Time to switch on to digital ethics

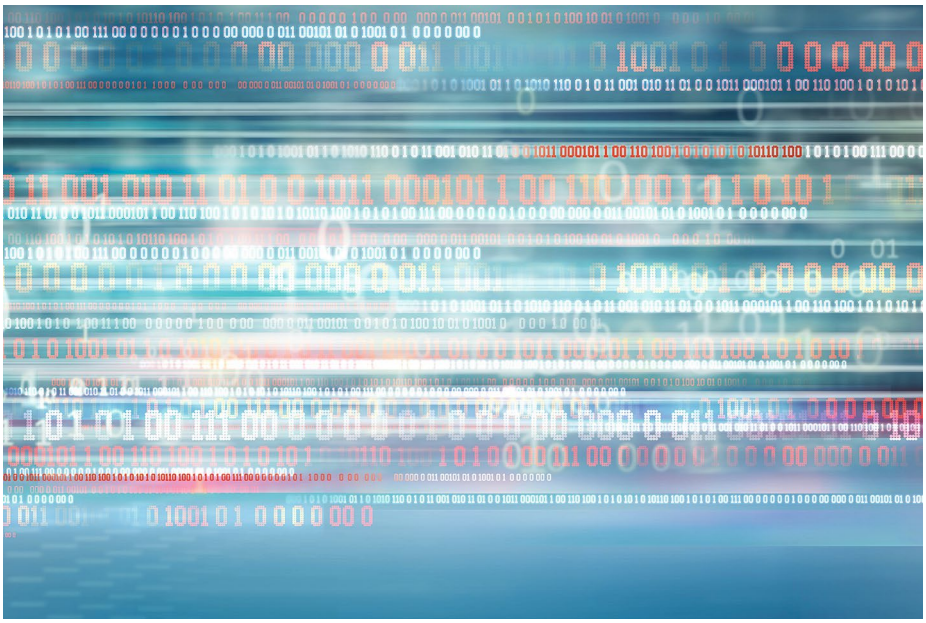
The ethical challenges created by a new digital technology need to be considered at the earliest stages of the development process.

In November 2017, the US Food and Drug Administration approved its first digital pill[1]. Developed by Otsuka Pharmaceutical and Proteus Digital Health, the pill is called Abilify MyCite and contains an ingestible sensor that can record whether the medication — a drug known as aripiprazole, which is used to treat schizophrenia and bipolar disorder — has been taken. When it reaches the stomach, the sensor sends a signal to a patch worn on the body, which, in turn, transfers information — the date and time the pill was ingested, plus the patient's activity level — to an app on a nearby smartphone.

Abilify MyCite is expensive: US$1,650 per month, which is around 30 times more than a sensor-free, generic version of the drug[2]. A recent study has also suggested that regulatory approval was based on limited data and there is no evidence that a digital version of the drug improves treatment adherence[3]. This smart pill is though only one of a number of emerging ingestible devices and their unique capabilities suggest that there is a place for them in the future of healthcare.

Ingestible sensors are not a new idea: an ingestible electronic capsule that could potentially be used to transmit internal pressure and temperature readings was reported back in 1957[4]. But more recently, the miniaturization of electronic circuits has led to the development of devices of increasing sophistication. An ingestible sensor that can measure different gases in the gut, and could be used to help develop personalized diets, was, for example, demonstrated last year[5]. This was followed by work on an ingestible sensor capable of detecting gastrointestinal biomolecules[6].

But technological development is one thing, the public's appetite for such sensors another. The devices do, in particular, raise a range of ethical and legal issues — and these issues need to be considered by all stakeholders, particularly the scientists and engineers involved in the creation of the devices. In a Perspective in this issue of *Nature Electronics*, Sara Gerke and colleagues at Harvard Law School and the University of Copenhagen examine the key ethical issues surrounding ingestible sensors, including those related to patients, physicians, and society more generally. They also provide a comparative analysis of legal regulation of the sensors in the US and Europe.



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The issues surrounding ingestible sensors are just one facet of the ethical challenges created by the advance of digital technology. In a Comment article elsewhere in this issue, Carissa Véliz at the University of Oxford highlights that there has been a recent 'techlash' against the big tech companies, as various data misuse scandals have come to light. This has been accompanied by attempts to establish better digital ethics, which has so far had limited success. To provide a way forward, Véliz suggests we turn to medical ethics.

Medical ethics matured as a discipline in the 1970s, confronted with technological advances, such as the mechanical ventilator, and various medical scandals. Three elements were key to this development: ethical codes, ethics committees and respect for personal autonomy. As Véliz argues, digital ethics would be well advised to try to emulate these.

For emerging technologies, such as robotics and artificial intelligence, the development of new ethical standards can also play a role in their successful adoption[7]. Alongside such ethical endeavours, appropriate legislation remains essential — and the need for data protection laws to evolve in order to cope with nascent digital technologies has recently been highlighted[8].

The point at which potential ethical dilemmas are considered is also important and, in the long run, could be a factor in determining whether a technology is successfully adopted or not. As Gerke and colleagues emphasize in their Perspective: "Such issues should be considered at the earliest stages of the development process of such products — the goal is ethics by design — rather than after a product has been designed and tested." ❐

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