Alternative Delivery Systems for Family Planning

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Distribution Systems for Hormonal Contraceptives (HC)

- Historically...
  - Clinician prescribed, pharmacy filled
  - Clinician prescribed, clinic furnished
  - Nurse (RN) furnished, via standing orders
- Current alternatives
  - Pharmacist prescribed and furnished
  - Telemedicine: On-line clinician prescribed
- Near-future possibility
  - Over-the counter HC
Pharmacy Access to Hormonal Contraception

- “Behind-the-counter” status
- Pharmacist screens women for eligibility
- Washington State: pharmacy access model found to be safe, effective and acceptable to women
- Concerns: reimbursement and refusals—and must be done state by state
- Starting in 2016
  - Oregon (House Bill 2879)
  - CA (Senate Bill 493)

Gardner et al, 2008
## Pharmacy Access to HC

<table>
<thead>
<tr>
<th></th>
<th>Oregon</th>
<th>California</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>*18+</td>
<td>No restriction</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td>OC, patch</td>
<td>OC, patch, CVR, DMPA</td>
</tr>
<tr>
<td><strong>Training</strong></td>
<td>5 hours</td>
<td>1 hour</td>
</tr>
<tr>
<td><strong>Self-screening required?</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Law addresses billing?</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

* Women <18 are eligible only if they have obtained at least one previous prescription from a clinician
Telemedicine: On-line HC Prescription

- Nurx
- Maven
- PRJKT Ruby
- Lemonaid Health
- Planned Parenthood Direct
Birth Control
Delivered to you without a visit to the doctor. With or without insurance. Starting at $15/month.
Available in CA and NY
Get Started
nurx

- Offer combination pills, progesterone-only pills, patch, vaginal ring, and emergency contraceptives
- Contracted with Aetna, Blue Shield, Cigna, and United Healthcare
- Most requests are approved within 40 minutes and pills arrive the next day
  - The goal is to deliver within two to four hours
Health & wellness designed for women

Get prescriptions or advice instantly, all from the comfort of your home.

Your first appointment is FREE with your first order.
Visits start at $18...price stated at booking

Variety of clinicians: OBG, pediatrician, NP, dietician

No coordination with insurance for visit cost

Prescription transmitted to pharmacy
projectruby.com

Tarina® Fe
$20.00/cycle

Aubra
$20.00/cycle

Chateal
$20.00/cycle

Lyza
$20.00/cycle

Cyred
$20.00/cycle

I don't know
Help me select

Ella®
$67.00

EContra™ EZ
$25.00

Free shipping on all orders!

ORDER IN 4 SIMPLE STEPS

STEP 1
Select birth control product†

STEP 2
Register if you're a new customer, or login

STEP 3
Complete the free online consultation

STEP 4
Checkout. It's that simple!

†We will walk you through the selection process if you don't know which product to choose.
PRJKT Ruby

- Online questionnaire; which pill is best for you
- Reviewed by a U.S.-licensed MD, very same day
- If approved, shipped out (free) same or next day
- Cost is $20 per monthly cycle
- Initial 3-month supply
  - After that, answer a few questions online
  - If all’s good, 12 cycles without consultation
- Physicians and pharmacists are always available
HEALTHCARE. REFRESHINGLY SIMPLE.

Get a doctor's prescription for $15.

<table>
<thead>
<tr>
<th>Acid Reflux</th>
<th>Acne</th>
<th>Birth Control Pills</th>
<th>Erectile Dysfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flu</td>
<td>Hair Loss</td>
<td>Sinus Infection</td>
<td>Urinary Tract Infection (UTI)</td>
</tr>
</tbody>
</table>

Lemonaid Health

- Available in CA, NY, PA, MI
- Doctors write 3-month prescriptions for over 100 brands of birth control pills
- You need to know your BP
- Smile and take a picture
- Select a pharmacy, pay $15 visit fee
- Pick up and pay at a user-selected pharmacy
- If you're 35 and over we can only prescribe a progestin-only pill.
Lemonaid Health

Won’t prescribe COCs if

• Under 18
• You're a man
• Don't know your blood pressure
• Pregnant or may be pregnant
• Experiencing unusual vaginal bleeding
• Experience migraines with aura
• Liver or gall bladder problems
• Want the pill to treat acne or control your period
Planned Parenthood Direct: CA

1. Select your pill brand or let us help you select one
2. Answer a few questions about your health history
3. Select a pharmacy
4. Pay $15 service fee
5. A doctor will review your request and submit a prescription to the pharmacy of your choice
   • If they have concerns or follow-up questions, they will contact you via secure message within the app.
6. Pick up and pay for your prescription
   • If insured, you can use it to pay for your Rx
Are you currently taking any medicines?

Include any migraine headache treatments, as well as any over-the-counter products, vitamins, and herbs (including St. John’s Wort)

☐ No
☐ Yes

Treatment

The prescription medicine we’re giving you to treat a simple UTI is called Nitrofurantoin Monohydrate (Macrobid).

- How to take
- Who shouldn’t take
- Side effects
- Other important information
Telemedicine Prescription of HC

- Convenience...no clinic visit, no exam
- Don’t need a relationship with a PCP
- Confidential
- Inexpensive (no cost, if insurance used)
- No legislative approval; clinicians write Rx
- Targeted to millennials
  - Love technology
  - Prefer on-line shopping
  - Believe seeing a doctor is too much of a “pain”
Telemedicine Prescription of HC: Benefits

• Clients have access to most contraceptives (except DMPA, implant, IUD)
• Remove the barrier of time lost at a clinic (and lessen opportunity cost)
• No travel and parking expense
• Reduction in unintended pregnancies?
Telemedicine Prescription of HC: Risks

• Some women will miss the opportunity for detailed counseling and shared decision making
  – Loss of educational opportunity for LARCs
• More women will forego well woman visits
• Visits at some family planning clinics will continue to decline, in some cases to the point of insolvency
# OTC? FDA Criteria

<table>
<thead>
<tr>
<th>FDA criteria</th>
<th>Oral contraceptives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug has no significant toxicity if overdosed</td>
<td>True</td>
</tr>
<tr>
<td>Drug is not addictive</td>
<td>True</td>
</tr>
<tr>
<td>Users can self-diagnose conditions for appropriate use</td>
<td>Women determine if they are at risk of unintended pregnancy</td>
</tr>
<tr>
<td>Users can safely take the medication without a clinician’s screening</td>
<td>Women can self-screen for contraindications without involving a clinician</td>
</tr>
<tr>
<td>Users can take the medication as indicated without a clinician’s explanation</td>
<td>Continuation is similar/higher among women obtaining pills OTC compared to in a clinic</td>
</tr>
</tbody>
</table>
Continuation of OCs Obtained OTC

Discontinuation 60% higher for those obtaining pills in clinics

Discontinuation 80% higher for those who obtained 1-5 packs in a clinic

Potter et al., 2011
Which Pill? POP vs. Combined Oral Contraceptive (COC)

- Consensus around POP as first OTC pill in US
- FDA has indicated that OTC approval of estrogen-containing product very unlikely
- Fewer and rarer contraindications for POP
- Incremental step from OTC LNG emergency contraceptive pill (ECP) to OTC daily POP
- Eventual goal of advocates is OTC combined oral contraceptive
Progestin-only Pills (POPs)

- Only about 4% of US OC users use POPs
  - Postpartum; contraindications to combined OCs
- One formulation registered and marketed in US: norethindrone
- Norgestrel POP also registered but no longer marketed
- Levonorgestrel and desogestrel POPs registered and marketed elsewhere

Liang et al., 2012
Support Among Professional Organizations

- APHA policy in support of insurance coverage for OTC contraception – 2011
- ACOG Committee Opinion – 2012, 2015
- AMA resolution recommending FDA to encourage pharma – 2013
- AAFP resolution in support of OCs OTC with insurance coverage - 2014
How Can You Respond to Alternative Delivery Systems?

• “Same things a bit better”
  – Devise and implement a strategy to market “value added” when receiving care in a FP clinic
  – Counseling, IUDs, implants, injections
• Capture new markets by embracing new technologies
  – Band together to quickly develop and market competing telemedicine technologies (e.g., app)

• *Ignoring these developments is NOT an option!*