



EDITORIAL

Transforming the health system through data: access and governance as pivotal elements



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Artificial Intelligence (AI) is present in the day-to-day life of society in aspects as standardised and everyday as making use of language translators, video subtitles, Internet search engines, etc. AI will undoubtedly be responsible for industrial and social transformation in the next decade and will mark a before and after in the development of countries' economies and in the welfare state, so we are probably facing a new industrial revolution.

One of the main challenges facing the public health system is ageing populations, to which we must add other highly prevalent risk factors (obesity, sedentary lifestyle, poor eating habits, alcohol and smoking), chronicity, multimorbidity, dementia and frailty etc. It is clear that changes are needed in the current healthcare model that would include organisational, pharmaceutical and technological innovation while adapting to citizens' expectations of the health care system and adding value to health care.¹

Against this backdrop, AI can have significant advantages. In general, it contributes to broad aspects of current health care; the digitalisation of care and telemedicine makes it possible to increase adherence to treatments, empower patients, optimise time and resources, and prevent and diagnose early. It can also increase diagnostic accuracy or

improve the skills of people with disabilities and rare diseases. Therefore, the applicability of AI in the field of health care favours precision medicine and is important as it can be preventive, curative, palliative and predictive. That is why the recent approval in 2024 of both the European Artificial Intelligence Regulation and the Regulation on the European Health Data Space constitutes a real window of opportunity in the health sector.

Some of their many applications include:

- Early detection and prevention of diseases: predictive algorithms can identify risk factors and foresee the likelihood of developing certain diseases, enabling more effective preventive interventions.²
- Contributing to the improvement of medical diagnosis: AI has proven its usefulness in the interpretation of medical images, such as X-rays, computed tomography (CT) scans and magnetic resonance imaging (MRI), helping clinicians to identify patterns and abnormalities more accurately, thanks to the development of predictive algorithms.^{3–5}
- Clinical decision-making assistance: AI systems can analyse large amounts of clinical data to help clinicians make informed decisions about treating patients.^{6,7}
- Telemonitoring: AI enables telemonitoring of patients, as well as the design of personalised treatments based on patient-specific data.⁸
- Optimisation of resources in the management and automation of administrative processes: AI can improve

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efficiency in the management of resources and the administration of hospitals and health care systems, as well as enabling automation of routine administrative and clinical tasks, freeing up time for health care professionals to focus on higher-value activities.^{9,10}

- Personalisation of treatments: AI makes it possible to analyse genomic and clinical data and thus be able to personalise treatments according to the individual characteristics of each patient, which improves efficacy and reduces side effects.¹¹
- Electronic medical records and data management: AI systems can organise and analyse large volumes of electronic medical record data to identify trends, improve diagnostic accuracy, and optimise clinical workflows and processes.¹²

There is no doubt that data is the cornerstone on which AI models are built and improved, allowing them to learn complex patterns and make accurate predictions that facilitate and support decision-making. Therefore, facilitating access to large amounts of high-quality data is crucial for training effective AI models. It is for this reason that having a European health data space has become one of the Commission's priorities for the period 2021-2025. It is essential to have a regulatory framework that takes into account ethical and privacy considerations when accessing and using data, safeguarding people's rights to privacy, while also ensuring that bias and discrimination do not occur.

The General Data Protection Regulation (GDPR) of 2016 has aimed to lay down rules and regulations for the processing of personal data and protecting the rights of citizens of the European Union. It arises as a response to the growing concern to guarantee the privacy and protection of personal data.¹³ To this end, it includes the creation of a legal framework, in terms of governance, data quality and operability with the aim of facilitating both access to and reuse of health care data, which will result in the improvement of healthcare, research and policy-making. Access to patients' health data through the single electronic medical record poses a challenge for the exploitation of not only structured data, but also unstructured data available in progress reports, discharge reports, radiological tests, electrocardiograms, etc.

The situation in Spain in relation to processing health data is regulated by the Seventeenth Additional Provision of Organic Law 3/2018, of 5th December, on the Protection of Personal Data and Guarantee of Digital Rights (LOPDGDD in its Spanish acronym). This additional provision lays down a series of specific measures for the processing of health data, recognising the importance of protecting medical information and ensuring the confidentiality of personal data in the sphere of health care. The impact assessment makes it possible to assess the risks presented by the different processes undertaken using the data and, specifically, Article 35 of the GDPR sets out the cases in which it is necessary to carry out an impact assessment.

In this direction, an analysis of the process of data management in health in Spain has been run and published as a Letter to the Editor in this same issue, and where preliminary

and unpublished data is provided that enables the identification of some of the main areas for improvement that could be taken into account in the development of strategies to improve access to - and governance of - data. Undoubtedly, an emerging line of work is opening up which we must continue to go deeper into, in order to optimise the potential that new tools, enriched by data, could bring to the health care system.

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