Smart sensors for daily-life data collection toward precision and personalized medicine: the TOLIFE project approach

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Abstract. Precision and personalized medicine is an advanced approach to healthcare that involves the use of smart technologies to collect population-wise data. It aims to empower clinicians to predict the most effective treatment for patients and to improve routine medical and public health practice. The potential clinical benefits of advancing precision and personalized medicine include early identifying people at risk for disease, modifying treatments based on large data sets, longitudinal monitoring of healthy people and patients, and better management and outcomes of diseases. Clinical data are largely based on this approach, and smart sensors will represent enabling technologies for personalized and precision medicine to consider also daily-life data of patients. TOLIFE is a project funded by the European Union to collect daily-life data of patients with complex chronic conditions, such as COPD, using non-invasive smart sensors. The sensor will be used to predict exacerbations, assess health outcomes, and characterize the patient's health status. The smart sensors will be commercial or adapted for TOLIFE purposes. This work focuses on the architecture of the data collection approach in TOLIFE, the rationale of the selection of each sensor, the associated raw data, and high-level health-related parameters.

Keywords: Sensors, daily-life, precision medicine, personalized medicine, complex chronic conditions, COPD

1 Introduction

Precision and personalized medicine aims to empower clinicians to predict the most effective treatment for patients and to improve routine medical and public health practice. An advanced approach to precision and personalized medicine involves the use of smart technologies to collect population-wise data for subsequent application on the individual patient level and it can use data from ”big data” sources [1, 2]. The potential clinical benefits of advancing precision and personalized medicine are: i) early identifying people at risk for disease with greater accuracy, ii) modifying treatments based on a variety of large data sets from both individual and population-based studies, iii) longitudinal monitoring of healthy people and patients to better understand the transition from healthy to diseased states, and iv) better management and outcomes of diseases, in particular in the case of complex chronic conditions (CCCs) [3].

Typically, precision and personalized medicine is largely based on clinical (especially -omics based) data and daily-life data (e.g. environmental, mobility, lifestyle) that can play a key role in a completed evaluation in particular for the patient with CCCs. For this reason, in recent years there has been an increasing interest in monitoring the patient with CCCs by integrating the clinical data with their daily-life data. Therefore, the availability of technological tools for non-invasive data collection in a daily-life context can play a key role in this scenario, smart sensors, in particular, will represent enabling technologies for personalized and precision medicine [4–6].

The collection of daily-life data of patients with CCCs, like chronic obstructive pulmonary disease (COPD), by using non-invasive smart sensors is one of the main aims of TOLIFE (”Combining Artificial Intelligence and smart sensing TOward better management and improved quality of LIFE in chronic obstructive pulmonary disease”) project recently funded by the European Union (project number: 101057103)[7]. More in detail, the TOLIFE project aims to clinically validate an artificial intelligence (AI) solution to enable optimized and personalized treatment and improved quality of life in COPD patients. TOLIFE AI tools will process daily life patient data captured by a set of non-invasive smart sensors to predict exacerbations, assess the patient’s health outcomes and characterize the patient’s health status. The smart sensors that will be used in TOLIFE will be both commercial (i.e. smartphone, smartwatch, and spirometer) or specifically developed or adapted for TOLIFE purposes (i.e. smartshoes, smart mattress cover, and environmental unit).

In this work, we describe the set of non-invasive smart sensors that we will employ in the TOLIFE clinical studies by focusing on the architecture of the data collection approach, the rationale of the choice of each sensor, the associated raw data, and high-level health-related parameters.

2 Methods

2.1 Smart sensors definition and architecture

The TOLIFE vision views each COPD patient as a complex system whose condition interacts with several comorbidities (Figure 1). The present medical treatment, history (e.g. previous exacerbations/hospitalizations, medical/treatment history), environment (e.g. indoor/outdoor air quality, temperature, humidity, weather condition), and lifestyle (e.g. smoking, exercise, diet, social interaction) are the inputs that "act" on the patient to modulate the disease progression. The severity of COPD and the comorbidities are related to the patient's health condition, which TOLIFE aims to quantify using AI algorithms on data collected by non-invasive smart sensors. The symptoms (e.g. shortness of breathing, wheezing, coughing, and non-respiratory symptoms linked to comorbidities), physical performance (e.g. exercise capacity, mobility, and gait characteristics), and altered patterns of psychophysiological signals are outputs "generated" by the patients, which depend on the inputs and the patient's health status (e.g. heart rate, breathing rate, temperature, oxygen saturation).

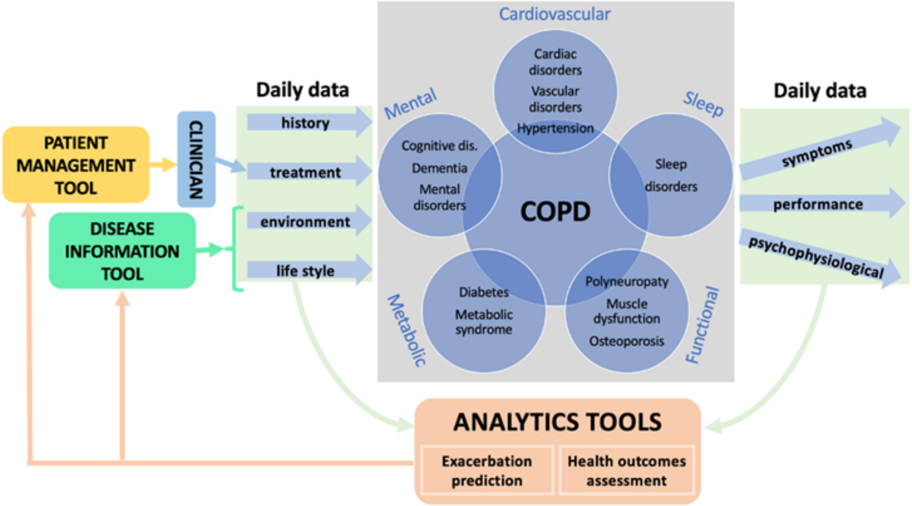

Fig. 1. TOLIFE personalized approach

The majority of input/output patterns associated with COPD and comorbidities are linked to the patient's daily-life activities and are either not available in the clinical routine or are only available occasionally. The TOLIFE research hypothesis states that daily-life patient-specific data linked to inputs (environment, lifestyle) and outputs (symptoms, performance, psychophysiological signals) contain a rich set of information for the continuous estimation of patient health status to support clinicians toward treatment of COPD patients based on precision and personalized medicine. The input/output patterns shown in Figure 1 will be used by TOLIFE's smart sensors to collect patient data. In particular, patient data on the environment, way of life, symptoms, performance, and psychophysiological signals will be measured by the smart sensors.

The selection of daily-life data that have the potential to reveal patient health status, COPD progression, early signs of exacerbations, and quality of life served as the foundation for the definition of TOLIFE smart sensors. Then, we chose non-invasive sensing tools that can identify such COPD-related input/output patterns without the patient having to exert much effort. Smart sensors are chosen to achieve the best compromise between the fewest devices the patient will use and the greatest number of pertinent parameters. Smart sensors have also been chosen to enable continuous, non-invasive monitoring of the patient's activity without affecting their daily lifestyle.

2.2 Smartwatch

A smartwatch will be used to collect patient data for the TOLIFE clinical studies regarding lifestyle, symptoms, performance, and psychophysiological signals. The smartwatch's raw sensor data includes details about the environmental sounds (microphone), sleep quality (accelerometers, gyroscopes, PPG sensor), walking speed (accelerometer, GPS), heart rate (HR) and heart rate variability (HRV) (PPG sensor and electrodes), oxygen saturation (PPG sensor), physical activity (accelerometer, gyroscope, GPS), social interaction (microphone), and daylight exposure (light sensor).

The smartwatch selected for the project was the Samsung Galaxy Watch 5 considering the literature analysis [8–12] and market research (version 5, to date the newest). The Galaxy Watch 5 has all the sensors required to measure the data from TOLIFE patients (accelerometers, gyroscopes, GPS, PPG sensor, microphone, light sensor, electrodes). According to the manufacturer, the battery's 41 mAh capacity and estimated lifespan of 40 to 50 hours should provide enough power for at least one whole day of continuous sensor use. The relatively low cost (around 290€) is another important feature. Additionally, unlike "closed" devices like Garmin or Fitbit, which extract high level parameters using exclusive and closed algorithms, the Galaxy Watch 5 permits the collection of sensor raw data because it is equipped with the Wear OS operating system. This operating system enables the creation of custom applications that can turn on the device's various sensors and extract the raw sensor data from them. In order to avoid losing any data during the data collection phase of the TOLIFE clinical study, the possibility to collect and store raw data at custom sampling frequency is essential for the project. In any case, we will also collect pre-elaborated device data (such as step count, mean heart rate, and SpO2) to potentially use them as input data for the TOLIFE AI tools. Table 1 lists the Galaxy Watch's raw sensor data that we will extract as well as the chosen sampling frequencies for each one. The sampling frequencies were chosen to balance power consumption and the dynamics of the signals to be collected. For accelerometers and gyroscopes (physical activity related sensors), the sampling frequency was set to 50 Hz. For the HR raw sensor, we selected the highest frequency available (25 Hz).

2.3 Smartphone

A smartphone will be used in the TOLIFE clinical studies to collect patient's data about lifestyle, symptoms, and performance. Particularly, the smartphone's

Table 1. Galaxy Watch 5 raw signals

Sensors	Data output	Sampling frequency
Accelerometer	Acc x, Acc y, Acc z	50 Hz
Gyroscope	Wx, Wy, Wz	50 Hz
GPS	Absolute position	5 Hz
HR raw sensor	Photoplethysmogram (PPG)	25 Hz
Light sensor	Light intensity	1 Hz
Microphone	Sound intensity	10 Hz

raw sensor data includes details about patient sounds (microphone), walking speed (accelerometer and GPS), physical activity (accelerometer, gyroscope, GPS), and social or digital interaction (microphone, interaction with the phone). Given the vast selection of smartphones with the same essential features (Bluetooth low energy, Wi-Fi, and data connection), we chose the Samsung M13 as our smartphone because it provides access to raw sensor data, has a long battery life (5000mAh), and is reasonably priced (about 180€). Table 2 reports the raw sensor data that we will collect from the smartphone and the associated sampling frequencies.

Table 2. Samsung M13 raw signals

Sensors	Data output	Sampling frequency
Accelerometer	Acc x, Acc y, Acc z	50 Hz
GPS	Absolute position	5 Hz
Microphone	Sound intensity	10 Hz

2.4 Smartshoes

The ”smartshoes” are a research prototype that will be modified for the TOLIFE clinical study. Three pressure sensors will be integrated under the insole of the smartshoes to track how the foot interacts mechanically with the ground. Additionally, smartshoes will incorporate a digital inertial measurement unit, consisting of an inertial platform with a 3D accelerometer and a 3D gyroscope. To enable low-energy data transmission to a mobile device, a Bluetooth transmission module will be integrated with the rest of the electronic unit in the heel of the smartshoes. A rechargeable battery allows a complete operation of the system for 48 hours. The main adaptation with respect to the previous prototype will be related to the sensor number and the structure of the shoe model.

Smartshoes will be used in the TOLIFE clinical studies to gather patient data on performance and lifestyle. Raw sensor data from the smartshoes contains details about the patients’ gait activity, including gait speed and gait patterns.

Gait speed is correlated with clinical symptoms, pulmonary functions, and quality of life scores and slows down as COPD severity increases [13]. In patients hospitalized for an acute COPD exacerbation, gait speed is a predictor of the risk of readmission [14]. Additionally, COPD patients have altered gait patterns, including shorter steps, longer double supports, slower cadences, and more variable walking [15].

The number of pressure sensors used and their locations are the main adaptation of smarthoes for TOLIFE project. In order to achieve the smallest possible number of sensors placed in the best possible location, the distribution of the pressure sensors was analyzed, taking into account both static and dynamic aspects of foot movement during typical user activities. Also the technical factors like the PCB integration, the physical area of the sensor, the material of the sole, and the geometry of the shoe were analyzed for TOLIFE purposes. The result of this analysis is the selection of three main points of contact between the foot and the sole of the shoe (the base of the big toe, the base of the little toe and the center of the heel). Thus, three pressure sensors (FSR 402 manufactured by Interlink) will be embedded in a custom flexible circuit board integrated in the shoe insole, as shown in Figure 2.

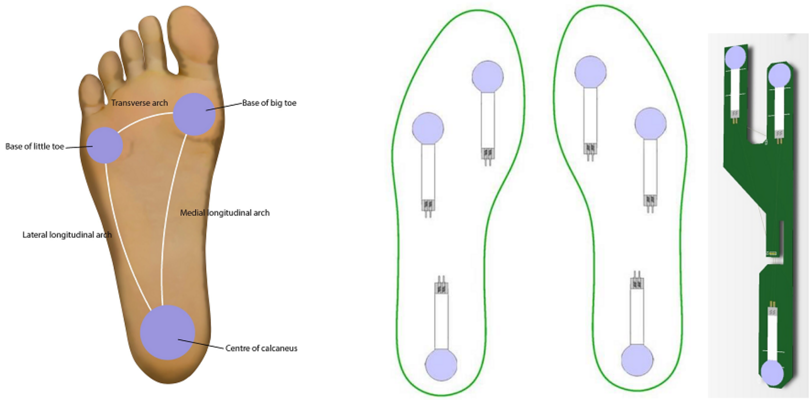

Fig. 2. Main points of contact between the foot and the sole and flexible PCB for the integration of the pressure sensors

Direct integration of the inertial measurement unit with a 3-axis accelerometer and gyroscope into the electronic module is planned. All sensor data is sampled at 50 Hz before being sent to the smartphone via Bluetooth. The electronic module also incorporates the parts required to control battery charging. Table 3 lists the raw sensor data from the smartphone that we will be collecting as well as the corresponding sampling frequencies.

Table 3. Smartshoes raw signals

Sensors	Data output	Sampling frequency
Accelerometer	Acc x, Acc y, Acc z	50 Hz
Gyroscope	Gyro x, Gyro y, Gyro z	50 Hz
Pressure Sensor	P0, P1, P2	50 Hz

Compared to the prototypes developed in previous projects, the smart shoes for the TOLIFE project will have a customized model with structural modifications (Figure 3). The smartshoe will have a more comfortable insole and a reduced weight because of the Strobel construction method. The Strobel method is an optimal technique for producing flexible and light shoes. Regarding the construction material, suede leather has been chosen for the upper portion while vulcanized rubber will be used for the sole. Some prototypes have been created, as seen in Figure 3, to test the new model's structural and building qualities.

Fig. 3. Design sketch and picture of the model selected for the TOLIFE smartshoes

2.5 Smart mattress cover and environmental unit

Sleep disturbances and COPD are strictly related; sleep has effects on breathing (e.g. changes in central respiratory control, airway resistance and muscular contractility) that can cause severe issues in patients [16]. Obstructive sleep apnoea (OSA) is a common sleep disorder, and overlap syndrome, which occurs when OSA and COPD coexist, is prevalent in COPD patients [17]. In TOLIFE, a smart mattress cover with embedded pressure sensors and accelerometers coupled with an environmental unit will be adapted and used to non-invasively assess the COPD patients' sleep quality and detect OSAs.

The smart mattress cover will be placed over the subjects' mattress to track their motion, position, and physiological signals (i.e. heart rate and breathing rate). The environmental unit that will be used in the bedroom to measure air quality, humidity, temperature, environmental sound, and luminosity will be the final component of the smart mattress cover. The raw data measured by the mattress cover and environmental unit will be fused in accordance with the methodology outlined in earlier works in order to extract a sleep quality index [18]. Data from the smart mattress cover will be used to to gather additional pertinent physiological parameters (heart rate [19][13], breathing rate [20] with the potential to detect sleep apnoea events). In order to extract information about the indoor air quality, temperature, and humidity, which can be thought of as modulating factors of COPD [21–23], data from the environmental unit will be used. Additionally, correlations between symptoms linked to abnormal patient sounds and patient sounds detected by the environmental unit are possible (snoring, wheezing, and coughing). Figure 4 shows a sketch of the placement of the smart mattress cover and environmental unit within the patient's room (left panel in figure 4) and the associated system architecture (right panel in figure 4).

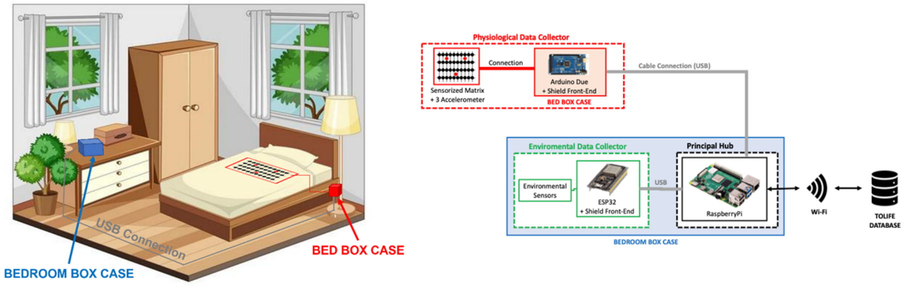

Fig. 4. Sketch and architecture of the smart mattress cover and environmental box

The smart mattress cover will include a textile-based pressure sensing array (40 pressure sensors over an area of 50 by 40 cm) and a set of 3 accelerometers. The raw signals from the pressure sensing array will be analysed to extract position and movements of the subject over the mattress, respiratory activity and abnormal breathing events such as coughing or apnoea. The accelerometers will be used to extract information about the cardiac activity through the analysis of the ballistocardiographic signal. Table 4 reports the raw sensor data that we will collect from the smart mattress cover and the environmental unit.

The smart mattress cover architecture is composed by following three main blocks (see Figure 4):

- Physiological Data Collector (PDC): the block has the objective of extracting the raw sensor data from the smart mattress cover of the subject lying on the mattress. The sensors involved are the pressure sensor array and the 3 accelerometers. Data reading will be managed through a dedicated front-end

Table 4. Smart mattress cover and environmental box raw signals

Sensors	Data output	Sampling frequency
Accelerometer	Acc x, Acc y, Acc z	128 Hz
Matrix Pressure Sensor	40 Pressure values	8 Hz
Air Quality	Air Quality Index	1 Hz
Environmental Temperature	Temperature	1 Hz
Environmental Humidity	Relative Humidity	1 Hz
Environmental Sound	Sound intensity	1 Hz
Environmental Light	Light intensity	1 Hz

electronics coupled with an Arduino Due board. The acquired data will then be sent via serial (USB cable) to the Principal Hub

- Environmental Data Collector (EDC): the block has the objective of collecting environmental data. The parameters to be measured concern the environmental conditions of the room and will be respectively temperature, relative humidity, atmospheric pressure, air quality index, ambient brightness, noise and/or ambient sounds. The management of environmental sensors data will be based on a commercial platform, such as ESP32 board; the sensors will interface with a front-end electronics, directly plugged on the commercial platform. The acquired data will be sent via serial (USB cable) to the Principal Hub.
- Principal Hub (PH): this block is a single board computer (i.e., a Raspberry Pi) that will manage the data collected by the PDC and EDC, saving them locally and sending them to the TOLIFE database when the internet connection is available.

The patient's mattress will have the smart mattress cover placed over it at the thoracic area and the PDC electronics will be placed in a box (bedroom box case) and placed in proximity of the bed or bedside table. The environmental unit, which consists of the EDC electronics and environmental sensors, will be positioned inside the room, perhaps on top of a dresser or table. The Raspberry Pi and environmental unit will be housed in a special case (the bedroom box case shown in Figure 4).

2.6 Mini-spirometer

Mini-spirometers will be used in the TOLIFE clinical studies to obtain a more complete characterization of the patients' respiratory capacity. After a market search, we chose the mini-spirometer that allows us to measure clinically significant parameters like the FEV1 in addition to peak flow. Because it is a peak flow device that can precisely measure peak expiratory flow (PEF) and FEV1, the Smart One OXI device (MIR company) was chosen. It also has BLE connectivity and an Android SDK, which enables the device to be integrated with TOLIFE's sensor platform. In fact, the device has a Bluetooth connection that enables data collected from the patient to be transferred directly to a smartphone. The Smart One OXI is specifically designed for personal use at home by the patient. In addition, it is also able to measure oxygen saturation (SpO2) and heart rate. Other characteristics are the low cost (around 100€) and availability of SDK for custom application development. Table 5 reports the data that we will collect from the mini-spirometer.

Table 5. Mini-spirometer raw signals

Sensors	Data output	Sampling frequency
Air flow	PEF, FEV1	On demand
Optical sensor	SpO2, HR	On demand

3 Data integration and communication

The architecture of TOLIFE sensor platform is described in Figure 5. The sensor platform foresees the smartphone as a central node. The smartphone will allow the creation of an internet connection through which all the smart sensors will be able to transmit the recorded data to the cloud. The smartphone will allow direct interfacing with smartshoes and the mini-spirometer using the Bluetooth connection.

Fig. 5. Architecture of smart sensors platform

The software applications for data collection from the smart sensors described in previous sections were firstly developed as prototypes. We specifically e developed a smart watch application, a smartphone application and a Linux application to be deployed on the Raspberry Pi of the smart mattress cover. Android apps on the smartwatch and smartphone are designed to gather data from embedded sensors, save the data locally on each device, and then offload the data to the TOLIFE cloud database.

The application for the smart mattress cover and environmental unit is designed to collect data from the embedded sensors, save it locally and offload the data as soon as a connection is available. An initial implementation of the data offloading process is currently under development. We conducted preliminary tests to verify the ability of the developed applications to extract raw data from the sensors of smartwatches and smartphones. Signals related to the relevant sensors present in the smartwatch are shown in Figure 6, while signals obtained from smartphone sensors are shown in Figure 7.

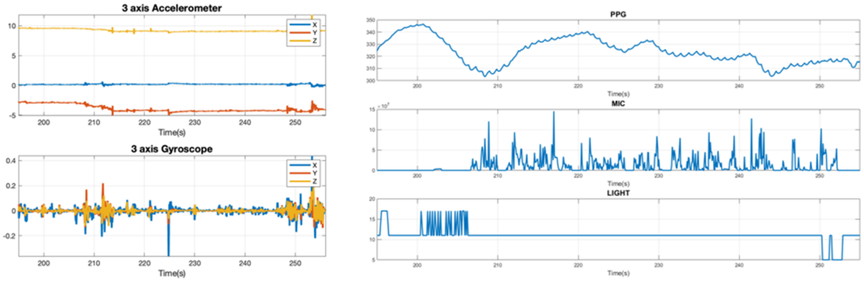

Fig. 6. Smartwatch sensors output. In the left signals related to 3-axis Accelerometer and Gyroscope are shown. In the right the signal related to the plethysmographic sensor and microphone are shown.

4 Discussion and Conclusion

This paper outlines the sensing technologies, or ”smart sensors,” that have been selected for the TOLIFE clinical study, outlining the raw data that we will gather and their applicability to the ongoing evaluation of COPD patients’ health outcomes. To enable uploading sensor data to the TOLIFE database, all chosen devices—commercial sensors and the research prototypes will be integrated into the TOLIFE platform. The completion of the software applications for data

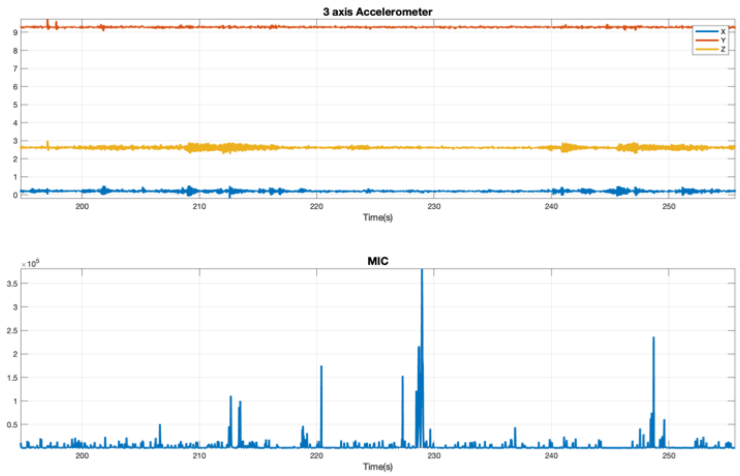

Fig. 7. Smartphone sensors output. In top figure 3-axis Accelerometer signals are reported, while in the bottom the microphone raw data is shown

collection from the testing of smart sensors, integration of the smart mattress cover and environmental unit, and experiments to gauge the effectiveness of the smart sensors will be the following activities. The TOLIFE project approach represents the smart sensors for non-invasive data collection in a daily-life context and smart sensors will represent enabling technologies for personalized and precision medicine.

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