Levonorgestrel intrauterine system (LNG IUS): new research in Kenya

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Presentation Outline

• Brief background on technology
  – Development, profile, LNG release, uptake in USA, cost barrier

• New research in Kenya

• Broader questions about future role of product
Mirena® - A Levonorgestrel Intrauterine System

- Basic technology is 40 years old
- 1990 (Finland was first)
- 1990s (Europe)
- December 2000 (USA)
- 2009: USFDA approved Mirena as treatment for heavy menstrual blood loss
Profile of LNG IUS

- 99+ % effective
  - WHO top tier of effectiveness
- Lasts for 5+ years, 80% continuation rate at 1 yr.
- Easy to insert/remove
  - No scalpel or lidocaine needed
- Many non-contraceptive benefits: promotes women’s health
  - Generally reduces menstrual blood loss
  - Increases hemoglobin
  - Likely alleviates or prevents anemia
  - Effective treatment for menorrhagia
  - Reduces blood loss from uterine fibroids
Key to Technology: Localized Release of LNG

- 20 mcg per day release in uterus
- **Not systemic** jolt like other hormonal methods
- **No peaks and troughs** of LNG in plasma
  - steady, low release

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![Graph showing plasma concentrations of LNG](image)

*After steady state is reached, daily look at levels*
Impact of Mirena in USA – Women Like It

Percent of US contraceptors using an IUD

Introduction of Mirena
Recap on LNG IUS

- 40-yr old technology
- Proven product
- More than just a contraceptive
- Great potential worldwide

Question:
Why can’t women in other countries have it?
Cost as a Barrier for Donor Procurement

- Current price: $850 in US, $160 in India, $200 Kenya
- Donor discounted price: Non-existent
- ICA Foundation (International Contraceptive Access)
  - Partnership between PopCouncil and Bayer
  - Mirena in old inserter system = LNG IUS
  - Donated 47,000 units in 19 countries since 2004
  - Bangladesh, Dominican Republic, Ecuador, El Salvador, Ethiopia, Ghana, Indonesia, Kenya, Nigeria, South Africa, Zambia
ICA Foundation is not the long-term answer

Imagine a $6 to $10 LNG IUS

- Would women in Asia/Africa want this product?
- Will LNG IUS attract new users to long-acting?
- What features of LNG IUS are attractive?
- Can demand for product materialize?
New Research in Kenya

• Offer LNG IUS to recent postpartum women
  – (donation of LNG IUS from ICA Foundation)

• Study Objectives
  – Measure uptake relative to other methods
  – Describe participant reasons for choosing or not choosing the LNG IUS
  – Measure and compare continuation rates
    • (Not reporting this aspect today)
Study Details

- Observational prospective cohort study
- Women aged 18-39: offered LNG IUS alongside other options
  - DMPA, POP, subdermal implant, CuIUD
- Population: women at 6-12 weeks postpartum
  - Why this group?
    - Returning for well-baby check
    - Highly effective contraception to avoid short interval
    - Variability in return to menses may hide early LNG IUS hormonal effects
    - Increase hemoglobin, alleviate possible anemia
How Was LNG IUS Described?

• Comparisons:
  – copper IUD is non-hormonal, lasts up to 10 yrs, generally increases menstrual blood loss
  – implant releases hormones in arm, full body (systemic) action, lasts up to 5 yrs
  – LNG IUS: hormonal, lasts up to 5 yrs, generally decreases menstrual blood loss, localized release of hormone in uterus

• All methods: all approved, none are experimental, remove whenever you wish, breastfeeding OK
Recruitment Results

- July 2011 to May 2012
- N=671 enrolled
  - 109 chose LNG IUS (16%)
  - 202 implant (30%)
  - 17 copper IUD (3%)
  - 244 injectable (36%)
  - 99 progestin only pills (15%)
### Background characteristics

<table>
<thead>
<tr>
<th>Background Characteristics</th>
<th>Pills (n=99)</th>
<th>Injectable (n=244)</th>
<th>Subdermal implant (n=202)</th>
<th>LNG IUS (n=109)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-19</td>
<td>5.0</td>
<td>9.0</td>
<td>12.4</td>
<td>9.2</td>
</tr>
<tr>
<td>20-24</td>
<td>40.4</td>
<td>54.5</td>
<td>44.1</td>
<td>42.2</td>
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<tr>
<td>25-29</td>
<td>33.3</td>
<td>25.8</td>
<td>27.2</td>
<td>32.1</td>
</tr>
<tr>
<td>34+</td>
<td>21.2</td>
<td>10.7</td>
<td>16.3</td>
<td>16.5</td>
</tr>
<tr>
<td><strong>Number of children</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>48.5</td>
<td>31.1</td>
<td>30.7</td>
<td>30.3</td>
</tr>
<tr>
<td>2-3</td>
<td>45.4</td>
<td>61.9</td>
<td>57.9</td>
<td>61.5</td>
</tr>
<tr>
<td>4+</td>
<td>6.1</td>
<td>7.0</td>
<td>11.4</td>
<td>8.3</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed primary or less</td>
<td>62.6</td>
<td>78.3</td>
<td>65.9</td>
<td>61.5</td>
</tr>
<tr>
<td>Completed secondary</td>
<td>24.2</td>
<td>18.8</td>
<td>29.7</td>
<td>27.5</td>
</tr>
<tr>
<td>Higher</td>
<td>13.1</td>
<td>2.9</td>
<td>4.5</td>
<td>11.0</td>
</tr>
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</table>
### Background characteristics (cont.)

<table>
<thead>
<tr>
<th>Background Characteristics</th>
<th>Contraceptive Method Chosen</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pills (n=99)</td>
</tr>
<tr>
<td>Unintended last pregnancy (%)</td>
<td>33.3</td>
</tr>
<tr>
<td>Ideal timing of next pregnancy</td>
<td>Not sure</td>
</tr>
<tr>
<td></td>
<td>Within 3 years</td>
</tr>
<tr>
<td></td>
<td>3+ years</td>
</tr>
<tr>
<td></td>
<td>Never</td>
</tr>
</tbody>
</table>
Why LNG IUS was chosen*, instead of...

<table>
<thead>
<tr>
<th>Reason LNG IUS was chosen (n=109)</th>
<th>Copper IUD</th>
<th>Subdermal implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fewer side effects with LNG IUS</td>
<td>44%</td>
<td>91%</td>
</tr>
<tr>
<td>LNG IUS is more effective</td>
<td>24%</td>
<td>6%</td>
</tr>
<tr>
<td>Less menstrual bleeding with LNG IUS</td>
<td>43%</td>
<td>4%</td>
</tr>
<tr>
<td>The LNG IUS is expensive but free now</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Nobody will know I’m using LNG IUS</td>
<td>N/A</td>
<td>23%</td>
</tr>
<tr>
<td>Only need a 5-year product</td>
<td>47%</td>
<td>N/A</td>
</tr>
</tbody>
</table>

* multiple reasons allowed; does not sum to 100%
<table>
<thead>
<tr>
<th>Reason</th>
<th>Percent*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fewer side effects</td>
<td>24%</td>
</tr>
<tr>
<td>Less pain with insertion/removal</td>
<td>33%</td>
</tr>
<tr>
<td>Prefer to expose arm rather than private parts</td>
<td>22%</td>
</tr>
<tr>
<td>Implant won’t fall out or move</td>
<td>22%</td>
</tr>
<tr>
<td>Implant well known and widely used</td>
<td>11%</td>
</tr>
<tr>
<td>Does not want device in uterus</td>
<td>11%</td>
</tr>
</tbody>
</table>

* multiple reasons allowed; does not sum to 100%
Method would have chosen if LNG IUS were not available (n=109)

<table>
<thead>
<tr>
<th>Method</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral contraceptives</td>
<td>2.8</td>
</tr>
<tr>
<td>Injectable</td>
<td>25.9</td>
</tr>
<tr>
<td>Condoms</td>
<td>1.8</td>
</tr>
<tr>
<td>Subdermal implant</td>
<td>48.2</td>
</tr>
<tr>
<td>Copper IUD</td>
<td>21.3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

Short-acting methods
Research Conclusions

• Participants cited variety of reasons for choosing particular method
  – Some reasons were accurate others were not
• Without LNG IUS option, 30% would have chosen short-acting method
• LNG IUS acceptors: seeking more than just intrauterine contraception
Next Steps in Kenya Study

• Continued follow-up, thru June 2013
• Record menstrual changes with long-acting methods and user satisfaction
• Document incidence of other side effects
• Tally early removals of long-acting methods
Previous Research in Ghana

- Study by Population Council in 2009
- 71 LNG IUS acceptors
- “Widely acceptable” to both providers and users

Nyarko et al., Acceptability and promotion strategies for LNG-IUS in Ghana: A Public Health Assessment

Future, Broad Discussions

- Is the LNG IUS ready for wider distribution?
- Where will it come from?
- Can a good public sector price be negotiated?
- Will donors buy it?
- Can traditional program obstacles to IUD services be overcome?
- Can programs rally around the LNG IUS enthusiasm?
- Promoting substantial health benefits: key to success?