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The Future of Medicine Is Digital: Exploring the Ethics of Digital Pills

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Abstract

Digital Pills are a drug-device technology that allow for the combination of traditional medications with a monitoring system that automatically records data about medication adherence and patients' physiological data. They are a promising innovation in digital medicine; however, their use has raised a number of ethical concerns. In this paper, we outline some of the main Digital Pills technologies and explore key ethical challenges surrounding their use. In this paper, we introduce educational materials we have developed that provide an insight into the technologies and ethical aspects that underpin Digital Pills.

Keywords:
Digital Pills, Ethics; Privacy

Introduction

The 1966 science fiction film "Fantastic Voyage" saw a group of heroic medical pioneers shrunk to microscopic size in a submarine and injected into a critically ill patient, and the film allows the protagonists to explore the patient's body from within. Although we cannot yet achieve such medical miracles, in the past five years we have developed technologies that allow us to come close, with devices that monitor patients from the inside out.

Digital Pills (or Smart Pills) are ingestible pills that incorporate sensors and other devices that transmit useful medical data to an external device [1]. Examples of the types of Digital Pills that exist include:

- *Medication Adherence Pills*: Ensuring that patients adhere strictly to medical advice is a serious challenge across all fields of medicine, and identifying nonadherence in a reliable fashion is clinically important. These digital pills address some of these challenges by incorporating an ingestible sensor into the medication that emits a weak signal when it reaches the stomach acid, and that signal is relayed via a patch worn on the abdomen to a smartphone app which records that the medication was taken [2].
- *Imaging Pills*: Given the challenges that some patients face with endoscopies, including feelings of nausea, pain, and sedation issues, it is not surprising that imagining capsules (which typically incorporate digital cameras and LED lighting) are the largest part of the Digital Pills market [3].
- *Temperature Sensing Pills*: These consist of ingestible temperature sensors to monitor body temperature and measure heat stress. They often use magnets to navigate to an intended site [3].
- *pH Monitoring Pills*: Devices include sensors to monitor the pH of the gastrointestinal tract [3].
- *Gas Sensing Pills*: These devices are particularly focused on detecting gases as by-products of the gut activities. The capsules typically monitor gases such as oxygen, hydrogen, carbon dioxide, and methane. These sensors typically operate in both aerobic and anaerobic environments [3].
- *Pressure Sensing Pills*: Devices include sensors to obtain pressure profiles of the gastrointestinal tract. These devices remain at the experimental stage and are still under development [3].
- *Electrochemical Sensing Pills*: Devices that are capable of sensing and performing electrochemical measurements [4].

The ethical challenges of these devices are numerous, and a key issue is privacy. Philosophers such Jürgen Habermas [5] and Hannah Arendt [6] typically discuss privacy in the differentiation between public and private spaces, explored through questions of ownership, and questions such as; "Who owns resources in these spaces?" and "What is truly private?". The Digital Pills add a new level of complexity and intimacy to the privacy issue.

Other key ethical challenges include [2]:

- *Informed Consent*: With the use of this type of advanced technology, it can be more difficult for patients to give true informed consent when they may not be able to fully comprehend the nature and implications of the use of these devices.
- *Therapeutic Misconception*: It is possible patients may not be fully aware of the differences between Digital Pills that monitor patient vitals, and those Digital Pills that provide active treatments.
- *Data Management*: The nature of data being collected by these devices by its nature confidential, but the legal position of the ownership of the data depends on a range of factors, including whether the data is anonymised or not [7], the jurisdiction where the data was collected, and whether the patients have signed any form of legal agreement on the matter.

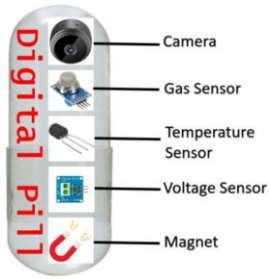

Figure 1– Schematic of Digital Pill with a range of potential sensors and other devices.

- *Security*: As many of these devices emit signals, and some can be controlled wirelessly, there exists the possibility of hackers intercepting these signals, and potentially endangering lives [8].
- *Dependability*: Even if devices are fully secure, they may still fail, batteries may unexpectedly wear out, or some other failure may occur.

Methods

Our research is taking place in the context of the Ethics4EU project [9] which has as one of its aims, the development of educational materials (learning outcomes, lessons, assessments, and an instructor guide) on topics in digital ethics. The content is primarily aimed at Computer Science students but is designed to be modular and flexible and so can be used in the education of other students (e.g. medical students). As such, materials can be used to provide an overview and raise awareness of existing and emerging technologies and associated ethical aspects in professional domains. Educational materials are developed following a case study methodology. Case studies provide students with an opportunity recognize dilemmas, to employ moral imagination promoting active learning often requiring them to assume the role of participants. A Digital Pills case study been developed to explore the intersection of technology and ethical issues outlined above.

Results

The Digital Pills case study is openly available online at [10]. The content of this lesson begins with a discussion of medical ethics, followed by the ethics of the Internet-of-Things, and finally the ethics of Digital Pills. Readers are encouraged to visit the site in order to view the different materials provided to teachers – teaching method support, scientific publications, books, journalistic articles from the popular press, social media posts, video and audio file links. This material is being continually updated.

Educational content is evaluated using a framework involving a range of stakeholders. The teacher who delivers the lesson records their views in a reflective diary, and once the lesson is complete, students in the class are surveyed. Finally, a panel of expert evaluators (both Ethicists and Computer Scientists) review content using a questionnaire based on a combination of two teaching assessment instruments (The Learning Object Review Instrument, and the Technology Acceptance Model). The Digital Pills lesson is currently being delivered to students at Institut Mines-Télécom Paris and we will report results of its evaluation in future work.

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