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Ethical Responsibility of Digital Pills Technology -- Take Abilify Mycite For Example

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Abstract

Digital pills are new medicine combining digital technology with traditional medicine. Therefore, investigation of digital pills is an emerging field of drug research and development. Abilify MyCite, as the first digital pill around world, was approved by FDA in November, 2017. The original intention of digital pills technology is to continuously monitor patients' diseases at a distance and improve medication compliance of patients, so that the treatment effect could be increased. The development of digital technology and the advent of digital medicine created ethical challenges to patients, health care workers and medical practice. Taking Abilify MyCite as an example, this paper studied the digital medicine which may bring ethical problems, and put forward the idea that integrating responsible innovation into the research and development of digital medicine as well as solving the ethical problems in aspects of technology, law, management and ethics is an effective way to solve the ethical dilemma.

Keywords

Digital pills, medical ethics, ethical responsibility.

1. Introduction

Medication compliance refers to the extent to which a patient performs a medication program. Poor medication compliance directly led to a result of the losses in two aspects. One was the health care costs and resources. According to the data from IMS Institute for Healthcare Informatics in 2013, economic burden of $100 billion per year was produced because patients were non-compliance with medication which resulted in delay of diseases, and then they needed additional treatment. Due to poor medication compliance, avoidable costs of inpatient, outpatient, and prescription accounted for 8% of all medical care costs in the United States. The other is that forgetting to take medicine will decrease the treatment effect, seriously leading to the aggravation of diseases or death of patients.

People have been looking for a method to improve medication compliance. With the inevitable combination of human body and technology, digital medicine have gradually became the focus of new drug research and development. People hope that digital drugs can improve medication compliance of patients. At present, most of the research focuses on the technology of digital medicine, and little research is done on the moral and ethical consequences caused by digital medicine. The technology is advancing so fast that people have not thought through it in terms of ethical responsibility.

2. Ethics Concerns about Digital Pills Technology

The first smart pill approved is Abilify MyCite, an anti-psychotic drug used in the treatment of schizo- phrenia, bipolar disorder and depression. It combines aripiprazole with a digital sensor which, once in the stomach, communicates with a patch attached to the patient. The patch

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automatically records the date, time and dosage of the drug. The information is then transmitted via the patch to a smartphone or other bluetooth device. It is eventually excreted by normal metabolism after the chip completes its tasks.

While the world is cheering on new technologies, Ameet Sarpatwari from Harvard Medical School says that although "digital tablets" may play an important role in improving public health in the future, the abuse could exacerbate a crisis of trust between doctors and patients.

At the same time, many patients and professional doctors have raised doubts from the psychological and moral aspects of patients. For patients, this technology not only has no privacy, but even has the feeling of being "monitored" all the time, which will form a certain pressure in the medical treatment stage.

The ethical problems of digital pills technology are mainly as follows:

One is the safety of data. Huge amounts of medical data, including those of pharmaceutical companies, hospitals and individuals, are digitally stored, subjecting to the quality control of digital devices. Its risks include physical risk, i.e. equipment failure can cause permanent loss of data, system vulnerability can leak the personal data of doctors and patients and illegal invasion endangers the information security of hospitals, doctors and individuals.

Second is privacy. In the traditional medical system, the disclosure of patient privacy can be well solved and controlled by means of physical isolation, but it becomes difficult in the Internet age. The storage and transmission of medical and scientific data may result in the disclosure of patient privacy. In this way, insurance companies can even collect public information for commercial purposes through this system. There have been few cases that medical care institutions sell personal information and other private data of patients to obtain improper benefits. The development of digital pills technology can make the implementation of this unreasonable behavior more convenient and covert.

Third is informed consent. Informed consent means that patients exercise autonomy by voluntarily agreeing (or not) to participate in tests or studies. In contrast, digital pills present a new challenge. In addition to traditional informed consent procedures, the use of digital pills may be constrained to agreements of users. This mainly occurs in the process of clinical consultation, teaching and scientific research using patients' health data. The time and scope of the use of digital data belong to the objects of informed consent. However, due to the changes in the way of data storage and transmission, the difficulty of informed consent is increased.

3. Effective Way to Solve the Ethical Dilemma

In response to the ethical issues in the digital drug technology described in the second part of this paper, this paper proposed that responsible innovative ideas could be injected into the development and application of digital pills, and put forward the ethical countermeasures of digital pills technology from aspects of the law, management, technology and ethics.

The OCC defines responsible innovation as the use of new or improved financial products, services and processes to meet the evolving needs of consumers, businesses, and communities in a manner that is consistent with sound risk management and is aligned with the bank's overall business strategy.

We could inject the idea of responsible innovation into digital pharmaceutical technology, specifically the following four aspects

In the legal construction of data security and privacy protection of digital pills technology, we could firstly establish a legal system specifically for personal data protection, clarify the scope of protected data, and then make legal provisions for data security of digital drugs stored on huge cloud platform of data, as well as for the data shared and utilized in service and business

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cooperation of health care in the area of commercial application, so that we could achieve the compulsory legal construction of data security and privacy protection of digital drug technology.

We could also solve the ethical problems of digital pills technology in the aspect of management through the followings. Firstly, we could establish a data protection supervision and control department to prevent the abuse of power by the relevant government departments and the leakage of data and privacy. Secondly, we could accelerate the introduction of national data protection standards and strengthen industry self-discipline. Finally, we could improve the traceable responsibility mechanism in the process of data using to ensure the reasonable access of data.

In the aspect of technology, because the data of digital pills cover a wide range of fields and the link of data flow is complex, we put forward the technical protection measures of digital pills, which are the followings. We could firstly establish a hierarchical and classified data management and control model including the protection level of data content and the multi-level guarantee of data flow, and actively adopt multiple guarantee technology of data encryption and identity authentication technology used to control data access. In addition, the devices'recognition ability of scene switching and the remote control ability of remotely clearing and missing reminders should be optimized.

To solve the ethical dilemma of digital pills technology, we need to build ethical awareness, including not only the training of relevant practitioners to ensure rights of users' informed consent and balance the benefits and risks of data using, but also the promotion of data security and privacy protection awareness of users with appropriate information reminders.

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