Chapter 5
A Big Data Infrastructure in Support of Healthy and Independent Living: A Real Case Application

Valerio Bellandi

Abstract This chapter illustrates how the SMART BEAR project aims to integrate heterogeneous smart devices, including wearables and environmental sensors, to enable the continuous data collection from the everyday life of the elderly, which will be processed by an affordable, accountably secure, and privacy-preserving eHealth platform applying Machine Learning algorithms to deliver interventions such as personalized notifications and alerts to each patient, thus promoting their healthy and independent living.

Keywords Smart healthcare · Machine learning · Analytics · Cloud computation

5.1 Introduction

A rapid increase in the elderly European population is predicted for the coming decades, due to the ageing of those born after WWII. Within Europe's ageing population, Hearing Loss, Cardio Vascular Diseases, Cognitive Impairments, Mental Health Issues, and Balance Disorders, as well as Frailty, are prevalent conditions, with tremendous social and financial impact. Preventing, slowing the development of, or dealing effectively with the effects of the above impairments can have a significant impact on a person's quality of life and lead to significant savings in the cost of healthcare services at the same time.

This chapter describes the approach adopted by the SMART BEAR (**Smart Big Data Platform to Offer Evidence-based Personalised Support for Healthy and**

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Independent Living at Home) project [1,2] to design the data-driven decision-making process supporting the creation of personalized interventions, in order to sustain the healthy ageing of people.

SMART BEAR (SB) targets participants who are between 67 and 80 years old and have a clinical history including at least two of the following conditions: Hearing Loss, Cardio Vascular Diseases, Cognitive Impairments, Mental Health Issues, and Balance Disorders, as well as Frailty. In addition to the conditions mentioned above, during the initial testing phase, which is hereby called "**Pilot of the Pilots**" and has been set up **in Madeira** as the trial scenario for technical requirements, *low back pain* is also targeted.

The aim of the SMART BEAR platform is to integrate heterogeneous sensors, assistive medical and mobile devices to enable the continuous data collection from the everyday life of the participants, which will be analysed to obtain the evidence needed in order to offer personalised interventions promoting their healthy and independent living [1].

eHealth platforms hold promise for many health benefits that can enhance the overall well-being of the elderly,through promotion of a healthier lifestyle and facilitation of the self-monitoring and self-management of their comorbidities. SMART BEAR is built on the eHealth platform developed by the H2020 project EVOTION[3] to support evidence-based public health policies formation and monitoring, which supports: (a) the continuous collection of medical, physiological and lifestyle data from heterogeneous resources (hospitals, biosensors,advanced hearing aids and mobile phones), and (b) the analysis of these data, driven by high level big data analytics and decision models to generate evidence useful for making public health policy level interventions [2].

The data processing schema encompasses a collection phase, where data are transmitted from the smart devices to the repositories in the SMART BEAR platform, and a data analysis phase, where the data are ingested by the Big Data Analytics (BDA) engine. The engine is designed to manage Data Analysis Workflows (DAWs), whose results are eventually relayed to the Dashboard, where overview charts are visualized for the clinicians. Finally, the Decision Support System (DSS) component provides suggestions for the personalized interventions to be delivered to the patients in form of app or dashboard alerts.

The raw data collected from the environment, the wearable devices, and the SB@App are continuously ingested in the FHIR and non-FHIR Data Repositories. In particular, the former is built based on the FHIR (Fast Healthcare Interoperability Resources) framework[4] and provides also the developers with a standard code based

[1] https://www.smart-bear.eu.

[2] https://cordis.europa.eu/project/id/857172.

[3] https://h2020evotion.eu.

[4] https://www.hl7.org/fhir/.

on HL7[5], which can be complemented with medical terminologies defined in the standards SNOMED-CT,[6] LOINC,[7] and MeSH.[8]

Then, the **BDA Engine**, based on the Hadoop stack,[9] exposes a set of APIs to get raw data from the Data repositories and to perform pre-processing procedures such as aggregations or filtering, the outcome of which supports the execution of Machine Learning (ML) analytics in scheduled jobs to run periodically at fixed times, dates, or intervals. This allows the execution of multiple data-driven procedures that, after an evaluation step, can be eventually selected to support decision making.

The **DSS component** is designed to assist the clinicians in the initial assessment of every patient in terms of the optimal clinical tools (i.e., questionnaires, exams) that must be used to assess a patient and then provide them with the optimal combination of the devices to monitor their health during the monitoring phase. The DSS will continuously be trained by the data that will be digested into the platform.

The **Dashboard** is the component aimed at providing a user-friendly graphical interface for the clinicians involved in the project. The Dashboard supports the clinicians to register, create, and manage a patient, taking into account his/her devices and medication, conduct the first visit and the checkup, verify patient's questionnaire score and medical history, in addition to the delivered interventions, perform analytics on medical data, and create interventions to be delivered.

Finally, all the components need to be integrated into the SMART BEAR cloud platform. The complexity of the project and the necessity of delivering new releases of the components at high velocity require a DevOps-like integration culture.[10] That is specially important when the pilots are running and the initial requirements are evolving and functionalities need to be improved, testing and released in a very short period of time.

5.2 Architecture

The SMART BEAR platform leverages big data analytics and learning capabilities, allowing for large scale analysis of the data collected, to generate the evidence required for making decisions about personalised interventions.

The SMART BEAR platform architecture consists of the following main components: the *HomeHub*, the *SB@App*, and the *SB@Cloud* (Fig. 5.1). The SB@Cloud is the core system of the architecture and covers the main functionalities of SMART BEAR such as: secure storage, collection, and analysis of medical data.

[5] https://hl7.org/fhir/.

[6] https://www.snomed.org.

[7] https://loinc.org/.

[8] https://www.nlm.nih.gov/mesh/meshhome.html.

[9] https://hadoop.apache.org/.

[10] https://about.gitlab.com/topics/devops/.

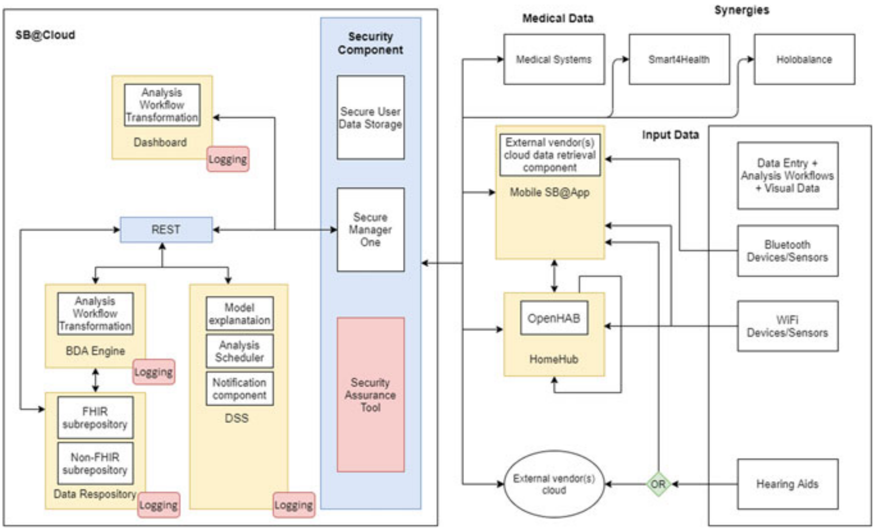


Fig. 5.1 The architecture of the SMART BEAR platform

In turn, it consists of the following modules: *Dashboard*, *BDA engine*, *Data Repository*, *Decision Support System (DSS)*, and *Security Component (SC)*.

The Dashboard is the entry point of user interaction with the SMART BEAR system for configuration and data visualization. The user interface allows to input data, set up Analysis Workflow data models and interventions, register or disconnect external data sources, execute data analytics workflows, and retrieve executions results.

The BDA Engine is responsible for the actual data analysis and retrieves the data from the Data repository for further processing, the results are written back to be accessed by users via the Dashboard. The Data repository includes FHIR and non-FHIR compliant sub-repositories. The FHIR component provides the storage for the medical data. The rest of the information is stored in the non-FHIR component. Some clinical repository interfaces allow data collection from external Electronic Health Records (EHRs) and synergistic projects (such as Smart4Health,[11] Holobalance.[12]).

The DSS provides the functionalities for interventions, reasoning behind the decisions proposed, and analysis scheduling and notifications, while the SB@App is responsible for the data collection from all portable devices connected to the patient's smartphone, such as pulse/steps measurements and portable medical sensors.

Finally, the HomeHub accumulates data from home-based devices, like smart weight scales and movement sensors. It collects data directly as well as from the device's vendor private clouds. On the backend level, all components are communicating via REST interfaces. The information exchange between components,

[11] https://smart4health.eu/en/.

[12] https://holobalance.eu/.

as well as authentication at the Dashboard, is secured according to GDPR through the Security Component. In particular, the Security Assurance Tool module put in place all mechanisms to enforce security policies.

eHealth platforms can actually support the overall well-being of the elderly, yet, their use is often perceived to have technological and privacy risks. Being SMART BEAR an eHealth platform, but like the majority of platforms integrating external solutions that interconnects software and hardware components, it presents challenges in relation to how to cope with security and privacy issues that could emerge due to different underneath technologies and different levels of compliance. In particular, external devices serve different purposes and, consequently, the aggregated system of devices is not implemented as a whole. In fact, each specific implementation considered a variety of protocols and best practices, not necessarily targeting security and privacy.

In this context, and in addition to the well-known security/privacy provisions [3] any modern eHealth system should support (e.g., Role-based access control, Data validation and encryption, end-users authentication, authorisation of users and M2M services, security monitoring and audit, logging mechanisms), developers must take into consideration the legislation that imposes tough obligations in the framework of the European General Data Protection Regulation (GDPR) [4], technical guidelines for minimum security measures suggested by organisations (e.g., Security and Resilience in eHealth Infrastructures and Services guidelines of ENISA [5], encryption guidelines of NIST [6]), and best practices for privacy like the one described in [7]), along with encryption, protocol e.g., the Bluetooth 4.0 Security Modes [8]) and vendor-specific data integrity advancements in Io(M)T.

5.2.1 HomeHub

The SB HomeHub defines both the hardware and the software that is installed inside the patient's home. In the case of SB, the HomeHub integrates the following sensors: a motion sensor, one or more smart bulbs, and a temperature sensor. These sensors are grouped in the SB@Home kit. In order to control sensors and devices from a central access unit, a *hub* is required. SMART BEAR must use and integrate multidisciplinary devices and sensors in the simplest and more robust way. For this purpose, the OpenHAB3[13] architecture is implemented in a Raspberry PI4[14] aiming to serve the technology-agnostic integration and functionality through a unified way by a single management and access interface, common to all actors of the process.

The architecture of the SB HomeHub can be abstracted in the following layers:

(a) *Sensors' installation Layer*: The physical sensors that are installed by a technician (or the person itself) in the patient's house.

[13] https://www.openhab.org/blog/2020-12-21-openhab-3-0-release.html.

[14] https://www.raspberrypi.com/products/raspberry-pi-4-model-b/.

(b) *Sensors' communication Layer*: This is a layer hidden from the user that explicitly defines the communication protocol that a sensor is using to communicate with the hub. The communication in most cases is based on ZigBee5 or WiFi6 protocols.
(c) *Sensors' configuration Layer*: This layer includes all the devices. The sensors cannot operate without the appropriate hardware that fits their communication protocol.
(d) *Home Local Area Network (LAN) Layer*: This layer explicitly defines the communication of the Raspberry PI board with the gateways and bridges. In this way, Raspberry interconnects and unifies all different devices and sensors. In SMART BEAR this means that the network communication with at least a LAN switch and a ZigBee USB stick, plugged in the Raspberry PI, is considered a requirement.
(e) *Home Control Layer*: This is the high-level layer and the actual HomeHub. The main building block is a Raspberry PI equipped with the openHAB software, actually hosting the HomeHub. In particular, the heart of the HomeHub is the openHAB technology-agnostic platform that unifies all home installations and allows access through the REST API by the SB@App (that in turn integrates the HomeHub with the SB@Cloud).

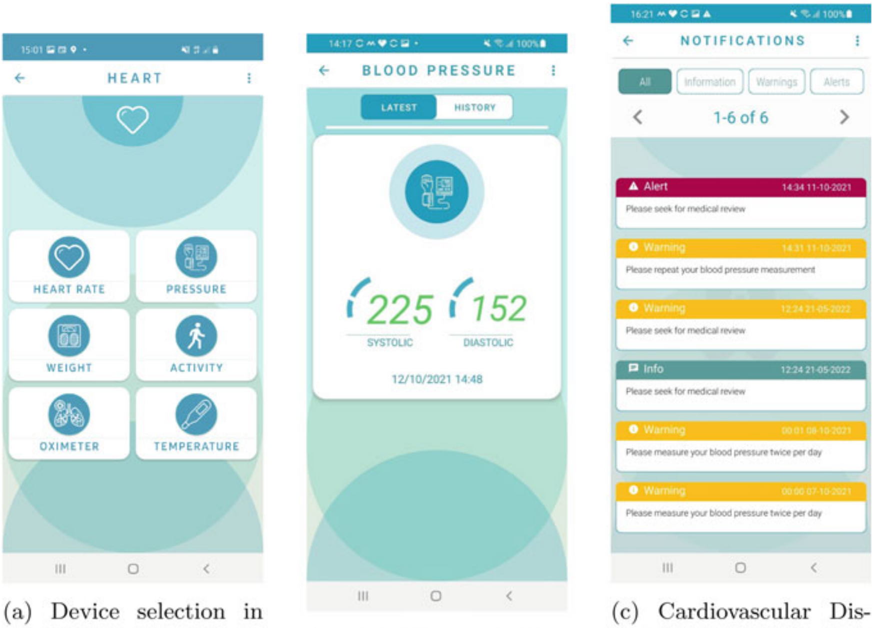
5.2.2 SB@App

The SMART BEAR mobile application (SB@App) is a component aimed at providing a user-friendly graphical user interface for the participant. The application handles the communication between the wearable devices and the SMART BEAR platform while accessing the Platform utilities and functionalities. Through the SB@App, a patient has access to all the data being collected by the wearable devices and the SB@Home kit An example of a usage scenario is depicted in Fig. 5.2a, b, where a patient with Cardiovascular Diseases **CVDs** can select a device and take a measurement, in this case, a Blood Pressure monitor to measure Systolic and Diastolic Blood Pressure.

The SB@App has also been designed to deliver to the patient alerts and notifications as part of an Intervention. In Fig. 5.2c, alerts and notifications concerning Blood Pressure are shown. The alerts and notifications feature a color coding based on the severity gradation that is described in Sect. 5.2.3.3.

5.2.2.1 Wearable Devices and IoT

All the patients receive a set of the following devices based on their clinical history considering the medical conditions that are targeted in SMART BEAR and are indicated in Sect. 5.1:



(a) Device selection in the case of Cardiovascular Diseases.

(b) Blood Pressure measuring.

(c) Cardiovascular Diseases notifications and alerts.

Fig. 5.2 SB@App interface

- *Smartphone* (all conditions), which is equipped with the SB@App and used by the patients to execute exercises and receive notifications.
- *Smartwatch* (all conditions), which is used to measure the steps walked by the patient and his/her location.
- *Smart thermometer* (all conditions), whose functionalities are exploited once a day to monitor the user's body temperature and check COVID-19 symptoms.
- *Smart pulse oximeter* (all conditions), which is used to measure the Blood Oxygen saturation and check COVID-19 symptoms.
- *Smart Blood pressure monitor* (CVDs), which retrieves the patient's vital signs about systolic and diastolic pressure and heart rate data.
- *Smart weight scale* (CVDs), which is used to retrieve a patient's data about body weight and composition.
- *SB@Home kit* (Cognitive Disorders), which is used to monitor the environment where the patient lives, more in detail air pressure, temperature, and light level are detected.
- *Hearing Aids* (Hearing Loss), which are used to retrieve patient's data about the usage time and to perform auditory training. The training procedure is described in Sect. 5.3.

5.2.3 Security Component

Concerning security and privacy at the backend, since the platform deals with the distribution of sensitive data and its processing, it adopts new distributed and/or collaborative paradigms of cloud computing. Among the main techniques to prevent sensitive cloud information leakage, we can cite the obfuscation and pseudonymization of uploaded data. Such cryptographic mechanisms are used not only for protecting data in the cloud but also as end-to-end mechanisms for protecting data in transit. However, cryptography alone cannot sufficiently preserve user privacy therefore additional forms of privacy enforcement are employed such as proper identity and authorization management, by specifying and enforcing security, access control, and privacy policies [9]. The SMART BEAR Security Component (SC) supports authentication of the entities (devices, applications, end-users, etc.) and protection of their data and resources, addressing security and privacy concerns.

Supported workflows allow the creation of secure and privacy-preserving communications within and from the SB@Cloud infrastructure to uniquely paired smartphones in an end-to-end manner. In this context:

Pseudonymisation a process that ensures that a record *after-the-fact* can no longer be attributed to a specific data subject without having previously been associated with additional information, is utilised to separate any key information (i.e., personal data, Personal Identifiable Information—PIIs) that may lead to subject's identification. This small critical dataset is stored encrypted in a separate repository, whose use is monitored continuously (i.e., usage logs can provide evidence in case of a GDPR audit), and it is the one that allows data controllers to meet specific GDPR obligations. Subsequently, its existence (during SMART BEAR project's lifecycle) allows the exercise of all GDPR individual rights (such as subject's request to know who viewed his/her pseudonymised data, also known as "Right to be informed") or the data controller's obligation to keep records, while its absence will convert all big data collected and produced to a fully anonymised dataset and as such it can be used under specific conditions ("appropriate safeguards") even beyond the duration of the project ("storage limitation"). A unique identifier (Pseudo-ID1) provided by the SC, is used to configure all the devices (e.g., smartwatch, (m)IoT, sensors, wearables) handed to a particular patient, while all associated data (PIIs have been removed or altered prior to this) reside in the main repository having a different identificator (Pseudo-ID2), allowing any analysis without revealing end-users identity. Since the SC is the only component that maintains encrypted this association, whenever it will be necessary to send or receive data, changes are made by the SC prior to transmission or digestion respectively, while the real ID of the patient will not be conveyed to SB@Cloud. The full process is depicted in Fig. 5.3.

Pseudonymised data personal health records, devices/sensors big data, questionnaires, interventions, usage data from synergies projects, stored in the Data Repository are subjected to different types of analysis, including statistical analysis techniques and data mining techniques, to obtain the evidence needed in order to offer personalised interventions promoting their healthy and independent living.

PIIs removal techniques used were introduced in [10] and properly enhanced to meet SMART BEAR needs. By design, data kept in the SC will no longer be needed to conduct the research (e.g., analytics, interventions), and consequently will be erased and not further used for any data processing.

Device security two main components are exploited for authenticating a device (SMART BEAR smartphone, or devices of any collaborating project): (*i*) a unique identity key or security token for each device; (*ii)*) an on-device X.509 certificate and private key. In a typical operation, the token is used for authentication for each message transmitted. The certificate file and private key are used to secure the communication among devices by validating the transmitted messages and encrypting data at rest.

Connectivity security seamless communication is supported by relevant protocols, such as the Advanced Message Queuing Protocol (AMQP),[15] Message Queuing Telemetry Transport (MQTT),[16] and HyperText Transfer Protocol (HTTP), and is safeguarded by their own security mechanisms, like for instance TLS for HTTP (HTTPS).

Within the SC, a security/privacy platform provides privacy-preserving and secure by design data handling capabilities, covering data at rest, in processing, and in transit, and all components and connections, offering a real-time healthcare monitoring framework, under which key functional, quality, usability, security and privacy conditions will be fulfilled to ensure the acceptability of SMART BEAR by its targeted users.

In conclusion, the SC provides a service to manage *privacy-related requests* issued by the end-users and forward them to the responsible System Administrators for processing. The end-users may issue a request via the mobile application (SB@App) by which they can also track status, follow-up, and provide feedback to those handling their requests. In this context, an Auditor may also track the progress of the request and see who is currently working on it.

5.2.3.1 Data Repository

The Data Repository component of the SB@Cloud exploits a combination of FHIR-compliant and non-FHIR databases. All the data that represent medical entities are stored in the FHIR database while data related to non-medical entities are stored in a relational database of the Cloud back-end. The latter contains elements that are not mapped to FHIR models (such as the SB Dashboard user settings), and intermediate results of the analytic models, which in turn can relay data back to the FHIR database after additional processing. The SMART BEAR FHIR database stores HL7 FHIR standardized medical data. HL7 FHIR is based on the concept of "resource", which are medical-related concepts; being the basic pieces of information that makes sense

[15] https://www.amqp.org/.

[16] https://mqtt.org/.

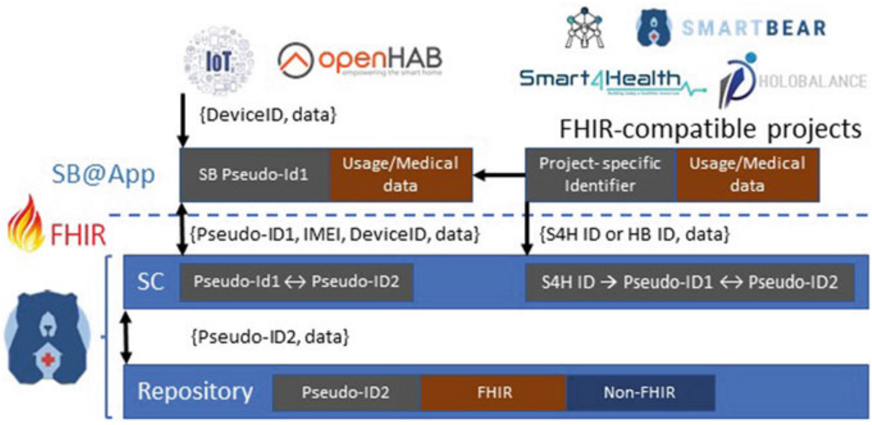


Fig. 5.3 SMART BEAR pseudonymisation supported mechanism

to exchange. The HL7 FHIR integrates medical terminologies such as SNOMED-CT and LOINC that complement the FHIR HL7-based coded values.

5.2.3.2 BDA Engine

The BDA Engine mainly addresses the functionalities required for processing Data Analysis Workflows (DAWs) and providing/storing their execution results. The BDA engine exposes a set of APIs to compute and get raw data in order to perform analyses from the FHIR and non-FHIR repositories. In terms of Machine Learning (ML), a preliminary extraction of data analytics, that will be carried out on pre-processed datasets, are going to indicate variables or combinations of variables for the feature selection approaches.

The preliminary extraction of data analytics is performed by the following sub-components, featured in the BDA Engine architecture: Delta Lake,[17] Spark,[18] Trino,[19] and Airflow.[20] The components are described below by following a bottom-up approach, the layer at the bottom being the closest to the data repositories. The architecture is shown in Fig. 5.4 and is an extended version of the one presented in [11].

Delta Lake is an ACID table storage layer over cloud object stores and is the component closest to the repositories. Delta Lake enables incremental data update, data versioning, and schema evolution.

[17] https://delta.io/.

[18] https://spark.apache.org/.

[19] https://trino.io/.

[20] https://airflow.apache.org/.

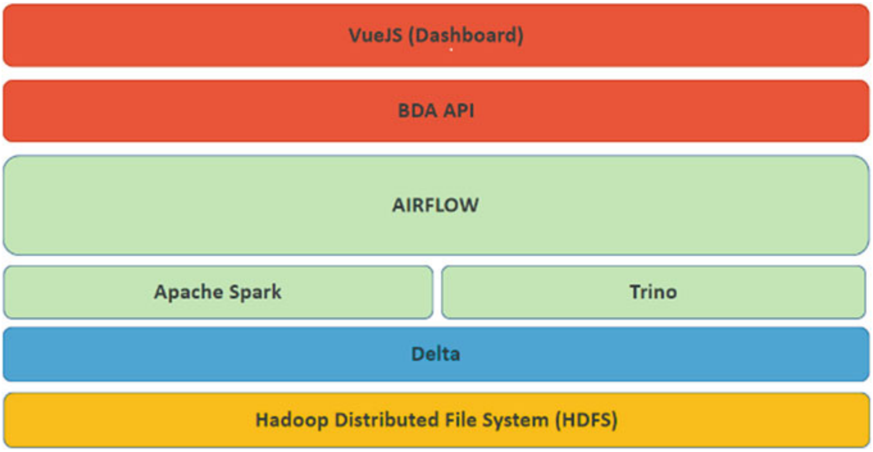


Fig. 5.4 The SMART BEAR BDA engine architecture

Spark and Trino are the components that provide the capability to access data and perform queries on the datasets. Concerning Spark, it is a multi-language engine for executing data processing and ML routines on single-node machines or clusters. Spark was chosen thanks to its capability of processing tasks that encompass custom analytics on large data volumes. In addition, it features many bindings with other commonly used Data Science and ML libraries. Spark is also capable to work both on batch and stream data.

Trino is the component providing the capability to access and perform parallel and distributed queries on data from multiple systems. Trino was chosen because it provides the BDA Engine with the capability of managing On-Line Analytical Processing (OLAP) queries and data warehousing tasks, and also because it can operate on many data sources in addition to data that is stored on HDFS.

Finally, Airflow is the component providing the capability to programmatically author, schedule, and monitor workflows written in Python language.

5.2.3.3 Decision Support System

The DSS provides functionalities for managing the Interventions, reasoning behind decisions proposed, analysis scheduling, and notifications for the clinicians and the patients.

Starting with the initial assessment, the DSS will assist the clinicians in terms of choosing the optimal set of clinical tools (i.e. exams, questionnaires, measurements) that will be used to assess each patient. Subsequently, by setting personalized thresholds for each patient individually, the clinicians configure the variables that will trigger the generation of Interventions for the patients.

For the first pilot of SMART BEAR, named Pilot of the Pilots (PoP), the DSS will rely on standard clinical practice, based on the clinical guidelines, to generate interventions for the patients, that will be delivered in the form of notifications and alerts to the smartphone of the participant. For each condition targeted in SMART BEAR (Hearing Loss, Cardio Vascular Diseases, Cognitive Impairments, Mental Health Issues, Balance Disorders, and Frailty), the clinicians are providing the rule-based conditions that trigger the corresponding Interventions, which act as a ground truth system, based on state-of-the-art medical knowledge. The interventions are regulated by the personalized thresholds for each patient and trigger notifications or alerts with severity gradation to both patients and clinicians as shown in Fig. 5.2c. For example, optimal and extreme cut-off values for Blood pressure are set for a patient with CVDs during the initial assessment, leading to a green notification when the Blood pressure measurement is within the optimal range, a yellow alert when a measurement is outside of the optimal range, and red alert when the measurement exceeds the extreme cut-off values. Utilizing the color coding for the generated notifications, the patients are getting feedback from the platform to stay healthy or seek medical advice in case the measured values are detected to be out of the limits set by the clinicians.

This initial version of the DSS is designed to evolve throughout the project, towards an ML-assisted DSS. Starting with the PoP, this evolution will be accomplished through the continuous training of the DSS by feeding the collected data to the models of the BDA engine. The outcome of the analytics following the measured parameters will provide suggestions on Interventions, targeting individuals or subgroups of patients, such as personalised thresholds modifications. For these suggestions to be integrated into the system, clinicians' approval will be required.

5.2.3.4 Dashboard

The SMART BEAR Dashboard is a component aimed at providing a user-friendly graphical user interface for the clinicians of the platform. The application is responsible for managing the interactions between the cloud platform and the users who must use it, to introduce patients into the system, enter clinical data, perform analytics on aggregated data and set the threshold value of parameters (e.g. Blood Pressure in the case of CVDs) that trigger the corresponding Interventions. For instance in Fig. 5.5 the Home page of the Dashboard is shown, and in Fig. 5.6 the form for creating Intervention is shown.

5.2.3.5 Continuous Integration and Continuous Deployment

The implementation of the above-described components and full platform integration process is performed by using well-known DevOps tools. This includes GitLab[21] for

[21] https://about.gitlab.com/.

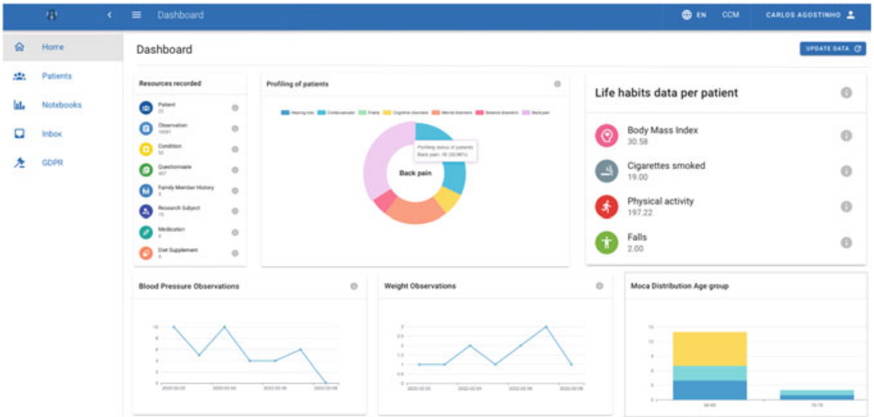


Fig. 5.5 The SMART BEAR dashboard

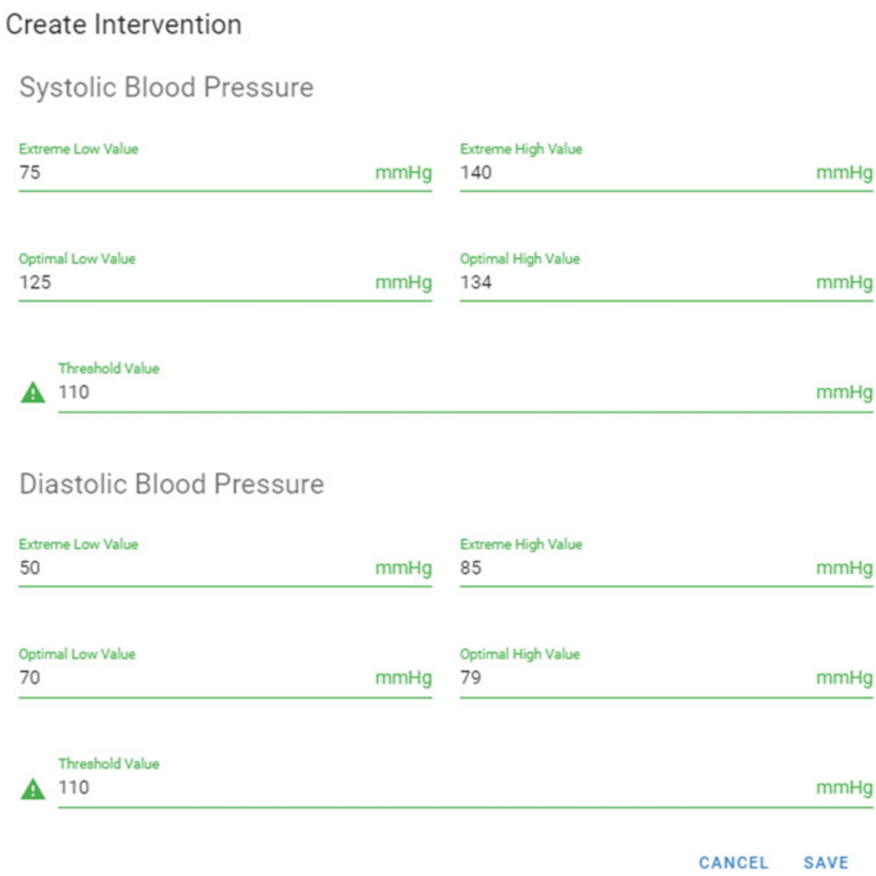


Fig. 5.6 The create intervention form on the SMART BEAR dashboard

source code repository and manage CI/CD practices, and the use of Kubernetes[22] clusters set up to provide test and production environments and managing the resulting containerized application. The SMART BEAR Gitlab repository[23] and CI/CD setup is administrated and maintained by Atos and the GitLab runner, that carries the process load needs, is installed in the Kubernetes cluster taking advantage of the same infrastructure.

CI/CD processes are based on the concept of pipelines, which describes the actions to be executed (build, test, deploy, etc.) and that are triggered automatically or manually when a component changes, automating those repetitive and worthless processes during development. Most of the configuration is concentrated in a component .gitlab-ci.yml description file.

Kubernetes is a portable, extensible, open-source platform for managing containerized workloads and services (containers orchestration), that facilitates both declarative configuration and automation. The clusters for test and production environments are each based on three nodes (independent Virtual Machines based on Ubuntu), one in the role of master (*smartbear-k8s-master*, control-plane node) and two others with the effective load of the application (*smartbear-k8s-node-0* and *smartbear-k8s-node-1*, worker nodes). In addition, the system itself provides security tools and permissions management via role-based access control, as well as resources grouping and isolation based on *namespaces*.

Having two worker nodes also allows the flexibility to reallocate resources, balance the load, perform any maintenance independently and, in the event of failure of one of them, keep the service available.

In practice, by preparing the appropriate manifest files and making them available to the CD mechanism, the rebuild and deployment of the platform are fully automatized to the cluster, which can be also monitored. In the case of needing to scale the infrastructure, along with providing the necessary resources, only minimal configuration adjustments would be necessary.

Another advantage of using this type of environment is the incorporation of the configuration and auxiliary infrastructure modules into the platform. For example, installing the GitLab runner or the NFS service that provides the persistence is performed via *Helm Charts*, which is a system that facilitates the installation of packages with the only need of informing the necessary variable parameters. In the case of the GitLab runner is enough to inform the *gitlabUrl* and a *runnerRegistrationToken*.

During the development of new functionalities for the platform as well as making corrections, the two differentiated environments allow the application to evolve with greater agility and less risk, facilitating the validation of changes and fixes before moving the changes and affecting the production environment.

22 https://kubernetess.io/.

23 https://scm.atosresearch.eu/ari/smartbear.

5.3 Clinical Interventions

As it has been mentioned in Sect. 5.1, SMART BEAR is a platform for elaborating and delivering personalized interventions, supporting Healthy Ageing through the monitoring of everyday activities. In the case of the Pilot of the Pilots, which serves as the scenario for testing the technical requirements, *Low back pain* is also targeted in addition to the six medical conditions mentioned in Sect. 5.1. The results from the Pilot of the Pilots are described in more detail in Sect. 5.4.

In general, from a clinical point of view the personalised interventions cannot substitute or replace the medical prescriptions and therapies doc in any way, instead, they will support both the patients in doing their daily activities and the clinicians or caregivers assisting them. Also, the SMART BEAR platform will deliver messages inviting the user to schedule an appointment with a doctor in the worst cases.

The description of Hearing Loss and its treatment is provided here in Sect. 5.3.1, demonstrating how the clinical knowledge is exploited in SMART BEAR to perform a specific training or collecting massive data from the devices in a fully transparent way for the patients. In the case of Balance Disorders, some patients will benefit from HOLOBalance https://holobalance.eu/., which is a virtual coaching platform for performing physiotherapy sessions and the description is provided here in 5.3.2.

5.3.1 Hearing Loss

Hearing Loss (HL) is affecting one out of three people over 65, while debilitating HL is observed in 6% of the global population (466 million people) [12]. It is currently estimated that, by 2050, HL will affect more than 900 million people, reaching 10% of the global population. Its management cost is estimated at 213 billion Euros for the European countries and 750 billion dollars, per annum, globally.

HL should not be considered an isolated health problem. Apart from the associated financial cost, HL is related to significant comorbidities as well. According to the Global Burden of Disease study, it is one of the 8 leading causes of living years with disability [13]. Multiple studies imply association of hearing impairment with psychological and physical diseases, such as cognitive disorders and dementia (reduction in cognitive performance associated with a 25 dB elevation of hearing threshold is equivalent to the reduction associated with an age difference of 7 years [14]), anxiety and depression [15] and higher mortality rate [16].

Although the only available and validated management solution that currently exists for HL is the fitting and use of hearing assistive devices, only 20% of the people needing one will seek, acquire, and continue using it [17, 18]. Key points to the efficacy of the use of such assistive devices, to the satisfaction and improvement of quality of life of their users and thus the minimization of drop-out risk is their proper fitting, the affordability, and accessibility of the follow-up services, and their proper combination with thorough and evidence-based personalized counseling and training.

The principal goal in current hearing aid fitting practices is the improvement of patients' overall quality of life. This improvement is significantly related to patients' participation in daily activities and to their listening ability [19]. Modern counseling is trying to take into account both these parameters, which are not static but rather change over time, by means of extensive interviews and frequent follow-ups. Nevertheless, recall bias, assessment in office conditions and limited time make optimal HAs configuration according to patients' individual needs still very challenging [17, 20, 21]. Therefore, "real-life" monitoring of patients' hearing and cognitive capacity, medical, and behavioral assessment in a continuous way is an important element of HA fitting, fine-tuning, and counseling [22, 23]. Consequently, it is evident that achieving the goal of hearing aid fitting and thus hearing rehabilitation demands knowledge, active monitoring, and dynamic adaptation of many more factors than the pure tone audiogram of the patients. Furthermore, although hearing assisting devices remain the main current approach for hearing rehabilitation and improvement of communication and life quality in Hearing Loss, there is evidence that additional practices, such as Auditory or cognitive Training (AT), may be able to elicit optimal conditions for neural plasticity and associated improvements in cognitive function [24]. SMART BEAR is by default designed to address all the aforementioned requirements for optimal hearing loss management and rehabilitation.

In SMART BEAR, we are addressing Hearing Loss through 12-month continuous monitoring of each HL participant (collection of heterogeneous data, such as demographics, audiometric data, information about the use of their HA or their performance on serious cognitive games or the auditory training, cognitive status, mental status, habits, biological and other information) through sensors and face-to-face and remote counseling and fitting/remote fine-tuning sessions with the audiologists of the project. A total of 1000 HL patients (200 patients per pilot) will be included in the study during a 2-year period. During their initial assessment, those HL participants will undergo otoscopy, tympanometry, pure tone audiometry (according to the British Society of Audiology standards). Moreover, their lifetime noise exposure will be estimated through a structured interview with the help of the clinician. According to the observations of this assessment, SMART BEAR audiologists will fit the SMART BEAR hearing aid unilaterally or bilaterally, according to each participant's needs. Fitting protocol and HA model will be common for all 1000 HL participants and will follow the common fitting practices. Moreover, HL participants will have access to the SMART BEAR Auditory Training mobile application and will be encouraged to complete a certain number of sessions (minimum 1 per week). During the project, according to predefined rules set by the SMART BEAR clinical researchers and based on previous literature and EVOTION experience, participants will be notified about how efficiently they are using their HA and about their performance on auditory training. According to the same rules, they will also receive notifications on how to improve their overall adherence to their hearing rehabilitation program (hearing aid +/− AT +/− serious cognitive games, etc). Predefined rules are currently based on established clinical guidelines. An example of such an evidence-based, predefined management scenario

Table 5.1 Interventions of the SMART BEAR platform for patients with HL

Scenarios*	Intervention	Frequency
Module A—HA compliance (Hours of usage)		
A1. Hours of usage within the target (>=10h per day)	A1. Green code: congratulating message through the SMART BEAR App	A1. Daily
A2. Hours of usage below the target (<10h per day)	A2. Yellow code: reminder of target hours of HA usage	A2. Daily
A3. Hours of usage below the target (<10h per day) on weekly average	A3. Yellow code: advice to consult SMART BEAR audiologist	A3. Weekly
A4. Hours of usage below the target (<10h per day) on weekly average for 2 consecutive weeks	A4. Red code: advice to consult SMART BEAR audiologist and repeat counselling or fine tuning	A4. Biweekly
PM1, PM4 and PM5 may affect this scenario: e.g., High levels of satisfaction in correlation with other than 10h of usage could modify this scenario; 10h is based on previous literature		
Module B—manual changes of HA program		
B1. Average number of manual changes of HA program per day over week, within accepted limits	B1. Green code: congratulating message	B1. Weekly
B2. High average number of manual changes of HA per day over a week	B2. Yellow code: Advice to consult SMART BEAR Audiologist and repeat counselling or fine tuning	B2. Weekly
* PM9 may affect this scenario: e.g., limits of number of manual changes of program may be altered during the project, according to their relationship to (GHABP) [24] satisfaction scores degrees of hearing loss, hours of usage, hours of usage in environments with various noise levels or other hearing-related factors and according to their relationship with other parameters, such as participant' comorbidities, age, sex, etc.		
Module C—auditory training (AT) compliance		
C1. Completion of target number of AT sessions per week	C1. Green code: congratulating message	C1. Weekly
C2. Omission of one AT session	C2. Green code: reminder that one AT session was missed. Reminder of benefits of AT	C2. Daily
C3. Omission of the AT sessions for a week	C3. Yellow code: advice to consult SMART BEAR audiologist	C3. Weekly
C4. Omission of the AT sessions for two consecutive weeks	C4. Red Code: advice to consult SMART BEAR audiologist	C4. Biweekly
* PM2, PM3 and PM6 may affect this scenario: e.g., the number of target AT sessions per week could be adjusted according to relations discover between AT adherence and satisfaction scores (GHABP), degrees of hearing loss, hours of usage, hours of usage in environments with various noise levels or other hearing-related factors and according to their relationship with other parameters, such as participant's comorbidities, age, sex, etc.		

for patients with Hearing Loss is provided in Table 5.1, along with the possible clinical implications ML-analysis outcomes could have. Variables that will be assessed throughout the project are reported in Tables 5.2, 5.3, 5.4, 5.5, and 5.6.

In particular, during the project, dynamic analysis of the collected data prediction models will be developed in order to enable a better understanding of those factors that play a significant role in the success of a hearing rehabilitation program:

PM1 Identification of those characteristics that make patients more prone to drop out and quit using their hearing aid (*Prediction model for HA dropouts*).

PM2 Identification of those characteristics that make patients more prone to drop out from their rehabilitation program (AT) (*Prediction model for hearing rehabilitation dropouts*).

PM3 Identification of those characteristics that can predict patients' adherence (number of sessions) to AT (*Prediction model for AT adherence*).

PM4 Identification of those characteristics that make patients more prone to use their hearing aid efficiently long during the day (*Prediction model for hearing aid hours of usage*).

PM5 Identification of those factors augmenting the satisfaction of patients from using their hearing aid (*Prediction model for HA usage satisfaction*).

PM6 Identification of those characteristics that make patients more prone to perform better in AT tasks (*Prediction model for AT performance*).

PM7 Identification of those factors decreasing the number of needed face-to-face sessions with their Audiologist for counseling and/or hearing aid fine-tuning (*Prediction model for a number of visits at the Audiologist's office*).

PM8 Identification of those factors decreasing the number of needed remote sessions with their Audiologist for counseling and/or hearing aid fine-tuning (*Prediction model for some remote fine-tuning sessions with the Audiologist*).

PM9 Identification of those factors decreasing the number of manual changes of hearing aid program (as an indication of poor sound quality and bad adaptation of hearing aid configuration to patients' real needs and daily challenges, *Prediction model for a number of changes of hearing aid program*).

As a results, our findings shall provide insights on the optimal way patients with hearing loss should be classified into patients of high or low risk of hearing rehabilitation dropout, patients with higher probability to benefit from the hearing aids or the AT, patients that will likely seek more frequently the remote or face-to-face help of their Audiologist. This newly gained insight will help the SMART BEAR clinical researchers in two directions:

1. Optimization of the SMART BEAR DSS will be considered. Following validation for their safety and relevance by SMART BEAR clinicians, models will be evaluated in the production environment. In other words, knowledge gained through the analysis will be evaluated by the SMART BEAR clinical researchers for its relevance and its safety and then it will be directly implemented in the SMART BEAR project.
2. New research hypotheses will be created and shall be tested in the context of future clinical trials.

Table 5.2 Outcome variables for hearing loss—related prediction models

Prediction models	Outcome variables	Acronym	Description	Value type
PM1 dropouts	Dropout number	DROPOUT	No. participants who stopped using the hearing aid (HA)	Integer
	Dropout	DROP	Dropout of HA usage, as no usage for more than 7 consecutive days	YES/NO
PM2 hearing rehabilitation dropouts	Drop out of auditory train. (AT)	DROPAT	No. session of AT for 3 consecutive days	YES/NO
PM3 AT adherence	AT sessions per week	AT	no. AT sessions per week	Integer
PM4 hearing aid active use	Time of HA usage	HAUSAGE	Average time of usage	Minutes/day
PM5 hearing aid satisfaction	Overall HA usage satisfaction satisfaction	GHABP	Score on GHABP	Integer
PM6 AT performance	AT score	ATSCORE	Average score of AT sessions till that particular point	Integer
PM7 no. visits at the Audiologist's office office	Visits to audiologist's office	VISIT	No. necessary audiologist's visits to the audiologist's office	Integer
PM8 Remote fine tuning sessions with the audiologist	Remote sessions with the audiologist	FINETUN	No. necessary remote meetings for counselling or remote fine tuning with the audiologist	Integer
PM9 changes of HA program	Need for manual change of HA program by the user	PROGR	No. changes of HA program per day till that point	Integer

5.3.2 Balance Disorders

Basic human behaviors such as maintaining posture at rest and in motion, keeping clear vision while moving and navigating through complex urban environments, are highly sophisticated functions. They rely on the harmonized integration of afferent sensory signals, mainly from visual, vestibular and musculoskeletal systems, within the Central Nervous System. Common everyday activities, such as walking and talking to the phone, demand additional attention, and thus specific cognitive functions, named as executive function, plays a crucial role for normal postural control.

Unavoidably entropy forces these functions to decline over the years, making age related progressive loss of sensory information one of the major factors responsible for the increase in fall risks in older adults [43]. Comorbidities like sarcopenia, cognitive impairment, neurogenerative diseases, ageing vision, polypharmacy, mood disorders, decreased intrinsic motivation, deprives elderly from proper sensory re-weighting. As a result, physical inactivity and increased sedentary time produce a continuous spiral of organs degeneration leading to additional functional impairments, fear of falling and eventually frailty [44]. These factors raise the risk of injury-related falling and interfere with the body's effort to restore homeostasis [45].

Table 5.3 Covariates—predictor variables for hearing loss

Covariates	Acronym	Description	Value type
Time	TIMEC	Time as continuous variable in order to link each data item to specific time points	Continuous
Age	AGE	Years of age	Years
Biological gender	SEX	Female or male	F/M
Hearing loss type	HLTYPE	Predefined text for specific types of hearing loss	–
Hearing loss chronicity	HLCHRNCTY	Years since diagnosis of hearing loss	Years
Side of hearing loss	SIDE	Right, left, bilateral	–
Ear side	EAR	Right/left (in	Order to correspond HL/fitting)
Fitting side	FIT	Right/left/bilateral	–
Degree of hearing loss	HLDGREE	Predefined text for clinician to choose according to part. pure tone audiogram	–
Baseline pure tone threshold per frequency for right ear	PTAR	Mean value of PTA threshold at 0.5–4 kHz (right ear)	dB HL
Baseline pure tone threshold per frequency for left ear	PTAL	Mean value of PTA threshold at 0.5–4kHz (left ear)	dB HL
Baseline pure tone threshold per frequency for right ear	PTAR0.5-8kHz	Mean value of PTA threshold at 0.5–8kHz (right ear)	dB HL
Baseline pure tone threshold per frequency for left ear	PTAL0.5-8kHz	Mean value of PTA threshold at 0.5–8kHz (left ear)	dB HL
Drop out	DROP	Dropout of HA usage	YES/NO
Time of HA usage	HAUSE	Average time of usage per day till that particular point	Minutes
Number of visits to audiologist's office	VISITS	Number of necessary visits to the audiologist's office	Integer
Overall HA usage satisfaction	GHABP	Total score on GHABP and per situation	Integer
Percentage of usage per environment	ENVRNMT	Average percentage of time spent in the predefined environments per day	%
Noise exposure	NOISE	Average noise exposure per day	dB SPL × Time AND dB TWA
Manual adjustments of volume	VOLUME	Average number of manual adjustments of volume by the part	Integer
Manual adjustments of program	PROGRAM	Average number of manual adjustments of programs (already loaded on the HA)by the participant	Integer

Table 5.4 Covariates—predictor variables for hearing loss

Covariates	Acronym	Description	Value type
Age	AGE	Years of age	Years
Age group	AGEGROUP	Per 5 years (65–70, 71–75, 76–80)	–
Biological gender	SEX	Female or male	F/M https://bit.ly/35jmbwQ
Ethnicity	ETHNOS	Predefined text for ethnic groups	–
Education level	EDU	Predefined text for education levels (categorical)	–
Living situation	LIVST	Predefined text for living status (categorical)	–
Diabetes (Mellitus)	DM	Predefined text for diabetes type (categorical)	–
Diabetes	DIABETES	Diagnosis or not of diabetes of any type	YES/NO
Hearing loss	HL	Diagnosis of hearing loss of any type	YES/NO
Fall over the last 12 months	FALL	Occurrence of fall during the last 12 months	YES/NO
Number of falls over the last 12 months	FALLS	Number of falls during the last	Integer
Weight Loss	WL	Unexplained significant weight loss during the last 12 months	YES/NO
Depression disorder	DPRSSN	Diagnosis of depressive disorder of any type/degree	YES/NO
Anxiety disorder	ANX	Diagnosis of anxiety disorder of any type/degree	YES/NO
Other medical history	MH	Diagnosis of any other comorbidity	YES/NO
Cognitive issues	CGNT	Diagnosis of cognitive issues of any type	YES/NO
CVD history	CVD	Diagnosis of CVD of any type	YES/NO
Score of geriatric depression scale [25]	GDS	Total score of GDS	Integer
Dexterity question (From HUI3 questionnaire)[26]	DXT	Score	Integer
MOCA questionnaire[27]	MOCA	Total score	Integer
MOCA—Alternating trail making	MOCA1	Alternating trail making relevant question score—Q1	Integer

According to the WHO global report, one out of three people older than 65 years old fall each year and this prevalence increases for people older than 70 years old. Falls are the second leading cause of accidental death after road traffic accidents. In the EU, an average of 35,848 older adults (65 and above) are reported to have died on an annual basis due to serious injuries caused by falls. This figure is expected to be an underestimation of the true deathly falls rate which probably is much higher. A recent study analyzing data from more than 200 hospitals from across Europe has estimated that every year within the EU, 3.8 million older people attend emergency

Table 5.5 Covariates—predictor variables for hearing loss

Covariates	Acronym	Description	Value type
MOCA visuoconstructional skills	MOCA2-3	Sum of visuoconstructional skills relevant questions score—Q1 and Q2	Integer
MOCA—naming	MOCA4	Naming related question score—Q4	Integer
MOCA—Memory 1st trial	MOCA51	Memory related question score—Q5 1st trial	Integer
MOCA—Memory 2nd trial	MOCA52	Memory related question score—Q5 2nd trial	Integer
MOCA—attention	MOCA6-8	Sum of attention-related questions score—Q6-8	Integer
MOCA—attention	MOCA9-10	Sum of language-related questions score—Q9-10	Integer
MOCA—abstraction	MOCA11	Abstraction-related question score—Q11	Integer
MOCA—delayed recall	MOCA12	Delayed recall-related question score—Q12	Integer
MOCA memory index score (MIS)	MIS	MIS score	Integer
MOCA—orientation	MOCA13	Orientation-related questions score—Q13	Integer
Drinking OH	OH	Average units per day (self-reported)	OH Units
Smoking habits	SMOKING	Pack of smoked cigarettes per day × years of active smoking	Pack years
PHQ-9 questionnaire [28]	PHQ9	Score	Integer
MDPQ questionnaire [29]	MDPQ	Score	Integer
EQ-5D questionnaire [30]	EQ5D	Score	Integer
FES-I questionnaire [31]	FESI	Score	Integer
EFS questionnaire [32]	EFS	Score	Integer
Godin leisure time questionnaire [33]	GLTQ GLTQ	Score score	Integer
Single item sleep scale [34]	SSQ	Score	Integer
IADL questionnaire [35]	IADL	Score	Integer
RGA questionnaire [36]	RGA	Score	Integer
FGA questionnaire [37]	FGA	Score	Integer
Mini BEST questionnaire [38]	MBEST	Score	Integer
RAPA questionnaire [39]	RAPA	Score	Integer
ABC questionnaire [40]	ABC	Score	Integer
MNA questionnaire [41]	MNA	Score	Integer
HEART score [42]	HEART	Score	Integer
Diastolic blood pressure	DIASTLC	mmHg	Integer
Systolic blood pressure	SYSTLC	mmHg	Integer
Heart pulse	PULSE	Number of heart beats per min	Integer
Irregular heart beat	IRR	Detection of irregularity in heart rate	Integer, 0= not present, 1=present
Number of episodes of irregular heart beat	IRRN	Number of episodes of irregularity of heart beat till that time point	Integer

Table 5.6 Covariates—predictor variables for hearing loss

Covariates	Acronym	Description	Value type
Body temperature	Tbody		°C, integer
Body weight	BW	Timestamped AND average body weight per week	kg, floating point
Body fat	BF	Timestamped AND average body fat per week	%, floating point
Body mass index (BMI) (advertised)	BMI	$weight/height^2$, Timestamped AND average per week	Floating point
Body water	BWATER	Timestamped AND average per week	%, floating point
Body lean mass (advertised)	BLM	Timestamped AND average per week	kg, floating point
Body muscle mass	BMM	Timestamped AND average per week	kg, floating point
Blood oxygen saturation	Bloodoxygen	Timestamped and average per day and per week	%, integer
No. desaturation episodes	DESATURATION	SaO_2<92% episodes	Integer
Active kcal (dietary cal.) burned through actual movement and activity during the monitoring per period	ActiveKilocalories	Average per day	kcal, integer
Cumulative duration of activities of moderate intensity, lasting at least	moderateIntensity DurationInSeconds 600 s at a time. Moderate intensity as activity with MET value range 3–6	Average per day	Seconds, integer
Minimum of heart rate values captured during the monitoring period, in beats per minute	minHeartRate InBeatsPerMinute	Per day	BPM, integer
Average of heart rate values captured during the last 7 days,in beats per minute	averageHeartRate InBeatsPerMinute	Per week	BPM, integer
Average heart rate at rest during the monitoring period, in beats per minute	restingHeartRate InBeatsPerMinute	Timestamped Timestamped	BPM, integer BPM, integer

departments (ED) with a fall-related injury; 1.4 million people need to be admitted to hospital for further treatment [46]. This fact makes falls the predominant cause (58%) of injury-related to ED attendances and costs to the EU at least 25 billion euros every year [46, 47]. As the population of the elderly in Europe is expected to grow by 60% by 2050, the number of fall-related deaths is expected to increase to almost 60,000 by 2050. This could result in annual fall-related expenditures exceeding 45 billion euros by the year 2050. Vestibular deficits are diagnosed in the majority of the fallers, since 80% of the adults with an unexpected fall suffer by an inner ear pathology affecting postural control [48]. Older adults with moderate cognitive impairment tend to fall twice as often as older adults with no cognitive decline [49].

The necessity to develop more efficient prevention strategies is widely recognized [50]. Worldwide interest has been focused on promotion of physical activity, muscle strengthening, gait and balance physiotherapy and cognitive training as the major pillars integrating to a multi-factorial, physical rehabilitation protocol, targeting falls prevention. Additionally, vision management, for the avoidance of further sensorial deprivation, concomitant medication for the identification of side effects or potential interactions, are functions that should be assessed in the context of an individualized multifactorial integrated solution [50].

A balance exercise regime, provided by a physiotherapy and/or a certified health professional, is an effective method for reducing the postural instability [51], symptoms arising from vestibular deficits [52], fear of falling and eventually falls [53] as well as for increasing functionality, physical activity and consequently social participation. Balance rehabilitation protocols are either personalized [54] and/or home-based [55] consisting of a multi-sensory set of exercises, having as a goal the re-weighting of sensory inputs, central nervous adaptation, coordination of the body segments, optimal selection of postural adjustments, strengthening and stretching used as appropriate. Both types of intervention are considered as a safe and effective treatment methods and minor side effects have reported.

Supervision promotes adherence to the program, ideally improving it, but its absence increases the withdrawal rates from rehabilitation protocols [56, 57]. Additionally, low levels of motivation [58], lack of information regarding on health benefits gained from targeted exercise [59], lack of specialized health care personnel and socio-economic factors [60] raise barriers to adherence.

Nowadays, most of the efficient falls prevention rehabilitation programs involve either a group-based practice or a home-based exercise regime [61] producing benefits in functional ability and mobility, without any reported clinically important difference [62]. The OTAGO exercise program (OEP) it is a well described falls prevention program, flexible in its implementation, which can be either home or community based. It consists of warm up and cool down phase, strengthening balance and gait exercises as the main pillars of the program, and can be performed either on a group or in personal [63–65]. It is a well-documented and structured tool, disseminated widely to the physiotherapy community as it offers a significant reduction of morbidity and mortality and falls for the participants in a one-year prevalence time [66]. Participants usually perform the exercises at least three times per week at home with each session last no more than 30 min. The closest supervision is performed by the clinician in the first 8 weeks of the program which is suggested to last in total 12 months. In order to promote more efficient outcomes, OEP is also given as an illustrated booklet in four different levels of difficulty (beginners, intermediate, advanced and experts). Several modified versions of OEP including augmented reality [67], extra exercise modules [68, 69] or a DVD [70] are targeting to increase efficiency through more customized approaches. As far as we know, there was not a solely personalized solution in order to overcome hazards arising during the assessment and /or intervention for people with Balance Disorders, that took into account all the aforementioned factors.

HOLOBalance is a beyond the state-of-the-art, virtual coaching platform for engaging patients with recorded falls and/or tendency to fall, into a multimodal balance and gait physiotherapy exercise protocol, including balance and gait exercises, gamified exercises, cognitive games, auditory training and a physical activity application designed and performed by a multidisciplinary consortium (otolaryngologists, physiotherapists, neurologists, gerontologists) provides participants with individualized exercises according to their needs by displaying a 3d hologram reproducing a physiotherapist via an augmented reality environment. Data from motion capture sensors and wearable sensors (smart bracelet, smart glasses, pressure insoles) are feeding AI algorithms for exercise performance, behavioral analysis in terms of frustration, and a Decision Support System for progression of the exercise plan. These deep reinforcement learning models are continuously updating the patients' profiles with respect to their compliance to the exercises, their performance and their longitudinal progress, providing feedback to the clinicians through platform's dashboard. The HOLOBalance ecosystem through its multi-layer modules helps users comply with their treatment plan and coach them in order to achieve maximum effect [71].

On the SMART BEAR platform, Balance Disorders are monitored and discriminated through a six steps ruled-based screening procedure:

1. A history of previous falls
2. Medications intake
3. Presence of at least two of the following symptoms: unsteadiness, motion sickness, oscillopsia, difficulty walking on uneven surfaces, difficulty walking in the darkness, drunken feeling, lightheadness, disorientation, tendency to fall
4. A score greater than 9 in the short form of Falls Efficacy Scale- International [72]
5. Abnormal score at least on the Timed Up and Go test [73] (AND/OR)
6. Abnormal score on the Romberg test on foam are the indications for a more detailed functional assessment of postural control.

SMART BEAR participants with confirmed balance disorders will be considered eligible for one of the two interventions offered during a multi-centre clinical study for balance rehabilitation, HOLOBalance intervention at home and OEP intervention via a mobile phone, lasting for eight consecutive weeks.

The OEP intervention is a fully automated modified version of the fall's prevention program described above. The training preparation procedure is defined in Algorithm 1. Specific scenarios were developed for addressing issues that may arise from the occurrence of yellow and red flags or CVDs-related and/or issues related to compliance and safe implementation of the OEP program (muscle soreness, persistent pain, chest pain, severe dizziness, shortness of breath, fall). These scenarios are addressed with messages in compliance to Algorithm 2. Predefined rules for progressing levels had been also established and are described in Algorithm 3.

The HOLOBalance has already been proved a safe, feasible and effective intervention. Its implementation to a larger sample size will give a better understanding

Table 5.7 The prediction models for HOLOBalance

Prediction models	Outcome variables	Description	Modelling tools	Expected impact relevant actions
PM1 HOLOBalance outcome measures improvement	HOLOBalance score	Average score for each performed exercise	Random Forest + SHAP (Explainability) instances: daily usage data	Patients with high expected outcome will be endorsed. Patients with low expected benefit will be considered for a more intensive training
PM2 HOLOBalance deviation in exercises performance	Number and degree of dedication in exercises, in terms of speed,range of movement and duration	Average number of reported symptoms for each performed exercise	Bayesian classifier+time series instances: dropout patients	Deviations which do not affect the outcome will be adapted. Exercises will be optimised and re-evaluated if the thresholds in speed,range and repetitions are effective
PM3 HOLOBalance technical issues	Technicians' involvement	Number of times technicians should be involved in HOLOBalance operation remotely	Random Forest + SHAP (Explainability) instances: daily usage data	Increased time and effort for education and explanation will be allocated during initial assessment
PM4 HOLOBalance occurrence of symptoms related to time	This model will predict the onset of symptoms during the exercises	Severity of symptoms provoked by the completion of the exercises (mild-moderate-severe) and recorded by the HOLOBalance platform with voice recognition	Bayesian classifier+generative models instances: dropout patients	Reduced time for particular exercises will be considered if symptom occurrence is predicted.HOLOBalance will stop an exercise a few seconds before any symptoms occur automatically. (generic time 1 min)

of parameters and patient profiles that could affect outcome on a beyond the-state-of-the-art balance rehabilitation program delivered in a mixed reality environment. The prediction models which will be developed are presented in Table 5.7. Following the same brainstorming procedure, clinical researchers developed prediction models for analyzing data collecting for the implementation of the OEP intervention in order to understand not only the factors that could affect outcome but also variables which will determine the profile of the people who will benefit the most as well as safety and Optimization.

Algorithm 1 OTAGO training preparation scenarios

if All features are within optimal range on daily average /weekly average / average of 2 consecutive days measurements **then**
    Practice is allowed - The following message will appear:
    Allow to practice. Please proceed.
end if
if BP values are outside the optimal range (yellow code in case of CVDs) in average daily /weekly average / average of 2 consecutive weeks measurements **then**
    Te following message will appear
    BP levels seems to be out of range. Ask for clinician's permission. Proceed with caution.
end if
if BP values are outside of optimal levels of CVDs at any time point **then**
    Red alert - Practice is not allowed - The following message will appear:
    Enter is not allowed. Please ask for help.
end if
if A fall has occurred on practice day **then**
    if The clinician has allowed the exercise **then**
        Practice is allowed with caution - The following message will appear:
        Exercise with caution. Do you have freed up the space where you will exercise? (YES/NO)
        if YES **then**
            Please have fully hand support despite the level of the platform.
            Set off the messages
        end if
    else
        Red alert - The following message will appear:
        Enter is not allowed. Please ask for help.
    end if
end if
if The user is experiencing a persistent pain OR severe shortness of breath OR significant unsteadiness on a scale 1-10 **then**
    Red alert - Practice is not allowed - The following message will appear:
    Enter is not allowed. Please ask for help.
else
    if Score 0-5 out of 10 **then**
        Access is allowed
    else
        if Score 6-7 out of 10 **then**
            Practice is allowed with caution - The following message will appear:
            Fully hand support despite the level of perform. Exercise with caution.
        end if
    end if
end if

Algorithm 2 Rules for Messages

```
while Doing exercises do
  Are you feeling well? (YES/NO)
  if no answer for > 1 minute then
    Screen will switch off
    Recorded action will be NOCOMPLIANCE
  end if
  if answer = YES then
    Proceed
  end if
  if Answer = NO then
    The following messages will appear:
    Q1. Are you experiencing joints/muscles pain during exercises? (YES/NO)
    if Answer = NO then
      Proceed
    else
      if Answer = YES then
        Please check your position for proper performance
      end if
    end if
    if no answer for > 1 minute then
      Screen will switch off
      Recorded action will be NOCOMPLIANCE
    end if
    Q2. Are you experiencing chest pain? (YES/NO)
    if Answer = NO then
      Proceed
    else
      if Answer = YES then
        The user has to ask for medical advice
      end if
    end if
    if no answer for > 1 minute then
      Screen will switch off
      Recorded action will be NOCOMPLIANCE
    end if
    Q3. Are you experiencing severe dizziness? (YES/NO)
    if Answer = NO then
      Proceed
    else
      if Answer = YES then
        The user has to ask for medical advice
      end if
    end if
  end if
end while
```

Algorithm 3 Rules for Level Progression in the OTAGO training

if in 3 consecutive sessions question answer in A6 scenario $<$ 2/10 **then**
  ADD the following message in same session:
  Do you feel that you could perform the balance exercises easily? (YES/NO)
end if
if YES **then**
  proceed to the next level
else
  if NO **then**
    Keep the same level, repeat the question above in the next session
  end if
end if

5.4 Initial Implementation and Testing

Five large-scale pilots, spanning across six different countries (Greece, Italy, Portugal, France, Spain, Romania), will be developed to demonstrate project achievements, recruiting 5100 elderly participants. The research project and its protocol are designed under the same philosophy in all involved pilot countries.

As said above, the Pilot of Pilots in Madeira, Portugal, is a smaller pilot that will include 100 patients to demonstrate, early in the project, the concept feasibility prior to the kick-off of the large-scale ones. It has the main objective to test the first release of the SMART BEAR technical infrastructure, and demonstrate the synergies implemented with other EU projects such as Smart4Health[24] and HOLOBalance, highlighting mutual cooperation and interaction between complementary solutions.

Concerning the synergies, Smart4Health aims to empower EU Citizens with an interoperable and exchangeable European Electronic Health Record (EHR) that will allow EU citizens to be active participants in managing their own health: in particular the synergy with Smart4Health focused on the Low Back Pain (LBP), which is included as additional condition [74].

The initial phases of the PoP were more of technical nature, configuring the necessary infrastructure for secure data collection from low-back pain and balance rehabilitation programs in the frame of the synergies. The selection and preparation of the wearable devices have been among the main activities, proving the initial sets of data for the SMART BEAR platform to provide early analytics and personalization strategies.

An initial demographics assessment of the target population was made to prepare the patient recruitment and a small-scale procurement has been done according to the estimates of comorbidities. At the time of writing, with a few months into the patient monitoring phase, 22 elderly participants were recruited and fully evaluated in the baseline assessment, providing individual medical background to the SMART BEAR platform.

[24] https://smart4health.eu/en/.

During the baseline assessment the candidates share their demographics information with the clinicians and they are visited by them based on their clinical history.

All the candidate participants must be of age between 65 and 80 years old and their clinical history including at least two of the following conditions: Hearing Loss, Cardio Vascular Diseases, Cognitive Impairments, Mental Health Issues, and Balance Disorders, as well as Frailty.

In order for the research to be compliant with the GDPR, the clinicians must provide clear information about the SMART BEAR project to the candidates, in particular concerning the data to be collected. An Informed Consent Form (ICF) signed by the candidates as a statement of the willingness to participate to the subsequent phases of the project.

Concerning the case of the Pilot of the Pilots all the patients have LBP in addition to two other comorbidities, 18 of them are already following the Smart4Health MedX physiotherapy sessions protocol, and three the HOLOBalance program, hence are sharing data between projects and demonstrating the technical synergies. In addition, over 18,000 observations have been collected from the wearable devices and more than 400 questionnaires are available in the data repository. Also two specific ICFs must be handed for the participants to express their willingness to participate respectively to the HOLOBalance and Smart4Health projects.

5.4.1 Data Insights on the Platform

The triggered clinical activities were enough to collect the first impressions from the clinical team. Data resulting from SMART BEAR will undoubtedly be promising, allowing a better understanding of the health of the elderly and helping in the future to establish predictive data associated with the comorbidities under study and their interaction with one another, creating personalized data for better and sustainable population aging. Thus, SMART BEAR could pave the way for new trends at the primary health care level allowing an early and predictive intervention within the comorbidities under analysis. Up to the moment, with the numbers involved, the analytic models provided in Sect. 5.3.1 is under development and the team is confident they will improve significantly during the project duration as it is possible to verify through the continuous updates to the platform being released on a periodic basis.

As described in Sect. 5.2.3.4, one of the key challenges of the project is to develop an easy-to-use Dashboard to provide clinicians access to all key capabilities of the platform, including data management or data analytics functionality, support decision making, and interventions, through different types of visualization techniques. The Dashboard is being used to register participants and upload assessments results and questionnaires and is providing some baseline descriptive analytics.

On the top left side of Fig. 5.5, one can see the navigation menu of the Dashboard, providing data directly taken from the first testing activities. The home page is the entry point for the clinician and displays a number of insights on the data being collected as well as some descriptive analytics.

On the top center of the figure, the clinicians have access to a simple pie chart where they can see the distribution of patients per comorbidity. For instance, at the moment 18 patients marked with LBP (33.96% of the sum of comorbidities in patients with data) are already sending data corresponding to back pain. This number corresponds to the patients that have initiated the MedX exercises.

Also, going into the detail of the observations being collected per device type per day, visible in the bottom left side of Fig. 5.5, the variation of the observations being taken by the patients becomes clear. As expected, the number of readings from the Smart Blood pressure monitor is higher than the ones from the smart scale, which according to the clinical protocol are expected to be taken once a week. Nevertheless, the numbers of the blood pressure readings are lower than expected. Each patient should take at least one measurement per day (the clinical protocol of SMART BEAR recommends two), and since the PoP has 17 patients with Cardiovascular Diseases that have already received a Blood pressure monitoring device, this figure highlights that not all patients are complying with the expected measurements and they should be contacted.

The Dashboard also provides a quick outlook on some health and well-being indicators (right side of Fig. 5.5). Indicators such as average body mass index, calculated using the initial assessment data and the collected weight from the smart scales use, physical activity, calculated using smartwatch data, or questionnaire results analysis per patient profile are already available. MoCA questionnaire results distributed by age group illustrate that in the group between 70 and 79 years old, MoCA results are lower, with zero questionnaires scoring above 26. Predictive analytics are currently being developed and not yet available for the PoP public use, which will allow automatic understanding and provision of interventions based on the collected data.

5.4.2 Data Insights on the SB@App

Discussions with the recruited participants reveal that they are overall satisfied with the technological solutions presented. They seem to have the general feeling of empowerment for their health and are effectively active on the path to healthy and independent living, seeking alternative solutions to monitor their health conditions. Participants recognize the innovative solution presented and the effectiveness of the equipment. They also note that the delivered devices are new-generation ones, making it possible to collect information that they would otherwise have no way of obtaining. On the downside, dealing with technology is often challenging for the elderly, and participants often struggle with uploading and updating data, device synchronization issues, and the number of tasks to perform daily with SMART BEAR that sometimes is overwhelming for them (e.g. too many devices and too many measurements). Fewer devices will probably produce better long-term results.

Through the SB@App, the patient has access to all the data being collected by the wearable devices and the SB@Home kit. As depicted in Fig. 5.7, it is possible to see live measurements as, for instance, the weight (“peso” in Portuguese) collected by the Smart scale, daily statistics such as sleep statistics (“estatisticas do sono” in

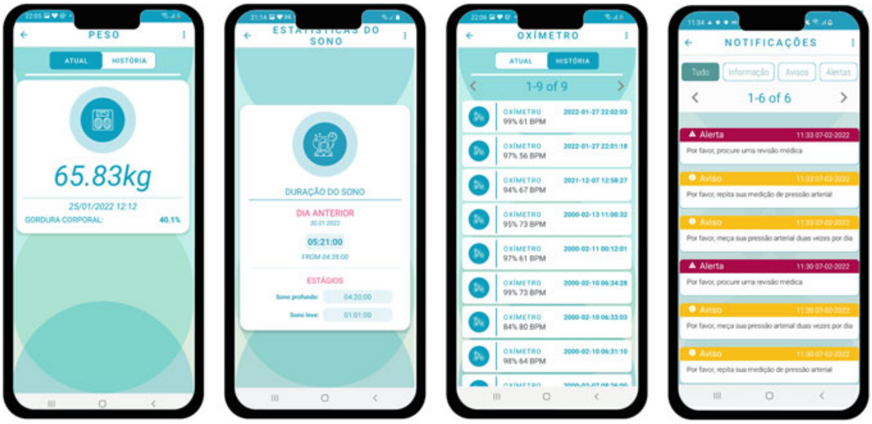


Fig. 5.7 SB app interface (Portuguese version)

Portuguese), collected by the smartwatch, or even historical data on oxygen levels collected by the oximeter ("oximetro"). All these data are interesting for the patients so that they can regularly check their health parameters. The values are then shared with the SMART BEAR platform and become part of the FHIR repository. Using such data, the BDA Engine component of the platform can send back notifications to the mobile app. As illustrated in Fig. 5.7 (right side), there are three types of notifications: information, warnings represented by the yellow color, and alerts represented by the red color. The warnings related to insufficient blood pressure monitoring, hence the message states that the user should take the blood pressure twice a day ("por favor, meça a sua pressão arterial duas vezes por dia") and requests to repeat the measurement ("por favor, repita a sua medição de pressão arterial"). The alerts are generated in this case due to an abnormal value of blood pressure and request the patient to seek a medical review ("por favor, procure uma revisão médica"). The more serious warnings (alerts) are also being displayed in the clinicians' message board on the Dashboard.

5.5 Data Analytics

Getting value from data implies understanding how to acquire knowledge from them. More generally, we can state Science is the process of organizing knowledge from the particular to the general and from the general to the particular. In SMART BEAR this process is realized according to the principles of the *Knowledge Uplift Model* (KUM) illustrated in Fig. 5.8. The data generated by the SB platform offer *descriptive knowledge* on the observed population or specific patients. For example, we can report about the dropouts, i.e. the number of participants who stopped using the provided devices. Besides, we can report on specific results obtained by a patient, e.g.

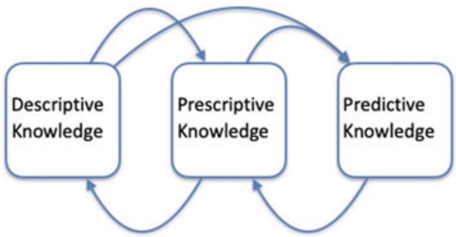


Fig. 5.8 The knowledge uplift model adopted in SB

the `head turns per second` registered for a patient during a HOLOBalance physiotherapic exercise.

Descriptive knowledge can be turned to *prescriptive knowledge*. For example, triggering a notification to the case manager of the dropping out patients, or defining personalized exercise levels for a specific patient. Descriptive knowledge can be turned to *predictive knowledge* by using the collected data to verify specific hypotheses on the relationships between the observed factors. For example, creating predictive models to identify those factors that contribute to the prediction of the dropouts or to the number of tuning sections to set with the audiologist.

Predictive knowledge can also be exploited to generate prescriptive knowledge, for example defining a special communication plan for those patients with factors predicting dropout. Prescriptive knowledge also generates new descriptive knowledge when we observe the response to prescriptions. *Are the notified case managers able to reduce the dropout numbers? Is a patient with a personalized exercise level improving faster?* These examples clarify the KUM cycle can be continuously brought up.

In the context of medical research, the generic KUM of Fig. 5.8 can be further specified in terms of the data flow we have to support to drive it.

Even if in principle this process can significantly variate, depending on the needs, its concrete implementation in SMART BEAR follows the workflow described in Fig. 5.9. *Descriptive analytics* are initially identified to test the data quality. The SMART BEAR infrastructure acquires data from multiple sources such as device sensors and manually filled questionnaires. Sensors can have failures and send inaccurate data. A device can be disconnected or a user can refuse to fill a questionnaire. Data can be incomplete or not delivered in the appropriate time frame. Before including the records of a patient in data analytics a test is required to verify the required data quality level is achieved. Records not passing the test are excluded.

For example, Fig. 5.12 presents a dotted chart used to assess the completeness of sensor data. The collected observations are organized on a timeline, in our example with a periodicity of one day. Data imputation techniques can be considered to improve data completeness but supporting conditions must be verified. If we have a few missing observations we can apply multiple imputation if missing data are completely at random error on the effect size but not bias, if missing data are not at random the risk of bias is relevant [75].

A second assumption relates to the need of validating the feasibility of the prognostic models we want to verify based on the quality of the ML models we

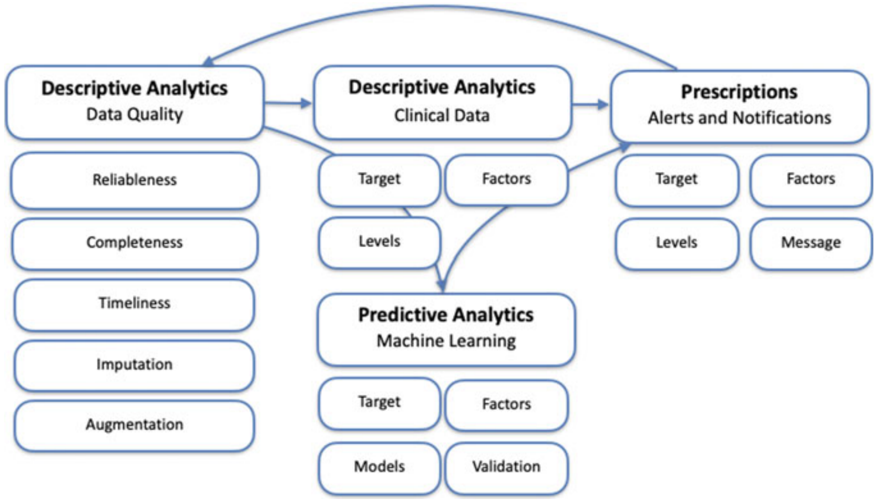


Fig. 5.9 The knowledge uplift model adopted in SB

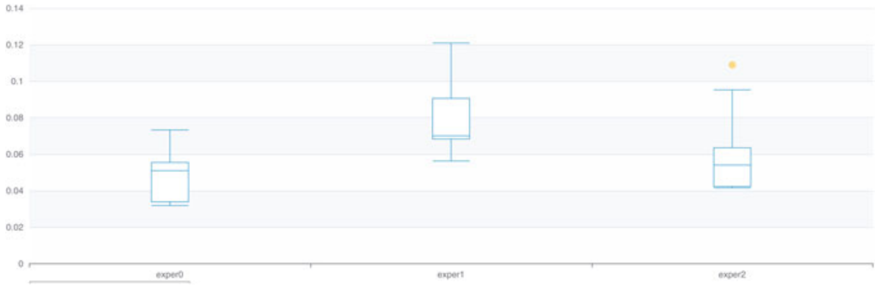


Fig. 5.10 Evaluating multiple predictive models

can expect given the data availability. The sample size must be evaluated with a temporal plan to define a credible timing for getting realistic volumes of data. We cannot plan using complex models if the data size is not appropriate. For example, experimental evidence from the literature [76] shows Random Forest is reliable with a sample size of 200 times the number of features in the feature space. This means once we know the sample size we can also identify the dimension of the feature space to be used and the modeling tool to select.

Figure 5.10, shows multiple predictive models on blood pressure evaluated using mean absolute percentage error (MAPE). More specifically, we tested an univariate model, a multivariable model, and a multivariable and multitarget model. Based on the best performance we obtained we can now select the model to be used in executing predictions. Figure 5.11, shows the predictive trend produced by the model for a specific patient (Fig. 5.12).

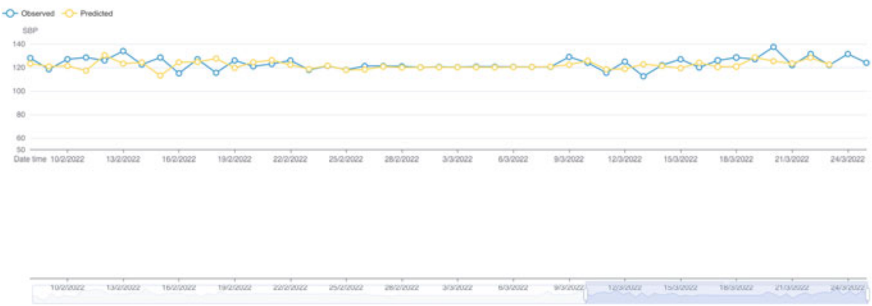
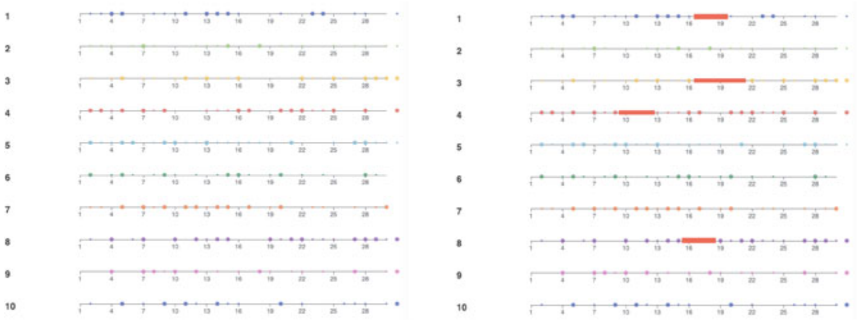


Fig. 5.11 Predicting the systolic blood pressure trend of a specific patient



(a) Recordings coverage per day.

(b) Red bars refer to three or more days of missing values.

Fig. 5.12 Recordings coverage per day. The dimension of the dots refers to how many parts of the day are (i) recording in

5.6 Conclusion

Smart healthcare systems are based on wearable or IoT devices placed at the patients' homes. They are becoming more and more popular because the technology of such devices is mature enough and the costs are affordable. Moreover such systems are an attracting alternative to hospitalization of elderly people, especially those who need to be monitored for long-term non-acute diseases.

In this chapter, we have focused on the description of the e-Health platform provided by the SMART BEAR project, leading to a data-driven decision-making process supporting the creation of personalized interventions for the healthy ageing's sake. As described in Sect. 5.2, the SMART BEAR platform has been designed to collect data from a broad variety of devices handed to the patients, including smartphones, wearable devices and home sensors, and deliver interventions consisting of personalized notifications and alerts, in addition to specific training protocols, that are elaborated on the basis of the data collected.

The next step will be to implement the ML-based algorithms to provide and adjust the threshold values triggering the intervention delivery in the course of the monitoring, nonetheless some the rule-based interventions are already available for CVDs and are triggered if the collected data do not comply with the value or range to be set by the clinicians from the beginning.

Concerning the implementation of the clinical interventions according to the protocol, two examples have been envisaged in Sects. 5.3.1 and 5.3.2. The next step will be to implement the analytics for monitoring the Auditory Training and the training for Balance Disorders, in addition to all the other clinical scenarios.

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