

**Committee of the Regions****NAT-V-040****109th plenary session, 3-4 December 2014****OPINION****"mHealth"****THE COMMITTEE OF THE REGIONS**

- points out that competence for organising and providing healthcare services rests with the Member States and their local and regional authorities. The latter have a key role in the development of health care and in its digitisation by means of eHealth and mHealth;
- stresses that mHealth is a key factor in efforts to empower the public and to put them in a better position to gain control over their own health. Particularly for older people and people with disabilities or chronic illnesses, mHealth can make a significant contribution to improving their safety and independence in daily life;
- highlights that expanding digitisation and increasing levels of health-related knowledge may help to give more people in remote, sparsely populated or otherwise disadvantaged regions access to high-quality information and preventative healthcare measures, as well as to easily accessible medical treatment and follow-up;
- notes that mHealth and eHealth are high on the agenda for many of Europe's local and regional authorities, but that progress in development varies between countries and regions. There is a need for more interregional cooperation and exchanges of practical and policy experience, to enable those at the forefront of mHealth to transfer their knowledge;

Rapporteur

Martin Andreasson, Member of Västra Götaland Regional Council (SE/EPP)

Reference document

Green paper on mobile health ("mHealth")
COM(2014) 219

Opinion of the Committee of the Regions – "mHealth"

I. POLICY RECOMMENDATIONS

THE COMMITTEE OF THE REGIONS

General comments

1. welcomes the open consultation that the European Commission has launched to canvas opinions on the Green Paper on mobile health ("mHealth"). The development of mHealth highlights a number of the most pressing issues for European healthcare systems, such as making more efficient use of existing resources, improving health, empowering residents, improving working conditions for healthcare workers, improving the uptake of innovations, and improving the quality of health care;
2. points out that success in developing mHealth will depend heavily on how those developments can be coordinated with other healthcare-related developments, and on how key challenges such as interoperability, privacy and quality control of data are handled;
3. particularly highlights the importance of public confidence in local and regional authorities' handling of information. The development of mHealth must take account of people's justified interest in protecting their privacy. The specific privacy risks connected with the public's use of mobile solutions to handle sensitive health-related and personal information must be resolved;
4. points out that the development of mHealth must benefit all EU citizens, and must not lead to further inequalities in terms of access to and use of healthcare services: steps must therefore be taken towards the use, free of charge, of networks providing access to mHealth services. The public interest in high-quality, secure health care must be at the heart of the developments brought about by mHealth;
5. stresses that mHealth is a key factor in efforts to empower the public and to put them in a better position to gain control over their own health. Particularly for older people and people with disabilities or chronic illnesses, mHealth can make a significant contribution to improving their safety and independence in daily life. Developments must therefore take account of people's different circumstances. New technical applications must be easily accessible, and give disabled, older and vulnerable people greater autonomy. Local and regional authorities have an important role to play in promoting training in the use of new technology and management of sensitive data, both for nursing and care workers and for the general public;

II. RELEVANCE FOR THE COMMITTEE OF THE REGIONS

6. notes that, in many EU Member States, local and regional authorities bear some of the responsibility for planning, designing, implementing and funding health and welfare policy. It is therefore evident that local and regional authorities must be closely involved in any reforms that impact healthcare and welfare;
7. notes that mHealth and eHealth are high on the agenda for many of Europe's local and regional authorities, but that progress in development varies between countries and regions. There is a need for more interregional cooperation and exchanges of practical and policy experience, to enable those at the forefront of mHealth to transfer their knowledge. The European Commission can play a role here, by collecting and collating knowledge and best practice;
8. notes that European healthcare systems face similar challenges: for example, rising healthcare costs, ageing populations, greater risks of chronic illnesses and multiple illnesses, shortages of certain health professionals, and inequalities in care provision and access to health care. Some of these challenges are also particularly evident in sparsely populated areas where people are widely dispersed. mHealth is one of a number of tools that can be used to tackle these challenges. One important factor in the development of health care and the future health and quality of life of people in Europe is therefore how well the development of mHealth is handled and translated into practical benefits for patients and health professionals;

Opportunities

9. feels that one of the success factors both in efforts to improve health care and in increasing the well-being of the population is for the public to have greater influence on and involvement in issues surrounding health and health care. mHealth is one of the basic preconditions for the provision of health-related information and the reinforcement of shared decision-making that will put people in a better position to monitor their health data, stay healthy and, where necessary, to manage their illnesses. It also provides new opportunities for family members and others, with the customer's permission, to be involved and properly informed and to play an active role when it comes to their relatives' health and contact with health and social care services;
10. would particularly highlight the fact that expanding digitisation and increasing levels of health-related knowledge may help to give more people in remote, sparsely populated or otherwise disadvantaged regions access to high-quality information and preventative healthcare measures, as well as to easily accessible medical treatment and follow-up; They will also help to provide better conditions for people to stay in their own homes and take care of themselves for longer. mHealth can contribute in a number of ways to a more person-centred healthcare system;

11. believes that mHealth has considerable potential in terms of promoting an evidence-based approach and of simplifying and improving the working environment for health professionals. It could do this by ensuring that the right information is available at the right time, by documenting important information prior to a meeting with the patient or by arranging a distance consultation with the patient. If mHealth is to become a real force for improvement and efficiency, it will therefore be necessary to ensure that the services developed and used genuinely do support health staff in their work with patients;
12. believes that good-quality and well-designed mHealth services can play an important part in increasing the quality and efficiency of health care. mHealth can, for example, help reduce the number of patients with chronic diseases entering hospital and shorten their stays, and help them to manage their own care to a greater degree. It is therefore important to ensure that mHealth is not developed entirely separately, outside healthcare systems, but is integrated as closely as possible, with the understanding that it is a tool for achieving better results for the public;
13. believes that a greater focus on mHealth could have a positive impact on entrepreneurship and employment in the regions. It would also contribute to the development of services that can be provided both nationally and internationally. A range of different initiatives will be needed to stimulate entrepreneurship further, including for example educational programmes, business competitions and guidance on market penetration. In order to be able to develop services that can exchange information with social and healthcare providers, entrepreneurs also need a better understanding of the technical and semantic standards followed by operators in the social and healthcare sector. Development activity must establish effective cooperation between the public sector and business;

Relationships

14. stresses that mHealth is both complementary to and an integral part of what has traditionally been regarded as health care. It is not a question of developing a parallel system, or of replacing the professional skills of healthcare staff. Nor is there any question of replacing all personal contact between patients and health professionals. Rather, mHealth helps to empower patients and make them better informed, and to forge new relationships between patients and health professionals. Therefore, if mHealth is to be an effective tool both for the public and for health professionals, there is a need for action in the form of communication tailored to the target audience, the development of competences, and effective change management;
15. notes that, to date, developments in eHealth have largely been led by the public health sector. However, the successful development of mHealth will require a broader perspective, and closer cooperation between public and private healthcare providers, suppliers and entrepreneurs, and of course patients and patient organisations;

Economics

16. notes that, while there are significant variations in this area, many of the reimbursement models in European healthcare systems are based on interventions, physical visits and the number of patients treated. As a rule, reimbursement is based on physically seeing a person who needs care, whereas helping someone stay healthy or manage their own care to a greater degree is not reimbursable. In order to achieve the full potential of mHealth – not least with regard to health promotion activities – it may therefore be necessary to discuss new, more value-based reimbursement models;
17. points out that, according to the EU's Economic Policy Committee (EPC), people aged over 65 account for 30-40% of Member States' healthcare expenditure, and their proportion of the total population is forecast to rise from 17% in 2010 to 30% in 2060. This also means that, by 2050, there will be only two people of working age to every person over 65, compared with four to one in 2004. mHealth has the potential to help face up to these demographic challenges and rising healthcare costs, among other things by helping to reduce hospital admissions, promote self-care and improve public health among EU citizens;

Interoperability

18. believes that mHealth highlights the need for legal, linguistic and technical interoperability. Effective electronic sharing of data between different care providers, and between patients and care providers, is crucial to improving quality and effectiveness and empowering patients. This includes ensuring that the mHealth solutions developed allow data to be transmitted both between different applications and between applications and the working systems used in health care. These are essential requirements, because the countries of Europe are facing the same challenges. The EU has an important role to play here in efforts to push forward to the development of common standards and specifications. At the same time, greater interoperability also entails an important balance between openness and security, as increasing interoperability must not result in an uncontrolled flood of information. It remains essential for communication to be based on informed choices in the context of applicable regulations and security requirements;

Safety and privacy

19. stresses that the successful development of mHealth depends on ensuring that people's privacy is protected. It is vital for people to trust the health services and information about the health services if local and regional authorities are to be able to deliver good and safe health care. Among other things, this involves ensuring that sensitive information cannot be accessed by unauthorised persons and that data cannot be used for secondary purposes without the individual's consent. It may therefore be appropriate to discuss whether there is a need for further monitoring, guidelines or certification of the mHealth services that suppliers

provide, on top of existing legislation in this field. The development of reliable and secure devices that identify individuals by means of biometric data should also be encouraged;

20. considers it important to ensure, when drafting legal acts, that they do not hinder research and systematic quality-improvement efforts above what is needed to ensure the protection of patient data. As broad a balance as possible needs to be struck between the need to protect people's privacy and the tradition in the healthcare sector of using collated information to try to improve quality and results for current and future patients. In this connection, the Committee of the Regions would particularly highlight the need to take account of this perspective when drafting a proposal for a new data protection regulation to ensure that a suitable balance is struck between the two objectives with a view to optimisation;
21. considers it extremely important for the public to be secure in the knowledge that the mHealth services they are being offered or recommended by health professionals are safe to use and will help to improve their health and quality of life. Among other things, this makes it necessary to guarantee the quality of mHealth services from a medical point of view as far as possible. In this connection, the Committee recommends making a clear distinction between lifestyle applications and medical devices. mHealth services in the latter category must be evaluated using widely agreed models for evaluating medical devices and methods, and must be subject to the Medical Devices Directive 93/42/EEC. There is also a need for clear information so that consumers, patients and health professionals can choose the mHealth service best suited to their current needs;

Subsidiarity

22. points out that competence for organising and providing healthcare services rests with the Member States. In many Member States, local and regional authorities are responsible for all or a significant part of health and welfare policy. This means that local and regional authorities have a key role in the development of health care and in its digitisation by means of eHealth and mHealth. It is therefore necessary to work closely with local and regional authorities and to ensure that the EU takes account of the principle of subsidiarity in its ongoing work on mHealth.

Brussels, 4 December 2014.

The President
of the Committee of the Regions

Michel Lebrun

The Secretary-General
of the Committee of the Regions

Jiří Buriánek

III. PROCEDURE

Title	mHealth
Reference(s)	COM(2014) 219
Legal basis	Article 307(1) TFEU
Procedural basis	Optional referral
Date of Commission letter	8 May 2013
Date of Bureau decision	6 May 2014
Commission responsible	Commission for Natural Resources
Rapporteur	Martin Andreasson (SE/EPP) Member of Västra Götaland Regional Council
Analysis	July 2014
Discussed in commission	3 October 2014
Date adopted by commission	3 October 2014
Result of the vote in commission	Majority
Date adopted in plenary	3-4 December 2014
Previous Committee opinions	CoR 2063/2013 – <i>eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century</i> . Rapporteur: Johan Sauwens (BE/EPP) CoR 348/2008 – <i>Cross-border healthcare</i> . Rapporteur: Karsten Uno Petersen (DK/PES)
Date of subsidiarity monitoring consultation	N/A