Defining Wearable Technologies for Optimal Use:
Considerations and Recommendations

Presenting Author: Blondell (Paula) Glover

PSM Internship Project Presentation

November 21, 2019

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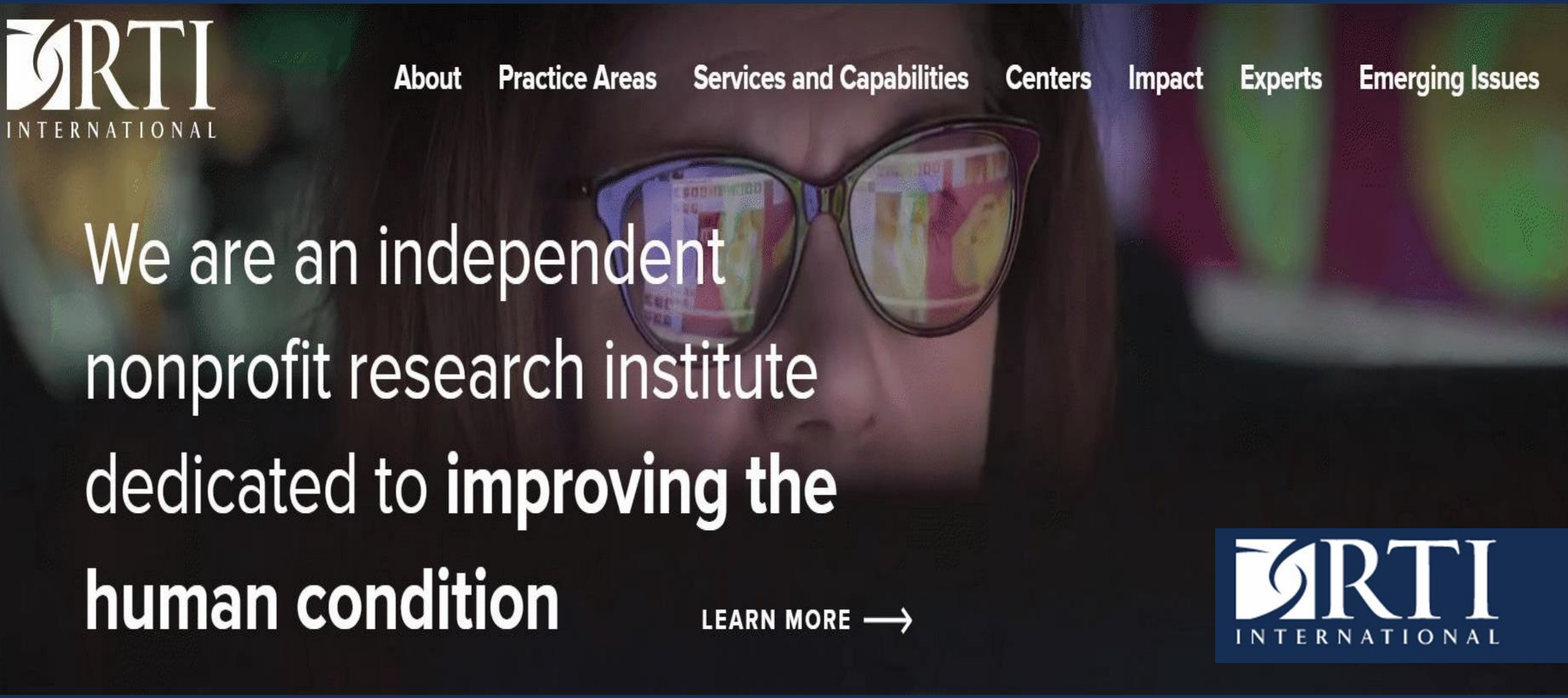
Carolina Health Informatics Program

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL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Headquartered in Research Triangle Park, North Carolina, RTI was founded in 1958 with support from North Carolina government, education, and business leaders to provide **multidisciplinary expertise and research insights for a variety of policy, practice and program areas**.

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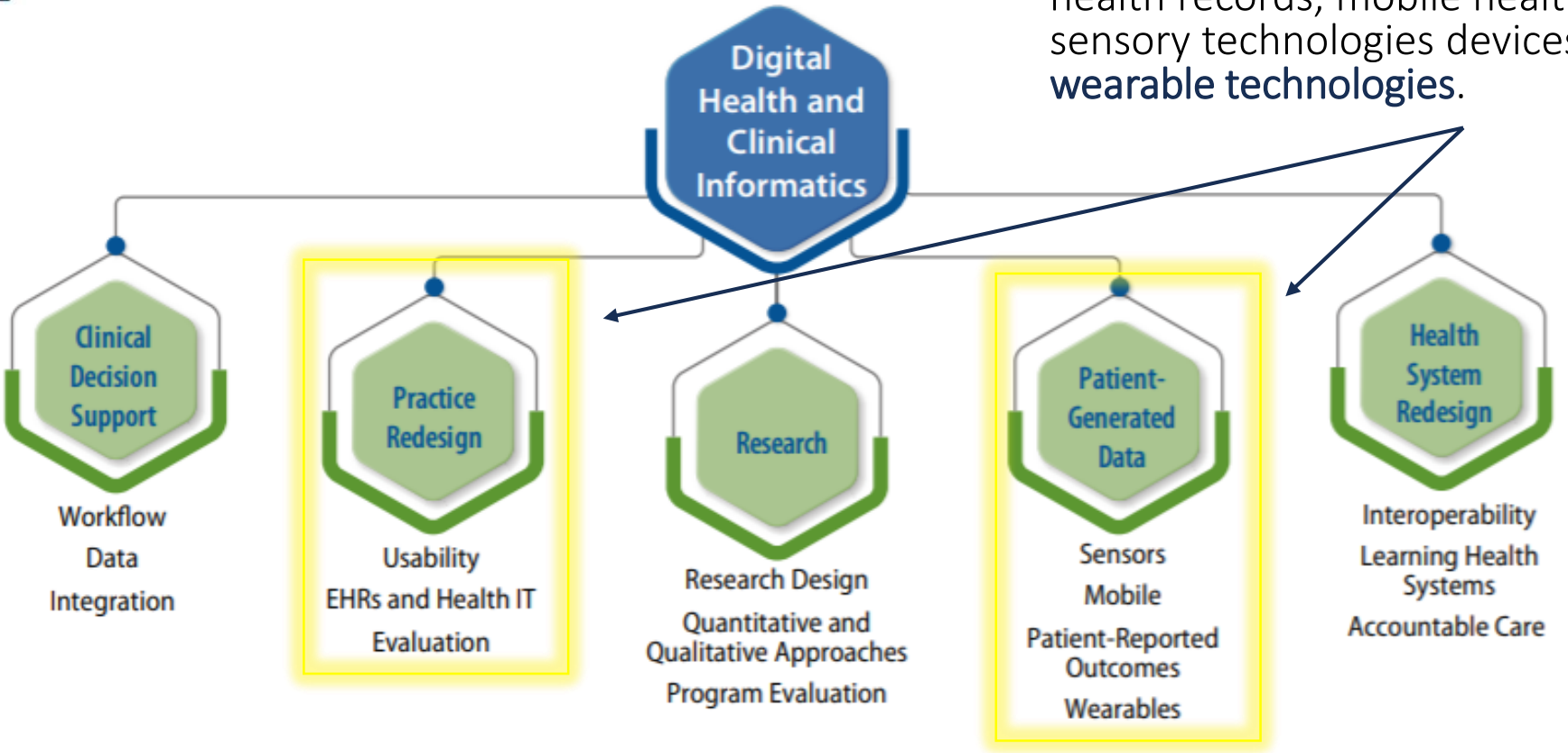
They provide **evaluation for the design, usability, and impact of health information technology (health IT)** such as electronic health records, mobile health devices, and sensory technologies devices, such as **wearable technologies**.

RTI's **Digital Health and Clinical Informatics (DHCI) team** works with clients to explore how patients and clinicians can **use technology to improve individual health, self management, population health, and provider-based health care.**



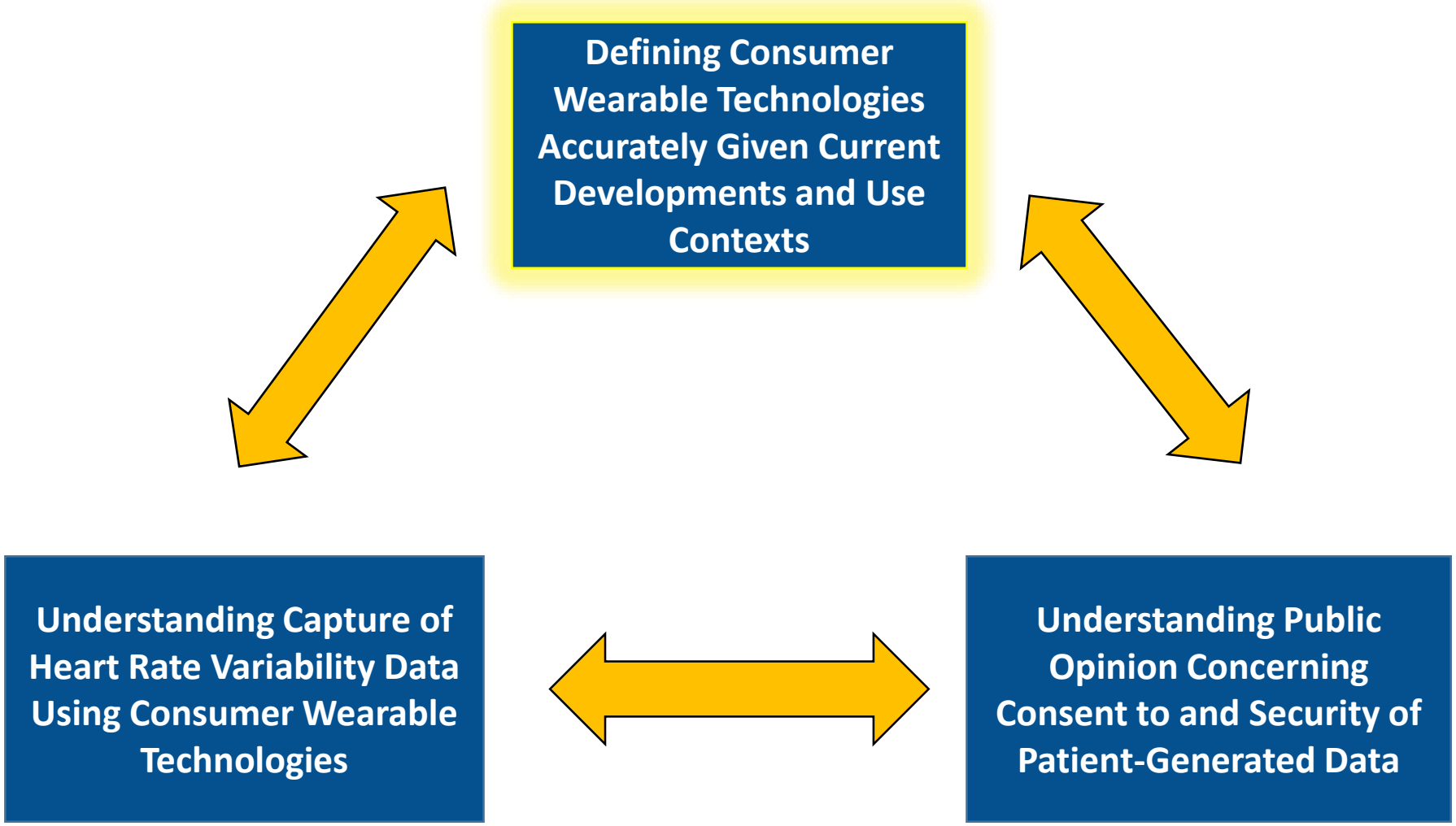
THE DIGITAL HEALTH INTERNSHIP

Robert Furberg, MBA, PhD leads interdisciplinary research and development teams at RTI for the implementation and evaluation of digital interventions for health promotion, primary and secondary disease prevention, and treatment adherence across a variety of patient populations.

The Digital Health Internship, in collaboration with DHCI, is designed to teach students skills in implementing and evaluating digital health devices within health care projects.

Alexa Ortiz, RN, MSN works on innovative uses of health IT to promote healthy behavioral changes, improve health care quality and bridge gaps across care.

THEME: CONSUMER WEARABLE TECHNOLOGIES



DEFINING CONSUMER WEARABLE TECHNOLOGIES THROUGH EVALUATION OF KEY PRODUCT ATTRIBUTES

Project Objective

1. *Develop a qualitative review of the current landscape of consumer wearable technologies and define them comparatively against other devices within the field of wearable technology so as to contribute to their appropriate usage*
2. *Evaluate consumer wearable technologies outside of traditional quantitative comparisons.*

Questions Addressed

- How can we synthesize the available literature surrounding consumer wearable technologies currently?
- What are the characteristics of consumer wearable technologies?
- How do these characteristics compare with clinical-grade devices?
- How much overlap exists between consumer wearable technologies and clinical-grade devices? How do we define/categorize this area of overlap?
- Is there any current literature seeking to address classification and guidelines of use of consumer wearable technologies qualitatively?
- Is there an available framework or set of guidelines for use of wearable technologies? If not, how might we establish a basis for this?

1. SYNTHESIS OF LITERATURE ON THE CURRENT LANDSCAPE OF CONSUMER WEARABLE TECHNOLOGIES

SEARCH STRATEGY

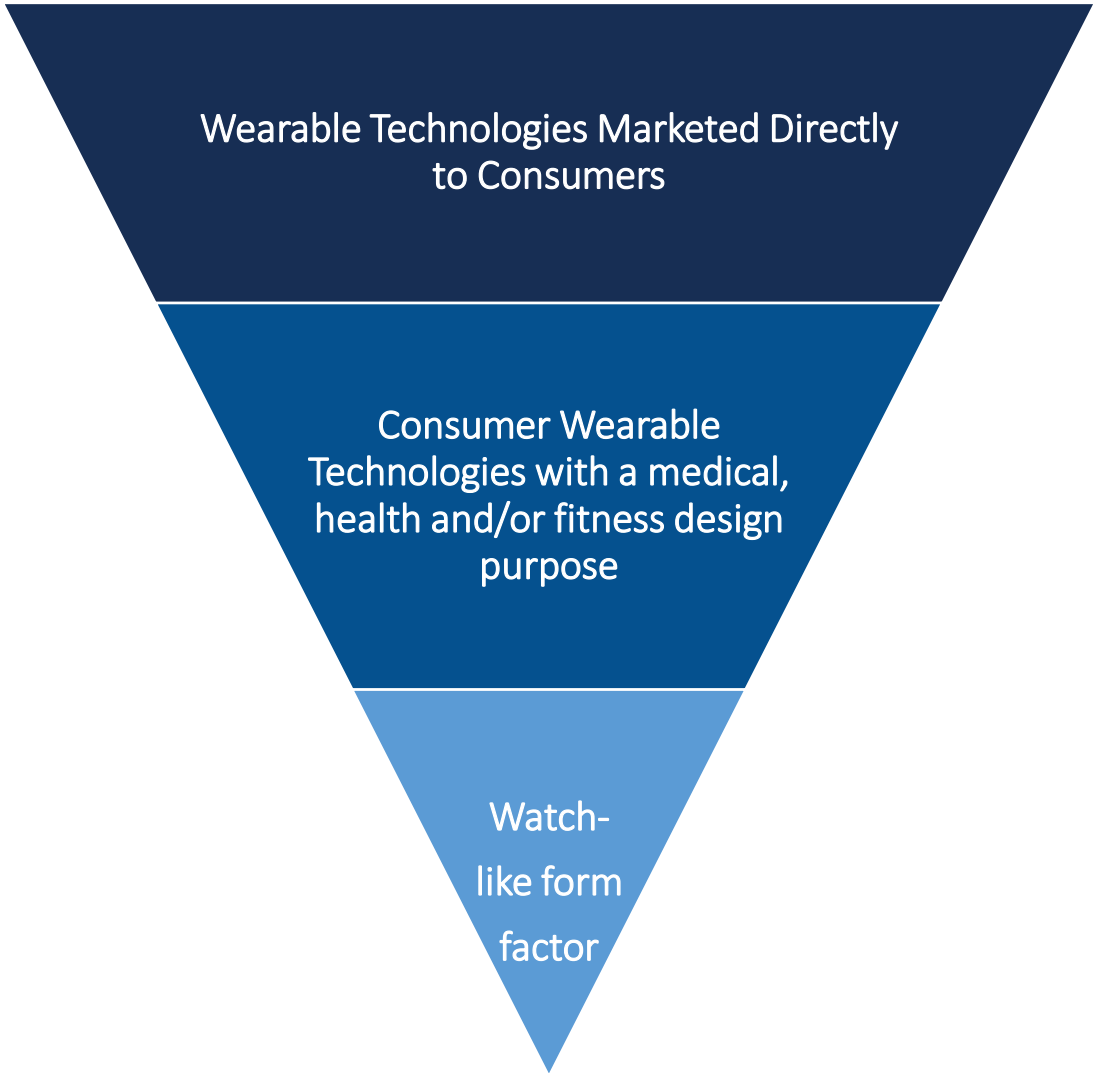
Reviewed publications from the Journal of Internet Medical Research (JMIR), PubMed and ScienceDirect (more generally), and publications from consumer technology and healthcare innovation websites using Google.

Search terms included "consumer wearable technology," "wearable technology," "consumer wearable(s)," "wearable(s)," "activity trackers," "fitness trackers," and "photoplethysmography."

Inclusion criteria for technologies included in review:

1. Must be marketed to everyday consumers
2. Must have some sort of health or fitness purpose in its design
3. Must be available in watch-like form.

Selection of Sources Reviewed

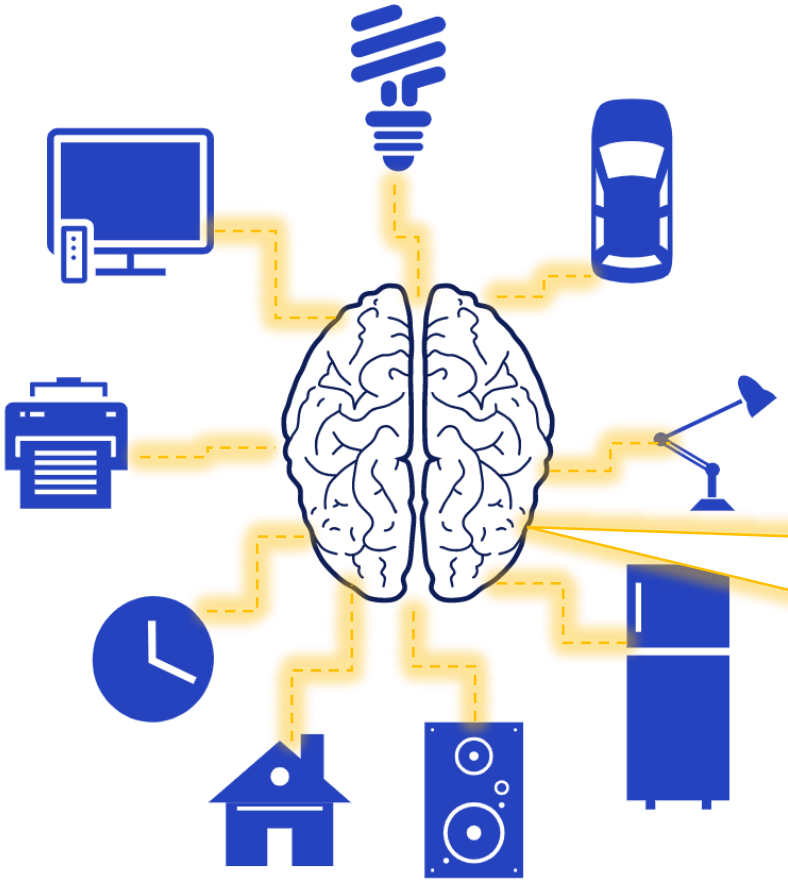


Sources Used for Review = 40*

*No true count for how many sources were actually reviewed, since the purpose was to create a qualitative review

BACKGROUND CONTEXT—THE INTERNET OF THINGS (IoT)

The Internet of Things (IoT) describes the **connection of material objects to the internet** via embedded sensory technology.



IoT represents a **state of heightened communicative intelligence**, wherein objects can interact with one another, end users, and/or their environment in informative and meaningful ways.

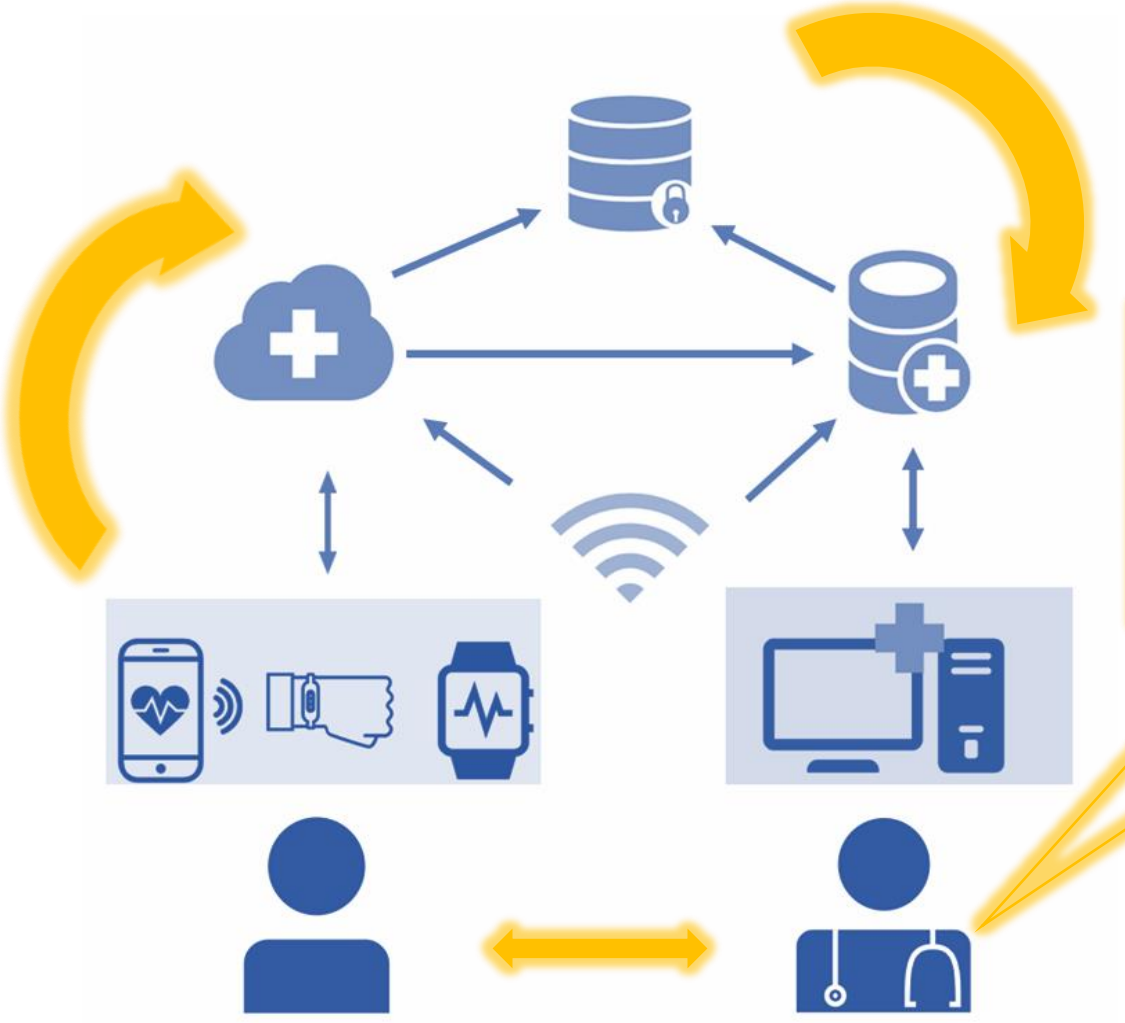
IoT is currently being used to transform many industries including retail, manufacturing, transportation, government and health care.

The term was coined by entrepreneur **Kevin Ashton** in 1999 in reference to the linking of objects to the internet via radio-frequency identification tags.

THE INTERNET OF HEALTH THINGS (IoHT)

The **Internet of Health Things (IoHT)** (or the Internet of Medical Things (IoMT)) is the **application of IoT concepts to health care**.

IoHT transforms the treatment process by way of **sensory machines and devices that continuously monitor, collect and transfer patient data electronically** both within and outside of physical presence in a traditional healthcare setting.



IoHT data supports more precise clinical diagnoses and decisions, improves patient safety and outcomes, and streamlines health care delivery.

IoHT APPLICATIONS IN DIGITAL HEALTH

IoHT is the foundation of **digital health architecture**, which supports the connection between patient and healthcare services through technology.

Digital health consists of internet-focused applications and media that are **designed to improve medical content, commerce, and connectivity through robust health monitoring processes.**

Digital Health Application Areas

Remote Monitoring of Health Data in Real-Time

Smartphone Health Applications

Support clinical diagnosis, communication, and education based on collected health data

Ambient Assisted Living Support

Uses health data to promote patient autonomy and safety within the context of personal health goals

Wearable Technologies

Sensory devices (and associated mobile/electronic health applications) that continuously monitor physiological activity without interruption or limitation

WEARABLE TECHNOLOGY IN DIGITAL HEALTH

Wearable technologies have emerged at the forefront of digital health investment due to their **broad applicability in health care, clinical research and personal health education**.

$8.2 billion in investments in 2018 and $8.4 billion projected for 2019

Wearable technologies **continuously collect health data using a multitude of form factors over a wide breadth of measurement areas**.

PROBLEMS POTENTIALLY ADDRESSED BY WEARABLE TECHNOLOGIES

Traditional patient data collection may contribute to a very **limited narrative of a patient's actual health**

- Patient data only recorded when a patient is seen by a clinician at a healthcare facility
- Breakdowns in patient memory recall for clinically significant information
- Insufficient health information transfer between healthcare systems
- Inadequate comparisons between individual and population health data averages

Frequent data collection over extended periods of time as supported by wearable technologies helps to provide larger and denser datasets.

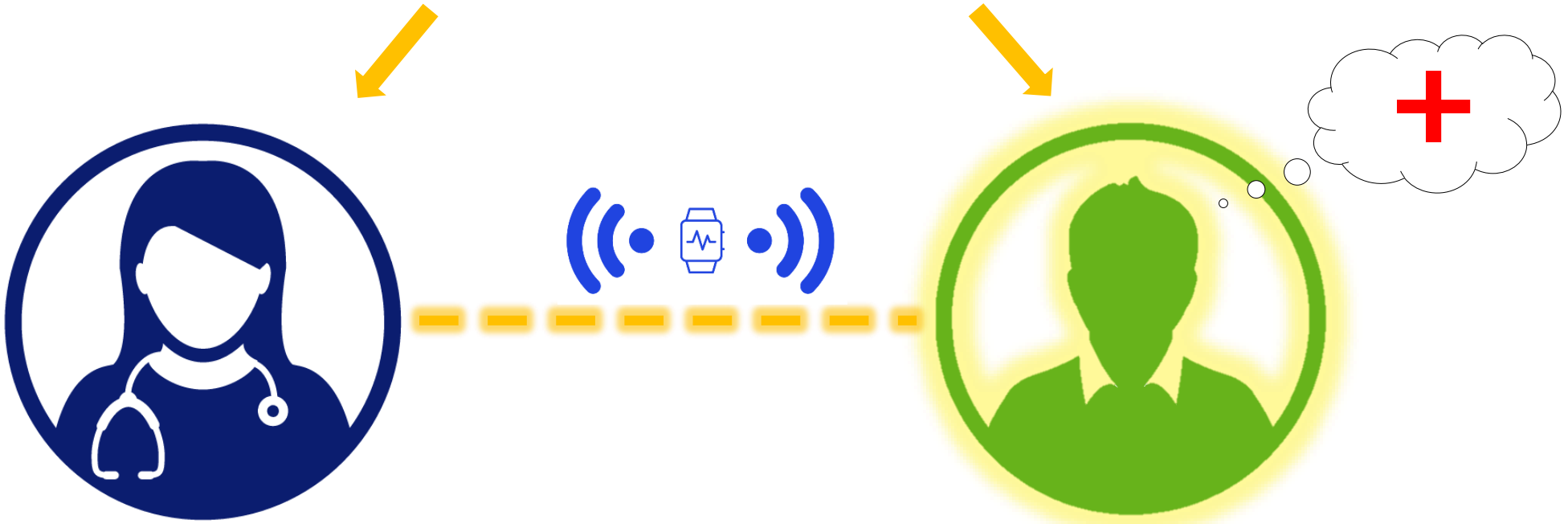
Creates greater quality of data, in turn supporting a deeper understanding of disease and treatment variability.

WEARABLE TECHNOLOGIES IN SUPPORT OF THE QUANTIFIED SELF MOVEMENT

The Quantified Self movement aims to better inform people about their health through quantifiable self-monitoring actions.

Wearable technologies offer an avenue by which patients can independently understand their health outside of clinical interpretations made by medical professionals.

This is most apparent in the rise of wearable technologies marketed directly to consumers for tracking of fitness, heart health and sleep.



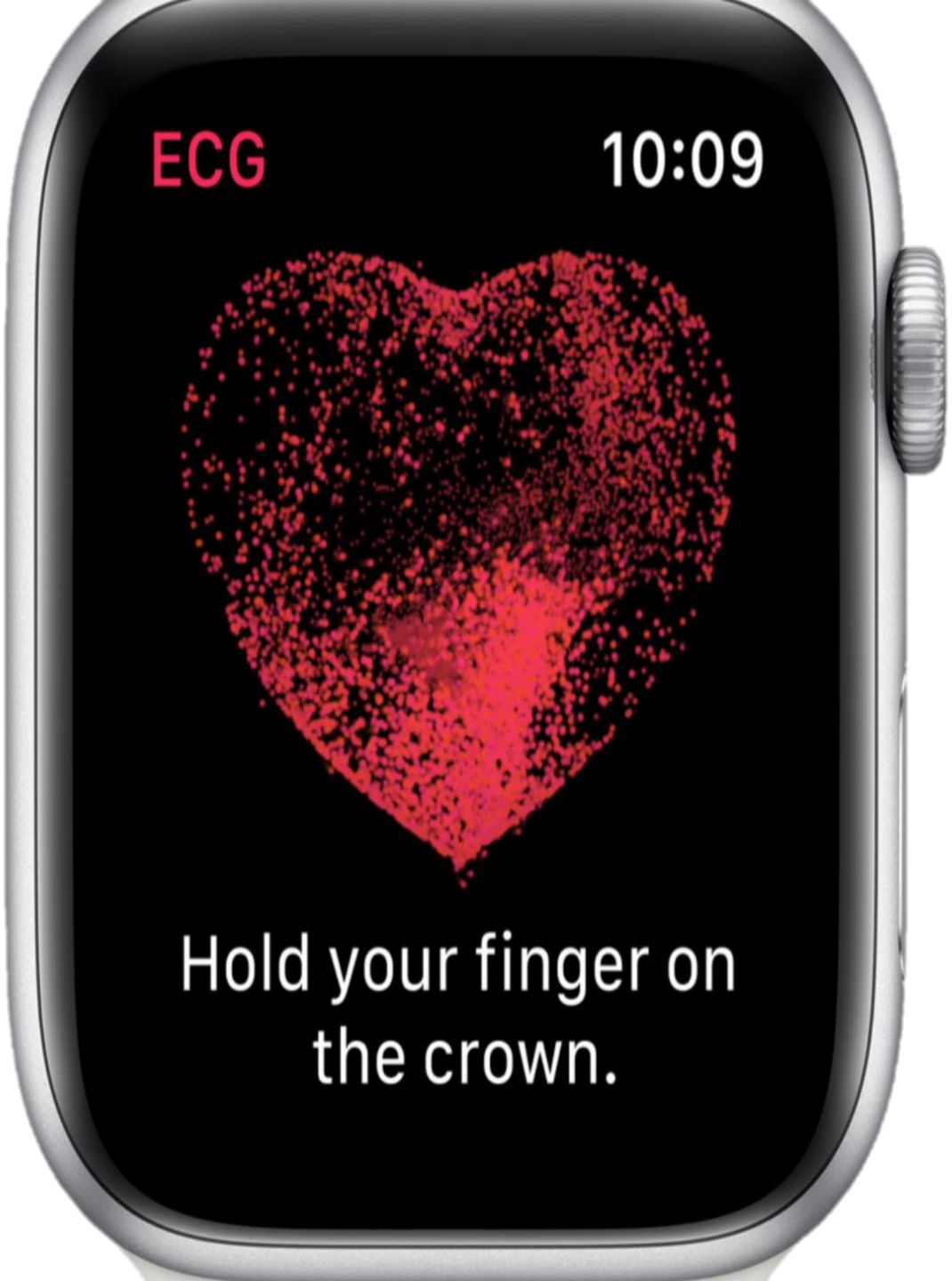
All around, Apple Watch inspires a healthier life. It monitors your heart rate and lets you know if something is wrong. Helps you keep track of your menstrual cycle and taps you if noise levels rise to a point that could impact your hearing. You can also add complications like Breathe, Heart Rate, and Noise to your watch face and keep them top of mind throughout your day. It's the first watch that really watches out for you.

Proactive Health Monitor

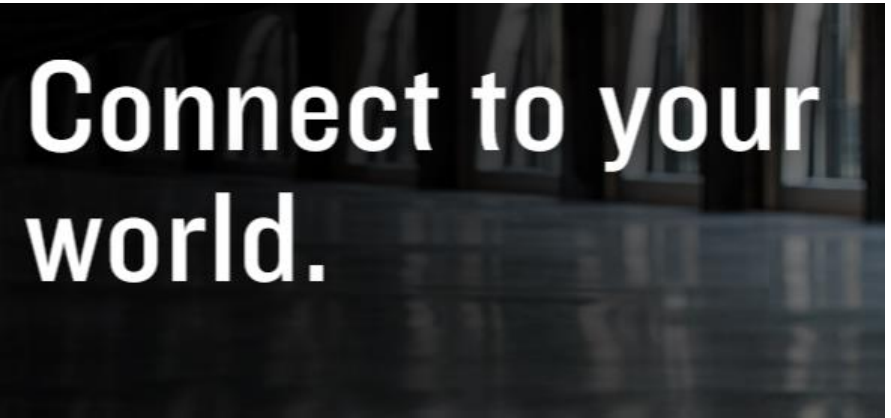
Always in sight. Always insightful.

ECG on your wrist. Anytime, anywhere. With the ECG app,[1] Apple Watch Series 5 is capable of generating an ECG similar to a single-lead electrocardiogram. It's a momentous achievement for a wearable device that can provide critical data for doctors and peace of mind for you.

Your finger can tell you a lot about your heart. Electrodes built into the Digital Crown and the back crystal work together with the ECG app to read your heart's electrical signals. Simply touch the Digital Crown to generate an ECG waveform in just 30 seconds. The ECG app can indicate whether your heart rhythm shows signs of atrial fibrillation — a serious form of irregular heart rhythm — or sinus rhythm, which means your heart is beating in a normal pattern.



GARMIN VENU FITNESS TRACKER



GARMIN VENU FITNESS TRACKER

ADVANCED SLEEP MONITORING

Get a full picture of how you're sleeping, with a breakdown of your light, deep and REM sleep stages as well as Pulse Ox[1] and respiration data.

WRIST-BASED HEART RATE

The watch constantly samples your heart rate[2] and will alert you if it stays high while you're at rest. It also helps gauge how hard you work during activities even underwater.

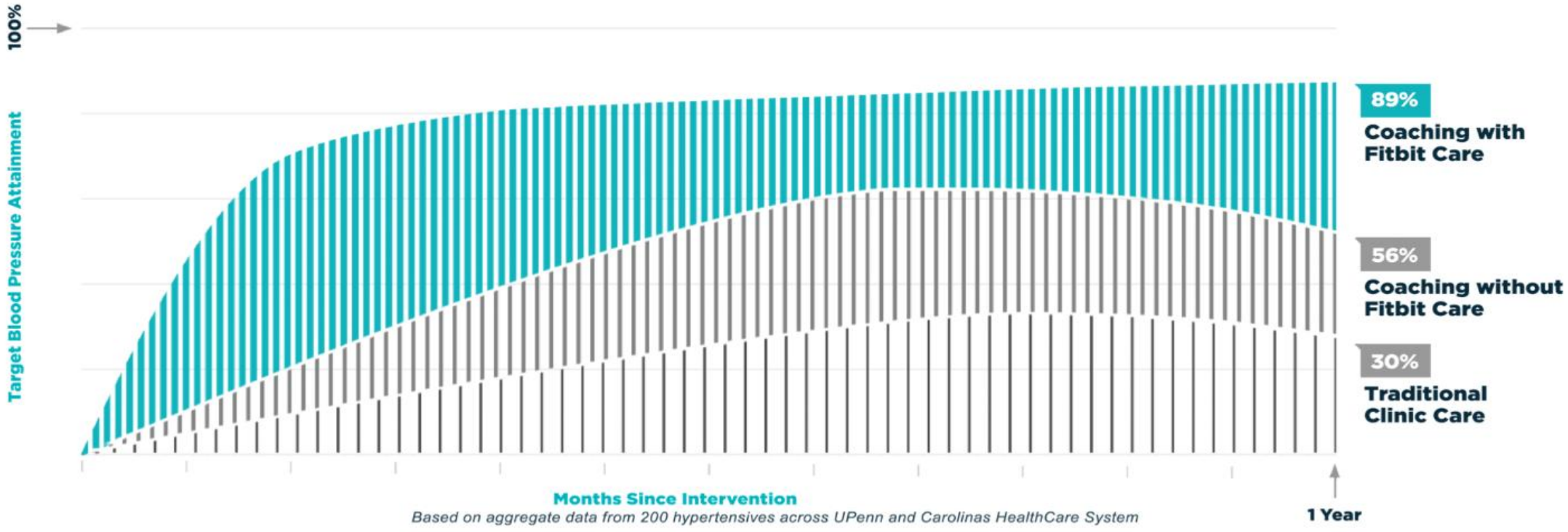
Fitbit Versa 2

HEALTH COACHING REIMAGINED

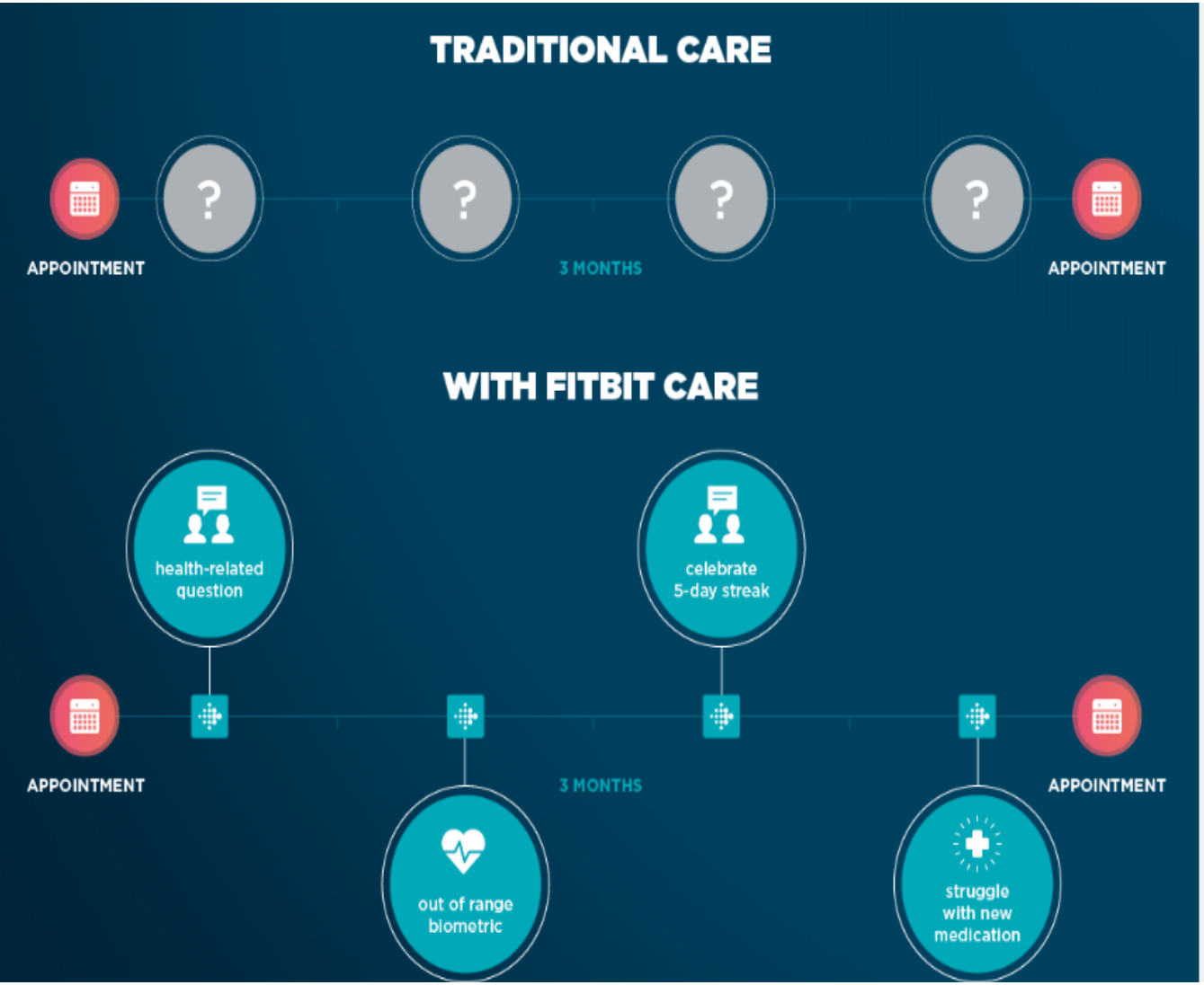
Fitbit Care health coaching helps people take ownership of their health by providing the essential human touch through engaging, scalable technology. Our health coaching services and software platform address the full spectrum of care from wellness and prevention to chronic condition and complex care management.

HEALTH OUTCOMES ACCELERATED

Fitbit Care's digital experience and anytime access to health coaching has helped individuals reach their goals faster than traditional coaching and other forms of care.



Based on aggregate data from 200 hypertensives across UPenn and Carolinas HealthCare System

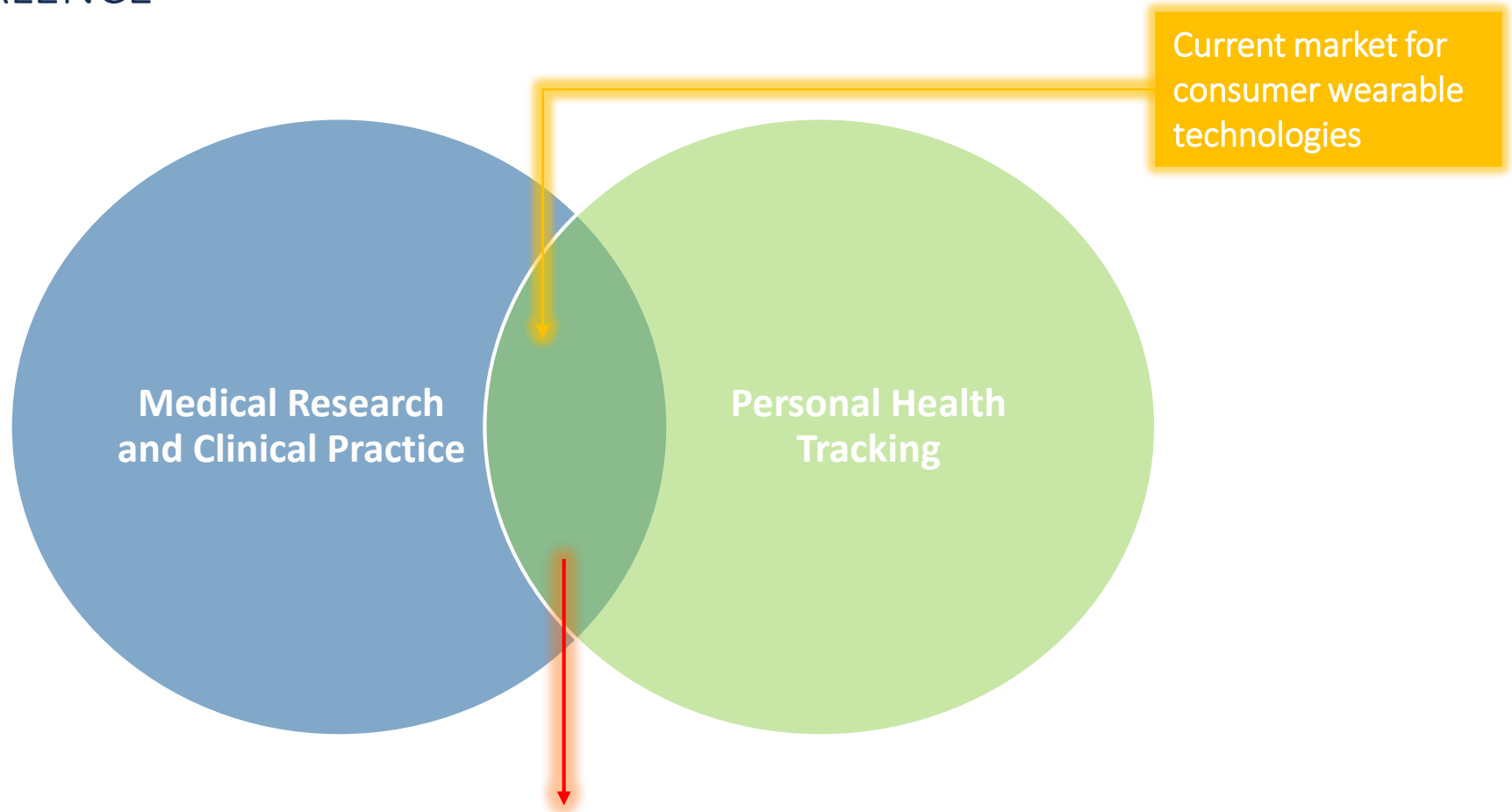


MIND THE GAPS IN CARE

Fitbit Care fills in the blanks between appointments with key health data and timely, right-touch interactions between participants and healthcare professionals. Providers get a more complete picture of every participant's health that can inform how they engage and encourage behavior change.

CONSUMER WEARABLE TECHNOLOGY CLAIMS FOR MEDICAL DEVICE EQUIVALENCE

As consumer wearable technologies continue to take on more attributes of validated medical devices in their marketing claims, there is now a potential for the emergence of a single class of wearable device that can support both personal health initiatives and patient monitoring activities necessary for medical practice and clinical research activities.



Should the current market of consumer wearable devices be considered as equivalent to validated medical devices?

DATA OUTPUT FROM CONSUMER WEARABLES DOES NOT ALWAYS MATCH DATA OUTPUT FROM VALIDATED MEDICAL DEVICES

Systematic review of the validity and reliability of consumer-wearable activity trackers

Kelly R. Evenson, Michelle M. Goto & Robert D. Furberg

International Journal of Behavioral Nutrition and Physical Activity **12**, Article number: 159 (2015) | Cite this article

Systematic review of the validity and reliability of consumer-wearable activity trackers across five activity parameters (steps, distance, physical activity, energy expenditure, and sleep) showed high validity and reliability only for steps. All other measurements, demonstrated high instances of over-estimation in measurement.

JAMA Intern Med. 2016 May 1;176(5):702-3. doi: 10.1001/jamainternmed.2016.0152.

Accuracy of Wearable Devices for Estimating Total Energy Expenditure: Comparison With Metabolic Chamber and Doubly Labeled Water Method.

Murakami H[1], Kawakami R[2], Nakae S[1], Nakata Y[3], Ishikawa-Takata K[1], Tanaka S[1], Miyachi M[1].

Study on the accuracy of wearable devices in estimating total energy expenditure demonstrated wide differences in absolute values both between devices and in comparison to established forms of measurement for this parameter, with all devices being subject to under-estimation of actual energy expenditure.

JMIR Mhealth Uhealth. 2019 Mar 11;7(3):e10828. doi: 10.2196/10828.

Accuracy of Consumer Wearable Heart Rate Measurement During an Ecologically Valid 24-Hour Period: Intraindividual Validation Study.

Nelson BW[1,2], Allen NB[1,2].

"The **Apple Watch 3 and the Fitbit Charge 2 provided acceptable heart rate accuracy**…these findings provide preliminary support that these devices **appear to be useful for implementing ambulatory measurement of cardiac activity** in research studies.

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Issues Undermining the Consumer Wearable Technology Equivalence to Validated Medical Devices

Lack of Standardized Methodology for Evaluation and Validation

Differences in parameters used for comparison, focus of validation and definition of what is being evaluated for validation between devices and practice areas.

Differences in Proprietary Algorithms

Differences in algorithms for data collection and sampling between devices of the same and of different brands can result in inconsistent measurements of health data.

Testing of Device Efficacy versus Efficiency

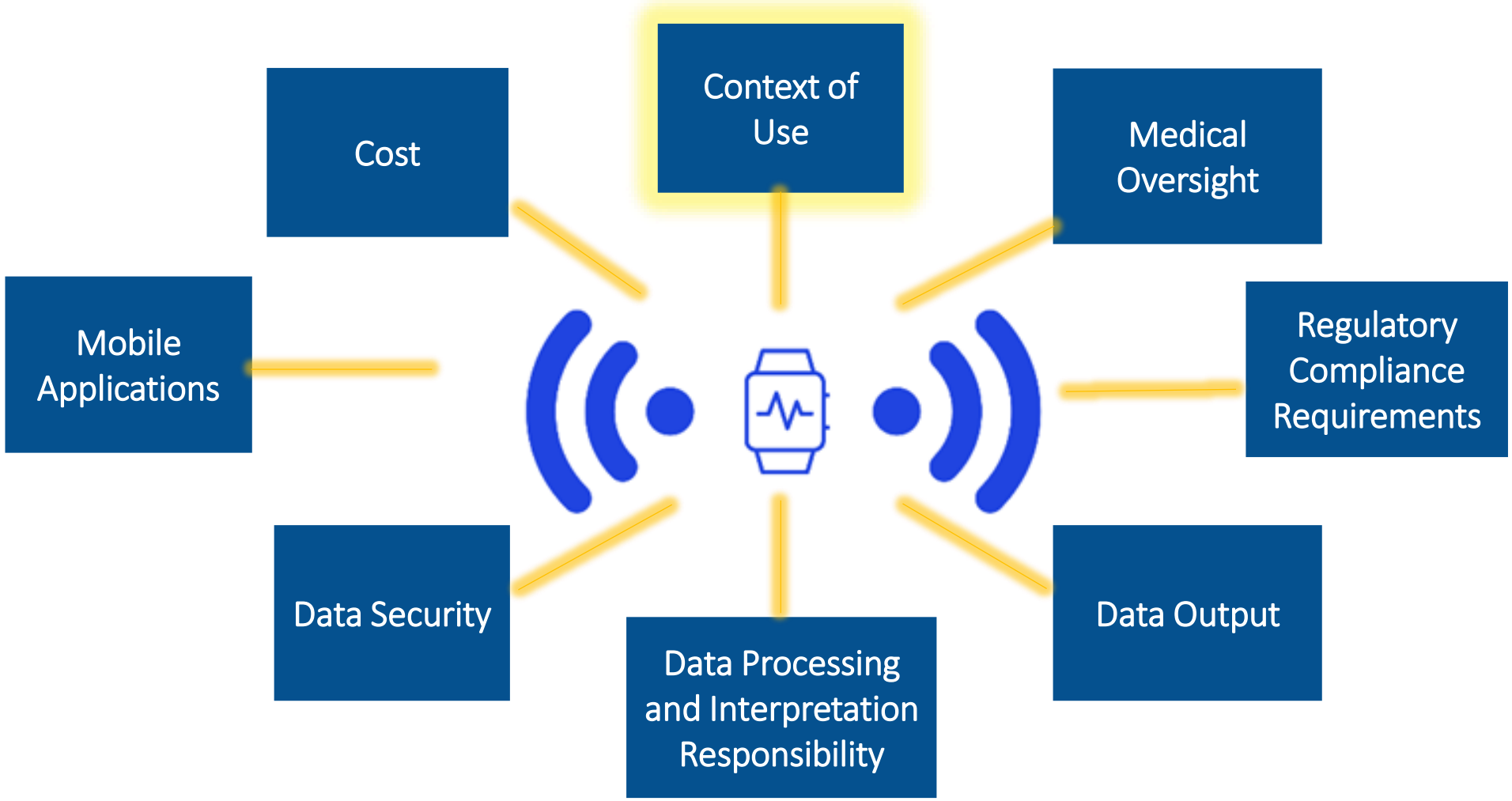
Many of these devices are tested in controlled laboratory settings, which creates an artificial environment that does not reflect normal use conditions. Thus, the accuracy of wearables in controlled settings may deviate from accuracy during the daily living conditions of consumers.

Outpacing of Validation Efforts by Wearable Development Cycle

Wearable technological advancements are subject to high frequency design and development iterations, often without adequate validation (may simply prove validation based on a reference design).

2. IDENTIFICATION OF KEY ATTRIBUTES OF WEARABLE TECHNOLOGIES

IDENTIFICATION OF KEY WEARABLE TECHNOLOGY ATTRIBUTES



3. IDENTIFICATION OF USE CONTEXTS FOR WEARABLE TECHNOLOGIES

TYPES OF CONTEXTS OF USE FOR WEARABLE TECHNOLOGIES

Context of Use describes how and in what context (environment, interaction, process, etc.) a wearable technology is intended to be used.

Context of Use can be used as the basis of comparison between wearable technologies.

4. QUALITATIVE COMPARISON OF WEARABLE TECHNOLOGIES BASED ON USE CONTEXTS AND KEY ATTRIBUTES

DETAILED REVIEW OF KEY ATTRIBUTES ACROSS WEARABLE DEVICES

	Consumer Wearable Technologies	Wearable Medical Devices	Research-Grade Wearable Technologies
Context of Use	Supports personal health awareness, self-tracking, and behavioral changes	For use in clinical practice in association with medical diagnosis and treatment (ambulatory and in-hospital care settings)	Facilitates clinical trials and medical research projects as a means for capturing endpoints and supporting adherence/accountability
Medical Oversight	Usually none, but medical professionals may be interested in data output.	High degree of medical oversight by clinicians. Used primarily in traditional patient-provider interaction.	High degree of medical and professional oversight by clinicians and research specialists.
Regulatory Compliance Requirements	Majority of devices cleared under Section 510(k) of the Food, Drug and Cosmetic Act	FDA 510(k)-cleared devices that support an efficacy claim by demonstrating link between device readout and efficacy parameter(s)[3]	FDA 510(k)-cleared devices that support an efficacy claim by demonstrating link between device readout and efficacy parameter(s)
Data Output	Processed data with interpretation (health information and/or indicators)	Raw (unprocessed) data	Raw (unprocessed) data
Data Processing/ Interpretation Responsibility	Algorithms and data processing procedures as determined by companies in ownership/production of device	Medical professionals (usually any clinicians overseeing care for the patient)	Individual researchers, data analysts, contract research organizations
Data Security	Data can be shared in a de-identified, aggregate manner without explicit stipulation concerning access	HIPAA compliant and may require patient consent for data collection and sharing	HIPAA compliant and require patient consent for data collection and sharing (always de-identified)
Mobile Applications	Very likely (for personal health tracking and notifications)	Not likely to have associated mobile applications	May be present, depending on
Cost	$$-$$$	$$$-$$$$	$$$-$$$$
Examples	Fitbit Activity Trackers, Apple Watch Series 4, Garmin wearables/smartwatches, Samsung Fitness Trackers	Nonin Pulse Oximeters	E4 by Empatica, ActiGraph Link by ActiGraph, EMOTIV EPOC by Emotiv

CONTINUUM OF WEARABLE TECHNOLOGY CHARACTERISTICS

- Healthcare Setting Only
- Operated by Trained Medical Professionals
- Produces Raw Data (May Possess Some Preliminary Interpretations)
- Data Interpretable by Medical Professionals
- Strict FDA Clearance
- Strict HIPAA Regulations for Data Sharing
- No Associated Mobile Apps
- Higher Cost

Wearable Medical Devices

Research-Grade Wearable Devices

Consumer Wearable Technologies

- Used Anywhere
- Operated by Anyone
- Produces Processed Data with Interpretation
- Data Interpreted by Proprietary Algorithms
- No Strict FDA Clearance
- No Strict Regulations for Data Sharing
- Many Associated Mobile Apps
- Lower Cost

PROPOSED DEFINITIONS FOR WEARABLE TECHNOLOGIES

Clinical Grade Wearable Technology

Designed to support medical services and research through the through enhancement of communication of patient health data to medical professionals.

Consumer Wearable Technology

Offers increased connectivity to internet services via wireless applications. Designed to add convenience to daily life, but may also have support health, educational, and lifestyle goals (not definitively).

Wearable Medical Device

Supports the delivery of healthcare services by providing clinically relevant patient data to inform diagnoses or treatment decisions.

Research-Grade Wearable Technology

Supports the collection of health data in relation to clinical trials (including protocol adherence and patient tracking). May also inform treatment decisions

CONSIDERATIONS FOR WEARABLE TECHNOLOGY USAGE

Understanding the **performance characteristics** and **context of use** of a wearable technology is essential for **optimal use**. The following considerations should be made when choosing a wearable technology:

1. **What is your context of use?** What do you seek to observe or measure?
2. **What device is capable of capturing the data** intended to answer your questions?
3. **How accessible are the data** that are collected/stored by the device?
4. **How likely is the device to be used** (compliance, costs, availability, etc.)?

PARTING CONSIDERATIONS

1. In what ways should we try to validate wearable technologies?
2. Does quantitative validation equate to better outcomes of use?
3. How should we weigh efficacy versus efficiency when seeking to validate these technologies?
4. Should we hold wearable technologies of different use contexts to different standards of validation?
5. Does every device need to be clinically validated to improve health?

REFLECTION ON THE DIGITAL HEALTH INTERNSHIP

Paula Glover

DIGITAL HEALTH INTERN

SSES: RTP, NC

Send them a Message

ABOUT

MPS, Biomedical and Health Informatics, UNC-Chapel Hill, 2019

BA, Biology; and BA, Health & Societies, University of Pennsylvania, 2017

Defining Wearable Technologies for Optimal Use: Considerations and Recommendations

Blondell (Paula) Glover, MPS(1); Alexa Ortiz, RN, MSN(2); Robert Furberg, PhD, MBA(2)
(1)UNC-Chapel Hill, Chapel Hill, NC; (2) RTI International, Research Triangle Park, NC

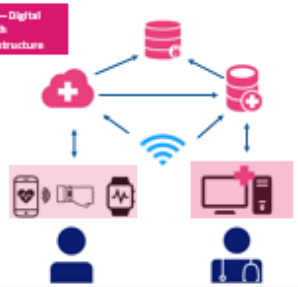
Background

The **Internet of Things (IoT)** is the connection of physical objects to their environments via the Internet.[1]

The **Internet of Health Things (IoHT)** is the application of IoT concepts to health care. IoHT is the foundation of **digital health** architecture, which supports the connection between patient and healthcare services through technology.[2]

IoHT applications include remote healthcare monitoring, mobile health apps, electronic health records (EHRs), and **wearable technologies**.

IoHT—Digital Health Infrastructure



Wearable Technology in Digital Health

Wearable technologies are sensor and/or software applications that collect and communicate health data continuously.[1]

Continuous data collection over extended time periods can provide **deeper understanding of disease and treatment response variability**.[3]

Current Landscape of Wearable Technologies

Digital health technologies undergo **rapid creation, iteration, and distribution**.[4]

There has been an increasing emergence of **wearable technologies advertised directly to consumers** with claims for personal and research/clinical use.

Invalidated wearable technologies may create health risks due to **incorrect data interpretations** and/or **ineffective use in informing clinical care**.

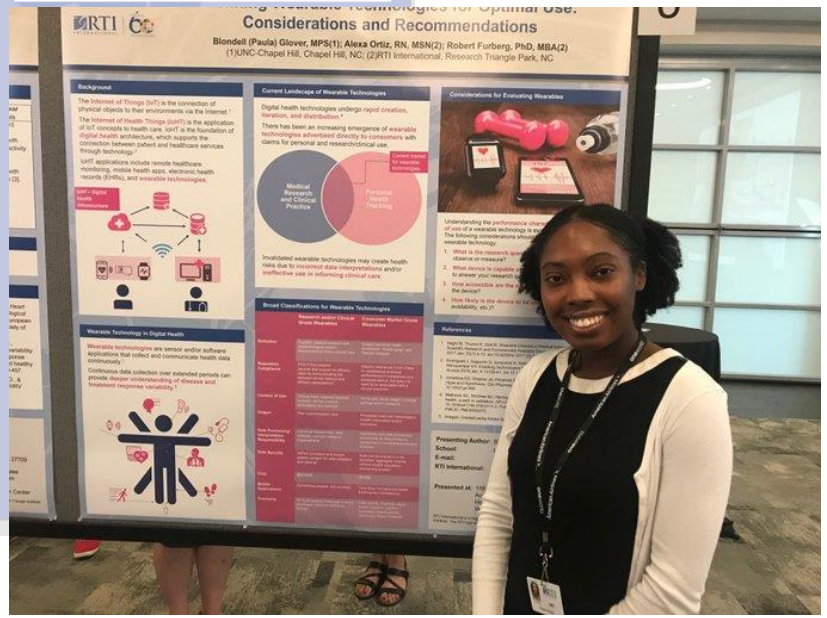
Broad Classifications for Wearable Technologies

	Research and/or Clinical Grade Wearables	Consumer-Market Grade Wearables
Definition	Support medical research and epidemiological partners discovered to inform clinical care	Support personal health awareness, fitness goals, and lifestyle changes
Regulatory Compliance	FDA 510(k)-cleared devices that support an efficacy claim by demonstrating link between device readout and efficacy parameter(s)[5]	May not be cleared as 510(k)-Class II—establishes technical performance comparison to a predicate device, but does not need to be associated with a clinical outcome[6]
Context of Use	Clinical trials, medical research projects, clinical practice, ambulatory care settings	Home-use, some usage in clinical settings and in research
Output	Raw (unprocessed) data	Processed data with interpretation (and the information and/or indicators)
Data Processing/ Interpretation Responsibility	Individual researchers, data analysts, contract research organizations	Algorithms and data processing procedures as determined by companies or ownership/production of device
Data Security	HIPAA compliant and require patient consent for data collection and sharing	Data can be shared in a de-identified, aggregate manner without explicit stipulation concerning access[7]
Cost	$$$-$$$$	$$-$$$
Mobile Applications	Sometimes present, but not likely	Very likely (for personal health tracking and self-collect)
Examples	Fitbit Inspiration, Actigraph Link by Actigraph, Shimmer Sense by Shimmer	Fitbit Activity Trackers, Apple Watch Series 4, Garmin wearables/smartwatches, Samsung Fitness Trackers

Considerations for Evaluating Wearables

Understanding the **performance characteristics** and **context of use** of a wearable technology is essential for **optimal use**. The following considerations should be made when choosing a wearable technology:

1. **What is the research question?** What do you seek to observe or measure?
2. **What device is capable of capturing the data** intended to answer your research question?
3. **How accessible are the data** that are collected/stored by the device?
4. **How likely is the device to be used** (compliance, costs, availability, etc.)?



RTI Intern Showcase—August 12th, 2019

Defining Wearable Technologies for Optimal Use:

Considerations and Recommendations

Presenting Author:
Blondell (Paula) Glover

Authors: Blondell (Paula) Glover, MPS(1); Alexa Ortiz, RN, MSN(2); Robert Furberg, PhD, MBA(2)

(1)UNC-Chapel Hill, Chapel Hill, NC; (2) RTI International, Research Triangle Park, NC

Abstract:

Defining Wearable Technologies for Optimal Use: Considerations and Recommendations

The last decade has seen increased investment in digital health solutions, with roughly $8.2 billion in investments recorded in 2018, and $8.4 billion projected for 2019. Much of the focus for this investment has been around the development of wearable technologies due to their broad applicability in health care, clinical research and personal health education. Consumer wearable technologies represent the subset of wearable technologies that are marketed directly to every-day consumers as having the ability to promote self-education about personal health through quantifiable self-monitoring actions outside of traditional health assessments made by medical professionals. Despite the great economic and intellectual fervor surrounding consumer wearable technologies, there exists equal debate as to their clinical efficacy for use in clinical and research settings as these devices are now being marketed with claims of synonymy with validated medical devices. Claims that consumer wearable technologies can be used in the same way that clinical grade wearable technologies can be used are potentially deleterious to health given that many consumer wearable technologies remain medically unsubstantiated and subject to variation in clinical measurement. Overall, there currently exists no reliable mechanism for identifying and using validated wearable technologies. In this project, an attempt is made to design a base framework for the characterization and summarization of wearable technologies according to essential device qualities. Additionally, recommendations are offered for ideal selection of wearable technologies given three defined usage contexts.

Biosketch:

Blondell P. Glover is a Master's Student at University of North Carolina-Chapel Hill studying Biomedical and Health Informatics with a concentration in Public Health Informatics. She recently completed an internship working with the Digital Health and Clinical Informatics (DHCI) Group at RTI International on a project defining wearable technologies optimally for usage in both clinical and personal contexts. She currently works in clinical research for the University of North Carolina at Chapel Hill in the Division of Pulmonary and Clinical Care Medicine overseeing the administration of clinical trials for pulmonary hypertension. She is graduating in Fall 2019, after which she plans to enroll in a doctoral program in a subspecialty of public health.

Duke Informatics Research Seminar—September 4th, 2019

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