DIGITAL MEDICINE SOCIETY

VA | U.S. Department of Veterans Affairs

The Playbook:
Digital Healthcare Edition

How you can *share* and *adapt* *The Playbook:* Digital Healthcare Edition

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Source: Creative Commons, DiMe-VHA The Playbook: Healthcare team analysis

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

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Digital health is a key enabler for a more connected and integrated health care ecosystem.

The question is no longer ***"should we"*** transform, but ***"how do we"*** transform to deliver care and provide immediate value today, and deliver increasing value over time.

OUR GOAL

To innovate the pathway to high value care, the Veterans Health Administration (VHA) and Digital Medicine Society (DiMe) co-developed *The Playbook*: **Digital Healthcare Edition** to deliver ethical, effective, equitable, and safe use of digital health to redefine healthcare and improve lives.

Source: DiMe-VHA The Playbook: Digital Healthcare team analysis

Complex US healthcare market, evolving digital health solutions. Where do you start? *The Playbook:* Digital Healthcare Edition

In Scope

- The opportunity that digital health solutions bring to patients and the people and systems that care for them.
- Key terms and definitions in digital healthcare, new care delivery models, product classifications, and regulations.
- The challenges and opportunities associated with digital health solutions available today.

Out of Scope

- Pricing, reimbursement and market access for the digital health solution; markets and regulations outside of US.
- Technical, operational and in-depth solution evaluations for decision making.
- Data integration, interoperability, operational rigor for implementation success in US markets.

Source: DiMe-VHA The Playbook: Healthcare team analysis

Introducing Phase I of *The Playbook:* Digital Healthcare Edition

Phase 1

Explore opportunities digital health solutions have to deliver ***high value care***

- **Disciplines** to drive innovation in healthcare forward.
- **Definitions, regulations and classifications.**
- **New care delivery models** which incorporate technology.
- Eight **digital health solutions** with **case studies** showcasing each one's ability to deliver **high-value care**.

Phase 2

Share digital health ***adoption and deployment resources***

- **Successful implementation** of digital health solutions.
- **Legal and ethical considerations** when using digital health solutions.
- Putting the **patient at the center** of care.
- Other factors to consider when putting a digital health solutions in practice.

Phase 3

Provide digital health product ***evaluation framework***

- A **framework** to **access, evaluate, and inform** resource allocation and executive decisions for successful translation to clinical and production environments across the health system.
- **Guide decision maker** on whether a digital health solution is valuable to patients, the organization and fit-for-purpose for transition into the clinical pathway.

Phase 2 and 3 of ***The Playbook*: Digital Healthcare** Edition will launch over the next year

Source: DiMe-VHA The Playbook: Healthcare team analysis

What was our motivation for *The Playbook:* **Digital Healthcare Edition**

Access

- **15 to 20% of the U.S. population lives in rural areas** and **face inequalities resulting in worse health care** than that of urban and suburban residents.
- **1 in 11 adults** reported **delaying or going without** medical care **due to affordability** in a 2020 NHIS survey.

Efficiency

- The current system is **disorganized, inefficient and under-resourced** wasting **$266 billion** a year in administrative costs.
- The World Health Organization (WHO) estimates around **20–40% of resources** spent on health-care **are underused** by all health-care systems.

Health care is arguably the most well-known determinant of health and yet...

Effectiveness

- Our healthcare system is **uncoordinated, fragmented** and **emphasizes sick care, not healthcare.**
- Despite high spending, the US scores poorly on many key health measures, including life expectancy, preventable hospital admissions, suicide, and maternal mortality.

Equity

- **Systematic differences** exist, **negatively affecting poor households** and **racial and ethnic minority groups** and **patient in rural areas**.
- **Care is often denied or delayed** to those who are most in need of it but can least afford its high cost.
- The US could **eradicate $150 billion** in medical care expenses if we could eliminate health disparities by 2050.

Source: DiMe-VHA The Playbook: Healthcare team analysis

The Playbook: Digital Healthcare Edition was designed to be valuable to multiple stakeholders

The current economic realities confronting healthcare systems globally are forcing new ways of care delivery that include digital health solutions

Organizational leaders

Strategically **drive digital transformation** into action with a clear vision which includes utilizing digital health solutions to provide **high-value care** and improve the Quadruple Aim.

Health professionals

Digital health solutions help **reduce inefficiencies, improve access, reduce costs, increase quality** and make care more personalized for patients.

Policy makers

Encourage **multi-sector/multidisciplinary collaboration** and partnerships that promote policies and regulations which **support a holistic innovation ecosystem**.

Industry Innovators

With the right approach and investment, digital health solutions will transform healthcare delivery. Innovators need to continue working to **validate performance of the solutions, their effectiveness and quantify ROI**.

Researchers

An enabling, inclusive research environment is essential for the **production, coordination and diffusion of the evidence-based quality research** with digital health solutions and the data produced from them.

Source: DiMe-VHA The Playbook: Healthcare team analysis

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- **Engagement and Social Media**
- **Virtual care**

The Playbook: **Digital Healthcare Edition** can help you answer questions such as:

How do digital health solutions deliver **high-value health care**?

Start at slide 16

What new **innovative care delivery models** are emerging?

Start at slide 30

With emerging digital health solutions, how can I **classify** them based on **clinical/functional type**?

Start at slide 47

How are digital health solutions **regulated by the FDA in the US**?

Start at slide 37

What are **various types of digital health solutions** used in health care delivery?

Start at slide 22

Where can I find digital health solutions that **deliver high-value care?**

Start at slide 56

Source: DiMe-VHA The Playbook: Healthcare team analysis

Resources in *The Playbook*: Digital Healthcare Edition

PRO TIPS

We will review definitions and/or common pain points so you don't get tripped up along the way.

SPOTLIGHT

Summaries of peer-review articles, regulatory guidances, and other reference materials.

We recommend you read the full articles, which we won't copy-paste in full form here in ***The Playbook:*** **Digital Healthcare Edition**

LEARN FROM EXPERTS

Learn from leaders and experts in the industry who are able to provide valuable insight and perspectives regarding digital health solutions.

Source: DiMe-VHA The Playbook: Healthcare team analysis

PRO TIP

Take your time

We don’t expect you to learn all of this in one go! This is a marathon, not a sprint. This is a set of tools along your journey.

In addition to *The Playbook:* **Digital Healthcare Edition** itself, you can view our **“Glossary”** and **“Library of Resources”** series on our website that contains **70+ publically available resources** in the *The Playbook:* **Digital Healthcare Edition** cabinet to help you you expand further understanding of various digital health solutions for effective healthcare delivery.

Source: DiMe-VHA The Playbook: Healthcare team analysis

The Playbook: **Digital Healthcare Edition** was reviewed by leading partners in the field across the healthcare innovation ecosystem. **Many thanks to these industry leaders and experts** who took the time to provide valuable feedback:

- **Lucia Savage, J.D**. - Chief Privacy & Regulatory Officer, Omada Health
- **Jon Bloom, MD** - CEO, Podimetrics
- **Pete Celano, MBA** - SVP, Business Development, Heartbeat Health, Inc
- **Gary Manning** - SVP and GM of Healthcare Delivery, physIQ
- **Karen Larimer, PhD, ACNP-BC, FAHA, FPCNA** - Vice President, Clinical Development, physIQ
- **Steve Steinhubl, MD** - Chief Medical Officer, physIQ, Cardiologist, Alaska Native Tribal Health Consortium
- **Megan Coder**, **PharmD, MBA**, - Chief Policy Officer, Digital Therapeutics Alliance (DTA),
- **Eric Perakslis, PhD** - Chief Science and Digital Officer at the Duke Clinical Research Institute
- **Timothy Aungst, PharmD** - Associate Professor of Pharmacy Practice, Massachusetts College of Pharmacy and Health Sciences
- **Benjamin Vandendriessche**, **PhD** - CMO, Byteflies
- **Ariel D. Stern, PhD** - Associate Professor of Business Administration, Technology and Operations Management Unit, Harvard Business School

Driving value in healthcare innovation starts with a simple framework

"To innovate the path to high value care, we must first redefine value beyond just dollars and cents. To ensure that every dollar invested returns value to the Veterans we serve, we need to focus on measuring value across access, effectiveness, efficiency, and equity."

Ryan Vega, MD, MHSA
Chief Officer, Office of Healthcare Innovation and Learning, U.S. Department of Veterans Affairs

Figure: A Value-Driven Framework for Evaluating Healthcare Innovations

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.va.gov/INNOVATIONECOSYSTEM/views/who-we-are/VBIF.html

Case study: Digital health solutions help aid provider shortages amid a national mental health crisis

The Challenge:

Nearly **1 in 5 adults in the U.S. experiences a mental disorder** within any given year according to the National Alliance on Mental Illness. Shortages of qualified mental health professionals, **fragmented care delivery models, coverage and reimbursement issues** related to **parity** make it challenging for patients to access mental healthcare and for healthcare organizations to support the need. As of September 2021, HRSA designated **3,426 Mental Health Professional Shortage Areas** in rural areas.

The Approach:

Two approaches were utilized for comparison in the study:
1) Telepsychiatry or telepsychology–enhanced referral (TER)
2) Telepsychiatry collaborative care (TCC)

Participants were adult patients being **treated** at 24 primary care clinics **without on-site psychiatrists or psychologists** from 12 federally qualified health centers in 3 states.

The Result:

Improved outcomes were demonstrated with both approaches. During the study period, **virtual care remained the predominant mode of care delivery** for mental health care visits. Study findings represented the experiences of **1,004 patients** from rural clinics in Arkansas, Michigan and Washington.

JAMA Psychiatry

A five-year study, published in JAMA Psychiatry found that telepsychiatry in rural, federally qualified health centers was a resounding success for patients who had screened positive for bipolar disorder and/or PTSD.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2783602

Case study: Remote thermal monitoring SmartMats prevent diabetic limb amputations

The Challenge:

Approximately **422 million people** worldwide **have diabetes; 1 in 4 Veterans have diabetes.** Diabetic foot ulcers (DFUs), a disease complication, are responsible for **80 percent of the non-traumatic amputations** at the VA. **In 2018** alone, **the VA treated 75,000 diabetic foot wounds** and spent more than **$3 billion on diabetic foot ulcers**, a precursor to amputations. The most at-risk Veterans face **a 5-year mortality rate of 43%** after developing their first DFU.

The Approach:

The SmartMat solution was implemented at 15 VA Medical Centers. Veternan's utilized a cellular-connected in-home mat which uses machine learning coupled with thermal imaging to **measure the daily temperature of the patient's feet in 20 seconds.**

Clinicians utilized a dashboard for viewing the data which allowed them to take **preventative** action as needed. This solution **brings value** by **detecting diabetic foot ulcers (DFUs) up to five weeks before** they would normally present.

The Result:

The use of the SmartMat resulted in a **97% early detection rate of DFU, 5 weeks before the onset** of symptoms, with **total elimination of all major amputations. Cost avoidances** were demonstrated with a **52% reduction in hospitalizations** and **40% reduction in ER visits.**

With a **86% patient engagement rate after 12 months**, this innovative care model helps reduce diabetes care disparities related to the geographical location of Veteran patients.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://marketplace.va.gov/innovations/reducing-hospital-admissions-and-amputation-prevention-remote-temperature-monitoring

Disciplines to drive successful digital transformation

Disciplines for sustainable transformation

- **Committed Ownership** that includes an iterative design, strategy and infrastructure allowing for testing of innovative ideas quickly with execution on those which prove value.
- **Disruption Empowerment** or the creation of the conditions for leaders to make the changes needed (top-down, bottom up).
- **Effective Change Management** strategy that allows for transformation across the entire organization.
- **Digital Reorganization** around key areas such as business, internal applications, external products or applications, digital health, cybersecurity, talent management, Saas/cloud delivery and audits.
- **Agile Culture** that is wholescale, not just within IT or business teams. The concept of "fail fast, learn faster" has never been more prevalent. You need to move quickly to test innovations while also monitoring what others are doing. As you gain clarity, you can act decisively to capitalize on the direction you choose.
- **Staying Current** Knowledge is power. Develop tech-savvy networks and make innovation an ongoing discussion within your organization.

"We have an opportunity to redefine the blueprint for successful healthcare innovations. To be transformational, evaluation frameworks need to define true value as that which matters most to our Veteran patients."

Carolyn Clancy, MD
Assistant Under Secretary for Health for Discovery, Education, and Affiliate Networks

Source: DiMe-VHA The Playbook: Healthcare team analysis, Salidanha, T. *Why Digital Transformations Fail The Surprising Disciplines of How to Take Off and Stay Ahead.* Berrett-Koehler Publishers; 2019.

PRO TIP

Today's **patients have more choices** about care and are more **empowered with information** about what they want their care experience to be.

US healthcare organizations can accelerate their path to real-time **connected health care** by using **digital health solutions** and **transforming** how they **deliver care.**

Source: DiMe-VHA The Playbook: Healthcare team analysis

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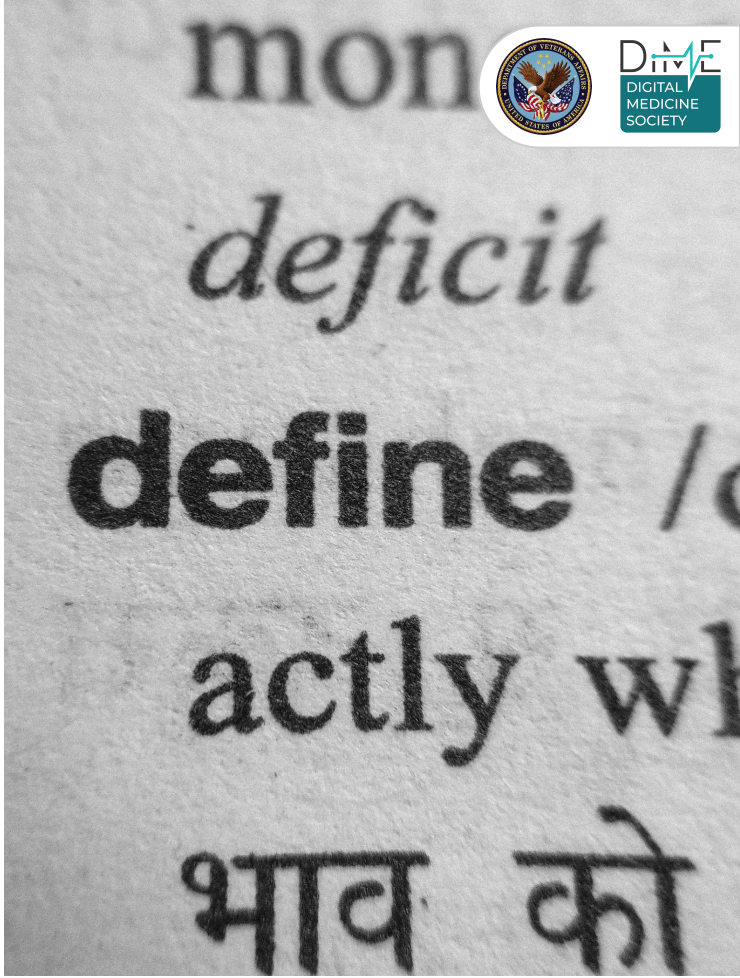
One of the key questions across the industry clarifying what's what first, and move the industry with a common language, "***how do we define various terms in the field of digital health***"?



Source: Photo by Ravi Kant from Pexels

The digital health industry – defined by function

Digital health

Digital medicine

Digital therapeutics

Clinical evidence	Typically **do not require clinical evidence**.	**Clinical evidence is required** for all digital medicine products.	**Clinical evidence and real world outcomes are required** for all DTx products.
Regulatory oversight	These products **do not meet the regulatory definition of a medical device,** according to local regulatory requirements in each jurisdiction the product is manufactured, registered, or used in, and do not require regulatory oversight.	**Requirements for regulatory oversight vary**. Digital medicine products that are classified as medical devices required clearance or approval. Digital medicine products used as a tool to develop other drugs, devices, or medical products require regulatory acceptance by the appropriate review division.	DTx evidence **must be reviewed and cleared or certified by regulatory bodies** as required to support product claims of risk, efficacy, and intended use.
Product Examples	**Data & information capture, storage, and display** ▸ User-facing technologies ▸ Health Information Technology (HIT)1 ▸ Consumer health information **Data & information transmission** **Telehealth** ▸ Decision support software* ▸ Enterprise support ▸ Clinical care administration & management tools	**Measurement products** ▸ Digital diagnostics ▸ Digital biomarkers ▸ Electronic clinical outcome assessments ▸ Remote participant monitoring ▸ Decision support software* **Measurement & intervention products** ▸ Digital companions ▸ Digital products that both 1) measure and intervene, and 2) do not require human intervention to serve primary purpose	**Software that delivers a therapeutic intervention** *Medical claims include:* ▸ **Treat a disease** Digital therapeutics that deliver a medical intervention to treat a disease. ▸ **Manage a disease** Digital therapeutics that deliver a medical intervention to manage a disease. ▸ **Improve a health function** Digital therapeutics that deliver a medical intervention to improve a health function and/or prevent a disease.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.dimesociety.org/digital-health-digital-medicine-digital-therapeutics-dtx-whats-the-difference/ https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework, https://www.medtecheurope.org/wp-content/uploads/2019/04/30042019_eHSGSubGroupReimbursement.pdf

Case study: Digital health decision support tool reduces diagnostic errors

The Challenge:

In the U.S., an estimated **40,000 to 80,000 deaths occur annually related to misdiagnosis**. Approximately **71%** of these diagnostic errors **occur in the ambulatory settings**, specifically in outpatient clinics or emergency departments (EDs). Clinical decision support systems can improve diagnostic accuracy, save time, and reduce patient misdiagnosis and medical errors.

The Approach:

UCLA-Harbor Medical Center and University of Rochester Strong Memorial Hospital **sought to determine the misdiagnosis rate of cellulitis** and if a visually-based computerized diagnostic decision support system (VisualDx) could generate an improved differential diagnosis (DDx). Attending dermatologists or infectious disease specialists evaluated all consecutive patients hospitalized for "cellulitis" by the emergency department.

The Result:

Study results demonstrated that physicians using VisualDx:

- **4 times more likely to suggest the correct diagnosis** for patients admitted to the hospital for serious infections.
- When VisualDX was **not utilized,** admitting physicians made **diagnostic errors 28% of the time.**

Source: DiMe-VHA The Playbook: Healthcare team analysis

Case study: Digital medicine tools can significantly improve glycemic control for T1D and T2D

The Challenge:

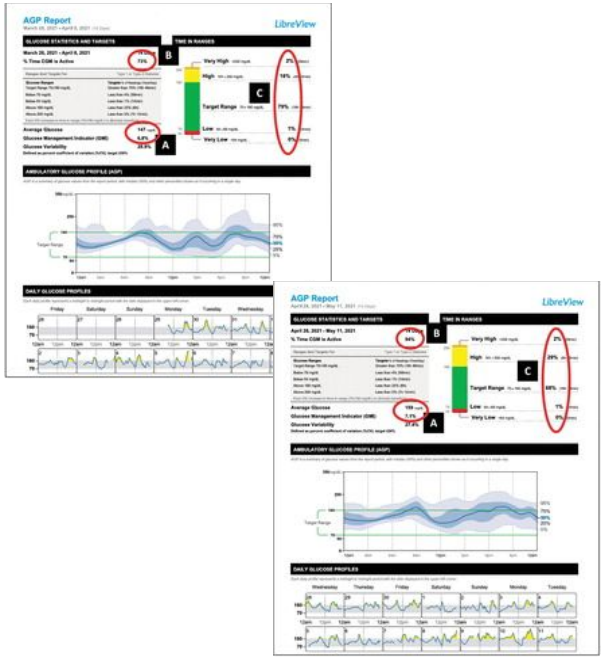
Dramatic reductions in outpatient visits and laboratory testing early in the COVID-19 pandemic raised concerns about gaps in diabetes management and glycemic control for patients with **type 1 diabetes (T1D)** and **type 2 diabetes (T2D)**. This compounded existing barriers to achieving good glycaemic control: poverty and its impact on the dietary requirements of diabetes, poor treatment adherence, lack of knowledge of treatment targets and lack of doctors at the primary health care centres in the rural areas.

The Approach:

Patients using non insulin therapy are referred by their physician to meet with a diabetes educator when HbA1C levels are rising and they are willing to use a **continuous glucose monitor (CGM)**. After initial training on the CGM, patients meet with their certified diabetes care and education specialist (CDCES) via virtual visits monthly until they can interpret their CGM data to self-manage their diet, exercise and fluid intake using their CGM data.

The Result:

By their third visit, patients can often manage and share detailed meal and snack notes in their **CGM smartphone app**. Without changing medication plans, rising HbA1c levels can be reversed and patients report being able to **understand their CGM data** and **feeling confident** in the changes they have made in order to **avoid insulin therapy**.



Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.liebertpub.com/doi/full/10.1089/dia.2021.0241

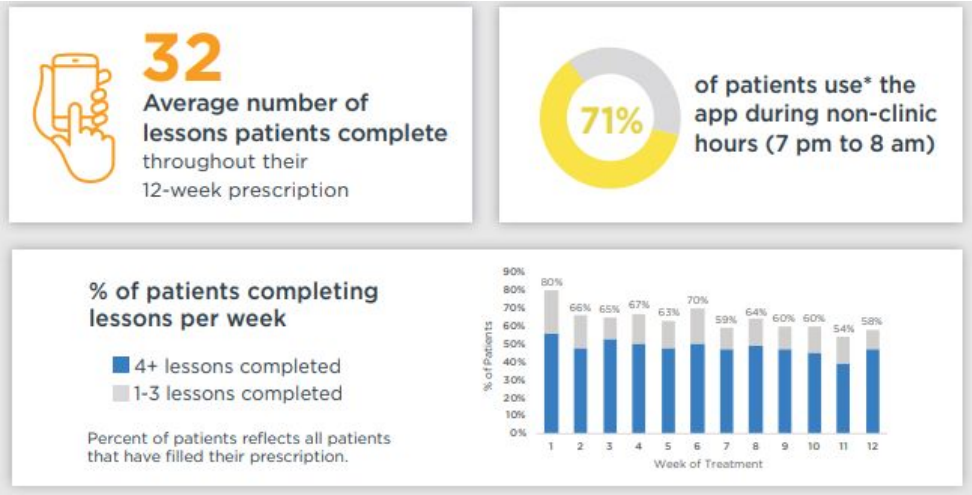
Case study: Digital therapeutics (DTx) are a new treatment modality

The Challenge:

Approximately **2.1 million people aged 12 or older** have an opioid use disorder (OUD). For people battling **opioid use disorder (OUD)**, counseling and case management happens in-office and there is a great need to expand care capabilities for patients into their everyday lives.

The Approach:

Pear Therapeutics' DTx solution, reSET-O®, was prescribed to patients in a buprenorphine-assisted treatment program. reSET-O® is a **remote tool for behavioral therapy support** and provides digital care support when counselling offices are closed outside business hours or provides an alternate option for otherwise hard to reach patients.



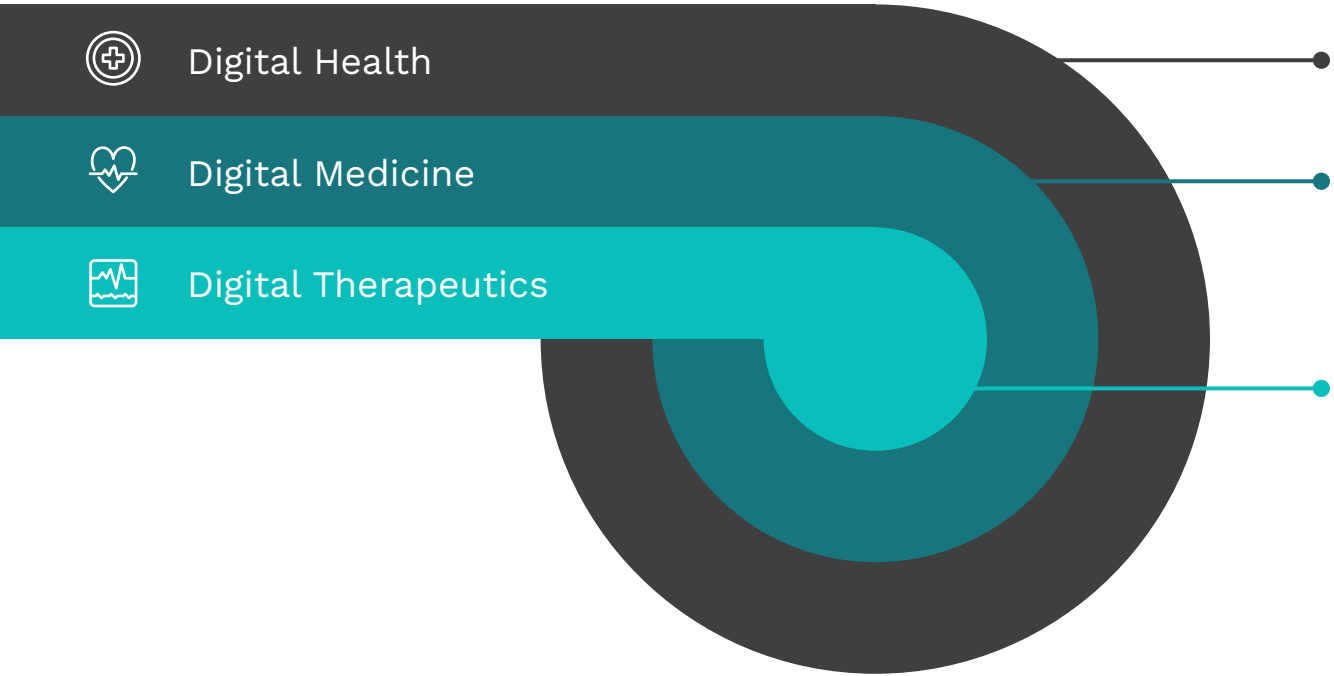
The Result:

Alongside positive feedback from patients:

- **71% non-office hour DTX usage** showing high need for digital companion tool
- Clinic prescribed it to 870 patients and **44% renewal rate**
- **15% increased retention** of patients with OUD

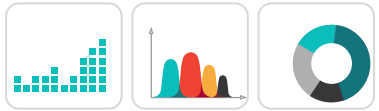
Source: DiMe-VHA The Playbook: Healthcare team analysis

Digital health industry categorization



Broader Term w/o Clinical Evidence

Clinical Evidence



Clinical Evidence + Real World Outcomes

Source: DiMe-VHA The Playbook: Healthcare team analysis, View full infographic at http://bit.ly/DiMe_Categorization

PRO TIP

Be intentional about using the right terminology because ***language matters.***

Using a ***shared, common language*** will allow us to truly ***collaborate*** in the best interests of humankind, ***leading to solutions much faster.***

Source: DiMe-VHA The Playbook: Healthcare team analysis

Before we dive into the role of regulations in the field of digital health, "***what are current and emerging innovative care models for digital health delivery***"?

Source: Source: DiMe-VHA The Playbook: Healthcare team analysis
Photo by Artem Podrez from Pexels

Innovative models of care delivery continue to to emerge

IMPACT
Virtual First Medical Practice Collaboration

Virtual First Care (V1C)

V1C is medical care for individuals or a community accessed through digital interactions where possible, **guided by a clinician**, and **integrated into a person's everyday life.**

Multidisciplinary Virtual Care

Care teams integrate telehealth and other virtual approaches into their **multidisciplinary care models** to **better engage** with patients throughout their care or treatment.

Hospital at Home

An innovative care model that **provides hospital-level care in a patient's home** for certain diagnosis or conditions that would typically require hospitalization.

Core similarities shared with these care delivery models:

- **Patients** are able to **receive care where, when and how they need it.**
- **Providers gain efficiency** with the digital health solutions used in the models.
- Total **cost** of care **goes down** while **health outcomes improve.**

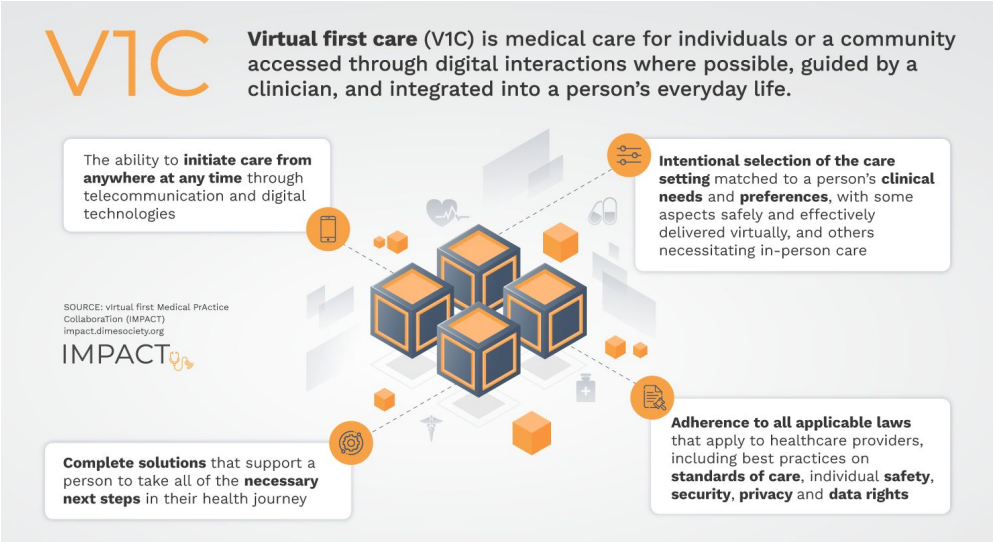
Innovative care models require **transitioning our approach** to care from an **"encounter"** to a **"continuum"**. Care models should be **proactive.** We should not be wondering why patients are non-compliant or non-adherent, but rather what is it about the current approach to their care that is not enabling them to take full advantage of it.

Source: DiMe-VHA The Playbook: Healthcare team analysis

Have you heard virtual first care (V1C) the new care model that builds care around the patient, not the clinic?

Virtual-first care, or V1C, is exactly that — care that is accessed first in a virtual way. **V1C allows patients to have 24/7 access** to a **full care team of doctors**, including their primary care physician, condition-specific specialist, and certified coaches.

Using digital platforms, patient data is collected in real-time (with the patient's full knowledge). The electronic medical records created are then accessible to everyone on the healthcare team and the patient, making it easy for both **clinical collaboration** and for patients to become more involved in taking control of their own health.



Learn more from the IMPACT consortium, the home of virtual-first care https://impact.dimesociety.org

Source:DiMe-VHA The Playbook: Healthcare team analysi, https://impact.dimesociety.org/v1c/, https://www.omadahealth.com/news/what-is-virtual-first-care

Multidisciplinary virtual care implemented at UT Health Austin

"Not being able to bring patients into our traditional care environment because of COVID-19 presented a real challenge, but our team immediately stepped up and found innovative ways to deliver the same experience virtually, with the goal of continuing to deliver what our patients need in a valuable, yet safe way."

Karl Koenig, MD
Medical Director and Orthopedic Surgeon,
Musculoskeletal Institute, UT Health Austin

The University of Texas at Austin
UT Health Austin

Patient's are offered telehealth appointments with a **uniquely designed** workflow centered around a waiting room and a care room.

Prior to each appointment, the Musculoskeletal Institute care team meets as a group to discuss each patient's case and possible treatment plans.

This allows patients who see multiple providers to **benefit from one seamless encounter** that has been coordinated efficiently.

In 2021, the Musculoskeletal Institute was awarded the Value-Based Health Care Prize in recognition of their **success in improving patient outcomes** using the **360-degree care model**. This award recognizes inspiring initiatives that have adopted a fundamentally **new line of thinking** in **creating excellent patient value** in terms of real outcomes and costs.

Source: DiMe-VHA The Playbook: Healthcare team analysis

Case study: Hospital at home innovative **model**

The Challenge:

When it comes to expenditures, **costs related to providing hospital-based services**, particularly inpatient care, **contribute significantly to overhead expenses.** In 2017, 3.5 million potentially preventable adult inpatient stays accounted for $33.7 billion in aggregate hospital costs. In 2019, the Medicare population had more than 800,000 hospitalizations, which could have qualified for Hospital at Home.

The Approach

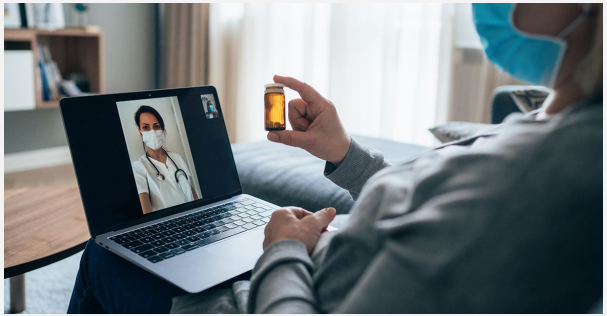
Brigham and Women's Hospital conducted a two-month-long randomized, controlled study with **21 patients who presented to the ED** and met specific eligibility criteria. Patients admitted to home hospital care benefited from:

- Diagnostic work performed at home.
- Continuous monitoring with access to virtual visits and texting via a tablet.

The Result:

Aside from patient's feeling more independent and empowered, the study demonstrated:

- **40% reduction in cost of care** for home patients than control patients
- **Fewer lab orders, imaging and consultations**.
- **70% lower 30-day readmission rates.**



As of April 2022, **56 health systems and 127 hospitals across 29 states have been accepted** as participants in the Centers for Medicare & Medicaid Services' (CMS) hospital-at-home initiative.

Source: DiMe-VHA The Playbook: Healthcare team analysis

Case study: Mount Sinai's hospital at home program

The Challenge:

In the 19th and early 20th centuries, receiving care from providers at home was the norm; 40% of home visits **in the 1930s were physician-patient encounters**. **Today, patients are attracted to the same convenience and comfort of receiving care in their own homes**. The hospital at home model allows caregivers or family members to remain at the patient's bedside.

The Approach:

In 2014, a Mount Sinai program was awarded a $9.6 million dollar grant from the CMS Innovation Center. The program was aimed at **freeing up beds across Mount Sinai's 8 hospital campuses** by **shifting vital services into the patient's home** for those who qualify. The program provided:

- Comfort and convenience of quality care in the home setting.
- Communication with doctors, nurse practitioners, and nurses face-to-face or via video without ever leaving the home.
- A single point of contact available to answer questions and manage care-team communications.
- Regular home visits from registered nurses, physical or occupational therapists, and other specialists.

The Result:

Patients participating in the Hospitalization at Home program had:

- **8.6% 30-day readmission rate, compared to 16.1 percent for similar hospitalized patients**, according to a case study from the American Hospital Association.
- Patients who received home-based care also **had fewer ED visits** (5.8 percent versus 11.9 percent) and **reported a better patient experience** (67.8 percent versus 45.6 percent).

Mount Sinai

Hospital at Home Programs Offered Currently:

- Hospitalization at Home (HaH)
- Palliative Care at Home (PCaH)
- Rehabilitation at Home (RaH)

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.mountsinai.org/care/geriatrics/services/outpatient/hospitalization

SPOTLIGHT

The **importance of technology** in healthcare **cannot be overlooked**.

Innovation has taken center stage. Healthcare organizations need to **create** and **maintain** a **culture of innovation.** This should include a **common language**, **definitions** and **promote new care delivery models** that utilize technology to its fullest extent to improve the lives of patients and the people and systems that care for them.

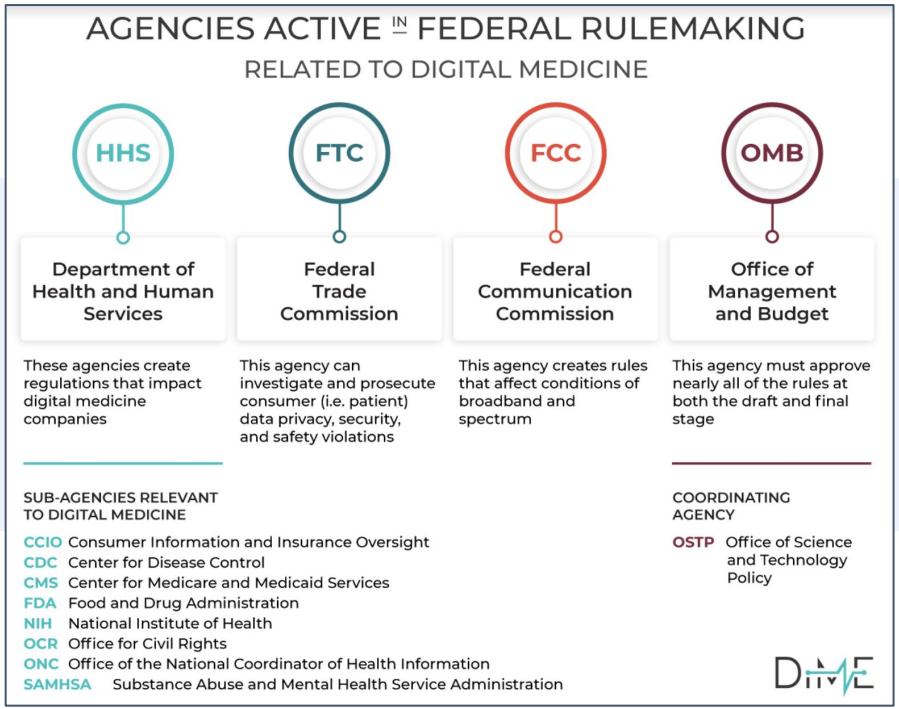
As healthcare organizations advance their innovation ecosystem, it is **critical** that solutions are equitable, safe, effective, and ethical.

Source: DiMe-VHA The Playbook: Healthcare team analysis

Before we go into classification of medical devices in the US and discuss the tools in the toolbox, let's answer the question "***what role do FDA regulations play in the field of digital health***"?

Source: DiMe-VHA The Playbook: Healthcare team analysis, Image credits - cottonbro from Pexels

Here are the regulatory bodies involved in rulemaking related to digital medicine



Steps in federal rulemaking:

1. Congress passes statute
2. Proposed rule
3. Public comments
4. Response to comments/draft of final rule
5. Publication of final rule
6. Rule takes effect

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.dimesociety.org/federal-comment-toolkit/, Lucia Savage

Regulation in the US healthcare ecosystem

PRO TIP

As defined by HHS, regulations or 'rules', are developed under the authority of Congress to help the government carry out public policy.

Our goal in this section of ***The Playbook***: **Digital Healthcare Edition** is to discuss regulatory pathways and classification of digital health solutions.
Only FDA is in scope for this playbook.

In the highly regulated healthcare industry, there are many other regulations that must be considered. However, these are out of scope for this first phase of ***The Playbook***: **Digital Healthcare Edition**.

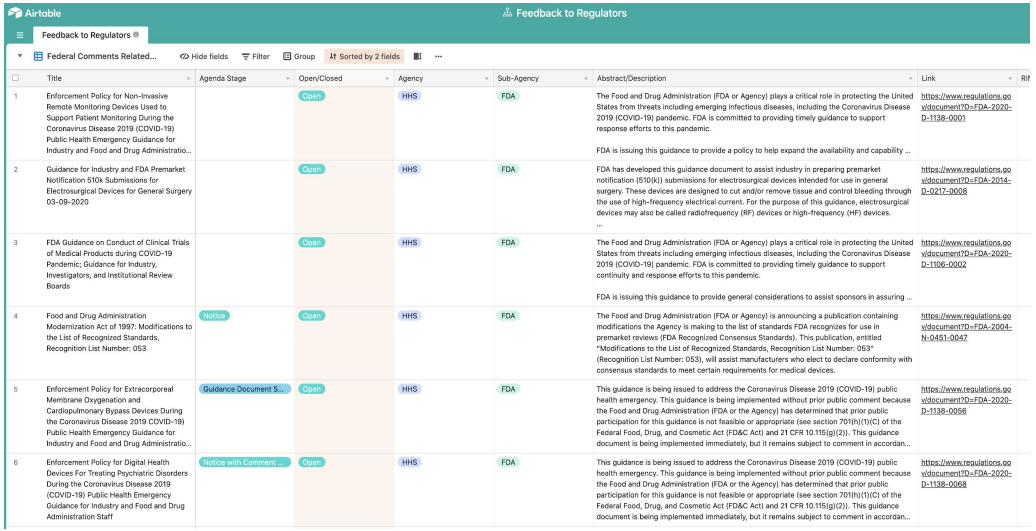
Source: DiMe-VHA The Playbook: Healthcare team analysis, FDA

How do I keep pace with the rapidly changing landscape of digital health policy and regulation?

When a Federal Agency issues regulations —they are legally bound to solicit public input on the rule.

The FDA places an announcement in the Federal Register. **The public is welcomed to submit** comments **for new rules** and regulations and these suggestions can, and do, influence the agency's actions.

The Digital Medicine Society (DiMe) maintains a **list of upcoming federal regulations for comment** relevant to digital medicine. Access here.

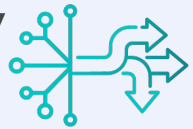


DiMe's Public Comment Toolkit

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.dimesociety.org/federal-comment-toolkit

We are prioritizing the development of resources to clarify FDA regulatory pathways

Digital Health Regulatory Pathways



Navigating digital health regulations to optimize product development, strategy, and decision-making.

Project Partners

Abbott
abbvie
AETIC
AMA American Medical Association
AMGEN
AstraZeneca
Consumer Technology Association
Digital Therapeutics Alliance
FDA
Genentech A Member of the Roche Group
Google Health
Harvard-MIT Center for Regulatory Science
Janssen Pharmaceutical Companies of Johnson & Johnson
Otsuka
ROCK HEALTH
sidekick
TIDEPOOL

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.dimesociety.org/tours-of-duty/digital-health-regulatory-pathways/

FDA doesn't regulate healthcare, only products

PRO TIP

Regulatory oversight of a technology does **not** necessarily indicate *fit-for-purpose.*

FDA clearance of a technology and/or the presence of a CE mark should not be used in place of the evaluation processes to determine the suitability of a technology for a given context of use. A rigorous clinical, technical, operational and economic evaluation should be conducted.

Source: DiMe-VHA The Playbook: Healthcare team analysis

Who regulates digital health products?

HHS (Health and Human Services)

HHS has **11 operating divisions** and 1-of-11 agency regulates clinical investigations of products under its jurisdiction (drugs, biological products, and medical devices).

FDA (Food and Drug Administration)

Authority to regulate **medical devices** as defined by the Federal Food, Drug, and Cosmetic Act (FDCA).

Government entities and agencies with oversight of the digital health ecosystem

CPSC	FTC	CISA	SEC	State laws
Consumer patient safety commission	**Federal Trade Commision**	**Cybersecurity and Infrastructure Security Agency**	**Securities and Exchange Commission**	**State's individual protection laws**

Source: DiMe-VHA The Playbook: Healthcare team analysis

The value of digital health regulation

Ensuring **evidence-based** digital health solutions goes in the hands of consumers.

Creating baseline gold-standards of measurements of health using digital solutions.

Increase trust in the digital tool by ensuring security, privacy, and compliance.

To bring **safe, effective, ethical and equitable** digital health products that deliver high value are to consumers by improving health, wellness, and experience.

Ensure **harmonization of best practices by multi-stakeholder community** (innovators, regulators, payers, developers, health systems, etc).

Reduce misleading or **misaligned claims** for digital health solutions

How would you differentiate from 350,000+ digital health products in today's market with with 200+ new ones added daily?

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.mobihealthnews.com/news/digital-health-apps-balloon-more-350000-available-market-according-iqvia-report

What is a medical device as per US regulations?

Section 201 (h) of the Federal Food, Drug, and Cosmetic Act ("FDCA") defines a medical devices as:
An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

1. Recognized in the official National Formulary, or US Pharmacopoeia, or any supplement to them.

which is...

2. Intended for use in the **diagnosis** of disease or other conditions, or in the **cure, mitigation, treatment, or prevention of disease**, in man or other animals, or
3. Intended to affect the **structure or any function of the body** of man or other animals.

How you should read it:

which is...

1. **Intended** for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
2. **Intended** to affect the structure or any function of the body of man or other animals.

...and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.fda.gov/medical-devices/classify-your-medical-device

SPOTLIGHT

Can software act as a medical device?
Yes, software alone can be a medical device, aka **'software as a medical device' (SaMD)** when a "*software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device*." But, just because it uses software does not make it a medical device. Check out some of the examples: FDA - examples of Software as a Medical Device.

Is a digital health solution a medical device?
If a digital health solution (a product with medical claims not a service) is labeled or used in a manner that meets this definition, it will be regulated as a medical device and is subject to the the regulator's laws and regulations before, during, and after it is offered for sale or use in the country in question.
The FDA has offered guidance: FDA - How to Determine if the Product is a Medical Device.

Source: DiMe-VHA The Playbook: Healthcare team analysis, FDA

Classification of medical devices in the US

CLASS	RISK	POTENTIAL HARM	REGULATORY CONTROLS	SUBMISSION TYPE OR EXEMPTION	% DEVICES IN CLASS*	Examples
I	**Lowest risk**	○ Lowest risk devices ○ Subject to only general controls ○ Most Class I devices "exempt" from premarket notification	General	**510(k)** **510(k) Exempt** ***93% are exempt from 510(k)**	35%	Podimetric's SmartMats
II	**Moderate risk**	○ Higher risk than Class I but lower risk than Class III ○ Subject to general controls and special controls ○ Requires premarket notification	General and special (if applicable)	**510(k)** **510(k) Exempt**	53%	Apple's ECG software app or Photoplethysmogra-ph Analysis Software
III	**Highest risk**	○ Highest risk to patients - usually life-supporting, life-sustaining, or used to prevent unreasonable risk of illness or injury ○ Subject to general controls and special controls ○ Require premarket notification	General and Premarket approval (PMA)	**Premarket approval (PMA)**	9%	Abbott's Freestyle Libre 14-Day Flash Glucose Monitoring System or RX Herculink Elite Renal Stent System

*3% of devices are unclassified

Source: DiMe-VHA The Playbook: Healthcare team analysis, FDA

FDA regulatory pathways

510(k) pathway or Pre-market notification (PMN)

Used for devices to demonstrate that the device is substantially equivalent to an existing device on the market. Most **common pathway** and used by vendors to **market products** as FDA "cleared"

Medtronic, biobeat, Renovia, Apple, GE, Abbott

De Novo pathway

Used for medical devices with **novel** claim with low to moderate risk that have **never been marketed** in US before

NIGHTWARE, mahana THERAPEUTICS, Roche, AKILI, dexcom, PEAR THERAPEUTICS

Pre-market approval (PMA)

Applies to most of **Class III (high risk)** medical devices require PMA before they may be legally marketed. Approval undergoes rigorous evaluations in of safety, effectiveness, and labeling claims

Humanitarian Device Exception (HME)

Applies to medical devices that help people with rare diseases or conditions that affects <4k individuals in US

Pre-certification (Pre-cert) program

Currently **in pilot**, participating orgs **get"precertified"** status to participate in a streamlined premarket review and collect and leverage postmarket RWD .

Apple, fitbit, Johnson&Johnson, PEAR THERAPEUTICS, Phosphorus, Roche, SAMSUNG, TIDEPOOL, verily

Breakthrough classification program*

Applies to medical/combination products that provide **more effective diagnosis or treatment to life-threatening** or irreversibly debilitating diseases or conditions

MEDRhythms, cognoa, appliedVR, COGNITO THERAPEUTICS

*Note: The Breakthrough Devices Program isn't a traditional FDA pathway but a voluntary program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards and pathways.

Source: DiMe-VHA The Playbook: Healthcare team analysis, FDA

FDA regulatory pathways for cleared, granted and approved products

Regulatory pathway	510k	De novo	Premarket approval
Product risk levels	Class I and II	Class I and II	Class III
FDA decision type	Cleared	Granted	Approved
Requires a predicate	Yes	No	No
Decision criteria	Product demonstrates "substantial equivalence" to a predicate (e.g., no independent assessment of the product required)	Probable benefits of the product outweigh probable risks	Requires independent assessment of the product's safety and effectiveness

- **Class I require little safety testing.** Today, around 35% of medical devices fall under this category, and 95% of these are exempt from the regulatory process.
- **Many developers will aim for Class II.** Still low risk class and covered by insurance, enabling greater access.
- **Clearances** rely heavily on a predicate--legally marketed device (e.g., already on the market) to which a new device would claim equivalence.
- **Approval** is granted for higher risk devices.

Source: DiMe-VHA The Playbook: Healthcare team analysis, Fast Facts: Digital Medicine

Language matters

FDA "Cleared"

- A manufacturer can **show** that their product has the **potential to perform** and other **similar devices in the market** (already FDA cleared/approved). E.g. If a company wants to a smartwatch with similar features to one already in the market, they have to prove that it can effectively perform the same way and is as safe as the competition.
- FDA **clears Class I and II** medical devices. Company needs to provide a **510(k) to get cleared.**
- "Cleared" products are **endless** and can be searched in FDA's public database(s)
- E.g Podimetrics SmartMats are FDA "cleared" as class I medical device vs Apple ECG's software as class II medical device for monitoring electrical impulses from the heart through the Apple Watch Series 4.

FDA "Granted"

- FDA "grants" medical products **before they can be legally marketed** in the United States.
- This is a relatively **new term in the FDA lexicon.**

FDA "Registered"

- Vendors involved in the production and distribution of medical devices intended for use in US are required to **re**gister annually with FDA.
- **Every medical device has to be FDA "registered" before** it's released in US **market**.

FDA "Approved"

- When a product is FDA-approved, it has been determined that it has **more benefits than risks**.
- Requires **a premarket approval (PMA) application**, know as the premarket notification, and clinical testing results
- However, if a product or medical device carries significant risk but at the same time the benefit is essential, then the FDA will approve it. The **FDA approval will be more or less stringent depending on the risk involved.**
- E.g. Pacemaker that will be surgically implanted in your body and regulate the heart rhythm will fall into higher risk category than the plaster and bandage.

Source: DiMe-VHA The Playbook: Healthcare team analysis, FDA

PRO TIP

Know the difference between FDA terminologies as *Cleared*, *Granted*, *Registered*, and *Approved*

Source: DiMe-VHA The Playbook: Healthcare team analysis, FDA

Think twice before you use the word “device”

PRO TIP

A ***‘device’*** *is a Term of Art* with regulators, such as the FDA. Try to minimize using the term ‘device’ unless the product is actually a medical device.

Instead, use a more specific term such as a **digital sensing product, connected sensor product**, **etc.**

Source: DiMe-VHA The Playbook: Healthcare team analysis, FDA

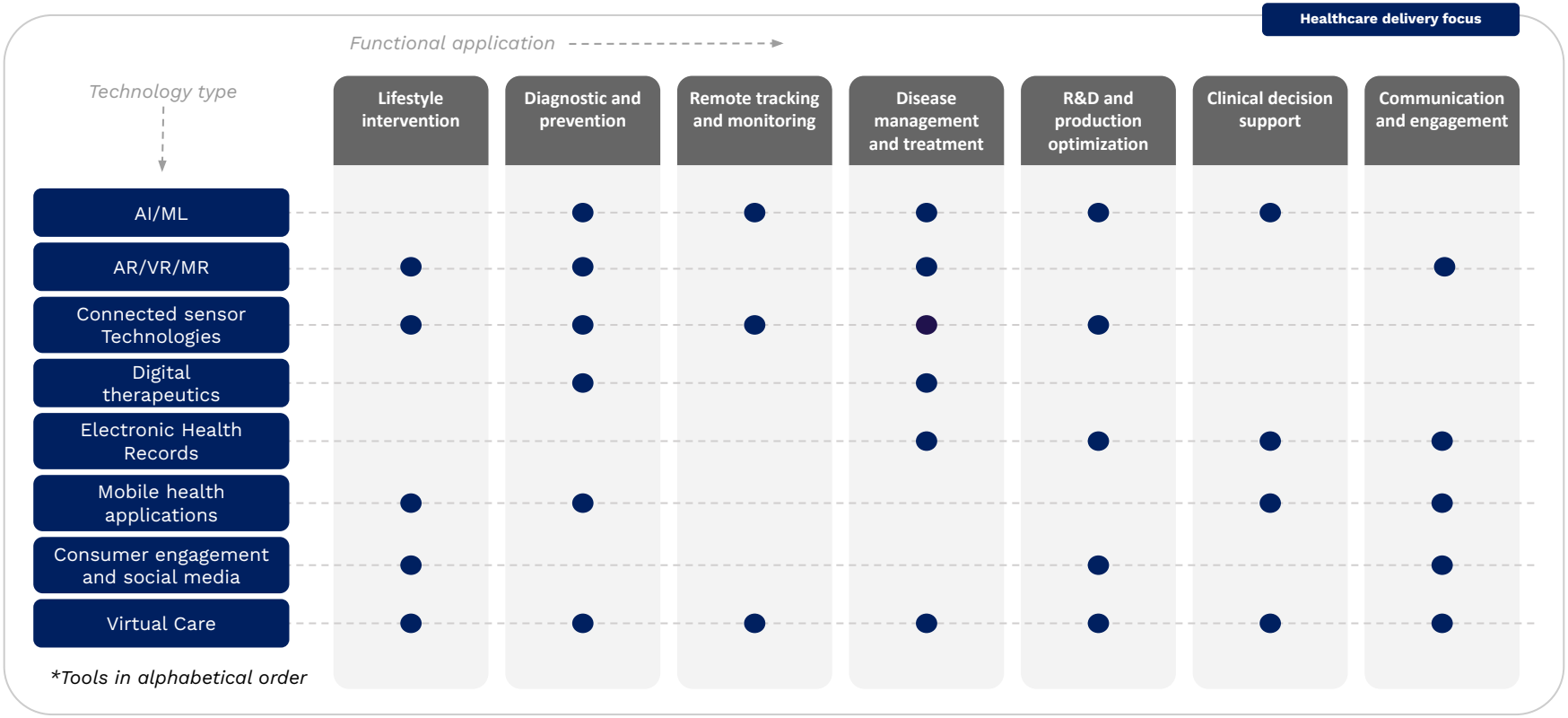
LEARN FROM THE EXPERTS

Source: DiMe-VHA The Playbook: Healthcare team analysis, FDA

You have the big picture now on industry and FDA regulatory classification and, you may wonder, “***how is digital health classified for clinical care delivery*** *in healthcare?*”

Source: DiMe-VHA The Playbook: Healthcare team analysis

Digital health landscape map for healthcare delivery



Source: DiMe-VHA The Playbook: Healthcare team analysis

Not all digital health tools are the same

"The COVID-19 pandemic has accelerated use of Digital Health Technologies as a feature in all aspects of healthcare. Let's work together to harness the potential to engage patients, minimize bias and make care available to all through evidence based medical products."

Bakul Patel, MSEE, MBA
Sr Director, Global Digital Health Strategy & Regulatory
Google

The next section of *The Playbook:* **Digital Healthcare Edition** will help provide help provide you with some answers to questions you may be asking:

- How should each solution be used?
- What are the benefits? Risks?
- What should expectations be about outcomes?
- How much evidence is needed to be implemented clinically?

The 8 micro-playbooks will help you grasp the scope of emerging digital health solutions and the value they provide.

Source: DiMe-VHA The Playbook: Healthcare team analysis

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

Artificial Intelligence/Machine Learning (AI/ML)

TL;DR

AI/ML are new tools for deriving insights from healthcare data

What is **AI/ML?**

- In the context of healthcare, **Artificial Intelligence and Machine Learning (AI/ML)** are the human-like capabilities of specific mathematical algorithms processed by computers. It refers to software applications that, using advanced statistical methodologies, can learn patterns and derive insights from seemingly complex datasets.
- **Deployed throughout the compendium of care delivery** for a range of purposes including processing pathology images, retinal imaging or electronic health records at scale, deriving digital clinical measures, care delivery or decision support systems.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://rockhealth.com/insights/demystifying-ai-and-machine-learning-in-healthcare/ https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-021-00577-8

AI/ML tools offer health systems an opportunity to accelerate, personalize, and lead efficient clinical delivery

Opportunities to create value for patients, providers and healthcare systems

Advanced accuracy of diagnostics (e.g., read medical images faster, and provide accurate assessments)

Curate and de-identify data to **enhance the value of EHR data** for development of predictive analytics.

Detects and **prevents fraud, waste and abuse.**

Early risk predictions for comorbidities, diseases progressions, symptom deteriorations, etc

Optimize workforce management with automation (E.g. EHR documentation, admin reporting, CT scan triage, etc)

Reduce medical errors by up to 60%

Support precision-medicine and care personalization for more complex diseases

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781688, https://pubmed.ncbi.nlm.nih.gov/31367026/, https://pubmed.ncbi.nlm.nih.gov/31367026/

How Is the FDA Considering Regulation of AI/ML Medical Devices?

- Traditionally, the **FDA reviews medical devices through an appropriate premarket pathway(s)**:
  - Premarket clearance (510(k))
  - De Novo classification
  - Premarket approval
  - Others - Risk-based approach for a change to existing device

- As this **traditional approach was not designed for adaptive AI/ML technologies**, under the risk-based approach to software modification FDA anticipates these AI/ML-driven software changes to a device may need a premarket review.So the action plan highlights FDA's intention to develop an update to the proposed regulatory framework through a guidance document.

- As of March 1, 2022, there are **343 AI/ML-enabled medical devices marketed** in the United States. Full list here.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device

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.

Case study: AI/ML may help transform breast cancer screening

The Challenge:

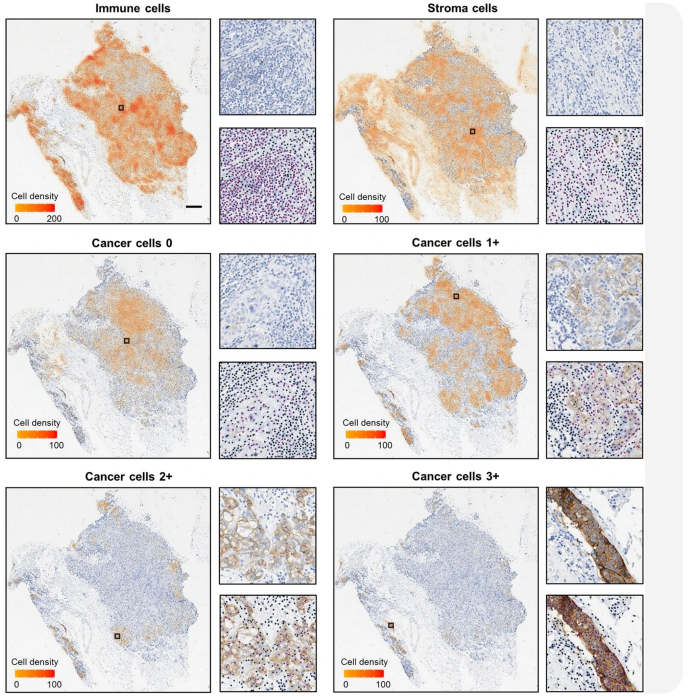
Non-digital pathology performance **could not, at scale, generate accurate and reproducible** clinically relevant **scores for breast cancer** (HERS 2 score). It is estimated that 4% of negative cases and **18% of positive cases are misdiagnosed.**

The Approach:

AI/ML-based models for the **automated quantification of HER2 pathology images** in breast cancer tissue first deconvolve raw staining images to generate separate images for haematoxylin and HER2 staining, then **cells are then classified using deep learning** into relevant types.

The Result:

In a cohort of 71 breast tumor resection samples, **automated scoring** showed a **concordance** of **83%** with a **pathologist**. This desmontrasted a **proof-of-concept** that deep learning analysis of breast tissue samples **enables automated and accurate scoring** of a tissue biomarker.



Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.nature.com/articles/srep45938

Case study: Swarm AI diagnoses pneumonia better than an individual computer or provider

The Challenge:

In the US, **pneumonia is the most common cause** of **adult hospital admissions** and 50,000 die annually. Pneumonia remains **challenging to diagnose** on radiographs because its appearance appears similar to other diseases.

The Approach:

Using small groups of Stanford radiologists, a combination of Swarm AI technology developed by Unanimous AI, and deep-learning technology developed at Stanford was applied to the diagnosis of pneumonia on chest radiographs. This **technology was compared against human experts** as well as two state-of-the-art deep learning AI models (CheXNet and CheXMax).

Stanford HEALTH CARE

The Result:

- The work demonstrated that both the **swarm-based technology and deep-learning technology** achieved **superior diagnostic accuracy** than the radiologists.
- When used in combination, swarm-based technology and deep-learning technology outperformed either method alone.

Source: DiMe-VHA The Playbook: Healthcare team analysis https://news.stanford.edu/2017/11/15/algorithm-outperforms-radiologists-diagnosing-pneumonia/

Challenges and high risk prevalence in AI/ML field impedes widespread scale, integration, and adoption

Despite striking advances, the field of AI/ML faces major technical challenges, particularly in terms of building user trust in AI systems and composing training datasets. Questions also remain about the regulation of AI in medicine and the ways in which AI may shift and create responsibilities throughout the healthcare system, affecting researchers, providers and patients alike. Finally, there are important ethical concerns about data use and equity in medical AI.

Challenge

Uncertainty and distrust of AI predictions based non-transparent data modeling

Challenge

Biased results that create harm to marginalized populations and exacerbates the digital divide

Risk

Errors and injury caused by the decisions made by an artificial intelligence-based clinical tool

Risk

Data transparency, explainability, **privacy** and **security**

Challenge

Shifts in responsibility and accountability introduced by using AI in **practice**

Challenge

Regulation and governance of medical AI

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7133468/, https://www.nature.com/articles/s41591-021-01614-0

Case study: Tempus is building the ECG of the future with AI

The Challenge:

Over **100 million** 12-lead electrocardiograms (**ECGs**) are **performed in the U.S.** each year. ECG is the most common diagnostic tool to identify and combat heart disease, yet ECG interpretation frustratingly unchanged. Important insights live within this **large amount of ECG data** and that those insights can revolutionize the way we **use** ECGs **to help diagnose and treat** patients.

The Approach:

With Geisinger, Tempus conducted mortality prediction study from 1**2-lead ECG using deep neural network**. Step further, they used AI to **predict risk of** new atrial fibrillation **(A.Fib) and** A.Fib-related **stroke**.

The Result:

FDA grants breakthrough device designation to Tempus' A.Fib ECG analysis platform t**o aid clinicians in identifying patients at increased risk of developing AFib or atrial flutter** for use with patients 40 years of age and older.

Tempus

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.120.047829

Case study: Using AI to reducing administrative burden

The Challenge:

Healthcare staff burnout has remained at dangerously high over the past 10 years with staff stating citing **administrative burden** and tasks such as **charting and paperwork** as the top drivers of burnout. According to a report from Fierce Healthcare, **34% of nurses report it's very likely they will leave their roles by the end of 2022.** Healthcare organizations and providers are seeking ways to combat burnout and cut back on the associated costs — opening an opportunity for AI-based solutions.

The Approach

Advocate's clinical contact center is the largest of its kind in the Chicago area. Nurse triage is widely valued as an essential entry point to clinical care. To streamline and automate workflows, Advocate looked to Keona Health and their AI-powered solution to help nurses conduct triage over the phone.

The Result:

Aside from high patient satisfaction rate, Advocate found:

- optimized and automated workflows,
- average handle time was down 34%
- physician complaints were kept to a minimum
- 100% encounter documentation and reporting

Advocate Health Care

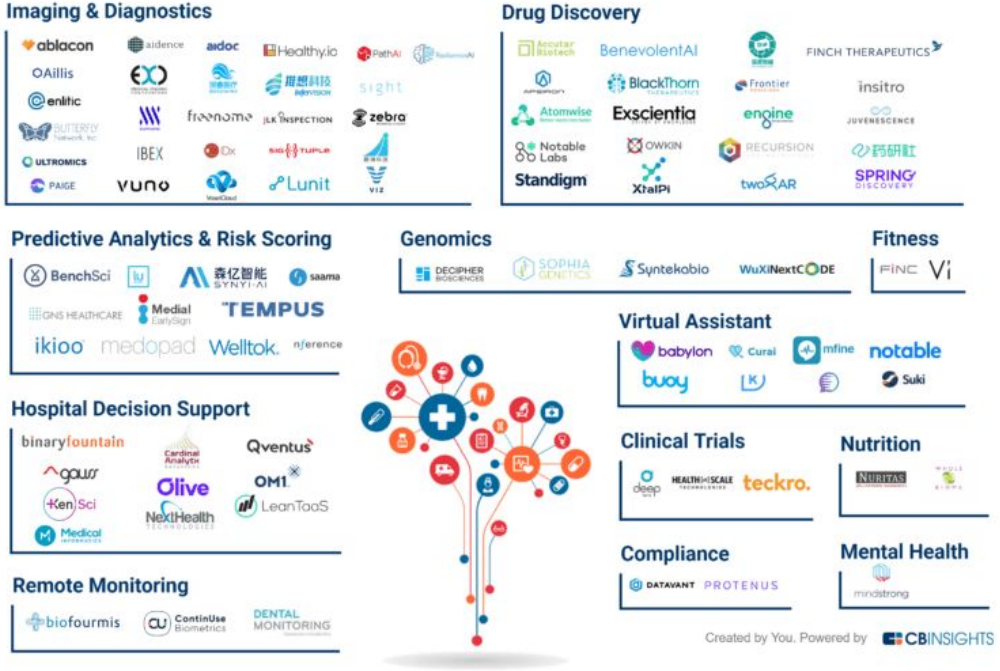
Keona's AI software has streamlined the triage process and improved patient outcomes.

Source: DiMe-VHA The Playbook: Healthcare team analysis

Market map for healthcare AI startups

Top areas of development in AI include:

- AI-driven **imaging & diagnostic solutions** comprise of of 30% of startups raising $1.5B in financing.
- **Drug discovery** is another popular sector, accounting for 23% of the companies with 23% of total disclosed funding.



Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.cbinsights.com/research/artificial-intelligence-startups-healthcare/

Biases built into algorithms can widen health disparities

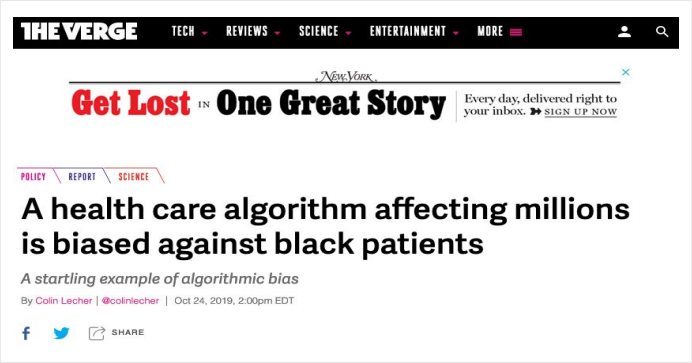
SCIENTIFIC AMERICAN 175

COMPUTING

Racial Bias Found in a Major Health Care Risk Algorithm

Black patients lose out on critical care when systems equate health needs with costs

By Starre Vartan on October 24, 2019



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POLICY REPORT SCIENCE

A health care algorithm affecting millions is biased against black patients

A startling example of algorithmic bias

By Colin Lecher | @colinlecher | Oct 24, 2019, 2:00pm EDT

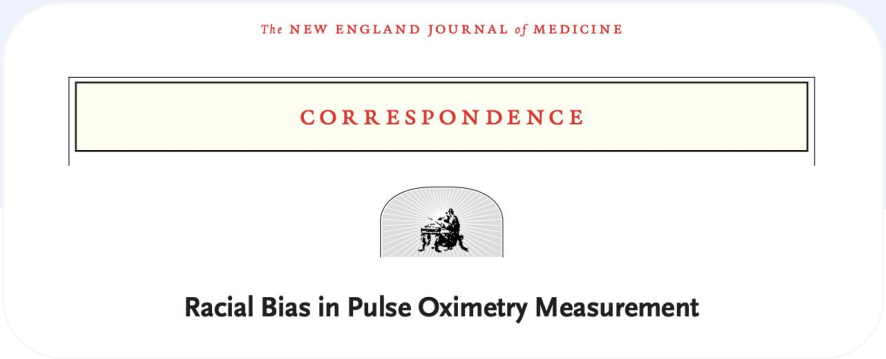
SHARE

- In 2019, news outlets reported on a Science article finding that algorithms that affected the care for hundreds of millions of patients made Black patients substantially less likely than white patients to receive medical treatment.
    - **The reason?** A false assumption baked into the algorithm whereby cost of care was used as a proxy for severity of a patient's illness.
    - **The assumption**: The sicker the patient, the more costly their healthcare tab.
    - **The catch:** Unequal access to healthcare and biases in how healthcare is delivered could be behind lower healthcare costs rather than less actual need for healthcare.
- Appropriately allocating scarce resources to those that need it most is a laudable goal. Lack of understanding or culture of ethics—by those creating the technology or those using the technology—can derail the best of intentions.

Source: The Playbook: Digital Clinical Measures, Scientific American - Racial Bias Found in a Major Health Care Risk Algorithm, The Verge - A health care algorithm affecting millions is biased against black patients

Considerations of Algorithmic bias

- **Algorithms are human creations and are not flawless.** Ethically evaluating digital measurement product also requires attention to algorithmic bias.
- Algorithmic bias can lead to inappropriate distribution of healthcare resources or that technology does not work for one community as it does for another—for example **skin cancer detection apps that are less likely to accurately diagnose patients of color.**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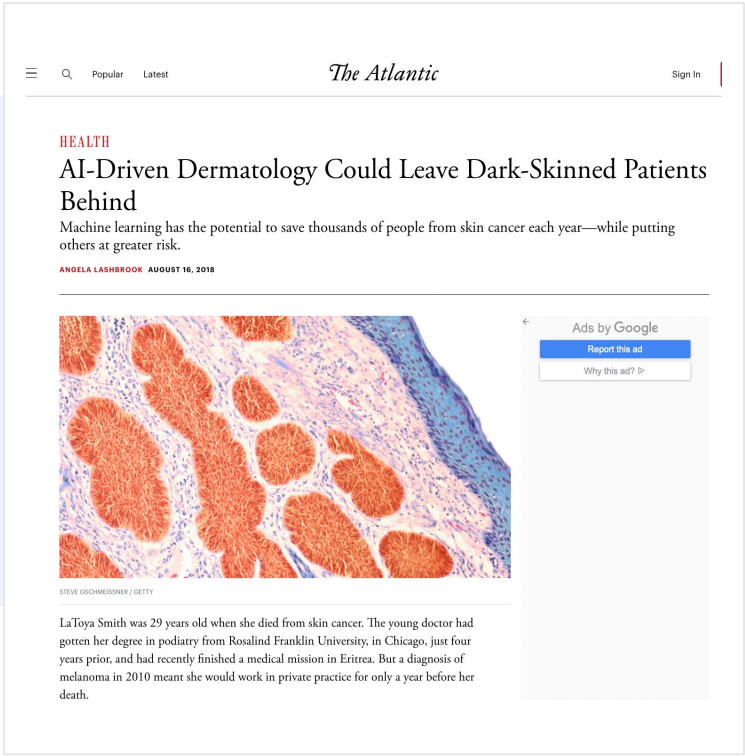
CORRESPONDENCE

Racial Bias in Pulse Oximetry Measurement


Popular Latest

The Atlantic

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HEALTH

AI-Driven Dermatology Could Leave Dark-Skinned Patients Behind

Machine learning has the potential to save thousands of people from skin cancer each year—while putting others at greater risk.

ANGELA LASHBROOK AUGUST 16, 2018

STEVE GSCHMEISSNER / GETTY

LaToya Smith was 29 years old when she died from skin cancer. The young doctor had gotten her degree in podiatry from Rosalind Franklin University, in Chicago, just four years prior, and had recently finished a medical mission in Eritrea. But a diagnosis of melanoma in 2010 meant she would work in private practice for only a year before her death.

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Why this ad?

Source: DiMe-VHA The Playbook: Healthcare team analysis, The Playbook: Digital Clinical Measures, The Atlantic - AI-Driven Dermatology Could Leave Dark-Skinned Patients Behind, NEJM - Racial Bias in Pulse Oximetry Measurement

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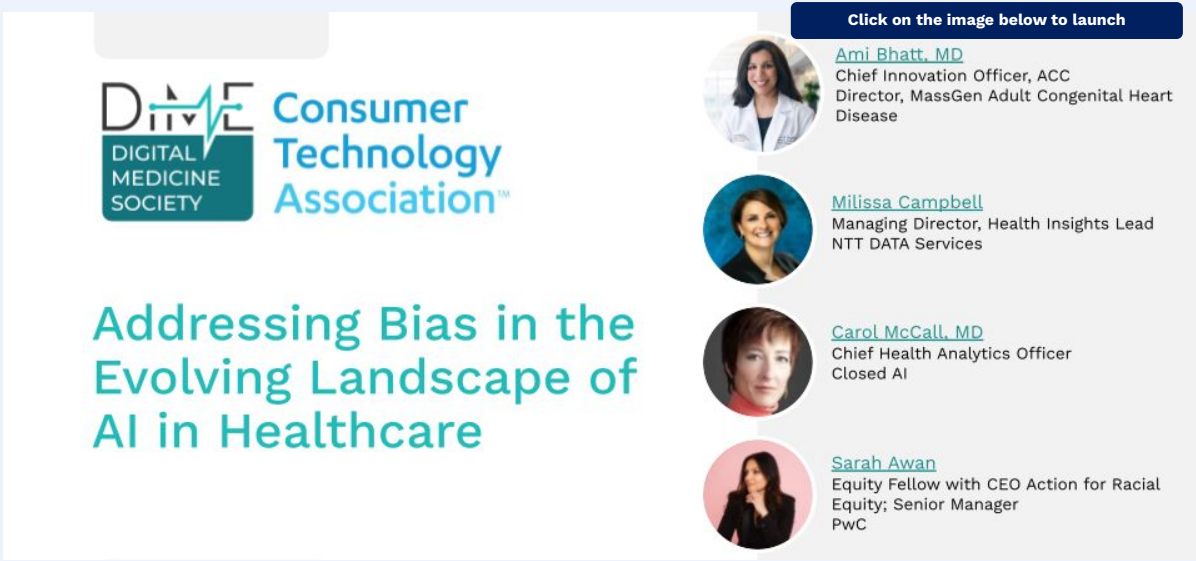


Source: DiMe-VHA The Playbook: Healthcare team analysis, https://youtu.be/BU4y9ENxshI

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

Augmented Reality(AR), Mixed Reality(MR), Virtual Reality(VR)

TL;DR

XR = {AR/MR/VR}
Extended reality (ER) encapsulates current and future developments in augmented reality, mixed reality and virtual reality

What is **AR/MR/VR?**

- **Extended reality (XR)** is a collective term for real-and-virtual combined environments and human-machine interactions generated by computer technology and wearables. XR includes:
  - **Augmented reality (AR)**
  - **Mixed reality (MR)**
  - **Virtual reality (VR)**

- **Deployed throughout the continuum of care delivery** for a range of purposes including, but not limited to, diagnosis or prediction of anxiety, depression, schizophrenia, addiction, ADHD, autism spectrum disorder and about a person's cognitive and physical function.

Applications

- Lifestyle intervention
- Diagnostic and prevention
- Remote tracking and monitoring
- Disease management and treatment
- R&D and production optimization
- Clinical decision support
- Communication and engagement

Source: DiMe-VHA The Playbook: Healthcare team analysis, "The Lengthy History of Augmented Reality". Huffington Post. 15 May 2016, https://www.wired.com/story/what-is-xr/, https://www.alice.id.tue.nl/references/milgram-kishino-1994.pdf

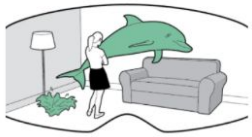
What is the difference between AR <> MR <> VR?

- **Augmented reality (AR)** is an interactive experience of a real-world environment where the objects that reside in the real world are enhanced by computer-generated perceptual information, sometimes across multiple sensory modalities, including visual, auditory, haptic, somatosensory and olfactory.
- **Mixed reality (MR)** is the merging of real and virtual worlds to produce new environments and visualizations, where physical and digital objects co-exist and interact in real time. Mixed reality does not exclusively take place in either the physical world or virtual world, but is a hybrid of augmented reality and virtual reality.
- **Virtual reality (VR)** is a simulated experience that can be similar to or completely different from the real world. Applications of virtual reality include entertainment (video games), education (medical or military training) and business (virtual meetings).

XR = {AR/MR/VR}

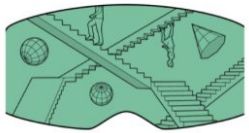
Augmented Reality

In augmented reality—like Google Glass or the Yelp app's Monocle feature on mobile devices—the visible natural world is overlaid with a layer of digital content.



Mixed Reality

In technologies like Magic Leap's, virtual objects are integrated into—and responsive to—the natural world. A virtual ball under your desk, for example, would be blocked from view unless you bent down to look at it. In theory, MR could become VR in a dark room.



Virtual Reality

VR places the user in another location entirely. Whether that location is - computer-generated or captured by video, it entirely occludes the user's natural surroundings.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.wired.com/2016/04/magic-leap-vr/

The promise of immersive digital tools for care delivery

Opportunities to create value for patients, providers and healthcare systems

Large amount of biometric tracking data collected from micro-movements of head, torso, hands, and eyes

Create safe **experiential learning** environment

Facilitate analyzation and **application of real world evidence** and/or product performance data

Provides learners with **hard skills** (motor functioning) and **soft skills** (empathy) through virtual interactions

Convenient to **scale and reuse** of equipment can support product sharing

Support diagnoses or prediction of various **cognitive and physical function**

Collects **metrics to track** individual progress and knowledge of the skills

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://itif.org/publications/2021/08/30/promise-immersive-learning-augmented-and-virtual-reality-potential

20 min in a XR session can record 2 million data points about an individual's body movement!

XR solutions are being used to improve key areas of patient care including mental health, elder-care, physiotherapy, and pain management. Experts estimate the market for XR in healthcare could reach $7B by 2026.

Risk

Reliability, validity, and accuracy of data may vary greatly based on various factors

Challenge

High upfront unit cost have limited widespread use of AR tools

Risk

Non-transparent **privacy policies** for the purpose and use of user-generated data has discouraged progress

Risk

Intellectual property (IP) infringement is seen as a prime legal risk for stakeholders

Risk

Sprawling psychographic profiles coupled with medical inputs could leave people vulnerable

Risk

Lack in anonymity tracking data is serious concern due to individual's unique movement patterns

Source: DiMe-VHA The Playbook: Healthcare team analysis

The challenges of applying real-world regulations to XR

- XR technologies are evolving fast – and our **legal systems are unprepared.**
- Despite the multitude of opportunities, some real **risks and regulatory challenges exist** like:
  - Questions about privacy and copyright
  - Disputes over the speech rights and physiological tracking
  - Threat to geolocation of individuals
  - Risks of property damage and destructions and more
- **Currently,** there are **no regulations** or guidance on AR/VR/MR usage. However, **FDA is taking steps to identify critical gaps** that may impede medical XR products **development**, innovation, and to advance the **evaluation** of medical XR products and **applications**, thus accelerating the development of safe and effective medical XR products benefiting patients and healthcare. View recordings: 1, 2, 3, 4

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://itif.org/publications/2021/03/04/balancing-user-privacy-and-innovation-augmented-and-virtual-reality

Case study: VR for orthopedic surgical training

The Challenge:

Video learning before surgery is common practice for surgical trainees and surgeons. This study is designed to evaluate whether **Immersive virtual reality (IVR)** improves **learning** effectiveness for **surgical** trainees and to validate a VR rating scale through **correlation to real-world performance.**

The Approach:

An **IVR training platform** providing a case-based module for reverse shoulder arthroplasty (RSA) for advanced rotator cuff tear arthropathy. Participants were permitted to repeat the module indefinitely. The **primary outcome measure was a validated** performance metric (Objective Structured Assessment of Technical Skills [OSATS]). Secondary measures included transfer of training (ToT), transfer effectiveness ratio (TER), and cost-effectiveness (CER) ratios of IVR training compared with control.

RCT: Effectiveness of Immersive Virtual Reality on Orthopedic Surgical Skills Among Senior Surgical Residents

POPULATION

14 Men, 4 Women

Orthopedic postgraduate residents in years 4 and 5

Mean (SD), age 31 (27-36) y

INTERVENTION

18 Participants randomized and analyzed

9 Immersive virtual reality (IVR) simulation

Precision orthopedic surgery virtual reality simulator with reverse shoulder arthroplasty training module

9 Technical instructional video

Technical instructional video of reverse shoulder arthroplasty

SETTINGS / LOCATIONS

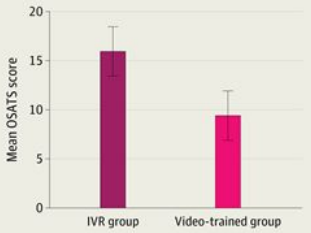
Single-site simulation center in Ottawa, Ontario, Canada, with participants from 9 training institutions

PRIMARY OUTCOME

Objective Structured Assessment of Technical Skills (OSATS) score (range 0-21) during masked cadaveric evaluation in performing reverse shoulder arthroplasty

FINDINGS

Participants trained with IVR had significantly higher OSATS scores than participants trained with video



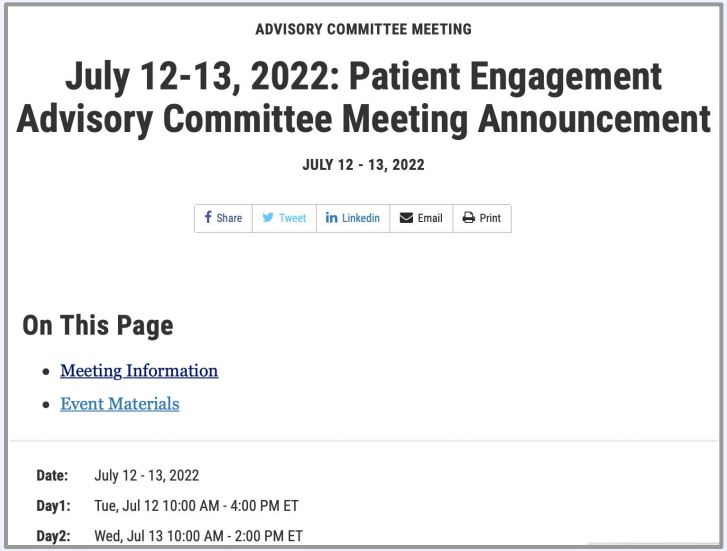
Difference, 6.9; 95% CI, 3.3-9.7; *P* < .001

The Result:

Surgical training with IVR demonstrated **superior learning efficiency, knowledge, and skill transfer.** The control group with receiving only technical instructional video missed a mean of 67% of the key steps while the IVR group outperformed The IVR training is at minimum **34.1 times more cost-effective** than our control.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774493?resultClick=1

SPOTLIGHT



ADVISORY COMMITTEE MEETING

July 12-13, 2022: Patient Engagement Advisory Committee Meeting Announcement

JULY 12 - 13, 2022

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On This Page

- Meeting Information
- Event Materials

Date: July 12 - 13, 2022
Day1: Tue, Jul 12 10:00 AM - 4:00 PM ET
Day2: Wed, Jul 13 10:00 AM - 2:00 PM ET

> "AR/VR devices are increasingly applied to healthcare settings across the patients' care continuum. From diagnostics to clinical decision making, to surgical support, and to directly treating patients, AR/VR devices are used across multiple medical specialties."

On July 12 and 13, 2022, the CDRH Patient Engagement Advisory committee met to discuss and make recommendations on the topic of "Augmented Reality (AR) and Virtual Reality (VR) Medical Devices."

Source: DiMe-VHA The Playbook: Healthcare team analysis, FDA

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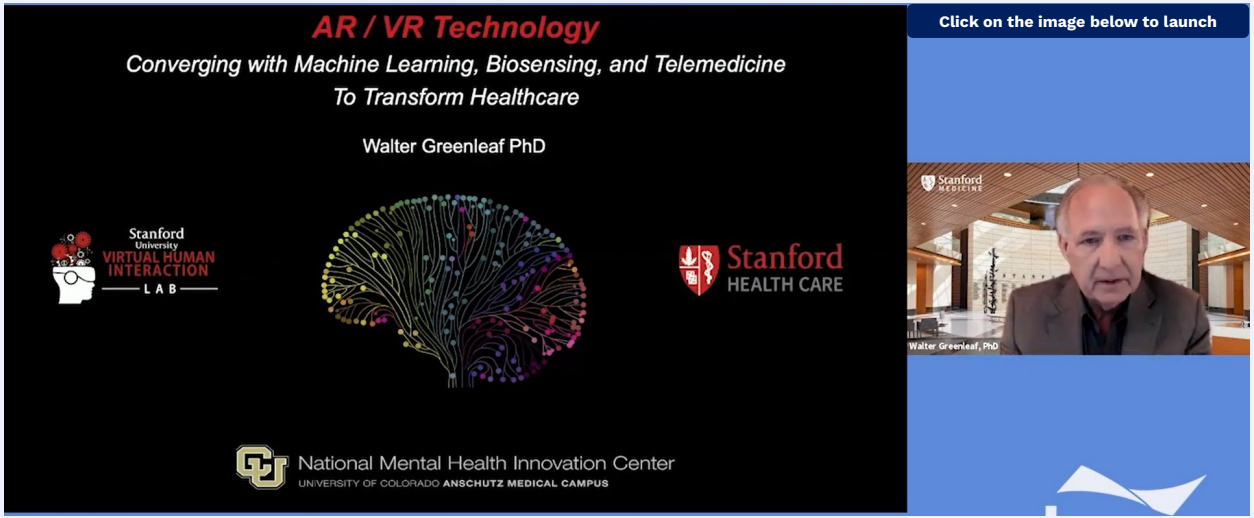

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://youtu.be/BU4y9ENxshI

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- **Mobile health applications**
- **Engagement and Social Media**
- **Virtual care**

Connected sensor technology

TL;DR

Connected Sensor Technology products process data captured by mobile sensors using algorithms to generate measures of behavioral and/or physiological function

What is **connected sensor technology?**

- **Connected sensor technologies** includes **wearables**, **activity trackers,** heart rate monitors, smart scales, sensors embedded in smartphones (e.g. microphone), **Ingestibles** such as smart pills (e.g., MyCite), **Implantables** (e.g., pacemaker, subdermal wearable).
- Defined characteristics that are measured as indicators of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions
  Connected sensor products:
  - Also known as **biometric monitoring technologies (BioMeTs)**
  - Sometimes these technologies are worn and thus called **"wearables"**
  - And/or **internet of medical things (IoMT)** (e.g., smart speakers, internet connected scale)

Applications

- Lifestyle intervention
- Diagnostic and prevention
- Remote tracking and monitoring
- Disease management and treatment
- R&D and production optimization
- Clinical decision support
- Communication and engagement

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://playbook.dimesociety.org/tools/glossary/#digital-clinical-measure%20&%20%20https://www.karger.com/Article/FullText/500413

Sensor tech bringing value with passively collected information

Opportunities to create value for patients, providers and healthcare systems

Monitoring and tracking for any ongoing health condition or clinical intervention.

Maximize the biometric physiology **information collected** for the end users

Facilitate analysis and **application of real world evidence** and/or product performance data

Facilitate **collection of richer data** and insights to enhance understanding of the effects of treatment

Connectedness creates efficiencies for the information collection and exchange

Provide **invasive and non-invasive** capabilities to understand patients health better

Reusable product that offer process data accurately, reliably, and continuously

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.nature.com/articles/s41746-020-0237-3

With the rising tide of connected sensor technology comes questions around variability, security & utilization

The connected sensor industry continues to grow, reaching more people with the healthcare they need while reducing the associated burdens for both patients and healthcare professionals. However, the evolving field also poses risks from the technology variability from data to security to its right utilization.

Risk

Reliability, validity, and accuracy of data may vary greatly based on various factors

Challenge

Tech barriers can be an impediment to effective and appropriate **utilization and usage** of the technology

Risk

Cybersecurity vulnerabilities can emerge when connected to another electronic device or network

Challenge

Disparities of reach and impact with barrier of technical literacy and digital knowledge

Risk

Concerns about **privacy and security** of users

Challenge

Existing systems of care **not utilizing the advantage** of home sensor data.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://pubmed.ncbi.nlm.nih.gov/32393301/, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4732146/

What does the FDA say about connected sensor technology?

- Regulatory environment is **far from established for governing "digital specimens"** (e.g., data generated from connected sensor technologies).
- FDA **only oversees** digital specimen-collecting tech like wearables, **if classified as medical devices**.
- Today, narrow definition of device and revisions with the 21st Century Cures Act, leaves **connected sensor. technologies outside the purview of FDA**.
- So its oversight of functionality and health claims are under Federal Trade Commission, which policies unfair and deceptive trade practices, including enforcing rules against false or misleading advertising.
- In US, **NIST, FCC and ONC may each have oversight of components** of connected sensor technologies, but **no regulator has full responsibility for digital specimens.**

3 key de-facto agreements for the data rights disclosure that has become a common practice

Privacy policies (PP) disclose the terms for collection and use of the app/website user's personal information.

Terms of service (ToS) disclose the rules and requirements of website and/or app use, for example, copyright, allowed uses, and the definition of abusive use.

End-user license agreements (EULAs) are a form of intellectual property licensing that tell people who have purchased software if/how many times they can copy the software and how they can or cannot use those copies.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.karger.com/Article/FullText/500413, https://www.wsj.com/articles/the-internet-of-bodies-is-here-are-courts-and-regulators-ready-1542039566

Case study: Using connected technology to understand variations in constipation symptoms and med management

The Challenge:

Understanding day-to-day variations in symptoms and **medication management** can be important in describing patient-centered **outcomes** for people with constipation. **Patient Generated Health Data (PGHD)** from digital sensing products is a potential solution.

The Approach:

- Opportunity to enrich and **characterize treatment response** in subset of participants.
- Faster recruitment and shorter trial duration
- Trial risk reduction for disruption (drop out, non-adherence, inconclusive study).
- **Better inform regulatory approval, reimbursement strategies and adoption.**

The Result:

- **Evidation Health** and **Sanofi-Aventis** designed a virtual, 16-week prospective study of 1540 individuals with frequent constipation from an online wellness platform that connects mobile consumer digital devices that described the association between passively collected PGHD and constipation symptoms and severity at a day-to-day granularity level. 38 predetermined day-level behavioral activity metrics were computed from minute-level data streams for **steps**, **sleep**, and **heart rate.**
- At a daily-level, **22 of 38 activity metrics were significantly associated with bowel movement or medication treatment patterns** for constipation.
- Constipation status, irregular or constipated, was associated with a number of activity metrics in steps and sleep, and likelihood to treat with medication increased with increasing severity for a number of constipation symptoms.
- These findings provide evidence that:
  - **Better characterization of real-world experiences** could lead to better understanding of the **meaningfulness to patients.**
  - Objective insights can **aid monitoring** and **management.**

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://ieeexplore.ieee.org/document/8964569; Learn more about gait differences in healthy adults using wearables https://youtu.be/duhrERQx4_E

Case study: Gait as a digital clinical measure to identify early signs of Parkinson's disease

The Challenge:

The fastest growing brain disease in the world, **Parkinson's disease** (PD), currently, has **no objective biomarker** to measure onset, progression, and severity. Despite millions of dollars invested into genetics, molecular, and imaging modalities, diagnostic accuracy to differentiate PD from other neurological disorders by movement disorder specialists ranges between 74% and 80%.

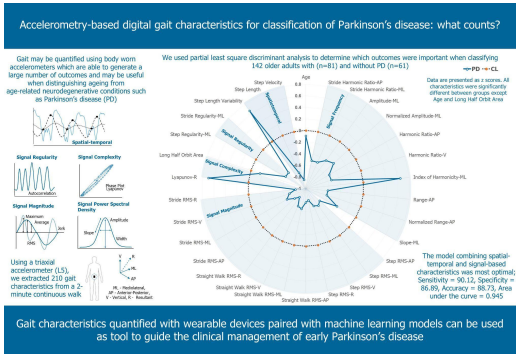
The Approach:

With **low cost, objective** and **scalable** digital clinical measures, walking patterns (gait) have been shown to be useful tools in measuring health and brain function in PD. Using **wearables** (e.g. accelerometry) and machine learning models this study:

- Quantifies a digital battery of commonly utilized **gait characteristics** (spatiotemporal and signal-based),
- Identifies the most informative **digital clinical measures** of gait for classification of PD.

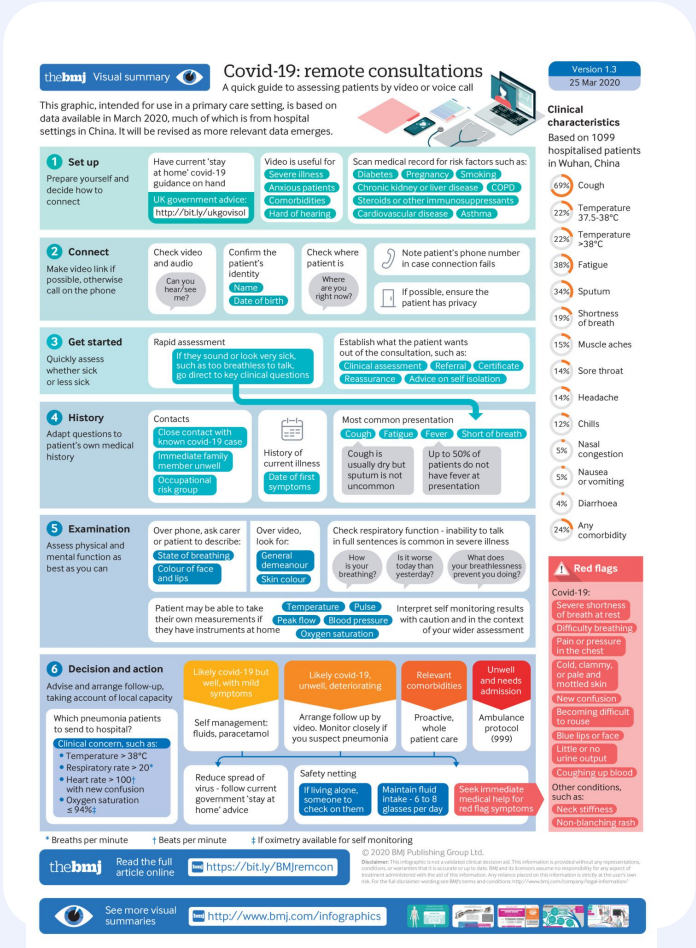
The Result:

The study highlights the importance of using **connected sensor technology** to measure the **gait characteristics** in the development of tools to help **classify early PD**.



Gait characteristics quantified with wearable devices paired with machine learning models can be used as tool in early clinical management of Parkinson's disease.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://ieeexplore.ieee.org/document/8964569; Learn more about gait differences in healthy adults using wearables https://youtu.be/duhrERQx4_E



SPOTLIGHT

A remote assessment in the primary care setting

This manuscript in BMJ presents some guiding principles on how to choose between telephone and video appointments and **also considerations for when and how** to collect **digital clinical measures** using connected sensors a virtual visit.

Source: DiMe-VHA The Playbook: Healthcare team analysis

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Click on the image below to launch

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://playbook.dimesociety.org/dossiers/clinicians/#learnlet-4-evaluate-the-utility-of-digital-clinical-measures-in-different-clinical-settings-and-in-different-patient-populations

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Digital Therapeutics (DTx)

TL;DR

DTx are new care modularity tools that deliver care through high quality software programs

What is the difference between **DTx vs PDT?**

- **DTx** are evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease.

  PDTs are a subset of DTx. **In the US, PDTs** deliver similar to DTx and are:
  - **authorized** by the FDA (i.e., cleared or approved) with approved directions for use;
  - undergo **rigorous evaluation** for safety and effectiveness in clinical trials with clinically-meaningful results;
  - **prescribed** and initiated by a licensed healthcare practitioner.

- **Deployed throughout the compendium of care delivery** for a range of purposes including chronic disease management, mental health, addiction and sleep medicine, oncology, neurology, and more. Newer areas include ophthalmology and female health

Applications

- Lifestyle intervention
- **Diagnostic and prevention**
- Remote tracking and monitoring
- **Disease management and treatment**
- R&D and production optimization
- Clinical decision support
- Communication and engagement

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf
https://dtxalliance.org/understanding-dtx/product-library/

Realizing the potential value of DTx and PDTs for evidence-based therapeutic interventions

Opportunities to create value for patients, providers and healthcare systems

Produce **novel medical intervention** that is driven by software

Maximize patient engagement by engaging end users in product development and usability processes

Collect, analyze, and **apply real world evidence** and/or product performance data

Providing meaningful insights on **personalized goals** and outcomes to patients and providers

Provide convenience care outside doctors office, outside clinic hours, etc

Deliver high quality therapies **to underserved populations**

Providing therapies in **various languages,** such as English, Spanish, Arabic, German, and French

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf

The missing pieces of the digital therapeutics that still needs to be addressed

Although the clinical safety profile of DTx to date is low risk, the surveillance of the clinical efficacy and safety of these new tools still need to be considered in real-world setting. Market access pathways and reimbursement are vital to the adoption and success of DTx in mainstream healthcare, yet these are still nascent. Better collaboration among digital innovators and payors, providers, and pharmaceutical is necessary to continue forward progress.

Challenge

Clarity on what quality, sufficient clinical evidence is and what's needed to support clinical decision making

Challenge

Challenges in **pricing, regulations, and reimbursement** prevents access to novel treatments

Challenge

Low translatability of solutions from controlled to real world settings

Challenge

High **adoption barrier** due to lack of implementation infrastructure

Challenge

Lack of standardization of evidence for underlying therapeutic outcomes

Challenge

Lack of skilled workforce to support initiation and deployment

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.statnews.com/2021/12/29/digital-therapeutics-pear-health-payers/

Outlook on the DTx regulatory landscape in US

- DTx are most **commonly regulated under Software as a Medical Device (SaMD)** framework, developed by the International Medical Device Regulators Forum (IMDRF). Learn more about SaMD:
  - SaMD Definitions
  - SaMD Framework for Risk Categorization
  - SaMD Application of quality system
- **DTx clearances** are usually granted by the FDA Center for Devices and Radiological Health.
- In wake of Covid-19 we have seen FDA also **allowing** certain digital health products focused on psychiatric conditions to **go-to-market temporarily.**

UNITED STATES Regulatory

Category Name	Medical Device—includes Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD)		
Responsible Regulatory Agency	Food and Drug Administration (FDA), specifically the Center for Devices and Radiological Health (CDRH)		
Product Risk Classifications	**Exempt Medical Devices** Class I Exempt, Class II Exempt, or Enforcement Discretion (including COVID-19 public health emergency (PHE))	**Class II** Pre-market Notification 510(k) or De Novo pathways	**Class III** Premarket Approval (PMA)
Regulatory Review	Exempt from a marketing submission: Most Class I and some Class II devices are 510(k) exempt devices, but must register and list. Enforcement discretion devices may not be required to register and list. Enforcement discretion is a risk-based decision by FDA to decline enforcing certain regulatory requirements and is not specific to a classification.	510(k): Marketing submission required to demonstrate substantial equivalence to predicate device. General controls are required. Special controls may also be required, which may require a clinical trial (see regulation to determine requirements). De Novo: Marketing submission required to demonstrate reasonable assurance of safety and efficacy. General controls are required. Prospective clinical trial generally required.	PMA: Most stringent market submission application to demonstrate safety and effectiveness. General controls are required. Prospective clinical trial generally required.
Pre-Submission Opportunities	513(g) can be submitted to confirm the regulatory pathway, but is not required: *Timeline: 60 days* *Cost: $2,530 small business* / $5,061 standard*	Pre-submission strongly recommended, especially for De Novo: *Timeline: 70 days* *Cost: no charge* 513(g) may be submitted to confirm regulatory pathway. Breakthrough Devices request may be possible for highly innovative products: *Timeline: 60 days* *Cost: no charge*	Pre-submission strongly recommended. Pre-IDE should be submitted for feedback on significant risk clinical studies. 513(g) may be submitted to confirm regulatory pathway. Breakthrough Devices request may be possible for highly innovative products.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://dtxalliance.org/wp-content/uploads/2022/01/US-Regulatory-and-Reimbursement-Pathways.pdf

SPOTLIGHT

The opportunity: novel approaches for evidence generation to support broad acceptance of DTx

THE LANCET
Digital Health

Viewpoint

Advancing digital health applications: priorities for innovation in real-world evidence generation

Ariel D Stern, Jan Brönneke, Jörg F Debatin, Julia Hagen, Henrik Matthies, Smit Patel, Ieuan Clay, Bjoern Eskofier, Annika Herr, Kurt Hoeller, Ashley Jaksa, Daniel B Kramer, Mattias Kyhlstedt, Katherine T Lofgren, Nirosha Mahendraratnam, Holger Muehlan, Simon Reif, Lars Riedemann, Jennifer C Goldsack

In 2019, Germany passed the Digital Healthcare Act, which, among other things, created a "Fast-Track" regulatory and reimbursement pathway for digital health applications in the German market. The pathway explicitly provides for flexibility in how researchers can present evidence for new digital products, including the use of real-world data and real-world evidence. Against this backdrop, the Digital Medicine Society and the Health Innovation Hub of the German Federal Ministry of Health convened a set of roundtable discussions to bring together international experts in evidence generation for digital medicine products. This Viewpoint highlights findings from these discussions with the aims of (1) accelerating and stimulating innovative approaches to digital medical product evaluation, and (2) promoting international harmonisation of best evidentiary practices. Advancing these topics and fostering international agreement on evaluation approaches will be vital to the safe, effective, and evidence-based deployment and acceptance of digital health applications globally.

The health innovation hub of German Ministry of Health (hih) and DiMe released global priorities highlighting global best practices and a roadmap for the continued methodological advancements necessary for the acceleration of DTx innovation.

In 2019, Germany's DVG act created a **regulatory and reimbursement pathway** for various digital health applications including DTx in the German market. The **"Fast-Track" pathway** set the legal framework for **doctors to prescribe** certain categories of digital health applications (known by their German acronym, **DiGA**), while evidence demonstrating a positive healthcare effect is still being collected.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.thelancet.com/action/showPdf?pii=S2589-7500%2821%2900292-2

Examples of regulated DTx in the German market

- **Positive effects of care** for DTx under the DiGA may be **defined as either**:
  1. **A medical benefit** (i.e., a therapeutic improvement by positively influencing patient-relevant endpoints such as quality of life, reduction in disease duration, improved survival), or
  2. **Patient-relevant improvements in structure and process**, such as adherence, better coordination of treatment processes, health literacy, patient safety, patient autonomy, etc.

- Access the full DiGA directory here
- Information for DiGA users here
- Information for service providers here
- Information on the Fast Track application here

An example of an early digital health application that completed the Fast-Track process is the digital therapeutic Elevida (GAIA; Hamburg, Germany), a digital health application for individuals with multiple sclerosis who also suffer from fatigue. For this product, evidence of positive care effects was generated from a randomised controlled trial of 275 patients with multiple sclerosis with fatigue. The trial compared the use of the Elevida application as well as standard multiple sclerosis care (the intervention group) with standard multiple sclerosis care alone (the control group). A significantly lower Chalder Fatigue Scale score was found in the intervention group compared with the control group after 12 weeks (the primary survey time endpoint) and differences were also detectable at 24 weeks.[13]

Many analogous products have gone through other regulatory approval processes internationally. For example, reSET (Pear Therapeutics; Boston, MA, USA) had the first de-novo approval of a digital therapeutic by the US Food and Drug Administration.[14] In the case of reSET, real-world evidence observational studies have been used to examine efficacy and product usage. Other examples include the use of BlueStar (Welldoc; Columbia, MD, USA) for people with diabetes and EaseVRx (AppliedVR; Los Angeles, CA, USA) for treating pain.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.thelancet.com/action/showPdf?pii=S2589-7500%2821%2900292-2, German Digital Healthcare Act (Digitale–Versorgung–Gesetz or DVG)

Case study: Managing PTSD, panic disorder, and panic attack with digital therapeutics

The Challenge:

In the US, **17.1 million people** have frequent **panic attacks** and **8.7 million** people have **PTSD** (Post-traumatic stress disorder). PTSD is **significantly higher in the Veteran population** with as high as **30% of** Veterans diagnosis of PTSD**.**

The Approach:

Freespira® FDA-cleared DTX that normalizes exhaled **CO2 and Respiratory Rates** (RR) in a single **28-day at-home treatment**. Guided, **twice-daily (17-minute)** treatments use a sensor sampling the patient's exhaled air (measure CO2 levels & RR).

These physiological markers are displayed in real-time on a tablet as visual feedback along with **rising and falling audio tones** to teach patients how to **normalize respiration rate** and expired CO2 levels.

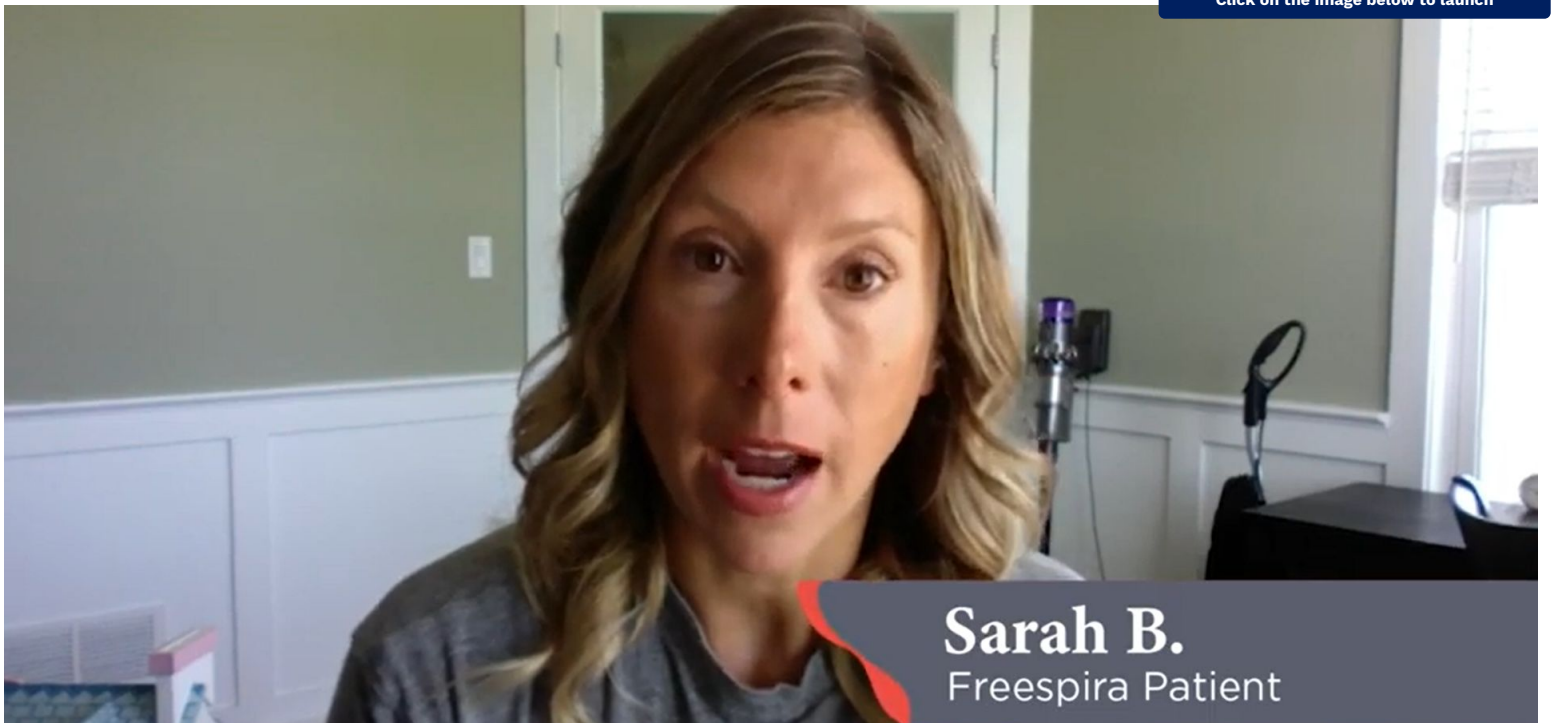
The Result:

- **89%** Clinically significant **symptom reduction**
- **50%** in **remission** at 6 months
- **41% decrease in suicidality**
- **29% decrease in depression**
- **77%** increase in treatment **adherence**
- **91% satisfaction** rate

Source: DiMe-VHA The Playbook: Healthcare team analysis, Ostacher, M.J., Fischer, E., Bowen, E.R., Lyu, J., Robbins, D.J., and Suppes, T. Journal of Applied Psychophysiology and Biofeedback, September 1, 2021, https://www.ptsd.va.gov/understand/common/common_veterans.asp

Patient's story with Freespira®

Click on the image below to launch



Source: DiMe-VHA The Playbook: Healthcare team analysis, View the video https://youtu.be/Vg-uH8h0CgA

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Source: DiMe-VHA The Playbook: Healthcare team analysis, https://youtu.be/BU4y9ENxshI

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- Digital Therapeutics
- Electronic health records
- Mobile health applications
- Engagement and Social Media
- Virtual care

Electronic Health Records

TL;DR

Electronic Health Records (EHRs) contain individual health records for patients and are used in care delivery.

What are **EHR and its tools?**

- An **Electronic Health Record (EHR)** is an electronic version of a patient's medical history, that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that persons care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports
- EHR tools are traditionally an extension of the an EHR or hospital system. Some of them may include:
  - **Patient portals**
  - **Personal health records**
  - **Provider data management tools**

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.cms.gov/Medicare/E-Health/EHealthRecords

From patient portals, personal health records to data systems: EHR tools offer value to many

Opportunities to create value for patients, providers and healthcare systems

Improved care coordination between provider-provider, patient-provider, and provider-system

Multi-device access to providers helps seamless **navigation** for decision-making

Identify and **reduce medical error** by improving accuracy and clarity of medical records

Faster, inclusive, and efficient **communication** system

Maximize patient engagement with patient having access to personal health information

Improved **all-time access to patients** health information

Support **large information storage** and data operations from multiple sources

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3270933/,

Collaboration between clinical teams, health IT professionals and EHR Vendors is critical

EHRs function as a system required in health care and less of a tool to aid in organization and communication of high-quality, patient centric care. **By design, they do not align with the cognitive and/or workflow requirements of clinicians or patients** using the portals. In order to advance the delivery of high-value quality care:

1. **Collaborative partnerships** are needed that work to **understand clinicians' EHR needs** related to usability and efficiency, while working to nimbly make changes
2. EHR's need to **pivot and re-design system** elements **to support** the practice patient-centered care
3. Better support digital health solutions which expand care delivery for clinicians beyond the hospital or exam room

Health System, Vendor Collaboration Needed to Improve EHR Functionality

Industry collaboration is needed to improve EHR functionality and protect the cognitive attention of clinical teams, according to a JAMA Network Open viewpoint.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.healthit.gov/curesrule/

In 2021, HHS reported data breaches from 578 healthcare organizations, impacting 41.5+ million individuals

Despite the growing benefits of various EHR tools and functionalities, there are potential disadvantages associated with this technology. One of the is the risk of patient privacy violations, which is an increasing concern for patients due to the increasing amount of health information exchanged electronically. Even with HIPAA and security policies in place, this still does not deter entities with malicious intent, from trying to obtain sensitive patient information.

Risk

Easily prone to **phishing attacks** via email to reveal login credentials or installing malicious software

Risk

With **cloud tools**, scale of attack is larger to compromise EHR

Challenge

Interoperability challenges makes systems **inefficient, costly, and ineffective**

Risk

EHR tools can have an attached Malware that can impact **data leak, steal, loss**, etc

Risk

Usability and navigation issues that can lead to safety concerns

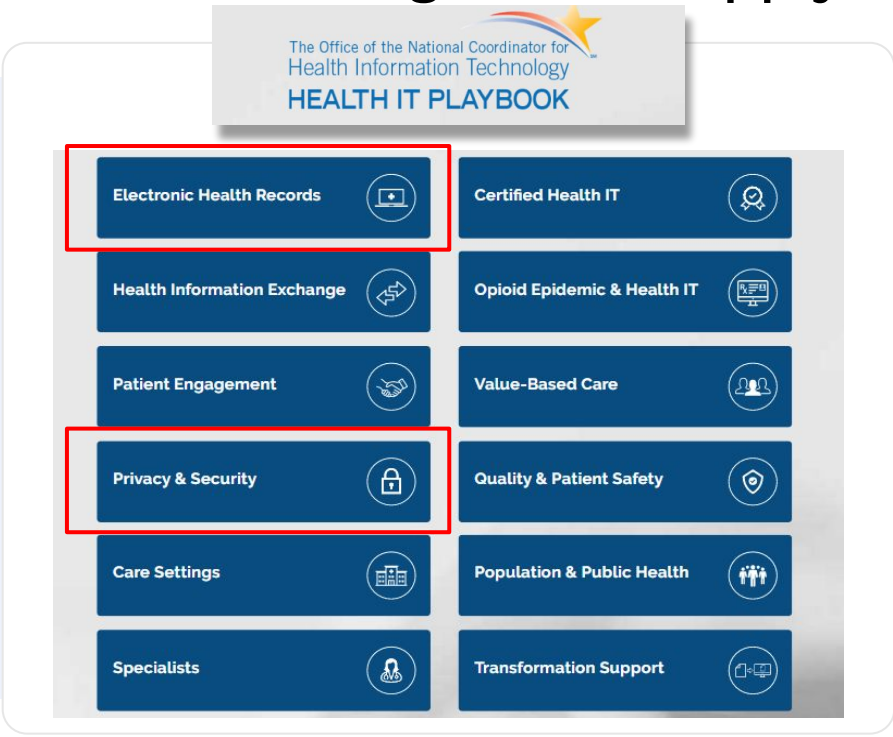
Risk

Insufficient encryption of tools make data in transit vulnerable to exploitive attack

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.hhs.gov/sites/default/files/2022-02-17-1300-emr-in-healthcare-tlpwhite.pdf https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3270933/, https://www.hhs.gov/sites/default/files/electronic-health-record-systems.pdf

As EHRs are not medical products, they are not regulated by FDA. However, other critical regulations apply

- In 2020, the Department of Health and Human Services (HHS) issued two final rules aimed at improving patient access to electronic health information (EHI), as well as the standardization of modes of exchange for EHI.
  - The rules, implement provisions of the 21st Century Cures Act and introduce new requirements for increasing interoperability and also make it possible for patients to access their records digitally from any provider, organize the information in smartphone apps, and share their health data with other providers.
- Agencies like FDA, CMS and other direct stakeholders to the **Office of the National Coordinator (ONC)** within the U.S. Department of Health and Human Services (HHS)'s Health IT Playbook for **strategies, recommendations, and best practices to implement** in the clinical settings.



Source: DiMe-VHA The Playbook: Healthcare team analysis

Digital health depends on interoperability

Interoperability

The ability for two EHR systems to exchange and use data.

Improving interoperability remains a top priority for health systems. Fundamentally, high value digital health runs on flows off of **high quality data.**

- Improved care coordination
- Better performance
- Improved experiences (patient and provider)
- Improved research capabilities
- Cross-functional use of AI and big data
- Improved communication

Barriers need to be addressed such as physician dissatisfaction with EHRs, overregulation, hidden isolated data silos and incompatible systems, and cost. The government will need to consider stronger incentives for both providers and EHR vendors to promote interoperability.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.himss.org/resources/interoperability-healthcare

Case study: Mercy health network's success with healthcare data platform

The Challenge:

MercyOne, is a large Accountable Care Organizations (ACO) in the US with **400+ service locations**, managing **310,000+ patients** and has over **3,500+ providers** under 20+ value-based agreements. With such enormous stature of the ACO, **designing engaged and patient-centric care** across the care continuum was **challenging** along with having with multiple practice sites. The organization had data sources lacking a common standard.

The Approach:

Mercy health network and Innovaccer **co-developed data activation platform** to **identify patient risk** and stratify to align services provided by MercyOne and to provide:

- **Health coaching**
- **Community-based patient engagement** resources
- **Seamless data integration** and information exchange

The Result:

- **7. 14% reduction** in the 30-day **readmission rate.**
- **14.26% increase** in the p**rimary provider services** per 1,000.
- **300% increase in health coach** interventions to 95.7 new engagements per health coach per month.

Mercy ACO

INNOVACCER

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://innovaccer.com/resources/case-study/streamlining-care-processes-in-healthcare-organizations/, https://youtu.be/EAhu9Jsgc-Q

Case study: Nebraska Medicine combines voice technology with Epic EHR to boost provider efficiency

The Challenge:

Nebraska Medicine's 2 hospitals have **1,000+ physicians** and **uses EPIC's EHR** since 2009. With providers dissatisfaction of **inefficient approaches** to **clinical documentation**, spending great amount of time and effort to manually document patient notes into the EHR, the organization aimed to increase physician satisfaction by making documentation faster and more efficient.

The Approach:

In 2016, Nebraska Medicine introduced Nuance Communications' Dragon Medical One, an enterprise-wide, cloud-enabled, voice recognition platform with PowerMic Mobile, enabling **physicians** to **use their mobile devices** to **dictate notes** from anywhere.

The Result:

- **23% reduction** in **transcription costs**
- **94%** users report software enables them **to do their jobs better**
- **71%** users report the **quality** of their **documentation** improved significantly
- **50%** users report software **saves** time (**>30mins/day**).

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.healthcareitnews.com/news/nebraska-medicine-links-voice-technology-epic-ehr-boosts-physician-performance

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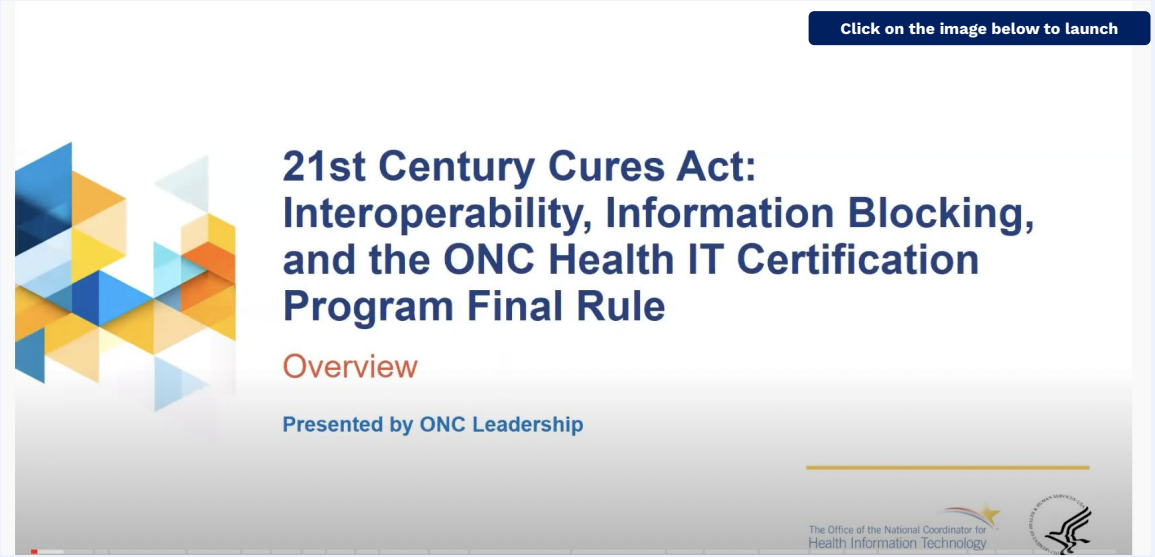

Source: DiMe-VHA The Playbook: Healthcare team analysis, View video at https://www.youtube.com/watch?v=sukhXi1Ur40

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- Virtual care

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?
- Can the user **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

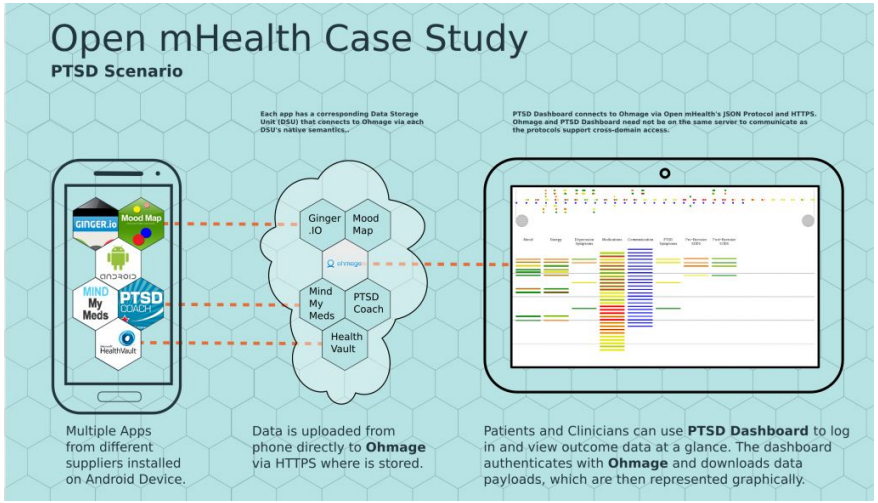
Case study: Open mHealth case study of PTSD

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

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

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- Virtual care

Consumer engagement and social media

TL;DR

Consumer engagement and social media tools offer interventions with no “one-size-fits-all” approach

What are consumer **engagement and social media tools?**

- **Consumer engagement:** According to AHIMA, it refers to diverse set of activities that can include interacting with healthcare providers, seeking health information, maintaining a personal health record, and playing an active role in making decisions in regard to personal healthcare.
- **Social Media tools:** According to FDA, they are web-based tools that are used for computer-mediated communication. Social media may include but is not limited to: (1) blogs (eg, WordPress), (2) microblogs, (eg, twitter) (3) social networking (eg, Facebook), (4) professional networking (eg, LinkedIn, Sermo), (5) thematic networking (eg, 23andMe), (6) wikis (eg, Wikipedia), (7) mashups (eg, HealthMap), (8) collaborative filtering (eg, Digg), (9) media sharing (eg, YouTube, Slideshare), and others (eg, SecondLife).

Applications

- Lifestyle intervention
- Diagnostic and prevention
- Remote tracking and monitoring
- Disease management and treatment
- R&D and production optimization
- Clinical decision support
- Communication and engagement

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://bok.ahima.org/pdfview?oid=301404, ttps://www.fda.gov/drugs/development-approval-process-drugs/patient-focused-drug-development-glossary

The opportunity for consumer engagement tools and social media to improve outcomes

Opportunities to create value for patients, providers and healthcare systems

More consumer **prefer partnership with provider** instead of being passive receivers of information

Consumer **trust in reliability of information** is rising as more seek towards engaging

Expansion of consumer use of technology to monitor health and wellness of individuals

Easy-to-use solutions provides higher utilization and usability of the healthcare services

Readily scalable with low technical specs through patient-owned devices

Provide consumers with **public health information** about health concerns and options

Deliver high quality therapies **to underserved populations**

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4103576/

Case study: How social media platform partnered with digital provider to promote well-being solutions

The Challenge:

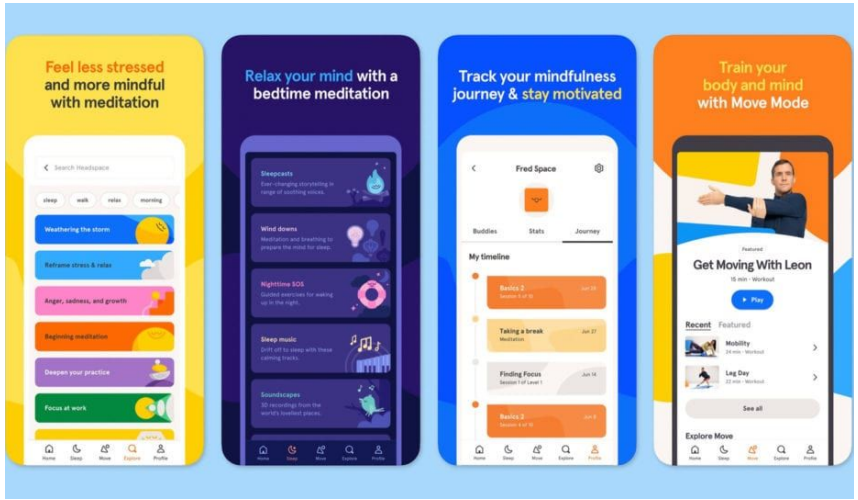
Mental health issues are a leading cause of workplace disability. And **Hootsuite, a leading social media management platform**, believes that it's not enough for employers to simply talk about healthy **well-being**; they need to provide solutions for it.

The Approach:

Headspace health, a leading provider of mental health and wellbeing solutions with science-backed **meditation and mindfulness solution** for the workplace, **partnered with Hootsuite for well-being initiative** to provide employers with **wellness solutions,** a toolkit of resources, and best practices for mental health like mindfulness tips, live meditation events, etc.

The Result:

Some positive outcomes for employer well-being includes **43.9% adoption rate** and **36.3% engagement rate.**



Case study: Engaging patients via Xhealth helps patients kick the tobacco habit

The Challenge:

Cigarette smoking remains the leading cause of preventable disease, disability, and death in the United States, accounting for more than 480,000 deaths every year, or about 1 in 5 deaths. Currently, 16 million Americans live with a smoking-related disease.

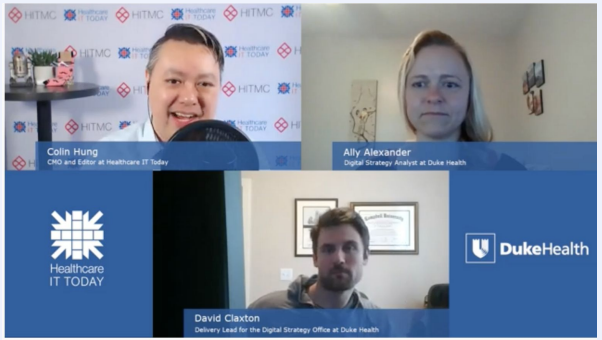
The Approach:

To increase engagement in their smoking cessation program, Duke leverages Xealth to automatically send an email that contains a video explaining the benefits of smoking cessation to all patients who were identified tobacco users in the EMR. If patients indicate they'd like more information, the clinical team is alerted and reaches out.

The Result:

Since implementing Xhealth in their program, Duke has seen a **20% increase** in the likelihood of a patient to **attend their first smoking cessation appointment**. The **success rate** of Duke's program is **30-35%**; 10x the unassisted success rate.

DukeHealth



Collaboration with Duke Digital Strategy Office Key to Smoking Cessation Success

Case study: Leveraging social media for patient engagement and education

The Challenge:

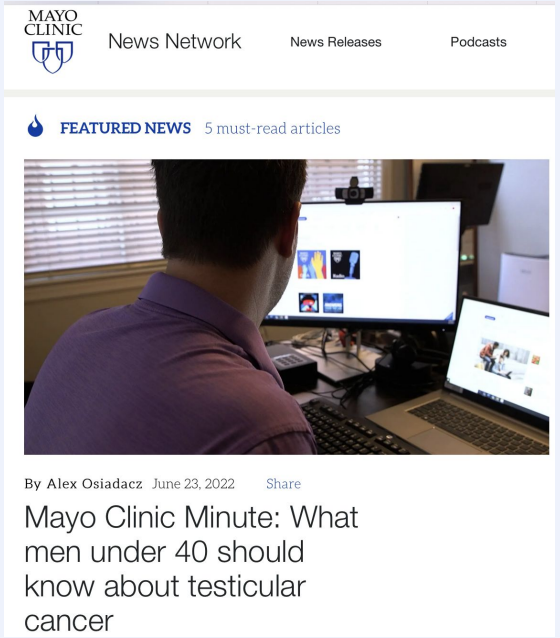
Over the last 20 years, people across the world have **increased their usage of social media** with the **objective to become more informed,** particularly when it comes to learning more about their health and treatment options. This trend has resulted in a decrease of printed material being used to communicate health information, leaving healthcare organizations to seek alternate ways to reach patients and the community.

The Approach:

Recognizing that patients are turning to social media as a resource in healthcare, Mayo Clinic launched their Center for Social Media in 2010. Shortly after, they launched the Mayo Clinic News Network, which **provides access** to **tools, resources and guidance** for individuals and organizations seeking information about health and health care.

The Result:

To date, Mayo Clinic has approximately **1.2 million Facebook followers** and **2 million Twitter followers**. They utilize social media to help **create authentic connections with patients, post uplifting stories and inspiring articles**. During the Public Health Emergency, information was shared about COVID-1, outbreaks, and vaccinations sites.



With low trust and high privacy risk, consumer engagement & social media tools needs more work

In the US alone, **8 in 10 internet users search for health information online**; **74% use social media**. 99% of hospitals in the US have at least 1 active social media channel. However, there is a gap between what consumers are interested in doing and what they have experienced for their healthcare. Misinformation or poorly communicated information, lack of governance over social media, and handling of or mishandling of patient and user data raise many questions.

Challenge

Low trust in the consumer tools is by far the main challenge

Risk

Privacy of patient data is at high-risk

Challenge

Widespread misinformation with non-credible opinions from non-healthcare professionals

Challenge

Unclear governance and policies has created **skepticism related data** and personal information

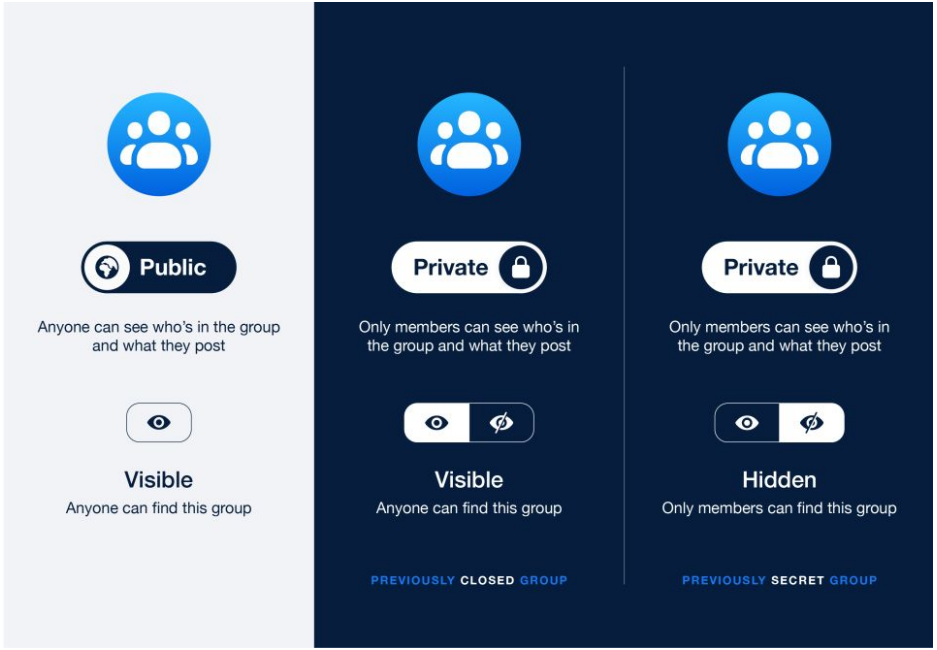
Challenge

Misunderstanding of **consumer health** vs **medical** health **data** putting clinical decisions at risk

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4103576, https://lightcollective.org/2019/09/12/sicgrl-update/

"New" Facebook vulnerability was reported…by patients

- Discovered first by Andrea Downing, SicGRL, a **massive cybersecurity vulnerability in health support groups on Facebook** that impacted millions of people.
  - Any group member (E.g. a malicious attacker) **can download the real names**, **locations, and contact information** of all members of the group. Attackers would scrape data from thousands of "Closed" groups at once without even being a member of the group, and without any group member knowing that a fake user had done this.
- After the problem was reported through **Facebook's white hat portal**, **Facebook changed their design and made it so only members** of the group could download the information. While this vulnerability is partially closed, it has **not been fixed** by Facebook.
- Recently, Facebook has announced that it will rename "closed" groups to "private visible" and its "secret" groups to "private hidden". But has not actually seen this change on the platform itself. **Not only does this not fix the privacy problems with clinical support groups, it makes it worse.**



Source: DiMe-VHA The Playbook: Healthcare team analysis, https://lightcollective.org/2019/09/12/sicgrl-update/, https://tincture.io/new-facebook-vulnerability-was-reported-a-year-ago-by-patients-609623eb4dce

Tip of the iceberg? Hospital websites send personally identifiable information (PII) to Facebook

Home » Security Boulevard (Original) » News » HIPAA FAIL: ~33% of Hospital Websites Send PII to Facebook

HIPAA FAIL: ~33% of Hospital Websites Send PII to Facebook

by Richi Jennings on June 17, 2022

A study shows many U.S. hospitals are leaking personal information to Facebook. Patients' data is silently scarfed up by the *Meta Pixel* tracking widget.

Hospitals often utilize a **tracking tool, such as** Meta Pixel (a subsidiary of Facebook) on their websites. While this tool tracks how people are using a hospitals website, it could also track sensitive health information, particularly if installed in a patient portals, and **connects that information to a patient's IP address**.

A class action lawsuit has now been filed against Meta, alleging the company **did not attempt to gain "patient knowledge, consent, or valid HIPAA authorizations."**

Source: DiMe-VHA The Playbook: Healthcare team analysis

Safeguarding patient data is a safety issue

While the **most likely** and **most harmful** data risks stem from **data loss** through **accidental deletion** or **failure of continuity measures**, it is also critical to protect against data abuse:

Theft is a **data security** issue.

Although the **security of a system cannot be guaranteed,** quality design and execution can decrease the risk of harm from code flaws, configuration weaknesses, or other issues.

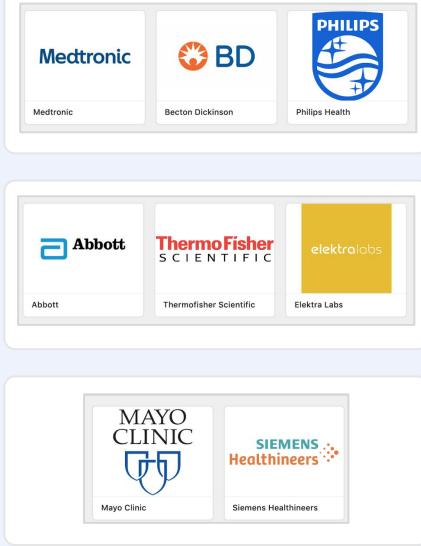
Misuse is a **data rights** issue.

Notably, some data and system **access *may be* authorized** (or perhaps "not forbidden"), though unwelcome or undisclosed to the patient or other stakeholders. This type of access will also be covered in the next section.

Failure to safeguard against security threats and violations of individuals' data rights is also a risk to researchers and clinicians.

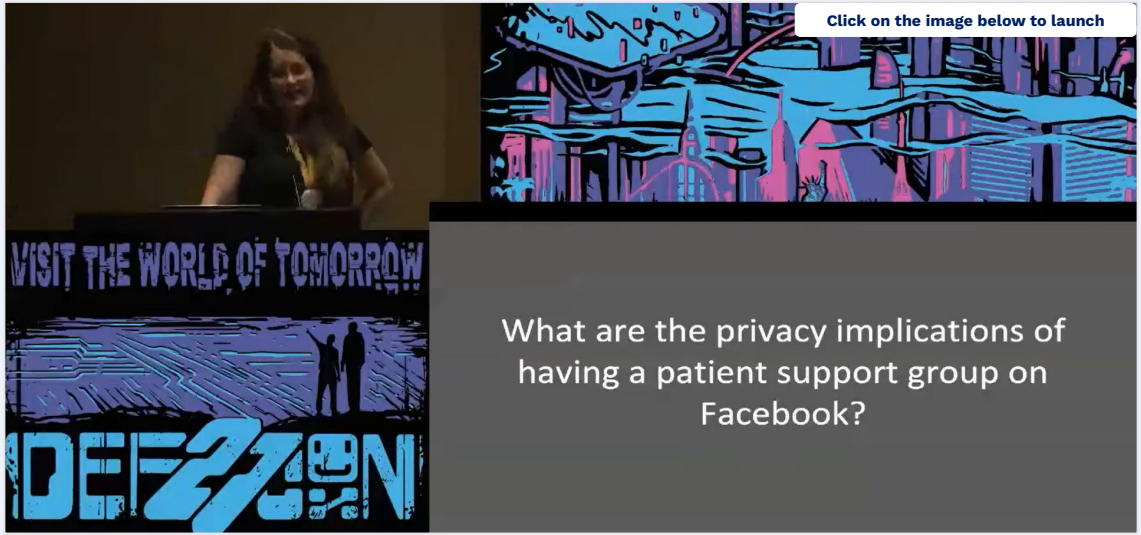
Source: DiMe-VHA The Playbook: Healthcare team analysis, The Playbook: Digital Clinical Measures, Coravos A. et al

FDA has built relationships with security researchers through initiatives like WeHeartHackers.org at DEFCON



Source: DiMe-VHA The Playbook: Healthcare team analysis, The Playbook: Digital Clinical Measures, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - FDA, We heart hackers

LEARN FROM THE EXPERTS



Source: DiMe-VHA The Playbook: Healthcare team analysis, View video from DEFCON Conference: https://youtu.be/lb2p212rc6o

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

Virtual care

TL;DR

Virtual care is the practice of using technologies such as video, audio, and instant messaging to connect patients and providers regardless of location

What is **virtual care?**

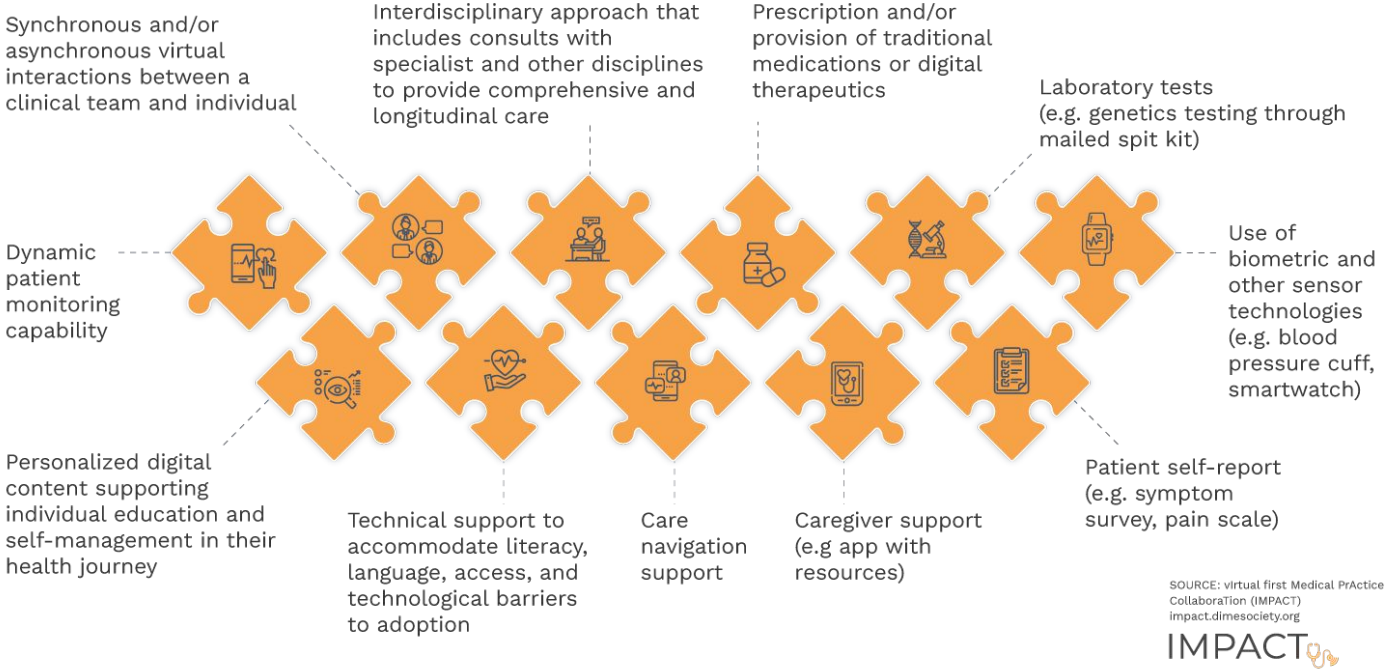
- **Virtual care** is a broad term that often encompasses the practice of **telehealth** and **telemedicine**. Definitions vary at the federal and state levels however. A few resources exist to help policy makers, national organizations, health systems, providers, and the public. with defining or differentiating these terms:
  - The American Telemedicine Association has a guide on standardized telehealth terminology.
  - The Center for Connected Health Policy (CCHP) offers a definition resource.
- **Virtual first care (V1C)** is medical care for individuals or a community accessed through digital interactions where possible, guided by a clinician, and integrated into a person's everyday life.
- The virtual care approaches are applied throughout the compendium of care delivery from the use of **virtual assistants, chat-based interactions, remote patient monitoring, remote patient management, and other technology-enabled modalities.**

Applications

- Lifestyle intervention
- Diagnostic and prevention
- Remote tracking and monitoring
- Disease management and treatment
- R&D and production optimization
- Clinical decision support
- Communication and engagement

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.americantelemed.org/resource/why-telemedicine/, https://impact.dimesociety.org/

V1C providers integrate fit-for-purpose components to deliver complete care solutions



Source: DiMe-VHA The Playbook: Healthcare team analysis, https://impact.dimesociety.org/v1c/

Designing care around the patient instead of care around the physical sites of care

Opportunities to create value for patients, providers and healthcare systems

Provide **timeliness, convenience**, and seamless integration into a person's everyday life

Creates **cost-effective solution** for individuals and systems

Improves outcomes via process improvement and efficiency in care coordination, navigation, and oversight

Allow individual **flexibility** for on-demand healthcare services when they need. Healthcare needs are not 9am-5pm Monday to Friday.

Provide **interdisciplinary approach** that includes consults with specialist and other disciplines to provide comprehensive and longitudinal care

Potential to narrow the digital divide by delivering high quality care accessible **to the most underserved populations**

Coordinate transitions across the care ecosystem with **data connectedness**

Personalize digital content supporting individual **education** and self-management in their health journey

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.americantelemed.org/resource/why-telemedicine/, https://impact.dimesociety.org/v1c/

The gap map for the virtual care solutions that stifles its broad acceptance

While many are optimistic about the potential of virtual care to improve health outcomes and economics, others in the industry still have reservations. With the breakneck speed of evolving virtual care delivery models, the policy landscape is struggling to keep up. We must partner with policy makers to pursue for fit-for-purpose policies and standards around virtual care practice to promote equitable, successful, and standardized implementation.

Challenge

Technological limitations like broadband access, advanced tech tools, etc creates a digital divide

Challenge

Lack of **interstate licensure** for medical practice

Challenge

Lack of **accessible data,** regardless of patient's location, that is **viewable for treatment.**

Risk

Patient **safety**, **integrity** and **privacy** of data, large due to rapid implementation without adequate due diligence

Challenge

Lack of and uncertainty with parity **laws** for virtual care services

Challenge

Patient-Provider bonding may suffer with loss of personal touch in virtual interaction

Source: The DiMe-VHA The Playbook: Healthcare team analysis, ttps://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/virtual-health-a-look-at-the-next-frontier-of-care-delivery

Case study: Virtual COPD care - address access issues and provides care at scale

The Challenge:

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable chronic lung condition. With **25M+ COPD patients**, most are **concentrated in rural and low-income areas** where healthcare access and quality suffers. People with COPD are unable to access appropriate care before reaching the hospital for a myriad of reasons, including **cost, location, and low awareness of treatment options**. The chronic lung disease increases risk for heart, metabolic, and mental health comorbidities, which only exacerbate the healthcare experience.

The Approach:

Wellinks' approach reinvents the COPD experience, connecting patients, caregivers, services, and information to enable truly integrated care. It serves people at all stages of their COPD journey, be it an individual in the community needing support to improve health and avoid an exacerbation, or one who is post-acute care transitioning to pulmonary wellness at home. Wellinks meets patients where they are with an access to kit of devices, software, and a coach.

The Result:

Wellinks users with a **mean age of 79** and advanced disease reported the solution **easy to use (94%)** and showed **excellent engagement (100%) over 8 weeks**.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.wellinks.com/

Putting V1C in action

"With better COPD-specific virtual tools, we can detect exacerbations, understand medication compliance and usage, and adjust therapy to prevent clinical worsening. This could be immensely useful."

Brian Gelbman MD
Pulmonologist and Associate Clinical Professor, Weill Cornell Medical College;New York Presbyterian Hospital

V1C in Action

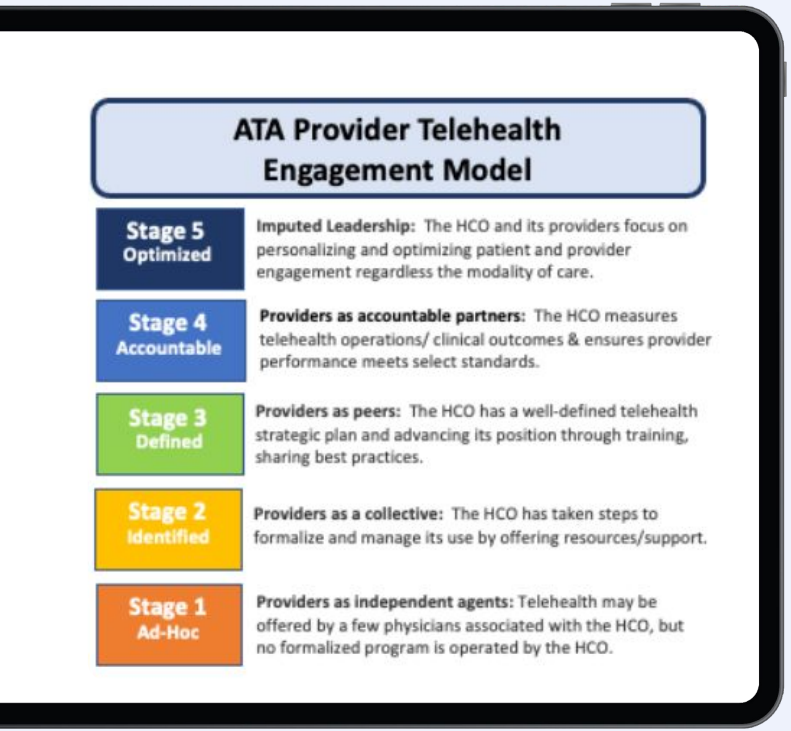
COPD V1C addresses access issues and provides care at scale

wellinks

Components:

- Synchronous and/or asynchronous virtual interactions between a clinical team and individual
- Interdisciplinary approach that includes consults with specialists and other disciplines to provide comprehensive and longitudinal care
- Use of biometric and other sensor technologies (e.g. blood pressure cuff, smartwatch)
- Patient self-report (e.g. symptom survey, pain scale)
- Technical support to accommodate literacy, language, access, and technological barriers to adoption
- Care navigation support
- Personalized digital content supporting individual education and self-management in their health journey
- Dynamic patient monitoring capability

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://impact.dimesociety.org/v1c/



SPOTLIGHT

How to access provider engagement in Telehealth programs?

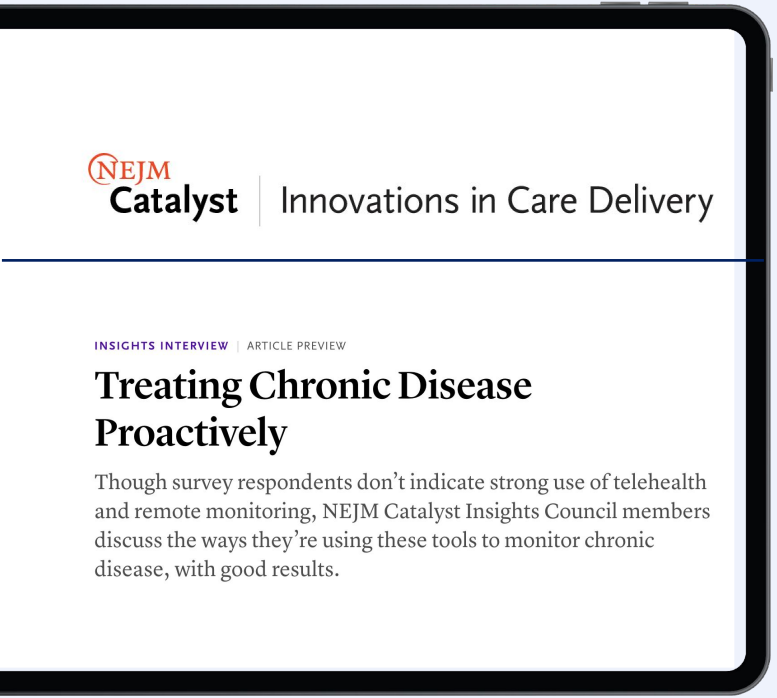
Many health systems didn't have a telehealth program in place pre-pandemic, but quickly put one in place during in need. Many organizations are now asking **"what now"?**

American Telemedicine Association built and launched a **Provider Telehealth Engagement Model (PTEM)**, an objective way to **assess where an organization is in the effective deployment** of telehealth programs – **synchronous, asynchronous, remote monitoring** – and determine where and how one can improve.

PTEM's output:
A customized report to showcase:

- where any healthcare organization is today,
- where the organization is relative to its peers,
- and evaluate each of their delivery points.

Source: DiMe-VHA The Playbook: Healthcare team analysis, PTEM by American Telemedicine Association



SPOTLIGHT

Developing operational procedures for managing information generated by remote monitoring

Ochsner Medical Center in New Orleans developed and deployed a digital hypertension program staffed by pharmacists.

These pharmacists monitored 6,000 high-risk patients' **blood pressure (BP) readings remotely** and followed up with patients via **text** and **email** when data from remote monitoring indicated poor BP control.

This program increased in the proportion of patients who **met their blood pressure goals** from **30% to 79%** over 180 days.

Source: DiMe-VHA The Playbook: Healthcare team analysis, NEJM - Treating Chronic Disease Proactively

Case study: Virtual first sleep clinic provides comprehensive consult, diagnosis and treatment solution

The Challenge:

1B people suffer from sleep apnea globally and people face **barriers to diagnosis, treatment and adherence**. If sleep apnea is suspected, patients are referred to a sleep study for diagnosis, and then, in the case of Obstructive Sleep Apnea (OSA) are **left alone to navigate CPAP therapy** - a treatment that dominates the sleep care market, but that has **poor compliance (~50%)**, which leads to **increased risk of stroke** and cardiovascular diseases.

The Approach:

Dreem is the **first virtual sleep clinic**. For OSA, **remote coaching** by healthcare professionals supports patients through their adoption of CPAP. An **insomnia diagnosis is treated with digital therapy sessions**. A unique finding from CPAP adherence in OSA patients is that 38% of them also suffer from comorbid insomnia and sleep apnea (COMISA). Dreem uses specific **behavioral coaching program** for patients who suffer from both conditions.

The Result:

Using a V1C approach adherence to CPAP for COMISA patients report **15% higher adherence**. This increase compliance leads to **better quality of life, increased productivity and low risks**. The program demonstrates reduced insomnia symptoms, supported by greater access to evidence-based, virtual therapy. With **-8 points on the Insomnia Severity Index** scale on average, and **more than 70% retention**, Dreem's digital insomnia therapy is equivalent to an in-person therapy.

dreem

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://impact.dimesociety.org/wp-content/uploads/2021/06/V1C-vignette-Dreem.pdf

Putting V1C in action

"I was tired of the medical system not being able to help me. Endless prescriptions and lack of funding for behavioural/cognitive help is a real problem. Dreem helps by being there for you, for the long haul. The support is receptive, and the tech has made a huge impact. It assists every day to make the behavioural changes needed to help with sleep, and more.

Crystal
Patient testimony

V1C in Action

Virtual Sleep Clinic Provides Comprehensive Consult, Diagnosis and Treatment Solution

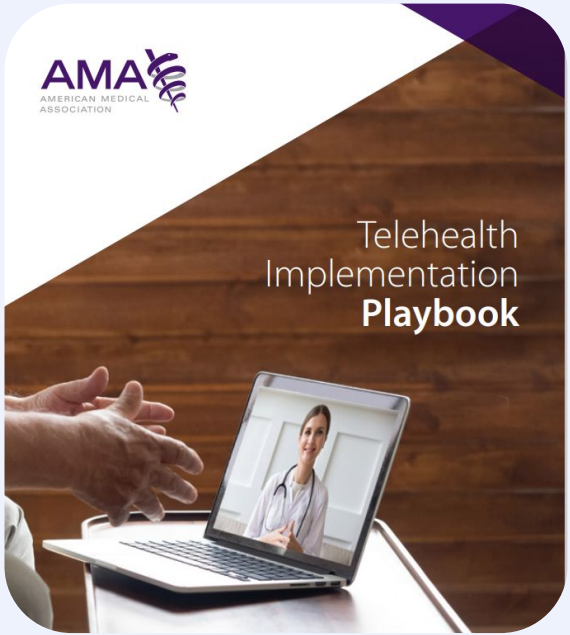
dreem

Components:

- Synchronous and/or asynchronous virtual interactions between a clinical team and individual
- Interdisciplinary approach that includes consults with specialists and other disciplines to provide comprehensive and longitudinal care
- Personalized digital content supporting individual education and self-management in their health journey
- Technical support to accommodate literacy, language, access, and technological barriers to adoption
- Prescription and/or provision of traditional medications or digital therapeutics
- Caregiver support (e.g app with resources)
- Care navigation support
- Patient self-report (e.g. symptom survey)
- Dynamic patient monitoring capability

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://impact.dimesociety.org/v1c/. Image from by Pexels

SPOTLIGHT



Recommendation from AMA's Telehealth Implementation Playbook

Part 1: Introduction

Part 2: Pre-game:

- **Identifying a need**: What's the problem
- **Forming the team**: Who needs to be involved and when?
- **Defining Success**: What are we trying to achieve?
- **Evaluating the vendor**: What's the right technology
- **Making the case:** How do we get political and financial buy-in?
- **Contracting:** What's expected timing, budget, and plan with vendor?

Part 3: Game time

- **Designing the workflow**: What will need to change to integrate technology?
- **Preparing the care team**: Does everyone know what they need to do?
- **Partnering with the patient**
- **Implementing**: How does it work in practice?
- **Evaluating success**: Did it work?
- **Scaling**: What's next?

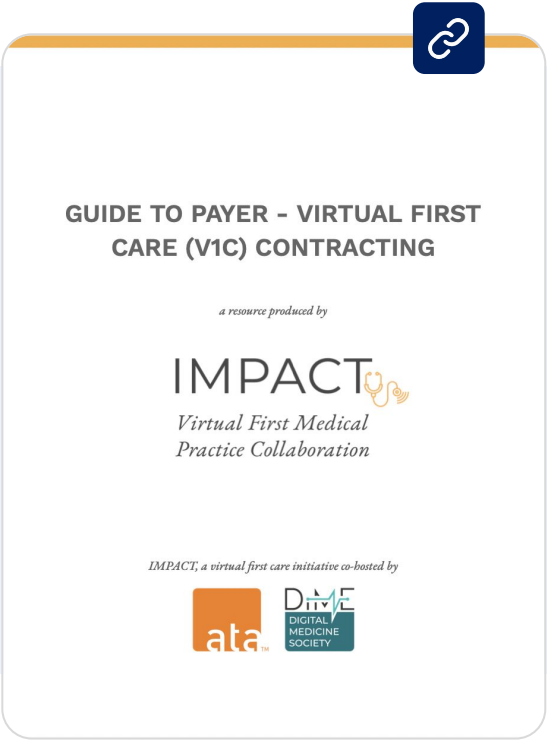
Source: DiMe-VHA The Playbook: Healthcare team analysis

IMPACT resource: Guide to Payer-V1C Contracting

Outlines each section of the contract with detail on:

- Specific considerations that should be accounted for in V1C
- Practices that are ideal, acceptable and to avoid
- What should be included in phase 1/phase 2 contracts
- Sample language

Launched June 2021



Source: IMPACT Payment & Coding Toolkit

5 ways to check your claims

Healthcare providers must ensure they're in compliance with coding standards for their claims to be processed and paid. Here are a few considerations for finalizing claims for submission.

IMPACT
Virtual First Care
V1C Initiative

- Double-check claims to ensure all data elements are populated, including member demographics (i.e., Member ID).
- Ensure the appropriate modifiers or place of service code is used based on procedure codes or coverage agreements.
- Check new patient vs. established patient billing restrictions.
- Confirm CPT and ICD-10 code combinations are reimbursable and not subject to payer-specific billing edits.
- Confirm QHP billing and incident-to rules where applicable.

Source: IMPACT Payment & Coding Toolkit

IMPACT Payment & Coding Toolkit

IMPACT
Virtual First Care
V1C Initiative

Quickstart Guide: How to get paid for V1C

Use the Quickstart Guide to ensure your V1C claims are primed for reimbursement.

Supplemental Guide: Billing & Coding basics

Use the Supplemental Guide to enrich and elevate your knowledge and expertise in billing and coding.

The IMPACT Coding Library

Use this comprehensive coding library to see how new or existing care model components might qualify for reimbursement.

5 ways to check your claims

Healthcare providers should use these five essential best practices to streamline the processing and payment of their claims.

Payment & Coding vignettes

Use these vignettes to understand the complexities of coding practices and tangible approaches for navigating reimbursement for V1C delivery models.

Source: IMPACT Payment & Coding Toolkit

LEARN FROM THE EXPERTS

Click on the image below to launch

Source: DiMe-VHA The Playbook: Healthcare team analysis, View video from DEFCON Conference: https://youtu.be/lb2p212rc6o

Harvard Business Review

TECHNOLOGY

How to Make Remote Monitoring Tech Part of Everyday Health Care

by Samantha F. Sanders , Ariel D. Stern and William J. Gordon

July 02, 2020

Samantha F. Sanders, MD, is an internal medicine resident physician at NYU Langone Health.

Ariel D. Stern is the Poronui Associate Professor of Business Administration at Harvard Business School, where she is a faculty affiliate of the Health Care Initiative and the Digital Initiative. She is also a faculty member at the Harvard-MIT Center for Regulatory Science and Ariadne Labs.

William J. Gordon, MD, is a member of the faculty of the Division of General Internal Medicine and an associate physician at Brigham and Women's Hospital. He is also an instructor at Harvard Medical School and the medical director of the Health Innovation Platform team at Mass General Brigham (formerly Partners HealthCare).

SPOTLIGHT

Recommendation proposed by teams at NYU and Harvard

- The technology must be **easy** for both patients and clinicians to adopt and continue using.
- The tools should be incorporated into clinician **workflows.**
- Sources of **sustainable funding** must be identified and tapped.
  - Note: this implicitly disadvantages care settings where such funding doesn't exist /is limited.
- Dedicate sufficient non-physician staff to **operate** the program.
- Focus on digital health **equity.**
- Start with an initial pilot and expand after **demonstrated successes.**

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://hbr.org/2020/07/how-to-make-remote-monitoring-tech-part-of-everyday-health-care

VA Video Connect allows Veterans and their caregivers to quickly connect

Click on the image below to launch

The enormous value and excitement surrounding digital health solutions will empower patients

As the number of digital health solutions continues to grow and these solutions mature, we need **objective**, **transparent**, and **standards-based evaluation** of these products to ensure they **integrate** into **patients' lives**, **provider workflows**, and **healthcare systems**. Most importantly, they must be used to improve lives.

Source: DiMe-VHA The Playbook: Healthcare team analysis

Patients belong at the center of care

Health and healthcare has been put front and center for the entire world by the COVID pandemic.

Now is the time to **seize the opportunity** and embrace health as a priority. **Digital health solutions imbedded into the culture and practice** of healthcare will **drive individualization of care** in a way that will truly benefit our most important stakeholders: our patients.

Health is more than absence of disease; it is about economics, education, environment, empowerment, and community. The health and well-being of the people is critically dependent upon the health system that serves them. It must provide the best possible health with the least disparities and respond equally well to everyone"

Joslyn Elders
15th Surgeon General of the United States
September 8, 1993 – December 31, 1994

Source: DiMe-VHA The Playbook: Healthcare team analysis

We *can* and we *must* do better

"I personally had a flip phone until two years ago. And most Vets have flip phones. It's automatically assumed everybody knows how to use Zoom or connect to telehealth, and it's just not true."

Michael Borges
Veteran Patient Expert, U.S. Air Force Retired

We have to ensure that these digital health solutions work for everyone.

This new era will not lead to innovations which are responsive to the specific needs of our diverse population unless we consider new ways of delivering health using digital solutions discussed in *The Playbook*: **Digital Healthcare Edition.**

Source: DiMe-VHA The Playbook: Healthcare team analysis

Value, discipline and digital health solutions will shape the future of healthcare

With a disciplined culture that uses **human-centered design** to successfully implement digital health solutions, we will create a thriving healthcare ecosystem worthy of the **patients** we're here to serve, and the **people** and **systems** that care for them.

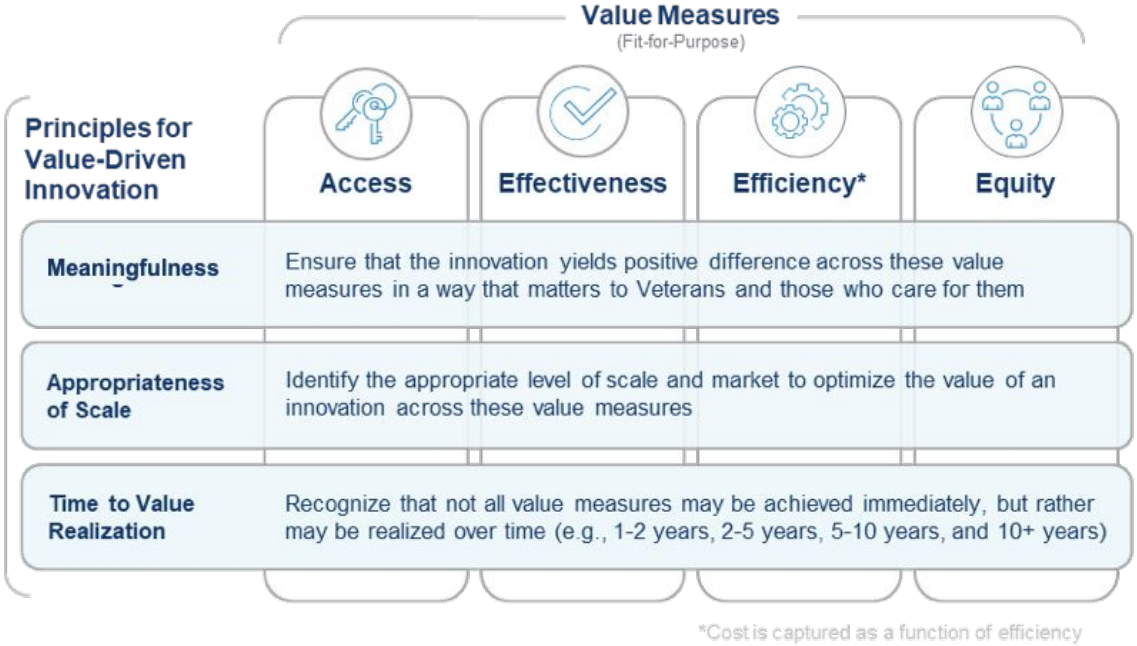


Figure: A Value-Driven Framework for Evaluating Healthcare Innovations

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.va.gov/INNOVATIONECOSYSTEM/views/who-we-are/VBIF.html

What's next?

Phase 1

Explore opportunities digital health solutions have to deliver ***high value care***

- **Disciplines** to drive innovation in healthcare forward.
- **Definitions, regulations and classifications.**
- **New care delivery models** which incorporate technology.
- Eight **digital health solutions** with **case studies** showcasing each one's ability to deliver **high-value care**.

Phase 2

Share digital health ***adoption and deployment resources***

- **Successful implementation** of digital health solutions.
- **Legal and ethical considerations** when using digital health solutions.
- Putting the **patient at the center** of care.
- Other factors to consider when putting a digital health solutions in practice.

Phase 3

Provide digital health product ***evaluation framework***

- A **framework** to **access, evaluate, and inform** resource allocation and executive decisions for successful translation to clinical and production environments across the health system.
- **Guide decision maker** on whether a digital health solution is valuable to patients, the organization and fit-for-purpose for transition into the clinical pathway.

Phase 2 and 3 of ***The Playbook*: Digital Healthcare Edition** will launch over the next year

Source: DiMe-VHA The Playbook: Healthcare team analysis

To maintain *The Playbook*: Digital Healthcare Edition as an evergreen resource, we're seeking your *feedback*!

The Playbook: **Digital Healthcare Edition** is essential guide to successfully employing digital health solutions to improve patient outcomes, streamline operational efficiencies, lower costs, and create a better atmosphere for the workforce.

As you read and use ***The Playbook***, we're curious what you would:

Keep

What are your favorite parts of ***The Playbook***?

Start

What should we add in the next iteration?

Stop

Have you found any errors and omissions?

Submit your feedback: Click here

Prepared by DiMe and U.S. Department of Veterans Affairs

Last Updated October 23, 2023

linkedin.com/company/dime-society