Fertility Apps:
Concerns & Opportunities

Rebecca Simmons, PhD, MPH

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 Leading The Charge In Femtech, A $50B Industry
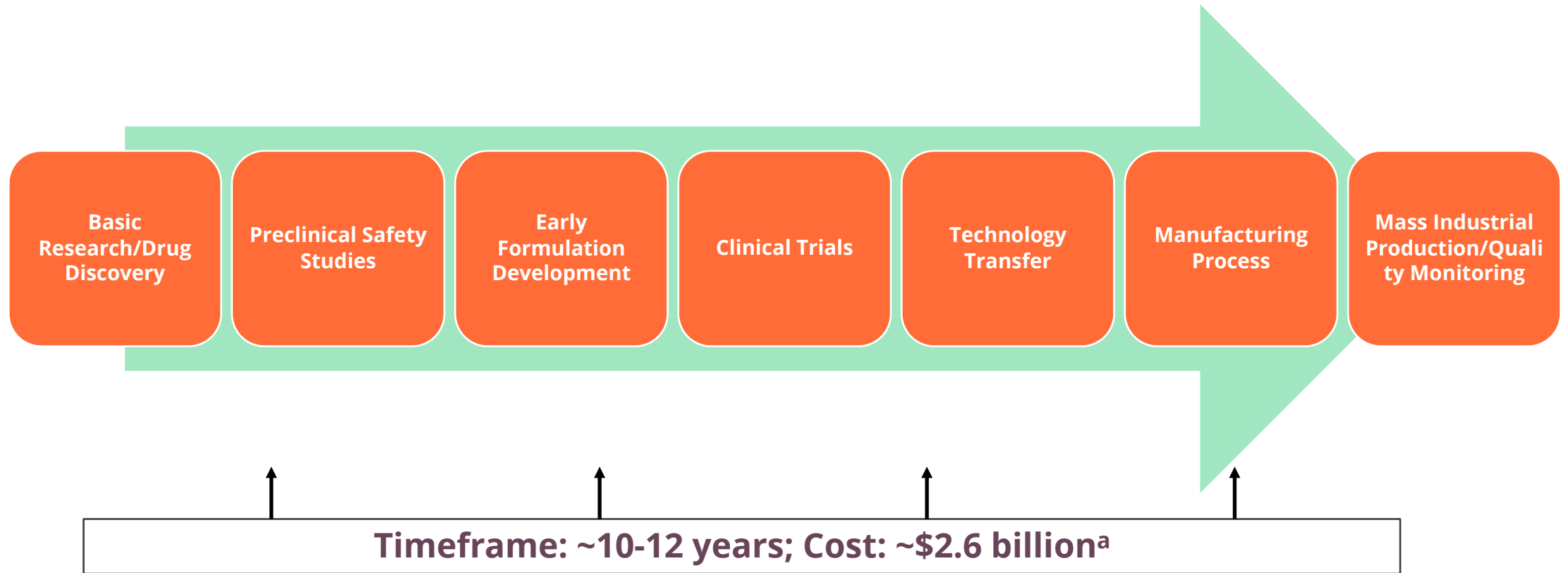
Bryan Collins Contributor ⓘ
Careers
I cover topics like creativity, productivity, and leadership

Ida Tin   PROVIDED BY BRYAN COLLINS

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

| Basic Research/Drug Discovery | Preclinical Safety Studies | Early Formulation Development | Clinical Trials | Technology Transfer | Manufacturing Process | Mass Industrial Production/Quality Monitoring |

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

[a] Source: "Biopharmaceutical Research and Development: The process behind new medicines." www.PHRMA.org

FUNDING for Reproductive Health

National Institutes of Health 2020

FEMTECH Industry 2020

$958 Million Allocated [a]

(contraception/reproductive health/infertility/pregnancy)

$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"
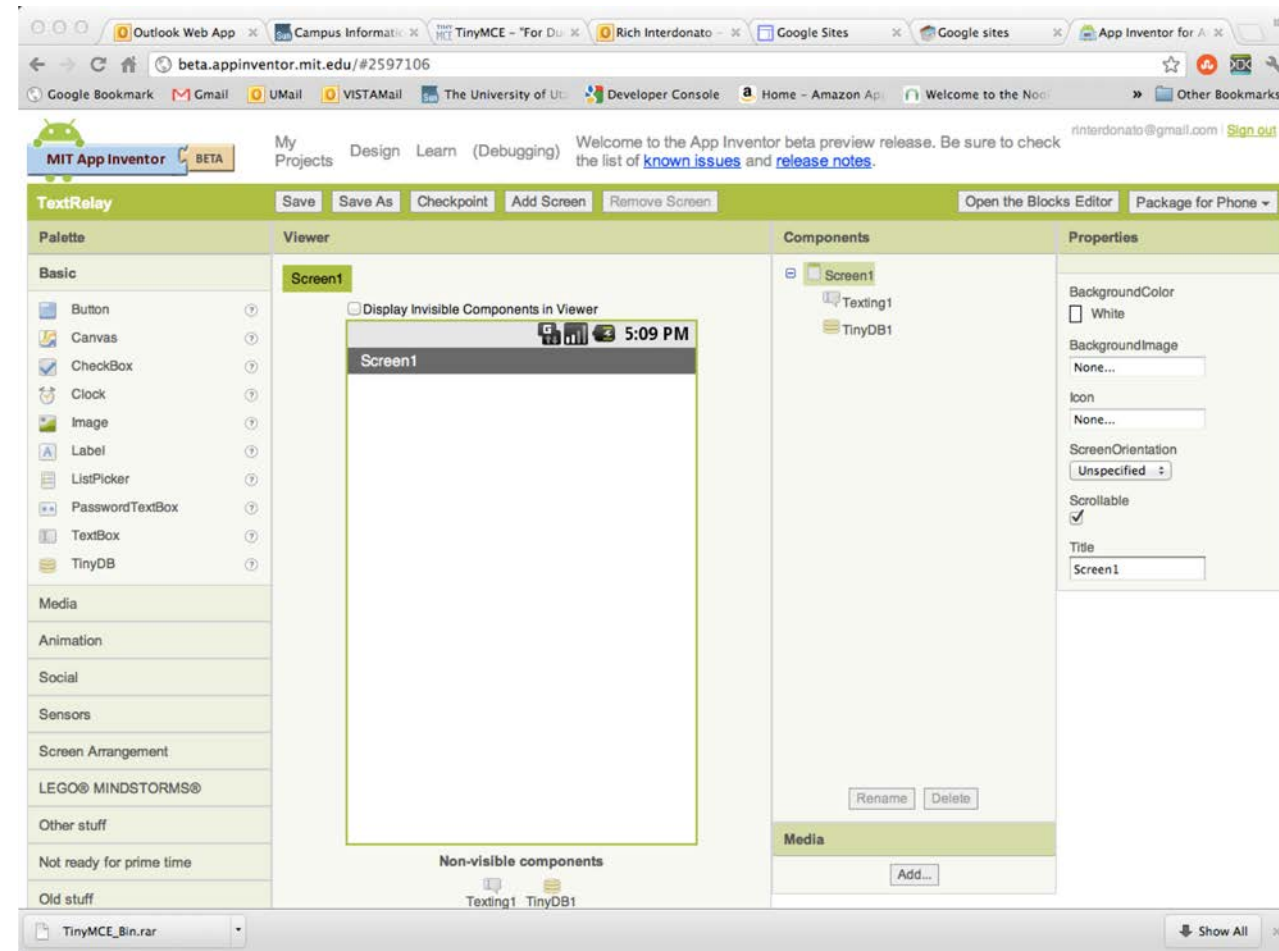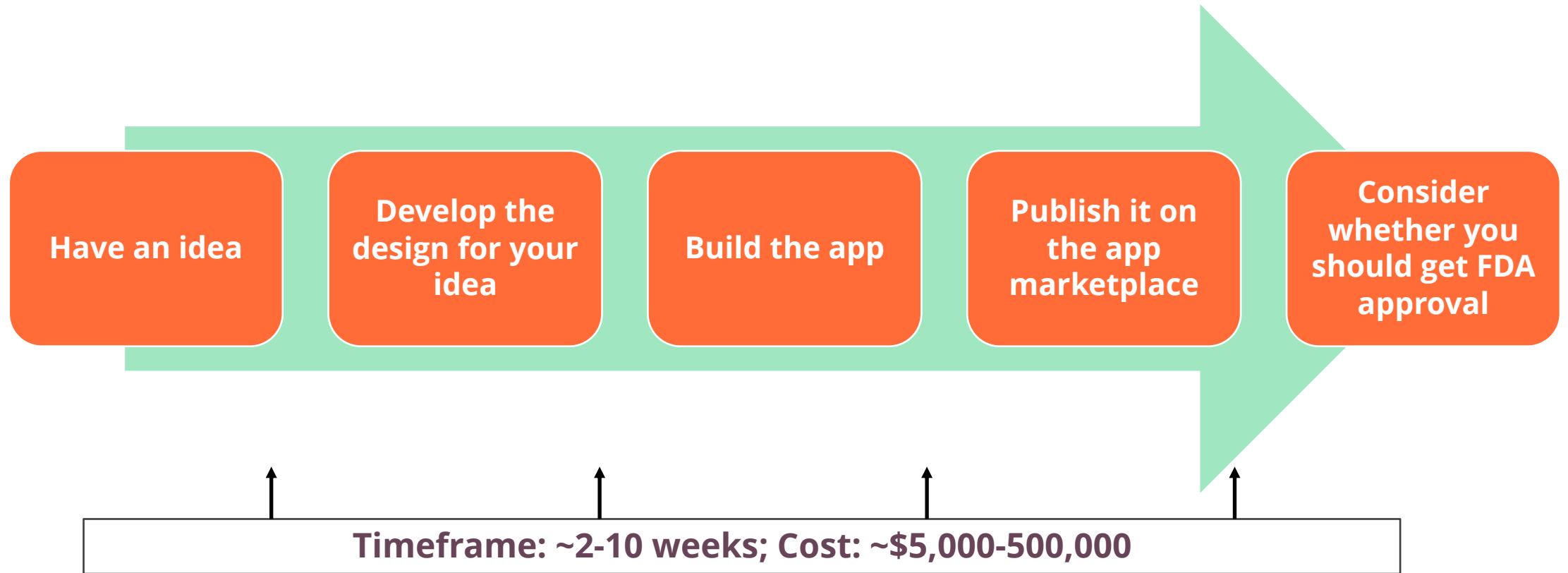
Fertility Apps

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.....

*Most prolific area of femtech

*Low barrier to entry

*Shorter lifespan (<1 in 10,000 apps will be financially profitable)

App Development Cycle

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

FDA Regulation of Apps

8

FDA Regulation of Apps

Fertility Apps: 4 Categories for Consideration

Menstrual cycle trackers

Fertility apps

Fertility awareness-method charting apps

App-based FAM
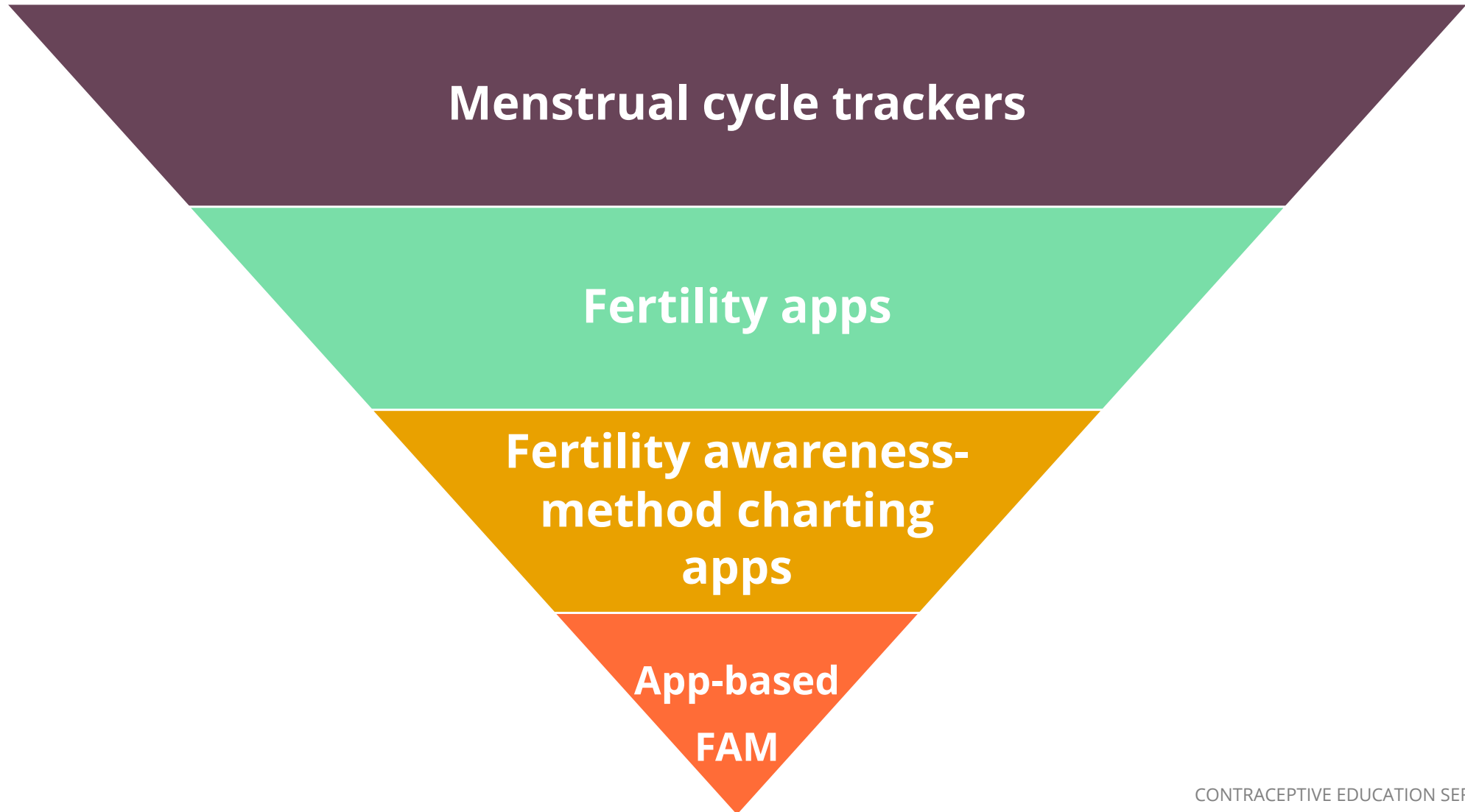
Menstrual Cycle Trackers

- 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
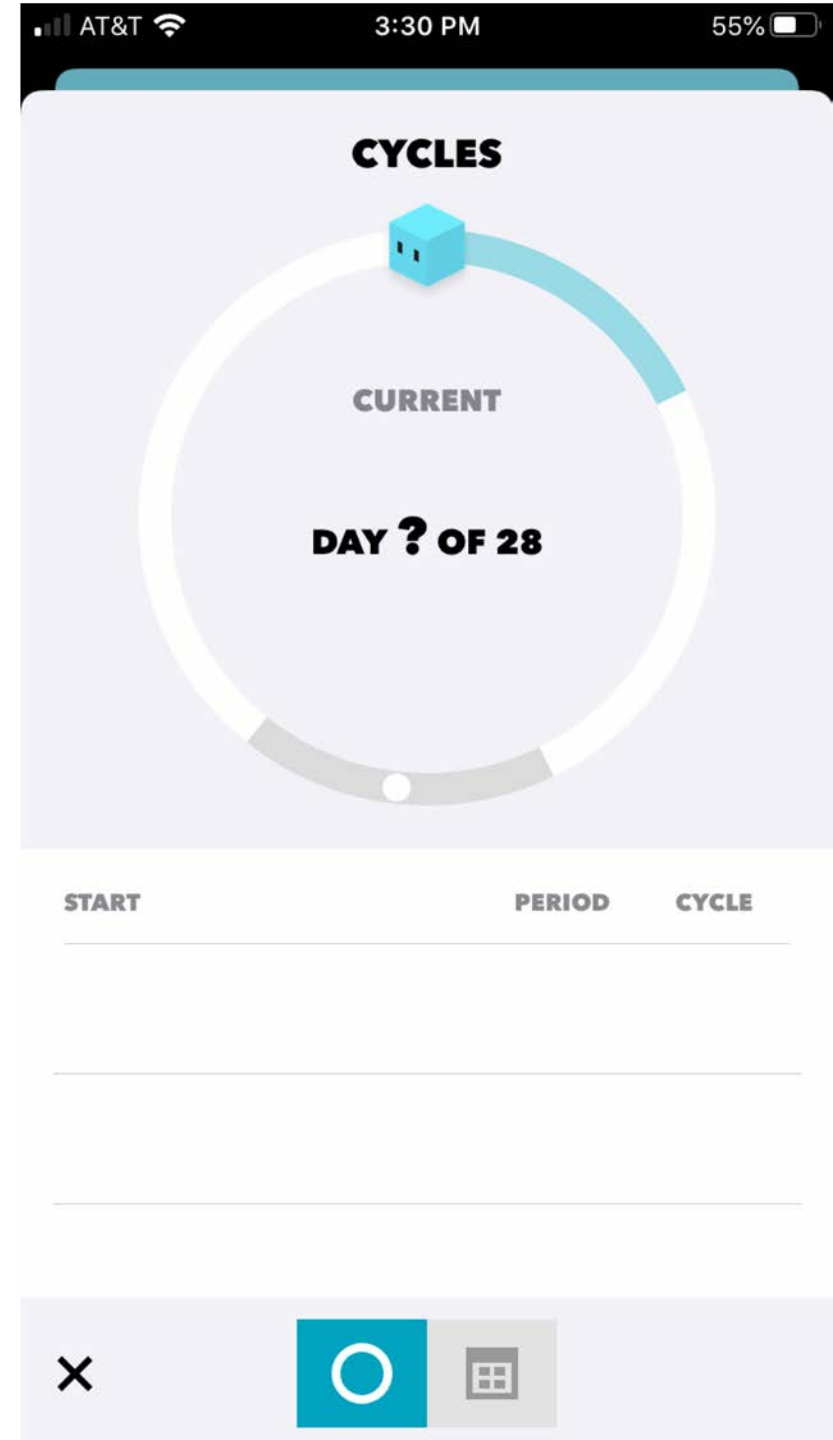
"Fertility" Tracking Apps

- 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,
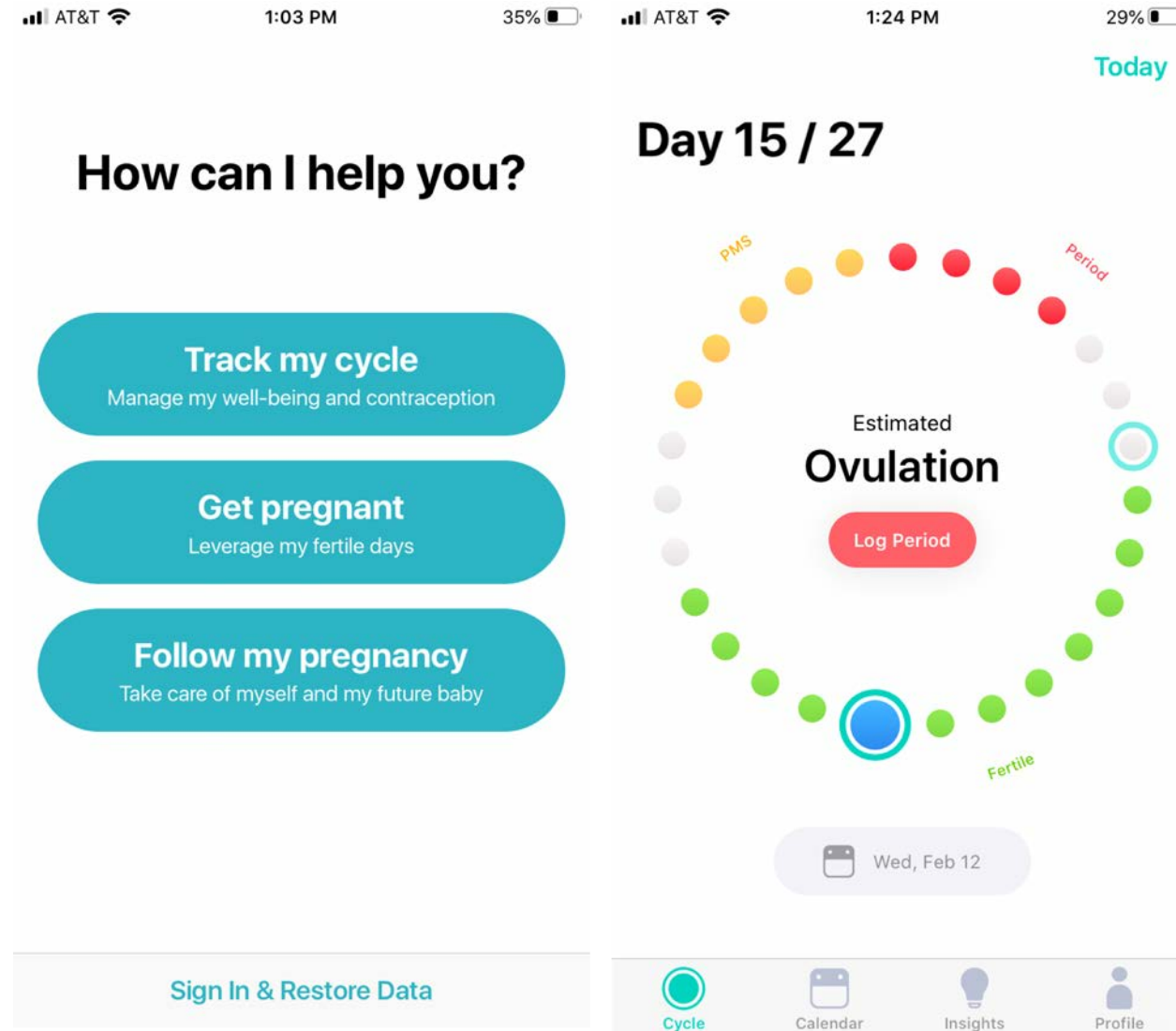
Fertility Awareness-Based Method (FABM) Charting Apps

- 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
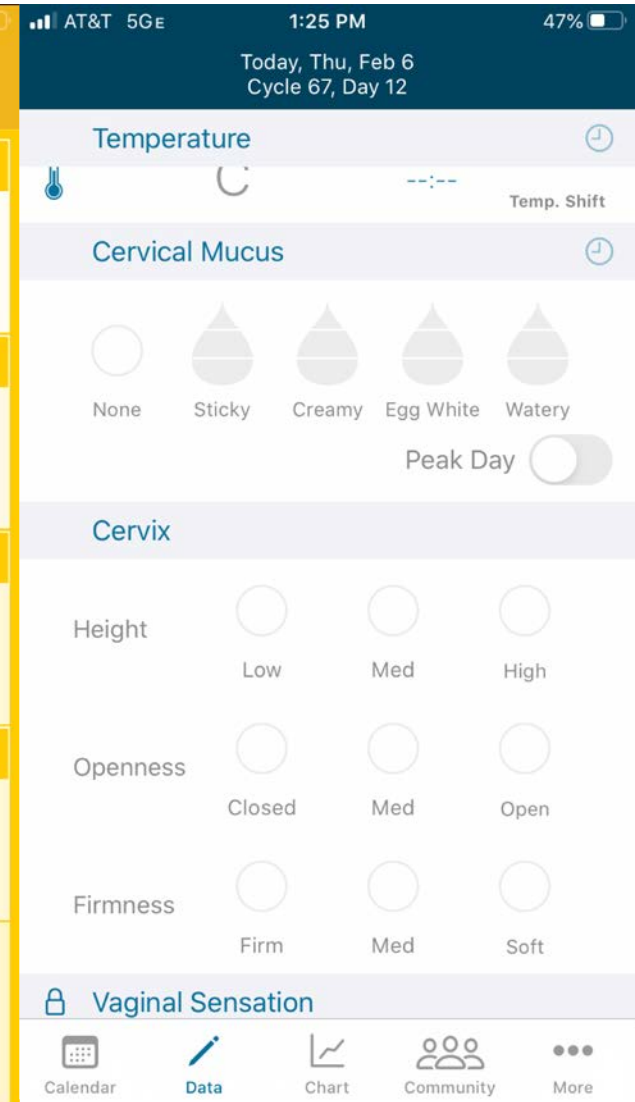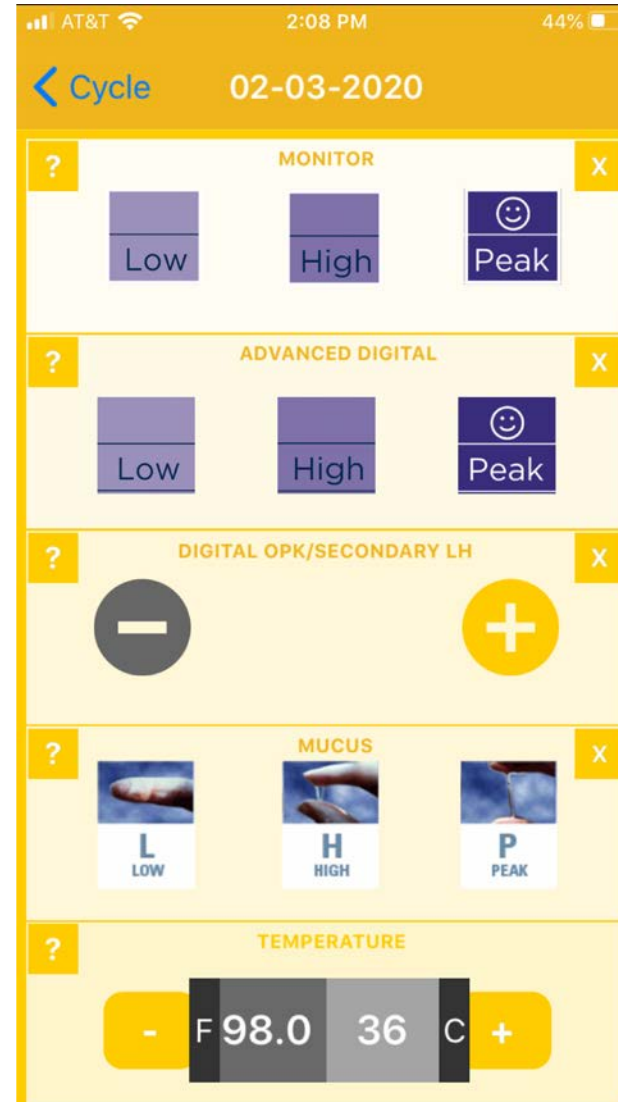
App-Based Fertility Awareness Methods

- 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
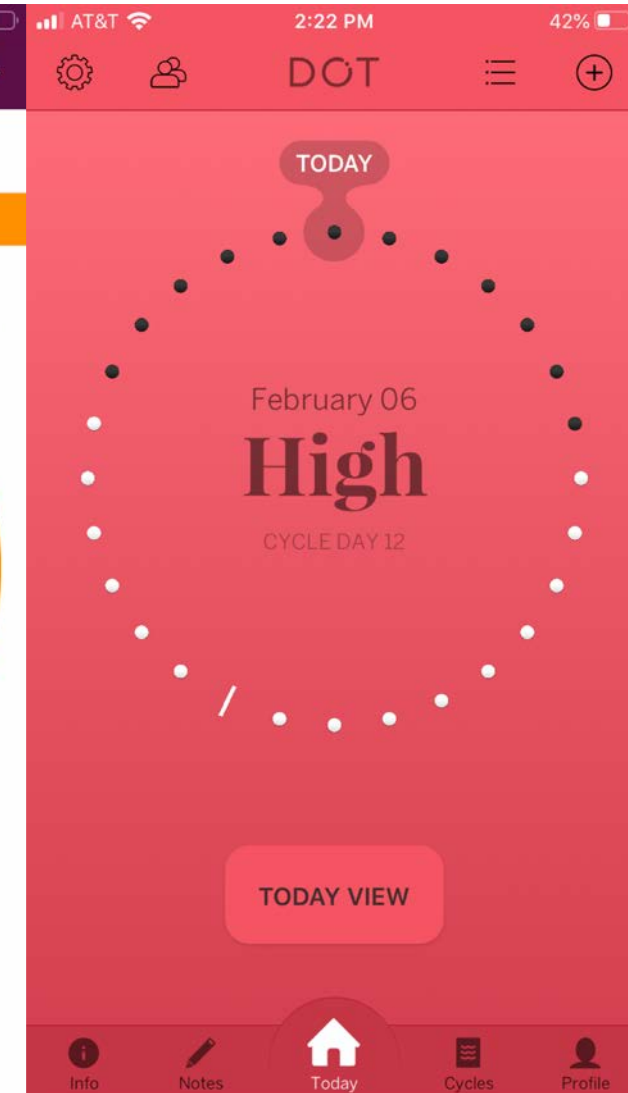
WHAT IS IT?

WHAT IS IT?

WHAT IS IT?

Why does my fertile window move suddenly throughout the month?

Support Team
9 months ago · Updated

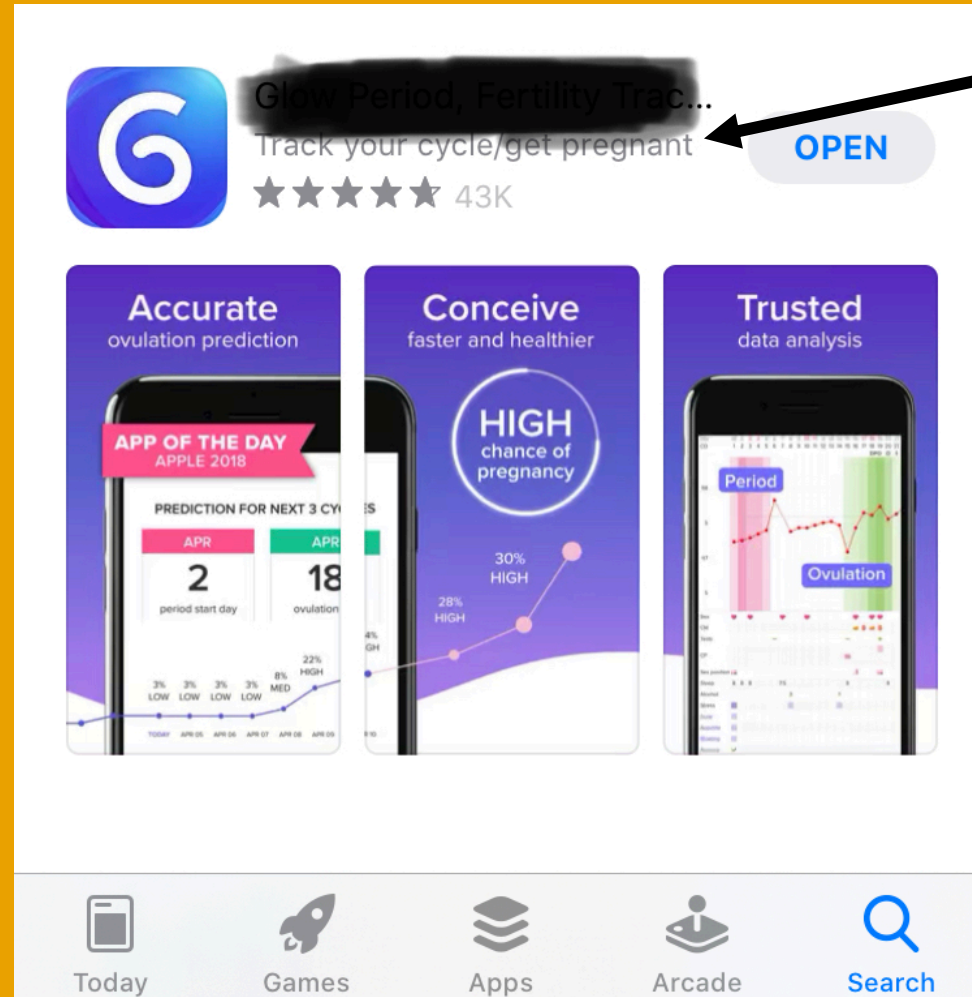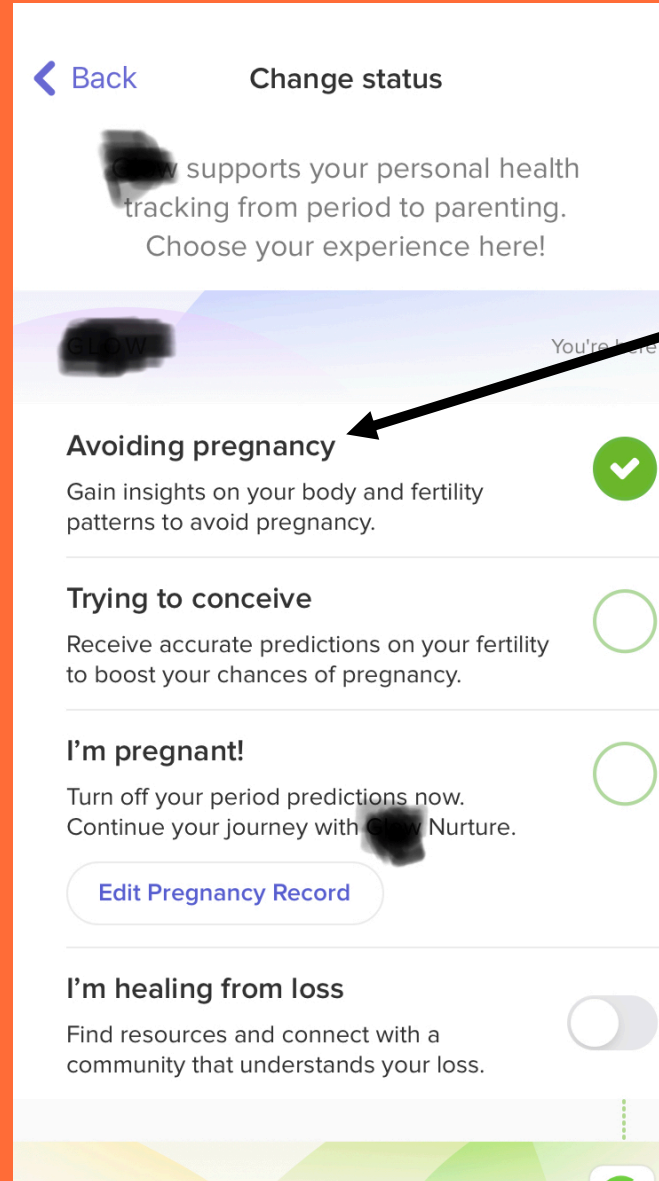In ████, your fertile window adjusts retroactively in response to your logs. These types of tracking are by nature "retroactive" in the sense that the temperature spike or the peak OPK result shows that you have ovulated the day before.

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

Alexander Freis[1], Tanja Freundl-Schütt[2], Lisa-Maria Wallwiener[3], Sigfried Baur[4], Thomas Strowitzki[1], Günter Freundl[4] and Petra Frank-Herrmann[1]*

🖨 Print

lberg,

Evaluation of Smartphone Menstrual Cycle Tracking Applications Using an Adapted APPLICATIONS Scoring System

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

+ | Brief Report | Brief Report

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

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

Gynecology

Can apps and calendar methods predict ovulation with accuracy?

Sarah Johnson ✉, Lorrae Marriott & Michael Zinaman
Pages 1587-1594 | R

❝ Download citati

CONTENTS: ORIGINAL RESEARCH

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

Setton, Robert MD; Tierney, Christina MD; Tsai, Tony MD Author Information ⊘

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?
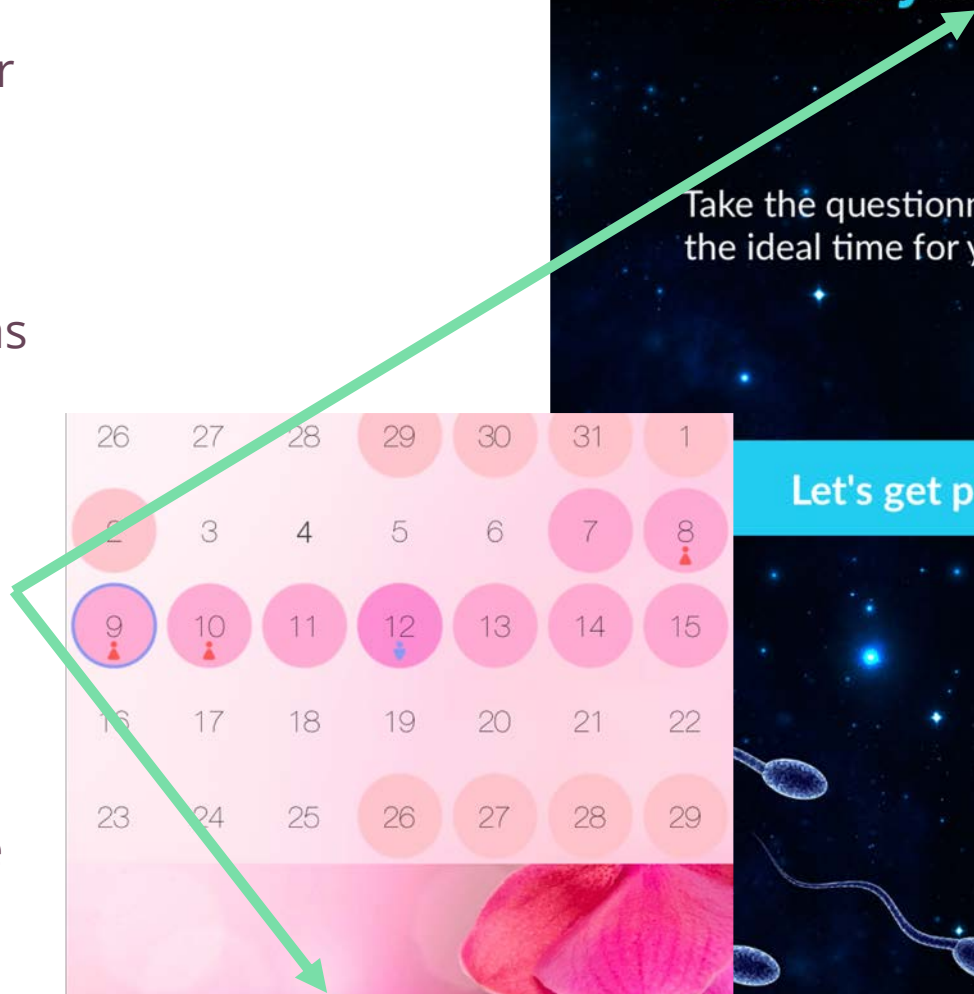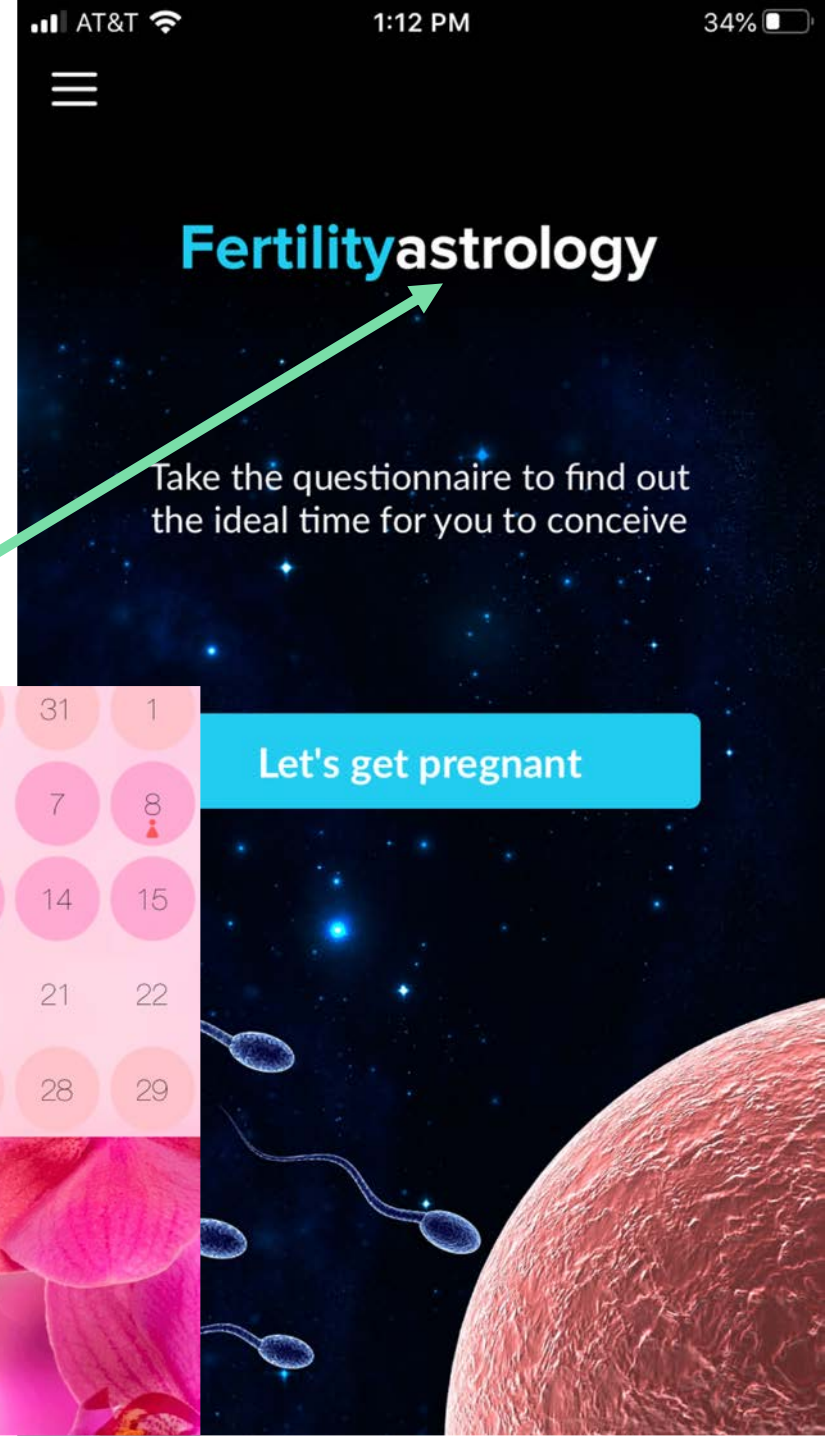
Examples: Apps With Citations/References About Efficacy

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-

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Cycle Science

References:

1. Wilcox AJ.Timing of sexual intercourse in relation to ovulation. Effects on the probability of conception, survival of the pregnancy, and sex of the baby. New England Journal of Medicine. 1995.

2. Suarez SS, Pacey AA. Sperm transport in the female reproductive tract. Human Reproduction Update. 2006.

3. Dunson DB et al. Day-specific probabilities of clinical pregnancy based on two studies with imperfect measures of ovulation. Human Reproduction. 1999. 14(7):1835-1839.

4. Collins, WP. Biochemical indices of potential fertility. International Journal of Gynecology and Obstetrics, Supplement, 1, pp. 35-44, 1989.

5. Fehring RJ, Schneider M, Raviele K. Variability in the phases of the menstrual cycle. Journal of Obstetric, Gynecologic, and Neonatal Nursing. 2006 May-Jun;35(3):376-84.

6. Lenton EA, Landgren BM, Sexton L. Normal
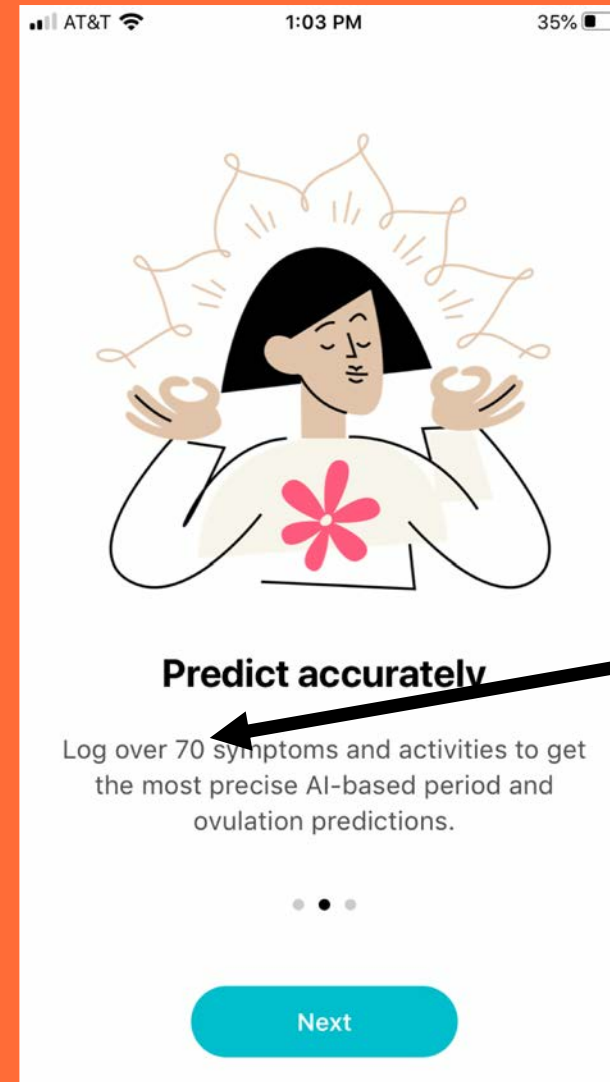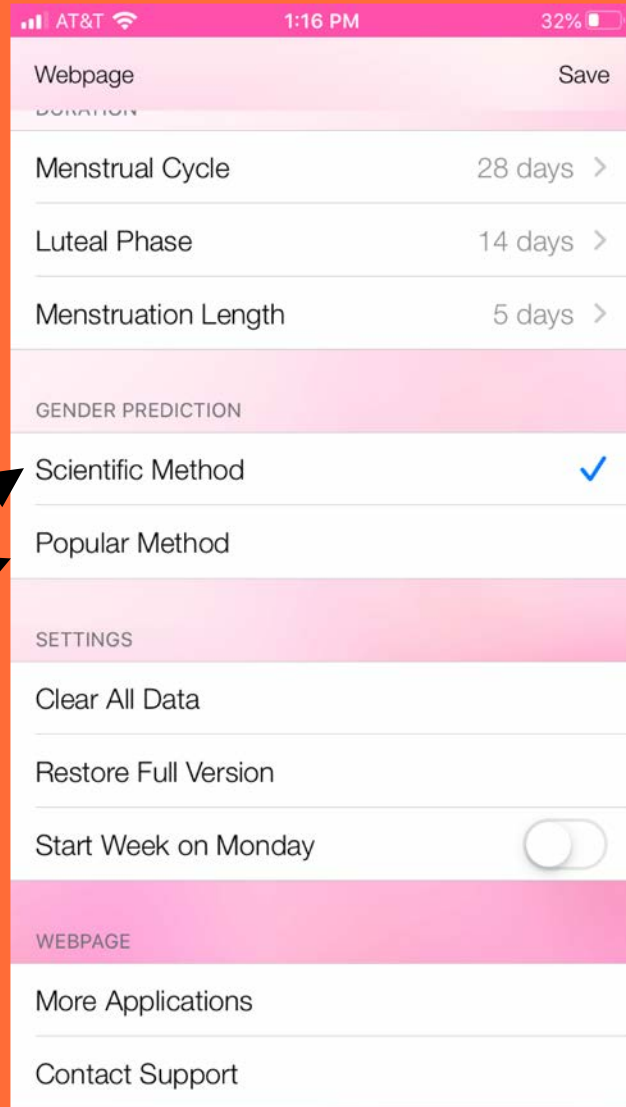

KNOWLEDGE BASE

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:

Calendar   Data   Chart   Community   More

Examples: Apps Making Questionable Efficacy Claims

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
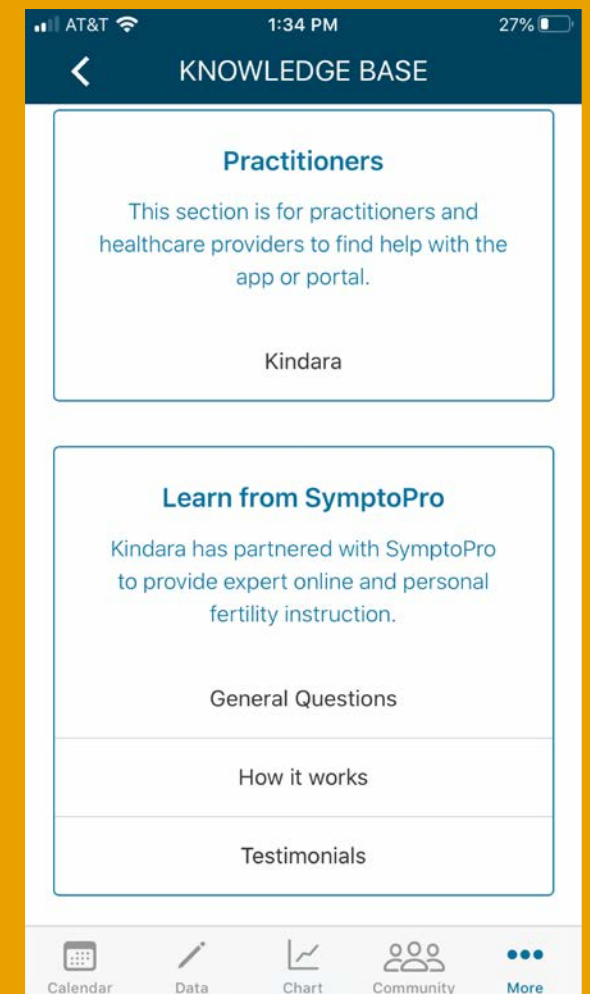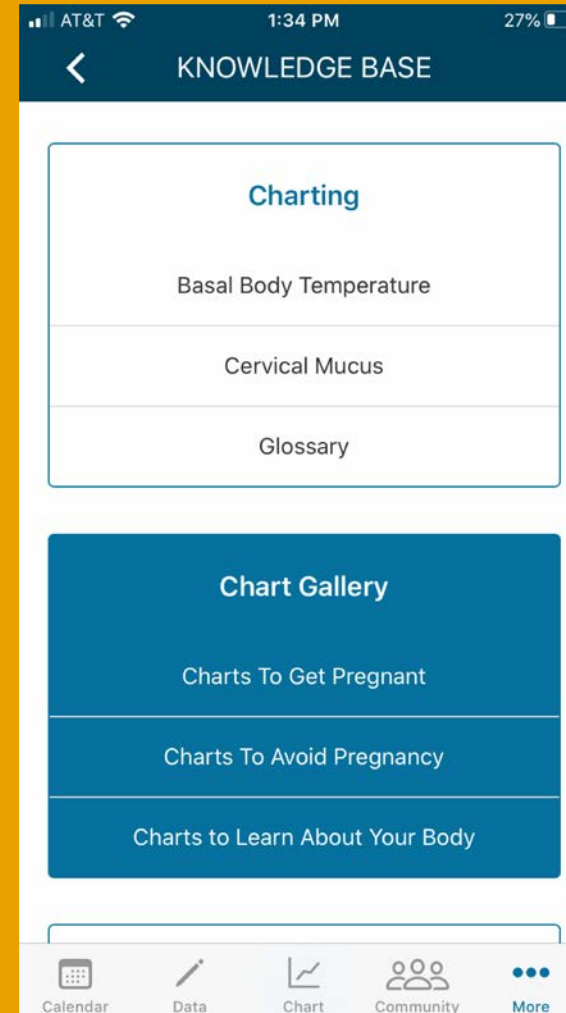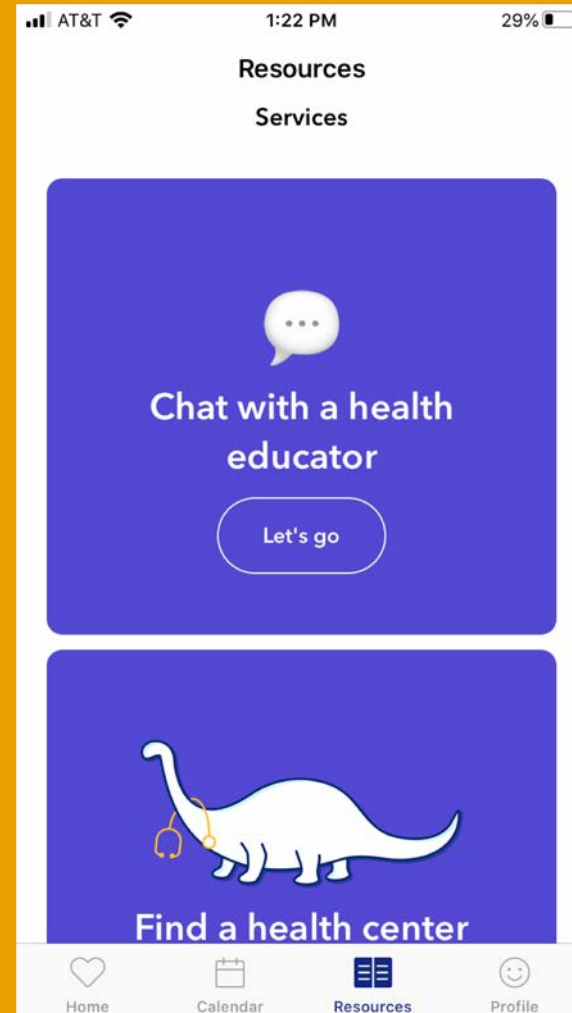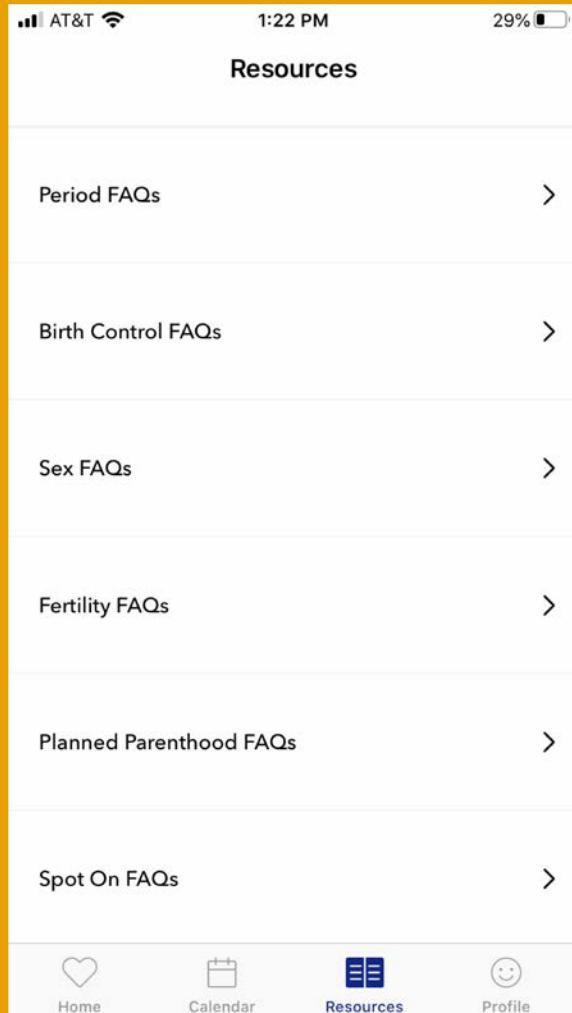
Examples: Reinforcing Harmful Or Inaccurate Body Literacy Information

Stereotype?
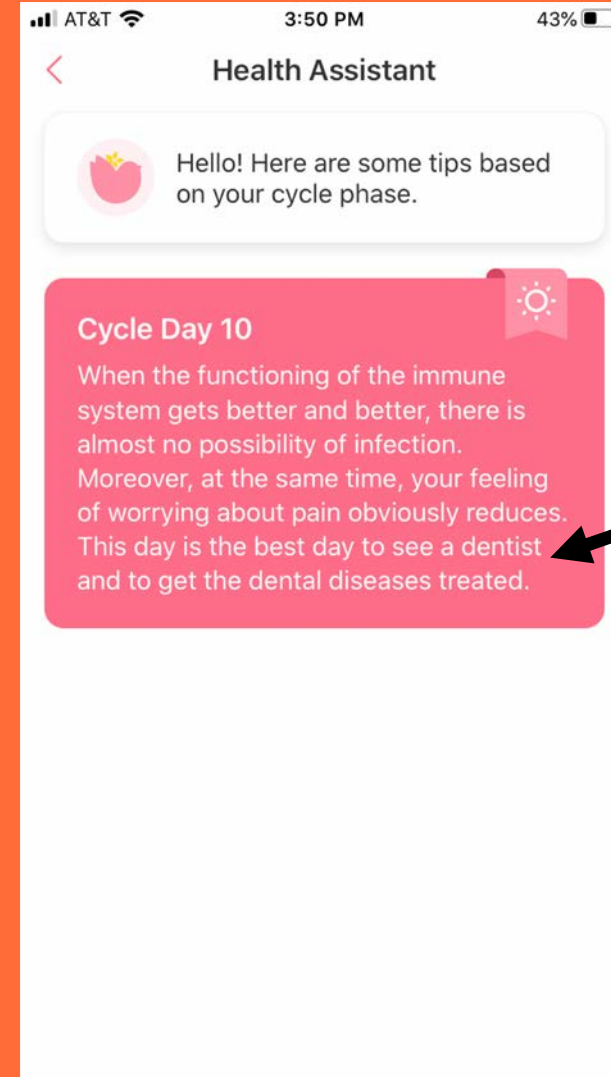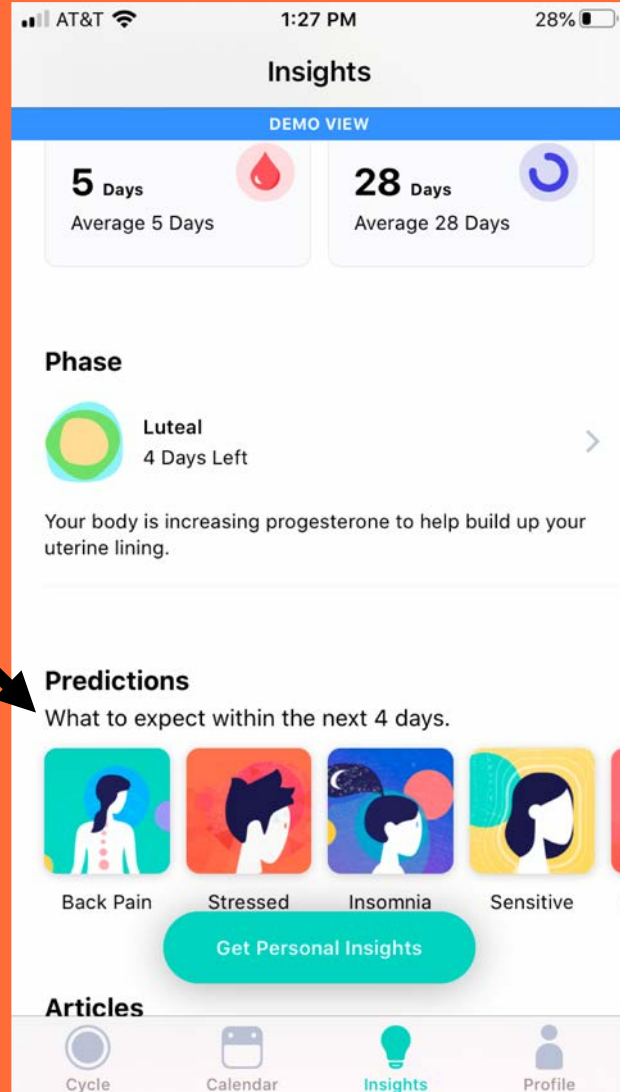
False teeth?

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

OUT OF CONTROL

How consumers are exploited by the online advertising industry
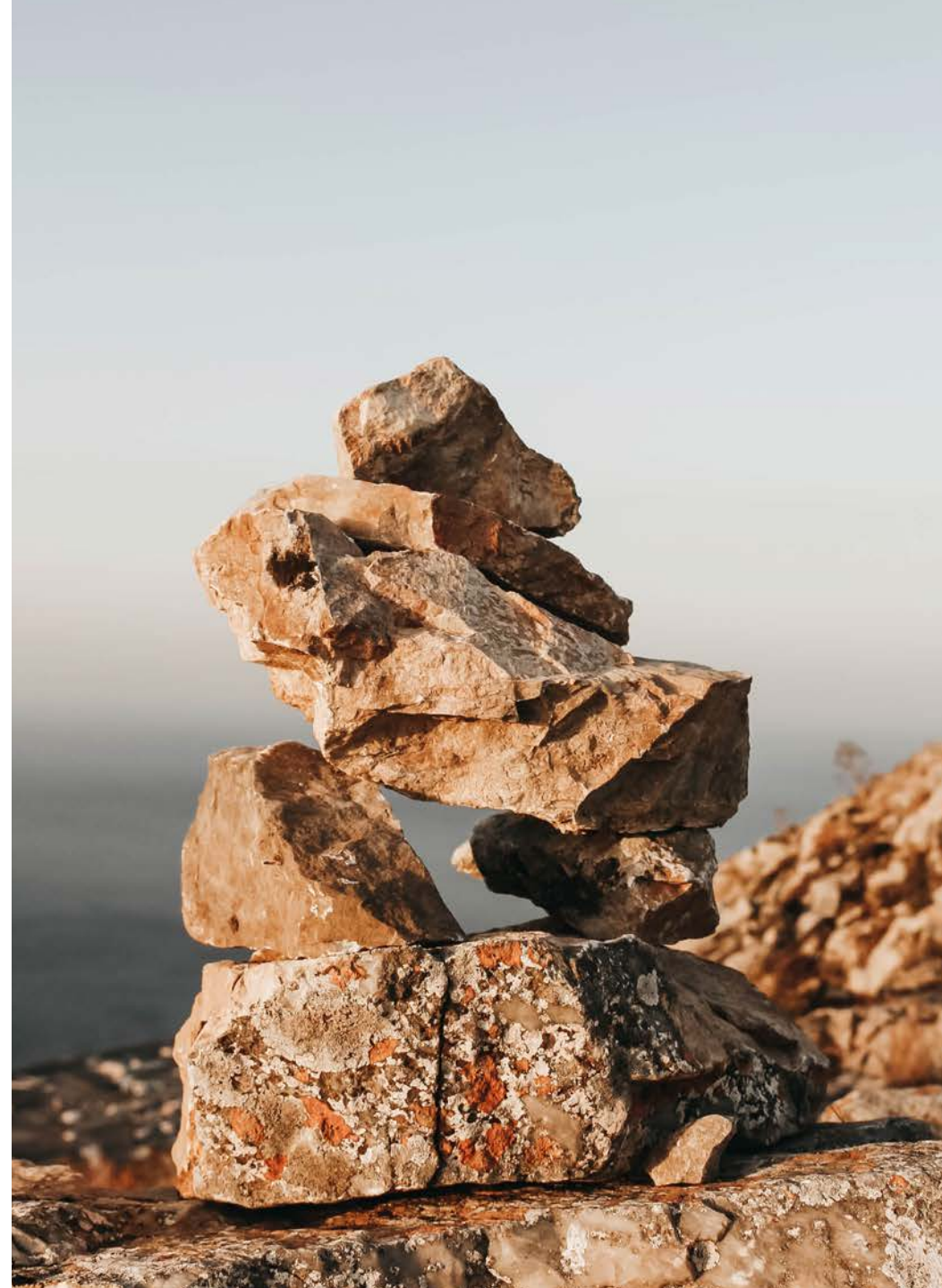14.01.2020

FORBRUKERRÅDET

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
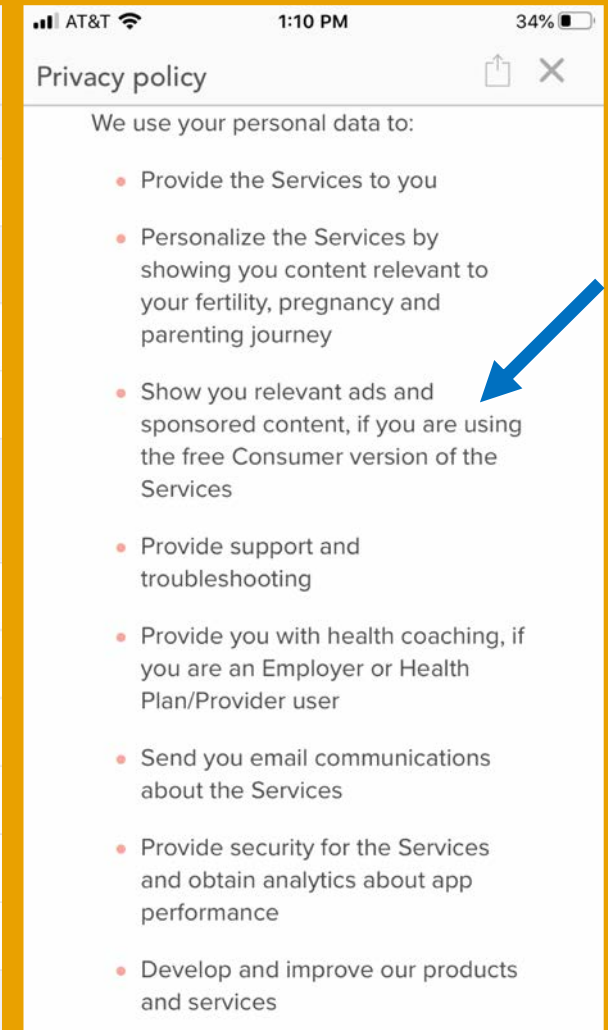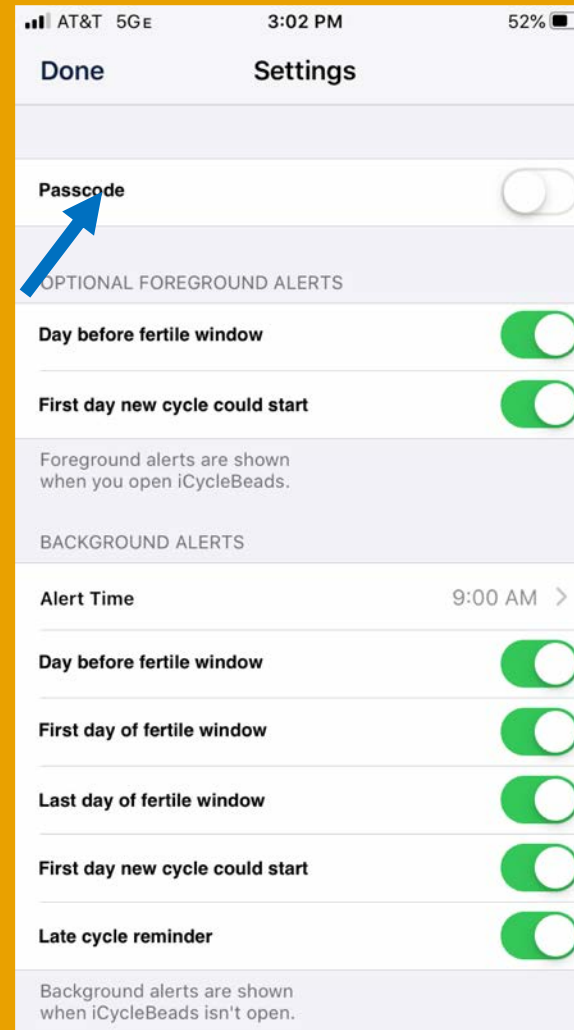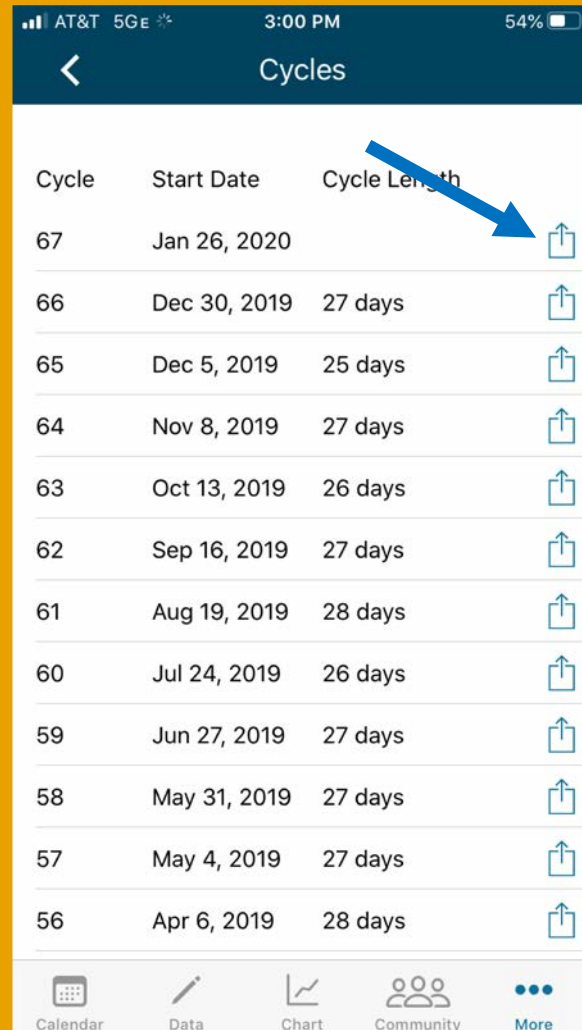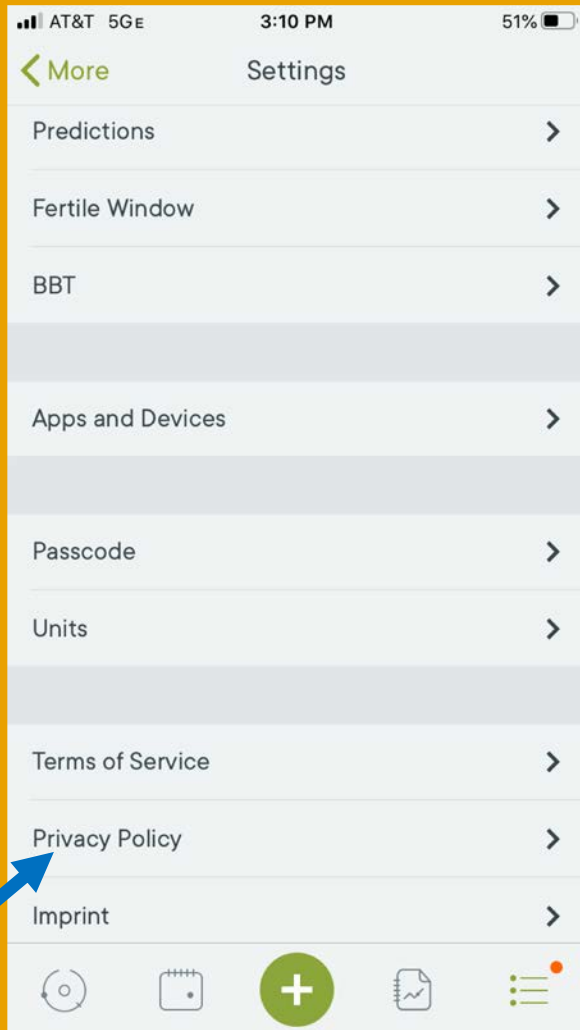
Examples: Apps That Have Room For Improvement On Privacy Or Data Ownership

Jargon
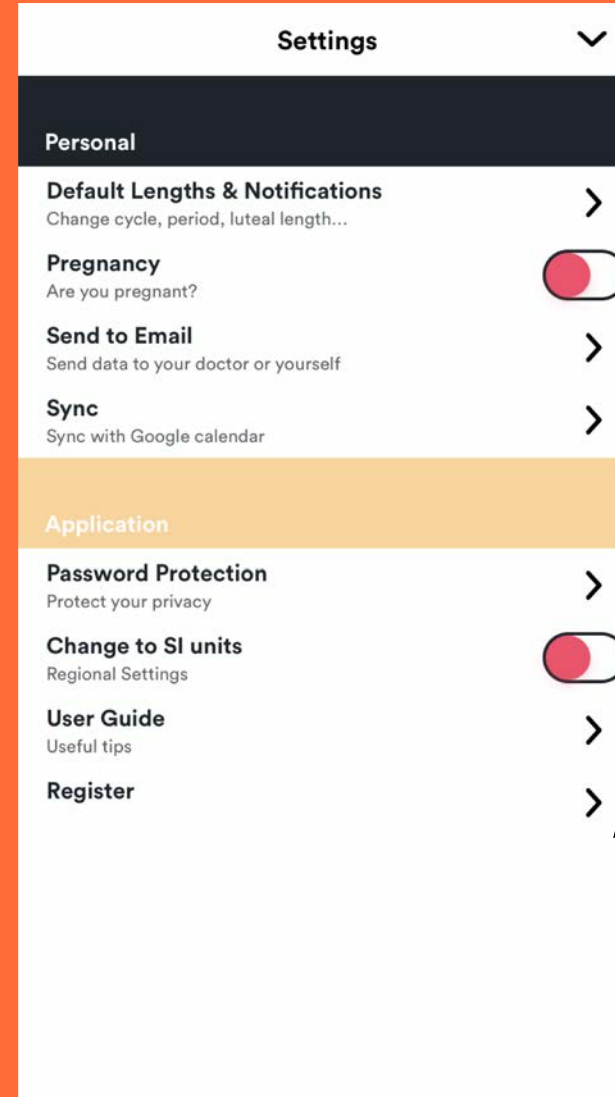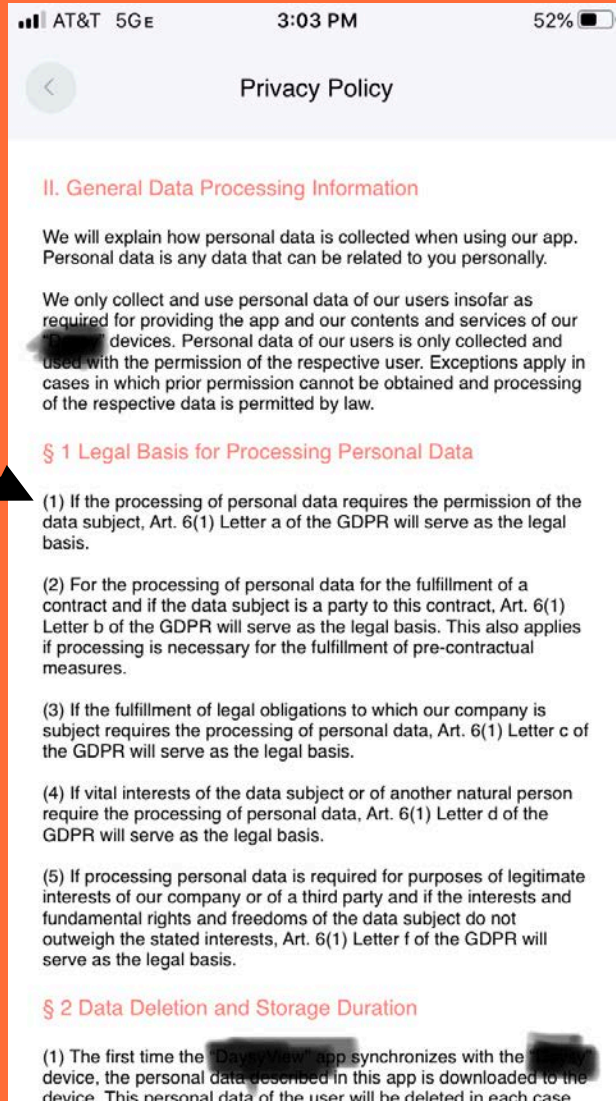
In-app policy?

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)

■ Free to use basic version

■ Cost for basic version