

Guidance for Wearable Health Solutions

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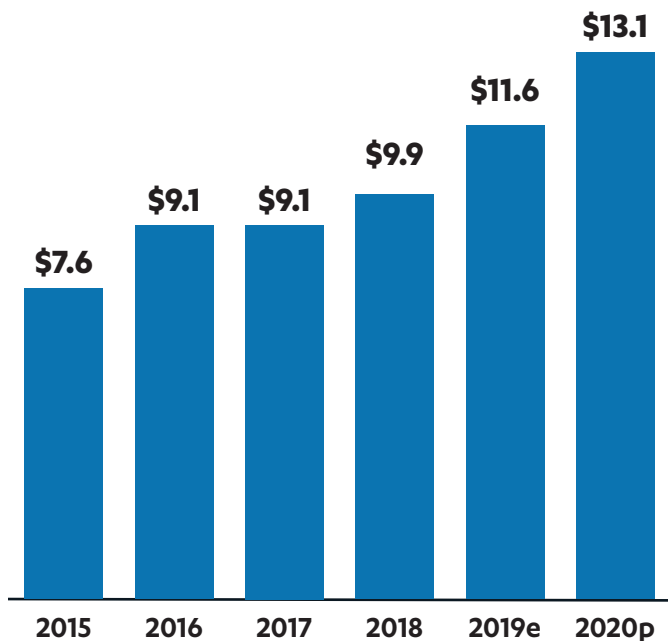


Guidance for Wearable Health Solutions

Since the release of the first smartphone more than a decade ago, the pace of innovation has been dizzying. Smartphones and the mobile apps we download have disrupted countless industries. Publishing, music, television and film, photography, navigation, banking and transportation have been transformed. Even as we try to keep up with these advances, the next wave of technology is here, and we're wearing it.

Wearable technology includes everything from fitness trackers, smartwatches, virtual and augmented reality headsets, smart glasses, earwear, smart clothing and even smart jewelry. It is one of the fastest growing sectors of the technology industry.

HEALTH AND FITNESS TECH REVENUE (\$ Billions)



(Consumer Technology Association, Fig. 1)

WHAT CONSUMERS WANT TO BUY

55% Fitness monitors

46% Smartwatches/Smartglasses

25% Wrist sensors

15% Smart clothing

4% Smart contact lenses

3% Smart tattoos

(Soloman MR. Fashion Or Functionality? Consumers Try To Make Sense Of Wearable Technology. Forbes.com. Fig. 2)

The earliest wearables collected the most basic health information, primarily related to exercise. As they have become smaller, faster and more powerful, they track far more than steps and heart rate. Now, wearables monitor, detect, store and transfer more sophisticated health data. These biometric data include heart rhythm, blood pressure, oxygen levels and more.

As more consumers capture more personal health information with wearables, questions arise:

- How can information from wearables help me better understand and manage my health?
- Can sharing this information help my doctor or nurse better understand my health and manage my care?
- Is my personal health information secure and protected?

Popular Wearables

- Pedometers
- Activity-tracking bands
- Smartwatches
- Smart glasses
- Virtual reality and augmented reality headsets
- Earwear (“hearables”)
- Smart shoes
- Smart clothing
- Smart jewelry
- Mobile electrocardiogram (ECG)
- Mobile blood pressure monitors
- Chest, calf and ankle straps/bands

Most wearables interface with mobile apps.

WHAT CONSUMERS WANT TO TRACK NEXT

55% Would like to monitor blood pressure, up from 46% in 2016.

49% Would like to monitor heart health.

50% Would like to monitor stress, down from 55% in 2016.

33% Would like to monitor blood sugar levels.

(Kraudel, Ryan. National Wearables Survey Reveals Accelerating Convergence of Consumer Wearables and Personal Health & Medical Devices. Valencell., Fig. 3)

Types of Biometric Data Collected

- Steps
- Time of activity
- Calories burned
- Heart rate (heart rate variability)
- Heart rhythm
- ECG
- Blood pressure
- Sleep quantity and quality
- Glucose level
- Oxygen level
- Body temperature
- Brainwaves (electroencephalogram)
- Muscle biosignals (electromyography)
- Cardiorespiratory function
- Movement patterns
- Sweat analysis
- Tissue oxygenation
- Emotional state
- Cognitive function



Participating in your own health

Wearable technology helps us understand our health¹ in three ways:

1. By tracking our own daily activity
2. By sharing daily activity with friends, peers and family
3. By sharing personal health information with a clinician (e.g., doctor, nurse, physician assistant, physical or occupational therapist or other professional providing medical care), coach or trainer

Today's wearable technologies, with sensors and mobile applications, have made tracking our activity effortless. Most are widely available, affordable, easy to use, comfortable and even fashionable. Tracking can boost our motivation to exercise and adopt healthy lifestyle changes.² When mobile apps make it easy to share our achievements with others, take part in fitness challenges or get real-time feedback and coaching,³ motivation increases.⁴ This accountability to one's self, and to peers, has been shown to increase physical activity and healthy behaviors.³

Individuals motivated to take part in their own health are enthusiastic about tracking data not only for

their own use but also to share. One survey found that 58% are willing to share their health data with their doctor⁵ to get a more accurate diagnosis and treatment solutions. Nearly three in four individuals believe that these data will one day be able to directly affect their health.⁶

Sharing data with your doctor or nurse

Many clinicians share this optimism. Wearable technology has the potential to help them access the right data at the right time. This offers promise for earlier and more accurate diagnoses, more personalized treatments and better outcomes. In a recent survey, 62% of doctors said they believe wearable devices would increase the overall quality of care for their patients.⁷ Nearly two-thirds are excited about the growing use of technology within their field of medicine.⁵

Two-thirds of users believe wearable technology has positively affected their health and activity.⁸ At the same time, evidence suggests a gap between wearable use and changing behavior. Some studies show fitness trackers do not lead to weight loss, a reduction in cholesterol or blood pressure or fewer heart attacks or strokes or extend life.² But the underlying premise holds strong for many clinicians: better engaged patients can lead to better outcomes.

Active engagement in managing chronic health conditions such as diabetes or heart disease does have an upside. For conditions such as these and many others, prevention is essential, as is screening to identify individuals at risk. Potential benefits of wearables in chronic disease include:

- Promotion of healthy behaviors to improve the course of the disease (e.g., a sense of empowerment to take control of one's disease)
- Increased feelings of safety and confidence, and reduced fear and stress
- Detection of life-threatening conditions or of underlying disease when there are no signs or symptoms
- Collection of valuable biometric data to share with a clinician, coach or trainer
- Elimination of office visits when clinicians have remote access to data
- Actionable alerts that can serve as medication

reminders or notify emergency medical services in the case of a life-threatening medical event

Wearables allow clinicians to look at biometric data in context. When captured over time, versus in limited episodes, data can offer a more complete perspective of an individual's health. This brings a new dimension to clinical monitoring, particularly in a nonclinical setting.

Widespread use of these technologies is not without its challenges. For some individuals, access to this technology is not a given. Some wearables can be expensive, and almost all rely on access to smartphones and/or internet connectivity. For clinicians and health systems, managing and interpreting large volumes of continuous monitoring data from wearables presents an enormous challenge. To make most effective use of these data, it will need to be integrated into clinicians' workflow. This is an important step in overcoming obstacles related to the storage, privacy and security of data.

TYPES OF DATA COLLECTION

1. Random or periodic data collection

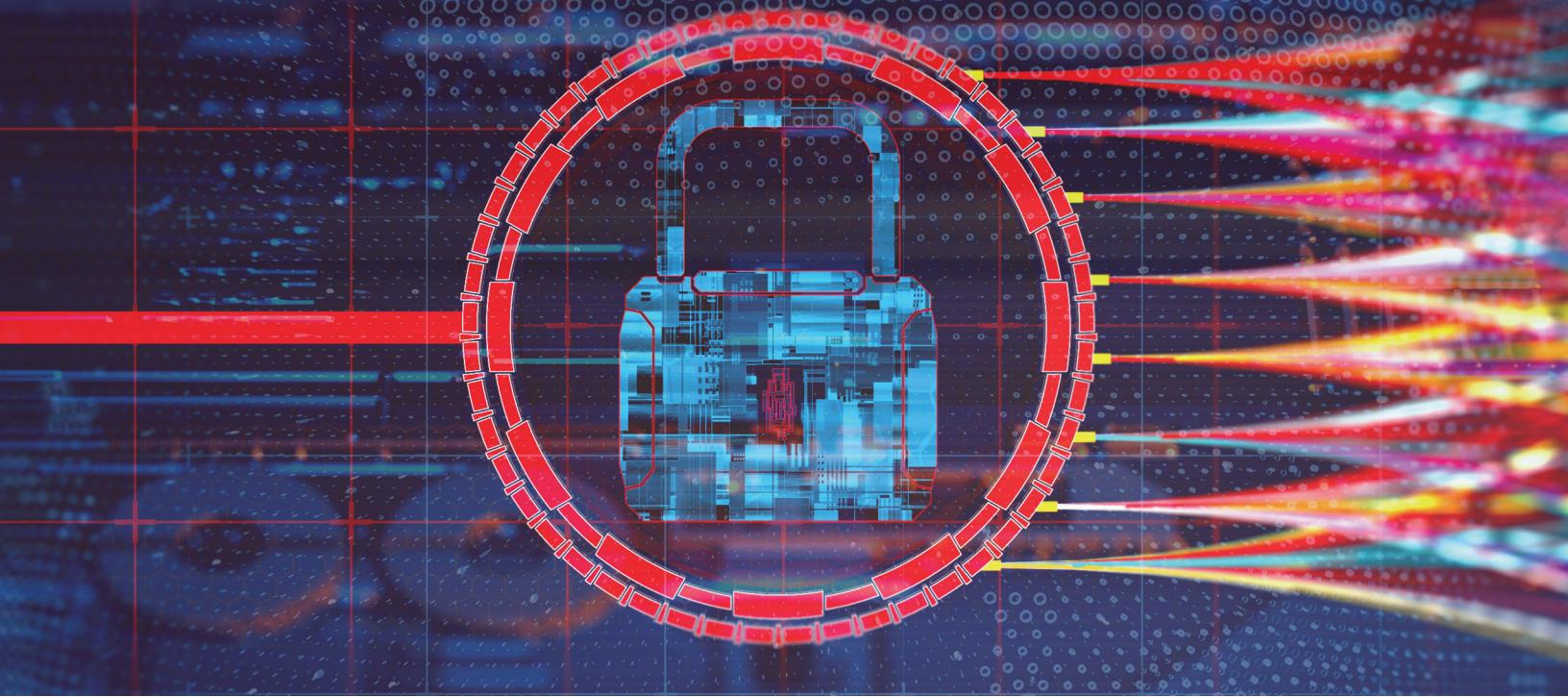
- We've been collecting data randomly or periodically for decades. Think blood pressure or weight.
- Digital technology enables efficient data storing, monitoring and tracking of long-term progression.
- Wearables enable more frequent measurements to reflect changes over time.

2. Intermittent or symptom-driven data collection (*for patients with symptoms*)

- When we know symptoms are episodic in nature, such as heart palpitations, we can be prepared to record biometric data as symptoms occur. The user activates a device to initiate data collection.
- Wearables are ideal for recording a variety of biometric data points during an episode of symptoms.
- Analysis of these data can help with diagnosis, follow-up, management and response to treatment.

3. Continuous data collection (*for patients without symptoms*)

- Data collection is done continuously in order to record accurate and valuable information over time, often to identify patterns (e.g., daily activity, sleep pattern, fall risk*).
- * Although certain conditions such as atrial fibrillation or sleep apnea would be considered intermittent, continuous monitoring helps identify the conditions when symptoms are not present. Continuous monitoring is important because medical intervention may be required.*
- It does not rely on the user to activate but instead passively collects biometric data.



Tackling data privacy and security

As wearable technology becomes integrated with our personal health, innovation meets regulation. Several federal agencies play a role in regulating wearable technologies. These include the Department of Health and Human Services (HHS), Food and Drug Administration (FDA), HHS Office of Civil Rights, Federal Communications Commission and Federal Trade Commission.

The Health Insurance Portability and Accountability Act, known as HIPAA, created sweeping safeguards for data privacy and security for health records and has been the standard for the past 25 years. Innovation has since led to new challenges in protecting consumers' private health data and, in particular, data obtained from wearable health devices or health and wellness apps. In the state of California, a new wide-reaching data privacy law impacts wearables, fitness and lifestyle apps and personal health records. Many see it as an example for other states.

Nongovernmental groups have also recognized the pressing need for guidelines around personal health

information. Professional medical societies, technology associations and advocacy groups have established their own guidelines, standards and regulations. The Consumer Technology Association recently published its *Guiding Principles for the Privacy of Personal Health and Wellness Information*,⁹ a voluntary roadmap for companies to be good data stewards and maintain consumer trust.

Are you reading the fine print?

For consumers, reading the fine print is a crucial step when it comes to protecting personal health information. What should I look for? Is the company open and transparent about the data they will collect and how it will be used and/or shared? Do they ensure you have access and control over your data? Do they detail the security and safeguards in place to protect your data?

When you look closely at the privacy policy, you may learn that although you own your device, you may not own your data, and that data may be shared with third parties. Consider what data to share, as "anonymous data" can include your location, age, sex, height and weight. Current federal laws do not prevent the sale of most fitness-related information to third parties.

Managing a wave of data

The potential tsunami of data from wearables presents issues beyond privacy and security. Healthcare organizations will need to invest in robust technology and infrastructure. They will need to ensure the data collected are properly encrypted, summarized and imported into an electronic health record.

For clinicians already facing time constraints, reviewing data from tens or hundreds of patients can be daunting. That's not the only change. Clinicians have traditionally been the gatekeepers of health information. That role is changing as patients want access to, and control of, their own health data.

The makers of wearable devices find themselves right in the middle of this relationship. These companies recognize the growing potential for wearables in the clinical setting. Wearables also promote empowerment by helping individuals take control over their own health. At the same time, these companies need to address the challenges of integration, readability and understandability of the captured health data in order to ensure its proper use.

Guidelines can serve as guardrails to help avoid unintended consequences. This is especially true when developed with input from consumers and patients, healthcare providers and specialty groups, technology firms, public health and/or policy experts and device manufacturers. Guidelines also need to adhere to a version of the physician's Hippocratic Oath, "first do no harm," to minimize downsides such as unnecessary testing, inaccurate test results, inequity in access, increased costs or frustration among any of the stakeholders.

SIMPLE ADVICE WHEN CONSIDERING BUYING WEARABLE TECHNOLOGY

- **Take control of your health.**
 - o Wearables provide real-time information for monitoring, motivating and managing your health.
- **Focus on prevention.**
 - o Wearables can support activities for healthy living.
- **Know your data.**
 - o The ability to track and monitor your health over time with wearables can help you identify the normal versus abnormal.
- **Set goals.**
 - o Identify one to two goals that are realistic and fit your personal lifestyle.
- **Keep it simple.**
 - o Choose the technology and apps that support your goals.

PROS AND CONS OF WEARABLE TECH

Pros

- Immediate access to real-time health data
- Motivation and encouragement, particularly when engaging with social communities
- Accountability through tracking and monitoring progress
- Potential for early detection of acute and chronic conditions
- Enhanced patient-clinician relationship
- Improved clinical decision-making

Cons

- Varying data accuracy and potential for false readings
- Unproven health benefits
- Limited accessibility due to costs or internet access
- Data overload for you and your clinician
- Not yet able to integrate with health records
- Data security and privacy concerns

FAQs: Wearable tech and heart health

I have the technology; now how often should I check my heart rate?

It is important to remember that most people do not need to have continuous activity or heart rate monitoring for clinical reasons. Most wearables are primarily suited for fitness and wellness. Second, wearables are not a substitute for medical devices prescribed by a clinician. For example, your doctor might give you a 24-hour blood pressure monitor or continuous ECG monitor to wear for several days. These devices are medically approved and will give your doctor the information they need to manage your health.

What is a high heart rate?

Many wearable devices can detect and record heart rate for you and help spot changes over time. Your heart rate can go up or down for a variety of reasons. For example, if you have a cold or fever, you may see an increase in your heart rate. Abrupt changes in heart rate, or an irregular rhythm notification seen in some smartwatches, may signify an abnormal heart rhythm. You should contact your clinician if you notice any changes that concern you.

What if my device detects something abnormal?

When using a wearable to track heart rhythm or blood pressure, it is important to understand what's normal for you as an average adult. Talk to your clinician about what is normal for you. If you experience symptoms such as a rapid heart rate, or the feeling that your chest is pounding, fluttering or flopping, your clinician may use a medically approved device to detect your heart rhythm via an ECG. An ECG is a graph of the electrical activity of your heart and can determine heart rate and rhythm.

What do I do with the data?

Most wearables come with a mobile app that collects and tracks data for you. These apps will help you understand what the data means and track it for you over time. If you notice significant changes over time or repeating events, you may have a health problem. The collection of data over time will help your clinician understand what's going on and help him or her determine the next best course of action, if any.

When do I call my doctor?

It is important, even in healthy individuals, to have regular checkups with your doctor or other clinician. If you're not feeling well or have symptoms such as rapid heart rate, dizziness or fluttering or flopping in your heart, you should talk to your clinician. If you get a notification, such as "possible atrial fibrillation," from your device or something is not normal (e.g., high or low heart rate, high or low blood pressure), continue to monitor and talk to your clinician. If you get a notification from your device and you're taking medication, do not start, stop or make any changes to your medications without speaking to your clinician first.

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Sources

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Fig. 2 Solomon MR. Fashion Or Functionality? Consumers Try To Make Sense Of Wearable Technology. Forbes.com. Published July 2018. <https://www.forbes.com/sites/michaelsolomon/2018/06/21/how-will-consumers-make-sense-of-wearable-technology/#3c51823b6e9b>

Fig. 3 Kraudel R. National Wearables Survey Reveals Accelerating Convergence of Consumer Wearables and Personal Health & Medical Devices. VALENCELL. Published November 29, 2018. <https://valencell.com/press/2018/11/national-wearables-survey-reveals-accelerating-convergence-of-consumer-wearables-and-personal-health-medical-devices/>

CONTRIBUTING AUTHORS

Nassir F. Marrouche,¹ David Rhew,² Nazem Akoum,³ Heidi Dohse,⁴ Tony Faranesh,⁵ Robin A. Leahy,⁶ Jim Li,⁷ Nicholas S. Peters,⁸ René Quashie,⁹ Khaldoun G. Tarakji,¹⁰ Mintu P. Turakhia,¹¹ Christina J. Wurster¹²

¹Tulane University School of Medicine, New Orleans, Louisiana, ²Microsoft, Seattle, Washington, ³University of Washington, Seattle Washington, ⁴Tour de Heart, Hailey, Idaho, ⁵FitBit, San Francisco, California, ⁶Sanger Heart and Vascular Institute, Charlotte, North Carolina, ⁷Omron, Chicago, Illinois, ⁸St. Mary's Hospital, Imperial College, London, England ⁹Consumer Technology Association, Arlington, Virginia, ¹⁰Cleveland Clinic, Cleveland, Ohio, ¹¹Stanford University, Palo Alto, California, ¹²Heart Rhythm Society, Washington, District of Columbia.

About



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Heart Rhythm Society

The Heart Rhythm Society (HRS) is the leading global resource on heart rhythm disorders. HRS represents medical, allied health and science professionals from more than 72 countries. Its mission is to improve the care of patients by promoting research, education and optimal health care policies and standards.

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