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## CLINICAL VIGNETTE

# The Digital Pill – Crossing Boundaries?

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A 62-year-old female with a history of major depression with paranoia presents with her brother for primary care and mental health treatment. The patient verbally consented to share medical information with her brother. She reports being functional until a “mental breakdown” from a stressful job situation a few years ago. Since then, she has been suffering from schizoaffective disorder, diagnosed by her prior physician. Her family history is significant for depression and she has been on “a couple of different medications” in the past but does not recall the names. However, her brother remembers that she did not tolerate mirtazapine as it worsened her anxiety and manic symptoms. Currently she takes aripiprazole 10mg daily.

They both agree that it is a struggle to adhere to the daily dosing schedule for her current medication. The patient reports apathy about the medication’s effectiveness, and her brother reports delusions about her husband trying to “poison her”. Therefore, the brother became actively involved in administering her medication. Overtime, however, this has become more of an effort and they both inquire about a monthly injectable formulation. The psychiatrist, who currently prescribes her oral aripiprazole, does not have access to a longer acting injectable formulary so they have come to evaluate options.

This case highlights the common issue of non-adherence to prescriptions, particularly for patients with psychiatric illness. Up to one-half of prescriptions are not picked up from the pharmacy and up to three quarters of prescriptions are not taken properly.<sup>1</sup> There are two categories of non-adherence: intentional and unintentional.<sup>2</sup> Unintentional nonadherence is a passive process as opposed to a patient actively deciding not to take prescribed medications. For instance, a patient with hypothyroidism takes levothyroxine 75mcg daily at the same time as multiple vitamins and other prescribed medications. Levothyroxine should be taken by itself on an empty stomach for 30-60 minutes prior to breakfast or 3-4 hours after last meal. Other substances could affect its absorption, especially calcium and iron. Medication adherence is not just about taking the medication, it means taking the right drug at the correct dose at the appropriate time and schedule under the right conditions and precautions.

Determinants of adherence are categorized in three groups: patient, provider and external factors.<sup>3</sup> The patients’ demographic and sociocultural background, including gender, family size, education, employment and income, medication beliefs, and social network could all contribute to non-adherence. The physician-patient relationship and communication are modify-

able factors that affect adherence. Lastly, external factors such as medication costs and storage requirements, medication adverse effects, disease duration or access to care, each affect patients’ ability to take medication as directed.

Bringing this analysis back to the case, consider the medication formulation and reminder system. Medications come in different formulations to assist with this adherence, e.g. liquid solution, pills (including extended release), dissolvable films, chewables and injectables. Modifying these external factors would help our patient adhere to aripiprazole. In fact, there is a new development that may help patients meet their goals. Abilify MyCite is the first FDA approved digital pill<sup>4</sup>- a new technology that allows tracking of medication adherence with the cooperation of the patient. It requires informed consent from the patient prior to the prescribing and use of this medication.

How does the digital pill work? The digital pill has an edible microchip that is activated in the stomach’s acid and transmits electrical signal to a patch on the arm.<sup>5</sup> The patch then sends a Bluetooth signal to the patient’s smartphone. The patch records the medication and physiologic data. (See Figure 1<sup>6</sup>). The patient controls sharing of data. With patient’s consent, this information may be shared with physician and caregiver via web-based portal. The application can keep track of medication intake and timing, mood, rest, exercise as well as vital signs.

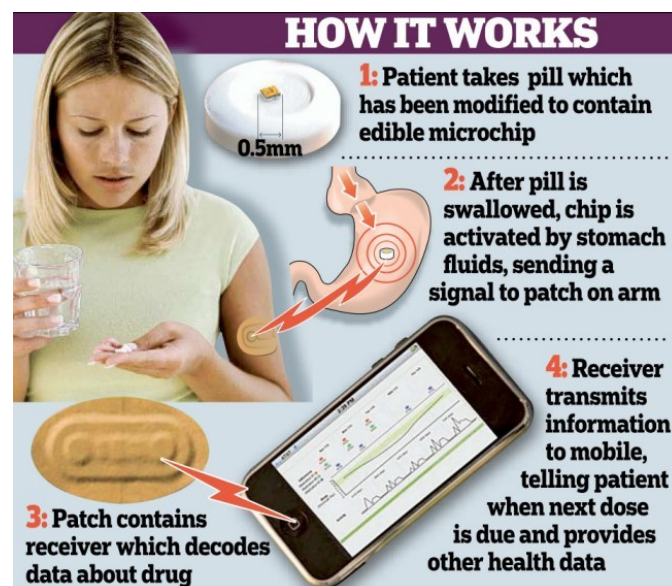


Figure 1. How it works – the mechanics of the Digital Pill.<sup>6</sup>

The remaining question is, does monitoring medication intake improve medication adherence? There are no significant studies yet to suggest this digital pill significantly improves medication adherence. However, similar investigations have found impact on adherence. For instance, a currently marketed sleep apnea machine has a monitoring instrument that measures time of actual use. In recent a Kaiser Permanente study, *ResMed monitoring* and automated coaching has significantly improved adherence to CPAP machine use in the first 90 days.<sup>7,8</sup> A separate control group, for web-based education only, did not have significant improvement in adherence as the monitoring did. Therefore, there is potential for increase adherence to medication intake based on monitoring that engages the patient and provides more information to the physician. So, for our patient above, this may be a good option for her as she could become more engaged in her healthcare, monitor her progress and share information to her brother, husband and physician as she desires.

Like any other treatment plans, there are potential positive and negative outcomes. The goal of improved health outcome may be achieved with this new technology, which may encourage adherence to treatment regimen via monitoring and engaging patient. It also allows for better quality research studies as the information gathered is less dependent on patient's recall and record keeping. On the other hand, use of digital pill challenges the ethics of consent and data sharing. This is particularly true for mental health patients, such as our patient. Will vulnerable patients consent or not consent due to poor judgment from uncontrolled mental illness? Furthermore, as the medicine is more frequently prescribed, will there be pressure from insurance companies to share this medical data with them? There are often unintended consequences to new technology. Other authors have written about the privacy concerns their patients express when discussing mental health, medical diagnoses and sexually transmitted infections.<sup>9</sup>

Despite this "big brother" concern, the digital pill has exciting potential if it expands to other type of medications. For instance, one can monitor treatment of tuberculosis. Moreover, digital pain pills may be very beneficial, especially during the current opioid crisis, and help deter divergence with monitoring. Lastly, this digital pill will likely be a stepping-stone for yet another new technology to develop to reach the goal of more personalized medicine.

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