

# Navigating *The Playbook*: Digital Healthcare Edition

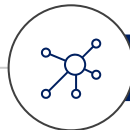
- Your user guide to *The Playbook*: Digital Healthcare Edition



- 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.

# 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), **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

# 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



# 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.

# 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.

# 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.**

# 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:

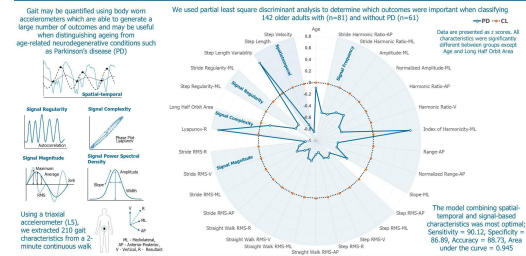
- ▶ Quantifies a digital battery of commonly utilized **gait characteristics** (spatiotemporal and signal-based),
- ▶ Identifies the most informative **digital clinical measures** of gait for classification of PD.



## 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**.

Accelerometry-based digital gait characteristics for classification of Parkinson's disease: what counts?



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

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



thebmj Visual summary

## Covid-19: remote consultations

A quick guide to assessing patients by video or voice call

Version 1.3  
25 Mar 2020

This graphic, intended for use in a primary care setting, is based on data available in March 2020, much of which is from hospital settings in China. It will be revised as more relevant data emerges.

- ### 1 Set up

Prepare yourself and decide how to connect

  - Have current 'stay at home' covid-19 guidance on hand
    - UK government advice: <http://bit.ly/ukgovisol>
  - Video is useful for
    - Severe illness
    - At-risk patients
    - Comorbidity
    - Hard of hearing
  - Scan medical record for risk factors such as:
    - Diabetes
    - Pregnancy
    - Smoking
    - Chronic kidney or liver disease
    - COPD
    - Stroke or other major neurological disease
    - Cardiovascular disease
    - Asthma
- ### 2 Connect

Make video link if possible, otherwise call on the phone

  - Check video and audio
    - Can you hear/see me?
  - Confirm the patient's identity
    - Name
    - Date of birth
  - Check where patient is
    - Where are you right now?
  - Note patient's phone number in case connection fails
  - If possible, ensure the patient has privacy
- ### 3 Get started

Quickly assess whether sick or less sick

  - Rapid assessment
    - If they sound or look very sick, such as too breathless to talk, go direct to key clinical questions
  - Establish what the patient wants out of the consultation, such as:
    - Clinical assessment
    - Referral
    - Certificate
    - Reassurance
    - Advice on self-position
- ### 4 History

Adapt questions to patient's own medical history

  - Contacts
    - Close contact with known covid-19 case (immediate family member unwell)
    - Occupational risk group
  - History of current illness
    - Date of first symptoms
  - Most common presentation
    - Cough
    - Fatigue
    - Fever
    - Short of breath
  - Cough is usually dry but sputum is not uncommon
  - Up to 50% of patients do not have fever at presentation
- ### 5 Examination

Assess physical and mental function as best as you can

  - Over phone, ask carer or patient to describe:
    - State of breathlessness
    - Colour of face and lips
  - Over video, look for:
    - General distended
    - Skin colour
  - Check respiratory function - inability to talk in full sentences is common in severe illness
    - How is your breathing?
    - Is it worse today than yesterday?
    - What does your breathlessness prevent you doing?
  - Patient may be able to take their own measurements if they have instruments at home
    - Temperature
    - Pulse
    - Peak flow
    - Blood pressure
    - Oxygen saturation
  - Interpret self monitoring results with caution and in the context of your wider assessment
- ### 6 Decision and action

Advise and arrange follow-up, taking account of local capacity

  - Likely covid-19 but well, with mild symptoms
    - Self management: fluids, paracetamol
  - Likely covid-19, unwell, deteriorating
    - Arrange follow up by video. Monitor closely if you suspect pneumonia
  - Relevant comorbidities
    - Proactive, whole patient care
  - Unwell and needs admission
    - Ambulance protocol (999)

Which pneumonia patients to send to hospital?

**Clinical escalation triggers:**

  - Temperature > 38°C
  - Respiratory rate > 20\*
  - Heart rate > 100\* with new confusion
  - Oxygen saturation ≤ 94%†

Reduce spread of virus - follow current government 'stay at home' advice

Safety netting

  - If living alone, someone to check on them
  - Maintain fluid intake - 6 to 8 glasses per day
  - Seek immediate medical help for red flag symptoms

### Clinical characteristics

Based on 1099 hospitalised patients in Wuhan, China

- 69% Cough
- 22% Temperature 37.5-38°C
- 22% Temperature >38°C
- 38% Fatigue
- 34% Sputum
- 19% Shortness of breath
- 15% Muscle aches
- 14% Sore throat
- 14% Headache
- 12% Chills
- 5% Nasal congestion
- 5% Nausea or vomiting
- 4% Diarrhoea
- 24% Any comorbidity

**Red flags**

Covid-19:

- Severe shortness of breath at rest
- Difficulty breathing
- Pain or pressure in the chest
- Cold, clammy, or pale and mottled skin
- New confusion
- Becoming difficult to rouse
- Blue lips or face
- Little or no urine output
- Coughing up blood

Other conditions, such as:

- Neck stiffness
- Non-blanching rash

## 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.

\* Breaths per minute † Beats per minute ‡ If oximetry available for self monitoring

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*The Playbook*  
Fundamentals for clinicians



**Learning objective:**  
Digital Measures For Clinical Use



**Xuemei Cai**  
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