

G-Lens: Using HL7 FHIR International Patient Summary to Highlight Key Information in Medication Leaflets

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Abstract

Medication therapy adherence remains an important problem in health care, and information about medicines from electronic product information is large and untapped resource. The Gravitate-Health project is a large European Union Public Private Partnership that aims to elicit value for electronic product information, starting with information in a patients International Patient Summary.

Keywords:

Interoperability Standards, International Patient Summary, ePI, electronic Product Information, medication leaflets

Introduction

Empirical studies of health information flows in health care and specifically for information about a person's medication the chains of information and accompanying activity is broken, largely due to lack of interoperability. Medication information is fragmented, unavailable or not used, introducing risks of which the user may be unaware, including risk of errors [1], adverse events, disability, and even death [2]. WHO reports that more than 50% of all medicines are prescribed, dispensed, or sold inappropriately worldwide [3], and OECD estimates that around 200,000 premature deaths annually in Europe relate to poor medication adherence [4]. There should be opportunities for considerable improvements if citizens are equipped with access to actionable, understandable, relevant, reliable and evidence-based health information that meets their specific needs, capabilities, health context, and literacy level.

The primary source of medicinal product information intended for patients, the Patient Information Leaflet (PIL), is the paper-based product leaflet that comes to the user with the medicinal product as “paper in the pack”. This means that important health information comes as a “one size” fits all, and for purposes of providing comprehensive and detailed information every time, with little attention to previous experiences, languages, understanding and goals. Furthermore, production, maintenance and dissemination of such information is time-consuming and costly. Furthermore, the information should come in the language where medication is dispensed, and sometime the information may not be up to date by the time a medicine is dispensed. Electronic formats and dissemination for medicinal product information, the so-called electronic Product Information (ePI), have been recognized to offer important public

health benefits. ePI will be the authorized, statutory product information for medicines in Europe, going forward in a semi-structured format that combines the Summary of Product Characteristics (SmPC), PIL and labeling, and using FHIR resources to create the new electronic standard, adapted for dissemination via various e-platforms and print. Key principles for the ePI have recently been defined by the European Medicines Agency [5]. These principles give direction for how ePI will be developed to benefit public health, and create efficiency gains for regulatory systems, aligning with the existing legislative framework and complementing the paper package leaflet. Furthermore, the ePI should be fitting the EU's multilingual environment, and interacting with other ongoing digital initiatives at EU and global level. In addition to the formal definition of ePI there is a proposal for evolution of a common electronic standard to ensure digital availability of regulator-approved medicinal product information is a trusted authorized source fundamental to support the digital transformation of healthcare across the EU that is currently validated by EMA. Gravitate-Health looks into this common standard that is based on HL7 FHIR® and explores how it can benefit from the personal focus provide by the HL7 FHIR® International Patient Summary (IPS).

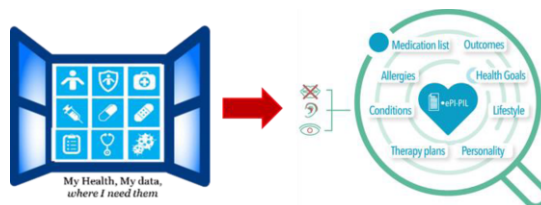


Figure 1: HL7 FHIR® IPS helps focus the medication leaflet to what is important for the patient given conditions, allergies, therapy plans, but also health goals, lifestyle and personality.

Methods

Digital ePI platforms can address interoperability with e-prescription, e-dispensation and EHR systems to meet needs for accessible, up-to-date information on medicines available for the citizen at the right time. IPS contains curated and selected information about personal health and follows regulatory requirements and ensures trust by balancing the legal and practical demands for privacy, integrity and availability of high-quality

ity information [6] (see Figure 1). The HL7 FHIR® IPS [7] information includes medication, allergies, conditions, procedures, therapy plans (see Figure 2). Gravitate-Health will develop a federated open-source platform to deliver the G-lens with a set of rules that will allow to highlight important information in the medication leaflet.

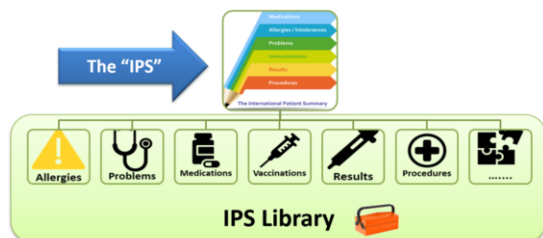


Figure 2: Components of the HL7 FHIR IPS

Patient profile reflecting on their capabilities will help further tailor the presentation of the medication information. Appropriate questionnaires will allow to assess the level of understanding of the information provided. Thus, the patient profile is combined with the IPS information, and a set of rules, to present focused ePI information. Project activities will proceed in multiple phases across 8 countries. The first phase will address content translation and presentation. The second phase will take into account the IPS information. In the next, third phase, information from multiple medications, part of the patient therapy will be combined to deliver a single ePI. Working along these phases, and integrating with the online services of the health system, such as ePrescription/eDispensation, eConsultation, and Patient reported outcomes, Gravitate-Health aims to prove that technology can help improve the resilience of health systems, minimizing risks, while putting the patient at the center of their health care, and wellness.

Results

Combining elements from the ePI and IPS is expected to lead to novel resources for patients, their support network and the health professionals' constituencies involved in medication management (prescribing, dispensing and administrating), and come with significant public health benefits. Amongst the benefits foreseen are speed of update, ability to better provide content to meet the needs of the individual and to link with other health information systems, e.g., Electronic Health Records and the International Patient Summary (IPS).

Conclusions

Gravitate-Health aims to tackle the problem of medical adherence, hypothesizing that if people are respected for their choices and preferences and provided with focused information that is relevant to them, they can be an equal partner in their healthcare pathway. The Gravitate-Health approach will be tested in 8 countries across Europe and United States. Further exploratory actions are planned for Africa, Australia, South America and Europe.

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