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ARTÍCULO

Trust and Autonomy in the age of Digital Patient Monitoring

Confiança i autonomia en temps de vigilància digital dels pacients

Confianza y autonomía en tiempos de vigilancia digital de los pacientes

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Abstract

The Internet of Things (IoT) is revolutionizing precision medicine and patient care by enabling connectivity between treatments with integrated technology and the healthcare professional. The pharmaceutical industry views IoT as an opportunity for innovation and profit, particularly as drug patents expire. The emergence of Pharma IoT firmly places patients in center of precision medicine, in which pharmaceutical products increasingly integrate digital components. IoT applications in healthcare include smart drug delivery systems, remote monitoring, and real-time data collection, improving patient outcomes and treatment personalization. Despite these advancements, IoT implementation in healthcare raises ethical, legal, and regulatory challenges. This contribution focuses on analysing how such digital therapies affect two fundamental values. Firstly, trust, a pillar on which the care relationship is based. The value of reasonable trust in the care relationship in a context of digitalised medicine will be addressed. Secondly, the principle of autonomy, which informs clinical practice. This section focuses on the imbalances of power and external influences on patient autonomy, the risks and biases inherent in the operation of sophisticated technologies, and the search for a balance between autonomy, transparency and the protection of public health. The conclusion underscores the need to balance technological progress with ethical and legal considerations. While IoT offers promising advancements for personalized medicine, its successful implementation depends on robust regulatory frameworks that protect patient rights while fostering innovation.

Keywords: Precision medicine, trust, autonomy, Pharma IoT, digital medicine, digital health, e-health, digital pills.

Resum

La Internet de les coses (IoT) està revolucionant la medicina de precisió i l'atenció al pacient en permetre la connectivitat de tractaments terapèutics amb tecnologia integrada amb el professional. La indústria farmacèutica observa en el IoT una oportunitat d'innovació i benefici, perquè implica una forma d'innovació incremental davant la previsió d'expiració d'una patent. L'aparició del Pharma IoT situa fermament als pacients en el centre de la medicina de precisió, en la qual els productes farmacèutics integren progressivament més components digitals. Les aplicacions de IoT en l'atenció sanitària inclouen sistemes intel·ligents d'administració de fàrmacs, monitoratge remot i recopilació de dades en temps real, la qual cosa millora els resultats dels pacients i la personalització dels tractaments. No obstant això, pesar d'aquests avanços, la implantació del IoT en l'atenció sanitària planteja reptes ètics, legals i normatius. Aquesta contribució se centra en analitzar com afecten aquestes teràpies digitals a dos valors fonamentals. En primer lloc, la confiança, pilar sobre el qual es construeix la relació assistencial. S'analitzarà el valor de la confiança raonable en la relació assistencial en un context de medicina digitalitzada. En segon lloc, el principi d'autonomia, que informa la pràctica clínica. S'analitzaran els desequilibris de poder i les influències externes sobre l'autonomia del pacient, els riscos i biaixos inherents al funcionament de tecnologies sofisticades, i la cerca d'un equilibri entre autonomia, transparència i protecció de la salut pública. Se subratlla la necessitat d'equilibrar el progrés tecnològic amb consideracions ètiques i jurídiques. Encara que el IoT ofereix avanços prometedors per a la medicina personalitzada, la seva aplicació satisfactoria depèn de marcs normatius sòlids que protegeixin els drets dels pacients i fomentin al mateix temps la innovació.

Paraules clau: medicina de precisió; confiança; Pharma IoT; medicina digital; salut digital; medicaments digitals.

Resumen

El Internet de las cosas (IoT) está revolucionando la medicina de precisión y la atención al paciente al permitir la conectividad de tratamientos terapéuticos con tecnología integrada con el profesional. La industria farmacéutica observa en el IoT una oportunidad de innovación y beneficio, pues implica una forma de innovación incremental ante la previsión de expiración de una patente. La aparición del Pharma IoT sitúa firmemente a los pacientes en el centro de la medicina de precisión, en la que los productos farmacéuticos integran progresivamente más componentes digitales. Las aplicaciones de IoT en la atención sanitaria incluyen sistemas inteligentes de administración de fármacos, monitorización remota y recopilación de datos en tiempo real, lo que mejora los resultados de los pacientes y la personalización de los tratamientos. Sin embargo, pesar de estos avances, la implantación del IoT en la atención sanitaria plantea retos éticos, legales y normativos. Esta contribución se centra en analizar cómo afectan estas terapias digitales a dos valores fundamentales. En primer lugar, la confianza, pilar sobre el que se construye la relación asistencial. Se analizará el valor de la confianza razonable en la relación asistencial en un contexto de medicina digitalizada. En segundo lugar, el principio de autonomía, que informa la práctica clínica. Se analizarán los desequilibrios de poder y las influencias externas sobre la autonomía del paciente, los riesgos y sesgos inherentes al funcionamiento de tecnologías sofisticadas, y la búsqueda de un equilibrio entre autonomía, transparencia y protección de la salud pública. Se subraya la necesidad de equilibrar el progreso tecnológico con consideraciones éticas y jurídicas. Aunque el IoT ofrece avances prometedores para la medicina personalizada, su aplicación satisfactoria depende de marcos normativos sólidos que protejan los derechos de los pacientes y fomenten al mismo tiempo la innovación.

Palabras clave: Medicina de precisión, confianza, autonomía, Pharma IoT, medicina digital, salud digital, medicamentos digitales.

1. The role of IoT in precision medicine and patient care

The term 'Internet of Things' (IoT) refers to the connectivity between objects with integrated technology that communicate information among themselves and with the outside world using an Internet connection network (Dimitrov, 2016, p. 156; Haghi *et al.*, 2017, p. 4; Pedersen 2020, pp. 24 and 25; Gregorio *et al.*, 2020, p. 218; Shackelford, 2020, p. 21) The pharmaceutical industry has seen in the emerging field of IoT a possibility for innovation and a seed of prosperity, since it opens the door to a new form of business and, therefore, to a new source of profit, especially when drug portfolios run out or their patents expire (Song & Han, 2016, p. 697 et seq.) In this way, the appearance of the Pharma IoT places definitely the patient in a digital medicine environment, given that it is increasingly common to find pharmaceutical products that integrate digital components (Pollicino *et al.*, 2022, p.11).

In a digital environment, clinical processes are digitised, making it possible to track health parameters continuously and remotely, to carry out health reports in real time, to automatically manage information or to facilitate a precise and remote treatment and diagnosis (Shaffer *et al.*, 2002, p. 200; Turcu & Turcu, 2013, p. 255; De Montalvo Jääskeläinen, 2021, p. 218) Crossing information provided by images, vital signs and genomics yields results that are transmitted between health systems and other entities such as health insurers, government entities, researchers and a long list of agents. This helps research, improves healthcare, expands its access, and ultimately saves lives (Belle *et al.*, 2015. Pp. 1-2) In short, digitising medicine processes leads to a more precise, effective, and innovative healthcare.

We are currently witnessing the entry into the market of digital devices that contribute to the creation of this precision medicine, such as digital tattoos (Patel and Castro, p. 162) or other sort of digital devices that integrate medical software for the precise treatment of the patient. We are getting to a point in which some of these medical devices integrate the medication with the technological component and its connection with a wearable device, which largely facilitates both obtaining patient information and processing it. The objectives of this study are, firstly, to understand their great usefulness in effectively monitoring the patient, and secondly, to analyze in different ways how this sort of digital therapies affect two pillars that have been identified as basic in the clinical relationship: autonomy and trust.

2. Digital Pills: A Medical Breakthrough under debate

The development in 2017 of the very first digital pill (Fleisch *et al.*, 2021, pp. 34-36) has open the door to an intense debate. The initial purpose of this advance is to alleviate the serious problem of poor adherence to treatments (WHO, 2003, p. 11; Palop Larrea 6 Martínez Mir, 2004, p. 113; Haddad *et al.*, 2014, p. 48; Byerly et al, 2007, p. 439; Polonsy et al, 2016, p. 1299; Sansone and Sansone, 2012, pp. 41-46) This digital pill contains an integrated sensor that has proven to track medicine intakes with 50% more precision than with direct observance techniques (Scooter et al, 2019, p. 850) When the sensor components come into contact with the gastric fluids, an electrochemical signal is being emitted until the sensor electrodes are depleted —about four minutes—, when a code has been sent to the other device carried by the patient (e.g., an electronic patch) indicating what medication has been ingested at the time recorded by the phone. This portable device can also track other information autonomously, e.g., heart rate, physical activity, physiological response to medication, sleep quality, etc. (Hafezi *et al.*, 2015, p. 99-100) Data collected by the portable device will be subsequently sent to some other computational devices: using Bluetooth connection to the patient's smartphone and, further on, to the cloud server, where the caregiver and the healthcare professional can access all the information collected.

The main characteristic of digital pills is that they manage to provide a potentially definitive solution to a widespread health problem, particularly significant in chronically ill patients: poor adherence to treatments. This phenomenon has negative effects for the patient, results in a significant economic cost for healthcare systems, and is detrimental to pharmacological research. This cutting-edge innovation that aims to solve the poor adherence problem in healthcare systems, is a representation of what it has been called “medical social control” (Burrows, p. 195)

In a digital pill, not only the active principle remains the same as in the traditional version of the drug —thus providing the patient with the therapy they need to improve their health status or overcome a disease— but they also include the added value provided by the information transmission system, which allows the patient, the caregivers and the doctor to know some key information during the treatment, such as medication intake patterns and drug effects.

This advance in medicine represents a substantial improvement in the care of chronic patients, who may experience difficulties in following their treatments. They also help to ease the burden of family caregiving, as they allow the caregiver to know in real time whether their loved one has taken their medication when it is due. Ultimately, it facilitates the doctor to know whether that specific treatment or the dosage is the most appropriate for their patient, making it easier for them to adapt it to the patient's personal clinical picture.

In addition, this type of digital therapy has three major advantages over traditional medicines: it would allow greater knowledge of drug efficacy in clinical trials (EMA, 2016, pp. 4 and 24), it would potentially reduce the waste on public resources on mismanaged medicines (Bonacini *et al.*, 2020, pp. 4,5 and 7), and ultimately, it would make it possible to control and reduce ineffectiveness or resistance to certain treatments due to incorrect ingestion (Noble *et al.*, 2016, p. 314).

There seems to be obvious advantages in the use of digital therapies (Chai *et al.*, 2015; Van Biesen *et al.*, 2019) Nevertheless, several legal and ethical concerns have raised regarding this short of healthcare innovation (Klugman *et al.*, 2018, p. 43; Martani *et al.*, 2020, pp. 1-13;) In this study we try to analyse whether this pharmaceutical innovation has a negative impact on two basic pillars in the clinical relationship: autonomy and trust.

3. The value and affectation of trust and autonomy in the clinical relationship

Literature has identified two main risks in the use of digital pills as the preferent option for the treatment of chronic patients. The first one is related with trust, the foundation on which doctor-patient relationship stands (Chevance, A. *et al.*, p. 12), and the second one is related with the autonomy, the principle that informs clinical relationships nowadays (Müller *et al.*, 2023, 316-317).

3.1. The value of reasonable¹ trust

Trust, as a social value, unfolds a series of benefits both for the individual and for life in society (think of the trust between children and their parents, between seriously ill or disabled people towards their caregivers, or between the general population towards the healthcare system) A person who requires any kind of support to exercise their autonomy needs to rely on external agents, as the rights at stake are all those necessary for a dignified life. Besides, the value of trust also goes beyond the mere cooperation in order to promote individual interests and lies in its

¹ Following in this point O'Neils philosophical account for trust developed in bioethics, where trust is well-placed if the agent is trustworthy, regarding his specific areas of competence. O'Neill, O. (2014) Trust, Trustworthiness, and Accountability. In Capital Failure: Rebuilding Trust in Financial Services. Oxford: Oxford University Press.

capacity to build meaningful relationships or bonds, or to extend knowledge, as almost all knowledge about a fact depends on trust in the testimony of others.

Oppressive environments inhibit autonomy, and only when trustworthy institutions and people foster the necessary conditions for the individual to become autonomous, autonomy explicitly appears (e.g. by providing adequate and complete information to make informed decisions, respecting their privacy, etc.) Thus, a subject becomes autonomous in social environments when he can trust other people or institutions to support their autonomy (Ishmaey, 2018, 209-212) Coexistence in society is precisely the product of a pact of trust between citizens and the state (Llamazares, 2011, p. 350).

In this sense, trust placed by the patient on the physician and the rest of the agents (Triviño Caballero, 2014) that participate in providing healthcare services is essential for an optimal healthcare system (Dawson, 2015), and it becomes consequently the prerogative for a fully functional autonomy (Rambaran & Harmon, 2024, pp. 7-8).

Inside the personal interaction between a doctor and a patient, the patient places his trust in the hands of his professional, hoping that he will act in accordance with good practice, looking after the best interests of the patient, far from personal interests or benefits (Camps Cervera, 2001, p. 184) In the same way, the professional trusts that the patient will act in a way that is consistent with his desire to achieve good health conditions. In this clinical scenario, trust is a fundamental value, a cornerstone on which doctor-patient relationship rests.

Even when the doctor-patient relationship was governed by paternalistic schemes, trust also had a significant value. In this case, trust was not so much reasonable, but rather conditioned by the patient's vulnerability towards the doctor. Nevertheless, the birth of Bioethics called for the need to build a reasonable trust that guides the doctor-patient relationship, stripped of paternalistic tensions (O'Neill, 2009, pp. 17-18) Reasonable trust is symptomatic of a doctor-patient relationship in which there is a horizontal balance between the two, in which treatment is administered on the premise that the patient has given adequate informed consent², in which

² In this sense, it is worth mentioning the argumentation of the Spanish Constitutional Tribunal (STS 8 September 2015, RJ 2015/3712, JF 3) developing the content of an adequate informed consent: "es evidente que esta falta de información implica una mala praxis médica que no solo es relevante desde el punto de vista de la imputación sino que es además una consecuencia que la norma procura que no acontezca, para permitir que el paciente pueda ejercitar con cabal conocimiento (consciente, libre y completo) el derecho a la autonomía decisoria más conveniente a sus intereses, que tiene su fundamento en la dignidad de la persona que, con los derechos inviolables que le son inherentes, es fundamento del orden político y de la paz social (art. 10.1 CE -RCL 1978, 2836-), como precisa la Sentencia de 2 de julio de 2002 (RJ 2002, 5514) [...] La actuación decisoria pertenece al enfermo y afecta a su salud y como tal es la información que recibe, lo que le permite adoptar la solución más favorable a sus intereses".

patient satisfaction becomes an indicator of the quality of professional practice, and in which the patient is seen as an informed adult and regarded with respect, and not infantilised or treated in a paternalistic manner because of his condition of sick. Thus, the authority of the professional is balanced by the consideration of the patient as an autonomous being (Hope & Fulford, 1993) It could be said that, in this relationship, informed consent is the modern liturgy of trust (Faden & Beauchamp, 1986), and constitutes the institutionalisation of respect for the patient's autonomy (O'Neill, 2009, p. 19).

In this clinical relationship there may be certain circumstances that put trust at risk, for instance, when the treatment does not show the expected results, the professional may distrust the patient's testimony as to whether he is really following the indicated guidelines correctly (Klugman *et al.* 2018, p. 43).

As it has been pointed out, today's Biomedicine is assimilating practices within a digital globalisation, which allows the doctor to objectively know relevant patient information without the need for the patient's collaboration (O'Neill, 2009, p. 8), as it happens with digital pills.

In this fast-paced technological revolution in medicine, two positions could be adopted regarding the care for trust. The first is a favorable position, considering that there is actually a strengthening of trust as long as the monitoring device makes it easier for the professional to know treatment intake patterns, thus paving the way for a constructive dialogue between the two, in which both explore the beliefs and conducts informing medication ingestion patterns, and ultimately addressing obstacles in an optimal way (Rosembaum, 2017, p. 3) The second position is unfavorable and takes into consideration that the fact that the practitioner can spy patient's behavior through smart devices may erode trust, since after accepting undergoing such a treatment, it is no longer necessary for the patient to voluntarily disclose health information to his doctor. In other words, digital monitoring takes away the patient's freedom to give his testimony—even eliminating the possibility or freedom to lie to the doctor— (Klugman *et al.*, 2018, p. 43; and on an eventual right to lie, see Fernández Domínguez, 1999, pp. 184-203) Hence, it rests on the physician the decision of trusting patient's oral report instead the digital device's records.

There is one premise that may overcome risks projected on trust in a digitalised clinical context, which is to reinforce the reasonable aspect of trust. Thus, trust will be ensured as long as the patient has a constructive dialogue with his doctor and feels an active and useful agent in the relationship, and not only an object of inspection (Broholm-Jørgensen, *et al.*, 2017; Lafata *et al.*, 2013) Using smart devices as part of the treatment does not necessary erode or reinforce trust

between patient and doctor, it will rather depend on the intended use, the consideration both have on the benefits and risks derived from its use and the dialogue behind its use for patient's behavior tracking. Involving the patient through dialogue and active listening is a moral obligation for health professionals, also in digital medicine practices. Not fulfilling this mandate will not result in legal responsibility as long as the practitioner fulfil their obligation to obtain the informed consent, but from a moral point of view it could be appreciated a very poor content in the care provided (Simón Lorda, 2000, p. 174-175).

3.2. Health dataveillance and its impact on fundamental values

Precision treatments or diagnostic procedures that use smart medical devices require two informational and authorisation processes prior to their use. On the one hand, the patient will receive information about the clinical features of the treatment, its benefits and possible side effects and all other relevant information that will allow the patient to make a conscious decision. On the other hand, the patient will receive information about the features of the technological device to be used. In this sense, he will have to authorise the use of the device connected to the Internet, as a general rule, by ticking a box in which it is said that he accepts the device terms and conditions of use³. These terms and conditions are an adherence contract —i.e., if the consumer does not accept the conditions, he will not access the service— drawn up by the technological company, usually, in complex legal and technical terms. Thus, acceptance of these terms becomes a condition for the patient for accessing the treatment.

Fundamental values in the clinical relationship are eroded as a result of the processing of patient's personal data, in the first place, because of power imbalances and external influences on patient autonomy; in the second place, because of the risks and biases arising in the functioning of digital health technologies, and ultimately, in the aim of balancing autonomy, transparency and public health in digital therapies.

3.2.1. Power imbalances and external influences on patient autonomy

When the individual contracts digital services that require the signing and acceptance of a legally and technically complex privacy policy, it is likely that the subject will not be able to properly understand the content of such a contract. As long as accepting personal data processing is conditional on the acceptance of such an adherence contract —the terms and conditions of use—

³ In this sense, the ruling of the European Court of Justice, on the 1st of October 2019 (C-673/17) on the Case *Bundesverband der Verbraucherzentralen und Verbraucherverbände — Verbraucherzentrale Bundesverband eV, versus Planet49 GmbH*.

the individual may feel pressured to agree, thus accepting conditions that internally they do not really desire (Klugman, 2018, p. 40) Some authors warn of the need to consider that when offering these sorts of services, the developer focuses such a privacy policy on its commercial interests rather than on the protection of the consumer's interests (Veliz, 2021, p. 73)⁴. In this scenario, imbalance of power between the patient and the professional may constitute a significant factor that conducts the decision of the patient, since the complexity of the digital pill system may tend to defer the decision to the doctor who “owns” the knowledge (Joseph, 2014, p. g3178).

In addition to that, the role of third parties in the healthcare sector deserves special attention in this context. The possibility for external stakeholders to access individual's data collected by smart devices can have a significant influence on the decisions made by the patient. When the user gives up sensitive health information, the technology company will carry out its decryption according to the terms and conditions of use accepted by the user. In this way, when these terms and conditions permit so, the company may transfer such data to third parties. And this is where the risks for the data subject can best be seen (Merchán Murillo, 2021, pp. 108-109).

When health data are at stake, these risks are higher (Khamdaker, 2018; Saiz Arnaiz, 1999, p. 137; Tarodo Soria, 2005, pp. 155-157) If an insurance company had access to health data which reveals sensitive information about chronic diseases, genetic disorders, lifestyle, or medication patterns, it would be easier to take decisions on the basis of its client's present and future health risks and could therefore refuse their coverage or increase their premium for coverage (Klugman, 2018, p.43; Martínez Velencoso, 2021, pp. 106-107) A similar situation could be considered in the labor environment (Rodríguez Escanciano, 2007) If a company were to gain access to their employees' personal information such as their health data (Fernández Domínguez, 1999, p. 70 and 184 et seq.; Fernández-Costales Muñiz, 2021, p. 83), it would facilitate the control of multiple situations in the workplace (Pollicino *et al.*, 2022, p. 15; Döog Gunnarsdóttir *et al.*, 2022, p. 53), i.e. absenteeism or accurate profiling for decision making (which could lead to discriminatory situations on the basis of their health) (Fernández-Costales Muñiz, 2021, p. 233 and 237) Ultimately, knowing this information about potential employees can be a key information to

⁴ These practices have been described as new forms of mild authoritarianism. The author warns of the case of giants like Google and their aspirations to become something similar to God, since this giant has become omniscient –it tries to collect all possible information–, omnipresent –it has become the main platform through which we access the Internet, use email, download apps, communicate with each other, etc.–, and omnipotent –it tends to establish its conditions under which to operate with the information collected–. For this reason, Google is the company in America that invests the most in lobbying at a commercial level.

whether or not to grant the job (Fernández Domínguez & Rodríguez Escanciano, 1997, pp. 101-102).

3.2.2. Risks and biases in digital health technologies

There are inherent risks in the use of digital technologies in healthcare, including potential distortions in decision making and the influence of massive data: risks of bias in precision medicine: the impact of Big Data on autonomy; the impact of data surveillance on patient decision-making; and the risks of persuasion and autonomy erosion in personalised digital services.

Firstly, personalised precision medicine assisted by digital devices (such as digital pills) which track and process all sorts of information from the individual may pose some risks on how the crossed data may drive the doctor's recommendation, since when the decision-making process is assisted —or even governed— by algorithmic automatized processes, situations of discrimination may emerge (Andreu-Pérez, 2021, p. 605; Rotenberg, 2022, pp. 153-154).

Big data analytics facilitates the categorization of individuals into specific groups that meet certain patterns, such as race, sexual orientation, religious tendency, and also health status. This sort of categorization may involve some kind of covert discrimination behind an apparently innocuous correlation of personal data, therefore affecting the individual's right of informational self-determination (Alkorta Idiakez, 2020, p. 20; Fernández Domínguez & Rodríguez Escanciano, 1997, pp. 101-102) Categorization resulting from massive data analysis place individuals into groups that may recommend the doctor to include or exclude them from receiving certain kind of diagnose or treatment, which inevitably limits the possibility of forming one's own conscience and private sphere, hence impeding the possibility of making an autonomous decision in accordance with one's own beliefs and opinions. It is precisely this type of covert discrimination that is harder to detect because of the numerous and complex variables used in the massive data cross-referencing (Naudts, 2018, p. 77; Véliz, 2021, pp. 75-77; Pollicino *et al.*, 2022, p. 21).

Secondly, when people have the feeling of being surveilled, they may alter their behavior. This is what has been called the 'chilling effect' of personal data processing (Büchi *et al.*, 2022) The mere fact of collecting such data may affect the autonomous behavior to seek information, to express an opinion or to make a decision (Véliz, 2021, p. 72; Klugman, 2018, p. 43).

Even if the effects of personalisation and the tendency to control individual's beliefs, opinions, as well as behaviors would be minor nowadays, the opacity surrounding these trends and the cumulative effects they give off are the evidence of a serious affectation to the individual's autonomy (Lightart *et al.*, 2022, p. 38) This opacity leads to a double affectation of autonomy,

either because the individual is self-censuring in his behavior when he knows that his patterns are being tracked, or because the process of forming his own conscience and behaving in accordance with it is being hindered (Ostveen & Irion, 2018, p. 18) The complexity of algorithms and how they work may not be fully understood by practitioners and patients when undergoing a digital therapy. This suggests that both should be provided with evidence-based information that enable them to understand the significance of undergoing such treatments (Pollicino *et al.*, 2022, p. 15).

Lastly, there is a tremendous risk of persuasion when implementing technologies that allow personalization of services for the individual (Berkovsky *et al.*, 2012, p. 7) Directing personalised information as a result of a massive data analysis may result in the creation of a limited information bubble that leads to continuously confirm the individual's personal beliefs and opinions, avoiding exposure to divergent information. This way, he may believe that is making independent and autonomous decisions when in fact is influenced by limited and personalised information. Subject's autonomy is only respected if he knows and is relatively well informed about the context in which he takes a decision. When the individual does not know the context, or the information available has been misrepresented or manipulated, he will mistakenly believe that he knows or that he is right, and this will influence his decisions and how he lives and feels (Véliz, 2021, p. 73).

This type of functioning makes it possible for the individual to be actively persuaded or manipulated through personalisation strategies. In this scenario, the limited provision of information and the restricted proposal of alternatives to choose from, coupled with active persuasion or manipulation towards a certain decision, inevitably reduce personal autonomy (Ostveen & Irion, 2018, p. 17)⁵.

3.2.3. Balancing Autonomy, transparency and public health in digital therapies

If the patient does not wish to undergo this type of treatment, he cannot be forced to do so unless there are good public health reasons that make this advisable, or he is in a state of a full lack of competence without the possibility of obtaining the consent of those close to him, and this measure would be in his best interests. However, this is a matter of concern. There is a traditional moral —and legal— mandate on patients to provide truthful data on his physical condition or health, as well as to collaborate in obtaining it, especially when it is necessary for reasons of public

⁵ On nudges and undermining voluntary consent, see Kiener, M. (2021) When do nudges undermine voluntary consent? *Philosophical Studies*. (178), 4201 - 4226.

interest or for healthcare purposes. Nevertheless, this mandate raises serious questions about its interpretation within the framework of a digital therapy when there is the possibility of obtaining objective information without the need to be disclosed based on the patient's voluntariness.

It may be premature to speculate on whether this premise justifies the prescription of digital pills as the preferred (or even compulsory) option by the professional over the traditional treatments, since this therapy allows to obtain objective and truthful information from the patient. If digital pills are prescribed as the first option over the traditional version of the drug, we run the risk of reverting to paternalistic schemes in which the patient becomes an object of inspection, and his behavior is diverted from undesirable conducts from the healthcare system point of view. Nevertheless, this preference —or imposition— of digital therapies may be feasible, either because obtaining information with high standards of objectivity would be shown to be the most beneficial option for the patient from a public health protection perspective, or because the use of digital therapies implies avoiding health resources wastes, which leads to considering these therapies as the optimal alternative.

Current automated decision-making processes being partially or even completely opaque are a symptom for a system which lacks two basic principles: justice and transparency (Lainjo, B., p. 10), which makes it impossible to determine responsibility for the consequences of the decision made. It is imperative that, in the face of a massive use of these techniques —especially when it comes to decision-making in the healthcare sector— the process should be open, demonstrable and accountable (Bygrave, 2022, p. 172)⁶.

Harnessing the potential of artificial intelligence in healthcare should not prevent people from knowing the basis of the decision-making process. There remains, in any case, a right to know (Magdalena Layos, 2021, p. 634), and a right to decide on the basis of what the patient considers is best for him (Rosembaum, 2017; Pérez Álvarez, S., p. 484).

Regulations governing the protection of personal data, particularly health data, evolve and change over time⁷. It is not possible to anticipate what the future regulation of health data protection will be, so it is advisable that before consumers —and patients— expose their data to

⁶ On many occasions, not only the reasoning behind this type of decision remains unknown to people, but neither does it coincide with the logic of the human decision-making process.

⁷ A good example to illustrate this evolution is the current European Health Data Space Regulation (EHDS) (Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847. Retrieved from:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327

third parties, thus putting their privacy at risk, they should be aware of the transcendence of authorising its management by a technological company, the potential risks involved and how they could anticipate them, as it is not advisable to assume that the collection of personal data will always be done seeking the best interest for the user.

4. Adherence to digital treatments: autonomy, flexibility, and the complexity of patient behavior

Poor adherence to treatments is a complex biosocial phenomenon that is produced by various factors (WHO, 2003, p. 11; Biswas, 2014, p. 11), those related to the patient himself (e.g., his attitude towards medication and towards the disease, the social stigma that following a medication), others related to the characteristics of the disease (e.g., patient's view of his disease, whether he suffers from cognitive impairment or depression), the characteristics of the treatment (e.g., efficacy, side effects, dosage frequency, formulation, economic cost, complexity of the instructions), those related to professional sphere and service provision (e.g., shared planning, accompaniment of the patient, accessibility of the professional, attitude of the professional, communication between services), or service provision (Haddad, 2014, p. 48; Dilla *et al.*, 2009, p. 344).

Incorrect adherence to treatments due to any of the above-mentioned factors implies potential risks for the patient: more intense relapses that are more difficult to overcome (Byerly *et al.*, 2007, p. 439), greater risk of dependence (Bush *et al.*, 1984, p. 681), greater risk of withdrawal and rebound effect (Demyttenaere & Haddad, 2000, pp. 54-55), greater likelihood of generating resistance to therapy (as is the case with antiretroviral treatments (Paterson *et al.*, 2000, p. 21) or antibiotic treatments (WHO, 2020; Yach, 1988, pp. 683, 688-689), greater likelihood of intoxication, especially in older patients or those with psychiatric disorders (if poor adherence is due to taking too much medication), as well as a greater likelihood of accidents, especially in the case of incorrect adherence to treatments that have side effects (e.g. sedatives) (WHO, 2007, p. 22) In the worst-case scenario, this lack of adherence could lead to death (Rodríguez, 2018).

The multiple and complex life and social factors that influence patient behavior recommend not to address the problem of poor adherence in a single way. A patient undergoing a digital pills treatment may improve his adherence rates (Zhou, J. *et al.*, p. 341) if the system support his compliance with treatment instructions, but their use does not solve the root cause of the problem. There is evidence that strict adherence to treatment can be difficult or even detrimental

in terms of quality of life for the patient, either because of unpleasant side effects, or because it involves lifestyle changes that are unaffordable for the patient. The patient, in the exercise of his autonomy, may prioritise health care understood as the achievement of a broader wellbeing, a self-determined quality of life that may imply not following strictly the recommended guidelines for treatment follow-up (Harris, 2019); whereas the professional may conceive health care differently, for example, linked to a perfect adherence to treatment instructions. For the patient, however, the two positions may be incompatible.

It seems reasonable to grant some flexibility to the patient regarding his pharmacological management in the exercise of his autonomy, as only the patient knows what behavior is best to achieve an optimal quality of life in accordance with his preferences and convictions (Maeckelberghe, E. *et al.*, p. 3) Each patient responds differently to each treatment and therefore, it should not be assumed that a deviation from the recommended dose means a worse performance of the treatment for the patient, worse health outcomes or lower quality of life (Bandura, 1997).

5. Conclusion. Navigating the reinforcement of trust and autonomy: unlocking the future of precision medicine

The integration of technology into pharmaceuticals reflects the relentless advance of precision medicine. The opportunities offered by digital pills are many, encompassing improvements in disease prevention, treatment and cure as well as biomedical research.

However, there remain certain legal and ethical dilemmas that still merit reflection. This contribution has attempted to shed light on what are considered to be the greatest challenges in the implementation of sensor-integrated medicines for patient monitoring and is intended to help clarify discussions on this debate in order to pave the way for a safe implementation of digital pills, for both patients and professionals.

References

- ◆ Alkorta Idiakez, I. (2020) La protección del derecho a la autodeterminación informativa de los mayores en entornos conectados. In E. Atienza Macías (coord.) and I. Alkorta Idiakez (dir.), *Soluciones tecnológicas para los problemas ligados al envejecimiento*, Dykinson: Madrid, 13 – 56.
- ◆ Andreu-Pérez, J. *et al.* (2021) Avances científico-tecnológicos en inteligencia artificial responsable. In F. Lledó Yagüe, I. Benítez Ortúzar, O. Monje Balmaseda. *La robótica y la inteligencia artificial en la nueva era de la revolución industrial 4.0 (Los desafíos jurídicos, éticos y tecnológicos de los robots inteligentes)* Dykinson: Madrid, pp. 593 a 616.
- ◆ Bandura A. (1997) *Self-efficacy: the exercise of control*. New York: W.H. Freeman and Company, 259–318.
- ◆ Belle, A. *et al.* (2015) Big Data Analytics in Healthcare. *BioMed Research International*. (370194), 1 – 16.
- ◆ Berkovsky, S. *et al.* (2012) Influencing Individually: Fusing Personalization and Persuasion. *ACM Transactions on Interactive Intelligent Systems*. 2 (2), 1- 8.
- ◆ Biswas, K. (2014) *Pharma's Prescription: How the right technology can save the pharmaceutical sector*. Elsevier: London.
- ◆ Bonacini, M. *et al.* (2020) Wirelessly Observed Therapy to Optimize Adherence and Target Interventions for Oral Hepatitis C Treatment: An Observational, Pilot Study. *Journal of Medical Internet Research*. 22 (4), 1 – 26.
- ◆ Broholm-Jørgensen, M., *et al.* (2017) Balancing Trust and Power: A Qualitative Study of GPs Perceptions and Strategies for Retaining Patients in Preventive Health Checks. *Scandinavian Journal of Primary Health Care* 35, 89-97.
- ◆ Büchi, M. *et al.* (2022) The Chilling Effects of Digital Dataveillance: A Theoretical Model and an Empirical Research Agenda. *Big Data & Society*. 9 (1), 1 – 14.
- ◆ Burrows, K. (2024) *Medical Technology and the Social: How Medical Technology Is Impacting Social Relations, Institutions, and Beliefs about What Is Normal*, Bloomsbury Publishing: London, p. 195.
- ◆ Bush, P. J. *et al.* (1984) Use of Sedatives and Hypnotics Prescribed in a Family Practice. *Southern Medical Journal*. 77 (6), 677 – 681.
- ◆ Byerly, M. J. *et al.* (2007) Antipsychotic Medication Adherence in Schizophrenia. *Psychiatric Clinics of North America*. 30, 437 – 452.
- ◆ Bygrave, L. A. (2022) Machine Learning, Cognitive Sovereignty and Data Protection Rights with Respect to Automated Decisions. In M. Ienca, O. Pollicino, L. Liguori, E. Stefanini, R. Andorno. *Information technology, life sciences and human rights* (pp. 166 – 188, 172) Cambridge University Press: UK.
- ◆ Camps Cervera, V. (2001) *Una vida de calidad: Reflexiones sobre bioética*. Ares y Mares: Barcelona.

- ◆ Chai, P. *et al.* (2015) Utilizing an Ingestible Biosensor to Assess Real-Time Medication Adherence by practicing pharmacists using digital health care. *Journal of Medical Toxicology*. 11 (4), 439 – 444.
- ◆ Chevance, A. *et al.* (2022) Acceptability of and Willingness to Take Digital Pills by Patients, the Public, and Health Care Professionals: Qualitative Content Analysis of a Large Online Survey, *Journal of Medical Internet Research*, 24(2), 1-19.
- ◆ Dawson, A. (2015) Trust, trustworthiness and health. *Indian J Med Ethics*. 12 (3), 129-130, 129; Tranter, I. *et al.* (2022) Doctor! Did You Google My Symptoms? A Qualitative Study of Patient Perceptions of Doctors' Point-of-Care Information Seeking. *BMJ Open*. 12.
- ◆ De Montalvo Jääskeläinen, F. (2021) El uso secundario de los datos de salud en el marco del desarrollo de la e-health. In C. Gil Membrado. *E-Salud, autonomía y datos clínicos* (pp. 217 a 259) Dykinson: Madrid.
- ◆ Demyttenaere, K, y Haddad, P. (2000) Compliance with antidepressant therapy and antidepressant discontinuation symptoms. *Acta psychiatrica Scandinavica*. Supplementum. (403), 50 – 56.
- ◆ Dilla, T. *et al.* (2009) Adherencia y Persistencia Terapéutica: Causas, Consecuencias y Estrategias de Mejora. *Atención Primaria*. 41(6), pp. 342 a 348.
- ◆ Dimitrov, D. V. (2016) Medical Internet of Things and Big Data in Healthcare. *Healthcare Informatics Research*, 22(3), 156 – 163.
- ◆ Döög Gunnarsdóttir, H. *et al.* (2022) The Ethics and Laws of Medical Big Data. In M. Ienca, O. Pollicino, L. Liguori, E. Stefanini, R. Andorno. *Information technology, life sciences and human rights* (pp. 48 a 55)
- ◆ EMA. (2016) Committee for Medicinal Products for Human Use (CHMP) *Qualification opinion on ingestible sensor system for medication adherence as biomarker for measuring patient adherence to medication in clinical trials*. Retrieved from:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/qualification-opinion-ingestible-sensor-system-medication-adherence-biomarker-measuring-patient_en.pdf.
- ◆ Faden, R & Beauchamp, R. (1986) *A history and theory of informed consent*. Oxford University Press: Oxford.
- ◆ Fernández Domínguez, J. J. & Rodríguez Escanciano, S. (1997) *Utilización y control de datos laborales automatizados*, Agencia de protección de datos: Madrid.
- ◆ Fernández Domínguez, J. J. (1999) *Pruebas genéticas en el Derecho del Trabajo*. Madrid: Civitas.
- ◆ Fernández-Costales Muñiz, J. (2021) *Salud pública y prevención de riesgos laborales*. Reus: Madrid.
- ◆ Fleisch, E., Franz, C. & Herrmann, A. (2021) *The digital pill: what everyone should know about the future of our healthcare system*. Emerald Publishing: UK.
- ◆ Gregorio, F. *et al.* (2020) *Signal Processing Techniques for Power Efficient Wireless Communication Systems, Signals and Communication Technology*. Springer: Switzerland.

- ◆ Haddad, P. M. *et al.* (2014) Nonadherence with Antipsychotic Medication. *Dovepress*. 5, 43 – 62.
- ◆ Hafezi, H. *et al.* (2015) An Ingestible Sensor for Measuring Medication Adherence. *IEEE Transactions on Biomedical Engineering*. 62(1), 99 – 109.
- ◆ Haghi, M., Thurow, K. & Stoll, R. (2017) Wearable Devices in Medical Internet of Things: Scientific Research and Commercially Available. *Healthcare Informatics Research*. 23(1), 4 – 15.
- ◆ Harris, L. (2019) The Rise of the Digital Asylum. *Mad in America*. Retrieved from: <https://www.madinamerica.com/2019/09/the-rise-of-the-digital-asylum/>.
- ◆ Hope, R. A. and Fulford, K. W. M. (1993) Medical Education: Patients, Principles, Practice Skills. In R. Gillon (ed.) *Principles of Health Care Ethics*. John Wiley & Sons: England.
- ◆ Ishmaev, G. (2018) Rethinking Trust in the Internet of Things. In R. Leenes, R. Van Brakel, S. Gutwirth y P. De Hert. *Data protection and Privacy; The Internet of Bodies* (pp. 203 – 230, 2018), UK: Hart.
- ◆ Joseph Williams, N. *et al.* (2014) Power imbalance prevents shared decision making. *BMJ*. 348.
- ◆ Khandaker, T. (2018) Canada is Using Ancestry DNA Websites to Help it deport people, *Vice*, retrieved from: <https://www.vice.com/en/article/wjxmy/canada-is-using-ancestry-dna-websites-to-help-it-deport-people>.
- ◆ Kiener, M. (2021) When do nudges undermine voluntary consent? *Philosophical Studies*. (178), 4201 - 4226.
- ◆ Klugman, C. M. *et al.* (2018) The Ethics of Smart Pills and Self-Acting Devices: Autonomy, Truth-Telling, and Trust at the Dawn of Digital Medicine. *American Journal of Bioethics*. 18(9), 38 – 47.
- ◆ Lafata, J.E., *et al.* (2013) Patient-Reported Use of Collaborative Goal Setting and Glycemic Control among Patients with Diabetes. *Patient Education and Counseling*, 92, 94 – 99.
- ◆ Lainjo, B., (2024) Integrating artificial intelligence into healthcare systems: opportunities and challenges, *Academia Medicine*, 1, 1-10.
- ◆ Lightart, S. *et al.* (2022) Persuasive Technologies and the Right to Mental Liberty. In M. Ienca, O. Pollicino, L. Liguori, E. Stefanini, R. Andorno. *Information technology, life sciences and human rights* (pp. 32 a 47) Cambridge University Press: UK.
- ◆ Llamazares Fernández, D. (2011) *Derecho de la Libertad de Conciencia, vol. I. Conciencia, tolerancia y laicidad*. Civitas: Navarra.
- ◆ Maeckelberghe, E. *et al.* (2023) The ethical challenges of personalized digital health, *Frontiers in Medicine*, 10, 1 – 14.
- ◆ Magdalena Layos, L. (2021) ¿Por qué debería confiar en ti (máquina)? In F. Lledó Yagüe, I. Benítez Ortúzar, O. Monje Balmaseda. *La robótica y la inteligencia artificial en la nueva era de la revolución industrial 4.0 (Los desafíos jurídicos, éticos y tecnológicos de los robots inteligentes)* Dykinson: Madrid, pp. 617 a 641.

- ◆ Martani, A. et al (2020) Digital pills: a scoping review of the empirical literature and analysis of the ethical aspects. *BMC Medical Ethics*. 21 (3), 1 – 13.
- ◆ Martínez Velencoso, L. M. (2021) *La protección jurídica de la persona en el ámbito de la Biotecnología y del Big Data*. Dykinson: Madrid.
- ◆ Merchán Murillo, A. (2021) El derecho a la propiedad de los datos. In F. Bueno De Mata. & I. González Pulido. *FODERTICS 9.0*. Comares: Granada.
- ◆ Müller, R. et al. (2023) You have to put a lot of trust in me': autonomy, trust, and trustworthiness in the context of mobile apps for mental health. *Medicine, Health Care and Philosophy*. 26. 313 – 324.
- ◆ Naudts, L. (2018) How Machine Learning Generates Unfair Inequalities and How Data Protection Instruments May Help in Mitigating Them. In R. Leenes, R. Van Brakel, S. Gutwirth y P. De Hert. *Data protection and Privacy: The Internet of Bodies Hart*: UK, 72 – 91.
- ◆ Noble, K., et al. (2016) Medication adherence and activity patterns underlying uncontrolled hypertension: Assessment and recommendations by practicing pharmacists using digital health care. *Journal of the American Pharmacists Association*, 56, 310 – 315.
- ◆ O'Neill, O. (2009) *Autonomy and Trust in Bioethics*. Cambridge University Press: Cambridge.
- ◆ O'Neill, O. (2014) *Trust, Trustworthiness, and Accountability*. In *Capital Failure: Rebuilding Trust in Financial Services*. Oxford University Press: Oxford.
- ◆ Oostveen, M. & Irion, K. (2018) The goldenage of personal data: how to regulate an enabling fundamental right? In M. Bakhoun, B. Conde Gallego, M. Mackenrodt, G. Surblyt Namaviciene. *Personal Data in Competition, Consumer Protection and Intellectual Property Law*. Springer: Berlin, 22 – 23.
- ◆ Palop Larrea, V. and Martínez Mir, I. (2004) Adherencia al tratamiento en el paciente anciano. *Información terapéutica del sistema Nacional de Salud*. 25 (5), pp. 113 a 120.
- ◆ Patel, D. and Castro H. (2025) Hiospital to home: bridging the gap with personalized medicine. In: D. Patel (ed.), *Digital Health*, Academic Press: Pittsburgh, 143 – 169.
- ◆ Paterson, D. L. et al. (2000) Adherence to Protease Inhibitor Therapy and Outcomes in Patients with HIV Infection. *Annals of Internal Medicine*. 133(1), 21 – 30.
- ◆ Pedersen, I. (2020) Will the Body Become a Platform? Body Networks, Datafied Bodies, and AI Futures. In I. Pedersen & A. Iliadis, *Embodied Computing: Wearables, Implantables, Embeddables, Ingestibles* The MIT Press, Massachusetts Institute of Technology: Massachusetts, 21 – 47.
- ◆ Pérez Álvarez, S. (2025) Digital medication and patients' right of autonomy in Spain, *Bioethics*, 39, 482 – 491.
- ◆ Pollicino, O. et al. (2022) M-Health at the Crossroads between the Right to Health and the Right to Privacy. In M. Ienca, O. Pollicino, L. Liguori, E. Stefanini, R. Andorno, *Information technology, life sciences and human rights*. Cambridge University Press: UK, 11 – 25.

- ◆ Polonsky, W. H. *et al.* (2016) Poor Medication Adherence in Type 2 Diabetes: Recognizing the Scope of the Problem and Its Key Contributors. *Patient Preference and Adherence*. 10, 1299 – 1306.
- ◆ Rambaran, S. and Harmon, D. (2024) “Trust in Clinical Practice: A Systematic Review”. *Pain Studies and Treatment*. 12, 1 – 11.
- ◆ Rodríguez Escanciano, S. (2007) La potencialidad lesiva de la informática sobre los derechos de los trabajadores. *Revista Española de Protección de Datos*. (2), pp. 95 a 158.
- ◆ Rodríguez, C. (2018) ¿Por qué es importante investigar la adherencia al tratamiento en la práctica clínica? *Adherencia & Cronicidad & Pacientes*. Retrieved from: <https://www.adherencia-cronicidad-pacientes.com/adherencia/por-que-es-importante-investigar-la-adherencia-al-tratamiento-en-la-practica-clinica/>.
- ◆ Rosembaum, L. (2017) Swallowing a Spy — The Potential Uses of Digital Adherence Monitoring. *The New England Journal of Medicine*. 1 – 3.
- ◆ Rotenberg, M. (2022) Artificial Intelligence and the Right to Algorithmic Transparency. In M. Ienca, O. Pollicino, L. Liguori, E. Stefanini, R. Andorno. *Information technology, life sciences and human rights*. Cambridge University Press: UK, 153 – 165.
- ◆ Saiz Arnaiz, A. (1999) *La apertura constitucional al derecho internacional y europeo de los derechos humanos. El artículo 10.2 de la Constitución Española*. Consejo General del Poder Judicial: Madrid.
- ◆ Sansone, R. A. and Sansone, L. A. (2012) Antidepressant Adherence: Are Patients Taking Their Medications? *Innovations in Clinical Neuroscience*. 9 (5 – 6), 41 – 46.
- ◆ Scooter Plowman, R. *et al.* (2019) Digital medicines: clinical review on the safety of tablets with sensors. *Expert Opinion on Drug Safety*. 17(9), 849-852.
- ◆ Shackelford, S. J. (2020) *The Internet of Things: what everyone needs to know*. Oxford University Press: USA.
- ◆ Shaffer, D. W. *et al.* (2002) What is Digital Medicine? In R.G. Bushko. *Future of Health Technology* (pp. 195 – 204) IOS Press: Amsterdam.
- ◆ Simón Lorda, P. (2000) *El consentimiento informado*. Triacastela: Madrid.
- ◆ Song, C.H. & Han, J.W. (2016) Patent cliff and strategic switch: exploring strategic design possibilities in the pharmaceutical industry. *SpringerPlus*. 5(1), 692 – 706.
- ◆ Tarodo Soria, S. (2005) *Libertad de conciencia y derechos de usuario de los servicios sanitarios*. Servicio editorial de la Universidad del País Vasco: Bilbao.
- ◆ Triviño Caballero, R. (2014) *El peso de la conciencia. La objeción en el ejercicio de las profesiones sanitarias*. Plaza y Valdés: Madrid – México.
- ◆ Turcu, C. E. & Turcu, C. O. (2013) Internet of Things as Key Enabler for Sustainable Healthcare Delivery, The 2nd International Conference on Integrated Information. *Procedia Social and Behavioral Sciences*. (73), 251 – 256.

- ◆ Van Biesen, W. et al (2021) Remote digital monitoring of medication intake: methodological, medical, ethical and legal reflections. *Acta Clinica Belgica*. 76(3), 209-216.
- ◆ Véliz, C. (2021) *Privacy is Power. Why and how you should take back control of your data*. Bantam Press: London.
- ◆ WHO (2020), *Resistencia a los antibióticos*. Retrieved from: <https://www.who.int/es/news-room/fact-sheets/detail/resistencia-a-los-antibi%C3%B3ticos>.
- ◆ WHO. (2003) *Adherence to long term therapies. Evidence for action*. World Health Organization: Geneva.
- ◆ Yach, D. (1988) Tuberculosis in the western cape health region of South Africa. *Social & Science Medicine*. 27(7), 683 – 689.
- ◆ Zhou, J. et al. (2025) Randomized clinical trial of a digital medication system to enhance adherence in patients with severe mental disorders, *NPJ Digital Medicine*, 8, 333 – 343.

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