A pilot study of a randomized controlled trial
Immediate postpartum vs. 6 week postpartum IUD insertion in Malawi:

UNC School of Medicine
Obstetrics and Gynecology

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International Family Planning Conference
Dakkar, Senegal
December 1, 2011
IUD Use in Malawi

- High maternal mortality
- High unintended pregnancy
- Low contraceptive use—especially IUDs

Immediate postpartum period (10 minutes to 48 hours postpartum)
  » Ideal and convenient
  » Inadequate evidence

Objectives

- Assess feasibility of a RCT of immediate postpartum vs. interval insertion of the IUD
- Assess patient satisfaction with the IUD
Methods

Pilot study of a non-blinded, parallel RCT

» Comparing immediate to 6 week postpartum IUD insertion

Lilongwe, Malawi

• Target population: postpartum women

• IRB approval from Malawi and UNC

• Provider Education and Training
Eligibility Criteria

- Ages 18-45
- >34 weeks EGA
- Plan to stay in the area for 5 months
- If HIV+, WHO Stage 1 or 2, or well on ARVs
- No prior cesarean delivery
Post-Delivery Eligibility Criteria

- Vaginal delivery in the last 48 hours
- No postpartum hemorrhage
- No prolonged rupture of membranes (>24 hr)
- No infection
- No fever during labor or delivery
- Any other condition at clinician’s discretion
Randomization

• 1:1 Computer-generated scheme in blocks of 4 and 6
• Sequentially numbered, sealed opaque envelopes
• If criteria met, patient randomized to:
  » Immediate postpartum insertion
  » 6 week postpartum insertion
Plan for analyses

- CONSORT Guidelines
- Bivariate analyses
- Intention-to-Treat
- Sample size:
  » convenience sample of 140 women to insert 100 IUDs within 6 months
  » 70% of women enrolled to receive IUD
RESULTS
123 women screened

Enrolled
N = 115

Hospital Delivery
N = 80

Randomization
N = 49

Immediate Postpartum Insertion
N = 26

4-6 Week Postpartum Insertion
N = 23

8 Ineligible

35 Discontinued
16 Delivered elsewhere
10 Withdrew
9 Lost to follow-up

11 Discontinued
5 withdrew
6 switched

31 Discontinued
Screening and Enrollment

- 123 Women Screened
- 115 Consented
  Oct 10, 2010-Feb 28, 2011
- 8 Ineligible
- 35 Discontinued
  16 delivered elsewhere
  10 withdrew
  9 lost to follow-up
- Hospital Delivery
  N=80
Delivery and Randomization

Hospital Delivery
N = 80

Randomized
N = 49

31 Discontinued
13 Medically Ineligible
3 Missed Deliveries
9 Withdrawn due to husband’s request
6 Declined to participate
Randomized
N = 49

Immediate Postpartum Insertion
N = 26
6 withdrew
6 switched
2 withdrew due to husband’s request

Received Immediate
N = 12

6 Week Postpartum Insertion
N = 23
3 withdrew
4 missed 6-wk visit

Received 6 week
N = 16
### Demographics and Baseline Characteristics*

<table>
<thead>
<tr>
<th></th>
<th>Immediate Insertion (n=26)</th>
<th>6 Week Insertion (n=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>26 (22,30)</td>
<td>25 (20,25)</td>
</tr>
<tr>
<td><strong>EGA (weeks)</strong></td>
<td>34 (34-36)</td>
<td>34 (34-34)</td>
</tr>
<tr>
<td><strong>Gravidity</strong></td>
<td>3 (2,5)</td>
<td>3 (2,5)</td>
</tr>
<tr>
<td><strong>Parity</strong></td>
<td>2 (1,4)</td>
<td>1 (1,3)</td>
</tr>
<tr>
<td><strong>HIV+</strong></td>
<td>3 (12%)</td>
<td>2 (9%)</td>
</tr>
<tr>
<td><strong>Education (Primary or Less)</strong></td>
<td>13 (50%)</td>
<td>12 (57%)</td>
</tr>
<tr>
<td><strong>Employed (% yes)</strong></td>
<td>3 (12%)</td>
<td>3 (13%)</td>
</tr>
</tbody>
</table>

*Data expressed as Median (IQR) or N(%)
Follow-up

• In immediate group:
  » 1 IUD expelled
  » 1 IUD removed
  » 2 women received IUD at 6 weeks

• 93% (28/30) women completed all three follow-up visits

• 93% (28/30) had IUD in place at 12 weeks
# Satisfaction at 12 weeks

<table>
<thead>
<tr>
<th>Planning to keep using the IUD for the next year</th>
<th>Immediate Insertion (n=12)</th>
<th>6 Week Insertion (n=16)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning to keep using the IUD for the next year</td>
<td>11(92)</td>
<td>15(94)</td>
<td>0.86</td>
</tr>
<tr>
<td>Would recommend the IUD to a friend</td>
<td>12(100)</td>
<td>16(100)</td>
<td>-</td>
</tr>
<tr>
<td>Would like to switch contraceptive methods</td>
<td>2(17)</td>
<td>1(6)</td>
<td>0.38</td>
</tr>
</tbody>
</table>
Conclusions

- 26% of women who enrolled received the IUD
  - ½ enrolled unable to be randomized
  - ½ lost to follow-up after randomization
  - Study design

Not feasible to conduct study with current design
Conclusions

• IUD acceptable to the women who received it

• But, Barriers to acceptability identified
  » Partner influence
  » Myths about IUDs
  » Infrequent contact with enrolled women
Future directions

• Mixed methods study to evaluate women’s (and partners’) experiences with the IUD
• Pilot study to enroll women at 20 weeks EGA
The Study Team
Collaboration

- Fellowship in Family Planning
- Emory University
- Bwaila/KCH Dept of Ob/Gyn
- UNC Project
- Malawi Ministry of Health
Acknowledgements

• Gretchen Stuart
• Lisa Haddad
• Denise Jamieson
• Grace Phiri
• Gift Kamanga
• Erica O’Neill
• Sydney Hartsell
• Mina Hosseinipour
• Paul Blumenthal

• Irving Hoffman
• David Grimes
• Joanne Garrett
• Guesthouse Folks
• Co-Fellows
  Christie, Erica, Matt, Jen
• Tarek Meguid
• Innocent Mofolo
• Aileen Gariepy
Zikomo Kwambiri!!!