

## ***Review on: Smart Pills***

***Anjali Soni<sup>1\*</sup>, Aanveekshikee Rathore<sup>2</sup>***

*Assistant Professor<sup>1</sup>, Lecturer<sup>2</sup>*

*Department of Pharmacy*

*Chameli Devi Institute of Pharmacy, Indore*

***Corresponding Author's Email: - anjali.soni@cdgi.edu.in<sup>1\*</sup>***

### ***Abstract***

*Digital Pills (DP) are a new drug-device technology that allows standard pharmaceuticals to be combined with a monitoring system that automatically records data on medication adherence as well as physiological data from patients. DPs are a potential invention in the realm of digital medicine, but their use has created several ethical problems. However, these ethical concerns have primarily been articulated from a theoretical standpoint, but an experimentally oriented ethical analysis is scarce. There is also a lack of clarity on the empirical proof available for this novel digital medicine's application.*

***Keywords:*** *Digital Pills, Monitoring System, Medication Adherence, Automatically Records Data*

### **INTRODUCTION**

Drugs must be more effective and inexpensive to improve global health. While there are numerous branded and generic pharmaceuticals accessible, a major reason of ineffectiveness is the partial or complete loss of responsiveness to chronic treatments. When this is combined with a lack of patient adherence,

even additional healthcare difficulties arise.

In the medical field, smart pills, sometimes known as digital pills, are gaining popularity. Medication non-adherence is a major problem in which patients do not take their medications as prescribed. Other sorts of technology have been developed to assist patients in taking their

prescription; however these technologies do not track whether or not the patient has consumed their tablets. Because doctors and medical professionals have no way of knowing whether or not a patient has consumed the pill, their methods of medication adherence are unreliable.

As a result of this problem, the smart pill, often known as a digital pill, was created. In 2017, the FDA authorised the first digital pill, which contains a built-in digital ingestion tracking system. The pill is named AbilifyMyCite and was created by Otsuka Pharmaceutical Co. The pill may identify whether or not a person has taken the drug. A sensor consisting of silicone, copper, and magnesium is included in the pill. A gadget connected to the pill can receive a particular electrical signal from the sensor. When the pill has successfully mingled with the person's stomach juices, a signal is sent to the external receiver.

The patient will need to wear an external receiver on a patch on their rib cage during this time. The patch uses Bluetooth to transfer the data it collects to a phone app. The app collects and saves information such as when the drug was taken, the date, and the time. This important information can be shared with medical professionals,

family members, and caretakers to ensure that the patient is taking the tablets and following the directions correctly.

A sensor is placed in a digital pill that can effectively track drug compliance. Essentially, the pill can convey critical information to a medical practitioner from a person's bloodstream or digestive tract, letting them know how the drug is working, whether the medication is working, and if the patient ever took the tablets in the first place.

### **Will Medication Adherence Be Improved by Digital Pills?**

One of the most pressing concerns about digital pills is whether or not they would genuinely assist patients with medication adherence issues. It is too early to say how successfully these smart tablets will improve medication adherence at this time. It will most likely take several years to collect enough data and information to see a significant influence on drug adherence.

There's still a chance that people who are prescribed smart tablets may wear the skin patch that allows the smart pill to communicate with their phone and provide information and data. Patients may forget to apply the patch to their skin, or they may refuse to wear the patch in the first

place. The patch must also be replaced every seven days at this time, which may be a concern for some people — forgetting to change the patch is a typical occurrence.

### **How Does the Future Appear?**

While the future of smart pills is yet uncertain, there is a lot of potential for both medical professionals and patients. The capacity to collect vital data and assist patients in improving their drug adherence would only benefit and improve their overall health. This form of smart pharmaceutical and smart pill has the potential to change the way people take their prescriptions and how medical professionals help their patients recover.

### **The digital medical system's technology**

The goal of digital medicines is to improve patient adherence to pharmaceutical therapy. In the realm of mental health research, the utilisation of Smartphone-based data streams is quickly gaining traction. The most recent advancement is the usage of a digital medicine system in which a drug is paired with an indigestible sensor that can transmit a signal when the drug-device combination is exposed to gastric acid in the stomach, providing real-time information regarding medication ingestion. It is thought that by doing so, drug adherence will improve, resulting in

better health outcomes and cost savings. It has the potential to enhance health outcomes while also saving money. Digital medicine systems have the potential to improve patient care by enhancing prescription adherence, enabling real-time drug usage tracking, and reducing the danger of overdose and abuse. The DSM is a personal digital instrument (smartphone) that connects wirelessly to the patient's records and uploads their medicine prescriptions mechanically. Alternatively, a wireless device using electrochemical sensing techniques can be deployed. An ingestible sensor of 1 -2 (mm) in sizes that are placed in an oral solid preparation such as a tablet, a wearable sensor patch, and a mobile computing device make up digital medicine. Digestible metals like copper and magnesium are used to coat the sensor. The sensor generates an indication that the patch perceives after being eaten and triggered by stomach fluid. When compared to the daily permitted limits for human consumption of 0.3 percent (7.7 mg) and 0.003 percent (9.8 mg), the quantity of copper and magnesium that can be absorbed by the gut from the ingestible sensor is very little. The wearable sensor patch is a 10 cm long body-worn sensor that detects and records the date and time of drug ingestion.

The adhesive is held in place by a foam surface, which also serves as a water-resistant housing for the electronics of the gadget. It should be worn on the upper body (torso) throughout most activities, such as exercise and bathing. The glue should be updated weekly due to high levels of exercise and water. A new Digital Medicine System (DMS) has been created to objectively measure and report aripiprazole, an atypical antipsychotic, consumption in patients with significant mental illness. DMS is a smart medicine reminder system that is designed to assist elderly people in taking their medications on time and in the correct dosage. The prescription is entered into the system.

### **Precautions when using medicine**

1. Wait until the software instructs you to set up a fresh patch.
2. Wait until the app instructs you to take the first DMS pill.
3. Do not stop taking your prescription or adjust the dosage based on what you've learned. Consult your health care physician about the information supplied by the DMs kit.
4. Do not change your medicine until your doctor says so.
5. Avoid chewing the pill.
6. Never put a tablet in water.

7. If you are allergic to adhesives, do not use the patch.

### **LITERATURE REVIEW**

Following the momentous regulatory clearance of digital aripiprazole (AbilifyMycite™) in late 2017, digital medications have begun to make the transition from clinical trials to widespread use. The ingestible sensor that ushered in the era of Digital Medicines was previously approved under the FDA's de novo procedure for innovative low-risk devices in 2012, and commercial use began soon after.

### **Method**

We conducted a scoping analysis of the empirical literature on DP to identify the studies in which DP was tested on patients and analyse the ethical difficulties raised therein.

### **RESULT**

We found 18 papers in our search that reported on research in which DP was tried on patients. These trials featured a variety of designs and patients with a variety of diseases. A variety of ethically relevant issues were obvious in the empirical literature. Users' interactions with DP, personal sphere, health-related hazards, and patient benefits are all ethical concerns

at the patient level. At the provider level, ethically significant concerns include the doctor-patient connection and data access. They involve social benefits, evidence quality, and the device-medicine dichotomy at the societal level.

## CONCLUSION

We conclude that the evidence for DP is insufficient, and that further research and study findings should be made available in order to assess this digital medication. Furthermore, our examination of ethically important components in empirical literature reveals that there are clear and specific unresolved problems that need to be addressed in the ethical debate over this new technical solution.

## REFERENCES

1. Peters-Strickland T, Hatch A, Adenwala A, Atkinson K, Bartfeld B (2018) Human factors evaluation of a novel digital medicine system in psychiatry. *Neuropsych Dis Treat* 14: 553.
2. Martani A, Geneviève LD, Poppe C, Casonato C, Wangmo T (2020) Digital pills: a scoping review of the empirical literature and analysis of the ethical aspects. *BMC med ethics* 21: 1-3.
3. Peters-Strickland T, Pestreich L, Hatch A, Rohatagi S, Baker RA, et al. (2016) Usability of a novel digital medicine system in adults with schizophrenia treated with sensor-embedded tablets of aripiprazole. *Neuropsych Dis Treat* 12: 2587.
4. Focsa S (2017) What can be done for access and reimbursement processes to reward innovation in digital “beyond the pill” solutions?. *Value Health* 20: A708.
5. Mc Caffrey C, Twomey K, Ogurtsov VI (2015) Development of a wireless swallowable capsule with potentiostatic Figure 3 Current adherence modalities © Under License of Creative Commons Attribution 3.0 License 5 2021 Vol.13 No.6:26 *Archives of Medicine* ISSN 1989-5216 electrochemical sensor for gastrointestinal track investigation. *Sensor Actuat B-Chem* 218: 8-15.
6. Venuturupalli RS, Sufka P, Bhana S (2019) Digital medicine in rheumatology: challenges and

- opportunities. *Rheum Dis Clin* 45: 113-26.
7. Vayena E, Ienca M (2018) Digital medicine and ethics: rooting for evidence. *Am J Bioeth* 18: 49-51.
  8. Plowman RS, Peters-Strickland T, Savage GM (2018) Digital medicines: clinical review on the safety of tablets with sensors. *Expert Opin Drug Saf* 17: 849-852.
  9. Mulder T, Jagesar RR, Klingenberg AM, Bonnici JP, Kas MJ (2018) New European privacy regulation: Assessing the impact for digital medicine innovations. *Eur Psych* 54: 57-58.
  10. Cosgrove L, Cristea IA, Shaughnessy AF, Mintzes B, Naudet F (2019) Digital aripiprazole or digital evergreening? A systematic review of the evidence and its dissemination in the scientific literature and in the media. *BMJ Evid Based Med* 24: 231-238.
  11. Akkermans J, de Lange AH, van der Heijden BIJM, Kooij DTAM, Jansen PGW, Dijkers JSE (2016) "What about time? Examining chronological and subjective age and their relation to work motivation". *Career Dev Int* 21: 419-439.
  12. Egilman AC, Ross JS (2019) Digital medicine systems: an evergreening strategy or an advance in medication management?. *BMJ Evid Based Med* 24: 203-204.
  13. Vallejos X, Wu C (2017) Digital medicine: innovative drugdevice combination as new measure of medication adherence. *J Pharm Tech* 33: 137-139.
  14. Abdul Minaam DS, Abd-El-Fattah M (2018) Smart drugs: Improving healthcare using Smart Pill Box for Medicine Reminder and Monitoring System. *Future computing inform J* 3: 28.
  15. Frigerio M (2016) Getting approval for new therapeutic medical devices versus drugs: are the differences justified?. *EurResp Rev* 25: 223-226.

16. Chevance, A., Fortel, A., Jouannin, A., Denis, F., Mamzer, M.F., Ravaud, P. and Sidorkiewicz, S., 2022. Acceptability of and Willingness to Take Digital Pills by Patients, the Public, and Health Care Professionals: Qualitative Content Analysis of a Large Online Survey. *Journal of medical Internet research*, 24(2), p.e25597.
17. Jacquemard, T., Doherty, C.P. and Fitzsimons, M.B., 2020. Examination and diagnosis of electronic patient records and their associated ethics: a scoping literature review. *BMC medical ethics*, 21(1), pp.1-13.
18. Gooding, P. and Kariotis, T., 2021. Ethics and law in research on algorithmic and data-driven technology in mental health care: scoping review. *JMIR Mental Health*, 8(6), p.e24668.
19. Martani, A., Geneviève, L.D., Poppe, C., Casonato, C. and Wangmo, T., 2020. Digital pills: a scoping review of the empirical literature and analysis of the ethical aspects. *BMC medical ethics*, 21(1), pp.1-13.
20. Gooding, P., 2019. Mapping the rise of digital mental health technologies: Emerging issues for law and society. *International journal of law and psychiatry*, 67, p.101498.
21. Gooding, P. and Kariotis, T., A Scoping Review of Algorithmic and Data-Driven Technology in Online Mental Healthcare: What is Underway and What Place for Ethics and Law.