

The Digital Pill

Ten years ago, the smartphone united two existing technologies — the telephone and Internet — to revolutionize global communication. Today, we are experiencing a revolution in healthcare, with powerful medicine and innovative technology coming together to transform the way we treat patients and manage diseases.

On November 13, 2017, the U.S. Food and Drug Administration (FDA) approved Abilify MyCite (aripiprazole tablets with sensor), the first pill to include a digital sensor that tracks if and when it has been ingested. Developed by Otsuka Pharmaceuticals, the non-digital form of Abilify was first approved by the FDA in 2002, and has since become the top-selling drug in the United States. Abilify, and its generic version, aripiprazole, are used to treat schizophrenia, bipolar disorder and — in combination with other medications — major depressive disorder. Abilify MyCite combines the traditional pharmaceutical formulation with an ingestible sensor technology, made by Proteus Digital Health, to enable patients and their caregivers to monitor — and ultimately increase — medication adherence and treatment compliance.

Though it has yet to be proven, the digital pill's potential to improve medication adherence is significant. According to an article published in Risk Management and Healthcare Policy, medication nonadherence poses a substantial public health concern, affecting patients from all socioeconomic backgrounds and disease states. Rates of nonadherence range from 25% to 50%, contributing to poor clinical outcomes and representing \$100 to \$300 billion of avoidable healthcare costs each year.

Medication nonadherence is particularly likely to occur in patients receiving treatment for mental illness, and the more vulnerable the patient is, the less likely they are to be compliant with their treatment. In severe cases, this noncompliance can lead to deterioration and hospitalization. The typical hospital stay for mental health treatment can be up to 30 days, and with every relapse, a patient's prognosis worsens.

The purpose of the digital pill is to give patients greater control over their healthcare. By supporting adherence to a voluntary treatment regimen, the digital pill is giving patients the tools to manage their treatment and

activate their support systems (caregivers, treatment providers) to minimize the risk of relapse. For psychiatric patients, it is an alternative to more invasive interventions, such as mandatory hospitalizations, long-acting antipsychotic injections and home visits. For the broader patient population, it can be used to guard against forgetfulness, or to ensure that medication is taken as prescribed.

Once adopted, the digital pill will facilitate the collection of accurate, objective data on medication adherence. A treasure trove for researchers, data collected from the digital pill could aid in the development of proactive, evidence-based screening methods — like questionnaires — that clinicians could use to identify the patients most likely to struggle with compliance. With a triage method in place, providers would be better able to deploy limited resources in support of high-risk individuals.

Advances in Digital Health

For decades, clinicians have viewed the pa-

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tient through a narrow lens. But the aperture is beginning to widen. Advances in digital health allow us to collect and measure all of the data we emit as patients — from smartphones and watches to other wearable devices — and transform it into useable, meaningful information. Smartphone activity in the middle of the night could indicate disturbed sleep patterns, while changing language patterns in text messages might reveal a dangerous shift in mood. By piecing together genetic, behavioral and social clues, clinicians will be able to deliver a more personalized and predictive form of patient care.

Although there are certainly ethical considerations to address, the promise of digital health is undeniable. Where data and medicine intersect, there will always be questions regarding privacy and choice. And just as we have since the arrival of the smartphone, we will reason ourselves through the adoption of rules and guidance that make sense, because we recognize that the greatest risk is maintaining the status quo. ^{PV}

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