Deep Dive + Empower

Overview of Methods | Michael Policar
Addressing Client Concerns | Erica Torres
LARC Procedure Set-Up | Caitlin Stearns
Jeopardy-Style Review
Overview of Contraceptive Methods

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DISCLOSURES

- Sebela Pharmaceuticals
- Investigator proctor for Phase III copper IUD study
- Bayer Healthcare
- Litigation consultant (defense expert witness)
HISTORY OF CONTRACEPTION IN THE U.S.

1830s
Rubber condom, diaphragm

Early 1960s
First oral contraceptive pills (estrogen plus progestin)

Late 1960s
First IUDs (non-hormonal)

1970s
Progestin-only oral contraceptive pills

1980s
Vaginal sponge

1990s
Subdermal implants, depot progestin injections, emergency contraception

2000s
LNG IUDs, transdermal patch, intravaginal ring, hysteroscopic sterilization

1800s
CONTRACEPTIVE METHODS IN THE U.S.
HOW WELL DOES BIRTH CONTROL WORK?

Really, really well
- The Implant ( Nexplanon)
- IUD ( Kylea)
- IUD ( Mirena)
- IUD ( ParaGard)
- Sterilization, for men and women

Works, hassle-free, for up to...
- 3 years
- 3 years
- 5 years
- 12 years
- Forever

What is your chance of getting pregnant?

Less than 1 in 100 women

Okay
- The Pill
- The Patch
- The Ring
- The Shot (Depo-Provera)

For it to work best, use it...
- Every Single Day
- Every Week
- Every Month
- Every 3 months

Not so well
- Withdrawal
- Diaphragm
- Fertility Awareness
- Condoms, for men and women

For each of these methods to work, you or your partner have to use it every single time you have sex.

6-9 in 100 women, depending on method

12-24 in 100 women, depending on method

FVI, without birth control, over 90 in 100 young women get pregnant in a year.

#FPEconf
### MOST EFFECTIVE METHOD USED IN THE PAST MONTH

US WOMEN, 2014

<table>
<thead>
<tr>
<th>Method</th>
<th>% of users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral contraceptives</td>
<td>25.3</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>21.8</td>
</tr>
<tr>
<td>Male condom</td>
<td>14.6</td>
</tr>
<tr>
<td>IUD</td>
<td>11.8</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>8.1</td>
</tr>
<tr>
<td>Male sterilization</td>
<td>6.5</td>
</tr>
<tr>
<td>Injectable</td>
<td>3.9</td>
</tr>
<tr>
<td>Implant</td>
<td>2.6</td>
</tr>
<tr>
<td>Vaginal ring</td>
<td>2.4</td>
</tr>
<tr>
<td>FABM</td>
<td>2.2</td>
</tr>
<tr>
<td>Patch</td>
<td>0.2</td>
</tr>
<tr>
<td>Other methods</td>
<td>0.8</td>
</tr>
</tbody>
</table>
COMBINED ORAL CONTRACEPTIVES

• > 60 products on the US market
  • Some are brand name; most are generic
  • Generics as effective as brand name
• All have progestin and estrogen (e.g., “combined OCs”)
  • Vary by progestin generation and estrogen dosage
• MOA: prevent ovulation, thicken cervical mucus
• AE: Increased relative risk of venous complications
• Dispensing: 3-13 cycles
• **Hot Topic**
  • Relationship of long term use to breast cancer
PROGESTIN ONLY PILLS (POPs)

- One version on the US market
  - Norethindrone only (no estrogen)
  - One brand name (Micronor®); a few generics
- Use: 1 tablet daily at same time (no break for menses)
- MOA: thicken cervical mucus
- AE: none major. Spotting is common
- *Hot Topic*
  - Likely to be the first over-the-counter OC in the US
FEMALE STERILIZATION

- Two major varieties
  - Interval tubal occlusion (ligation)
  - Post-partum tubal occlusion
- Interval procedures
  - Laparoscopic: rings, bands, cautery
  - Mini-laparotomy: ligation
- **Hot Topics**
  - Hysteroscopic tubal occlusion (Essure®) no longer in US
  - Should salpingectomy replace occlusion procedures owing to reduced risk of later ovarian cancer?
MALE CONDOM

- Protection against pregnancy and most STD transmission (less for herpes and HPV)
- Many types and sizes
- Covered by Medicaid, though Rx may be required

**Hot Topics**
- Personalized condom fit (ordered on-line)
- Direct marketing to women
INTRAUTERINE CONTRACEPTION (IUD)

- Two major categories
  - Copper (Paragard®)
  - Levonorgestrel-releasing (4 types)
- MOA
  - Copper: toxic to sperm and egg
  - LNG: thickens cervical mucus; toxic to egg
- AE: expulsion, perforation, infection (PID), pregnancy
- **Hot topics**
  - Maximizing number of trained providers
  - Avoidance of coercion as reproductive justice issue
## CHOOSING WHICH IUD

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Skyla®</th>
<th>Kyleena®</th>
<th>Mirena®</th>
<th>Liletta®</th>
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</thead>
<tbody>
<tr>
<td>LNG content (mg)</td>
<td>13.5</td>
<td>19.5</td>
<td>52</td>
<td>52</td>
</tr>
<tr>
<td>Max duration, years</td>
<td>3</td>
<td>5</td>
<td>5 (7)</td>
<td>4 (7)</td>
</tr>
<tr>
<td>T-frame, mm</td>
<td>28 x 30</td>
<td>28 x 30</td>
<td>32 x 32</td>
<td>32 x 32</td>
</tr>
<tr>
<td>Insertion tube diameter (mm)</td>
<td>3.80</td>
<td>3.80</td>
<td>4.40</td>
<td>4.80</td>
</tr>
<tr>
<td>String color</td>
<td>Brown</td>
<td>Blue</td>
<td>Brown</td>
<td>Blue</td>
</tr>
<tr>
<td>Silver ring</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Parentheses refer to evidence based duration.
INJECTABLE CONTRACEPTION (DMPA)

- One product in US: DepoProvera®
  - 150 mg (IM) and 105 mg (sub-Q) dosages
- Injected every 12 wks (works through end of 14th week)
- MOA: prevents ovulation, thickens cervical mucus
- Menstrual periods cease entirely in most women
- AE: weight gain in adolescents, reversible bone loss
- **Hot topic**
  - DP-105 used for self-injection
CONTRACEPTIVE IMPLANT

• One product in US: Nexplanon®
• One silastic capsule placed under skin of upper arm
• Duration: up to 3 years
• MOA: prevents ovulation, thickens cervical mucus
• Unpredictable spotting; periods cease entirely in some
• AE: rare difficult removal

• Hot topics
  • Maximizing number of trained providers
  • Avoidance of coercion as reproductive justice issue
CONTRACEPTIVE VAGINAL RING (CVR)

- One product in US: NuvaRing®
- Contains progestin and estrogen
- Duration: monthly (21 days in vagina, 7 days out)
- MOA: prevent ovulation, thicken cervical mucus
- AE: Increased relative risk of venous complications
- Dispensing: 1-3 cycles
- Hot Topics
  - Very low acceptance rates in US
  - FDA approved Annovera® (1 year ring) in 2018; will become available in 2019
CONTRACEPTIVE PATCH

• One product in US: Xulane
  • OrthoEvra has been discontinued
• Contains progestin and estrogen
• Duration: monthly (7 days x 3 patches, then 7 days off)
• MOA: prevent ovulation, thicken cervical mucus
• AE: Increased relative risk of venous complications
• Dispensing: 1-3 cycles (3-9 patches)
• *Hot Topic*
  • Very low acceptance rates in US
FABM: CORRECT USE OF TERMS

- **Fertility Awareness Method (FAM)**
  - Barrier method(s) used on fertile days
  - Avoids adverse effects of hormonal contraception

- **Natural family planning (NFP)**
  - Abstain from intercourse on fertile days
  - No “mechanical” contraceptives used
# OVERVIEW OF FABMs

<table>
<thead>
<tr>
<th>Tracking Days of the Menstrual Cycle</th>
<th>Observation of Cervical Secretions (CMMs)</th>
<th>Multiple Indicators of Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Days Method [Cycle Beads]</td>
<td>[2Day Method]</td>
<td>Symptothermal Method (STM) [Sensiplan™]</td>
</tr>
<tr>
<td>Calendar Rhythm Method</td>
<td>[Billings] Ovulation Method®</td>
<td>Calculothermal [NaturalCycles]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Symptohormonal Methods (SHM) [Marquette]</td>
</tr>
</tbody>
</table>

CMMs: cervical mucus methods
FABM: DISADVANTAGES AND CAUTIONS

- Unforgiving of incorrect or inconsistent use
- No protection against STIs, including HIV
- Lack of partner cooperation can be an obstacle for some
- Conditions that increase the likelihood of irregular cycles may make FABMs more difficult to use
  - May require more extensive counseling and follow-up
LACTATIONAL AMENORRHEA METHOD (LAM)

- **Effectiveness**
  - Pregnancy rate: 1-2% by 6 months postpartum
  - 7% by 12 months; 13% by 24 months

- **Bellagio Conference Consensus (1989)**
  - Nurses "on demand" ( $\geq 5$ feeds/day; $> 65$ min total)
  - Breast milk is only nutrition to newborn; no supplementary bottle feedings or other foods
  - No bleeding episode beyond 56 days from delivery
  - Nursing of newborn for less than 6 months
LACTATIONAL SUMMARY

- LAM works well, but return of fertility is multifactorial and unpredictable
- Ovulation may precede bleeding ≥10 wks post-partum
  - LAM is less effective from 10 wks-6 months
- LAM is unforgiving of imperfect use
- Use another method at 6 months, or sooner if menstrual bleeding occurs
PROVIDING FABMs

- All clinicians must understand fundamentals of FABMs
- Evaluation of patient interest in FABM
  - Do you use your cycle to decide when to have (or not have) sex? Would you like to?
  - Have used fertility apps? What’s your experience been?
- A counseling service, not necessarily a clinician-provided
  - Similar to diabetes education
  - On-site counselors with special training can educate patients in their chosen method, or by referral
OTHER METHODS
FEMALE BARRIERS: DIAPHRAGM

- Latex barrier lodged between pubic bone and back of vagina
- Two types
  - Caya (a.k.a. SILCS)
  - Milex: traditional
- 8 sizes in 5 mm increments
- Coated with spermicide before each intercourse
- Don’t remove till 6 hours after last intercourse
- **Hot topic**
  - Difficult to obtain!
FEMALE BARRIERS: CERVICAL CAP

• Comes in 4 sizes
• Practice necessary to insert and remove
• Used with or without spermicide
• Leave in 6 hrs. after last intercourse

Hot topics
• Only product: FemCap
• FDA approved, but no US distributor
FEMALE BARRIERS: TODAY SPONGE

• Impregnated with nonoxynol spermicide; must be activated with fluid to create foam
• Can be inserted up to 24 hours prior to intercourse
• Continuous protection throughout that period - for as many acts of intercourse as desired
• It must be left in place for 6 hours after last sex
• Should not be worn for > 30 consecutive hours
FEMALE BARRIERS: TODAY SPONGE
FEMALE BARRIERS: REALITY FEMALE CONDOM

Female controlled STI + pregnancy prevention

#FPEconf
EMERGENCY CONTRACEPTIVE PILLS (ECPs)

- Levonorgestrel ECPs
  - Single dose 1.5 mg LNG tablet
  - Labeled for use within 72 hours of UPI
  - Efficacy is good 0-72 hours; “moderate” 72-120 hrs.
- MOA: Toxic to egg and sperm
- Products
  - Plan B One-Step®
  - Generic one-dose tablets
  - Two-tablet products now obsolete
EMERGENCY CONTRACEPTIVE PILLS (ECPs)

**Ulipristal Acetate (UPA)**
- Product: ella® (Actavis)
- Selective progesterone receptor modulator
- Mechanism of action
  - Prevents ovulation, with follicles up to 18-20 mm
- Taken orally in single 30 mg dose
- Labeled for use up to 5 days from last UPI
ACQUIRING ECPs

- LNG ECPs available OTC
  - No age restrictions; no ID needed
  - Prices range from $40 (generic) - $50 (brand name)
- UPA requires a prescription
- ECPs are included in “preventive services without cost sharing” feature of the ACA
  - Health plans may cover some or all EC products
  - Require a prescription for both LNG and UPA
THE COPPER IUC AS EC

- Effectiveness: pregnancy rate is 0.1%
- Use as emergency contraception
  - Effective when placed up to 5 days from ovulation
  - If can’t determine ovulation, insert ≤ 5 days from UPI
  - Off label use
- Most cost effective when continued long term (10 years)
  - Duration of use similar to routine Cu-IUD placement
U.S. Selected Practice Recommendations for Contraceptive Use, 2013
Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition

U.S. Selected Practice Recommendations for Contraceptive Use, 2016. MMWR July 29, 2016. 65(4);1–66
2016 U.S. MEC & SPR APP

US MEC
US Medical Eligibility Criteria for Contraceptive Use, 2016

US SPR
US Selected Practice Recommendations for Contraceptive Use, 2016

CDC
U.S. Department of Health and Human Services Centers for Disease Control and Prevention

Select Method (MEC)
- Intrauterine Contraception
- Progestin-only Contraceptives
- Combined Hormonal Contraceptives
- Barrier Methods
- Fertility Awareness-based Methods
- Lactational Amenorrhea Method
- Colitis Interruptus
- Female and Male Sterilization
- Emergency Contraception (IUDs and ECPs)

SPR
- How To Be Reasonably Certain That A Woman Is Not Pregnant
  - Cu-IUD
  - LNG-IUD
  - Implants
  - Injectables
  - Combined Hormonal Contraceptives
  - Progestin Only Pills
  - Standard Days Method
  - Emergency Contraception (IUDs and ECPs)
  - Female Sterilization
  - Male Sterilization
THE "SUITE" OF CDC FAMILY PLANNING RECOMMENDATIONS

- Achieving Pregnancy Guidelines
- Contraception Guidelines
- STD & HIV Guidelines
- Preconception Guidelines

Quality Family Planning

United States Medical Eligibility Criteria for Contraceptive Use (US MEC)
United States Selected Practice Recommendations for Contraceptive Use (US SPR)

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DISTRIBUTION SYSTEMS FOR HORMONAL CONTRACEPTIVES (HC)

• Historically…
  • Clinician prescribed, pharmacy filled
  • Clinician prescribed, clinic furnished

• Newer alternatives
  • Nurse (RN) furnished, via standing orders
  • Pharmacist prescribed and furnished
  • Clinical services at retail sites
  • Telemedicine: On-line clinician prescribed
There's finally an Uber for birth control

In 2016, the number of goods and services available on demand is stunning. With just a few swipes and taps, I can summon a ride, dinner, pot, or even a parrot. One product, though, that has remained difficult to obtain for most women is birth control: it still usually involves a doctor's
TELE-HEALTH: ON-LINE PRESCRIPTIONS FOR HORMONAL CONTRACEPTION

- Nurx
- Maven Clinic
- PRJKT Ruby
- Lemonaid Health
- Pandia Health
- The Pill Club
- Virtuwell
- HeyDoctor
- PlushCare
- Planned Parenthood Direct; Get Care On-Line
APP-BASED CARE

nurx.com

Birth Control
Delivered to you without a visit to the doctor. With or without insurance. Starting at $15/month.

Get Started

mavenclinic.com

Health & wellness
designed for women

virtuwell.com

So many reasons to visit
In just minutes our certified nurse practitioners diagnose and treat dozens of conditions. We ask the same questions you'd hear in a doctor's office, but online. Take a look and find your reason to give us try.

projectruby.com

Here to help
FPEconf

The Easiest Way To Get Birth Control
- Free Delivery
- Online Prescriptions
- Automatic Refills

HEALTHCARE. REFRESHINGLY SIMPLE.
lemonaidhealth.com

- Birth Control Pills
- Urinary Tract Infection (UTI)
- Sinus Infection
- STD Testing
- A1C Blood Sugar Test
- Erectile Dysfunction
- Cholesterol
- Hair Loss
- Acne
- Flu
- Acid Reflux
Waiting rooms suck. Get medical care at your convenience.
Get treatment, prescriptions, and labs from expert doctors right from your pocket.

Get Treated Today

- Get UTI (Urinary Tract Infection) Antibiotics and Treatment Now: $25
- Get Birth Control Prescription Today: $15
- Acne Treatment and Prevention: $25
- Get Cold Sore Treatment Now: $25
- Hair Loss Prevention and Regrowth: $30
- Eyelash Growth with Latisse: $30
- Acute Sinus Infection Treatment: $25
- Quit Smoking: $5
- Female Condom Prescription: $5
plushcare.com

Office co-pay (if insured) or $99 flat rate
TAKE IT HOME

• A variety of new options for contraceptive distribution
• Access to all CHCs thru telemedicine now exists in many states and is growing
  • Little known about % acquisition by this route or why
• Main customers
  • Millennials who don’t have time for clinic visits
  • Women who live in “contraceptive deserts”
  • Women who want to avoid receiving in-clinic services
• Transition phase until OTC availability of all CHCs
• Likely will impact financial viability of some FP clinics