Navigating *The Playbook:* Digital Healthcare Edition

Your user guide to *The Playbook:* **Digital Healthcare Edition**

The **opportunities** digital health solutions bring to deliver high-value healthcare.

Industry definitions, classification and **regulation** of digital health solutions.

Your micro-playbooks to digital health solutions

- **AI/ML**
- **AR/VR/MR**
- **Connected Sensor Technology**
- **Digital Therapeutics**
- **Electronic health records**
- **Mobile health applications**
- **Engagement and Social Media**
- **Virtual care**

PRO TIP

Throughout the slides you will see ***'TL;DR'***. This is a common acronym for '***Too Long; Didn't Read.***'

We are acknowledging how busy you are and that a **small chunk of text is easier to digest** than a large portion of text on a slide.

mHealth

TL;DR

mHealth is easily accessible and scalable mobile applications delivering care everywhere

What is **mHealth?**

- **Mobile Health Applications** medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices. Usually they have no regulatory oversight.
- **Mobile Medical Apps (MMAs)** are medical devices that are mobile apps, and meet the definition of a medical device, and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device.
- **Deployed across therapeutic areas** including Diabetes, Cardiovascular health, Wellness, Pregnancy, Chronic illness and so on.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications, https://www.businessinsider.com/mhealth-apps-definition-examples, https://www.europeansources.info/record/green-paper-on-mobile-health-mhealth/

PRO TIP

For the last decade, mHealth has constantly expanded and these technologies have changed the **way we deliver** and **think about delivering care** to patients and how individuals in the community **manage their own health and wellness.**

mHealth solutions can be:

- Direct to the consumer (D2C)
- Non-direct to consumer
  or,
- Utilize Bring-your-own-device (BYOD) model

Source: FDA, DiMe-VHA The Playbook: Healthcare team analysis, Digital Medicine: A Primer on Measurement, mHealth and Mobile Medical Apps: A Framework to Assess Risk and Promote Safer Use - PMC (nih.gov)

mHealth has evolved over years… and our understanding must, too!

Mobile Health Applications

European commission and WHO defines the term

Apps include **lifestyle and wellbeing apps** that may connect to medical devices or sensors as well as personal guidance systems, health information and medication reminders provided by sms and telemedicine provided wirelessly

Regulatory oversight depends on functionality. Examples of Mobile app functionalities that FDA does not regulate

Different types of mHealth technologies available worldwide

Mobile Medical Applications (MMAs)

FDA defines the term MMA

They **meet the definition of a medical device**. It is intended to be used as an accessory to a regulated medical device or transforms a mobile platform into a regulated medical device.

Regulatory oversight for the the safety and effectiveness of MMA's Read more

Examples of premarket submissions of MMAs that are **cleared or approved by the FDA**

Source: DiMe-VHA The Playbook: Healthcare team analysis, Device Software Functions Including Mobile Medical Applications | FDA, https://www.europeansources.info/record/green-paper-on-mobile-health-mhealth/

PRO TIP

The **consumer-grade tools and mobile apps** are intended to be **consumer-facing** rather than used in clinical care as these products often **lack evidence** necessary to support the medical use of the information they produce and usually **lack regulatory oversight**. **Sometimes** these tools are **used** for measurement **in clinical research**. E.g. accelerometer manufactured for the consumer market to measure physical activity in a clinical trial. However, it would require evidence to support this use

The **medical-grade tools and MMAs** are intended for the use in healthcare settings that are **patient-facing and claims to improve health and care** for individuals. Such tools with software-based functionalities and applications falls under the purview of medical devices classification in US with regulatory oversight for safety and effectiveness

Examples of Mobile Apps That Are NOT Medical Devices

Source: FDA, DiMe-VHA The Playbook: Healthcare team analysis, Digital Medicine: A Primer on Measurement, mHealth and Mobile Medical Apps: A Framework to Assess Risk and Promote Safer Use - PMC (nih.gov)

What opportunities do mHealth apps provide to patients and the people who care for them?

Opportunities to create value for patients, providers and healthcare systems

High contact speed with patients and ease of use makes it easily **accessible**

Facilitate engagement with low to no-training for use of applications

Low cost of deployment for clinical solution to vast population

Deliver quality information to **underserved populations**

Easy to scale applications via patient-owned devices

Increasing consumer demand for mhealth applications to monitor health and wellness

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.nature.com/articles/s41746-019-0206-

From ubiquity to non-uniqueness: mHealth is everywhere in the US but is it opportunistic?

85% of adults in the US use smartphones. While smartphone technology has increased the potential impact and scope of mHealth dramatically, challenges to scale remain. mHealth offers a pathway to provide more affordable healthcare and is anticipated to play an important role for management of personal health. However, with no regulatory oversight, the overcrowded mHealth app space raises concerns about safety and trustworthiness.

Challenge

Ubiquitous mHealth solutions creates challenges in the selection of the right tool

Challenge

Regulatory oversight proportional to the degree of risk(s) that apps pose to the user

Challenge

Limitation of evidence based retrospective analyses of patient generated outcomes in mHealth

Challenge

Lack of interoperability of systems to exchange and interpret data

Challenge

Evidence to demonstrate reliability and **utilization** for high-value, quality clinical care

Source: DiMe-VHA The Playbook: Healthcare team analysis https://www.nature.com/articles/s41746-019-0206-x
https://www.statista.com/statistics/779910/health-apps-available-ios-worldwide/

SPOTLIGHT

Evolution of mobile applications to software-based, regulated Medical Mobile Applications (MMAs)

Mobile apps or Mobile health apps can help people manage their own **health and wellness**, promote healthy living. There are 325,000+ health care applications were available on smartphones.

Users include
1) Health care professionals
2) Consumers
3) Patients

In 2013, **FDA** issued policy of MMA guidance for **oversight of software functions**, as devices.

Focus is on **software with a greater risk** to patients if it doesn't **work as intended** and one that causes smartphones, computers, or other mobile platforms to **impact the functionality or performance** of traditional medical devices.

In 2019, with Section 3060 of the 21st Century Cures Act, FDA updated which created a function-specific definition for device that are **independent of the platform** on which they might run.

Therefore, instances of **"mobile application" in the guidances** and in FDA's lexicon have been **changed to "software function."**

Source: DiMe-VHA The Playbook: Healthcare team analysis,
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications,
https://research2guidance.com/product/mhealth-economics-2017-current-status-and-future-trends-in-mobile-health/

Case study: Developing ‘novel systems of care’

Dr. Steve Steinhubl

Scripps Research

Scripps Research

Steve has been thinking recently **about the major barrier to getting digital products into clinical practice.**

While most folks are focused on just getting the data from digital products to a healthcare provider, this falls well short of creating something of value for either providers or the people using the technology. Instead, it will be necessary to engineer novel systems of care around the unique capabilities that the full range of digital measurement products provide.

He’s thinking through:

- **Replacing ‘episodes’ of care with real-world and near-real time monitoring** - as passive as possible.
- **Creating interactive digital platforms** that can provide actionable feedback to users when requested, and also send an alert to the appropriate caregiver when needed.

Source: DiMe-VHA The Playbook: Healthcare team analysis, The Playbook: Digital Clinical Measures

Case study: What questions is Steve asking to integrate mHealth tools in his clinical practice?

Dr. Steve Steinhubl
Scripps Research

Scripps Research

Steve knows that **no matter the quality of the data** generated by a specific technology, it is worthless if the anticipated user can't or won't use it as is needed in order to **answer the clinical question**. To use digital technologies effectively as a solution to an unmet need in health care, it is critical to have a clear answer to each of the following:

- What is the information needed and **what technologies exist to enable an individual to capture that information**? e.g. for atrial fibrillation there are multiple different personal ECG devices, from watches to patches. But there are also photoplethysmography (PPG)-based devices and blood pressure cuffs.
    - Which, if any, will provide me the data needed? e.g. are intermittent spot checks enough, or is continuous data needed?
- Is the **user experience** such that the intended user can initiate and maintain using the technology as intended?
    - How can we best create **value for the end user** to best **incentivize** longitudinal, high quality data collection?
    - How do we return the information in a meaningful, individualized way?
- Can the entire experience be **integrated** into a learning platform that enables rapid iteration - building on what works and eliminating what doesn't?

Source: DiMe-VHA The Playbook: Healthcare team analysis, The Playbook: Digital Clinical Measures

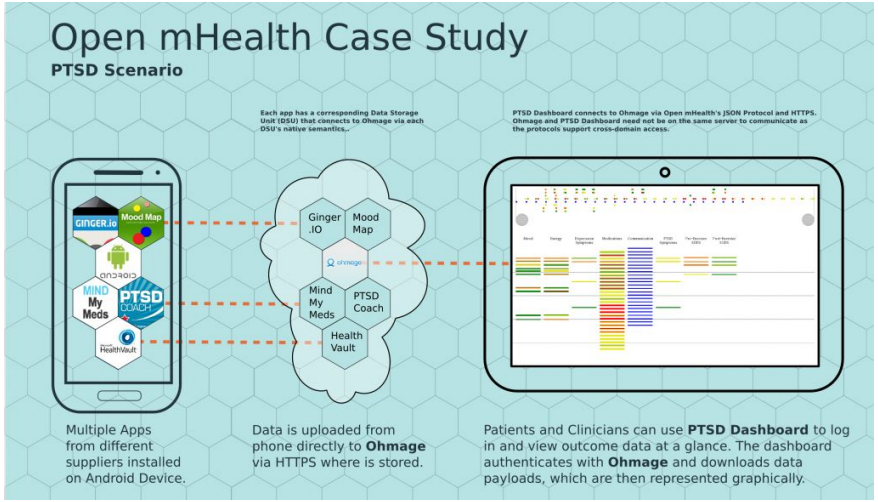
Case study: Open mHealth case study of PTSD

The Challenge:

Joe, a 34-year old **Army veteran** who served in Afghanistan is diagnosed with PTSD. He uses a combination of medication and avoidance coping to balance his life, work and family. He wants to get better, and his clinician, Dr. Hoffman, wants to help him use mobile health tools to better track and manage his symptoms.

The Approach:

Using the Open mHealth, data from the above devices and apps was uploaded and integrated into Ohmage, an Open mHealth compliant, cloud-based data storage app. Data was then pulled from Ohmage into a custom-designed data visualization. Through this integrated solution. Joe and Dr. Hoffman were able to gain insights about Joe's health, improve his safety, and provide Dr. Hoffman with evidence that allowed her to take discrete clinical actions.



The Result:

Dr. Hoffman has **increased insight into symptoms and functioning** lead to **dynamic treatment** planning with increased sense of connection. Joe continued to use SMS as a primary form of communication throughout, with his texting frequency paralleled his mood and recovering well with better symptoms management

Source: DiMe-VHA The Playbook: Healthcare team analysis

Case study: mHealth in the wild: Using novel data to examine the reach, use & impact of PTSD Coach

The Challenge:

58% american now use smartphones, making it possible for **mental mhealth apps to reach population at scale** living with untreated, or under-treated, mental health symptoms. Although early trials suggest positive effects for mHealth interventions, little is known about its potential impact.

The Approach:

- The Design of PTSD Coach was informed both by subject matter experts in evidence-based treatment of PTSD, Veterans, and others living with PTSD. The app provides:
  - Authoritative information about PTSD and professional care,
  - Symptom self-assessment
  - Access to support
  - Cognitive-behavior therapy (CBT) based interactive tools to help users manage PTSD symptoms

The Result:

- **>60% of users engaged** with PTSD Coach on multiple occasions
- Most app usage occurred between 8am and 10pm (of the user's time zone).
- On average, users opened PTSD Coach 6.3 times with a median time spent of 5mins.
- Android vs iPhone use was 28% vs 25%.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.ptsd.va.gov/professional/articles/article-pdf/id44576.pdf

LEARN FROM THE EXPERTS

Click on the image below to launch

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://youtu.be/A5hSs8yTXvc, https://www.who.int/goe/publications/goe_mhealth_web.pdf