CSM 2016 | Anaheim, CA

Practicality of Wearable Technology in Physical Therapy

Promises, pitfalls, and pathways for effortless streams of flowing data and knowledge from wearables

Daniel J. Vreeman, PT, DPT, MSc

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Associate Director for Terminology Services, Regenstrief Institute, Inc

@djvreeman

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DEPARTMENT OF MEDICINE
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Promises

Everyone has great expectations…

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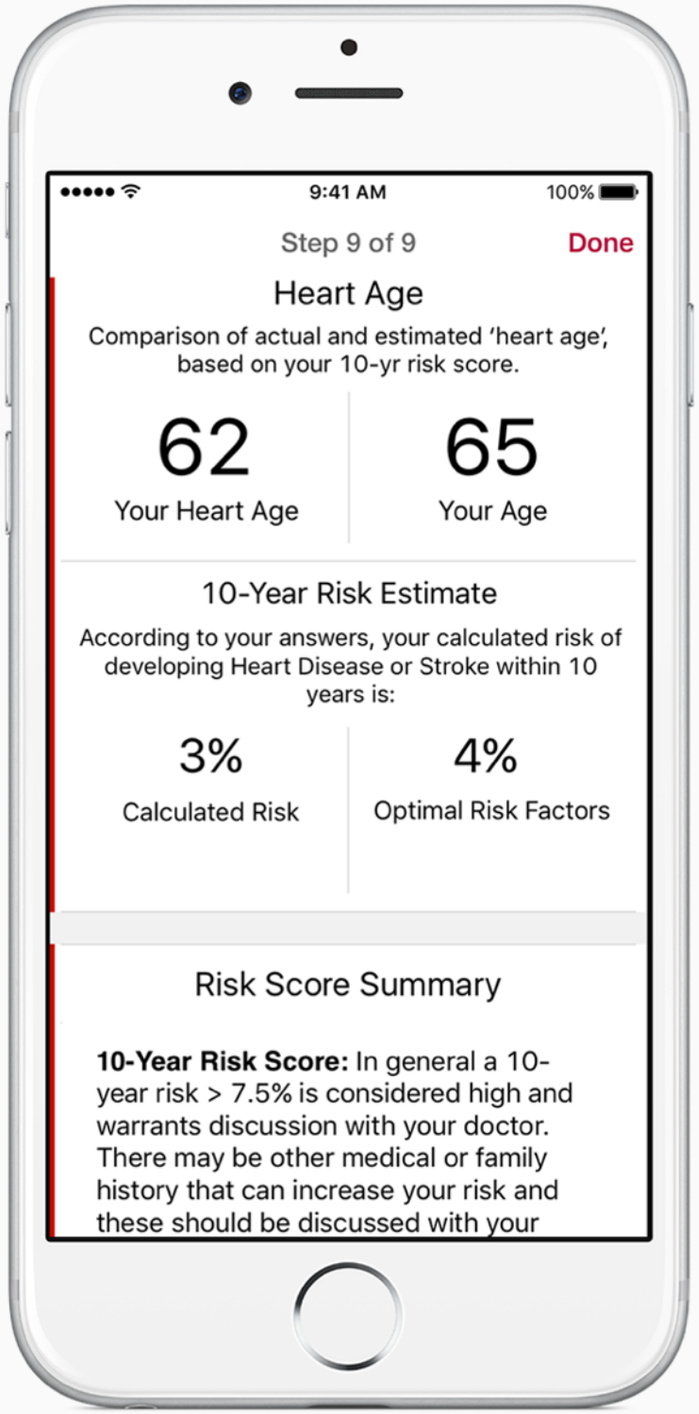
A comprehensive picture of a patient's health

Efficient, accurate, real-world data capture


RECORD
JOURNAL
INSIGHTS
73


AliveCor

- Autism
- Epilepsy
- Melanoma
- Asthma
- Parkinson’s Disease
- Diabetes
- Breast Cancer
- Cardiovascular Disease



Assessing the risks of cardiovascular disease with MyHeart Counts.

Stanford Medicine and the University of Oxford have collaborated to create the MyHeart Counts app. It uses surveys and tasks to help researchers more accurately evaluate how participants’ activity and lifestyle relate to their risks of cardiovascular disease. By identifying these correlations, researchers can begin to better understand how to keep hearts healthier.

MyHeart Counts
View in the App Store ↗

The activity data that can be measured with your iPhone can be assessed against your diet and lifestyle information to give you a much more objective Lifetime Risk Estimate for cardiovascular disease.

Smart systems that help clinicians turn data into actionable, patient-specific knowledge

The secret sauce of the Health IT chicken soup

photo via liber

Pitfalls

Danger Will Robinson!

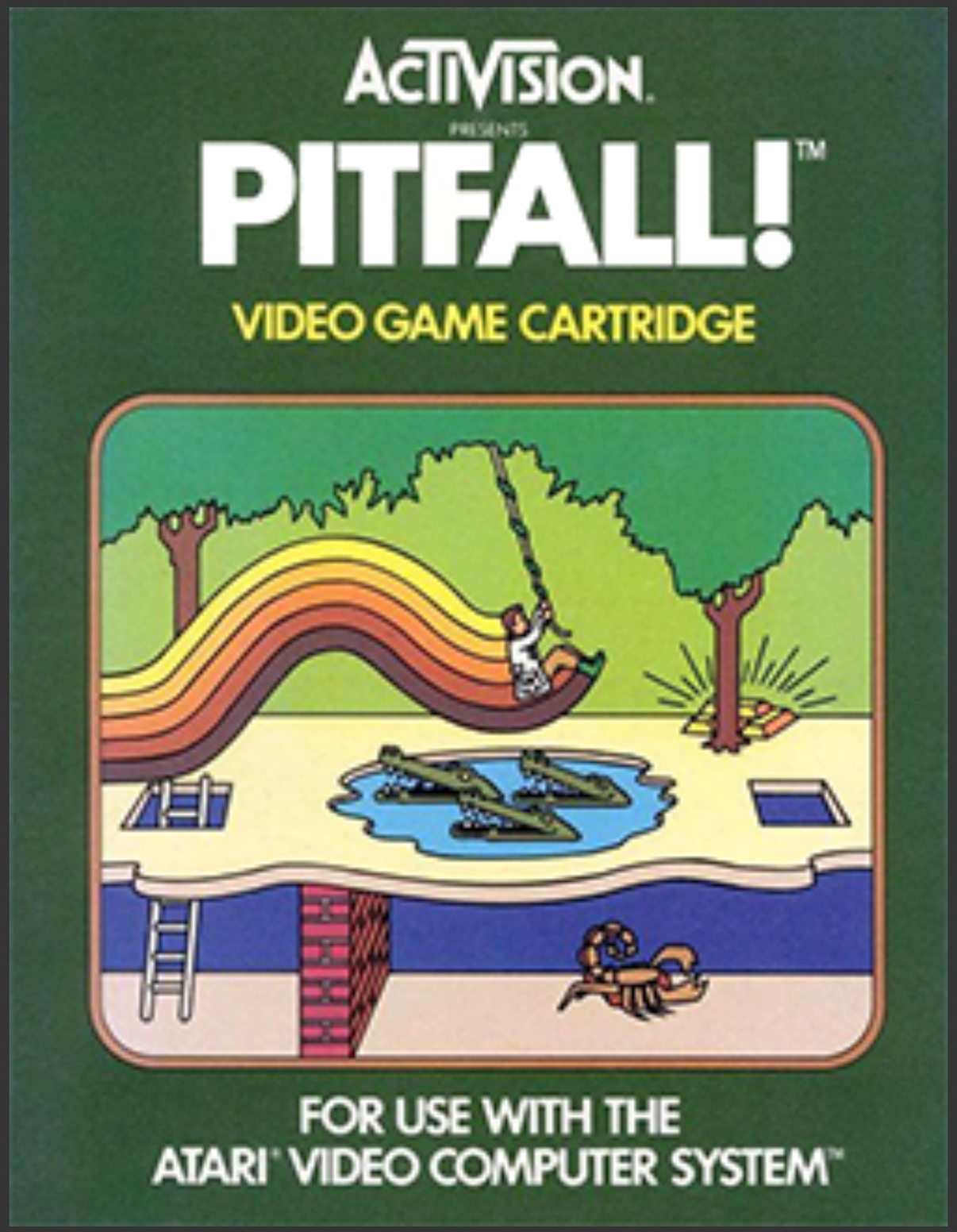
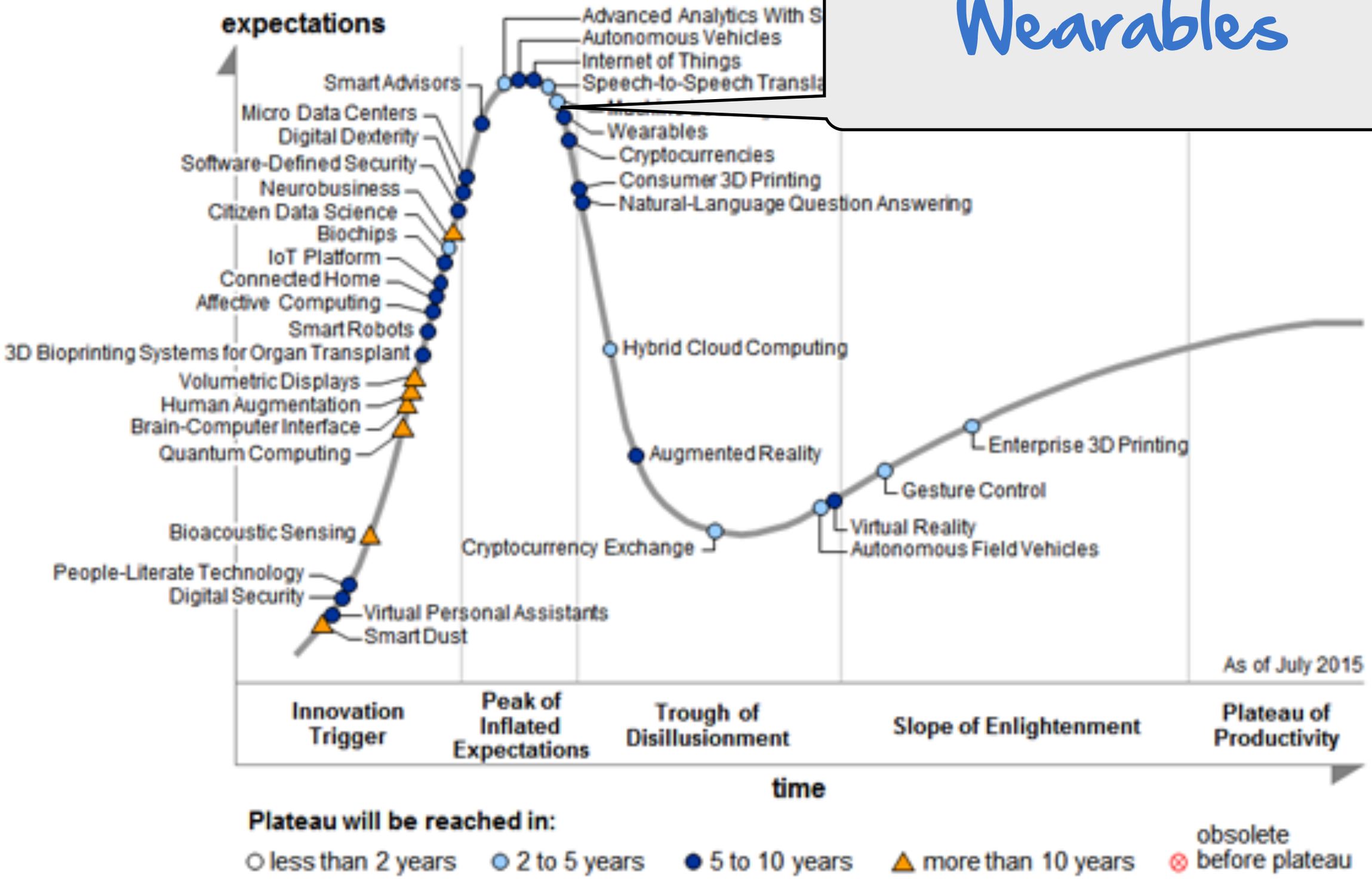


photo via duncan

Hype Cycle for Emerging Technologies, 2015. Source: Gartner (August 2015)

Wearables



Hype Cycle for Emerging Technologies, 2015. Source: Gartner (August 2015)

“Rookie” informatics mistakes

TRENDING IN AAPL COMPANY
Opinion: Apple's software bugs may be overplayed, but they do still need faster fixes

TRENDING IN APPLE MUSIC
Feature Request: 7 ways Apple Music Connect could be improved to prevent it from being the next Ping

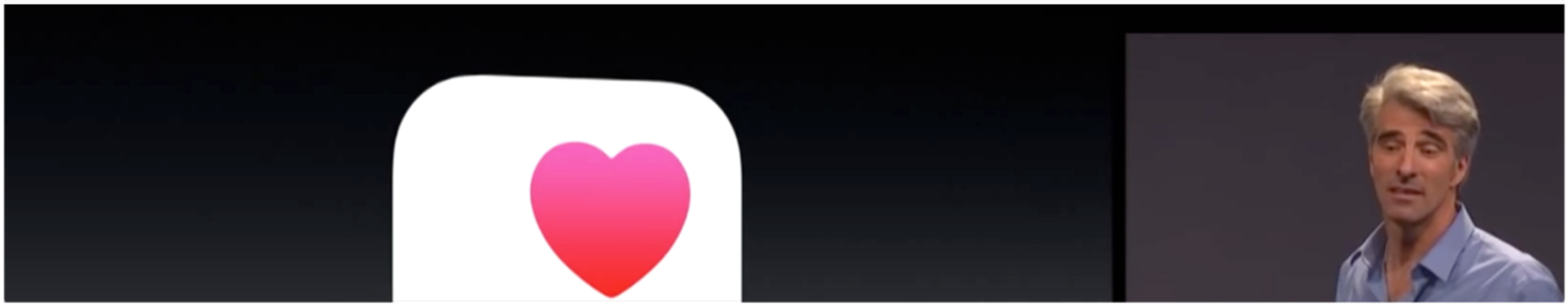
TRENDING IN IOS DEVICES
Jeremy's 5: HoverDock for Apple Watch / iPhone, Error 53, Apple in Small Business + Apple Pay

OCTOBER 15, 2014

Apple to disable another Health feature as UK and Australian users report blood glucose measurement issues

Mike Beasley - 1 year ago @MikeBeas

IOS



Validic API

Return Value	Type	Description
timestamp	String	Timestamp for the measurement set
utc_offset	String	Timezone information for the measurement set
source	String	The short name of the application that recorded the activity
source_name	String	The display name of the application that recorded the activity
last_updated	String	Date and time when the measurement set was last updated
_id	String	Unique identifier of the activity (required for POST requests)
c_peptide	Double	The value of the measured quantity in ng/mL
fasting_plasma_glucose_test	Double	The value of the measured quantity in mg/dL
hba1c	Double	The value of the measured quantity in %
insulin	Double	The value of the measured quantity in U
oral_glucose_tolerance_test	Double	The value of the measured quantity in mg/dL
random_plasma_glucose_test	Double	The value of the measured quantity in mg/dL

https://docs.validic.com/docs/data-retrieval

Validic API

"Flat" data model

Proprietary names

Bound units

. . .

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https://docs.validic.com/docs/data-retrieval

Validic API

"Flat" data model

Proprietary names

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...

4 standardization protocols exist today... which one do I have?

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https://docs.validic.com/docs/data-retrieval

Tracking devices users may not appreciate issues of privacy, data sharing, and data control

Opportunities and challenges in the use of personal health data for health research

RECEIVED 1 May 2015
REVISED 8 June 2015
ACCEPTED 26 June 2015

Matthew J Bietz[1,2], Cinnamon S Bloss[2,3,4], Scout Calvert[5], Job G Godino[2,4], Judith Gregory[1], Michael P Claffey[6], Jerry Sheehan[7], and Kevin Patrick[2,4]

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ABSTRACT

Objective: Understand barriers to the use of personal health data (PHD) in research from the perspective of three stakeholder groups: early adopter individuals who track data about their health, researchers who may use PHD as part of their research, and companies that market self-tracking devices, apps or services, and aggregate and manage the data that are generated.

Materials and Methods: A targeted convenience sample of 465 individuals and 134 researchers completed an extensive online survey. Thirty-five hour-long semi-structured qualitative interviews were conducted with a subset of 11 individuals and 9 researchers, as well as 15 company/key informants.

Results: Challenges to the use of PHD for research were identified in six areas: data ownership; data access for research; privacy; informed consent and ethics; research methods and data quality; and the unpredictable nature of the rapidly evolving ecosystem of devices, apps, and other services that leave "digital footprints." Individuals reported willingness to anonymously share PHD if it would be used to advance research for the good of the public. Researchers were enthusiastic about using PHD for research, but noted barriers related to intellectual property, licensing, and the need for legal agreements with companies. Companies were interested in research but stressed that their first priority was maintaining customer relationships.

Conclusion: Although challenges exist in leveraging PHD for research, there are many opportunities for stakeholder engagement, and experimentation with these data is already taking place. These early examples foreshadow a much larger set of activities with the potential to positively transform how health research is conducted.

Keywords: mobile health (mHealth), wearable sensors, Internet of Things (IoT), big data, personal data, data sharing

Bietz MJ, Bloss CS et al. Opportunities and challenges in the use of personal health data for health research. J Am Med Inform Assoc. 2015 Sep 2. pii: ocv118. doi: 10.1093/jamia/ocv118. [Epub ahead of print] PubMed PMID: 26335984.

Importantly, many {users} thought that they actually did own these data, even though many have almost certainly entered into "click-through" agreements in which they have given those rights away to companies.

Bietz MJ, Bloss CS et al. Opportunities and challenges in the use of personal health data for health research. J Am Med Inform Assoc. 2015 Sep 2. pii: ocv118. doi: 10.1093/jamia/ocv118. [Epub ahead of print] PubMed PMID: 26335984.

Most of the focus has been on the wellness market

Most of the focus has been on the wellness market

How do gamification effects differ across populations?

Drowning in the “datanami”

Pathways

Getting from here to there

photo via sherifx

Capitalize on the alignment of individual, corporate, and government momentum

FEB 17, 2016 @ 09:31 AM

Wearable Tech Market To Be Worth $34 Billion By 2020

Paul Lamkin, CONTRIBUTOR

I write about wearable and connected self technology.

FOLLOW ON FORBES (12)

Opinions expressed by Forbes Contributors are their own.

FULL BIO

CCS Insight has updated its outlook on the future of wearable tech, indicating that 411 million smart wearable devices, worth a staggering $34 billion, will be sold in 2020.

The analyst claims the industry will hit $14 billion this year, with wrist-based devices – such as smartwatches and fitness trackers – continuing to dominate. Its forecast states half of all wearable tech sales over the next 12 months will be from these genres, with smartwatches making up 50% of the estimated 60 million shipments.

Back in mid-2015 CCS claimed that around 20 million Apple Watches would be sold in the calendar year but it is now stating that just over 9 million Cupertino smartwatches were sold before 2016 arrived. That's a number that gives it, according to the report, a 41 percent market share.

Earlier this month Canalys estimated that Apple shipped 12 million smartwatches in 2015 – a figure it claimed was worth two-thirds of the total smartwatch market. Gartner had stated a week earlier that around 30 million

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 495

[CMS-3310-FC and CMS-3311-FC]

RINs 0938-AS26 and 0938-AS58

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rules with comment period.

SUMMARY: This final rule with comment period specifies the requirements that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under the Medicare EHR Incentive Program. In addition, it

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Measure 3: Patient generated health data or data from a nonclinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rules with comment period.

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Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: January 26, 2016

Submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, email them to: DigitalHealth@fda.hhs.gov;
For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

IEEE STANDARD

1073.1.1.1-2004 - Standard for ISO/IEEE Health Informatics - Point-of-care medical device communication - Part 10101: Nomenclature

Description: Replaced by ISO/IEEE 11073-10101-2004. Within the context of the ISO/IEEE 11073 family of standards for point-of-care (POC) medical device communication (MCD), this standard provides the nomenclature that supports both the domain information model and service model components of the standards family, as well as the semantic content exchanged with medical devices. The nomenclature is specialized for patient vital signs information representation and medical device informatics, with major areas including concepts for electrocardiograph (ECG), haemodynamics, respiration, blood gas, urine, fluid-related metrics, and neurology, as well as specialized units of measurement, general device events, alarms, and body sites. The standard defines both the architecture and major components of the nomenclature, along with extensive definitions for each conceptual area.

STATUS:
Superseded Standard

Working Group: PoCD - Point-of-Care Devices

Oversight Committee: EMB/11073 - IEEE 11073 Standards Committee

Sponsor: IEEE Engineering in Medicine and Biology Society

RELATED STANDARDS

Healthcare IT Standards

ADDITIONAL RESOURCES

Request Interpretation

Related Products

Standards Distributors & Resellers

IEEE

Regenstrief and IEEE are working together to support interoperable communications of medical and personal health devices

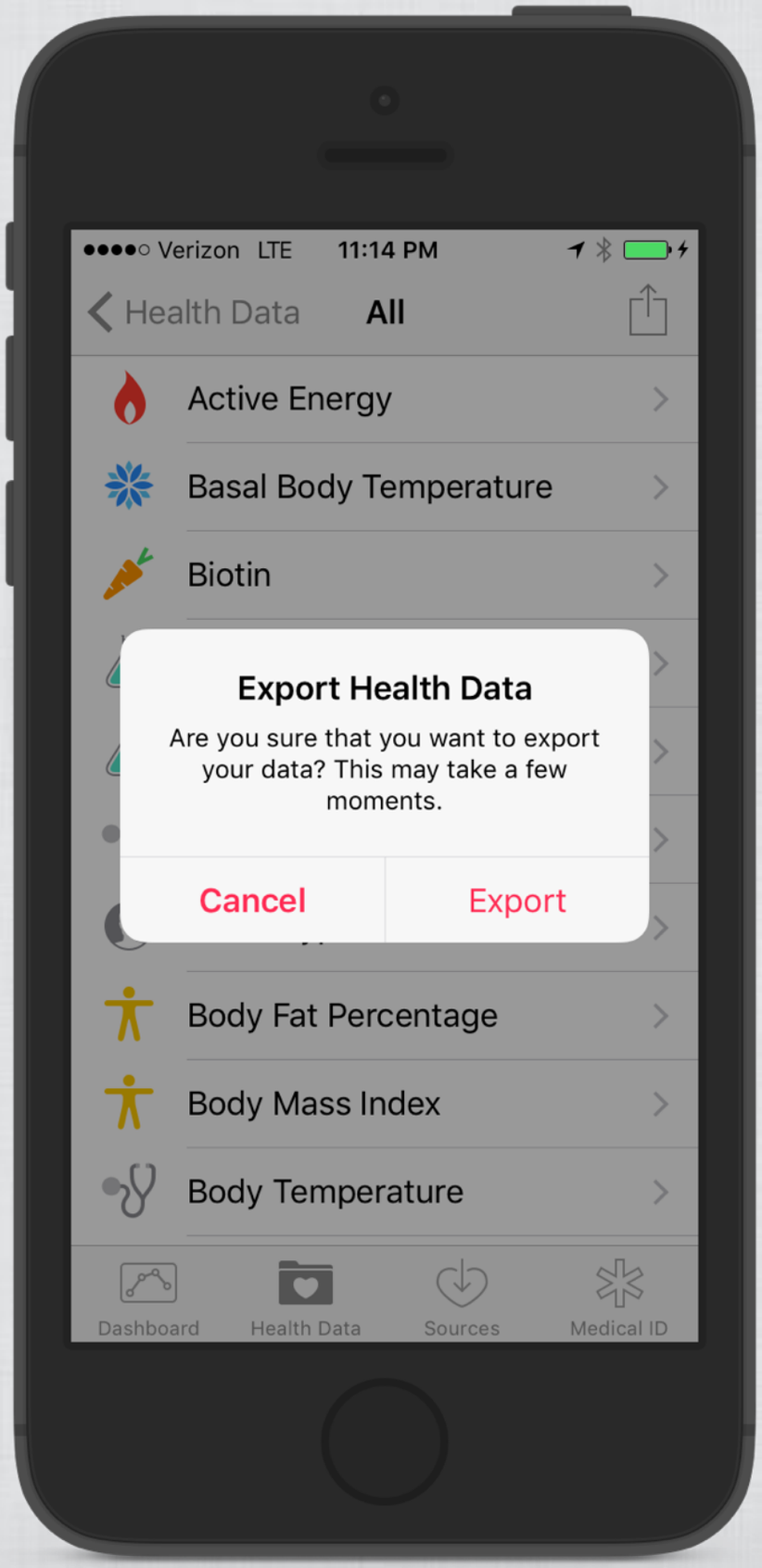
Regenstrief Institute and the IEEE Standards Association (IEEE-SA) have signed a memorandum of understanding (MoU) for collaboration in standards development. Regenstrief, developers of LOINC®, and IEEE, developers of the 11073™ standards, are connecting standardized terminology and methods of data communication to enhance the interoperability of traditional medical devices and personal health devices. These standards facilitate communication between medical, health care, and wellness devices and with external computer systems. By enabling interoperable data exchange, this work will support patients living independently with chronic diseases.

Together with the U.S. National Institute of Standards and Technology (NIST), Regenstrief and IEEE-SA are creating ways for hospital, healthcare software engineers, and device manufacturers to integrate clinical data from these devices using standards.

LOINC/IEEE Medical Device Code Mapping Table

LOINC/IEEE Medical Device Code Mapping Table File (20.1 kB)

The LOINC/IEEE Medical Device Code Mapping Table is distributed by Regenstrief as product of collaboration between the IEEE-SA and Regenstrief Institute, Inc. The main file contains linkages between LOINC terms and content from IEEE EMB/11073 standard. From the current version of LOINC, it includes the LOINC code, Long Common Name, and any applicable attribution statement. From IEEE 11073-10101, it includes the Reference ID, Numeric code, Dimensionality, and Description (when available). This zip file archive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All
Active Energy
Basal Body Temperature
Biotin
Export Health Data
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Cancel
Export
Body Fat Percentage
Body Mass Index
Body Temperature
Dashboard
Health Data
Sources
Medical ID

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Apple Health Export in C-CDA Format

LOINC codes! Oh snap!

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Apple Health Export in C-CDA Format

Extracting and using knowledge from the proliferating data sources

Guidelines You Can Follow and Can Trust

An Ideal and an Example

Guidelines are popular these days. They are mentioned in journal articles,[1-3] editorials,[4] insurance company contracts, and federal legislation. The Institute of Medicine has dedicated two reports to the subject.[5,6]

Unfortunately, the word *guideline* covers a broad spectrum of intellectual products. Some are hard to follow. They use weasel words instead of numeric thresholds or explicit criteria at their decision points and do not really tell you what to do. We say these are not *decidable*. Drug package inserts are notorious: "Serum electrolytes (particularly potassium), CO_2, creatinine and BUN should be determined frequently during the first few months of Lasix therapy and periodically thereafter."[7] Guidelines for isoniazid prophylaxis, in contrast, are explicit and easy to follow.[8]

Some are simple, describing the indications for a single action and requiring access to only a few variables for their execution. The Centers for Disease Control and Prevention guidelines for influenza vaccine are a good example.[9] Others are complex and define the behavior required to achieve a diagnostic or therapeutic goal (eg, the diagnosis of jaundice or the treatment of heart failure). These may require access to hundreds of variables for their execution. The HELP system algorithm for ventilator management of acute respiratory distress is the best example.[10]

See also p 827.

Guidelines vary in their validity—the degree we can trust they will guide us in the right direction. Some are pure opinion or the musings of "expert" committees (Woolf's class I guidelines[2]). Others are products of formal processes and rooted in solid scientific data.[2,11] Some, like the rules reported in this issue of *JAMA*,[12] raise their validity to a new high by proving their benefit in a clinical trial.

For 20 years, we, and others in medical informatics, have been seeking valid and decidable guidelines (or scientific results that can easily be translated into such guidelines[13]) because we believed that we could improve the quality and reduce the costs of care by automating these guidelines within computer-stored medical record systems.[14-18] Many years of scouring the literature for such guidelines and implementing them in medical information systems have given us strong opinions about what we should call guidelines and how they should be developed.

First, the word *guideline* has been stretched to include too many different kinds of guidance. The definition should be narrowed to include only rules about when to initiate and/or when to avoid medical interventions (tests, treatments, and other clinical actions) that are valid and decidable within specified medical contexts. By this definition, prediction rules[19] designed to decide when to intervene are guidelines.

Second, guideline developers should recognize that for many, if not most, medical subjects, the information needed to construct a valid guideline is simply unavailable—medicine's immense ignorance has not been diminished by the so-called information explosion. So, guideline developers should be prepared to collect the information prospectively rather than waste time trying to draw inferences from inadequate medical literature.

Third, whether the data come from the literature or prospective data collection, we should be realistic about what we try to build. Because even when the literature provides much information about when to intervene and when not to intervene, the data are usually not detailed enough to shape prescriptive (how-to-do-it) rules. In most cases we should limit our scope to simple issues ("Give influenza shot when patient is older than 65 years.") or plan to build guidelines that are approximations or bounds on the fully prescriptive ideal for complex matters.

Bounding rules that specify what should be done at the very least and/or at the very most without speaking to all of the cases in between serve as guardrails to practice decisions rather than cookbooks. An example of an "at-least" rule would be to order cervical Papanicolaou tests every 3 years among sexually active women without addressing when or whether the tests should be performed more frequently. Another "at-least" rule would be to treat congestive heart failure patients with systolic dysfunction (defined explicitly as ejection fraction <40%) with an angiotensin converting enzyme inhibitor. This does not say that they should not be treated with any other drugs, and it does not specify the exact set of drugs and doses required for every patient.

From the Department of Medicine, Indiana University School of Medicine and the Regenstrief Institute for Health Care, Indianapolis.

Reprint requests to Regenstrief Institute, 5th Floor RHC, 1001 W 10th St, Indianapolis, IN 46202 (Dr McDonald).

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1. Push Button

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1. Push Button

2. Get Bacon

photo via karen_d

A prospective randomized trial examining health care utilization in individuals using multiple smartphone-enabled biosensors

Cinnamon S. Bloss[1,*], Nathan E. Wineinger[1,*], Melissa Peters[1], Debra L. Boeldt[1], Lauren Ariniello[1], Ju Young Kim[2], Judith Sheard[1], Ravi Komatireddy[1], Paddy Barrett[1] and Eric J. Topol[1,3,4]

[1] Scripps Translational Science Institute, La Jolla, California, United States
[2] Department of Family Medicine, Seoul National University Bundang Hospital, Seoul, South Korea
[3] Department of Molecular and Experimental Medicine, The Scripps Research Institute, La Jolla, United States
[4] Division of Cardiovascular Diseases, Scripps Health, San Diego
* These authors contributed equally to this work.

ABSTRACT

Background. Mobile health and digital medicine technologies are becoming increasingly used by individuals with common, chronic diseases to monitor their health. Numerous devices, sensors, and apps are available to patients and consumers–some of which have been shown to lead to improved health management and health outcomes. However, no randomized controlled trials have been conducted which examine health care costs, and most have failed to provide study participants with a truly comprehensive monitoring system. **Methods.** We conducted a prospective randomized controlled trial of adults who had submitted a 2012 health insurance claim associated with hypertension, diabetes, and/or cardiac

Bloss CS, Wineinger NE, Peters M et al. A prospective randomized trial examining health care utilization in individuals using multiple smartphone-enabled biosensors. PeerJ. 2016 Jan 14;4:e1554. doi: 10.7717/peerj.1554. eCollection 2016. PubMed PMID: 26788432;

PeerJ

A prospective randomized trial examining health care utilization in individuals using multiple smartphone-enabled biosensors

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[1] Scripps Translational Science Institute, La Jolla, California, United States
[2] Department of Family Medicine, Seoul National University Bundang Hospital, Seoul, South Korea
[3] Department of Molecular and Experimental Medicine, The Scripps Research Institute, La Jolla, United States
[4] Division of Cardiovascular Diseases, Scripps Health, San Diego
* These authors contributed equally to this work.

Measurement alone won't change much

ABSTRACT

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Tone is in Your fingers

photo via scragz

via scragz

Though Wooten's basses receive much attention, his most frequent and consistent response when asked by his fans about his equipment is that "the instrument doesn't make the music ... ***you do***".

via scragz

The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine

Precision Medicine Initiative (PMI) Working Group Report to the Advisory Committee to the Director, NIH

September 17, 2015

Table 5.1: Categories, Sources, and Uses of Data				
Category	**Examples**	**Source(s)**	**Example Uses**	**Core/ Subgroup**
Individual demographics and contact information	Date and place of birth, sex and gender, detailed and multiple races/ethnicities (e.g., Asian of Indian descent, Asian of Chinese descent), name, mailing address, phone number, cell phone number, email address, marital status, educational status, occupation/income	Study participant, healthcare provider organizations	Participant-specific communications, analytics, risk stratification, assessment of covariates and confounds, study appointment reminders, invitations to participate in sub-studies	C
Terms of consent and personal preferences for participation in the project	Fine-grained consent for options to participate e.g., receive research results	Study participant	"Precision Participant Engagement"	C
Self-reported measures	Pain scales, disease-specific symptoms, functional capabilities, quality of life and well-being, gender identity, structured family health history	Study participant	Many	C/S
Behavioral and lifestyle measures	Diet, physical activity, alternative therapies, smoking, alcohol, assessment of known risk factors (e.g., guns, Illicit drug use)	Study participant (retrospective and prospective) and healthcare provider organizations	Correlation with clinical events, drug response, and health outcomes	C/S
Sensor-based observations through phones, wearables, home-based devices	Location, activity monitors, cardiac rate and rhythm monitoring, respiratory rate	Smartphone sensors, commercial and research-grade physiologic monitors	Functional ability and impairment assessment	C/S
Structured clinical data derived from Electronic Health Records (EHRs)	ICD/CPT billing codes, clinical lab values, medications, problem lists	Multiple provider organizations per study participant, via institutionally managed channels or direct from	Correlation of clinical events with other categories of data	C

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Individual demographics and contact information	Date and place of birth, sex and gender, detailed and multiple races/ethnicities (e.g., Asian of Indian descent, Asian of Chinese descent), name, mailing address, phone number, cell phone number, email address, marital status, educational status, occupation/income	Study participant, healthcare provider organizations	Participant-specific communications, analytics, risk stratification, assessment of covariates and confounds, study appointment reminders, invitations to participate in sub-studies	C
Terms of consent and personal preferences for participation in the project	Fine-grained consent for options to participate e.g., receive research results	Study participant	"Precision Participant Engagement"	C
lifestyle measures	alternative therapies, smoking, alcohol, assessment of known risk factors (e.g., guns, Illicit drug use)	(retrospective and prospective) and healthcare provider organizations	events, drug response, and health outcomes	C/S
Sensor-based observations through phones, wearables, home-based devices	Location, activity monitors, cardiac rate and rhythm monitoring, respiratory rate	Smartphone sensors, commercial and research-grade physiologic monitors	Functional ability and impairment assessment	C/S
Structured clinical data derived from Electronic Health Records (EHRs)	ICD/CPT billing codes, clinical lab values, medications, problem lists	Multiple provider organizations per study participant, via institutionally managed channels or direct from	Correlation of clinical events with other categories of data	C

Sensor-based observations through phones, wearables, home-based devices | Location, activity monitors, cardiac rate and rhythm monitoring, respiratory rate | Smartphone sensors, commercial and research-grade physiologic monitors | Functional ability and impairment assessment | C/S

Why shouldn't physical therapists lead on this path?

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slides available at:

danielvreeman.com/csm2016