Contraceptive Counseling and Fertility Awareness

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Michigan Department Health and Human Services
The Year’s Don’t Miss News

- Bayer stops selling ESSURE
- Current litigation-16,000 women
- Annovera enters the ring(segesterone acetate and ethinyl estradiol vaginal system) 3 weeks usage, wash, store for 1 week, cycle repeated for 1 year, not studied in women w/ BMI >29
What’s New in Contraception

• Contemporary Hormonal Contraception and Breast Cancer Risk
  • 1 extra case for every 7690 using hormonal contraception for 1 year
• NOWAC 4 years duration, ovarian risk is decreased 50%, no change in breast
• Increased Risk of Continuation of DMPA w/ self administration
• Relationship between Progestin Hormonal Contraception and Depression-no increased risk found
• Oral or transdermal progestin combined testosterone, noninvasive reversible male hormonal contraception
Historical Record-Setting Trends in IUD use in US

• 4.4 million women users
• 7.8% of all women
• 12% of women using contraception
• 16% of women using reversible contraception
“Repeal and Replace” increased demand for IUDs following the 2016 presidential election

- Google search (google.com/trends) 1/2004-10/2017
- OCP, condoms, IUD
- Compared monthly search volumes
- IUD searches—all time highs following 2016 election, 10-21 million excess searches
- Above and beyond what is expected based on historical trends
- 1st study to link timing of the change in administration with potential changes in medical decision making using data
<table>
<thead>
<tr>
<th>Mona Lisa NT Cu380 Mini™</th>
<th>VeraCept™</th>
<th>LevoCept™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper IUD with 380 mm² copper surface</td>
<td>Copper IUD with 175 mm² copper surface</td>
<td>52 mg levonorgestrel-releasing system</td>
</tr>
<tr>
<td>Plastic frame</td>
<td>Nitinol wire frame</td>
<td>Nitinol wire frame</td>
</tr>
<tr>
<td>24 mm (arm span) × 30 mm (vertical)</td>
<td>32 mm (arm span) × 30 mm (vertical)</td>
<td>32 mm (arm span) × 30 mm (vertical)</td>
</tr>
<tr>
<td>Diameter of insertion tube: 3.7 mm</td>
<td>Diameter of insertion tube: 3.7 mm</td>
<td>Diameter of insertion tube: 4.3 mm</td>
</tr>
<tr>
<td>Mona Lisa, N.V., Belgium</td>
<td>ContraMed, LLC, CA, USA</td>
<td>ContraMed, LLC, CA, USA</td>
</tr>
</tbody>
</table>
CHOICE Project: cost savings analysis

- 9256 women enrolled 2007-2011
- 5061 Contraceptive CHOICE Participants, current Missouri Medicaid beneficiaries
- Simulation model
- Contraceptive Cost 4 million vs 2 million
- Cost savings 5 million
Opposition to Coercive Contraception Practices and Policies

• ACOG-approved by executive board 3/2019

• ACOG opposes coercive practices that inappropriately incentivize LARC or permanent methods at expense of individual patient preferences

• Making contraception a condition of substance abuse disorder treatment

• A condition for release from confinement

• Between 1909 and 1979 20,000 people involuntarily sterilized in California

• “Can the IUD prevent poverty and save taxpayers billions?”
Effects of 2 Educational Posters on Contraceptive Knowledge and Intentions

• Comparison CDC Control and prevention poster w/ a more patient centered poster
• More effective at increasing knowledge
• Allows more time answering clients questions about specific needs versus educating on basics
# What Are My Birth Control Options?

<table>
<thead>
<tr>
<th>Least Effective</th>
<th>Using Your Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unprotected Sex</td>
<td>Use emergency contraception after unprotected sex to lower your pregnancy risk.</td>
</tr>
<tr>
<td>% Pregnant Within 1st Year</td>
<td></td>
</tr>
</tbody>
</table>

## NO BIRTH CONTROL

- **Unprotected Sex**: 85%

## NON-HORMONAL METHODS

- **Condom**: 18%
- **Withdrawal**: 22%
- **Fertility Tracking**: 24%

## HORMONAL METHODS

- **Injectable (Depo-Provera)**: 6%
- **Pill**: 9%
- **Ring**: 9%
- **Patch**: 9%

## LONG-LASTING METHODS

- **Implant** (Mirena/DMPA): 0.05%
- **IUD**: 0.2% (hormonal) / 0.8% (non-hormonal)

## SURGICAL METHODS

- **Vasectomy**: 0.1%
- **Having Tubes Tied**: 0.9%

## Most Effective

- **Always use condoms to prevent STIs.**
- **Condom**: Use during sex.
- **Withdrawal**: Ejaculation inside woman.
- **Fertility Tracking**: Abstain on fertile days.
- **Injectable (Depo-Provera)**: Injected by doctor every 3 months.
- **Pill**: Taken at the same time daily.
- **Ring (NuvaRing)**: Replace in vagina monthly.
- **Patch**: Replace sticker weekly.
- **Get inserted by doctor into arm (implant) or uterus (IUD)**. Lasts up to: 5 years.
- **Contraceptive IUD (Mirena/DMPA)**: 3-7 years.
- **Non-Hormonal IUD (ParaGard)**: 10+ years.
- **Vasectomy**: Permanent.
- **Having Tubes Tied**: Permanent.

Take to your doctor to find a method of birth control that works best for you.

These estimates are based on each birth control method's assumed effectiveness in the population, including women using their method inconsistently or incorrectly.

Self Administered Vaginal Lidocaine

- IUD insertion pain
- 20 ml 2% lidocaine gel vs placebo
- Primary outcome=pain
- 220 women randomized
- Median pain scores-not statistically significantly different
- Women are willing to wait to reduce pain
Do Women know whether their hospital is Catholic?

- What hospital would you go to for reproductive care?
- What is the religious affiliation of your hospital?
- 1/3 unaware of the Catholic affiliation of their hospital
- More Accurate identification if name has religious sound
- Call for increase transparency
Factors Associated with DMPA to adolescents by US health care providers

• 95% consider safe but 89% public and 64% private actually utilize

• Public sector factors that decrease provision
  • Setting without Title X funding
  • Primary care vs reproductive or adolescent focus
  • Providing fewer patients with contraceptive counseling

Office based factors that decrease
  specializing in ob/gyn or fp
  completing training >15 vs <5 years ago

Provider training on evidence based contraceptive counseling
Contraceptive Effect on Women’s Sexual Experiences

- Product administration
- Product awareness
- Emphasizes need to expand discussion
10 Years to a Male Contraceptive

• LA Biomed Research institute-combining-modified testosterone w/ 2 actions: 1 to decrease sperm production, 1 to preserve libido
• Male Contraceptive Clinical Trial Network: oral synthetic androgen DMAU-dimethandrolone undecanoate
• Parallel trials
• Human Reproduction 2005, multinational study 9000 men, 55% in stable relationships would try new male hormonal contraceptive if reversible
Future Directions

• Longer acting injectable: 6-month or 9-month injectable progestin
• Biodegradable implants - eliminates need for removal
New Progestin-Only Contraceptive Pill

- FDA approval 5/2019
- 1st new POP in 45 years
- Slynd
- 24/4
- 4mg drospirenone
- Higher than dose in combination ocps
- 1st year failure rate=4%
IUD Insertion-Never Sexually Active Adolescents

• No difference in insertion rates on 1st attempt
• Less likely to tolerate procedure
• More likely to have unsuccessful insertion
• Office setting 94.5% sexually active
• 52.4% never sexually active
• ACOG survey-only 43% considered appropriate for adolescents
Barriers to Abortion Training in ob/gyn residency

• Mandated by ACGME since 1995-core curriculum
• 1/3 program directors, programs deficient
• 80% face institutional or government restrictions
• Most common-hospital policy
• Opposition-most commonly hospital administration and or and l/d nurses
HIV Incidence by Contraceptive Method in High HIV Incidence Areas

- HIV seronegative women 16-35 seeking contraception
- Randomly assigned 1:1:1 DMPA, Copper IUD, LNG Implant
- 7828 women randomized
- No substantial difference in HIV risk
Planned Parenthood Ousts President 7/17/19

• Seeking a more Political Approach
• Disagreement with board over management style
• 1ST Physician to lead organization in decades
• “the best way to protect abortion care is to be clear that it is not a political issue but a health care one, and that we can expand support for reproductive rights”
• Board felt it needed a more aggressive political leader
• Ohio, Alabama, Indiana, Louisiana, Missouri-restricted abortion access as they take aim at Roe v Wade
My Birth Control - Before the Family Planning Visit

- Need for improvement in patient centered and comprehensiveness of contraceptive counseling
- Tablet designed decision support tool to improve women’s experience of contraceptive counseling
- Help women select methods consistent with their values and preferences
- No effect on continuation
- Enhanced contraceptive counseling experience and informed decision making as well as contraceptive knowledge
Influence of Preconception Smoking on Birth Defect Risk

• No prior studies on influence of periconception smoking and birth defects
• Population based retrospective cohort
• Smoked during preconception 3 months before /not 1st trimester
• Smoked during preconception 3 months plus 1st trimester
• Referent group-nonsmokers
• Smoking during preconception had a 40% increase risk of gastroschisis
Pharmacist Prescribed Birth Control

- Oregon
- Increased access: 90% of all Americans live within 5 miles of a pharmacy
- Decreased cost Jan 2016-December 2017, 51 averted pregnancies
- 1.6 million dollars in savings
- 162 pharmacists/367 women: Oregon Health Plan
- 1313 filled prescriptions
- 10% of women under this plan received rx from a pharmacist
Justice Based Intersectional Approach to research on contraception and disability

- 12% reprod age women: 1 or more disabilities
- Wide spectrum of functional abilities
- Higher sterilization, LARC, and hysterectomy rates
- Reproductive justice - extends beyond abortion rights
- United Nations Convention on the Rights of Persons with Disabilities
- American with Disabilities Act
Adolescent Dilemmas

- 15 yo, sexually active, requests IUD, parents can’t know
- Michigan: STI services, contraception
- Abortion - parental consent
What happens beyond the clinic?

- Political threats: literature on home based abortion is lacking in North America.
- Anonymous online survey: community engagement, home abortion network.
- 75 respondents: 73% in 19 states, 24% 4 Canadian provinces serving 39 states and territories and 8 Canadian provinces.
- Average in practice 5 years, served between 1 and 40 people in last year.
- Herbs and misoprostol most commonly used: 91-100% effective.
- 88% want to collaborate with clinics.
2 Free Contraceptive Apps for Providers of Family Planning

• CDC MEC app

• iContraception app - allows user to input multiple clinical and demographic characteristics to determine an individual’s eligibility for a specific method (it incorporates a clinical decision tree)
What is Natural Cycles?
Natural Cycles

• 1st Digital method of birth control cleared by FDA
• An app
• Fertility awareness based contraceptive
• Uses a sophisticated algorithm to determine fertility based on bbt
• Can be used for pregnancy planning
FAB-Fertility Awareness Based Methods

• Periodicity of fertility/infertility
• A single ovulation each cycle
• Limited viability of ovum – can only be fertilized 12-24 hours post release
• Limited viability of sperm - 3-5 days in cervical mucous and upper genital tract
• A woman’s ability to monitor cycle length and/or cycle-related signs and symptoms
Reasons Women Choose FAB

• Concern about health consequences and side effects of other contraceptive methods
• Religious constraints—a smaller role
• 1% utilization US
• 3.6% worldwide
• Possible explanations: lack of information, inconvenience, concerns about efficacy
Lack of Information re FAB Methods

• Absence of profitable product to advertise and sell
• Provider concerns re efficacy
• Time constraints re counseling
• Survey of 500 physicians: 1/3 no mention of FAB during counseling, 40% only for selected populations
Convenience

- Labor intensive: provider-education
- Client: ongoing effort/impact on spontaneity
- Potential for digital applications (smart phone apps)
Fertile Days

- From 5 days before ovulation to 24 hours after ovulation

PROBABILITIES OF PREGNANCY
- 4% 5 days before ovulation
- 25-28% 2 days preceding ovulation
- 8-10% during the 24 hours after ovulation
- 0% remainder of cycle
Fertile Window

- Cycle length
- Cervical secretions: abundant clear wet sticky
- Basal Body temperature: 0.5 degree elevation in luteal phase- retrospective identification of ovulation, signifies end of fertile phase
Possibility of pregnancy from intercourse on days relative to ovulation

Ideal Candidates

• Women who desire alternatives to other methods
• Able to comply
• Willing to abstain or use barrier methods during fertile times
• Supportive partner
Relative Contraindications to FAB

- Recent menarche, childbirth, discontinuation of some hormonal method
- Perimenopause
- Breastfeeding
- Instructions have been developed for these “special circumstances”
  - *The Art of Natural Family Planning Postpartum Guide and Premenopause Guide*- available from the Couple to Couple League
Standard Days Method

• Probability of pregnancy with respect to ovulation
• Probability ovulation occurs near midpoint of cycle
• Easiest to teach
• Fewest days requiring abstinence or barrier contraception
• Appropriate for cycles between 26-32 days (78%)
• Correct use <5, typical use 12 pregnancies per 100 women per year
• Typical education time - 20 min
• Visual tools: Cycle Beads or Icyclebeads app
Probability of ovulation relative to midpoint of the cycle

Analysis of WHO 1981 data.
Reproduced with permission from the Institute for Reproductive Health, Georgetown University.
CycleBeads® used with the standard days method

The red bead marks the first day of your menstrual period. On the day your period starts, move the ring to the red bead. Continue moving the ring one bead each day.

If your period does not start by the day after you move the ring to the last brown bead, your cycle is longer than 32 days.

The dark brown bead helps you know if your cycle is less than 26 days long. If your period starts before you move the ring to the dark brown bead, your cycle is shorter than 26 days.

All white beads mark the days when you are likely to get pregnant. Do not have unprotected sex on the white bead days if you do not want to get pregnant.

All brown beads mark the days when you are not likely to get pregnant if you have unprotected sex.

Reproduced with permission from: The Institute for Reproductive Health, Georgetown University.
After the woman enters the start date of her most recent period into her private account, the web app shows her where she is in her cycle and whether she is on a day when pregnancy is possible (fertile day) or unlikely (non-fertile day) according to the Standard Days Method of family planning. The information is provided both on a color coded calendar and on a virtual representation of CycleBeads®. She can also receive alerts telling her the day is a fertile or non-fertile day and reminding her when she is about to get her next period.

Copyright © 2002-2012 Cycle Technologies. Photo reproduced with permission.
### Criteria for starting the standard days method

<table>
<thead>
<tr>
<th>Women whose menstrual cycles are usually between 26 and 32 days</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of last period known</strong></td>
</tr>
<tr>
<td>Start immediately</td>
</tr>
<tr>
<td><strong>Date of last period unknown</strong></td>
</tr>
<tr>
<td>Start on first day of next period</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Special circumstances</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Postpartum/breastfeeding</strong></td>
</tr>
<tr>
<td>Wait for at least 4 periods</td>
</tr>
<tr>
<td>Start after two most recent periods are about a month apart</td>
</tr>
<tr>
<td><strong>Three-month DMPA injection used for contraception</strong></td>
</tr>
<tr>
<td>Wait for at least 90 days after last injection</td>
</tr>
<tr>
<td>Start after two most recent periods are about a month apart</td>
</tr>
<tr>
<td><strong>Pill, patch, implant, emergency contraception, intrauterine contraception, miscarriage or abortion</strong></td>
</tr>
<tr>
<td>Cycles before using method or pregnancy were 26 to 32 days long</td>
</tr>
<tr>
<td>Start on first day of next period</td>
</tr>
</tbody>
</table>

DMPA: depot-medroxyprogesterone acetate.

Reproduced with permission from the Institute for Reproductive Health, Georgetown University.
Cervical Mucous or Ovulation Method

• Need to avoid intercourse 14-17 days of each cycle
• Billings/Creighton Methods
• Efficacy WHO 3/100 correct use vs 23/100 real life use
• Two Day Method - avoid intercourse on all days w/secrections and next day 450 women up to 13 cycles pregnancy rate correct use-3.5/100 women years vs typical use <14/100 women years - rationale is its simplicity
Two day method algorithm

Did I note secretions today?

No

Did I note secretions yesterday?

Yes

I can get pregnant today

No

Pregnancy not likely

Yes

I can get pregnant today

Multimodal Methods

- Symptothermal Method - slippery mucous begins, thermal rise ends
  fertile period: cumbersome - no advantage
- Mini-microscopes (PG53, PC2000, Maybe Baby)
- Hand held computer (Babycomp, Ladycomp, Bioself 2000, Cyclotest 2 Plus) Marquette
- Clearblue Easy Fertility Monitor - best when used with a calendar based method
- Dynamic Optimal Timing (DOT)
Symptothermal chart

Natural Family Planning Chart

Month & Year: May '98

EXAMPLE

- **Cycle Length:**
  - Fertile Days Indicate:
  - Days 1-14: No intercourse
  - Days 15-28: Interceptive
  - Days 29-1: Avoid intercourse

- **Temperature:**
  - Time of taking test positive
  - Days 1-5, 9, 13, 17

- **Menstrual History:**
  - Ovulation
  - Menstrual
  - Menopause
  - Amenorrhea

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Historical Methods

• Calendar rhythm: determine length of last 6 cycles
  • Shortest -18
  • Longest -11
  • Determines fertile period
  • Requires mathematical calculations monthly

• BBT avoid unprotected intercourse beginning of cycle until 3 days of temp elevation-not popular
On Line Resources

• Standard and 2 day methods www.irh.org
• Billings ovulation method www.thebillingsmethod.org
• Creighton model www.creightonmodel.org
• Symptothermal method www.fertilityuk.org
• Marquette model http://nfp.Marquette.edu
FAB-Fertility Awareness Based Methods

• Periodicity of fertility/infertility
• A single ovulation each cycle
• Limited viability of ovum – can only be fertilized 12-24 hours post release
• Limited viability of sperm-3-5 days in cervical mucous and upper genital tract
• A woman’s ability to monitor cycle length and/or cycle-related signs and symptoms
<table>
<thead>
<tr>
<th>Method</th>
<th>Typical use</th>
<th>Correct use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Most effective</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intrauterine device</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Copper T or Mirena</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Etinogestrol implant</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Effective</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depo-Provera (DMPA) injection</td>
<td>6</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Contraceptive patch</td>
<td>9</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Contraceptive pills</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Progestin-only or combination estrogen-progestin</td>
<td>9</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Contraceptive vaginal ring</td>
<td>9</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td><strong>Least effective</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condom</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>18</td>
<td>2</td>
</tr>
<tr>
<td>Female</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td>Sponge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous births</td>
<td>24</td>
<td>20</td>
</tr>
<tr>
<td>No previous births</td>
<td>12</td>
<td>9</td>
</tr>
<tr>
<td>Cervical cap (FemCap)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No previous births</td>
<td>14</td>
<td>N/A</td>
</tr>
<tr>
<td>Previous births</td>
<td>20</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Fertility awareness-based methods</strong></td>
<td></td>
<td></td>
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<tr>
<td>Cervical mucus or ovulation</td>
<td>24</td>
<td>3</td>
</tr>
<tr>
<td>Symptothermal</td>
<td>24</td>
<td>0.4</td>
</tr>
<tr>
<td>TwoDay</td>
<td>24</td>
<td>4</td>
</tr>
<tr>
<td>Standards days</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>22</td>
<td>4</td>
</tr>
<tr>
<td>Spermicides</td>
<td>28</td>
<td>18</td>
</tr>
<tr>
<td>No method</td>
<td>85</td>
<td>85</td>
</tr>
</tbody>
</table>

Data refer to number of pregnancies per 100 women during first year of use.

Typical use: Refers to failure rates for women and men whose use is not consistent or always correct.

Correct use: Refers to failure rates for those whose use is consistent and always correct.

N/A: Indicates data are not available.

Data from:
Cervical secretion variations during a menstrual cycle

Record date you started your period

Look for the day of the week you started your period and begin marking on that day.

• Mark a the days you have your period
• Mark x the days you do not have secretions
• Mark X the days you have secretions

Remember to mark every evening before going to bed.

When can you get pregnant?

Yesterday
Today
Pregnancy is likely if you marked X today or yesterday.
To prevent pregnancy, do not have unprotected sex.

When is pregnancy unlikely?

Pregnancy is unlikely when you are having your period, or when you do not have secretions today AND yesterday.

When you start your next period, begin marking on a new card.

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**Example of cervical secretion variations during a menstrual cycle**

| Cycle day |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 |
| **Fertile** |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **Date** |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **Cervical secretions** |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| (Feel, look and touch) |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Wet, slippery, transparent or stretchy |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Thick, cloudy or sticky |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Dry, no secretions seen or felt |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Period |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

Unprotected intercourse should be avoided during menses, on preovulatory days following days with intercourse, on all days with wet, slippery, transparent or stretchy secretions, and for four days past the last day with wet secretions.

*Modified with permission from: The Institute for Reproductive Health, Georgetown University.*
What is Natural Cycles?

The Daily Routine

1. Wake up and measure BBT temperature sublingually

2. Record data

3. Check fertility status

BBT, basal body temperature.

Who are the Users and why do they use Natural Cycles?
Unmet Need in Contraception

Effectiveness and discontinuation rates of the wide range of available contraceptive methods vary greatly\(^1\)-\(^3\)

Intolerance of side effects and health risks are common reasons women change contraceptive methods

The contraceptive priorities of women change throughout their lives; a wide informed choice of methods is important to suit these changing needs.\(^1\),\(^2\),\(^7\),\(^8\)

Traditional fertility awareness-based contraceptive methods can be effective when used perfectly but effectiveness is reduced if not used optimally (<5% vs ~24% of unintended pregnancies/year, respectively)\(^3\),\(^9\)

Smartphone app technology may provide an opportunity to deliver contraceptive information to women, to help in the analysis and interpretation of personalised data\(^10\)

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Unmet Need

Contraception: State of the Art

Key Message: More options are needed for women seeking effective, non-hormonal and non-invasive contraception.

From ‘Contraceptive Technology: 21st Edition’
Women's needs over a reproductive lifetime

A wide informed choice of methods is important to suit the changing contraceptive needs of women throughout their lives.

Changing contraceptive method:
4–36% of oral hormone contraceptive users are likely to change method.

Reasons include:
1. Intolerance/side-effects
2. Health risks
3. Changing needs

Desire for:
Hormone-free methods, e.g. FABMs.

Traditional FABMs effective when used perfectly (<5% unintended pregnancies/year vs ≤34% with typical use).

Enhance fertility awareness:
Most women have no (38%) or poor (48%) fertility awareness.
37% of women have actively tried to improve their fertility awareness.

References:
Natural Cycles: The Only Certified Digital FABM

Increases contraceptive choice and fertility awareness for women and their partners

- Natural Cycles is a fertility awareness-based method (FABM) of digital contraception that uses a sophisticated algorithm to accurately predict personalised daily fertility (can also be used for pregnancy planning).
- The app is backed by clinical evidence and had been CE certified in Europe as a class IIb medical device intended to be used for contraception.
- Fertility indicators utilised include:
  - Temperature
  - Menstruation
  - LH (optional)

LH, luteinizing hormones
What is Natural Cycles?

The Daily Routine\(^1,2\)

1. Wake up and measure BBT temperature sublingually

2. Record data

3. Check fertility status

BBT, basal body temperature.
What is Natural Cycles?

Fertile (Red) and Non-Fertile (Green) Days

The Natural Cycles algorithm determines whether there is a risk of conception on a specific day

Green day = Not fertile

Red day = Fertile

In order to prevent conception, women must abstain or use protection (e.g. condoms)

Natural Cycles Users

The Natural Cycles User

- Survey of Natural Cycles Users (June 2018, live for 2 weeks)
- Inclusion Criteria: Using in ‘prevent a pregnancy’ mode for at least 3 months
- 6194 respondents (10% response rate)

Natural Cycles may be suitable for women who are looking for a natural method of contraception and have a lifestyle that enables them to take their temperature first thing most mornings
### The Natural Cycles User: Previous Contraception

<table>
<thead>
<tr>
<th>What method of contraception did you use before Natural Cycles?</th>
<th>Number of Women</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hormonal contraception</strong></td>
<td></td>
</tr>
<tr>
<td>Pill (oral contraceptive)</td>
<td>2863 (46.2%)</td>
</tr>
<tr>
<td>Injection, Implant, Patch or Ring</td>
<td>490 (7.9%)</td>
</tr>
<tr>
<td>Hormonal IUD (hormonal coil)</td>
<td>334 (5.4%)</td>
</tr>
<tr>
<td><strong>Hormonal contraception (All)</strong></td>
<td>3687 (59.5%)</td>
</tr>
<tr>
<td><strong>Non hormonal contraception</strong></td>
<td></td>
</tr>
<tr>
<td>Male condom</td>
<td>1097 (17.7%)</td>
</tr>
<tr>
<td>No sex or Withdrawal method</td>
<td>542 (8.7%)</td>
</tr>
<tr>
<td>Copper IUD (non-hormonal coil)</td>
<td>284 (4.6%)</td>
</tr>
<tr>
<td>Nothing</td>
<td>279 (4.5%)</td>
</tr>
<tr>
<td>Natural Family Planning</td>
<td>161 (2.6%)</td>
</tr>
<tr>
<td>Female condom or Diaphragm</td>
<td>23 (0.4%)</td>
</tr>
<tr>
<td><strong>Non hormonal contraception (All)</strong></td>
<td>2386 (38.5%)</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>121 (2.0%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>6196</td>
</tr>
</tbody>
</table>
Why do Women Switch to Natural Cycles?

Reason for choosing Natural Cycles? (Previous Hormonal Contraception)

→ 41% I want to understand better my body and my cycle
→ 32% I was suffering from side effects
→ 15% Worried about long term health risks of hormonal contraception

Reason for choosing Natural Cycles? (Previous Non-Hormonal Contraception)

→ 26% I want to understand better my body and my cycle
→ 22% I want to reduce my risk of unintended pregnancy
→ 18% I want to use less condoms

Many of our users have, for whatever reason, chosen to discontinue hormonal contraception - for example, if they are considering a pregnancy in the near future and wish to get to know their natural cycles. Many others were previously relying on less effective methods of contraception such as withdrawal or condoms.
What contraception would you choose if Natural Cycles had not been an option?

Cohort: Previous Hormonal Contraceptive Users
Natural Cycles Users

What contraception would you choose if Natural Cycles had not been an option?

Cohort: Previous Non-Hormonal Contraceptive Users

![Chart showing contraception choices](chart.png)
Mechanism of Action

Natural Cycles: Daily Use

The user measures her temperature sublingually first thing every morning.

Temperature data is inputted manually into the app.

The algorithm analyses the temperature data to determine if the user is within her fertile window.

Fertility and the Menstrual Cycle


- Temperature acts as an indirect measure of progesterone level\(^1\)
- Increased LH levels trigger ovulation\(^1-3\)
- Conception can occur only within ~24 hours of ovulation\(^3\)
  - Sexual intercourse up to 5 days prior to ovulation can result in pregnancy due to ability of sperm to survive\(^3\)
  - Different days in the fertile window have different probabilities of conception\(^2,3\)

\(\text{LH, luteinizing hormone}\)

\(\text{Green = non-fertile days}\)
\(\text{Red = fertile days}\)
How Natural Cycles Maps out the Fertile Window

The algorithm predicts ovulation using weighted averages of previous ovulation days

- As more of an individual’s cycles are known, the SD becomes smaller, leading to fewer days indicated as ‘fertile days’

Safety margin added:
- Allows for uncertainty in ovulation day prediction (based on individual’s variance)

Minimum 6-day fertile window identified:
- 5 days pre-ovulation (sperm survival)
- 1 day post-ovulation (viability of ovum)
Mechanism of Action

Ovulation Detection

N=317 users and 1501 menstrual cycles

Inclusion Criteria: Women 18–40 years (sexually active) using only Natural Cycles to prevent pregnancy. Temperature data recorded for ≥30 days

Mean ± SD delay from the first positive ovulation test to the Natural Cycles estimation was 1.9 ± 1.4 days

Mean ± SD delay associated with ultrasound detection was 1.5 ± 0.6 days

Non-fertile days were falsely assigned within the fertile window in 0.05% of cases

The proportion of green (non-fertile) days per cycle was, on average, 55–61% after 3 months

Natural Cycles Determines Fertility Status By:

1. **Identifying the users day of ovulation**
   - By analysing a series of BBT readings and identifying the small but definite change that happens at the time of ovulation
   - The algorithm is able to detect (and discard) abnormal temperature readings.

2. **Mapping out the fertile window**
   - Based on the survival of sperm and life span of the ovum, with extra days added to account for an individual users’ variation in ovulation day
   - The app also learns the individual user’s pattern to enable it to predict the ovulation and fertile days in upcoming cycles

BBT, basal body temperature.
### Mechanism of Action

**Natural Cycles Detects Ovulation Based on User Data**

<table>
<thead>
<tr>
<th>Data input by the user</th>
<th>In-app calculations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily temperature readings</td>
<td>• Recent temperature vs luteal phase temperature</td>
</tr>
<tr>
<td>Monthly menstruation data</td>
<td>• Luteal vs follicular phase temperature</td>
</tr>
<tr>
<td>LH/ovulation tests*</td>
<td>• Current stage of cycle</td>
</tr>
<tr>
<td>Collected/input individual cycle data</td>
<td>• Time point when ovulation usually occurs</td>
</tr>
</tbody>
</table>

*Includes:
- Previous use of hormonal contraception
- Recent pregnancy
- Cycle length/frequency
- Last menstruation date

The Natural Cycles app computes uncertainties around these parameters to accurately detect ovulation.

**Assessment:**
- has ovulation occurred?
  - Yes/No

*Optional
LH, luteinising hormone
### Natural Cycles vs Traditional FABMs

<table>
<thead>
<tr>
<th>Mechanism of Action</th>
<th>Ovulation Detection</th>
<th>Fertile Days Prediction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Natural Cycles</strong>&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>Algorithm detects BBT rise; performs calculations to allow for temperature fluctuations</td>
<td>Uses weighted BBT averages from prior cycles + extra fertile days to allow for variation in individual cycles</td>
</tr>
<tr>
<td><strong>Standard Days</strong>&lt;sup&gt;3&lt;/sup&gt;</td>
<td>None</td>
<td>Uses standard rule to determine fertile days in women with regular cycles</td>
</tr>
<tr>
<td><strong>Calendar method</strong>&lt;sup&gt;4&lt;/sup&gt;</td>
<td>None</td>
<td>Uses charted previous menstrual cycle length data</td>
</tr>
<tr>
<td><strong>Cervical Mucous Method</strong>&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Changes in cervical mucus</td>
<td>Uses current cycle increase in cervical mucus volume and fluidity</td>
</tr>
<tr>
<td><strong>Basal Body Temperature</strong>&lt;sup&gt;3 Method&lt;/sup&gt;</td>
<td>BBT rise</td>
<td>Uses charted previous BBT ovulation detection data</td>
</tr>
<tr>
<td><strong>Symptothermal Method</strong>&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Combination of BBT and cervical mucus methods</td>
<td>Uses charted previous BBT data and increase in cervical mucus volume and fluidity</td>
</tr>
<tr>
<td><strong>Biochemical fertility monitoring</strong>&lt;sup&gt;5&lt;/sup&gt;</td>
<td><em>Test strips detect the presence of hormones (e.g. LH) in urine</em></td>
<td>Uses current cycle rise in urinary hormones</td>
</tr>
</tbody>
</table>

**BBT, basal body temperature; FABM, fertility awareness-based methods; LH, luteinizing hormone**

*Non-traditional FABM

Real-World Effectiveness Study

- N=22,785 users and 18,548 woman-years, published in Contraception 2017\(^1\)
- Inclusion Criteria: Women 18+ years who had registered to use Natural Cycles (Aug 2014–Aug 2016) and recorded data for ≥20 days; women used Natural Cycles for an average of 9.8 months\(^1\)
- Life table analysis calculated a 13-cycle pregnancy probability of 8.3% (95% CI: 0.5–1.5) with typical use

<table>
<thead>
<tr>
<th></th>
<th>Pearl Index*</th>
<th>Pregnancies</th>
<th>Woman-years</th>
<th>Cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perfect Use</td>
<td>1.0</td>
<td>17</td>
<td>1,661</td>
<td>21,597</td>
</tr>
<tr>
<td>Typical Use</td>
<td>6.9</td>
<td>1,273</td>
<td>18,548</td>
<td>224,563</td>
</tr>
</tbody>
</table>
Impact of previous method of contraception

- **n=16,331** Natural Cycles users from Sweden
  
- Women who had previously used any non-hormonal method (n=6,147) had a 13-cycle failure rate of 4.8% ± 0.9%
  
- Women who had recently used any hormonal method (n=5,218) had a 13-cycle failure rate of 8.2% ± 1.0%

Natural Cycles users who previously used condoms had the highest effectiveness rate (n=2,411, PI 3.5 ± 0.5, 13 cycle failure rate 3.6% ± 1.0%)

Those from contraceptive pills had the lowest (n=4,023, PI 8.1 ± 0.6, 13 cycle failure rate 8.7% ± 1.3%)
Natural Cycles Effectiveness in Women With Irregular and Short Cycles

- Prospective observational study (women 18–45 years; data for ≥20 days; 30% of users contributed >1 year of data)
- Cycle length had no significant effect on the contraceptive effectiveness of Natural Cycles
- Cycle-by-cycle effectiveness of Natural Cycles is not reduced for women with irregular menstrual cycles

Non-pregnancy probability irregular vs regular users (6 months observation)
Cycle length had no significant effect on the contraceptive effectiveness of Natural Cycles.

Cycle-by-cycle effectiveness of Natural Cycles is not reduced for women with short menstrual cycles.

Women with irregular/short cycles typically experience more fertile (red) days, potentially contributing to the higher discontinuation rate in this group.
<table>
<thead>
<tr>
<th>Rating</th>
<th>Review</th>
</tr>
</thead>
</table>
| ★★★★★ | **“Revolutionary”**  
“Amazing app, never felt more in-control of my body. Natural Cycles is a contraceptive that has freed me from the awful side effects of contraceptives that were prescribed by different GPs. I am more educated on cycles and my body, I feel empowered. Even better, I no longer suffer from chronic pain, anxiety and weight gain. This should be offered on the NHS.” |
| ★★★★★ | **“Empowering”**  
“Easy to use, habitual in the morning although it take a few seconds longer than the pill. Definitely feel more in-tune with my body, healthier and more feminine. I can even share it with my partner so he knows when to buy chocolates and when to buy prosecco!” |
| ★★★★★ | **“Yayyyyy”**  
“Literally changed my life! I have been trying over 20 different pills the past year and it was hell. My body hated all of them. This has given me the freedom from all those horrible side effects. Best solution ever. Thank you” |
| ★★★★★ | **“Off birth control pills after 15 years”**  
“Well designed app backed by real science. I’m a doctor and I have read the studies and recommended it to all my female friends. (not my patients since it’s not officially approved in Canada yet).” |
User Ratings

Apple App Store: Customer Ratings

Overall: ★★★★★
(based on over 8,000 reviews) 4.6/5 stars

“I love this form of birth control! It’s liberating and easy and accurate!”
“I am 24 and have been on and off birth control since I was 18. I’ve never really liked the idea of being on long-term (or short-term, honestly) hormonal birth controls. I tried a copper IUD but my uterus rejected it. I was so close to getting an implant because I was getting pretty bad at taking my pill but then I heard about this app.”

“Answer to my prayers!”
“Okay that may be a bit dramatic... but seriously it is how I feel about this app. I’ve only recently become sexually active and my friends were like you better go on the pill. And I’ve honestly always been pressure and questioned for not going on the pill. Yes my period is not my favorite thing but I feel like it’s my body doing it’s thing.”

“Happy doesn’t cover it”
“I’m thrilled to have found this app! I ran across it in a fandom Facebook article about a month before it was accepted by the US and waited impatiently for it to be approved! I’m allergic to birth control, literally, I get very sick and not to be TMI but on it I’m constantly dealing with yeast infection issues and migraines.”
Google Play App: Customer Reviews

User Ratings

4.6

5 stars: 4,015
4 stars: 1,032
3 stars: 136
2 stars: 63
1 star: 233
5,479 total reviews

“This app is great for getting to know your cycle well and one can use it for....”

“This really was easy to use and I love getting to know my body better. I really wish that I had...”

“Wish I’d got the app much sooner! Only been taking temperatures for one cycle so...”

“It feels so empowering to be educated and congratulated for difference aspects of my cycle....”