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A tailored pregnancy test offers new possibilities to women for follow-up after medical abortion

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Reproductive Health Research

From bench- to bed- to roadside and the hands of women
to improve women's health



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Disclosures of Financial Relationships

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Questions

1. Do women want self-assessment of the outcome of medical abortion?

- a) Yes
- b) No
- c) NA

Questions

2. When should the urinary test be done?

- a) 2 weeks after the MToP treatment
- b) 4 weeks after the MToP treatment
- c) NA

Questions

3. How should the urinary test be done?

- a) Home use
- b) Done in hospital setting
- c) Other

Questions

4. Can this approach be used by illiterate women?

- a) Yes
- b) No
- c) NA

Women prefer fewer clinical visits in connection with their abortion

Kopp Kallner H, Fiala C, Stephansson O, Gemzell-Danielsson K. Hum Reprod 2010; 25: 1153-7

Visit to the abortion clinic

Visit for mifepristone

Visit for misoprostol, stay in clinic

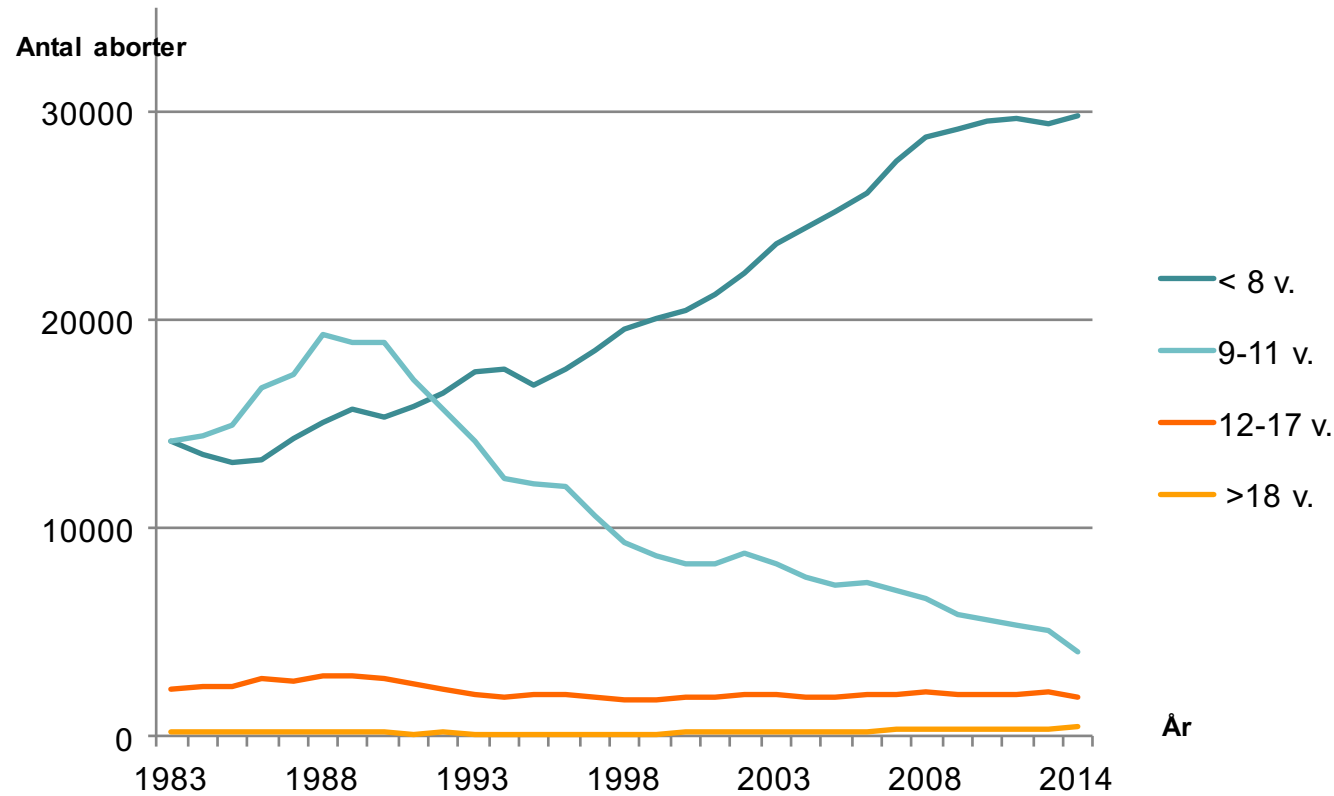
Follow-up after 3-4 weeks

Impact of reducing barriers in access



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Abortions 1983 - 2014



Källa: Socialstyrelsens abortstatistik

2012 Updated WHO guidance on safe abortion

- Emphasizes the simplifying or streamlining of abortion care,
- Notes a high value on research to demedicalize abortion care
- Affirms that home use of misoprostol is a safe option for women

The Guidance suggests the evaluation of internet provision and telemedicine, as further alternative service delivery channels of safe abortion, as a subject for future research

Medical abortion, Sweden

- Telephone booking (self referral)
- Visit 1 on Day 1 to midwife (healthy women) or gynaecologist;
 - counselling, examination, incl contraceptive counselling and provision,
 - mifepristone, misoprostol to take 24-48h later @ home/clinic, pain medication
- FU since 90ies with a midwife at 3-4 weeks, 500 IU uhCG-test.
- An increasing number of women do not come back for a scheduled FU
- **2011:** Symptom history alone unreliable to detect ongoing pregnancy (Grossman et al.,)



www.womenonweb.org

I need an abortion

- 1 Mifepristone
- 2 Misoprostol
- 3 Repeated misoprostol if necessary
- 4



Do you have an unwanted pregnancy? Click here. This online medical abortion service helps women gain access to a safe abortion with pills in order to reduce the number of deaths due to unsafe abortions.

K.Gemzell Danielsson

I had an abortion



Every year 42 million women have an abortion. Every 7 minutes a woman dies unnecessarily from an illegal abortion. Show your face, share your story, donate your money and help women around the world get access to safe abortions. Discuss and share information with others. Look for support if you are considering an abortion. Participate to support abortion rights, also if you did not have an abortion. Click on one of the portraits to find our more....

Telephone FU and self-performed urine pregnancy testing after early medical abortion: a service evaluation

Cameron ST, Glasier A et al., *Contraception*, 2012

- Tel FU + LS hCG test introduced at Royal Infirmary, Edinburgh, as an alternative to routine US at 2 w following MA
 - Evaluation of the first 8 months; 476/ 619 choose tel. FU (77%).
 - 4 (1%) attended the clinic before tel. FU (pain/bleeding).
 - 410/472 (87%) were successfully contacted.
 - 60 (15%) screened 'positive', 3 ongoing pregnancy, 1 false 'negative'.
 - sensitivity tel.FU:75% [95% CI 30.1–95.4], specificity 86% (95% CI 82.2–89).
 - All women surveyed (n=75) would recommend tel. FU to a friend.
-

Follow up: routine vs. self assessment

Sunde Oppegaard K, Qvigstad, E, Fiala, C, Heikinheimo, O, Benson, L, Gemzell-Danielsson K. THE LANCET 2015; 385: 698–704.

Objectives.

- To evaluate self-assessment using a low sensitivity u-hCG test (DUO-test, VedaLab, France)
 - at home and telephone FU
 - versus routine FU in the clinic
- in medical abortion up to 63 days' gestation

Additional questions:

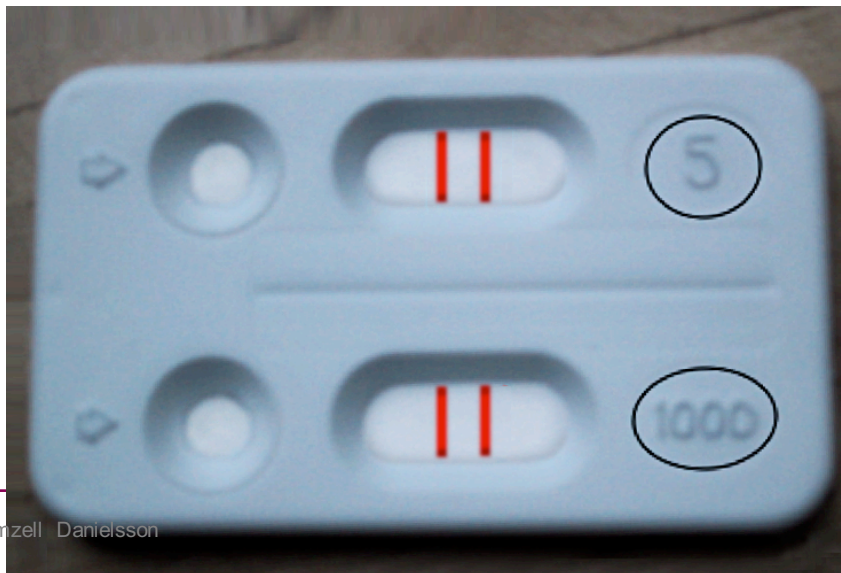
- Is the test easy to use?
 - Do women prefer one-stop treatment compared to hospital FU?
-

Home self test

Sunde Oppegaard K, Qvigstad, E, Fiala, C, Heikinheimo, O, Benson, L, Gemzell-Danielsson K. THE LANCET 2015; 385: 698–704.



Complete abortion



**Incomplete abortion
or failed test → 'Call the Clinic**

Follow up: routine vs. self assessment

Sunde Oppegaard K, Qvigstad, E, Fiala, C, Heikinheimo, O, Benson, L, Gemzell-Danielsson K. THE LANCET 2015; 385: 698–704.

Design.

- Multinational, multicentre, randomized. non-inferiority trial

Inclusion criteria:

- Women $>$ or $=$ 18 years,
 - Opting for medical abortion at 63 days of gestation and
 - Home administration of misoprostol
 - Randomized prior to treatment
-

Assessment of outcomes

Sunde Oppegaard K, Qvigstad, E, Fiala, C, Heikinheimo, O, Benson, L, Gemzell-Danielsson K. THE LANCET 2015; 385: 698–704.

- Group 1: Follow-up after 2-3 weeks at outpatient clinic: 466 women
 - Group 2: Women responsible for own evaluation of treatment success using the commercially available hCG test (DUO-test) at two weeks at **home**: 458 women. Telephone follow-up within one month to evaluate success and satisfaction with method.
 - All patient records reviewed after three months to control for abortion-related complications
-

Results

Sunde Oppegaard K, Qvigstad, E, Fiala, C, Heikinheimo, O, Benson, L, Gemzell-Danielsson K. THE LANCET 2015; 385: 698–704.

No difference in efficacy (complete abortions) and safety between groups

Per protocol population

Home	Clinic	Crude risk difference (95% CI)	p 0.513
94%	95%	-1.0 (-4.0-2.0)	

No difference in efficacy (complete abortions) and safety between countries

p 0.216

Results

Sunde Oppegaard K, Qvigstad, E, Fiala, C, Heikinheimo, O, Benson, L, Gemzell-Danielsson K. THE LANCET 2015; 385: 698–704.

- No difference in demography
 - Median gestational length 6 (4-9) weeks
 - Rate of surgery was 4% in both groups
 - 91% found the semi-quantitative urine hCG-test easy to use.
 - No difference in telephone calls or extra visits ($p=0.479$)
-

Results

Sunde Oppegaard K, Qvigstad, E, Fiala, C, Heikinheimo, O, Benson, L, Gemzell-Danielsson K. THE LANCET 2015; 385: 698–704.

- 17/446 in the u-hCG arm had positive hCG screens
- 27/446 were uncertain whether the test was positive or negative
- Two ongoing pregnancies in Oslo and one in Helsinki, all in the Home group, initially undiagnosed by the patients
- Significantly more women were lost to FU in the control group (29%) vs. the intervention group (1%) ($p < 0.001$)
- 82% in the intervention group preferred self-assessment vs. 59% in the control group in case of a future abortion ($p < 0.001$).

But does it work in other settings?

Self-assessment of the outcome of early medical abortion versus clinic follow-up in India: a randomised, controlled, non-inferiority trial



Kirti Iyengar, Mandira Paul, Sharad D Iyengar, Marie Klingberg-Allvin, Birgitta Essén, Johan Bring, Sunita Soni, Kristina Gemzell-Danielsson



Summary

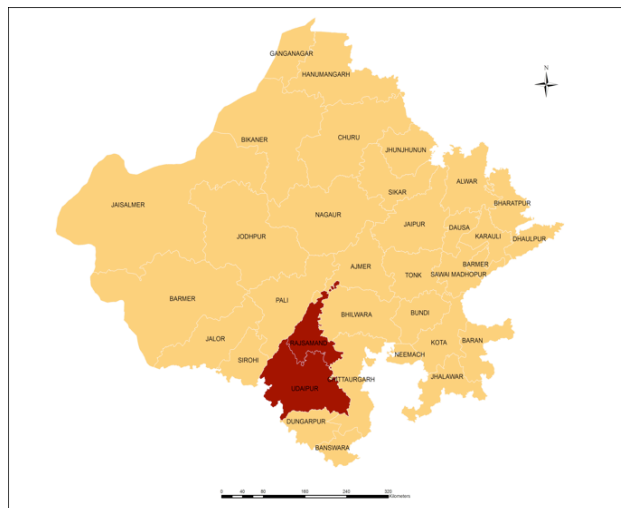
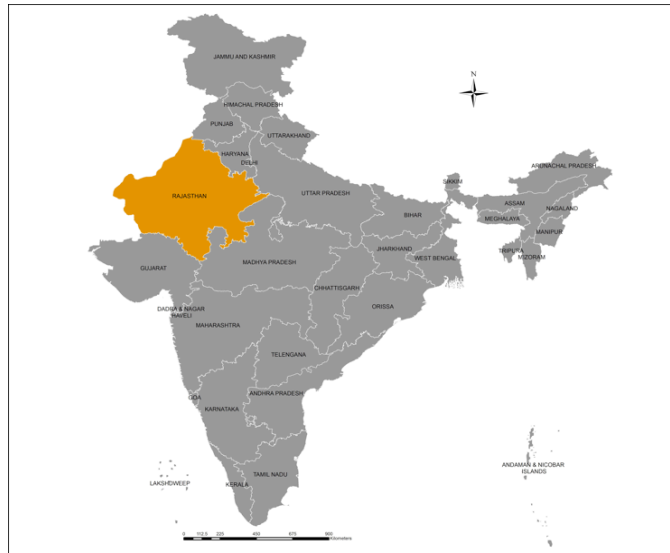
Background The need for multiple clinical visits remains a barrier to women accessing safe legal medical abortion services. Alternatives to routine clinic follow-up visits have not been assessed in rural low-resource settings. We compared the effectiveness of standard clinic follow-up versus home assessment of outcome of medical abortion in a low-resource setting.

Lancet Glob Health 2015;
3: e537–45

See [Comment](#) page e504

Department of Women's and
Children's Health, Division of

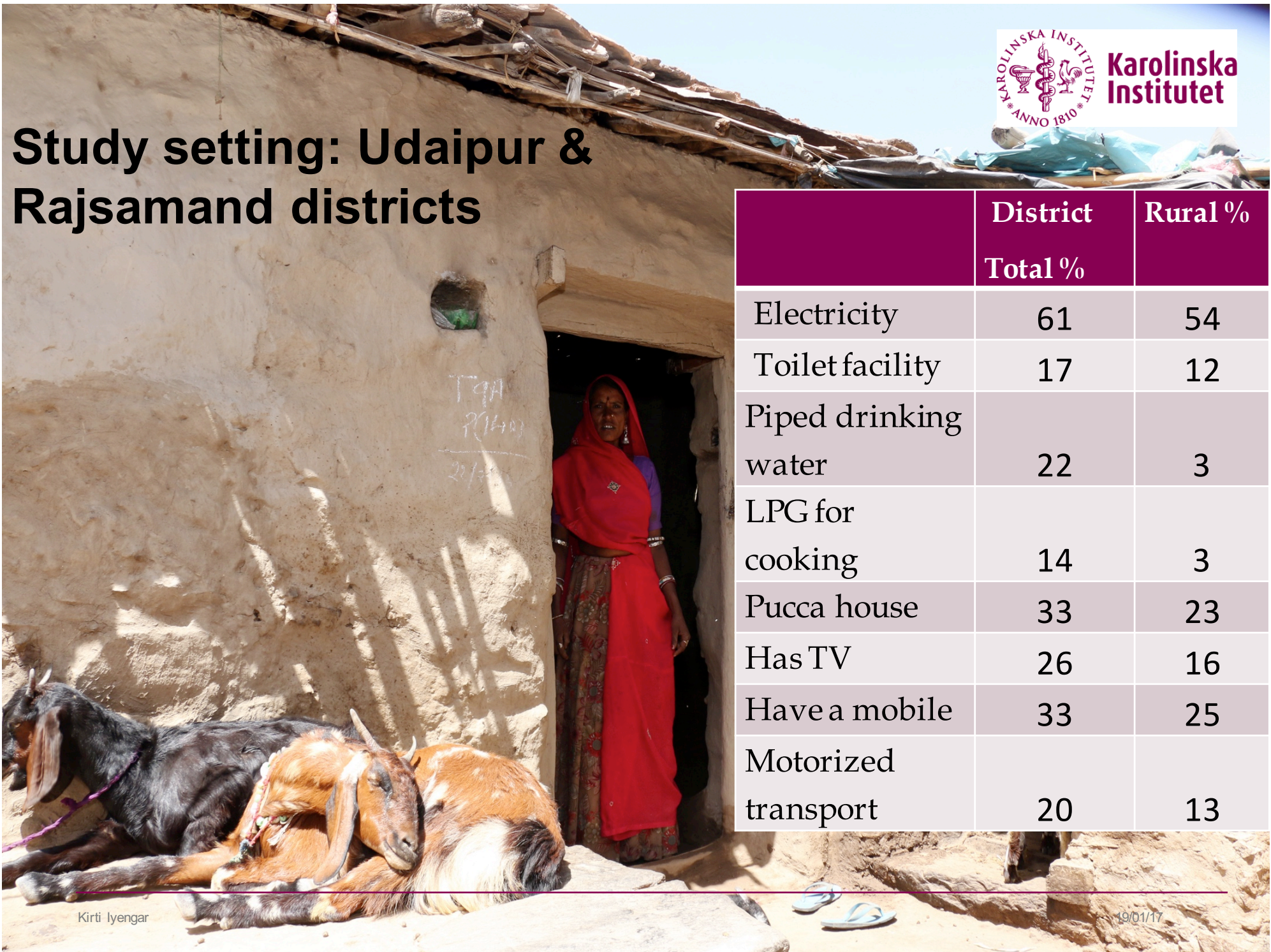
Study setting



Rajasthan	%
Rural (%)	75.1
Literacy rate (%)	52.7
Maternal mortality ratio	244
Total fertility rate	2.9
Scheduled caste and tribe	29.6
Sex ratio at birth	875

Study setting: Udaipur & Rajsamand districts

	District Total %	Rural %
Electricity	61	54
Toilet facility	17	12
Piped drinking water	22	3
LPG for cooking	14	3
Pucca house	33	23
Has TV	26	16
Have a mobile	33	25
Motorized transport	20	13



Eligible women randomized into one of the groups

Clinic follow up group

Routine follow up at 10- 14 days at clinic

Clinical exam. by doctor

LSUP test

Follow-up interview by RA



Home-assessment group

Woman asked to assess her outcome of abortion at 10-14 days using:

→ low sensitivity pregnancy test (LSUP)

→ pictorial instruction sheet

Home visit / phone call by RA

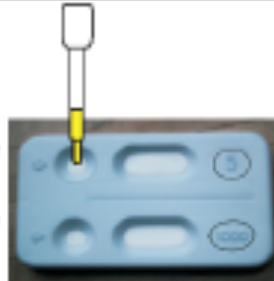
Pictorial instruction sheet

अर्थ (सफल परिणाम)
मदित्व द्वारा घट घट मृत्युआंकक हेतु वैकरीसेट
पेक्षाक की लॉच कैसे करें?

किरिचक पर लोरी लेने की तरीक

घर पर प्रेग्नेसी टेस्ट करने के निर्देश

1. इस आणकी का-का दे लो है-
 - परकिचक का किचक
 - पेक्षाक की लॉच की पट्टी
 - ड्रॉपर
2. _____ तरीक,का लो आणकी पेक्षाक की लॉच काकी है।
3. पेक्षाक की लॉच कैसे काकी है-
 - पेक्षाक की लॉच मरिचककन काकाके के काद 12 से 14 दिन के काद काकी है।
 - इसकी किच परकिचक को किचक के लोका का पेक्षाक लो।
 - ड्रॉपर के एक डिच को पेक्षाक में काकी म उमपी डिच को काकी। इसकी लोका का पेक्षाक ड्रॉपर से आ काकीक।
 - पेक्षाक की लॉच को लोरी म उमपी डिच काके लोका काके पेक्षाक की 5-5 लोरी काकी।
 - 10 से 20 किचिक काके ड्रॉपर करे।



परिचाम

1. यदि लाल रंग की 2 या 3 लाईन आती हैं तो इसका अरथ है कि आपका मरिचककन पूर्ण हो गया है।



मरिचककन पूर्ण हो गया है

2. यदि लाल रंग की 4 लाईन आती हैं, तो शक्य आपका मरिचककन पूर्ण नहीं हुआ है और आणकी दुबले लककक केक काके की आणकककक है।



मरिचककन पूर्ण नहीं हुआ है, आणकक केक पर काके।

3. यदि इसकी आणकी लो है तो लो दुबले लककक आणक काकीक। आणक यदि 5 लोरी आणकी है और 1 इसकी लककक है तो लो दुबले काद आणकी लो आणकी काकीक लो। किरिचक पर काका लोरी।

किचक और प्रकाश के किच करे।

घर आणकी किचक में लो लोरी आणक है-

यदि आणकी घर काके के का किरिचकिकल में लो लोरी लो लककक लो लो दुबले किच आणकी 12-13 दिन काके ड्रॉपर काके की आणक लोरी है। आण आणकक केक पर लुका आणक-

1. का आणकी लुका लककक लुका लो का है ?
(का की लो 2-3 दिन लो आणक काके)



हाँ नहीं

2. का आणकी (किचिक) लेके के 3 की काद लो? ड्रॉपर आणक काकी लोरी है ?



हाँ नहीं

3. किच लो आणकक लेक करे है ?



हाँ नहीं

4. का आणकी आणकक काकीक लो ?



हाँ नहीं

5. का आणकी पेक्षाक की लॉच पर काद लाकी (किचिक लेके के 1-4 दिन काद) आणक ?



हाँ नहीं

झाकी लो लोरी लो लककक लोके पर लुका आणककक काके।

यदि उमकेस में लो लोरी लो लककक लो लो दुबले लककक केक पर लुका करे।

आणक आणकक केक लुकेली कोक नं. 9799007133	आणक आणकक केक लकककककरी का लुका कोक नं. 9799490344	आणक आणकक केक लककक कोक नं. 9799490340	आणक आणकक केक लुका कोक नं. 9001999349	केकक लोकिचक किचकककरी को लककरी कलककक कोक नं. 0294-2451013
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किचक और प्रकाश के किच करे।

Checklist MA Home Assessment

Check the box when the answer is YES 

Complete abortion (when 2 or more):

- Did you see expulsion of products?
- If you had any pregnancy symptoms before, are they gone?
- Did the pregnancy test (1000) show negative?



Incomplete abortion/complications (when 1 or more):

- Are you still bleeding?
 - If **yes**, more than a normal period?
- Do you have severe abdominal cramps?
- Did the pregnancy test (1000) show positive?
- Do you feel sick?
 - Have you had a fever?
 - Have you had prolonged abdominal pain?
- Do you have excessive blood loss?
- Do you feel weak/ the whole body is aching?



**Contact
the clinic**

Results

Background characteristics of women (n= 731)

Rural	73%
Illiterate	55%
One or more children	95%
Previous induced abortion	32%
Paid employment	18%
Owned a phone	44%

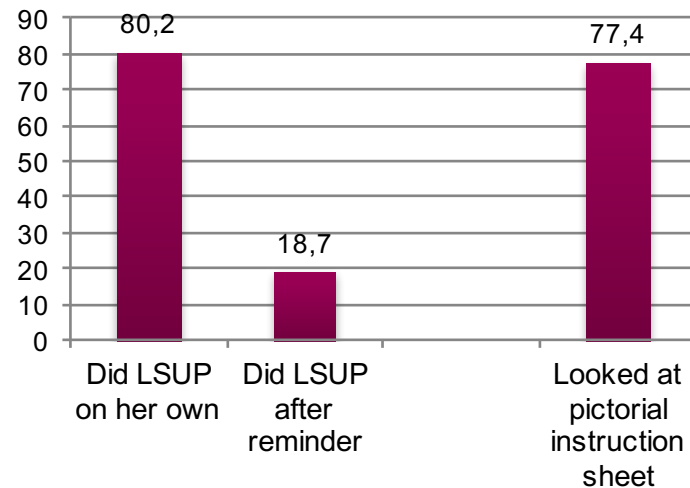
Results:

Outcome of abortion in two groups

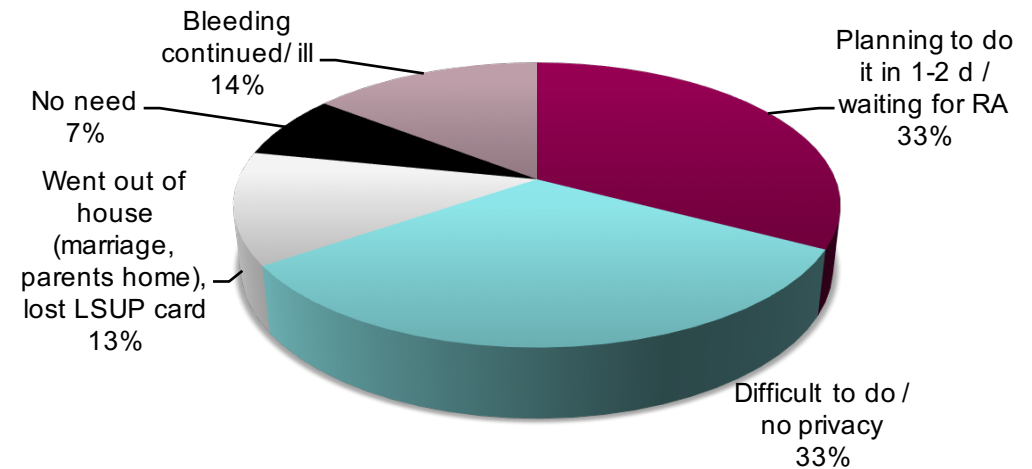
	Clinic follow-up group	Home- assessment group	Difference in outcome rates (95% CI)
ES analysis (n= 700)	n=336	n=364	
Complete abortion	313 (93·2%)	347 (95·3%)	- 2·2%(-5·9 – 1·6%)
Unsuccessful abortion	23 (6·8%)	17 (4·7%)	
o <i>Ongoing</i>	5 (1·5%)	2 (0·5%)	
o <i>Incomplete</i>	18 (5·4%)	15 (4·1%)	
ITT analysis (n= 731)	n= 366	n=365	
Complete abortion	340 (92·9%)	347 (95·1%)	- 2·2% (-5·9% - 1·5%)
Unsuccessful abortion	26 (7·1%)	18 (4·9%)	
o <i>Ongoing</i>	7 (1·9%)	3 (0·8%)	
o <i>Incomplete</i>	19 (5·5%)	15 (4·1%)	
Lost to follow-up	11 (3·1%)	7 (1·9%)	
Violation of protocol	6 (1·7%)	7 (1·9%)	

Feasibility & safety

Whether women did LSUP /
looked at instruction sheet
(n= 289)



Reasons for not doing pregnancy test on
her own



- Rate of adverse events after MA (0.27%)
- 75% women in clinic FU group and 25% in home assessment group visited the clinic

Knowing whether the abortion is complete

- *“I knew because (after I took 4 tablets), the bleeding started. When my pieces fell down, then I came to know that nothing is there”.*
- *“One thing is there - when anyone gets pregnant, then appetite is lost, you do not feel hungry, you feel irritable, there is nausea. After (taking the tablets), I was not feeling anything, I was eating timely, and there was no nausea so it means that abortion was complete. The pregnancy test was given from clinic to test after 15 days, I did the test, and it was negative”.*



Women with low literacy can feasibly assess the outcome of an early medical abortion

Majority had no concerns related to home use of misoprostol, and home-assessment.

- *“I was not worried at all”*
 - *“Since I had taken tablets earlier too, I was not worried”*
 - *“I was a bit afraid, but my husband was home. He said that if anything happens to you, we will take you to hospital in a jeep.”*
-



Conclusion

Self-assessment as an alternative to clinic follow-up for women having early medical abortion *in low resource settings*

- Effective - Self-assessment is non-inferior to clinic follow-up after early medical abortion
- Safe - Very low rate of adverse events of medical abortion
- Feasible-
 - most did their LSUP test on their own (80%) and interpreted it correctly
 - Only 25% had to make a visit to the clinic



The use of a low sensitivity pregnancy test to assess early medical abortion outcome in the South African public sector setting

D. Constant¹, K Daskilewicz¹ J. Harries¹ L. Myer² K. Gemzell-Danielsson³

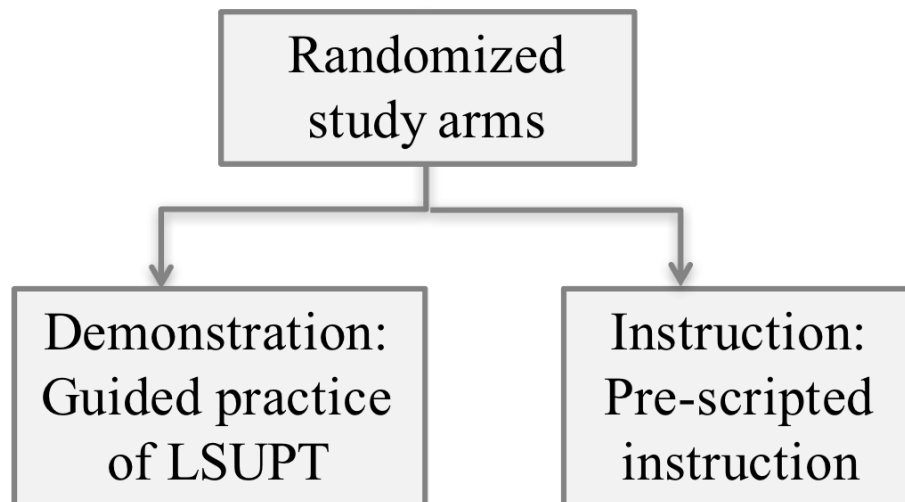
¹*Women's Health Research Unit, University of Cape Town, South Africa*

²*Division of Epidemiology and Biostatistics, University of Cape Town, South Africa*

³*Department of Women's and Children's Health, Karolinska Institutet, Sweden*

Study background and aim

- Previously in CoCT CHCs (2012): A set of questions on the MTOP symptoms experienced did not identify all cases requiring additional treatment at FU, when women completed these by themselves
- To improve the accuracy of self-assessment we offered women the low sensitivity pregnancy test (LSUPT; hCG>1000mIU/ml) combined with paper symptom checklist (CL) and SMS reminders



Demonstration (n=263, 88%) vs Instruction-only (n=262)

One ongoing pregnancy not identified by LSUPT

Home self-assessment



Women are able to safely have a medical abortion with home use of misoprostol 63 days of gestation and self assessment of the outcome of the treatment using a low sensitivity urine hCG-test.

Self assessment is resource-saving. A step in demedicalising abortion and women prefer it.

Women need to be counselled of the risk of an undiagnosed ongoing pregnancy. Any introduction of self-assessment will need a careful evaluation of the test as well as of user performance.

Women with low literacy can feasibly assess the outcome of an early medical abortion.

D. Constant ^{et al.},
Sunde Oppegaard K, et la., Lancet 2015; 385: 698–704.

Kirti Iyengar, et al., Lancet Global Health 2015

Conclusion

Simplifying medical abortion can help to increase access to safe abortion services through:

- Even women with low literacy can feasibly assess the outcome of an early medical abortion using the DuoTest (VedaLab, Paris France)
 - New LSUP available in Europe (checkToP, Exelgyn, Paris, France)
Investigated in SA, used in clinical routine in Sweden
 - Cost:
 - DuoTest 1.05 Euro/test
 - checkToP approx 5 Euro/test
-

Questions

5. Is urinary test reliable?

- a) Yes
- b) No
- c) NA



Questions

6. If tests are available, will you use them?

- a) Yes
- b) No
- c) NA



Acknowledgement



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-