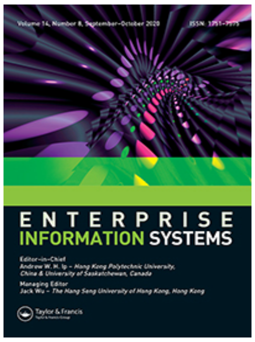

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Enterprise Information Systems

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/teis20

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To cite this article: Kostas M. Tsiouris , Dimitrios Gatsios , Vassilios Tsakanikas , Athanasios A. Pardalis , Ioannis Kouris , Thelma Androutsou , Marilena Tarousi , Natasa Vujnovic Sedlar , Iason Somarakis , Fariba Mostajeran , Nenad Filipovic , Harm op den Akker , Dimitrios D. Koutsouris & Dimitrios I. Fotiadis (2020) Designing interoperable telehealth platforms: bridging IoT devices with cloud infrastructures, Enterprise Information Systems, 14:8, 1194-1218, DOI: 10.1080/17517575.2020.1759146

To link to this article: https://doi.org/10.1080/17517575.2020.1759146

ENTERPRISE INFORMATION SYSTEMS
2020, VOL. 14, NO. 8, 1194–1218
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Designing interoperable telehealth platforms: bridging IoT devices with cloud infrastructures

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ABSTRACT

A platform offering web technologies and interoperable components is proposed, allowing integration of different technologies into a robust system. Key modules are provided in home, to support integration of IoT devices, and in the cloud, offering centralised services and storage. Communication between the two is performed using the open FIWARE-Orion protocol. Data are not tied to methods and resources, so the platform can handle multiple types of requests and data formats. The platform is deployed in HOLOBALANCE, a tele-rehabilitation system for balance disorders, providing surrogate holographic physiotherapists, real time evaluations of task performance and cloud-based data analytics for personalised coaching.

ARTICLE HISTORY

Received 14 February 2020
Accepted 19 April 2020

KEYWORDS

Interoperability models; component-oriented architecture; EIS for health care; component-based development; data integration

1. Introduction

Nowadays, healthcare provision is enhanced by telehealth platforms that aim to facilitate access to services and improve quality of care (Dinesen et al. 2016). Telehealth platforms are typically categorised as either provider-to-provider solutions or direct-to-consumer systems. The latter include virtual care and remote patient monitoring (Downes, Horigan, and Teixeira 2019), extending healthcare delivery to in-home environment via sensing technologies (Joshi et al. 2019). Despite their great potential, the transition of telehealth systems from proof of concept applications at research-level, into actual real-life healthcare solutions has been rather lacklustre. One of the main challenges hindering the wider adaption of telehealth is the lack of interoperability, which according to the Healthcare Information and Management Systems Society (HIMSS),[1] is defined as

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> the ability of different information systems, devices or applications to connect, in a coordinated manner, within and across organizational boundaries to access, exchange and cooperatively use data amongst stakeholders, with the goal of optimizing the health of individuals and populations.

Within the healthcare ecosystem, interoperability serves the goal of optimising treatment, rehabilitation and health management as a whole, by providing seamless access to comprehensive information that is necessary to understand and address the needs of both individuals and entire patient populations (Lamprinakos et al. 2015).

The lack of focus on interoperable platforms in healthcare can be partially attributed to the fact that the evidence about its efficacy is still limited and, thus, policymakers hesitate to allocate the necessary funds to enable existing platforms and systems to function in an interpretable fashion. Consequently, statutory restrictions exist on how insurance covers and pays for telehealth (Edmunds et al. 2017). Moreover, many providers are still unwilling to make their data and systems accessible to others, in an attempt to maintain full autonomy in scheduling, care coordination, referrals and data tracking, associating interoperability with loss of control and complications to their daily practices. Despite its slow realisation (Holmgren, Patel, and Adler-Milstein 2017), the concept of telehealth interoperability has been constantly gaining interest in the last decade, since it provides the framework for: (a) increased efficiency of care, with emphasis in the continuum of care, (b) decision support functionality, as treatment and rehabilitation data are accessible in real-time for streamlined operational decisions, (c) reduced costs for healthcare systems, primarily due to the digitisation of the entire healthcare workflow, and (d) precision medicine to allow for better patient outcomes using patient (meta)data that can be further analysed (Chan et al. 2010).

At system level, interoperability in telehealth platforms facilitates the integration and communication of different modules, and ensures that data are reusable and readily available to be shared without requiring additional effort by the end user. The value of interoperable health IT systems is being progressively recognised (Perlin 2016; Lancet 2018; Pronovost et al. 2018), as they are acknowledged as critical assets for digital innovations in healthcare (Lehne et al. 2019b). Following this notion, an interoperable by-design platform is presented in this study, targeting telehealth rehabilitation applications. The platform is developed using web technologies and interoperable components, to succeed integration of heterogeneous technologies into a robust system. The architecture is designed to be modular, efficient and interoperable, in order to support communication across different modules, connecting home-based IoT devices and cloud backend services.

Telehealth systems for in-home rehabilitation interventions have been previously evaluated with mixed results. Virtual reality (VR) systems have been commonly employed as a means to compensate for the need of repetitive task training (Thomas Lois et al. 2017). In a recent trial, VR-based rehabilitation of balance was compared to conventional balance exercises in adults with unilateral peripheral vestibular loss (Meldrum et al. 2015). Participants in the VR group performed their rehabilitation regime at home using a Wii Fit Plus and a rocker board that transforms the Wii Board into an unstable surface (Frii Board, Swiit Game Gear). The results revealed that VR-based balance exercises for vestibular rehabilitation were not superior compared to conventional exercise regimes for either short- or long-term interventions, but presented a more enjoyable and less difficult method of balance retraining. Another VR system for vestibular rehabilitation was evaluated with patients suffering from intractable Meniere's disease and chronic vestibular dysfunction (Hsu et al. 2017). The system enabled hierarchical and customised delivery of realistic environmental stimuli, adjusting the level of exercise dynamically to match each patient's balance improvement. Patients from the VR group, especially those in the early stages of Ménière's, showed significantly greater improvement in the centre of gravity sway and trajectory excursion in the mediolateral direction, while patients in the control group showed no significant improvement of their condition.

The proposed platform was used to deploy the HOLOBALANCE healthcare platform, which is a novel IT system for tele-rehabilitation of balance disorders, targeting vestibular rehabilitation therapy (VRT) at in-home environment (Kouris et al. 2018). The HOLOBALANCE system introduces augmented reality (AR), in the form of a holographic surrogate physiotherapist, since, as it was demonstrated in the studies above, VR devices can distress patients with dizziness. The holographic coaching system is complemented with IoT device-based monitoring to measure and evaluate the performance of the VRT exercises, and enable real-time interaction with the patients, through the virtual physiotherapist, aiming to actively engage them and increase their adherence (Gatsios et al. 2019). The rehabilitation regime of exercises is carefully planned for each patient during the initial assessment of the sensory function and dizziness to cover particular needs individually and maximise the expected outcome of the VRT. The architecture and the main components of the interoperable platform are described in Sections 2.1–2.3 and the HOLOBALANCE use case is presented in detail in Section 2.4. Preliminary results from patient–system interactions that were acquired from focus group evaluations are presented in Section 3. The key outcomes of the proposed interoperable telehealth rehabilitation platform and the HOLOBALANCE system are discussed in Section 4, followed by concluding remarks in Section 5.

2. Materials and methods

2.1. Platform architecture

The system architecture was designed following the guidelines from IEEE Standard 1471–2000 (IEEE 2000), with some necessary adaptations to design an evolutionary, interoperable platform. The architecture is part of the rehabilitation system, which aims to provide surrogate coaching with real-time performance evaluations with interoperable software and hardware components. The architectural description identifies the involved stakeholders (i.e. clinical experts, patients, data analysts), establishes current and expected user needs and provides the technological capabilities (i.e. IoT and user interaction devices) and functionality (i.e. cloud, edge computing), in order to meet the requirements and rationale of the platform. The main motivation for adopting the iterative architecture design of IEEE 1471 is that the architecture, the delivered systems and the stakeholders coevolve, and as a result, architectural descriptions and models have to be developed emphasising on flexibility and adaptability. Thus, all technologies used are platform agnostic and each system module is required to implement a predefined contract for data exchange, using a common communication protocol to ensure seamless connectivity between IoT devices and cloud infrastructures.

The architecture of the platform is presented in Figure 1. It consists of three primary components: (a) the edge computing unit, which is the central point in the user side that hosts all the necessary components to support the required functionality for the end user, (b) the cloud infrastructure, which provides access to web services, a centralised remote repository for data storage and advanced processing capabilities, and (c) an FIWARE-Orion enabled communication module that handles data flow between different hardware and software modules. In that sense, there are two primary nodes of the system, one placed near the user (in-home environment) and one on the cloud, which can interact through a FIWARE enabled network that acts as a communication bridge. The exact characteristics and scale of each component depend on the intended application and the required functionality on each side. The primary target of the proposed platform is to lift most restrictions in terms of system development, as it does not limit or lock the designer of any potential application to specific f hardware or software components. The goal is to simplify the hustle of integrating all the different components and ensure compatibility and data interactions, shifting this effort to the process of designing an innovative application and deploying smart use cases of available technologies to the end user.

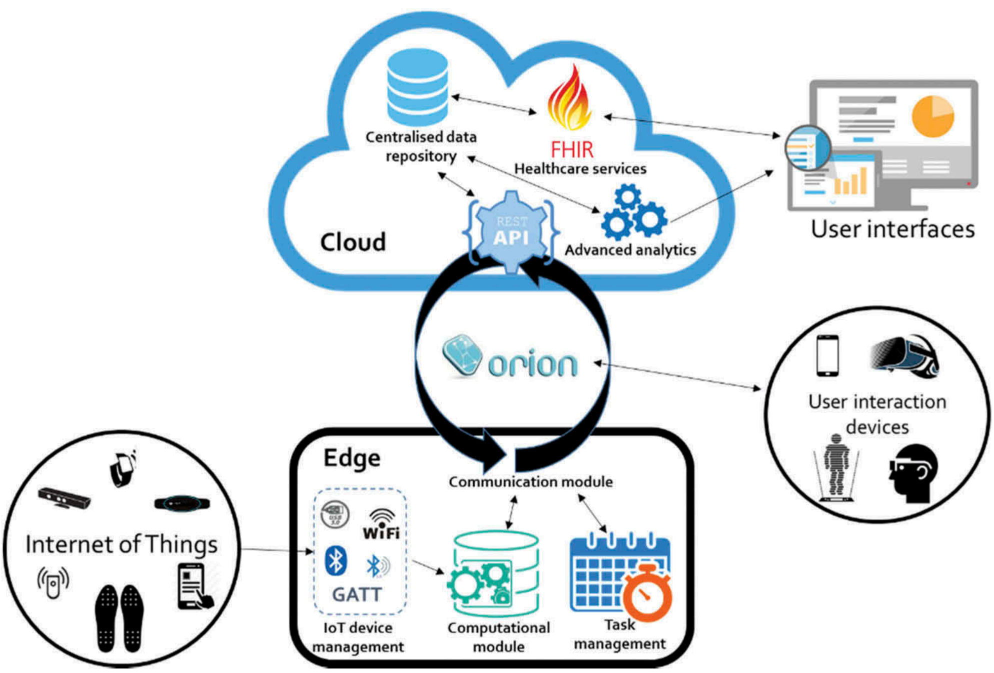


Figure 1. The architecture of the proposed interoperable platform, including the primary components and the main interactions between them.

2.2. FIWARE–Orion communication module

This is the primary component of the platform that provides the communication channels to facilitate the integration of every subsequent module in a coherent way. For this reason, a communication scheme for increasing and enhancing the interoperability of the system with other solutions has been designed and developed. The proposed scheme involves Orion,[2] one of the General Enablers of the FIWARE ecosystem,[3] which is the outcome of an open-source initiative to define a universal set of standards for context data management, enabling cross-platform compatibility and easy integration of different components. Orion is a C++ implementation of the NGSI v2 REST API reference data context model that was developed as a part of the FIWARE ecosystem. As it is shown in Figure 2, the FIWARE Generic Enabler – Orion implementation is used to handle all communication between the edge computing unit, the cloud backend and external user interaction devices.

The Orion Context Broker is used to create and manage the entire lifecycle of context information, which consists of unique entities and their respective attributes, allowing any part of the platform to push and get updates, queries, registrations and subscriptions. Orion implements the Publisher-Subscriber pattern, which enables an application to announce events to multiple interested consumers asynchronously, without coupling the sender(s) to the receiver(s). This process is presented in Figure 3. Asynchronous messaging is an effective way to decouple senders from consumers, and avoid blocking the sender to wait for a response. However, using a dedicated message queue for each consumer does not effectively scale with many consumers. Also, some of the consumers might be interested in only a subset of the information. Data to be exchanged is formatted in JSON objects. JSON is the abbreviation for 'JavaScript Object Notation' which is designed to exchange data as a standard format. It is a simple text-based and lightweight data standard, which is intended for human-readable data exchange. More technical details regarding the communication protocol are presented in the Appendix.

By integrating Orion as the basic message broker of the proposed architecture, an abstraction layer is formulated among the system and third-party devices that would like to interface with the platform's services. Communication with any external module, such as alternative user interaction devices or additional healthcare services and registries, can be established seamlessly, as long as they implement the FIWARE-NGSI v2 REST API, which

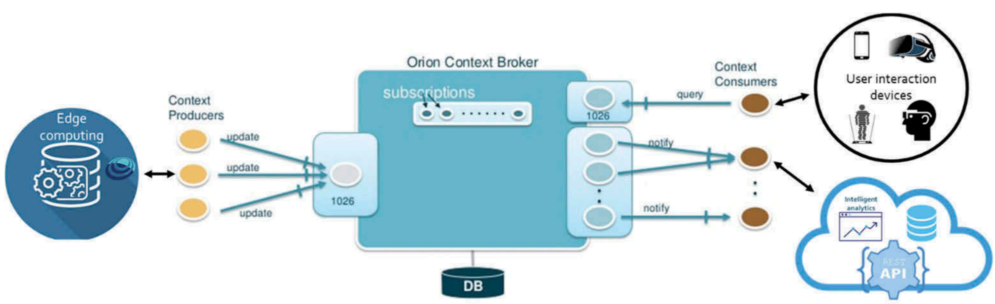


Figure 2. Schematic representation of the FIWARE-Orion enabled communication protocol. Adapted from FIWARE Foundation (2018).

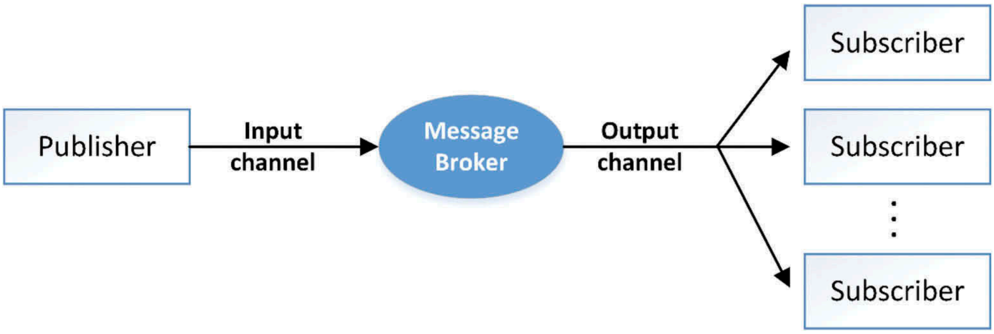


Figure 3. The FIWARE-Orion implementation with the Publisher-Subscriber pattern.

is published under open source licence. Therefore, once this protocol 'handshake' is established, there is not further communication customisations required to integrate and support external modules, devices or data models with the core platform functionality modules, which are presented in detail in Section 2.3.

2.3. Platform modules

The core functionality of the platform is supported by a range of key modules that can be interchangeably added upon demand and adapt to specific needs, depending on the targeted system application. These modules are comprised of either software or hardware infrastructure with their main purpose being to enhance the modularity of the platform and simplify the interactions between the different components. By using this approach, we can achieve loose integration, which is a priority of the entire platform's design. All modules are completely independent, without any specific dependencies in codebase, following a by-design advanced separation of tasks and responsibilities, during the initial process of defining the architecture of the platform.

2.3.1. Edge computing unit modules

The edge computing unit acts as the central point to host and connect all the necessary components and modules that are located at the user side (e.g. user's home), and establish the communication with the cloud infrastructure for data exchange. The motivation of including the edge computing unit is to allow for data that are produced by interconnected Internet of Things (IoT) and/or other devices to be processed closer to their point of creation, instead of sending large chunks of data across long routes to data centres in the cloud. A primary set of modules providing the key functionality to facilitate the needs of different applications, adopting the proposed interoperable platform, is presented in the subsections below. It should be noted, that these modules can be adjusted, expanded, removed or even replaced with existing solutions, depending on the specific needs of each application and use case.

2.3.1.1. IoT device management module. This module is responsible for integrating a wide set of sensing devices, which can be used to track and monitor user actions, behaviour changes, level of activity, well-being, medical conditions, etc. The module consists of a set of hardware–software interfaces that provide an interoperable, standardised, physical layer to communicate with different sensor devices and acquire their respective data (e.g. IMU sensors for motion tracking, capture of bio-signals like ECG/EEG/EMG, bio-specimen analytics, pressure data from smart insoles). Supported protocols include both wireless communication through Bluetooth 5.0, Low Energy Bluetooth or WiFi and wired communication through USB3.0, along with older versions that these protocols are backwards compatible with, respectively. Interoperability is further enhanced with the implementation of Generic Attribute Profile (GATT) services, which define a new standard that Low Energy Bluetooth enabled devices can transfer with each other and the edge computing unit. As required by the GATT services, a dedicated connection is established between the edge computing unit and any compliant device.

The key requirements for this module include the ability to

- automatically pair with IoT devices and establish a connection,
- withstand a continuous connection and handle interrupts (reconnection),
- provide the necessary bandwidth to ensure maximum data flow, and
- minimise transfer latency to reduce the impact in latency-sensitive applications.

This module is also equipped with its own local database to handle raw data storage, as this is expected to be a necessity for the majority of the applications. This local database is a design by default as a MongoDB in our platform but could be of any either type that better fits specific needs. Finally, the IoT device management module implements a global clock policy to synchronise incoming data streams and forward them to the analytics computational module via synchronous TCP/IP sockets. For security and efficiency reasons, all transmitted data are converted to byte-steams using Protocol Buffers.[4]

2.3.1.2. Analytics computational module. Raw data from IoT devices may require subsequent analysis in order to extract practically or medically relevant information in a more abstract manner. For example, reporting the exact accelerometer and gyroscope measurements as obtained in a rate of hundreds of values per second from an IMU sensor has little value in manually interpreting the level of a subject's daily activities. Using this data to estimate the number of steps in the same day, however, is an easy way to report an indicative measure of activity tracking. In the same way, most applications would require similar estimations to extract meaningful aggregated data from the actual device measurements. This functionality is provided through the analytics computational module.

The capability and supported complexity in calculations depend on the processing power that is available on the edge computing unit, which directly relies on the type of device being used (e.g. a smartphone would provide better performance compared to a smartwatch, but in turn would not match a PC). In reality, however, it is more typical to assess the computational needs based on each use case during system design (e.g. basic activity tracking can be done with a wristband, while real-time precise activity tracking of different body parts would require an array of multiple sensors), and then tackle these requirements accordingly with the appropriate hardware. Due to the targeted openness of our design, this module can also hosts external services (e.g. Google's Speech-to-Text API) to allow quick integration of ready-to-use functionality. Similar to the IoT device management module above, a local database is also provided to handle potential needs for aggregated data storage, should this is necessary depending on the targeted application. This local database is also a design by default as a MongoDB. Regarding the communication interfaces of this module, it implements the server-side of the TCP/IP connection with the IoT device management module described above. The output of the analytics computational module can be transferred to the rest of the platform via the communication module, described in Section 2.3.1.4.

2.3.1.3. Task management module. This module provides all the necessary tools to control the between-modules high-level interactions and automate the use of the services in the edge computing unit to enhance user experience, by micro-managing the supported functionality in a smart way. Complex scenarios can be created according to the intended use case so that the system can execute different tasks, respond to a given input, stop or initiate activities, assess critical changes to user's environment and respond accordingly. Essentially, this module is responsible for supervising the modules in the edge computing side, in order to ensure that the system operates within the intended limits and provides all supported functionality. This module handles the workflow between the IoT devices by creating virtual chains of processes. For each virtual chain, a separate thread is created within the module, which setups, monitors and terminates the involved devices and services throughout the lifecycle of the task. This module can receive input from the cloud infrastructure to enable remote access and control from users with administrative rights. For example, a clinician can request that a notification is pushed to improve adherence to treatment or change a scheduled programme of activities depending on the subject's progression.

2.3.1.4. Communication module. As described in Section 2.2, all interactions between the key components of the platform are handled using the FIWARE-Orion API, which manages both data traffic between the edge computing unit and the cloud and most between-modules communication within the edge computing unit. From the context management solutions that Orion offers, the proposed approach relies on subscription functionality. Two special entities have been developed and deployed within the Orion Broker. The first entity (toUser) is used to handle the communication between the edge computing unit and any user interaction devices (e.g. holographic unit, VR/AR device), while the second entity is used to handle the communication between the edge computing unit and the cloud services. All platform modules subscribe to these entities and get notifications each time they alter their content through an accumulator server, which is also implemented in the edge computing unit. The role of the accumulator server is to collect all messages that are produced by the Orion's subscription mechanism and forward them to the appropriate endpoints. Following this rationale, each time the edge communication module needs to interact with an external device, it commits a POST action to the Orion Broker, and the accumulator server sends a specific message, based on a common protocol that is shared among all modules. Thus, in terms of integration, it is quite straightforward to interface the edge computer with any user device. The same process applies to cloud data transfers as well.

It is important to mention the interoperable aspect that the FIWARE-Orion API induces to the overall architecture of the proposed platform. Besides serving all user interface devices, the communication module acts as a decoupling agent among the different software modules of the system. Thereby, any module can seamlessly be integrated into the system, as long as it complies with the messaging REST API and the relative subscription protocol. For instance, in case an updated analytics computational module needs to interact with the rest of the ecosystem, it can replace the running version of the module, without interfering with the rest of the system's functionalities. Given the advanced role of the Orion Broker in managing all communication channels, the main database of the edge computing unit is also incorporated in this module; by default as MongoDB. Data stored on the local databases of other modules are transferred in the main database, to provide the Orion Broker with better control and easy access when handling data requests. Depending on the application, case-sensitive data can then be transferred from the main edge database to the centralised database in the cloud.

2.3.2. Cloud infrastructure modules

The cloud services of the platform are provided by the 'Roessingh Research and Development Database R2D2 API'. It is a secure REST/JSON API over HTTPS that provides generic database queries for Create, Read, Update, and Delete (CRUD) operations, as well as authentication, authorisation and user management. The cloud backend infrastructure provides all the necessary services for the interaction between its different modules and performs all actions related to data exchange, processing, advanced analytics estimation and representation. The functional specifications of each module within the cloud are presented in detail in the following subsections to provide a clear view on the services that are provided and the required interactions with the other modules of the platform.

2.3.2.1. Centralised data repository. Centralised data storage is a core functionality of every cloud-based platform, as it is typically the safest and most cost-effective way to maintain large volumes of data, without requiring any effort from the end users. In addition, the hardware storage capabilities on the edge side might be very limited, especially when using small-factor, unobtrusive devices. Combined with the ever-increasing amount of data generated by IoT devices, abundant storage on the cloud is a preferable solution. Thus, this module is responsible for providing all the necessary space and redundancy to collect and permanently store all useful information that is continuously sent from the edge computing unit. Furthermore, as it also the centralised point of data storage from multiple edge clients, it allows the accumulation of useful data from large patient groups to perform extensive population-based analytics.

The R2D2 API internally supports various database engines to address different storage needs. It primarily stores aggregated sensor data, but it can be used for any other type of data. It also supports replication, and push notifications through Firebase cloud messaging. The centralised cloud database is also used to store user profiles and roles. All information gathered is associated with each user in the database and role-dependent access is provided. Edge clients, external devices and mobile applications can both commit and access data from and to the centralised cloud database, through the FIWARE-Orion communication module and via authorisation endpoints. The centralised database can also exchange data directly from third-party systems and tools, including mobile applications. The communication with the cloud backend is performed using standard communication solutions, over HTTP protocol as RESTful APIs with SSL certificates, to provide secure data exchange.

2.3.2.2. Advanced data analytics module. Tasks that are very computationally demanding to be performed in the respective edge analytics computational module, are transferred for execution to the cloud infrastructure, where computational resources can be scaled with ease. This allows researchers to design and deploy complex analytics to perform advanced user behaviour and condition evaluation tasks, using machine learning models and deep learning algorithms, on data collected from edge devices. Thus, the extraction of more such features can lead to more meaningful evaluations that enhance the impact of the platform's outcomes for both the end user and the involved stakeholders. As mentioned before, another aspect that makes the deployment of complex analytic models possible on the cloud is the centralised database. Having high volumes of data is crucial in advanced analytics, especially for machine learning-based models, for both personalised evaluations (e.g. progressive learning) and large-scale population analysis.

2.3.2.3. User interface module. This module supports the design and development of user interface software using PHP/JavaScript/HTML5 to provide access for displaying/editing stored data through graphical interfaces (GUIs). It is essentially the web interface of the entire platform. The user interface module is connected to the backend portal of the R2D2 services, which provide user-dependent access to the centralised data repository. If necessary, an auxiliary local MySQL database can also be used for storing data structures that are internally crucial to the operation of the module. This module consists of a collection of processes, roles, policies, standards, and metrics to ensure the effective and efficient use of information, which in turn enables any organisation to achieve its goals when using the platform. It establishes all processes and responsibilities to ensure that quality and security of data being used or shared is maintained, by defining who can take what action, upon which data, in specific situations, using predefined methods. The use of the SQLDBM platform,[5] which is a free web application providing an easy to use interface to design Entity-Relationship (ER) models, is preferred for this module, as it is compatible with several DBMS (MySQL, PostgreSQL, Access, etc.) and is also capable of automatically generating the SQL code needed to create the actual database, based on the given ER model.

Depending on the use case, the module can be set up with different user interfaces to serve users with different roles (e.g. edge user, expert-professional, administrator, researcher, etc.). The administrator of the platform can set distinct users and their respective roles, while also defining their privileges in accessing and manipulating data and platform's functionality, by setting the basic rules for user interaction. The interface for the edge user is designed to offer end users access to their collected data, information from advanced analytics and system notifications. The focus is to provide personalised feedback using mostly graphical elements to show the current status and comparison to the recent history of tracking, in an attempt to motivate the user to set and achieve his/hers personal goals. A reward system can also be implemented for succeeding timely performance targets, adding to a feeling of accomplishment and satisfaction. User motivation can be further enhanced by deploying a virtual social network to allow edge user interactions and competitive performance metrics against each other, in a ladder-scheme community context. Newsfeed services can also be implemented. The expert user interface is targeted towards the professional stakeholders of the platform (e.g. clinicians, physical therapists of any kind). It allows them to register new users in the system, define their activities plan and schedule, view and assess their performance, send notifications for new tasks or in case of poor adherence, see summaries of advanced analytics and even results of digital questionnaires and self-evaluation tests (if implemented).

User authentication is handled from the R2D2 API using JSON web tokens (JWT) and typical email address and password credentials for identification. Each token is an encrypted object with certain expiration time that carries details about the user's identity, which are passed in a header X-Auth-Token format. This action is stateless, as there are no sessions on the cloud server. If the token has expired, the query will return an appropriate error and the user will need to login again to get a new token. Single sign-ins for specific projects can also be supported. In these cases, the authentication is handled by a trusted third party and access is granted only to a specific portion of the R2D2 cloud services. When the third party makes a request, it includes a special JWT token with non-sensitive authentication details signed with a private key.

2.3.2.4. Healthcare services module. This module aims to provide mechanisms to allow interactions between the cloud and existing healthcare services, through a specifically developed API. The scope of this API is to integrate the Fast Healthcare Interoperability Resources (FHIR) standard for healthcare data exchange, as published by HL7®.[6] FHIR is an international standard for exchanging digital health data and is increasingly used in health information technology. FHIR streamlines the enrichment of electronic health records (EHRs) by integrating any data sources that can provide clinically meaningful information. FHIR also enables telehealth technologies (Lehne et al. 2019a) and makes health data accessible to advanced, large-scale and population analytics (Braunstein 2019). From the FHIR data models, the proposed API utilises the 'Observation' and 'PlanDefinition' models. The 'Observation' model is used to exchange measurements and metrics between different services to monitor patient progression, determine baselines and patterns that can help clinical decision-making, while the 'PlanDefinition' model is used to facilitate patient management. A plan definition is a pre-defined group of actions to be taken in particular circumstances, often including conditional elements, options, and other decision points. Patient data and any other information are transferred in the centralised data repository for storage.

2.4. The HOLOBALANCE use case

Using the above described interoperable platform we developed the HOLOBALANCE system, a cloud-based platform, through which patients with balance problems can have access to remote physiotherapy and cognitive training sessions, guided by a virtual holographic physiotherapist. The platform uses a set of sensors and image capture devices, to monitor the execution of the balance training exercise program and provide real-time feedback to the user. Besides real-time evaluations, the system streams processed data and patient-specific outcomes from the execution of balance exercises, cognitive games and auditory training sessions, along with data of general physical activity levels, to the centralised data storage in the cloud, where they can be further analysed to extract detailed insights, that can be used to track balance symptoms' progression and behavioural changes.

2.4.1. Balance Physiotherapist Hologram

The Balance Physiotherapist Hologram (BPH) unit is responsible for projecting a holographic virtual physiotherapist in the users' in-home environment using augmented reality functionality. The virtual physiotherapist provides instructions for the personalised rehabilitation training, demonstrates the exercises that need to be performed and motivates the patient to follow the exercise program more precisely by giving proper and real-time feedback. The BPH module relies on the edge task management module in order to get the daily sessions that each user has to perform and on the edge communication module in order to receive commands that allow it to interact with the user in real time. The BPH unit communicates with the Motion Capture and Wearable Sensors unit that is described below, via the communication module (i.e. Section 2.3.1.4). There are two versions of the BPH that are evaluated in terms of user experience. The first one is an ARCore Unity app for Android, using a smartphone that is attached on a head-mounted device (e.g. Haori Mirror). The other solution consists of a Holobox, which is an interactive hologram projector that creates virtual images of real human-sized objects, as it is shown in Figure 4. Despite its size limitations, the Holobox is an alternative for patients who have trouble performing their exercise regime with the head-mounted device. All movements of the holographic physiotherapist demonstrating the exercises were captured with a commercial marker-based tracking system (www.mocap.me) and then transferred to the digital augmented environment.

Following the adaptation of an iterative architecture design approach (i.e. evolutionary systems, IEEE 1471), a user-centred design (UCD) approach was also used for the implementation of the AR user interface environment, targeting the specific needs of the balance disordered patient population. UCD follows an iterative development circle, which consists of repetitive steps of requirement analysis, prototype implementation and evaluation of the developed concepts, to end up with a system with optimal usability

Figure 4. A schematic representation of Holobox that can project real human-sized 3D animations.

(Mostajeran et al. 2019). During each iteration, actual patient feedback provided new insights to enhance various aspects of the hologram–user interface, which are integrated in the design. Therefore, the end users were constantly involved throughout the development and testing phases, in order to ensure all requirements will be met in the final version (Mostajeran et al. 2020).

2.4.2. Motion Capture and Wearable Sensors

The Motion Capture and Wearable Sensors (MCWS) unit is deployed in the edge computing side and is responsible for capturing and evaluating the entire workflow during the performance of each exercise of the VRT plan, mimicking the reasoning of a clinical expert. Its main functionalities include precise patient movement tracking and evaluation to assess whether the exercises are performed as intended. Motion capture is implemented using two inertial measurement units (IMUs), a pair of pressure insoles and a depth camera. In addition to motion tracking, the HOLOBLANCE system implements heart rate monitoring using the Polar H10 sensor, to estimate stress levels before and during rehabilitation training and evaluate potential adverse effects to patient's condition. The complete set of sensors is presented in Figure 5. Besides the depth camera, the measurements from all other sensors are collected wirelessly and in real time through the IoT device management module.

Exercise evaluation is performed by analysing all captured data in the analytics computational module. The primary outcome of exercise evaluation is to assess in real time if the patient follows the instructions being virtually presented regarding the specific way that each exercise needs to be performed. If the exercise is not performed as intended, the system triggers the hologram to intervene and stop the patient, as the VRT regime would not be effective. Once patient compliance is achieved, further analysis is performed to estimate the level of patient's performance in each exercise (scoring), in order to adjust the level of difficulty accordingly. The aggregated information, which is extracted in the MCWS module from the raw sensor data, is also transferred to the centralised data repository in the cloud through the FIWARE-Orion communication module. The communication module is also used to allow interactions with the rest of the system. For example, whenever the MCWS module needs to send a message to the Hologram, it posts the message to the Orion Broker, which in turn pushes the message to the accumulator server and the server post the message to the BPH module.

2.4.3. Intelligent data analytics

The aggregated information that is extracted from the raw sensors data and stored on the cloud backend can be then used to perform further analysis and extract even more useful outcomes to evaluate the efficacy of VRT. The HOLOBALANCE system incorporates intelligent processing components that exploit the advanced analytics module in the cloud infrastructure to (a) detect and evaluate stress levels before and after each task, using mainly the RR intervals from ECG signals that are captured by Polar H10, and have been shown to provide quality data even in intensive training (Gilgen-Ammann, Schweizer, and Wyss 2019); (b) evaluate patient frustration during VRT, using Dynamic Bayesian Networks (DBNs) and input features from emotional computing, symptoms and the performance in exercises, games and auditory tasks (i.e. scores, duration, intensity, adherence, etc.); and (c) recommend and optimise personalised weekly plans to each user

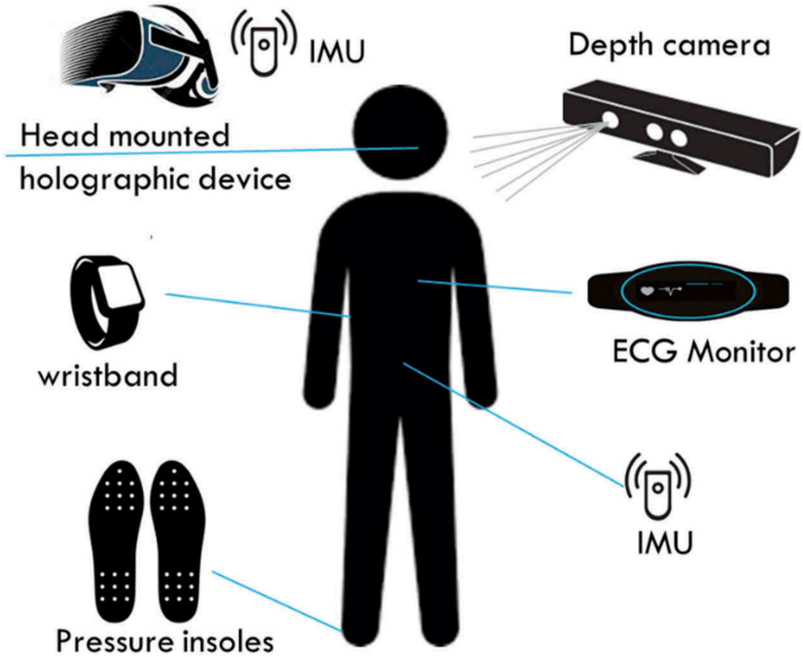


Figure 5. The complete set of sensors and IoT devices used to monitor patients in HOLOBALANCE.

needs, in an autonomous way using reinforcement learning algorithms, to improve balance and alleviate symptoms faster, provide better feedback and keep the user motivated and involved in the system by setting new goals.

2.4.4. Cognitive and auditory training

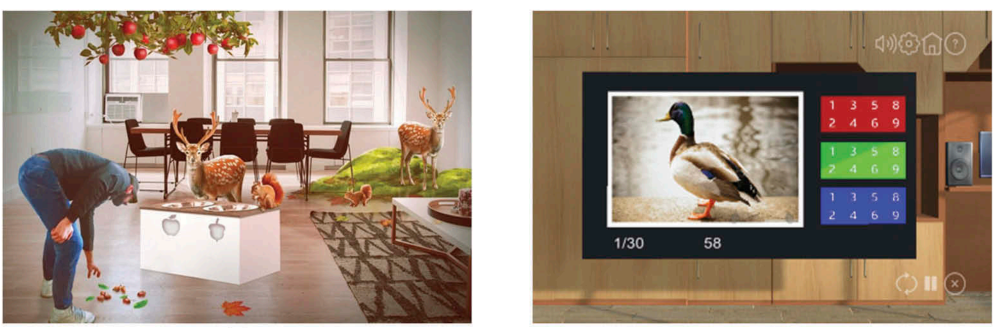
Gamification of training has been also included in the HOLOBALANCE system using specialised mobile applications that can enhance cognitive and auditory functions, since these are common issues in elders with balance disorders. Both mobile apps were developed using ARCore Unity for Android and the games are projected through the AR interface in the user's environment, using the same head-mounted smartphone adapter solution as in the holographic representation of the physiotherapist in the BPH module. The cognitive and auditory training unit depends on the task management module of the edge computer to control which games have to be performed in each rehabilitation session, and on the MCWS unit to evaluate user's performance during the games and allow real-time feedback reporting back to the user. Evaluation scores and other user interaction-related outcomes are transferred to the centralised data repository in the cloud to be used for advanced analytics. These results are then transferred to the Dashboard (described in the next section) via asynchronous REST calls to be presented (with different levels of detail) to clinicians and patients.

The cognitive training tasks include augmented reality games that aim to stimulate and improve cognitive skills, such as attention and working memory, using exergames that essentially are gamified versions of the balance physiotherapy exercises. For example, patients are required to move around objects, extend or bend over to reach stuff in order to collect or transfer across things that are required to fulfil the game's objectives. The auditory training tasks aim at assisting patients in improving speech perception and auditory memory. To accomplish that, the system replicates real-life conditions in which a patient has to perform complex tasks under non-optimal conditions, like reading a book in a noisy cafeteria. A snapshot of the training games used in HOLOBLANCE system is shown in Figure 6. Both categories of games also aim to keep the users stimulated and motivated in using the system.

2.4.5. Dashboard

The HOLOBALANCE Dashboard provides and controls the two main graphical interfaces for the primary users of the system (i.e. patients and physiotherapists), using functionality that is provided by the user interface module from the cloud services. A snapshot of the two interfaces is presented in Figure 7. The Professional Web Portal web-based interface is shown on the left and covers all interactions with healthcare professionals; mainly physiotherapists in the case of HOLOBALANCE. They can use the Dashboard to (a) register new patients in the system, (b) import the results of offline questionnaires and other patient evaluations, (c) define VRT schedules for each patient, feeding the task management module, (d) view and analyse patient's performance in exercise execution and other tasks (i.e. cognitive and auditory training), and revise the rehabilitation plan accordingly. This information is provided by the Dashboard through GUIs, along with data editing and correction capabilities.

In contrast to the professional web portal, the main user interface for the patients is developed as a native mobile application, which allows them to monitor their activity history and obtain an overview of their progress while using the HOLOBALANCE system. The primary reason for deploying a mobile interface for the patients is that a smartphone is used either way in the edge side of HOLOBLANCE, and it can be operated by elders with less hassle, as the mobile environment has fewer chances for technical issues to emerge. Through the app, patients can monitor the distribution of their daily activities at any time of the day, and check their performance in executing the exercises of their personalised VRT regime and the games. Furthermore, the app informs patients on how close they are in achieving the goals set for their VRT plan. A rewarding system of badges is used to



(a) (b)

Figure 6. A representation of the user experience with the games for (a) cognitive and (b) auditory training, as projected in the surrounding in-home environment using augmented reality.

(a) (b)

Figure 7. The primary user interface of HOLOBALANCE for (a) physiotherapists and (b) patients.

compensate their efforts and reinforce the engagement over prolonged time periods, based on various motivational techniques deriving from the COM-B model (Michie, van Stralen, and West 2011). The patients are also informed through the app about upcoming events and interesting health topics through a newsfeed component, while an entire social network of users is also available, to support their virtual community where they can post about issues they want to communicate with others. All information within the app is shared back with the centralised cloud repository to update and retrieve user-specific data.

2.4.6. Integration of third-party tools

The Fitbit activity tracker is used as a stand-alone solution to monitor daily patient activity. As Fitbit does not allow for direct data sharing, all data must be initially synced with the Fitbit cloud, which in turn provides a Web API for accessing the information gathered using their activity trackers. The Fitbit API provides access tokens upon user consent, which can then be used to connect with the R2D2 API backend cloud services to execute data sharing requests. The cloud backend service is authorised via Fitbit OAuth 2.0 Authorization Code Grant, as specified in RFC 6749. All activity information can then be presented through the Dashboard module to both healthcare professionals and patients in an easy and more comprehensible way.

2.4.7. Data flow and communication model

The primary functional units of the HOLOBALANCE system that were described in the previous sections create a closed-loop ecosystem, which produces data by capturing patient movements, processing them in real-time to generate patient feedback, and tracking multiple time points of exercise performance to provide advanced analytics regarding symptoms' progression to physiotherapists. A comprehensive model of data flow and between-modules communication within the HOLOBALANCE system is presented in Figure 8. The MCWS unit captures raw sensor data and transforms them into a meaningful aggregated format of movement analytics, through the analytics computational module. The latter interacts with the BPH unit to provide real-time feedback to the patient, as well as with the intelligent data analytics unit in the cloud to store aggregated

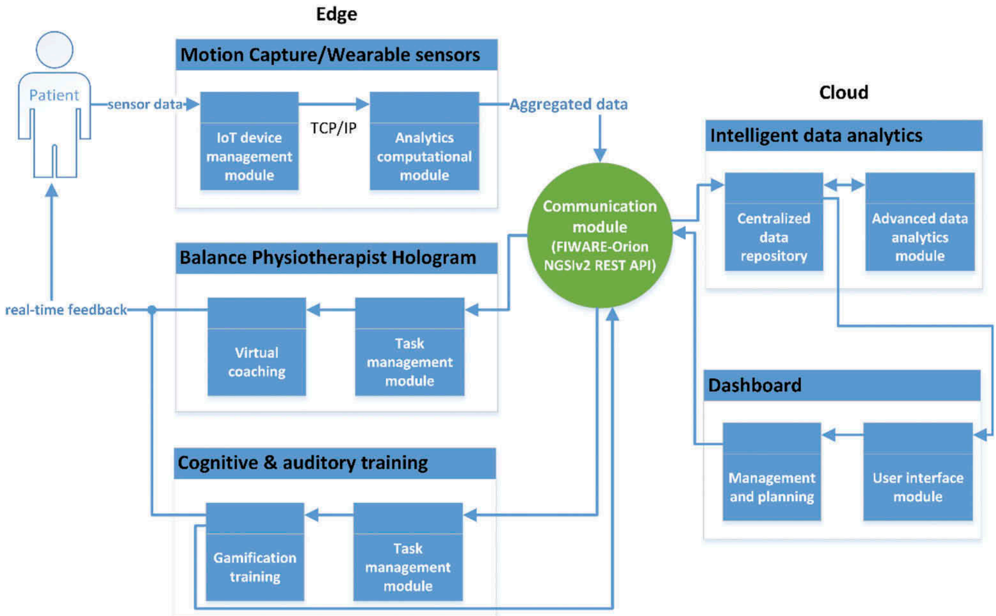


Figure 8. Schematic representation of dataflow and between-modules communication of HOLOBALANCE.

data into the centralised data repository module, and extract updated information on symptoms' progression (i.e. advanced data analytics module). Dashboard is also updated to display patient's current condition after completing the scheduled exercise regime. The same rationale is followed when evaluating patient performance during cognitive and auditory training. Communication between units and modules is handled entirely through the FIWARE-Orion broker in a rather transparent fashion, enabling the straightforward integration of any additional modules and functionality in the future.

3. Results

A small-scale pilot study was performed to evaluate the usability and functionality of HOLOBALANCE and acquire patient feedback regarding its practicality in managing their balance disorders. Patient inclusion criteria for this study included: (a) independent community-dwelling elders, able to walk 500 metres independently or with a stick, (b) have experienced at least one fall during the last year or have an assessment for high risk of falls or significant fear of falling, (c) aged above 65 years old, and (d) without cognitive impairment. Eight consenting subjects (3 males, 5 females) were recruited to perform individualised vestibular rehabilitation exercises guided by the virtual physiotherapist, in order to evaluate the main functionality of the system. All evaluation tests were performed in a controlled lab environment and under medical supervision. Each patient performed up to 36 VRT exercises, which consisted of sitting, standing and walking tasks, according to exercise regimes that were designed following formal guidelines and rehabilitation protocols (Hall et al. 2016). The exact number and type of VRT exercises that had to be performed was subject-dependent, as patients had different balance disorders, and therefore different interventions were required.

In total, 141 exercises were executed and monitored using the HOLOBALANCE system. The modular architecture of the system allowed the different units to work interdependently, while the usage of FIWARE-Orion simplified the integration process. For each one of the 141 recorded exercises, the MCWS unit produced about 1,358 ± 125.31 kB of data from the sensing devices. The latency of the collected data, after the synchronisation process was about 3.9 ± 0.24 msec. The analytics computational module produced on average 9.3 ± 1.5 messages, based on the sensor data stream during the performance of each exercise, which were delivered through the communication model with a delay of 6.02 ± 2.12 msec to the BPH unit. Finally, processed results were uploaded to the centralised data repository module in the cloud with an average data batch of about 872.34 kb per exercise. This analysis indicates that the proposed dataflow model of transmitting aggregated data minimises the required capacity to fulfil the communication requirements of complex ecosystems like HOLOBALANCE, which relies on various technologies, such as ARCore, Python multiprocessing library, network programming, BLE stack programming, REST web programming, etc.

Regarding the technical aspect of the system's stability and monitoring performance, problems were reported during patient movement tracking in 13% of the exercises, which were easily resolved with a soft system reset and re-initiation of the exercise. This low rate of run time errors highlights the robustness of the proposed platform and the technologies being used to monitor VRT physiotherapy, minimising platform-induced patient frustration. Upon later inspection of log files, no case of system failure was associated with the execution or evaluation of any particular exercise, rather than random communication issues between monitoring sensors and the edge computing unit. The main cause was located in certain bottlenecks in the internal data management module in the edge computing that would occasionally delay, leading to overwhelming buffered data that are continuously sent to cover the real-time monitoring requirements of HOLOBALANCE. These issues were resolved with appropriate modifications in the IoT device management module.

Regarding user experience, the evaluation of the system was focused on three main aspects: usability, task load and immersiveness to assess adaptation (Cimperman et al. 2013). Patient feedback for system usability was found overall very good and only minor concerns were raised for the weight of the head-mounted device, which were addressed with the use of Holobox as an alternative virtualisation solution. Task load from the human-machine interaction was well received by all patients. Only the assessment of descriptors that convey psychological perceptions of discomfort related to emotional concerns, such as worries about how the subject looks while wearing the device, suggested that subjects felt a bit tensed. This finding highlights the advantage of in-home interventions as with HOLOBALANCE, as privacy is guaranteed and can mitigate the psychological concerns of using such systems in public. Finally, the vast majority of the patients reported that their interaction with the hologram was considered as a novel and stimulating solution for the visualisation of their VRT regime.

4. Discussion

Interoperability in telehealth platforms provides the ability to connect and exchange data from different information systems, devices and mobile applications, promoting more effective personalised interventions. This multidirectional sharing of information allows patients to access specialised information related to their condition provided by clinical experts (e.g. handouts, videos), while also being able to communicate directly with them via the telehealth platform (Powell et al. 2017). Furthermore, in-home monitoring using sensing devices can allow them to keep track of their condition, promoting self-engagement in medical interventions, since they will be provided with more detailed reports and enabling them to demonstrate and share their achievements with similar patients and family members. Clinicians are also met with new communication channels to share relevant patient knowledge and obtain feedback from other care providers, such as physiotherapists, formal and informal caregivers. Each specialist can enrich patient records with more details and further evaluations, which are directly shared to optimise patient management planning. Alarming signs can be quickly identified, allowing clinicians to initiate prompt interventions and, as patient monitoring can be continuous, progression rates and adherence can be estimated on the fly.

Other stakeholders that can benefit from such telehealth platforms are the medical research community and the formal policymakers. For the first ones, these platforms enable the admission of large patient populations and the accumulation of big data, enabling both massive group analytics but also more precise interventions at per subject level, as more longitudinal follow up data and evaluation parameters become available for each case. The latter will have access to big population data that can potentially enable them to identify which measures promote long-term behavioural changes in different patient subgroups (in terms of socioeconomic-/mental-/mood-related factors) and, thus, adjust the related health service provision priorities accordingly. More information will be accumulated at the end of each project that could be used to inform a better planning of next stage applications, by identifying, for example, intervention strategies with better outcomes in shorter time periods or limiting the number of follow up visits, which increase costs in health systems. Cost reduction leads to cheaper services that become accessible to more patients who were previously not catered. Then, since the interventions are home-based, these services can also reach to patients in rural areas, who previously needed to travel a long distance to access a similar quality of healthcare.

To enable the above, the proposed interoperable architecture streamlines communications and data exchange between independent modules, responsible for data storage, processing and advanced visualisation with virtual user interaction, while facilitating the integration of third-party tools, off-the-shelf IoT devices and cloud infrastructures. The edge computing unit handles the integration of different devices, which can be instantly connected, replaced or swapped, as long as they use standard communication protocols (e.g. Bluetooth, BLE, Wi-Fi and USB). The platform is scalable, as the core, interoperable technologies in the cloud backend, can support and coordinate an increasing number of users depending on the needs of each telehealth application and the requirements of the healthcare provider. In addition, to serve a broad ecosystem of existing infrastructures, both ends of the platform (i.e. edge and cloud) can operate across various hardware devices and under different operating systems. There is support for PC and different types of smartphones as edge computing devices and the modules can be migrated to their respective operating systems accordingly (e.g. Android and iOS). All main technologies are supported by design, enabling wider adoption from developers with different backgrounds and preferences. Furthermore, by supporting FHIR and automated data sharing between different healthcare providers and EHR systems, the proposed platform can exchange data and patient information with existing systems and cloud infrastructures that comply with the protocol.

The deployment of HOLOBALANCE as a use case of the proposed platform has provided insights into the potential benefits of interoperable systems for the involved stakeholders in this domain (i.e. patients with balance disorders, their significant others, physiotherapists, ENTs and geriatricians involved in patient supervision, healthcare system regulators). The preliminary feedback from the patients who participated in the focus groups provided valuable information is system design according to their particular needs and characteristics. Following a user-centric approach is system development was a key factor in identifying early design flaws and, therefore, enhance usability and user acceptance as the evaluation is performed by the targeted audience in advance. In addition, as a good practice the platform was designed and developed in order to address all potential risks for end users as assessed according to ISO 14791–2012, Medical devices-Application of risk management to medical devices (ISO 2010). Thus, HOLOBALANCE, as a test case, contributes to better showcasing the benefits of utilising a by-design interoperable telehealth platform in reducing architectural costs and development effort, focusing instead on making the final product appealing to the end users.

This early evidence from the HOLOBALANCE system suggests that besides vestibular rehabilitation, the proposed platform can be utilised for treating patients with other neurological or orthopaedic disorders, as well as for engaging older citizens in a healthier and more active lifestyle. Specifically, with appropriate adaptations, the platform can be used for the rehabilitation of patients suffering from Parkinson's disease (PD), for whom there is evidence that person-centred in-home rehabilitation interventions can provide positive outcomes and improved balance, similar to what can be achieved in a clinical environment (Flynn et al. 2019; Vaartio-Rajalin, Rauhala, and Fagerstrom 2019). The applicability of the platform in PD is further supported by the positive effects that were previously reported from virtual reality-based rehabilitation (Cano Porras et al. 2018; Wang et al. 2019) and game-based training (Perrochon et al. 2019; Santos et al. 2019). Moreover, similar home-based post-stroke tele-rehabilitation programmes have being also tested to evaluate their effectiveness in improving patients' motor skills and balance (Darekar et al. 2015; de Rooij, van de Port, and Meijer 2016; Chen et al. 2019), making them ideal candidates for the proposed platform as well. Multiple sclerosis is another domain where holistic digital coaching and sensor-based monitoring systems have not been widely used (Khan et al. 2015), besides promising results from studies using basic patient monitoring solutions such as Kinect console (Ortiz-Gutiérrez et al. 2013). Besides neurological disorders, similar benefits from using tele-rehabilitation have been reported after severe orthopaedic surgeries, such as total knee arthroplasty and total hip replacement (Tousignant et al. 2011; Nelson et al. 2017; Correia et al. 2018). The proposed platform has been adapted to provide a complete treatment program for these cases. Then, the platform could be also adjusted for motivational and personalised exercise programs, such as yoga and Pilates, which improve the functionality of older adults and promote healthy and more active lifestyles regardless of age (Bueno de Souza et al. 2018; Moreno-Segura et al. 2018). Such health-promoting interventions can be also very beneficial for managing patients with heart failure (Crundall-Goode and Goode 2014).

Finally, the robustness of the platform, as a whole, and of each corresponding module will be validated to its full extend during the main pilot study of the HOLOBALANCE system. The system will be tested with 80 patients over an 8-weak follow up period and compared against an equally sized group of control subjects, following a conventional rehabilitation training, with no virtual coaching interactions or real-time monitoring. This proof of concept telehealth-based pilot study will not only investigate the feasibility and acceptability of introducing the HOLOBALANCE system to a community of dwelling elders, but will also gather and report information concerning all technical aspects of the platform, including big data storage and processing challenges, between-module communication issues, user interface faults and overall system stability. Useful metadata will be also collected to explore potential changes in patient behaviour due to the novel rehabilitation approach and associations between stimuli and motivation when using such innovative interventions. All such findings and outcomes are to be further investigated and reported in our future work.

5. Conclusions

The proposed platform contributes to the advancement of telehealth, which is a critical component of the evolving digital-health transformation, providing a more effective and efficient way to use limited staff and resources. Compared to previous designs, the interoperable nature of the proposed platform is the key factor that allows it to be easily deployed in different domains, offering significant reduction in design time investments, allowing this effort to be spent in areas that matter most, developing specialised models with advanced analytics, more precise outcomes and treatment plans, in a user-friendly product with innovative solutions. In addition, current home-based rehabilitation programmes do not focus on customised interventions and do not address inner ear balance dysfunction, which requires individualised VRT plans to optimise recovery. To make matters worse, the increasing number of elders suffering from balance disorders with high risk of fall overwhelming exceeds clinical experts' capacity to continuously monitor the effectiveness of their interventions. Using holograms to deliver in-home coaching and precise sensor-based exercise monitoring, the HOLOBALANCE system could address all these challenges, empowering active engagement, improving access and quality of healthcare, and increasing convenience for both patients and domain experts.

Notes

1. https://www.himss.org/.
2. https://fiware-orion.readthedocs.io/en/master/.
3. https://www.fiware.org/.
4. https://developers.google.com/protocol-buffers.
5. https://sqldbm.com/.
6. www.hl7.org/fhir/.
7. https://github.com/telefonicaid/fiware-orion/blob/master/scripts/accumulator-server.py.

Disclosure statement

No potential conflict of interest was reported by the authors.

Funding

This work has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No [769574].

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Appendix

A more detailed description of the low-level communication between the different entities of the system is provided in this section. The systemic communication workflow includes the following steps:

- The module creates a subscription registry using the following NGSI call:

```
curl -iX POST \
  'http://localhost:1026/v2/subscriptions'
  -H 'Content-Type: application/json'\-d '
 { "description": "COMMUNICATION END POINT",
  "subject": {
   "entities": [
    { "idPattern": ".*",
     "type": "patient"}]
  "notification": {
   "http": {"url": "http://localhost:1026/COM_ACCUM"},
   "attrs": ["request1"],
  "expires": "2039-04-05T14:00:00Z" }
  }'
```

- On http://localhost:1026/COM_ACCUM, an accumulator server is deployed, following the recommendations and design patterns of the FIWARE community.[7]
- The other platform modules subscribe on the ORION broker.

In the use case of the HOLOBALANCE system, whenever, for example, the MCWS unit needs to send a message to the Balance Physiotherapist Hologram, it just posts the message to the ORION, which in turn pushes the message to the HLB_ACCUM server. The HLB_ACCUM server posts the message to the Balance Physiotherapist Hologram unit which updates the displayed information of the hologram. Thus, the communication between the modules is performed in the rather transparent fashion, enabling the future straightforward integration of additional software or hardware modules. It should be mentioned that the local database for the edge computing unit is a MongoDB, as suggested for operating the ORION Context Broker.