Diaphragms—an underused method in India

Evidence and best practices on new & underutilized contraceptives

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What is a diaphragm?

- Soft latex or silicone cup that covers the cervix.
- Flexible rim keeps diaphragm in place.
- Used with spermicide to improve effectiveness.
- Comes in different sizes and requires fitting by a trained provider.
  - A one-size-fits-most device may be available soon that would not require fitting- SILCS
- Prevents Pregnancy by blocking sperm from entering cervix.
- Protects cervix from infection
Advantages of diaphragms

- Non-hormonal, no systemic side effects.
- User-initiated. Use only when needed.
- Appropriate for almost all women.
- Reusable.
- Discreet—more so than male or female condom.
- Protects from pregnancy and possibly some STIs that infect the cervix.
## Diaphragm - evidence for disease protection

<table>
<thead>
<tr>
<th>Design</th>
<th>Sample</th>
<th>STI</th>
<th>Odds ratio</th>
<th>95% C.I.</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case control</td>
<td>STI clinic</td>
<td>GC</td>
<td>.45</td>
<td>.15-1.3</td>
<td>Austin et al</td>
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<tr>
<td>Cross sectional</td>
<td>STI clinic</td>
<td>GC</td>
<td>.8</td>
<td></td>
<td>Madger et al</td>
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<tr>
<td>Cross sectional</td>
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<td>GC, CT, TV</td>
<td>.32*</td>
<td>.16-.45</td>
<td>Rosenberg et al</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>.24*</td>
<td>.05-1.36</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>.25</td>
<td>.12-.48</td>
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<td>CIN 1,2</td>
<td>.3*</td>
<td>.1-.8</td>
<td>Becker et al</td>
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<tr>
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<td>.09-.75</td>
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<td>Case control</td>
<td>Hospital</td>
<td>PID</td>
<td>.4</td>
<td>.2-.7</td>
<td>Kelaghan et al</td>
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</tbody>
</table>
## Contraceptive failure rates of barrier methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Typical use</th>
<th>Perfect use</th>
<th>Continue at 1 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diaphragm with spermicide</td>
<td>16</td>
<td>6</td>
<td>57%</td>
</tr>
<tr>
<td><strong>Condom</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>21</td>
<td>5</td>
<td>49%</td>
</tr>
<tr>
<td>Male</td>
<td>15</td>
<td>2</td>
<td>53%</td>
</tr>
<tr>
<td>Spermicide</td>
<td>29</td>
<td>18</td>
<td>42%</td>
</tr>
</tbody>
</table>

*Source: Trussell; Contraceptive Technology, 2007.*
Challenges with traditional diaphragms

- Service delivery:
  - Provider bias
  - Multiple-sized device: requires fitting exam from trained provider; complicates supply.
  - Providers don’t feel confident assessing size; requires additional time for counseling in method use.
  - Need appropriate contraceptive gel (alternative to N-9)
  - Assumption that women will be hesitant to insert
  - Hygiene issues
- User perspective: Can be difficult to learn to insert/remove.

SILCS has been developed to address these challenges
Diaphragm research in 12 countries
Diaphragm acceptability among low-income women, Madras, India*

- Study group: 97 currently married women (15–49 years), from urban, low income settlements, recruited at 3 family planning clinics in Madras.

- Collected user perspectives after 6–7 months use on:
  - User experience;
  - Consistency of use and sexual life;
  - Support from partners;
  - Positive factors; and
  - Service delivery.

- Follow-up after 18 months of diaphragm use, found almost 70% of women contacted were still using diaphragm.

*Ravindran and Rao. In Beyond Acceptability
SILCS Diaphragm: one-size-fits-most

Diagram showing features of the SILCS Diaphragm:
- Fingertip removal dome
- Firm insertion edge
- Grip dimples
- Cervical cup membrane
- Relief arch

Dimensions:
- Posterior: 67 mm
- Anterior: 75 mm
SILCS Diaphragm: status

• Evaluated in 7 studies in 5 countries for safety, acceptability, fit, and ease of use.
• Contraceptive effectiveness study in United States completed in 2010. Effectiveness similar to traditional diaphragm.
• In 2010, PATH licensed SILCS to Kessel Marketing, Germany, for commercialization.
• Regulatory applications underway in Europe and United States.
• PATH working to raise awareness and explore feasibility for low resource countries.
• PATH and CONRAD evaluating alternative contraceptive gel product for use with SILCS. Contragel is a lactic-acid based contraceptive gel with CE Mark approval, available in European countries.
SILCS Diaphragm: cost

• SILCS is reusable for 2 years. Initial product cost spread over the use life results in a low-cost contraceptive method.
• Manufacturing cost for public sector in developing countries not yet determined.
• Kessel Marketing committed to providing product at affordable price for low resource countries.
• What is a reasonable cost for a reusable contraceptive that lasts 2+ years?
• Diaphragms recommended for use with a contraceptive gel. The gel is a recurring cost.
Could diaphragms improve reproductive health options in India?

- Family planning (FP) in India has a high reliance on sterilization and low availability of birth spacing methods.
- Lack of female initiated methods
- Lack of methods without systemic side effects
- Will introducing a single-size diaphragm improve women’s RH options in India?
- Who are the groups of women who would benefit from access to a non-hormonal barrier method for birth spacing?
Health Systems Assessment for SILCS - India

Ashodaya, a local NGO, is implementing a health systems assessment in 2012 to identify opportunities and challenges for future introduction of SILCS in India

Key areas being explored:
- Facility based opportunities
- Procurement logistics
- Community level opportunities
- Communication channels with key target audience
- Training needs for SILCS introduction
- Stakeholder assessment & mapping
Urgent need to expand basket of contraceptive choices in India

Time to Act!

Thank you!