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Big Ideas In The Big Easy

Integrating Consumer-Facing Devices Into Clinical Care

by Brian Bossetta

Medical experts at the American College of Cardiology Expo in New Orleans discussed the latest trends in wearable health technology and what it all means for patients receiving clinical care.

Medtech innovators have flooded the market with wearable devices that have forever changed the healthcare landscape, according to a top cardiologist who discussed the technology at the American College of Cardiology Expo (ACC.23) in New Orleans earlier this month.

Mostafa Al-Alusi, a cardiologist at Massachusetts General Hospital in Boston, said wearable cardiac devices from tech manufacturers that monitor the heart and can take an electrocardiogram (ECG) at the touch of a finger have shifted the healthcare paradigm.

“Physicians are no longer the gatekeepers to physiologic data,” Al-Alusi said.

Since Fitbit released its fitness tracker in 2009, wearable cardiac devices – such as watches from Apple, Samsung, and Pixel and the handheld cardiac monitor KardiaMobile from AliveCor – have become ubiquitous.

Athletes wear them to improve performance and patients use them to send vital data to their doctors to manage conditions such as atrial fibrillation (AF), a common type of arrythmia many of these devices are designed to detect.

There are more than 100,000 mobile health apps – of which 500 target AF – and 400 wearable activity monitors currently on the market, according to the *Expert Review of Medical Devices*, a monthly peer-reviewed journal on medical device research.

Yet, despite its skyrocketing popularity, wearable technology is relatively new. As Al-Alusi

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noted, the Apple Watch ECG feature wasn't released until 2018. "So, we're still in the early phase of the exponential rise of wearables," he said.

The more significant trend, however, is that the data generated from these devices are increasingly being incorporated by physicians into the clinical care of the patients wearing them.

And while this has enormous benefits for patients, such as potentially detecting a rhythm disturbance like AF that might have otherwise gone undiagnosed, the technology presents challenges as well – both for physicians and patients.

Data Overload

Because so many people are wearing smart watches today for tracking workouts and checking text messages, millions of ECGs are being recorded that never would have been before the technology became widely available, Al-Alusi said, which means there are more ECGs being taken outside of the clinical setting than ever before.

So, what does the prevalence of these wearables and the data they collect ultimately mean? Difficult challenges, in Al-Alusi's view, but incredible opportunities as well.

For doctors, the main challenge is processing the amount of data pouring in from patients using and wearing these devices. To illustrate this point, Al-Alusi titled his presentation at ACC.23, "Doc, I Just Sent You 25 ECGs, Can You Look At Them?"

> *"If AF is detected, you will see the message 'Possible AF Detected.' This result is not a diagnosis, only a possible finding." – AliveCor*

But the opportunity from these devices, in Al-Alusi's view, presents a more interesting question – that being, how do doctors harness the ability to check an ECG taken anytime from anywhere to promote the health of patients?

Al-Alusi offered the common scenario of an unsuspecting runner whose smart watch detects AF. The next step would be to order a clinical test to confirm the accuracy of the wearable result.

But this protocol presents further problems.

First, the only check on the volume of data being sent to physicians from wearable devices is the

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patient wearing the device and sending the data. On top of that, Al-Alusi noted, as these devices become even more popular and the population using them ages, more abnormal ECGs will be sent to doctors with the expectation that each one will be reviewed.

“That is hardly sustainable,” he said.

Panel member Jeff Healey, Yusuf Chair of Cardiology at McMaster University, Hamilton, Ontario, also weighed the pros and cons of the growing technology.

While wearable devices might pick up AF or some other issue, the downside includes the anxiety of false positives, over-use of the technology by those with low disease prevalence, as well as the substantial workload the massive amounts of data these devices generate imposes on clinicians and staff.

Still, Healey said the technology is a net positive for patients, though he added further diagnostics in a clinical setting to confirm readings from a smart watch should occur as soon as possible.

Another problem for doctors is not only uploading all the data from these devices but integrating that data into a patient’s electronic health record.

“So, the end result is that all these devices might help us diagnose AF, but they do so at the cost of duplicative testing and a high administrative burden,” Al-Alusi said. “I think we can do better.”

And he has a solution.

Wearables Clinic

A “wearables clinic,” in Al-Alusi’s view, could potentially solve the problem posed by data from wearable devices. He proposes that these clinics would operate similarly to clinics for patients with pacemakers and other implantable cardiac devices, where health care professionals directly monitor the flow of data.

In such a clinic, patients would register their devices with physicians, allowing for the transmission of ECGs in real time. Though the device manufacturer’s algorithms would still read the ECGs, a second set of ECG interpretation algorithms particular to that clinic would process them.

“The key here is that instead of the data being self-filtered by patients, we would collect all of it,” Al-Alusi said. “And we would filter it using these algorithms whose performance in the real world we can monitor on an ongoing basis.”

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Using this method, medical staff would view an abnormality detected by an algorithm. A cardiologist would then follow up a patient about abnormal results to collect history, modify or begin therapy, or facilitate more testing as needed.

Further, the collected data would be integrated automatically into the electronic health record to document new diagnoses, which reduce the problem of duplicative testing.

"So, this system addresses the volume of wearables data by filtering it in a scalable, evidence-based manner," Al-Alusi said.

AliveCor offers a similar service for KardiaMobile users, but for a fee. The "clinician review" feature sends ECGs directly to a cardiologist for $25 per review. ECGs, according to AliveCor, are reviewed within 24 hours either confirming the device's reading or providing a different analysis.

Deep Learning

With all these challenges, however, comes opportunity; most importantly, Al-Alusi said, the ability to promote the health of patients "in ways that were previously impossible."

And what makes this possible?

Deep learning, a branch of artificial intelligence that specializes in extracting information from high-dimensional input, such as raw ECG data.

Al-Alusi said that recent studies have shown ECGs and deep learning have the capacity to assess not only AF, but other risk factors, such as left ventricular systolic dysfunction (LVSD), and even heart transplant rejection risk based on ECGs that might appear normal to even an experienced cardiologist.

As it stands now, a patient with only normal ECGs gets no benefit from sending those scans to a physician. However, if a patient with normal ECGs has other risk factors, applying deep learning algorithms could provide a multi-tiered screening strategy for the early detection of cardiac disease.

Deep learning is also rapidly improving the accuracy of automated ECG interpretation, Al-Alusi added.

"In this type of system, we seize that opportunity afforded by wearable ECGs to benefit patients in ways that were not previously possible," he said.

Al-Alusi emphasized that such a system is not a "distant dream." Research is already validating the fusion of deep learning and wearable ECGs for diagnostic purposes.

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For example, a 2022 study published in the American Heart Association's *Circulation* showed "deep learning models using ECG to estimate AF risk are robust and valid across contrasting populations when assessed using rigorous epidemiologic metrics."

So, if the technology to enhance ECGs with deep learning already exists, what is standing in the way of its implementation?

Financial models, or lack of them, according to Al-Alusi.

While Medicare expanded reimbursement for remote monitoring in its 2022 Physician Fee Schedule, billing for it requires impractically high minimum thresholds, Al-Alusi said. Traditional billing codes for ECGs require a physician order, which does not support patient-initiated transmissions from wearable devices.

Though Al-Alusi noted there are promising steps that would remove these barriers, such as new billing codes for patient-initiated blood pressure monitoring, they do not yet apply to patient-initiated ECGs.

Legal Questions

While algorithms that interpret ECGs are good, Al-Alusi cautioned "they are not perfect," which brings up the question of liability when there's patient harm due to a faulty reading or interpretation.

"Until providers are comfortable with the risks they bear in using AI, this will remain a significant barrier," he said. "There's also the question of privacy and securing the personal data sent to clinicians from patients as well as questions of data ownership to ensure that the data is accessible wherever patients receive their care."

Jessica Orchard, a senior cardiac research fellow at the University of Sydney, Australia, who also has a legal background, noted that the security of the data generated by these devices is not sufficiently covered by most regulatory regimes, including in the US under the Health Insurance Portability and Accountability Act, or HIPAA.

For its part, AliveCor says it is HIPAA-compliant and that all data on its servers are encrypted at rest and in transit.

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But as Orchard pointed out, data collected in the US that are anonymous or not sent to a physician are not considered "personal health information" and therefore not protected under HIPAA.

"So even though consumers do have a legitimate expectation of privacy in relation to their health data, they often do not own the data generated by these apps and have little control or knowledge about how the information or digital footprint is actually used," Orchard said.

This ambiguity is concerning because it could result in the sharing of wearable data with third parties, such as advertisers, social media sites, insurance companies, and even employers.

> ***"Consumers may not understand that these devices at the moment focus much more on heart rhythm than anything else, and that a normal result doesn't necessarily preclude other cardiac conditions." – Jessica Orchard***

Worse for device wearers, user agreements are essentially "take it or leave it" choices with varying degrees of protection and are usually neither read nor understood by most consumers.

"And even if you did read it there's no opportunity to amend or negotiate the terms," Orchard said. "Basically, people are taking a lot on trust here with their personal information."

Apple says its watches are designed with security and privacy in mind and that when iPhones are locked, the health data of the owner is encrypted even when that data is synched with the iCloud.

Not a Diagnosis

The legal and ethical questions that arise from wearables are not just for patients and consumers. They concern physicians as well.

For instance, with no established process for review or standard of care for managing AF from wearable devices – and no system in place to manage the data overload sent from patient devices – physicians have to balance doing too much to treat AF against doing too little.

Manufacturers like Apple, however, are quick to point out that their products are intended to aid, not replace, medical professionals.

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Irregular rhythms detected by an Apple Watch, the company says, "may be suggestive" of AF. The company says that the feature "won't detect all instances" of AF but could provide patients with an early indication of something "that may warrant further evaluation."

Apple also points out that its ECG app cannot detect a heart attack, blood clots or stroke and that wearers should immediately contact 911 if they experience heart-related symptoms.

And while AliveCor says its AF detector is highly accurate – 97% sensitivity and 98% specificity – the result "is not a diagnosis, only a possible finding" and recommends sharing the result with a medical professional.

So, what then are the legal ramifications for a physician who fails to provide appropriate care to a patient to prevent a pending health problem that might revealed in the uploaded data from a wearable device? Should physicians allow patients to email them all their data? Or should they require patients to make an appointment to discuss the data? How do physicians navigate this changing landscape?

The problem for physicians, Orchard said, is that there is not much case law or precedent to guide them. Physicians that allow patients to email data but fail to review it or respond to the sender, she cautioned, are taking a potential legal risk.

"I think the only thing you can't do is nothing," she said.

> ***"The pace of technological advancements in wearable sensors and AI is outstripping our ability to incorporate them into clinical practice." – Mostafa Al-Alusi***

But Orchard remains optimistic that as time passes and technology advances there will be more answers and guiding documents produced to help physicians take advantage of these tools so they can better care for their patients while managing the benefits and risks of these devices.

And that's just not good news for physicians, but consumers and patients as well. Because these devices, Orchard said, have an enormous upside, particularly the ability for a patient to record an event that can lead to a quicker diagnosis, treatment, and improved health outcome.

Limitations

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As with all technology, however, ECGs from wearables, even those enhanced by deep learning, has its limitations – and it's incumbent on providers and manufacturers to communicate these limitations to patients, especially as the number of conditions these devices can detect increases.

Consumers should know that these devices, no matter how advanced, are not always accurate, Orchard said, and that uncertainty over indeterminate readings can create unnecessary anxiety.

"Also, consumers may not understand that these devices at the moment focus much more on heart rhythm than anything else, and that a normal result doesn't necessarily preclude other cardiac conditions," she said.

What is certain, however, is that wearable ECGs and other smart devices are here to stay and the technology that powers them is only getting more sophisticated and more deeply integrated into health care.

Orchard said there are regulatory gaps that need to be closed as well as better enforcement of legislation that already exists concerning this technology, particularly around data sharing.

But realizing the full potential and promise of these devices, Al-Alusi said, will require cooperation across the entirety of the health care continuum.

"We live in a truly exciting time when the pace of technological advancements in wearable sensors and AI is outstripping our ability to incorporate them into clinical practice," he said. "So, while the technology is all there, it's on us to make sure we use it for the benefit of our patients."

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