European Association of Hospital Pharmacists (EAHP)

Consultation Response to DG Connect's mHealth Green Paper

June 2014

Getting mHealth right – learning from experience

Getting mHealth right – learning from experience

The European Association of Hospital Pharmacists (EAHP) welcomes the opportunity to respond to DG Connect's consultation on its Green Paper on mHealth. mHealth is a feature of change in healthcare in Europe and we welcome early considerations of the best ways forward to ensure the technological possibilities reap maximum rewards for the operation of safe, effective and high quality patient care within European health systems.

A key message that EAHP wishes to convey to DG Connect is that, although the use of smartphone technology for healthcare purposes is comparatively novel, health systems themselves have been adapting to new technologies for many decades – with accompanying good and bad practices from which lessons may be learnt.

The bedside scanning case study

An example that EAHP would like to highlight in this regard is the use of bedside scanning in hospitals. Since the 1980s health systems have been aware of the patient safety benefits that can be achieved by conducting a scan of a medicine's bar code prior to administration to a hospitalised patient. The practice of scanning a patient bracelet and then the medicine about to be given enables a final check that the medicine about to be given is indeed the correct medicine, in the correct dose, is about to be given at the right time (and has not been administered already), and is being given by the right route of administration. Studies suggest it can reduce medication error by over 40% [1].

Yet, in contrast to the United States, the safety benefits of bedside scanning remain largely unrealised in the European hospital system. Why?

In short, because bar codes are not typically included on the single primary packaging unit of medicines, (as opposed to the outer packaging) the typical form by which medicines are held in the hospital ward. This means, without the barcode placed on the primary package at manufacturing point, hospitals must place bar codes on the medicines themselves, an operation that dissuades most hospitals from implementing bedside scanning, despite the patient lives it can save.

The lessons from history to guide future mHealth activity

Lessons here for mHealth include:

- The need for European health systems, and parts of the health system within a country, to speak to each other in terms of clarifying their shared needs and aspirations from new technologies;
- The need for regulators, Governments and pan-European institutions to take an active interest in the possibilities offered by new and emerging technologies and assist in their realisation, such as through ensuring common standards and helping the private sector understand the opportunities and needs to be met in order to respond to the demand; and,
- The general need for European countries to set common goals and aspirations in areas such as improving patient safety and to then examine, promote and support the technological (and other) possibilities that can bring achievement of these aspirations into being.

EAHP is content for this response to be made public and welcomes further opportunities to engage with DG Connect on the topic, and ensuring the healthcare professional perspective on mHealth is understood and appreciated by relevant Commission officials.

We further encourage cooperation and communication across Commission DGs, including DG SANCO and DG Enterprise, in order to ensure a joined up approach, and to prevent unnecessary fragmentation and duplication of effort.

ANSWERS TO CONSULTATION QUESTIONS

Data protection

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

Patient data must be protected against unauthorised access by, for example, 3rd parties seeking information for direct marketing and advertising purposes. At the same time, patient medical information is important for healthcare professionals delivering elements of care, such as doctors, nurses and hospital pharmacists. Finally patient data can also be of great value in research and the development of evidence-based medicine and health policy.

Therefore, as a means of balancing these factors in regards to health data and the development of Apps, EAHP recommends that any user of health app be taken through a transparent and straight forward consent procedure as to what data any app collects and holds, how that data may be used, and by whom. Such consent procedures may require a former of agreed standards to protect against 'tick box' consent by individuals, where terms of that consent have not been fully understood, or even read, as is often lamented to be the case with the use of many downloadable applications ('blind acceptance')[2].

Advice to the Commission on specific technological solutions for the safeguard of health data is outside the remit of the respondent organisation. However, EAHP recommends DG Connect seek advice from the IT industry on this point on a regular basis as it develops its mHealth policy further.

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

EAHP supports the realisation of 'big data' possibilities in improving the provision of evidence-based healthcare, assisting decision-makers and aiding epidemiology and public health activities.

Whilst there is clearly a role for mHealth in generating this data, EAHP does not feel qualified at the particular moment of this consultation to offer advice to the Commission on specific measures required to ensure compliance with legal and ethical requirements, other than suggesting the need to ensure clear and workable processes for user consent and understanding about how data related to an app they utilise may be used. EAHP's general sense is that the public, if engaged in an informed discussion on the point, can also see the overall benefits of 'big data' and will respond constructively in relation to proposals focused on how to achieve its benefits whilst respecting legal and ethical requirements.

It is desirable however, that in relation to big data and its use for the purposes of healthcare policy making, the information being used be made transparent in order that there may be third party scrutiny of its validity.

Some care may be needed in respect of 'big data' and rare disease for example, in respect of small patient cohorts potentially being vulnerable to identification. EAHP recommends a particular thought be given by DG Connect to this point within its deliberations on mHealth and 'big data'.

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

Lifestyle and wellbeing apps do appear to offer potential value to patients, with possible benefits including assisting individual motivation to improve nutrition, fitness and general health, as well as appropriate reminders to assist medication adherence [3, 4] (for example dose reminders).

However there also appears to EAHP to be a lack of oversight arrangements for these apps, including ensuring their reliability – and in respect of anything relating to medicines use – their safety.

For example, as healthcare professionals, hospital pharmacists use their expertise to advise patients on therapy, treatments and counsel them (their families, and carers) on potential side effects, interactions and dosing regimens. The advice they give is based on scientific

based evidence and given within a highly regulated framework which has emerged over time out of necessity, experience and desirability.

If mHealth is to become more integral within the healthcare system it is important that the introduction of such tools does not have the unintended consequence of creating new weaknesses within well established systems for patient safety. Therefore, EAHP sees important value in healthcare professional review of Apps before introduction, and other assurance frameworks such as certification systems.

In short, EAHP considers that there is more that can and should be done to ensure the safety and performance requirements of lifestyle and wellbeing apps are adequately covered by the current EU legal framework - especially where these apps have any relation to medicines use.

We therefore encourage DG Connect to conduct review activity in this direction.

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

As the adoption of mHealth remains in its infancy in Europe, EAHP has not yet become aware of good practices of the nature requested by the question. However, EAHP would be willing to work with DG Connect on this question, and is open to future joint working on the topic e.g. by surveying our national member networks on the question, opinion surveys of hospital pharmacists on good practices that are referenced to the Commission by others within this consultation exercise.

In general however, the introduction of credible and independent certification schemes appears a sensible response to the potential concerns of 'rogue' health apps emerging, and such certification and oversight is **especially** important in cases where an app relates to medicines use, for example medication adherence apps for patients, or dose calculators for healthcare professionals. The potential results from faulty or badly designed apps in this regard could be fatal.

We note, for example, moves in the United States to regulate certain categories of App via the Food and Drug Administration (FDA) [5]. We recommend DG Connect review this development for lessons that might be learned for the European context.

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

Ensuring and verifying efficacy suggests an element of independent testing and trialling of an mhealth solution. In view of the risks inherent in use of medicines, EAHP suggests rigorous trialling and testing of apps intended to be used in this way be a central requirement before health systems promote wide uptake e.g. adherence tools, dose calculators etc. Such trial and testing should involve end users such as patients, and experts in medicines such as pharmacists. Accuracy and reliability should be core elements of such testing, as well as user response. Furthermore, taking into consideration that many apps can be seamlessly 'updated' or changed, without any action by the customer, some oversight may be required of this update process in the case of apps with medical/pharmaceutical use.

In terms of the narrow legal remit of the EU in this area, explicit policy actions for the European Commission may include:

- the formation of recommendations to Governments on this point;
- the promotion and sharing of good (and bad) practices in this area;
- conduct, collection and dissemination of research into the topic; and,
- continual monitoring of the development and uptake of health apps, and the safety associated with their use.

Reliable and independent schemes of certification, as discussed in a previous question, are supported by EAHP.

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

Again – to ensure safe use of mHealth solutions, independent trial and testing of the proposed technology before uptake is very important, and this should include the intended users, such as patients, and the views and perspectives of healthcare professionals. In the case of any application involving medicines, pharmacists, the health system's experts in medicines, should be involved in the testing and oversight, and ideally the development.

The patient safety concerns about potential 'rogue' applications are real. Incorrect information about pharmaceutical products, interactions and doses, has the potential to be fatal. Examples that EAHP can reference to the Commission of safety concerns about apps

include the inaccuracies found within an application regarding anti-cancer medicines, and an application that gave flawed recommendations to healthcare professional about the safe and effective use of antibiotics [6-8].

Risks are also present in badly designed health apps resulting in a patient delaying seeking advice from a healthcare professional and incorrect self-management leading to either avoidable worsening of a health condition, hospitalisation or mortality.

For these reasons, the case can be well made for a testing, trial and certification framework for mHealth apps used in European health systems.

Further to this, EAHP recommend Commission liaison with international organisations such as HL7 and IHE about use-cases for healthcare apps.

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

As the adoption of mHealth remains in its infancy in Europe, EAHP has not yet become aware of widespread uptake within the health systems of our member associations. However, EAHP is open to working with DG Connect on this question e.g. by surveying our national member networks on the question, opinion surveys of hospital pharmacists on the uptake of mHealth solutions referenced to the Commission by others within this consultation exercise.

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

As the adoption of mHealth remains in its infancy in Europe, EAHP has not yet become aware of good practices in the organisation of healthcare to maximise the use of mHealth for higher quality care. However, EAHP is open to working with DG Connect on this question e.g. by surveying our national member networks on the question and opinion surveys of hospital pharmacists.

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

EAHP does not have research of its own to contribute in response to this question, however savings can be imagined through Apps that support:

- improved adherence by patients to their medication/s;
- the achievement of healthier lifestyles by the general public;
- improved communication between healthcare professionals;

- easier access by healthcare professionals to educational and professional development opportunities;
- reduction in missed appointments through patient reminder systems;
- improved health literacy;
- pharmacovigilance; and,
- increased patient safety (e.g. scanning of medicines before administration to check if is the right medicine, at the right time, for the right patient, by the right route of administration).

Moreover, EAHP consider there is a lack of collected evidence in this regard, and would support, and be willing to assist, the Commission in this area.

As a final point in answer to this question, EAHP expresses some concern to DG Connect that the consultation Green Paper only asks stakeholders for evidence relating to how mHealth can reduce healthcare costs.

EAHP strongly advise that the Commission take a wider sense of the benefits that can be delivered by mHealth, and include other criteria for success, such as:

- evidence of mHealth improving patient outcomes;
- evidence of mHealth improving patient safety;
- evidence of mHealth improving workforce competence and skills; and
- evidence of mHealth addressing inter-sector and inter-professional communication barriers.

Taking a view of mHealth only offering cost saving opportunities to health systems risks repeating past mistakes about the possibilities of new technologies and we refer DG Connect to the case study of bedside scanning mentioned in the introduction to our consultation response.

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

In terms of the narrow legal remit of the EU in this area, explicit policy actions for the European Commission may include:

- the formation of recommendations to Governments on this point;
- the promotion and sharing of good (and bad) practices in this area;
- conduct, collection and dissemination of research into the topic; and,
- continual monitoring of the development and uptake of health apps, and the safety associated with their use.

At a national level, EAHP encourages EU Member States to participate in Commission led activity of the nature described above.

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

EAHP consider fruitful potential for European Commission led activity to enable interoperability in respect of aspects of mHealth such as cloud computing(as defined in the report)[9] e.g. in enabling apps to work across countries[9].

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

Yes, by the European Commission, as an independent organisation that can also take the responsibility of ensuring any interoperability is only envisaged for appropriate circumstances, and of ensuring healthcare professionals, patients and other stakeholders can contribute to the work, and share perspective and needs.

13. Which mHealth services are reimbursed in the EU Member State(s) you operate in and to what extent?

As the adoption of mHealth remains in its infancy in Europe, EAHP has not yet become aware of examples of reimbursement for the use of mHealth solutions across our member countries. However, EAHP is open to working with DG Connect on this question e.g. by surveying our national member networks on the question and opinion surveys of hospital pharmacists.

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

As the adoption of mHealth remains in its infancy in Europe, EAHP has not yet become aware of examples of reimbursement for the use of mHealth solutions across our member countries. However, EAHP is open to working with DG Connect on this question e.g. by surveying our national member networks on the question and opinion surveys of hospital pharmacists.

15. 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?

As referred to previously there are undoubtedly benefits to be realised by the potential of mHealth solutions, including increased fitness of the general population, increased health literacy and potential increased adherence to treatment. The potential risks however include inaccurate information being provided by the app itself, referral to inappropriate references and the possible decreased role of the healthcare professional when providing healthcare. This could result in missed diagnosis, delay in treatments and negative health outcomes.

Recommendations to mHealth manufacturers to mitigate against these risks include:

- Involving healthcare professionals and patients in both the development and testing of applications
- Involving pharmacists in the development and testing of applications wherever these have relation to the use of medicines
- Willing involvement in independent testing, trial and certification schemes to validate the appropriateness of applications.

For healthcare professionals to mitigate against the risk:

- Formal CPD opportunities should be offered by employers to improve individual understanding in mHealth
- Reliable and independent certification schemes should be developed to give healthcare professionals assurance of the safety and status of devices

There has even been suggestions of incorporating mHealth technology into the pharmacist's curriculum[10].

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

For the healthcare professional point of view it is important that mHealth applications have the appropriate level of evidence behind them to enable confidence that they are effective, safe and can provide the patient with added benefit.

As noted elsewhere in this response, EAHP considers there is a lack of published evidence about the efficacy of mHealth solutions and this should be addressed, with the Commission playing a role in good (and bad) practice awareness, evidence dissemination and sponsoring of research.

Specific topics for EU level research could include:

- The role and evidence for mHealth and improved patient outcomes
- the role and evidence for mHealth and patient safety

- the role and evidence for mHealth and adherence to treatment
- the role and evidence for mHealth and healthcare professional education
- the role and evidence for mHealth and improved inter-sector and inter-professional communication

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

There is a potential benefit for patients needing to identify a source of supply (e.g. a hospital pharmacy) of a medicine when in a different country. This might have particular benefit for patients with rare diseases, who may require medications not typically available outside of the hospital setting.

There could also be benefits for traceability of medicines e.g. recalls and locating stock in the event of a shortage.

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

Priority issues for international cooperation and mHealth occur to EAHP as:

- Interoperability of systems;
- Coordination of regulatory requirements where practical, respecting that regulatory preference may differ in regions of the globe, and that European perspectives must be pursued as a priority (e.g. data protection);
- Accumulation, sharing and distribution of evidence and good (and bad) practices;
- Discussions between international health systems about commonly shared aspirations from the new technological possibilities (refer to bedside scanning case study in introduction to this response); and,
- Translation of apps into the mother tongue of patients (e.g. to prevent new health inequalities opening up in respect of countries with comparatively small language populations).

Cooperation of this nature should be conducted in a transparent manner, with opportunities provided for stakeholders such as healthcare professionals and patients to contribute their perspectives.

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

As the adoption of mHealth remains in its infancy in Europe, EAHP has not yet become aware of good practices in other major markets. However, EAHP is open to working with DG Connect on this question e.g. by collecting views from our counterpart organisations in other parts of the world (e.g. USA, Canada, South America, China, Japan, Australia).

Cited References:

1. Poon, E.G., et al., *Effect of Bar-Code Technology on the Safety of Medication Administration.* New England Journal of Medicine, 2010. **362**(18): p. 1698-1707.
2. Malenkovich, S. *Click Here to Accept: The Terms of Service Conundrum*. 2012 [cited 03/07/2014]; Available from: https://usblog.kaspersky.com/click-here-to-accept-the-terms-of-service-conundrum/.
3. Wike, K. *mHealth Key To Pharmacy Adherence?* . 2014 [cited 25/06/2014]; Available from: http://www.healthitoutcomes.com/doc/mhealth-key-to-pharmacy-adherence-0001.
4. Javitt, J.C. *mHEALTH tools: A bond between patients and pharmacists* 2013 [cited; Available from: http://drugtopics.modernmedicine.com/drug-topics/news/mhealth-tools-bond-between-patients-and-pharmacists?page=full.
5. FDA. *Mobile Medical Applications*. 2014 [cited 03/07/2014]; Available from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm?utm_source=twitterfeed&utm_medium=twitter.
6. Slabodkin, G. *Pharmacist: Epocrates app is flawed, should be removed from iTunes*. 2013 [cited 25/06/2014]; Available from: http://www.fiercemobilehealthcare.com/story/article-app-flawed-should-be-removed-itunes/2013-11-25.
7. Aungst, T. *Popular Epocrates Bugs & Drugs App used by Physicians is flawed, should be removed from App Store*. 2013 [cited 25/06/2013]; Available from: http://www.imedicalapps.com/2013/11/epocrates-bugs-drugs-app-antibiogram/.
8. Pandey, A., et al., *Smartphone Apps as a Source of Cancer Information: Changing Trends in Health Information-Seeking Behavior.* Journal of Cancer Education, 2013. **28**(1): p. 138-142.
9. *eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century* 2012 [cited 03/07/2014]; Available from: http://ec.europa.eu/health/ehealth/docs/com_2012_736_en.pdf.
10. Aungst, T.D., *Integrating mHealth and Mobile Technology Education Into the Pharmacy Curriculum.* American Journal of Pharmaceutical Education, 2014. **78**(1): p. 19.

Additional information:

- Toh, T., W. Chui, and K. Yap, *Development of a virtual patient record mobile app for pharmacy practice education*. Vol. 5. 2014. 66-71.
- Margolis, K.L., et al., *Effect of home blood pressure telemonitoring and pharmacist management on blood pressure control: A cluster randomized clinical trial.* JAMA, 2013. **310**(1): p. 46-56.
- Clauson, K.A., et al., *Opportunities for pharmacists in mobile health.* American Journal of Health-System Pharmacy, 2013. **70**(15): p. 1348-1352
- Seto, E., *Cost Comparison Between Telemonitoring and Usual Care of Heart Failure: A Systematic Review.* Telemedicine and e-Health, 2008. **14**(7): p. 679-686.
- AbuDagga, A., Helaine E. Resnick, and M. Alwan., *Impact of Blood Pressure Telemonitoring on Hypertension Outcomes: A Literature Review.* Telemedicine and e-Health, 2010. **16**(7): p. 830-838.
- Haffey, F., R.W. Brady, and S. Maxwell, *A Comparison of the Reliability of Smartphone Apps for Opioid Conversion.* Drug Safety, 2013. **36**(2): p. 111-117.
- Nosta, J. *Digital Health And The Pharmacy: A Prescription For Success*. 2013 [cited 25/06/2013]; Available from: http://www.forbes.com/sites/johnnosta/2013/08/20/digital-health-and-the-pharmacy-a-prescription-for-success/.