Abstract

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Establishing multi-lingual, multi-modal pharmacogenomic decision support across seven European countries

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The Ubiquitous Pharmacogenomics (U-PGx) project is an international, multidisciplinary effort aiming to implement pharmacogenomics-guided drug dosing across seven European countries. Over the course of three years 8,100 patients are pre-emptively genotyped for a panel of 48 clinically relevant pharmacogenomic markers across 13 important pharmacogenes, and test results are used to guide pharmacotherapy.

The international, multi-centered setting of the U-PGx project poses several special and unique challenges for the conception and realisation of such a large-scale multi-lingual pharmacogenomic decision support intervention; above all the need to implement a standardized intervention in the presence of substantial differences in existing health IT infrastructures and technical capabilities. Technical infrastructures between participating countries range from complete absence of IT infrastructure to full-fledged integration of decision support alerts in the electronic health record.

To bridge these immense gaps, we developed a unique multi-modal approach for delivering pharmacogenomics decision support that offers a standardized intervention while being flexible enough to be integrated into existing infrastructures and workflows. At the heart of the U-PGx decision support infrastructure lies the U-PGx Genetic Information Management System (GIMS) developed by the German company and U-PGx partner bio.logis Genetic Information Management GmbH. U-PGx GIMS incorporates a centralized knowledge base that contains the mappings between raw genotyping results, phenotype designations and pharmacogenomics-based therapeutic recommendations including translations to the local languages of all participating countries. This knowledge base is built around a subset of the Dutch national drug database G-Standaard, which contains up-to-date and actionable pharmacogenomics therapeutic recommendations for 41 drugs authored by the U-PGx partner Dutch Pharmacogenetics Working Group.

The systems provides a central and secure pipeline for uploading genetic samples and the retrieval of pharmacogenomic test results and individualized recommendations in the local languages of the seven participating countries in one or more of the following optional formats: (1) Semi-structured data for incorporation into local electronic health records, (2) a digital

pharmacogenomic report in PDF or ODT format that can be filed in the patients' digital or paper-based health records, (3) a 'safety-code' card that is part of a mobile-based clinical decision support system and allows for the retrieval of patient-specific pharmacogenomic dosing recommendations via a smartphone or tablet.

As of June 2017, all clinical decision support tools have been finalized and rolled out. The adoption and usability of the different clinical decision support tools deployed in the U-PGx project will be continuously evaluated; results will be used for constant improvement of the tools during the study period. The multi-modal pharmacogenomics decision support concept of U-PGx demonstrates how the challenge of fragmented healthcare infrastructures can be tackled to advance the implementation of pharmacogenomics into clinical practice in Europe.

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