

◆ Revisão Bibliográfica

Uma revisão sobre modelos e iniciativas bem-sucedidas de utilização de standards o sumário do paciente em aplicações de mSaúde

A review of successful initiatives and models on Patient Summary standards in mHealth apps

Una revisión de iniciativas y modelos exitosos en los estándares de Resumen del Paciente en aplicaciones de mHealth

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Resumo:

Este artigo fornece uma visão geral de iniciativas bem-sucedidas no âmbito do International Patient Summary (IPS) em aplicativos mHealth, analisando modelos existentes na Europa e no mundo e descrevendo aqueles que são considerados os mais eficazes no suporte a um desenvolvimento ágil.

As principais tendências e desenvolvimentos prospectivos são brevemente apresentados, com ênfase nos serviços mais requeridos pelo cliente num aplicativo de saúde móvel, os principais fornecedores e as tendências predominantes na evolução do mercado.

Foi realizada uma pesquisa documental sobre os resultados europeus relevantes nesta área, destacando o enquadramento e os resultados da consulta aberta sobre o formato de troca padrão do Roteiro para o Registo Eletrónico de Saúde (EHR), que são apresentados e analisados de forma breve.

As diferentes formas pelas quais a adoção de padrões IPS pode ser estimulada e incentivada são analisadas e categorizadas, distinguindo os principais tipos de modelos de adoção, dependendo se eles influenciam a procura (modelos orientados pelo governo) ou a oferta (modelos orientados pelo mercado).

É também apresentada uma revisão dos sistemas de certificação e acreditação existentes para a funcionalidade EHR do mHealth, com um foco em exemplos significativos no Reino Unido e em Espanha - Andaluzia e Catalunha.

Palavras chave: Resumo do paciente; Standards; aplicativos mHealth; Registo Eletrónico de Saúde; Modelos de negócio

Abstract

This article provides an overview of successful initiatives on International Patient Summary (IPS) standards in mHealth apps, analysing existing models both in Europe and worldwide and describing those that are considered to be the most effective in supporting agile deployment.

Key trends and prospective developments of this lively market are briefly presented with specific emphasis on what are the most demanded services and features that clients want from an mHealth app, who the key providers are and what the predominant trends are in the evolution of the market.

A desk research on relevant European outcomes on this area has been performed, highlighting the framework and results of the open consultation about the Roadmap for Electronic Health record (EHR) standard exchange format, that are displayed and briefly analysed. The different ways adoption of IPS standards may be prompted and fostered are analysed and categorised, distinguishing the main types of adoption models depending on whether they leverage the influence that such standards might exert on either the demand (government driven models) or the offer of mHealth apps (market driven models).

A review of existing certification and accreditation schemes for mHealth EHR functionality is also presented, with a specific focus on significant examples in UK and in Spain - Andalusia and Catalonia.

Keywords: Patient Summary; Standards; mHealth apps; Electronic Health Records; Business models

INTRODUCTION

The impact of digital health on patient care is accelerating with the increasing adoption of mobile apps and wearable sensors. According to a study delivered by Research2Guidance, health-related mobile applications (mHealth apps, hereafter) available to consumers surpassed 325,000 in 2018 — nearly double the number available just two years previously. This rapid app expansion, coupled with various consumer wearable devices on the market worldwide, provides evidence of digital health’s accelerating innovation and increasing demand. While the majority of mHealth apps available are general wellness apps, the number of health condition management apps—those often associated with patient care — are increasing at a faster rate, and now represent 40 percent of all health related apps.

Consumers are increasingly using self-service digital health tools that go beyond websites. A study delivered by Accenture analyzed the findings of the consumer survey on digital health carried out by the consulting firm in 2018 in seven countries to assess consumers’ attitudes towards healthcare technology, modernization and service innovation.

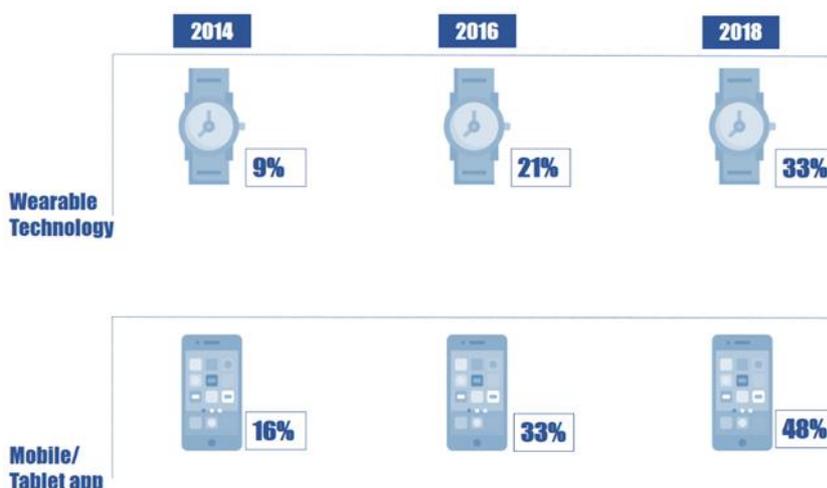


Figure 1 - Significant increase in use of health apps and wearable devices (source: Accenture 2018)

The survey shows increases in the use of mobile, electronic health records (EHRs), social media, wearables, smart scales and online communities. In this regard, a Deloitte study of 4,530 healthcare consumers and 624 physicians in the United States found that half of all respondents used wearables and other technologies to track their health information (Betts and Korenda, 2018). In particular, the use of mHealth apps by clinicians, patients, and others has grown dramatically since the introduction of mobile phones and tablet computers.

According to a report from the Iqvia Institute in 2017, there was in that year twice more apps than in 2015 and nearly five times more than those available in 2013, which represents more than 200 new health apps per day on average.

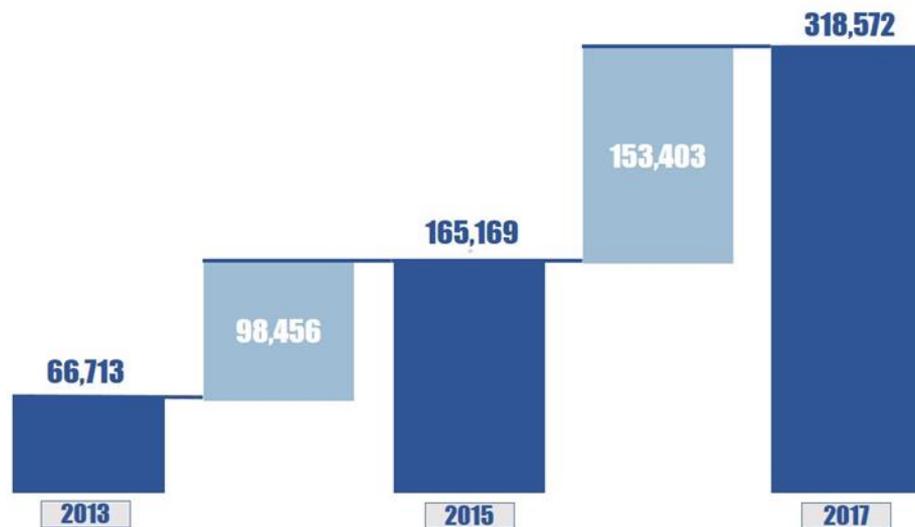


Figure 1 - Number of Digital Health apps in 2017, 2015 and 2013

Recent studies show that mobile devices and apps can support a variety of routine medical tasks including clinical reference, drug dose calculation, patient education, accessing medical records, and clinical decision support. Mobile apps have also been shown to benefit patients in a range of interventions across numerous medical specialties and treatment (online or blended) modalities. Medical apps offer clinicians the ability to access medical knowledge and patient data at the point of care with unprecedented ease. However, the intersection of mobile technology, apps, and health care is currently in its most dynamic phase, meaning that there is a need to ensure that patient safety is not compromised whilst this field matures (Lewis and Wyatt, 2014).

Despite progress to date, a number of barriers still exist to widespread adoption of digital health by patient care institutions; only an intermediate level of adoption has yet occurred. A variety of industry and policy initiatives are emerging to address these barriers and accelerate the ongoing adoption of digital health tools by care provider organizations, so that, in ten years, the use of digital health may be mainstream for most organizations delivering human health and care just in time and at a lower cost.

As a framework, it is of interest to re-visit the Communication on enabling the Digital Transformation of Health and Care in the Digital Single Market, adopted by the European Commission in April 2018, as referred in section 5.

The results of the public consultation carried out in 2017 show that the majority of the respondents (93%) either agreed (28%) or strongly agreed (64%) with the statement that: "Citizens should be able to manage their own health data". In addition, more than 80% of respondents believe that sharing data could improve treatment, diagnosis and prevention of diseases across the EU. A large majority of respondents (almost 60%) identified the heterogeneity of electronic health records as one of the main barriers for exchange of health data in Europe. Several respondents have pointed out the need to adopt standard technical specifications for cross-border access to health data, to address the heterogeneity of technical specifications supporting EHR systems, and to encourage best-practices around data quality which could facilitate technical and semantic interoperability.

The main options proposed by all respondents in order to overcome barriers to access and sharing of data in the EU are to develop harmonised standards for data quality and reliability (59.6%), to standardise EHRs (56.8%), to propose health-related cybersecurity standards (54.4%) as well as including the support for interoperability with open exchange formats (53.5%).

METHODS

The construction of all the materials and data presented in this document were essentially based on extensive inspection of available documentation derived from different European and worldwide projects and initiatives, as well as from collection of up-to-date examples of business exploitation of the IPS in different contexts, serving as use cases for IPS adoption in real world practices.

All the data collected were then analysed and discussed between the different consortium partners of Workpackage 7 of the Trillium Bridge II project, namely the organisations authoring the present article.

The methodology of work carried out by the authors mainly followed this workflow whereas the outcomes of each phase of the study have been translated and organized in a section of the present report:

1. mHealth market analysis: key trends and prospected developments of this lively market are briefly presented with specific emphasis on what are the most demanded services and features that clients seek in an mHealth app, the key providers and the predominant trends in the evolution of the market.
2. Review of the open consultation about the Roadmap for Electronic Health record (EHR) standard exchange format.
3. Review and categorisation of possible adoption models: the different ways adoption of IPS standards may be prompted and fostered are analysed and categorised. We distinguish the

main types of adoption models depending on whether they leverage the influence that such standards might exert on either the demand (government driven models where the adoption is enforced by law, regulation or certification) or the offer of mHealth apps (market driven models, where the adoption is voluntarily decided by the developers to exploit the competitive advantages and business opportunities it conveys).

4. Analysis of four use cases that enforce interoperability standards in mHealth, approaching also existing certification and accreditation schemes (with a specific focus on significant examples in UK and in Spain, Andalusia and Catalonia).

RESULTS

The envisaged adoption models of IPS standards in mHealth may be divided into 3 main strategies:

- Market driven: this category refers to those cases where adoption is voluntarily made by developing companies and driven by the industrial and commercial advantage attached to the standards' adoption, that facilitates the information exchange and sharing
- Government driven: in this case the standards adoption is enforced by public authorities.
- Labelling embedded in conformity assessment schemes and related criteria: the adoption is in this case usually government driven, although mediated by certification entities, either governmental or appointed by accreditation bodies under ISO 17065 for specific conformity assessment schemes. Incorporating IPS standards in the requirements is an incentive to spread adoption, not only in formal certification schemes coming from authorities (e.g. the Spanish or NHS cases), but also to different enforcement degrees and extents in curation or review schemes offered by independent platforms or organizations (such as ORCHA for instance).

The words “market-driven” as well as “customer-centric” imply an in-depth understanding of market trends and target customers. The development of market-driven products should be endorsed by a company that believes and invests in such market research.

In the specific case of the IPS standards for mHealth apps, this implies the commercial advantage for developers (either small companies and start-ups or mainstream providers), i.e. the benefit they would gain from changing the current mindset oriented to just launch the app in the market and “operate” to a more forward-looking vision oriented towards “share” and “integrate”. The second approach would allow reuse of information and remove the current silo effect that is currently the main issue in mhealth apps.

In this case it is also relevant to mention what benefits IPS adoption would bring to patients – citizens: why should they want IPS integrated into the app they use?

The second model referred to above is based on a government-driven approach, which means health authorities would enforce the adoption of standards. Enforcement is the process of ensuring compliance with laws, regulations, rules, standards, or social norms. By enforcing laws and regulations, governments attempt to effect successful implementation of policies.

Regulatory compliance describes the goal that organizations aspire to achieve in their efforts to ensure that they are aware of and take steps to comply with relevant laws, policies, and regulations. Due to the increasing number of regulations and need for operational transparency, organizations are increasingly adopting the use of consolidated and harmonized sets of compliance controls. This approach is used to ensure that all necessary governance requirements can be met without the unnecessary duplication of effort and activity from resources.

In the specific case of IPS standards for mHealth apps, health authorities may claim the advantages in terms of efficiency gains/cost reductions for governments, adoption of new reimbursement models based on data efficiency and proof of efficiency for public health expenditures, as it is specifically described in some of the use cases presented below in this section.

In the same situation of a government-drive approach, it is relevant to consider also the changing role of insurance companies and their increasing interest in data to better assess risks, thus trying to figure out what could be the advantage for them to incorporate IPS in their own apps. This can be better understood, for example, in the Hancock use case described in the next-but-one page.

The following paragraphs will be illustrative of practical adoption models that could be used to enhance IPS standards in mHealth apps across Europe.

The first two cases presented – Big corporates (e.g. Apple) and Hancock - are market-driven initiatives; in the first one, IPS is used as a competitive factor to present Apple as a market-leader on mHealth, targeted to a holistic B2C, B2B and B2G strategy.

As for the second business case, a company searches a way to provide the customers with a competitive advantage on prices as a reward system for healthier behaviours. This strategy is based on a digital platform that registers patient data, which could be replicated in order to enhance the broad adoption of IPS standards.

The following two examples are government-driven, being the first - NHS – a case of mandatory compliance with established guidelines applicable to all staff and services of the NHS in agreements and contracts with third parties. It may be mainly understood as a legal requirement to provide services or sell products to the Health authorities.

The second example – Andalusia - is also government-driven but not based on a mandatory approach. It is much more oriented to engage different stakeholders and promote guidelines

and standards through a positive and participatory recognition, that may be an appealing strategy for mHealth app developers and that is also well perceived by citizens that will, in this sense, pressure mHealth developers and suppliers to comply to recognised standards and best practices.

BUSINESS CASE 1 - Market-driven: Big corporations “business move” on PS interfaces for mHealth apps

Big Tech corporates have been disrupting healthcare with examples such as Alexa, from Amazon or Fitbit from Google. In January 2018, Apple introduced a significant update to the Health app with the iOS 11.3 beta, debuting a feature for customers to see their medical records right on their iPhone. The updated Health Records section within the Health app aims to bring together hospitals, clinics and the existing Health app to make it easy for consumers to see their available medical data from multiple providers.

Previously, the patients’ medical records were held in multiple locations, requiring patients to log into each care provider’s website and piece together the information manually. Apple worked with the healthcare community to take a consumer-friendly approach, accessing the provider’s Health Records based on HL7 FHIR (Fast Healthcare Interoperability Resources), a standard for exchanging detailed parts of electronic medical records. HL7 FHIR would serve as the point of reference for contracts, privacy impact analysis and cybersecurity risk analysis. Apple released a press note stating:” Now, consumers will have medical information from various institutions organized into one view covering allergies, conditions, immunizations, lab results, medications, procedures and vitals, and will receive notifications when their data is updated”.

The marketing messages enhance that Apple is putting the patient at the center of their care by enabling them to direct and control management of their own health records. Apple took the lead in bringing several healthcare providers to agree on using their app by enabling access for consumers to their medical information on their iPhones. Apple gained advantage to help scale adoption because they have both a secure and trusted platform and have adopted the latest industry open standards at a time when the industry is well positioned to respond.

In June 2018, Apple continued on the route to exploit this subject by delivering a Health Records API for developers and researchers to create an ecosystem of apps that use health record data to better manage medications, nutrition plans, diagnosed diseases and more. The Health Records feature allows patients of more than 500 hospitals and clinics to access medical information from various institutions organized into one view on their iPhone. For the first time, consumers will be able to share medical records from multiple hospitals with their favorite trusted apps, helping them improve their overall health. The US government supported

this movement mandating providers to provide Application Programming Interface (API) access to patient data.

Health Records data is encrypted on iPhones and protected with the consumer's iPhone passcode. When consumers choose to share their health record data with trusted apps, the data flows directly from HealthKit to the third-party app and is not sent to Apple's servers, that do not have access to encrypted data.

Despite these measures, it is fair to leave a note on the ethical concerns that must be still discussed regarding big corporations having massive access to health data and users awareness on the use given to it.

BUSINESS CASE 2 - Market-driven: Hancock insurance

All life insurance companies want their customers to live longer – it's basic economics. The longer a customer lives, the longer life insurance companies can invest customer premiums before delivering death benefits. But for too long, this industry wasn't truly investing in the very thing it is designed to protect: life.

Furthermore, as currently lifestyle diseases are the primary cause of death, just four behavioural choices — physical inactivity, an unhealthy diet, excessive alcohol and smoking — cause more than 60 percent of deaths and 80 percent of the disease burden in the United States, for instance.

These facts led to a fundamental question: "How can insurance companies do business in a way that also creates value for society, and to customers, by addressing their needs and challenges? And how can they use technology to help make healthy choices easier choices?". Vitality aims to be an engaging, tech-enabled wellness platform that rewards customers for the everyday things they do to live longer, healthier lives. Instead of asking, "Did you pass your cholesterol screening when you purchased life insurance several years ago?" the platform will enable the company to understand if customers were walking 10,000 steps, meditating more, and managing to sleep eight hours a night — and reduce their premiums as a reward for healthier behaviours. Just like car insurers can offer a safe-driving discount, Hancock began understanding the power of rewarding healthy living.

This is an example of life insurance making positive, quantifiable contributions to addressing public health concerns. This will improve lives and business, but also serves a greater good, providing lessons that can be shared with relevant government and NGOs to improve customer choices and advance public policy, further enriching the shared value cycle.

When a life insurance policy holder dies, the company pays a lump sum to the living spouse or children. So life insurance companies want to keep their costumers alive as long as possible so that they keep paying monthly premiums.

BUSINESS CASE 3 - Government-driven: NHS certification criteria for third party apps

NHS Digital and NHS England are enhancing the Apps Library to make it the go-to place for patients to access safe and effective digital tools. The Apps Library currently contains just over 80 health & care apps to help patients manage a variety of conditions such as diabetes, mental health and COPD with the latest one to be added promoting mindfulness to support improved mental health.

It intends to help patients navigate the many digital healthcare tools available, providing trusted digital tools for patients and citizens to manage and improve their health and well-being. The objective of this UK strategy is to set national standards and help patients and citizens better manage their health, since they can be confident that the apps they are using are safe and trusted. This is also seen as an opportunity for many developers to put forward their apps for assessment. Developers can submit their applications and then be assessed to see if they meet published criteria, to ensure apps meet NHS technical, clinical and safety standards, and help connect people to the information and services they need easily and effectively.

The National Institute for Health and Care Excellence (NICE) has worked with partner organisations to develop a set of evidence standards for digital health technologies, including apps. They are designed to ensure new technologies are clinically effective and offer value for money to the healthcare system. The NHS also intends to incorporate these standards into future versions of the Digital Assessment Questions (DAQ) .

BUSINESS CASE 4 - Government-driven: Andalusian and Catalan labelling models

'Safety and Quality strategy in Mobile Healthcare Apps' is a project created in 2012 within the Andalusian Agency for Healthcare Quality (ACSA). The aim was to ensure that processes and developments resulting from mobile health enable the enhancement of services offered to the citizens. It is a dynamic and integrated process which holds suggestions and advice for general citizenship and a list of recommendations is recognised with the granting of the AppSaludable Quality Seal.

The process is mainly based on the self-assessment of the app in accordance with recommendations included in the guide, and the assessment carried out by a committee of Agency's experts in order to identify possible improvements. Once the seal is awarded, the app becomes part of a list of mobile health apps of exceptional safety and quality.

Safety and Quality Strategy in Mobile Health Apps also provides users with a resource to improve quality and reliability guarantees in the use of mobile health apps. The Mobile Health Apps Catalogue shows those apps with remarkable quality, safety and reliability, including those granted with the AppSaludable Quality Seal, those in the assessment process or those that have applied for this acknowledgment.

Also, the apps granted with the AppSaludable Quality Seal are linked to an information sheet which includes remarkable aspects and improvements which have been identified after the assessment process.

After accreditation, professionals can recommend the use of certified apps to patients. When downloading an app the patient is asked to accept a legal disclaimer specifically integrated in the app to agree to share their data with the Catalan Health Department. The health professional will then be able to access the data generated by the patient and to integrate it into the patient's medical record, using an innovative Digital Health Platform.

DISCUSSION

As recognized by the WHO, the spread of digital technologies and global interconnectedness has significant potential to accelerate Member States' progress towards achieving universal health coverage, including ensuring access to quality health services. Increasing the capacity of Member States to implement digital health, and in particular mHealth, could play a major role in realizing that potential, particularly by increasing the safety and quality of care.

The concept of making international patient summary (IPS) data available through mobile technologies will increase the safety and quality of care by providing secure access to the information needed by the attending physicians at the time of care. This is particularly important in the event of disasters, emergencies and other unplanned care. Mobile technologies allow individuals to have access to their own summary health records and give physicians timely access to these records, which is particularly important when patients seek care outside of their normal care settings.

To this purpose, it is crucial to build a business case for mHealth app developers to adopt IPS standards.

The commercial and competitive advantages as well as the relevant adoption models and a set of practical business cases have been presented and argued in the present document with the aim to support such business case and foster widespread adoption.

In business case 1, IPS standards are being used as a competitive advantage against competitors on a B2C approach, since they may differentiate the Apple's product making it more reliable to the consumer. The integration of this advantage with the creation of an ecosystem where several healthcare providers willing to join a B2B or B2G approach towards a quite strong strategy pursued by this brand. This business case needs to address though several patient privacy issues and may not be the best fit for the highly regulated EU market. Such market driven approaches can nevertheless increase maturity and adoption in similar cases based on reusing well established brands and services.

As for the second case presented, insurance companies can offer a similar incentive to customers that use mHealth apps that comply with IPS standards or if they adopt them directly and then reward costumers that use them, they are creating market-driven adoption models that allow broad adoption of these standards, as they would be relevant for the customer to differentiate the product.

The two last initiatives presented offer similar advantages, namely enhanced connectivity and higher efficiency. They will specifically improve interconnectivity between apps and (1) other apps; (2) GP systems of choice and (3) secondary care systems (e.g. Cerner etc.), enabling the NHS/Andalusia and Catalonia governments to save resources and diminishing costs, since they can (1) promote self-care (2) reduce duplication of data collection and (3) improve clinical efficiency. The last two use case have the advantage to provide an incentive to early adopter to join, promote and invest in mhealth ecosystems that would be beneficial for all stakeholders. As such patient may have the opportunity of free selection of validated and compatible IPS applications from a variety of competitive products, while public health authorities can expand their public health infrastructures with rapid deployment patterns supported by the market under a regulated circle of trust.

Moving forward it is also important to consider scaling up comprehensive educational initiatives on the IPS and some time of startup kit that would make IPS implementation the easy road to interoperability and acceptance. In essence, offering interoperability standards as infrastructure to innovation.

Both IPS and HL7 FHIR are enablers for the future to come scenarios in healthcare concerning patient empowerment, prevention and monitoring of chronic conditions and comorbidities, secondary use of patient driven data for research and public health.

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