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Telemedicine, today more than ever. The ABBRACCI design concept for COVID-19 patient monitoring.

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Abstract | In times of COVID-19, where keeping distances is essential to safeguard people's health and life, remotely monitoring infected patients both in hospitals and homes becomes vital. Telemedicine is the key to ensure healthcare assistance by minimizing human-to-human exposure and the spread of the virus. Evidence suggests that during the first pandemic wave in 2020, COVID-19 spreading took place to a great extent in hospitals, nurse houses, senior living communities, and more generally among healthcare workers and patients. Today more than ever, technological solutions that provide remote healthcare are needed to mitigate the infections among health system personnel and patients. In this paper, we propose a multidisciplinary design solution: ABBRACCI, an AI-based smart wearable device for COVID-19 patient monitoring and care, that is meant to be a tool to monitor the health and wellbeing of people diagnosed with COVID-19 – both critical hospitalized patients and non-severe ones that have been confined at home – but also people at high risk of infection who suffer from chronic diseases and multimorbidity.

KEYWORDS | TELEMEDICINE, COVID-19 MONITORING, WEARABLE DEVICE, MEDICAL DESIGN, ARTIFICIAL INTELLIGENCE

1. Introduction

The Coronavirus epidemic has created an unprecedented situation due to the great number of people infected, the virulence and morbidity of the virus and its geographical extension. It has also brought new attention to healthcare workers (doctors, nurses, paramedics, family doctors, pharmacists, and even cleaning attendants) who must manage a complex and critical relationship with patients. Data reported by the Italian National Institute of Health (ISS, 2021) shows that COVID-19 virus has spread to a great extent in the health system: from the crisis' start until March 24, in Italy about 127.581 healthcare operators had been infected, in a total of 3.402.290 cases of COVID-19. Medical action cannot be separated from direct contact with patients, therefore the interaction between medical staff and patients represents a risk of infection for both of them. First of all, in hospitals or nurse houses where patients and health personnel interact on a daily basis. Second, in patients' homes where infected people are quarantined and visited regularly by family doctors or healthcare workers. And third, in older people's homes or senior living communities where patients are not infected but are at high risk of contracting the virus due to their compromised health status (chronic diseases and multimorbidity). Thus, it appears evident that the pandemic represents an enormous risk to both sides (patients and healthcare workers), and technological solutions to give response to this current issue are essential.

The question then arose: how could *design* contribute to enabling healthcare workers to operate minimizing contacts with COVID-19 patients while ensuring safety and effective assistance? And, on the other side, allowing both hospitalised and non-hospitalised patients to feel monitored and assisted? To answer this present question, European institutions and research centers (Unimore; RE:Lab; Università Iuav di Venezia; Fondazione Democenter - SIPE; Pannon Business Network Nonprofit KFT; August Pi i Sunyer Biomedical Research Institute IDIBAPS; Humatects GmbH) have pooled their ideas and know-how to come up with a design concept: *ABBRACCI, AI-based smart wearable device for COVID-19 patient monitoring and care*. That, in a future perspective, it could respond to new potential dangers and emergency situations.

2. The ABBRACCI concept: a possible multidisciplinary response

2.1 Design and use cases

The vision of ABBRACCI begins with the acknowledgment of two primary needs of healthcare during a pandemic: the first is the need to keep healthcare workers safe to avoid the disruption of the healthcare systems, and the second is the need of a continued, effective, and prolonged monitoring of the patients in a safe environment.

ABBRACCI concept combines a wearable device, which integrates a set of measurement sensors of physiological data, to an AI-based platform specifically developed for patients' parameters analysis and for predicting potential disease deterioration. It consists of a smart wristband (a silicon band and a removable integrated sensor as shown in Figure 1) that detects heartbeat, arterial oxygen saturation, body temperature and dehydration − as suggested by the evidence, these parameters are relevant to detect COVID-19 physiological changes (Seshadri et al., 2020; Islam et al., 2020; Ates et al., 2021) − and a multiple-device monitoring application (both smartphone and desktop) for real-time viewing and storage of data collected, in order to maintain prompt caring attention continuously.
Since healthcare has spread across different areas, ABBRACCI would adapt to three use cases (hospitals, assisted living facilities, and home) related to two user groups (healthcare workers and patients) – Table 1:

Table 1. The ABBRACCI use cases.

Place	**Healthcare workers**	**Patients**
Hospitals	Doctors, nurses, hospital staff	Hospitalised patients
Home	Family doctors, healthcare workers	Non-hospitalised patients
Home, senior living communities	Family doctors, healthcare workers, caregivers	People at high-risk of infection (elderly, chronic disease sufferers)

As shown in Table 1, ABBRACCI concept is intended to those hospitalised patients with severe COVID-19 complaints; to non-hospitalised patients who are recovering at home from mild symptoms; and also, to high-risk of infection people such as elderly, chronic disease suffers who need to be monitored in their domestic environment or in senior living communities.

Hospital healthcare providers are the most at risk, having to deal with extremely symptomatic patients and highly contaminated places of work. Due to the difficulty in replacing personal protection equipment (PPE) and the general shortage of them, even a simple operation such as consulting the health condition of each patient can be difficult and potentially dangerous for nurses and doctors. ABBRACCI would allow healthcare operators to look at the parameters of their patients both at a safety distance and constantly. Possibly they would be able to consult vital signals even more than in the usual situation, where they are usually collected two or three times a day. Moreover, this operation can be conducted by fewer people than before, leaving the others available to work on emergency cases.
In this way, patients can stay in the infection department and in the meantime, doctors and medical staff would receive and visualize the updating of the parameters from distance.

Figure 1. The ABBRACCI kit and the doctor version smartphone App

The role of family doctors has gained a renovated attention as well. Since their duties have much increased, they had to deal with new forms of stress caused also from the lack of protection. Although some academics point out that

> "physical distancing in family practice is operationalised by a variety of measures, such as triage, phone or teleconsultation, removing chairs from waiting rooms and putting up Plexiglas screens at the reception, making it possible to keep the practice open and to welcome the patients who need seeing us" (de Sutter et al, 2020, p.59),

in the case of a home visit, distance is almost impossible to maintain, and family doctors are exposed to great risks. Even so, they play a crucial role in COVID-19 research thanks to their careful registration of all their patients, especially those with typical COVID-like symptoms who were not hospitalised but recovering at home. Therefore, ABBRACCI can allow them to consult the health parameters of their isolated patients without physically going near them and without exposing themselves to unnecessary risks.

Quarantined patients receive from the hospital the ABBRACCI kit (which integrates two sensors to guarantee constant monitoring and the patient version smartphone application) and family doctors visualize the updating of the parameters on their App version – Figure 1. They can consult the parameters in every moment and, thanks to the AI-system, potentially prevent the rise of emergencies. Involving family doctors, the same procedure will be run

also with no-COVID patients during their cure at home, to have more data and compare different parameters, progresses and outcomes. This is also important for the category of 'fragile' patients, such as elderly, with chronic conditions and multimorbidity, which also include the ones in nurse houses and other kinds of healthcare facilities or senior living communities. Since the practices and gestures of care have changed so much to avoid the risk of infection, patients have also suffered from isolation and loneliness. ABBRACCI has the potential of reassuring patients thanks to wearing the remote-control system and making them feel close to their family doctor. The simple and intuitive app interface provides a practical utility as well as brings psychological benefits to all kinds of patients.

2.2 The Artificial Intelligence's role and technological integration

The integration of Artificial Intelligence and wearable biometric monitoring devices can ease the medical and care operations. Indeed, AI-based devices enable the monitoring and measuring patients' data in real time, supporting the diagnosis, and predicting patient's status while helping health operators to provide the appropriate treatment or prompt intervention. Decision-making algorithms incorporating telemedicine, designed through the utilization of Artificial Intelligence tools, could be used to assist with definitive disposition of the evaluated patients by remote analysis (Chauhan et al., 2020).

The AI and machine learning solution can enhance every stage of patient care, from research and discovery, to diagnosis, to selection of therapy.

> "As a result, clinical practice will become more efficient, more convenient, more personalized, and more effective. [...] Physicians have long needed to identify, quantify, and interpret relationships among variables to improve patient care. AI and machine learning comprise a variety of methods that allow computers to do just this, by algorithmically learning efficient representations of data" (Johnson et al., 2018, p. 2668-69).

The integration of AI applications with wearable sensors can help detect the disease and predict the potential evolution in the patient based on the analysis of the personal history and the comparative analysis with vast amounts of unstructured medical data.

On these premises, the project ABBRACCI supports the product innovation of a smart, AI-based wearable device for the monitoring, recording and analysis of significant physiological data for the screening, diagnosis, and prognosis of COVID patients, elderly and 'fragile' users, to be accessible by medical staff through a monitoring application (smartphone and department computers). The continuous recording of real-time data would allow health workers to compare information extracted from historical datasets − considering that Health Systems are digitising their patients medical histories and collecting them into Electronic Health Records (EHRs) (Caceres, 2013). Moreover, integration among all the tools characterizing the proposed solution would identify individual personalized treatment based on recorded parameters and the clinical history of the patient. The AI platform built on the Dynamic Bayesian Networks would help evaluate and optimise strategies for controlling the

spread of the epidemic and it would detect the presence of the pathogen related parameters especially in an early stage of infection, helping medical staff for diagnostics, prevention, treatment, or rehabilitation. It is important to note that, to obtain an AI component with high performance level, many data are required, which could only be collected by using the monitoring application over time. Therefore, in this project the initial model for the AI component would be trained from clinical data, which would be collected from hospital partners of the project (AOU Policlinico di Modena and August Pi i Sunyer Biomedical Research Institute). While testing and validating the monitoring system, the AI component would collect patients' symptoms data and, once enough data are collected, the level of services provided by the monitoring application will be increased.

Going into details, the technology instruments to be integrated are sensors for the detection of physiological parameters, the AI-based software, the monitoring application used by medical staff and, in some cases, by non-hospitalised patients, and the geographical network for sharing and transmission of notifications. Sensors and software have already designed, developed, and validated in laboratory during the project AGEDESIGN Interreg V-A Italia-Austria - Call 2016 in which it has been developed a kit of devices (wearable and portable) for the daily monitoring of physiological parameters (heartbeat, cardiac frequency, arterial oxygen saturation and body dehydration) of the older population. The validated results of AGEDESIGN feed into this ABBRACCI design concept that would embrace emerging technologies as Artificial Intelligence tools. Therefore, ABBRACCI integrates a set of sensors into a wristband to measure vital parameters of the patient, such as heartbeat (BPM), arterial oxygen saturation (SpO2), body temperature and dehydration. The choice of these parameters provides required information for the remote medical staff and can be used as an effective framework for detecting alarm situations in patients with related diseases, both at home and in residences for the elderly.

As shown in Figure 2, the sensors embedded in ABBRACCI concept would be:

- an optical sensor (photoplethysmography) for the detection of the heartbeat (BPM) and SpO2;
- a thermistor for the temperature;
- and a bioelectrical impedance sensor for body hydration.

As for the AI component, the processing unit would be realized as a probabilistic model, specifically as Dynamic Bayesian Networks (DBN). The DBNs capture temporal evolutions and statistical relationships between the model variables, including the sensor data, and the patients' symptoms and disease histories. The probabilistic model would be trained as a data-driven and expert-driven model, meaning that it would be used both data and expert knowledge to build the structure of the model. The probability distribution of parameters and the statistical relationship between variables would be learned from available data.

The training of the model is repeated when a new set of data samples is collected to increase the accuracy of the model prediction over time – Figure 3.

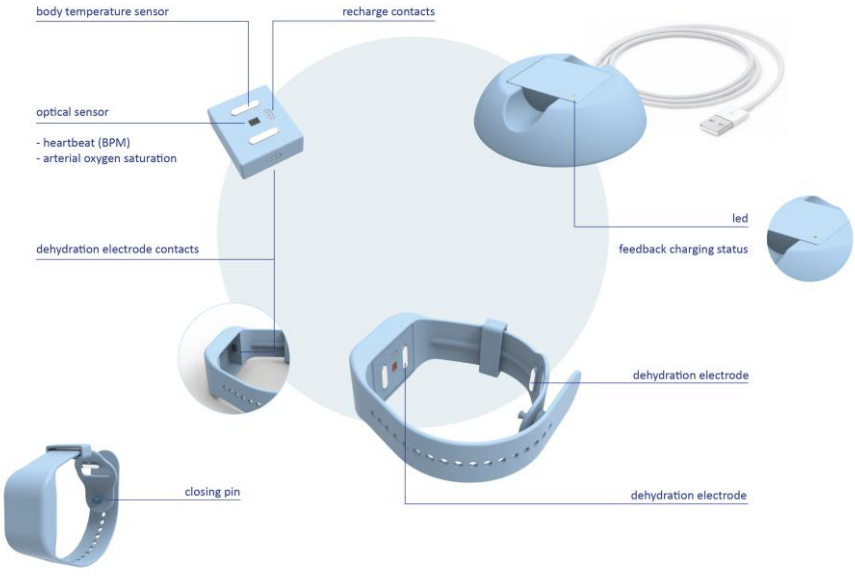

Figure 2. The ABBRACCI technological components

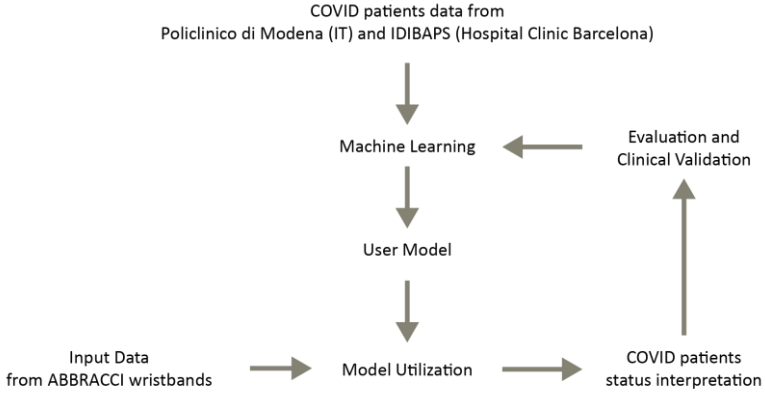

Figure 3. The ABBRACCI overall concept

2.3 Toward validation and medical certification

Since ABBRACCI is intended to be a wearable medical device, it is fundamental to go through a medical certification process.

User pilots represent the possibility to demonstrate the efficacy of the kit, the measured parameters, its usability (user experience, perceived usefulness and acceptability), the technological and innovation potential of the project, and the benefits for users. The device would be compared with similar solutions already in use and certified. In order to provide evidence of the sustainability and maturity of the solution, the pilot phase would be run in the project partner hospitals:

- AOU Policlinico di Modena (Hospital connected to UNIMORE), Italy;
- August Pi i Sunyer Biomedical Research Institute IDIBAPS (connected to Hospital Clinic Barcelona), Spain.

The validation of the device would be first carried out through the involvement of healthy users. This is also due to the uncertainty about the evolution of the COVID-19 disease in the next months and the difficulty to predict whether there will be COVID-19 patients to be involved in the test. In addition, to test the accuracy and the feasibility of the system the project does not necessarily need ill users (for example, it may involve patients with heart failure or COPD, where SpO2 monitoring is important). Another phase of the validation would involve COVID-19 patients, both inpatient and non-hospitalised ones. Starting from the COVID databases from Italian and Spanish Hospitals, the aim is to verify accuracy of ABBRACCI in detecting symptoms and related alarm signals by obtaining a specific algorithm. The table below shows the alarm levels considered for each parameter – Table 2:

Table 2. The ABBRACCI alarm levels

Parameters	**Mild**	**High**
Rest heart rate	> 95/min	> 110/min
SpO2	< 95% in ambient air	< 90%
SpO2 in COPD	< 90% in ambient air	< 87%
Hematocrit (HTC)		
Male	> 53%	
Female	> 50%	
Body temperature	> 37,5 °C	
High alert level		
Rhr	> 100/min	
SpO2	< 90%	
HTC	> 55%	
Temperature	> 38 °C	

The parameters shown in the table have been chosen for the following reasons:

- High heart rate at rest is an indicator of disease and indirectly also of febrile state and dehydration. It becomes a high alarm in resting tachycardia (>110 / min);
- Low SpO2 (partial oxygen saturation) is the most accurate sign of COVID pneumonia; the alarm level is inferior in COPD (Chronic Obstructive Pulmonary Disease) patients;
- Haematocrit (HCT) is an indirect sign of dehydration and therefore of fever and disease status (it is usually lower in females);
- Body temperature greater than 37.5°C is suggestive of possible infection.

It may be assumed that the combination of the four parameters with alarm level at maximum values configures a state of high probability of COVID infection. It is possible that the combination of two or three of them with high levels could also constitute a high suspicion of disease.
These parameters will be tested in hospitals as well as in nurse houses and patient homes. In hospital the validation would be done with the parameters derived from hospital instruments, the results would be compared to ABBRACCI's data to validate the level of accuracy and the ability of the algorithm and AI model to predict the evolution or deterioration of the disease.

Regarding the medical certification, the kit could be classified as Class I of medical devices with measuring function. It is intended to pursue a certification process based on the requirements of the MDR 2017/745, European regulation on medical devices. From the architectural point of view, the project foresees a connection between mobile phone and sensor-based wristband via Bluetooth protocol. There is no interaction between the wristband and the mobile phone that interacts on the hospital's monitoring systems and IT infrastructures. Obviously, the mobile phone can provide some form of interaction with the hospital network, but this would not concern any critical IT systems. In other words, complete independence of the networks would be ensured according to the directives of the MDR itself and with reference to IEC 80001. The MDR 2017/745 specifies that devices that are intended to be operated together with other devices or products should be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe. Compatibility refers to the ability of a device, including software, when used together with one or more other devices, to perform without losing or compromising the ability to perform as intended. Interoperability refers to the fact that the two or more devices, including software, should exchange information and use the information that has been exchanged for the correct execution of a specified function. Other fundamental aspects for Class I of medical devices are compliance with the metrological requirements. This activity would be carried out by comparison with reference certified instrumentation adopted as "gold standard" for the different types of measurements performed by ABBRACCI kit.
In addition, the guidelines EN 60601-1 and EN ISO 14971:2020 should also be considered.

2.4 Market analysis

To understand the ABBACCI level of innovation and its positioning compared to competitors[1], a market analysis was carried out. Compared to the current devices available in the market and in use to detect vital parameters, the project grants the contactless real-time detection and remote transmission of patient physiological data to the doctor.
The analysis of the state-of-the-art places ABBRACCI to be the only wearable device that continuously detects heart rate (BPM), saturation of arterial oxygen (SpO2), body temperature and hydration status through a single and integrated device. Another distinctive element of the project ABBRACCI could be the accuracy of the data, that would be certified and allow the project ABBRACCI to be classified as a medical device. In fact, no wearable devices exist for the detection of certified data regarding the vital parameters considered. Moreover, the feature of the device is the way the data are read: they cannot be viewed on the display (i.e., directly on the wristband) but only on the smartphone monitoring application supplied to medical and nursing staff, to control their patients without direct contact, and non-hospitalised patients.

Based on the results of the market analysis, as shown in the positioning maps below (Figure 4), ABBRACCI could be the only device with continuous monitoring with certified data, which continuously stores it and makes it viewable on the monitoring application used by medical staff and patients at home. It could be the only one, in the category of wearable devices, able to combine heart rate detection (BPM), arterial oxygen saturation (SpO2), temperature and body dehydration.

[1] Referred competitors: TENSORTIP MTX (Cnoga Medical); iHEALTH AIR (iHealth Labs); FOX-300 (I-Tech Medical Division); HONOR BAND 5 (Huawei); CHECKME O2 (Viatom); CHECKME PRO (Viatom); GARMIN VENU (Garmin), O2RING (Wellue Health); HEALBE GOBE2 (Healbe); COSINUSS TWO (Cosinuss).

Figure 4. ABBRACCI vs Competitors

3. Conclusion

Dealing with the emergency caused by the pandemic required enormous efforts from all citizens. It certainly was not the first global threat, but, for the first time, we saw a global response. The technological tools have helped us be truly cohesive in understanding how we could defend ourselves, how and what to design and build to protect us, those who cared for us and generally all vulnerable people. Designers were called to prompt action to suggest a wide variety of solutions to the problems that covid-19 continually introduced; in this context, the ABBRACCI concept was born.

Given the essentiality of maintaining distance from one another in the COVID-19 era, the ABBRACCI project is meant to be a telemedical tool for safer monitoring by the health workers of the infected patients, both hospitalised and those confined at home. The design concept integrates Artificial Intelligence as a way to better prevent, diagnose, treat and predict the course of the disease. The global spread of COVID-19 provides a large amount of data regarding citizens health, supplying a way to the enhancement of the Artificial Intelligence system and employing it in healthcare. Artificial intelligence thrives on data, and in healthcare, there has never been a more fruitful opportunity to feed clinical research and fulfil the AI in the medical field itself. ABBRACCI might also contribute to the digital transformation of the health system and medical practice by providing tested and demonstrated tools, practices, skills, and services hoping to extend this approach also to the treatment of other diseases (the detected parameters might also point out other pathologies and, in the worst scenario, might be useful in the next pandemic).

Over the past year, the pandemic has accelerated the technological development of remote monitoring devices for Covid-19 patients or potentially at risk of infection (Best, 2021). However, current solutions (like ABBRACCI) are still under research and need further experimentation to reach the marketplace. Several companies in the biomedical industry and some clinicians have adapted existing solutions to the new requirements and challenges dictated by the coronavirus pandemic, but, to date, there is no specially designed solution.

The effect of this project in the market would consist in responding to a specific user's need in a more integrated, faster, and evidence-based way creating new perspectives for multidisciplinary collaboration. In fact, the conception of ABBRACCI has involved many professionals, such as doctors, engineers, designers; and it highlights the potential of the design discipline: it is not just the design of an intelligent wearable product; it is the design of it into an extended design service.

Nevertheless, given the urgency of designing new solutions and the promptness with which the idea was conceived, this project needs further insights and analysis of strengthens and weaknesses.

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