DIGITAL TRACKING MEDICATION: BIG PROMISE OR BIG BROTHER?

Dr Imogen Goold
Associate Professor
Faculty of Law, University of Oxford

Biographical note
Imogen Goold studied Law and Modern History at the University of Tasmania, Australia, receiving her PhD in 2005. Her doctoral research explored the use of property law to regulate human body parts. She also received a Masters degree in Bioethics from the University of Monash in 2005. From 1999, she was a research member of the Centre for Law and Genetics, where she published on surrogacy laws, legal constraints on access to infertility treatments and proprietary rights in human tissue. In 2002, she took up as position as a Legal Officer at the Australian Law Reform Commission, working on the inquiries into Genetic Information Privacy and Gene Patenting. After leaving the ALRC in 2004, she worked briefly at the World Health Organisation, researching the provision of genetic medical services in developing countries. She is now examining the impact of moral arguments on the regulation of IVF and also writing a book based on her work on body part ownership.

Digital tracking medication: big promise or Big Brother?

Imogen Goold

ABSTRACT

In late 2017, the United States FDA approved the first example of a new generation of medication – a pill with a 'digital ingestion tracking system' that transmits data that the pill has been taken enabling doctors (and patients) to track whether and when the patient has taken their medication. The technology offers considerable benefits by improving patient adherence to medication regimes. This paper explores a range of possible concerns raised by this new technology including privacy considerations and secondary use of collected data; use by policing and other state agencies; and conditional and coercive use. It argues that the potential for function creep and the undermining of privacy protections mean we would be wise to consider these concerns and potential regulatory controls to avoid them before they become an unwanted reality, but that existing regulatory regimes may be sufficient to protect against these problems.

ARTICLE HISTORY Received 13 August, 2018; Accepted 15 April, 2019

KEYWORDS Tracking; adherence; secondary use of data; privacy; confidentiality

1. Introduction

In late 2017, the United States Food and Drug Administration (FDA) approved the first example of a new generation of medication – a pill with a 'digital ingestion tracking system' embedded at the point of manufacture.[1] The drug, Abilify MyCite, is an antipsychotic used to treat schizophrenia and bipolar disorders and includes a sensor that transmits data that the pill has been taken, so that for the first time, doctors (and patients) can track whether and when the patient has taken their medication. The release made headlines, some neutral, some warning of 'the frightening promise of self-tracking pills'[2] and worrying about a 'Biomedical Big Brother'.[3] The technology offers potentially huge benefits in terms of improving patient adherence to medication regimes, particularly those who suffer conditions associated with low adherence such as some mental disorders. Its approval has been welcomed by many who regard it as a step towards reducing the harms (and costs) associated with nonadherence with medication regimens. However, there are a range of possible concerns raised by this new technology which this paper explores. These include privacy considerations and secondary use of collected data; use by policing and other state agencies; and conditional and coercive use. While these problems are speculative and some way in the future at this early stage of the technology's introduction, the potential for function creep and the undermining of privacy protections mean we would be wise to consider these concerns and potential regulatory controls to avoid them before they become an unwanted reality.

To undertake this analysis, the paper begins by outlining the development and capacities of this new technology, then describes some of the potential benefits it offers to a range of users and stakeholders, particularly increased adherence and improved patient care. It then divides the concerns into three strands: privacy, consent, and forms of coercive use (ranging from

[1] United States Food & Drug Administration, 'FDA approves pill with sensor that digitally tracks if patients have ingested their medication' November 13th 2017 <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm584933.htm> Last accessed 18th July 2018. While the headlines reacted to the release of Abilify MyCite as though this was an entirely new approach to medication, in fact the technology had been available for some years. The novelty of Abilify MyCite was the embedding of the ingestible sensor at the point of manufacture. The sensor itself had been permitted for marketing by the FDA in 2012 and had been encapsulated with medications, but not combined during drug manufacture.

[2] The Verge, Russell Brandrom, 'The Frightening Promise of Self-tracking Pills' October 7 2015 < https://www.theverge.com/2015/10/7/9466121/proteus-digital-pill-tracking-privacy-quantified-self> Last accessed 18th July.

[3] Pam Belluck, 'First Digital Pill Approved to Worries About Biomedical 'Big Brother'' *New York Times* New York 3rd November 2017 < https://www.nytimes.com/2017/11/13/health/digital-pill-fda.html>.

insurance and employment to a number of potential uses within the criminal justice system). In examining these concerns, the paper explores whether existing regimes seem likely to be sufficient to regulate this new technology, and takes the view that it is preferable to avoid the proliferation of new regulatory schemes in response to new technology unless there is a genuine need to do so. The paper argues that for the most part, there is no need to develop new, tailored legislative solutions to the possible problems this tracking technology raises. It concludes that as the technology currently stands, the issues it raises can be largely managed via existing laws and that this approach is to be preferred to reactively developing new laws specific to digital medications. That said, it does recognise that some of the transactional justifications for using the technology (such as in the employment context) may give rise to situations in which a consent-framework will not be sufficiently robust to protect individual privacy and autonomy. If such deployments of the technology do raise such concerns, then a regulatory intervention to address these may become desirable.

2. The technology

Abilify MyCite is a drug-device combination that comprises aripiprazole tablets (produced by Otsuka Pharmaceutical Co) embedded with an Ingestible Event Marker (IEM) sensor, developed by Proteus Digital Health.[4] Manufactured from copper, magnesium and silicon (which Proteus points out are 'ingredients found in food'), the sensor is activated by contact with stomach acid. When activated, it produces an electrical signal which is transmitted to a patch worn on the skin covering the rib cage. Patches can be worn for up to seven days. The sensor is the size of a grain of sand, and after activation is digested and expelled from the body. The patch transmits data to a mobile phone app (MyCite App) via Bluetooth, telling the app that the pill has been ingested and the time of ingestion as well as some physiological data such as activity level. It takes between 30 minutes and two hours for the ingestion of medication to be detected by the app.[5] The data is encrypted before being sent to the phone app.[6] The wearer can also add their own data to the app, such as mood. The app connects to a web portal, where doctors and others can view the data. Access is controlled by the wearer

[4] Proteus, 'Otsuka and Proteus Announce the first US FDA Approval of a Digital Medicine System: Abilify MyCite (aripiprazole tables with sensor)' 14th November 2017 <https://www.proteus.com/press-releases/otsuka-and-proteus-announce-the-first-us-fda-approval-of-a-digital-medicine-system-abilify-mycite/> Last accessed 18th July 2018.
[5] Ibid.
[6] etectRx, 'etectRx, Inc. Announces Issuance of US Patent for Ingestible Medication Compliance System' September 7th 2017 < http://etectrx.com/etectrx-inc-announces-issuance-of-u-s-patent-for-ingestible-medication-compliance-system/>. Last accessed 18th July 2018.

via the app, and the wearer can prohibit access instantly if they wish, and can opt out of the data-sharing system at any time.

MyCite is not the only trackable medication system currently available. The New York Times reported at the release of Abilify MyCite that a Florida-based company, etectRx, was also producing a similar product called ID-Cap, which had been used in conjunction with HIV medications and opioids. The etectRx system is encapsulated, rather than embedded, and works by sending a low-level radio transmission to a reader device rather than a patch. etectRx is currently working on encompassing the reader into wristbands and mobile phone cases.[7]

MyCite is currently used only in Abilify, but the technology could be applied in any medication where adherence is important, such as antibiotics and medication used in the treatment of psychiatric disorders. It has been suggested that it could be used to monitor opioid intake in post-surgical patients to prevent over-use; in clinical trial patients to ensure accurate reporting of intake; and in medications directed at older patients who are more likely to forget to take their medication.[8]

3. The promised benefits: improved adherence and improved patient care

In their press release, Otsuka and Proteus emphasise two key benefits of the technology – improved compliance with medication regimens and enhanced dialogue between patients, carers and medical practitioners. For example, Dr John Kane is cited by Proteus as commenting that the technology is:

> an innovative way to provide individuals with serious mental illness, and selected members of their families and care teams, with information on objective medication taking patterns to help inform the patient's illness management and personalized treatment plan. This information allows the opportunity for an open dialogue with the patient.[9]

Each of these claimed benefits merits consideration.

3.1 Increased adherence

[7] Belluck (n3).
[8] Ibid.
[9] Proteus (n4).

Failure to follow a medication regimen is a serious problem in the treatment of some patients. 'Compliance' or 'adherence' means the extent to which the patient follows his or her treating physician's advice. In this context, that means taking medication as directed. These terms are largely synonymous, and 'adherence' will be used in this paper to mean taking medication as advised by a medical professional.[10]

In a review of non-adherence studies, Beena Jimmy and Jimmy Jose report that the consequences of non-adherence are 'waste of medication, disease progression, reduced functional abilities, a lower quality of life, increased use of medical resources such as nursing homes, hospital visits and hospital admissions'.[11] Non-adherence was also found to double the risk of hospitalization in patients with diabetes mellitus, hypercholesterolemia, hypertension, or congestive heart failure who were non-adherent to prescribed therapies compared with a general population'.[12] If successful in improving adherence for patients, tracking medications may therefore have individual health benefits. Not surprisingly, Otsuka and Proteus have emphasised this benefit of the technology, with Kabir Nath, CEO of Otsuka's North American arm, stating that non-adherence was 'an issue across all areas of chronic medicine' but particularly in the context of serious mental illness, where '[It] can lead to dramatic healthcare consequences quickly in a way that doesn't always [occur] in other chronic healthcare conditions'.[13] Jimmy and Jose argue that the data also suggest that non-adherence has wider public health implications as well as negative consequences for health care providers, physicians and medical researchers. They conclude that:

> helping people take their medicine appropriately would be a better achievement to avoid higher risk of severe relapses, antibiotic resistance, and preventable hospitalizations.[14]

[10] There is some debate about the distinction between 'compliance' and 'adherence', and they are sometimes given distinct meanings (see, eg: B. Jimmy and J. Jose, 'Patient Medication Adherence: Measures in Daily Practice' (2011) *Oman Medical Journal* 155; E. Sabaté, *Adherence to Long-Term Therapies: Evidence for Action* (World Health Organization, Geneva, Switzerland, 2003)). Others consider them largely synonymous but prefer 'adherence' as it lacks the paternalistic undertones of 'complying' with a doctor's 'orders' (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4087153/). Hence, there has been a shift to the use of 'adherence' and this terminology will be preferred in this paper.

[11] Jimmy and Jose (n 10).

[12] Ibid

[13] S Neville, 'US regulators approve first digital pill with tracking system', *Financial Times (online)*, 14th November 2017 <https://www.ft.com/content/267b890a-a9b5-11e7-ab55-27219df83c97> Last accessed 25th April 2019.

[14] Jimmy and Jose (nbv10)

A systematic review by Viswanathan et al pointed out at the time of release that non-adherence to medical treatment costs between US$100 billion to US$289 billion as patients require extra treatment when their conditions worsen.[15]

Whether the technology will actually improve adherence is not yet clear, although its release will allow for data collection on this question. Underlying the claims that digital tracking medications will have beneficial health consequences is the assumption that tracking ingestion will improve adherence. If tracking does not, in fact, promote adherence, then the use of the technology may not be warranted. In a patient context, this would merely amount to a wasted intervention. However, if tracking medication is used in other contexts, such as insurance, policing, sentencing and the like, the negative impacts explored below may not be outweighed by the benefits if these expected benefits prove to be unfounded.

The likelihood that tracking will produce the touted benefits depends on the reasons for non-adherence in relation to a particular drug or patient (or both). These will be both person-specific and condition-related. Adherence rates also vary with the complexity of the drug regimen and efficacy of patient-doctor communication. Some people will find tracking improves their adherence, while others may not, although a person who wants to ensure they take their medication is probably likely to improve their intake adherence if reminded to do so. Tracking in such contexts is not aimed at overriding resistance to taking medication but instead at enabling the patient to behave as he or she wishes to when they are in a fully competent state.

However, patients fail to take their medications for many reasons, some of which will not be ameliorated by telling them they have not taken it. One reason patients avoid medicating is because they do not like the side effects associated with the drug. Another is that they do not wish to have the effects the drug produces. This is true of some mental health disorders. Bipolar sufferers are the archetypal example, many of whom do not wish to avoid the manic phase of their condition, preferring it to the way they feel when effectively medicated.[16] In cases of this kind, tracking is unlikely to make a difference.

[15] M. Viswanathan, C.E. Golin, C.D. Jones, et al., 'Interventions to improve adherence to self- administered medications for chronic diseases in the United States: a systematic review' (2012) 157 *Ann Intern Med* 785–95.
[16] Phillip Polatin and Ronald R. Fieve, 'Patient Rejection of Lithium Carbonate Prophylaxis' (1971) *Journal of the American Medical Association* 218; T Van Putten, 'Why do patients with Manic Depressive Illnesses Stop their Lithium' (1975) *Comprehensive Psychiatry* 179.

The negative impacts of some other factors are likely to be offset by tracking. Age of patients is a factor, with some studies reporting adherence rates of below 50% in elderly populations.[17] Complicated regimens which are difficult to remember and follow are also associated with lower adherence, particularly in populations with low literacy.[18] Adherence is further undermined where patients cannot recall or understand the physician's directions about medication.[19] Some mental disorders cause those affected to suffer impaired executive control or short-term memory loss. In these cases, a tracking device may make a substantial difference to adherence by reminding the willing patient that they have failed to take their medication.[20] These are also patient factors that are not always apparent to physicians, and tracking will enable them to tailor care to improve adherence.

There are also cases in which it cannot be clearly determined without data whether tracking will have an impact. Some people simply do not accept that they are unwell, particularly once their symptoms have subsided. It is at this point that many people cease their course of medication, especially those taking antibiotics. Some such patients might respond to a reminder about the importance of finishing the course, but the fact that this message is usually given to patients prescribed drugs such as antibiotics, yet many do not finish the course regardless suggests that tracking may not be entirely effective as a solution to this problem. So, for people directed by courts to take medication, such as anti-psychotics, a tracking device may make a difference, or it may not.

3.2 Improved patient care

For the individual patient, ingestion tracking will mean that doctors will not need to rely on patient reporting to know if they are actually taking medication. This will enable doctors to take a more informed approach to the patient's care, which may mean better health outcomes. For example, if a doctor is aware that a patient is regularly taking the medication at the wrong time or in the wrong dosage, she can investigate the reasons. If this is due to a misunderstanding about how and when to take it, clarifying the directions or offering them in

[17] D.L. Sackett and J.C. Snow, 'The magnitude of compliance and non-compliance' in N.R.B. Haynes, D.W. Taylor, D.L. Sackett (eds) *Compliance in Health Care* (John Hopkins University Press, 1979) 11-22. J. Dunbar 'Issues in assessment' in N.S.J. Cohen (ed) *New Directions in Patient Compliance* (Lexington Books, 1979) 41-57.
[18] Jimmy and Jose (n 10).
[19] Ibid.
[20] Amanda MacMillan, 'A New Pill With a Digital Tracker Can Tell Your Doctor If You Swallow It' *Time Magazine* New York, 14th November 2017 <http://time.com/5023712/fda-approves-digital-pill-abilify/> Last accessed 18th July 2018.

a different format may improve the situation. Without tracking, a doctor relies solely on patient reporting of intake, which in cases of misunderstanding may not reveal the incorrect intake and hence the doctor will not have an accurate picture of why the patient's condition is progressing as it is. In such cases, tracking pills may be a highly valuable tool.

In its press release, Proteus touted the capacity of MyCite to support this relationship by enabling doctor and patient to collaboratively manage the patient's adherence. According to Proteus, recording and sharing medication intake promotes 'a more informed dialogue with [the patient's] healthcare team'.[21] Open, honest communication between doctors and patients is clearly vital to effective health management. A more informed doctor is better-placed to engage the patient about their intake issues, and then address them. For example, a patient may be avoiding medication due to side-effects, but may resist telling the doctor because he knows he ought to be taking his medication. Tracking will let the doctor know about non-adherence, and she might then be able to broach the issue and help the patient feel more able to explain his resistance and they can collaboratively work on a more appropriate regimen or discuss how the patient can manage the side-effects rather than avoiding treatment.[22]

Dolores Malaspina has also pointed out that in some cases, the tracking and reminders may help patients to remain self-sufficient:

> For many people who have to go into assisted living or nursing homes, the point is that they can't keep track of their medication. This could be an intervention for individuals and their families that would allow them to check in every day or two, without having to go to a higher level of care.[23]

Drug-devices that track medication intake certainly have the potential to improve healthcare generally and for the particularly individual, and might well save valuable healthcare resources that would otherwise go to treating the consequences of missed medication. However, the technology is not without its potential drawbacks, both in its healthcare use but more importantly in the wider areas in which might be deployed in the future. These are considered in the next section.

4. Raising some concerns

[21] Proteus (n4).
[22] Jimmy and Jose (n 10) 157.
[23] MacMillan (n 20).

When a new technology emerges, it often holds both the promise of benefits and the potential for harm. The MyCite system offers considerable benefits in terms of improved healthcare and patient outcomes, but raises concerns about consent, privacy, the erosion of patient-doctor trust and a range of 'function-creep' worries around use of the technology outside its originally-conceived purpose. These include medication intake tracking as a condition of probation or suspended sentencing, and its use by employers and insurance agencies. Some concerns may warrant legal controls on the use of tracking medication technologies, other concerns relate to the use of the technology by government itself and may give rise to a need to protections to be put in place to prevent inappropriate or unacceptable uses.

4.1 Privacy

The essential purpose of drug-devices is to generate data about medication adherence, that is to collect and store private information about patient behaviour. This raises privacy issues about collection, storage, access and sharing. The transfer of data from sensor to patch to mobile device may also pose risks of hacking, interception and interference.

The question is whether this is in any sense a novel problem that requires a legal response beyond the measures already in place to protect patient privacy. English law protects privacy via a number of legal mechanisms. In the medical context specifically, doctors are under a common law duty (in both tort and equity) to respect confidential patient information. Indeed, the Court of Appeal in *McKennit v Ash* referred to medical information shared in the context of a relationship of medical confidentiality as 'doubly private', because the information itself is private and also shared within a relationship of confidence.[24] While there is no free-standing right of privacy in English law,[25] breaches of confidence can be actionable in tort via the equitable doctrine of breach of confidence.[26] Under this duty, medical professionals are bound to keep information confidential where the information is private, shared in a relationship of confidence, and where harm would result from the release of that information.[27] Human rights law also offers some protection of privacy in the medical context. The protection of medical information has been held to be of 'fundamental

[24] *McKennit v Ash* [2005] EWHC 3003 at 23.
[25] Confirmed in *Wainwright v Home Office* [2003] UKHL 53.
[26] *A v B plc* [2003] QB 195.
[27] *Campbell v MGN* [2004] UKHL 22.

importance' to the enjoyment of Article 8[28] and this entails a positive obligation to take steps to protect medical confidentiality.[29]

More generally, the Data Protection Act 2018 (DPA) protects 'personal data', which means 'any information relating to an identified or identifiable living individual' (s.3(2)). The Act enshrines the EU General Data Protection Regulation (GDPR)[30] in English law, which sets out seven principles to protect individuals in relation to the use of their data. These are: lawfulness, fairness and transparency; purpose limitation; data minimization; accuracy; storage limitation; integrity and confidentiality; and accountability. 'Processing' includes collecting, recording, using and disclosing data, and so encompasses what is likely to be done with data obtained via digital medications. The GDPR and DPA also afford individuals a range of protective rights in relation to their data, including the rights to be informed of collection; to have access to the data; and to have inaccuracies rectified; and they may ask for the data to be erased in certain circumstances. The regulations make clear that people may also withdraw consent to processing at any time although these principles and rights apply slightly differently in some contexts where they are balanced against other considerations, such as in the law enforcement context. It is beyond the scope of this article to go through these in detail here, but in general the new data protection regime offers a fairly high degree of protection for those whose data is collected via digital medications, including when it is used for purposes other than those collected.

These protections would extend to information generated by drug-devices where the information is shared within the doctor-patient relationship. This would restrict doctors receiving the information from sharing it without patient consent. While the mechanism for collection is distinct, the information itself is no different to other information collected by doctors – it is effectively the same as the doctor's own knowledge of a patient's reporting of adherence, which would fall within the information protected by the laws outlined here. Adherence data itself is very similar to other information provided to doctors, and will be obtained in the form of records of drug taking to the doctor's computer or phone. There is no reason why the current legal measures should require amendment – they should capture this kind of data and offer protection as they currently do to other information. Therefore,

[28] *Z v Finland* (1998).
[29] *I v Finland* (2008).
[30] Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016.

concerns about medical professionals sharing data outside the doctor-patient relationship without consent are likely to be captured by existing laws and adequately regulated.

Beyond general concerns about privacy and data-sharing, are worries about data obtained via hacking. In 2017, the United States Food and Drug Administration (FDA) regarded the possible hacking of biodevices such as a pacemakers as sufficiently concerning to order a recall (via a requirement for a firmware update) of certain pacemakers it considered vulnerable to hacking.[31] In those cases, the risk was considered one of hackers interfering with devices to run down the batteries or affect their operation. In the context of MyCite-type devices, the concern would be hackers intercepting and using tracking data. A hacker might also wish to interrupt tracking, alter data or prevent tracking altogether. If such information becomes valuable, then such hacking may become a real concern, but at present it remains rather remote.

Should hacking become a problem, it is likely, however, that such acts would already be caught by a range of legal mechanisms. In the UK, the hacking of devices is a criminal offence under the Misuse of Computers Act 1990. This includes all devices used for 'storing, processing and retrieving information' and would include mobiles phones and wearable devices such as those used with tracking pills.[32] The offences committed under the Act are relevant to wearable technology in two ways. First, it is an offence to intentionally gain unauthorised access to a computer under Section 1 and a further offence if this is done with the intention of the commission of further offences under Section 2. The second type of offence is the commission of 'unauthorised acts with intent to impair the operation of a computer' under Section 3. These would include cases where a hacker sought to interrupt the exchange of information between the pill, wearable pad and mobile phone such as to prevent the tracking function from working. There are also offences defined under Section 55 of the Data Protection Act 1998 (now Section 170 of the 2018 Act) where an unauthorised person, obtains or discloses personal data, procures the disclosure of personal data or sells or offers to sell personal data.

[31] Alex Hearn, 'Hacking Risk Leads to recall of 500,000 pacemakers due to patient death fears' *The Guardian* London, 31st August 2017 https://www.theguardian.com/technology/2017/aug/31/hacking-risk-recall-pacemakers-patient-death-fears-fda-firmware-update. Last Accessed 18th July 2018.

[32] See *DPP v McKeown, DPP v Jones* [1997] 2 Cr App R 155 HL.

That said, as the technology plays out and the actual nature of hacking concerns emerges more clearly, it may be beneficial to also develop approaches that require technology producers to build in protections (as the FDA has required in relation to pacemakers). This might be achieved via the 'compliance by design' approach suggested by Eleni Kosta, Bert-Jaap Koops and Nadezhda Purtova.[33]

4.2 Consent concerns and the erosion of doctor-patient trust

Patient trust is a crucial dimension in the doctor-patient relationship. While collaborative collection of medication intake may enable more informed dialogue between patient and physician, some have suggested it may have a negative impact. Ameet Sarpatwari, for example, has commented that 'if used improperly, [tracking medication] could foster more mistrust instead of trust'.[34] A *New York Times* piece on Abilify MyCite quoted a number of patients who had suffered from psychiatric disorders who commented that being tracked would actually have undermined their relationship with their doctor. One said it could stymie the patient's progress in becoming well and managing their condition, but another did suggest it might help a patient prove to their doctor that they were taking their pills and so build trust.[35] Trust between doctor and patient is very often necessary to achieve optimal health health outcomes. As explained in *Z v Finland*:

> Without such protection, those in need of medical assistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even, from seeking such assistance, thereby endangering their own health and, in the case of transmissible diseases, that of the community.[36]

As Mark Henaghan has pointed out, this trust works in both directions:

> patients have to trust healthcare professionals to fulfil their professional duties on a daily basis. Healthcare professionals have to trust their patients to give them accurate information about the patients' health.[37]

It may be that tracking pills undermine trust if patients feel doctors are 'checking up on them', but where there is an absence of trust on the part of the doctor, their use may promote

---

[33] N. Purtova, E. Kosta, and B.-J. Koops, 'Laws and Regulations for Digital Health' in Samuel A Fricker, Christoph Thuemmler, Anastasius Gavras (eds) *Requirements Engineering for Digital Health* (Springer, 2014) 47-75.
[34] Belluck (n3).
[35] Ibid
[36] *Z v Finland* (n 28) [95].
[37] Mark Henaghan, *Health Professionals and Trust: The Cure for Healthcare Law and Policy* (Routledge 2012). See also Mark A. Hall, 'Law, Medicine and Trust' (2002) 55 *Stanford Law Review* 463.

this side of the trust relationship by enabling the doctor to believe the information about adherence he or she receives. Whether, on balance, this will be a positive use of tracking pills therefore depends on the context, the particular patient-doctor relationship and the importance of trust within that relationship.

Under English law, competent patients cannot be required to take medication, so any use of drug-device tracking such as MyCite in these patients would have to be consensual.[38] While there may be complexities around that consent and the relationship, as a concern about the technology it is one best managed by individual doctors and the particular patient. More difficult are patients who lack capacity to consent. Under the Mental Capacity Act 2005, where a patient lacks capacity to give consent for treatment[39], a decision about care can be made on their behalf and must be made in their 'best interests'.[40] Tracking pills are most likely to be useful in cases where a patient lacks full capacity but could still be expected to take their medication. These cases may be quite limited, as this may not apply to many patients who lack capacity.

But where it does arise, it will raise difficult issues around whether it is can be in a patient's best interests to track their medication intake without their understanding that such tracking is occurring, or in some cases without their knowledge that it is. Clearly, in many cases of lost capacity, the patient's behaviour may be controlled already, as in instances of people who have been placed into care under the Mental Health Act 1983 as amended by the 2007 Act. A person may be detained under a 'section' of the Act under a wide range of circumstances. This ranges from short periods under which a person may be held under section where the mental illness is so serious that there is a need to protect the health or safety or for the protection of others up to a Section 37 or Section 41 order, made by the court which can hold an individual for up to six months, with periodic renewals.[41]

---

[38] See, eg: *Re T (Adult: Refusal of Treatment)* [1993] Fam 95; *Montgomery* v *Lanarkshire Health Board* [2015] UKSC 11: 'An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken'.

[39] *Mental Capacity Act* 2005, Section 2.

[40] ibid, Section 1(5) and Section 3.

[41] For a full list of the circumstances in which a person may be held under Section: Section 5(2) allows a doctor to make a 'detention section' where this 'ought to be made' for a voluntary in-patient up to 72 hours. Section 5(4) permits a specially trained nurse to detain an individual for up to six hours, subject to strict conditions. Section 17 provides the clinician the power to grant leave to a patient, subject to conditions. Sections 35, 47 and 49 relate to the detention of persons accused of criminal offences and those transferred from prison to psychiatric hospitals. Under Section 135 a person may be detained for up to 24 hours where there is reasonable

But some capacity cases are more subtle, such as patients with some mental disorders like anorexia or bi-polar disorder. In these cases, non-adherence may be an element of the disorder and it may be important to monitor intake while attempting to build the patient's capacity to be self-sufficient. For example, as noted above, some bi-polar sufferers resist medication during some phases of the condition, while desiring it at others. Similarly, anorexia sufferers are sometimes medicated with appetite-enhancing anti-psychotics which they may agree to at one point but later wish to cease taking. Schizophrenia medications may also fall into this group of medications that a patient may agree to and want to be encouraged to take when they move into a phase where they know they may no longer self-medicate. One novel aspect of the MyCite technology is the capacity to some degree to bind oneself to reporting when one moves into a phase where one prefers not to take medication. This opens up potentially complex consent questions, and questions about when consent to tracking may no longer hold. Woven into such questions are those about a patient wishing to bind themselves to tracking during phases when they expect to lose capacity but wishing to be tracked in their non-compliance to help them address the problem. Such steps pose the question of whether tracking would continue to be permissible during such phases. This would turn on whether the patient had become non-capactious (in which case the tracking could continue if it is considered in their 'best interests'). Such seeming 'Ulysses contracts'[42] might also be conceptualized as advance directives, permitting the patient to express her wishes about treatment (including tracking) prior to the loss of capacity.

At present, however, these cases probably do not require a legal response as the 'best interests' test is sufficiently flexible to allow a court to determine whether tracking medications would be an appropriate treatment measure. The legal mechanism for making this determination is in place; the difficult aspect is *how* the question might be answered under best interests. This latter question is one that may be difficult to answer in practice, and requires exploration of the ethical issues raised by tracking medications and their role in appropriate medical care of incapacitous patients. However, where the phases in which the patient does not wish to take medication does not equate to one where their capacity has actually been lost, these analyses may not hold and, depending on the particular facts,

cause to suspect a person has a mental disorder and is being ill-treated and unable to live independently. Section 136 gives a police officer the power to detain a person who appears to have a mental disorder 'in need of immediate care or control' for up to 24 hours.

[42] An agreement to bind oneself to a prior decision and be prevented from changing that decision even if one says one wishes to do so.

ongoing tracking may become non-consensual and hence unlawful. A detailed exploration of the consent issues this raises are beyond the scope of this paper, but may warrant further consideration. Within this consideration, there may also be questions about authenticity.

One specific potential use of tracking medication in persons lacking full capacity is children. Younger children requiring medication will obviously not be left to take it for themselves, but older children might be considered able to manage their own medication regimes yet it may be considered useful to monitor them to ensure they are doing so. This might be with the knowledge of the child, and they may see it as a means to build trust in their ability to self-manage, or they may feel coerced, watched and distrusted, all of which may undermine the relationship between physician and child.

More importantly, from a legal perspective, is the use of tracking medication without the child's knowledge. Parents, or physicians who prescribe such medications, will be legally permitted to do so on the basis of parental authority or best interests.[43] The issue is whether in older children, tracking medication intake is sufficiently intrusive to justify limiting the medication's use without a child's knowledge. Given that even *Gillick* competent children do not have the legal capacity to refuse treatment where their parent decides it is in their best interests, if a doctor is prepared to prescribe a pill that includes tracking technology and the parent consents to this, then it would seem there is no legal barrier to this being done. There are, of course, moral concerns with deceptive treatment of children, and we might think particularly with older children that this raises such concerns. This might be particularly so given that the process of tracking will generate data about the child that may be retained, placing the child at risk of privacy invasions, especially if the data is used for other purposes subsequently. For children close to adulthood, there may be a case for restricting deceptive use of tracking pills on this basis, and hence this is an issue that might demand further consideration.

4.3 Incentives, coercion and mandated use

Much of the publicity material around MyCite stresses that patients have complete control over who may access their data and are fully consensual in their use. It is easy to suggest, as etectRx senior vice president Eric Buffkin does, that people who are concerned about privacy

[43] For parental responsibility see: The Children's Act 1989, s 3. For physicians' authority on the basis of best interests see: *Re A (Children)* [2001] 1 Fam 147 (HL), [2001] 2 W.L.R. 480; *In Re T (A Minor) (Wardship: Medical Treatment)* [1997] 1 W.L.R. 242.

can simply not take the digital pill. The reality is, however, more complex. There are multiple contexts in which a person might be subject to incentives, pressure or even something close to coercion to take a tracking version of their medication (once available). For example, Eric Topol argues that it is feasible that patients may feel 'so much incentivised that it almost is like coercion' if (in the United States context) medical insurers create incentives to patients to use digital tracking medications.[44] In some contexts, intake of pills that contain tracking sensors might be made compulsory, in others the pressure or incentives to track and share data might border on unreasonable or even coercive. Some people may not be in a position to refuse to track and share data, and it may be that the law ought to protect their decision as an element of respect for privacy and the right to self-determination. In other contexts, however, we might welcome the capacity to track intake in a mandated way. This section outlines some of these contexts and examines the potential implications in relation to consent.

While in the previous section the potential for undermining consensual use of tracking was explored and found to be relatively unproblematic, medication intake tracking technology has applications well beyond the purely healthcare context and it is these that pose greater concerns. Many organisations, including schools, courts and government, have an interest in tracking medication intake and data about past medication adherence patterns.

4.3.1 Insurance and employment

Health and life insurance companies have a clear vested interest in patients taking their medication as adherence can avoid the added costs associated with prolonged or worsening illness. However, in the United Kingdom, the issues that have been raised by United States commentators—concerns relating to potential pressure from insurance companies for digital tracking to be used to confirm medication adherence, or the use of extra co-payments for non-adherence—are less of a worry. Health insurers wield less influence over patients in the United Kingdom as all can access healthcare free at the point of service via the National Health Service. However, this does not mean such concerns are irrelevant in this country, as many people do have private health insurance. It is entirely feasible that medical insurers in the United Kingdom might press members to taking tracking pills to reduce premiums or as a condition of coverage.

[44] Belluck (n 3).

Other insurers may also have an interest in tracking medication intake as a data source for evaluating risk. This would extend to access to data collected generally, which might be sold on in anonymised form by Proteus or other providers. It might also have value in relation to individuals, as information about a person's behaviour that may affect the premiums they are offered for many types of insurance. For example, a person with epilepsy who is interested in car insurance might be asked to provide any data on their adherence to a regimen of epilepsy medication. Low adherence might see their premiums rise or they may be denied insurance due to the risk of accident. Adherence data might also be sought by insurers when processing claims, for example to determine whether a party had been taking their medication prior to an accident. Insurers might also make taking tracking medication and sharing the data with the insurance company a condition of insurance, which raises issues about consent.

Similar issues could arise in the employment context. Employees affected by a medical condition that might affect their performance in the workplace could be required, as a condition of employment, to consent to tracking and data-sharing to demonstrate the employer that they are managing their condition. This could be considered coercive and inappropriate, as well as an invasion of privacy. It could also form the basis of a claim for unfair dismissal or discrimination on the ground of disability, if the condition in question constitutes a disability, under the Employment Act 2010 unless the employer can justify it, by showing that the employee is unable to perform the job for which they were employed. Under s60 of the Act, the conditions on which an employer may ask for such medical information are strictly curtailed.

Why is this a problem? At one level, it might be said to undermine autonomy, pressuring a patient to accept a treatment she might not otherwise have chosen. For example, in *In Re T (Adult: Refusal of Treatment)* the court required 'real consent' and looked at the influence of others on consent to treatment. In the court's view, 'Every decision is made of a person's free will, and is voluntary, unless it is effected by compulsion'. It recognised that a level of persuasion is permitted, but that 'A special problem may arise if at the time the decision is made the patient has been subjected to the influence of some third party'.[45] Ethically, too, autonomy might be considered to be undermined by pressure from insurance companies for people to use the tracking form of a medication to ensure better adherence. It could also be

[45] *Re T (Adult: Refusal of Treatment)* [1993] Fam 95, 622.

considered an inappropriate use of the power insurers wield in relation to users if the requirement undermines consent.

However, in both the employment and insurance contexts we could regard this as merely another aspect of the transactional relationship between employer and employee, or insurer and insured. In both, each party has goals. Both parties accede to the other's demands to some degree, although the power imbalance means that the insured and the employee do so to a much greater extent. But in both contexts, the insured and the employee can make a free choice that the benefits of insurance or employment are worth the 'cost' of being tracked and providing data. This cost may not be terribly high, either, given that the patient arguably loses little by being tracked. If he or she gains lower premiums or can demonstrate desired adherence to an employer, they may in fact benefit in return for agreeing to be tracked.

This, however, assumes a degree of freedom of choice in relation to employment that may not reflect reality. We have seen in the development of rules around the volenti defence in the context of negligence that employment-related decisions are not regarded as entirely free. Similarly, the insured party is at a severe disadvantage in relation to the insurer when he or she is seeking insurance, so it is perhaps unrealistic to conceptualise their exchange as entirely freely transactional. But if we consider the points at which the law tends to consider consent to transactions vitiated, such pressure falls well short of the requirements for duress in contract, and is closer really to the kinds of commercial pressures accepted as the norm in contract negotiations.

Whether this requires legal controls is a similar debate to that around the collection of genetic information that arose in the early 2000s, which engaged with issues of secondary data use, consent, information sharing and the like. Tracking medication intake is similar in the sense that it generates personal information about a person's lifestyle and behaviour, and also in the sense that it may alter a person's behaviour. This was a key issue raised by the use of genetic tests for disease diagnosis and the detection of genetic predisposition to disease. When these tests became available, there were concerns that a person might avoid taking tracking medication, even though it would benefit them in terms of personal healthcare, because they may be concerned about demands to disclose tracking data to an insurer, just as there were concerns that patients would be required to reveal the results of genetic tests and hence avoided taking them for insurance reasons. According to the Association of British Insurers (ABI), the results of a predictive genetic test will not currently affect a person's ability to take

out insurance, except life insurance over £500,000 (and then only in the case of Huntington's disease). This is enshrined in the Code on Genetic Testing and Insurance (which largely follows the previous *Concordat and Moratorium on Genetic tests and Insurance*). The Code is a voluntary code of practice agreed by HM Government and the ABI,which was developed in response to concerns about genetic testing. Under the Code, whether insurance is offered and the terms on which it is offered, will depend on medical history, including any *diagnostic* genetic tests. *Predictive* tests will be taken into account solely in the case of Huntington's Disease for life insurance policies valued at over £500,000. Predictive tests may be taken account of for some critical illness and income protection insurance if they are for listed conditions, but at present no conditions have been listed for these types of insurance. The Code makes clear that '[p]redictive genetic test results will not be asked for, or taken into account whatever the level of cover' for any other types of insurance.[46] Further, while a patient must provide the results of diagnostic tests if requested, predictive test results need not be disclosed (except for Huntington's Disease) and a patient may instruct their GP not to send such information to insurers, unless they wish to do so because the results come in their favour.

Such an approach might be instructive in placing reasonable limits on what information can be sought and used in both insurance and employment contexts. We might also pick up the contract dimension and consider how the law has offered some protection in consumer contracts due to the power imbalance in such relationships. The principles underpinning consumer protection could play an informative role in developing some controls on what is appropriate and acceptable in insurance and employment arrangements. The general principles protecting employees from employers ought also to apply, but may need adapting to address the particular nuances of tracking pills. If the use of such tracking medication technology becomes a reality in the workplace, this would be the appropriate starting place for thinking about solutions.

In considering these issues further, one point made by Jennifer Chandler in relation to neurotherapies may also be important. Chandler argues that it is possible that employers may face civil consequences if they fail to take reasonable steps to prevent harm to employees for

[46] Association of British Insurers and HM Government, *Code on Genetic Testing and Insurance*, October 2018, Commitments 2 and 3, and see further p.4–5. Previously reflected in Concordat and Moratorium on Genetic tests and Insurance 2014 at 21(d)(ii)

whom they are responsible.[47] As she points out, 'a professional's liability insurer has an economic incentive to monitor the insured professional and to reduce the risk of liability by encouraging them to take reasonable steps to avoid harm to their clients'.[48] Applied to tracking medications, it is feasible that an employer who employs someone with a condition that requires medication to keep either the employee safe in the workplace, or prevent them causing harm to others while working, could be expected to take steps to ensure the employee takes medication as needed. It is possible that a failure to do so could be regarded as negligent or fall within a failure to provide a safe place of work. If the employee harms someone, the employer might be liable for this failure. One example might be an epileptic lorry driver, another a surgeon with a known condition that affects her ability to perform her duties.[49]

4.3.2 Conditional release and court-mandated medication

While employers and insurers might exert pressure on individuals to acquiesce to tracking, the justice system might feasibly use the technology in a more conditional or even compulsory way. Russell Brandom refers to the right to refuse treatment as 'an important, fragile principle in health care', one which he says may be threatened by the use of tracking technology to enable courts to more effectively mandate treatment. He points out that at present, mandated treatment is difficult to police, but tracking devices such as MyCite changes this and offers a means for courts to effectively determine whether an offender has breached conditions of parole or a suspended sentence. Arthur Caplan raises similar concerns, commenting:

> The temptation in the legal system to say, 'I can monitor you and make sure you're not a threat' is going to be huge. Maybe that's good, maybe it's bad, but it's a different world than saying I consent to taking these pills.[50]

One context in which tracking may be to some extent coerced, or at least pressured, is in relation to conditional release of psychiatric patients. In *SH v Mental Health Review*

[47] Jennifer Chandler, 'Autonomy and the Unintended Legal Consequences of Emerging Neurotherapies' (2011) *Neuroethics* 255, 255
[48] Ibid 255.
[49] See further the dicta in *Mansfield v Weetabix Ltd* [1998] 1 WLR 1263 involving a lorry driver who crashed while suffering a hypoglycaemic attack. The driver was not found to be negligent as he was not aware that he suffered from the underlying condition that led to the attack (malignant insulinoma) and rendered him incapacitated, but the court made clear that had he continued to drive once aware that his ability was impaired, he would have been negligent.
[50] Brandrom (n 2)

Tribunal[51] the court considered a case with significant importance in the context of tracking drugs used to treat serious mental health issues. In this case, the court had to consider a requirement that a person 'shall comply with medication prescribed by [a named doctor] or his successor, which is likely to be by depot for several years' as a condition of his discharge from a psychiatric hospital. In particular, this patient did not wish to cease taking the medication Risperidone, but nor did he wish to take it under compulsion. Conditions on discharge that require a patient to take medication are governed by Section 73 of the *Mental Capacity Act* 2005. In *SH*, it was argued that the condition requiring him to take medication was unlawful because it contravened the principle that requires consent to medical treatment.[52] This argument was unsuccessful, however, with the court holding that on each occasion on which SH submitted to the injection of medication he had an 'absolute right to refuse' and the administering medical professional had therefore obtained a 'real consent', notwithstanding the compulsory element of his conditions of release. Importantly, the court stated that non-compliance with this condition did not lead to *automatic* re-call or any other sanction and further, that re-call can only be lawful if based on 'up to date' medical justifications.[53] The condition was treated as analogous to 'strong medical advice or the persuasion of a relative'.

The implication of this case in the context of tracking medication is that requiring a patient to take a tracking variant of medication and have their data sent to a doctor or the hospital (or even a governmental agency) is unlikely to be found to be 'non-consensual' treatment and hence will probably be considered lawful. Indeed, as the problematic aspect relates only to the *tracking*, not even the ingesting of medication *per se*, this is even more likely to fall within the bounds of 'consensual' treatment in a fact situation similar to that in *SH*. This suggests that under the current law there is little barrier to the imposition of a condition of tracking on those being discharged.

The question is whether this is a problem. On the one hand, it is an undermining of consent as it was in *SH*, despite the court's best efforts to regard it as consensual treatment. However, the impact is less concerning as it is only the tracking, rather than medication itself (and the related bodily integrity infringements) that are at issue. Further, if the patient agrees that the

[51] [2007] EWHC 884 (Admin).
[52] *In Re T (Adult: Refusal of Treatment)* [1993] Fam 95.
[53] *Kay v UK* (1998) and *B v Mental Health Review Tribunal and Secretary of State for the Home Department* [2002] EWHC 1553 (Admin).

medication is beneficial, then the tracking is arguably less problematic as it is in part intended to support (or at least will act as support) for the patient adhering to a regimen to which she has already agreed. That said, the condition raises similar issues about doctor-patient trust and authenticity as it did in the patient-doctor relationship discussed above. Here, too, the transactional dimension undermines the consensual nature – the patient may be consenting to tracking only because she will obtain her freedom. This is a far cry from full consent, but it may be justifiable given the benefits she receives (the transaction) bolstered also by the community benefits that accrue from being able to track intake by newly released psychiatric patients, particularly if this prevents relapses or dangerous behaviours that harm others.

Similar issues arise in relation to court-mandated treatments, which may be relevant in relation to a number of disorders. Primary among these will be medication for mental disorders that may be associated with behaviours the court considers likely to lead to offending. This might include schizophrenia, bipolar and other similar conditions, but also encompass disorders that may increase the likelihood of harm to others in different ways, such as epilepsy, hypoglycaemia and diabetes, which can require medical management to maintain fitness to drive. All three conditions, when poorly managed, can (and have) led to motor vehicle accidents.[54]

In the United Kingdom, the courts and police services are already authorised to require certain behaviours of suspects and offenders, which are implemented via forms of tracking device. These conditions can be placed on a suspect prior to being charged under s37 of the Police and Criminal Evidence Act 1984, backed by the power of arrest under s46A(1A); *however* for pre- and post- charging police bail, the police cannot impose electronic monitoring as a condition. In respect of bail granted by the court conditions can be attached, including in respect of electronic monitoring. The current test is that these conditions can be imposed where they are necessary, reasonable, proportionate and *capable of being enforced.* These can include electronic tagging under s3AB of the Bail Act 1976. Prisoners released on parole may also be subject to electronic tracking under s4 of the Criminal Justice (Sentencing) (Licence Conditions) Order 2015. A requirement to take medication, tracked via a drug-device system could be an appealing means of ensuring offenders comply with medication conditions. Mandated treatment might occur as a condition of parole or suspended

[54] See variously: *Mansfield v Weetabix* [1997] EWCA Civ 1352; *R v Akinyeme* [2007] EWCA Crim 3290.

sentencing, requiring the offender to have their intake tracked and the data shared with the court to ensure continuing adherence. Many prisoners will be subject to hearings before a parole board and will be released on licence, and these can include attending appointments with a medical professional under s7(2)(c)-(d) of the Licence Condition Order 2015, which also includes that they cooperate fully with their care or treatment plans if this is necessary and proportionate and where the offender consents to the treatment. However, this requirement for consent is quite thin as failure to adhere to a treatment plan or refusal to accept such a condition will mean there could be a risk of serious harm and a failure to address the purposes of the conditional release, meaning the individual can be recalled under a standard condition of licence rather than an additional medical condition.[55]

Those convicted of offences carrying a tariff of between 14 days and two years may be granted a suspended sentence,[56] subject to conditions imposed by the court under Section 190 of the CJA 2003. This can include, for example, a mental health treatment requirement under s190(1)(h) and defined under s207.[57] However, again, such a requirement must obtain the offender's willingness to comply under s207(3)(c). The Court can (or is bound to) order electronic tagging under s190(3), so electronic monitoring of a condition is already permitted. Failure to adhere to these conditions may mean the offender serves the original custodial sentence.

A similar approach to electronic tagging could be taken with tracking medications for offenders and suspects who suffer from a condition of the kind noted above, such as bipolar and other psychiatric disorders associated with behaviour that can be harming to others. This could be a good development for both courts and offenders, enabling courts to set conditions on release that can be meaningfully applied, while enabling offenders to avoid incarceration via the capacity to demonstrate adherence. However, concerns have been raised about the use of electronic tagging, and many of these apply very similarly to tracking medication intake. The core of these concerns is that while in the UK consent to any treatment remains crucial, there can still be a coercive element to mandated treatment plans, as failure to act in accordance with such plans can be seen as a refusal to adhere to the purposes of parole or as increasing risks under licence. Therefore, what appears to be a consented condition is really

[55] Section 3(2)(a) Criminal Justice (Sentencing) (Licence Conditions) Order 2015).
[56] Section 189 of the Criminal Justice Act 2003, as amended by Section 68 of the Legal Aid, Sentencing and Punishment of Offenders Act 2012.
[57] As amended by Section 73 of the Legal Aid, Sentencing and Punishment of Offenders Act 2012.

only a highly constrained choice between two unappealing options – incarceration or invasion of privacy or bodily integrity.

That said, there is one important distinction. Tagging offers very little benefit to the person tagged, beyond the increased freedom it may provide them with (as a result of the giving up of liberty and privacy). Those who acquiesce to using a tracking variant of their medication, however, are adding only a data-tracking dimension to a behaviour that is itself largely for their benefit. A patient will be medicated to improve their own health first and foremost. This may also reduce their problematic behaviours or the risk they pose to others, but this is a secondary concern. Tracking them will bring them benefits (being permitted to return to society, to drive and so on) but it will also support their health. This cannot be said of tagging. The benefits gained in the latter are solely transactional. From this perspective, if tagging is deemed acceptable, then tracking seems to fall well within the bounds of what is currently accepted. This might be undermined only if concerns arise about secondary and tertiary use of data collected, including subsequent use of data in the future in relation to offending. This might create an added disincentive to tracking that more deeply undermines the person's full consent.

Some suggest this is not necessarily problematic. For example, Tom Douglas has argued that, in the particular case of sex offenders, consent should not be necessary because by committing such a crime, an offender becomes morally *liable* to undergo certain medical interventions, and that even the strong principle of bodily integrity should not bar such action.[58] His argument is that there are biological and neural traits which increase the tendency for certain forms of offending and medications that can reduce this risk, improving the possibility of rehabilitation. We already largely accept that, in committing a crime, an offender becomes liable for minimal incarceration, but also a whole other range of coercive and non-consensual sanctions. Bodily integrity is not more 'robust' a right than freedom of movement or association. Further, neither recourse to the harm caused nor the threat to agency can straightforwardly deny the liability to undergo such treatment. On this view, tracking of medication intake would appear to be quite easily justified (separating out the

[58] Tom Douglas, 'Criminal rehabilitation through medical intervention: moral liability and the right to bodily integrity' (2014) 18 *The Journal of Ethics* 101.

question of mandated medication itself, which would be a more problematic bodily integrity issue, but still justifiable from this perspective).

4.3.3 Conditional use requirement

Falling short of mandated tracking treatment, might be the *conditional* requirement that a person takes tracking medication and share data with a government body. A prime example would be to make obtaining a driver's licence for those with conditions that affect driving to take a tracking version of their medication and share adherence data with the DVLA. A similar approach might be used for pilots, police, military personnel and others in positions of care or responsibility where they suffer conditions that could affect performance and cause harm to others. Such conditional use could be considered analogous requirements that doctors undergo vaccinations to practice --- there is a transactional dimension to this kind of conditional consent, where the consenting person agrees to be tracked to access a service such as driving a car.

Are such conditionals problematic? Arguably they are no different to current requirements such as regular eye-testing and possibly less onerous. However, the data sharing aspect makes them a greater incursion on individual privacy and liberty. The protective benefits to the community of being able to track adherence (and being able to sanction it or remove privileges where non-adherence is detected) may outweigh these concerns. The right to bodily integrity under Article 8 ECHR is not absolute, and interferences may be justified where they are necessary and proportionate to pursue 'public safety' and 'health' aims.

As an analogy, under the Road Traffic Act 1988 persons with a 'relevant disability' where driving is likely to be a source of danger to the public are subject to specific licensing regulations. Persons with epilepsy, for example, must disclose this fact to the DVLA and can have their licence taken away from them under the Motor Vehicle (Driving Licences) Regulations 1999 (as amended). However, epileptic drivers may be allowed to drive but may be required to take medication. In the case of 'Group 2' drivers with bus, coach and lorry licences, they are already required to prove that they have taken epilepsy medication for at least five or ten years, depending on the circumstances. In any of these cases, failure to make such disclosures are punishable by a fine and accidents that occur as a result can be prosecuted as dangerous driving under Section 2 of the Road Traffic Act 1988. The Sentencing Council includes as an aggravating factor 'driving when knowingly suffering from a medical condition which significantly impairs the offender's driving skills', including

any failure to take prescribed medication. In addition, some insurance companies would not cover situations in which a driver fails to take prescribed medication and causes an accident. This requires medical professionals to make assessments about the driver's safety and to communicate this advice to the patient. The same sorts of considerations are true of diabetic drivers who fail to disclose their condition, but the list of relevant disabilities is extensive and many of these conditions may similarly entail that medication is taken before the driver is granted a licence. Therefore, this sort of intervention is already common, and the introduction of a new technology that monitors drug usage could be used to enforce such requirements more stringently. It would also be no more or less intrusive or invasive of privacy than such measures, therefore it should fall within existing legal boundaries.[59]

For some, such tracking could actually be beneficial. A driver could use tracking data to ensure she retains her licence and her insurance coverage in the case of an accident. Tracking in such cases can, then, give someone with a medical condition greater freedom than they might otherwise have had. If tracking increases adherence, or alerts authorities to a person being unfit to drive, this may reduce accidents and consequently save lives. However, such tracking generates data on a person's medication intake which is then held by organisations other than his or her medical professional. This raises the possibility of secondary use of that data beyond the purposes for which it was collected. For example, a person might fail to take her medication and rather than this affecting her driving (the reason she agreed to tracking), she is arrested for some other offence (say, assault). Should the data collected by the DVLA be available to the police when they conduct their investigations? Should it be available to the court when considering sentencing? These could be legitimate uses, but if the initial collection was legitimate only due to her consent (as a condition of obtaining a licence), do these secondary uses require justification beyond their value for policing or sentencing? And if the data is used in this way, should consideration be given to how this might affect initial agreement to the collection? Such secondary use might prompt those who wish to obtain a

[59] Cases such as *R v Remi Akinyeme* (n 54) demonstrate the problematic consequences of failure by drivers to follow a medication regimen. In that case, the defendant had an epileptic fit while driving, leading him to hit and kill a cyclist. He had not taken his medication prior to driving, and was aware of the risk of seizure and its possible consequences if he did not self-medicate, yet drove regardless. While tracking intake could not prevent such a incident without much more serious interventions (tracking driving via GPS and tagging followed by police intervention to prevent driving, which would involve both huge resources and substantial invasions of privacy), if a pattern of failure to medicate could be detected, a person could have their licence revoked, which might incentivise some to avoid driving.

licence to refuse collection (possibly an unreasonable disbenefit) or incentivize them to circumvent the tracking process.

Conditional use could be more problematic in other contexts. One primary one is custody of children, where courts might require that a parent, as part of child custody arrangements, agrees to tracking to ensure medication intake as a condition of access of custody. However, in situations like child custody, the condition moves beyond a mere transaction to access something desired as the stakes are substantially higher. This kind of conditional access might be moving towards the kinds of overt pressures to which Chandler avers in the context of neurotherapies.[60]

4.3.4 Secondary use of data in other legal contexts

Data about a person's prior medication adherence may emerge as a desirable form of evidence in any number of legal contexts. One obvious example would be custody disagreements. One parent may allege the other is unstable or incapable of taking on the care responsibility due to a medical condition, particularly a mental disorder. Being able to demonstrate past adherence to medication that manages the condition might be a powerful defence, but data demonstrating patchy adherence might be damning – legitimately or otherwise. Data could also be led as evidence in cases of negligence (especially negligent driving). Past intake behaviour might be relevant to criminal sentencing, including the evaluation of whether the offender poses any risk of harm to others.

This kind of secondary use of data would very likely go beyond the original consent to tracking, and therefore its use in this manner would require significant justification. In some cases, its use would entail use of confidential medical information. However, such use would likely be captured by the current regulations governing disclosure of information. In criminal cases, the test for disclosure is whether the information 'might reasonably be considered capable of undermining the case for the prosecution or of assisting the case for the accused'.[61] This test should not be met easily, and as stated in *R (B) v Crown Court at Stafford* with regard to medical records (which are likely to encompass data collected via tracking technology)*:*

[60] Chandler (n 47).
[61] Criminal Procedure and Investigations Act 1996, as then amended by the Criminal Justice Act 2003.

> the duty of confidence owed by a medical professional to a competent young person is a high one which should not be overridden except for a very powerful reason.[62]

In civil matters, such as negligence, medical records and compliance data are covered by the Civil Procedure Rules. Rule 31.16 holds that disclosure (where information is held by the respondent) may be ordered if disclosure before proceedings have started is desirable in order to dispose fairly of the anticipated proceedings; assist the dispute to be resolved without proceedings; or save costs.

5. Conclusion

This paper does not purport to propose how we ought to regulate tracking pills. The technology is at too early a stage. Rather, it is an attempt to sketch out the areas of potential concern to which attention ought to be given. This section draws together some of the concerns raised in the foregoing sections as a 'road map' for future thinking, but it begins with a caveat that simply because a new technology emerges, this does not necessarily mean it raises new issues nor requires a new, tailored regulatory regime. It may be that the concerns raised, once thoroughly considered, can be met via existing legal mechanisms. As Lyria Bennett Moses has pointed out in warning against being too ready to create technology-specific *sui generis* regimes:

> while *sui generis* legal rules enable a more finely tuned approach to law making, there are also drawbacks. These are: (1) the problem of completeness (or the creation of 'gaps' in the law), (2) the problem of administrative costs associated with creating (and amending and interpreting) multiple legal regimes, possible additional bureaucracy, and the need for the community (especially the legal profession) to navigate multiple legal regimes, (3) the risk that a *sui generis* regime might be overtaken by technological change to the extent it makes assumptions based on the technological landscape at the time of its creation.[63]

The analysis in this paper suggests that tracking pills do not raise concerns that demand a *sui generis* regulatory framework to manage them, but rather for the most part can be addressed via existing laws but not entirely.

There are numerous contexts in which existing laws will very likely be sufficient to address the concerns raised here, or indeed where the use of tracking pills falls within the kind of uses that are judged legitimate and lawful by current standards. For some uses, this is because those uses are sufficiently similar to uses of other technology that raise similar considerations

[62] [2006] EWHC 1645 (Admin) [18].
[63] Lyria Bennett Moses, 'The Problem with Alternatives: The Importance of the Property Law in Regulating Excised Human Tissue and *In Vitro* Human Embryos' in I. Goold, J. Herring, K. Greasley and L. Skene (eds) *Persons Parts and Property* (Oxford University Press 2014) 200.

and which are regarded as lawful. In these contexts, we can apply both the same laws and the same justifications to regard analogous uses of tracking pills as justified. We can also draw on the same limits used in these areas of law to manage tracking pills. The use of digital pills to track adherence to medication in persons on parole is a good example, where this use is sufficiently akin to the use of electronic tagging devices that we can regulate digital pills via the same legal framework.

Other applications, however, emerge as not quite so easily dealt with via current laws and they may put some pressure on existing legal frameworks. Some uses of the technology in the medical context might fall within this category, where this kind of observance of patient adherence may go beyond what has been regarded as reasonable behaviour by doctors. However, with some work (probably via the courts), the privacy and consent aspects of these uses could probably be managed via existing rules around patient consent, standards of information provision by the medical profession (particularly now these have been made more robust post-*Montgomery*) and also rules around the protection of confidential information and data sharing.[64] We may see, in such contexts, a need to offer greater guidance on how existing laws will apply, and perhaps need to develop some Codes of Practice to guide use, but the law as it stands very likely already offers the tools via which we can manage this.

The analysis in relation to the insurance and employment contexts, however, demonstrates that there are some risks that employees or those seeking insurance will be subjected to a degree of effective coercion via the transactional nature of requests for them to use the technology. While it may be that existing laws (both legislative and common law) around these areas may be sufficient, this is not necessarily the case. Merely relying on a consent framework here, conceptualising the employee, say, as agreeing to be tracked as a free and voluntary act may be insufficient. This is one area where it is important that a close watch is kept on practices in these areas and consideration given to whether more robust protective mechanisms need to be put in place if such tracking technology comes to be used in ways that infringe privacy, affect access to insurance or place employees under pressures that we consider to be unreasonable.

[64] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

A very serious concern about which we must remain vigilant is the likelihood that as the technology develops and is deployed in more medications, there will be problematic 'function creep' without appropriate consideration. The potential for such expansion needs to be kept under close observation and subject to proper scrutiny. While use in the medication context with full patient consent may be a useful tool that improves adherence and, consequently, health outcomes, expansion of the use of tracking medication intake by government agencies should be introduced only with sufficient justification, transparent procedures and only insofar as is necessary to achieve the valid purposes of those agencies. For example, tracking could be a useful tool in recently paroled offenders, but only in cases where the right balance is struck between enabling parole, protecting privacy and protecting the wider community. There are numerous such contexts in which this technology could play a useful role, but also many where its use would unreasonably invade individual privacy and subject persons to unacceptable pressures to take treatments they would otherwise avoid. More detailed exploration of the consent issues such uses raise may be necessary if the technology comes to be used in this context.

The technology has appeal outside the governmental and policing sphere, and we have seen that for both employers and insurers, tracking medication intake may be a very attractive mechanism for managing employers or ensuring better health (and hence lower care costs) for those insured. Some such uses might be reasonable, and in some cases even desirable if they prevent workplace accidents or decrease healthcare costs (and hence premiums). However, such private sphere use of this technology needs to be closely monitored to avoid the concerns raised above about non-consensual or pressured use. It may be that restrictions need to be put in place to prevent such use, and these might include restrictions on making employment or insurance contingent on the taking of tracking medication, or linking premiums to agreeing to the tracking of intake. This is not to say that such restrictions should *necessarily* be put in place; it may be that thorough consideration reveals that they are not needed if the use of the technology can be otherwise adequately regulated and the concerns met. The point here is simply that we should be mindful of the potential concerns and evaluate the options that might be used to address them. We should also be mindful of the particular landscape in England, where the NHS removes some of the incentives that might drive groups to pressure individuals into acceding to being tracked.

As this new era of so-called 'e-medicine' continues to develop and present us with new ways to improve health, we should welcome these technologies but with a degree of wariness about

the implications they may have for our privacy and our agency. We should be mindful of the ways in which accepting such tracking may itself shape new norms about reasonable behaviour in particular contexts, such as normalisation of tracking as a condition of child custody or employment. We may regard this as unproblematic, but it is worth keeping a weather-eye out for creeping normalisation of a privacy invasion we may not fully welcome. In our desire to improve health, we need not be over-cautious, but should keep in mind the importance of protecting individual privacy and autonomy, and where such new technologies undermine this, consider carefully how we might reap their benefits while ameliorating their potential harms. There is big promise in this technology, and some risk of Big Brother, but we need to be careful to observe and manage the drawbacks via existing schemes (and new ones where needed) while taking the benefits this new technology offers.

Declaration of Interest

No conflicts of interests to declare

Acknowledgements

The author would like to thank Professor Roger Brownsword (Kings College London), Dr Catherine Kelly (University of Bristol), Charlotte Elves (University of Oxford) and Tristan Cummings (University of Oxford) for their very valuable comments on drafts of this paper.