Navigating *The Playbook:* Digital Healthcare Edition

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

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

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

Your micro-playbooks to digital health solutions

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

PRO TIP

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

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

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 upto 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

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

The Challenge:

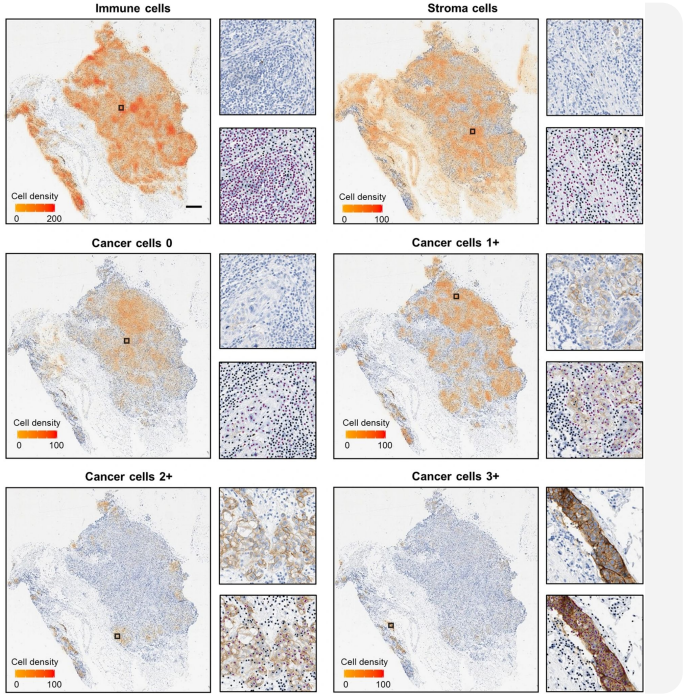
Non-digital pathology performance **could not, at scale, generate accurate and reproducible** clinically relevant **scores for breast cancer** (HERS 2 score). It is estimated that 4% of negative cases and **18% of positive cases are misdiagnosed.**

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

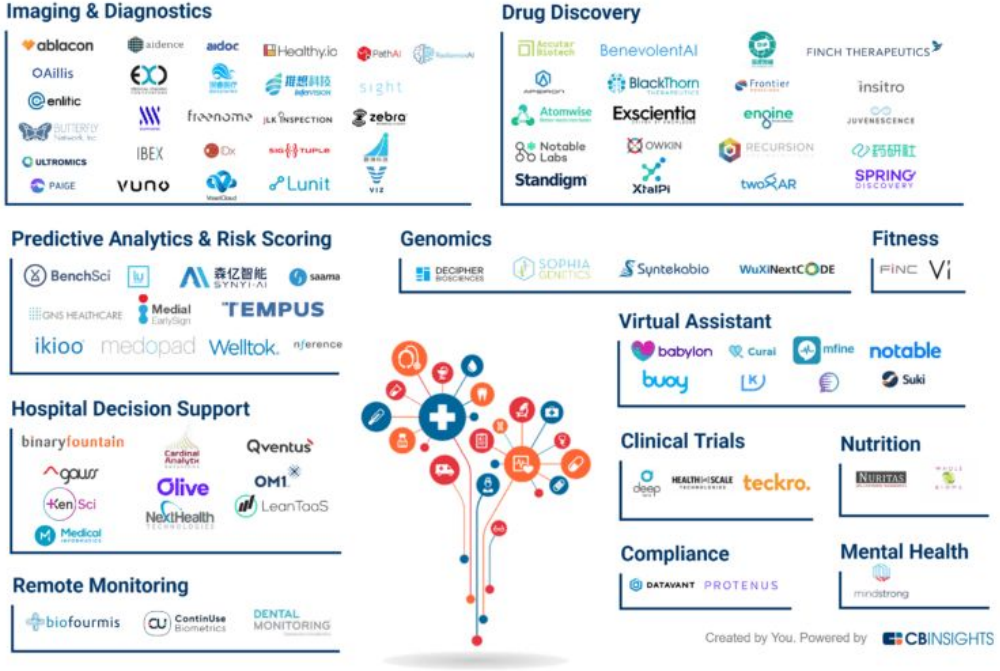
Keona's AI software has streamlined the triage process and improved patient outcomes.

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

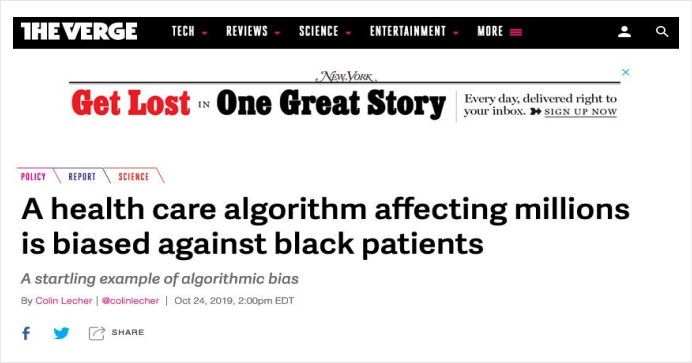
SCIENTIFIC AMERICAN 175

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

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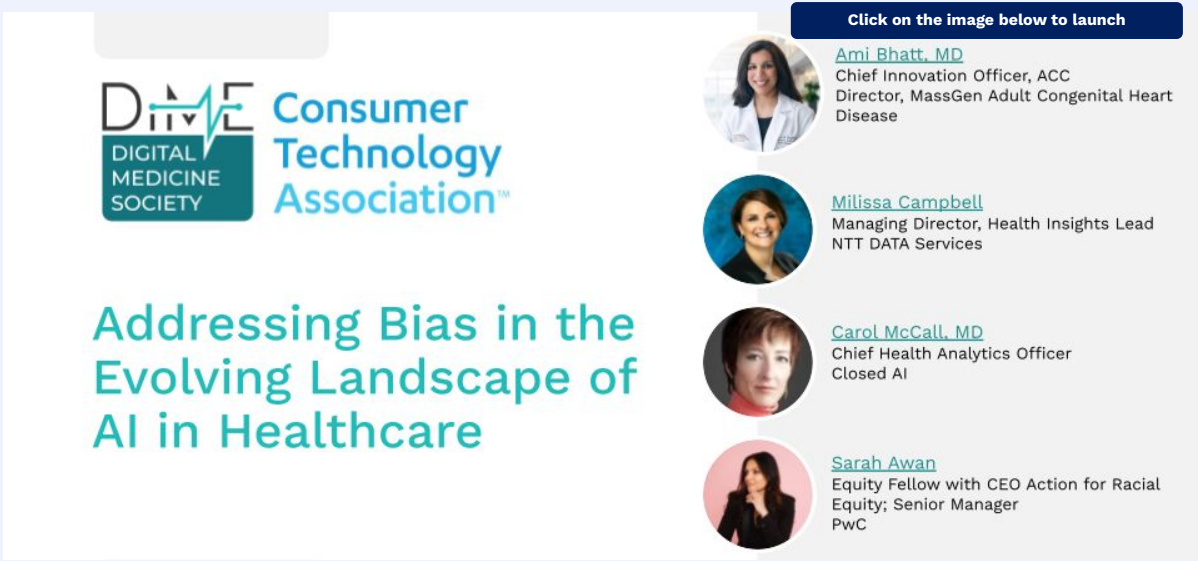
- In 2019, news outlets reported on a Science article finding that algorithms that affected the care for hundreds of millions of patients made Black patients substantially less likely than white patients to receive medical treatment.
    - **The reason?** A false assumption baked into the algorithm whereby 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

LEARN FROM THE EXPERTS

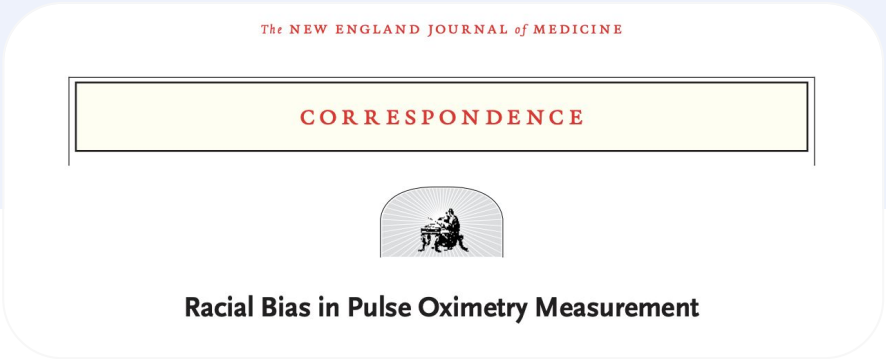
Click on the image below to launch



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

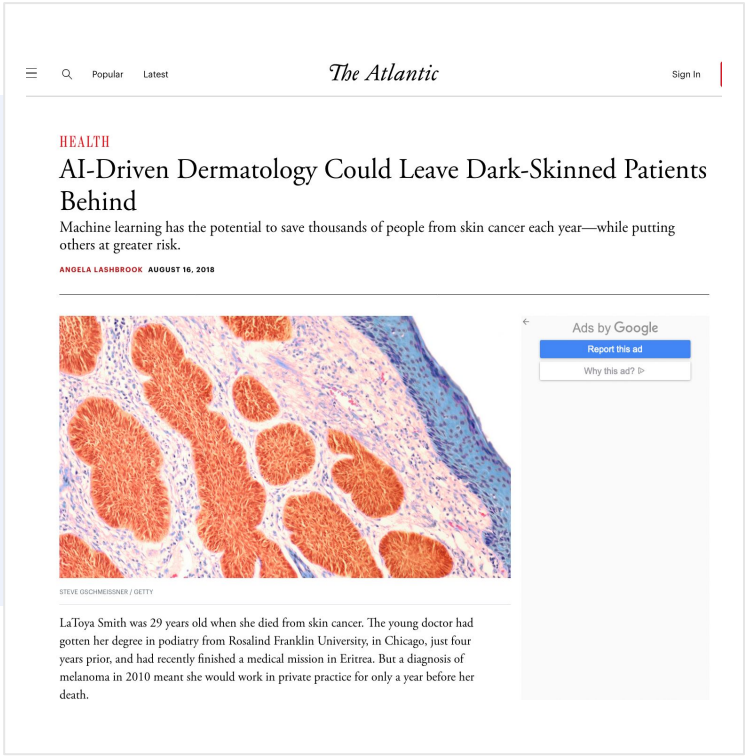
Considerations of Algorithmic bias

- **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.**


The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Racial Bias in Pulse Oximetry Measurement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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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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