POSTPARTUM IUCD in Paraguay:
Review of 3000 Cases

Vicente Bataglia Araujo
Limpia Ortiz Guerrero
Gladys Vazquez
Jeffrey Michael Smith
Presentation Outline

- Context and background
- Study design
- Main findings
- Reasons for findings
- Implications for practice

Presented on behalf of Drs. Vicente Bataglia, Limpia Ortiz and Jeffrey Smith
Context and Background

- Postpartum FP and Postpartum IUCD services are expanding in many countries
- Efforts to increase facility births offers more opportunities to provide this service
- Provider impressions of PPIUCD include:
  - Risky: possibility perforation and infection
  - High expulsion rates: 10 – 14%
  - Better provided when the woman returns PP
PPIUD in Paraguay: 3000+ Cases

- Study Design:
  - Retrospective case series
  - Review of delivery room registers
  - Women who had PPIUCD insertion were searched for in register of hospital family planning clinic
  - Chart review and data abstraction
Study Population at National Hospital, Asuncion 2000 – 2009

**Total** number of PPIUD insertions from delivery and cesarean log books 2000 – 2009

- **8499** (100%)
  - **3358** (39.5%)
  - **5141** (60.5%)

- Number of women who had an insertion and whose hospital clinical record was found
- Number of women who had an insertion but whose hospital clinical records were not found
- Number of women who did not have a follow up visit in the FP clinic more than 7 days after insertion
- Number of women who had a follow up visit in the FP clinic 7 or more days after insertion

**Number of women who had a follow up visit in the FP clinic 7 or more days after insertion**

- **2112** (24.8% of total)
- **3029** (35.6% of total)
# Study Population at National Hospital, Asuncion 2000 – 2009

<table>
<thead>
<tr>
<th>VISITA DE SEGUIMIENTO POS INSERCIÓN</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 SEMANA</td>
<td>186</td>
<td>503</td>
<td>206</td>
<td>378</td>
<td>209</td>
<td>65</td>
<td>111</td>
<td>273</td>
<td>105</td>
<td>76</td>
<td>2112</td>
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<tr>
<td>1-6 SEMANAS</td>
<td>476</td>
<td>111</td>
<td>139</td>
<td>188</td>
<td>38</td>
<td>249</td>
<td>32</td>
<td>174</td>
<td>160</td>
<td>172</td>
<td>1739</td>
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<tr>
<td>7 SEMANAS - 3 MESES</td>
<td>161</td>
<td>15</td>
<td>7</td>
<td>33</td>
<td>3</td>
<td>100</td>
<td>15</td>
<td>20</td>
<td>93</td>
<td>90</td>
<td>537</td>
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<tr>
<td>4-6 MESES</td>
<td>68</td>
<td>10</td>
<td>13</td>
<td>11</td>
<td>5</td>
<td>29</td>
<td>8</td>
<td>8</td>
<td>29</td>
<td>19</td>
<td>200</td>
</tr>
<tr>
<td>7-12 MESES</td>
<td>82</td>
<td>7</td>
<td>6</td>
<td>17</td>
<td>3</td>
<td>4</td>
<td>15</td>
<td>11</td>
<td>18</td>
<td>0</td>
<td>163</td>
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<tr>
<td>&gt; 12 MESES</td>
<td>47</td>
<td>60</td>
<td>39</td>
<td>77</td>
<td>65</td>
<td>18</td>
<td>39</td>
<td>24</td>
<td>18</td>
<td>3</td>
<td>390</td>
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<tr>
<td><strong>TOTALES:</strong></td>
<td><strong>1,020</strong></td>
<td><strong>706</strong></td>
<td><strong>410</strong></td>
<td><strong>704</strong></td>
<td><strong>323</strong></td>
<td><strong>465</strong></td>
<td><strong>220</strong></td>
<td><strong>510</strong></td>
<td><strong>423</strong></td>
<td><strong>360</strong></td>
<td><strong>5,141</strong></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>VISITA DE SEGUIMIENTO POS INSERCIÓN</th>
<th>% 2000</th>
<th>% 2001</th>
<th>% 2002</th>
<th>% 2003</th>
<th>% 2004</th>
<th>% 2005</th>
<th>% 2006</th>
<th>% 2007</th>
<th>% 2008</th>
<th>% 2009</th>
<th>TOTAL %</th>
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<tbody>
<tr>
<td>&lt; 1 SEMANA</td>
<td>18.24</td>
<td>71.25</td>
<td>50.24</td>
<td>53.69</td>
<td>64.71</td>
<td>13.98</td>
<td>50.45</td>
<td>53.53</td>
<td>24.82</td>
<td>21.11</td>
<td>41.08</td>
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<tr>
<td>1-6 SEMANAS</td>
<td>46.67</td>
<td>15.72</td>
<td>33.9</td>
<td>26.7</td>
<td>11.76</td>
<td>53.55</td>
<td>14.55</td>
<td>34.12</td>
<td>37.83</td>
<td>47.78</td>
<td>33.83</td>
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<td>7 SEMANAS - 3 MESES</td>
<td>15.78</td>
<td>2.12</td>
<td>1.71</td>
<td>4.69</td>
<td>0.93</td>
<td>21.51</td>
<td>6.82</td>
<td>3.92</td>
<td>21.99</td>
<td>25</td>
<td>10.45</td>
</tr>
<tr>
<td>4-6 MESES</td>
<td>6.67</td>
<td>1.42</td>
<td>3.17</td>
<td>1.56</td>
<td>1.55</td>
<td>6.24</td>
<td>3.64</td>
<td>1.57</td>
<td>6.86</td>
<td>5.28</td>
<td>3.89</td>
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<td>7-12 MESES</td>
<td>8.04</td>
<td>0.99</td>
<td>1.46</td>
<td>2.41</td>
<td>0.93</td>
<td>0.86</td>
<td>6.82</td>
<td>2.16</td>
<td>4.26</td>
<td>0</td>
<td>3.17</td>
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<tr>
<td>&gt; 12 MESES</td>
<td>4.61</td>
<td>8.5</td>
<td>9.51</td>
<td>10.94</td>
<td>20.12</td>
<td>3.87</td>
<td>17.73</td>
<td>4.71</td>
<td>4.26</td>
<td>0.83</td>
<td>7.59</td>
</tr>
</tbody>
</table>
Main findings:

Complications
- Perforation
- Infection
- Removals
- Expulsion

Categories
- Experienced provider
- Parity of woman
- Age of woman
- Gestational age at delivery
- ANC
**Main Results: The bottom line**

- **Total number of cases:** 3029

<table>
<thead>
<tr>
<th>Complication</th>
<th>Number of cases</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perforation</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Infection</td>
<td>4</td>
<td>0.1%</td>
</tr>
<tr>
<td>Removal (any reason)</td>
<td>102</td>
<td>3.4%</td>
</tr>
<tr>
<td>Spontaneous expulsion</td>
<td>43</td>
<td>1.4%</td>
</tr>
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</table>

**Total number of cases:** 3029
### Experience of Provider

- Did more experienced providers have fewer complications?

<table>
<thead>
<tr>
<th>Complication</th>
<th>Interns</th>
<th>R2, R3, R4 and Consultants</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Perforation</td>
<td>0</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Infection</td>
<td>2</td>
<td>0.1%</td>
<td>2</td>
</tr>
<tr>
<td>Removal</td>
<td>57</td>
<td>3.6%</td>
<td>45</td>
</tr>
<tr>
<td>Expulsion</td>
<td>30</td>
<td>1.9%</td>
<td>13</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1606</td>
<td></td>
<td>1423</td>
</tr>
</tbody>
</table>
### Age of Patient

- Did adolescent acceptors have more complications?

<table>
<thead>
<tr>
<th>Complication</th>
<th>Adolescents (age 11 – 19)</th>
<th>Age ≥ 20</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Perforation</td>
<td>0</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Infection</td>
<td>2</td>
<td>0.3%</td>
<td>2</td>
</tr>
<tr>
<td>Removal</td>
<td>22</td>
<td>3.3%</td>
<td>80</td>
</tr>
<tr>
<td>Expulsion</td>
<td>10</td>
<td>1.5%</td>
<td>33</td>
</tr>
<tr>
<td>TOTAL</td>
<td>667</td>
<td>1.5%</td>
<td>2362</td>
</tr>
</tbody>
</table>
## Parity of Patient

- Did primiparous acceptors have more complications?

<table>
<thead>
<tr>
<th>Complication</th>
<th>Parity = 1</th>
<th>Parity ≥ 2</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Perforation</td>
<td>0</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Infection</td>
<td>2</td>
<td>0.1%</td>
<td>2</td>
</tr>
<tr>
<td>Removal</td>
<td>56</td>
<td>3.6%</td>
<td>46</td>
</tr>
<tr>
<td>Expulsion</td>
<td>27</td>
<td>1.7%</td>
<td>16</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1573</td>
<td></td>
<td>1456</td>
</tr>
</tbody>
</table>
**Gestational Age at Time of Delivery**

- Did women with pre-term births experience more complications?

<table>
<thead>
<tr>
<th>Complication</th>
<th>Full term birth (Gest Age ≥ 37 w)</th>
<th>Pre-term birth (Gest Age &lt; 37 w)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Perforation</td>
<td>0</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Infection</td>
<td>1</td>
<td>0.04%</td>
<td>3</td>
</tr>
<tr>
<td>Removal</td>
<td>93</td>
<td>3.4%</td>
<td>9</td>
</tr>
<tr>
<td>Expulsion</td>
<td>40</td>
<td>1.5%</td>
<td>3</td>
</tr>
<tr>
<td>TOTAL</td>
<td>2738</td>
<td></td>
<td>291</td>
</tr>
</tbody>
</table>
Prenatal Care for Patient

- Did women who did NOT receive antenatal care have more complications?

<table>
<thead>
<tr>
<th>Complication</th>
<th># ANC visits ≥ 1</th>
<th># ANC visits = 0</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Perforation</td>
<td>0</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Infection</td>
<td>3</td>
<td>0.1%</td>
<td>1</td>
</tr>
<tr>
<td>Removal</td>
<td>96</td>
<td>3.4%</td>
<td>6</td>
</tr>
<tr>
<td>Expulsion</td>
<td>41</td>
<td>1.4%</td>
<td>2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>2876</td>
<td></td>
<td>173</td>
</tr>
</tbody>
</table>
### String management at 6+ week follow up

<table>
<thead>
<tr>
<th>String Management</th>
<th>Yes</th>
<th>No</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strings visible at cervical os</td>
<td>2798</td>
<td>231</td>
<td>92.4%</td>
</tr>
<tr>
<td>Ultrasound done to locate IUD?</td>
<td>25</td>
<td>206</td>
<td>0.8%</td>
</tr>
<tr>
<td>Ultrasound identified IUD?</td>
<td>22</td>
<td>3</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

**Note:** Data reflects the number of cases where the management of strings is indicated for follow-up at 6+ weeks.
Reasons for Findings

- Careful selection of clients
- Integration of PPFP services into routine maternal health program
- Attention to insertion technique, including use of longer instrument to ensure fundal placement
Resurgence of Interest in the PPIUCD

- Global changes in thinking about IUCD
- New advances and new understanding about IUCD
  - Recent research has lead to important changes in WHO Medical Eligibility Criteria (MEC)
- Increases in facility-based births offer opportunities to provide women with this long-acting reversible method before they leave the hospital
- Rediscovering a “languishing innovation” – PPIUCD
Limitations

- Retrospective
  - Research questions constrained by available data
- Incomplete data
  - Hospital records systems in developing countries have significant gaps
- Significant loss to follow up / non return to same facility for follow up
  - 60.5% for this group, compared to 68% national average
Implications for Practice

- **Perforation:**
  - Not a valid concern during PPIUCD insertion

- **Infection:**
  - Good client selection reduces risk of infection
  - No need for prophylactic antibiotics

- **Removal:**
  - Good counseling is critical to reduce pre-mature removal
Expulsion Rates Related to Technique

- To reduce expulsion:
  - Use correct technique
    - place all the way at fundus
    - sweep instrument to the side
    - take care that IUCD does NOT come out during withdrawal
  - Use correct instrument
    - Kelly placental forceps (33 cm long) may be better than ring forceps
  - Insert at the correct time
    - Postplacental/intracesarean is better
Training

- Reference Manual and Course Materials for Trainers/Participants
- Modified Zoe anatomic model with postpartum insert
- Instructional animation that shows insertion technique
THANK YOU!
Association of Reproductive Health Professionals New Orleans September 21, 2012

The Costs of Contraception in a Rapidly Changing Field

Michael S. Policar, MD, MPH
Clinical Professor of Ob, Gyn, RS
UCSF School of Medicine
policarm@obgyn.ucsf.edu
Where Have We Been?

Contraceptive Costs

Contraceptive Cost-Effectiveness
Where Are We Now?

Contraceptive Costs

Contraceptive Cost-Effectiveness
<table>
<thead>
<tr>
<th>Method</th>
<th>Brand Name</th>
<th>AWP 2007*</th>
<th>AWP 2012**</th>
<th>Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNG IUS</td>
<td>Mirena</td>
<td>$586</td>
<td>$844</td>
<td>44%</td>
</tr>
<tr>
<td>Copper IUC</td>
<td>ParaGard</td>
<td>$494</td>
<td>$718</td>
<td>45%</td>
</tr>
<tr>
<td>ENG Implant</td>
<td>Nexplanon</td>
<td>$627</td>
<td>$791</td>
<td>26%</td>
</tr>
<tr>
<td>DMPA</td>
<td>DepoProvera</td>
<td>$76</td>
<td>$102</td>
<td>34%</td>
</tr>
<tr>
<td>CVR</td>
<td>NuvaRing</td>
<td>$50</td>
<td>$95/mo</td>
<td>90%</td>
</tr>
<tr>
<td>Transdermal</td>
<td>OrthoEvra</td>
<td>$56</td>
<td>$110/mo</td>
<td>96%</td>
</tr>
<tr>
<td>Oral Contraceptive</td>
<td>OrthoNovum</td>
<td>$53</td>
<td>$60/mo</td>
<td>13%</td>
</tr>
<tr>
<td>LNG EC</td>
<td>Plan B (2 tabs)</td>
<td></td>
<td>$37</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Plan B OneStep</td>
<td></td>
<td>$41</td>
<td></td>
</tr>
<tr>
<td>Ulipristal acetate</td>
<td></td>
<td></td>
<td>$42</td>
<td></td>
</tr>
</tbody>
</table>

** Trussell J, et al. Contraception 2012; 85: 611
Where Are We Now?

Prices have increased significantly for all contraceptives in the past few years

• Are they any safer? No!
• Are they more effective? No!
• Are more convenient for consumers? No!
• Are they still a cost-effective? Yes
The Economic Value of Contraception

- **Objective**
  To determine the clinical and economic impact of alternate contraceptive methods

- **Outcome measures**
  Cost of method
  + cost of side effects
  + cost of unintended pregnancy
  Compared with cost of using no method

Chiou CF, et al. *Contraception*. 2003;68:3-10
Five Year Costs of Contraception: 1995

The bar chart compares the five-year costs of various methods of contraception as of 1995. The methods included are C-IUD, Vasectomy, Impln, DMPA, OC, P-IUD, M cond, BTL, Withd, P Abs, Diaph, S'cide, F cond, Cx cap, and NONE. The costs are represented in thousands of dollars, with NONE being the most expensive option.
# Five-Year Contraceptive Costs

Trussell J, Contraception 2009; 79:5-14

<table>
<thead>
<tr>
<th>Method</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper T IUD</td>
<td>$647</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>$713</td>
</tr>
<tr>
<td>LNG-IUS</td>
<td>$930</td>
</tr>
<tr>
<td>Male condom</td>
<td>$1,575</td>
</tr>
<tr>
<td>Fertility Awareness</td>
<td>$1,892</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>$2,017</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>$2,171</td>
</tr>
<tr>
<td>Implant</td>
<td>$2,178</td>
</tr>
<tr>
<td>Spermicide</td>
<td>$2,647</td>
</tr>
<tr>
<td>Injectable (DMPA)</td>
<td>$2,681</td>
</tr>
<tr>
<td>Tubal ligation</td>
<td>$2,978</td>
</tr>
<tr>
<td>Vaginal ring</td>
<td>$3,158</td>
</tr>
<tr>
<td>Oral contraceptive</td>
<td>$3,381</td>
</tr>
<tr>
<td>Transdermal patch</td>
<td>$3,458</td>
</tr>
<tr>
<td>No method</td>
<td>$4,739</td>
</tr>
</tbody>
</table>

Update on and correction to the cost-effectiveness of contraceptives in the US. Trussell J, Contraception 2012;85: 611
LARC Cost Effectiveness Study
Trussell J, Contraception 2012 (in press)

- Annual cost of unintended pregnancy in US: $4.5B

<table>
<thead>
<tr>
<th>Assumption</th>
<th>Cost saving/yr</th>
<th>Cost neutrality (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>age 20-24</td>
</tr>
<tr>
<td>10% OC → LARC</td>
<td>$288 M</td>
<td>1.33</td>
</tr>
<tr>
<td>10% SARC → LARC</td>
<td>$375 M</td>
<td>1.62</td>
</tr>
<tr>
<td>10% SARC or no method → LARC</td>
<td>$436 M</td>
<td>1.63</td>
</tr>
</tbody>
</table>

SARC (short acting rev contraceptive): OC, patch, CVR, injection, condom
Cost Efficiency Curve

Pregnancies averted per 100 clients vs. Cost per client user

- Implant
- IUC
- Injectable
- OCs
- Ring
- Patch
- ECPs
- Condoms

Cost savings per dollar expenditure by contraceptive method, Family PACT 2003

- Tubal: $3.79
- Implant: $15.00
- IUC: $6.50
- Injectable: $5.46
- Ring: $2.56
- Patch: $3.12
- OCs: $4.28
- Barrier methods: $1.48
- ECs: $1.47
The Family PACT Program is Cost-Saving

<table>
<thead>
<tr>
<th>Time Frame</th>
<th>Total Costs Averted</th>
<th>C/B Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(CY 2002)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 yrs following</td>
<td>$1.1 billion</td>
<td>$2.76</td>
</tr>
<tr>
<td>birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 yrs following</td>
<td>$2.2 billion</td>
<td>$5.33</td>
</tr>
<tr>
<td>birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>(CY 2007)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 yrs following</td>
<td>$1.9 billion</td>
<td>$4.30</td>
</tr>
<tr>
<td>birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 yrs following</td>
<td>$4.1 billion</td>
<td>$9.25</td>
</tr>
<tr>
<td>birth</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Impact of Contraceptive Cost on Clients

<table>
<thead>
<tr>
<th>Payer</th>
<th>Payer rate</th>
<th>Client cost sharing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid</td>
<td>AWP, less rebates, 340-B acquisition cost</td>
<td>None</td>
</tr>
<tr>
<td>State family planning program</td>
<td>AWP, less rebates, 340-B acquisition cost</td>
<td>None</td>
</tr>
<tr>
<td>Title X-supported clinic</td>
<td>Contract rate, 340-B acquisition cost</td>
<td>None</td>
</tr>
<tr>
<td>Student health center</td>
<td>Contract rate, 340-B acquisition cost</td>
<td>None or nominal</td>
</tr>
</tbody>
</table>
YASMIN 28

Rx Price

The prices are displayed below for your selected products in your selected pharmacies

JACKS DRUG STORE

121 Tunstead Ave, San Anselmo, CA 94960-2616

Phone: (415) 454-1451 Fax: (415) 454-2865

YASMIN 28 TABLET

- 28 Units: $88.58
- 84 Units: View Price
- 56 Units: View Price
Rx Price

The prices are displayed below for your selected products in your selected pharmacies.

**JACKS DRUG STORE**

121 Tunstead Ave, San Anselmo, CA, 94960-2616

Phone: (415) 454-1451  Fax: (415) 454-2865

**OCELLA 3 MG-0.03 MG TABLET**  $7.00
Product Resources

Type in any product name, generic name, product class or manufacturer name to filter the list below, then click on the product name to find all of the resources currently available. All resources are **FREE** to you and will be stored in a shopping cart.

**ethinyl estradiol**

Showing 97 results that contain **ethinyl estradiol**

**ALTAVERA**
- levonorgestrel, **ethinyl estradiol**
- **Sandoz** Contraception/Oral Contraception

**APRI**
- desogestrel, **ethinyl estradiol**
- **Teva Pharmaceuticals** Contraception/Oral Contraception

**ARANELLE**
- norgestimate, **ethinyl estradiol**
- **Teva Pharmaceuticals** Contraception/Oral Contraception
Specified preventive services must be covered with no cost-sharing (no out-of-pocket costs)

- Applies to private and public programs
  - (New) Private insurance policies 2010
  - Medicare, Medicaid 2011
  - State insurance exchanges 2014

- Improves coverage for preventive services in many individual and small group plans
Preventive services include all services categorized by USPSTF with a grade [A] or [B] recommendation.

- Bright Futures recommendations for adolescents from the American Academy of Pediatrics.
- Vaccinations specified by the CDC ACIP.
- IOM to recommend to HRSA additional women’s prevention benefits...intended to “fill the gaps”
Non-grandfathered plans are required to provide coverage without cost sharing in the first plan year that begins on or after August 1, 2012.
### Women's Preventive Services

<table>
<thead>
<tr>
<th>HHS Guideline for Insurance Coverage</th>
<th>Frequency</th>
<th>USPSTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>All FDA approved contraceptive methods, sterilization procedures, and patient education &amp; counseling for women with reproductive capacity</td>
<td>As prescribed</td>
<td>Not addressed</td>
</tr>
</tbody>
</table>

- All methods must be covered, but not all products
- Limited exclusion for religious institutions (e.g., churches) from providing contraceptive coverage for insured employees
## When Does the “Contraception As Prevention” Benefit Start?

<table>
<thead>
<tr>
<th></th>
<th>Definition</th>
<th>Cost-sharing?</th>
<th>Cost-sharing prohibited</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New Plan</strong></td>
<td>Created after 8/1/2012</td>
<td>None</td>
<td>Now</td>
</tr>
<tr>
<td><strong>Non-grandfathere d</strong></td>
<td>Created 3/23/10-8/1/12</td>
<td>Yes*</td>
<td>Next “new plan year”; mostly by 1/1/2013</td>
</tr>
<tr>
<td><strong>Grandfathere d plan</strong></td>
<td>Created before 3/23/2012</td>
<td>Yes*</td>
<td>Once plan changes; mostly in 2014</td>
</tr>
</tbody>
</table>

*Unless plan agrees to remove cost sharing earlier than deadline.*
Contraception as a Preventive Service
What Happened?

- **July 2011**: IOM recommendations published
- **Aug 2011**: HRSA adds 8 women’s health benefits
- **Jan 2012**: Religious exemption regulations published
  - Applies to “houses of worship” that object to contraception
- **Within hours**
  - Public rejection by the US Conference of Catholic Bishops
- **4 days later...**
  - White house responded with new regulations delaying implementation for a broad array of religious institutions
• Pregnancy is not a disease
  – The mandate treats a healthy pregnancy as a disease in need of "prevention," like breast cancer or AIDS.
  – Some of the mandated contraceptives are associated with an increased risk of AIDS and stroke
  – The claim that greater access to contraceptives will reduce abortions is not supported by facts
• Requires coverage of abortifacient drugs (EC)
  – With EC coverage, the mandate includes drugs that interfere with implantation and destroy the embryo
  – "Ella" (ulipristal) is very similar to the abortion drug RU-486 in its formula and its ability to cause abortion

http://www.usccb.org/about/pro-life-activities/preventive-services-backgrounder.cfm
Violating Religious Freedom and Rights of Conscience

- Incredibly narrow exemption for religious employers
- Most religious institutions providing health, educational or charitable services to others have no protection
- HHS says this exemption is like those enacted by states that have a contraceptive coverage mandate, but that is false
- Many Federal laws exempt individuals and institutions from participating in health services
Contraception as a Preventive Service...

as of September 2012

- **Exempt employers** (mainly churches)
  - Exists for the purpose of Inculcating religious values
  - Primarily employs & serves persons who share religious tenets
  - Meets certain provisions of the tax code

- **Accommodation** (mainly hospitals, universities)
  - Religiously-affiliated employers who do not meet exemption but who have a religious objection
  - Insurer offers rate that excludes contraceptives, but health plan covers contraceptive benefit
  - One year safe-harbor from enforcement
How to Respond to Public Objections?

• This is a government handout of free contraceptives!
  – No, this is a mandate that *health plans* cover all of the costs of contraceptives rather than some of them

• I don’t want to pay for “her” lifestyle drug
  – The costs of contraception are shared between the employer and the employee
  – Women are receiving this drug coverage benefit as a form of payment for the work that *she does*...

• Tell women to buy their own contraceptives!!
  – Even small cost-sharing requirements
Contraceptive Failure Rates of Etonogestrel Subdermal Implants in Overweight and Obese Women
Financial Disclosures

- No financial conflicts of interest
Objectives

• Estimate the contraceptive failure rates of the ENG implant among overweight and obese women

• Compare failure rates with women of normal weight and women using intrauterine devices (IUDs)
Etonogestrel subdermal (Implanon) implant

- Introduced in 2006
- Approved for 3 years of use
- 4cm long, 2mm diameter
- 68mg etonogestrel

Hatcher et. al. Contraceptive Technology. 2009
Implants are among the most effective forms of contraception.

First Year Failure Rates (%)

- No Contraception
- Spermicides
- Condom
- Pill/Patch/Ring
- Injectable (DMPA)
- IUD-Cu T
- IUD-LNG
- Implant

Hatcher et. al. Contraceptive Technology. 2009
Pregnancy in the United States

- 6 million pregnancies per year in the US
- Half are unintended
- 60% of unintended pregnancies report contraception used that month
- Contraception requires strict adherence/compliance
Obesity in the United States

- Increased morbidity
- Pregnancy complications
Controversy

- Failure rate for implant: 0 per 100 women-years of use

- Clinical trials excluded subjects >130% of their ideal body weight
Hypothesis

- There is no significant difference in failure rates by body mass index (BMI) status among implant users as compared to the reference group of IUD users
The Contraceptive CHOICE Project

- Prospective cohort study
- 9,256 women
- Ages 14-45
- St. Louis region
- Long-acting reversible contraceptives
- Reduce unintended pregnancies
Study Subject Timeline

Survey

STI screen

Month 0 3 6 9 12 15 18 21 24 27 30 33 36

enrollment
Recruitment

- August 2007 to October 2010
- Analysis on 8,445 women
- Phone follow-up rates:
  - 98% at 6 months
  - 95% at 12 months
  - 88% at 24 months
  - > 80% at 36 months
Secondary Analysis

- **BMI at baseline visit**
  - Normal weight: BMI 18.5-24.9
  - Overweight: BMI 25-29.9
  - Obese: BMI 30 or higher

- **Missed menses and possible pregnancies**
  - Method use at the time of conception
  - Date of last menstrual period
  - Plans for pregnancy (intended?)

- **Contraceptive method failure**
Data Analysis

- Demographic characteristics
  - Means and standard deviations
  - Frequency and percentage

- Implant vs. IUD
  - Continuous variables → Student’s t-test
  - Categorical variable → Chi square test
  - Contraceptive failure rates → Kaplan-Meier survival curves and log-rank tests
Sample Size Calculation

- Post-hoc calculation

- A sample size of 1,168 participants

- Greater than 80% power to detect a difference in contraceptive failure rates of:
  - 0.5% in the normal weight group
  - to 0.8% of the overweight group
  - To 3% in the obese group
Demographics of Implant Users

- Significantly more likely to be:
  - Younger
  - Black
  - Never married
  - Lower educational level
  - Lower income
  - Lower parity
BMI Distribution

IUD users
4,200 (50%)  
- 35% normal weight (BMI 18.5-24.9)
- 38% overweight (BMI 25-29.9)
- 27% obese (BMI >30)

Implant users
1,168 (14%)  
- 35% normal weight (BMI 18.5-24.9)
- 37% overweight (BMI 25-29.9)
- 28% obese (BMI >30)
Demographics of Overweight and Obese Participants

- Significantly more likely to be:
  - Older
  - Black
  - Married
  - Lower educational level
  - Lower income
  - Greater parity
IUD users

- 5,985 women-years of IUD use
  - Normal weight: 5 unintended pregnancies
  - Overweight: 0 unintended pregnancies
  - Obese: 7 unintended pregnancies
Unintended Pregnancies- Implant users

- 1,377 women-years of implant use
  - Normal weight: 0 unintended pregnancies
  - Overweight: 0 unintended pregnancies
  - Obese: 1 unintended pregnancies
    - Participant BMI 30.7
    - Reported pregnancy 4 days after insertion
**Strengths**

- **CHOICE Project** is a large prospective cohort study.
- Low rate of loss of follow-up through 36 months.
- Diverse group of US women.
- Wide BMI range.
Limitations

- Non-randomization of study participants
- Convenience sample
- Must initiate new contraceptive method
- Underpowered to show small differences
Conclusion

- Efficacy of the implant does not vary based on BMI
- Both implant and IUD have very low failure rates
- Clinicians can recommend implants for contraception to women of any weight
Acknowledgments

- Jennifer A. Wade, Jeffrey F. Peipert, Qiuhong Zhao, Tessa Madden, Gina M. Secura
- Mentor: Dr. Jeff Peipert
- The Contraceptive CHOICE Project Staff and Participants!
- Washington University in St. Louis School of Medicine Clinical Research Training Center
- The Doris Duke Charitable Foundation
- Association of Reproductive Health Professionals
Thank you

ANY QUESTIONS?
## Baseline Demographics (N=8,445)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>IUDs (N=4200)</th>
<th></th>
<th>Implant (N=1168)</th>
<th></th>
<th>p-value&lt;sup&gt;1&lt;/sup&gt;</th>
<th>p-value&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal Weight (N=1584)</td>
<td>Over-weight (N=1149)</td>
<td>Obese (N=1467)</td>
<td>p-value&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Normal Weight (N=439)</td>
<td>Over-weight (N=324)</td>
</tr>
<tr>
<td>Age (Mean, SD)</td>
<td>25.3 (6)</td>
<td>26.5 (6)</td>
<td>27.5 (6)</td>
<td>&lt;0.01</td>
<td>21.5 (5)</td>
<td>23.1 (6)</td>
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<tr>
<td>Race</td>
<td></td>
<td></td>
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<tr>
<td>Black</td>
<td>471 (30)</td>
<td>549 (48)</td>
<td>965 (66)</td>
<td>&lt;0.01</td>
<td>218 (51)</td>
<td>199 (62)</td>
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<tr>
<td>White</td>
<td>980 (62)</td>
<td>513 (45)</td>
<td>418 (29)</td>
<td></td>
<td>174 (40)</td>
<td>93 (29)</td>
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<tr>
<td>Others</td>
<td>125 (8)</td>
<td>83 (7)</td>
<td>82 (6)</td>
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<td>40 (9)</td>
<td>28 (9)</td>
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<tr>
<td>Marital Status</td>
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<tr>
<td>Never married</td>
<td>918 (58)</td>
<td>616 (54)</td>
<td>756 (52)</td>
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<td>322 (74)</td>
<td>204 (63)</td>
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<tr>
<td>Cohabitng</td>
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<td>252 (22)</td>
<td>336 (23)</td>
<td></td>
<td>78 (18)</td>
<td>68 (21)</td>
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<tr>
<td>Married</td>
<td>219 (14)</td>
<td>179 (16)</td>
<td>248 (17)</td>
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<td>23 (5)</td>
<td>36 (11)</td>
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<tr>
<td>Divorced/Separated/Widowed</td>
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<td>101 (9)</td>
<td>126 (9)</td>
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<td>14 (3)</td>
<td>16 (5)</td>
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<tr>
<td>Education</td>
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<td>&lt;0.01</td>
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<td>≤HS</td>
<td>432 (27)</td>
<td>376 (33)</td>
<td>479 (33)</td>
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<td>232 (53)</td>
<td>179 (55)</td>
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<tr>
<td>≥Some college</td>
<td>1152 (73)</td>
<td>771 (67)</td>
<td>988 (67)</td>
<td></td>
<td>206 (47)</td>
<td>145 (45)</td>
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<td>Receiving public assistance&lt;sup&gt;3&lt;/sup&gt;</td>
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<tr>
<td>No</td>
<td>1156 (73)</td>
<td>686 (60)</td>
<td>717 (49)</td>
<td></td>
<td>303 (69)</td>
<td>167 (52)</td>
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<tr>
<td>Yes</td>
<td>428 (27)</td>
<td>463 (40)</td>
<td>750 (51)</td>
<td></td>
<td>136 (31)</td>
<td>157 (48)</td>
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<td>Parity</td>
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<td>0</td>
<td>838 (53)</td>
<td>402 (35)</td>
<td>378 (26)</td>
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<td>279 (64)</td>
<td>141 (44)</td>
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<tr>
<td>1</td>
<td>381 (24)</td>
<td>312 (27)</td>
<td>406 (28)</td>
<td></td>
<td>91 (21)</td>
<td>88 (27)</td>
</tr>
<tr>
<td>2+</td>
<td>365 (23)</td>
<td>435 (38)</td>
<td>683 (47)</td>
<td></td>
<td>69 (16)</td>
<td>95 (29)</td>
</tr>
</tbody>
</table>