Design of a clinical decision support system powered by mhealth for the management of Parkinson's disease

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***Abstract*—In this work we present the design of an EHR-agnostic, clinical decision support system (CDSS) enabling personalized medicine in the management of Parkinson's disease (PD) that complements symptomatic treatment by adopting passive (with IoT devices) and active (with mobile apps) patient monitoring and evaluation. The design is largely based on the current literature on CDSS, the findings of recent studies evaluating mhealth for PD and the analysis of user needs that well-defined shared decision making, flexibility addressing variations among clinicians and integration of data and information from various sources as the main design principles. The CDSS functional and dashboard requirements are presented as well as the overview of the platform components.**

Keywords—Parkinson's disease, clinical decision support system, mhealth

I. INTRODUCTION

Parkinson's disease (PD) is a progressive, neurodegenerative condition which affected more than 6 million people in 2016 with this number expected to double by 2040 [1]. The management of Parkinson's disease is largely symptomatic and relies, apart from the clinical examination to the reporting of symptoms by the patients and their relatives during the visits which take place every 3 to 6 months in most European healthcare systems. Thus, the ability to continuously report symptoms and assess the response to medication is of paramount importance for a personalized and optimized treatment.

Fortunately, it is anticipated that within a few years, most PD patients will use patient portals and interoperable and substitutable mhealth technology that can interact with their Electronic Health Records (EHR) [2] in order to update the information about their symptoms in daily basis thus enabling individualized treatment approaches. Such digital means are already considered efficient for patient empowerment, since they promote health literacy and activate patients manage their condition leading to an improved quality of life.

Clinical decision support systems (CDSS) [3] on the other hand are tools developed for clinicians. CDSS are intended to improve healthcare delivery by enhancing medical decisions with targeted clinical knowledge (deriving from clinical practice Guidelines, as well as machine learning for instance for identifying similar cases from the EHR repository), patient information (monitoring and evaluation of motor symptoms, self-reporting of non-motor symptoms), and any other relevant health information (e.g. medication, adherence to treatment plans etc.).

Herewith, we present the process for the design of the powered by mhealth, CDSS PRIME. The primary objective of PRIME is to provide a personalized medicine approach for the management of Parkinson's disease that complements symptomatic treatment by adopting a holistic strategy which takes into account genes, clinical subtypes, neuroimaging, lifestyle, co-morbidities etc. The secondary goal is to use mhealth, mainly a patient portal implemented as a mobile app and Internet of Things (IoT) devices to improve the knowledge about the individual course of the disease and the response to treatment so as to support tailored self-management approaches.

II. METHODS

In order to identify the basic requirements for the patient tools, firstly a narrative review of mhealth systems for Parkinson's management was conducted. The review also confirmed the feasibility of the concept and the acceptability to patients as well as the clinical usage of such systems. Two experts searched articles in PubMed with queries using quotes such as mhealth, Parkinson, treatment etc. and the abstracts of more than 300 articles were screened. 15 articles qualified for full text assessment and the 8 most relevant to PRIME articles are included in this work. CDSS were also reviewed to inform the required functionality for clinicians with a similar approach during which more than 100 articles were screened with only one being qualified as most relevant to PRIME since the others concerned decision support for specific symptoms and not a system. Then the findings were analyzed by a Movement Disorders Expert and two experienced software engineers and a consensus on the core requirements of the PRIME CDSS functionality and dashboard was reached. Finally, the information flow was defined, and the main components were designed.

III. RESULTS

A. Review of mhealth systems for Parkinson's

In PD_manager [4] a smartphone, a smartwatch and a pair of smart insoles constituted the mhealth system used to collect clinically meaningful data (on tremor and dyskinesias) in a sample of 75 patients using the system for 14 days. In the REMPARK study [5, 6], 41 patients used a system consisting of a sensor and a smartphone for 3 days and completed a diary of their motor state once every hour which demonstrated excellent sensitivity (97%) and specificity (88%) in detecting fluctuations. mPower [6] which was an observational, smartphone-based study developed using Apple's ResearchKit library, aimed at a 6-months data collection period, but the findings clearly indicate that the 150 participants were adherent for up to 2 weeks with minimal data contribution afterwards. In the CIS-PD study [7] 51 patients were monitored for 6 months with a smartwatch and a mobile app with the findings being controversial as individual patients tended to have either high or low

compliance across all compliance metrics. The Parkinson@home study [8] showed that it is feasible to collect objective data using a smartphone and a smartwatch during daily life in a large cohort of 953 patients. Fischer et al. [9] based on the analysis of the data collected from 34 study participants who wore bilateral wrist-worn sensors for 4 h in a research facility and then for 1 week at home, further confirmed that long-term monitoring with wrist-worn sensors is acceptable to PD patients. In the study of Heijmans et al [10], during a period of two consecutive weeks, 20 participants were instructed to wear three wearable sensors and to complete questionnaires at seven semi-random moments per day on their smartphone. Results indicated that the patients wore the wearable sensors over 94% of the instructed timeframe and an initial analysis showed that the gathered sensor data could consistently predict OFF periods. In the most relevant to PRIME study, Heldman et al. [11] assessed the impact of motion sensor-based telehealth diagnostics on PD clinical care and management with 18 patients with PD who were instructed to use a finger-worn motion sensor and tablet-based software interface at home one day per week for seven months. Home-based assessments were completed with a median compliance of 95.7%. Importantly, for a subset of participants, the neurologist successfully used information in the reports, such as quantified responses to treatment or progression over time, to make therapy adjustments. In this study the patient management aided by telehealth diagnostics provided comparable outcomes to standard care.

B. Defining the PRIME CDSS Functionality

PD_manager [12], to the best of our knowledge, is the only holistic mHealth CDSS for PD as the other systems target specific symptoms. The design of PD_manager [13] was a result of a suite of user needs studies that was conducted in 4 European countries (Greece, Italy, Slovenia, the UK) and constitutes the main source of requirements and design also for PRIME. In fact, the resulting treatment DSS [14], apart from indicating that the experts-based models are applicable for making "second-opinion" suggestions to clinicians, provided important lessons for the design of PRIME. The required functionality of any CDSS as comprehensively presented by Sutton et al., complemented the other methods adopted for the definition of the PRIME CDSS the main functionality of which is included in Table I.

C. PRIME CDSS Dashboard Requirements

After defining the main functionality, we have also analyzed and reported the dashboard requirements which are included in Table II and are expected to be further adapted and enriched during the development process and after iterations with clinicians. Empowerment of shared decision making, addressing the varying needs and approaches of clinicians and integration of heterogeneous information are the main design principles.

D. PRIME platform overview.

As depicted in Fig. 1, the platform consists of an IoT API that fetches data from different mhealth medical and experimental devices for the evaluation of motor symptoms. The collected data are temporarily stored in the mobile app along with patient reported data. The aggregated information is permanently stored in the backend and are available in the EHR. The CDSS component provides the described in Table I functionality which is available for the clinicians in their dashboard (see Table II).

TABLE I. PRIME CDSS FUNCTIONAL REQUIREMENTS.

Functions of CDSS	**How they are addressed in PRIME**
Patient decision support	PRIME will integrate certified devices (smartphones, insoles, IMUs, smartwatches) that are passively monitoring patients' symptoms and practically the patients will only need to activate them and then only charge them. PROs ranging from Activities of Daily Life (ADL) to adherence to medication, will be asked with notifications in the mobile app that the patients will access with one-click and will then have drop down menus so that it is clear what kind of data are expected. Moreover, PRIME will enable shared decision making with visualizations that the patients and caregivers can understand that will be used during visits.
Patient Safety	Possible drug interactions, especially in patients with comorbidities, will be explored on the valid and up to date DrugBank (www.drugbank.ca) which is a unique resource of bioinformatics and cheminformatics that combines detailed data on drugs and their interactions. Possible drug-gene interactions will be checked with databases such as DGIdb (www.dgidb.org) and drug-protein interactions with STITCH (bio.tools/stitch). These mechanisms will also work offline and will be updated regularly.
Clinical management	It will be implemented with Guidelines and ontologies. The ontology of Parkinson's disease PDON, represents the terminology for Parkinson's disease in a standard, compact, computer-readable format that can be further processed, be enriched and also used for the construction, representation and automatic expansion of the PRIME CDSS. The medical knowledge will be derived primarily from the Guidelines of the International Parkinson and Movement Disorder Society (MDS) [15, 16], as well as from NICE Guidelines.
Interoperability	PRIME will establish repeatable conventions with a FHIR API (see the specification in www.hl7.org/fhir), to pass data and context/situational info from the EHR to the CDSS and to accept recommendations from the CDS back to the EHR in the appropriate context. Additionally, historical data, imaging, previous diagnoses, treatments, etc. will be available from the connection with any FHIR compliant EHR and the integration with DICOM compliant RIS and PACS.
Diagnostics support	PRIME will develop a standard set of each of the core CDSS operational elements such as EHR trigger points, action items, and supporting data, leveraging existing work and existing Health Level Seven international standards (HL7), so that CDSS can be developed with confidence that these elements will be present in each EHR environment. Moreover, similar cases extracted with machine learning methods from the EHR repository will indicate possible diagnosis and prognosis based on patients' baseline (or current) characteristics.
Administrative function/	The adopted EHR on top of which the CDSS will be implemented will be integrated with the e-Prescription system. Moreover, the EHR suite provides administrative support and integration with public insurance, it uses ICD10 coding etc.

automation	Availability of the FHIR API ensures expandability.
Workflow improvement	Rigorous and iterative usability evaluations and pilot testing will be conducted on CDSS before using them in clinical settings since the integration in the current workflow is a must for the adoption of PRIME. The CDSS distribution should be anchored in the basic principles of being actionable/reportable, integrated into the workflow, interoperable, and available as a web service.

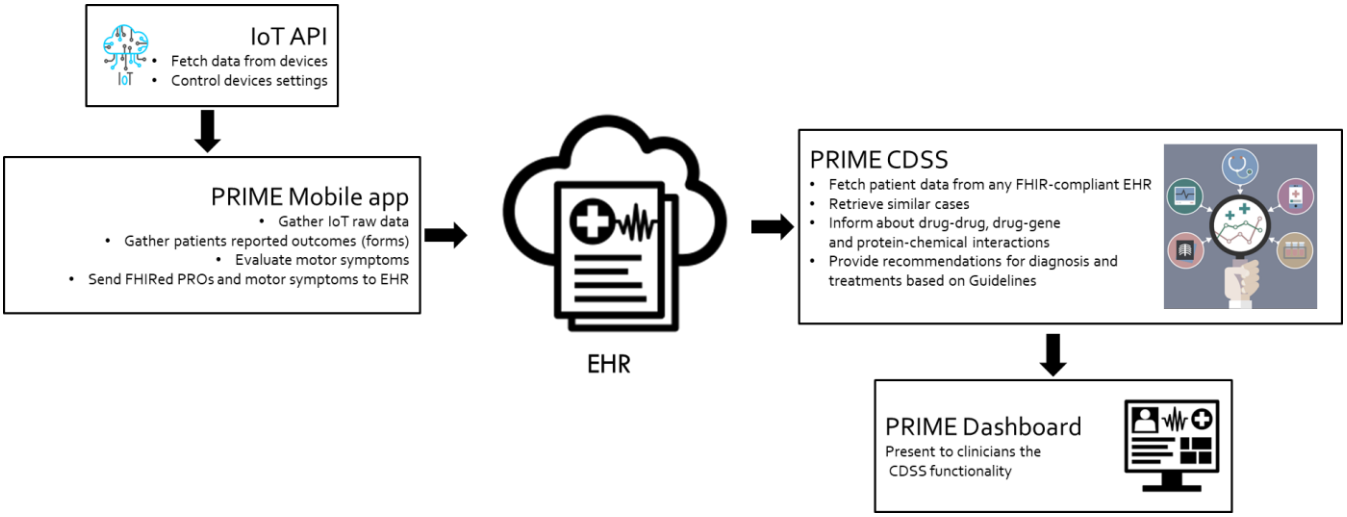

Fig. 1. PRIME platform main components.

IV. Discussion

The key findings from relevant mhealth projects and studies that inform the design of the tools for the patients and the design of the subsequent clinical study for the evaluation can be summarized as follows:

- Ecologically valid, accurate and objective monitoring and evaluation of motor symptoms with both experimental and certified devices consisting of smartphones and wristbands is feasible. In PRIME medical devices (PDMonitor® manufactured by PD Neurotechnology) will be adopted for the monitoring and evaluation of motor symptoms during a prospective clinical study. Insoles (manufactured by Moticon) and IMUs will also be integrated in order to perform specific tests for gait and tremor respectively. PRIME will also address non-motor symptoms evaluation with a patient portal developed for that purpose.
- mHealth for the monitoring of PD patients' symptoms is feasible, at least for a period of 2 weeks since after that timeframe a decrease in compliance is noted in most studies. The design of PRIME will be in this direction since patients will be asked to wear the devices for 5-7 days monthly for the period that will be needed in each case.
- Future clinical studies, such as the one to be conducted in PRIME, should confirm its efficiency to support clinical decisions and improve patients' management; this is the most important step for wide adaptation by clinicians and for mid-term integration of mhealth and CDSS in the daily clinical practice.

TABLE II. Dashboard requirements.

Nr.	The dashboard shall:
UR1	Offer discrete and standardized neurologic examination documentation options
UR2	Enable tracking of changes to neurologic examination findings or severity (summary)
UR3	Automatically integrate patient portals and import patient reported outcomes (PROs)
UR4	Incorporate PD specific clinical data (neuroradiology, neurophysiology)
UR5	Present to the clinicians similar patients cases to the one being assessed
UR6	Provide clinicians with suggestions based on Guidelines (MDS, NICE) to guide their diagnosis, visualizing relevant historical data, e.g. from motor fluctuations.
UR7	Present motor and non-motor symptom outputs in a quick and easy to understand, preferably graphical format.
UR8	Enable clinicians to easily identify/compare changes in symptoms overtime and drill down into different time periods depending on the needs of the patient, i.e. calendar
UR9	Enable to establish the co-occurrence of, and comparison of, motor with non-motor symptoms, along with medication adherence in a single view

UR10	Provide flexibility for the clinician to choose, in conjunction with the patient which symptoms, comorbidities and data collection options/time periods are of most interest for a particular patient and be able to explore these in the context of a personalized integrated data output.
UR11	Provide clinicians with tables summarizing medication options for treating different motor and non-motor symptoms based on MDS Guidelines to guide their medication decisions
UR12	Include drug-drug interactions, drug -gene interactions, drug protein interactions (whenever data on genetics is available) to support prescribing
UR13	Provide the clinician and patient/caregiver with data on patient's adherence to pharmacological and supporting therapy care plans over time.
UR14	Present to the clinician the up-to-date list of the prescribed pharmacological care plan (e.g. drug name, format, dosage etc.) and supporting therapies (e.g. physiotherapy)
UR15	Enable the clinician to monitor the effectiveness of the step-by-step changes made to pharmacological care plans both at and between face-to-face consultations (i.e. remotely) to establish if the change has resulted in a positive/negative outcome.
UR16	Enable the clinician and patient/caregivers access data on patient's activity and (optionally) sleep levels/duration in their home environment.
UR17	Provide the clinician with data on patient's adherence/performance indicators when they have engaged with supporting therapies
UR18	Support data sharing between clinicians
UR19	Provide a communication platform to facilitate the sharing of information and alerts between clinicians participating in the care of a patient in the context of a multidisciplinary care team.

From the neurologist's perspective, PRIME is a traditional CDSS in the sense that it is comprised of interoperable, FHIR compliant, software designed to be a direct aid to clinical decision making. The characteristics of each patient derived from EHRs, mobile apps and wearable devices, and processed with machine learning methods, are matched to a computerized clinical knowledge base (derived from Clinical Guidelines). Integration with e-prescription systems incorporating drug interaction DBs further ensure the safety of the patient. Patient-specific recommendations are then presented to the clinician through a well-designed dashboard developed to support management decisions.

Since the components serving the required CDSS functions are already developed, future work includes the finalization of the interfaces, i.e. the patient portal and the clinicians' dashboard. Then, the main hypothesis, which is that mhealth and CDSS are feasible and acceptable to end users and can improve the management of Parkinson's, will be evaluated within a prospective proof of concept study.

V. Conclusions

PRIME is designed so as to be an evidenced-based CDSS capable of leveraging data and observations otherwise unobtainable or uninterpretable by clinicians (processing of patient reported and sensor data collected at the community setting with mhealth), supporting them optimize PD patients' treatment plans.

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