Safe abortion commodities are reproductive health supplies too: ensuring access and availability of comprehensive abortion commodities for the women who need them

Evidence supporting use of MLPTs in medical abortion follow-up and update on global product availability

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GENERAL MEMBERSHIP MEETING
of the
REPRODUCTIVE HEALTH SUPPLIES COALITION

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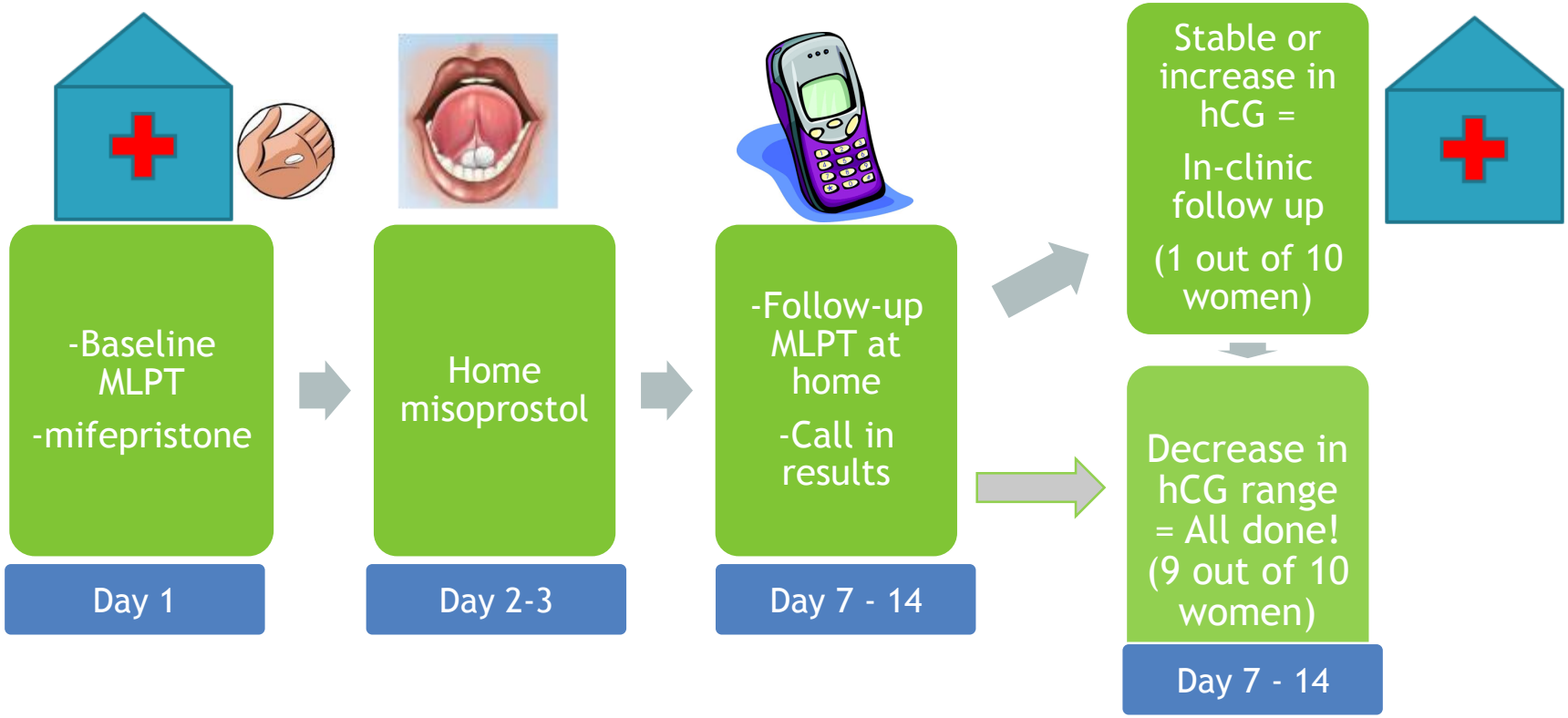
Reproductive Health SUPPLIES COALITION

What is an MLPT?

- Urine pregnancy test that identifies hCG using antigen/antibody reaction, like all other pregnancy tests
- Does not give a precise concentration of hCG in test liquid
- Does not give only a “yes/no” readout
- Identifies a range in which the precise level falls

Current strategy for using MLPT to assess MA outcome



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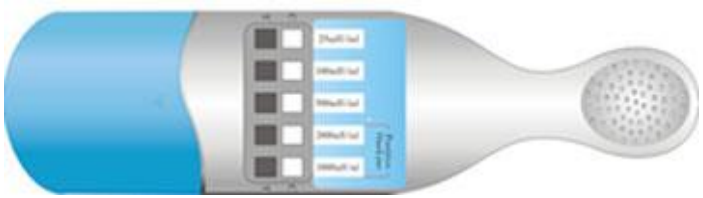
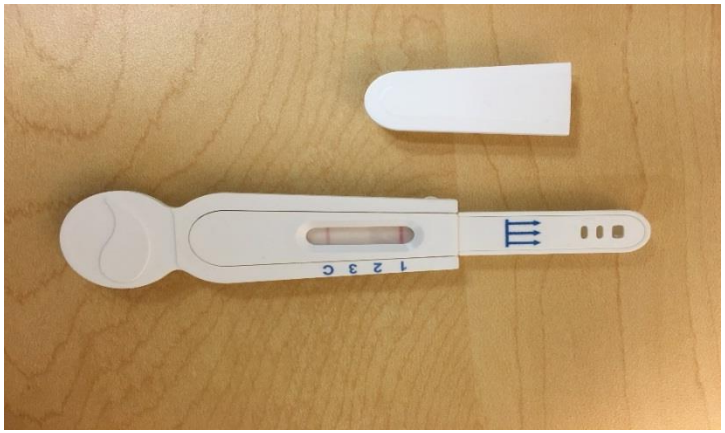
Different Products





Meta-analysis supports use of MLPT for MA follow-up

7 Gynuity studies in which a 5-bracket MLPT was used to ascertain ongoing pregnancy following MA

- All conducted since 2010
- 6 published, 1 pending

Two analyses

1. Diagnostic accuracy of strategy
2. Comparison to routine clinic follow-up

Diagnostic Accuracy for Identifying Ongoing Pregnancy

HCG level	Ongoing pregnancy yes	Ongoing pregnancy no	Total
No decline	21	96	117
Decline	0	1482	1482
Total	21	1578	1599

Sensitivity: **100%** (95% CL 84%, 100%)

Negative predictive value: **100%** (95% CL 99.8%, 100%)

% with decline: **93%** (95% CL 91%, 94%)

Analysis 2: Comparison to Routine Follow-up

Two RCTs:
Women presenting for MA
at ≤ 63 days

MLPT Group

- MLPT before and 2 weeks after mife
- Ultrasound or exam if no decline in HCG or specified symptoms

Clinic Assessment Group

- Ultrasound or exam 2 weeks after mife

No difference in detection of ongoing pregnancy, by service delivery strategy

	MLPT Strategy	Standard Clinic Assessment
Enrolled	1913	1920
Followed	1900 (99%)	1862 (97%)
Ongoing pg	23 (1.2%)	25 (1.3%)

1 missed w/PT

RR = 0.90 (95% CI 0.51-1.58)

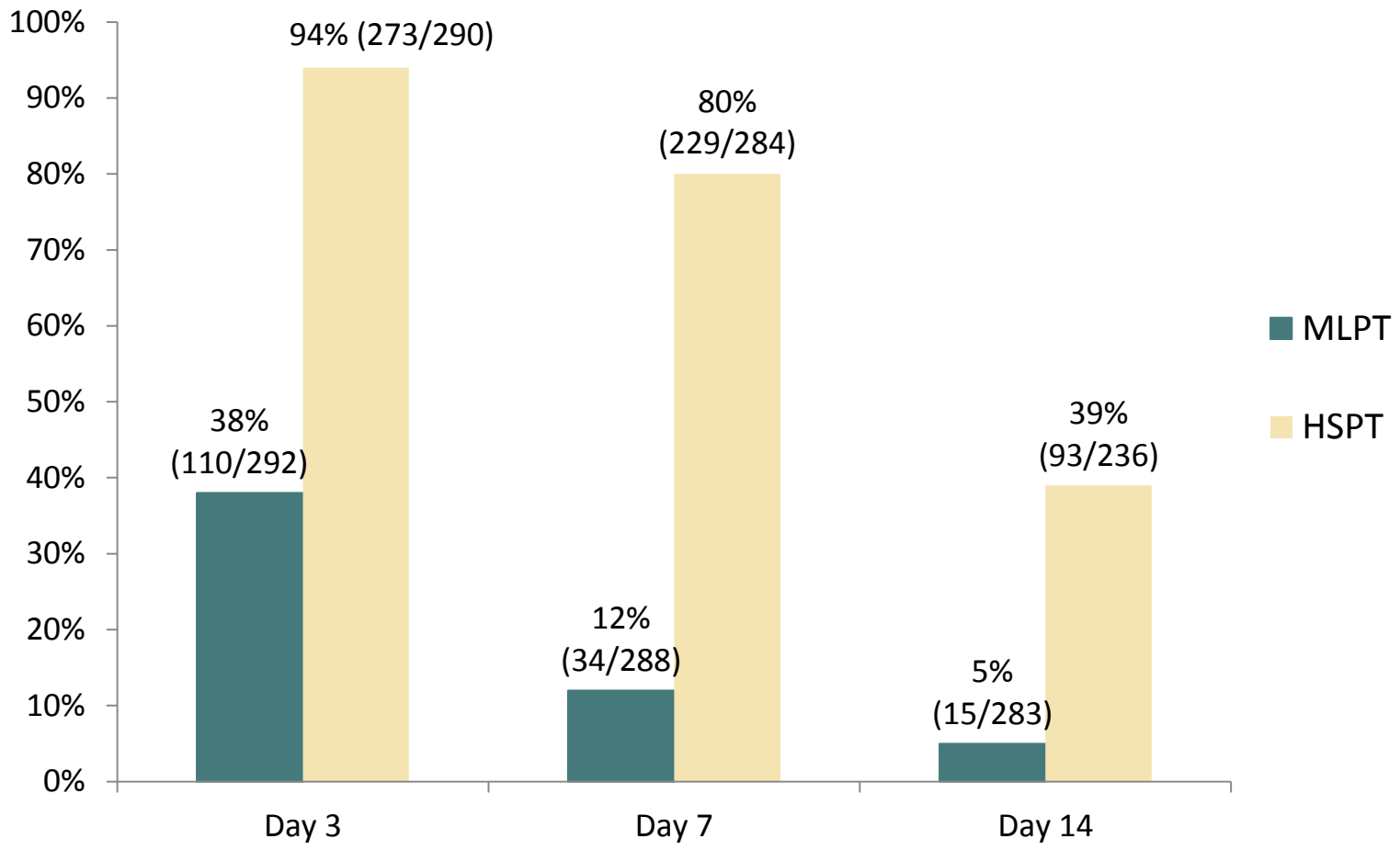
Ngoc et al 2014, Platais et al 2015.

How Soon Can the Follow-Up Test Be Used?

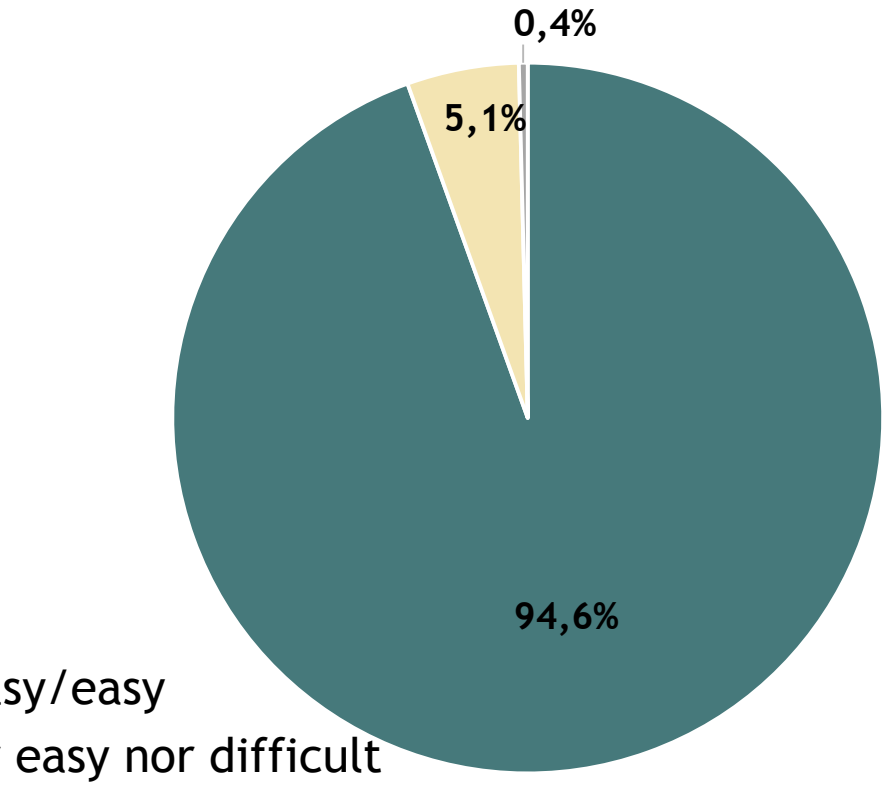
Data from Vietnam (N=292)		
Days post-mife	**Specificity**	**Sensitivity**
3 days	64%	100%
7 days	90%	100%
14 days	97%	100%

Blum et al 2016.

Proportion of women for whom clinic-based follow-up would be recommended



Ease of use (n=3,453)



Conclusions

Strengths:

- MLPT strategy is highly reliable for excluding ongoing pregnancy after MA at ≤63 days; most women can avoid clinic visit
- No difference in detection of ongoing pregnancy between MLPT strategy and standard clinical evaluation
- Follow-up can be as early as 3 days after mifepristone, but a 7-14 day follow-up results in fewer false positives
- Women report that they find the test easy to use and would like the option to use the MLPT for home follow-up in the future

Weaknesses:

- Nothing in life is perfect: strategy missed 1 ongoing pregnancy
- Insufficient data are available in women treated after 63 days

Potential other marketable uses of MLTP

- Monitoring hCG in assisted fertility setting: Pilot study in 2 countries showed high concordance between urine hCG using MLPT and serum hCG for tracking increase in hCG (above 90%)
- Identification of pregnancy (similar to commonly available HSPT)
- Ectopic and molar pregnancy evaluation & follow-up

Update on Global Availability

Manufacturer	Design of test	Countries where currently distributed	Anticipated market
Ameritek device, marketed as dBest®	5 bracket panel test, urine dipstick	Kazakhstan, China	Additional countries in the EE, Caucus region
Ameritek device to be marketed as Quanti5®	5 bracket panel test, urine dipstick	None	US (FDA application to be submitted soon)
CEMAG device to be marketed as TBD name	3 bracket panel test, urine dipstick	None	US (possibly Canada and Mexico)
TBD PHS - India product	5 bracket panel test, urine dropper	None	India, potentially global
Low sensitivity PTs (LSPTs)	2 bracket urine test, dipstick and dropper	Global	BUT, not enough!

Thank you!

Any questions?

On behalf of all my co-authors and collaborators
www.gynuity.org