European Federation of Nurses Associations

EFN input to the EC Public Consultation on the Green Paper on Mobile Health July 2014

Section 1: Data protection including security of health data

1. Which specific security safeguards in mHealth solutions could help prevent unnecessary and unauthorised processing of health data in a mHealth context?

It is important to distinguish between mHealth solutions that involve the entry and processing of highly sensitive personal health data and those that do not. For those solutions that do relay on collecting personal health data, the principles of the revised Personal Data Protection Directive must apply, and, given that the Information and Communication Technology (ICT) sector advances very rapidly, further refinement will be required in the long run, specifically for the mHealth context.
Being health a sensitive area that for many people forms an integral part of their identity, it should be mandatory to have additional safeguards in place to avoid misuse and data theft. It is equally important that the networks used in healthcare setting which transfer mHealth data are secured and that no data interception can occur when interacting with users' personal mobile devices. (EPHA, 2014)

2. How could app developers best implement the principles of "data minimisation" and of "data protection by design", and "data protection by default" in mHealth apps?

When app developers design apps related to health, it becomes crucial that the patient is put at the very centre of their activities, also because only people who fully trust mHealth will use it and thus developers' success relies on building up trust. Citizens are not convinced that data security concerns are taken seriously enough and handled in the best possible way. Doubts already arise when users wish to download an app and are then requested to agree with a number of terms and conditions that give the impression companies are being provided with personal information including users' contacts.
It would be advantageous to develop a common, international language of consent that any user can understand. Hence, it may be good to consider introducing legislation for companies across Europe that provide mHealth solutions for the healthcare sector. While overregulation could oppress innovation, the European Commission should instigate a European debate involving all relevant stakeholders (including also professional groups and civil society) on how best to ensure that interesting companies will comply with the existing legal provisions. Given the speed of technological process, it is critical to establish

whether or not additional safeguards are required, e.g. specific mHealth guidelines or legislation. Overall, developers should be obliged to apply 'data protection by design' in such a way that apps are meeting required data security standards and transparency requirements. (EPHA, 2014)

Section 2: Big Data

3. What measures are needed to fully realise the potential of mHealth generated "Big Data" in the EU while complying with legal and ethical requirements?

The potential of big data sets, either created by users themselves or in collaboration with health professionals via mHealth applications may make new things possible that were never considered when informed consent was obtained. In practice this means that if a company wants to look for things it does not really know what they are, it has to find a way to obtain informed specific consent for this.
The future General Data Protection Regulation must be able to accommodate both the possibilities afforded to health research by technological progress while satisfying increased concerns over health data protection. Since this may be difficult to achieve in practice, mHealth may require the development of specific security standards for health data in order to safely and successfully deploy various mHealth solutions. (EPHA, 2014)
However, separate information systems with many common data items serve: clinical care; audit; research; management; public health; and consumer health applications. Within each of these silos of data-processing there are further cultural, organisational and technical barriers to sharing data – for example barriers to performing research and auditing the outcomes of patients outcomes within an "integrated" care pathway across primary and secondary care. As such, data warehouses have been a 'first' option to integrating health data, compounding some of the silos and restricting access to people who might add value to the data (public health research). As health science and care is experiencing a tsunami of data, a blizzard of methods for processing the data and a drought of human expertise to harness the value from the data in conventional ways, there is an urgent need to rethink the "big warehouses" (I. Buchan, 2013). The e-infrastructure, governance and culture for achieving sense-making data and processes, the engineering still needs to start. Nurses should have the opportunity to contribute to the design of the "sense-making data".

Section 3: State of play on the applicable EU legal framework

4. Are safety and performance requirements of lifestyle and wellbeing apps adequately covered by the current EU legal framework?

Unfortunately, this is not currently the case in spite of the fact that safety and performance requirements are vital in other areas of healthcare delivery. Hence it is fundamental to foster the use of recognised standards in this sector, too. This is especially important given the lack of robust evidence pertaining to the health benefits of apps. There is no requirement to prove that lifestyle and wellbeing apps are working to obtain a license and hence certain solutions could be completely ineffective.

5. Is there a need to strengthen the enforcement of EU legislation applicable to mHealth by competent authorities and courts?

Given that EU legislation is weak and not clear enough, competent authorities will need to look at what is permissible under the banner of mHealth. In a European Union where the cross-border mobility of (health) professionals, patients and data is encouraged, the European Commission should have a coordinating role to play in helping competent authorities and courts decide what is appropriate and what is not. Moreover, there should be a monitoring and alert mechanism in place throughout the life cycle of apps so that users can report faults (and manufacturers can fix them).

Section 4: Patient safety and transparency of information

6. What good practice exists to better inform end-users about the quality and safety of mHealth solutions e.g. certification schemes?

In order to allow mHealth to become fully efficient in all EU Member States, the development of standards, protocols and guidelines for the deployment of these services is urgently required. Having such quality checks in place for the benefit of end users can remove some of the uncertainties related to apps. There is a strong need to work on a harmonised approach to be able to come up with common frameworks. This presupposes that information and decision-making support systems are employed so as to take account of individual needs, i.e. person-centred care. Studies have commonly shown that evidence-based clinical guidelines can be effective in improving the process and structure of care.
One of the main problems of using mHealth apps concern the lack of competent contact in case problems or questions arise. With this regard, the EFN is developing evidence-based guidelines for nurses and social workers on the use of eHealth services (ENS4Care project, DG CONNECT). Part of this project relates to the use of mHealth applications as tools to enhance healthy lifestyles, boosting prevention from a life circle approach. Guidelines and criteria will be developed to enable nurses and social workers to make appropriate decisions and will guide them to encourage patients and citizens to use such technologies. Being designed under the criteria of patient safety and quality of care, the guidelines implementation will imply the adoption of those principles. Both nurses and social workers need to receive adequate information about the benefits and risks of these tools, especially in relation to the patient safety, so they will be able to make informed choices about an app's quality and safety. Sharing health data instantaneously with qualified health professionals can provide an added layer of security for patients and reassure them of a product's quality. Moreover, an active information exchange between healthcare professionals about the relative advantages and disadvantages of mHealth solutions and their own recommendations could contribute to improve clinical practice. Better integration of mHealth could also increase formal acceptance by end users.

7. What policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?

The efficacy of mHealth solutions is difficult to prove and long-term studies will need to be undertaken in combination with health impact assessments in order to obtain better information about what they can actually do. Therefore, the European Commission should allocate and invest an adequate amount of

resources within Horizon 2020 framework, in order to work not only on the efficacy of mHealth solutions but also in their effectiveness and efficiency. Recommendations from the Council of the European Union encouraging Pilot studies in different EU regions to implement mHealth tools may be considered as the best way to find out concrete results and to undertake valid and realistic evaluations, both from a quantitative and a qualitative point of view. Stakeholders representing patients, social and health care professionals would need to be involved in these studies, as the best placed to provide valuable feedback and input from a users' perspective. In fact, it becomes critical to foster health and social care professionals- and patients-led mHealth solutions, which strengthen integrated care and workforce development. mHealth data gathered through evaluation process would need to be analysed to identify systematic features, which can be used to improve the further design of the care pathways from a quality, safety and cost-effective perspective.

In addition, policy action aiming at up scaling the education of health and social care professionals should be foreseen and put in place to ensure the efficacy of mHealth applications. The promotion of advanced roles for nurses in ICT enabled integrated care is proven to boost quality, safety and cost-effectiveness of the healthcare delivered. These roles have made an enormous difference on the governance and management of healthcare, and have improved efficiency and health outcomes, enhanced patient care, contributing ultimately to the sustainability of health systems.

8. How to ensure the safe use of mHealth for citizens assessing their health and wellbeing?

Given that technology is not infallible, mHealth apps could pose potential problems for patient safety. Therefore, patient empowerment and involvement are central when using mHealth solutions as the main goal is to enhance their satisfaction during the care process. Within this context, it is important that nurses encourage patients and citizens to be more active, becoming responsible for their health management. Individuals, including chronic disease patients and older people, wish to be more informed and engaged in their own self-care, therefore coaching becomes a key factor. In order to acquire sufficient knowledge and be able to take advantage of personalised care, they require technologies 'fit for practice'. In this regard, mHealth can offer customisable 'toolkits' for predictive, participatory and preventative care. Managing the condition on a daily basis and throughout different stages of life can be very challenging. Therefore, it is impostant to bring about the right balance between conventional and ICT-enabled healthcare supporting the work of health professionals, while expanding patients' knowledge and health literacy to get empowered in a complex system of health and healthcare.

Section 5: The role of mHealth in healthcare systems and equal access

9. Do you have evidence on the uptake of mHealth solutions within the EU's healthcare systems?

The ENS4Care project shares good nursing and social work practices in eHealth/mHealth services and, through evaluation and consensus building, will create a set of guidelines focusing on healthy lifestyle and prevention, early intervention and clinical practice in integrated care, skills development for advanced roles and nurse ePrescribing. In less than two month, more than 120 practices on eHealth in the areas previously mentioned have been collected throughout the EU and Europe and an analysis has been carried out, highlighting major trends and common features. Some of the practices collected focused on mHealth

tools and their up-take at regional or national level. Some examples are: COPD RehabApp (support for COPD rehabilitation) eRehab (support for cardiac rehabilitation) and Heart Age JBS3 (risk calculator for cardiovascular disease). The final results of ENS4Care, where these practices will be further documented, will be available by the end of 2015.

10. What good practice exists in the organisations of healthcare to maximise the use of mHealth for higher quality care e.g. clinical guidelines for the use of mHealth?

Advanced Nurse Practitioners (ANP) are becoming leaders in eNursing practice, and recognise the important policy issues to further advance the use of telecare, telehealth and mHealth. Key issues such as technology selection and implementation principles, interstate licensure, malpractice, and telehealth/mHealth reimbursement are important to further advance health system reform in the EU. In addition, evidence-based clinical guidelines enabling integrated care with the support of mHealth tools are key for advancing the healthcare system reform.
Easily accessible and appropriate nursing information can facilitate decision-making and coordination of care interventions. This is enabled by integrated care systems and in doing so, mHealth innovation has the potential to lower down the workload of health professionals, facilitating knowledge acquisition, transfer, and exchange, which then directly impact on many aspects related to the quality of their professional lives and their levels of work satisfaction.
Freeing up time for service delivery is key for sustainable healthcare systems. As such, data collection cannot become an administrative burden, pulling the nurses away from the bedside. Data capturing the main activities in nursing care – data on hygiene, feeding, mobility and several technical interventions – have been collected for many years in some EU Member States and have gradually been taken up by policy-makers to introduce nursing quality data into national and regional healthcare financing systems. However, the time nurses spent to collect these data have resulted in pulling the nurses towards administrative tasks instead of closer to the bedside of patients. Freeing up working time by using mHealth solutions can support nurses to focus on direct patient care and improve the quality and safety of care delivery. Therefore, it is essential that nurses are involved into the design of integrated care pathways based on the already agreed international terminology for nursing (ICNP) with the use of mHealth solutions, strengthening the nursing workforce intelligence and bringing them back closer to patients. This will allow nursing care to become visible in patient records, national quality registers, guidelines and accreditation systems.

11. Do you have evidence of the contribution that mHealth could make to constrain or curb healthcare costs in the EU?

mHealth apps have a great potential to reduce healthcare costs, for instance by automatizing appointments and reducing the number of unnecessary physical consultations and hospital visits. By using mobile and wireless devices to improve health outcomes, the financial models underpinning EU healthcare systems require a shift from the current quantitative financing methods based on Diagnoses Related Groups (DRGs) towards a financing methodology incorporating indicators that capture integrated care and patient empowerment next to quality, safety and cost effective patient outcomes. The Diagnoses Related Groups (DRGs), measuring only medical components of service delivery, drive healthcare systems to the decrease of hospital stay, resulting in an inevitable moving of complex care to community and home care

settings, which have difficulties responding to the demand, while keeping a high quality and safety standard. Although the DRG system is widely implemented in benchmarking and financing healthcare systems in many EU Member States, the increased GDP shows that medical diagnoses and services mainly determine healthcare costs and ignore the cost-effective nursing and social care services in prevention and the existing cost-effective integrated care models.
In contrast to the DRG financing system, the International Classification for Nursing Practice (ICNP®) is not recognised as a method to improve the sustainability of the healthcare systems in the EU. Although ICNP is a tool that allows documentation of the clinical practice of nursing and provides support for clinical reasoning and decision-making, nursing sensitive data are still invisible in health statistics and even in patient records. Therefore, when redesigning the healthcare systems in the EU, the financing methodology underpinning the sustainability of the healthcare system should deploy quality and safety nursing indicators to be part of the designed integrated care pathways. Findings show that the use of evidence based care pathways can turn the entire health and social care sector into a key driver of well-being, productivity and growth.

12. What policy action could be appropriate at EU and national level to support equal access and accessibility to healthcare via mHealth?

Granting access to authorised and quality mHealth information and health services could be one policy tool to extend the basic basket of healthcare services to everybody living in Europe, which might prove beneficial for at-risk populations experiencing difficulty in accessing healthcare for a variety of reasons.
It is however equally important to acknowledge that healthcare is not only about access: especially in an online environment, health literacy represents a challenge as many individuals are unable to make positive health decisions based on the information they encounter. Moreover, content needs to be flexible so that it can adapt to different needs. mHealth information, communication and interventions are only meaningful if they can lead to actual better health outcomes for their targets. Therefore, digital literacy must be enhanced so that the widest possible population is aware of the advantages and the consequences of using health technology. Pressing a wrong button should not mean increased responsibility for patients. In this case for instance the use of quality labels would give less experienced users more confidence in trying out mHealth.
In addition to access and literacy, other factors need to be addressed, e.g. ensuring reimbursement for mHealth solutions and ensuring real integration of tools into European health systems, which would allow for better interactivity between patients and health professionals. Moreover, there needs to be training and time for health professionals to integrate mHealth into daily practice. (EPHA, 2014)

Section 6: Interoperability

13. What do you think should be done in addition to the proposed action of the eHealth Action Plan 2012-2020 in order to increase interoperability of mHealth solutions?

The eHealth Stakeholder Group has developed a report on interoperability and points out that '*Interoperability between vendors and systems enhances the choice for consumers and healthcare providers. Interoperability also opens the market for new entrants, increasing competition and innovation*'.

The recommendations on interoperability of the report include the following, the latter making specific reference to the areas of mHealth and Big Data:

- Focus on priority use cases which have been widely adopted and for which mature specifications exist.
- Clarify privacy and data protection requirements and establish general principle for organisational requirements for each of the use cases.
- Foster the use of international standards and market focused profiles to deliver ready to implement specifications that result in successful interoperability
- Educate local level on eHealth interoperability to transfer the knowledge gathered at European level to the national, regional and local level, for a better use and adoption of interoperable solutions.
- Address semantic interoperability incrementally (step by step) by selecting a small number of widely needed terminologies for a start.
- Investigate the particular interoperability requirements of mHealth, Big Data, and online social networks to ensure the vast amount of data originating from mHealth solutions and apps can be leveraged for better health care.

14. Do you think there is a need to work on ensuring interoperability of mHealth applications with Electronic Health Records?

There can be a relevance on allowing mHealth applications to get information from the Electronic Health Records (EHR) in order to function based on real parameters. However, the fact that unsolicited disclosure of health information can have a serious detrimental impact on users' lives, including their reputation, EHRs should not simply be accessible 'on the move' (e.g. by individuals travelling on public transport). The introduction of an added layer of authentication, e.g. via 'digipass' type technologies mentioned above, or in combination with national ID cards would at least encourage the vast majority of users to access and update their personal health information in more 'private' environments where the chances that data can be spied upon or stolen by third parties are lower. Up till now, the access that mHealth applications had on citizen's information was strictly the one included by the end-user or the professional. It can be worth considering the possibilities of allowing mHealth applications to have direct access to Electronic Health Records. In this case, partnerships between those owning the data, those saving it, those using it and the industry behind the applications should be made to look for solutions.

Section 7: Reimbursement models

15. Which mHealth services are reimbursed in the EU Member States you operate in and to what extent?

There are different experiences in the EU countries. In Sweden, for instance, the healthcare system gets some reimbursement for telephone contacts with patients, i.e. test results, but does not include services as mHealth applications.

16. What good practice do you know of that supports the refund of mHealth services e.g. payer-reimbursement model, fee-for-a service?

mHealth services that can be classified as clinical interventions or as integral elements of healthcare treatments should be available to all patients and therefore reimbursed by payers throughout the EU depending on the existing arrangements in the Member States. At least this should cover basic mHealth services which will become part and parcel of healthcare anyway and may also play a large role in the provision of cross-border healthcare, ensuring also continuity of care.
If in addition Member States wish to refund mHealth services that are less critical and aim more to support the provision of health and wellbeing information – which can be extremely valuable when it comes to the public health priorities of prevention and health promotion– then they should introduce legislation to ensure that everyone is able to access this information and share experiences at EU level so that other countries can follow them.

Section 8: Liability

17. What recommendations should be made to mHealth manufacturers and healthcare professionals to help them mitigate the risks posed by the use and prescription of mHealth solutions?

The following recommendations should be considered:

- Involve end users in the design and trial and quality control of mHealth solutions
- Conduct evaluation studies of the impact of apps and other mHealth solutions
- Design easy-to-identify data protection symbols and provide product information without resorting to small print
- Envisage mHealth solutions as part of healthcare
- Create flexible solutions that can be tailored to the needs of non-traditional end users and vulnerable individuals and groups
- Introduce training to ensure that all professional users of mHealth are aware of the technology's advantages and limitations
- Make adequate working time available for interaction with new media
- Ensure that mHealth solutions can be traced and that there is a reporting mechanism in case of problems
- Introduce a 'helpline' for users of mHealth solutions prescribed by health professionals

Section 9: Research and innovation

18. What specific topics would you provide for EU level research, innovation and deployment priorities for mHealth?

The EFN believes that in order to promote healthcare system reform, the role played by innovation in the field of healthcare, including mHealth, is crucial and therefore it is necessary to invest and allocate

resources in order to carry out objective evaluation studies and obtain concrete results on whether or not mHealth is producing better health outcomes.
The key topics may be: how to enhance prevention and health promotion; the developments of integrated care; the role of advanced roles and need of eSkills; cost-effectiveness and patient empowerment analysis of apps; research on nursing sensitive criteria. Additionally, there should also be more research to demonstrate what types of apps are on the market and what purposes they serve, which would help national and EU policymakers to create guidelines for different kinds of products. Currently very different products are being described under the mHealth umbrella.

19. How do you think satellite applications based on EU navigation systems (EGNOS & Galileo) can help the deployment of innovative mHealth solutions?

The EFN does not have specific knowledge in this field. Nevertheless, the EFN is open to any innovative approach that could support the use of mHealth applications.

Section 10: International Cooperation

20. Which issues should be tackled (as a priority) in the context of international cooperation to increase mHealth deployment and how?

Good practices, guidelines and experiences should be shared particularly on burning issues such as data protection, establishing user trust, quality and efficacy and patient safety. A common understanding and terminology of mHealth could also help increase interest at all levels. Given the many possible implications for society, mHealth deployment calls for a structured, systematic and transparent approach.
The increased trend towards international and transatlantic agreements, such as the Transatlantic Trade and Investment Partnership (TTIP), will impose unfavourable regulatory conditions on European legislators as it is yet unclear what implications it will have on healthcare and areas of particular concern such as data protection and security.
In this context it is particularly important to be transparent and involve civil society to avoid serious consequences which may not even be foreseeable. Given health's 'technological turn', which is largely driven by private companies, mHealth could pose a threat to the goal of universal healthcare provision as international agreements can be a vehicle for companies "to flex their muscles" and override national legislation.

21. Which good practice in other major markets e.g. USA and Asia could be implemented in the EU to boost mHealth deployment?

Europe has an overall more inclusive and socially oriented society than our homologues in Asia and North America and European values, including universality, inclusion, solidarity etc. must continue to be protected, especially when it comes to healthcare provision. If this implies that European entrepreneurs are not always the very first to exploit certain technology opportunities, they should be encouraged to design better solutions which are ultimately safer and provide better quality, thereby not infrequently winning out over their global competitors in the long run. (EPHA, 2014)

Section 11: Access of web entrepreneurs to the mHealth market

22. Is it a problem for web entrepreneurs to access the mHealth market? If yes, what challenges do they face? How can these be tackled and by whom?

While we do acknowledge that mHealth represents a big global opportunity for Europe, and that it is important not to fall behind other global competitors, the concerns over usability, quality, safety, data protection and efficacy are more urgent than market access barriers.
Everybody, including web entrepreneurs, will be a patient during the life cycle, therefore health has consistently been identified as the most important priority for Europeans for many years, more important than employment and business matters.
Another issue is that web entrepreneurs who wish to access the mHealth market may not have a broad knowledge about health and health policy. Therefore, the development and adoption of EU wide quality criteria for apps and other mHealth solutions would help mHealth developers to understand the criteria their products need to meet in order to be effective, user-friendly and safe.

23. If needed, how could the European Commission stimulate industry and entrepreneurs' involvement in mHealth e.g. through initiatives such as "Startup Europe" or the European Innovation Partnership on Active and Healthy Ageing?

Within the context of the EIP on Active and Healthy Ageing, the industrial sector is already well represented, therefore the EFN believes that more emphasis should go on ensuring appropriate involvement of other stakeholders and civil society.