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Telemedicine and Mobile Apps Accessing Birth Control Without Stepping Foot in a Clinic

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Dr. Ring

- Dr. Brandi Ring, MD, FAWM, is originally from Westminster, CO. After graduating from CU Boulder, she completed her Master's degree and then Medical School at Boston University School of Medicine. She developed a deep passion for serving the underserved and developing health policy and became an advocate for patients and physicians through her work with the American Medical Association. She completed her residency in OB/GYN at York Hospital in York, PA. Dr. Ring actively advocates for her patients, her colleagues and her specialty. She can frequently be found in state and national capitols discussing health policy. Her specialty interests include high-risk and low-risk pregnancy, family planning, wilderness medicine, LGBT care, well-women care and preventative health.

- She is the President of the Aurora-Adams County Medical Society, serves on the Colorado Medical Society board and is honored to be the CMS Medical Student Component Board Liaison. She is also active in her specialty society, the American College of Obstetricians and Gynecologists where she serves on the executive

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Risk of Pregnancy in the US

- 61 Million women (age 15-44)[1]
    - 70% sexually active with male partner and at risk for pregnancy
- In one year – 85% of couples would get pregnant with no method[3]
- The average desired family size is 2 children[4]

So on average women need some form of contraception for ~34 years!!

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So who uses Contraception?

- 99% of women have used some contraceptive in their life[5]
- At any given time 60% are currently using some method.[6]
  - 10% are not (and are not trying to get pregnant)
    - Increased in younger women (18%) vs older women (9%) [2]
- Varies by ethnicity
  - 83% of Black women
  - 91% of Hispanic women
  - 90% of Asian women
  - 91% of White women

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Who uses contraception?

- Varies by Income[2]
- 92% if at 300% of Federal Poverty Level
- 89% if below 150% of FPL

- Varies by Religion[7]
  - 89% Catholics
  - 90% Protestants
- Varies by Marital Status[2]
  - 93% Married
  - 90% Unmarried / Cohabitating
  - 83% Never married

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How well does contraception work?

- 68% consistent use = 5% unintended pregnancies
- 18% inconsistent use = 41% of unintended pregnancies,
- 14% who do not use contraceptives at all or have a gap in use of at least one month account for 54% of unintended pregnancies.[4]

CONTRACEPTIVE EFFECTIVENESS

Proportion of women who will become pregnant over one year of use, by method

METHOD	Perfect use	Typical use
Implant	0.05	0.05
Vasectomy (male sterilization)	0.10	0.15
Intrauterine device (IUD)		
Levonorgestrel-releasing	0.2	0.2
Copper-T	0.6	0.8
Tubal (female) sterilization	0.5	0.5
Injectable	0.2	4
Pill	0.3	7
Vaginal ring	0.3	9
Patch	0.3	9
Diaphragm	6	12
Sponge**	9/20	12/24
Male condom	2	13
Female condom	5	21
Withdrawal	4	20
Fertility awareness methods***	0.4–5	24
Spermicides	18	28
Emergency contraception	*	*
No method	85	85

*The effectiveness of emergency contraception is not measured on a one-year basis like other methods. It is estimated to reduce the incidence of pregnancy by approximately 90% when used to prevent pregnancy after one instance of unprotected sex. **For sponge, first figure is for women who have not given birth and second is for women who have given birth. ***Includes cervical mucus methods, body temperature methods and periodic abstinence. NOTES: u=unavailable. "Perfect use" denotes effectiveness among couples who use the method both consistently and correctly; "typical use" refers to effectiveness experienced among all couples who use the method (including inconsistent and incorrect use).

www.guttmacher.org

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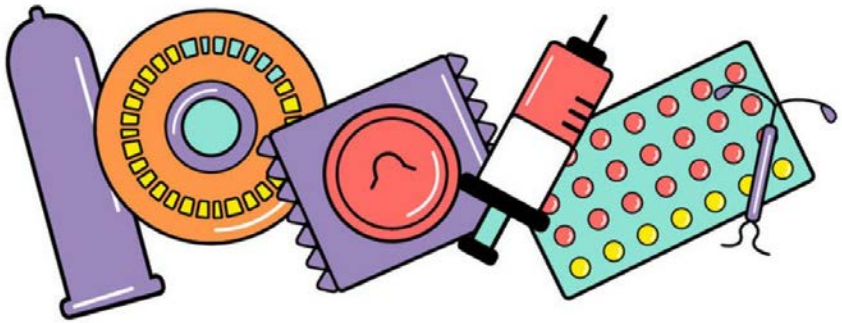
What Contraceptive do they use?

- 72% use non-permanent method
- 29% use permanent method
  - 22% Female
  - 7% Male



- **Pill – 25.3%**
- **Condoms – 14.6%**
- **IUD – 11.8%**
- **Withdrawal – 8.1%**
- **Depo Provera – 3.9%**
- **Implant 2.6%**
- **Ring - 2.4%**
- **Patch – 0.2%**
- **Plan B / EllaOne– 0.2%**

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CONTRACEPTIVE METHOD CHOICE

Most effective method used in the past month by U.S. women, 2014

METHOD	No. of women	% of women aged 15–44	% of women at risk of unintended pregnancy	% of contraceptive users
Pill	9,572,477	15.6	22.7	25.3
Tubal (female) sterilization	8,225,149	13.4	19.5	21.8
Male condom	5,496,905	8.9	13.0	14.6
IUD	4,452,344	7.2	10.6	11.8
Vasectomy (male sterilization)	2,441,043	4.0	5.8	6.5
Withdrawal	3,042,724	5.0	7.2	8.1
Injectable	1,481,902	2.4	3.5	3.9
Vaginal ring	905,896	1.5	2.1	2.4
Fertility awareness-based methods	832,216	1.3	2.0	2.2
Implant	965,539	1.6	2.3	2.6
Patch	69,106	0.1	0.2	0.2
Emergency contraception	69,967	0.1	0.2	0.2
Other methods*	234,959	0.4	0.6	0.6
No method, at risk of unintended pregnancy	4,408,474	7.2	10.5	na
No method, not at risk	19,302,067	31.4	na	na
Total	61,491,766	100.0	100.0	100.0

*Includes diaphragm, female condom, foam, cervical cap, sponge, suppository, jelly/cream and other methods. NOTE: "At risk" refers to women who are sexually active; not pregnant, seeking to become pregnant or postpartum; and not noncontraceptively sterile. na=not applicable.

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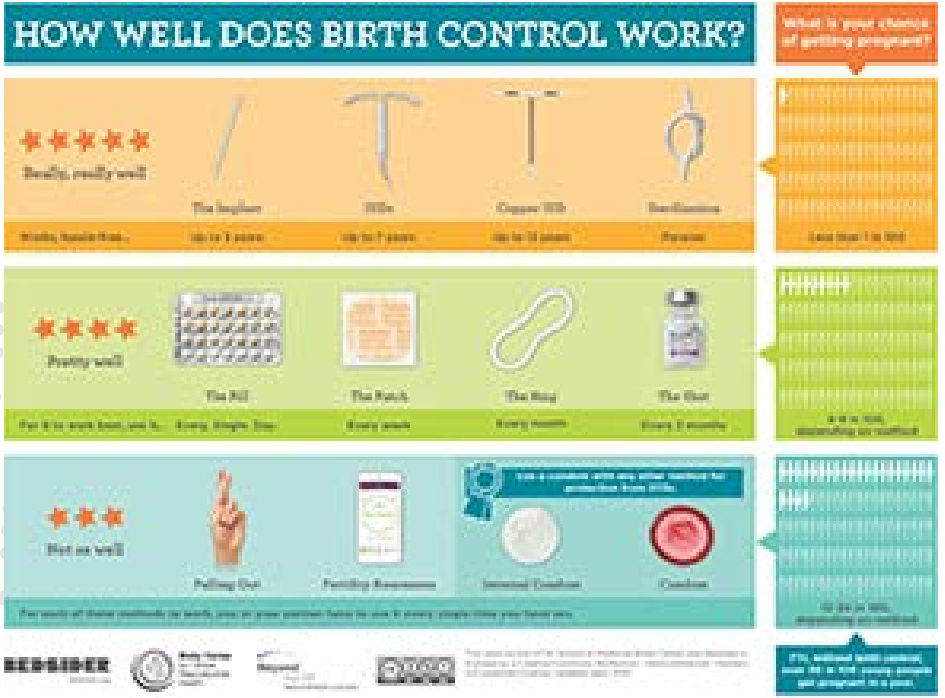

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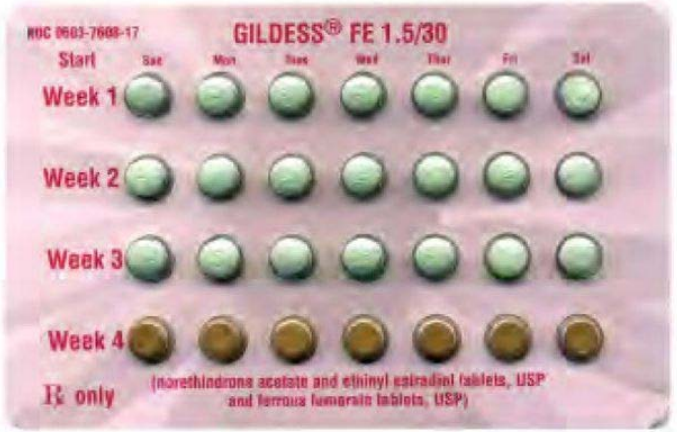
Who uses the pill?

- 4 of every 5 women [5]
- Most widely used by
  - white women
  - Women in teens and 20’s
  - never-married and cohabiting women
  - childless women
  - college graduates.[2]



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How do women get Birth Control?

- Traditional
  - Visit physician – get prescription – fill it at pharmacy every month
- Barriers
  - Physician – Have one, See one, Willing to prescribe – REPEAT EVERY YEAR
  - Pharmacy – Get prescription there, Get to the pharmacy to pick up, Afford to pay – REPEAT EVERY MONTH
- So is there a better way?
  - How can we reduce barriers

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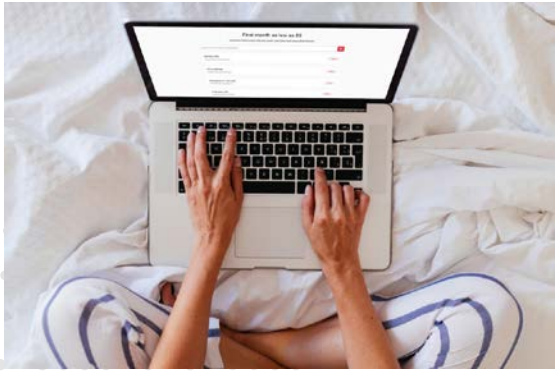
Why?



Study participants cited:

- cost barriers or lack of insurance (14%)
- challenges obtaining an appointment or getting to a clinic (13%)
- the clinician requiring a clinic visit, examination, or Pap test (13%)
- not having a regular doctor or clinic (10%)
- difficulty accessing a pharmacy (4%)

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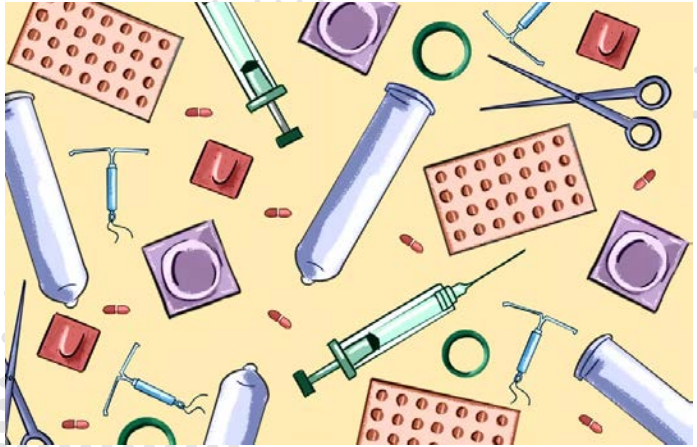
Over The Counter Access



- Endorsed by ACOG – Committee Opinion[28]
- Regulatory Change by the FDA
- ameliorate some of the aforementioned barriers
- 70% of the world already does this[29]
- But recommendations have not translated into regulatory changes
    - SO – FOR now telemedicine of birth control is the middle ground option available

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History of Birth Control Outside the Office

- 1999 – First online pharmacy
- 2005 – First ability to fill out questionnaire online and get birth control
- 2018 - 8 online companies focused on birth control alone
  - One has over 200,000 users
- But even if all 8 companies had 200,000 users –
  - Only 1.6 million women (of the ~60.3 million that need it or 2.7% of women)

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Why?

- Ease of Access
  - 24/7 access instead of 9a-5p
  - Open holidays / weekends
  - Shipped to home – no travel
  - Covered through insurance or very low cost (as low as $21 for a 3 month supply)

Availability: 24 hours

Cost: Varies

Service Areas: Worldwide

Insurance Accepted: Medicare, Medicaid, most private insurance plans

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Questions to Ask

- Do women need to see a physician to get birth control?
- Do they need an exam? Testing?
- Do they need to be seen again to get refills?
- How do we still keep women safe?

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Safety

- Concern that increased access may increase complications
  - Two studies have evaluated the safety of self-administered checklists to screen for contraindications.[12,13]
  - As effective, if not more effective, than physician or nurse practitioner screening
    - The only exception may be hypertension
- Direct-To-Consumer
  - Safety Guidelines
  - 2019 study showed that all online companies were providing appropriate screening and provision of contraceptives

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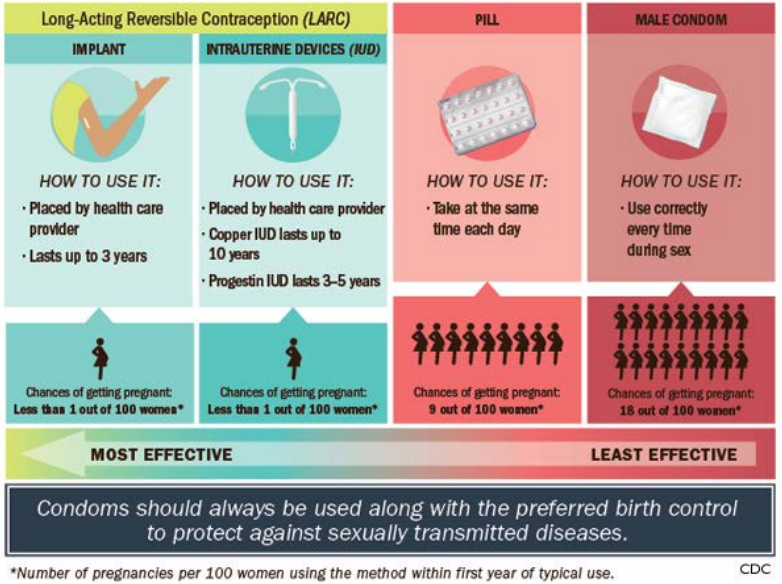
Concerns

- No physical exam
  - No vital signs
  - Can we request patients check BP

  and enter prior to ordering
- Limited Options
  - Can only prescribe limited options – “formulary restrictions”
  - Unable to do LARCs or those requiring in-person administration
  - Full counseling of all options available – not just available through site



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Off Label Use

- Multiple other reasons we prescribe birth control
  - dysmenorrhea, menorrhagia, endometriosis, menstrual-related migraines, acne, uterine leiomyomas, and polycystic ovarian syndrome
- Legal for physicians to prescribe for off label use
- Illegal to advertise/promote for off label use

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Proposed Guidelines[32]

1) Direct-to-consumer companies should offer first-line, standard-of-care treatment for appropriate indications. They may also offer second- or third-line treatments for patients with contraindications or when standard-of-care treatment fails, as long as it is safe and appropriate without an in-person visit or physical examination.

2) Direct-to-consumer companies should have a licensed health care provider with prescribing privileges review individual prescriptions.

3) Direct-to-consumer companies should have appropriate systems in place to screen people for relative and absolute contraindications, taking care to ensure these are appropriate for many levels of health and general literacy. Furthermore, we encourage direct-to-consumer companies to use validated screening questionnaires to ensure adequate screening.

4) Direct-to-consumer companies should have clear disclosures about the possible side effects of medications and have systems in place to monitor patients for these side effects.

5) Direct-to-consumer companies should use language that avoids medical jargon and is readily understandable for patients accessing materials online, bearing in mind potential limited health literacy and language barriers.

6) In the event of medical complications resulting from online therapy, there should be systems in place to refer patients for appropriate in-person routine or emergent care as needed.

7) Direct-to-consumer companies should not advertise the use of prescription medication for off-label uses and should prescribe these only if they are deemed safe by a physician or health care provider with prescribing privileges.

8) Direct-to-consumer companies should have an obstetrician–gynecologist, certified nurse-midwife, certified midwife, or similarly licensed women's health care provider in their clinical team if providing hormonal treatment to women.

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Guidelines[32]

1) Offer first-line therapy and second- or third-line treatments contraindications or when treatment fails when safe and appropriate

2) Licensed health care provider with prescribing privileges review prescriptions

3) Screen for relative and absolute contraindications, use validated screening questionnaires

4) Clear disclosures of side effects with systems to monitor for side effects

5) Use readable language online

6) systems to refer for appropriate in-person routine or emergent care

7) should not advertise the use of prescription medication for off-label use and only if safe

8) should have a licensed women's health care provider if providing hormonal treatment

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How to . . .[33]

- *28H – Twentyeight Health*
- *HeyDoctor*
- *Nurx*
- *Pandia Health*
- *The Pill Club*
- *PillPack*
- *Planned Parenthood Direct*
- *PRJKT RUBY*
- *Simple Health*
- *Hers*

Google

Birth Control + Online

Enter Info online

Screening Survey

Wait for approval

Delivered to you

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How can you help you patients?

- Willing to talk about it
- Willing to write prescriptions to access online delivery service
- Willing to write for 90 day supply, full year refills
- Willing to refill without visits, exams, tests
- Explain reasons to make appointments / annual exam
- Explain things to watch for / side effects / problems
- Counsel on LARC options

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How to stay out of trouble

- Know the laws in your state
  - Age laws for consent to sexual health services
  - Confidentiality laws
- Know the FDA laws regarding promotion of drugs
  - Monitor site advertising
- Give patients accurate information, precautions on side effects, discuss risks
  - If only in written form – make sure it is readable, comprehensive

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New Innovation Everyday

- Onsite Telemedicine
- Pharmacist Standing Prescriptions
- Over The Counter Access

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Questions?

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Resources

Guttmacher - https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states

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