Safety and effectiveness of termination services performed by doctors versus midlevel providers: a systematic review and analysis

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Objective: Training midlevel providers (MLPs) to conduct surgical abortions and manage medical abortions has been proposed as a way to increase women’s access to safe abortion. This paper reviews the evidence that compares the effectiveness and safety of abortion procedures administered by MLPs versus doctors.

Methods: A systematic search was conducted of published trials and comparison studies assessing the effectiveness and/or safety of abortion provided by MLPs compared to doctors. The Cochrane Central Register of Controlled Trials, EMBASE, MEDLINE, and Popline were searched. The primary outcomes of interest were: (1) incomplete or failed abortion; and (2) measures of safety (adverse events and complications) of abortion procedures administered by MLPs and doctors. Odds ratios (ORs) and their 95% confidence intervals (CIs) were calculated for each study. Data were synthesized in a narrative fashion.

Findings: Five studies were included in this review (n = 8539 women), comprising two randomized controlled trials (RCTs) (n = 3821) and three prospective cohort studies (n = 4718). In total, 4198 women underwent a procedure administered by an MLP, and 4341 women underwent a physician-administered procedure. Studies took place in the US, Nepal, South Africa, Vietnam, and India. Four studies used surgical abortion with maximum gestational ages ranging from 10 to 16 weeks, while a medical abortion study had gestational ages up to 9 weeks. In RCTs, the effect estimates for incomplete or failed abortion for procedures performed by MLPs compared with doctors were OR = 2.00 (95% CI 0.85–4.68) for surgical abortion, and OR = 0.69 (95% CI 0.34–1.37) for medical abortion. Complications were rare among both provider types (1.2%–3.1%; OR = 1.80, 95% CI 0.83–3.90 for surgical abortions), and no deaths were reported.

Conclusion: There were no statistical differences in incomplete abortion and complications for first trimester surgical and medical abortion up to 9 weeks performed by MLPs compared with physicians. Further studies are required to establish more precise effect estimates.

Keywords: abortion, misoprostol, manual vacuum aspiration, medical abortion

Introduction
Unsafe abortion remains a major public health concern in developing countries. Despite the existence of safe and effective surgical1 and medical2 methods to induce abortion, an estimated 22 million abortions are performed unsafely each year, resulting in the deaths of 47,000 women and disabilities for an additional 5 million women.3 Most of these deaths and disabilities could be prevented through the provision of safe and legal induced abortion by qualified providers.

To ensure that women living in developing countries can readily access safe termination services, the World Health Organization (WHO) recommends that abortion...
can be provided at the lowest level of the health care system. However, in many developing countries, even in settings where abortion is legal, access to abortion remains limited due to a shortage of trained physicians (gynecologists and obstetricians). Irrespective of legal conditions, in settings where access to safe abortion care is lacking, women often obtain termination services from unqualified or unskilled providers. Therefore, training midlevel providers (MLPs – midwives, nurses, and other nonphysician providers) to conduct first-trimester aspiration abortions and manage medical abortions has been proposed as a way to increase women’s access to safe termination services.

Authorizing and training MLPs to provide abortion could reduce the number of unsafe procedures and alleviate burden on the health care system. A review of medical abortion service delivery suggests that the provision and management of medical abortion by MLPs is cost-effective in resource-limited settings due to the salary costs and scarcity of obstetrician-gynecologists. However, only a few countries across the world adopt this practice. In developed settings (France, Sweden, the UK, and the USA), nurses and midwives are not permitted to manage and administer abortion procedures independently. Only a handful of countries in the developing world permit midwives to perform surgical abortion (Cambodia, South Africa, and Vietnam) or paramedics to carry out “menstrual regulation” procedures (Bangladesh). In these countries, national policies limit access to medical abortion by restricting its prescription and provision to certified physicians.

Restrictions on midlevel provision are mainly due to concerns about the standard of care and safety of abortions provided by MLPs. The evidence on the effectiveness and safety of abortion procedures performed by midlevel providers compared with doctors was reviewed. A similar study was published during the finalization of this present review, but this present paper discusses the implications of the evidence with specific reference to settings with a shortage of physicians and high incidence of unsafe abortion procedures.

Methods
Published studies assessing the effectiveness and/or safety of abortion provided by MLPs compared with procedures provided by doctors were reviewed. Trials, comparison studies, and observational studies were eligible for inclusion. For the purposes of this review, MLPs are defined as any trained health professionals who are not physicians. No ethics approval was required for this systematic review.

Selection criteria
Inclusion criteria include the following:

- Trial (randomized or not) or comparison study in any setting exploring effectiveness or safety of abortion procedures (surgical or medical) provided by MLPs and physicians
- Report of at least one of the outcome measures described below
- Any language
- No limits on gestational age.

Exclusion criteria include the following:

- No comparison group
- Focus on support role of providers in abortion provision, eg, pre-abortion counseling, post-abortion care
- Focus on provider attitudes or experiences of abortion with no measure of effectiveness or safety
- Policy statement or technical report.

Participants
Participants of interest were women in any setting who were seeking a termination of pregnancy.

Outcomes
The primary outcomes of interest were: (1) measures of effectiveness or efficacy of abortion procedures provided by midlevel providers compared with doctors (for the purposes of analysis, incomplete or failed abortion were the main outcomes); and (2) measures of safety of abortion procedures administered by midlevel providers versus doctors, namely adverse events and complications (excess bleeding, cervical injury, uterine perforation, adverse drug reaction, retained products of conception, hematometra, pelvic infection, excessive post-abortion bleeding, and abortion-related death.

Search strategy
Ovid MEDLINE (1948 to February week 2, 2012), EMBASE (1980 to week 6, 2012), Popline, and the Cochrane Central Register of Controlled Trials were searched electronically for studies assessing the effectiveness and safety of midlevel provision of abortion, using the following terms: (1) mid-level provider.mp; (2) nurse.mp; (3) midwife.mp; (4) nurse practitioner.mp; (5) physician assistant.mp; (6) or/1–5; (7) abortion, legal/or abortion, incomplete/or abortion.mp; and (8) 6 and 7. Relevant publications were also hand-searched for further studies. Search results were restricted to studies published after 1980. No limits were placed on language.
Study quality
Studies were assessed for quality based on a scale adapted from the Newcastle–Ottawa Scale. They were awarded points based on the following domains: (1) selection bias (for observational studies, one point if the study inclusion criteria were applied before allocation to study arms; for trials, one point if participants were randomly allocated to groups and allocation was concealed); (2) confounding (one point if the study demonstrated comparability of gestational age at baseline in study arms or controlled for gestational age in analysis; one point if the study controlled for any other potential confounder); (3) assessment of outcomes (one point if outcomes assessed by a trained health professional or information extracted from clinic records; for trials, one point if blinding of study participants occurred); and (4) adequacy of follow-up (one point if all subjects were accounted for at follow-up; one point if the number of subjects lost to follow-up was ≤20% or a description of those lost to follow-up indicated no difference from those that were followed up). Studies that met criteria in all four domains were classed as high quality.

Data abstraction
Two independent reviewers (TDN and MHP) screened the data for initial assessment of eligibility. Inter-rater agreement was assessed using a kappa coefficient. Disagreements were resolved through discussion. Data were double-extracted by the reviewers using a pre-designed form; the study design, study population, study inclusion criteria, interventions, primary outcomes, and methods of assessing outcomes were recorded.

Data synthesis
The principal measure of effect was the odds of incomplete or failed abortion administered by MLPs, relative to the odds of incomplete or failed abortion administered by a physician, and the 95% confidence interval (CI) of this odds ratio (OR). The OR for overall complications was also examined, which had been categorized in some of the included studies as either immediate (complications occurring during the procedure or up to discharge from the clinic) or delayed (occurring any time between discharge and follow-up). Due to the small number of retrieved studies and diversity of study designs and abortion methods, outcome measures were synthesized in a narrative fashion.

Results
Description of included studies
Five studies were included in this review (Figure 1), comprising three prospective cohort studies and two randomized controlled trials (RCTs). A total of 8539 women were included across the five studies; of these, 4198 underwent a procedure administered by a midlevel provider (3680 had surgical abortion; 518 had medical abortion) and 4341 women underwent a physician-administered procedure (3827 had surgical abortion; 514 had medical abortion). All studies took place in either a hospital or specialist health clinic, such as a women’s health center or sexual and reproductive health clinic. Studies are described in detail in Table 1.

Study participants
All studies included women aged from <20 to >40 years. In the four studies of surgical abortion,11,13–15 maximum gestational ages ranged from 10 to 16+ weeks. In the RCT of medical abortion,12 women with gestational ages of up to 9 weeks were included. Gestational age was estimated using pelvic examination, or a combination of pelvic examination, ultrasound, and last menstrual period (Table 1).

Interventions
The RCT conducted in South Africa and Vietnam compared outcomes of MVA procedures for pregnancies up to 12 weeks gestation delivered by MLPs with government-accredited training in abortion, and those administered by physicians. All participants were offered lidocaine and additional oral analgesia; in one of the study locations (South Africa), misoprostol 400 mg was administered 2–3 hours before the procedure.11 The other RCT used a medical abortion regimen of 200 mg mifepristone orally followed by 800 µg of misoprostol vaginally 1–2 days later, delivered by MLPs (staff nurses and auxiliary midwives) trained in MVA, or doctors (obstetricians, gynecologists, general practitioners, and other doctors) across five district hospitals in Nepal.12 In both RCTs, women were followed up 10–14 days after the procedure.

The three prospective cohort studies used surgical abortion methods.13,14 One study conducted in the US used early uterine evacuation or suction curettage,13 delivered by either a physician assistant or physician; women arriving at the clinic...
were seen by the next available provider and were followed up within four weeks of the procedure. In the other US study, physicians with at least 5 years experience in abortion procedures performed standard vacuum curettage procedures for pregnancies up to 12 weeks gestation, while physician assistants with the same level of experience provided MVA or standard vacuum curettage procedures for pregnancies up to 14 weeks gestation. Follow-up was within 14 days of the procedure. The study conducted in India used MVA delivered by nurses or physicians with no previous experience of providing any type of abortion, who underwent MVA training as part of the study. All abortion procedures were conducted in the presence of a qualified supervisor. Women were followed up after 7 days.

**Study quality**

The two RCTs met all four quality criteria described previously, and were considered to be high quality. In the
medical abortion trial, loss to follow-up was 4%, while in the MVA trial, these figures were 0.1% in South Africa and 5.7% in Vietnam. These rates were similar in both study arms (MLPs versus physicians).

Two of the three prospective cohort studies met all quality criteria for non-RCTs, both of which reported loss to follow-up at 4%. One US study did not meet quality criteria for minimizing selection bias, as eligibility criteria and interventions were different for study arms. Women in the MLP group underwent vacuum curettage or MVA through to 14 weeks gestation, while those in the physician group underwent vacuum curettage up to 12 weeks gestation. This study used self-reported outcomes, and had loss to follow-up of 30%.

Incomplete or failed abortion
In the two RCTs, data on incomplete or failed abortion were available for 1918 women who had procedures administered by MLPs (Table 2). The proportion of incomplete or failed abortion among this group was 1.1% for surgical abortion in South Africa and Vietnam, and 2.7% for medical abortion procedures in Nepal. Among 1903 women who had abortion procedures provided by physicians in these trials, the proportion of incomplete or failed abortion was 0.6% for surgical procedures in South Africa and Vietnam (OR of incomplete or failed abortion provided by MLPs = 2.00; 95% CI 0.85–4.69) and 3.9% for medical procedures in Nepal (OR = 0.69; 95% CI 0.34–1.37).

In one US cohort study of surgical abortion, there were increased odds of incomplete or failed abortion among women who had a procedure provided by MLPs compared with those who had a procedure administered by a physician (OR = 4.03; 95% CI 1.07–15.28). In the study conducted in India, the proportion of incomplete abortion was 1.2% for procedures administered by MLPs, and 0.9% for those administered by physicians (OR = 1.25; 95% CI 0.33–4.69). Data on incomplete or failed abortion were not available for the other cohort study.

Complications
Complications of abortion were generally reported as immediate or delayed. Immediate complications included excess bleeding, cervical injury, uterine perforation, and adverse drug reaction on the day of the procedure up to discharge. Delayed complications included retained products of conception, hematometra, pelvic infection, excessive post-abortion bleeding, and abortion-related death up to the date of follow-up.

The RCT of surgical abortion showed that the overall complication rate for MLP-delivered procedures was 1.3% (n = 18), while the rate for physician administered procedures was 0.7% (n = 10). All of the complications in the MLP group were delayed complications (two pelvic infections; 16 retained products). In the physician group, there was one immediate complication (adverse drug reaction), and the rest were delayed complications (eight retained products; one pelvic infection). This study found no difference in odds of overall complications by provider type (OR = 1.80; 95% CI 0.83–3.90).

In the three cohort studies, the overall complication rate for MLP-administered surgical procedures ranged from 1.4% to 2.7%, while the rate was 0.9%–3.1% for physician-administered procedures. The majority of complications in the MLP group (39 out of 47 cases, 83.0%) and in the physician-administered group (44 out of 55 cases, 80.0%) were delayed complications. These delayed complications included continued pregnancy, ectopic pregnancy, infection, hemorrhage, and retained products. None of the three studies found a difference in the odds of overall complications by provider type.

Discussion
Based on data from trials, there was no strong evidence for differences in odds of incomplete or failed abortion for first trimester medical or surgical abortions performed by MLPs versus physicians. Incomplete or failed abortions were rare (less than 4%) for MLPs and physicians. One cohort study, which had a high risk of selection bias, reported increased odds of incomplete or failed abortion for procedures administered by MLPs compared with those administered by physicians. Complications were rare for medical and surgical procedures, administered by either MLPs or physicians.

Strengths and limitations
The inclusion of non-randomized studies in this review increased the likelihood of biases. Of particular concern is selection bias due to un concealed allocation or different eligibility criteria in study arms, which could lead to systematic differences between participant characteristics in the intervention groups. This is problematic where these participant characteristics may be associated with abortion outcomes, leading to differences between the two groups which cannot be attributed solely to the intervention. There were too few trials of each type of abortion to pool the effect
<table>
<thead>
<tr>
<th>Study name</th>
<th>Study design</th>
<th>Study setting and period of data collection</th>
<th>Intervention</th>
<th>Providers</th>
<th>Outcome(s)</th>
<th>N</th>
<th>Characteristics of women</th>
<th>Gestational age</th>
</tr>
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<tbody>
<tr>
<td>RCTs</td>
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<tr>
<td>Warriner et al&lt;sup&gt;11&lt;/sup&gt;</td>
<td>Multicentre randomized controlled equivalence trial</td>
<td>MSI clinics providing FP and abortion services. Four clinics in South Africa and four in Vietnam. September 2003–June 2004 in South Africa, May–December 2003 in Vietnam</td>
<td>MVA: All participants offered paracervical block with lidocaine and additional oral analgesia. Misoprostol 400 mg administered sublingually or orally in South Africa 2–3 hours before abortion (not used in Vietnam). Follow-up 10–14 days later</td>
<td>Midlevel providers with government-accredited training in abortion, or doctors</td>
<td>Immediate complications: excess bleeding &gt; 500 mL, cervical injury, uterine perforation, adverse drug reaction Delayed complications: retained products of conception necessitating re-evacuation, hematometra, post-abortion pelvic infection, excessive post-abortion bleeding (&gt;500 mL), abortion-related death</td>
<td>South Africa: 1160 Vietnam: 1734</td>
<td>Age 18 to &gt;40 years</td>
<td>Up to 12 weeks (LMP, pelvic examination, and ultrasound)</td>
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<tr>
<td>Warriner et al&lt;sup&gt;12&lt;/sup&gt;</td>
<td>Multicentre randomized controlled equivalence trial</td>
<td>Five rural/peri-urban district hospitals in Nepal April 2009–March 2010</td>
<td>Medical abortion: Day 1: 200 mg mifepristone orally Day 3: 800 µg misoprostol vaginally and monitored for 3 hours Follow-up 10–14 days later</td>
<td>Providers trained in MVA: staff nurses, auxiliary midwives, obstetricians/gynecologists, general practitioners, doctors</td>
<td>Complete abortion without MVA within 30 days of treatment Serious adverse events (hemorrhage necessitating transfusion, conditions necessitating hospitalization)</td>
<td>1104</td>
<td>Mean age: 28.0 ± 5.9 years</td>
<td>Mean: 6.9 ± 1.0 weeks (range 5–9) (LMP and bimanual pelvic examination; ultrasound used in 2.3% women)</td>
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<td>Prospective cohort studies</td>
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<tr>
<td>Freedman et al&lt;sup&gt;13&lt;/sup&gt;</td>
<td>Prospective cohort</td>
<td>Vermont Women’s Health Center, USA January 1981–December 1982</td>
<td>Early uterine evacuation or suction curettage up to 8 weeks LMP. Follow-up visit within 4 weeks, at clinic or by personal physician</td>
<td>Physician assistant or physician. Women seen by next available provider</td>
<td>Complications (immediate or delayed): excessive bleeding, uterine perforation, cervical laceration, incomplete abortion/retained products, infection, post-abortion syndrome, vagal reaction</td>
<td>2458</td>
<td>Age: 29% &lt; 20 years, 42% 20–24 years</td>
<td>Up to 12 weeks (pelvic estimate)</td>
</tr>
<tr>
<td>Goldman et al&lt;sup&gt;14&lt;/sup&gt;</td>
<td>Prospective cohort</td>
<td>1. Feminist Health Center of Portsmouth, New Hampshire, USA 2. Vermont Women’s Health Center, USA July 1996–October 1997</td>
<td>1. Standard vacuum curettage performed by physicians through to 12 weeks gestation. 2. MVA or standard vacuum curettage performed by physician assistants through to 14 weeks gestation. Follow-up within 2 weeks of discharge</td>
<td>Physician assistant or physician with ≥5 years experience in abortion procedures</td>
<td>Complications (immediate or delayed): incomplete abortion, failed abortion, ectopic/extrauterine pregnancy, perforation, cervical laceration, infection, hemorrhage, others</td>
<td>1363</td>
<td>Age: 23.7% &lt; 20 years, 23.3% 20–24 years, 21.4% 25–29 years</td>
<td>1. Up to 13–15 weeks 2. Up to 16+ weeks (LMP, pelvic examination and ultrasound)</td>
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Prospective cohort
Five clinics of non-government organization Janani in Bihar and Jharkhand states, India
One provider type (nurse or physician) assigned to each facility at any given time
July 2009–January 2010

MvA: Day 1 – intramuscular prostaglandin analog injection administered 1–2 hours before procedure; MvA performed with double-valve syringe; provider could call upon supervisor for assistance; antibiotics and pain relief prescribed
Follow-up 7 days later

Nurse or physician with no previous experience of providing abortion or pelvic examination
All providers underwent standard MvA training

Complete abortion by day 7
Complications: incomplete abortion or ongoing pregnancy, blood transfusion or hospitalization, injury to cervix, uterus or bowel, signs of infection
Unscheduled contacts
Accuracy of assessment of gestational age; failure to assess complete abortion
Women’s satisfaction with experience and provider

Mean age: 27–28 years
Mean: 8.6 weeks (range 5–11 +; inclusion criterion: gestational age 10 weeks)

Abbreviations: LMP, last menstrual period; MSI, Marie Stopes International; MvA, manual vacuum aspiration; RCT, randomized controlled trial.

Estimates. Although only two high quality RCTs were identified in this review, they included 3821 women. The demographic data of the participants from the medical abortion trial were similar to the socio-demographic characteristics of women typically seeking abortions in Nepal. The surgical trial conducted in South Africa and Vietnam took place in Marie Stopes International (MSI) clinics, which serve a population that is slightly more educated and well-off than clients in the public sector; therefore, the women in this trial may not be representative of women living in rural areas in these countries.

In the Nepali medical abortion trial, the training that the providers received was part of the first training curriculum in the country. MLPs had more years of professional experiences than doctors; however, multivariate analysis showed that years of experience did not have an effect on safety and effectiveness. In the surgical abortion trial, MLPs in South Africa and Vietnam were private providers working at MSI clinics, who had routinely undertaken first-trimester abortions; therefore, no additional training was required. These individuals may not be representative of the skills and training level required of providers working in public facilities, who might require formal training programs. However, South African providers simultaneously worked at MSI and public facilities, while Vietnamese providers had previous experience working in public health facilities.

The findings from this review are only applicable to pregnancies up to 9 weeks for medical abortion, and up to 12 weeks for surgical procedure. Data cannot be generalized to settings where misoprostol-only regimen is used in higher doses to induce abortion. This review focuses on clinical measures of effectiveness and safety as the outcomes. Assessment of the feasibility, acceptability, and barriers of midlevel provision were beyond the scope of this review.

Implications
Due to the shortage of physicians, MLPs are often the only health professionals available in many settings. Given the potential to expand women’s access to safe abortion in underserved areas, midlevel provision has been widely advocated. Training MLPs to provide first trimester medical abortion and surgical abortion up to 12 weeks could facilitate widened access to safe termination, with the potential of reducing the number of unsafe abortions and related deaths and disabilities.

Taking the greatest difference in complication rates between physicians and MLPs (1.4%; 95% CI 0.4–2.7 in South Africa), employing MLPs instead of physicians in this setting would mean one additional complication for every 37 procedures. However, in the context of settings
### Table 2 Percentage and OR of incomplete abortion and complications in included studies, by provider type

<table>
<thead>
<tr>
<th>RCTs</th>
<th>Number of women</th>
<th>Incomplete or failed abortion, % (n)</th>
<th>Incomplete or failed abortion, OR (95% CI)</th>
<th>Immediate complications, % (n)</th>
<th>Immediate complications, OR (95% CI)</th>
<th>Delayed complications, % (n)</th>
<th>Delayed complications, OR (95% CI)</th>
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<tbody>
<tr>
<td></td>
<td>MLP</td>
<td>Physician</td>
<td>MLP</td>
<td>Physician</td>
<td>MLP</td>
<td>Physician</td>
<td>MLP</td>
</tr>
<tr>
<td>Warriner et al (surgical abortion)</td>
<td>1400</td>
<td>1389</td>
<td>1.1 (16)</td>
<td>0.6 (8)</td>
<td>2.00 (0.85–4.68)</td>
<td>1.3 (18)</td>
<td>0.7 (10)</td>
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<tr>
<td>Warriner et al (medical abortion)</td>
<td>518</td>
<td>514</td>
<td>2.7 (14)</td>
<td>3.9 (20)</td>
<td>0.69 (0.34–1.37)</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Total</td>
<td>1918</td>
<td>1903</td>
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<tr>
<td>Cohort studies</td>
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<tr>
<td>Freedman et al</td>
<td>1285</td>
<td>1173</td>
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<tr>
<td>Goldman et al</td>
<td>546</td>
<td>817</td>
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<tr>
<td>Jejeebhoy et al</td>
<td>449</td>
<td>448</td>
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<tr>
<td>Total</td>
<td>2280</td>
<td>2438</td>
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</tbody>
</table>

**Notes:** *Incomplete abortion (retained products) and failed abortion (continuing pregnancy); °OR of incomplete or failed abortion for MLP group compared with physician group; *OR of overall complications for MLP group compared with physician group; n/a indicates that information on this outcome was not available.

**Abbreviations:** CI, confidence interval; MLP, midlevel provider; OR, odds ratio; RCT, randomized controlled trial.

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**Conclusion**

Based on a small number of studies, there is no strong evidence for differences in effectiveness or safety of abortion procedures performed by MLPs compared with physicians. In settings with a shortage of trained providers, coupled with high incidence of unsafe abortion, midlevel provision of terminations could potentially reduce complications and death related to unsafe abortion. Further studies are required to establish more precise effect estimates.

In settings with a high incidence of unsafe abortion, midlevel provision of terminations could potentially reduce complications and death related to unsafe abortion. Further studies are required to establish more precise effect estimates.

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Even based on the conservative assumption that the complications (a 23% complication rate) and 47,000 deaths. Even based on the conservative assumption that the complications (a 23% complication rate) and 47,000 deaths. Even based on the conservative assumption that the complications (a 23% complication rate) and 47,000 deaths. Even based on the conservative assumption that the complications (a 23% complication rate) and 47,000 deaths.
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Disclosure
The authors report no conflicts of interest in this work.

References