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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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

Day 1
- Baseline MLPT
  - mifepristone

Day 2-3
Home misoprostol

Day 7 - 14
- Follow-up MLPT at home
  - Call in results

Day 7 - 14
Stable or increase in hCG =
In-clinic follow up
(1 out of 10 women)

Day 7 - 14
Decrease in hCG range = All done!
(9 out of 10 women)
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

<table>
<thead>
<tr>
<th>HCG level</th>
<th>Ongoing pregnancy</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>No decline</td>
<td>21</td>
<td>96</td>
</tr>
<tr>
<td>Decline</td>
<td>0</td>
<td>1482</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>1578</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th></th>
<th>MLPT Strategy</th>
<th>Standard Clinic Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled</td>
<td>1913</td>
<td>1920</td>
</tr>
<tr>
<td>Followed</td>
<td>1900 (99%)</td>
<td>1862 (97%)</td>
</tr>
<tr>
<td>Ongoing pg</td>
<td>23 (1.2%)</td>
<td>25 (1.3%)</td>
</tr>
</tbody>
</table>

RR = 0.90 (95% CI 0.51-1.58)


1 missed w/PT
How Soon Can the Follow-Up Test Be Used?

<table>
<thead>
<tr>
<th>Days post-mife</th>
<th>Specificity</th>
<th>Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 days</td>
<td>64%</td>
<td>100%</td>
</tr>
<tr>
<td>7 days</td>
<td>90%</td>
<td>100%</td>
</tr>
<tr>
<td>14 days</td>
<td>97%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Data from Vietnam (N=292)

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

- Day 3: 38% (110/292)
- Day 7: 12% (34/288)
- Day 14: 5% (15/283)

MLPT: 94% (273/290)
HSPT: 80% (229/284)

#RHSUPPLIES2016
Ease of use (n=3,453)

- Very easy/easy: 94.6%
- Neither easy nor difficult: 5.1%
- Difficult: 0.4%
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

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

Any questions?

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