Medical abortion implementation in Moldova: from the clandestine use to the incorporation into National abortion Standards

Dr. Rodica Comendant
Reproductive Health Training Cent
Chisinau, Moldova,
Gynyity Senior Consulting Associate,
ICMA coordinator

Gynuity Health Projects, Conference "Medical abortion in Former Soviet Union countries: Challenges and Promises"

Tbilisi, Georgia

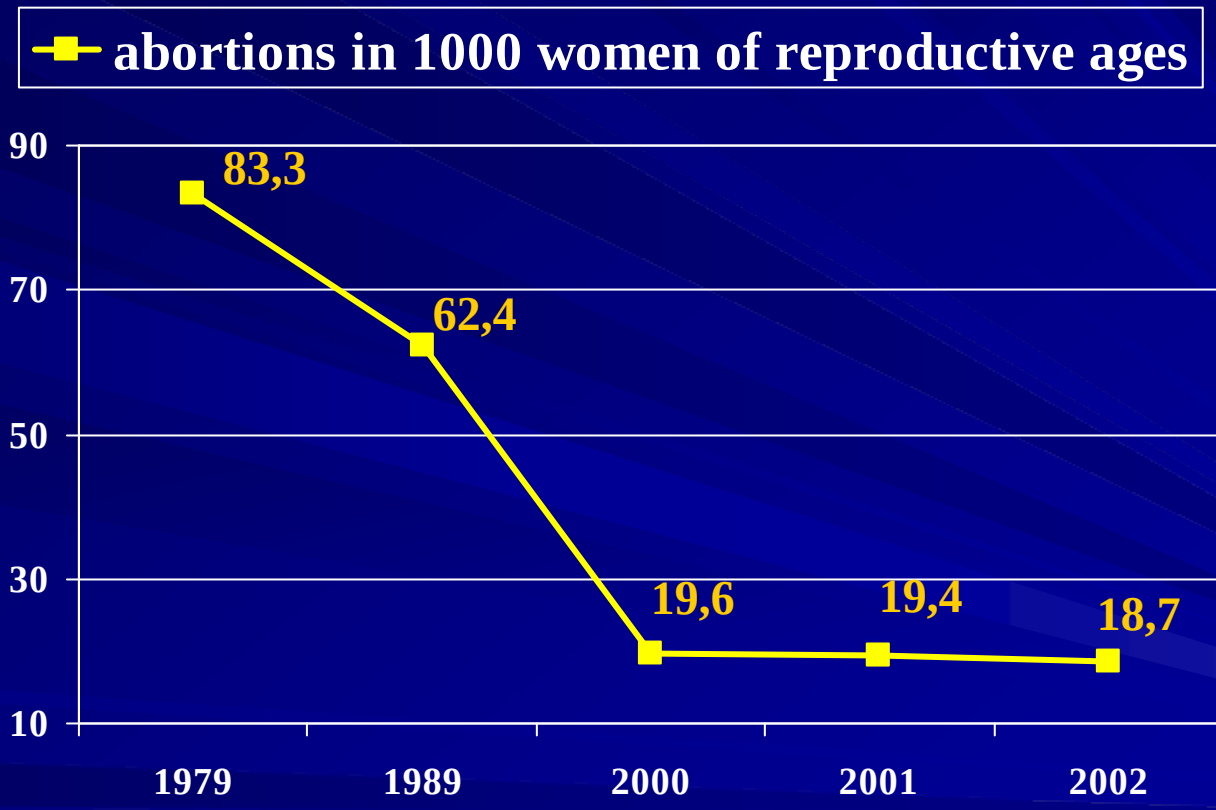
Legal context of abortion

- Legalized in 1955
- The law permits pregnancy termination on the request up to 12 weeks, provided only by ob/gyns in hospitals.
- Up to age 16 parental consent is required
- In the second trimester abortion is permitted on medical or social reasons (6), with the approval of special commission ONLY up to 22 weeks
- Practice has been based on ministerial orders

Historical context of abortion 1955-2005

- Evidence-based guidelines didn't exist
- The trainings of providers – during the postgraduate studies, with no other formal trainings on abortion
- The main method D&C, general anesthesia
- The concept of "patient centered care" not known
- Poor data collection, only quantitative indicators, many unregistered abortions
- Any concept of "audit", of quality of care

The ratio in 2007 was 17,3 abortion per 1000 fertile age women, 5 times lower than in 1979.



Efforts to improve the quality of abortion care

- MVA implementation: Training of Trainers in 2002 (NAF, Ipas)
- National trainings (10 % of providers were trained)
- 2004 - MoH approved MVA and the first evidence-based MVA Guideline
- Training MVA materials were published
- MVA was incorporated in University curricula.
- Educational campaigns on safe abortion

Introduction of medical abortion: misoprostol alone use

- Misoprostol (Cytotek) approved in 2000 for gastric ulcer
- Misoprostol became available with no prescription in the pharmacies
- Providers started to offer medical abortion with miso alone, for first and second trimester
- No official statistics on the use of this method
- Effectiveness of the regimen of 200 mcg Miso, four times orally for abortion in the first trimester 82-84% (case-study at Ob/Gyn department of the University, 2002)

Institutionalization of medical abortion with mifepristone: partnership with Gynuity Health Projects

- Training of trainers on using medical abortion and conducting clinical study in Paris, France, in 2003, attended by a team of specialists
- Clinical study on the evaluation of acceptability of medical abortion in low-resources settings (Gynuity Health Projects) started after
- Education and information campaign on medical abortion, reproductive rights, the right to choose the abortion method has continued (radio broadcasts, leaflets, posters, information placed on the website)

Institutionalization of medical abortion

- September 2004 Shell Pharma registered mifepristone (MtPill, Cipla, India)
- Its label was translated into Romanian, with indications for pregnancy termination up to 49 days LMP, with the regimen of 600mg mifepristone followed by 400mcg oral misoprostol.
- The price for 1 pill - 220 lei (US$20)

Findings of medical the first clinical MA study in Moldova

- Study conducted September 2004 – January 2005 to assess the feasibility and acceptability of medical abortion introduction in a tertiary-level facility
- Reduced dose of mifepristone (200 mg) on Day 1 + misoprostol (400 µg orally) on Day 3 with option of home or clinic administration of misoprostol
- 156 women enrolled with gestational ages of ≤ 56 days LMP
- 95.8% of participants successfully terminated their pregnancies, and 96.1% reported that they were satisfied or very satisfied with the method
- Almost all women who were given the option chose to administer misoprostol at home (96%). These women were able to manage the medical abortion process on their own.

Findings of Strategic Assessment of Abortion Services, conducted with WHO in 2005 :

- Doctors consider Medical abortion with Mifepristone good but expensive method
- Service delivery should be organized to unable them to use officially the method
- Women are aware of medical abortion and want to have access to it
- There are cases when women bye in the pharmacies misoprostol and self-administer it, when denied from obtaining permission from the commission for second trimester

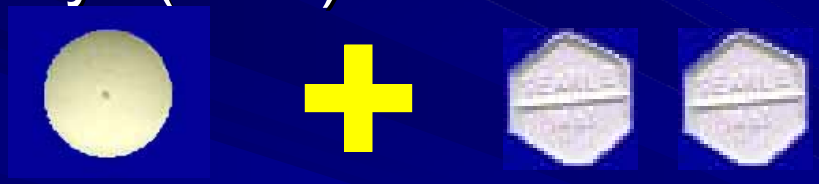
II Study: A randomized study of sublingual and oral misoprostol following 200mg mifepristone for abortion up to 63 days gestation in Moldova

Study design

Study period: **July 2005 – December 2006**

Regimen used:

- ≤ 63 days (LMP)



- Mifepristone (200 mg) on Day 1 + misoprostol (400 μg) at home 24 hours following mifepristone administration
- Women randomized to sublingual or oral misoprostol administration
- Women return to clinic two weeks after initial visit for assessment of abortion status

Efficacy (%)[1]

	Sublingual (n=183)	Oral (n=180)
Success rate[2]	**98.4%***	**93.9%**
All surgical interventions	**1.6%**	**6.1%**
Ongoing pregnancy	**0.5**	**2.2**
Medically indicated	**0.0**	**1.7**
Woman's request	**1.1**	**1.7**
Unknown[3]	**0.0**	**0.5**

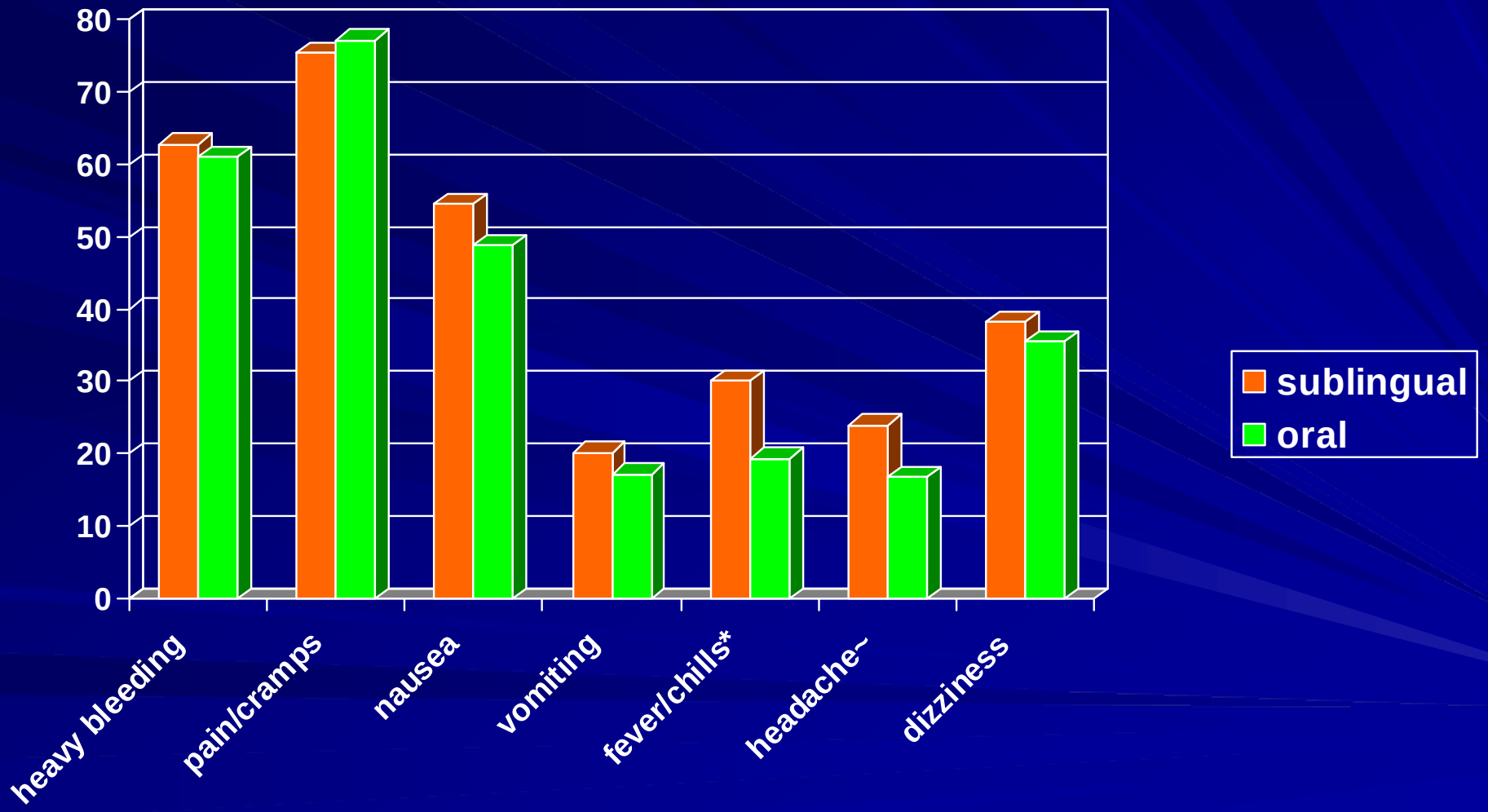
* $p<0.05$

[1] Women who were lost to follow up (n=6) or did not administer misoprostol (n=1) were excluded from the analysis

[2] Successful cases were defined as complete abortions without recourse to surgical evacuation at any point during the study period

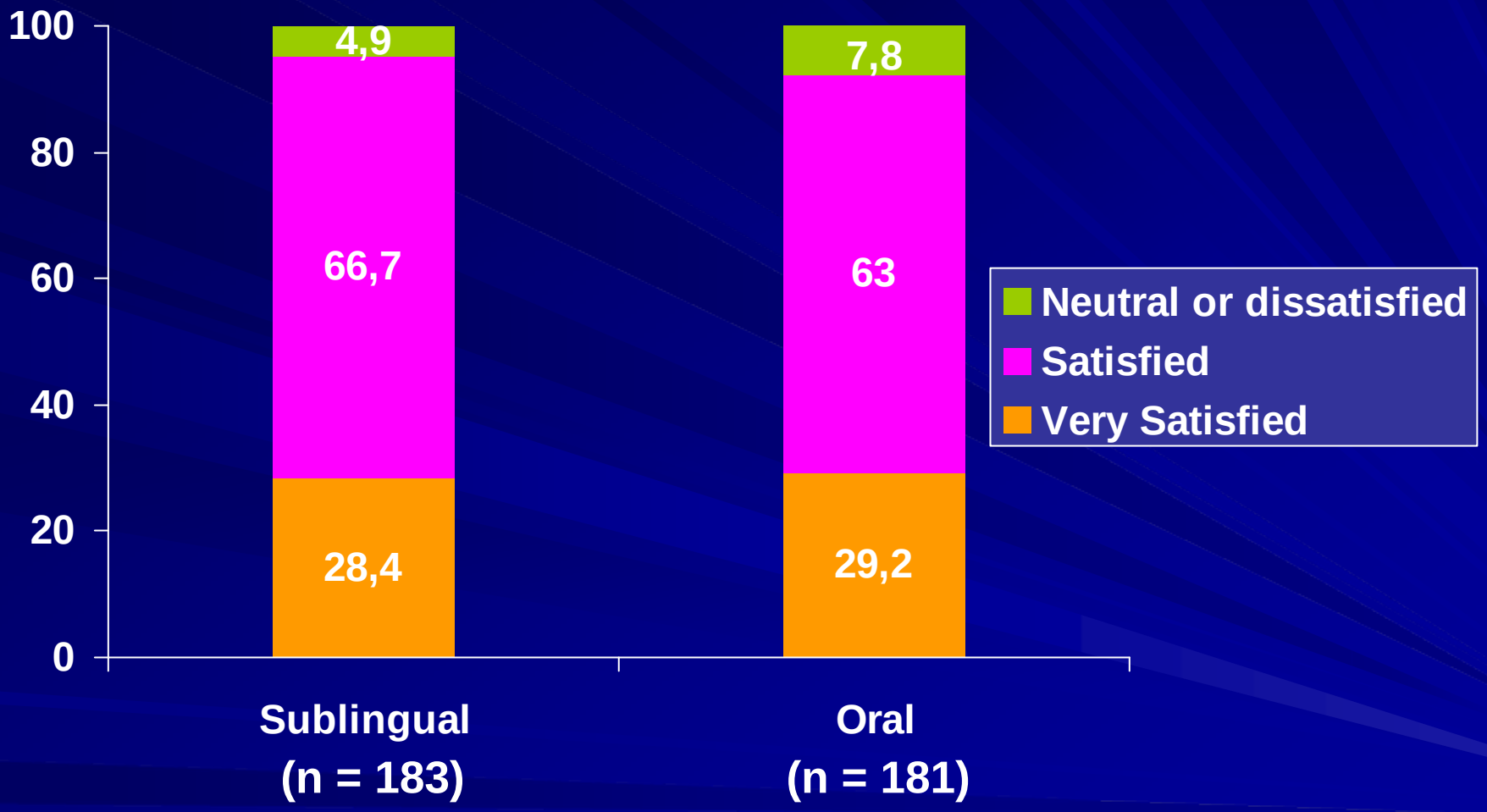
[3] Surgery occurred in hospital other than study clinic; reason unknown

Side Effects



*p<0.05 ~p<0.10

Satisfaction (%)



* Women who were lost to follow up (n=6) or did not administer misoprostol (n=1) were excluded from the analysis.

Conclusion

- 400 μg of sublingual misoprostol after 200 mg mifepristone is more effective than 400 μg oral misoprostol taken after 200 mg mifepristone
- Sublingual administration is as acceptable as oral administration in inducing abortion in women up to 63 days gestation

National dissemination meeting, with the participation of the team from Gynuity, December, 2006

- The studies data have been presented
- Implementation strategies have been discussed
- MoH expressed concerns regarding the efficacy and safety of using MA for women from rural area
- Training for abortion providers has been conducted after the meeting

IIIrd Study objectives

- To determine if 400 mcg sublingual misoprostol is effective and safe following mifepristone 200 mg for pregnancy termination up to 63 days' LMP
- To investigate the acceptability, satisfaction, and side effects associated with the new regimen

Study sites and timeframe

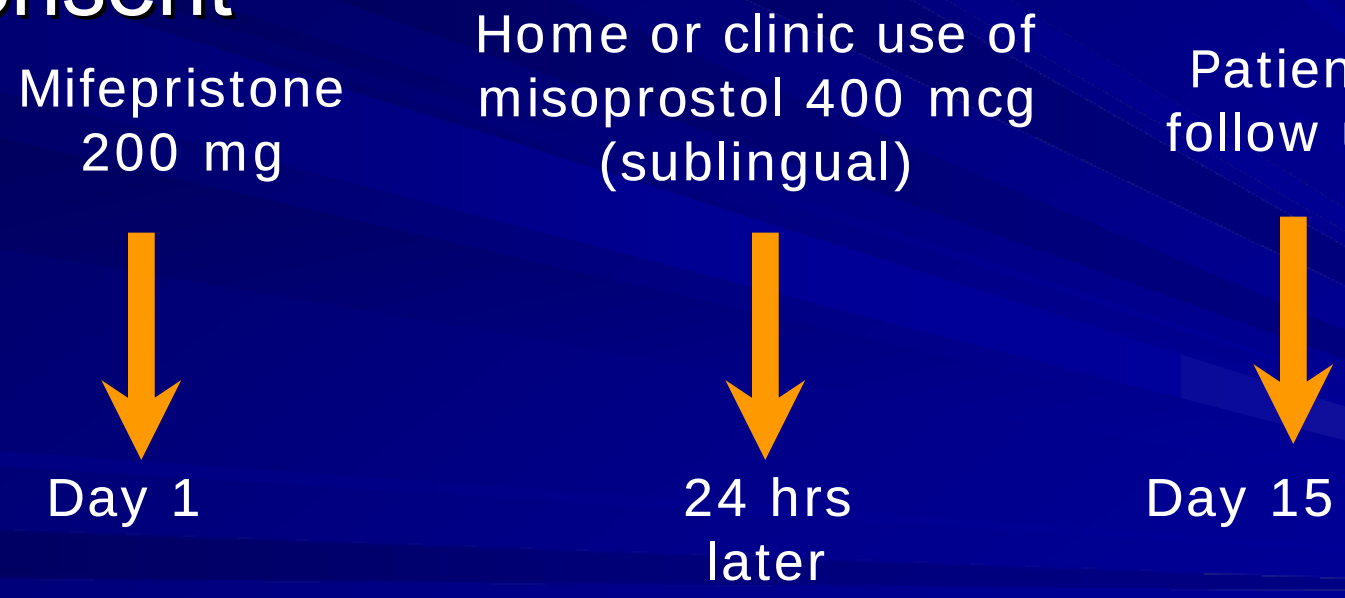
Study sites:

- The National Center of Reproductive Health and Medical Genetics, Chisinau
- The Perinatalogy Center, Balti
- The Center of Women Health “Ana”, Drochia

Study period: March-November 2007

Study design

- 300 women over 18 years seeking abortion ≤63 days LMP or 16-17 yrs with parental consent



Efficacy

Success is defined as complete evacuation of the uterus without recourse to surgical back-up

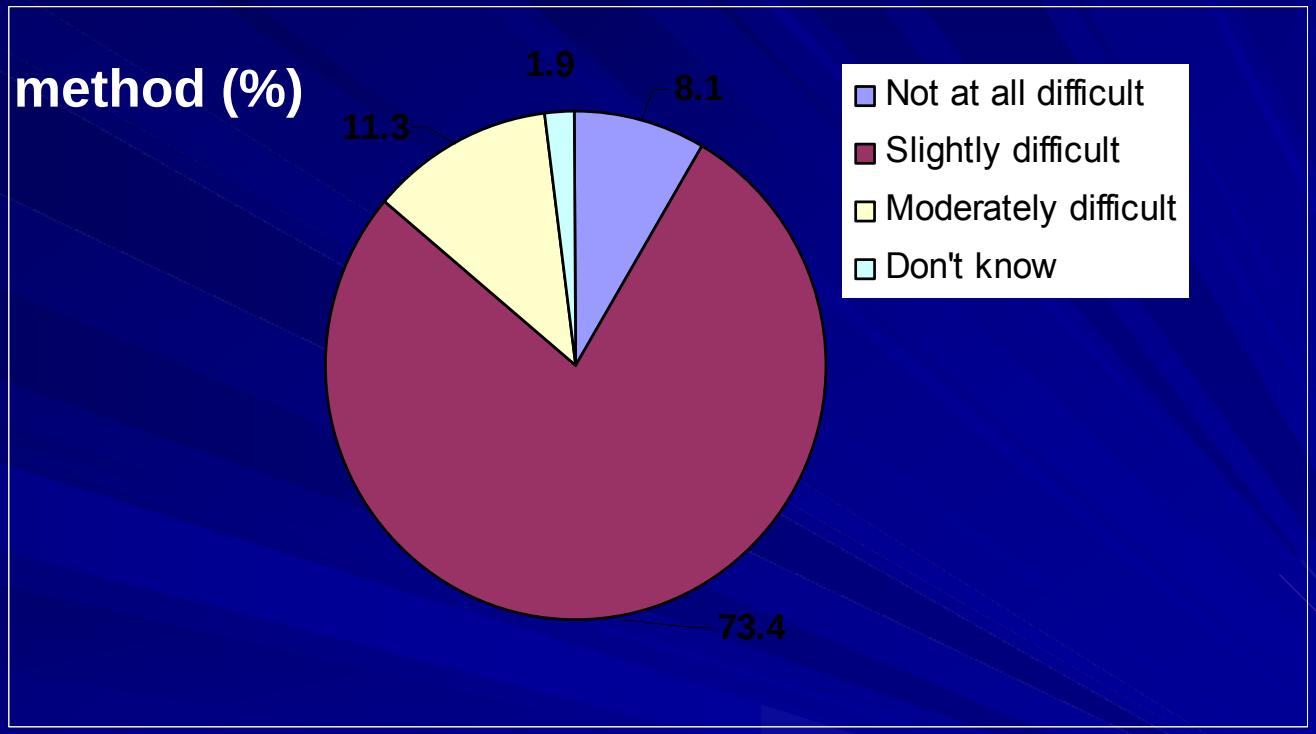
	Balti	Chisinau	Drochia
Overall success rate* (%)	95.9	100.0	95.9
Success by gestational age interval (days LMP)			
≤ 49 days	96.3 (77/80)	100.0 (79)	93.8 (61/65)
50-63 days	94.1 (16/17)	100.0 (21)	100.0 (33/33)

* Does not include 7 women lost to follow up

**For overall results and gestational age interval > 49 days, significant site differences between

Experience & Satisfaction

Experience with the method (%)



“Satisfied” or “Very Satisfied” with method

Site1	Site2	Site3
91.8%	99.0%	95.9%

p<0.05 for satisfaction between sites 1 and 2; some differences for experience with the method

Conclusions

- Sublingual administration of 400 mcg misoprostol after mifepristone is safe and effective through 63 days' LMP, for women from rural area too
- Side effects profile is as expected and similar at 3 sites
- Women report high satisfaction with regimen
- 400 mcg sublingual regimen is a good option for mifepristone abortion through 63 days' LMP

IV Study

- **Two-pill regimens of misoprostol after mifepristone medical abortion through 63 days' LMP: A randomized controlled trial of buccal and sublingual misoprostol**

Results:

- 96.7% of women in the buccal arm and 97.4% in the sublingual arm had successful abortions, with no statistically significant difference in success rates (p=.798).
- Over 91% of women in both groups reported being satisfied or very satisfied with the method.
- Most side effects were low and comparable in both arms, with only fever and/or chills reported by significantly more women in the sublingual arm (28.9% vs. 18.8% buccal arm, p=0.02).

Ongoing Studies:

- Uptake and acceptability of home-use of mifepristone for medical abortion

- Mifepristone and misoprostol versus misoprostol alone for mid trimester termionation of pregnancy (14-21 weeks LMP): A randomized-controlled double-blinded trial

Clinical study: an important strategy of the institutionalization of medical abortion

- Trained involved providers, offered clinical experience with evidence-based protocol
- Built providers' confidence on home-use of misoprostol, countered providers' fear on off-label use
- Providers became the "pioneers" of the method
- The studies provided useful data to official approval of the method and of the guideline and protocols

National Standards and protocols on CAC

- Developed by an working group in 2009, revised by WHO, submitted to the MoH
- The protocol for MA:
- 200mg mifepristone, followed 24 hours by 400 mcg misoprostol, up to 63 days LMP, with the offered choice to use misoprostol at home
- Statistical package for MA registration developed and submitted, along with new indicators of the quality of abortion care

Next steps: National trainings on Medical Abortion

- First two trainings on medical abortion for 65 ob/gyns in 2005
- The curriculum has been developed, tested and is based on interactive work and principles of adult learning, case studies, modules on regimens for first and second trimester abortion, pre- and post-abortion counseling, supervision and management of side effects and complications
- Incorporation of MA curricula in the study programmes
- Trainings for abortion providers are planned after the last approval of the Standards

Barriers, challenges

- Organization of service delivery (rural area??)
- The cost of the pills, higher than for vacuum aspiration (Medabon registration process has started)
- The drugs sustainability
- Doctor's reluctance to a new method
- The misuse of the drugs
- Lack of counseling skills
- Low level of community education and demand for better services, including for MA, especially in the rural area

Acknowledgements:

- Gynuity Health Projects: Dr. Beverly Winicoff, Hillary Braken, Sheila Raghavan, Erica Chong, Caitlin Shannon
- Centre for Training in Reproductive Health Technologies, Paris, Dr. Danielle Hassoun.
- State Medical and Pharmacy University of Moldova (Professor Valentin Friptu, Dr. Stelian Hodorogea),Dr. Irena Digol, Dr. Sergiu Ungureanu

Acknowledgements, cont.

- The National Center of Reproductive Health and Medical Genetics, Chisinau
  - Veacheslav Moshin
  - Mihai Stratila
  - Victoria Turuta
  - Alina Hotineanu
  - Maria Croitor
- ***Balti, Perinatal Center***
  - Petru Nedelciuc
  - Veronica Dorogoi
  - Adela Chiaburu
  - Maria Capatina

Acknowledgements continued…

- The Center of Women Health “Ana”, Drochia
  - Svetlana Nicov
  - Elena Deleu
- ***Municipal Clinical Hospital No.1***
  - Iurie Dondiuc, Vice-Director

Thank you!
Welcome to Moldova!