Fertility Apps: Concerns & Opportunities

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Objectives

• Understand the existing evidence landscape of fertility technology and emerging research

• Compare and contrast various aspects of different fertility apps that could be included in patient education and decision-making

• Opportunity to discuss concerns and challenges around fertility technology with others
“FEMTECH”

Digital or software-based products/services including mobile apps, wearables, web-connected or paired medical devices, hygiene products, etc. that are aimed at reproductive health

Ida Tin is credited with coining the term femtech, that is technology which addresses women's biological needs. It's expected to be worth $50 billion
Normal Contraceptive Drug Development Cycle

Timeframe: ~10-12 years; Cost: ~$2.6 billion

Source: “Biopharmaceutical Research and Development: The process behind new medicines.”
www.PHRMA.org
FUNDING for Reproductive Health

National Institutes of Health 2020

$958 Million Allocated \(^a\)

(contraception/reproductive health/infertility/pregnancy)

FEMTECH Industry 2020

$1.3 Billion Projected \(^b\)

\(^a\) National Institutes of Health: https://report.nih.gov/categorical_spending.aspx#legend

\(^b\) Forbes Magazine. “Is Technology Pink? Investments in Femtech to cross the $1.3 Billion Mark in 2020”
Fertility Apps

* Most prolific area of femtech
* Low barrier to entry
* Shorter lifespan (<1 in 10,000 apps will be financially profitable)

A screenshot of the beginning of an app I created in a class in 2013... it was a picture of a cat that would purr when you touched it....
Have an idea

Develop the design for your idea

Build the app

Publish it on the app marketplace

Consider whether you should get FDA approval

Timeframe: ~2-10 weeks; Cost: ~$5,000-500,000

Source: G2-Learning Hub: https://learn.g2.com/how-much-does-it-cost-to-make-an-app
FDA Regulation of Apps

WHICH LAWS APPLY TO MY MOBILE HEALTH APP?

1. Do you create, receive, maintain, or transmit identifiable health information?
   - YES
     - GO TO QUESTION 2 to determine if HIPAA applies.
   - NO

2. Are you a health care provider or health plan?
   - YES
   - NO
     - GO TO QUESTION 3 to see if HIPAA applies.

3. Do consumers need a prescription to access your app?
   - YES
   - NO
     - GO TO QUESTION 4 to see if HIPAA applies.
5. Is your app intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease?

- **YES**

  Your app is a medical device subject to the FD&C Act.

  [GO TO QUESTION 6](#) to see if the FDA intends to apply its regulatory oversight for your type of app.

- **NO**

6. Does your app pose “minimal risk” to a user?

According to the FDA, “minimal risk” apps are those that are only intended for one or more of the following:

- helping users self-manage their disease or condition without providing specific treatment suggestions;
- providing users with simple tools to organize and track their health information;
- providing easy access to information related to health conditions or treatments;
- helping users document, show or communicate potential medical conditions to health care providers;
- automating simple tasks for health care providers;
- enabling users or providers to interact with Personal Health Records (PHR) or Electronic Health Record (EHR) systems; and
- transferring, storing, converting format or displaying medical device data, as defined by the FDA's Medical Device Data Systems regulations.

- **YES**

  The FDA considers your app to be of minimal risk, and does not intend to enforce compliance with its regulatory requirements.

  [GO TO QUESTION 8](#) to see if the FTC Act applies.

- **NO**
Fertility Apps: 4 Categories for Consideration

- Menstrual cycle trackers
- Fertility apps
- Fertility awareness-method charting apps
- App-based FAM
Menstrual Cycle Trackers

- Help keep track of menstrual cycle/pill reminders
- Don’t provide predictions/feedback
- May allow “notes” around signs or symptoms experienced during the menstrual cycle
- Typically very simple or part of functionality in a larger health app
“Fertility” Tracking Apps

- Offers to help people track/plan and sometimes prevent pregnancy
- Users select their goal and are given different information based on the intent
- Generally marketed toward conception as the primary market
- Often provides estimates or predictors of the “fertile window” or “ovulation” (regardless of setting)
- Extra features – community boards,
Fertility Awareness-Based Method (FABM) Charting Apps

- Electronic charting functions for existing FABM methods
- User needs to know how to use the particular method in order to input and interpret their data
- Meant to replace paper charting (and add reminder notifications!)
- May have additional technology add-ons
App-Based Fertility Awareness Methods

- Considered “new” fertility awareness-based methods (an expansion of the contraceptive offering)

- Rely on an underlying algorithms (+ possibly another technological device, such as a thermometer) to determine fertile window

- May also offer to help people achieve pregnancy or track cycles
WHAT IS IT?
WHAT IS IT?

Avoiding pregnancy
Gain insights on your body and fertility patterns to avoid pregnancy.

Trying to conceive
Receive accurate predictions on your fertility to boost your chances of pregnancy.

I'm pregnant!
Turn off your period predictions now. Continue your journey with Nurture.

I'm healing from loss
Find resources and connect with a community that understands your loss.
Why does my fertile window move suddenly throughout the month?

Support Team
9 months ago · Updated

In your fertile window adjusts retroactively in response to your logs. These types of tracking are by nature "retroactive" in the sense that the temperature spike or the peak OPK result shows that you have ovulated the day before.

As you enter data into uses it to calculate and adjust the fertile window to match what it has learned. The algorithm weighs all of the data you enter - periods, OPKs, BBTs - when making its predictions. Occasionally there is a conflict between the data, for example, an OPK may indicate you ovulated on one particular day, while your BBT indicates another, or you enter a period that makes it unlikely that the original prediction was correct. When that happens, the algorithm will calculate the most likely fertile window based on all the data together, and as a result, you may see the fertile window change.
Reality
Challenge 1: Quality

How do I know if the information I’m being provided is accurate?
Current Research

CONSENSUS on App Quality: NOT SO GREAT

Plausibility of Menstrual Cycle Apps Claiming to Support Conception

Michelle Moglia; Henry Nguyen; Kathy Chyjek; Katherine Chen; Paula Castaño;

The Performance of Fertility Awareness-based Method Apps Marketed to Avoid Pregnancy

Marguerite Duane, Alison Contreras, Elizabeth T. Jensen and Amina White

Can apps and calendar methods predict ovulation with accuracy?

Sarah Johnson, Lorrae Marriott & Michael Zinaman

The Accuracy of Web Sites and Cellular Phone Applications in Predicting the Fertile Window

Setton, Robert MD; Tierney, Christina MD; Tsai, Tony MD

Obstetrics & Gynecology: July 2016 - Volume 128 - Issue 1 - p 58-63
doi: 10.1097/AOG.0000000000001341
Getting Curious

Incorporating questions about app use into reproductive health visits

“Are you using any app or other approach to keep track of your menstrual cycle or reproductive health?”

“What are you currently using?”
Possible Discussion Points With Clients

• What is the main purpose for using XX app?
  (tracking? help with a particular outcome? FABM charting? contraception?)

• How important is it to the client that the information be accurate?
  
  • **Avoiding pregnancy**: How important is it to the client to avoid a pregnancy right now?
  
  • **Achieving a pregnancy**: How important is it to the client to achieve a pregnancy right now?
  
  • **Tracking/Repro Health**: What would a client feel/do if the app told them that something was wrong with their health/cycle?
Additional Quality Discussion Points

• Does the app provide interpretations or predictions based on user data?
  • Do they provide publicly-available data on how that interpretation was developed?

• Do the predictions seem “too good to be true”?

• Has anyone evaluated whether the predictions/interpretations are accurate?
Examples: Apps With Citations/References About Efficacy

Did you know that we have a dedicated team committed to research? We regularly contribute with scientific involvement in the historically overlooked area of fertility and women’s health. Check out our published studies on Natural Cycles below:

1. Perfect-use and typical-use Pearl Index of a contraceptive mobile app
2. Fertility awareness-based mobile application for contraception
3. Short- and long-term effect of contraceptive methods on fecundity
4. Real-world menstrual cycle characteristics of more than 600,000 menstrual cycles
5. Typical use effectiveness of Natural Cycles: postmarket surveillance study investigating the impact of previous contraceptive choice on the risk of unintended pregnancy
6. Advantages of determining the fertile window with the individualised Natural Cycles algorithm over calendar-

**References:**


First, some basics:

During your cycle, there are typically 6 days when you are fertile (6). This is due to the combined fertility of a couple: an egg will only survive for 12-24 hours after being released from the ovary (4), sperm can survive in fertile cervical mucus for up to 5 days (5). In other words, 5 days for the sperm lifespan plus the day of ovulation is 6 days total.

The quantity and quality of your cervical mucus is key to whether you are fertile or not. Without cervical mucus, the vagina is very acidic to protect against infection (8). Because sperm requires a more alkaline environment (such as seminal fluid) to survive, it typically will not survive in the vagina for more than 1-2 hours if cervical mucus is not present (9, 10).

**Important Note:** While this is a great summary, before relying on STM as birth control, we recommend you do the following:
Examples: Apps Making Questionable Efficacy Claims

[Images of app screens showing menstrual cycle tracking and symptom logging features.]
Challenge 2: Literacy

Does the user have enough knowledge to use an app correctly?
Current Research

CONSENSUS on Fertility Knowledge: NOT SO GREAT
Creating Opportunities

“What types of data does the app ask you to collect?”

“Do you have any questions about how to collect [type of data] that I can help with?”
Possible Discussion Points With Clients

• Does the app offer FREE in-app FAQs about how to use it correctly?

• Does the app give instructions about how to derive or input other data? (Are the descriptions in multiple formats – words, pictures, videos?)

• Are any citations or literature provided when educating on fertility topics?

• Does the app offer live or online support if a user has questions? (not community-led)

• Does the app provide a tutorial on correct use when a person first downloads it?

• Does the app provide additional education on reproductive topics?
Examples: Apps With User Education

- Period FAQs
- Birth Control FAQs
- Sex FAQs
- Fertility FAQs
- Planned Parenthood FAQs
- Spot On FAQs

Chat with a health educator
Let's go

Find a health center

Knowledge Base

Charting
Basal Body Temperature
Cervical Mucus
Glossary

Practitioners
Kindara

Learn from SymptoPro
Kindara has partnered with SymptoPro to provide expert online and personal fertility instruction.

General Questions
How it works
Testimonials
Examples: Reinforcing Harmful Or Inaccurate Body Literacy Information
Challenge 3: Data Privacy & Ownership

Who can access the information being input in the app?
TO DATE, FERTILITY APP MAKERS HAVE BEEN SOME OF THE WORST OFFENDERS OF DATA PRIVACY
What About My Data?
Balancing Informed Use

• Does this app have a way for you to back-up or send your data to yourself?

• Does this app have a passcode that ensures that your information is private?

• Do you know what the app is doing with your data? (does it matter to you?)
Possible Discussion Points With Clients

• Is the app’s privacy policy findable in the app?
  • Is it written at a reading level that someone could understand?

• Is data sharing opt-out/opt-in/inherent?

• Is it required to share data with 3rd parties in order to use the app?

• Are there options provided to withdraw consent for data use/data sharing?
Examples: Apps With Clear Privacy & Data Information
Examples: Apps That Have Room For Improvement On Privacy Or Data Ownership

II. General Data Processing Information

We will explain how personal data is collected when using our app. Personal data is any data that can be related to you personally.

We only collect and use personal data of our users insofar as required for providing the app and our contents and services of our own devices. Personal data of our users is only collected and used with the permission of the respective user. Exceptions apply in cases in which prior permission cannot be obtained and processing of the respective data is permitted by law.

§ 1 Legal Basis for Processing Personal Data

(1) If the processing of personal data requires the permission of the data subject, Art. 6(1) Letter a of the GDPR will serve as the legal basis.

(2) For the processing of personal data for the fulfillment of a contract and if the data subject is a party to this contract, Art. 6(1) Letter b of the GDPR will serve as the legal basis. This also applies if processing is necessary for the fulfillment of pre-contractual measures.

(3) If the fulfillment of legal obligations to which our company is subject requires the processing of personal data, Art. 6(1) Letter c of the GDPR will serve as the legal basis.

(4) If vital interests of the data subject or of another natural person require the processing of personal data, Art. 6(1) Letter d of the GDPR will serve as the legal basis.

(5) If processing personal data is required for purposes of legitimate interests of our company or of a third party and if the interests and fundamental rights and freedoms of the data subject do not outweigh the stated interests, Art. 6(1) Letter f of the GDPR will serve as the legal basis.

§ 2 Data Deletion and Storage Duration

(1) The first time the device synchronizes with the device, the personal data stored in this app is downloaded to the device. This personal data of the user will be deleted in each case.
Other Fertility App Considerations

- Data challenges (e.g., what if a person has a miscarriage/abortion?)
- Community functions (unmoderated hotbeds of misinformation or supportive spaces)
- Design (inclusive or exclusive?)
- How can providers interpret/use app data to benefit clients?
I Don’t Have Time to Deal with Apps

In-clinic information sheets?

ID one or two personal recommendations?

Use where it makes sense in your practice

Be part of the solution – which isn’t to discount apps
Thank You!

Questions?
My Recommendations as of now:

**Tracking apps:**
- Kindara
- ReadYourBody
- Clue

**Method-related apps:**
- Kindara (symptothermal)
- ReadYourBody (symptothermal)
- CycleBeads (Standard Days)
- 2Day (2Day)
- Marquette* (NFP) (symptohormonal)
- Natural Cycles (BBT plus)