THE DIGITAL PILL

E-Business and E-Commerce Systems Report

V & E Informatics

Table of Contents

Abstract
The digital pill, made up of a medication and a sensor, enables the Internet of Things to make a foray into the healthcare industry in the United States. The digital pill has been created in hopes of tracking and improving medication adherence. However, there are concerns over the ethics and security of digital health. This report gives an introduction to the digital pill and its role in the healthcare industry.

Background
The Internet of Things (IoT) refers to the connection of devices to the Internet. These devices range from sensors to kitchen appliances to other electronics. IoT is a rapidly growing field, with "more IoT connected devices than humans" (Sas.com, 2020). The Internet of Things is used in many different industries, one of which is healthcare. IoT has the potential to radically change the healthcare industry in the United States and worldwide.

One of the recent advancements in healthcare IoT is the digital pill. The digital pill combines medication with a sensor that, when in contact with stomach fluid, sends a signal out of the body to either a patch or antenna to track medication adherence. While numerous companies are working on digitalizing medicine with these sensors, Proteus Digital Health and pharmaceutical company Otsuka have combined a sensor and medication that reached approval from the Food and Drug Administration (FDA) in the United States in 2017 (Belluck, 2017).

This report aims to discuss the advantages and concerns of the digital pill for patients, caregivers, and healthcare professionals. It will also discuss the technologies available for this new business and the questions surrounding privacy and ethics.

Discussion
The digital pill is comprised of a sensor and corresponding medication. The sensor is made up of three layers. These three layers are "1) the active layers, 2) the integrated circuit (IC), and 3) the insulating skirt disk" (Hafezi et al., 2015). Upon contact with stomach fluid, these layers work together to create a battery for the sensor to be able to emit a weak signal. The insulating skirt targets the signal to the patch worn on the skin.

An adhesive patch is placed on a patient's abdomen in order to collect the signals sent from the sensor. The sensor sends information about the dosage taken and for which medication. The patch then sends the information to the patient's smartphone via a Bluetooth connection.

The smartphone acts as a gateway device. Once the smartphone receives the information from the patch, the phone sends the data to a database (Eisenberger et al., 2013). The database feeds the data into a web portal, where information can be seen by patients, caregivers, and healthcare professionals.

There are many advantages of the digital pill. First, the sensor is included in the same pill as the medication, so there aren't any extra steps for the patient to complete when they take each dose. The wearable patch adds their health metrics to the smartphone app to be sent along with the dosage data, such as sleep patterns, heart rate, and physical activity (DiCarlo et al., 2012). Additionally, if patients miss a dose or forget to place the adhesive patch, they will receive SMS messages on their smartphone to remind them. This alleviates the burden of reminding patients to take their medication from caregivers. From a healthcare professional point of view, it is

revolutionary to be able to make correlations between medication adherence and physiological metrics. These correlations could mean a more tailored approach to each patient's treatment plan, which could, in turn, elevate patient outcomes. Healthcare professionals are also able to get these updates in real-time, thanks to IoT capabilities. This advancement also ties in with the recent trend of telehealth, where healthcare professionals can reach patients over longer distances.

One of the biggest advantages for the digital pill is the opportunity to track and improve medication adherence. In the United States alone, researchers estimate that billions of dollars are wasted every year due to medication inadherence (McGuire and Iuga, 2014). Inadherence may be accidental or purposeful, ranging from forgetting to take a dose to not filling the prescription at the pharmacy. Inadherence causes this waste not only because of unused medication, but also because of the additional emergency room or doctor visits that patients end up needing because they didn't follow their treatment plan (McGuire and Iuga, 2014). The digital pill has the potential to improve medical adherence. Healthcare professionals are able to have more productive conversations with patients about medications because of the tracking mechanisms, and patients are able to receive reminders about doses.

Finally, the digital pill also has an advantage for businesses. This digital pill also has the potential to save millions, if not billions, of dollars with the correct implementation and focus on increasing medication adherence. The sensor, which is small enough to fit in half of a pill, has the capability to function as its own battery. This allows the sensor to be self-sustaining while still being lightweight. The sensor is simple enough to manufacture as well, with researchers calling it "low cost, high volume manufacturing" (Hafezi et al., 2015). Hafezi et al. also make a point to note that the design of the sensor also makes it possible to increase the signal strength if needed. That being said, the signal strength in the sensor has advantageous security factors. The sensor signal lasts for only a short time, estimated at only 5-10 minutes, with the signal only strong enough to be picked up by the patch adhered to the patient's abdomen (Eisenberger et al., 2013). These advantages allow the business the means to scale production, as the sensor is a small size, is low cost, has a short signal range, is self-powered, and has the capability to fold into the pharmaceutical drug as a single capsule.

While there are many advantages to the digital pill, there are also many concerns. One of those concerns centers around the adhesive patch. As with many adhesives, problems have been cited surrounding skin conditions. In a study with kidney transplant patients, 35% of participants experienced reactions because of the adhesive, with 10% of participants discontinuing the study due to discomfort (Eisenberger et al., 2013). Without the patch, this particular type of sensor cannot transmit information, but its properties make it difficult for people with sensitive skin.

Another concern centers around accessibility. First, this system requires the use of a smartphone. In this day and age, smartphones are increasingly common, but not yet universal. This creates a barrier for some users. Additionally, users must be in range of their smartphone in order to connect via Bluetooth, which then must be able to connect to a cellular network. In the kidney transplant study, researchers found that many patients often spent time away from their phones, as evidenced by transmit times. While this isn't a cause for immediate

concern, as the patch can hold the data until it comes into range of the phone (Eisenberger et al., 2013), it might pose a problem if it occurs over longer instances of time, or it might prove an annoyance for patients if they are sent SMS messages reminding them to take a dose that they already took. Another concern lies in cellular coverage. Patients must be connected to a cellular network in order to send the data to the database and web portal, which may restrict usage to non-rural areas. One final accessibility concern lies with the demographic of patients using the digital pill. Generally speaking, elderly patients tend to have more difficulties with smartphones and other newer technologies. As some studies have found, medication adherence activities that rely on technological inputs, such as entering data into an app, aren't always helpful for elderly populations (Serdaroglu, Uslu and Baydere, 2015). While the dosage can be tracked without patients needing to input anything into an app, additional information such as symptom tracking and sleep patterns may not be able to be inputted. Additionally, these patients may not feel comfortable with the web portal used with this system. This could put an undue burden on healthcare professionals and caregivers in this situation.

Another concern about the digital pill is data security and privacy. With the frequent news articles circulating about data breaches, the general population has cause to be concerned over protected health information, also known as PHI, being hacked. However, in the United States, the data privacy laws leave a muddled area where these digital pill sensors would fall. Due to the nature of the business processes surrounding such sensors, say, of the company Proteus Digital Health, may not fall under the Health Insurance Portability and Accountability Act (HIPAA) and corresponding Privacy Rules. As Montgomery argues, Proteus provides health information to the patients themselves. The patients then decide whether their doctors can access their information. This technicality allows the company to argue that HIPAA does not apply to them, meaning that they do not have to follow so many regulations (Montgomery, 2016).

Another data security issue comes with the sensor data itself. The sensor records and transmits data that is unique to the patient. The data, in this way, is considered sparse, or that an individual can be determined using only a few data attributes (Montgomery, 2016). Since a person can be determined using only a handful of attributes, this makes the process of "anonymizing" data difficult. This, paired with sensors being more prone to hacking due to their limited size and battery power, leads to considerable concern over the safety of information.

Two final concerns for the digital pill are the ethics surrounding this surveillance. First, there are concerns over patient consent. While medical consent already, at times, falls into grey area, it is important to establish initial consent for the digital pill. Using the digital pill opens a person up to having a digital record opened for them, and it can be difficult to truly delete data. In addition, it is impossible to detail all possible uses for data when new technologies are developing every day (Effy et al., 2018). Another concern over the ethics of the digital pill is if patients are able to opt out of using the sensor. In a vein similar to the GDPR in Europe, will patients be able to stop tracking their dosages without repercussion? As Effy et al. aptly put it, it is important for there to be transparency, accountability, and trust in order for digital healthcare, such as a digital

pill, to be effective for all involved (Effy et al., 2018).

The other ethical concern for the digital pill is that of liability. From a healthcare provider's point of view, what are the legalities? As Megan Ehret, associate professor at the University of Maryland, said in an article, "'If a physician is aware the patient is not taking the medication, is the physician liable if something happens [with the patient's behavior] because of it?'" (D'Arrigo, 2018). These legal issues have the potential to make healthcare providers hesitate to prescribe the digital pill, especially if they come under fire for a situation involving this product.

Recommendations

The digital pill has the potential to change the healthcare industry. However, while there are advantages to using this sensor, there are also many concerns surrounding the product. The pill has the potential to be revolutionary, but it all depends on how it is introduced and used in society. The technology is feasible and scalable, but now digital health businesses must focus on their marketing and public relations in order to build up trust and transparency.

One way for these businesses to improve their transparency and build accountability in the eyes of the public is to write and release clear privacy policies. Unlike in Europe with the GDPR, data privacy laws in the United States are passed on a state-by-state basis. Privacy policies are often written entirely in legal jargon and opt-out options are hidden behind dozens of clicks and menus. Businesses could build trust with the public by writing their policies in laymen's terms and give clear opt-out routes.

Another way to gain trust in the public is by regulating the digital pill. While overregulation could stifle innovation in the digital healthcare field, leaving the field unregulated opens it up to unethical business practices, whether they be accidental or purposeful. There exists some regulation already, as the FDA must approve the use of a drug in order for it to go on the market. An example of a future regulation includes a process for obtaining consent from patients. This ensures that patients are theoretically aware of what data they are recording with the use of the digital pill.

Finally, in order for the digital pill to change the healthcare industry for all people in the United States, it must be accessible. The digital pill system needs to improve in multiple ways. First, research must be done into new ways of capturing the data, as the adhesive patch has caused skin problems in studies (Eisenberger et al., 2013). This could be done by creating an adhesive for sensitive skin, or by creating a new device altogether.

Another way to improve the accessibility of the system is to reduce the socioeconomic barriers surrounding the system. In order for the system to work properly, patients must own a smartphone and have a strong enough cellular connection. This is not possible for all populations in the United States. In addition, the cost of the pill itself may pose an undue financial burden onto patients, as health insurance is not universal in the United States. There is no simple solution for the socioeconomic barriers surrounding this digital medication system.

Finally, it is important for the digital pill and its corresponding system to be accessible to people of all technical backgrounds. As Serdaroglu et al. mention, it is important for the systems to be as simple as possible, especially since some populations, such as the elderly, are "not proficient in using computing devices" (Serdaroglu et al.,

2015). Thus, the app and the web portal must be designed with these populations in mind. It is important that these applications undergo design reviews and user testing with a variety of users in order to make the final product as simple as possible.

Conclusion

The Internet of Things has the capability to revolutionize the healthcare industry in the United States, especially in regard to medication adherence. However, while the technology is feasible and scalable for a business, it must be implemented in an ethical and accessible way, else society will not accept it as the new norm.

References

Belluck, P. (2017). *First Digital Pill Approved to Worries About Biomedical 'Big Brother'*. [online] Nytimes.com. Available at: https://www.nytimes.com/2017/11/13/health/digital-pill-fda.html [Accessed 11 Jan. 2020].

DiCarlo, L., Moon, G., Intondi, A., Duck, R., Frank, J., Hafazi, H., Behzadi, Y., Robertson, T., Costello, B., Savage, G. and Zdeblick, M. (2012). A Digital Health Solution for Using and Managing Medications: Wirelessly Observed Therapy. *IEEE Pulse*, 3(5), pp.23-26.

D'Arrigo, T. (2018). First medication with embedded ingestible sensor tracks adherence. Pharmacy Today, 24(1), p.20.

Effy, V., Tobias, H., Afua, A. and Alessandro, B. (2018). Digital health: meeting the ethical and policy challenges. Swiss Medical Weekly, 148(34).

Eisenberger, U., Wüthrich, R., Bock, A., Ambühl, P., Steiger, J., Intondi, A., Kuranoff, S., Maier, T., Green, D., DiCarlo, L., Feutren, G. and De Geest, S. (2013). Medication Adherence Assessment. *Transplantation Journal*, 96(3), pp.245-250.

Hafezi, H., Robertson, T., Moon, G., Au-Yeung, K., Zdeblick, M. and Savage, G. (2015). An Ingestible Sensor for Measuring Medication Adherence. *IEEE Transactions on Biomedical Engineering*, 62(1), pp.99-109.

McGuire, M. and Iuga, A. (2014). Adherence and health care costs. *Risk Management and Healthcare Policy*, 7, pp.35-44.

Montgomery, Amelia R. (2016). Just What the Doctor Ordered: Protecting Privacy Without Impeding Development of Digital Pills. *Vanderbilt Journal of Entertainment & Technology Law*, 19, pp.147–177. Available at: https://heinonline-org.ezproxy.sussex.ac.uk/HOL/Page?collection=journals&handle=hein.journals/vanep19&id=149&men_tab=srchresults [Accessed: 22 Nov 2019].

Sas.com. (2020). *Internet of Things (IOT)*. [online] Available at: https://www.sas.com/en_us/insights/big-data/internet-of-things.html [Accessed 10 Jan. 2020].

Serdaroglu, K., Uslu, G. and Baydere, S. (2015). Medication intake adherence with real time activity recognition on IoT. In: *11th International Conference on Wireless and Mobile Computing, Networking and Communications (WiMob)*. [online] IEEE, pp.230-237. Available at: https://ieeexplore.ieee.org/abstract/document/7347966 [Accessed 14 Jan. 2020].

Bibliography

Hugtenburg, J., Vervloet, M., van Dijk, L., Timmers, L. and Elders, P. (2013). Definitions, variants, and causes of

nonadherence with medication: a challenge for tailored interventions. *Patient Preference and Adherence*, 7, pp.675-682.

Noble, K., Brown, K., Medina, M., Alvarez, F., Young, J., Leadley, S., Kim, Y. and DiCarlo, L. (2016). Medication adherence and activity patterns underlying uncontrolled hypertension: Assessment and recommendations by practicing pharmacists using digital health care. *Journal of the American Pharmacists Association*, 56(3), pp.310-315.

Proteus Digital Health (2017). *Otsuka and Proteus® Announce the First U.S. FDA Approval of a Digital Medicine System: Abilify MyCite® (aripiprazole tablets with sensor)*. [online] Available at: https://www.proteus.com/press-releases/otsuka-and-proteus-announce-the-first-us-fda-approval-of-a-digital-medicine-system-abilify-mycite/ [Accessed 28 Nov. 2019].