



**European Committee
of the Regions**

NAT-VI/33

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OPINION

Digitalisation in the health sector

THE EUROPEAN COMMITTEE OF THE REGIONS

- calls on the Commission to promote the alignment between European, national and regional digital plans, strategies and funding in order to complete the large-scale roll out of integrated, digital and people-centred care services;
- calls on the EU co-legislators to increase the proposed budget allocations for the digital transformation in Europe in the EU Multiannual Financial Framework for the 2021-2027 period;
- suggests that the Commission should go further than developing a European format for the exchange of electronic medical records and promote a fully-fledged European electronic health record;
- calls on the Commission to work towards closing the gap in terms of access to ICT services in disadvantaged areas;
- urges the Commission to assess the possibility of assigning a unique identifier to genetic studies carried out on European citizens for clinical reasons and urges also Member States to sign the declaration "Towards access to at least 1 million sequenced genomes in the EU by 2022";
- calls on the Commission to promote better coordination between regions, the public and private sectors (including eHealth SMEs), research bodies and other players involved in eHealth.

Rapporteur

Fernando López Miras (ES/EPP), President of the Region of Murcia

Reference document

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society
(COM(2018) 233)

Opinion of the European Committee of the Regions - Digitalisation in the health sector

THE EUROPEAN COMMITTEE OF THE REGIONS

General comments

1. welcomes the Commission's initiative to promote cooperation among EU countries in order to speed up the digital transformation of the health sector, with the aim of achieving more effective healthcare in Europe, advancing research, improving disease prevention and personalised care and healthcare, as well as providing citizens with equal access to high-quality care services, bearing in mind at all times that the organisation of healthcare systems is a competence of the Member States;
2. is aware of the challenge faced by decentralised levels of government all over the European Union: the ageing of the population and the consequent increase in chronic disease and multimorbidity, resulting in growing demand for resources and a new approach to the care model;
3. points to the large volumes of health data currently stored in separate systems and argues that more efficient use of them, through interconnectedness and big data analysis, could improve healthcare and social systems in addition to making them sustainable;
4. underlines the need for a digital transformation in health and care to address the challenges facing Europe;
5. considers that the adoption of digital solutions for health and care continues to be slow and varies considerably between Member States and regions. Moreover, there is a risk that metropolitan areas and more developed regions will reap most of the benefits of the information society. This would sideline the more remote regions, rural areas or areas with low population density and islands, whereas the latter should be priority recipients since these solutions could make them less isolated;
6. recognises that, despite the efforts made so far, mutually incompatible formats and standards in electronic medical records systems still persist across the EU;
7. considers secure access and cross-border exchange of genomic and other health data to be needed in order to advance research and to allow more accurate diagnoses and more personalised treatment of illnesses, thus making progress in the area of personalised medicine;
8. welcomes the Commission's initiatives on rolling out eHealth in the regions as a tool to address the challenge of ageing and frameworks for cooperation such as the European Innovation Partnership in Active and Healthy Ageing, the designation of AHA Reference Sites or support for the Blueprint for Digital Transformation of Health and Care for the Ageing Society;
9. welcomes the new funding proposals for the period 2021-2027, in which digitalisation of health has a prominent place; in particular, welcomes the draft Regulation on the Digital Europe

programme for the period 2021-2027 and insists on the need to ensure that the public sector and areas of public interests, such as health and care, education, etc. can deploy and access state-of-the-art digital technologies, in particular high performance computing, artificial intelligence, information security and cybersecurity;

European electronic medical records and cross-border health: secure access for citizens to their health-related data

10. welcomes the fact that the Commission's proposals consider the principle of data protection to be a key element, while at the same time taking into account the opportunities offered by the new General Data Protection Regulation (GDPR) for making progress in terms of secure access to health data;
11. points out that it is necessary to improve capacity for self-care and the health literacy of citizens both because of the impact on health and in order to improve the sustainability of healthcare systems. ICTs are a key support in this regard. Also takes the view that health authorities must provide proper guidance to counteract the overload of scientifically-unsubstantiated information on the internet regarding health issues;
12. notes that most citizens do not know about the potential implications linked to personal data exposure or about the complex rules governing access to them;
13. regrets, therefore, that the Commission's proposals lack concrete measures to raise public awareness and to ensure that citizens and patients fully understand the legislative framework protecting the privacy of health data and recommends that the Commission support communication campaigns across the EU to explain how the privacy of health data will be protected under the new legal framework;
14. urges the Commission to continue to promote initiatives for eliminating obstacles to the interoperability of eHealth systems, resulting in more efficient systems, as the lack of interoperability has real and measurable costs;
15. supports the adoption of a Commission Recommendation on the technical specifications for a European form of exchange of electronic medical records and the further development of eHealth digital service infrastructure to enable citizens and patients to access and use their personal health data for public health and research purposes, as well as to facilitate the free movement of people, which is currently discouraged where complex diseases are involved;
16. calls on Member States to avoid localising services centrally on the basis of the misconception that localised services are more secure, and to archive data decentrally using technologies that make this possible, such as block chain technologies. It is also important to promote the use of international and open standards to avoid solutions that create dependency on a specific provider;
17. insists that patients' data should be protected and properly secured so that their information is not misused. Similarly, stresses that the opportunities stemming from the increased access to

patient data must in no way contribute to a development that is detrimental to the rights of patients, but rather of benefit to them. In this respect, urges the Commission to look at measures to protect patients from the potential imbalances of power - between them and health professionals - that may be created through this increased access to health data;

18. notes that digital medical records can improve coordination of care at national and regional level as it allows the real time exchange of health data between health providers, particularly in the case of patients with complex multi-systemic and rare diseases;
19. at the same time notes that in some Member States, the public authorities have invested very significant amounts in developing electronic health records and digital platforms that give people access to all or part of their own health data. It is essential to take these substantial investments into account, to learn from these Member States' experiences and to avoid saddling national, regional and local bodies with additional, unnecessary expenses in this area;
20. suggests that the Commission should go further than developing a European format for the exchange of electronic medical records and promote, together with this form, a fully-fledged European electronic health record. While secure access to medical records would be provided, the patient would be the owner of the data, authorising access to it and subsequently auditing this access;
21. notes at the same time that the public authorities in some Member States have either built, or are in the process of building, digital governance structures and systems for consent statements, log information, etc. regarding patient data and access to it. It is important for work on the EEHR to take account of national, regional and local experience in this area;

Better databases to promote prevention, research and personalised medicine

22. believes that exchange of personal health data is crucial for public health research and clinical research, so that Member States are able to transform data into knowledge that benefits citizens, without breaching the fundamental right to data protection;
23. considers that better coordination between existing national and regional initiatives is needed in order to pool genomic and other health data in the areas of research and personalised medicine and urges Member States to sign the declaration "Towards access to at least 1 million sequenced genomes in the EU by 2022";
24. urges the Commission to assess the possibility of assigning a unique identification to genetic studies carried out on European citizens for clinical reasons, which would allow the information to be used for preventative, diagnostic or therapeutic measures that the individual may need throughout the course of their life. This would always require their consent as the patient remains at all times the owner of the data. "Blockchain" is currently a secure protocol that ensures the availability of data, keeping them confidential and under the individual's control;
25. calls on the Commission to take secure measures that guarantee anonymity in order to drive forward the implementation of technology relating to the use of health data, taking into account

the potential of key technologies such as artificial intelligence or high-performance computing, by promoting better coordination between different stakeholders in the system, which includes regions, the public and private sectors (including eHealth SMEs), research bodies and other players involved;

26. welcomes the Commission's intention to support the development of technical specifications to facilitate secure access to and cross-border exchange of genomic and health information for research, along with the practical implementation of pilot projects to coordinate programmes, initiatives and relevant actors at national and EU levels, while at the same time pointing out the need to adopt better guarantees concerning the use of the genomic data;
27. considers the Commission's intention to establish a voluntary coordination mechanism between EU national authorities for the sharing of genomic and other health data to be suitable in terms of advancing in the areas of prevention and research on population health and personalised medicine;
28. calls on the Commission to ensure coordination between measures it adopts in relation with access to and reuse of data held by public administrations and its other initiatives, such as the Commission Communication Towards a common European data space (COM(2018) 232);
29. asks the Commission to take on board the possibilities offered by the European Reference Networks within the framework of the Directive on patients' rights in cross-border healthcare, in order to help facilitate the implementation of translational cross-sectoral research, including, where appropriate, into personalised medicine for patients suffering from rare, low-prevalence or complex diseases;
30. encourages the Commission to initiate a European level discussion on the ethical, legal and social implications of the use of genomic and health data in public health and research; believes that the implications of the use of genomic and health information in these fields should be included in the regulatory approach taken by the Commission and the Member States, an approach that should also take into account the role of ethics and expert committees, not to mention the autonomy of health service users;
31. encourages Member States to strengthen, and where necessary expand, existing capacity so as to ensure ongoing and regular collection of health-related data, as this will contribute to the quality of international data available in organisations such as WHO and the OECD;
32. encourages the Member States to pool data in order to implement open access policies, in line with the objectives of open science and the creation of a European Open Science Cloud;

Digital tools for empowering patients and patient-centred care: integration of care, ageing, integration of care, chronicity, multimorbidity

33. points out that the ageing of the population and the consequent increase in chronic disease and multimorbidity, and therefore care costs, require a multidisciplinary and integrated approach to care. eHealth services and the electronic exchange of data between patients, their carers and

their caregivers and care providers facilitates patient-centred care and the transition from institutional to community-based care;

34. notes that education is a key element in enabling citizens to participate actively in the digital transformation and therefore calls on the Commission and Member States to place greater emphasis on improving the digital literacy of citizens and patients by developing appropriate education programmes; recalls equally that there are still groups of European citizens who do not have internet access or sufficient digital skills to use digital services, and that proactive efforts need to be made to improve digital inclusion;
35. notes that the success of the digital transformation in healthcare will not be possible without adapting education, training and continuous professional development for health professionals;
36. stresses that digital technology can enable or improve access to health services, especially for persons with reduced mobility. It is crucial to take account of the territorial focus, in order to make it easier for more people in remote, sparsely populated or disadvantaged regions, who might be excluded or underserved by health systems, to have access to high-quality information and preventative health measures, as well as to easily accessible medical treatment and monitoring;
37. underlines that it is important to ensure that the digitalisation of health reduces social inequalities and promotes accessibility for persons with disabilities and the elderly;
38. points out that there are still marked differences between regions in access to ICT services, and therefore calls on the Commission to continue promoting policies to facilitate access in disadvantaged areas;
39. stresses that mHealth is a key factor in efforts to empower the public, as well as being necessary for the sustainability of care systems, and considers the use of digital solutions that are effective in terms of costs and health outcomes as a means of moving towards sustainable social and healthcare systems;
40. considers it essential to create appropriate tools guaranteeing a dynamic balance between supply and demand and to promote co-creation processes relating to digital solutions, drawing on the experience that some regions have in this field¹;
41. calls on the Commission to provide new instruments to promote the public procurement of innovation (PPI) in addition to current pre-commercial procurements (PCPs) and PPIs, which are complex to implement and depend heavily on ad hoc funding, by combining, for example, European funding programmes and the Structural Funds;

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<https://www.indemandhealth.eu/>;

The inDEMAND project: promotes innovation by combining two factors: demand, which identifies what is needed and the development of the solution as the result of a co-creation process between healthcare professionals and technology companies.

42. welcomes the fact that the proposal for a regulation on Health Technology Assessment extends the scope of action to medical technologies and devices, while also considering it desirable for EU legislation to facilitate the procedures for authorising medical devices and make progress in order to ensure that procedures raise the existing standards for approval;
43. considers that, in order to make progress towards sustainable systems, the scope of the regulation should be extended to all stages of technological development, including the impact assessment;
44. stresses that as new applications and devices for patients and health professionals (applications, external measuring devices or on mobile phones, etc.) emerge, this should lead to a process of accreditation, certification or marking valid at European level, to determine those that are really considered useful or that may even be subject to prescription by a health professional. This would reduce red tape so that solutions approved in one Member State could easily be marketed in another, and therefore urges the Commission to act in this regard;
45. insists that devices and applications for patients and health professionals should be simple and easy to use and should complement rather than adding to those already in place in Member States;
46. notes the difficulties of rolling out and adopting on a large scale technological solutions that have been tested and validated by pilot studies, and therefore requests that the Commission support the regions and promote cooperation between them in order to complete the roll-out of these technological solutions;
47. suggests, moreover, examining whether it is appropriate to include in project proposals for European funding a commitment to implement the project if it is successful, ensuring that it is mainstreamed throughout the population in the interest of equity, and providing consistency at the end of the innovation process by scaling up;

Funding

48. welcomes the redefinition of the scope of the new Connecting Europe Facility and the proposal for the Digital Europe 2021-2027 programme to accelerate the digital transformation of healthcare in Europe;
49. calls on the Commission to promote the necessary alignment between European, national and regional digital plans and strategies, along with, for the next programming period 2021-2027, sufficient complementarity between the different European funding programmes and public and private funding, in order to complete the large-scale roll out of integrated, digital and people-centred care services;
50. notes that often the technology exists and is operational, but red tape prevents or delays the adoption of solutions; therefore calls on the Commission to promote new reimbursement models for adopting digital innovation, geared, for example, to delivering payment in accordance with

health outcomes, so as to support the business models of eHealth and mHealth companies offering high-quality services supported by digital technology;

51. notes that for the next period, 2021-2027, the current health programme will be part of the ESF+, with a reduced allocation; therefore calls on the EU co-legislators to increase the proposed budget allocations for the digital transformation in Europe in the EU Multiannual Financial Framework for the 2021-2027 period;

Subsidiarity

52. urges the European Commission, when implementing the action plan, to take into account not only the Member States, but also the local and regional authorities that play a key role in communicating with and informing patients, in education and training for professionals, and in the development of eHealth.

Brussels, 7 February 2019

The President
of the European Committee of the Regions

Karl Heinz Lambertz

The Secretary-General
of the European Committee of the Regions

Jiří Buriánek

PROCEDURE

Title	Digitalisation in the health sector
Reference document	Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (COM(2018) 233)
Legal basis	
Procedural basis	
Date of Council/EP referral/Date of Commission letter	
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Commission responsible	Commission for Natural Resources
Rapporteur	Fernando LÓPEZ MIRAS (PPE/ES)
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Previous Committee opinions	
Date of subsidiarity monitoring consultation	