Patient Care in COVID Times: Telehealth & Consumer Health Apps

Stephanie Morain, PhD, MPH

10/17/2020



- Describe policy factors shaping current—and future—uptake of telehealth
- Recognize potential equity issues related to the shift towards telehealth
- Identify ethics & regulatory issues related to the rise of new digital health tech

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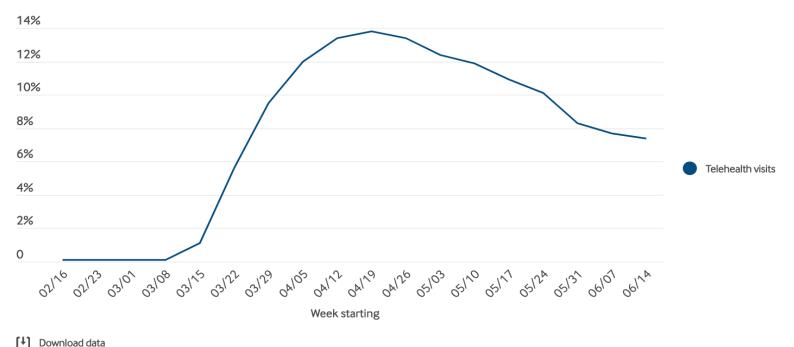


The Impact of the COVID-19 Pandemic on Outpatient Visits: Practices Are Adapting to the New Normal

June 25, 2020 | Ateev Mehrotra, Michael Chernew, David Linetsky, Hilary Hatch, and David Cutler

The number of telemedicine visits (as a percentage of visits during the baseline week) rose rapidly through mid-April but has since been steadily declining.

Number of telehealth visits in a given week as a percent of baseline total visits



Download data

Data are presented as a percentage, with the numerator being the number of telemedicine visits in a given week and the denominator being the number of visits in the baseline week (March 1–7). Telemedicine includes both telephone and video visits.

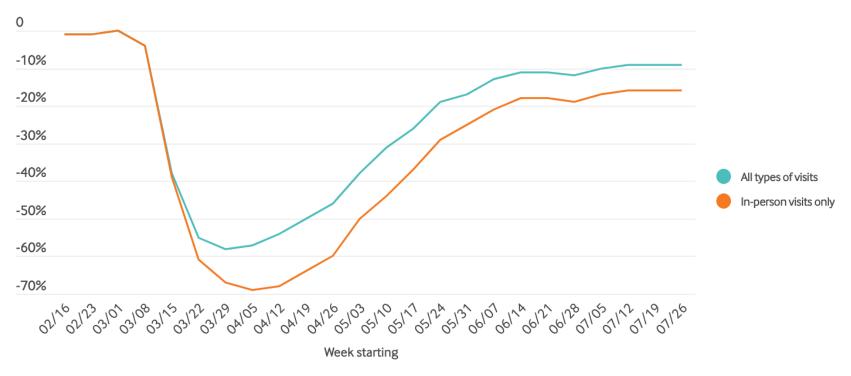
Source: Ateev Mehrotra et al., *The Impact of the COVID-19 Pandemic on Outpatient Visits: Practices Are Adapting to the New Normal* (Commonwealth Fund, June 2020). https://doi.org/10.26099/2v5t-9y63



The Impact of the COVID-19 Pandemic on Outpatient Visits: Practices Are Adapting to the New Normal

June 25, 2020 | Ateev Mehrotra, Michael Chernew, David Linetsky, Hilary Hatch, and David Cutler

Percent change in visits from baseline



Download data

Data are presented as percentage change in number of visits in a given week from baseline week (March 1–7). Telemedicine includes both telephone and video visits.

The Impact of the COVID-19 Pandemic on Outpatient Visits: Changing Patterns of Care in the Newest COVID-19 Hot Spots

August 13, 2020 | Ateev Mehrotra, Michael Chernew, David Linetsky, Hilary Hatch, David Cutler, and Eric C. Schneider



Note: Data are presented as a percentage change in the number of visits in a given week from the baseline week (March 1–7).

Source: Ateev Mehrotra et al., *The Impact of the COVID-19 Pandemic on Outpatient Visits: Changing Patterns of Care in the Newest COVID-19 Hot Spots* (Commonwealth Fund, Aug. 2020). https://doi.org/10.26099/yaqe-q550



The Impact of the COVID-19 Pandemic on Outpatient Visits: Changing Patterns of Care in the Newest COVID-19 Hot Spots

August 13, 2020 | Ateev Mehrotra, Michael Chernew, David Linetsky, Hilary Hatch, David Cutler, and Eric C. Schneider

There have been striking differences in speciality visit trends throughout the pandemic. Dermatology had one of the largest initial declines in visits but then rebounded above baseline. Behavioral health, which had one of the smallest initial declines, has only modestly rebounded, with visits plateauing at 15 percent to 20 percent below baseline.



Data for only four specialty areas shown to illustrate the range of trajectories. The decline shown is reflective of all visit types (in-person and telemedicine). Visits from nurse practitioners and physician assistants are not included. Behavioral health includes psychiatrists, psychologists, and social workers. Urgent care center visits are not included in adult primary care or pediatrics.

Source: Ateev Mehrotra et al., *The Impact of the COVID-19 Pandemic on Outpatient Visits: Changing Patterns of Care in the Newest COVID-19 Hot Spots* (Commonwealth Fund, Aug. 2020). https://doi.org/10.26099/yaqe-q550



- Social distancing requirements, patient concern about transmission
- Payment parity by CMS, private insurers for telehealth services
- CMS expanded coverage provisions for remote patient monitoring services (incl. care not related to pandemic)

HEALTH AFFAIRS BLOG

RELATED TOPICS:
TELEHEALTH | ORGANIZATION OF CARE | COVID-19 | VALUE | RESEARCH AGENDAS | COSTS AND SPENDING | ACCESS TO CARE

Establishing A Value-Based 'New Normal' For Telehealth

Christina Cutter, Nicholas L. Berlin, A. Mark Fendrick

OCTOBER 8, 2020

10.1377/hblog20201006.638022

Exhibit 1. Federal and state policy provisions during the COVID-19 Public Health Emergency.

POLICY THEME	KEY POLICY PROVISIONS
Regulatory	 Medicaid Section 1135 waivers granted Expanded eligible providers, patients, services Video requirement waived Telehealth waiver for treatment applied to all diagnoses Pre-existing, established relationship requirement waived HIPAA-compliant platform requirement waived
Payment	 Reimbursement rendered similar to in-person services Payment codes added for prolonged, audio-only evaluation Hospitals enabled to bill as originating site
Benefit Design	Cost-sharing waived or reduced for care furnished through telehealth

Baylor College of

Medicine[®]

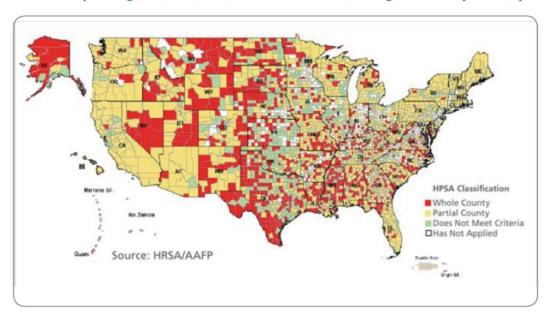
Ethically Relevant Impacts

- Protection from harm (disease exposure)
- Prevent abandonment of patients, maintaining continuity of care
- Reduce barriers for patients, families (transportation, wait times, etc.)

- Describe policy factors shaping current—and future—uptake of telehealth services
- Recognize potential equity issues related to the shift towards telehealth services
- Identify ethics & regulatory issues related to the rise of new digital health tech

Telehealth can expand access...

Federally Designated Health Professional Shortage Areas by County

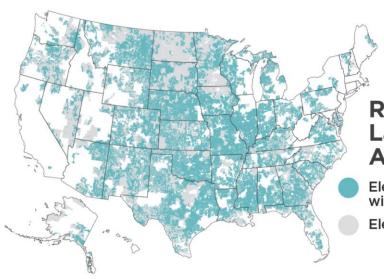


Rural areas

Incarcerated



Yet barriers remain....



Rural Americans Lack Broadband Access

- Electric co-op areas without broadband access
- Electric co-op service areas

Source: FCC Data



Research Letter | Health Care Policy and Law

August 3, 2020

Assessment of Disparities in Digital Access Among Medicare Beneficiaries and Implications for Telemedicine

Eric T. Roberts, PhD1; Ateev Mehrotra, MD, MPH2,3

≫ Author Affiliations | I Article Information

JAMA Intern Med. 2020;180(10):1386-1389. doi:10.1001/jamainternmed.2020.2666

Table. Limitations in Computer and Internet Access Among Community-Dwelling Medicare Beneficiaries in 2018a

Characteristic	Without desktop or laptop with high-speed internet ^b	computer	Without smartphone with for wireless internet ^c	a data plan	Without any digital access ^d		
	Proportion (95% CI), %	P value ^e	Proportion (95% CI), %	P value ^e	Proportion (95% CI), %	P value	
Among Medicare beneficiaries	41.4 (40.4-42.4)	NA	40.9 (40.0-41.8)	NA	26.3 (25.5-27.1)	NA	
Sex							
Male	39.2 (38.1-40.2)	<.001	38.6 (37.6-39.7)		24.0 (23.2-24.9)	. 001	
Female	43.3 (42.4-44.2)	_ <.001	42.8 (41.9-43.7)	_ <.001	28.1 (27.3-28.8)	<.001	
Age, y							
<64	46.8 (45.8-47.8)		35.2 (34.2-36.1)		24.4 (23.6-25.2)		
65-69	33.5 (32.5-34.3)		29.8 (28.8-30.7)		17.1 (16.4-17.8)	<.001	
70-74	36.2 (35.1-37.3)	4.001	36.1 (35.0-37.2)	<.001	21.1 (20.3-22.0)		
75-59	42.0 (40.8-43.1)	<.001	46.1 (44.9-47.3)		28.6 (27.5-29.6)		
80-84	49.9 (48.7-51.1)		56.9 (55.6-58.1)		38.4 (37.2-39.6)		
≥85	59.1 (57.9-60.2)		66.5 (65.3-67.7)		50.0 (48.7-51.2)		
Race/ethnicity							
Non-Hispanic White	38.6 (37.4-39.8)		40.7 (39.7-41.7)	<.001	24.5 (23.6-25.3)		
Non-Hispanic Black	56.3 (55.0-57.5)		47.9 (46.7-49.0)		37.3 (36.1-38.5)	<.001	
Hispanic	51.8 (50.7-53.0)	<.001	40.1 (38.9-41.2)		31.6 (30.5-32.7)		
Other	35.5 (33.4-37.5)		31.2 (29.3-33.1)		20.7 (18.9-22.6)		
Marital status							
Married	32.4 (31.4-33.5)		33.5 (32.5-34.5)	<.001	17.9 (17.2-18.7)	<.001	
Widowed	54.3 (53.3-55.4)	- 001	54.5 (53.4-55.5)		40.6 (39.6-41.7)		
Divorced or separated	49.2 (48.1-50.3)	 <.001	44.8 (43.8-45.8)		31.2 (30.3-32.2)		
Never married	51.7 (50.6-52.9)		47.6 (46.4-48.7)		34.3 (33.2-35.4)		
Educational attainment							
Less than high school	62.3 (61.2-63.4)		54.8 (53.6-56.1)		44.8 (43.7-46.0)		
High school	49.9 (48.9-50.8)	<.001	50.1 (49.2-51.0)	<.001	34.2 (33.5-35.0)	<.001	
Some college or higher	30.3 (29.5-31.1)		31.4 (30.7-32.2)		16.1 (15.5-16.6)		
Language spoken at home							
English	41.0 (39.9-42.1)		41.9 (40.9-42.8)	<.001	26.3 (25.4-27.1)		
Spanish	50.2 (49.0-51.4)	<.001	38.1 (37.0-39.2)		29.7 (28.6-30.9)	.01	
Other	36.7 (35.5-37.9)		34.6 (33.3-35.9)		22.5 (21.3-23.6)		
Household income, % of FPL ^f							
<100	67.5 (66.7-68.2)		61.9 (61.1-62.7)	<.001	50.1 (49.3-50.9)		
100 to <200	59.3 (58.5-60.1)		58.5 (57.5-59.4)		43.3 (42.4-44.2)		
200 to <300	44.1 (43.2-45.0)	<.001	45.5 (44.5-46.4)		27.9 (27.1-28.6)	<.001	
300 to <400	35.9 (34.9-36.8)		37.1 (36.2-38.0)		20.3 (19.6-21.0)		
≥400 FPL	25.0 (24.2-25.8)		24.5 (23.9-25.2)		11.5 (11.0-11.9)		
Enrolled in Medicaid							
Yes	54.4 (53.4-55.3)	. 001	47.3 (46.2-48.4)	. 001	36.1 (35.2-37.0)	. 001	
No	38.5 (37.5-39.5)	<.001	39.5 (38.5-40.4)	<.001	24.0 (23.2-24.8)	<.001	
Has disability ^g							
Yes	48.9 (48.0-49.9)	z 001	48.1 (47.1-49.0)	* 001	33.6 (32.8-34.4)	4 001	
No	36.9 (36.0-37.9)	<.001	36.7 (35.7-37.6)	<.001	21.8 (21.1-22.6)	<.001	

Table. Limitations in Computer and Internet Access Among Community-Dwelling Medicare Beneficiaries in 2018a Without desktop or laptop computer Without smartphone with a data plan with high-speed internet for wireless internet Without any digital access^d Characteristic Proportion (95% CI), % P value^e Proportion (95% CI), % P value^e Proportion (95% CI), % P value^e Among Medicare beneficiaries 41.4 (40.4-42.4) NA 40.9 (40.0-41.8) NA 26.3 (25.5-27.1) NA Sex Male 39.2 (38.1-40.2) 38.6 (37.6-39.7) 24.0 (23.2-24.9) <.001 <.001 <.001 Female 43.3 (42.4-44.2) 42.8 (41.9-43.7) 28.1 (27.3-28.8) Age, y <64 46.8 (45.8-47.8) 35.2 (34.2-36.1) 26% of Medicare 65-69 33.5 (32.5-34.3) 29.8 (28.8-30.7) 70-74 36.2 (35.1-37.3) 36.1 (35.0-37.2) <.001 <.001 beneficiaries lack digital 75-59 42.0 (40.8-43.1) 46.1 (44.9-47.3) 80-84 49.9 (48.7-51.1) 56.9 (55.6-58.1) ≥85 59.1 (57.9-60.2) 66.5 (65.3-67.7) access Race/ethnicity Non-Hispanic White 38.6 (37.4-39.8) 40.7 (39.7-41.7) Non-Hispanic Black 56.3 (55.0-57.5) 47.9 (46.7-49.0) 37.3 (36.1-38.5) Hispanic 51.8 (50.7-53.0) <.001 40.1 (38.9-41.2) <.001 31.6 (30.5-32.7) <.001 Other 35.5 (33.4-37.5) 31.2 (29.3-33.1) 20.7 (18.9-22.6) Marital status Married 32.4 (31.4-33.5) 33.5 (32.5-34.5) 17.9 (17.2-18.7) Widowed 54.3 (53.3-55.4) 54.5 (53.4-55.5) 40.6 (39.6-41.7) <.001 <.001 <.001 Divorced or separated 49.2 (48.1-50.3) 31.2 (30.3-32.2) 44.8 (43.8-45.8) Never married 51.7 (50.6-52.9) 47.6 (46.4-48.7) 34.3 (3 Digital access issues Educational attainment Less than high school 62.3 (61.2-63.4) 54.8 (53.6-56.1) 44.8 (4 greatest among those >85, High school 49.9 (48.9-50.8) <.001 50.1 (49.2-51.0) <.001 34.2 (3 Some college or higher 30.3 (29.5-31.1) 31.4 (30.7-32.2) 16.1 Language spoken at home Non-Hispanic Blacks, 26.3 (English 41.0 (39.9-42.1) 41.9 (40.9-42.8) 29.7 Spanish 50.2 (49.0-51.4) <.001 38.1 (37.0-39.2) <.001 Hispanics, <100 FPL Other 36.7 (35.5-37.9) 34.6 (33.3-35.9) 22.5 (2 Household income, % of FPLf <100 50.1 (4 67.5 (66.7-68.2) 61.9 (61.1-62.7) 100 to < 200 59.3 (58.5-60.1) 43.3 (42.4-44.2) 58.5 (57.5-59.4) 200 to <300 44.1 (43.2-45.0) <.001 45.5 (44.5-46.4) <.001 27.9 (27.1-28.6) <.001 300 to <400 35.9 (34.9-36.8) 20.3 (19.6-21.0) 37.1 (36.2-38.0) ≥400 FPL 25.0 (24.2-25.8) 24.5 (23.9-25.2) 11.5 (11.0-11.9) **Enrolled in Medicaid**

47.3 (46.2-48.4)

39.5 (38.5-40.4)

48.1 (47.1-49.0)

36.7 (35.7-37.6)

<.001

<.001

36.1 (35.2-37.0)

24.0 (23.2-24.8)

33.6 (32.8-34.4)

21.8 (21.1-22.6)

<.001

<.001

<.001

<.001

Yes

No

No

Has disability⁹ Yes 54.4 (53.4-55.3)

38.5 (37.5-39.5)

48.9 (48.0-49.9)

36.9 (36.0-37.9)

- Reimburse for audio-only visits (current)
- Consider telecommunication devices as "medically necessary" (& reimbursable via insurance)
- Expand access to broadband internet, phones for low-income populations



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Lifeline Program for Low-Income Consumers

Lifeline

Since 1985, the Lifeline program has provided a discount on phone service for qualifying low-income consumers to ensure that all Americans have the opportunities and security that phone service brings, including being able to connect to jobs, family and emergency services. Lifeline is part of the Universal Service Fund. The Lifeline program is available to eligible low-income consumers in every state, territory, commonwealth, and on Tribal lands.

The Lifeline program is administered by the Universal Service Administrative Company (USAC). USAC is responsible for data collection and maintenance, support calculation, and disbursement for the low-income program. USAC's website provides information regarding administrative aspects of the low-income program, as well as program requirements.

On March 31, 2016, the Commission adopted a comprehensive reform and modernization of the Lifeline program. In the 2016 Lifeline Modernization Order, the Commission included broadband as a support service in the Lifeline program. The Commission also set out

More Lifeline Information:

- Universal Service Administrative Company (USAC)
- FCC Consumer Guide: Lifeline Support for Affordable Communications
- Lifeline Across America Consumer Outreach
- Lifeline Broadband Provider Petitions
- Oklahoma Enhanced Lifeline Support Maps
- Lifeline Provider Compliance Plans and ETC Petitions
- Low-Income Broadband Pilot Program

Lifeline Fraud Tip Line: **1-855-4LL-TIPS (or 1-855-455-8477) or Lifelinetips@fcc.gov**. Please provide as much detail as possible, including your name and contact information and the company you are using to receive Lifeline-supported phone service.

- Describe policy factors shaping current—and future—uptake of telehealth services
- Recognize potential equity issues related to the shift towards telehealth services
- Identify ethics & regulatory issues related to the rise of new digital health tech

NEWS RELEASES

Tuesday, September 15, 2020

NIH awards contracts to develop innovative digital health technologies for COVID-19



The National Institutes of Health has awarded seven contracts to companies and academic institutions to develop digital health solutions that help address the COVID-19 pandemic. The work could lead to user-friendly tools such as smartphone apps, wearable devices, and software that can identify and trace contacts of infected individuals, keep track of verified COVID-19 test results, and monitor the health status of infected and potentially infected individuals.

The National Cancer Institute (NCI) and the National Institute of Biomedical Imaging and Bioengineering (NIBIB), both part of NIH, selected the seven projects from nearly 200 different ideas. The projects represent a broad range of solutions for immediate public health needs related to the pandemic, and several focus on solutions for medically underserved communities and people with limited access to health care, who are disproportionally affected by COVID-19.



Remote patient monitoring



At-home testing





Digital biomarkers



Amazon, Berkshire Hathaway and JPMorgan Team Up to Try to Disrupt Health Care



away and JPMorgan Chase to try to improve health care. Br

By Nick Wingfield, Katie Thomas and Reed Abelson

Jan. 30, 2018

UPDATE

January 24, 2018

Apple announces effortless solution bringing health records to iPhone



Health Records Brings Together Hospitals, Clinics and the Existing Health App to Give a Fuller Snapshot of Health



These Apps Are The Uber Of Birth Control

CARLI WHITWELL
LAST UPDATED JANUARY 22, 2020, 10:26 A.M.









The last time I had a <u>UTI</u>, I ended up in emergency. Not because it was a particularly terrible <u>bladder infection</u> (just your standard below-the-belt hell). But because, like <u>4.8</u> million Canadians, I didn't have a regular family doctor. As I sat in the waiting room for hours on a Sunday evening alongside people who needed actual help, I thought, *There has to be a better way*.

PARENTHOOD > PREGNANCY

The Best Fertility Apps of 2020

Clue | Flo | Glow | Fertility Friend | Ovia | Natural Cycles | Period Tracker |

Period Tracker Health Calendar | Ovulation Calendar | Eve | Bellabeat |

Cycles | Period Tracker Period Calendar | Life



Understanding your own biology can be particularly helpful if you're trying to conceive. And today, technology can make tracking your cycle and fertility days so much easier.

We rounded up the year's best fertility apps based on their useful content, excellent reviews, and consistent reliability.

Covid-19 is ushering in a new era of athome sexual health tests



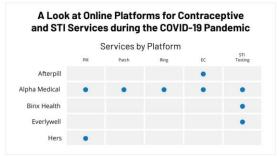
Home // Newsroom // Online Contraceptive and STI Services During COVID-19: What are the options?

Online Contraceptive and STI Services During COVID-19: What are the options?

Published: Apr 23, 2020



A new KFF issue brief provides an overview of online options for contraceptive and STI services during the COVID-19 pandemic. This resource also includes an interactive table that shows which platforms are available in each state and which accept private insurance or Medicaid.



The majority of traditional family planning clinics are still open for in-person care or are moving to telehealth services – but some clinics and providers have reduced hours and limited in-person visits to patients with urgent needs only. There are dozens of online platforms for contraception and STI management, which offer an alternative for obtaining care as clinics face staffing shortages and take measures to scale back in-person visits to reduce the risk of coronavirus transmission.

PEDIATRICS PERSPECTIVES

Teenage Use of Smartphone Applications for Menstrual Cycle Tracking

Leah R. Fowler, JD, a Charlotte Gillard, b Stephanie Morain, PhD, MPHc

American Journal of Law & Medicine, 46 (2020): 203-218 © 2020 American Society of Law, Medicine & Ethics Boston University School of Law DOI: 10.1177/0098858820933495

Schrödinger's App

Leah R. Fowler[†] and Stephanie R. Morain[‡]

Resources, Frameworks, and Perspectives

From Cervical Cap to Mobile App: Examining the Potential Reproductive Health Impacts of New Technologies

> Julie M. Dorland, BS, BA¹ Leah R. Fowler, JD² Stephanie R. Morain, MPH, PhD¹

and Perspectives

Readability and Accessibility of Terms of Service and Privacy Policies for Menstruation-Tracking Smartphone Applications

Leah R. Fowler, JD¹D
Charlotte Gillard²
Stephanie R. Morain, MPH, PhD³D

Rising use of telecontraception...aka "Uber for Birth Control"



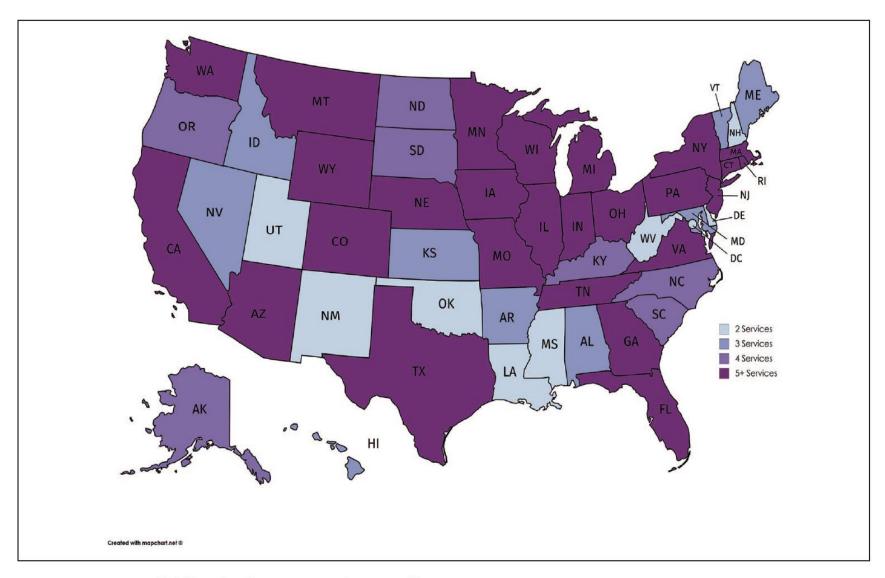


FIGURE 1 State Availability of Online Contraceptive Prescribers.

TABLE 1 Available Mobile Apps for Contraception

App	Age (Years)	Consultation Fee (\$)	Contraceptive Methods Available	Prescription Length	Communication Requirements		
HeyDoctor	18-50	15	Pill, ring, patch	3-6 months	Messaging		
Lemonaid	18+	25	Pill, ring, patch	1 year	Video call in some states		
Maven	13+	18-35	Information Unavailable	Varies by provider	Messaging or video call		
Nurx	12 ^a -50	None ^d	Pill	1 year	Messaging is optional		
Pandia Health	Any ^b	39 for home delivery, 59 for prescription to pharmacy	Pill, ring, patch, emergency contraception	1 year	Physician contacts patient if necessary		
Planned Parenthood Direct	14+ ^a	None	Pill	1 year	Video call in some states		
PlushCare	16-35 ^c	99	Pill, ring, patch, emergency contraception	6 months – 1 year	Video call required		
PRJKT RUBY	18+	None	Pill and emergency contraception	1 year	Video or audio call		
The Pill Club	12-44	15	Pill, ring, patch, emergency contraception	1 year	Messaging		
Virtuwell	18-59	49	Pill, ring, patch, emergency contraception	3 months – 1 year ^e	Audio call is optional		
Simple Health	18+	20	Pill, ring, patch	1 year	Physician contacts patient if necessary		
Hers	18-50	5	Pill	Varies by prescription	Messaging		
Twentyeight Health	18-49	20	Pill and emergency contraception	1 year	Messaging, optional audio call if new to contraception		

^aAvailability to minors varies by state law. ^bPer California law. ^cOther ages may receive contraception depending on provider. ^dIn North Carolina, fee is \$12. ^eThree months for new contraception users, 1 year for previous users.

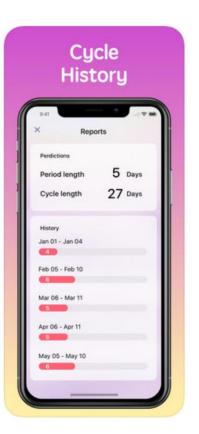
Questions for Population Health...

- Do apps expand access...or convenience?
- Impact on other preventative services?
- Integration with medical records?

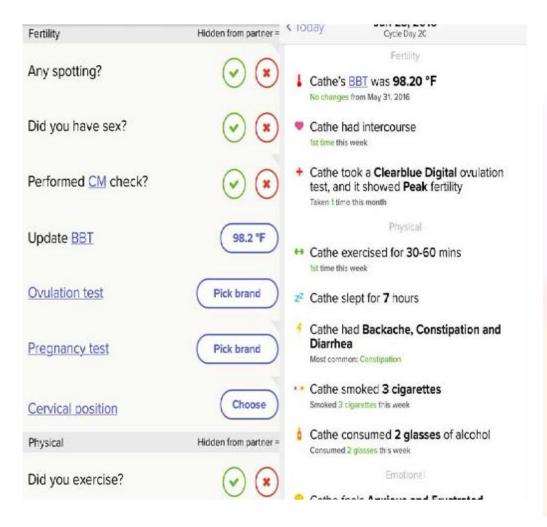
Rise of period tracking apps & "femtech"

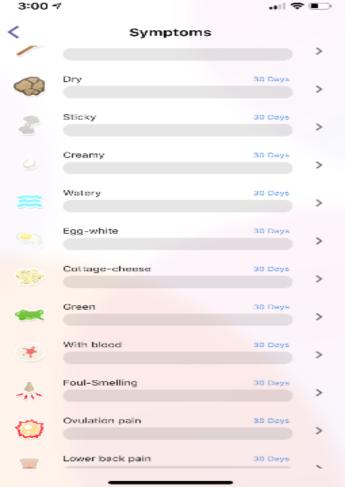






Apps collect—& share—intimate data





...raising (extensive) privacy concerns

January 24, 2019, 5:00 AM CST

Period-Tracking Apps Are Monetizing Women's Extremely Personal Data

 More than 100 million women monitor their cycles on their phones. Here come the ads.

Period-tracking apps are not for women

The golden age of menstrual surveillance is great for men, marketers, and medical companies.

By Kaitlyn Tiffany | @kait_tiffany | kaitlyn.tiffany@vox.com | Updated Nov 16, 2018, 12:35pm EST

By Jerry Beilinson

Technology

Is your pregnancy app sharing your intimate data with your boss?

As apps to help moms monitor their health proliferate, employers and insurers pay to keep tabs on the vast and valuable data

Glow Pregnancy App Exposed Women to Privacy Threats, Consumer Reports Finds

Glow has responded by fixing the problems and updating the app

HEALTH | SEPT. 9, 2019

Is Your Period-Tracking App Telling Facebook When You Last Had Sex?

By Amanda Arnold 🔰 @aMandolinz

Their accuracy is also often...questionable

You Probably Shouldn't Follow Medical Advice From Your Period Tracker The FDA continues to let startups turn medical diagnoses into a freefor-all, and apps like Clue and Flo are no exception. By Harnah Smethern Oct 28 2019, 2015cc Stare Fisher Fishe

HEALTH

1 in 5 period-tracking apps make errors, affecting chances of pregnancy: study

BY STAFF - THE CANADIAN PRESS

Posted January 6, 2020 4:42 pm Updated January 6, 2020 4:43 pm

Rhonda Zwingerman of Mount Sinai Hospital says 31 of the apps contained inaccuracies that could put users at risk of unintended pregnancy or delayed conception.

She says some apps made false guarantees about their efficacy as a contraceptive tool or unscientific claims that intercourse on certain days could influence a baby's sex.

More than half of fertility and period-tracker apps ineffective at predicting ovulation, study finds



Share on Twitter

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QUICK TAKE

Period-tracking apps get failing grade: They're not accurate. And they're way too pink

By USHA LEE MCFARLING / MAY 2, 2017

Terms of service & privacy policies are unreadable

App Name	Flesch-Kincaid Reading Level		Words per sentence (avg)		Passive voice (%)		# of Scrolls (iPhone 8)		Required In-App Viewing for Use	
	ToS	PP	ToS	PP	ToS	PP	ToS	PP	ToS	PP
Clue	12.4	12.8	19.8	23.3	23	29	17	34	No	No
Flo	15.1	13.7	28.4	24	20	10	29.5	42	No	No
Period Tracker	17.7	14	31	23.8	23	19	17.5	7.5	No	No
Ovia	14.2	13.6	25.3	23.6	16	17	42	17.5	No	No
Eve	15.2	15.3	28.7	29.5	15	14	57.5	62.5	No	No
Glow	15.2	15.3	28.7	29.5	15	14	59.5	60	No	No
Fertility Friend	14.1	12.1	22.8	17.3	33	29	4.5	9.5	No	No
Spot On	15.8	14.9	28.8	25.1	18	16	37	27	No	No
Kindara	15.5	13.1	28.9	20.3	23	17	84.5	16.5	No	No
Life	19.4	19.1	36.7	37	18	22	18 5	4	No	No
Cycles	12	12.5	19.9	22.4	27	19	13.5	24	No	No
Period Diary	15	14.7	29.4	25.6	14	17	27.5	25	No	No
Period Calendar	11	12.3	18.4	23.5	16.2	29	16.5	2.5	No	No
Dot	13.5	9.4	23.5	16.2	26	13	5	4	No	No
Natural Cycles	11.7	13.6	19.2	23.6	22	22.2	38.5	24.5	No	No

Leah R. Fowler, Charlotte Gillard, and Stephanie R. Morain, Readability and Accessibility of Terms of Service and Privacy Policies for Menstruation-Tracking Smartphone Applications HEALTH PROMOTION PRAC.

...yet many apps outside scope of HIPAA

Determining HIPAA Scope:

- Do you create, receive, maintain, or transmit identifiable health information?
- Are you a health care provider or health plan?
- Do consumers need a prescription to access your app?
- Are you developing this app on behalf of a HIPAA covered entity (such as a hospital, doctor's office, health insurer, or health plan's wellness program)?

https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool#identifiable

Some are FDA-cleared...but marketing can mislead







Learn about your unique cycle

- ✓ Track your period, symptoms, moods, and more!
- Receive accurate predictions for period and ovulation
- Explore articles, fertility facts, and health tips
- Read personalized summaries of your health and fertility
- Connect with an anonymous community of women





...& many exempted from FDA oversight

Section 3060(a) of the 21st Century Cures Act amended section 520 of the Federal Food, Drug, and Cosmetic Act, removing certain software functions, including those intended for maintaining or encouraging a healthy lifestyle that are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, from the definition of device in section 201(h) of the FD&C Act.

2019 Draft Guidance moves some mobile apps from the "enforcement discretion" category to the "not a medical device" category. This includes mobile apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness.

Apps raise special considerations for teen users





Leah R. Fowler, Charlotte Gillard, and Stephanie R. Morain, *Teen Use of Smartphone Applications for Menstrual Cycle Tracking*. PEDIATRICS. 2020.

Implications?

- COVID accelerated rise of new tech
- New tech platforms present challenges for policy & practice
- Existing regulations not well-suited to govern their use
- Key role for provider awareness to respond to--& influence—these trajectories

Telehealth & New Tech Takeaways

- Telehealth is "here to stay"...although form/scope TBD
- Disparities in access persist
- Traditional regulatory approach a poor fit for new health tech
- Providers should be aware of new tech, discuss with patients, and advocate for appropriate governance

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