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Ethical Implications of Digital Feedback in Psychiatric Medications

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Abstract

Given the significant burden of untreated mental health conditions as a result of medication non-adherence, new and innovative treatment methods are needed. In November 2017, the FDA released *Abilify (aripiprazole) MyCite*, the first psychiatric medication with a digital sensor that has the ability to track whether a pill has been ingested. *Abilify MyCite* has generated controversy and questions, including concern for unnecessary surveillance and the possibility of coercion for a vulnerable patient population. *Abilify MyCite* has the potential to improve medication adherence and outcomes in mental health conditions; however, innovation must be carefully balanced with autonomy and privacy to ensure the best interest of one of the most vulnerable populations in healthcare is upheld.

Key Words

Abilify MyCite, Ethics, Adherence, Technology

Introduction

Aripiprazole, a second generation antipsychotic, is known to effectively treat the effects of psychosis, mania, and depression. Consistent adherence to psychiatric medications such as

aripiprazole can stabilize symptoms, limit hospitalizations, and prevent the neurodegenerative effects of chronic mental health conditions. However, adherence to any medication, in particular psychiatric medications, can be difficult. With healthcare-related costs attributed to medication non-adherence estimated to be as high as $100 billion dollars (Osterberg & Blaschke, 2005), there is a significant need for innovative methods to improve the consistency in which all patients, not just patients with mental health conditions, take prescribed medications.

In November 2017, the FDA released *Abilify* (aripiprazole) *MyCite*, the first psychiatric medication with a digital sensor that has the ability to track whether a pill has been ingested. *Abilify MyCite* contains a sensor the size of a grain of salt, which becomes activated by digestive contents of the stomach. The sensor sends a Bluetooth signal to a wearable patch, and information is then recorded and sent to a smartphone-based application where adherence can be monitored. Patients can also opt to allow up to four people access to this information, including their physician (U.S. Food and Drug Administration, 2017). This process, known as digital feedback technology, does not come without controversy. Researchers and experts in the field recognize the importance and potential benefit of a medication that can improve adherence; however, some contend that there are significant ethical implications which should limit the use of *Abilify MyCite*, especially since there is currently no data yet to support its effectiveness in improving treatment adherence (U.S. Food and Drug Administration, 2017).

In Favor of Digital Feedback Therapies

Proponents of *Abilify MyCite* are encouraged that the unique monitoring system could help patients become more accountable to their medications and enhance motivation for establishing habits of adherence. Those in favor suggest that monitoring of adherence could

allow physicians to be more involved in their patient's treatment, allowing for earlier interventions and inquiries about possible side effects when medication non-adherence is identified. Close monitoring of adherence could provide frequent opportunities for contact by clinicians, helping patients with poor health literacy better understand their condition and the importance of medication adherence while building a more trusting alliance with their provider. By improving medication adherence, digital feedback therapy could improve quality of care, limit hospitalizations, and prevent the deleterious effects of untreated mental health conditions on brain integrity (Andreasen, Liu, Ziebell, Vora, & Ho, 2013).

Improved adherence would also mitigate the risk of significant psychiatric decompensation. Patients with poor medication adherence often have limited or no insight into their condition, which can result in involuntary treatments with intramuscular injections. Involuntary treatment is one of the most ethically challenging considerations in psychiatry; however, it is the standard of treatment when providers have determined that untreated mental illness would result in a significant and foreseeable risk to the patient or community. Involuntary treatment with intramuscular medications has inherent risk and trauma associated with it, and strategies such as digital feedback monitoring that can potentially improve adherence and enable treatment in a less restrictive and traumatic environment should be invited.

Initial studies with digital health feedback systems such as *Abilify MyCite* have yielded encouraging results. A small study in 2013 demonstrated that among 27 patients with schizophrenia or bipolar disorder, 70% found the technology to be an easy concept to understand, and 89% felt that the digital feedback technology would be helpful for adherence (Kane et al., 2013). The study also found that the majority of patients looked favorably on new digital strategies to improve adherence, including receiving text message alerts for missed

medication dose. Although the sample size was small, the study alleviated some of the concern that patients with disorders such as schizophrenia would become distrustful, paranoid, and distant from their providers if offered digital feedback therapies; instead, they appeared motivated and amenable to the technology.

Those in favor of digital feedback therapies suggest that patients are often able to differentiate the difference between a voluntary contract with their physician and a paranoid delusion. Experts also contend that limiting access of digital feedback therapies under the assumption that patients would refuse to engage with technology only perpetuates stigma regarding decision-making and autonomy among patients with mental health conditions (Rosenbaum, 2018).

In Opposition to Digital Feedback Therapies

For prescribers, a primary concern of *Abilify MyCite* is that its mechanism of monitoring adherence can be a source of fear and anxiety among those experiencing paranoid delusions rooted in technology and surveillance. Consistent medication adherence can significantly reduce these paranoid delusions and other psychotic symptoms which limit patient's social and occupational functioning. However, the unique challenge in treating this subset of patients is that those affected with severe psychotic symptoms and paranoid thoughts may be unwilling to engage in treatment with *Abilify MyCite* in the first place. Routinely, mental health professionals treat patients with concerns that they are monitored by Wi-Fi, tracked by Bluetooth, or are watched through their cell phone, among others. These severe forms of paranoia make it difficult for providers to establish trust and rapport, and offering an ingestible Bluetooth

microsensor-tracking device may prove to be more harmful than helpful in a very delicate relationship.

Opponents of *Abilify MyCite* argue that patients with mental health conditions are already disproportionately affected by surveillance, and digital feedback therapies would compromise privacy and autonomy even further. Those in opposition suggest valid concerns that objective data of medication non-adherence could prohibit those involuntarily committed to mental health facilities from reintegrating into the community or discharging from the hospital in a timely manner (Neumeier, 2017). Others fear the possibility of medical professionals, prisons, and other positions of authority using digital feedback as a point of leverage and coercion for child custody, shortened mandatory treatments, or lessened criminal charges (Powell, 2017). Even more concerning is that documented medication non-adherence could theoretically be used as a tool for justification of involuntary hospitalization or institutionalization (Perry, 2018).

These potential punitive outcomes are alarming given that most cases of poor adherence are not a conscious refusal to take medication (Osterberg & Blaschke, 2005), but a lapse in establishing routine or poor insight. In particular, patients with chronic mental health conditions become ensnared in a difficult cycle of medication non-adherence, as insight will improve with medication adherence, but adherence is difficult to establish without insight.

Another ethical concern includes access to care, as the ability to track a medication through a smartphone application may not be a viable option, as many patients with medication adherence difficulties often have poor social support systems in addition to unemployment, homelessness, and limited access to smartphone technology. If *Abilify MyCite* did in fact prove to be beneficial for improving psychiatric outcomes, it likely would not be available to the most vulnerable and marginalized populations who would need it most.

Conclusion

Abilify MyCite certainly could find its niche and positively influence treatment for those with medication adherence difficulties. Surveillance of adherence through microsensors could revolutionize psychiatric treatments; however, these new innovations carry a significant degree of ethical concern. Developing new strategies to empower patients with mental health conditions should be encouraged and celebrated; however, innovation must be carefully balanced with autonomy and privacy to ensure that the best interest of one of the most vulnerable populations in healthcare is upheld.

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