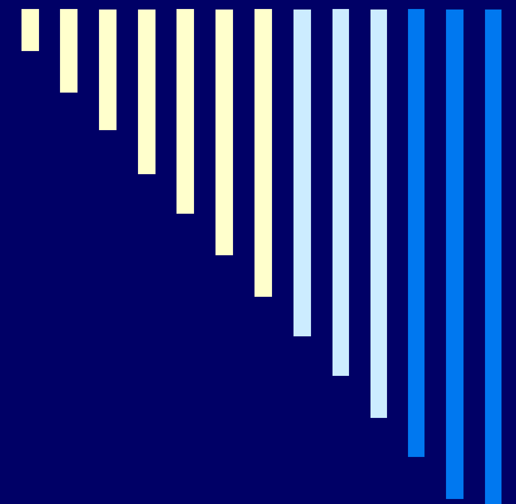
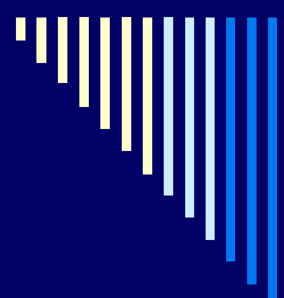


Preventing unsafe abortion

R Kulier

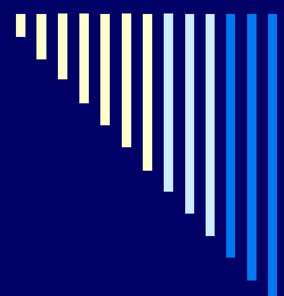
Geneva Foundation for Medical Education and Research

March 2006



Definition of Terms

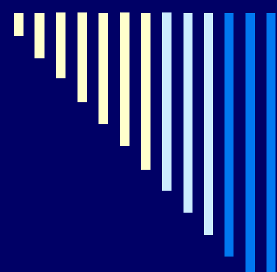
- "abortion" refers to the termination of pregnancy from whatever cause before the fetus is capable of extrauterine life.
- “spontaneous abortion" refers to those terminated pregnancies that occur without deliberate measures
- "induced abortion" refers to termination of pregnancy through a deliberate intervention intended to end the pregnancy (WHO, 1994).



Definition of unsafe abortion

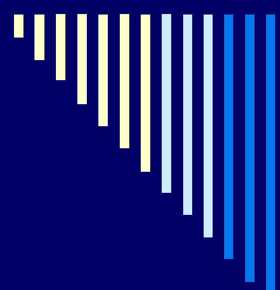
- **"...a procedure for terminating unwanted pregnancy either by persons lacking the necessary skills or in an environment lacking the minimal medical standards of both"** which therefore exposes the women to an increased risk of morbidity and mortality.

(WHO,1993)



“In no case should abortion be promoted as a method of family planning. All Governments and relevant intergovernmental and non-governmental organizations are urged to strengthen their commitment to women’s health, to deal with the health aspect of unsafe abortion as a major public health concern and to reduce the recourse to abortion through expanded and improved family-planning services. Prevention of unintended pregnancies must always be given the highest priority and every attempt should be made to eliminate the need for abortion. Women who have unintended pregnancies should have ready access to reliable information and compassionate counselling. Any measures or changes related to abortion
within the health system can only be determined at the national or local level according to the national legislative process. In circumstances where abortion is not against the law, such abortion should be safe. In all cases, women should have access to quality services for management of complications arising from abortion. Post-abortion counselling, education and family-planning services should be offered promptly, which will also help to avoid repeatabortions.”

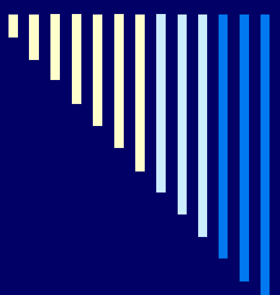
ICPD 1994, Cairo



Global annual estimates of incidence and mortality for unsafe abortions per year (2000)

WHO 2005

	World total	Africa	Asia	Europe	Latin America
Number of unsafe abortions *(thousands)*	19 000	4200	10 500	500	3700
Incidence ratio (*unsafe abortions per 100 live births)*	14	14	14	7	32
Estimated number of deaths due to unsafe abortion	67 900	29 800	34 000	300	3700
Proportion of maternal deaths (*% of maternal deaths due to unsafe abortion*)	13	12	13	20	17



Effects of the introduction of the anti-abortion law in Romania (1966)

Deaths per 100 000 live births

Maternal deaths per 100 000 live births

Abortion deaths per 100 000 live births

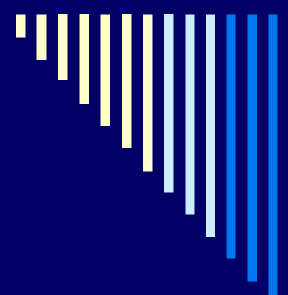
0 20 40 60 80 100 120 140 160 180

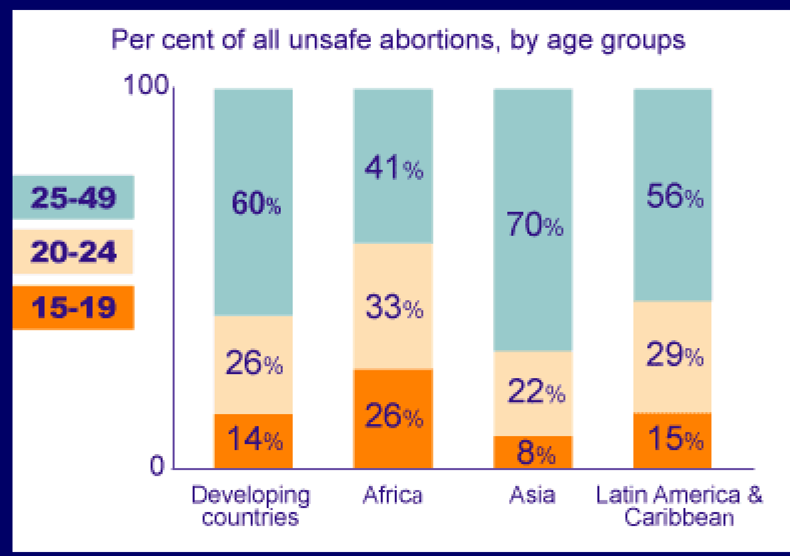
1960 1962 1964 1966 1968 1970 1972 1974 1976 1978 1980 1982 1984 1986 1988 1990 1992 1994 1996

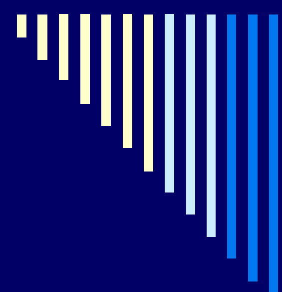
Table 1. Grounds on which abortion is permitted

	To save the woman's life	To preserve physical health	To preserve mental health	Rape or incest	Fetal impairment	Economic or social reasons	On request
All countries (n = 193)							
Permitted	189	122	120	83	76	63	52
Not permitted	4	71	73	110	117	130	141
Developed countries (n = 48)							
Permitted	46	42	41	39	39	36	31
Not permitted	2	6	7	9	9	12	17
Developing countries (n = 145)							
Permitted	143	80	79	44	37	27	21
Not permitted	2	65	66	101	108	118	124

Source: United Nations[15]

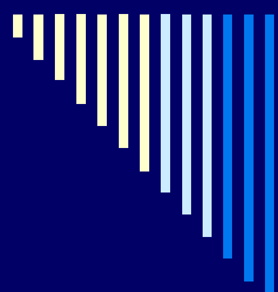



Per cent of all unsafe abortions, by age groups
100
0
25-49
20-24
15-19
60%
26%
14%
41%
33%
26%
70%
22%
8%
56%
29%
15%
Developing countries
Africa
Asia
Latin America & Caribbean



Abortion complications

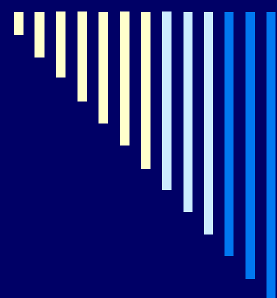
- WHO systematic review
- 1990-2000
- > 45 datasets
- most developing countries, facility based
- Hospital register, survey, X-sectional
- Haemorrhage , infection, perforation



Abortion complications

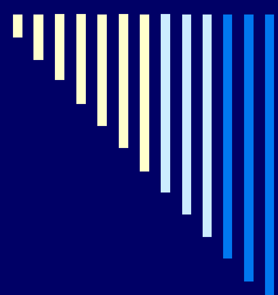
- Perforation, peritonitis, sepsis:
- Prevalence: 33.91 (28.92-38.91)

- *Goyaux 1998*



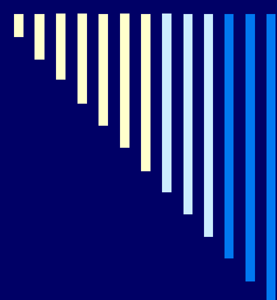
Methods

- Surgical
- Non-surgical
- Menstrual regulation (MR)
  - generally used to describe early evacuation of the uterus, after a delayed menses, often without confirmation of pregnancy



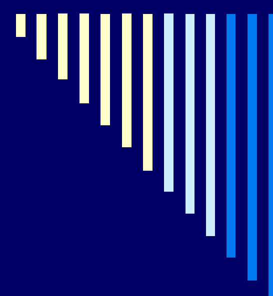
Antigestagen

- Developed during 1960s
- Mifepristone (RU 486)
  - Suppression of folliculogenesis and ovulation
  - endometrium



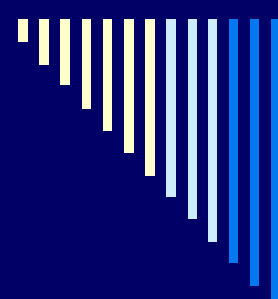
Mifepristone

- Pharmacokinetics
  - Linear 2-25 mg/day
  - Non-linear above 100 mg/day



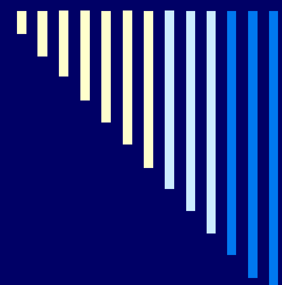
Misoprostol, Gemeprost

- Prostaglandin E1 + E2
- Effectiveness: < 90%
- Side effects



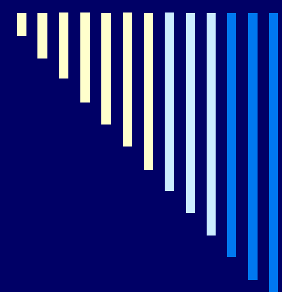
Strategy - Cochrane systematic review

- Randomised controlled trials
- Critical appraisal
- Meta - analysis where appropriate
- Search and methods according to Cochrane Fertility Regulation Group Guidelines



Approach

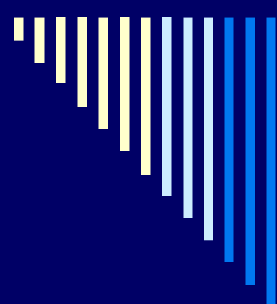
- Pregnant women, first trimester (<14 wks)
- Interventions
  - Medical
  - Surgical
  - Medical vs Surgical
- Outcomes
  - effectiveness, complications, side effects, acceptability



Medical abortion – structure of the review

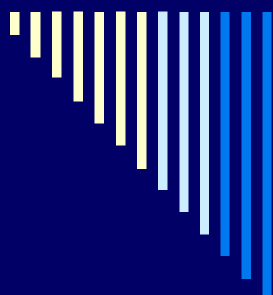
- Combined regime: mifepristone/prostaglandin
  - Dose, route, time of administration, type of PG, split dose
- Combined regime: methotrexate/prostaglandin
  - Dose, route, timing
- Single vs combined regime
- Others
  - Tamoxifen, laminaria etc

- 14 main comparisons



Medical methods for first trimester abortion

- > 100 studies identified; 40 trials included
- many different interventions
  - route-dose-type of agent-interval…...

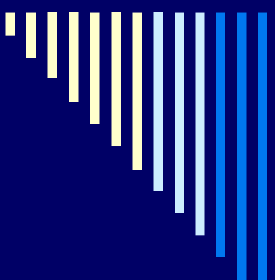


Medical methods Kulier 2004

Combination:

Mifepristone 200 – 600 mg
followed by
Prostaglandin

- Type
- Dose
- Route
- Time interval



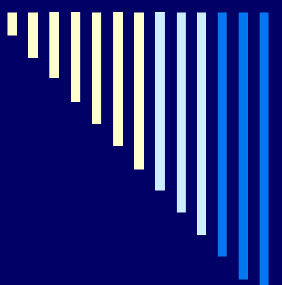
Medical methods

Kulier 2004

dose of mifepristone

Review: Medical methods for first trimester abortion
Comparison: 01 combined regimen mifepristone/prostaglandin: dose of mifepristone: 600mg vs 200mg
Outcome: 01 failure to achieve complete abortion

Study or sub-category	Treatment n/N	Control n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI	Quality
01 all						
McKinley M600po	7/110	7/110		4.66	1.00 [0.36, 2.76]	B
WHO 01 GP1pv	37/447	34/449		22.58	1.09 [0.70, 1.71]	A
WHO M400po	95/797	85/792		56.76	1.11 [0.84, 1.46]	A
WHO 00 GP1pv	22/389	24/388		16.00	0.91 [0.52, 1.60]	A
Subtotal (95% CI)	1743	1739		100.00	1.07 [0.87, 1.32]	
Total events: 161 (Treatment), 150 (Control)						
Test for heterogeneity: Chi² = 0.40, df = 3 (P = 0.94), I² = 0%						
Test for overall effect: Z = 0.63 (P = 0.53)						
Total (95% CI)	1743	1739		100.00	1.07 [0.87, 1.32]	
Total events: 161 (Treatment), 150 (Control)						
Test for heterogeneity: Chi² = 0.40, df = 3 (P = 0.94), I² = 0%						
Test for overall effect: Z = 0.63 (P = 0.53)						



Medical methods Kulier 2004

misoprostol po vs pv

Review: Medical methods for first trimester abortion

Comparison: 05 combined regimen mifepristone/prostaglandin: misoprostol po vs pv

Outcome: 01 failure to achieve complete abortion

Study or sub-category	Treatment n/N	Control n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI	Quality
El-Refaey M800MI600	17/130	7/133		64.36	2.48 [1.07, 5.79]	A
Schaff M800MI200	29/548	4/596		35.64	7.89 [2.79, 22.28]	B
Total (95% CI)	678	729		100.00	4.41 [2.32, 8.38]	

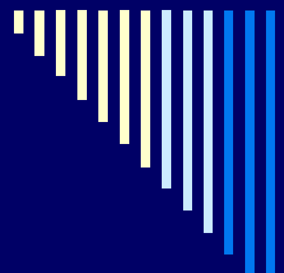
Total events: 46 (Treatment), 11 (Control)

Test for heterogeneity: Chi² = 2.97, df = 1 (P = 0.08), I² = 66.3%

Test for overall effect: Z = 4.53 (P < 0.00001)

0.1 0.2 0.5 1 2 5 10

Favours treatment Favours control

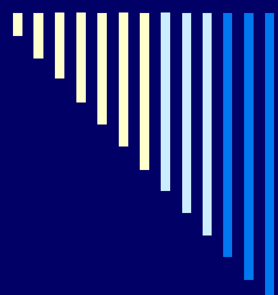


Medical methods Kulier 2004

misoprostol po vs pv

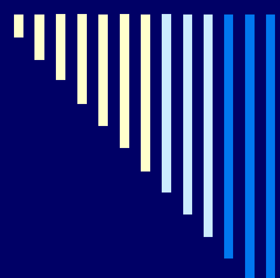
Review: Medical methods for first trimester abortion
Comparison: 05 combined regimen mifepristone/prostaglandin: misoprostol po vs pv
Outcome: 02 side effects

Study or sub-category	Treatment n/N	Control n/N	Weight %	RR (fixed) 95% CI	Quality
01 nausea					
El-Refaey M800MI600	81/116	72/121	21.21	1.17 [0.97, 1.42]	A
Schaff M800MI200	282/548	273/595	78.79	1.12 [1.00, 1.26]	B
Subtotal (95% CI)	664	716	100.00	1.13 [1.02, 1.25]	
Total events: 363 (Treatment), 345 (Control)					
Test for heterogeneity: Chi² = 0.16, df = 1 (P = 0.69), I² = 0%					
Test for overall effect: Z = 2.39 (P = 0.02)					
02 vomiting					
El-Refaey M800MI600	51/116	38/121	17.27	1.40 [1.00, 1.96]	A
Schaff M800MI200	144/547	160/435	82.73	0.72 [0.59, 0.86]	B
Subtotal (95% CI)	663	556	100.00	0.83 [0.71, 0.98]	
Total events: 195 (Treatment), 198 (Control)					
Test for heterogeneity: Chi² = 11.82, df = 1 (P = 0.0006), I² = 91.5%					
Test for overall effect: Z = 2.21 (P = 0.03)					
03 diarrhoea					
El-Refaey M800MI600	42/116	22/121	16.94	1.99 [1.27, 3.12]	A
Schaff M800MI200	179/548	110/594	83.06	1.76 [1.43, 2.17]	B
Subtotal (95% CI)	664	715	100.00	1.80 [1.49, 2.18]	
Total events: 221 (Treatment), 132 (Control)					
Test for heterogeneity: Chi² = 0.23, df = 1 (P = 0.63), I² = 0%					
Test for overall effect: Z = 6.14 (P < 0.00001)					



Medical methods WHO 2003

- Misoprostol: oral vs vaginal
- Multicentric RCT
- N=2219

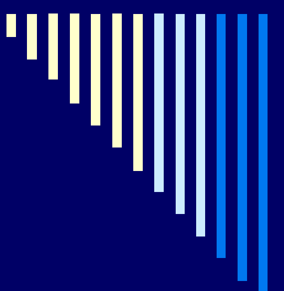


Medical methods WHO 2003

	O/O	V/O	V-only
Day 1	Oral mifepristone (200mg)	Oral mifepristone (200 mg)	Oral mifepristone (200 mg)
Day 3	Oral misoprostol (0.8 mg) and vaginal placebo	Vaginal misoprostol (0.8 mg) and oral placebo	Vaginal misoprostol (0.8 mg) and oral placebo
Days 4-10	Oral misoprostol (0.4 mg) twice daily	Oral misoprostol (0.4 mg) twice daily	Oral placebo twice daily

Medical methods – outcomes WHO 2003

Length of amenorrhoea (days)	Group	n/N	Relative risk	95% CI
< 49	O/O	15/236	1.2	0.6-2.4
	V/O	13/240	(ref)	
	V-only	11/223	0.9	0.4-2.0
50-56	O/O	16/240	1.0	0.5-1.9
	V/O	17/246	(ref)	
	V-only	16/242	1.0	0.5-1.9
> 57	**O/O**	**26/264**	**2.8**	**1.3-5.8**
	V/O	**9/254**	**(ref)**	
	V-only	**21/268**	**2.2**	**1.0-4.7**
All	O/O	57/740	1.5	1.0-2.2
	V/O	39/741	(ref)	
	V-only	48/738	1.2	0.8-1.9



Medical methods Kulier 2004

mifepristone vs combined regimen

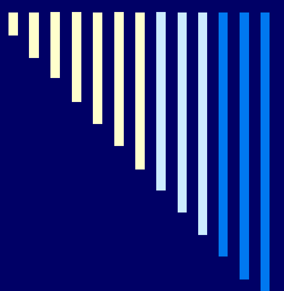
Review: Medical methods for first trimester abortion
Comparison: 07 mifepristone alone vs combined regimen mifepristone/prostaglandin
Outcome: 01 failure to achieve complete abortion

Study or sub-category	Treatment n/N	Control n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI	Quality
Cameron MI600GP1pv	8/20	1/19		6.30	7.60 [1.05, 55.14]	B
Swahn MI200MP1po	6/14	11/28		45.06	1.09 [0.51, 2.33]	B
Zheng MI600PGF2pv	45/95	8/97		48.64	5.74 [2.86, 11.53]	B
Total (95% CI)	129	144		100.00	3.76 [2.30, 6.15]	

Total events: 59 (Treatment), 20 (Control)
Test for heterogeneity: Chi² = 12.09, df = 2 (P = 0.002), I² = 83.5%
Test for overall effect: Z = 5.29 (P < 0.00001)

0.1 0.2 0.5 1 2 5 10

Favours treatment Favours control



Medical methods Kulier 2004

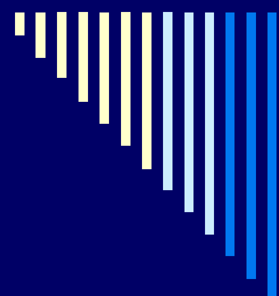
prostaglandin vs combined regimen

Review: Medical methods for first trimester abortion
Comparison: 08 prostaglandin alone vs combined regimen (all)
Outcome: 01 failure to achieve complete abortion

Study or sub-category	Treatment n/N	Control n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI	Quality
01 all						
Cheng PGE1&T	36/76	20/75		54.11	1.78 [1.14, 2.77]	A
Creinin M800&MT	16/30	3/31		7.93	5.51 [1.79, 17.00]	A
Jain M800&MI	15/125	5/119		13.77	2.86 [1.07, 7.61]	A
Jain M800&TM	7/75	5/75		13.44	1.40 [0.47, 4.21]	B
Ozeren MP800&MT	15/36	4/36		10.75	3.75 [1.38, 10.21]	A
02 =/< 49 days gestation						
Jain M800&MI	9/80	3/75		100.00	2.81 [0.79, 10.00]	A
03 > 49 days gestation						
Jain M800&MI	6/45	2/44		100.00	2.93 [0.63, 13.76]	A

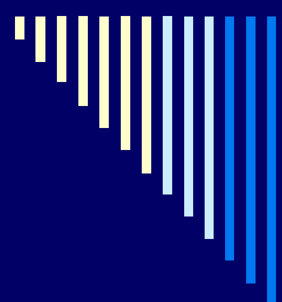
0.1 0.2 0.5 1 2 5 10

Favours treatment Favours control



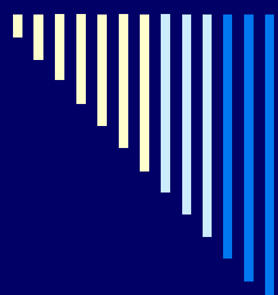
Methotrexate

- Folic acid antagonist
- Toxic on trophoblast
- Combination with prostaglandin
  - Effectiveness ~ 95 %
- Fetal anomalies



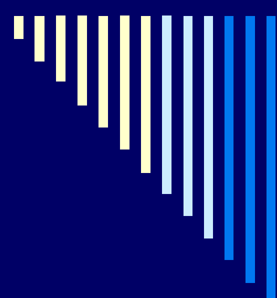
Conclusions - medical methods

- Combined regimes are more effective
- Mifepristone 200 mg seems adequate in the combined regime
- vaginal prostaglandin is more effective compared to oral



Medical methods - unresolved issues

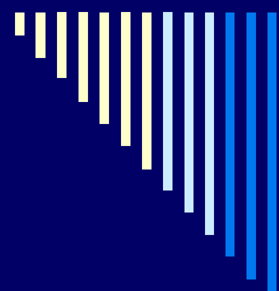
- No firm conclusion:
  - Effectiveness: dose, type or time of prostaglandin, splitting of dose
  - Acceptability po vs pv
  - Methotrexate: dose, time, route of PG
- Early vs late ?



Surgical

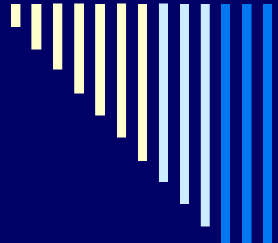
- Lowest complication rate between 49-56 days of amenorrhoea
- Increased morbidity with age, parity
- Major complication rate is 2.3 times higher with D&C compared to VA

  - *WHO 1997, Grimes 1979*



Medical vs Surgical Say 2004

- 6 randomised controlled trials
- 4 comparisons:
  - Prostaglandin vs vacuum aspiration
  - Mifepristone vs vacuum aspiration
  - Mifepristone/prostaglandin vs vacuum aspiration
  - Methotrexate/prostaglandin vs vacuum aspiration

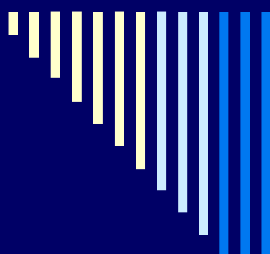


Medical vs surgical Say 2004

Comparison: **Prostaglandin vs vacuum aspiration**
Outcome: **Abortion not completed with intended method**

Study	Expt n/N	Ctrl n/N	Peto OR (95%CI Fixed)	Weight %	Peto OR (95%CI Fixed)
Amenorrhoea 49 days or less					
Rosen 1984	1 / 35	0 / 18		4.3	4.55 [0.07,285.14]
WHO 1987	15 / 203	6 / 216		95.7	2.63 [1.09,6.32]
Subtotal (95%CI)	16 / 238	6 / 234		100.0	2.69 [1.14,6.35]
Chi-square 0.06 (df=1) Z=2.26					
Amenorrhoea 63 days or less					
Subtotal (95%CI)	0 / 0	0 / 0		0.0	Not Estimable
Chi-square 0.00 (df=0) Z=0.00					
Total (95%CI)	16 / 238	6 / 234		100.0	2.69 [1.14,6.35]
Chi-square 0.06 (df=1) Z=2.26					

.1 .2 1 5 10
Favours treatment Favours control



Medical vs surgical

Say 2004

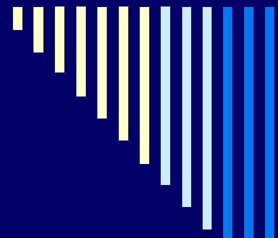
Prostaglandin vs VA

Comparison: Prostaglandin vs vacuum aspiration
Outcome: Duration of bleeding

Study	Expt n	Expt mean(sd)	Ctrl n	Ctrl mean(sd)	WMD (95%CI Fixed)	Weight %	WMD (95%CI Fixed)
Amenorrhoea less than 49 days							
WHO 1987	203	8.90 (0.90)	216	3.70 (1.40)		100.0	5.200 [4.976,5.424]
Subtotal (95%CI)	203		216			100.0	5.200 [4.976,5.424]
Chi-square 0.00 (df=0) Z=45.49							
Amenorrhoea less than 63 days							
Subtotal (95%CI)	0		0			0.0	Not Estimable
Chi-square 0.00 (df=0) Z=0.00							
Total (95%CI)	203		216			100.0	5.200 [4.976,5.424]
Chi-square 0.00 (df=0) Z=45.49							

-10 -5 0 5 10

Favours treatment Favours control



Medical vs surgical

Say 2004

Mifepristone/prostaglandin vs VA

Review: Medical versus surgical methods for first trimester termination of pregnancy
Comparison: 05 Mifepristone and prostaglandin vs vacuum aspiration
Outcome: 10 Duration of bleeding

Study	Treatment N	Mean (SD)	Control N	Mean (SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 Amenorrhoea less than 49 days							
Subtotal (95% CI)	0		0			0.0	Not estimable
Test for heterogeneity chi-square=0.0 df=0							
Test for overall effect=0.0 p=1.0							
02 Amenorrhoea less than 63 days							
Henshaw 1994	99	13.10 (2.90)	96	10.20 (4.40)		64.0	2.90 [1.85, 3.95]
Subtotal (95% CI)	99		96			64.0	2.90 [1.85, 3.95]
Test for heterogeneity chi-square=0.00 df=0							
Test for overall effect=5.42 p<0.00001							
03 Amenorrhoea more than 63 weeks							
Ashok 2002	118	14.21 (4.80)	111	11.21 (5.90)		36.0	3.00 [1.60, 4.40]
Subtotal (95% CI)	118		111			36.0	3.00 [1.60, 4.40]
Test for heterogeneity chi-square=0.00 df=0							
Test for overall effect=4.21 p=0.0000							
Total (95% CI)	217		207			100.0	2.94 [2.10, 3.78]
Test for heterogeneity chi-square=0.01 df=1 p=0.9107							
Test for overall effect=6.86 p<0.00001							

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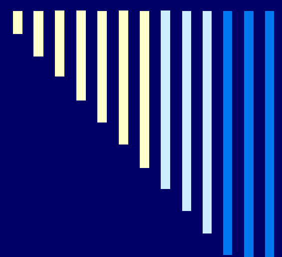
Favours treatment Favours control



Medical vs surgical Say 2004

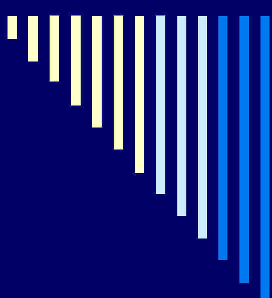
Mifepristone/PG vs VA

Review: Medical versus surgical methods for first trimester termination of pregnancy
Comparison: 05 Mifepristone and prostaglandin vs vacuum aspiration
Outcome: 13 Pain resulting from the procedure

Study	Treatment n/N	Control n/N	Odds Ratio (Fixed) 95% CI	Weight (%)	Odds Ratio (Fixed) 95% CI
01 Amenorrhoea 49 days or less					
Subtotal (95% CI)	0 / 0	0 / 0		0.0	Not estimable
Test for heterogeneity chi-square=0.0 df=0					
Test for overall effect=0.0 p=1.0					
02 Amenorrhoea 63 days or less					
Subtotal (95% CI)	0 / 0	0 / 0		0.0	Not estimable
Test for heterogeneity chi-square=0.0 df=0					
Test for overall effect=0.0 p=1.0					
03 Amenorrhoea more than 63 days					
Ashok 2002	182 / 186	163 / 180		100.0	4.75 [1.56, 14.39]
Subtotal (95% CI)	182 / 186	163 / 180		100.0	4.75 [1.56, 14.39]
Test for heterogeneity chi-square=0.00 df=0					
Test for overall effect=2.75 p=0.006					
Total (95% CI)	182 / 186	163 / 180		100.0	4.75 [1.56, 14.39]
Test for heterogeneity chi-square=0.00 df=0					
Test for overall effect=2.75 p=0.006					

.1 .2 1 5 10

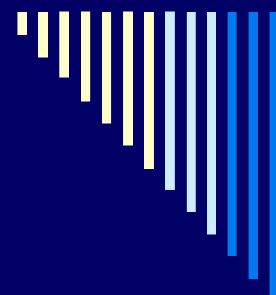
Favours treatment Favours control



Medical vs surgical Henshaw 1994

Mifepristone/PG vs VA

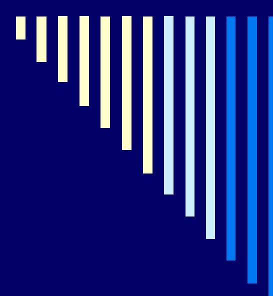
	Medical n = 172	Vacuum aspiration n = 191	95% CI for difference between proportions
Complete abortion	94.2%	97.9%	-0.003 to 0.078
Minor complications within	11.0%	15.7%	-0.116 to 0.023
Requiring uterine curettage	5.8%	2.1%	



Medical vs surgical Say 2003

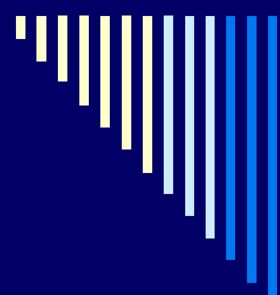
- Small sample sizes
- Medical:
  - Longer duration of bleeding
  - Single regimes less effective than vacuum

- Acceptability ?



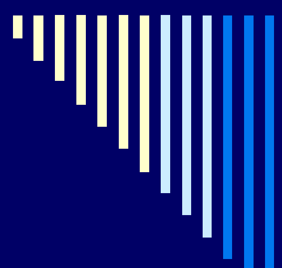
Surgical methods

- Vacuum aspiration
- Dilatation/curettage
- Manual vacuum aspiration (MVA)



Surgical methods for first trimester abortion Kulier 2003

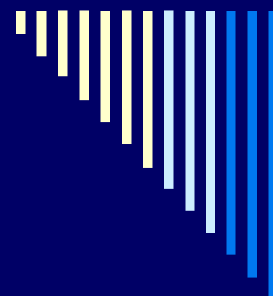
- 3 trials included
- 2 comparisons:
  - Vacuum aspiration vs dilatation &curettage
  - Metal vs plastic cannula for vacuum aspiration
- N = 767



Surgical methods Kulier 2003

VA vs dilatation/curettage

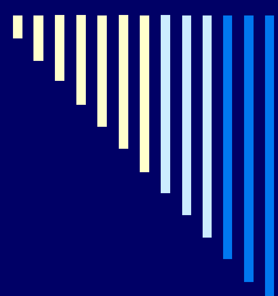
Outcome	No of trials	No of participants	RR (95%CI)
Excessive blood loss	2	257	1.02 (0.21-4.95)
Febrile morbidity	2	467	0.84 (0.26 – 2.71)
Incomplete evacuation	2	467	0.67 (0.11 – 3.95)
Abdominal pain	2	467	2.03 (0.38 – 10.97)



Surgical methods Hemlin 2001

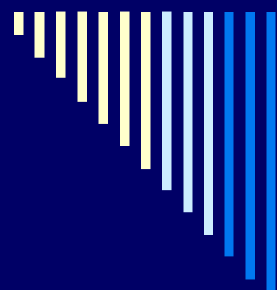
VA vs MVA

- RCT; < 56 days of amenorrhoea
  - MVA n = 91
  - VA n = 88
  - Effectiveness
  - Complications



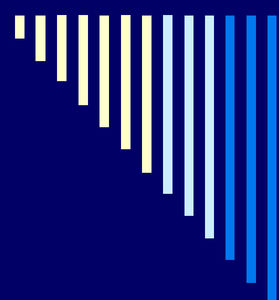
Surgical methods Hemlin 2001

Outcome	MVA (n=91)	VA (n=88)
Ongoing pregnancy	0	0
Re-curettage	2	2
infection	2	2



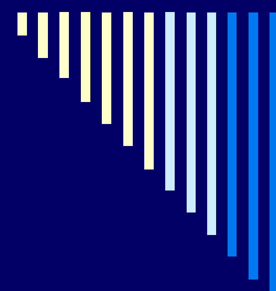
Antibiotic prophylaxis

- Universal AB prophylaxis
- Vs
- Screen-and-treat
  - Contact tracing & Treatment of sexual partners
  - Screening for other STDs
  - Counselling
  - Costly
  - Organisational matters



Conclusions

- Safe and effective methods for first trimester abortion are available
- Acceptability data scarce
- Medical methods:
  - Longer duration of bleeding
  - Single regimes less effective
- Serious complications are rare



Collaborators

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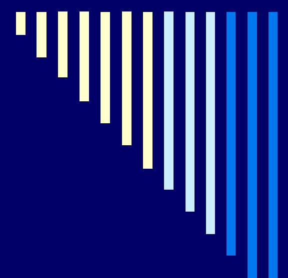
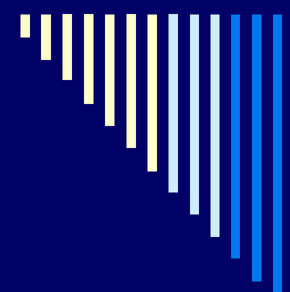
- Anis Feki
- Metin Gülmezoglu
- Justus Hofmeyr
- Lale Say



International Conference on Population and Development

In circumstances where abortion is not against the law… to ensure that abortion is safe and
accessible."
(Key actions ICPD+5, paragraph 63)

"In all cases,
women should have
access to quality services for the management of complications arising from abortion."
(Key actions ICPD+5, paragraph 63)

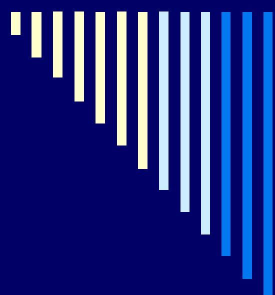


- F1. Promote policy dialogue on unsafe abortion, and provide guidance to countries on how to develop, implement and evaluate programmes to prevent and address unsafe abortion.

- F2. Promote the effective management of abortion complications and postabortion care, including its integration within other reproductive health services.

- F3. Develop and promote interventions to improve access to quality care in circumstances where abortion is not against the law, with special emphasis on underserved populations.

UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP)



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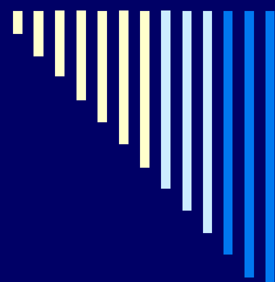

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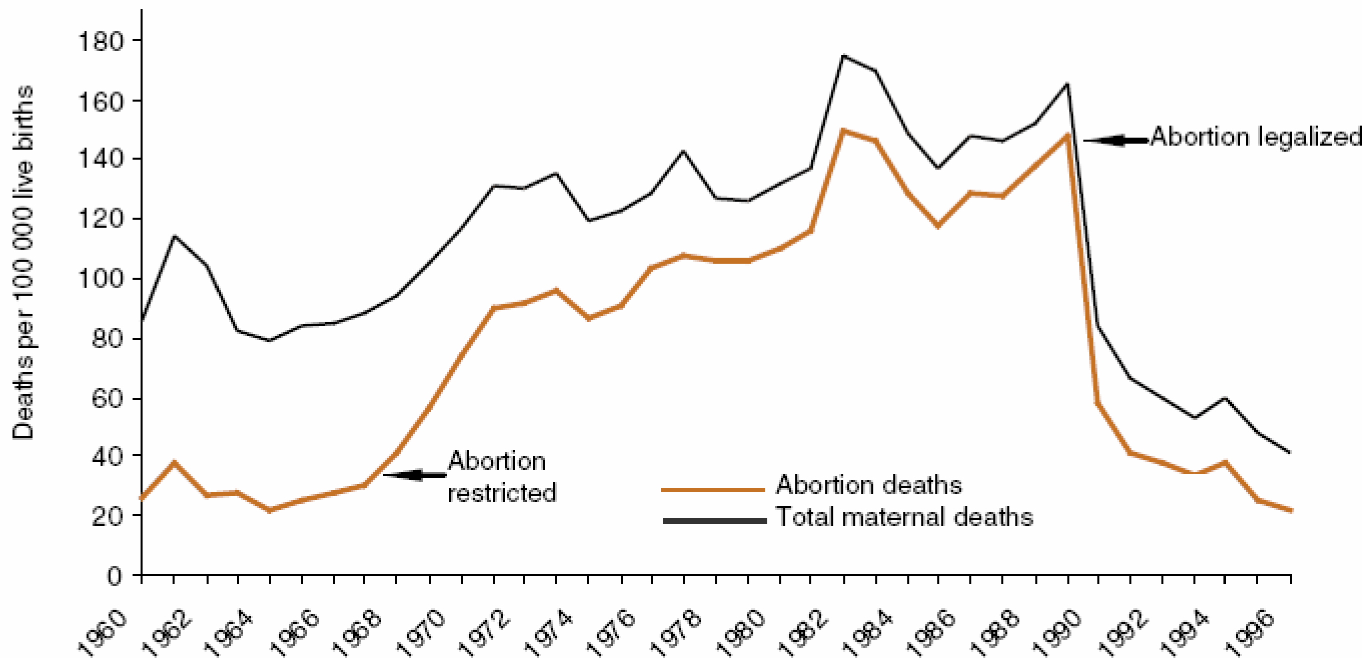
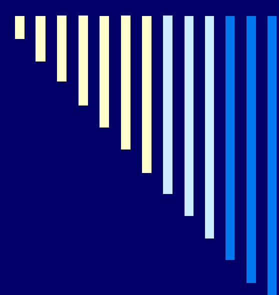
The incidence of unsafe abortion is affected by legal provisions governing access to safe abortion, as well as the availability and quality of legal abortion services. Restrictive legislation is associated with a high incidence of unsafe abortion. The outcome of complications of unsafe abortion will depend not only on the availability and quality of post-abortion services, but also on women's willingness to turn to hospitals in the event of complications, and the readiness of medical staff to extend services. It is thus the number of maternal deaths, not abortions, that is the most visible consequence of legal codes.[13] In the case of Romania, for example, the number of abortion-related deaths increased sharply after November 1966, when the government tightened a previously liberal abortion law (Figure 2). The figure rose from 20 to 100 000 live births in 1965 to almost 100 in 1974 and 150 in 1983.[14] Abortions were legalized again in December 1989 and, by the end of 1990, maternal deaths caused by abortion dropped to around 60 to 100 000 live births.

Figure 2. Number of maternal deaths to 100 000 live births, by year, Romania, 1960–1996



Source: *World health statistics annual*, various years



WHO database on unsafe abortion