

# Connected Health

# Mobile Health

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# Objectives

Identify the development and transition of mHealth

Identify technology growth that made and makes mHealth possible

Discuss regulatory mechanisms for mobile devices and apps

Discuss approved medical mobile devices/apps v. consumer facing

Identify populations mHealth has, can and will impact.

# **How did we get to Mobile Health - mHealth**

Technology has changed the way we communicate

Communication evolution has over the last 25-50 years

We live in a world of immediate gratification

# Telehealth to Mobile Health

Telehealth is an umbrella word

Telemedicine

Mobile Health

Health Mobile

mHealth

eHealth

Focus on mHealth or Mobile Health



# Evolution to mHealth

Smartphone technology became available/usable 2006-2008

Internet technology caught up to smartphones 2010

Applications for smartphones started to develop

Applications became more than games

Connectivity became more reliable and less fragile (converting to fiber networks)

Cost of Smartphones started coming down

Value of investment in Smartphones started to be realized

# Use of Mobile/Smartphones

2014 projections

2021 reality

The goal of mHealth is to connect electronically, through technology, with healthcare. This is most often done with a smartphone but can also be done with tablets, laptops, and “other” devices.

# Goal of mHealth

Connect people/populations with healthcare

Electronically - technology

Telehealth appointments - previous lectures

Mobile Medical Devices and Mobile Apps

- Synchronous monitoring (real time monitoring)

- Asynchronous monitoring (stored and forwarded monitoring)

# Lessons from COVID and the such

Accessibility through mobile and wireless technology was limited until COVID

Public Health Emergency quickly expanded guidelines and use of mHealth

No longer limited to rural and isolated populations

Unknown “at risk” populations



# Mobile Medical App and/or Device

The Food and Drug Administration (FDA)

Mobile medical app

Software

Smartphone, tablet or other communication device

Used to manage health and/or wellness

Mobile medical device

Device that is used to manage health and/or wellness

Some devices will have software that interfaces

# FDA/International Approval

In the United States, the FDA is the governing body that regulates, approves, certifies all Mobile Medical Devices and Mobile Apps that make claims of healthcare benefits.

In the UK the governing body is the Medicines and Healthcare Products Regulatory Agency

There is not one international organization that takes this responsibility for the world.

# Overview of FDA Approval Process

FDA registration and approval process takes time and money.

Registration cost is in the hundreds of dollars

Approval process cost is in the thousands of dollars (fees to the FDA, not the R&D)

The approval process has multiple steps that include labeling requirements, marketing approval, quality system regulation, adverse event reporting and problem correction.

There are many companies that will help with the navigation of this process.

# Medically Approved v. Consumer Facing

Medically Approved means there has been FDA approval

Consumer Facing means the product you are looking is is not sold as a medical device or app and does not have the approval of the FDA.

FDA approval cost lots of money, lots of time, probably lots of heart ache for someone.

Consumer Facing products do not go through this process.

# What Kind of Devices and Apps are Available

Medical Devices

Pacemakers

Internal automated defibrillators

Implantable impulse generator

Oxygen machines\*\*

C-Pap machines

Sleep Apnea implants

Insulin Pumps (implanted or external)



# Wellness Tracking

Consumer Facing

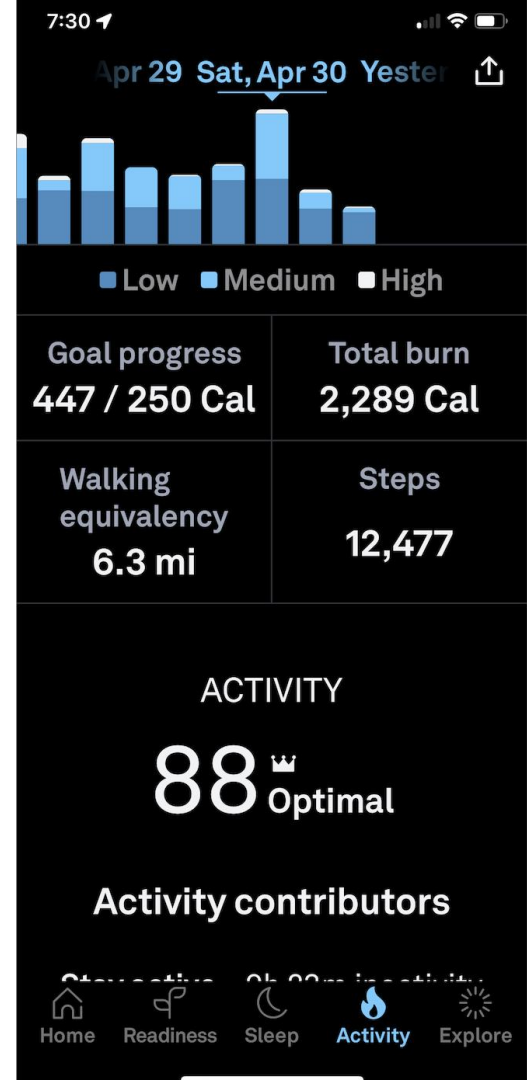
Fitness trackers

Wrist

Clip-on device

Earpiece

Smart fabric



# Wellness Tracking - Statistics

Women are more likely to purchase (and use) than men

61% of fitness tracker sales are made online

42% of the revenue in this area comes from North America

Asia is projected to become the next fastest growing market from 2021-2028

43% - fitness band

28% - smart watch

12% - smart clothing

11% - smart glasses

2% - other options

# Statistics - cont.

## Income

50% upper income households

33% middle income households

25% low income households

adults - 26%

## Geographic Location

Black adults - 23%

Urban 35% usage

White adults - 22%

Rural 30% usage

## Race & Ethnicity

Hispanic



# Other Devices and Apps

Fitbit - Apple Watch

Orua Ring

Portable EKG

Hearing Aids

Weight Loss apps

Exercise apps



# Psych/Mental/Behavioral mHealth

Behavioral Health (BH) has had a spotlight shined on it with COVID lockdowns

mHealth can provide support for some BH conditions

- Does the app meet appropriate federal and/or industry regulations
- Does the app use/supported by evidence-based research
- Is there a third-party certification
- Are there any legal or regulatory actions - settled or outstanding - against the vendor
- Does the vendor ensure social equity and diversity

# Psych/Mental/Behavioral mHealth

Offerings:

Telehealth for individual assessments

Group therapy can be offered via remote session

Behavioral Health apps can offer check-in and monitoring

Telehealth can offer prescription monitoring and refills

The flexibility of telehealth and mHealth allow the provider and the patient the opportunity for success and the portal for necessary brick and mortar treatment

# Additional mHealth Apps

Diet App

Exercise App

Nutrition/Good Eating - Education App

Smoking Cessation App

Habit reduction App

Social Media



# mHealth - Patient/Audience Engagement

350,000 wellness apps available

Voluntary v involuntary participation

What motivates the user

What is the functional ability of the user

What are the goals of the user



# Focus on Specific Populations

There are very young “old” people and very “old” young people

App design should be aimed at the targeted population

Is the app easy to learn

Can I see the app

How fast can the user perform on the app after learning

How are error accommodate for

Does the user feel satisfied when using the app

What type of support is available

# **Ethics, Data Collection, Storage**

US Department of Health and Human Services

Office of Human Research Protections

Health Insurance Portability and Accountability Act (HIPAA)

Research studies

Institutional Review Boards (IRBs)

Health data storage - long term

Office of Extramural Research, Education and Priority Populations

# Payment/Reimbursement for Telehealth

Currently the United States is in a declared Public Health Emergency

Covid-19 pandemic pushed the boundaries of telehealth

Emergency 1135 waiver

- Expands telehealth

- Extends telehealth coverage

<https://telehealth.hhs.gov/providers/telehealth-for-behavioral-health/billing-for-telebehavioral-health/>

<https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>



# Resources for Healthcare Professionals

Telehealth.HHS.GOV - specific to providers

Getting started

Planning telehealth workflow

Health equity

Preparing patients

Covid-19

Policy changes r/t Covid pandemic

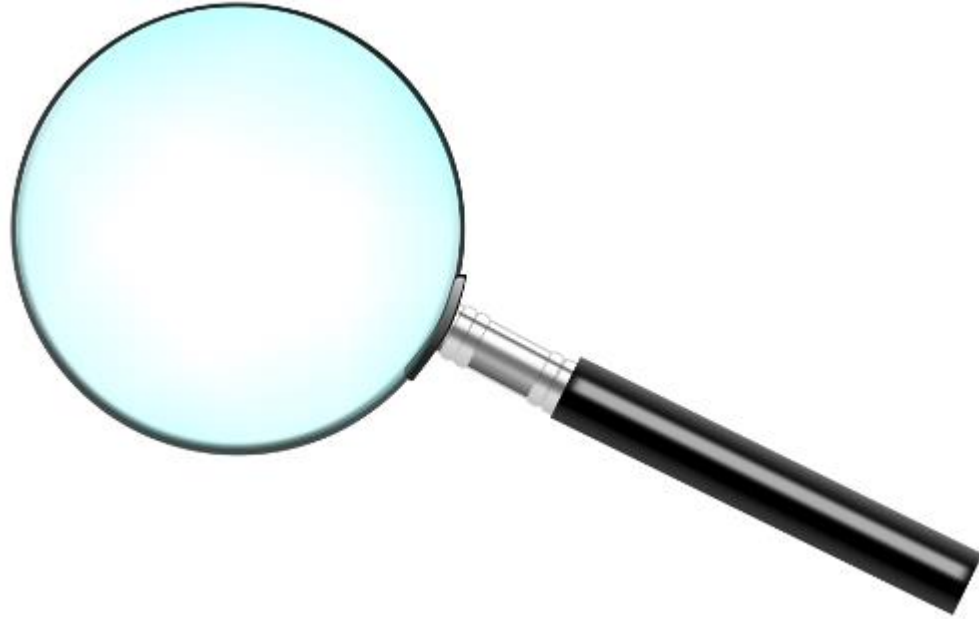
Billing r/t Covid

Legal considerations

Best practice Guides



*Questions*



## References

Pew Research Center (2021) Mobile fact sheet <https://www.pewresearch.org/internet/fact-sheet/mobile/>

US Food & Drug Administration (2022). What does FDA regulate? <https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate>

US Food & Drug Administration (2019). Policy for device software functions and mobile medical applications. <https://www.fda.gov/media/80958/download>

US Food & Drug Administration (2019). Device software functions including mobile medical applications. <https://www.fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications>

Rizzo, N., (2021). 50+ Wearable fitness tracker statistics 2021. RunRepeat. <https://runrepeat.com/fitness-tracker-statistics>

Muinon, L., (2022). Top 8 online psychiatry services in 2022. Healthline. <https://www.healthline.com/health/mental-health/online-psychiatrist#how-we-chose>

Telehealth Health and Human Services (2022). Telehealth for behavioral health care. <https://telehealth.hhs.gov/providers/telehealth-for-behavioral-health/>

Mercer, K., et al, (2015). Using a collaborative research approach to develop an interdisciplinary research agenda for the study of mobile health interventions for older adults. JMIR Publications. <https://mhealth.jmir.org/2015/1/e11/>

Telehealth Health And Human Services (2022). Billing for telebehavioral health. <https://telehealth.hhs.gov/providers/telehealth-for-behavioral-health/billing-for-telebehavioral-health/>

Centers for Medicare & Medicaid Services (2020). Medicare telemedicine health care provider fact sheet. <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>