

Comments on Abilify MyCite

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In mid-November 2017, the U.S. Food and Drug Administration approved the first medication in the U.S. with a digital ingestion tracking system. Abilify MyCite (aripiprazole tablets with sensor) has an ingestible sensor embedded in the pill that records that the medication was taken. The product is approved for the treatment of schizophrenia, acute treatment of manic and mixed episodes associated with bipolar I disorder and for use as an add-on treatment for depression in adults.

The sensor, containing copper, magnesium and silicon (safe ingredients found in foods), generates an electrical signal when it comes in contact with stomach fluid, like a potato battery. After several minutes, the signal is detected by a Band-Aid-like patch that must be worn on the left rib cage and replaced after seven days. The patch sends the date and time that the pill was taken and the patient's activity level via Bluetooth to a cell phone app. The app allows patients to add their mood and the hours that they have rested and then transmits the information to a database that physicians and others who have patients' permission can access.

In my opinion, the approval is a significant step in harnessing new technologies to assist in disease management. Those of us who treat individuals with any chronic illness know the challenge that adherence poses, and those of us who treat patients with schizophrenia are all-too-aware of the additional factors that can influence medication taking in such individuals. At the same time, we know that non-adherence is the most frequent reason for relapse/hospitalization.

Though the impact of MyCite on adherence and relapse rates has not been established, this will be the next step. When we first studied this technology several years

ago, our initial concern was acceptability to patients and whether or not the use of such technology would lead to an exacerbation of symptoms among individuals whose illness predisposes them to false beliefs regarding influence, outside control, the ill intent of others, etc.

In the June 2013 *Journal of Clinical Psychiatry*, we reported the results of using the digital sensor technology in 16 patients with schizophrenia and 12 patients with bipolar disorder. (For the purposes of the study, the pill with the embedded sensor was not pharmacologically active.) Study results were positive. No subjects experienced worsening of psychosis due to use of the digital tablets. Of the 27 patients who completed the study, 19 found the digital medicine concept easy to understand, and 24 said they believed it would be useful.

To me, the potential goal here is providing important information to patients about their own medication-taking habits and accurate data that can help to facilitate discussion between patient and psychiatrist (as well as loved ones or other members of the treatment team if the patient wishes).

I know that comments have been made as to how odd it is that psychosis was chosen as an indication for such technology, but such concerns can also result in our patients being the last to benefit from technological advances. As with any new technology, the benefits and risks need to be assessed and understood, but I am pleased that we chose not to discriminate against those who might in fact benefit most from such opportunities. Most non-adherence is not willful refusal to take medication on the part of the patient (and such patients would be unlikely to agree to use such technology); therefore, accurate information and feedback can be key in helping patients to derive the full benefits of the medication that has been prescribed.

I firmly believe that non-adherence has to be normalized—not stigmatized. It is human nature to have trouble taking medicine on a regular basis and the application of new technology should be done in that spirit. What the patient, the family and the treatment team need is an open dialogue, based on *accurate* information about medication-taking habits. This will enable us to better address the root causes of non-adherence, whatever they are.

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Of course, new technologies can be misused. Yes, there are privacy and data security issues, as there are across our modern, everyday lives and these are being addressed. Yes, there are potential ethical concerns and these too are being addressed. But in my opinion, the potential benefits can outweigh the potential risks, and this is a very exciting development. Our patients and we have never had real-time feedback on medication taking.

Disclosures

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Cellular Therapies, Janssen Pharmaceutica, Johnson and Johnson, Neurocrine, Otsuka, Pierre Fabre, Proteus Digital Health, Reviva, Roche, Sunovion, Takeda and Teva. Dr. Kane has received grant support from Otsuka, Proteus Digital Health and Janssen. Dr. Kane has participated in Advisory Boards for Alkermes, Intra-Cellular Therapies, Lundbeck, Neurocrine, Otsuka, Pierre Fabre, Takeda, Teva. Dr. Kane is a shareholder in Vanguard Research Group and LB Pharmaceuticals, Inc.

Kane JM, Perlis RH, DiCarlo LA, Au-Yeung K, Duong J, Petrides G. First experience with a wireless system incorporating physiologic assessments and direct confirmation of digital tablet ingestions in ambulatory patients with schizophrenia or bipolar disorder. *J Clin Psychiatry* 2013;74(6):e533-540. doi: 10.4088/JCP.12m08222.