From Wellness to Medical Diagnostic apps: The Parkinson's Disease Case

S. Kueppers[21], I. Daskalopoulos[1], A. Jha[3], N.F. Fragopanagos[4], P. Kassavetis[36], E. Nomikou[5],, T. Saifee[3], J.C. Rothwell[3], K. Bhatia[3], M.U. Luchini[2], M. Iannone[4], T. Moussouri[53], and G. Roussos[1]

No Institute Given

Abstract. This paper presents the design and development of the CloudUPDRS app and supporting system developed as a Class I medical device to assess the severity of motor symptoms for Parkinson's Disease. We report on lessons learnt towards meeting fidelity and regulatory requirements; effective procedures employed to structure user context and ensure data quality; a robust service provision architecture; a dependable analytics toolkit; and provisions to meet mobility and social needs of people with Parkinson's.

1 Introduction

It is well understood that modern smartphones present unique opportunities for mobile healthcare. Indeed, there are numerous wellness and self-tracking apps readily available in all major mobile phone platform markets and many more have been developed to conduct research in various aspects of mobile telecare. Yet, the vast majority of these apps do not conform to the safety, quality, performance and regulatory requirements set for medical devices and as such they can only be employed either to encourage a healthy lifestyle or for research purposes correspondingly, but are not tools for medical diagnosis. This fact is often explicitly reflected in their terms and conditions of use for example, quoting from a popular Parkinson's Disease app, the developers state that "we cannot, and thus we do not, guarantee or promise that you will personally receive any direct benefits." In contrast to this situation, this paper presents the design and development of the CloudUPDRS app and its associated information management and analytics platform, which meets the standards set for medical devices. In particular, we describe how CloudUPDRS achieves the accurate, precise, and repeatable assessment of motor symptoms for people with Parkinson's (PwP), which clinicians can use with confidence. The app is currently undergoing examination by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK towards its full registration as a medical device.

The successful development and operational deployment of the CloudUPDRS app and its supporting service at the level required to achieve conformal performance to medical device regulations, thus establishing it as a valuable diagnostic tool for clinicians, demanded that we address several key problems. In

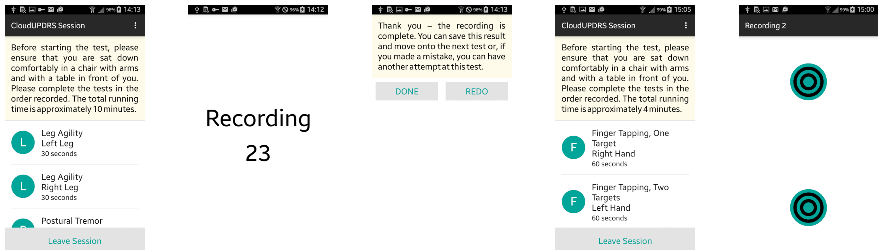

Fig. 1. Views of the user interface of the CloudUPDRS app showing session management, tremor recording and finger tapping activities..

this paper we present the key contributions of this work towards achieving this goal. Specifically, we describe:

– How to effectively combine a guided data collection procedure imposed by the app to provide structured user context, with a fully automated signal processing pipeline thus making possible the unsupervised but consistent interpretation of sensor data captured during the performance of motor assessment activities.
– The development of a data analytics toolkit for the assessment of tremor, bradykenesia and gait measurements following the MDS Unified Parkinson's Disease Rating Scale, the standard clinical tool for the diagnosis of PD.
– The development of an information management, data mining and dashboard service developed following the concept of microservices and the lambda architecture, incorporating stream and batch processing pathways to ensure scale out performance and responsiveness.

2 Background and Rationale

PD symptoms are typically caused by the loss of neurones that produce dopamine, a key chemical messenger in the brain, decreased levels of which lead to abnormal brain activity (cf. [1] for more details). Care for patients with PD involves the management of both motor and non-motor symptoms as well as palliative care.

Since symptoms vary greatly independent of treatment and PD progresses at different rates in different individuals, it requires regular clinical monitoring and medication adjustment. Monitoring and adjustment however require hospital visits and assessment under the standard Movement Disorders Society's Unified Parkinson's Disease Rating Scale (MDS-UPDRS) [2]. Due to these constraints, such reviews are relatively infrequent, carried out typically only a few times per year. This in turn limits opportunities to precisely quantify PD progression and the effectiveness of patient stratification [8]: the restricted availability of data concerning individual variability and actual symptom trends limit opportunities to adapt care to the needs of a particular individual at a specific time.

Indeed, it is possible to employ certain aspects of movement that are disrupted in Parkinson's as surrogate biomarkers of dopamine levels and in fact this is precisely the purpose of Part III of the MDS-UPDRS. Further pursuing this insight, in [3] we investigated the possibility to precisely quantify and implement the MDS-UPDRS methodology as a smartphone app to enable the assessment of motor performance through tremor, gait and bradykinesia measurements obtained from standard sensors embedded in smartphones within a clinical setting. By adopting this approach, we also intend to capture in-depth medical intelligence supporting the discovery of longitudinal trends, promoting deeper understanding of the patterns of normal daily symptom variations, and predicting the onset of dyskinesias thus facilitating high-precision personalised targeting of treatment.

3 The CloudUPDRS app

As discussed in the previous Section, in [3] we demonstrate the feasibility of using smartphones as a means to assess commonly occurring motor symptoms of PD in a clinical setting. Specifically, we designed, developed and validated in a field study a prototype app on Android implementing Part III of the MDS-UPDRS. Using the accelerometer and touch screen sensors commonly available in modern smartphones, we are able to carry out hand and leg tremor measurements, as well as gait and bradykinesia assessments using finger tapping tasks to replicate the majority of these tests. In [3] tests were administered by an experienced clinician in the lab using an HTC Desire device and the collected sensor data were extracted and processed using standard biomedical data analysis software. Participants were also tested in the same areas of motor performance using the standard lab procedure outlined in MDS-UPDRS and using bespoke biomedical data acquisition equipment to obtain a baseline for comparing the performance of the app.

In CloudUPDRS we employ the data collection and analysis techniques described in [3] to develop an app with extended functionality that enables its independent but dependable use by PwP and their carers at home and in their communities. The app implements a comprehensive workflow partially depicted in Figure 1, which provides audio, video and textual guidance on how to conduct the actions required by the tests and automatically adapts to match the specifications of its host device. The app is also provisioned with a delay tolerant background service to manage session data that ensures that information is safely submitted for further processing to a supporting online service also developed specifically to provide this function and described in more detail in Section 4 below.

Overall, the CloudUPDRS system consists of the following elements:

1. PD patient smartphone apps for Android and iOS that carry out motor performance measurements and wellness self-assessment; conduct session management; securely transfer captured data to the CloudUPDRS service; and, present an interface providing guidance and feedback.

2. Cloud-based scalable dat collection engine that safely and securely collects data from patients' smartphones; ensures secure data management; and applies the MDS-UPDRS processing pipeline.
3. Data-mining toolkit for medical intelligence incorporating quantitative and semi-structured data, and longitudinal analyses, clustering and classification; and a clinical user interface incorporating visualisation.

4 The CloudUPDRS Service Platform

The CloudUPDRS service platform enables the secure capture, management and analysis of data collected by the app and provides effective communication of insights generated to clinicians enabling them to explore alternative treatment scenarios. To cater for the diverse needs of the PwP population in the UK, the platform has been engineered to facilitate scalable performance by adopting the microservices architecture [9]. The microservices architectural style is set in contrast to traditional monolithic web applications and aims to maximise opportunities for vertical decomposition and scaling-out, which are critical for high performance and service resilience in data intensive situations.

In CloudUPDRS, microservices are loosely coupled and employ lightweight communication and coordination mechanisms such as the Consumer-Driven Contract pattern and implemented on Apache Thrift (cf. `https://thrift.apache.org/`) selected due to its highly efficient and compact protocol structure. System componentization follows the design displayed in Figure 2, enforced via versioning of published RESTful interfaces. CloudUPDRS microservices are deployed as docker containers (cf. `https://www.docker.com/`) although internal implementation details vary to match the specific preferences and expertise of project partners responsible for their implementation and their suitability for the task in hand. For example, while the data collection and signal processing APIs are implemented using python and django REST within an nginx/gunicorn container, semi-structured longitudinal analytics are implemented as Ruby bundles.

Finally, the service platform has been designed with the expectation that in order to meet performance metrics for its interactive features at full operation scale it will require the on the fly integration of archived information from its longitudinal datastore with real-time streams captured for example during concurrent patient consultations. To facilitate this modus operandi, we have structured workflows implemented through microservices following the lambda architecture [7], which provides an intuitive model for the fusion of both types of data on the fly.

5 Lessons Learnt and Conclusions

Bounded Context. The pervasive computing community has invested significant effort in techniques for modelling and adapting to user context, which is critical for the interpretation of sensor data streams. This role for context was

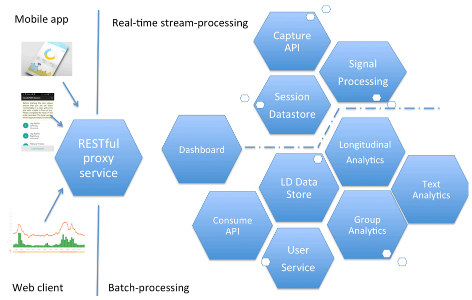

Fig. 2. CloudUPDRS microservices implementing the lambda architecture.

re-confirmed in our work and in the case of the Intel/Fox Foundation project discussed above. Yet, when context modelling is not possible or incurs prohibitively high costs, an effective alternative is to bound context by imposing structure and thus predictability to user actions during sensing, an approach that was successfully applied with the CloudUPDRS app. Guided user experiences can contain the degrees of freedom possible and as a consequence the computation of motor performance indicators becomes consistent and repeatable.

Choice of Analytics. Recent years have also witnessed the rapid growth of machine learning methods for sensed data as an active area of research. While there are clearly situations when the development of new algorithms and techniques is required, in other cases there seems to be good reason to opt for a more traditional approach. In CloudUPDRS we discovered that in full-scale operational systems predictability and consistency of algorithmic performance obtained through extensive experience with the tradeoffs related in tuning machine learning techniques, may be more valuable than higher but vacillating performance.

Data Quality. Data quality in pervasive computing has often been investigated by considering specific stages of the processing pipeline in isolation. In CloudUPDRS rather than optimise individual stages we engineer an end-to-end quality assurance strategy that we find to be more effective. It incorporates features of the user experience, which permit the user to initiate the repeat of tests when an external event has disrupted the session, to increasing the duration of individual tests so as to enable oversampling and cross-validation, to employing heuristics that allow us to quickly identify data quality problems in the captured signal. We find that it is the combination of these features rather than any single one alone that helps ensure a higher quality of data.

Certification. The higher standard of evidence demanded for the registration of an app as a conforming medical device has significant resource implications. Indeed, it is not surprising for development costs to be an order of magnitude higher than those of an equivalent research project. The need for formal quality assurance processes in particular adds considerable overheads. Consequently, it appears judicious to recognise commercial considerations from the earliest stages of the process.

Microservices architecture. Although our experience in this area is incomplete, claims in favour of architectures build around microservices appear justified, especially for sensor data streaming mobile systems with execution profiles similar to CloudUPDRS. Adoption of this approach has allowed greater flexibility during development, facilitated easy scaling-out of the service, and enabled the development team to gain operational experience and hence effectively evolve system features and performance.

In this paper we presented the design and development of the CloudUPDRS app which has achieved Class I medical device conformity and we presented key findings and techniques that helped us achieve this goal.

Acknowledgments

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