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Catherine Vidal, Jennifer Merchant

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La science pour la santé
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Inserm Ethics Committee

«Gender and
Health
Research»
Working group

Ethical challenges of
using digital menstrual
tracking apps for birth
control and conception.

September 2022

Inserm Ethics Committee

Note by the 'Gender and Health Research' Working Group

by Catherine Vidal and Jennifer Merchant

Ethical challenges of using digital menstrual tracking apps for birth control and conception

Plan

1. Introduction

2. Sociocultural context of the development of apps to track menstrual cycles and fertility

2.1. FemTech and digital menstrual tracking apps

2.2. Why the growing success of menstrual tracking apps?

2.3. An often ideological promotion of natural contraceptive methods

3. Ethical challenges of menstruation and fertility tracking apps

3.1. The apps' reliability called into question: between promises and reality

3.2. Is the protection of the users' personal data guaranteed?

3.3. Abortion: American women encouraged to uninstall their menstrual tracking apps

4. Conclusion and outlook

5. Bibliography

Ethical challenges of using digital menstrual tracking apps for birth control and conception

1. Introduction

The month of June 2022 marked a historic rollback of women's rights in the USA with the decision by its Supreme Court to overturn *Roe v. Wade*, a ruling which had guaranteed the right to abortion in each of the country's states¹.

Criminalising abortion has paved the way for the use of digital data by US authorities to identify women online who are seeking to terminate a pregnancy (Conti-Cook 2020). Purchasing a pregnancy test or an abortion pill online, or being geolocated in the vicinity of a family planning clinic, is information that could be exploited by the police. But other forms of personal data, particularly those derived from **menstrual cycle tracking applications** (apps), are also liable to be used to identify women who are either wishing to abort or have already done so.

A 2018 study by Privacy International, an NGO that works to defend the right to privacy in the realm of digital data, revealed that these apps transfer to social media (for example, Facebook) intimate information about women's sex lives, such as use of contraception, menstruation dates, menstrual symptoms, moods, etc.²

Such practices raise **ethical questions** of primary importance concerning the protection of personal data and the freedom of women to control their own bodies. Another subject of ethical concern is the lack of reliability of the apps' predictions in guiding women's birth control or conception choices.

In order to analyse the challenges represented by the use of these digital apps, the Inserm Ethics Committee Gender and Health Research Working Group conducted an investigation focusing on two areas:

- The sociocultural context of the development of apps to track menstrual cycles and fertility.
- The ethical questions raised by these apps: has their efficacy for birth control or conception purposes been proven? Is the protection of the users' personal data guaranteed?

These points were discussed during interviews held in 2022 with researchers who are experts in these areas:

¹<https://www.haut-conseil-egalite.gouv.fr/enjeux-europeens-et-internationaux/travaux-du-hce/article/cp-ivg-aux-usa-un-recul-historique-aux-repercussions-mondiales>

²<https://privacyinternational.org/long-read/3196/no-bodys-business-mine-how-menstruations-apps-are-sharing-your-data>

Marion Coville:

Lecturer in Information and Communication Sciences at the University of Poitiers. Administrator of the Observatory of Digital Worlds in Human Sciences (Omsh).

Mireille Le Guen:

Demographer-researcher at Université Catholique de Louvain, in partnership with the Sexual and Reproductive Health and Rights Unit of the French Institute for Demographic Studies (INED), member of Junior Lab Contraception & Gender.

Cécile Thomé:

Post-doctoral fellow in sociology at Sexual and Reproductive Health and Rights Unit of INED. Editor-in-Chief of *Socio-logos*, member of Junior Lab Contraception & Gender.

2. Sociocultural context of the development of apps to track menstrual cycles and fertility

2.1. FemTech and the digital menstrual tracking apps

The past decade has seen a boom in companies developing tech solutions for women's health, with the value of the FemTech market expected to reach 50 billion dollars by 2025. One leading sector is that of apps used to track menstrual cycles and fertility for the purposes of birth control and conception (Coville 2018, Kronemyer 2018, Loire 2017, (<https://appinventiv.com/blog/women-health-tracking-app-development>)). Hundreds of such apps can be found in the 'Health' categories of Apple and Google online stores. It is estimated that several hundred million women worldwide use them as part of their everyday lives. In the USA, one third of women use them (Ericson 2015) and in Africa and Asia the number of users is rising exponentially.

The most popular apps account for several tens of millions of downloads each: Clue, Flo, Natural cycles, Glow, Period Calendar, etc. The companies designing them are based mainly in the USA, Europe (Germany, Belarus, UK, Sweden, Switzerland), and Asia.

Different features are available, depending on the apps. The versions offered free-of-charge data collection that tracks the menstrual cycle: dates of periods, temperature, appearance of cervical mucus, symptoms related to the menstrual cycle, pain. Paid 'premium' options are also available (30-60 euros per year), *to refine predictions and advise users. Information of an intimate nature is collected*: moods, libido, sexual intercourse, condom use, health status, sleep, weight, diet, etc.

Specifically, the calendars of the cycles are represented on tables with coloured icons indicating the fertile period and day of ovulation. Users are sent regular messages predicting period and ovulation dates, along with personalised advice, references to women's health articles, quizzes, etc. On some apps, advertisements appear during the different personal data input steps. The apps all use external services (Google, Amazon) to store their data (Ali 2021).

2.2. Why the growing success of menstrual tracking apps?

The use of digital technologies to track periods and fertility forms part of a global context of changes in contraceptive practices observed in the USA and Europe for over 10 years (Bajos 2014, Foran 2019, Le Guen 2020, 2021). Since 3rd and 4th generation contraceptive pills first appeared on the market between 1990 and 2000, epidemiological studies have reported increased risks of venous thrombosis. During the same periods, health scandals related to the side effects of various drugs (Distilbène, Mediator, Valproate) were revealed. These events have generated a climate of distrust in the USA and Europe with respect to

pharmaceutical industry products, including contraceptive pills. In France, the use of hormonal contraception has decreased among women from all social groups.

The refusal of contraceptive pills is also part of a growing awareness of a 'global' ecology, which ranges from respecting the natural functions of the body to protecting the environment from the risk of polluting water with hormones. Other reasons for the reluctance to use hormonal contraception can be explained by the questioning of 'conventional' medicine, experiences of gynaecological violence, religious beliefs, etc. (El Aoufir 2021, Maudet 2021, Le Guen 2020, 2021).

It is in this context of demand for non-medical contraceptive methods that the market for menstrual tracking apps offering natural methods of family planning has developed. In addition, the use of digital technologies to track menstrual cycle and fertility is perceived by many young women as a guarantee of reliability, with the advantage of ease of use and minimal cost. The personalised services of the apps are presented by their designers as a vector for women's empowerment: their 'intimate journal' entrusted to artificial intelligence liberates them from medical consultations (Ford 2021, Lupton 2015).

2.3. An often ideological promotion of natural contraceptive methods

The return to 'Nature' with the aim of birth control and conception is a major argument advocated by certain religious and/or ecologist movements (Maudet 2021, Le Guen 2020). These movements are very active online in denigrating hormonal contraception and in encouraging women to use other methods, which include menstrual tracking apps. Cyclamen, which preaches for '*une écologie de la fertilité pour un amour durable*' – the ecology of fertility for lasting love – is a website by CLER Amour et Famille, a Catholic association that campaigns for natural family planning (<http://www.methodes-naturelles.fr/>). It was founded in 1962 in reaction to the creation of the French Movement for family planning in 1960³.

The website promoting *Symptothermie*, whose advocates consider it a natural method for managing one's fertility, (<https://symptothermie-suisse.ch>), contains slogans such as: '*Bienvenue chez les femmes libérées... des hormones de synthèse!*' – welcoming women into the fold of those 'liberated' from synthetic hormones or '*Le corps d'une femme est aussi une terre*' – considering the 'pollution' of women's bodies with synthetic hormones to be comparable to the pollution of the environment. Behind *Symptothermie* is a Swiss Catholic association with links to the European Institute for Family Life Education (EIFLE, <https://iedh.fr>). This Catholic affiliated institute also has as a member the association 'Billings WOOMB Ovulation Method', which claims to be as effective as the pill and totally natural (<https://www.methode-billings-woomb.fr/>).

An in-depth investigation by the *Guardian* in 2019 revealed that Femm (an app used in Europe, USA and Africa) receives funds from Catholic anti-abortion and anti-gay movements. These are primarily private donations from the Chiaroscuro Foundation based in New York, in connection with a Catholic university in Santiago, Chile, a country where abortion has long been banned. The investigation also revealed that the medical advisers of the Femm Foundation do not have medical diplomas that are recognised in the USA⁴.

³ https://fr.wikipedia.org/wiki/CLER_Amour_et_Famille
https://fr.wikipedia.org/wiki/Mouvement_francais_pour_le_planning_familial

⁴ <https://www.theguardian.com/world/2019/may/30/revealed-womens-fertility-app-is-funded-by-anti-abortion-campaigners>

3. Ethical challenges of menstruation and fertility tracking apps

The use of menstrual tracking apps raises important ethical questions when it comes to evaluating the efficacy of the services offered, and when it comes to the use of personal data and respect for privacy. A large number of bad practices have recently been uncovered.

3.1. The apps' reliability called into question: between promises and reality

Recent research has examined the methodologies proposed by the menstrual tracking apps (Ali 2021, Earl 2021, Freis 2018, Moglia 2016, Shantz 2021, Zwingerman 2019). It turns out that the majority of them (54.4%) use the period calendar method to predict the fertile period and date of ovulation. This is an alarming observation given that the calendar method, which is based on the date of ovulation 14 days after the start of the period, is widely recognised as being unreliable (Bull 2019, Johnson 2018). Even women with very regular cycles ovulate on different days. Variations in the length of cycles of 7 days or more affect half of the female population.

The most reliable physiological data are daily temperature measurements (+ 0.2/0.4°C after ovulation), change in the consistency of the cervical mucus in the run-up to ovulation, urinary levels of luteinising hormone (LH), which increase 24-36 hours prior to ovulation. Some of these parameters are recorded in 28.6% of the apps but they are not systematically included in the prediction algorithms.

Several studies have sought to evaluate the accuracy of the apps' predictions using menstrual calendar simulation tests from banks of real-world data (Duane 2016, Freis 2018, Moglia 2016). Out of the one hundred apps examined, between 9 and 19% made correct predictions concerning fertile periods. For a given cycle profile, the predicted ovulation dates vary according to the calculation methods with differences of between 2 and 9 days for 67% of the apps tested (Worsfold 2021).

Some apps claim to provide a pre-diagnostic tool for identifying abnormalities in the cycle related to conditions such as endometriosis or polycystic ovary syndrome (PCOS). In 2019, Flo issued a questionnaire to evaluate PCOS risk among several thousand users. A clinical trial setting to ensure accuracy of the reports was not used. In fact, several cases of false diagnosis were reported (Singer 2019).

Very rare are the apps that publish their results in peer-reviewed scientific journals. The articles in question are produced by companies that develop the apps, with the authors declaring their interests. Thus, the developers of the Natural Cycles app have since 2015 regularly published analyses derived from their databases following user anonymisation and consent. Their algorithm includes the period calendar and the temperature for calculating the ovulation date and fertile period. LH measurement is optional (Berglund 2015, Kleinschmidt 2019). In 2016, Natural Cycles funded a study to calculate the Pearl Index, namely the number of women who become pregnant despite using contraception for a period of one year. Natural Cycles reported an index of 8, which is comparable to that of the pill. This result contrasts with data from biomedical literature that attribute a Pearl Index of 24 for natural family planning methods.

Such methods are classified by the US Centers for Disease Control and Prevention (CDC) as being the least effective⁵.

The methodology of the Natural Cycles study received a large amount of criticism (Frank-Hermann 2017). In 2018, the UK Advertising Standards Authority (ASA) concluded that the advertising promotion of Natural Cycles on Facebook regarding the reliability of their method was exaggerated and misleading to the public. Despite these controversies, the US Food and Drug Administration (FDA) recognised Natural Cycles as being a contraceptive device (Hough 2019). In Europe, the app was granted the CE label for the thermometer it markets, but this does not guarantee its efficacy as a contraceptive medical device.

Digital health apps: are they medical devices?

From a legal viewpoint, depending on the features and claims of the apps, they may or may not be considered as medical devices. In practice, many of the FemTech apps claim to serve a medical purpose while qualifying themselves as apps for 'well-being', thereby circumventing medical device regulations. The latter involve complex processes and require the publishers of apps to demonstrate a level of quality and efficacy in compliance with the new Regulation on Medical Devices (EU 2017/745) in Europe and with the Public Health Code in France. Only then is the app is granted the CE medical label.

In France, the medical technologies industry association SNITEM considers menstrual tracking apps as belonging to one of two categories:

- Apps that track or display data relating to the menstrual cycle: these are not qualified as being medical devices
- Apps that claim efficacy in controlling contraception or conception: these are eligible for medical device status,

(<https://www.snitem.fr/wp-content/uploads/2020/01/AOUT-2021-DM-ou-pas-DM.pdf>)

The apps' lack of reliability for the purposes of birth control and conception is partly explained by the practical reality of their use. In a context of 'perfect' use, theoretical efficacy is very good. However, following instructions to the letter is burdensome. Noting the dates of one's periods, cycle after cycle, involves the risk of forgetting something; taking one's daily temperature requires strict discipline; misinterpretations can happen when observing cervical mucus, etc. Even the best prediction algorithms are fallible if the data they are given is incomplete or incorrect⁶.

What stands out from all of this research is that the majority of apps do not use adequate calculation methods and do not provide sufficiently correct information on the users' ovulation and fertile dates. We can only deplore the lack of independent scientific studies on the apps to evaluate their efficacy in terms of both the methods and reality of their use, whether for birth control or conception.

⁵ <https://www.cdc.gov/reproductivehealth/contraception>

⁶ <https://www.kff.org/womens-health-policy/fact-sheet/natural-family-planning-as-a-means-of-preventing-pregnancy/>

3.2. Is the protection of the users' personal data guaranteed?

Several international NGOs working to protect online privacy (Electronic Frontier Foundation, Privacy International, Coding Rights, Consumer Report CR's Digital Lab) have conducted a detailed analysis of the security policies of the most popular apps: information on data sharing, identification procedures, control of personal information by the users, methodologies to secure data⁷. The results of the investigations concur in showing flaws in personal-data protection procedures (Rosato 2020).

The majority of the apps share their data with 'third parties' (external partner companies such as Google, Facebook, Amazon, etc.), most often without the users' knowledge (Gupta 2021, Quintin 2017). The authorisation to collect data, which appears in the apps' terms of use, is frequently accepted without being read. What this actually means is that 'third parties' can identify your smartphone and the apps you use to send you personalised messages. Furthermore, even if your data has been rendered anonymous, it can be cross-referenced with other information (geolocation, online contacts, loyalty cards, etc.) to trace you. Specialised firms known as data brokers compile individual information to assemble detailed profiles that are then sold to companies wishing to target their customers as closely as possible (publicists, insurance companies, etc.).⁸

In 2019, an investigation published by the *Wall Street Journal* revealed that Flo transmitted its users' personal data to third-party companies, including Facebook and Google, despite the app claiming to guarantee their confidentiality. The media impact of the case led to hundreds of users filing a complaint with the US Federal Trade Commission (FTC). In exchange for undertakings to hold an internal audit on its data management and inform victims of the information leaks, Flo was not sanctioned.

It should be emphasised that in the USA, menstrual tracking apps are not covered by the Health Insurance Portability and Accountability Act (HIPAA), which regulates the conditions for sharing private health information. In 2021, the US Senate tightened up the law requiring that health apps enable consumers to verify, modify or delete their health data collected by public and private companies (The Protecting Personal Health Data Act). These measures had already been in force in the state of California since January 2020⁹.

In the European Union, the General Data Protection Regulation (GDPR) protects citizens from the collection and use of personal data by third parties, public and private. Explicit consent by the user is necessary in order for his or her data to be used. The GDPR applies to companies publishing menstrual tracking apps whose head office is based in Europe. However, for those apps whose mode of operation is not transparent, the place of registration is not clearly defined. The fact that the apps are available in European countries is no guarantee of personal data security. In 2020, the Norwegian Consumer Council closely examined two very popular menstrual tracking apps and showed that they share information with dozens of advertising companies, in violation of GDPR¹⁰.

⁷<https://www.eff.org/fr/node/96638>(<https://www.privacyinternational.org/long-read/3196/no-bodys-business-mine-how-menstruation-apps-are-sharing-your-data>

⁸<https://www.wedig.fr/blog/data-fidelisation/qui-sont-les-data-brokers-ces-nouveaux-courtiers-de-donnees>

⁹<https://www.consumerreports.org/privacy/popular-apps-share-intimate-details-about-you-a1849218122/>

¹⁰<https://fil.forbrukerradet.no/wp-content/uploads/2020/01/mnemonic-security-test-report-v1.0.pdf>

The processing of personal data by the apps: how does the GDPR apply?

Personal health data are data that reveal information about a person's past, present or future physical or mental health.

This definition encompasses certain measurement data from which information on the subject's health status can be deduced.

The data collected by the apps are potentially health data, with the specific protection regime that applies to them (GDPR, French Data Protection Act), (<https://www.cnil.fr/fr/quest-ce-ce-quune-donnee-de-sante>)

If the app records and stores personal data only locally, with no external connection, the GDPR does not apply.

If the app recording the data uses external services for cloud backup, the GDPR does apply, (<https://www.cnil.fr/fr/applications-mobiles-en-sante-et-protection-des-donnees-personnelles-les-questions-se-poser>)

3.3. Abortion: American women encouraged to uninstall their menstrual tracking apps

In the USA, social media and associations have mobilised to encourage American women to uninstall their menstrual tracking apps. The media has relayed alarming reports that demonstrate the ease with which personal data managed by Apple and Google can make it possible to target people looking for information on abortion. With the overturning of the constitutional right to abortion, over half of the US states are in the process of prohibiting abortion, obliging women to travel long distances to access an abortion centre that is safe and legal. Similarly, the use of abortion pills which have recently become more accessible thanks to their prescription by remote consultation and mailing to PO boxes, could also become illegal in those states that are hostile to abortion. Authoritarian abuses such as the abortion 'bounty' in Texas expose US women to the risk of misuse of their online browsing data and the data they enter into their period tracker apps. Indeed, the US Cloud Act can compel digital companies to pass on their data to the authorities, particularly as part of police and/or criminal inquiries, with the risk that personal data will be used to punish women for having an abortion as well as those who helped them¹¹.

4. Conclusion and outlook

For many young women in the Internet era, menstrual tracking apps represent a digital tool like any other. Evidence of this is a 2022 German survey of a representative sample of women who use these apps on a daily basis (Amelang 2022). The majority of the respondents consider the apps to be very practical for recording their cycles and they trust AI to calculate their fertile periods. The question of the calculation methods used by the algorithms and the reliability of the predictions is not a subject of concern. Many users are aware that beyond the 'private dialogue' with the apps, their data is managed by external servers and may be used by

¹¹https://www.markey.senate.gov/imo/media/doc/lettersapple_google_play_store_data_policies.pdf

third parties. But the benefit that they declare to derive from the apps outweighs their perception of the threats to their privacy.

The discovery of bad practices in the services provided by menstrual tracking apps that are used by millions of women calls for ethical vigilance in order to inform their choices of methods to track cycles and fertility.

Firstly, the app designers should use reliable methods for the prediction of fertile periods that are based on sound scientific knowledge. This is not the case for the majority of apps that offer minimum service in the form of the period calendar method whose shortcomings have been proven. We can only regret the absence of quality control procedures for apps to inform consumers.

Secondly, information that can be understood by all users regarding the functioning of the apps is essential to raise awareness of the often overlooked reality of the risk of seeing their intimate sexual data used by third parties for commercial or other purposes. To paraphrase Mar Hicks, a specialist in the history of women in computer science, the problem is not about wanting to track our periods, but about being tracked ourselves. The economic stakes represented by the menstrual tracking apps market allows a certain threat to hang in the air – that of favouring economic interests to the detriment of women's intimate lives.

In a desirable future in which the reliability of predictions and the security of personal data are guaranteed, the apps represent a potential tool for providing women with valuable information on their sexual and reproductive health. For example, information on sexually transmitted infections, on strategies for having children, access to medically assisted reproduction, abortion, access to support for victims of domestic violence... In this scenario, health professionals, family planning professionals, women's associations, etc. would play a central role in guiding women in their choices and in helping them. It remains to be hoped that, taking inspiration from the emergence of ethical awareness on the part of artificial intelligence stakeholders, (<https://www.unesco.org/en/artificial-intelligence/recommendation-ethics>), the designers of menstrual tracking apps adopt virtuous practices in order to reconcile the quest for profit with public health and solidarity objectives.

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