

# At what point does a consumer product become a medical device?

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# CONFLICT OF INTEREST STATEMENT

Founders and Co-Founders of Health Data Analytics



# Goals

- Our research
- Categories of wearable technology
- Evolving from consumer to medical device
- Future applications in health
- Question and answer period





**STUDY PROTOCOL**

**Open Access**

# The spinal stenosis pedometer and nutrition lifestyle intervention (SSPANLI) randomized controlled trial protocol

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## Abstract

**Background:** Because of symptoms, people with lumbar spinal stenosis (LSS) are often inactive, and this sedentary behaviour implies risk for diseases including obesity. Research has identified body mass index as the most powerful predictor of function in LSS. This suggests that function may be improved by targeting weight as a modifiable factor. An e-health lifestyle intervention was developed aimed at reducing fat mass and increasing physical activity in people with LSS.



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# Low back pain, obesity & activity

- ❖ Relationship between back pain, performance and obesity
- ❖ Increased BMI is a risk factor for low back pain
- ❖ Physical activity mitigates back pain risk – more so in overweight and obese



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THE  
SPINE  
JOURNAL

2013 Outstanding Paper Winner: Medical and Interventional Science

## Does physical activity influence the relationship between low back pain and obesity?

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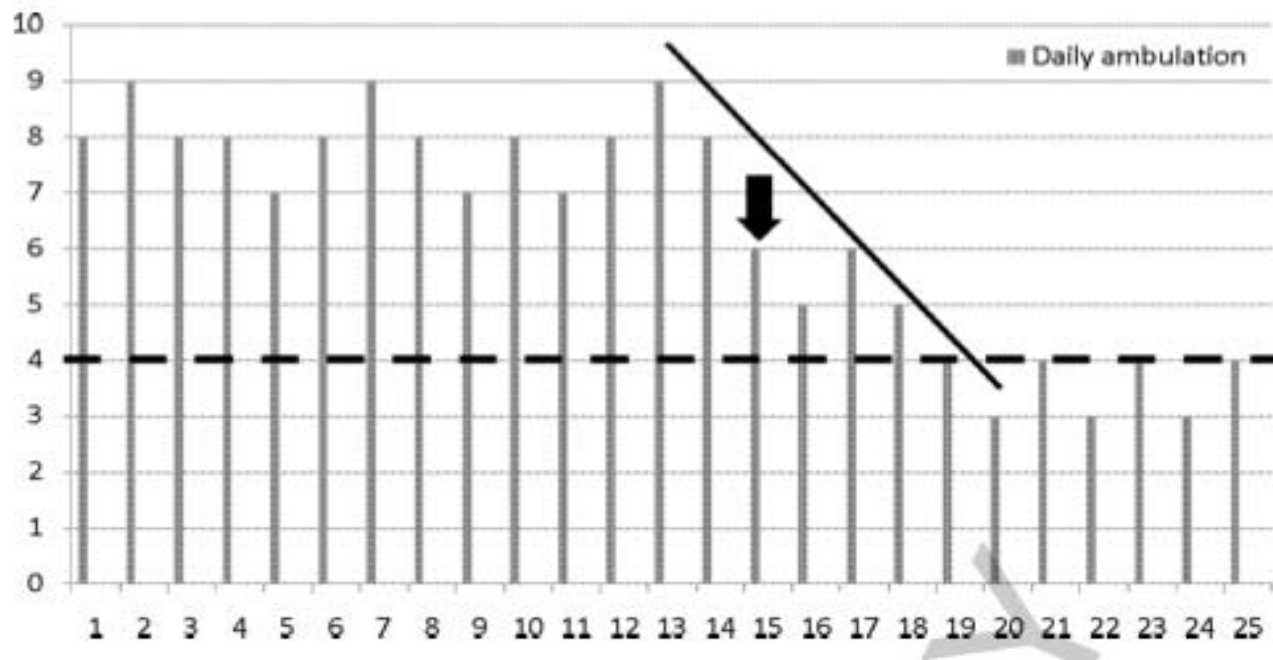
# A review of activity monitors as a new technology for objectifying function in lumbar spinal stenosis

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# Disease Monitoring



- Theoretical value of activity monitoring in clinical decision-making.
- Vertical arrow indicates a sudden decline in function that hypothetically should be investigated or treated.





# Wearable Technology Landscape

# A MUCH More Diversified Market Than Investors Realize



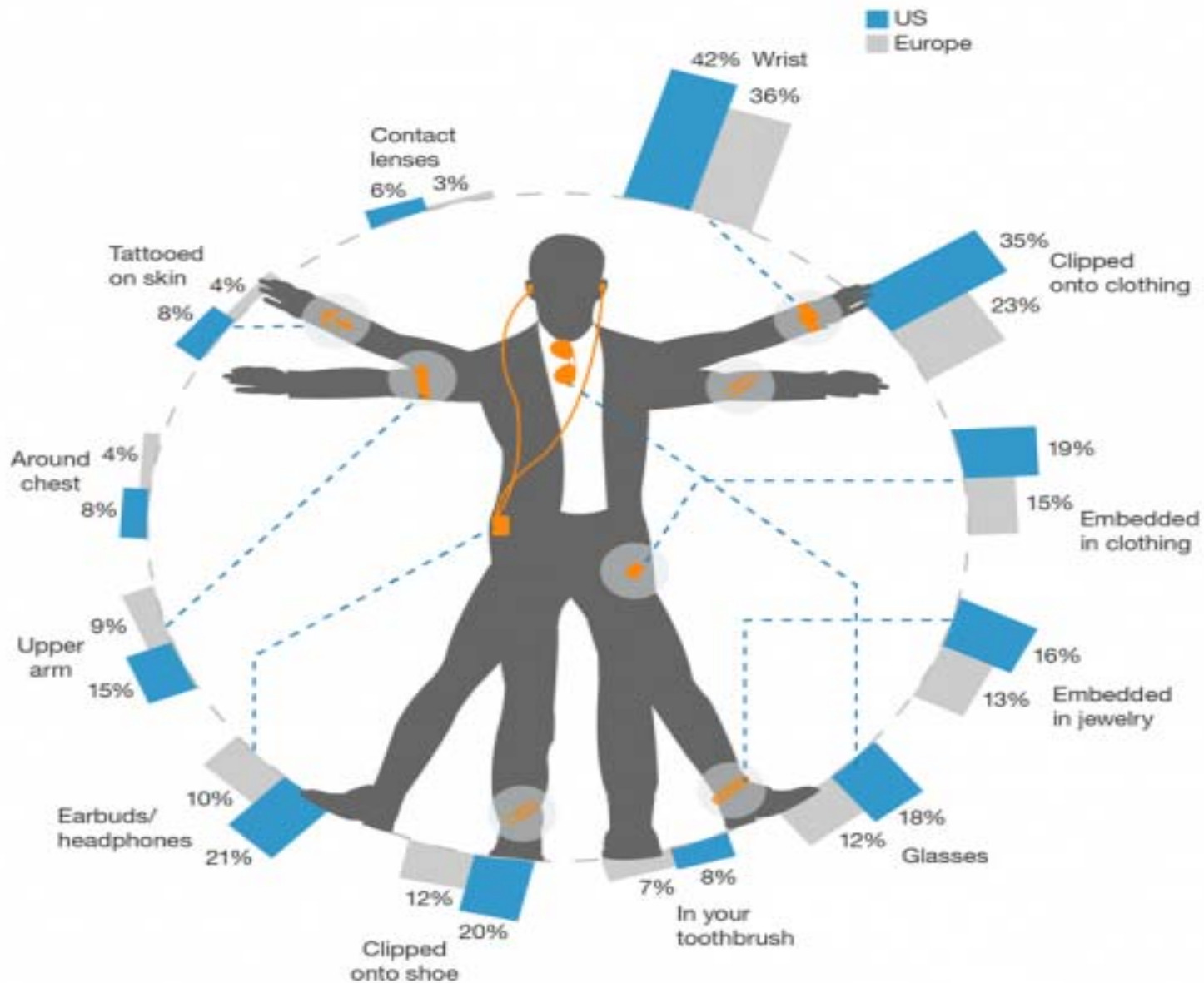
# Human-Computer Interface

- Inform (time/text/message)
- Sense (measure/feedback)
- Control (brain wave/gesture)



Focus on physical activity measured using wearable devices

**"How interested would you be in wearing/using a sensor device, assuming it was from a brand you trust or offered a service that interests you?"**



Base: 4,556 US online adults (ages 18+); 11,647 EU online adults (ages 18+)  
(multiple responses accepted)

Source: Forrester's North American Consumer Technographics® Consumer Technology Survey, 2014, and Forrester's European Consumer Technographics Consumer Technology Survey, 2014

# It's the Data!

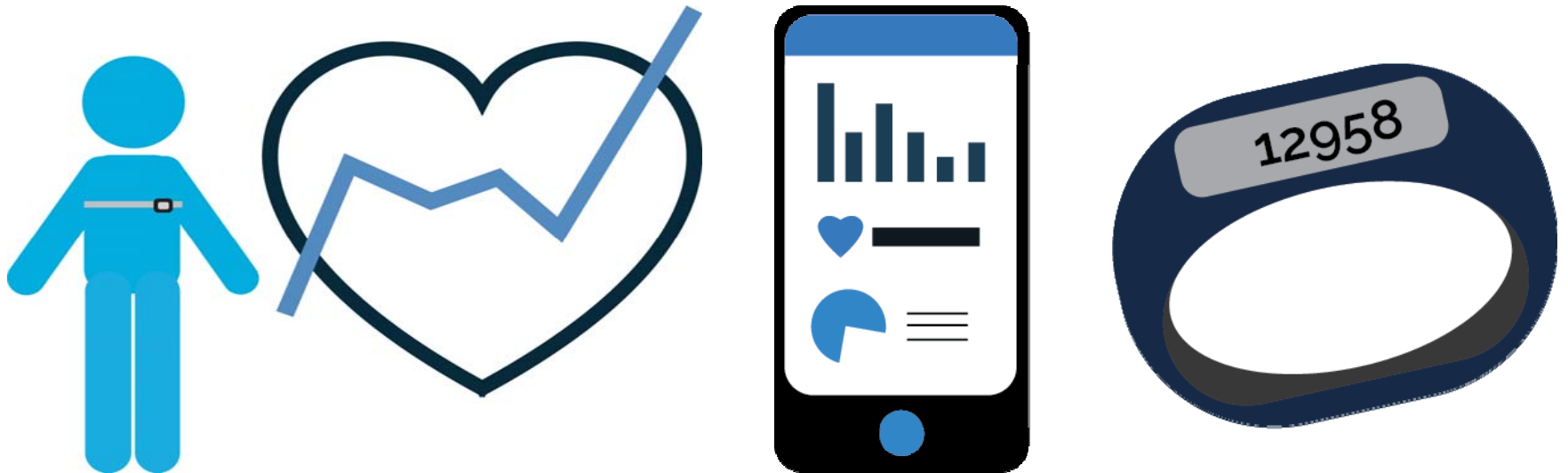


# Health Applications



# Current applications

- Fitness
- Some health applications
- Corporate wellness
- Primarily data visualization



# How are we using accelerometers?

## Clinical applications have begun:

- Outcomes of interventions
- Monitor rehabilitation
- Exercise prescription
- Gait, balance and falls risk
- Sleep



**Limited application so far in clinical care!**



# What makes data “health data”?

- Are steps/day considered health data?



# What makes data “health data”?

- Are steps/day considered health data?
- Not yet because no one knows what it means in the clinical context
- As soon as we UNDERSTAND the data it has the potential to become health data because it now has a clinical context
- What does 1000 mean vs. 10,000 steps?
- Diagnosis or treatment based on this data?

## WHAT SHOULD HEALTH DEVICES MONITOR?



**88%** physicians want patients to monitor health parameters **AT HOME**  
Their top priorities:



## HAVE YOU EVER USED A HEALTH DEVICE?

NO YES

**15%**

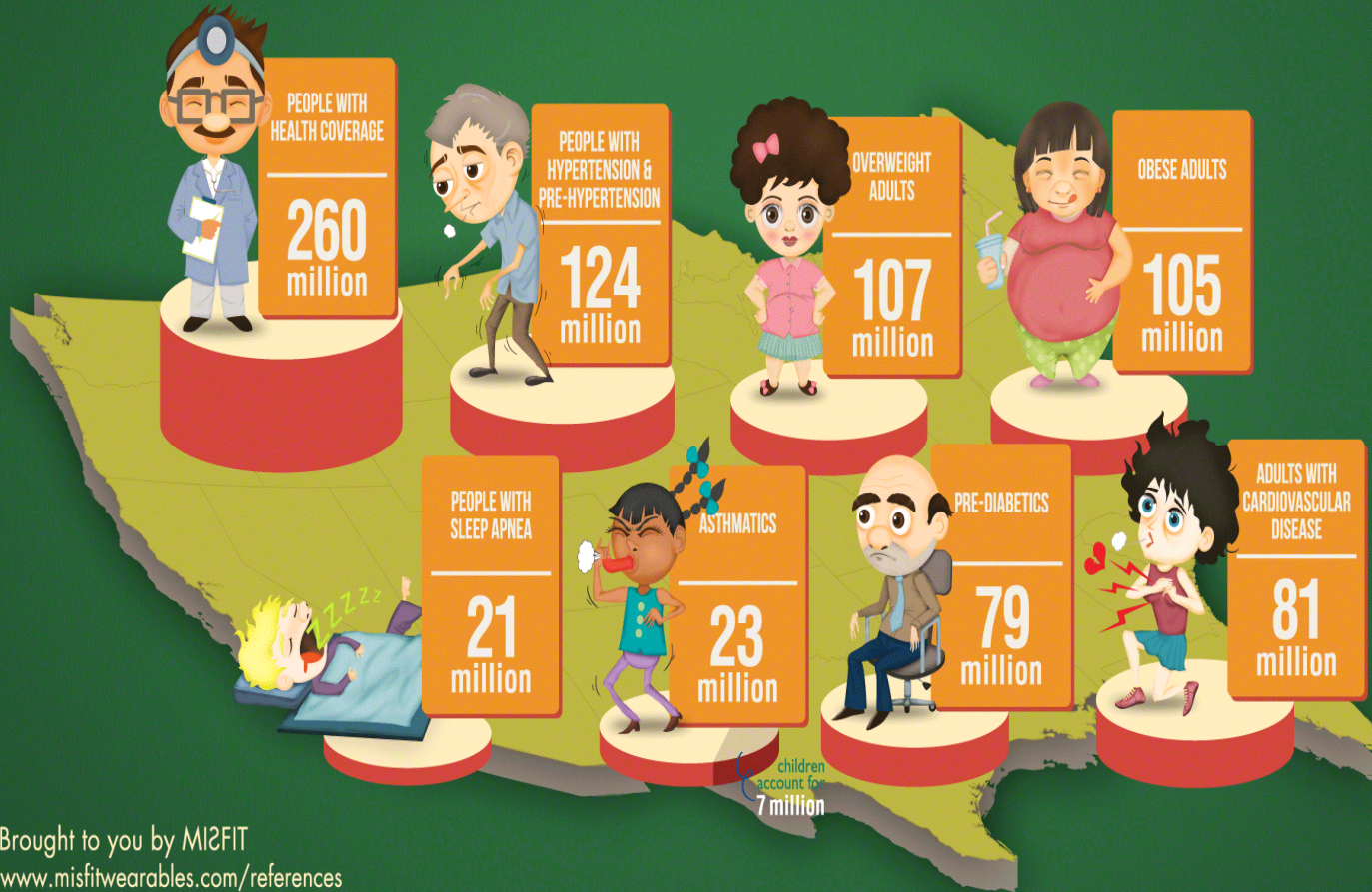


**6%** use devices for monitoring **FITNESS**

**9%** use devices for monitoring **HEALTH CONDITIONS**

AMONG 312 MILLION PEOPLE IN THE U.S

# WHOSE LIVES COULD MOBILE HEALTH IMPROVE?



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# FDA regulation

## Medical Device ?

- **Yes** - Intended for the diagnosis of disease or other conditions, or cure, mitigation, treatment or prevention of disease....
- **Maybe** (enforcement discretion) - help patients self-manage their disease or conditions without providing specific treatment or treatment suggestions

# Health Applications

- **Systems:** analyze and manage data on a large scale (Health care system, insurance)
- **Care providers:** diagnosis, prescription, follow-up
- **End user:** provide personalized analysis (health)



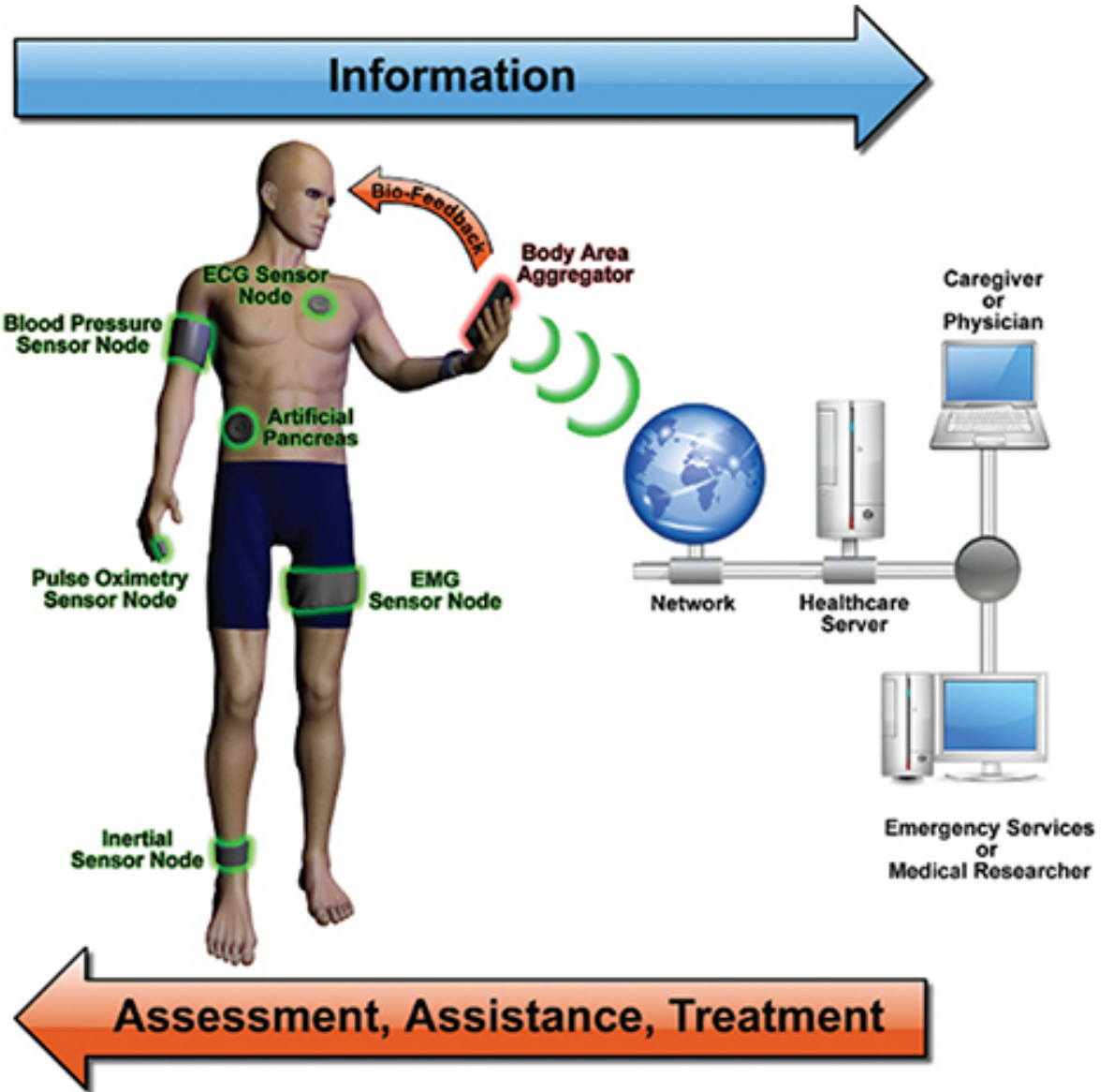
# Future directions

Data Standardization  
& Integration

Advanced analysis

Business  
opportunities

Applications  
in healthcare





# WEARABLE HEALTH LAB

## - Key Personnel and Collaborations

- Stanford Faculty

- Matthew Smuck, MD
- Christy Tomkins-Lane, PhD
- Ming-Chi Kao, MD, PhD



- Outside Collaborations:

- Matthew Buman, PhD (Arizona State U.)
- Andrew Haig, MD (U. of Michigan)



- Stanford Collaborations:

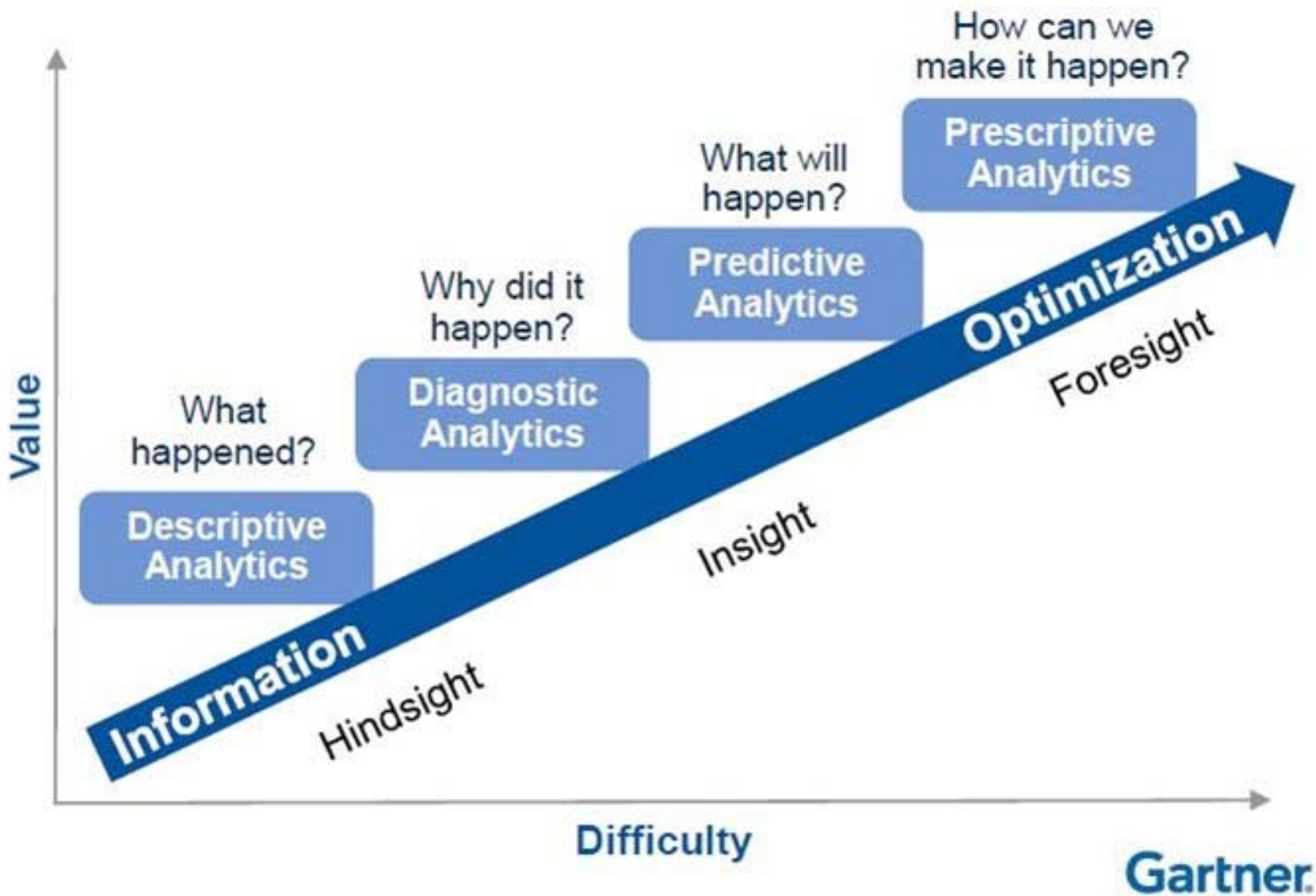
- William Haskell, PhD (Prevention Center)
- Constance Chu, MD (Orthopaedics)
- Scott Delp, PhD (Mobilize Center)



**Stanford**  
MEDICINE

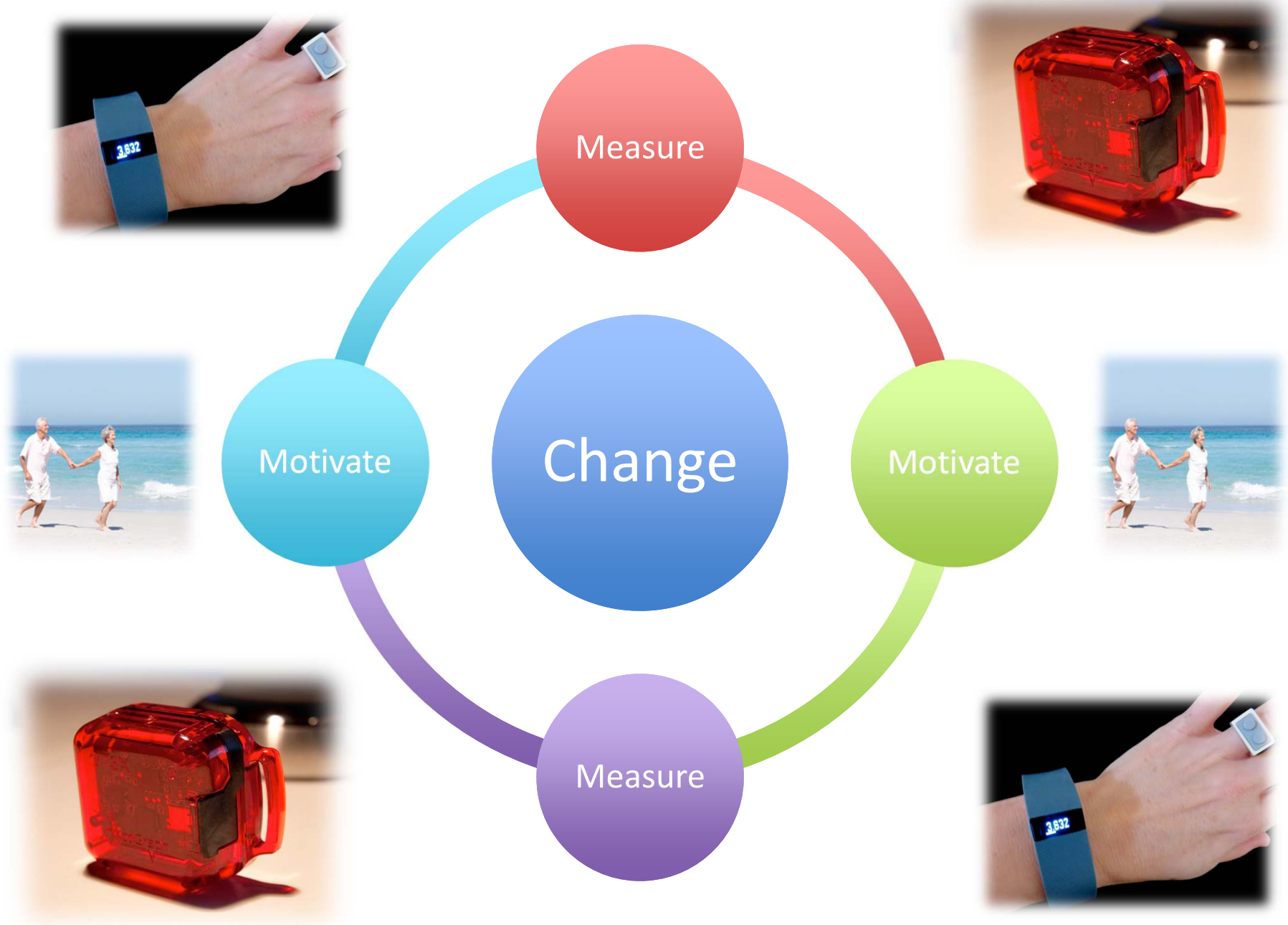
Physical Medicine  
& Rehabilitation





# Wearables and Osteoarthritis





# For discussion

- Are wearables here to stay?
- Do they provide accurate information?
- Is the information meaningful?
- Who determines what is important and how is that data managed?
- Do users self diagnose?
- Should physicians facilitate use of wearables?
- Will wearables save health care dollars for the patient? for the system?
- Who owns the data coming from the devices?
- If it is a consumer device can it or should it be used in a medical setting?