Abortion in resource-limited areas: The consequences of introducing medical abortion in areas with limited health care infrastructure

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Risks

- The risks to women who undergo medical abortion are directly linked to:
- The gestational age of the pregnancy.
- The drugs used.
- The medical support setting in which the medical abortion takes place

- What are the risks of medical abortion in nations with ample medical resources?
- What is the methodology of introduction of medical abortion in nations in which abortion is illegal?
- What effect will the introduction of medical abortion have on the health of women in your nation?

Risks of medical abortion depend on setting

- Mifepristone+misoprostol abortions were tested in the West while women were under strict medical scrutiny:

In the U.S:

- All patients had an ultrasound before receiving mifepristone to confirm exact gestational age.
- All patients were within 1 hour of a hospital which provided transfusions and emergency surgery.
- All patients were under the direct care of doctors with admitting priveleges at the hospital near the patient.
- Is this the case in remote areas of your nation?

Risks of medical abortion in the West

Immediate Complications After Medical Compared With Surgical Termination of Pregnancy

Maarit Niinimäki, MD, Anneli Pouta, MD, PhD, Aini Bloigu, Mika Gissler, BSc, PhD, Elina Hemminki, MD, PhD, Satu Suhonen, MD, PhD, and Oskari Heikinheimo, MD, PhD

OBJECTIVE: To estimate the immediate adverse events and safety of medical compared with surgical abortion using high-quality registry data.

METHODS: All women in Finland undergoing induced abortion from 2000–2006 with a gestational duration of 63 days or less (n=42,619) were followed up until 42 days postabortion using national health registries. The incidence and risk factors of adverse events after medical (n=22,368) and surgical (n=20,251) abortion were compared. Univariable and multivariable association models were used to analyze the risk of the three main complications (hemorrhage, infection, and incomplete abortion) and surgical (re)evacuation.

RESULTS: The overall incidence of adverse events was fourfold higher in the medical compared with surgical abortion cohort (20.0% compared with 5.6%, $P<.001$). Hemorrhage (15.6% compared with 2.1%, $P<.001$) and incomplete abortion (6.7% compared with 1.6%, $P<.001$) were more common after medical abortion. The rate of surgical (re)evacuation was 5.9% after medical abortion and 1.8% after surgical abortion ($P<.001$). Although rare, injuries requiring operative treatment or operative complications occurred more often with surgical termination of pregnancy (0.6% compared with 0.03%, $P<.001$). No differences were noted in the incidence of infections (1.7% compared with 1.7%, $P=.85$), thromboembolic disease, psychiatric morbidity, or death.

CONCLUSION: Both methods of abortion are generally safe, but medical termination is associated with a higher incidence of adverse events. These observations are relevant when counseling women seeking early abortion. *(Obstet Gynecol 2009;114:795–804)*

LEVEL OF EVIDENCE: II

From the Department of Obstetrics and Gynecology, Oulu University Hospital, the Graduate School of Circumpolar Wellbeing, Health and Adaptation, and the National Institute for Health and Welfare, Oulu, Finland; and the National Institute for Health and Welfare and the Nordic School of Public Health, the Department of Obstetrics and Gynecology, Helsinki University Central Hospital, Helsinki, Finland.

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Termination of pregnancy is one of the most common gynecologic procedures. For instance, in the United States, nearly half of pregnancies are unintended,[1] and 22% of all pregnancies (excluding miscarriages) end in termination.[2] Abortion practices have changed dramatically in recent years since the medical method with antiprogestin mifepristone and prostaglandins was introduced. For example, in 2007 in Finland 64%,[3] in Sweden 61%,[4] and in the United Kingdom 35%[5] of all abortions were performed using the medical method. Thus, the safety of induced abortion in general, especially that of the medical method, is of great public health interest.

Most previous studies focused on the short-term complications of induced abortion have been small or have not involved comparison of the two dominant methods of abortion (medical and surgical). In a large, register-based study, 5% of the patients had a complication (bleeding, infection, or (re)evacuation) after surgical abortion during a short-term follow-up period of 2 weeks.[6] In a previous meta-analysis in which medical and surgical termination of pregnancy in the

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- **Results:**
- **Overall medical abortion had four times higher total number of adverse events than surgical abortion.**
- **medical = 20% vs**
- **surgical = 5.6%**
- **p< 0.001**

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- **HEMORRHAGE:**
- **medical = 15.6%**

vs

- **surgical = 2.1%**
- **p< 0.001**

- **INCOMPLETE ABORTION:**
- **medical = 6.7%**
- **surgical = 1.6%**
- **p< 0.001**

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- **SURGICAL REEVACUATION:**
- **medical = 5.9%**

vs

- **surgical = 1.8%**
- **p< 0.001**

- **OPERATIVE INJURIES:**
- **medical = 0.6%**
- **surgical = 0.03%**
- **p< 0.001**

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- **"Because medical abortion is being used increasingly in several countries, it is likely to result in an elevated incidence of overall morbidity related to termination of pregnancy.**

- So in the first trimester medical abortions with mifepristone and misoprostol result in:
- 20 out of every 100 women with a significant adverse event
- 15 out of 100 women hemorrhaging,
- 7 out of every 100 women with tissue left inside,
- And 6 out of every 100 women needing surgery.

- What about second trimester abortion with mifepristone + misoprostol?

Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study

Maarit J. Mentula1, Maarit Niinimäki2, Satu Suhonen3, Elina Hemminki4, Mika Gissler4,5 and Oskari Heikinheimo1, Human Reproduction Jan 2011,

- **METHODS**
- register-based cohort study, 18 248 women who underwent medical TOP
- Adverse events related to medical TOP within 6 weeks from Hospital Discharge Registry.

- **RESULTS** : [vs. 1st trimester TOP]
- second trimester medical TOP increased the risk of surgical evacuation [Adj. odds ratio (OR) 7.8; (CI) 6.8–8.9], especially immediately after fetal expulsion (Adj. OR 15.2; 95% CI 12.8–18.0).
- The risk of infection was also elevated (Adj. OR 2.1; 95% CI

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- register-based cohort study, 18 248 women who underwent medical TOP
- Adverse events related to medical TOP within 6 weeks from Hospital Discharge Registry.

- **RESULTS** : [vs. 1st trimester TOP]
- This means that women who have a second trimester termination are
- 7.8 times more likely to need surgery than women who have a first trimester termination.
- And, twice as likely to get an infection.

What about the use of misoprostol alone?

Risks of medical abortion

ELSEVIER

Contraception

Contraception xx (2010) xxx – xxx

Original research article

Comparing two early medical abortion regimens: mifepristone+misoprostol vs. misoprostol alone☆

Nguyen Thi Nhu Ngoc[a], Jennifer Blum[b,*], Sheila Raghavan[b], Nguyen Thi Bach Nga[c], Rasha Dabash[b], Ayisha Diop[b], Beverly Winikoff[b]

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Received 2 June 2010; revised 2 September 2010; accepted 4 September 2010

Abstract

Background: Nonsurgical abortion methods have the potential to improve access to high-quality abortion care. Until recently, availability and utilization of mifepristone medical abortion in low-resource countries were restricted due to the limited availability and perceived high cost of mifepristone, leading some providers and policymakers to support use of misoprostol-only regimens. Yet, this may not be desirable if misoprostol-only regimens are considerably less effective and ultimately more costly for health care systems. This study sought to document the differences in efficacy between two nonsurgical abortion regimens.

Study Design: This double-blind randomized placebo-controlled trial enrolled women with gestational ages up to 63 days seeking early medical abortion from August 2007 to March 2008 at a large tertiary hospital in Ho Chi Minh City, Vietnam. Eligible consenting women received either (1) two doses of 800 mcg buccal misoprostol 24 h apart or (2) 200 mg mifepristone and 800 mcg buccal misoprostol 24 h later. Participants self-administered all study drugs and returned to the hospital for follow-up 1 week later. The trial is registered at ClinicalTrials.gov as NCT00680394.

Results: Four hundred women were randomized to either misoprostol-only (198) or mifepristone+misoprostol (202). Complete abortion occurred for 76.2% (n=147) of women allocated to misoprostol-only vs. 96.5% (n=194) of those given mifepristone+misoprostol (RR 0.79, 95% CI 0.73–0.86). Ongoing pregnancy was documented for 16.6% (32) of misoprostol-only users and 1.5% (3) of mifepristone +misoprostol users (1.62, 0.68–3.90). Side effects were generally similar for both groups, although significantly more women allocated to misoprostol-only reported diarrhea.

Conclusions: Mifepristone+misoprostol is significantly more effective than use of misoprostol-alone for early medical abortion. The number of ongoing pregnancies documented with misoprostol-only warranted an early end of the trial after unblinding of the study at interim analysis. Policymakers should advocate for greater access to mifepristone. Future research should prioritize misoprostol-only regimens with shorter dosing intervals.

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- "For example, misoprostol-only has been recommended for use in settings with limited access to surgical terminations
- and where legal abortions may be restricted [30,31].
- Yet, misoprostol-only regimens are associated with a significantly higher need for surgical terminations and require more follow-up care to ensure complete abortion, issues that may be complicated in the very settings for which the method is now being promoted."

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- "… the misoprostol alone regimen tested had a success rate of 76.2%." [This means that **for every four women treated, one would have to have surgery to complete the abortion**]
- "The rate of ongoing pregnancy was… 16.6% with misoprostol-alone. This means that for every seven women treated with misoprostol-alone, …

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- "Use of misoprostol-alone has been advocated in the absence of mifepristone availability in many regions, particularly sub-Saharan Africa and Latin America.
- Yet, the results from the present trial clearly document the inferiority of misoprostol-only compared to a combined regimen."

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Received 2 June 2010; revised 2 September 2010; accepted 4 September 2010

Abstract

Background: Nonsurgical abortion methods have the potential to improve access to high-quality abortion care. Until recently, availability and utilization of mifepristone medical abortion in low-resource countries were restricted due to the limited availability and perceived high cost of mifepristone, leading some providers and policymakers to support use of misoprostol-only regimens. Yet, this may not be desirable if misoprostol-only regimens are considerably less effective and ultimately more costly for health care systems. This study sought to document the differences in efficacy between two nonsurgical abortion regimens.

Study Design: This double-blind randomized placebo-controlled trial enrolled women with gestational ages up to 63 days seeking early medical abortion from August 2007 to March 2008 at a large tertiary hospital in Ho Chi Minh City, Vietnam. Eligible consenting women received either (1) two doses of 800 mcg buccal misoprostol 24 h apart or (2) 200 mg mifepristone and 800 mcg buccal misoprostol 24 h later. Participants self-administered all study drugs and returned to the hospital for follow-up 1 week later. The trial is registered at ClinicalTrials.gov as NCT00680394.

Results: Four hundred women were randomized to either misoprostol-only (198) or mifepristone+misoprostol (202). Complete abortion occurred for 76.2% (n=147) of women allocated to misoprostol-only vs. 96.5% (n=194) of those given mifepristone+misoprostol (RR 0.79, 95% CI 0.73–0.86). Ongoing pregnancy was documented for 16.6% (32) of misoprostol-only users and 1.5% (3) of mifepristone +misoprostol users (1.62, 0.68–3.90). Side effects were generally similar for both groups, although significantly more women allocated to misoprostol-only reported diarrhea.

Conclusions: Mifepristone+misoprostol is significantly more effective than use of misoprostol-alone for early medical abortion. The number of ongoing pregnancies documented with misoprostol-only warranted an early end of the trial after unblinding of the study at interim analysis. Policymakers should advocate for greater access to mifepristone. Future research should prioritize misoprostol-only regimens with shorter dosing intervals.

- "The number of ongoing pregnancies documented with misoprostol-only warranted an early end of the trial after unblinding of the study at interim analysis."

Method of Introduction of medical abortion

How does medical abortion get started in your nation?

How does medical abortion get started in your nation?

- Case study: IPAS and medical abortion in Nepal:

"Providing Medical Abortion Without Technology in Nepal. " IPAS August 2, 2010.

Evaluating rhetoric based on evidence in the medical literature.

IPAS's Unbelievable Claims

- *Providing Medical Abortion Without Technology in Nepal.* IPAS August 2, 2010.
- "*Before the legalization of abortion in Nepal in 2002, it was estimated that up to half of the maternal mortality was due to unsafe abortion.*
- *The maternal mortality rate prior to legalization of abortion was 539 per 100,000 live births."*

- Are these IPAS claims true?
- How does IPAS’s claim here relate to peer reviewed medical literature on maternal mortality?
- How does IPAS’s claims compare to peer reviewed medical literature on medical abortion risks?

WHO analysis of causes of maternal death: a systematic review

Khalid S Khan, Daniel Wojdyla, Lale Say, A Metin Gülmezoglu, Paul F A Van Look

Lancet 2006; 367: 1066–74

Published Online March 28, 2006

DOI:10.1016/S0140-6736(06)68397-9

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Summary

Background The reduction of maternal deaths is a key international development goal. Evidence-based health policies and programmes aiming to reduce maternal deaths need reliable and valid information. We undertook a systematic review to determine the distribution of causes of maternal deaths.

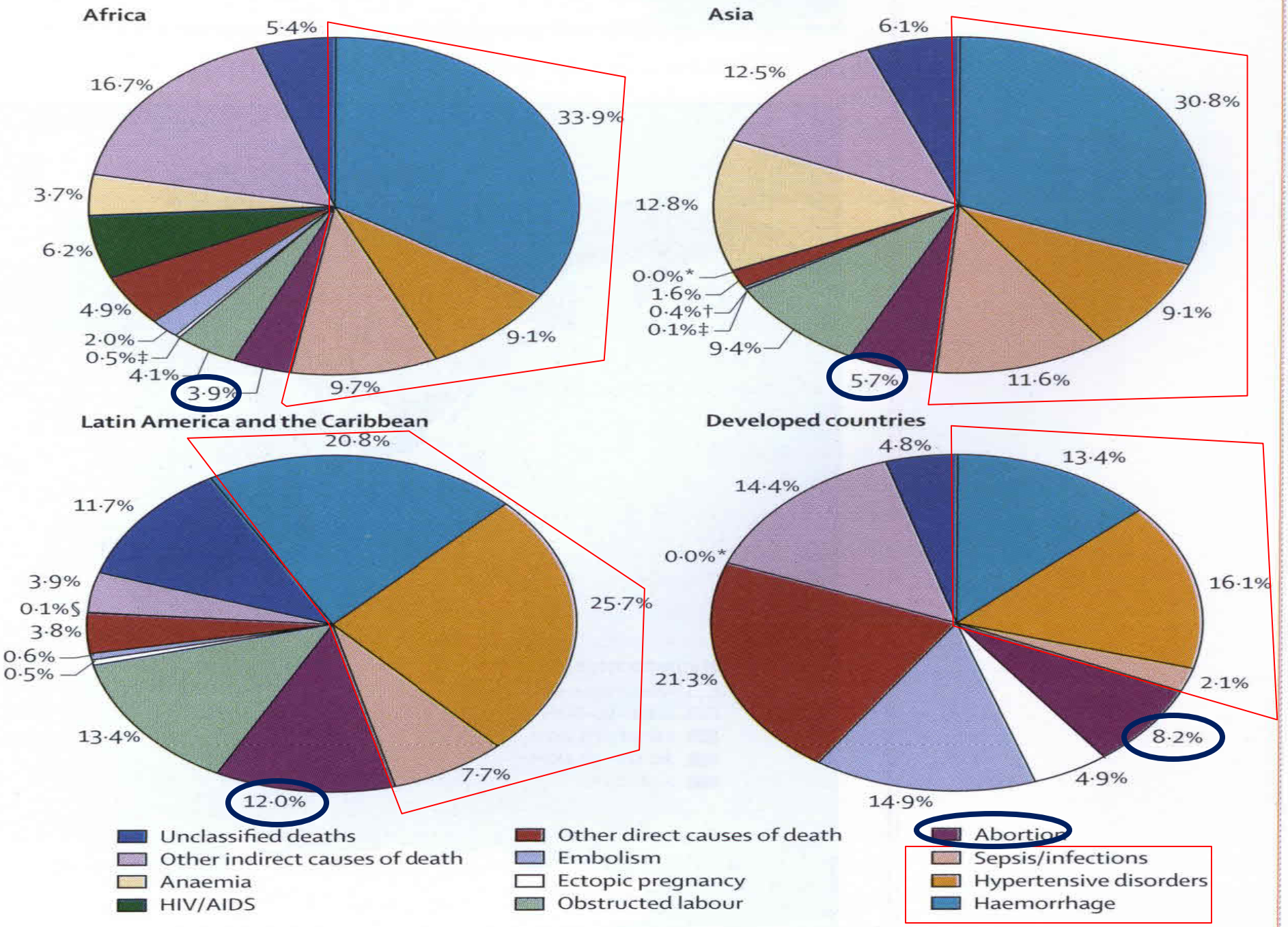
Methods We selected datasets using prespecified criteria, and recorded dataset characteristics, methodological features, and causes of maternal deaths. All analyses were restricted to datasets representative of populations. We analysed joint causes of maternal deaths from datasets reporting at least four major causes (haemorrhage, hypertensive disorders, sepsis, abortion, obstructed labour, ectopic pregnancy, embolism). We examined datasets reporting individual causes of death to investigate the heterogeneity due to methodological features and geographical region and the contribution of haemorrhage, hypertensive disorders, abortion, and sepsis as causes of maternal death at the country level.

Findings 34 datasets (35 197 maternal deaths) were included in the primary analysis. We recorded wide regional variation in the causes of maternal deaths. Haemorrhage was the leading cause of death in Africa (point estimate 33·9%, range 13·3–43·6; eight datasets, 4508 deaths) and in Asia (30·8%, 5·9–48·5; 11, 16 089). In Latin America and the Caribbean, hypertensive disorders were responsible for the most deaths (25·7%, 7·9–52·4; ten, 11 777). Abortion deaths were the highest in Latin America and the Caribbean (12%), which can be as high as 30% of all deaths in some countries in this region. Deaths due to sepsis were higher in Africa (odds ratio 2·71), Asia (1·91), and Latin America and the Caribbean (2·06) than in developed countries.

Interpretation Haemorrhage and hypertensive disorders are major contributors to maternal deaths in developing countries. These data should inform evidence-based reproductive health-care policies and programmes at regional and national levels. Capacity-strengthening efforts to improve the quality of burden-of-disease studies will further validate future estimates.

W.H.O. : 2006

- “Haemorrhage and hypertensive disorders are major contributors to maternal deaths in developing countries.”


Africa
5·4%
16·7%
33·9%
3·7%
6·2%
4·9%
2·0%
0·5%‡
4·1%
3·9%
9·7%
9·1%
Asia
6·1%
12·5%
30·8%
12·8%
0·0%*
1·6%
0·4%†
0·1%‡
9·4%
5·7%
11·6%
9·1%
Latin America and the Caribbean
20·8%
11·7%
3·9%
0·1%§
3·8%
0·6%
0·5%
25·7%
13·4%
12·0%
7·7%
Developed countries
4·8%
13·4%
14·4%
0·0%*
16·1%
21·3%
2·1%
8·2%
4·9%
14·9%
Unclassified deaths
Other indirect causes of death
Anaemia
HIV/AIDS
Other direct causes of death
Embolism
Ectopic pregnancy
Obstructed labour
Abortion
Sepsis/infections
Hypertensive disorders
Haemorrhage

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- 342,900 maternal mortalities worldwide.
- **In the absence of HIV, there would have been 281,500 (243 900–327 900) maternal deaths worldwide in 2008**

Maternal mortality for 181 countries, 1980–2008: a systematic analysis of progress towards Millennium Development Goal 5

Margaret C Hogan, Kyle J Foreman, Mohsen Naghavi, Stephanie Y Ahn, Mengru Wang, Susanna M Makela, Alan D Lopez, Rafael Lazano, Christopher J L Murray

Summary

Background Maternal mortality remains a major challenge to health systems worldwide. Reliable information about the rates and trends in maternal mortality is essential for resource mobilisation, and for planning and assessment of progress towards Millennium Development Goal 5 (MDG 5), the target for which is a 75% reduction in the maternal mortality ratio (MMR) from 1990 to 2015. We assessed levels and trends in maternal mortality for 181 countries.

Methods We constructed a database of 2651 observations of maternal mortality for 181 countries for 1980–2008, from vital registration data, censuses, surveys, and verbal autopsy studies. We used robust analytical methods to generate estimates of maternal deaths and the MMR for each year between 1980 and 2008. We explored the sensitivity of our data to model specification and show the out-of-sample predictive validity of our methods.

Findings We estimated that there were 342 900 (uncertainty interval 302 100–394 300) maternal deaths worldwide in 2008, down from 526 300 (446 400–629 600) in 1980. The global MMR decreased from 422 (358–505) in 1980 to 320 (272–388) in 1990, and was 251 (221–289) per 100 000 livebirths in 2008. The yearly rate of decline of the global MMR since 1990 was 1·3% (1·0–1·5). During 1990–2008, rates of yearly decline in the MMR varied between countries, from 8·8% (8·7–14·1) in the Maldives to an increase of 5·5% (5·2–5·6) in Zimbabwe. More than 50% of all maternal deaths were in only six countries in 2008 (India, Nigeria, Pakistan, Afghanistan, Ethiopia, and the Democratic Republic of the Congo). In the absence of HIV, there would have been 281 500 (243 900–327 900) maternal deaths worldwide in 2008.

Interpretation Substantial, albeit varied, progress has been made towards MDG 5. Although only 23 countries are on track to achieve a 75% decrease in MMR by 2015, countries such as Egypt, China, Ecuador, and Bolivia have been achieving accelerated progress.

Published Online April 12, 2010 DOI:10.1016/S0140-6736(10)60518-1

See Online/Comment DOI:10.1016/S0140-6736(10)60547-8

Institute for Health Metrics and Evaluation (M C Hogan MSc, K J Foreman AB, M Naghavi MD, S Y Ahn BA, M Wang BA, S M Makela BS, Prof R Lozano MD, Prof C J L Murray MD) and Department of Health Services, School of Public Health (M C Hogan), University of Washington, Seattle, WA, USA; and School of Population Health, University of Queensland, Brisbane, QLD, Australia (Prof A D Lopez PhD)

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Hogan et Al. 2010 Lancet

- More than 50% of maternal deaths occur within 6 countries. ((**India, Nigeria, Pakistan, Afghanistan, Ethiopia, and the Democratic Republic of the Congo**)

Maternal mortality for 181 countries, 1980–2008: a systematic analysis of progress towards Millennium Development Goal 5

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Hogan et Al. 2010 Lancet

	1980	1990	2000	2008
Asia, south				
Afghanistan	1640 (632-3527)	1261 (491-2703)	1957 (729-4356)	1575 (594-3396)
Bangladesh	1329 (800-2105)	724 (420-1196)	574 (344-900)	338 (195-546)
Bhutan	2116 (814-4749)	1145 (437-2539)	481 (186-1063)	255 (100-561)
India	677 (408-1080)	523 (310-835)	318 (190-506)	254 (154-395)
Nepal	865 (536-1351)	471 (290-722)	343 (213-533)	240 (149-370)
Pakistan	746 (411-1267)	541 (327-848)	415 (235-679)	376 (230-587)
Total	788 (568-1099)	560 (391-794)	402 (293-555)	323 (232-444)
Asia, southeast				

Ipas's Unbelievable Claims:

"*Before the legalization of abortion in Nepal in 2002, it was estimated that up to half of the maternal mortality was due to unsafe abortion.*
The maternal mortality rate prior to legalization of abortion was 539 per 100,000 live births."

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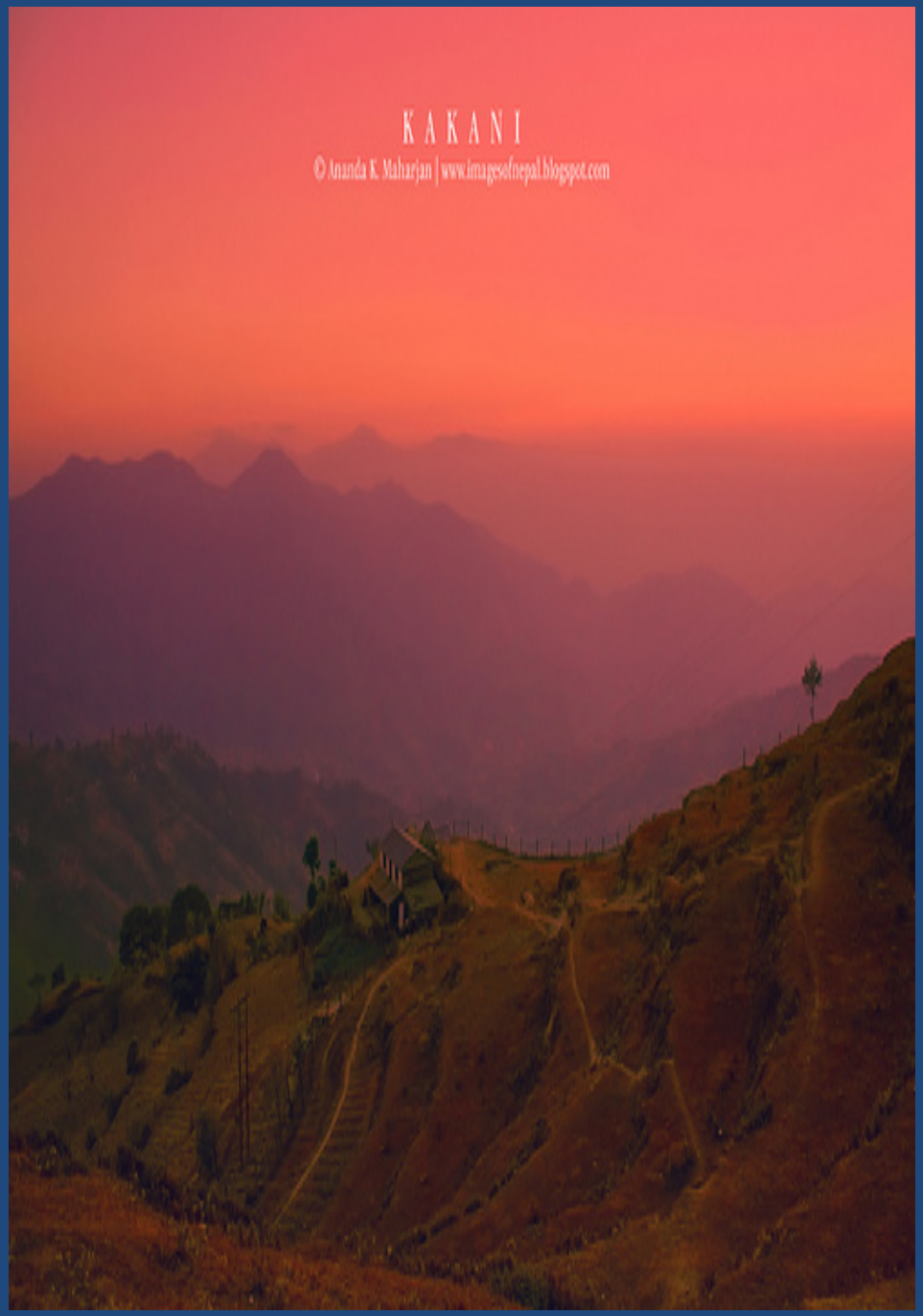
If this claim was true, then unsafe abortions must have been dramatically declining BEFORE legalization of abortion.

	1980	1990	2000	2008
Nepal	865 (536-1351)	471 (290-722)	343 (213-533)	240 (149-370)

IPAS's Unbelievable Claims

- ***Providing Medical Abortion Without Technology in Nepal.*** **IPAS August 2, 2010.**
- "*The Ministry of Health and Population (MoHP), the Nepal Society of OB/Gyns, Ipas, Marie Stopes International and Family Planning Association of Nepal with support of Gynuity Health Projects and the World Health Organization (WHO) among other organizations have worked to increase women's access to safe abortion services, especially through medical abortion expansion, which was piloted from December 2008 to June 2009.*
- *The program has been very successful — even in rural areas with good clinical training but lacking modern technology like ultrasound."*



Providing Medical Abortion Without Technology in Nepal. IPAS August 2, 2010.

"At many of the clinics and health posts, there is no electricity. Ultrasound is only available in hospitals.

Clinicians are adept at pelvic examination and estimating gestational age by physical examination alone."

“During the pilot phase, only 1.22 percent of the women had ultrasound examinations prior to receiving mifepristone.

No ultrasounds were performed at the follow-up.

In the six months following the pilot phase, no

Providing Medical Abortion Without Technology in Nepal.
IPAS August 2, 2010.
"*Similar to ultrasound technology, clinics below the hospital level lack the equipment to perform hemoglobin tests.*
So women are evaluated clinically for severe anemia.
During the pilot phase, 2.6 percent of the women had hemoglobin measurement at intake (and none were severely anemic).
Hemoglobin tests were not performed in the six months following the pilot"

“Women are followed up either by a return visit to the clinic or by telephone.”

IPAS's Unbelievable Claims

- "*The overall success rate of medical abortion during the pilot phase was 96 percent and in the six subsequent months it was 98 percent, thus demonstrating that the service can be provided with virtually no technology.*
- *Well-trained and experienced providers already provide care by relying on their clinical skills, history and evaluation to assess an array of health conditions. They've proven that the same skills are ample to assess a woman's condition and gestational age prior to medical abortion, assess and provide treatment should a rare complication arise, and evaluate success of medical abortion.*"

What happened to the women who didn’t report back to the clinic?

IPAS's Unbelievable Claims

- Can it be that women who go to rural clinics in Nepal somehow magically do better than Scandinavian women with nationalized health care
- who experience failure rates approaching 20% (one out of every five women who take mifepristone and misoprostol needed a surgical procedure) in the first trimester,
- and 7 times that rate in the second trimester?

Evaluating the effects of medical abortion in your nation

Evaluating the effects of medical abortion in your nation.

- The failure rates of mifepristone +misoprostol have been established for situations of optimal medical care in resource rich nations.
- Approx 1 out of every 5 women undergoing mifepristone+misoprostol abortions will need surgical completion for hemorrhage or retained tissue.
- The risk of fatal infection after mifepristone+misoprostol abortions is ten times the published risk of infection for surgical abortion, and this risk doubles in the second trimester.

Evaluating the effects of medical abortion in your nation.

- The failure rates of misoprostol have been established in the medical literature.
- Approx 1 out of every 4 women undergoing misoprostol abortions will need surgical completion for hemorrhage or retained tissue.
- 16% of women undergoing misoprostol abortions will have ongoing pregnancies—and misoprostol has been proven to cause severe deformities in babies exposed to misoprostol early in pregnancy.

Evaluating the effects of medical abortion in your nation.

- The causes of maternal mortality are clear:
- Lack of skilled birth attendance at delivery.
- Lack of adequately staffed delivery facilities located close to delivery sites.
- Lack of education and literacy for women, which prevents women from being able to adequately access the health care system.
- Lack of sufficient income at the family level.

Evaluating the effects of medical abortion in your nation.

- In order to evaluate the effect of a public health intervention in your nation, you need accurate information about the local causes of maternal mortality, done by unbiased researchers,
- not IPPF/Marie Stopes/UNFPA who stand to financially benefit from selling medical abortion to your people, or who are motivated by population control ideology.

Evaluating the effects of medical abortion in your nation.

- If medical abortion is already rampant in your nation:
- Insist on policies and programs which will gather accurate statistics from your hospitals about the true causes of maternal mortality,
- Insist on policies and programs which will investigate the true effect of medical abortion on the rates of admissions for “infection”, “sepsis”, “hemorrhage”, “anaemia”, “incomplete abortion” etc.

Evaluating the effects of medical abortion in your nation.

- Educate the people about the risks of medical abortion through public health campaigns or private initiatives.
- Give your people a place online to report complications and deaths from induced abortion, whether medical or surgical.

Evaluating the effects of medical abortion in your nation.

And critically evaluate information coming from WHO/ UNFPA/IPPF, who are often driven by a population-reduction agenda which may not have the best interests of the people of your nation at heart.