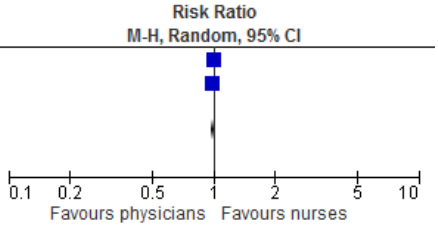
* 95% confidence interval.

Forest plots (MA1.2: Nurses)

Effectiveness: Appropriate administration of medication for medical abortion

Study or Subgroup	Nurses (n=18) Events	Total	Physicians (n=22) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Olavarietta 2014 Mexico	422	434	433	448	51.9%	1.01 [0.98, 1.03]
Warriner 2011 Nepal	518	542	516	535	48.1%	0.99 [0.97, 1.02]
Total (95% CI)		**976**		**983**	**100.0%**	**1.00 [0.98, 1.02]**
Total events	940		949			

Heterogeneity: Tau² = 0.00; Chi² = 0.79, df = 1 (P = 0.38); I² = 0%
Test for overall effect: Z = 0.15 (P = 0.88)



Note that there were 3 auxiliary nurse midwives and 15 nurses in this cadre. Disaggregated outcomes not reported in Warriner 2011.

GRADE (MA1.2: Nurses)

Author(s): Fonhus MS and Fretheim A
Date: 19.09.2014
Question: Should MA1.2 nurses vs physicians provide administration of medication for medical abortion provision (< 84 days)?
Settings: Mexico (7 nurses (503 women) and 8 physicians (514 women)) and Nepal (8 nurses and 3 ANMs (552 women) and physicians (6 Ob/Gyn, 3 GPs and 5 doctors (BM or BS degree)) (552 women))
Bibliography (systematic reviews): Primary studies included in review: Olavarrieta 2014 Mexico (RCT) and Warriner 2011 Nepal (RCT).

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1.2 Nurses	Physicians	Relative (95% CI)	Absolute (95% CI)		
Appropriate administration of medication for medical abortion (adherence to protocol for medication administration)												
2	randomized trials	not serious	not serious	not serious	not serious	none	940/976 (96.3%)	949/983 (96.5%)	RR 1 (0.98 to 1.02)	2 fewer per 1000 (from 19 more to 19 fewer)	⊕⊕⊕⊕ HIGH	

MD: mean difference; RR: relative risk.

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6.2f MA1.2: Auxiliary nurses/auxiliary nurse midwives

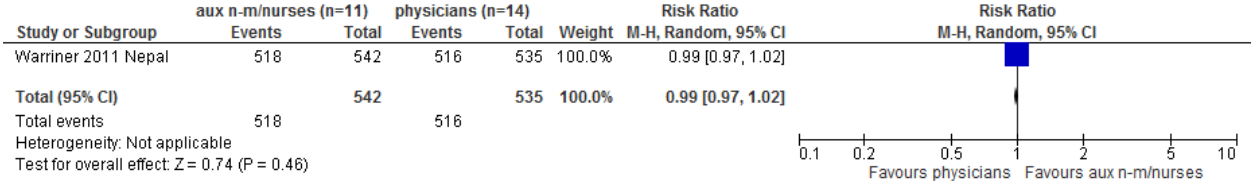
Summary of Findings table (MA1.2: Auxiliary nurses/auxiliary nurse midwives)

What happens?	Physicians informing/ instructing use	Auxiliary nurse midwives/nurses informing/ instructing use	Certainty of the evidence
Effectiveness: Appropriate administration of medication for medical abortion (adherence to protocol for medication administration) There is probably little or no difference in the rate of appropriate medication administration when auxiliary nurse midwives/nurses inform or instruct use.	964 per 1000	955 per 1000 (936 to 984 per 1000)*	⊕⊕⊕◯ Moderate

* 95% confidence interval.

Forest plots (MA1.2: Auxiliary nurses/auxiliary nurse midwives)

Effectiveness: Appropriate administration of medication for medical abortion



Note that there were 3 auxiliary nurse midwives and 8 nurses in this cadre. Disaggregated outcomes not reported.

GRADE (MA1.2: Auxiliary nurses/auxiliary nurse midwives)

Author(s): Fonhus MS and Fretheim A
Date: 19.09.2014
Question: Should MA1.2 ANMs/nurses vs physicians provide administration of medication for medical abortion provision (< 84 days)?
Settings: Nepal (8 nurses and 3 ANMs (552 women) and physicians (6 Ob/Gyn, 3 GPs and 5 doctors (BM or BS degree)) (552 women)
Bibliography (systematic reviews): Primary studies included in review: Warriner 2011 Nepal (RCT).

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1.2 Auxiliary nurse midwives /nurses	Physicians	Relative (95% CI)	Absolute (95% CI)		
Appropriate administration of medication for medical abortion (adherence to protocol for medication administration)												
1	randomized trial	not serious	not serious	not serious	serious [1]	none	518/542 (95.6%)	516/535 (96.4%)	RR 0.99 (0.97 to 1.02)	10 fewer per 1000 (from 19 more to 29 fewer)	⊕⊕⊕◯ MODERATE	

MD: mean difference; RR: relative risk
[1] One study only
High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6.2g MA1.2: Pharmacists or pharmacy workers

No direct evidence identified.

Annex 6.2h MA1.2: Pharmacy workers

No direct evidence identified.

Annex 6.3: MA1.3
(Management of common side-effects of medical abortion)

Annex 6.3b MA1.3: Doctors of complementary systems of medicine
No direct evidence identified.

Annex 6.3c MA1.3: Associate clinicians
No direct evidence identified.

Annex 6.3d MA1.3: Midwives
No direct evidence identified.

Annex 6.3e MA1.3: Nurses
No direct evidence identified.

Annex 6.3f MA1.3: Auxiliary nurses/auxiliary nurse midwives
No direct evidence identified.

Annex 6.3g MA1.3: Pharmacists
No direct evidence identified.

Annex 6.3h MA1.3: Pharmacy workers
No direct evidence identified.

Annex 6.3i MA1.3: Lay health workers
No direct evidence identified.

Annex 6.4: MA1.4

(Assessment of completion of medical abortion)

Annex 6.4b MA1.4: Doctors of complementary systems of medicine

Summary of Findings table MA1.4: Doctors of complementary systems of medicine

What happens?	Physicians assessing completion of medical abortion	Non-allopathic physicians assessing completion of medical abortion	Certainty of the evidence
Effectiveness: Assessment of abortion completion No direct evidence identified			
Effectiveness: Accuracy of medical abortion completion assessment There may be little or no difference in accuracy of assessment of abortion completion when non-allopathic physicians assess medical abortion completion.	956 per 1000	964 per 1000 (930 to 981 per 1000)*	⨁⨁◯◯ Low

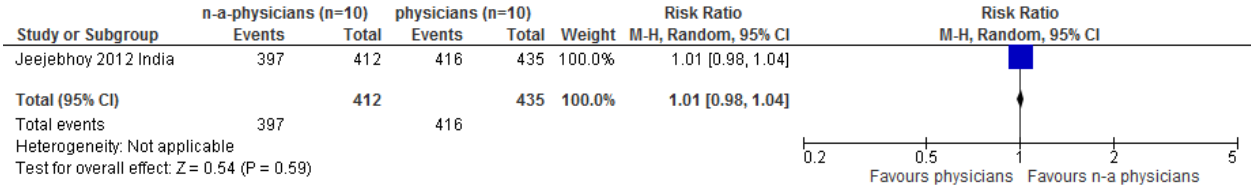
* 95% confidence interval.

Forest plots MA1.4: Doctors of complementary systems of medicine

Effectiveness: complete abortion assessment

No direct evidence identified.

Effectiveness: accurate assessment of abortion completion



GRADE MA1.4: Doctors of complementary systems of medicine

Author(s): Fonhus MS and Fretheim A
Date: 02.10.2014
Question: Should MA1.4 non-allopathic physicians vs physicians be used in assessment of medical abortion completion (< 84 days)?
Settings: India (10 Ayurvedic physicians (461 women) and 10 physicians (456 women))
Bibliography (systematic reviews): Primary studies: Jejeebhoy 2011 India (non-RCT)

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1.4 Non-allopathic physicians	Allopathic physicians	Relative (95% CI)	Absolute (95% CI)		
Effectiveness: assessment of abortion completion												
0												
Effectiveness: accuracy of abortion completion assessment												
1	observational study	not serious	not serious	not serious	not serious [1]	none	397/412 (96.4%)	416/435 (95.6%)	RR 1.01 (0.98 to 1.04)	10 more per 1000 (from 38 more to 19 fewer)	⊕⊕◯◯ LOW	

MD: mean difference; RR: relative risk.
[1] One study only, but not downgraded for this because the outcome is already graded as low

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6.4c MA1.4: Associate clinicians

No direct evidence identified.

Annex 6.4d MA1.4: Midwives

No direct evidence identified.

Annex 6.4e MA1.4: Nurses

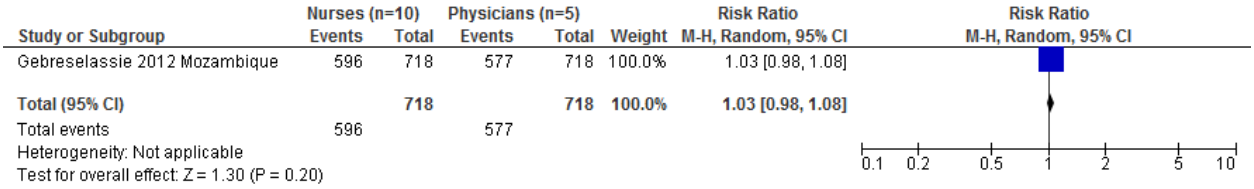
Summary of Findings table (MA1.4: Nurses)

What happens?	Physicians assessing completion of medical abortion	Nurses assessing completion of medical abortion	Certainty of the evidence
Effectiveness: Completion abortion assessment 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: Accuracy of medical abortion completion assessment (provider's assessment the same as verifier's) There may be little or no difference in the accuracy of medical abortion completion assessment when nurses assess completion of medical abortion.	956 per 1000	947 per 1000 (918 to 975 per 1000)	• ⨁⨁◯◯ Low

* 95% confidence interval.

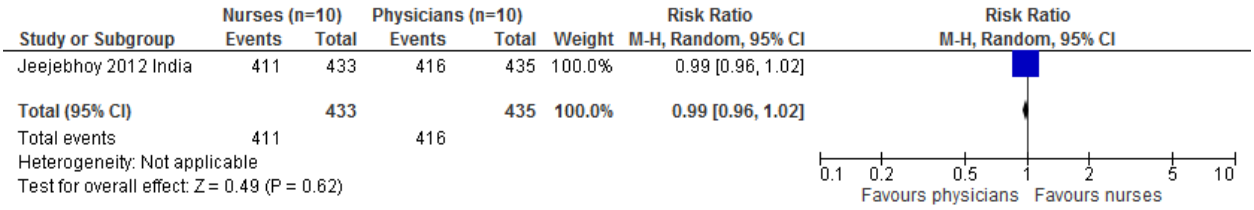
Forest plot (MA1.4: Nurses)

Effectiveness: complete abortion assessment



Note that they assessed the same group of women (n=718)

Effectiveness: accuracy of complete abortion assessment



Gebreselassie 2012 Mozambique:

Provider type	Diagnosis	Gynecologists' diagnosis[a]			
		CA[b]	IA	OP	Total *n* (%)
Nurses' diagnosis[c]	CA	533	59	4	596 (83)
	IA	41	60	6	107 (15)
	OP	3	0	12	15 (2)
	Total *n* (%)	577 (80)	119 (17)	22 (3)	718 (100)

[a] Gynecologists' diagnosis based on clinical examination and ultrasound findings.

[b] Diagnosis: CA, complete abortion; IA, incomplete abortion; OP, ongoing pregnancy.

[c] Nurses' diagnosis based on history and clinical examination.

Note that they assessed the same group of women (n=718)

GRADE (MA1.4: Nurses)

Author(s): Fonhus MS and Fretheim A
Date: 07.10.2014
Question: Should MA1.4 Nurses vs physicians be used in assessment of medical abortion completion (< 84 days)?
Settings: India (10 nurses (461 women) and 10 physicians (456 women) and Mozambique (10 nurses (577 women) and 5 gynaecologists assessing the same women (as verifiers)
Bibliography (systematic reviews): Primary studies: Jejeebhoy 2011 India (non-RCT) and Gebreselassie 2012 Mozambique

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1.4 Nurses	Physicians	Relative (95% CI)	Absolute (95% CI)		
Complete abortion assessment												
1	observational study	serious [1]	not serious	not serious	not serious [2, 3]	none	596/718 (83.0%)	577/718 (80.4%)	RR 1.03 (0.98 to 1.08)	24 more per 1000 (from 16 fewer to 64 more)	⊕◯◯◯ VERY LOW	
Accuracy of complete abortion assessment												
1	observational study	not serious	not serious	not serious	not serious [3]	none	944/1010 (93.5%)	416/435 (95.6%)	RR 0.99 (0.96 to 1.02)	10 fewer per 1000 (from 19 more to 38 fewer)	⊕⊕◯◯ LOW	

MD: mean difference; RR: relative risk.
[1] High risk of bias in included study
[2] Same group of women assessed
[3] One study only, but not downgraded for this because the outcome is already graded as low

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 6.4f MA1.4: Auxiliary nurses/auxiliary nurse midwives

No direct evidence identified.

Annex 6.4g MA1.4: Pharmacists

No direct evidence identified.

Annex 6.4h MA1.4: Pharmacy workers

No direct evidence identified.

Annex 6.4i MA1.4: Lay health workers

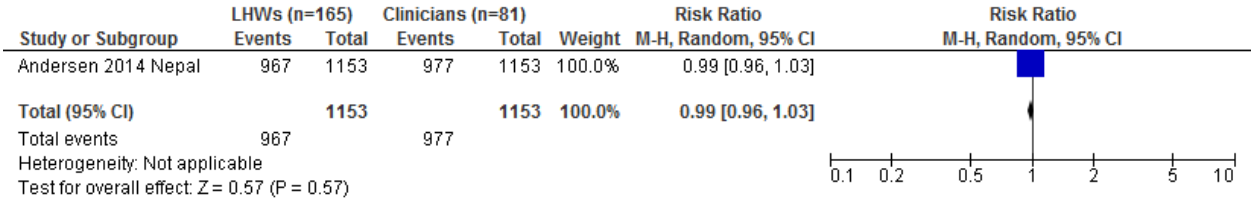
Summary of Findings table (MA1.4: Lay health workers)

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.

Forest plots (MA1.4: Lay health workers)

Effectiveness: complete abortion assessment



Note that there was a mix of both nurses and physicians in the clinician cadre. Disaggregated outcomes not reported.

Effectiveness: accuracy of abortion completion assessment

Andersen 2014:

Clinicians Assessment

	Successful MA		Need for Care	
FCHV's Assessment	n	(%)	n	(%)
Successful MA	868	(75)	99	(9)
Need for Care	109	(9)	77	(7)
Total	**977**	**(84)**	**176**	**(16)**

Note that there was a mix of both nurses and physicians in the clinician cadre. Disaggregated outcomes not reported.

Johnston 2014:

	4a. Checklist Tool validity (Clinician Checklist Tool vs Clinician Exam)						4b. CHW validity (CHW Checklist tool vs Clinician Exam)					
	India		Ethiopia		South Africa		India		Ethiopia		South Africa	
Diagnostics Test statistic	n_{CT}/N_{CE}		n_{CT}/N_{CE}		n_{CT}/N_{CE}		n_{CHW}/N_{CE}		n_{CHW}/N_{CE}		n_{CHW}/N_{CE}	
Accuracy (% of all cases correctly identified)	145/156	92.9%	148/156	94.9%	63/67	94.0%	134/156	85.9%	138/156	88.5%	55/67	82.1%
Sensitivity (95% CI)	15/24	62.5 (40.6, 81.2)	8/12	66.7 (34.9, 90.1)	11/14	78.6 (49.2, 95.3)	10/24	41.7 (22.1, 63.4)	7/12	58.3 (27.7, 84.8)	4/14	28.6 (0.08, 58.1)
Specificity (95% CI)	130/132	98.5 (94.6, 99.8)	140/144	97.2 (93.0, 99.2)	52/53	98.1 (89.9, 100.0)	124/132	93.9 (88.4, 97.4)	131/144	91.0 (85.1, 95.1)	51/53	96.2 (87.0, 99.5)
Predictive Value (+)	15/17	88.2 (63.6, 98.5)	8/12	66.7 (34.9, 90.1)	11/12	91.7 (61.5, 99.8)	10/18	55.6 (30.8, 78.5)	7/20	65.0 (40.8, 84.6)	4/6	66.7 (22.3, 95.7)
Predictive Value (-)	130/139	93.5 (88.1, 97.0)	140/144	97.2 (93.0, 99.2)	52/55	94.6 (84.9, 98.9)	124/138	89.9 (83.6, 94.3)	131/136	96.3 (91.6, 98.8)	51/61	83.6 (71.9, 91.9)
Likelihood ratio (+)	-	41.7	-	23.8	-	41.4	-	6.8	-	6.5	-	7.5
Likelihood ratio (-)	-	0.38	-	0.34	-	0.22	-	0.62	-	0.46	-	0.74

n_{CT} = cases identified by clinician tool, N_{CE} = cases identified by clinician physical exam (reference/gold standard)
n_{CHW} = cases identified by CHW tool, N_{CT} = cases identified by clinician tool (non-reference standard)
n_{CHW} = cases identified by CHW tool, N_{CE} = cases identified by clinician physical exam (reference/gold standard)
Note that there was a mix of both nurses (n=18 nurses/health officers) and physicians (n=7 Ob/Gyn) in the clinician cadre

GRADE (MA1.4: Lay health workers)

Author(s): Fonhus MS and Fretheim A
Date: 01.10.2014
Question: Should MA1.4 lay health workers vs clinicians be used in abortion completion assessment for medical abortion (< 84 days)?
Settings: Nepal (165 female community health volunteers and 81 comprehensive abortion care (CAC) providers (mix of physicians and nurses) assessing the same women (3131 women enrolled in study)) Ethiopia (n=9 health extension workers vs nurses n=6, 217 women assessed) India (ASHA n=7 village health workers n=5 vs Ob/Gyn n=7, 258 women assessed) South Africa (community-based educators n=7 vs nurses n=8, 236 women assessed)
Bibliography (systematic reviews): Primary studies included: Andersen 2014 Nepal and Johnston 2014 Ethiopia, India and South Africa

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA1.4 Lay health workers	Clinicians	Relative (95% CI)	Absolute (95% CI)		
Complete abortion assessment												
1	observational study	not serious	not serious	not serious	not serious [1]	none	967/1153 (83.9%)	977/1153 (84.7%)	RR 0.99 (0.96 to 1.03)	8 fewer per 1000 (from 25 more to 34 fewer)	⊕⊕◯◯ LOW	
Accuracy of abortion completion assessment												
2	observational studies								Not estimable			

MD: mean difference; RR: relative risk.
[1] One study only, but not downgraded for this because the outcome is already graded as low
High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 7: MA2

(Provision of misoprostol for incomplete abortion)

Annex 7b MA2: Doctors of complementary systems of medicine

No direct evidence identified.

Annex 7c MA2: Associate clinicians

No direct evidence identified.

Annex 7d MA2: Midwives

Summary of Findings table (MA2: Midwives)

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

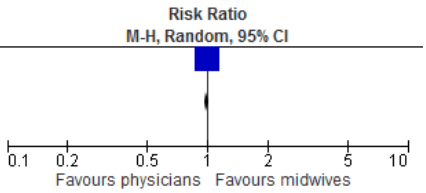
* 95% confidence interval.

[1]Hospitalization, blood transfusion or death.

Forest plots (MA2: Midwives)

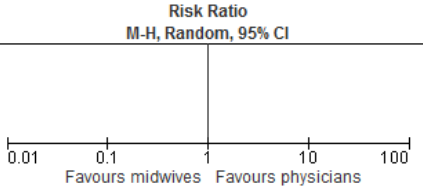
Effectiveness: complete abortion

Study or Subgroup	Midwives (n=29) Events	Total	physicians (n=13) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Klingberg-Allvin 2014 Uganda	452	472	467	483	100.0%	0.99 [0.97, 1.02]
Total (95% CI)		**472**		**483**	**100.0%**	**0.99 [0.97, 1.02]**
Total events	452		467			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.75 (P = 0.45)						



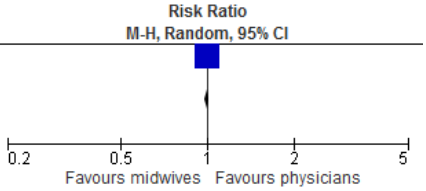
Safety: serious adverse events

Study or Subgroup	Midwives (n=29) Events	Total	physicians (n=13) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Klingberg-Allvin 2014 Uganda	0	472	0	483		Not estimable
Total (95% CI)		**472**		**483**		**Not estimable**
Total events	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						



Satisfaction with abortion service

Study or Subgroup	Midwives (n=29) Events	Total	physicians (n=13) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Klingberg-Allvin 2014 Uganda	465	472	477	483	100.0%	1.00 [0.98, 1.01]
Total (95% CI)		**472**		**483**	**100.0%**	**1.00 [0.98, 1.01]**
Total events	465		477			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.32 (P = 0.75)						



Satisfaction with abortion provider

No direct evidence identified.

GRADE (MA2: Midwives)

Author(s): Fonhus MS and Fretheim A
Date: 19.09.2014
Question: Should MA2 midwives vs physicians be used in management of incomplete abortion with medical abortion?
Settings: Uganda 29 midwives (506 women) and 13 physicians (504 women)
Bibliography (systematic reviews):Primary studies included: Klingberg-Allvin 2014 Uganda

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA2 Midwives	Physicians	Relative (95% CI)	Absolute (95% CI)		
Complete abortion												
1	randomized trial	not serious	not serious	not serious	serious [1]	none	452/472 (95.8%)	467/483 (96.7%)	RR 0.99 (0.97 to 1.02)	10 fewer per 1000 (from 19 more to 29 fewer)	⊕⊕⊕◯ MODERATE	
Serious adverse events												
1	randomized trial	not serious	not serious	not serious	serious [1]	none	0/472 (0.0%)	0/483 (0.0%)	not estimable		⊕⊕⊕◯ MODERATE	
Any complication												
1	randomized trial	not serious	not serious	not serious	serious [1]	none	11/472 (2.3%)	17/483 (3.5%)	RR 0.66 (0.31 to 1.4)	12 fewer per 1000 (from 14 more to 24 fewer)	⊕⊕⊕◯ MODERATE	
Overall satisfaction with abortion service (would you recommend the treatment to a friend?)												
1	randomized trial	not serious	not serious	not serious	serious [1]	none	465/472 (98.5%)	477/483 (98.8%)	RR 1 (0.98 to 1.01)	0 fewer per 1000 (from 10 more to 20 fewer)	⊕⊕⊕◯ MODERATE	
Overall satisfaction with provider												
0												

MD: mean difference; RR: relative risk.
[1] One study only.

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 7e MA2: Nurses

No direct evidence identified.

Annex 7f MA2: Auxiliary nurses/auxiliary nurse midwives

No direct evidence identified.

Annex 7g MA2: Pharmacists

No direct evidence identified.

Annex 7h MA2: Pharmacy workers

No direct evidence identified.

Annex 7i MA2: Lay health workers

No direct evidence identified.

Characteristics of primary studies included for medical abortion MA1, MA1.1, MA1.2, MA1.4 and MA2:

Andersen Nepal 2015 (*unpublished data*)

Methods	Prospective cohort study
Participants	3131 women seeking medical abortion ≤ 63 days' gestation (Phase 1); 1153 women presenting for two week follow up after medical abortion using a combined mifepristone/misoprostol regimen (Phase 2)
Interventions	Literate women, female community health volunteers (n=165) and trained comprehensive abortion care (CAC) providers (n=81), cadre unspecified, independently utilized a tool (MA Eligibility and Success Toolkit) to determine women's eligibility for MA and abortion status following medical abortion
Outcomes	Accurate determination of eligibility for MA, accurate determination of abortion completion
Notes	The toolkit included a gestational dating wheel and nine-point checklist of health questions to rule out contraindications for medical abortion to determine eligibility, and eight questions assessing bleeding, cramping and other symptoms following use of the combined mifepristone/misoprostol regimen for medical abortion designed to determine if women successfully aborted. The assessment of the CAC provider was taken to be the gold standard for comparison of female community health volunteer (FCHV) assessments.

Gebreselassie Mozambique 2012

Methods	Prospective cohort study
Participants	718 women seeking medical abortion < 12 weeks, treated with misoprostol 800 mcg x 2, doses separated by 24 hours, who returned for clinic follow-up to assess abortion status between days 12–21 by nurses and gynaecologists.
Interventions	Nurses (n= 10) conducted detailed interview about experience with medical abortion process, reviewed symptom diary, checked vital signs and performed physical examination with pelvic examination to determine abortion completion. Gynaecologists (n=5) reviewed the clinical examination findings of the nurses (blinded to diagnosis) and performed sonography to determine abortion completion. Nurse/physician rater pairs (2:1) independently assessed women's abortion status and diagnoses were compared
Outcomes	Complete abortion assessment
Notes	Different training by cadre: Nurses: 4 day training in history taking, physical exam and determining status of pregnancy expulsion; > 1 yr later, completed interactive, competency-based 5-day training with supervised clinical practice; most nurses had many years of professional experience and some med. ab. experience. Gynaecologists:1 day training emphasizing use of abdominal sonography for diagnosis of complete abortion.

Jejeebhoy India 2011

Methods	Prospective cohort
Participants	Women seeking medical abortion with 200 mg oral mifepristone followed two days later with 400 mcg oral misoprostol at ≤ 56 days' gestation managed either by 10 Ayurvedic physicians (n= 461), 10 nurses (n=497), or 10 allopathic physicians (n=497).
Interventions	Eligibility assessments for MA conducted by assigned provider using medical history, bimanual examination and urine pregnancy test. Provider evaluations immediately verified independently by a certified abortion provider. Successful completion of abortion determined at day 15 (up to day 21 in some cases) with pelvic examination by assigned provider. Provider evaluations immediately verified independently by a certified abortion provider.
Outcomes	Eligibility assessment, accuracy of complete abortion assessment
Notes	Allopathic physicians, Ayurvedic physicians and nurses, none of whom had experience in abortion provision, were trained to perform medical abortions. All completed same 10-day medical abortion training at baseline followed by field observation of minimum 10 cases. Providers rotated across sites and remained for approx. 6 weeks or 35–40 medical abortions. Certified abortion providers (verifiers) had a minimum of 5 years' professional experience.

Johnston Ethiopia, India, South Africa 2014 (*unpublished data*)

Methods	Prospective cohort
Participants	Women seeking medical abortion at ≤ 63 days' gestation in Ethiopia (217 women assessed by health extension workers (n=9) and nurses (n=6)), India (258 women assessed by either ASHA (n=7) or village health workers (n= 5) and Ob/Gyn (n=7)), or South Africa (236 women assessed by community-based educators (n=7) and nurses (n=8)). Women seeking follow-up after medical abortion in Ethiopia (156 women assessed by health extension workers (n=9) and nurses (n=6)), India (156 women assessed by either ASHA (n=7) or village health workers (n= 5) and Ob/Gyn (n=7)), or South Africa (67 women assessed by community-based educators (n=7) and nurses (n=8)).
Interventions	To determine eligibility for MA, all providers used a checklist comprising the results from a urine pregnancy test to confirm pregnancy, gestational age determination using last menstrual period (LMP) and a gestational age (GA) wheel and five screening questions to elicit possible medical contraindications. To assess abortion status following medical abortion, all providers used a follow-up checklist comprising seven screening questions to determine ongoing pregnancy and indications of abortion-related complications. All providers used the same instruments to independently determine eligibility and abortion completion. These results were compared to results of a reference clinical exam performed by the facility clinician.
Outcomes	Eligibility assessment and accuracy of complete abortion assessment
Notes	Different levels of professional experience and background training: CHW training consisted of basic repro physiology, use of pregnancy testing, GA wheels, contraindications to MA, signs for additional care. Clinicians had training to review study objectives and methods with review of study instruments.

Kallner Sweden 2014

Methods	Two-sided RCT
Participants	2 midwives treating 597 women; 34 physicians treating 538 women
Interventions	Provision of medical abortion ≤ 63 days' gestation with mifepristone 200 mg orally followed 2–3 days later by misoprostol 800 mcg vaginally managed by either nurse midwives or physicians
Outcomes	Complete abortion, serious adverse events, other complications, satisfaction with abortion provider
Notes	Women randomized to the nurse-midwife group (intervention) were examined, counselled, informed, and treated by one nurse-midwife. Women allocated to the standard treatment group (physicians) were examined and counselled by a physician and then received additional information about the practical details and medication from a nurse-midwife (not in the study) according to clinical routine. The nurse-midwives were experienced in medical TOP and contraceptive counselling and received theoretical and practical training in vaginal ultrasound examination of early pregnancy. The physicians had varying training and experience. Some had only a few months of training whereas others were senior consultants with many years professional experience. No formal pre study training for physicians.

Klingberg-Allvin Uganda 2015

Methods	Two-sided RCT
Participants	• 29 midwives treating 506 women; 13 physicians treating 504 women
Interventions	• Medical management of clinically stable women with incomplete abortion and uterine size < 12 weeks with misoprostol 600 mcg orally by either nurse midwives or physicians.
Outcomes	• Complete abortion, serious adverse events, other complications, satisfaction with abortion service
Notes	Eligible providers worked in the maternal health section and were already involved in post-abortion care (PAC) at the participating facilities. All received baseline standardized 5-day training module developed by Ipas.

Olavarrieta Mexico 2015

Methods	One-sided RCT (non-inferiority trial)
Participants	7 nurses treating 503 women; 8 physicians treating 514 women
Interventions	Provision of medical abortion ≤ 70 days' gestation with mifepristone 200 mg orally followed 2 days later by misoprostol 800 mcg buccally managed by either nurses or physicians
Outcomes	Eligibility assessment, appropriate administration of medication, complete abortion without surgical intervention, serious adverse events, other complications, satisfaction with abortion service
Notes	Included only providers with no previous experience with medical abortion or who had only managed MA under supervision. All received the same baseline training, were directly observed in practice and received 20 hours of training in sonography. On average, nurses managed eight MA cases each and physicians managed one to two MA cases each to reach competency pre study. Competency was certified by a supervising Ob/Gyn.

Warriner Nepal 2011

Methods	Two-sided RCT
Participants	11 non-physician providers (8 nurses and 3 auxiliary nurse midwives) treating 552 women and 14 physicians (6 Ob/Gyn, 3 GPs, 5 doctors with BM or BS degree) treating 552 women
Interventions	Provision of medical abortion ≤ 63 days' gestation with mifepristone 200 mg orally followed 2 days later by misoprostol 800 mcg vaginally managed by either non-physician providers or physicians
Outcomes	Eligibility assessment, complete abortion, serious adverse events, effectiveness (assessment of eligibility, complete abortion (no need for MVA), appropriate administration of medications for MA (adherence to regimen)), safety (serious adverse events or other complications)
Notes	Included providers already trained in MVA; all completed same 3-day training programme in medical abortion at baseline. Years of professional experience varied.

Annex 8: MA3

(Medical abortion < 84 days, self-administration)

Annex 8j MA3: Women

No direct evidence identified.

Annex 8.1: MA3.1
(Self-assessment of eligibility for medical abortion)

Annex 8.1j MA3.1: Women

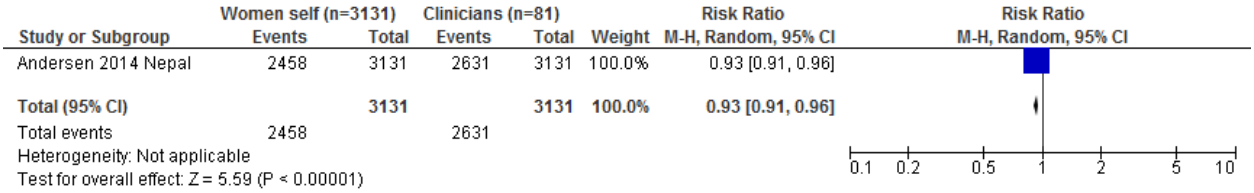
Summary of Findings table (MA3.1: Women)

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.

Forest plots (MA3.1: Women)

Assessment of eligibility



Note that there was a mix of both nurses and physicians in the clinician cadre. Disaggregated outcomes not reported.

Accuracy of eligibility assessment

Andersen 2014:

Table 3. MA eligibility assessment by women and CAC providers (n=3131).

	Provider Assessment			
	Eligible		Ineligible	
Women's Assessment	n	(%)	n	(%)
Eligible	2277	(73)	181	(6)
Ineligible	354	(11)	319	(10)
Total	**2631**	**(84)**	**500**	**(16)**

Grey cells indicate women who may be at increased clinical risk if they rely solely on the MA Eligibility Toolkit.

GRADE (MA3.1: Women)

Author(s): Fonhus MS and Fretheim A
Date: 04.10.2014
Question: Should MA3.1 women self/home vs clinical setting/office be used for assessment of eligibility for medical abortion (< 84 days)?
Settings: Nepal
Bibliography (systematic reviews): Primary studies included: Andersen 2014

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA3 Women self/home	Clinical setting/ office	Relative (95% CI)	Absolute (95% CI)		
Eligibility assessment for medical abortion												
1	observational study	not serious	not serious	not serious	not serious [1]	none	2458/3131 (78.5%)	2631/3131 (84.0%)	RR 0.93 (0.91 to 0.96)	59 fewer per 1000 (from 34 fewer to 76 fewer)	⊕⊕◯◯ LOW	
Accuracy of eligibility assessment												
1	observational study									Not estimable		

MD: mean difference; RR: relative risk.
[1] One study only, but not downgraded for this because the outcome is already graded as low.

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 8.2: MA3.2

(Self-administration of medication for medical abortion)

Annex 8.2j MA3.2: Women

Summary of Findings table (MA3.2: Women)

What happens?	Administration of medication by clinicians/ in clinical setting/office	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
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 the 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

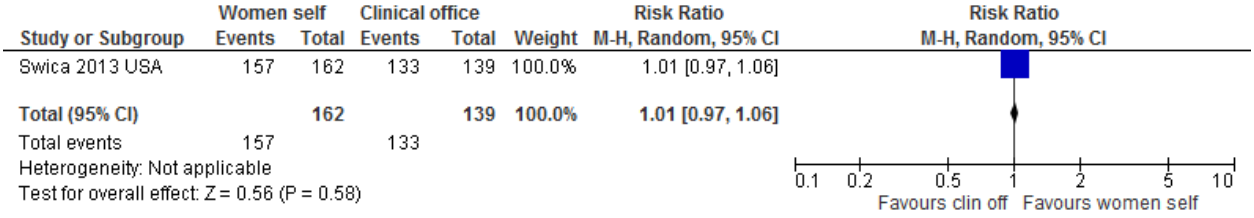
* 95% confidence interval.

[1]In most of the studies, however, some studies do not report.

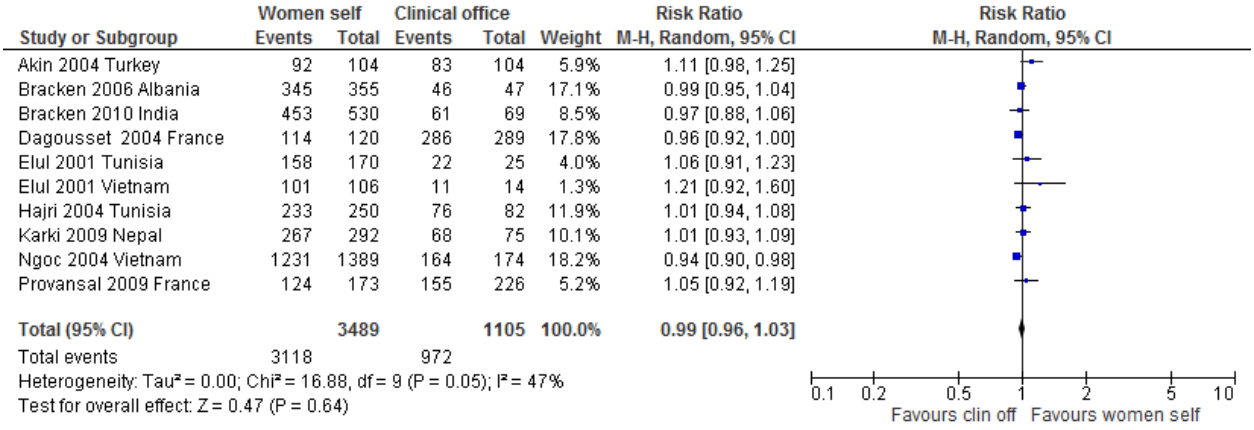
[2]Hospitalization, blood transfusion or death.
[3] Very or somewhat satisfied.
[4] Procedure is acceptable.

Forest plots (MA3.2: Women)

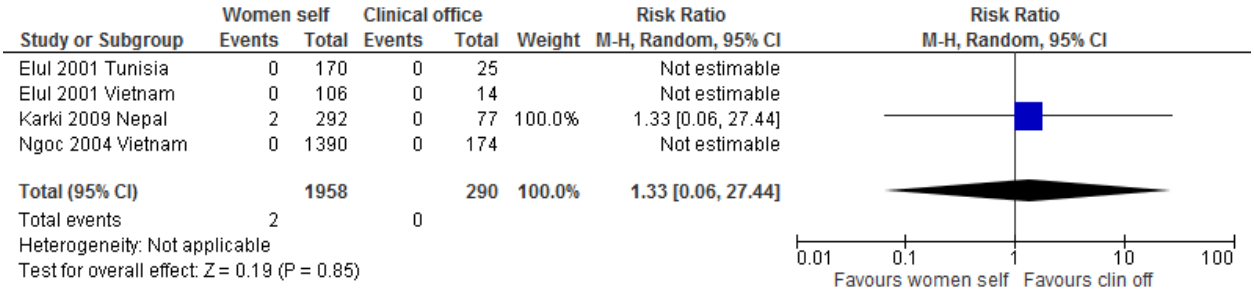
Effectiveness: complete abortion (self/home vs clinical setting/office administration of mifepristone)



Effectiveness: complete abortion (clinical setting/office administration of mifepristone followed by self/home vs clinical setting/office administration of misoprostol)

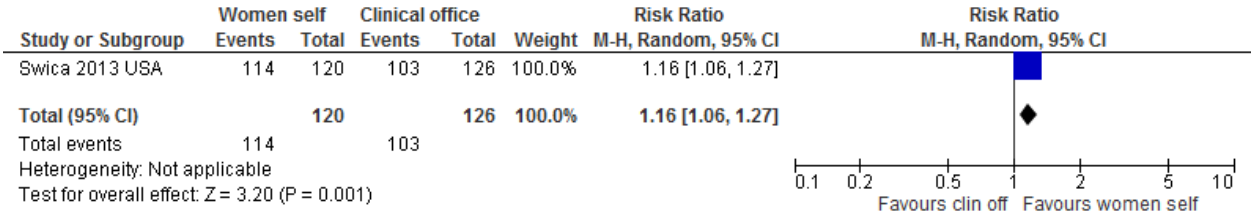


Safety: serious adverse events (clinical setting/office administration of mifepristone followed by self/home vs clinical setting/office administration of misoprostol)



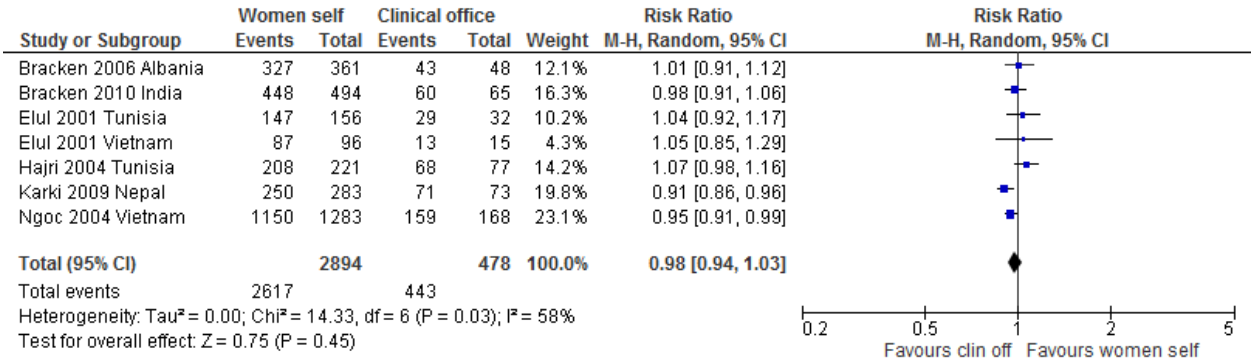
Satisfaction with service/method (self/home vs clinical setting/office administration of mifepristone)

Would take mifepristone in same place again

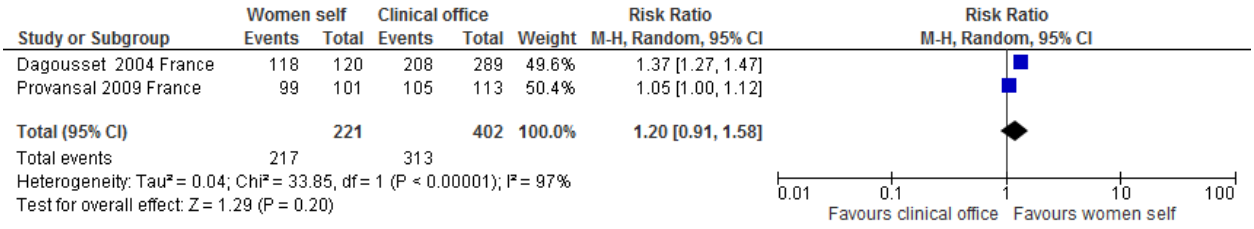


Satisfaction with service/method (clinical setting/office administration of mifepristone followed by self/home vs clinical setting/office administration of misoprostol)

Very satisfactory/somewhat satisfactory

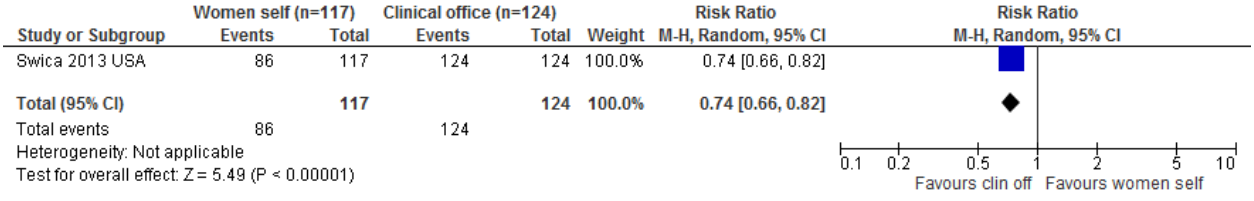


Procedure is acceptable



Appropriate administration of medication for medical abortion

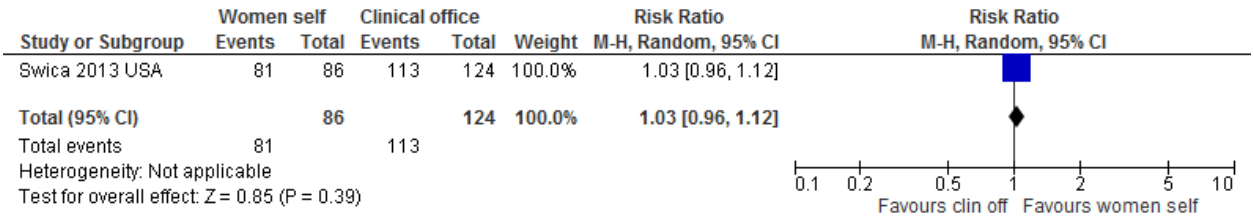
Mifepristone administration (home/self-administration versus administration in a clinical setting/office)



Misoprostol administration (home/self-administration versus administration in a clinical setting/office)

No direct evidence

Misoprostol self-administration (in the first step (mifepristone administration) women were assigned to the home/self or clinical setting/office. In the second step all women self-administered)



GRADE (MA3.2: Women)

Author(s): Fonhus MS and Fretheim A
Date: 06.10.2014
Question: Should MA3 self/home vs clinical setting/office be used for administration of medication for medical abortion (< 84 days)?
Settings: Turkey, Albania, India, Tunisia, Nepal, Viet Nam, USA and France
Bibliography (systematic reviews): Primary studies included: Swica 2013, Akin 2004, Bracken 2006, Bracken 2010, Dragousset 2004, Elul 2001, Hajri 2004, Karki 2009, Ngoc 2004 and Provansal 2009.

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA3 Women self/home	Clinical setting/ office	Relative (95% CI)	Absolute (95% CI)		
Complete abortion (mifepristone)												
1	observational study	not serious	not serious	not serious	serious [1]	none	3118/3489 (89.4%)	972/1105 (88.0%)	RR 0.99 (0.96 to 1.03)	9 fewer per 1000 (from 26 more to 35 fewer)	⊕◯◯◯ VERY LOW	
Complete abortion (mifepristone followed by misoprostol)												
9	observational studies	not serious	not serious	not serious	not serious	none	3118/3489 (89.4%)	972/1105 (88.0%)	RR 0.99 (0.96 to 1.03)	9 fewer per 1000 (from 26 more to 35 fewer)	⊕⊕◯◯ LOW	
Serious adverse events (mifepristone followed by misoprostol)												
3	observational studies	not serious	not serious	not serious	not serious [2]	none	2/1958 (0.0%)	0/290	not pooled		⊕⊕◯◯ LOW	
Satisfaction with service (mifepristone)												
1	observational study	not serious	not serious	not serious	serious [1]	none	114/120 (95.0%)	103/126 (81.7%)	RR 1.16 (1.06 to 1.27)	31 more per 1000 (from 49 more to 221 more)	⊕◯◯◯ VERY LOW	
Satisfaction with service/method (very satisfactory/somewhat satisfactory) (mifepristone followed by misoprostol)												
6	observational studies	not serious	not serious [3]	not serious	not serious	none	2617/2894 (90.4%)	443/478 (92.7%)	RR 0.98 (0.94 to 1.03)	19 fewer per 1000 (from 28 more to 56 fewer)	⊕⊕◯◯ LOW	
Satisfaction with service/method (procedure is acceptable) (mifepristone followed by misoprostol)												
3	observational studies	not serious	not serious [3]	not serious	not serious	none	331/341 (97.1%)	416/528 (78.8%)	RR 1.19 (1 to 1.41)	150 more per 1000 (from 0 fewer to 323 more)	⊕⊕◯◯ LOW	
Appropriate administration of mifepristone												
1	observational study	not serious	not serious	not serious	serious [5]	none	86/117 (73.5%)	124/124 (100.0%)	RR 0.74 (0.66 to 0.82)	260 fewer per 1000 (from 180 fewer to 340 fewer)	⊕◯◯◯ VERY LOW	
Appropriate self/home administration of mifepristone												
1	observational study	not serious	not serious	not serious	serious [5]	none	81/86 (94.2%)	113/124 (91.1%)	RR 1.03 (0.96 to 1.12)	27 more per 1000 (from 36 fewer to 109 more)	⊕◯◯◯ VERY LOW	

MD: mean difference; RR: relative risk.
[1] Only one small study
[2] Few events, but not downgraded for this
[3] Heterogeneity
[4] One study only with few participants
High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 8.3: MA3.3

(Self-assessment of completion of abortion)

Annex 8.3j MA3.3: Women

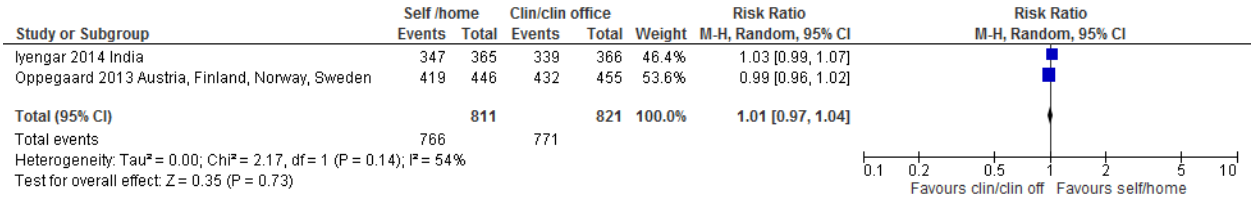
Summary of Findings table (MA3.3: Women)

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
Accuracy of complete abortion assessment (the same as verifier's) Not estimable			
Overall satisfaction with abortion services No direct evidence identified			
Overall satisfaction with provider No direct evidence identified			

* 95% confidence interval.

Forest plots (MA3.3: Women)

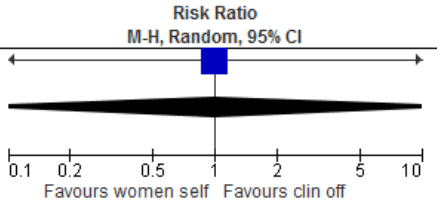
Effectiveness: Complete abortions



Safety: Serious adverse events

Study or Subgroup	Women self/home Events	Total	Clinicians/clin off Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Iyengar 2014 India	1	365	1	366	100.0%	1.00 [0.06, 15.97]
Total (95% CI)		**365**		**366**	**100.0%**	**1.00 [0.06, 15.97]**
Total events	1		1			

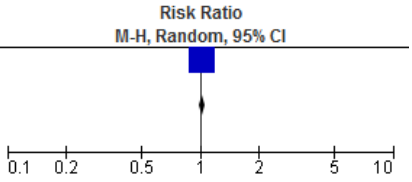
Heterogeneity: Not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Complete abortion assessment

Study or Subgroup	Women self (n=3131) Events	Total	Clinicians (n=81) Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Andersen 2014 Nepal	993	1151	975	1153	100.0%	1.02 [0.99, 1.06]
Total (95% CI)		**1151**		**1153**	**100.0%**	**1.02 [0.99, 1.06]**
Total events	993		975			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.16 (P = 0.24)



Accuracy of abortion completion assessment

Blum 2012:

190 out of 327 women:

"Approximately two thirds of clinical trial participants (58.1%, n=190) correctly determined their need to return to the clinic based on the home test reading being the same or higher than their baseline level."

Lynd 2013:

10 out of 11 women with positive pregnancy tests understood that the result meant an additional clinic visit was needed.

147 out of 252 women with a pregnancy test reading indicating no additional follow up was needed actually understood no additional clinic visit was necessary.

Satisfaction with abortion services

No direct evidence identified.

Satisfaction with abortion provider

No direct evidence identified.

GRADE (MA3.3: Women)

Author(s): Fonhus MS and Fretheim A
Date: 10.10.2014
Question: Should MA3 Self mifeprostol vs placebo be used for self?
Settings: Austria, Finland, Norway, Sweden, India, USA
Bibliography (systematic reviews): Included primary studies: Oppegaard 2013, Iyengar 2014, Andersen 2014 and Blum 2012

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MA3 Women self/home	Clinicians/ clinical setting/office	Relative (95% CI)	Absolute (95% CI)		
Complete abortion (no need for surgery, no pregnancy)												
2	randomized trials	not serious	not serious [1]	not serious	not serious	none	766/811 (94.5%)	771/821 (93.9%)	RR 1.01 (0.97 to 1.04)	9 more per 1000 (from 28 fewer to 38 more)	⊕⊕⊕⊕ HIGH	
Serious adverse events												
1	randomized trial	not serious	not serious	not serious	serious [2,3]	none	1/365 (0.3%)	1/366 (0.3%)	RR 1 (0.06 to 15.97)	0 fewer per 1000 (from 3 fewer to 41 more)	⊕⊕⊕◯ MODERATE	
Complete abortion assessment												
1	observational study	not serious	not serious	not serious	not serious [1]	none	993/1151 (86.3%)	975/1153 (84.6%)	RR 1.02 (0.99 to 1.06)	17 more per 1000 (from 8 fewer to 51 more)	⊕⊕◯◯ LOW	
Accuracy of complete abortion assessment												
1	observational study						190/327 (58.1%)		not estimable	not estimable		
1	observational study						10/11 (90.9%) 147/252 (58.3%)		not estimable	not estimable		
Satisfaction with abortion service												
0												
Satisfaction with abortion provider												
0												

MD: mean difference; RR: relative risk.
[1] Some heterogeneity
[2] One study only
[3] Few events
[4] One study only, but not downgraded for this because the outcome is already graded as low

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Characteristics of included studies for MA3.1, 3.2 and 3.3

Akin 2004 Turkey

Methods	Prospective cohort study
Participants	Home use of misoprostol n=104; clinic use of misoprostol n=104
Interventions	Mifepristone 200 mg orally administered in clinic followed by misoprostol 400 mcg orally administered 2 days later either in clinic or at home among women seeking medical abortion through 56 days' gestation
Outcomes	Complete abortion, overall satisfaction with services
Notes	The first twenty women at each site and nearly all women recruited at one of the five study sites were not given the option to choose the site of misoprostol administration. In total, 34/104 clinic users selected clinic administration of misoprostol. All women in the home use group selected this site for misoprostol use. 55% of women had supportive companion available during home administration of misoprostol

Andersen 2015 Nepal (unpublished data)

Methods	Prospective cohort study
Participants	3131 women seeking medical abortion ≤ 63 days' gestation (Phase 1); 1153 women presenting for two week follow up after medical abortion using a combined mifepristone/misoprostol regimen (Phase 2)
Interventions	Literate women (n=3131), female community health volunteers (n=165) and trained comprehensive abortion care providers (n=81), cadre unspecified, independently utilized a tool (MA Eligibility and Success Toolkit) to determine women's eligibility for MA and abortion status following medical abortion
Outcomes	Accurate determination of eligibility for MA, accurate determination of abortion completion
Notes	The toolkit included a gestational dating wheel and nine-point checklist of health questions to rule out contraindications for medical abortion to determine eligibility, and eight questions assessing bleeding, cramping and other symptoms following use of the combined mifepristone/misoprostol regimen for medical abortion designed to determine if women successfully aborted. The assessment of the CAC provider was taken to be the gold standard for comparison of women's self- assessments.

Blum 2012 USA

Methods	Prospective cohort study
Participants	490 women seeking medical abortion ≤ 63 days' gestation
Interventions	Women performed urine pregnancy test and self-assessment questionnaire at home to determine abortion completion at one week after mifepristone compared to health professional (unspecified cadre) verification/assessment later in the same day
Outcomes	Accurate determination of abortion completion
Notes	Results of uPT and questionnaire reviewed with health professional in clinic to determine the accuracy of women's assessments based on these results. If findings were inconclusive, the clinician completed further assessment using standard clinical means (e.g. physical examination, sonography, serum hCG)

Bracken 2006 Albania

Methods	Prospective cohort study
Participants	Women using misoprostol at Home n=361; clinic use of misoprostol n=48
Interventions	Mifepristone 200 mg orally administered in clinic followed by misoprostol 400 mcg orally administered 2 days later either in clinic or at home among women seeking medical abortion through 56 days' gestation
Outcomes	Complete abortion, overall satisfaction with services
Notes	The first ten women at all sites required to have clinic administration then able to respond to women's preference; one site did not routinely offer choice, but there was variable adherence to this requirement across sites.

Bracken 2010 India

Methods	Prospective cohort study
Participants	Home use of misoprostol n=530; clinic use of misoprostol n=69
Interventions	Mifepristone 200 mg orally administered in clinic followed by misoprostol 400 mcg orally administered 2 days later either in clinic or at home among women seeking medical abortion through 56 days' gestation
Outcomes	Complete abortion, serious adverse events, overall satisfaction with services
Notes	

Dagousset 2004 France

Methods	Prospective cohort study
Participants	Home use of misoprostol n=120; clinic use of misoprostol n=289
Interventions	Mifepristone 600mg orally administered at the hospital followed by misoprostol 400 mcg orally administered at home or in hospital among women seeking medical abortion through 49 days' gestation
Outcomes	Complete abortion, overall acceptability of services
Notes	Women in the hospital arm also received a supplementary dose of misoprostol 400 mcg orally administered if the pregnancy did not expel after 3 hours of observation.

Elul 2001 Tunisia

Methods	Prospective cohort study
Participants	Home use of misoprostol n=195; clinic use of misoprostol n=25
Interventions	Mifepristone 200 mg orally administered in clinic followed by misoprostol 400 mcg orally administered 2 days later either in clinic or at home among women seeking medical abortion through 56 days' gestation
Outcomes	Complete abortion, serious adverse events, overall satisfaction with services
Notes	

Elul 2001 Viet Nam

Methods	Prospective cohort study
Participants	Home use of misoprostol n=106; clinic use of misoprostol n=14
Interventions	Mifepristone 200 mg orally administered in clinic followed by misoprostol 400 mcg orally administered 2 days later either in clinic or at home among women seeking medical abortion through 56 days' gestation
Outcomes	Complete abortion, serious adverse events, overall satisfaction with services
Notes	

Hajri 2004 Tunisia

Methods	Prospective cohort study
Participants	Home use of misoprostol n=241; clinic use of misoprostol n=82
Interventions	Mifepristone 200 mg orally administered in clinic followed by misoprostol 400 mcg orally administered 2 days later either in clinic or at home among women seeking medical abortion through 56 days' gestation
Outcomes	Complete abortion, overall satisfaction with services
Notes	The first twenty women at two of four sites required to have clinic administration then women's preference observed.

Iyengar 2015 India

Methods	Two-sided RCT
Participants	Women seeking medical abortion through ≤ 63 days' gestation using a combined regimen of 200 mg oral mifepristone followed by 800 mcg vaginal misoprostol 24 to 48 hours later randomized to self-assessment (n=378) or routine follow-up (n=353)
Interventions	Women in the self-assessment group used a low sensitivity urine pregnancy test (LSUP) with written and pictorial instructions for use at home 10–14 days after mifepristone; a member of the research team contacted the woman during this time by telephone or home visit at one month to review the results of the test and women's help-seeking behaviour; women in the other arm underwent clinical follow up at 10–14 days and the LSUP and clinical examination to determine complete abortion.
Outcomes	Complete abortion and serious adverse events associated with medical abortion using an active self-assessment approach
Notes	

Karki 2009 Nepal

Methods	Prospective cohort study
Participants	Home use of misoprostol n=323; clinic use of misoprostol n=77
Interventions	Mifepristone 200 mg orally administered in clinic followed by misoprostol 400 mcg orally administered 2 days later either in clinic or at home among women seeking medical abortion through 56 days' gestation
Outcomes	Complete abortion, serious adverse events, overall satisfaction with services
Notes	

Lynd 2013 Viet Nam

Methods	Prospective cohort study
Participants	300 women seeking medical abortion ≤ 63 days' gestation
Interventions	Women performed urine pregnancy test and self-assessment questionnaire at home to determine abortion completion at one week after mifepristone compared to health professional (unspecified cadre) verification/assessment later in the same day
Outcomes	Accurate determination of abortion completion
Notes	Results of uPT and questionnaire reviewed with health professional in clinic to determine the accuracy of women's assessments based on these results. If findings were inconclusive, the clinician completed further assessment using standard clinical means (e.g. physical examination or sonography)

Ngoc 2004 Viet Nam

Methods	Prospective cohort study
Participants	Home use of misoprostol n=1390; clinic use of misoprostol n=174
Interventions	Mifepristone 200 mg orally administered in clinic followed by misoprostol 400 mcg orally administered 2 days later either in clinic or at home among women seeking medical abortion through 56 days' gestation
Outcomes	Complete abortion, serious adverse events, overall satisfaction with services
Notes	First 20 women at each of 5 new sites (out of 8 total included in study) required to have clinic administration, then women's preferences observed.

Oppegaard 2014 Austria Finland Norway Sweden

Methods	Two-sided RCT
Participants	Women seeking medical abortion through ≤ 63 days' gestation using a combined regimen of 200 mg oral mifepristone followed by 800 mcg vaginal misoprostol 24 to 48 hours later randomized to self-assessment (n=458) or routine follow-up (n=466)
Interventions	Women in the self-assessment group used a home two step urine pregnancy test 1–3 weeks after medical abortion to determine abortion completion; a member of the research team contacted the woman at one month to review the results of the test and women's help-seeking behaviour; women in the routine follow-up group underwent clinical follow up 1–3 weeks after medical abortion with a nurse or MD who assessed abortion completion with a low sensitivity urine pregnancy test or serum hCG and/or sonography.
Outcomes	Complete abortion and serious adverse events associated with medical abortion using an active self-assessment approach
Notes	

Provansal 2009 France

Methods	Prospective cohort study
Participants	Home use of misoprostol n=143; clinic use of misoprostol n=162
Interventions	Mifepristone 600mg orally administered at the hospital followed by misoprostol 400 mcg orally administered at home or in hospital among women seeking medical abortion through 49 days' gestation
Outcomes	Complete abortion, overall satisfaction with services
Notes	Women in the hospital arm also received a supplementary dose of misoprostol 400 mcg orally administered if the pregnancy did not expel after three hours of observation.

Swica 2013 USA

Methods	Prospective cohort study
Participants	Home use of mifepristone and misoprostol n=143; clinic use of mifepristone and home use of misoprostol n=162
Interventions	Mifepristone 200mg orally administered at clinic or at home followed by misoprostol 800 mcg vaginally administered at home among women seeking medical abortion through 63 days' gestation
Outcomes	Adherence to protocol for correct timing and use of medications, complete abortion, serious adverse events, overall satisfaction with services
Notes	

Annex 9: MA4

(Provision of medical abortion in the second trimester)

Annex 9a MA4: Non-specialist doctors

No direct evidence identified.

Annex 9b MA4: Doctors of complementary systems of medicine

No direct evidence identified.

Annex 9c MA4: Associate clinicians

No direct evidence identified.

Annex 9d MA4: Midwives

No direct evidence identified.

Annex 9e MA4: Nurses

No direct evidence identified.

Annex 9f MA4: Auxiliary nurses/auxiliary nurse midwives

No direct evidence identified.

Annex 10: COMP
(Management of non-life-threatening complications)

Annex 10a COMP: Non-specialist doctors
No direct evidence identified.

Annex 10b COMP: Doctors of complementary systems of medicine
No direct evidence identified.

Annex 10c COMP: Associate clinicians
No direct evidence identified.

Annex 10d COMP: Midwives
No direct evidence identified.

Annex 10e COMP: Nurses
No direct evidence identified.

Annex 10f COMP: Auxiliary nurses/auxiliary nurse midwives
No direct evidence identified.

Annex 11: MESSAGE1

(Provision of information on the availability of safe providers/care for complications)

Annex 11g MESSAGE1: Pharmacists

No direct evidence identified.

Annex 11h MESSAGE1: Pharmacy workers

Summary of Findings table (MESSAGE1: Pharmacy workers)

What happens?	No information (usual practice)	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	

We included one before and after study, conducted in a low-income country that assessed the impact of education on pharmacy worker knowledge. We also included two trials, one conducted in a high-income country and the other in a low-income country, in which contraception counselling was part of a larger intervention and provided indirect evidence. No studies assessed maternal mortality and morbidity post-abortion, proportion of safe abortions, correct knowledge of safe and appropriate abortion, or post-abortion care by women or other information seekers. No studies assessed correct knowledge of contraception options by women or cadre, number of unplanned pregnancies or the satisfaction with contraception advice.

Correct knowledge of safe abortion or post-abortion care by pharmacy workers was not estimable because of serious study limitations (only one control and intervention site and the presence of several potential confounders favouring the intervention). For contraception counselling, a post hoc definition was used for the mix in contraceptive types (use of long-acting reversible contraceptives [LARC]). For the two trials (1944 women), the uptake of LARC was similar when comparing care that included contraceptive counselling provided by nurses and nurse-midwives with similar care from doctors (RR 1.10, 95% CI 0.92 to 1.33).

Heterogeneity was very high (I^2=90%) and results were inconsistent. The certainty of this indirect evidence was therefore very low.

Annex 11i MESSAGE1: Lay health workers

No direct evidence identified.

Characteristics of primary studies included for MESSAGE1:

Tamang 2014 Nepal

Methods	Controlled before and after study with one intervention area and one control area. Pharmacies selected using cluster sampling.
Participants	Main person at each of 207 intervention pharmacies and 212 of the control pharmacies. The pharmacy workers included a mix of health cadres (including health assistants, staff nurses, auxiliary nurse midwives, and auxiliary health workers or community medical assistants)
Interventions	Two-day basic training and a one-day refresher 10 months later
Outcomes	The proportion of pharmacy workers with correct knowledge assessing abortion completeness and conditions/symptoms requiring immediate referral. The proportion of pharmacy workers with correct knowledge relating to the provision of medical abortion drugs
Notes	

Annex 12: MESSAGE2

(Provision of pre- and post-abortion counselling)

Annex 12b MESSAGE2: Doctors of complementary systems of medicine

No direct evidence identified.

Annex 12c MESSAGE2: Associate clinicians

No direct evidence identified.

Annex 12d MESSAGE2: Midwives

No direct evidence identified.

Annex 12e MESSAGE2: Nurses

No direct evidence identified.

Annex 12f MESSAGE2: Auxiliary nurses/auxiliary nurse midwives

No direct evidence identified.

Annex 12g MESSAGE2: Pharmacists

No direct evidence identified.

Annex 12h MESSAGE2: Pharmacy workers

No direct evidence identified.

Annex 12i MESSAGE2: Lay health workers

No direct evidence identified.

Annex 13: CONTRA1

(Insertion and removal of IUDs and implants and initiation/continuation of injectable contraceptives)

Annex 13b CONTRA1: Doctors of complementary systems of medicine

No direct evidence identified.

Annex 13g CONTRA1: Pharmacists

Summary of Findings table (CONTRA1: Pharmacists)

What happens?	Clinicians providing contraceptive injections/implants	Pharmacists providing contraceptive injections/ implants	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	

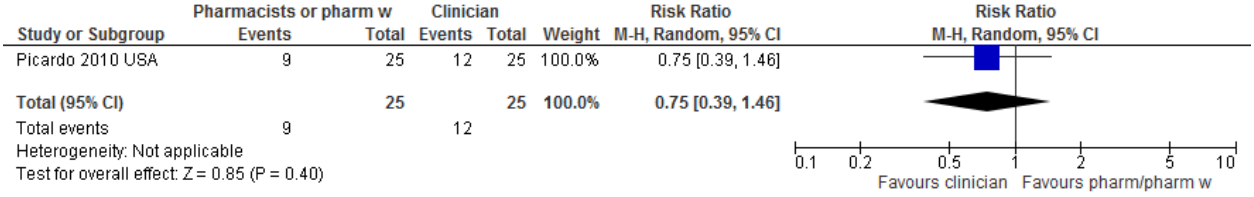
* 95% confidence interval.

Forest plots (CONTRA1: Pharmacists)

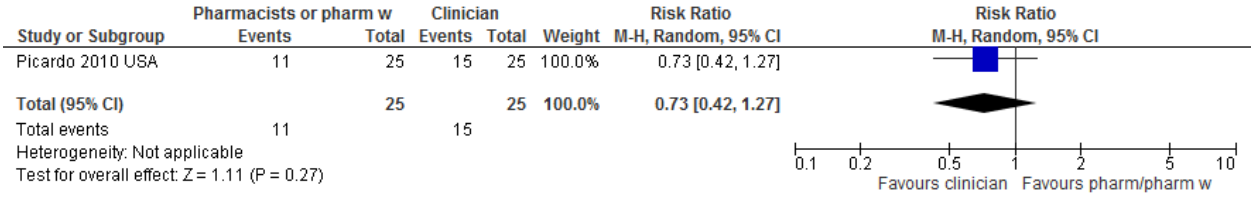
Effectiveness: uptake of injectable contraceptive

No direct evidence identified.

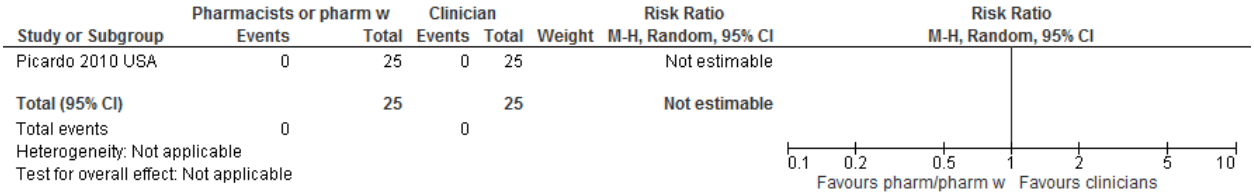
Effectiveness: continuation rates/re-injection at 6 months



Effectiveness: continuation rates/re-injection at 3 months



Safety: serious adverse events



Safety: other complications

No direct evidence identified.

Satisfaction with the contraception service/method

Picardo 2010:

Likert scale with 1=lowest rating, 5=highest rating

Quality assessed	**Pharmacy median score (N=11)**	**Clinic median score (N=15)**	***P* value**
3 month satisfaction with location	5 (4–5)	5 (4–5)	0.16
Quality assessed	**Pharmacy median score (N=11)**	**Clinic median score (N=9)**	***P* value**
6 month satisfaction with location	5 (3–5)	5 (1–5)	0.87

Group difference not estimable

Satisfaction with provider

Quality assessed	**Pharmacy median score (N=11)**	**Clinic median score (N=15)**	***P* value**
3-month satisfaction with DMPA	5 (5–5)	5 (4–5)	0.05
Quality assessed	**Pharmacy median score (N=11)**	**Clinic median score (N=9)**	***P* value**
6-month satisfaction with DMPA	5 (5–5)	5 (3–5)	0.37

Group difference not estimable

GRADE (CONTRA1: Pharmacists)

Author(s): Fonhus MS and Fretheim A
Date: 30.09.2014
Question: Should CONTRA1 pharmacists or pharmacy workers vs clinicians be used in provision of contraceptive injections/implants?
Settings: USA
Bibliography (systematic reviews): Primary studies included: Picardo 2010 USA

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	CONTRA1 Pharmacists or pharmacy workers	Clinicians	Relative (95% CI)	Absolute (95% CI)		
Effectiveness: uptake of injectable contraceptive												
0												
Effectiveness: continuation (non-interrupted use at 3 months)												
1	randomized trial	serious [1]	not serious	not serious	very serious [2]	none	11/25 (44.0%)	15/25 (60.0%)	RR 0.73 (0.42, 1.27)	162 fewer per 1000 (from 162 more to 348 fewer)	⨁◯◯◯ VERY LOW	
Effectiveness: continuation (non-interrupted use at 6 months)												
1	randomized trial	serious [1]	not serious	not serious	very serious [2]	none	9/25 (36.0%)	12/25 (48.0%)	RR 0.75 (0.39, 1.46)	120 fewer per 1000 (from 221 more to 293 fewer)	⨁◯◯◯ VERY LOW	
Safety: serious adverse events												
1	randomized trial	serious [1]	not serious	not serious	very serious [2]	none	0/25 (0%)	0/25 (0%)	not pooled	not estimable	⨁◯◯◯ VERY LOW	
Safety: other complications												
0												
Satisfaction with the contraception method at 3 months												
0							not estimable		not pooled	not estimable		
Satisfaction with the contraception method at 3 months												
0							not estimable		not pooled	not estimable		

MD: mean difference; RR: relative risk.
[1] High risk of bias in included study
[2] One study only with few participants

High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Annex 14: CONTRA1
(Self-administration of injectables)

Annex 14j CONTRA1: Women

Summary of Findings (CONTRA1: Women)

What happens?	Clinicians providing contraceptive injections/implants	Women self-administrating contraceptive injections/ implants	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 both higher and lower continuation rates.	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.

Forest plots (CONTRA1: Women)

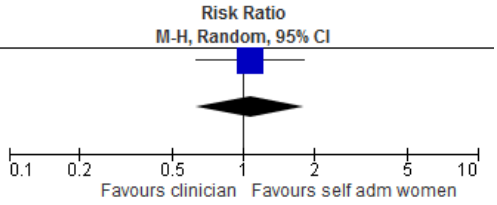
Effectiveness: uptake of injectable contraceptive

No direct evidence identified.

Effectiveness: continuation rates/ re-injection RCT at 12 months

Study or Subgroup	Women self-adm Events	Total	clinician Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Beasley 2014 USA	28	86	14	46	100.0%	1.07 [0.63, 1.82]
Total (95% CI)		**86**		**46**	**100.0%**	**1.07 [0.63, 1.82]**
Total events	28		14			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.25 (P = 0.80)

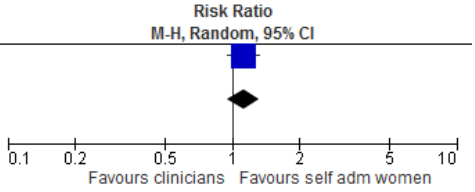


Effectiveness: continuation rates/ re-injection non-RCT

At 12 months

Study or Subgroup	Women self-adm Events	Total	clinician Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Cameron 2012 Scotland UK	51	58	50	64	100.0%	1.13 [0.96, 1.32]
Total (95% CI)		**58**		**64**	**100.0%**	**1.13 [0.96, 1.32]**
Total events	51		50			

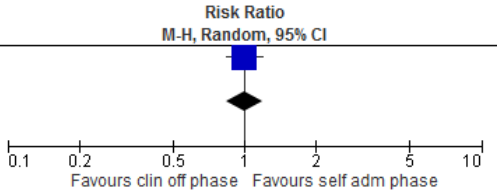
Heterogeneity: Not applicable
Test for overall effect: Z = 1.44 (P = 0.15)



At 3 months

Study or Subgroup	Self-adm phase Events	Total	clin office phase Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Stanwood 2006 USA	10	10	10	10	100.0%	1.00 [0.83, 1.20]
Total (95% CI)		**10**		**10**	**100.0%**	**1.00 [0.83, 1.20]**
Total events	10		10			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Safety: serious adverse events

No direct evidence identified.

Safety: other complications

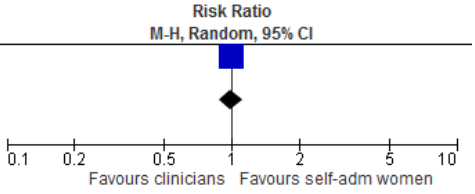
Not estimable

Satisfaction with the contraception service/method (want to continue this method)

At 12 months

Study or Subgroup	Self-adm women Events	Total	Clinicians Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Cameron 2012 Scotland UK	55	61	50	55	100.0%	0.99 [0.88, 1.12]
Total (95% CI)		**61**		**55**	**100.0%**	**0.99 [0.88, 1.12]**
Total events	55		50			

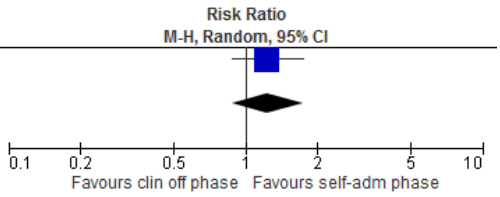
Heterogeneity: Not applicable
Test for overall effect: Z = 0.14 (P = 0.89)



At 3 months

Study or Subgroup	Self-adm phase Events	Total	Clin office phase Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Stanwood 2006 USA	10	10	8	10	100.0%	1.24 [0.87, 1.75]
Total (95% CI)		**10**		**10**	**100.0%**	**1.24 [0.87, 1.75]**
Total events	10		8			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.20 (P = 0.23)

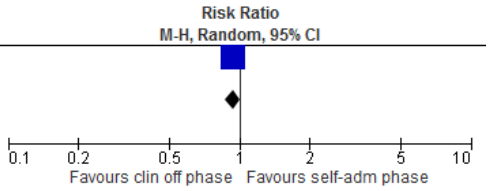


Satisfaction with the contraception service/method (recommend it to a friend)

At 12 months

Study or Subgroup	Self-adm women Events	Total	Clinicians Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Cameron 2012 Scotland UK	57	61	53	53	100.0%	0.94 [0.87, 1.01]
Total (95% CI)		**61**		**53**	**100.0%**	**0.94 [0.87, 1.01]**
Total events	57		53			

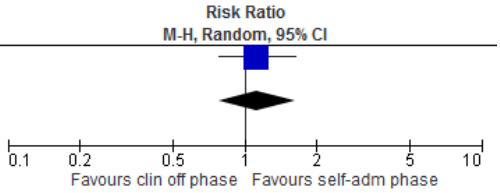
Heterogeneity: Not applicable
Test for overall effect: Z = 1.74 (P = 0.08)



At 3 months

Study or Subgroup	Self-adm phase Events	Total	Clin office phase Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Stanwood 2006 USA	9	10	8	10	100.0%	1.13 [0.78, 1.63]
Total (95% CI)		**10**		**10**	**100.0%**	**1.13 [0.78, 1.63]**
Total events	9		8			

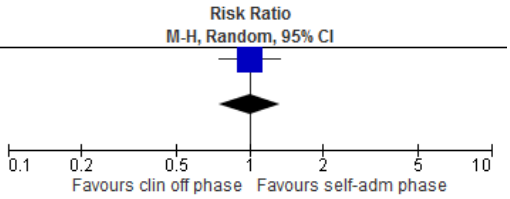
Heterogeneity: Not applicable
Test for overall effect: Z = 0.62 (P = 0.54)



Satisfaction with the contraception service/method (satisfaction in location (at 3 months))

Study or Subgroup	Self-adm phase Events	Total	Clin off phase Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Stanwood 2006 USA	9	10	9	10	100.0%	1.00 [0.75, 1.34]
Total (95% CI)		**10**		**10**	**100.0%**	**1.00 [0.75, 1.34]**
Total events	9		9			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



GRADE (CONTRA1: Women)

Author(s): Fonhus MS and Fretheim A
Date: 30.09.2014
Question: Should CONTRA2 women self vs clinician be used in contraceptive injections/implants?
Settings: USA and United Kingdom
Bibliography (systematic reviews): Included primary studies: Stanwood 2006 USA, Beasley 2014 USA and Cameron 2012 (United Kingdom)

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	CONTRA1 Women self	Clinicians	Relative (95% CI)	Absolute (95% CI)		
Effectiveness: uptake of injectable contraceptive												
0												
Effectiveness: continuation (non-interrupted use at 12 months) RCT												
1	randomized trial	not serious	not serious	not serious	very serious [2]	none	28/86 (32.6%)	14/46 (30.4%)	RR 1.07 (0.63 to 1.82)	21 more per 1000 (from 113 fewer to 250 more)	⊕⊕◯◯ LOW	
Effectiveness: continuation (non-interrupted use at 12 months) non-RCT												
1	observational study	serious [1]	not serious	not serious	very serious [2]	none	51/58 (87.9%)	50/64 (78.1%)	RR 1.13 (0.96 to 1.32)	102 more per 1000 (from 31 fewer to 250 more)	⊕◯◯◯ VERY LOW	
Effectiveness: continuation (non-interrupted use at 3 months) non-RCT												
1	observational study	serious [1]	not serious	not serious	very serious [2]	none	10/10 (100.0%)	10/10 (100.0%)	RR 1 (0.83 to 1.2)	0 fewer per 1000 (from 170 fewer to 200 more)	⊕◯◯◯ VERY LOW	
Safety: serious adverse events												
0												
Safety: other complications												
1									not estimable	not estimable		
Satisfaction with the contraception method (want to continue this method) at 12 months												
1	observational study	serious [1]	not serious	not serious	very serious [2]	none	55/61 (90.2%)	50/55 (90.9%)	RR 0.99 (0.88 to 1.12)	9 fewer per 1000 (from 109 more to 109 fewer)	⊕◯◯◯ VERY LOW	
Satisfaction with the contraception method (prefer to continue the method) at 3 months												
1	observational study	serious [1]	not serious	not serious	very serious [2]	none	10/10 (100.0%)	8/10 (80.0%)	RR 1.24 (0.87 to 1.75)	192 more per 1000 (from 600 more to 104 fewer)	⊕◯◯◯ VERY LOW	
Satisfaction with the contraception method (recommend to a friend) at 12 months												
1	observational study	serious [1]	not serious	not serious	very serious [2]	none	57/61 (93.4%)	53/53 (100.0%)	RR 0.94 (0.87 to 1.01)	60 fewer per 1000 (from 130 fewer to 10 more)	⊕◯◯◯ VERY LOW	
Satisfaction with the contraception method (recommend to a friend) at 3 months												
1	observational study	serious [1]	not serious	not serious	very serious [2]	none	9/10 (90.0%)	8/10 (80.0%)	RR 1.13 (0.78 to 1.63)	104 more per 1000 (from 176 fewer to 504 more)	⊕◯◯◯ VERY LOW	
Satisfaction in location (at 3 months)												
1	observational study	serious [1]	not serious	not serious	very serious [2]	none	9/10 (90.0%)	9/10 (90.0%)	RR 1 (0.75 to 1.34)	0 fewer per 1000 (from 225 fewer to 306 more)	⊕◯◯◯ VERY LOW	

MD: mean difference; RR; relative risk.
[1] High risk of bias in included study
[2] One study only with few participants
High certainty evidence: Further research is very unlikely to change our certainty of the estimate of effect. Moderate certainty evidence: Further research is likely to have an important impact on the certainty of the estimate of effect and may change the estimate. Low certainty evidence: Further research is very likely to have an important impact on the certainty of the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain. Very low certainty evidence: Any estimate of effect is very uncertain

Characteristics of primary studies included for CONTRA1:

Beasley 2014 USA

Methods	Randomized controlled trial
Participants	137 women with 91 women allocated to self-administration of the injectable and 46 women to the clinician administration
Interventions	To evaluate the feasibility, acceptability, continuation and trough serum levels following self-administration of subcutaneous depot medroxyprogesterone acetate (DMPA). Participants randomized to the self-administration group were taught to self-inject, were supervised in performing the initial injection, received printed instructions and a supply of injections for home use. Participants randomized to the clinician group received usual care
Outcomes	Effectiveness: uptake of injectable contraceptive, continuation rates/re-injection at 12 months Safety: serious adverse events, other complications Overall satisfaction with contraceptive service/method
Notes	

Cameron 2012 United Kingdom

Methods	Prospective cohort study
Participants	A total of 128 participants were enrolled. There were 64 women in the self-injection group and 64 women in the control group
Interventions	To assess the feasibility of self-administration of subcutaneous DMPA. Existing users of DMPA who desired to self-inject were taught self-administration of DMPA-SC. The control group continued to attend the clinic to receive the DMPA injection.
Outcomes	Effectiveness: uptake of injectable contraceptive, continuation rates/re-injection at 12 months. Safety: serious adverse events, other complications. Overall satisfaction with contraceptive service/method.
Notes	This study used existing DMPA users.

Picardo 2010 USA

Methods	Randomized controlled trial
Participants	A total of 50 women were enrolled. 25 women were allocated to the pharmacy group and 25 women to the clinic group
Interventions	To assess the feasibility of DMPA administration in the pharmacy setting. The participants presented to the family planning clinic with intent to initiate, continue or restart any form of DMPA. Those who were enrolled were then randomized to receive the 2 subsequent injections at a nearby pharmacy by trained pharmacists or at the clinic.
Outcomes	Effectiveness: uptake of injectable contraceptive, continuation rates/re-injection. Safety: serious adverse events, other complications, overall satisfaction with contraceptive service/method. Overall satisfaction with provider.
Notes	

Stanwood 2006 USA

Methods	Prospective cohort trial with crossover
Participants	A total of 16 subjects were enrolled to the study. Ten subjects completed the study protocol.
Interventions	To compare home self-injection of a monthly combined hormonal contraceptive with office administration. The participants were taught self-injection at the clinic, then performed three self-injections at home and then received three office injections by a nurse
Outcomes	Effectiveness: uptake of injectable contraceptive, continuation rates/re-injection. Safety: serious adverse events, other complications. Overall satisfaction with contraceptive service/method.
Notes	

Annex 15. Systematic review summary: Surgical management of induced and/or incomplete abortion performed by doctors of complementary systems of medicine, associate clinicians, midwives, nurses or auxiliary nurses or midwives

Background

Unsafe abortion remains an important cause of global maternal mortality. Health worker shortages and restrictive policies on who may provide abortion services limit access to safe abortion, potentially increasing the likelihood of unsafe abortion and its downstream consequences. A key strategy to improving access to safe abortion may include optimizing the available workforce offering these services.

Objectives

1. To evaluate the effectiveness, safety and satisfaction among treated women when ***surgical abortion with manual or electric vacuum aspiration (MVA or EVA) through 12 –14 weeks of gestation*** is provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with non-specialist or specialist doctors (obstetricians/gynaecologists).

2. To evaluate the effectiveness, safety and satisfaction among treated women when ***surgical abortion by dilatation and evacuation (D&E) beyond 12–14 weeks of gestation*** is provided by non-specialist doctors, doctors of complementary systems of medicine or associate clinicians compared with specialist doctors (obstetricians/gynaecologists).

3. To evaluate the effectiveness, safety and satisfaction among treated women when ***cervical preparation prior to surgical abortion using either medical means or osmotic dilators*** is initiated by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with non-specialist or specialist doctors (obstetricians/gynaecologists).

4. To evaluate the effectiveness, safety and satisfaction among treated women when ***surgical management of incomplete abortion by manual or electric vacuum aspiration (MVA or EVA) with uterine size < 13 weeks size*** **is provided** by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with non-specialist or specialist doctors (obstetricians/gynaecologists).

5. To evaluate the effectiveness, safety and satisfaction among treated women when ***management of surgical abortion-related complications other than incomplete abortion (e.g. bleeding, infection, cervical trauma, uncomplicated uterine perforation) in clinically stable women*** is performed by non-specialist doctors, doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with specialist doctors (obstetricians/gynaecologists).

Search methods

PubMed, Embase, CINAHL, Global Index Medicus, Popline and Clinicaltrials.gov were systematically searched from inception through 15 September 2014. There were no date or language restrictions. Reference lists of key review articles were also hand searched and external experts were contacted to identify any additional relevant studies for inclusion.

Selection criteria

Types of studies

The types of studies considered for inclusion were randomized controlled trials, including equivalence and non-inferiority trials as well as comparative observational studies (cohort and case–control).

Participants

Participants included women seeking management of induced or incomplete abortion or surgical abortion-related complications both before and after 12–14 weeks gestational age.

Interventions

Service delivery provided by various health worker cadres as defined in the objectives was compared to either or both non-specialist or specialist physicians (obstetricians/gynaecologists).

Manual and electric vacuum aspiration (MVA and EVA) are WHO-recommended methods for surgical abortion through 12–14 weeks of gestation and surgical management of incomplete abortion with uterine size < 13 weeks size. MVA relies on a hand-held aspirator to generate suction while EVA uses an electric pump to generate a vacuum; these procedures are performed similarly, regardless of the type of vacuum used. Dilation and evacuation is the WHO-recommended method for surgical abortion beyond 12–14 weeks of gestation. Cervical preparation with medication (e.g. misoprostol) or osmotic dilators prior to surgical management for induced abortion is not recommended routinely before 12 to 14 weeks; however, it may be considered. Routine cervical preparation is recommended beyond this threshold. These procedures are also associated with various other co-interventions such as diagnostic evaluation to determine eligibility and successful treatment (e.g. physical examination, ultrasound) as well as pain management and antibiotic prophylaxis.

Management of surgical abortion-related complications includes detection of a range of known potential complications and additional management (e.g. supportive care, resuscitation, further medical/surgical treatment, referral).

Outcomes

Effectiveness of surgical management (induced abortion or management of incomplete abortion) was defined as complete abortion following the procedure (e.g. absence of retained products of conception/incomplete abortion and/or need for additional uterine evacuation with medical or surgical treatment, ongoing pregnancy or ectopic pregnancy).

Successful management of surgical abortion-related complications among clinically stable women was defined as accurate determination of a complication followed by an offer of correct treatment or referral depending on professional capacity and clinical setting.

Effectiveness of cervical preparation was defined as degree of dilation and perceived ease of procedure. Safety outcomes included cervical or uterine injury/perforation, need for emergent surgical intervention or extramural expulsion of the products of conception/fetus.

Serious adverse events were defined as a need for hospital admission, need for further surgery (excluding treatment for incomplete abortion or ongoing pregnancy), blood transfusion, or death. When the severity of reported outcomes was uncertain and/or hospital admission and treatment was not clearly stated to accurately appraise reported abortion-related complications, we reported overall complications, including haematometra, bleeding/haemorrhage, infection, uterine perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death.

Measures of satisfaction included reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type. We also included studies reporting on women's overall abortion experience by provider type.

While the clinical contexts for a woman undergoing surgical management of an induced abortion versus emergency treatment for an incomplete abortion may be distinct, the procedure to evacuate the uterine cavity is the same. Any studies reporting on the effectiveness, safety or satisfaction among treated women with a given health worker cadre providing surgical treatment in one setting was considered indirect evidence for the other.

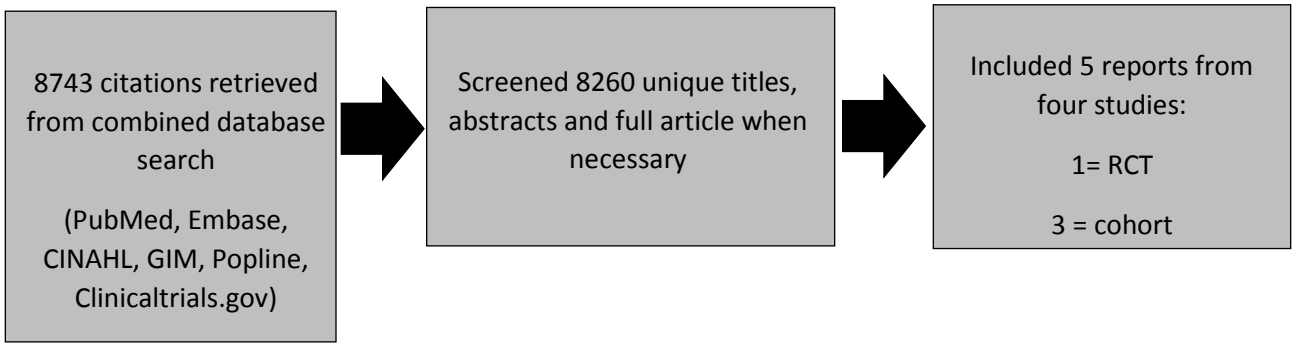
Data collection and analysis

Titles and abstracts were screened for inclusion. In the absence of direct evidence, potential papers were screened for indirect evidence. Two authors (MD and SJ) independently reviewed studies for inclusion in the review and independently extracted data for each study. Risk of bias was also assessed independently by two review authors (MD and MSF) according to study design using the criteria outlined in the *Cochrane handbook for systematic reviews of interventions*. We resolved disagreements

by discussion with the other review authors. The overall quality (certainty) of the evidence was classified according to the Grading of Recommendations Assessment, Development and Evaluation system (GRADE) (AF and MSF). The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. Evidence can be downgraded from "high quality" by one level for serious, or by two levels for very serious, limitations depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias. The GRADE profiler (Grade 2014) was used to import data from Review Manager 5.3 (RevMan 2014) to create GRADE evidence profiles and Summary of Findings tables. Forest plots were made to graphically illustrate the relative risk estimates. Meta-analyses were performed when more than one trial reported risk estimates relevant to critical outcomes by health worker cadre.

Main results

Figure 1. Identification of studies for inclusion



Overall, the search strategy generated 8743 citations. Of the 8260 unique citations identified and screened, five articles met inclusion criteria for this review [1–5]. One randomized, controlled equivalence trial evaluated performance of over 1000 MVA procedures for induced abortion by a mixed group of mid-level providers (midwives n=13 and 1 doctor assistant) compared with doctors (n=11) in South Africa and Viet Nam through 12 weeks of gestation (mean gestational age [GA] South Africa: 7.7 weeks; mean GA Viet Nam: 6.1 weeks) [1]. One prospective cohort study conducted in India compared outcomes associated with over 1000 MVA provided by 10 nurses and 10 physicians through 10 weeks GA (mean GA Nurses: 8.7 weeks; mean GA Physicians: 8.5 weeks) [2]. We also included three reports of two prospective cohort studies that were conducted in the United States and recruited women seeking surgical management of induced abortion through 12–14 weeks of gestation [3–5]. One study reported on effectiveness and safety of a total of approximately 1300 MVA and EVA procedures conducted by physician assistants (n=3) and physicians (n=3), and the other compared outcomes of 11 827 women treated by a mixed group of associate clinicians (n=35) and midwives (n=5) to physicians (n=96) offering MVA and EVA. Years of professional experience and training in surgical abortion prior to study participation varied by provider type and across studies.

Surgical abortion from 12 to 14 weeks (Annex 1)

One randomized, equivalence trial and four reports from three prospective cohort studies recorded effectiveness, safety and/or satisfaction with surgical abortion when provided by particular non-physician providers [1–5]. One study reported direct evidence regarding provision of surgical abortion by associate clinicians [3], and one study reported direct evidence regarding provision of surgical abortion by nurses [2]. Three studies evaluated performance tasks of mixed groups of associate clinicians and midwives and did not disaggregate outcomes [1, 4, 5]. No evidence regarding surgical abortion performed by doctors of complementary systems of medicine or auxiliary nurse midwives was identified.

Associate clinicians (Annex 1c)

Effectiveness: Probably no difference in effectiveness when surgical abortion was provided by mixed groups of associate clinicians, including nurse practitioners and physician or doctor assistants, compared with physicians was noted (1 RCT: RR 0.99, 95% CI 0.98, 1.00; 2 non-RCTs: RR 0.99, 95% CI 0.98, 1.00) [1, 3, 4]. These results from the RCT suggest that there is probably little or no difference in the rate of complete abortions when associate clinicians provide surgical abortion compared to physicians (evidence of moderate certainty); two non-RCTs were also identified for this outcome, but the evidence was of very low certainty.

Safety: Serious adverse events and any abortion-related complications were rare regardless of provider type. However, we are uncertain of the effect on serious adverse events as the certainty of the evidence has been assessed as very low. There is probably little or no difference in the rate of any surgical abortion-related complications when associate clinicians provide surgical abortion compared to physicians (evidence of moderate certainty).

Satisfaction: One non-RCT noted that the likelihood of reporting an “excellent” overall experience among women treated by different provider groups was similar, an outcome related to satisfaction 8(Evidence of low certainty). The certainty of the evidence has not been assessed because of limited data provided.

Midwives (Annex 1d)

Effectiveness: No difference in effectiveness when surgical abortion was provided by midwives (RCT: RR 0.99, 95% CI 0.98, 1.00; non-RCT: RR 1.0, 95% CI 0.99, 1.00) was noted; however, provider types were mixed and no disaggregated outcomes were available [1, 4]**.** These results suggest that there is probably little or no difference in the rate of complete abortions when midwives provide surgical abortion compared to physicians (evidence of moderate certainty). One non-RCT was also identified for this outcome and reported consistent results; however the evidence was of very low certainty.

Safety: Serious adverse events or any abortion-related complications were rare regardless of provider type. However, we are uncertain of the effect serious adverse events as the certainty of the evidence has been assessed as very low (one non-RCT). There is probably little or no difference in the rate of any surgical abortion-related complications when midwives provide surgical abortion compared to physicians (evidence of moderate certainty).

Satisfaction: No evidence was identified.

Nurses (Annex 1e)

Effectiveness: One cohort study from India reported performance measures comparing nurses and physicians [2]. Women in both groups had a similar likelihood of complete abortion suggesting that there may be little or no difference in the rate of complete abortions when nurses provide surgical abortion compared to physicians (evidence of low certainty).

Safety: Complications were rare (not reported or few events reported) regardless of provider type leading to a conclusion that there may be little or no difference in the rates of any surgical abortion-related complications when nurses provide surgical abortion compared to physicians (evidence of low certainty).

Satisfaction: Satisfaction with providers and the services they provided were equivalent. There may be little or no difference in satisfaction with abortion service and abortion provider when nurses provide surgical abortion compared to physicians (evidence of low certainty).

Surgical abortion > 12–14 weeks (Annex 3)

No studies were identified comparing the effectiveness, safety or satisfaction with surgical abortion beyond 12–14 weeks provided by non-specialist doctors, doctors of complementary systems of medicine or associate clinicians that met criteria for inclusion in this review.

Cervical preparation with medication or osmotic dilators (Annexes 4 and 5)

No studies were identified comparing the effectiveness, safety or satisfaction with cervical preparation prior to surgical abortion using either medical means or osmotic dilators provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with non-specialist or specialist doctors.

Surgical management of incomplete abortion (uterine size < 13 weeks) (Annex 2)

While no studies were identified comparing the safety, effectiveness or satisfaction among treated women of surgical management of incomplete abortion by non-physician providers that met criteria for inclusion in this review, evidence speaking to any of these providers' ability to effectively, safely and satisfactorily provide surgical induced abortion was considered relevant indirect evidence.

Management of surgical abortion-related complications in clinically stable women (Annex 10)

No studies were identified comparing the effectiveness, safety or satisfaction among treated women with management of surgical abortion-related complications other than incomplete abortion (e.g. bleeding, infection, cervical trauma, uncomplicated uterine perforation) in clinically stable women provided by non-specialist doctors, doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with specialist doctors.

Authors' conclusions

Evidence of low to moderate certainty suggests that associate clinicians, midwives and nurses probably can provide surgical abortion from 12 to 14 weeks with similar effectiveness and safety compared to physicians. Evidence of low certainty suggests that satisfaction among treated women may be similar when nurses provide surgical abortion from 12 to 14 weeks compared to physicians. There was no evidence or evidence of very low certainty for this outcome for the two other health worker cadres.

No evidence was identified regarding management of surgical abortion by doctors of complementary systems of medicine or auxiliary nurse midwives to this gestational limit. Further, there is no evidence to determine whether cervical preparation and provision of surgical abortion beyond 12–14 weeks is effective, safe and satisfactory to women when provided by various non-physician providers.

Given evidence for appropriate management of induced abortion with manual or electric vacuum aspiration through 12–14 weeks, it is possible that associate clinicians, midwives and nurses may be able to offer the same procedure for management of incomplete abortion for uterine sizes less than 13 weeks with similar effectiveness, safety and satisfaction among treated women compared to physicians; however, further research is necessary. Overall, serious adverse events and any abortion-related complications were rare (not reported or few events reported). No evidence was identified comparing identification and management of other surgical abortion-related complications among clinically stable women by different provider types.

Quality of evidence

Very low to moderate.

References

1. Warriner IK, Meirik O, Hoffman M, Morroni C, Harries J, My Huong NT, et al. Rates of complication in first-trimester manual vacuum aspiration abortion done by doctors and mid-level providers in South Africa and Vietnam: a randomised controlled equivalence trial. Lancet. 2006;368(9551):1965-72.

2. Jejeebhoy SJ, Kalyanwala S, Zavier AJ, Kumar R, Mundle S, Tank J, et al. Can nurses perform manual vacuum aspiration (MVA) as safely and effectively as physicians? Evidence from India. Contraception. 2011;84(6):615-21.

3. Goldman MB, Occhiuto JS, Peterson LE, Zapka JG, Palmer RH. Physician assistants as providers of surgically induced abortion services. American Journal of Public Health. 2004;94(8):1352-7.

4. Weitz TA, Taylor D, Desai S, Upadhyay UD, Waldman J, Battistelli MF, et al. Safety of aspiration abortion performed by nurse practitioners, certified nurse midwives, and physician assistants under a California legal waiver. American Journal of Public Hhealth. 2013;103(3):454-61.

5. Taylor D, Postlethwaite D, Desai S, James EA, Calhoun AW, Sheehan K, et al. Multiple determinants of the abortion care experience: from the patient's perspective. American Journal of Medical Quality. 2013;28(6):510-8.

Annex 16. Systematic review summary: Medical management of induced and/or incomplete abortion performed by doctors of complementary systems of medicine, associate clinicians, midwives, nurses or auxiliary nurses or midwives

Background

Unsafe abortion remains an important cause of global maternal mortality. Health worker shortages and restrictive policies on who may provide abortion services limit access to safe abortion, potentially increasing the likelihood of unsafe abortion and its downstream consequences. A key strategy to improve access to safe abortion may include optimizing the available workforce offering these services.

Objectives

1. To evaluate the effectiveness, safety and satisfaction among treated women when ***medical abortion with mifepristone and misoprostol or misoprostol alone up to 12 weeks of gestation*** is provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with non-specialist or specialist doctors (obstetricians/gynaecologists).

2. To evaluate ***eligibility assessments for medical abortion up to 12 weeks of gestation*** when performed by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with non-specialist or specialist doctors (obstetricians/gynaecologists).

3. To evaluate the effectiveness, safety and satisfaction among treated women when ***medication administration*** is performed by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with non-specialist or specialist doctors (obstetricians/gynaecologists).

4. To evaluate the effectiveness, safety and satisfaction among treated women of ***the management of common side-effects associated with medical abortion*** when performed by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with non-specialist or specialist doctors (obstetricians/gynaecologists).

5. To evaluate the ***successful determination of abortion completion*** by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with non-specialist or specialist doctors (obstetricians/gynaecologists) following medical abortion.

6. To evaluate the effectiveness, safety and satisfaction among treated women when ***medical abortion with mifepristone and misoprostol or misoprostol alone beyond 12 weeks of gestation is provided*** by non-specialist doctors, doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with specialist doctors (obstetricians/gynaecologists).

7. To evaluate the effectiveness, safety and satisfaction among treated women when ***medical management of incomplete abortion with uterine size up to 13 weeks size is performed*** by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with non-specialist or specialist doctors (obstetricians/gynaecologists).

8. To evaluate the effectiveness, safety and satisfaction among treated women when ***management of medical abortion-related complications other than incomplete abortion (e.g. bleeding, infection) in clinically stable women*** are performed by non-specialist doctors, doctors of complementary systems of medicine, associate clinicians, midwives, nurses, or auxiliary nurses or midwives compared with specialist doctors (obstetricians/gynaecologists).

Search methods

PubMed, Embase, CINAHL, Global Index Medicus, Popline and Clinicaltrials.gov were systematically searched from inception through 15 September 2014. There were no date or language restrictions. Reference lists of key review articles were also hand searched and external experts were contacted to identify any additional relevant studies for inclusion.

Selection criteria

Types of studies

The types of studies considered for inclusion were randomized controlled trials, including equivalence and non-inferiority trials and comparative observational studies (cohort and case–control).

Participants

Participants included women undergoing medical management of induced or incomplete abortion or care for medical abortion-related complications both before and after 12 weeks gestational age.

Interventions

Services delivered by various health worker cadres as defined in the objectives was compared to either or both non-specialist or specialist physicians.

The *WHO Safe abortion: technical and policy guidance for health systems* notes that the most effective regimens for medical abortion rely on a combination of mifepristone and misoprostol (up to 98%). Mifepristone inhibits the action of progesterone and interferes with the continuation of pregnancy. Misoprostol is a synthetic prostaglandin analogue which enhances uterine contractions and aids in expulsion of the products of conception [6]. Misoprostol can also be used alone to medically manage abortion when mifepristone is not available. Misoprostol-alone regimens are safe and effective; however, effectiveness is lower compared to combined regimens and the time to complete abortion is prolonged. Misoprostol as a single agent is recommended for medical management of incomplete abortion.

While complications associated with medical abortion are rare, known complications that may be potentially life-threatening can include bleeding/haemorrhage, infection, uterine rupture and drug or anaesthesia-related adverse events. Management of medical abortion-related complications includes detection of the range of these potential complications and additional management which can include supportive care, resuscitation, and referral for or provision of further medical/surgical treatment as necessary.

Outcomes

Effectiveness of medical management (induced abortion or management of incomplete abortion) was defined as complete abortion without need for additional intervention following the procedure (e.g. absence of retained products of conception/incomplete abortion, ongoing pregnancy or ectopic pregnancy).

Successful management of medical abortion-related complications in clinically stable women was defined as accurate determination of a complication followed by an offer of correct treatment or referral depending on professional capacity and clinical setting.

Serious adverse events were defined as a need for hospital admission, blood transfusion or death and indicated the safety of services by provider type.

Measures of satisfaction among treated women included reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type.

Correct identification of pregnancy status, pregnancy duration and other medical eligibility for treatment by a particular health worker cadre compared to a physician assessment defined accurate eligibility assessment. Appropriate administration of medications was measured by participants' adherence to the prescribed medical abortion regimen. Common abortion side-effects included fevers, chills, nausea, vomiting, diarrhoea, pain, and bleeding and evidence comparing management outcomes by provider types was sought. Accurate assessment of abortion completion was defined as correct determination of complete abortion (versus incomplete abortion or ongoing/ectopic pregnancy) compared to a physician assessment or other diagnostic standard. Methods to determine eligibility or completion could include clinical assessments and/or diagnostic testing (e.g. pregnancy testing, ultrasound), in some cases, guided by the use of job aids or checklists.

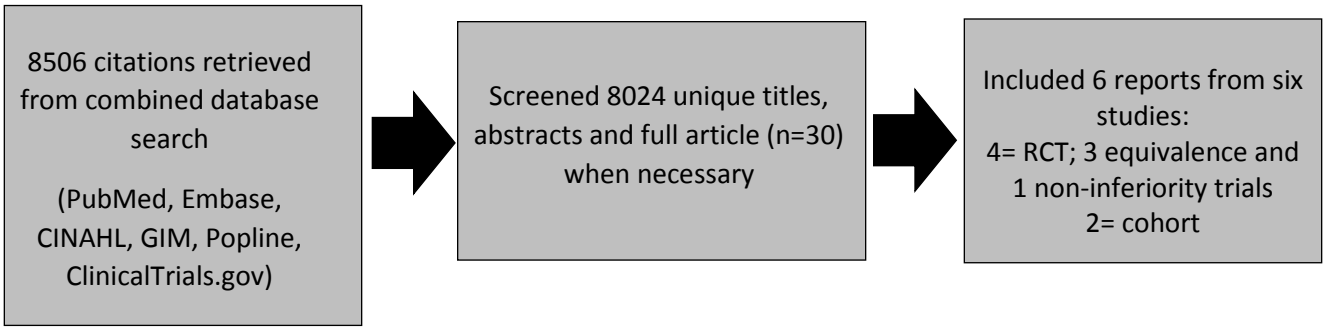
While the clinical contexts for a woman undergoing medical management of an induced abortion versus emergency treatment for an incomplete abortion may be distinct, many elements of the treatment are the same. Any studies reporting on the effectiveness, safety or satisfaction of a given health worker cadre providing medical management in one setting were considered indirect evidence for the other. Also, evidence for effective, safe and satisfactory medical treatment for medical abortion overall by provider type was considered indirect evidence for performance of the component subtasks when direct evidence was not identified.

Data collection and analysis

Titles and abstracts were screened for inclusion. In the absence of direct evidence, potential papers were screened for indirect evidence. Two authors (MD and SJ) independently reviewed studies for inclusion in the review and independently extracted data for each study. Risk of bias was also assessed independently by two review authors (MD and MSF) according to study design using the criteria outlined in the *Cochrane handbook for systematic reviews of interventions*. We resolved disagreements by discussion with the other review authors. The overall quality (certainty) of the evidence was classified according to the Grading of Recommendations Assessment, Development and Evaluation system (GRADE) (AF and MSF). The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. Evidence can be downgraded from “high quality” by one level for serious, or by two levels for very serious limitations depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias. The GRADE profiler (Grade 2014) was used to import data from Review Manager 5.3 (RevMan 2014) to create GRADE evidence profiles and Summary of Findings tables. Forest plots were made to graphically illustrate the relative risk estimates. Meta-analyses were performed when more than one trial reported risk estimates relevant to critical outcomes by health worker cadre.

Main results

Figure 1. Identification of studies for inclusion



Overall, the search strategy yielded 8506 citations. Of the 8024 unique citations identified and screened, 30 full text articles were evaluated with final inclusion of four published articles [7–10]. Two relevant ongoing trials were also identified via clinicaltrials.gov and the investigators were contacted. They shared draft manuscripts for appraisal by the evidence team and ultimately these data were included during the process of seeking peer-reviewed publication of the trial results; both are currently in press [11, 12].

Medical abortion up to 12 weeks (Annex 6)

Three randomized, equivalence trials and one prospective cohort study reported on effectiveness, safety and/or women's satisfaction when medical abortion was provided by particular non-physician providers [7, 8, 10, 11]. No studies reported on practice by associate clinicians. Years of professional experience and training to provide medical abortion varied by health worker cadre and across studies. All participants received a combined mifepristone misoprostol regimen, and these studies were conducted in India, Mexico, Nepal and Sweden. The maximum gestational limits for treatment in these studies were 56 days [8], 63 days [7, 10], and 70 days [11].

Doctors of complementary systems of medicine (Annex 6b)

One prospective cohort study conducted in India reported direct evidence regarding provision of medical abortion by Ayurvedic physicians (n=10) compared to allopathic physicians (n=10) through 56 days' gestation [8].

> ***Effectiveness:*** No differences were noted in treatment effectiveness by provider type (RR: 0.99, 95% CI 0.96, 1.02). Based on these findings, there may be little or no difference in complete abortions when doctors of complementary systems of medicine provide medical abortion compared to physicians (evidence of low certainty).
>
> ***Safety:*** No serious adverse events were reported, leading to a conclusion that there may be little or no difference in the rate of serious adverse events when doctors of complementary systems of medicine provide medical abortion compared to physicians (evidence of low certainty).
>
> ***Satisfaction:*** Both satisfaction with the provider and abortion services were similarly high and there was no difference across groups suggesting that there may be little or no difference in satisfaction with the abortion service or provider when doctors of complementary systems of medicine provide medical abortion compared to physicians (evidence of low certainty).

Midwives (Annex 6d)

One equivalence trial evaluated outcomes when medical abortions through 63 days' gestation were provided by experienced midwives (n=2) and physicians of varying professional experience (n=34) in Sweden [10].

> ***Effectiveness:*** This study noted that treatment effectiveness by provider type was similar (RR: 1.02, 95% CI 1.00, 1.03). Based on these findings, there is probably little or no difference in the number of complete abortions when midwives provide medical abortion compared to physicians (evidence of moderate certainty).

Safety: No serious adverse events were reported, leading to a conclusion that there may be little or no difference in the rate of serious adverse events when midwives provide medical abortion compared to physicians (evidence of moderate certainty).

Satisfaction: Women did report more satisfaction when midwives were their assigned provider (RR: 16.6, 95% CI 9.4, 29.4) suggesting that more women are probably satisfied when midwives provide medical abortion compared to physicians (evidence of moderate certainty).

Nurses (Annex 6e)

One equivalence trial and one prospective cohort study provided direct evidence for medical abortion provided by nurses compared to physicians [8, 11]. Another equivalence trial reported results from a mixed group of nurses (n=8) and auxiliary nurse midwives (n=3) compared to a mixed group of doctors with varying professional experience (n=14); disaggregated results were not reported [7].

Effectiveness: Overall, effectiveness did not vary by provider type (RCT RR: 0.97, 95% CI 0.89, 1.06; non-RCT RR: 1.00, 95% CI 0.97, 1.03) leading to the conclusion that there is probably little or no difference in the number of complete abortions when nurses provide medical abortion compared to physicians (evidence of moderate certainty).

Safety: Only one serious adverse event was noted across studies (in the physician group) suggesting that there is probably little or no difference in the rate of serious adverse events when nurses provide medical abortion compared to physicians (evidence of moderate certainty). One non-RCT was also identified for this outcome, but the evidence was of low certainty and did not give any additional information.

Satisfaction: High levels of satisfaction with both the provider type and abortion services they managed were similar across groups in the two studies reporting these outcomes. There is probably little or no difference in overall satisfaction with the abortion service and provider when nurses provide medical abortion compared to physicians (evidence of moderate certainty).

Auxiliary nurses or midwives (Annex 6f)

One equivalence trial reported results of a mixed group of nurses (n=8) and auxiliary nurse midwives (n=3) compared to a mixed group of doctors with varying professional experience (n=14) offering medical abortion; disaggregated results were not reported [7].

Effectiveness: This study noted that treatment effectiveness by provider type was similar (RR 1.01, 95% CI 0.99, 1.03) leading to the conclusion that there is probably little or no difference in the number of complete abortions when auxiliary nurses/midwives provide medical abortion compared to physicians (evidence of moderate certainty).

Safety: No serious adverse events were reported in this study suggesting that there is probably little or no difference in the rates of serious adverse events when auxiliary nurses/midwives provide medical abortion compared to physicians (evidence of moderate certainty).

Satisfaction: No evidence was identified.

Eligibility assessment (Annex 6.1)

Two equivalence trials and one prospective cohort study provided evidence regarding accurate determination of eligibility for medical abortion by doctors of complementary systems of medicine, nurses and auxiliary nurses or midwives [7, 8, 11]. No direct evidence was identified specifically regarding competency with this skill for associate clinicians or midwives; however, one equivalence trial reported medical abortion was safe, effective and satisfactory when midwives managed the entire medical abortion process (see above) [10].

Doctors of complementary systems of medicine (Annex 6.1b)

Ayurvedic physicians (n=10) and allopathic physicians (n=10) with no prior experience providing medical abortion through 56 days' gestation assessed women's eligibility for the procedure by conducting a medical history, physical exam and pregnancy testing [8]. Women were then evaluated independently by a certified abortion provider with a minimum of five years' professional experience; this assessment served as a standard against which to compare newly trained provider conclusions. Eligibility determinations by Ayurvedic physicians were concordant with the independent verifier's conclusions (RR 1.01, 95% CI 0.98, 1.03), similar to results for newly trained allopathic physicians. It appears that there may be little or no difference to the accuracy of eligibility assessments when doctors of complementary systems of medicine assess eligibility for medical evidence compared to physicians (evidence of low certainty).

Nurses (Annex 6.1e)

One equivalence trial and one prospective cohort study reported on eligibility assessment for medical abortion provided by nurses compared to physicians [8, 11]. Another equivalence trial reported results of a mixed group of nurses (n=8) and auxiliary nurse midwives (n=3) compared to a mixed group of doctors with varying professional experience (n=14). Disaggregated results were not reported [7]. Results from the two equivalence trials show that there was no difference in the proportion of women assessed as eligible for medical abortion following clinical examination and assessment by provider type (RR: 1.01, 95% CI 0.99, 1.02) [7, 11]. In the prospective cohort study, nurses and allopathic physicians with no prior experience providing medical abortion assessed women's eligibility for the procedure by conducting a medical history, physical exam and pregnancy testing. Women were then evaluated independently by a certified abortion provider with a minimum of 5 years' professional experience who served as a standard against which to compare provider conclusions. Eligibility determinations by nurses were concordant with the independent verifier's conclusions (RR: 1.00, 95% CI 0.97, 1.03), similar to results for newly trained allopathic physicians [8]. Overall, these results suggest that there may be little or no difference in the accuracy of eligibility assessments when nurses assess eligibility for medical abortion compared to physicians (evidence of low certainty).

Auxiliary nurses or midwives (Annex 6.1f)

One equivalence trial reported results of a mixed group of nurses (n=8) and auxiliary nurse midwives (n=3) compared to a mixed group of doctors with varying professional experience (n=14); disaggregated results were not reported [7]. There was no difference in the proportion of women assessed as eligible for medical abortion following clinical examination and assessment across groups (RR: 1.01, 95% CI 0.99, 1.03). It appears that there is probably little or no difference in the number of women assessed as being

eligible when auxiliary nurse midwives/nurses assess eligibility for medical abortion compared to physicians (evidence of moderate certainty).

Administration of medication for medical abortion with instructions for use (Annex 6.2)

Two equivalence trials reported on the proportion of women who were lost to follow up after administration of mifepristone to initiate medical abortion managed by nurses or a mixed group of nurses and auxiliary nurse midwives. There was no difference in the proportion of women not returning for further evaluation and/or confirmation of adherence to the medical regimen when compared to a mixed group of doctors with varying professional experience across studies [7, 11].

Nurses (Annex 6.2e)

These results suggest that there is little or no difference in the rate of appropriate medication administration when nurses inform or instruct use compared to physicians (evidence of high certainty).

Auxiliary nurses or midwives (Annex 6.2f)

And, that there is probably little or no difference in the rate of appropriate medication administration when auxiliary nurses or midwives inform or instruct use compared to physicians (evidence of moderate certainty).

No direct evidence was identified for this task for doctors of complementary systems of medicine, associate clinicians or midwives; however, indirect evidence was identified suggesting that management of medical abortion by doctors of complementary systems of medicine, associate clinicians or midwives was safe, effective and satisfactory overall (see above).

Management of common side-effects of medical abortion (Annex 6.3)

No studies were identified for inclusion.

Assessment of completion of medical abortion (Annex 6.4)

Two prospective cohort studies reported on determination of abortion completion following both induced medical abortion and/or spontaneous abortion by doctors of complementary systems of medicine and nurses [8, 9]. No direct evidence was identified regarding competency with this task for associate clinicians, midwives or auxiliary nurses or midwives; however, indirect evidence was identified suggesting that management of medical abortion by midwives and/or auxiliary nurses or midwives was safe, effective and satisfactory overall (see above).

Doctors of complementary systems of medicine (Annex 6.4b)

In one prospective cohort study, Ayurvedic physicians (n=10) and allopathic physicians (n=10) with no prior experience assessed abortion completion following medical abortion through 56 days' gestation by conducting a medical history and physical exam; ultrasound was not routine. Women were then evaluated independently by a certified abortion provider with a minimum of 5 years' professional experience. This assessment served as a standard against which to compare newly trained provider conclusions. Determinations of abortion completion by doctors of complementary systems of medicine were concordant with the independent verifier's conclusions (RR: 1.01, 95% CI 0.98, 1.04), similar to results for newly trained allopathic physicians [8]. There may be little or no difference in accuracy of

assessment of abortion completion when doctors of complementary systems of medicine assess medical abortion completion compared to physicians (evidence of low certainty)

Nurses (Annex 6.4e)

In one prospective cohort study, nurses (n=10) and allopathic physicians (n=10) with no prior experience assessed abortion completion following medical abortion through 56 days' gestation by conducting a medical history and physical exam; ultrasound was not routine. Women were then evaluated independently by a certified abortion provider with a minimum of five years' professional experience. This assessment served as a standard against which to compare newly trained provider conclusions. Determinations of abortion completion by nurses were concordant with the independent verifier's conclusions (RR: 0.99, 95% CI 0.96, 1.02), similar to results for newly trained allopathic physicians [8]. These results suggest that here may be little or no difference in accuracy of assessment of abortion completion when nurses assess medical abortion completion compared to physicians (evidence of low certainty).

Another prospective cohort study evaluated clinical diagnosis of completeness as determined by nurses attending to women following treatment with misoprostol alone through 12 weeks of gestation in Mozambique. Nurses' assessments with history and physical examination were compared to physician assessments of the same woman using physical examination and routine ultrasound. Using different diagnostic techniques, the authors reported a high rate of agreement with diagnosis of complete abortion among nurse–physician rater pairs; there was less agreement regarding diagnosis of incomplete abortion and ongoing pregnancy [9]. However, because the cadres were using different techniques to arrive at their conclusions, we are uncertain of the effect of the intervention on this outcome (evidence of very low certainty).

Medical abortion beyond 12 weeks of gestation (Annex 9)

No studies were identified for inclusion.

Misoprostol administration for incomplete abortion (uterine size < 13 weeks) (Annex 7)

One equivalence trial evaluated medical management of incomplete abortion in clinically stable women by midwives (n=29) compared to physicians (n=13) in Uganda. No evidence for medical management of incomplete abortion by other health worker cadres of interest was located.

Though no evidence for medical management of incomplete abortion by other health worker cadres of interest was available, previously noted studies offer indirect evidence with reports on the effectiveness, safety and satisfaction of induced medical abortion when provided by doctors of complementary systems of medicine, midwives, nurses and auxiliary nurses or midwives.

Midwives (Annex 7d)

> ***Effectiveness:*** This study noted that treatment effectiveness by provider type was similar (RR 0.97, 95% CI 0.94, 1.00) leading to the conclusion that there is probably little or no difference in the number of complete abortions when midwives provide medical management of incomplete abortion compared to physicians (evidence of moderate certainty).

Safety: No serious adverse events were reported in this study suggesting that there is probably little or no difference in the rates of serious adverse events when midwives provide medical management of incomplete abortion compared to physicians (evidence of moderate certainty).

Satisfaction: High levels of satisfaction with the provider type were reported (RR 1.00, 95% CI 0.98, 1.01). There is probably little or no difference in overall satisfaction with the provider type when midwives provide medical management of incomplete abortion compared to physicians (evidence of moderate certainty).

Management of medical abortion-related complications (other than incomplete abortion) in clinically stable women (Annex 10)

No studies were identified for inclusion.

Authors' conclusions

Limited evidence suggests that doctors of complementary systems of medicine, midwives, nurses and auxiliary nurses or midwives can provide medical abortion and associated component tasks up to 12 weeks of gestation with similar effectiveness, safety and satisfactory among treated women compared to physicians. One study suggested that medical management of incomplete abortion through uterine size up to 13 weeks by midwives was also effective, safe and satisfactory among treated women. No evidence was identified regarding management of medical abortion or incomplete abortion by associate clinicians.

Given the variation in training and professional experiences among the small number of recruited providers to these studies for comparison, generalizability may be impaired. Further, use of differing regimens for medical abortion were reported across studies and no studies reported on overall management of medical abortion between 9 and 12 weeks of gestation.

There is no evidence to determine whether management of medical abortion beyond 12 weeks or medical abortion-related complications other than incomplete abortion in clinically stable women is effective, safe or satisfactory to women when provided by these particular health worker cadres of interest.

Quality of evidence

Very low to high.

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Annex 17. Systematic review summary: Medical management of induced and incomplete abortion by women themselves

Background

Unsafe abortion remains an important cause of global maternal mortality. Health worker shortages and restrictive policies on who may provide abortion services limit access to safe abortion, increasing the likelihood of unsafe abortion and its downstream consequences. A key strategy to increase access to safe abortion may include optimizing the available workforce trained to provide safe abortion. This review was undertaken to evaluate women's role in managing their own safe abortion within the purview of access to a legitimate health source (e.g. health-care provider or website), emphasizing medical methods.

Objectives

Medical abortion up to 12 weeks of gestation

1. To evaluate effectiveness, safety and satisfaction among treated women overall when ***medical abortion with mifepristone and misoprostol or misoprostol alone up to 12 weeks of gestation*** is provided by women themselves compared to care delivered by trained health professionals.

Component tasks for medical abortion up to 12 weeks

2. To evaluate the accuracy of ***eligibility assessments for medical abortion up to 12 weeks of gestation*** when performed by women themselves compared to trained health professionals.
3. To evaluate effectiveness, safety and satisfaction with ***medication administration*** performed by women themselves at home compared to clinic use supervised by a trained health-care professional.
4. To evaluate the ***successful determination of abortion completion*** by women themselves compared to trained health professionals.

Medical management of incomplete abortion for uterine size up to 13 weeks

5. To evaluate the effectiveness, safety and satisfaction of ***medical management of incomplete abortion with uterine size up to 13 weeks*** size by woman compared to trained health professionals.

Search methods

PubMed, Embase, CINAHL, Global Index Medicus, Popline and Clinicaltrials.gov were systematically searched from inception through 15 September 2014; there were no date or language restrictions. Reference lists of key review articles were also hand searched and external experts were contacted to identify any additional relevant studies for inclusion.

Selection criteria

Types of studies

The types of studies considered for inclusion were randomized, controlled trials, including equivalence and non-inferiority trials and comparative observational studies (cohort and case-control).

Participants

Participants included women undergoing medical management of induced or incomplete abortion or medical abortion-related complications provided by themselves following instruction from a legitimate health source compared to trained health professionals.

Interventions

Services women managed for themselves as defined in the objectives were compared to either or both non-specialist or specialist physicians and/or other trained health professionals.

The WHO *Safe abortion: technical and policy guidance for health systems* notes that the most effective regimens (up to 98%) for medical abortion rely on a combination of mifepristone and misoprostol. Mifepristone inhibits the action of progesterone and interferes with the continuation of pregnancy. Misoprostol is a synthetic prostaglandin analogue which enhances uterine contractions and aids in expulsion of the products of conception (1). Misoprostol can also be used alone to medically manage abortion when mifepristone is not available. Misoprostol-alone regimens are safe and effective; however, effectiveness is lower compared to combined regimens and the time to complete abortion is prolonged. Misoprostol as a single agent is recommended for medical management of incomplete abortion.

Outcomes

Effectiveness of medical management (induced abortion or management of incomplete abortion) was defined as complete abortion (e.g. absence of retained products of conception/incomplete abortion, ongoing pregnancy or ectopic pregnancy) without need for additional intervention following the procedure. Serious adverse events were defined as a need for hospital admission, blood transfusion or death and indicated the safety of services by provider type. Measures of satisfaction included reports of overall satisfaction with care managed by themselves compared to care received from trained health-care providers and/or overall satisfaction with any of the various services.

We evaluated both the proportion of women deemed eligible for medical abortion when assessed by themselves or a trained health professional. To determine eligibility, one must correctly identify pregnancy status, duration and medical eligibility for treatment. We were only able to assess the accuracy of eligibility assessments when determinations by women and comparison clinicians were both measured against an independent verifier and/or diagnostic standard. Appropriate administration of medications was measured by the effectiveness, safety and satisfaction with home use versus supervised administration in a clinic by a health professional. We also evaluated the proportion of women assessed as having complete abortions (versus incomplete abortion or ongoing pregnancy) when self-evaluated compared to clinicians. For the purposes of this review, self-assessment was defined as both independent recognition of pregnancy status following medical abortion accompanied

by appropriate help-seeking behaviour, if necessary. We were only able to assess the accuracy of these assessments when determinations by women and comparison clinicians were both measured against an independent verifier and/or diagnostic standard. Methods to determine eligibility or completion could include clinical assessments and/or diagnostic testing (e.g. pregnancy testing, ultrasound), in some cases, guided by the use of job aids or checklists.

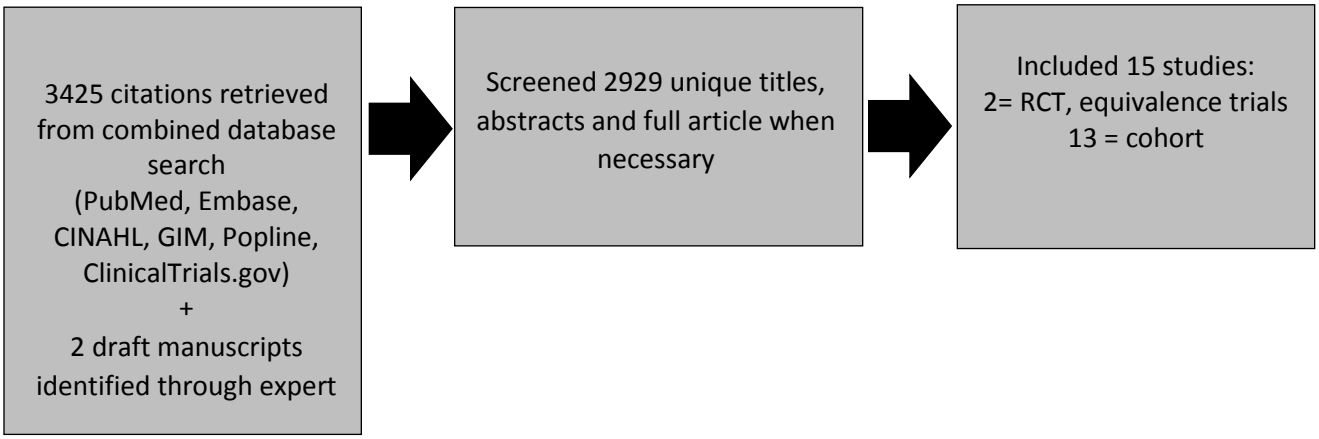
While the clinical contexts for a woman seeking medical management of an induced abortion versus emergency treatment for an incomplete abortion may be distinct, many elements of the treatment are the same. Any studies reporting on the effectiveness, safety or satisfaction of a woman providing medical management in one setting were considered indirect evidence for the other.

Data collection and analysis

Titles and abstracts were screened for inclusion. In the absence of direct evidence, potential papers were screened for indirect evidence. Two authors (MD and SJ) independently reviewed studies for inclusion in the review and independently extracted data for each study. Risk of bias was also assessed independently by two review authors (MD and MSF) according to study design using the criteria outlined in the *Cochrane handbook for systematic reviews of interventions*. We resolved disagreements by discussion with the other review authors. The overall quality (certainty) of the evidence was classified according to the Grading of Recommendations Assessment, Development and Evaluation system (GRADE) (AF and MSF). The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. Evidence can be downgraded from “high quality” by one level for serious, or by two levels for very serious, limitations depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias. The GRADE profiler (Grade 2014) was used to import data from Review Manager 5.3 (RevMan 2014) to create GRADE evidence profiles and Summary of Findings tables. Forest plots were made to graphically illustrate the relative risk estimates. Meta-analyses were performed when more than one trial reported risk estimates relevant to critical outcomes by health worker cadre.

Main results

Figure 1. Identification of studies for inclusion



Overall, the search strategy yielded 3425 citations. Of the 2929 unique citations identified and screened, 13 articles met inclusion criteria (2–15). Consultation with experts led us to two additional relevant studies to include in this review (3, 16). Draft manuscripts were shared for appraisal by the evidence team and ultimately these data were included during the process of seeking peer-reviewed publication of the trial results.

Medical abortion up to 12 weeks (overall)

No studies were identified for inclusion.

Eligibility assessment

One (unpublished) prospective cohort study reported eligibility assessments for medical abortion < 63 days' gestation by women seeking these services (3).

With the use of a toolkit containing a gestational dating wheel and nine-point eligibility checklist, women seeking medical abortion assessed themselves and then were independently assessed using the same toolkit by a female community health volunteer and both assessments were compared to eligibility determined by a comprehensive abortion care (CAC) provider using the standard of care at the sites in Nepal. The proportion of women assessed as eligible for medical abortion was lower when women performed this task compared to the CAC provider (RR 0.93, 95% CI 0.91, 0.96). The assessments of women and CAC providers were concordant for eligibility in 73% of all cases and ineligibility in 10% of all cases with disagreement in 17% of all cases. This was similar, if not somewhat better than the performance of female community health volunteer (FCHVs); compared to CAC providers, their assessments were concordant for eligibility in 65% and ineligibility in 10% with disagreement in 25% of all cases.

Overall, there may be fewer women assessed as eligible when women themselves assess eligibility for medical abortion compared to clinicians (evidence of low certainty). It was not possible to determine the accuracy of eligibility assessments across groups given that the direct group differences were inestimable.

Medication administration

A number of studies were identified that reported on the safety, effectiveness and satisfaction with self-administration of medical abortion drugs < 63 days' gestation at home by women compared to administration by health professionals in a clinical setting (2, 5–10, 12, 14, 15). One study reported on the proportion of women who adhered to the prescribed regimen according to site of medication administration (14).

Mifepristone and misoprostol

One prospective cohort study assessed the effectiveness, safety and satisfaction among women's initiation of the medical abortion process at home with mifepristone following consultation with a health professional to determine eligibility and provide instruction and access to medications for abortion (14). Women self-selected use of mifepristone at home compared to use at clinic to initiate the

medical abortion process. All women were instructed to take misoprostol between 6–48 hours after mifepristone at home.

Adherence to timing of medication administration: The majority of women took mifepristone at the scheduled time (73.5%); whereas, a small proportion took mifepristone before (7.7%) or after (18.8%) the time agreed upon for use with the provider. Similarly high proportions of women in both groups took misoprostol at the agreed upon time (mifehome: 94.2% vs mifeclinic: 91.1%).

Effectiveness: Regardless of the timing of administration and/or location for initiating the medical abortion, no difference in effectiveness was noted across groups (RR 1.01, 95% CI 0.97, 1.06) suggesting that there may be little or no difference in the number of complete abortions when women self-administer medications for medical abortion (evidence of low certainty).

Safety: Serious adverse events were rare. Overall, only one woman required hospitalization, though it was not clear to which treatment arm she was assigned.

Satisfaction: When asked whether they would take mifepristone in the same place again in the future, more women in the home use group responded affirmatively (95.0%) compared to the clinic group (81.7%). There may be more women that report satisfaction with medical abortion when they themselves manage medication administration (evidence of low certainty).

Misoprostol (after mifepristone in clinic)

Nine prospective cohort studies reported on the effectiveness, safety and/or satisfaction among treated women with misoprostol use at home following consultation with a health professional to determine eligibility and provide instruction, access to medications for abortion and initiation of the process with mifepristone administered in the clinic (2, 5–10, 12, 15).

Adherence to timing of medication administration: No direct evidence was identified.

Effectiveness: No difference in effectiveness was reported regardless of setting for misoprostol administration (RR 0.99, 95% CI 0.96, 1.03) (evidence of low certainty).

Safety: Serious adverse events were inconsistently reported across studies; however, when they were reported, they were rare. Two studies explicitly reported no blood transfusions among any study participants, but did not note whether or not participants required hospitalizations for any other complications (8, 12). Four women in two studies required blood transfusions. One study noted that two women had used misoprostol at home (10) and the other study only noted that two participants overall experienced this complication (one also had a suspected infection necessitating hospitalization), not specifying the site of misoprostol administration (6). While serious adverse events were rare when they were reported, limited reporting and non-disaggregated outcomes prevented further estimations of risk according to site of misoprostol use.

Satisfaction: When satisfaction with the abortion service was assessed in five studies, high degrees of satisfaction were reported with no difference in the likelihood of women noting that they were very satisfied or satisfied across groups (5, 6, 8–10, 12). Two other studies demonstrated that women found both home use and clinic use to be acceptable (7, 15). Overall,

there may be little or no difference in satisfaction with medical abortion when women themselves manage medication administration compared to a clinician (evidence of low certainty).

Determination of abortion completion

Three prospective cohort studies reported results related to women's use and interpretation of diagnostic tests and/or toolkits/checklists to determine successful abortion completion or need for further treatment.

In one study, women used a "Success Tool" consisting of eight questions regarding the experience of bleeding, cramping and other symptoms following administration of medical abortion. Women's conclusions were compared to a trained CAC provider's evaluation using the standard of care at the site. The likelihood that a woman would be assessed as having a complete abortion was similar in both groups (RR 1.02, 95% CI 0.99, 1.06) suggesting that there may be little or no difference in the number of women found to have a complete abortion when women themselves perform this task compared to a trained health professional (evidence of low certainty). While women and providers utilized different methods to draw their conclusions about abortion completion, both groups agreed on success following the procedure in 78% of all cases, and there was a concordance in assessments of need for further care in 7% of all cases (3).

Two other studies evaluated women's use and interpretation of low sensitivity pregnancy tests and self-assessment questionnaires to determine successful abortion completion or need for further care then reviewed by trained clinicians (4, 11). In both studies, women were provided with a semi-quantitative pregnancy test on the day of mifepristone administration to serve as a baseline, and then were given a similar test and short questionnaire to aid in determination of abortion success to take home and complete one week later prior to a clinic follow up visit on the same day. At the visit, women were interviewed about their pregnancy status and reviewed the pregnancy test results and questionnaire with a provider. The provider used this information to determine the outcome of the abortion. If there was concern that the results were inconclusive, women underwent additional diagnostic evaluation and received any additional necessary treatment. Among participants in one study conducted in the United States, the majority of women (58.1%) determined whether or not there was a need to return to clinic based on the home test reading being the same or higher than their baseline level in agreement with the clinician assessment (4). Among participants in a study conducted in Viet Nam, 10 out of 11 women with positive pregnancy tests understood that the result meant an additional clinic visit was necessary, and 58% of women with a pregnancy test reading indicating no additional follow up was needed actually understood that no follow up visit was necessary.

Overall, it was not possible to determine the accuracy of eligibility assessments across groups given that the direct group differences were inestimable.

Two randomized, non-inferiority trials reported on effectiveness and safety of the medical abortion process overall when women had responsibility for determining abortion completion by performing and interpreting a low sensitivity urine pregnancy test, noting signs and symptoms of pregnancy expulsion and determining need for further treatment reviewed with study staff during a telephone consultation at one month compared to routine clinical follow up (13, 16).

Effectiveness: No difference in effectiveness was noted when a self-assessment approach to determining abortion completion was compared to routine clinical follow up (RR 1.01, 95% CI 0.97, 1.04) (evidence of low certainty).

Safety: One study noted that one woman in the routine follow up group required hospitalization and transfusion for haemorrhage and another woman was admitted for IV hydration due to excessive bleeding suggesting that there is probably little or no difference in the number of serious adverse events when women themselves assess abortion completion (evidence of moderate certainty) (16). The other study did not report any blood transfusions or hospitalizations explicitly; it was noted that three women in the routine follow up group were treated with vacuum aspiration and antibiotics; however, need for hospitalization with treatment was not specified (13).

Satisfaction: No direct evidence was identified.

Medical management of incomplete abortion (uterine size < 13 weeks)

No studies were identified for inclusion.

Authors' conclusions

We identified no direct evidence to determine the effectiveness, safety and satisfaction among treated women overall when women themselves manage medical abortion (< 84 days' gestation) compared to care delivered by trained health professionals. However, limited evidence suggests that there may be little or no difference in the number of women found to be eligible for medical abortion when women complete this assessment compared to trained health-care providers. Self-administration of the medications following instruction by a legitimate health source results in equivalent effectiveness and safety compared to medications administered in a clinical setting supervised by a clinician, and women may be more satisfied with this approach. Limited evidence also suggests that there may be little or no difference in the number of women found to have a complete abortion following medical abortion when women complete this assessment compared to trained health-care providers. Use of a self-assessment approach to determining abortion completion does not demonstrate a significant difference in effectiveness or safety of medical abortion compared to routine follow up. It was not possible to determine the accuracy of eligibility and complete abortion assessments conducted by women themselves compared to trained health professionals.

There is no evidence to determine whether management of incomplete abortion (uterine size < 13 weeks size) is effective, safe or satisfactory among treated women when women themselves oversee this process compared to a trained health professional.

Quality of evidence

Low to moderate.

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Annex 18: Systematic review summary: Medical management of induced and/or incomplete abortion performed by lay health workers

Background

Unsafe abortion remains an important cause of global maternal mortality. Health worker shortages and restrictive policies on who may provide abortion services limit access to safe abortion, potentially increasing the likelihood of unsafe abortion and its downstream consequences. A key strategy to improve access to safe abortion may include optimizing the available workforce offering these services. Lay health workers are defined as any health worker who performs functions related to health-care delivery with some appropriate training but no formal professional or paraprofessional certificate or tertiary education degree. This review was undertaken to evaluate lay health workers' role in aspects of safe abortion service delivery.

Objectives

Medical abortion up to 12 weeks of gestation

1. To evaluate the effectiveness, safety and satisfaction among treated women overall when ***medical abortion with mifepristone and misoprostol or misoprostol alone up to 12 weeks of gestation*** is provided by lay health workers compared with non-specialist or specialist doctors (obstetrician/gynaecologists) or other professional facility-based health-care professionals (e.g. associate clinicians, midwives, nurses).

Component tasks for medical abortion up to 12 weeks

2. To evaluate ***the accuracy of eligibility assessments for medical abortion up to 12 weeks of gestation*** when performed by lay health workers compared with non-specialist or specialist doctors (obstetrician/gynaecologists) or other professional facility-based health-care providers.
3. To evaluate the effectiveness, safety and satisfaction among treated women when ***medication administration*** is performed by lay health workers compared with non-specialist or specialist doctors or other professional facility-based health-care providers.
4. To evaluate the effectiveness, safety and satisfaction among treated women when ***management of common side-effects associated with medical abortion*** is performed by lay health workers compared with non-specialist or specialist doctors (obstetrician/gynaecologists) or other professional facility-based health-care providers.
5. To evaluate ***determination of abortion completion*** by lay health workers compared with non-specialist or specialist doctors (obstetrician/gynaecologists) or other professional facility-based health-care providers.

Medical management of incomplete abortion for uterine size up to 13 weeks

6. To evaluate the effectiveness, safety and satisfaction among treated women when ***medical management of incomplete abortion with uterine size up to 13 weeks size*** by lay health workers compared with non-specialist or specialist doctors or other professional facility-based health-care providers.

Search methods

PubMed, Embase, CINAHL, Global Index Medicus, Popline and Clinicaltrials.gov were systematically searched from inception through 15 September 2014. There were no date or language restrictions. Reference lists of key review articles were also hand-searched and external experts were contacted to identify any additional relevant studies for inclusion.

Selection criteria

Types of studies

The types of studies considered for inclusion were randomized controlled trials, including equivalence and non-inferiority trials and comparative observational studies (cohort and case-control).

Participants

Participants included women undergoing medical management of induced or incomplete abortion provided by lay health workers compared to other trained health professionals.

Interventions

Services delivered by lay health workers as defined in the objectives were compared to either or both non-specialist or specialist physicians or other facility-based health-care providers.

The *WHO Safe abortion: technical and policy guidance for health systems* notes that the most effective regimens (up to 98%) for medical abortion rely on a combination of mifepristone and misoprostol. Mifepristone inhibits the action of progesterone and interferes with the continuation of pregnancy. Misoprostol is a synthetic prostaglandin analogue which enhances uterine contractions and aids in expulsion of the products of conception (1). Misoprostol can also be used alone to medically manage abortion when mifepristone is not available. Misoprostol-alone regimens are safe and effective; however, effectiveness is lower compared to combined regimens and the time to complete abortion is prolonged. Misoprostol as a single agent is recommended for medical management of incomplete abortion.

Outcomes

Effectiveness of medical management (induced abortion or management of incomplete abortion) was defined as complete abortion without need for additional intervention following the procedure (e.g. absence of retained products of conception/incomplete abortion, ongoing pregnancy or ectopic pregnancy).

Serious adverse events were defined as a need for hospital admission, blood transfusion or death and indicated the safety of services by provider type.

Measures of satisfaction among treated women included reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given health worker cadre.

We evaluated the proportion of women deemed eligible for medical abortion when assessed by lay health workers compared to a trained health professional. To determine eligibility, one must correctly identify pregnancy status, duration and medical eligibility for treatment. We were only able to assess the accuracy of eligibility assessments when determinations by lay health workers and comparison clinicians were both measured against an independent verifier and/or diagnostic standard. Appropriate administration of medications was measured by participants' adherence to the recommended medical abortion regimen following instruction by provider type. Common abortion side-effects included fevers, chills, nausea, vomiting, diarrhoea, bleeding, and pain and evidence comparing management outcomes by provider types was sought. We also evaluated the proportion of women assessed as having complete abortions (versus incomplete abortion or ongoing pregnancy) when managed by lay health workers compared to physicians or other facility-based health-care providers. We were only able to assess the accuracy of these assessments when determinations by lay health workers and comparison clinicians were both measured against an independent verifier and/or diagnostic standard. Methods to determine eligibility or completion could include clinical assessments and/or diagnostic testing (e.g. pregnancy testing, ultrasound), in some cases, guided by the use of job aids or checklists.

While the clinical contexts for a woman seeking medical management of an induced abortion versus emergency treatment for an incomplete abortion may be distinct, many elements of the treatment are the same. Any studies reporting on the effectiveness, safety or satisfaction of a lay health workers providing medical management in one setting were considered indirect evidence for the other. Also, evidence for effective, safe and satisfactory medical treatment for medical abortion overall by provider type was considered indirect evidence for performance of the component subtasks when direct evidence was not identified.

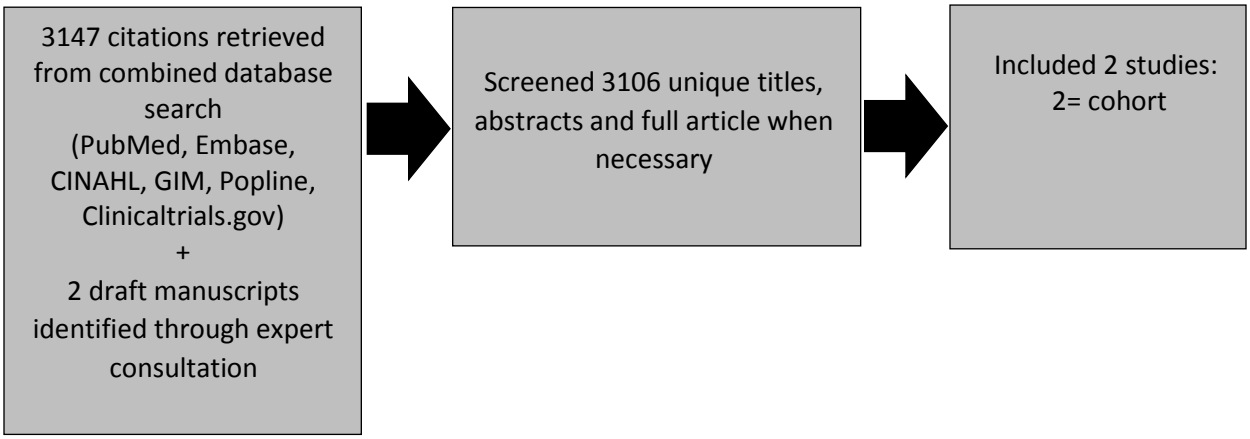
Data collection and analysis

Titles and abstracts were screened for inclusion. In the absence of direct evidence, potential papers were screened for indirect evidence. Two authors (MD and SJ) independently reviewed studies for inclusion in the review and independently extracted data for each study. Risk of bias was also assessed independently by two review authors (MD and MSF) according to study design using the criteria outlined in the *Cochrane handbook for systematic reviews of interventions*. We resolved disagreements by discussion with the other review authors. The overall quality (certainty) of the evidence was classified according to the Grading of Recommendations Assessment, Development and Evaluation system (GRADE) (AF and MSF). The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. Evidence can be downgraded from "high quality" by one level for serious, or by two

levels for very serious, limitations depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias. The GRADE profiler (Grade 2014) was used to import data from Review Manager 5.3 (RevMan 2014) to create GRADE evidence profiles and Summary of Findings tables. Forest plots were made to graphically illustrate the relative risk estimates. Meta-analyses were performed when more than one trial reported risk estimates relevant to critical outcomes by health worker cadre.

Main results

Figure 1. Identification of studies for inclusion



Overall, the search strategy yielded 3147 citations. Of the 3106 unique citations identified and screened, no articles met inclusion criteria. Consultation with experts led us to two relevant studies to be included in this review (2, 3). Draft manuscripts were shared for appraisal by the evidence team and ultimately these data were included during the process of seeking peer-reviewed publication of the trial results.

Medical abortion up to 12 weeks (overall)

No studies were identified for inclusion.

Eligibility assessment

Two prospective cohort studies were identified that reported on lay health workers' ability to determine eligibility for medical abortion $\leq$ 63 days' gestation (2, 3).

With the use of a toolkit containing a gestational dating wheel and nine-point eligibility checklist, women seeking medical abortion were assessed by female community health volunteers (FCHVs) in Nepal; subsequently, these same women were independently assessed for eligibility by a comprehensive abortion care provider using the standard of care and the conclusions were compared.

While FCHVs and providers utilized different methods to draw their conclusions about eligibility, both groups agreed on a woman's eligibility for the procedure in 65% of all cases, and there was a concordance in assessments of ineligibility in 10% of all cases [2].

Similarly, in the second study, a checklist tool was developed which required review of pregnancy test results, calculation of pregnancy duration and determination of contraindications to medical abortion. The use of the checklist by both community health workers (CHWs) and facility clinicians in India, Ethiopia and South Africa was tested against an evaluation by the same facility clinician history and physical examination (occasional ultrasound) to determine eligibility. Using the checklist, CHWs eligibility determinations for medical abortion compared to the clinicians were lower, all compared to standard clinical assessments (% of all cases correctly identified, clinicians: India, 96.4%; Ethiopia, 93.6%; South Africa, 90.3% vs CHWs: India, 79.6%; Ethiopia, 91.8%; South Africa, 76.9%) [3].

Overall, it is possible to conclude that there may be fewer women assessed as eligible when lay health workers assess eligibility for medical abortion (evidence of low certainty). We were unable to determine the accuracy of complete abortion assessments across groups given that the direct group differences were inestimable.

Medication administration

No studies were identified for inclusion.

Management of common side-effects of medical abortion

No studies were identified for inclusion.

Determination of abortion completion

The same studies reporting on the use of toolkits and checklists to determine eligibility included a phase where lay health workers used similar job aids to assess abortion completion following administration of mifepristone and misoprostol for medical abortion. In one study, FCHVs used a "Success Tool" consisting of eight questions regarding the experience of bleeding, cramping and other symptoms following administration of medical abortion. Their conclusions were compared to a trained CAC provider's evaluation using the standard of care at the site. The likelihood that a woman would be determined to have a complete abortion was similar across groups (RR lhw vs clinician 0.99, 95% CI 0.96, 1.03). While FCHVs and providers utilized different methods to draw their conclusions about abortion completion, both groups agreed on success following the procedure in 75% of all cases, and there was a concordance in assessments of need for further care in 7% of all cases [2].

The other study investigated use of a checklist tool for assessment of abortion completion and compared results when used by CHWs or facility clinicians tested against an evaluation by the same facility clinician history and physical examination (occasional ultrasound). Using the checklist, CHWs determined that fewer women had complete medical abortion compared to clinicians when compared to clinical assessments by the same facility clinician (% of all cases correctly identified, clinicians: India, 92.9%; Ethiopia, 94.9%; South Africa, 94.0% vs CHWs: India, 85.9%; Ethiopia, 88.5%; South Africa, 82.1%) [3].

Overall, there may be little or no difference in the number of women determined to have a complete abortion when lay health workers assess medical abortion completeness compared to other trained health professionals (evidence of low certainty). We were unable to determine the accuracy of complete abortion assessments across groups given that the direct group differences were inestimable.

Medical management of incomplete abortion (uterine size < 13 weeks)

No studies were identified for inclusion.

Authors' conclusions

No evidence was identified speaking to the effectiveness, safety or satisfaction among treated women of either medical management of induced or incomplete abortion when lay health workers assumed overall responsibility for these services. Limited evidence suggests that lay health workers may be capable of determining eligibility for and completion following medical abortion with the assistance of checklists; however, they may be less accurate in their assessments compared to trained health professionals.

Quality of evidence

Low.

References

1. Safe abortion: technical and policy guidance for health systems. Geneva: World Health Organization; 2012.

2. Andersen KL, Fjerstad M, Basnett I, et al. Determination of medical abortion eligibility and success by women and community health volunteers: a toolkit evaluation (unpublished).

3. Johnston HB, Ganatra B, Nguyen MH, Habib N, Afework M, Harries J, et al. Can community health workers assess eligibility for early medical abortion? Results of a multi-country validation study (unpublished).

Annex 19. Systematic review summary: Medical management of induced and/or incomplete abortion performed by pharmacists and pharmacy workers

Background

Unsafe abortion remains a health concern for women worldwide and is a driver of maternal mortality, especially in low- and middle-income countries. Given that pharmacies are often the first point of contact for many women with the health system and that many pharmacists and pharmacy workers dispense medical abortion medications, it is important to consider the role they can play in the provision of medical abortion. An existing review of pharmacy workers (Sneeringer et al., 2012) found numerous studies that showed that although pharmacists and pharmacy workers often sell abortion medications to women, accurate information about how to use the medications safely and effectively is rarely offered. The review did not identify any studies that described effective interventions.

The World Health Organization does not currently have a recommendation on the provision of medical abortion services, or other reproductive health services, by pharmacists and pharmacy workers. We sought to determine whether pharmacists, or pharmacy workers, can provide medical abortion to women at up to 63 days gestational age. Provision of information related to safe abortion or counselling is covered in a separate review (Annex 20).

Objectives

1. To evaluate the effectiveness, safety and satisfaction among treated women when ***medical abortion with mifepristone and misoprostol or misoprostol alone up to 12 weeks of gestation*** is provided by pharmacists or pharmacy workers when compared with a clinical facility-based provider.
2. To evaluate ***eligibility assessments for medical abortion up to 12 weeks of gestation*** when done by pharmacists or pharmacy workers when compared with a clinical facility-based provider.
3. To evaluate the effectiveness, safety and satisfaction among treated women when ***medication administration*** is provided by pharmacists or pharmacy workers when compared with clinical facility-based provider.
4. To evaluate the effectiveness, safety and satisfaction among treated women of ***the management of common side-effects associated with medical abortion*** when performed by pharmacists or pharmacy workers when compared with clinical facility-based provider.
5. To evaluate the ***successful determination of abortion completion*** by pharmacists or pharmacy workers when compared with clinical facility-based provider.

6. To evaluate the effectiveness, safety and satisfaction among treated women when ***medical management of incomplete abortion with uterine size up to 13 weeks size is performed*** by pharmacists or pharmacy workers when compared with clinical facility-based provider.

Search methods

We searched PubMed, Popline, Cochrane, CINAHL, and Embase databases, as well as the regional databases LILACS, IMSEAR, African Index Medicus, and IndMed for articles which investigated the safety of medical abortion provided by pharmacists. Databases were searched from inception to 15 September 2014 and without language filters. Reference lists of relevant existing review articles were also hand searched and external experts were contacted to identify any additional studies for inclusion.

Selection criteria

Types of studies

The types of studies considered for inclusion were randomized controlled trials, comparative observational studies (cohort and case–control) and controlled before and after studies.

Participants

Participants included women undergoing medical management of induced or incomplete abortion

Interventions

Services delivered by pharmacists or pharmacy workers as defined in the objectives were compared to either or both non-specialist or specialist physicians or other facility-based health-care providers.

The *WHO Safe abortion: technical and policy guidance for health systems* notes that the most effective regimens (up to 98%) for medical abortion rely on a combination of mifepristone and misoprostol. Mifepristone inhibits the action of progesterone and interferes with the continuation of pregnancy. Misoprostol is a synthetic prostaglandin analogue which enhances uterine contractions and aids in expulsion of the products of conception (1). Misoprostol can also be used alone to medically manage abortion when mifepristone is not available. Misoprostol-alone regimens are safe and effective; however, effectiveness is lower compared to combined regimens and the time to complete abortion is prolonged. Misoprostol as a single agent is recommended for medical management of incomplete abortion.

Outcomes

Effectiveness of medical management (induced abortion or management of incomplete abortion) was defined as complete abortion without need for additional intervention following the procedure (e.g. absence of retained products of conception/incomplete abortion, ongoing pregnancy or ectopic pregnancy).

Successful management of medical abortion-related complications in clinically stable women was defined as accurate determination of a complication followed by an offer of correct treatment or referral depending on professional capacity and clinical setting.

Serious adverse events were defined as a need for hospital admission, blood transfusion or death and indicated the safety of services by provider type.

Measures of satisfaction among treated women included reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type.

We evaluated the proportion of women deemed eligible for medical abortion when assessed by lay health workers compared to a trained health professional. To determine eligibility, the pregnancy status, duration and medical eligibility for treatment must be correctly identified. We were only able to assess the accuracy of eligibility assessments when determinations by lay health workers and comparison clinicians were both measured against an independent verifier and/or diagnostic standard. Appropriate administration of medications was measured by participants' adherence to the recommended medical abortion regimen following instruction by provider type. Common abortion side-effects included fevers, chills, nausea, vomiting, diarrhoea, bleeding, and pain and evidence comparing management outcomes by provider types was sought. We also evaluated the proportion of women assessed as having complete abortions (versus incomplete abortion or ongoing pregnancy) when managed by lay health workers compared to physicians or other facility-based health-care providers. We were only able to assess the accuracy of these assessments when determinations by lay health workers and comparison clinicians were both measured against an independent verifier and/or diagnostic standard. Methods to determine eligibility or completion could include clinical assessments and/or diagnostic testing (e.g. pregnancy testing, ultrasound), in some cases, guided by the use of job aids or checklists.

While the clinical contexts for a woman seeking medical management of an induced abortion versus emergency treatment for an incomplete abortion may be distinct, many elements of the treatment are the same. Any studies reporting on the effectiveness, safety or satisfaction of a lay health worker providing medical management in one setting were considered indirect evidence for the other. Also, evidence for effective, safe and satisfactory medical treatment for medical abortion overall by provider type was considered indirect evidence for performance of the component subtasks when direct evidence was not identified.

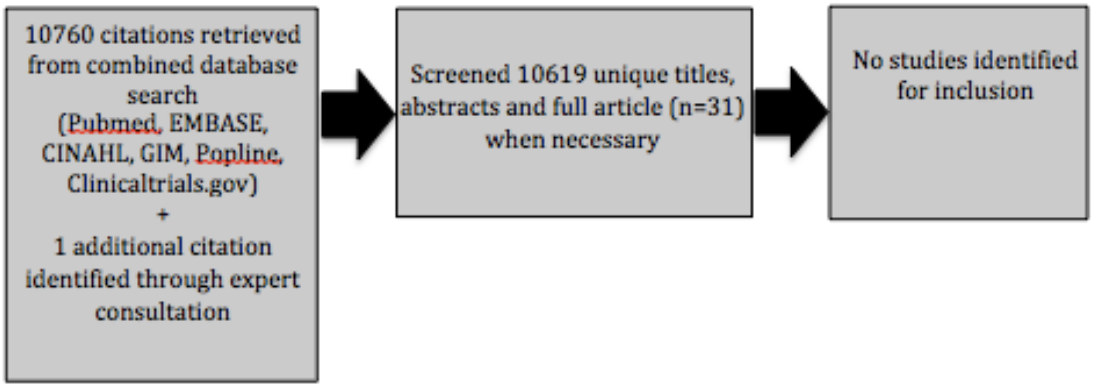
Data collection and analysis

Titles and abstracts were screened for inclusion. In the absence of direct evidence, potential papers were screened for indirect evidence. Two authors (SJ and BG) independently reviewed studies for inclusion in the review and independently extracted data for each study. We planned to assess the overall quality (certainty) of the evidence according to the Grading of Recommendations Assessment, Development and Evaluation system (GRADE). The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. Evidence can be downgraded from "high quality" by one level for serious, or by two levels for very serious, limitations depending on assessments for risk of bias,

indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias.

Main results

Figure 1. Identification of studies for inclusion



The search identified 10 619 unique references. Titles and abstracts were screened for inclusion and 31 were selected for full text review, full texts could not be located for four. All of the articles were excluded after full text review: Individual clinical outcomes unavailable: n= 16; pharmacists acting without training and supervision: n= 13; abstract only; full length report not identified n= 4; review article, no original data n= 2). Ultimately, no studies were identified for inclusion.

Discussion

We did not identify any articles that met search criteria. Most of the identified papers reported on knowledge and practices of pharmacists and pharmacy workers who had not received any intervention specific training or did not contain a comparisons group.

We did identify one comparative study reported on an intervention to improve knowledge of pharmacists and pharmacy workers regarding medical abortion. The pharmacy workers had a range of backgrounds, including non-physician clinicians (66%: health assistants, nurses, auxiliary nurse midwives, auxiliary health workers, community medical assistants), drug workers (27.2%), pharmacists (2.5%), untrained drug workers (2.5%), and other (1.5%). The comparison group was pharmacy workers with similar backgrounds who did not receive the intervention. The intervention group received a two-day training and were provided with referral vouchers to offer women to seek care with qualified medical practitioners for abortion.

Compared to baseline, pharmacists in the intervention group showed increased knowledge of upper gestational age permitted by law for medical abortion, the recommended MA regimen, and appropriate misoprostol administration route. The comparison group had improved knowledge on some variables and no change in others. The intervention group's knowledge of how to assess abortion completeness did not improve; however knowledge on these factors was relatively high at baseline. Finally, although the pharmacy workers did not typically refer women to qualified medical services (and often provided

medical abortion medications themselves) when gestational age was under 64 days, they reported that the 39% of women with gestational age over nine weeks were referred for MVA services. The study did not assess abortion outcomes in clients counseled by pharmacists, making it difficult to interpret the results in terms of the review objectives. Additionally, pharmacy workers represented many cadres, not only pharmacist and pharmacy workers (in fact, the majority of workers belong to another cadre, although they did work at a pharmacy) making it difficult to interpret results about pharmacists per se.

The role of pharmacists and pharmacy workers in other sexual and reproductive health-care services has been explored to some degree; for example, prescribing and administering hormonal contraceptive methods in the United States and Canada or in the diagnosis, management, and prevention of sexually transmitted infections in Peru. Several Cochrane reviews have explored pharmacist led interventions in education for chronic conditions and tobacco cessation (see Nkansah et al., Annex 22; Pande et al., Annex 23; and Sinclair et al., Annex 24).

Authors' conclusions

We did not identify any studies meeting our inclusion criteria reporting on the performance of pharmacists or pharmacy workers providing medical abortion. Due to insufficient evidence, we are unable to draw conclusions about the safety, effectiveness, or satisfaction of medical abortion services when provided by pharmacists or pharmacy workers.

References

1. Tamang, A., Puri, M., Lama, K., Shrestha P. Pharmacy workers in Nepal can provide the correct information about using mifepristone and misoprostol to women seeking medication to induce abortion. Reproductive Health Matters. 2015;22(44 Suppl 1):104-15. doi:10.1016/S0968-8080(14)43785-6.

2. Sneeringer RK, Billings DL, Ganatra B, Baird TL. Roles of pharmacists in expanding access to safe and effective medical abortion in developing countries: a review of the literature. J Public Health Policy. 2012;33:218-229.

3. Nkansah N, Mostovetsky O, Yu C, Chheng T, Beney J, Bond CM, Bero L. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. Cochrane Database of Systematic Reviews. 2010;(7):CD000336.

4. Pande S, Hiller JE, Nkansah N, Bero L. The effect of pharmacist-provided non-dispensing services on patient outcomes, health service utilisation and costs in low- and middle-income countries. Cochrane Database of Systematic Reviews. 2013;(2):CD010398.

5. Sinclair HK, Bond CM, Stead LF. Community pharmacy personnel interventions for smoking cessation. Cochrane Database of Systematic Reviews. 2004;(1):CD003698.

Annex 20. Systematic review summary: Provision of safe abortion information and counselling by non-medical cadres: a systematic review

Background

Access to accurate information on the availability of providers, post-abortion care, information about complications and contraception counselling is critical to safe abortion care. However, while there is some evidence that women with unplanned pregnancies seek information from local pharmacies little is known about effective ways that information or contraception counselling can be provided to women with unplanned pregnancies.

Objectives

To assess whether:

1) pharmacy workers and lay health workers can provide accurate information on safe abortion care (including the availability of providers and post-abortion care and complications); and
2) the provision of pre- and post-abortion counselling, including contraception counselling, by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and midwives, pharmacists, pharmacy workers and lay health workers, is effective, safe and acceptable.

Search methods

The Cochrane Controlled Trials Register, PubMed, Global Index Medicus, Embase, CINAHL, POPLINE and ClinicalTrials.gov were systematically searched. Reference lists of retrieved papers were also searched. Experts at WHO Department of Reproductive Health and Research were contacted. There were no date or language restrictions.

Selection criteria

The types of studies considered for inclusion were randomized controlled trials, quasi (or non-) randomized controlled trials, controlled before and after studies and cohort studies.

Participants included women or their agents seeking information about dealing with an unintended pregnancy, incomplete abortion or post-abortion care; or women seeking information about safe abortion care and contraception before and/or after abortion; and the following cadres: doctors of complementary systems of medicine, associate clinicians,

midwives, nurses, auxiliary nurses and midwives, pharmacists, pharmacy workers and lay health workers.

The comparison was usual care, including information from doctors or no information.

Outcomes common to both objectives were maternal mortality and morbidity, proportion of safe abortions, correct knowledge of safe and appropriate abortion (women, their agents and cadres); and correct knowledge of safe post-abortion care (women, their agents and cadres). Outcomes related to contraception counselling were the number of unplanned pregnancies, correct knowledge of contraception options (women and cadres), satisfaction with contraception advice to women and the mix of contraception types used.

Data collection and analysis

Titles and abstracts were screened for inclusion. In the absence of direct evidence, potential papers were screened for indirect evidence. Studies were included as indirect evidence if the intervention included information provision or contraception counselling by the cadres listed above.

Main results

We included one before and after study conducted in a low-income country that assessed the impact of education on pharmacy worker knowledge. We also included two trials, one conducted in a high-income country and the other in a low-income country, in which contraception counselling was part of a larger intervention and provided indirect evidence. No studies assessed maternal mortality and morbidity post-abortion, proportion of safe abortions, correct knowledge of safe and appropriate abortion, or post-abortion care by women or other information seekers. No studies assessed correct knowledge of contraception options by women or cadre, number of unplanned pregnancies or the satisfaction with contraception advice.

Correct knowledge of safe and appropriate abortion or post-abortion, care by pharmacy workers was not estimable because of serious study limitations (only one control and intervention site and the presence of several potential confounders favouring the intervention). For contraception counselling, a post hoc definition was used for the mix in contraceptive types (use of long-acting reversible contraceptives [LARC]). For the two trials (1944 women), the uptake of LARC was similar when comparing care that included contraceptive counselling provided by nurses and nurse-midwives with similar care from doctors (RR 1.10, 95% CI 0.92 to 1.33). Heterogeneity was very high (I^2=90%) and results were inconsistent. The certainty of this indirect evidence was therefore very low.

Authors' conclusions

There is insufficient evidence to determine whether pharmacy workers and lay workers can provide accurate information on safe abortion care. The certainty of the evidence for pharmacy workers is very low and considerable caution is needed because of serious study limitations. It is also uncertain whether doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and midwives, pharmacists, pharmacy workers and lay health workers can safely, effectively and acceptably provide pre- and post-abortion counselling, including contraception counselling, because no studies were found that provided direct evidence. The indirect evidence found had high heterogeneity and inconsistency and the certainty of the evidence was therefore very low. Education about safe abortion care may be needed for pharmacy workers.

Summary of Findings

Pharmacy workers and/or lay workers providing information on safe abortion care

Pharmacy workers and/or lay workers providing information on safe abortion care (including availability of providers and post-abortion care and complications)

Patients or population: Women or their agents seeking information about dealing with an unintended pregnancy, incomplete abortion or post-abortion care

Settings: Registered abortion services or other community-based services, including community pharmacies

Intervention: Information on safe care related to abortion provided by pharmacists, pharmacy workers, and lay workers working with abortion services or in the community

Comparison: No information (usual practice)

Outcomes	**Illustrative comparative risks*** (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Without information	**With information from cadre**				
Maternal mortality and morbidity post-abortion	No studies identified					
Proportion of safe abortions[1]	No data available for comparison					Referrals to registered abortion services differed by whether pharmacy workers reported that MA tablets were sold in their shop. Only those that did not sell MA tablets referred women. The proportion of shops selling MA tablets increased from 45% to 70% in the intervention group and from 39% to 50% in the comparison group.
Correct knowledge of safe and appropriate abortion[2] [4 items used]	**Women**		Not estimable			
	No studies identified					
	Other information seekers					
	No studies identified					
	Cadre[4]			460[4] (1 study)	⊟++ Very Low[5]	
	Not estimable					

Correct knowledge of safe post-abortion care[3] [2 items used]	**Women**	Not estimable	460[4] (1 study)	⊖+++ Very Low[5]	
	No studies identified				
	Other information seekers				
	No studies identified				
	Cadre[4]				
	Not estimable				

The **assumed risk, corresponding risk** and **relative effect** of the intervention could not be calculated.

CI: confidence interval; RR: risk ratio GRADE: GRADE Working Group grades of evidence (see explanations)

MA = medical abortion (using combination of mifepristone and misoprostol); GA= gestational age

[1] Data from intervention site in one controlled before and after study conducted in Nepal (Tamang et al., 2014), but risks are not estimable as baseline data or control data not reported. During the 11-month study period 11,480 women sought abortion advice from the 207 intervention pharmacy shops; 61% (7019 women) were assessed by the pharmacy workers to be legally eligible for MA (≤ 63 days of pregnancy LMP) and 80% of these were provided with MA tablets (5594). The remaining 20% were referred to clinical services. Referral was only by those pharmacy workers who did not keep MA drugs in their shops. Eighteen women (0.3%) reported symptoms of incomplete abortion and were referred to the nearest health-care facility for treatment. The GA of the remaining 4461 women seeking abortion advice (39% of total) was more than nine weeks and they were referred to a registered abortion clinic.

[2] The proportion of pharmacy workers with correct knowledge relating to the provision of medical abortion drugs: upper gestational age permitted under Nepalese law for medical abortion; recommended regimen up to 9 weeks GA; time interval between drugs; effective routes of administration. Knowledge about availability of mifepristone and misoprostol tablets reported to be “very high” in both treatment and comparison groups at baseline but the actual proportions were not reported (Tamang et al., 2014).

[3] The proportion of pharmacy workers with correct knowledge assessing abortion completeness and conditions/symptoms requiring immediate referral. Knowledge that women who experience excessive bleeding and excessive pain require immediate referral for treatment was very high in both groups at baseline (97.1% of intervention group and 100% of control group). This increased to 100% in the intervention group and fell in the control group (92.5%) (Tamang et al., 2014).

[4] The cadre included in Tamang et al. (2014) comprised a mix of occupations and were selected as the main person responsible for each pharmacy shop. Data for 207 of 230 selected shops were reported for the intervention district and 212 of 230 selected shops for the comparison district. The majority of the cadre comprised mid-level health-care providers (health assistants, staff nurses, auxiliary nurse midwives, and auxiliary health workers or community medical assistants). Study sites were selected by a cluster sampling technique (not described). Basic orientation training was provided to the intervention group over two days in 2011 with 1-day refresher 10 months later.

[5] Serious study limitations. The study design was a controlled before and after study with only one control and one intervention site. Data were collected contemporaneously, but several potential confounding factors favoured the intervention sites. For example, there was a higher proportion of pharmacy shops that had a separate space for providing counselling or examining patients (80% in intervention group cf 58% in comparison group); that provided treatment of sexually transmitted infections (68% cf 35%); that had mid-level health-care providers (66% cf 51%); that provided injectable contraceptives to women (76% cf 59%); and had a lower proportion of male pharmacy workers (82% cf 89%).

Tamang, A., Puri, M., Lama, K., Shrestha P. (2014) Pharmacy workers in Nepal can provide the correct information about using mifepristone and misoprostol to women seeking medication to induce abortion. Reproductive Health Matters. Supplement(43):1–12. doi:10.1016/S0968-8080(14)43785-6.

Doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and midwives, pharmacists, pharmacy workers and lay health workers providing pre- and post-abortion counselling, including contraception counselling

Doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and midwives, pharmacists, pharmacy workers and lay health workers providing pre- and post-abortion counselling, including contraception counselling						
Patients or population: Women seeking information about abortion care before treatment or following an incomplete abortion (including medical or surgical, at any gestational age) **Settings:** Registered abortion services or other community-based services, including community pharmacies **Intervention:** Pre- and post-abortion and contraception counselling by various cadres working with abortion services, in the community or in other locations **Comparison:** Usual care (contraceptive counselling from doctor or no counselling)						
Outcomes	**Illustrative comparative risks*** (95% CI) Assumed risk **Usual care**	 Assumed risk **Counselling from cadre**[1]	Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
Maternal mortality and morbidity post-abortion						No outcomes reported relating to adverse effects of counselling
Number of unplanned pregnancies						Outcome not reported
Proportion of safe abortions						Outcome not reported
Correct knowledge of contraception options	Women Cadre 	 				Outcome not reported
Correct knowledge of safe and appropriate	Women Cadre	 				Outcome not reported

abortion						
Correct knowledge of safe post-abortion care	Women					Outcome not reported
	Cadre					
Satisfaction with contraception advice						Outcome not reported
Mix in types of contraception used[2]	Uptake of long-acting reversible contraceptives (LARC) in control groups ranged from 456 per 1000 to 706 per 1000.	Uptake of LARC in intervention groups ranged from 545 per 1000 to 652 per 1000.	RR= 1.10 (0.92–1.33)	1944 (2 studies)	⊕◯◯◯ Very low[3]	Post-hoc definition used for mix in contraceptive types, that is, use of long-acting reversible contraceptives (LARC)

Range of **assumed risk** and **corresponding risk** reported where available. **Relative effect** of the intervention could not be calculated.

CI: confidence interval; RR: risk ratio GRADE: GRADE Working Group grades of evidence

[1] Cadre comprises nurse-midwives or nurses (intervention groups) or by doctors (control groups "usual care").

[2] Mix of long-acting reversible contraceptives (LARC) derived from reported contraceptive method taken by women in one study (Olavarrieta 2014); contraceptive injection, IUD, patch and implant.

[3] Two randomized controlled trials but indirect evidence. Primary aims of studies to compare effect of different providers on abortion outcomes. Contraceptive counselling included as part of intervention with contraception use as secondary outcome. High heterogeneity I^2=90% and inconsistent results. Cadres similar, nurse and nurse-midwife providers. Both compared with doctor providers but one in high-income country (Sweden) and the other in low-income country (Mexico).

Kopp Kallner, H., Gomperts, R., Salomonsson, E., Johansson, M., Marions, L., & Gemzell-Danielsson, K. (2014). The efficacy, safety and acceptability of medical termination of pregnancy provided by standard care by doctors or by nurse-midwives: a randomised controlled equivalence trial. BJOG: An International Journal of Obstetrics & Gynaecology. doi:10.1111/1471-0528.12982.

Olavarrieta, C. D., Ganatra, B., Sorhaindo, A., Karver, T.S., Seuc, A., Villalobos, A., García, S.G., Pérez, M., Bousieguez, M., Sanhueza, P. Nurses delivery of early medical abortion in Latin America: A randomized controlled non-inferiority trial comparing nurse provision of early medical abortion to physician provision in Mexico City (unpublished).

Background: Messages and PICOs

This rapid systematic review was conducted in September and October 2014. It addresses two messages relating to the provision of information and counselling on safe abortion care by a cadre of health workers including pharmacy workers, lay workers, doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and midwives. These were as follows:

- **MESSAGE1**: Can pharmacy workers and lay workers provide accurate information on safe abortion care (including availability of providers and post-abortion care and complications)?
- **MESSAGE2**: Is the provision of pre- and post-abortion counselling, including contraception counselling, by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses and midwives, pharmacists, pharmacy workers and lay health workers effective, safe and acceptable?

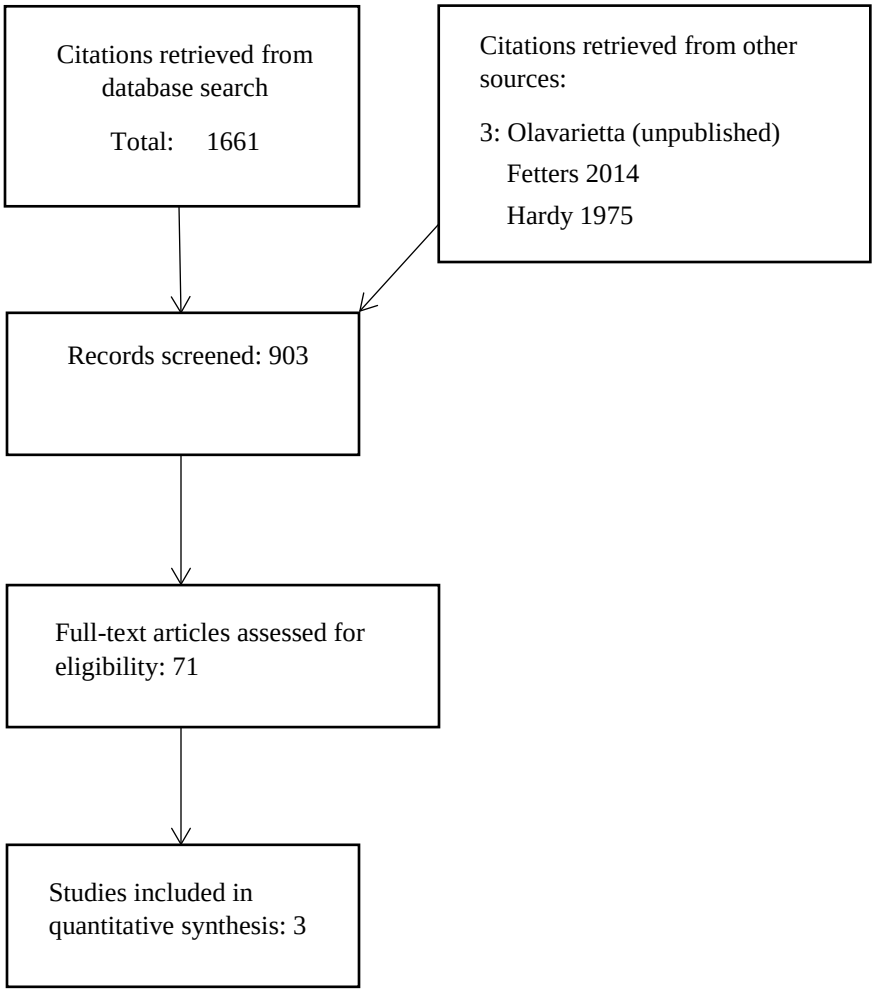
	Message 1	**Message 2**
P	Women or their agents seeking information about dealing with an unintended pregnancy, incomplete abortion or post-abortion care	Women seeking information about safe abortion care and contraception, including treatment for incomplete abortion, before and/or after abortion
I	Information on safe care related to abortion provided by pharmacists, pharmacy workers, and lay workers working with abortion services or in the community	Pre- and post-abortion and contraception counselling by various cadres working with abortion services, in the community or in other locations
C	No information (usual practice)	Usual care, which can include: • counselling by physicians • no counselling
O	• Reduced maternal mortality and morbidity post-abortion • Increased proportion of safe abortions • Reduced mean GA or increased proportion induced abortions with lower gestational age (as determined by study authors) • Correct knowledge of safe and appropriate abortion (women, other information recipients and cadre) • Correct knowledge of safe post-abortion care (women, other information recipients and cadre).	• Reduced maternal mortality and morbidity post-abortion • Reduction in number of unplanned pregnancies • Increased proportion of safe abortions • Reduced mean GA or increased proportion induced abortions with lower gestational age (as determined by study authors) • Correct knowledge of contraception options (women and cadre) • Correct knowledge of safe and appropriate abortion (women and cadre) • Correct knowledge of safe post-abortion care (women and cadre) • Acceptability of contraception advice to women • Increased mix in types of contraception used.

These terms were used to design the search strategy.

Results

In total 903 titles and abstracts were reviewed, and 71 full papers retrieved and assessed; 68 papers were excluded. Several studies were excluded for multiple reasons but the primary reason for exclusion was: study design (43 studies); inappropriate or inadequate description of the intervention (13 studies); inappropriate or inadequate description of the participant population (9 studies); or the choice of study outcomes (3 studies). There were three included studies.

Search outcome:



References

The three included studies were:

Tamang, A., Puri, M., Lama, K., Shrestha P. (2014) Pharmacy workers in Nepal can provide the correct information about using mifepristone and misoprostol to women seeking medication to induce abortion. Reproductive Health Matters. Supplement(43):1–12. doi:10.1016/S0968-8080(14)43785-6.

Kopp Kallner, H., Gomperts, R., Salomonsson, E., Johansson, M., Marions, L., & Gemzell-Danielsson, K. (2014). The efficacy, safety and acceptability of medical termination of pregnancy provided by standard care by doctors or by nurse-midwives: a randomised controlled equivalence trial. BJOG: An International Journal of Obstetrics & Gynaecology. doi:10.1111/1471-0528.12982

Olavarrieta, C.D., Ganatra, B., Sorhaindo, A., Karver, T.S., Seuc, A., Villalobos, A., García, S.G., Pérez, M., Bousieguez, M., Sanhueza, P. Nurses delivery of early medical abortion in Latin America: a randomized controlled non-inferiority trial comparing nurse provision of early medical abortion to physician provision in Mexico City (unpublished).

Annex 21. Systematic review summary: Provision of select methods of contraception by doctors of complementary systems of medicine, pharmacists, pharmacy workers and women themselves

Background

Existing WHO recommendations state that associate clinicians, midwives, nurses and auxiliary nurse midwives can provide IUD and implant insertion and removals (1). For contraceptive injectables, all of these provider types were recommended to administer injectable contraception, including lay health workers within the context of targeted monitoring. The role for provision of contraceptive injectables, implants and intrauterine devices (IUDs) by doctors of complementary systems of medicine, pharmacists/pharmacy workers and by women themselves had not previously been evaluated for recommendation formulation.

Objectives

1. To evaluate the effectiveness, safety and satisfaction with ***insertion or removal of intrauterine devices*** by doctors of complementary systems of medicine, pharmacists or pharmacy workers compared with other clinical facility-based providers.

2. To evaluate the effectiveness, safety and satisfaction ***with insertion or removal of contraceptive implants*** by doctors of complementary systems of medicine, pharmacists or pharmacy workers compared with other clinical facility-based providers.

3. To evaluate the effectiveness, safety and satisfaction with ***initiation or continuation of contraceptive injectables*** when provided by doctors of complementary systems of medicine, pharmacists or pharmacy workers or women themselves compared with other clinical facility-based providers.

Search methods

The following databases were searched: PubMed, Popline, Cochrane, CINAHL, and Embase for articles which investigated the provision of contraceptive injectables, implants, IUDs by doctors of alternate medicine, pharmacists and pharmacy workers and women (self-administration). The articles searched were in any language published from database inception through 15 September 2014. There were no language limits.

Selection criteria

Types of studies

The types of studies considered for inclusion were randomized controlled trials, comparative observational studies (cohort and case–control) and controlled before and after studies. Studies that did not have a comparison group of women who were treated by physicians or usual health-care providers and that did not report on clinical outcomes of interest were excluded.

Participants

Participants included women receiving select contraception (IUD, implant, injectables) by the following cadres: doctors of complementary systems of medicine, pharmacist or pharmacy workers, and women (self). The comparison was the usual health-care provider of contraception in a clinical service setting.

Interventions

Contraception provision by the following cadres compared to the usual contraception provider:

- IUD, implant or injectable provision by doctors of complementary systems of medicine
- IUD, implant of injectable provision by pharmacists or pharmacy workers
- injectable self-administration by the woman herself.

The selected contraceptive methods of interest are the IUD, implant and injectable. The IUD is a long-acting reversible contraceptive device that is placed in the uterus. There are two basic types of IUD: the copper-containing device and a hormone-releasing device. The effectiveness of preventing pregnancy is greater than 99%. The implant is another long acting reversible contraceptive method. The implants are small, flexible rods or capsules that are inserted under the skin of the upper arm. This device releases a progestogen hormone and also has greater than 99% effectiveness in preventing pregnancy. The injectables are another highly effective method of contraception. It is a hormonal method that is injected either monthly or every 2–3 months, depending on the product. When used correctly and consistently, the effectiveness of preventing pregnancy is greater than 99%.

Outcomes

Clinical outcomes of interest were the following:

- Effectiveness was defined as uptake of the contraception and/or continuation rates. The continuation rates looked at how many women continued the method either at the 3-month, 6-month or 12-month mark.
- Safety outcome had two subcategories: severe adverse effects and other complications. Severe adverse effects were defined as any serious adverse events such as method failure, infection, abscesses or hospitalization. The category of other complications included skin reactions or injection problems.
- Measures of satisfaction included reports of overall satisfaction with the contraception service and the method. Satisfaction towards the contraception provider was also recorded.

Data collection and analysis

Titles and abstracts were screened for inclusion. Of the included studies, data was extracted and risk of bias was assessed according to the criteria outlined in the *Cochrane handbook for systematic reviews of interventions*. The GRADE (Grading of Recommendations Assessment, Development and Evaluation) system was applied to assess the overall quality of the evidence. This approach takes into account five aspects (study limitations, consistency of effect, imprecision, indirectness and publication bias) to determine the quality of the body of evidence for each outcome. Evidence can be downgraded from "high quality" by one level for serious, or by two levels for very serious, limitations depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias. The GRADE profiler (Grade 2014) was used to import data from Review Manager 5.3 (RevMan 2014) to create GRADE evidence profiles and Summary of Findings tables. Forest plots were made to graphically illustrate the relative risk estimates.

Main results

Figure 1. Identification of studies for inclusion: Doctors of alternative systems of medicine

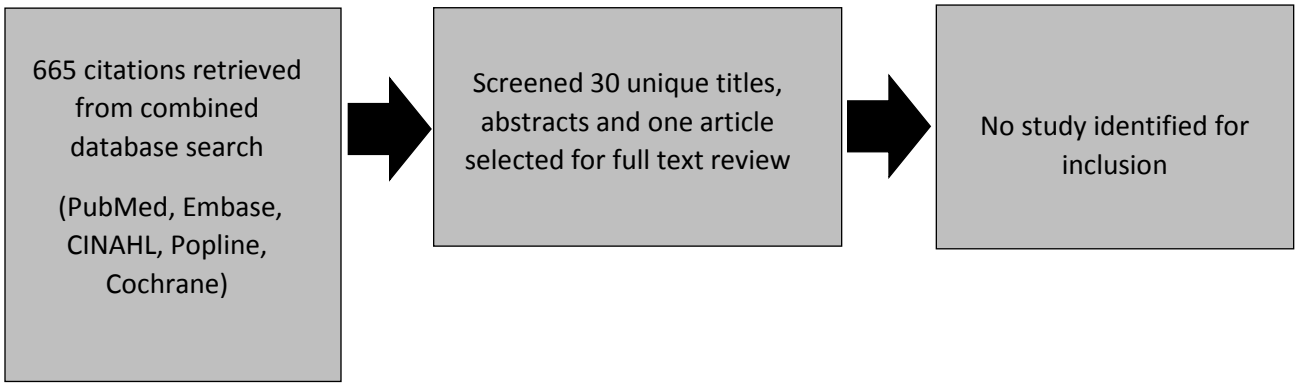
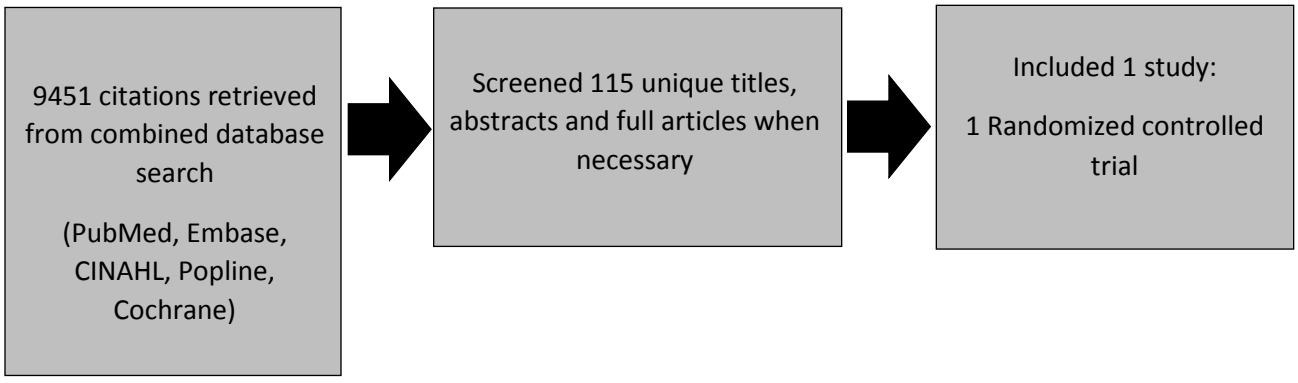


Figure 2. Identification of studies for inclusion: Pharmacists/pharmacy workers



References

World Health Organization (2012). Optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting.

Picardo C., Ferreri S. (2010) Pharmacist-administered subcutaneous depot medroxyprogesterone acetate: a pilot randomized controlled trial. Contraception. 82(2):160-167.

Beasley A, White KO, Cremers S, Westhoff C. (2014) Randomized clinical trial of self versus clinical administration of subcutaneous depot medroxyprogesterone acetate. Contraception. 89(5):352-6.

Cameron ST, Glasier A, Johnstone A. (2012) Pilot study of home self-administration of subcutaneous depo-medroxyprogesterone acetate for contraception. Contraception. 85(5):458-464.

Stanwood NL, Eastwood K, Carletta A. (2006) Self-injection of monthly combined hormonal contraceptive. Contraception. 73(1):53-55.

Annex 22. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns (Nkansah 2010)

Nkansah N, Mostovetsky O, Yu C, Chheng T, Beney J, Bond CM, Bero L. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. Cochrane Database of Systematic Reviews. 2010;(7):CD000336
(http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000336.pub2/abstract).

Abstract

Background

The roles of pharmacists in patient care have expanded from the traditional tasks of dispensing medications and providing basic medication counselling to working with other health professionals and the public. Multiple reviews have evaluated the impact of pharmacist-provided patient care on health-related outcomes. Prior reviews have primarily focused on in-patient settings. This systematic review focuses on services provided by outpatient pharmacists in community or ambulatory care settings. This is an update of the Cochrane review published in 2000.

Objectives

To examine the effect of outpatient pharmacists' non-dispensing roles on patient and health professional outcomes.

Search methods

This review has been split into two phases. For Phase I, we searched the Cochrane Effective Practice and Organisation of Care (EPOC) Group Specialised Register (January 1966 through March 2007). For Phase II, we searched Medline/Embase (January 1966 through March 2008). The Phase I results are reported in this review; Phase II will be summarized in the next update.

Selection criteria

Randomized controlled trials comparing:
1. Pharmacist services targeted at patients versus services delivered by other health professionals;
2. Pharmacist services targeted at patients versus the delivery of no comparable service;
3. Pharmacist services targeted at health professionals versus services delivered by other health professionals;
4. Pharmacist services targeted at health professionals versus the delivery of no comparable service.

Data collection and analysis

Two authors independently reviewed studies for inclusion, extracted data, and assessed risk of bias of included studies.

Main results

Forty-three studies were included; 36 studies were pharmacist interventions targeting patients and seven studies were pharmacist interventions targeting health professionals. For comparison 1, the only included study showed a significant improvement in systolic blood pressure for patients receiving medication management from a pharmacist compared to usual care from a physician. For comparison 2, in the five studies evaluating process of care outcomes, pharmacist services reduced the incidence of therapeutic duplication and decreased the total number of medications prescribed. Twenty-nine of 36 studies reported clinical and humanistic outcomes. Pharmacist interventions resulted in improvement in most clinical outcomes, although these improvements were not always statistically significant. Eight studies reported patient quality of life outcomes; three studies showed improvement in at least three subdomains. For comparison 3, no studies were identified meeting the inclusion criteria. For comparison 4, two of seven studies demonstrated a clear statistically significant improvement in prescribing patterns.

Authors' conclusions

Only one included study compared pharmacist services with other health professional services, hence we are unable to draw conclusions regarding comparisons 1 and 3. Most included studies supported the role of pharmacists in medication/therapeutic management, patient counselling, and providing health professional education with the goal of improving patient process of care and clinical outcomes, and of educational outreach visits on physician prescribing patterns. There was great heterogeneity in the types of outcomes measured across all studies. Therefore a standardized approach to measure and report clinical, humanistic, and process outcomes for future randomized controlled studies evaluating the impact of outpatient pharmacists is needed. Heterogeneity in study comparison groups, outcomes, and measures makes it challenging to make generalized statements regarding the impact of pharmacists in specific settings, disease states and patient populations.

Annex 23. The effect of pharmacist-provided non-dispensing services on patient outcomes, health service utilization and costs in low- and middle-income countries (Pande 2013)

Pande S, Hiller JE, Nkansah N, Bero L. The effect of pharmacist-provided non-dispensing services on patient outcomes, health service utilisation and costs in low- and middle-income countries. *Cochrane Database of Systematic Reviews.* 2013;(2):CD010398 (http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010398/abstract).

Abstract

Background

The role of pharmacists has expanded beyond dispensing and packaging over the past two decades, and now includes ensuring rational use of drugs, improving clinical outcomes and promoting health status by working with the public and other health-care professionals.

Objectives

To examine the effect of pharmacist-provided non-dispensing services on patient outcomes, health service utilization and costs in low- and middle-income countries.

Search methods

Studies were identified by electronically searching the Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library (February 2010), Medline (1949 to February 2010), Scopus (1960 to March 2010) and International Pharmaceutical Abstracts (1970 to January 2010) databases. An update of this review is currently ongoing. The search was re-run September 2012 and the potentially relevant studies are awaiting classification.

Selection criteria

Randomized controlled trials, non-randomized controlled trials, controlled before-after studies and interrupted time series analyses comparing:
1. pharmacist-provided non-dispensing services targeted at patients versus (a) the same services provided by other health-care professionals, (b) the same services provided by untrained health workers, and (c) usual care; and
2. pharmacist-provided non-dispensing services targeted at health-care professionals versus (a) the same services provided by other health-care professionals, (b) the same services provided by untrained health workers, and (c) usual care in low- and middle-income countries.

The research sites must have been located in low- or middle-income countries according to World Bank Group 2009 at the time of the study, regardless of the location or the origin of the researchers.

Data collection and analysis

Two authors independently reviewed studies for inclusion in the review. Two review authors independently extracted data for each study. Risk of bias of the included studies was also assessed independently by two authors.

Main results

Twelve studies comparing pharmacist-provided services versus usual care were included in this review. Of the 12 studies, seven were from lower middle-income countries and five were from upper middle-income countries. Eleven studies examined pharmacist-provided services targeted at patients and one study evaluated pharmacist interventions targeted at health-care professionals. Pharmacist-provided services targeting patients resulted in a small improvement of clinical outcomes such as blood pressure (-25 mm Hg/-6 mm Hg and -4.56 mm Hg/-2.45 mm Hg), blood glucose (-39.84 mg/dl and -16.16 mg/dl), blood cholesterol (-25.7 mg/dl)/ triglyceride levels (-80.1 mg/dl) and asthma outcomes (peak expiratory flow rate 1.76 l/min). Moreover, there was a small improvement in the quality of life, although four studies did not report the effect size explicitly. Health service utilization, such as rate of hospitalization and general practice and emergency room visits, was also found to be reduced by the patient targeted pharmacist-provided services. A single study examined the effect of patient targeted pharmacist interventions on medical expenses and the cost was found to be reduced. A single study that examined pharmacist services that targeted health-care professionals demonstrated a very small impact on asthma symptom scores. No studies assessing the impact of pharmacist-provided non-dispensing services that targeted health-care professionals reported health service utilization and cost outcomes. Overall, five studies did not adequately report the numerical data for outcomes but instead reported qualitative statements about results, which prevented an estimation of the effect size.

Studies for the comparison of patient targeted services provided by pharmacists versus the same services provided by other health-care professionals or untrained health workers were not found. Similarly, studies for the comparison of health-care professional targeted services provided by pharmacists versus the same services provided by other health-care professionals or untrained health workers were not found.

Authors' conclusions

Pharmacist-provided services that target patients may improve clinical outcomes such as management of high glucose levels among diabetic patients, management of blood pressure and cholesterol levels and may improve the quality of life of patients with chronic conditions such as diabetes, hypertension and asthma. Pharmacist services may reduce health service utilization such as visits to general practitioners and hospitalization rates. We are uncertain about the effect of educational sessions by pharmacists for health-care professionals due to the imprecision of a single study included in this review. Similarly, conclusions could not be drawn for health service utilization and costs due to lack of evidence on interventions delivered by pharmacists to health-care professionals. These results were heterogeneous in the types of outcomes measured, clinical conditions and approaches to measurement of outcomes, and require cautious interpretation. All eligible studies were from middle-income countries and the results may not be applicable to low-income countries.

Summary of Findings

Pharmacist-provided services targeted at patients versus usual care		
People	Pharmacists (or pharmacies) delivering services in outpatient settings	
Settings	Sudan (1), India (2), Egypt (1), Paraguay (1), Thailand (2), Chile (2), Bulgaria (2), and South Africa (1)	
Intervention	Counselling/patient education (3), counselling/patient education + booklet (4), counselling + drug review (1), pharmaceutical plan with scheduled follow-up + patient education + booklet (4), counselling + booklet + special medical container (1), counselling + special medical container (1)	
Comparison	Usual care provided by pharmacists	
Outcomes	• Impact	Certainty of the evidence (GRADE)
Clinical outcomes	• Additional pharmacist services may lead to small improvements in clinical outcomes* for diabetic and hypertensive patients	⨁⨁◯◯ Low
• Quality of life	• Additional pharmacist services probably leads to small improvements in quality of life	⨁⨁⨁◯ Moderate
• Health service utilization	Additional pharmacist services may reduce the rate of hospitalization, general practice visits and emergency visits.	⨁⨁◯◯ Low
• Medication costs	• Additional pharmacist services may reduce medication costs of patients with asthma and chronic obstructive pulmonary disease. Other costs were not reported.	⨁⨁◯◯ Low
GRADE: GRADE Working Group grades of evidence (see above and last page) * Fasting blood glucose, random blood glucose, glycosylated haemoglobin, systolic blood pressure, blood cholesterol, peak expiratory flow rate, clinical conditions and approaches to measurement of outcomes varied across studies.		

Annex 24. Community pharmacy personnel interventions for smoking cessation (Sinclair 2004)

Sinclair HK, Bond CM, Stead LF. Community pharmacy personnel interventions for smoking cessation. Cochrane Database of Systematic Reviews. 2004;(1):CD003698 (http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003698.pub2/abstract).

Abstract

Background

Smoking cessation is a potentially appropriate role for community pharmacists because they are encouraged to advise on the correct use of nicotine replacement therapy (NRT) products and to provide behavioural support to aid smoking cessation.

Objectives

This review assessed the effectiveness of interventions by community pharmacy personnel to assist clients to stop smoking.

Search methods

A search was made of the Cochrane Tobacco Addiction Group database for smoking cessation studies conducted in the community pharmacy setting, using the search terms pharmacist* or pharmacy or pharmacies. Date of most recent search: October 2007.

Selection criteria

Randomized trials which compared interventions by community pharmacy personnel to promote smoking cessation amongst their clients who were smokers compared to usual pharmacy support or any less intensive programme. The main outcome measure was smoking cessation rates at six months or more after the start of the intervention.

Data collection and analysis

Data were extracted by one author and checked by the second, noting: the country of the trial, details of participant community pharmacies, method of subject recruitment, smoking behaviour and characteristics of participants on recruitment, method of randomization, description of the intervention and of any pharmacy personnel training, and the outcome measures.

Methodological quality was assessed according to the extent to which the allocation to intervention or control was concealed. Because of the potentially important cluster effects, we also rated trials according to whether they checked for or adjusted for these but, in the absence of consensus on how to

pool cluster level data, we adopted a narrative approach to synthesizing the data, rather than a formal meta-analysis.

Main results

We identified two trials which met our selection criteria. They included a total of 976 smokers. Both trials were set in the United Kingdom and involved a training intervention which included the Stages of Change Model; they then compared a support programme involving counselling and record keeping against a control receiving usual pharmacy support. In both studies a high proportion of intervention and control participants began using NRT.

Both studies reported smoking cessation outcomes at three time points. However, the follow-up points were not identical (3, 6 and 12 months in one, and 1, 4 and 9 months in the other), and the trend in abstinence over time was not linear in either study, so the data could not be combined. One study showed a significant difference in self-reported cessation rates at 12 months: 14.3% versus 2.7% ($P < 0.001$); the other study showed a positive trend at each follow-up with 12.0% versus 7.4% ($P = 0.09$) at 9 months.

Authors' conclusions

The limited number of studies to date suggests that trained community pharmacists, providing a counselling and record keeping support programme for their customers, may have a positive effect on smoking cessation rates. The strength of evidence is limited because only one of the trials showed a statistically significant effect.

Annex 25. PICO questions

In addition to the identified outcomes on safety, effectiveness and satisfaction, acceptability and feasibility were assessed for all questions using qualitative data. Further details can be found in *Web Supplement 3*.

Surgical abortion

- **MVA1**: Is provision of **manual vacuum aspiration (MVA**) **for induced abortion** by *doctors of complementary systems of medicine, associate clinicians, midwives, nurses and auxiliary nurses* a safe, effective, and satisfactory option to provision of MVA by physicians?
    - P: Women having an induced abortion at < 12–14 weeks
    - I: MVA provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses or auxiliary nurses
    - C: MVA provided by non-specialist or specialist doctors (obstetrician/gynaecologists).
    - O:
        - Safety: Serious adverse events (e.g. hospital admission, need for further surgery (excluding treatment for incomplete abortion or ongoing pregnancy), blood transfusion, or death). When the severity of reported outcomes was uncertain and/or hospital admission and treatment was not clearly stated to accurately appraise reported abortion-related complications, we reported overall complications, including haematometra, bleeding/haemorrhage, infection, uterine perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death.
        - Effectiveness: Complete abortion following the procedure (e.g. absence of retained products of conception/incomplete abortion and/or need for additional uterine evacuation with medical or surgical treatment, ongoing pregnancy or ectopic pregnancy).
        - Satisfaction: Reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type.

- **MVA2**: Is provision of **manual vacuum aspiration (MVA**) **for incomplete abortion** by *doctors of complementary systems of medicine, associate clinicians, midwives, nurses and auxiliary nurses* a safe, effective or satisfactory option compared to provision of MVA by physicians?
    - P: Women having an induced abortion at < 12–14 weeks.
    - I: MVA provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses or auxiliary nurses.
    - C: MVA provided by non-specialist or specialist doctors (obstetrician/gynaecologists).
    - O:
        - Safety: Serious adverse events (e.g. hospital admission, need for further surgery (excluding treatment for incomplete abortion or ongoing pregnancy), blood transfusion, or death). When the severity of reported outcomes was uncertain and/or hospital admission and treatment was not clearly stated to accurately appraise reported abortion-related complications, we reported overall complications, including haematometra, bleeding/haemorrhage, infection, uterine

perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death.
        - Effectiveness: Complete abortion following the procedure (e.g. absence of retained products of conception/incomplete abortion and/or need for additional uterine evacuation with medical or surgical treatment, ongoing pregnancy or ectopic pregnancy).
        - Satisfaction: Reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type.

- **EVA1**: Is provision of **electric vacuum aspiration (EVA) for induced abortion** by *doctors of complementary systems of medicine, associate clinicians, midwives, nurses and auxiliary nurses* a safe, effective, or satisfactory option to provision of MVA by physicians?
    - P: Women having an induced abortion at < 12–14 weeks.
    - I: EVA provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses or auxiliary nurses.
    - C: EVA provided by non-specialist or specialist doctors (obstetrician/gynaecologists).
    - O:
        - Safety : Serious adverse events (e.g. hospital admission, need for further surgery (excluding treatment for incomplete abortion or ongoing pregnancy), blood transfusion, or death). When the severity of reported outcomes was uncertain and/or hospital admission and treatment was not clearly stated to accurately appraise reported abortion-related complications, we reported overall complications, including haematometra, bleeding/haemorrhage, infection, uterine perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death.
        - Effectiveness: Complete abortion following the procedure (e.g. absence of retained products of conception/incomplete abortion and/or need for additional uterine evacuation with medical or surgical treatment, ongoing pregnancy or ectopic pregnancy).
        - Satisfaction: Reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type

- **EVA2**: Is provision of **electric vacuum aspiration (EVA) for incomplete abortion** by *doctors of complementary systems of medicine, associate clinicians, midwives, nurses and auxiliary nurses* a safe, effective, or satisfactory option to provision of MVA by physicians?
    - P: Women having an induced abortion at < 12–14 weeks.
    - I: EVA provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses or auxiliary nurses.
    - C: EVA provided by non-specialist or specialist doctors (obstetrician/gynaecologists).
    - O:
        - Safety : Serious adverse events (e.g. hospital admission, need for further surgery (excluding treatment for incomplete abortion or ongoing pregnancy), blood transfusion, or death). When the severity of reported outcomes was uncertain and/or hospital admission and treatment was not clearly stated to accurately appraise reported abortion-related complications, we reported overall

complications, including haematometra, bleeding/haemorrhage, infection, uterine perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death.
        - Effectiveness: Complete abortion following the procedure (e.g. absence of retained products of conception/incomplete abortion and/or need for additional uterine evacuation with medical or surgical treatment, ongoing pregnancy or ectopic pregnancy).
        - Satisfaction: Reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type.

- **D&E1**: Is provision of **dilatation and evacuation (D&E) for induced abortion** by *generalist doctors, doctors of complementary systems of medicine and associate clinicians* a safe, effective, or satisfactory option to provision of D&E by specialist doctors?
    - P: Women having an induced abortion > 12–14 weeks.
    - I: D&E provided by generalist (non-specialist) doctors, doctors of complementary systems of medicine or associate clinicians.
    - C: D&E provided by specialist doctors (obstetrician/gynaecologists).
    - O:
        - Safety: Serious adverse events (e.g. hospital admission, need for further surgery (excluding treatment for incomplete abortion or ongoing pregnancy), blood transfusion, or death). When the severity of reported outcomes was uncertain and/or hospital admission and treatment was not clearly stated to accurately appraise reported abortion-related complications, we reported overall complications, including haematometra, bleeding/haemorrhage, infection, uterine perforation, injury to abdominopelvic viscera, cervical injury/lacerations, drug or anaesthesia-related complications, shock, coma or death.
        - Effectiveness: Complete abortion following the procedure (e.g. absence of retained products of conception/incomplete abortion and/or need for additional uterine evacuation with medical or surgical treatment, ongoing pregnancy or ectopic pregnancy).
        - Satisfaction: Reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type.

- **PRIME1:** Does the provision of **cervical priming using osmotic dilators** performed by *doctors of complementary systems of medicine, associate clinicians, midwives, nurses or auxiliary nurse midwives* safe, effective and satisfactory to women undergoing treatment to provision by physicians?
    - P: Women having an induced abortion with vacuum aspiration or D&E.
    - I: Cervical priming with osmotic dilators provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses or auxiliary nurse midwives.
    - C: Cervical priming done by doctors.
    - O:
        - Effectiveness: Degree of dilation and perceived ease of procedure by provider.
        - Safety: Cervical or uterine injury/perforation, need for emergent surgical intervention or extramural expulsion of the products of conception/fetus.

        - Satisfaction: Reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type

- **PRIME2:** Does the provision of **cervical priming using medications** performed by *doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurse midwives, pharmacists and pharmacy workers* safe, effective and satisfactory to women undergoing treatment to provision by physicians?
    - P: Women having an induced abortion with vacuum aspiration or D&E.
    - I: Cervical priming with medications provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurse midwives, pharmacists or pharmacy workers.
    - C: Cervical priming done by doctors
    - O:
        - Effectiveness: Degree of dilation and perceived ease of procedure by provider.
        - Safety: Cervical or uterine injury/perforation, need for emergent surgical intervention or extramural expulsion of the products of conception/fetus.
        - Satisfaction: Reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type.

Medical abortion and its component tasks

- **MA1:**[2] Is provision of **medical abortion (MA) for gestation < 84 days (< 12 weeks)** by *doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers and lay health workers* a safe, effective, or satisfactory option to provision of MA by physicians?
    - P: Women with pregnancies < 84 days (12 weeks) having an induced abortion.
    - I: MA provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers or lay health workers.
    - C: MA provided by non-specialist or specialist doctors (obstetrician/gynaecologists).
    - O:
        - Safety : Serious adverse events (hospital admission, blood transfusion or death).
        - Effectiveness: Complete abortion without need for additional intervention following the procedure (e.g. absence of retained products of conception/incomplete abortion, ongoing pregnancy or ectopic pregnancy).
        - Satisfaction: Reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type.

[2] Note: Provision of medical abortion assumes the ability to perform all the component tasks (determining eligibility, administering drugs, managing side-effects, assessing the need for repeat doses of misoprostol or of surgery and diagnosing ongoing pregnancy). The panel decided that the ability to perform surgical evacuation in case of failure is not considered an essential part of this package but a referral link to a provider (on-site or at another facility) able to perform a surgical evacuation is adequate.

- **MA1.1**: Can *doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers and lay health workers* **assess eligibility for medical abortion** as accurately as physicians?
    - P: Women with pregnancies < 84 days (12 weeks) having an induced abortion.
    - I: Eligibility assessment by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers, lay health workers.
    - C: Eligibility assessment by non-specialist or specialist doctors (obstetrician/ gynaecologists).
      O: Proportion of women deemed eligible for medical abortion by provider type and accuracy of these assessments when measured against an independent verifier and/or diagnostic standard.

- **MA1.2:** Can *doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers and lay health workers* correctly **administer medications for medical abortion with instructions for their use**?
    - P: Women with pregnancies < 84 days (12 weeks) having an induced abortion.
    - I: Administration of medications with instructions by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers or lay health workers.
    - C: Administration of medications with instructions by doctors.
    - O:
        - Participants' adherence to the recommended medical abortion regimen following instruction by provider type.

- **MA1.3**: Can *doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers and lay health workers* **manage the common symptoms and minor side-effects** associated with **medical abortion?**
    - P: Women with pregnancies < 84 days (12 weeks) having an induced abortion
    - I: Management of bleeding, pain, fever, nausea, vomiting or diarrhoea associated with medical abortion by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers or lay health workers.
    - C: Management by doctors.
    - O:
        - Effectiveness/safety: recognized problem and offered appropriate treatment and/or referral for further care.

- **MA 1.4** Can *doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers and lay health workers* **accurately assess successful completion of the medical abortion process**?
    - P: Women with pregnancies < 84 days (12 weeks) having an induced abortion
    - I: Assessment of completion of abortion by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers or lay health workers.

- C: Assessment of completion of abortion by doctors.
- O: Proportion of women assessed to have complete abortion by provider type and accuracy of these assessments when measured against an independent verifier and/or diagnostic standard.

- **MA2:** Is management of **incomplete abortion with misoprostol** by *doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers and lay health workers* a safe, effective, or satisfactory option to provision of MA by physicians?
  - P: Women with incomplete abortion.
  - I: Misoprostol management provided by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers or lay health workers.
  - C: misoprostol management provided by doctors.
  - O:
    - Safety : Serious adverse events (hospital admission, blood transfusion or death).
    - Effectiveness: Complete abortion without need for additional intervention following the procedure (e.g. absence of retained products of conception/incomplete abortion, ongoing pregnancy or ectopic pregnancy).
    - Satisfaction: Reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type.

- **MA3**[3]: Can women themselves **manage the process of medical abortion < 84 days** (< 12 weeks) **in whole or in part** (assessing eligibility, administration of mifepristone and or misoprostol, self-assessing completions) without direct provider supervision?
  - P: Women having a medical abortion at < 84 days (12 weeks).
  - I: Women acquiring the drugs from a legitimate health source and managing the process of medical abortion without direct provider supervision.
  - C: Medical abortion managed by trained health professional.
  - O:
    - Safety: Serious adverse events (hospital admission, blood transfusion or death).
    - Effectiveness: Complete abortion without need for additional intervention following the procedure (e.g. absence of retained products of conception/incomplete abortion, ongoing pregnancy or ectopic pregnancy).
    - Satisfaction: Reports of overall satisfaction with self-management.

- **MA3.1**: Can women themselves **assess eligibility for medical abortion** as accurately as physicians or other trained health-care providers?
  - P: Women having a medical abortion at < 84 days (12 weeks).
  - I: Eligibility assessment performed by women.

[3] Assumes that women have received information and instructions from a trained provider (face to face or via telemedicine) or from a legitimate health source and that they have access to a trained provider or other health services in case of questions or complications. It does not include clandestine and illegal use.

- C: Eligibility assessment performed by a trained health professional.
- O: Proportion of women deemed eligible for medical abortion by provider type and accuracy of these assessments when measured against an independent verifier and/or diagnostic standard.

- **MA3.2:** Can women themselves correctly **administer medications for medical abortion when provided with instructions for their use from a legitimate health source** compared with trained health professionals?
  - P: Women with pregnancies < 84 days (12 weeks) having an induced abortion.
  - I: Correctly administer medications with instructions.
  - C: Administration of medications with instructions by trained health professionals.
  - O:
    - Participants' adherence to the recommended medical abortion regimen following instruction by provider type.
    - Safety: Serious adverse events (hospital admission, blood transfusion or death).
    - Effectiveness: Complete abortion without need for additional intervention following the procedure (e.g. absence of retained products of conception/incomplete abortion, ongoing pregnancy or ectopic pregnancy).
    - Satisfaction: Reports of overall satisfaction with self-management.

- **MA3.3:** Can women themselves **assess completion of medical abortion** as accurately as physicians or other trained health-care providers?
  - P: Women having a medical abortion at < 84 days (12 weeks).
  - I: Assessment of abortion completion performed by women.
  - C: Assessment of abortion completion by a trained health professional.
  - O:
    - Proportion of women determined to have complete abortion by provider type and accuracy of these assessments when measured against an independent verifier and/or diagnostic standard.
    - Safety: Serious adverse events (hospital admission, blood transfusion or death).
    - Effectiveness: Complete abortion without need for additional intervention following the procedure (e.g. absence of retained products of conception/incomplete abortion, ongoing pregnancy or ectopic pregnancy).
    - Satisfaction: Reports of overall satisfaction with self-assessment.

- **MA4:** Is provision of **medical abortion (MA) for gestation > 84 days** (> 12 weeks) *by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses* a safe, effective, or satisfactory option to provision of MA by physicians?
  - P: Women with pregnancies > 84 days (> 12 weeks) having an induced abortion.
  - I: MA provided by non-specialist doctors, doctors of complementary systems of medicine, associate clinicians, midwives, nurses or auxiliary nurses.
  - C: MA provided by specialist doctors (obstetrician/gynaecologists).
  - O:

- Safety: Serious adverse events (hospital admission, blood transfusion or death).
- Effectiveness: Complete abortion without need for additional intervention following the procedure (e.g. absence of retained products of conception/incomplete abortion, ongoing pregnancy or ectopic pregnancy).
- Satisfaction: Reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type.

Counselling and information provision

- **MESSAGE1**: Can *pharmacy workers and lay health workers* provide accurate **information on the availability of safe providers** for abortion / care for complications?
  - P: Women seeking information about abortion care before treatment or following an incomplete abortion (including medical or surgical, at any gestational age)
  - I: Pre- and post- abortion and contraception counselling by various cadres working with abortion services, in the community or in other locations
  - C: no information (usual practice)
  - O:
    - Maternal mortality and morbidity post-abortion
    - Number of unplanned pregnancies
    - Correct knowledge of contraception options
    - Correct knowledge of safe abortion
    - Correct knowledge of safe post-abortion care
    - Acceptability of contraception advice
    - Mix in types of contraception used.

- **MESSAGE2**: Is provision of pre and post-abortion counselling by *doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers and lay health workers* safe, effective and satisfactory to women receiving services?
  - P: Women having an abortion.
  - I: Pre and post-abortion counselling by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses, pharmacists, pharmacy workers and lay health workers.
  - C: No counselling (usual practice).
  - O:
    - Reduced maternal mortality and morbidity post-abortion
    - Reduction in number of unplanned pregnancies
    - Increased proportion of safe abortions
    - Reduced mean GA or increased proportion induced abortions with lower gestational age (as determined by study authors)
    - Correct knowledge of contraception options (women and cadre)
    - Correct knowledge of safe and appropriate abortion (women and cadre)
    - Correct knowledge of safe post-abortion care (women and cadre)

        - Acceptability of contraception advice to women
        - Increased mix in types of contraception used. Reduced maternal mortality and morbidity post-abortion.

Recognizing and managing complications

- **COMP**: Can *doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses* diagnose and manage abortion-related complications in clinically stable women as safely and effectively as physicians?
    - P: Women presenting with a complication of an induced abortion and who are in a stable condition.
    - I: Diagnosis and management of infection and bleeding by doctors of complementary systems of medicine, associate clinicians, midwives, nurses, auxiliary nurses.
    - C: Diagnosis and management of infection and bleeding by specialist and non-specialist doctors
    - O:
        - Accurate determination of a complication followed by an offer of correct treatment or referral depending on professional capacity and clinical setting.

Contraception provision

- **CONTRA1**: Can *doctors of complementary systems of medicine, pharmacists/pharmacy workers or women themselves,* provide initiation or continuation of injectable contraceptives, insertion and removal of intrauterine devices, or insertion and removal of contraceptive implants following abortion as safely and effectively as trained health professionals?
    - P: Women in the post-abortion period needing contraception.
    - I: Delivery of injectable contraceptives, insertion and removal of IUDs, insertion and removal of contraceptive implants by doctors of complementary systems of medicine, pharmacists/pharmacy workers or women themselves.
    - C: Delivery of injectable contraceptives, insertion and removal of IUDs, insertion and removal of contraceptive implants by trained health professionals.
    - O:
        - Contraceptive uptake and continuation.
        - Safety: Serious adverse events included method failure, hospitalization or other complications related to provision of the method, such as skin reactions associated with injectables.
        - Satisfaction: Reports of overall satisfaction with the provider and/or overall satisfaction with any of the various services managed by a given provider type.

Annex 26. Common PubMed search terms used for systematic reviews

Non-specialty physicians

("Physicians, Primary Care"[Mesh] OR "General Practitioners"[Mesh]) OR "Physicians, Family"[Mesh] OR “Clinical officer” [tiab] OR “Non-specialist doctors” [tiab])

Non-allopathic physician

("Health Services, Indigenous"[Mesh] OR "Medicine, Traditional"[Mesh] OR "Integrative Medicine"[Mesh] OR "Complementary Therapies"[Mesh] OR "Herbal Medicine"[Mesh] OR "Osteopathic medicine"[MeSH Terms] OR "Chiropractic"[Mesh] OR "Naturopathy"[Mesh] OR "Medicine, Ayurvedic"[Mesh] OR "Medicine, Chinese Traditional"[Mesh] OR “complementary medicine” [tiab] OR “alternative medicine”[tiab] OR “chiropractic”[tiab] OR “osteopathic medicine”[tiab] OR “naturopathy”[tiab] OR “traditional medicine”[tiab] OR “ayurveda”[tiab] OR “Chinese medicine”[tiab] OR “TCM”[tiab]) AND ("Health Personnel"[Mesh] OR “personnel” [tiab] OR “provider”[tiab] OR “practitioner” [tiab] OR “professional” [tiab] OR “clinician”[tiab] OR “physician” [tiab])

Advanced level associate clinician and associate clinicians

“Assistant medical officer” [tiab] OR “clinical officer” [tiab] OR “medical licentiate” [tiab] OR “health officer” [tiab] OR “physician assistant” [tiab] OR “surgical technician” [tiab] OR “medical technician” [tiab] OR “non-physician clinician” [tiab] OR “Allied Health Personnel"[Mesh] OR "Hospital Auxiliaries"[Mesh] OR “Physician Assistants"[Mesh] OR "Nurse Clinicians"[Mesh]) OR "Nurse Practitioners"[Mesh]) OR “advanced practice nurse*” [tiab] OR “nurse practitioner*” [tiab] OR “Clinical officer” [tiab] OR “Medical assistant” [tiab] OR “health officer” [tiab] OR “clinical associate” [tiab] OR “physician assistant” [tiab] OR “clinical nurse specialist*” [tiab] OR Non-physician clinician* [tiab] OR “non-professional clinician” [tiab]

Midwives

“Midwifery” [MeSH] OR “midwifery” [tiab] OR “midwives” [tiab] OR “Registered midwife” [tiab] OR “midwife” [tiab] OR “community midwife” [tiab] OR “Nurse Midwife” [Mesh] OR “CNM”[tiab] OR “Certified nurse midwife”[tiab]

Nurses

Nurse [MeSH] OR “nurse*” [tiab] OR “Nursing Personnel” [tiab] OR “Registered nurse*” [tiab] OR “RN”[tiab] OR “practice nurse*” [tiab] OR “licensed nurse” [tiab] OR “diploma nurse” [tiab] OR “BS nurse*” [tiab] OR “nurse clinician*” [tiab] OR "Nurses, International"[Mesh] OR "Nurses, Community Health"[Mesh] OR "Nurses, Public Health"[Mesh] OR “nurse clinician*” [tiab] OR “LPN”[tiab] OR “ LP nurse”[tiab]

Auxiliary nurses and midwives

Nurses' Aides [MeSH] OR nurses' aides [tiab] OR nurses aide [tiab] OR Nurses Aides [tiab] OR Nurses' Aide [tiab] OR nurse aide* [tiab] OR Nursing Auxiliaries [tiab] OR Nursing Auxiliary [tiab] OR Auxiliary nurse* [tiab] OR auxiliary nurse midwife [tiab] OR auxiliary nurse midwives [tiab] OR auxiliary midwife [tiab] OR auxiliary midwives [tiab] OR nurse assistant [tiab]

Pharmacists and pharmacy workers

"Pharmacy"[Mesh] OR "Pharmacists"[Mesh] OR "Pharmacists' Aides"[Mesh] OR "Pharmacies"[Mesh] OR "Community Pharmacy Services"[Mesh] OR "Pharmaceutical Services"[Mesh] OR "pharmacist"[All fields] OR "pharmacists"[All fields] OR "pharmacies"[All fields] OR "pharmacy"[All fields] OR “pharmacist aide”[All fields] OR “pharmacists’ aide”[All fields] OR “pharmacists’ aides”[All fields] OR “community pharmacy services"[All Fields] OR "community pharmacies"[All Fields] OR “community pharmacy”[All fields] OR "pharmaceutical care"[All Fields] OR "pharmaceutical service"[All Fields] OR "pharmaceutical services"[All Fields] OR "chemist"[All Fields] OR “chemists”[All fields] OR "medicine counter assistant"[All Fields] OR "dispensing technician"[All Fields] OR "pharmacy intern"[All Fields] OR "pharmacy interns"[All Fields] OR "pharmacist intern"[All Fields] OR “pharmacist interns”[All fields] OR “pharmacy worker”[All fields] OR “pharmacy technician”[All fields] OR “pharmacy technicians”[All fields] OR “pharmacy-based intervention”[All fields] OR “pharmacy intervention”[All fields] OR “pharmacy-based”[All fields])

Lay heath workers

(Community Health Workers[Mesh] OR Allied Health Personnel[Mesh] OR Volunteers[Mesh] OR Hospital Volunteers[Mesh]) OR (Paraprofessional* [tw] OR paramedic [tw] OR paramedics [tiab] OR paramedical worker* [tiab] OR paramedical personnel [tiab] OR allied health personnel [tiab] OR allied health worker* [tiab] OR support worker* [tiab] OR home health aide*[tiab] OR trained volunteer* [tiab] OR trained health worker* [tiab] OR trained healthcare worker* [tiab] OR trained health care worker*[tiab] OR Lay health worker [tiab] OR lay health workers [tiab] OR lay health volunteer* [tiab] OR Community health worker* [tiab] OR treatment supporter* [tiab] OR birth attendants [tiab] OR Community Health Agents [tiab] OR Agente comunitário de saúde [tiab] OR Visitador* [tiab] OR Women Group Leader* [tiab] OR Maternal Health Worker* [tiab] OR Maternal Child Health Worker* [tiab] OR OR Postnatal Support Worker* [tiab] OR Village Health Promoter* [tiab] OR Rural Health Worker* [tiab] OR maternal and Child Health Promotion Worker* [tiab] OR Community based Workers [tiab] OR Community Health Volunteer* [tiab] OR Village Health Guide* [tiab] OR Female Community Health Volunteer* [tiab] Community Drug Distributor* [tiab] OR Lay Health Visitor* [tiab] OR Community Volunteer* [tiab] OR Community Health Advocate* [tiab] OR Community Health Aide* [tiab] OR Lay volunteer* [tiab] OR lay worker [tiab] OR lay visitor [tiab] OR lay attendant [tiab] OR lay aide [tiab] OR lay aides [tiab] OR lay support* [tiab] OR lay person* [tiab] OR lay helper [tiab] OR lay caregiver* [tiab] OR lay consultant [tiab] OR lay assistant [tiab] OR lay staff [tiab] OR lay visit* [tiab] OR lay midwife [tiab] OR lay midwives [tiab] OR volunteer worker [tiab])

Women/self-management

(“Self Administration"[Mesh] OR "Self Care"[Mesh]) OR "Consumer Participation"[Mesh] OR “Self Assessment” [Mesh] OR “Self Assessments”[Mesh] OR "Patient Participation"[Mesh] OR "Telemedicine"[Mesh] OR “self treatment*”[tiab] OR “self administer*”[tiab] OR “patient management*”[tiab] OR “self care” [tiab] OR “self

management” [tiab] OR “self monitor*”[tiab] OR “patient treat*”[tiab] OR “home” [tiab] OR “telemedicine” [tiab] OR “self screen” [tiab])

Medical abortion

"Abortion, Induced"[Mesh] OR "Abortion, Incomplete"[Mesh] OR "Abortion, Spontaneous"[Mesh] OR “abortion” [tiab] OR “miscarriage”[tiab] OR “pregnancy termination”[tiab] OR “termination of pregnancy”[tiab] OR “postabortion care” [tiab] OR “incomplete abortion”[tiab] OR "Mifepristone"[Mesh] OR "Misoprostol"[Mesh] OR “RU486”[tiab] OR “mifegyne”[tiab] OR “Cytotec”[tiab] OR “Medabon”[tiab] OR “medication abortion”[tiab] OR “medical abortion”[tiab]

Surgical abortion

"Abortion, Induced"[Mesh] OR "Abortion, Incomplete"[Mesh] OR "Abortion, Spontaneous"[Mesh] OR “abortion” [tiab] OR “miscarriage”[tiab] OR “pregnancy termination”[tiab] OR “termination of pregnancy”[tiab] OR “postabortion care” [tiab] OR “incomplete abortion”[tiab] OR "Extraction, Obstetrical"[Mesh] OR "Dilatation and Curettage"[Mesh] OR "Vacuum Curettage"[Mesh] OR “surgical abortion” [tiab] OR “dilation and evacuation”[tiab] OR “D&E”[tiab] OR “suction curettage”[tiab] OR “vacuum aspiration”[tiab] OR “D&C”[tiab] OR “menstrual regulation”[tiab]

Pregnancy

"Pregnancy"[Mesh] OR "Pregnancy, Unplanned"[Mesh] OR “pregnancy” [tiab] OR “IUP” [tiab]

Eligibility/completion assessment

("Eligibility Determination"[Mesh] OR "Ultrasonography"[Mesh] OR "Pregnancy Tests"[Mesh] OR "Checklist"[Mesh] OR "Medical History Taking"[Mesh] OR "Physical Examination"[Mesh] OR “eligibility”[tiab] OR “eligibility assessment”[tiab] OR “pregnancy dating”[tiab] OR “gestational age”[tiab] OR “pregnancy test”[tiab] OR “checklist”[tiab] OR “medical history”[tiab] OR “bimanual examination”[tiab] OR “ultrasound”[tiab] OR “ultrasonography”[tiab] OR “sonogram”[tiab] OR “last menstrual period”[tiab] OR “LMP”[tiab]

Common side-effects of medical abortion

"Nausea"[Mesh] OR "Fever"[Mesh] OR "Diarrhea"[Mesh] OR "Chills"[Mesh] OR "Pain"[Mesh] OR "Acute Pain"[Mesh] OR "Pain Management"[Mesh] OR “nausea” [tiab] OR “fever”[tiab] OR “diarrhea”[tiab] OR “diarrhoea”[tiab] OR “chills”[tiab] OR “pain”[tiab]

Abortion-related complications

"Hemorrhage"[Mesh]) OR "Postoperative Hemorrhage"[Mesh] OR "Uterine Hemorrhage"[Mesh] OR "Postpartum Hemorrhage"[Mesh] OR "Infection"[Mesh] OR "Pelvic Infection"[Mesh] OR "Uterine Perforation"[Mesh] OR "Uterine Rupture"[Mesh] OR "Pregnancy Complications"[Mesh] OR "Postoperative Complications"[Mesh] OR "Intraoperative Complications"[Mesh] OR "Emergency Treatment"[Mesh] OR “Abortion, Septic” [Mesh] OR “haemorrhage” [tiab] OR “haemorrhage”[tiab] OR “hemorrhage”[tiab] OR “bleeding”[tiab] OR “endometritis”[tiab] OR “parametritis”[tiab] OR “metritis” [tiab] OR “pelvic infection” [tiab] OR “uterine infection” [tiab] OR “uterine perforation” [tiab] OR “abortion-related complications” [tiab] OR “emergency care” [tiab] OR “ongoing pregnancy” [tiab] OR

“ectopic pregnancy” [tiab] OR “emergency treatment” [tiab] OR “EmOC”[tiab] OR “emergency obstetric care”[tiab] OR “complications”[tiab]

Contraception

Intrauterine Devices [MeSH] OR Intrauterine Devices [tw] OR Intrauterine Device [tw] OR Contraceptive IUD [tw] OR Contraceptive IUDs [tw] OR Intrauterine Contraceptive Device* [tw] OR Unmedicated IUDs [tw] OR Unmedicated IUD [tw]

Drug implants [MeSH] OR Drug implants [tw] OR drug implant [tw] OR Drug Pellets [tw] OR Levonorgestrel [MeSH] OR Norethindrone [MeSH] OR contraceptive implants [tw] OR progestogen only contraceptives OR contraceptive implant [tw] OR progestogen implants [tw] OR etonogestrel implants [tw] OR Implanon [tw] OR Subdermal contraceptive implant* [tw] OR Norplant [tw] OR Jadelle [tw] OR Sino-implant[tw] Nexplanon [tw] OR Norprogesterones [tw]

“injections”[MeSH] OR “injections”[tiab] OR “injectable”[tiab] OR “algestone acetophenide” [tiab] OR DMPA [tiab] OR deladroxate [tiab] OR “dihydroxyprogesterone acetophenide” [tiab] OR estradiol cypionate [tiab] OR estradiol 17 beta-cypionate [tiab] OR estradiol valerate [tiab] OR medroxyprogesterone acetate [tiab] OR medroxyprogesterone 17-acetate [tiab] OR medroxyprogesterone acetate-17 [tiab] OR 17-medroxyprogesterone acetate [tiab] OR mpa [tiab] OR NET-EN [tiab] OR NET-ENT [tiab] OR NET-OEN [tiab] OR noresterat [tiab] OR norethindrone enanthate [tiab] OR norethindrone oenanthate [tiab] OR norethisterone enanthate [tiab] OR norethisterone oenanthate [tiab] OR Depoprovera OR Depo-provera OR Curretab [tiab] OR Cycrin [tiab] OR “Depo-Provera” [tiab] OR “Depo Provera” [tiab] OR DepoProvera[tiab] OR Farlutal [tiab] OR Perlutex [tiab] OR Provera [tiab] OR Veramix [tiab] OR Clinovir [tiab] OR Gestapuran [tiab

Counselling and information

counseling OR counselling OR reminder* OR "peer counseling" OR "peer counselling"[Title/Abstract]) OR (counseling[MeSH Terms]) AND (("methods"[MeSH Subheading] OR "organization and administration"[MeSH Subheading] OR "standards"[MeSH Subheading])) OR (directive counseling[MeSH Terms]) AND (("manpower"[MeSH Subheading] OR "methods"[MeSH Subheading] OR "organization and administration"[MeSH Subheading] OR "standards"[MeSH Subheading] OR "utilization"[MeSH Subheading])) OR (access to information[MeSH Terms]) AND (("ethics"[MeSH Subheading] OR "organization and administration"[MeSH Subheading] OR "psychology"[MeSH Subheading] OR "standards"[MeSH Subheading] OR "trends"[MeSH Subheading])) OR (information centers[MeSH Terms]) AND (("organization and administration"[MeSH Subheading] OR "utilization"[MeSH Subheading])) OR (consumer health information[MeSH Terms]) AND (("manpower"[MeSH Subheading] OR "methods"[MeSH Subheading] OR "nursing"[MeSH Subheading] OR "organization and administration"[MeSH Subheading] OR "standards"[MeSH Subheading] OR "utilization"[MeSH Subheading]))