Using eHealth platforms and Apps to support monitoring and management of home-quarantined COVID-19 patients. Insights from the experience of the Province of Trento, Italy

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Abstract

Background: The large majority of patients infected by the latest coronavirus disease (COVID-19) reports mild symptoms and are usually recovering at their home (quarantine). A proper monitoring of such patients through a system user-friendly for patients and sustainable for healthcare staff is a key aspect to prevent potential worsening of symptoms and to ensure proper medical interventions.

Objective: The aim of this work was to pilot a telemedicine technical and organizational model specifically designed to provide dedicated healthcare staff with a sustainable and reliable tool for periodically monitoring patients with progressive COVID-19 who are home-quarantined.

Methods: An easy-to-use App was purposely developed to facilitate the monitoring of a selected number of home-quarantined patients affected by COVID-19. The App was accurately linked with a pre-existing e-health platform adopted by the local health trust to provide home care, allowing: (i) proper and safe link of collected data with demographic and clinical information related to the patients; (ii) a two-way communication between a multidisciplinary healthcare team and home-quarantined patients. The system supported patients to self-assess their conditions and to update the multidisciplinary team on the health status. The system was piloted between March and June 2020, in the Autonomous Province of Trento (Italy).

Results: A dedicated multidisciplinary group of healthcare professionals adopted the platform over a period of approximately 3 months (from end of March to June 2020) to monitor a total of 170 patients with confirmed COVID-19 while in home-quarantine. All the patients used the system until the end of the study.

Conclusions: The technological and organizational model adopted in the context of this piloting has proved to be acceptable for both patients and health care staff when monitoring the progression of COVID-19 during the quarantine period. The system was purposely developed to pilot an innovative system supporting healthcare staff involved in the periodic monitoring of a relevant number of quarantined patients. Clinical Trial: NA

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Original Manuscript

Using eHealth platforms and Apps to support monitoring and management of home-quarantined COVID-19 patients. Insights from the experience of the Province of Trento, Italy

Abstract

Background

Italy was the first country to largely experience the COVID-19 epidemic among Western countries during the so-called first wave of COVID-19 pandemic. Proper management of an increasing number of home-quarantined citizens created a significant challenge for healthcare authorities and professionals. This was especially true when considering the importance of remote surveillance to detect signs of disease progression and consequently regulate access to hospitals and intensive care units on priority basis.

Objective

In this paper authors report on an initiative promoted to cope with the first wave of COVID-19 epidemic in the Spring/Summer of 2020, in the province of Trento, Italy. A purposely-built app named TreCovid19 was designed to provide dedicated healthcare staff with a ready-to-use tool for remotely monitoring patients with progressive symptoms of COVID-19, who were home-quarantined during the first wave, and to focus on those patients who, based on their data, required a quick response from the healthcare professionals.

Methods

TreCovid19 was rapidly developed to facilitate the monitoring of a selected number of home-quarantined patients affected by COVID-19 during the very first epidemic wave. The app was built on top of an existing e-health platform, already in use by the local health authority to provide home care, having the following functionality: (i) securely collect and link demographic and clinical information related to the patients; (ii) provide a two-way communication between a multidisciplinary healthcare team and home-quarantined patients. The system supported patients to self-assess their condition and update the multidisciplinary team on their health status. The system was used between March and June 2020, in the Autonomous Province of Trento, Italy.

Results

A dedicated multidisciplinary group of healthcare professionals adopted the platform over a period of approximately 3 months (from end of March to June 2020) to monitor a total of 170 patients with confirmed COVID-19 while in home-quarantine. All the patients used the system until the end of the initiative. The TreCovid19 system has provided useful insights of possible viability and impact of a technological-organizational asset to manage a potentially critical workload for healthcare staff involved in the periodic monitoring of a relevant number of quarantined patients, notwithstanding its limitations due to the rapid implementation of the whole initiative.

Conclusions

The technological and organizational model adopted in response to the pandemic, was developed and finalized in a relatively short period of time during the initial few weeks of the epidemic. The system successfully supported the healthcare staff involved in the periodic monitoring of an increasing number of home-quarantined patients and provided valuable data in terms of disease surveillance.

Keywords: telemedicine; telemonitoring; quarantine management; COVID-19; connected care

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INTRODUCTION

Since the first cases in December 2019, the epidemic of the novel coronavirus SARS-CoV-2 (COVID-19) has spread rapidly, creating an unprecedent challenge to the health care systems globally[CITATION Ols20 \l 1033].

The COVID-19 pandemic has heavily altered the healthcare system worldwide and put at risk its sustainability, whilst boosting adoption of telemedicine designed to address the challenges related to COVID-19 patients [CITATION Hol20 \l 1033]. Medical institutions were rapidly facing a massive tsunami of patients requiring hospital treatment, with critical consequences in terms of healthcare staff workload and dwindling of medical care resources. To prevent the collapse of the global health care system, many countries have advocated for infected patients with mild symptoms to stay home and self-quarantine [CITATION Wor20 \l 1033]. However, it has been observed that the condition of some home-quarantined patients became severe or critical as the disease progresses [CITATION Wor201 \l 1033] leading to delay in timely treatment and hospitalization of these patients and consequently rapid deterioration or even death.

Italy was the first country to largely experience COVID-19 epidemic, among Western countries, and the first country in Europe to impose a general lockdown in March 2020 so as to limit the COVID-19 spread [CITATION Guz21 \l 1033]. From an epidemiological perspective, the COVID-19 epidemic had spread differently across the Italian regions with a significant geographic heterogeneity in terms of number of cases and dynamic of the outbreak [CITATION Rem20 \l 1033]. The first cases officially reported in the province of Trento were identified the 3rd of March 2020 (4 patients), whereas at the end of March the number of citizens infected with COVID-19 increased to 2.529 subjects. In terms of citizens infected per day, the peak of the first wave was reached on the 21st of March with 239 newly infected patients, whereas the highest number of daily deaths was reached the 30th of March (18 patients). The massive scale-up of infected patients exposed the provincial healthcare system to an urgent, wide, and rapid organizational and logistic rearrangement during the course of the very first epidemic wave.

In fact, in 4 weeks from the very first cases, an exponentially increasing number of patients needed monitoring, active support, prompt hospitalization and – for a significant proportion of cases – intensive care. The peak of the burden for the healthcare services was reached on the 8th of April, with 311 patients hospitalized at the Infectious Diseases Department, 77 patients managed by the intensive care units and 43 patients managed by high-intensity units. Only 3 months from the very onset of the pandemic, the first day with 0 reported COVID-19 cases was recorded in the province of Trento on the 2nd of June, whilst the last patient to be discharged from the intensive care unit was recorded on the 15th of June.

The COVID-19 pandemic had suddenly exposed deficiencies in the whole healthcare system, revealing high uncertainty on key issues, such as increasing difficulty in tracing the exact transmission route of the infection, inadequacy of diagnostic testing system, and the lack of clear monitoring procedures in case of home-quarantined patients and therapeutic approaches [CITATION Acu20 \l 1033]. Proper management of an increasing number of home-quarantined citizens represented a demanding challenge from the healthcare authorities and professionals, considering the key role of strict monitoring in order to detect aggravation of disease in view of prompt hospitalization and to regulate access to hospitals and intensive care units only when

needed.

Within this critical and rapidly-changing scenario, there was a scattered phenomenon of swift and spontaneous – albeit valuable – attempts to adopt digital tools to support the healthcare system in dealing with this unexpected epidemic, particularly in the field of remote monitoring. Whilst some experiences of remote monitoring of home-quarantine patients have been implemented worldwide in the very first stage of the pandemic [CITATION XuH20 \l 1033] [CITATION Tim20 \l 1033], there were no such initiatives in Italy. At the same time, the COVID-19 pandemic has been considered as a missed opportunity to improve telemedicine[CITATION Rem20 \l 1033] [CITATION Omb20 \l 1033], which is still a scattered and embryonic phenomenon at national level.

In this paper, we report on the initiative designed and implemented to cope with the first wave of COVID-19 epidemic in Spring/Summer 2020 in the province of Trento, Italy. A telemedicine tool was purposely developed to provide home-quarantined COVID-19 patients with an app named TreCovid19 in the very first weeks after the outbreak. The app was linked to an already existing telemedicine system which was in use by the nurses of the Home Care. The App and the platform were set up within an extremely short period of time to allow an automated monitoring system supporting healthcare staff when dealing with an always-increasing number of infected patients. This has been done by merging organizational and technological components, that is, by embedding a telehealth service and related activities into the framework of the healthcare procedures put in place to face the epidemic's impact, particularly in terms of monitoring of home-quarantined patients.

The TreCovid19 tool was developed within an initiative promoted and coordinated by the Competence Centre on Digital Health of the Autonomous Province of Trento, TrentinoSalute4.0 (TS4.0) [CITATION May19 \l 1033].

METHODS

Contextual factors: collaboration among healthcare bodies in Trentino

A key component of the initiative described in the present case study lies in a specific contextual factor characterizing the collaboration between healthcare bodies and policy and research stakeholders in the Province of Trento. TrentinoSalute4.0 (TS4.0), was formally established in 2016 with an Act of the Local Government as a partnership among three relevant stakeholders in Trentino: the Autonomous Province of Trento (PAT - Department of Health and Social Policies), the local Healthcare Trust (APSS), and the Bruno Kessler Foundation (FBK), a research entity with particular focus on the applicative dimension of technology in the field of digital health. This alliance has been established for strengthening cooperation among the three institutions and coordinating the eHealth agenda in Trentino; in May 2020, TS4.0 has officially become a Joint Research Unit. Specific financial funding has been allocated by the Province of Trento to support TS4.0 coordination activities, whilst a specific TS4.0 Steering Committee is composed of representatives of the institutions that are part of the partnership (PAT, APSS, FBK). The Steering Committee is in charge of defining and approving the TS4.0 overall strategy and prioritizing areas of action, as well as monitoring a smooth implementation of the related activities. Over the recent years, this pre-existing framework of collaboration has provided a solid basis to a number of initiatives in the field of digital health (from piloting to delivery of e-health services), including telemedicine projects [CITATION Ecc201 \l 1033].

Organizational response

In view of the first epidemic wave in the Province of Trento, healthcare authorities set up a “COVID-19 Special Unit”, purposely established to deliver a general strategy to cope with the pandemic and to ensure proper management of the positive cases, from monitoring to hospitalization and treatment. The Unit was strongly linked with the Autonomous Province of Trento (in particular, with the Department of Health and Social Policies), as well as with the local Healthcare Trust Directorate General, in order to ensure proper decision-making process. The Special Unit was also linked with ad hoc contact-points within the different public health institutions at local level (such as hospitals and local districts). Patients with a probable or a confirmed COVID-19 infection were reported to the Special Unit through different channels, namely: the provincial registry of citizens with positive swabs, the Prevention department and the General Practitioners (GP).

The monitoring of COVID-19 home quarantined patients was considered a key component in the management of the epidemic, particularly in the first phase of the outbreak. This was despite the fact that it represented a challenging action considering the relative uncertainty about the clinical manifestations and related indicators in the early stage of the epidemic [CITATION Acu20 \l 1033]. Therefore, within the COVID-19 Special Unit, a selected group of healthcare professionals were put in charge of monitoring patients at provincial level, namely:

2 medical doctors and 2 nurses' coordinators were in charge of managing and coordinating the monitoring activities; 13 nurses, 2 medical doctors (specialists) and 1 medical doctor from the Special Continuity Care Unit (so-called *USCA*) were in charge of performing the actual monitoring of the positive cases. A total of nearly 80 healthcare professionals were also involved in the monitoring phase at community level. The monitoring of the home-quarantined patients was initially set up with the following procedure: medical doctors and nurses from the COVID-19 Special Unit phoned twice a day (morning and afternoon) the home-quarantined patients to collect information about their clinical status and the progression of the disease symptoms (if any). Data collected included the patients' self-reported body temperature, perceived pain, level of fatigue, dyspnoea, level of consciousness, presence of deep vein thrombosis. This continuous and remote monitoring performed through periodical phone calls was set up to detect the progression of the diseases, to support direct referral to the GP for clinical assessment and access to the emergency room for evaluation with consequent hospitalization if necessary.

Within a few weeks since the onset of the outbreak in the Province, the rapidly increasing number of home quarantined COVID-19 patients to be monitored created a demanding challenge from the healthcare authorities and professionals.

Selecting a priority during the very first weeks of the COVID-19 outbreak

Since the onset of the COVID-19 outbreak in the Province of Trento, TS4.0, as the leading player in the field of digital health within the province, was immediately given the mandate to facilitate the process of designing and delivering e-health services to support a swift reaction to the pandemic. No specific extra-financial funding was acquired for this task to be implemented during the emergency period, as this has been considered part of the standard coordination activities of TS4.0.

Within this context, the TS4.0 Steering Committee identified the urgent need for core actions, such as the rapid implementation of a digital solution to support healthcare staff in charge of monitoring the COVID-19 patients, particularly those home-quarantined. This decision was the result of both internal consultations and a prompt negotiation with the abovementioned "COVID-19 Special Unit". The reasons behind this decision were both organizational and technological. From an organizational viewpoint, it was rapidly clear that i) the number of home-quarantined citizens was steadily increasing in the very first weeks since the onset of the epidemic and ii) healthcare staff in charge of monitoring these patients were extremely exposed to overwork; iii) because clinical management of the patients at the hospital was clearly a sole responsibility of the healthcare staff, the periodical collection of information on home-quarantined patients could be (partially) assigned to the patients themselves, by and with reliable and ready-to-use self-care / self-monitoring solutions. From a technological view-point, it was considered that specific Apps for telemonitoring and self-care of patients were already been piloted and used in the context of previous projects, a technological tool in use for the management of integrated-home care in Trentino Province was already available as part of the standard care (the so-called "@home platform").

In terms of technological assets, a multidisciplinary approach was also adopted. A working

group composed of medical doctors, nurses, IT specialists, technologists, researchers, and project managers from APSS, FBK, PAT was set up under the coordination of TrentinoSalute4.0, with the aim of collecting clinical requirements and designing, testing and implementing the technological tools.

As previously mentioned, the project was based on an already existing partnership among the Autonomous Province of Trento (PAT - Department of Health and Social Policies), the local Healthcare Trust (APSS), and the Bruno Kessler Foundation (FBK). This previous collaboration represented the ideal basis to quickly develop and deliver a ready-to-use tool for supporting healthcare staff in charge of monitoring patients. Clinical colleagues from APSS (including members of the COVID-19 Special Unit) were responsible for setting up the clinical assumptions and criteria behind the technological asset, whilst the IT colleagues from APSS and FBK were in charge of developing the App and linking the system with the already-existing telemedicine system which was in use by the nurses of the Home Care. PAT colleagues provided guidance and inputs in line with the Provincial strategy put in place during the COVID-19 emergency period, particularly the strategy related to patients' management.

Development of an App for monitoring home-quarantined patients

The aim of rapidly incorporating a technological and organizational approach towards COVID-19 monitoring in Trentino Province, was motivated on the need to support the healthcare staff in dealing with the sudden increase in the workload presented during the first stage of the virus spread.

To reach this objective, the TreCovid19 system was specifically set up: i) to regularly and automatically collect self-reported symptoms from COVID-19 home-quarantined patients through a smartphone App; ii) to translate symptoms' subjective self-reports into numerical scales; iii) to allow a set of alerts based on specific cut-offs, periodically informing healthcare staff about the status of the patients and optimizing interventions and direct contacts if required.

The mobile App was embedded into an already existing telemedicine platform, adopted by the Home Care. The core approach adopted for this endeavour was to merge organizational and technological components by embedding a telehealth service (mainly supported by a dedicated App) into the already-existing framework of the clinical procedures for home-quarantined patients monitoring.

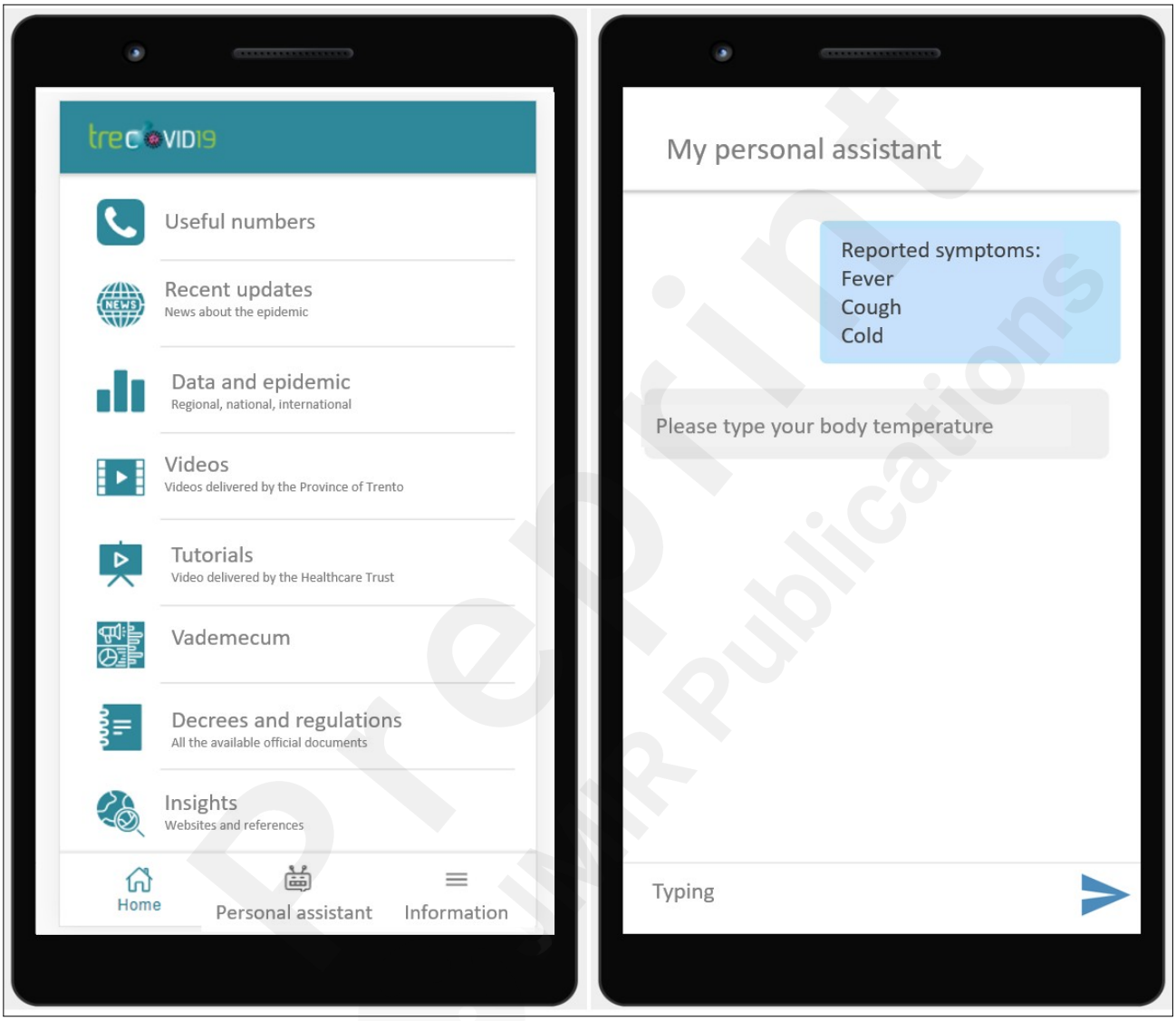
The system was rapidly developed by designing and delivering to components: i) an App for patients to support the daily self-collection of symptoms, and ii) a dashboard for medical doctors and nurses in charge of patients' monitoring.

Patients' App

The TreCovid19 App home page included a number of functionalities divided in two main types

(see Figure 1). The first one related to proving official information about the pandemic and general information to cope with it such as recent updates about the epidemic numbers, video tutorials delivered by the Healthcare trust and presenting tips and advices on specific safety procedures, information on the regional and national decrees and regulations linked with the COVID-19 pandemic.

Figure 1 – Layout of the TreCovid19 App and related functionalities



The second type constituted the core tool for patients and was represented by an automated chatbot functionality. The App was periodically activating a specific chat with the patient, administering a set of items to gather self-reported data on health status and related symptoms. The different pieces of information were collected twice a day, once in the morning and once in the afternoon, and communicated in real time to the central system. In case the level of self-reported symptoms was exceeding the cut-offs set by the healthcare staff (see table 1) a specific alarm was sent via email to the COVID-19 Special Unit for immediate (re)action.

Dashboard for healthcare staff

The dashboard for the healthcare staff was based on the so-called @home system [CITATION Fon19 \l 1033][CITATION Man17 \l 1033]. Such a system is constructed on top of the APSS technological tool currently in use for the management of integrated-home care in Trentino Province. The @home application was successfully adopted to improve efficiency in managing the reporting process of all interventions performed by the home care case managers. The adoption of the system reduced the workload for reports management, as well as limited paper-work for nurses.

The dashboard for healthcare staff was developed using a Customer Relationship Management commercial tool, whilst nurses can use a dedicated tool when delivering home visits. The dashboard uses a specific Platform as a Service (PaaS), which makes it possible to operate on isolated virtual environments.

The integration currently available in the @home platform allows a proper link with Consent and Privacy documentations available within the official Document Repository, plus a secure link and integration with the health register, with the register of operators/healthcare staff, and with the APSS notification system.

Setting up the clinical requirements

To set up the COVID-19 quarantine monitoring tool (Mobile App) for patients, a rapid review of available scientific literature, technical documents and reports was performed by the clinicians collaborating within the working group. A number of assessment scales were also reviewed by medical experts from the COVID-19 team, to identify potential items to be included in the monitoring tool, such as standard validated scales [CITATION Kar18 \l 1033]. A multi-disciplinary approach was adopted, setting up a working group composed of medical doctors, nurses, IT experts, project managers, to set up an automated monitoring tool to be used in the very first wave of the epidemic. The working group was constantly in contact with and reporting to the steering committee, to ensure an effective decision-making process. It should be underlined that the unexpectedness of the first COVID-19 outbreak and organizational complications attached to it were detrimental conditions both for healthcare staff and IT staff in developing the system in a very short period. Other major challenges rose due to relative uncertainty regarding clinical manifestations and related indicators of the infection in the first few months of the epidemic outbreak, rendering it difficult to construct a stable and reliable list of indicators to be translated into the App functionalities.

Therefore, a pragmatic decision process was adopted by the core group of medical doctors in charge of managing the provincial COVID-19 task force. After a round of internal meetings, a core set of key indicators and related cut-offs were identified (as well as the core IT functionalities). The proposal was negotiated and agreed with the Steering Committee group. In addition, a shared decision was taken to group the patients into two categories according to their clinical status, namely:

- Red group (Acv19): patients considered to be COVID-19 positive. Positive cases were determined based on one of the following criteria: reporting clinically relevant symptoms; reporting positive swab result; reporting relevant clinical parameters from

radiology.
- Blue group (AIOcv19): cohabitants/family members living with an identified COVID-19 positive case. The blue group was specifically initiated to monitor the developments of the conditions of the cohabitants, specifically to signal their potential infection by the virus.

Table 1 details the key pieces of information that have been identified by the team of medical doctors and nurses in charge of monitoring the disease progression (the detailed questionnaire is provided as supplementary material). An automated alarm system was designed considering the shown variables and their cut-off values.

Table 1 - Participants' grouping, variables and cut-offs adopted for the TreCovid19 App

Group	Variables	Cut-off
Red group (Acv19)	Body temperature	>= 39
	Pain (NRS)	>= 4
	Fatigue	>= 7
	Peripheral oxygen saturation (SpO2) *	<= 95
	Dyspnoea	>= 4
	Level of consciousness	Confused or coma
	Deep vein thrombosis (DVT)	Yes
	Respiratory rate	>= 22 (per min)
Blue group (AIO Cv19)	Body temperature	>= 37,5
	Pain (NRS)	>= 4
	Fatigue	>= 7
	Dyspnoea	>= 3
	Level of consciousness	Confused or coma
	Deep vein thrombosis (DVT)	Yes
	Respiratory rate	>= 22 (per min)
	Assumption of antipyretics	Yes

* Sp02 was considered only when oximeter was available

Selecting the patients

Considering the emergency context in which the telemonitoring system has been set up and delivered, researchers, healthcare staff and managers decided to adopt a conservative approach. In line with a precautionary principle, only patients with relatively stable medical conditions were contacted and provided with the App, restricting the use of App to a limited number of eligible patients. This was decided to allow i) proper adoption of the system and related procedures in view of a potential scale-up of the initiative and ii) to guarantee a controllable margin of safety for the patients in this first phase of emergency.

Therefore, patients were included based on the following inclusion criteria: being COVID-19 diagnosed home-quarantined patients; being residents in the province of Trento; reporting relatively stable medical conditions; being able to use a smartphone or living with a cohabitant

with a smartphone; voluntary participation. Medical doctors and nurses of the covid-19 special unit were in charge of the assessment of the medical conditions, based on the experience they gained through the very first group of patients monitored until that time. Exclusion criteria were: reporting severe medical conditions; reporting being part of vulnerable populations (e.g. having complex general and/or chronic health conditions); reporting specific social and/or psychological needs (e.g.: anxiety management).

It should be underlined that – mainly because of emergency issues – either the exact number of potential eligible patients nor precise clinical patterns were collected and registered. The participants were a limited number of patients mainly because of i) the unexpectedness of the COVID-19 epidemic, ii) the exponential increase of the number of infected patients, and iii) the relative uncertainty about the clinical manifestations and related indicators of the infection. In addition, the App has been developed within a period of two weeks, to ensure the availability of a monitoring tool to support healthcare staff in the shortest possible time: therefore, the App was adopted only for a convenient sample of patients. The decision of assigning the App to a patient was based on the clinical assessment performed by the healthcare staff in charge of monitoring the patients, following the available guidelines and experiences gained through the very first epidemic wave. Enlarging the number of patients and extending the service to patients that were not residents in Trentino was not considered feasible.

Setting up the procedural flow

The procedure of the telemedicine system is presented here below. Patients were contacted via phone by the "COVID-19 Special Unit" team in charge of the COVID-19 cases monitoring. Members of the team assessed potential eligibility via phone (for patients' criteria see dedicated section below).

After the eligibility for being enrolled in the project was confirmed, subjects were grouped according to the two abovementioned categories, namely Red group (Acv19 - patients considered to be COVID-19 positive), Blue group (AIOcv19 - cohabitants/family members living with a COVID-19 positive case). COVID-19 positive patients and their co-habitants were invited to access the web-App TreCovid19. Activation of the app was done by i) entering their health insurance code and ii) their fiscal code, matching with the healthcare platform. The App was then linked with the specific clinical profile of the patient.

Nurses and medical doctors were in charge of training and assisting patients in the process of downloading and activating the App, providing telephone support in case of issues related to installation and use. The participants underwent the remote quarantine management monitoring, and the App was used to automatically prompt the patients from both groups to fill in the requested information twice a day (morning and afternoon). Once an alert was received by the healthcare staff, the participant was contacted via phone by a trained operator (either a doctor or a nurse), to remotely assess the health status and the progression of the disease.

Two potential outcomes of the assessment were set up:

- Typing error: the alarm was triggered by an incorrect data, entered by mistake. In this

case, a manual correction of the parameter is performed to ensure correct track and recording of the data. Typing errors accounted for a very small part of the generated alarms.
- No typing error: the alarm was triggered by data correctly entered by the participants.

In the latter case, the healthcare staff performed a telephone-based in-depth assessment of patients' general conditions and previous parameters, resulting in one of the following scenarios: i) continuous use of the monitoring system based on the App; ii) intensify the remote monitoring by adding periodical phone calls to the App usage; iii) direct referral to the GP for clinical assessment, in view of the need to incorporate additional interventions (e.g. pulse oximeter delivery at home, home visits scheduling, access to the emergency room for evaluation with consequent hospitalization if necessary, etc.). In general, and based on the telephone-based in-depth assessment, healthcare staff considered that the validity of the self-reported data was appropriate, with few exceptions related to potential overestimation of some symptoms.

Ethical issues

Dedicated information sheets and informed consent were already available for the telemedicine system in use. A specific information sheet was developed for patients when downloading and activating the TreCovid19 App.

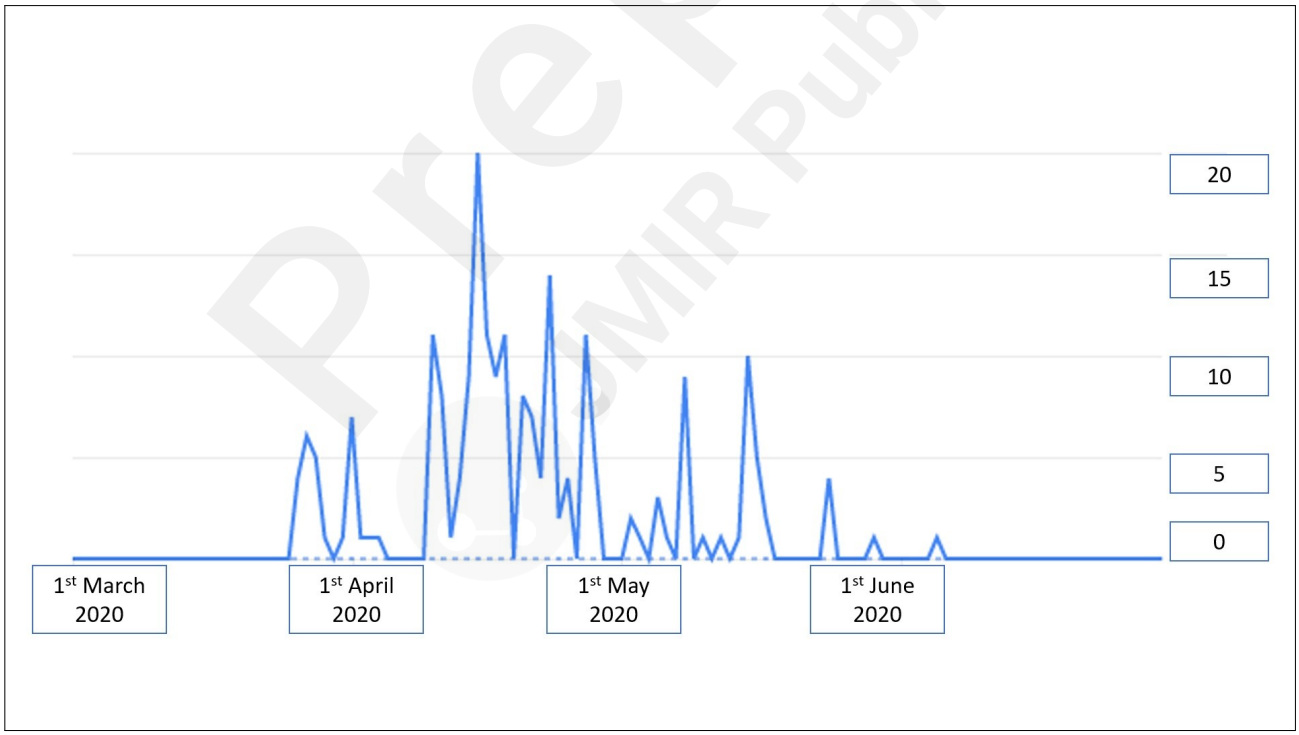
To further improve safety and reliability of the system, a set of piloting phases were performed to ensure secure transmissions of data and proper functioning of the alerting system and related cut-offs. Specific data to allow proper insights about validity of the self-reported data were not collected (e.g. comparison between self-collected versus healthcare worker-collected data). Nevertheless, based on the information gathered through the telephone-based in-depth assessments, the validity of the data collected through the app was considered acceptable. Constant supervision of the system has been guaranteed during the project piloting phase.

RESULTS

The multidisciplinary group developed the monitoring technological platform in time for wide use during the very first months of the epidemic in the Province of Trento. It should be underlined that the first cases officially reported in the province of Trento were identified the 3rd of March 2020 (4 patients), whereas at the end of March the number of citizens infected with COVID-19 increased to 2.529 subjects. The TreCovid-19 platform was developed and made available in an extremely short period of time (in two weeks approximately), and this was possible thanks to the existing infrastructure on which the new service has been constructed. This swift reaction enabled the monitoring of 170 home-quarantined COVID-19 patients from the end of March to June 2020 (see Figure 2). The large majority of patients monitored through the telemedicine system was enrolled in April.

Of the 170 patients, specifically selected for this piloting phase, 107 were assigned to the red group (Acv19), that is, COVID-19 positive patients in quarantine, whilst 63 participants were assigned to the blue group (AIOcv19), cohabitants and/or family members living with a COVID-19 positive case. Out of the enrolled patients, half were female (n=85) with an average age of 37.83. The red group sample was composed of 52 female patients and 55 male patients (average age of 38.95), whilst for the blue group 33 participants were female patients and 30 were male (average age of 35.92).

Figure 2 – timeline of project piloting and enrolment



With regards to the red group (Acv19), 2.570 monitoring measurements were collected by the App (24 measurements per subject on average), whilst considering the blue group (AIOcv19), 1.057 sets of measurements were gathered by the App (17 measurements per subject on average).

On be basis of the available data, none of the patients neither deteriorated nor needed prompt hospitalization. Once recovered, the patients were simply asked to uninstall the App, that was unlinked with the @home system as well.

DISCUSSION

To our knowledge, during the first COVID-19 wave the App TreCovid-19 represents a unique example of swift design and delivery of a technological innovation supporting healthcare staff dealing with the monitoring of home-quarantined patients, in Italy and in the European countries as well. Actually, the uniqueness of this experience lies in the fact that i) it can be considered as one of the very first telemonitoring experiences launched during the first COVID wave [CITATION Tim20 \l 1033] [CITATION XuH20 \l 1033] and ii) it has been launched in Italy, one of the first Western countries to be significantly hit with the COVID-19 epidemic[CITATION Rem20 \l 1033].

Despite the critical contextual situation, this project has successfully achieved its goals, thanks to the two key strengths that are identified and explained in this paragraph.

The first commendable strong point lies in the presence of a pre-existing joint centre for digital health at Province Level. In fact, the TreCovid-19 initiative was promoted and coordinated by the Competence Centre on Digital Health (TrentinoSalute4.0), a strategic alliance among the three core health stakeholders in the Province, namely: the Autonomous Province of Trento (PAT - Department of Health and Social Policies), the local Healthcare Trust (APSS), and the Bruno Kessler Foundation (FBK). Despite the unexpectedness of the first COVID-19 outbreak and organizational complications attached to it, the presence of this joint centre represented a pivotal asset to promote a swift development of the telemonitoring system within a considerably short period of time, promoting a prompt convergence of organizational, clinical and technological competences within the different institutions.

A second strong point is the integration of a specific telemedicine system (TreCovid-19) within the healthcare platform already in use by thousands of citizens and organizational asset, providing an immediately available tool for piloting a novel telemonitoring system. In fact, the pre-existing digital health infrastructures already in use for patients and healthcare staff in the Province of Trento [CITATION Ecc201 \l 1033] [CITATION Fon19 \l 1033] [CITATION Osm17 \l 1033] allowed an efficient development and delivery of a digital tool to tackle the epidemic, whilst the healthcare provincial institutions were under enormous pressure.

Limitations

The core limitation of this initiative is related to the swift and unstable scenario in which such a telemedicine system has been developed and adopted. Firstly, the unexpectedness of the first COVID-19 outbreak and organizational complications attached to it exposed healthcare and IT staff to a challenging scenario when developing the system within a very limited timespan.

Secondly, the relative uncertainty about the clinical manifestations and related indicators of the infection, made it difficult to construct a stable and reliable list of indicators and triggers to be translated into the App functionalities, at least in the first months since the beginning of the epidemic. Furthermore, no specific clinical, automated or laboratory-based indicators were

considered to triangulate the different pieces of self-reported information collected in this preliminary phase of the project. Because of the emergency situation and the pressing need for implementing an immediate action, the project team privileged a rough validation strategy based only on the completion of the requirements from the clinical team over a thorough trial analysis. For the same reason, the collection of specific data on this process was not considered critical in this phase, as – again – the urgency of having a platform immediately usable for the emergency purpose was the core priority, considering the increasing number of patients to be monitored. In addition, clinical evidence, as well as well-structured guidelines about specific cut-offs were not always available when the system was designed.

This explains why researchers, healthcare staff and health managers decided to adopt a conservative approach in line with a precautionary principle, and to enrol in the project a limited and convenient sample of patients with relatively stable medical conditions. This was decided i) to allow proper evaluation of the system and related procedures and ii) to guarantee a controllable margin of safety for the patients in this first phase. As a result, there was no possibility to obtain a larger sample size and therefore to test the App and its functionality on a larger audience, providing further validity and robustness of the findings.

The system has not been promoted as standard procedure nor scaled considering several organizational, technological and contextual factors of emergency during the very first wave. At the same time, proper qualitative and quantitative assessment is foreseen to explore the organizational and contextual factors (e.g. digital literacy, internal procedures, clinical requirements, etc.) that can potentially contribute to or hamper a larger adoption of the system. Likewise, an improved co-design of the App and an update of the clinical information and related cut-offs could further improve the usability of the system. In fact, a larger implementation of a reliable telemedicine system to support patients monitoring could be particularly important during the fall/winter season of 2020 and the first part of 2021, when a relevant increase of home-quarantine patients is more likely to occur.

Lessons learnt: do's and don'ts

When healthcare institutions are facing a sort of health tsunami as the one we all experienced during the first COVID-19 pandemic, there is a clear need for a rapid reaction and swift delivery of viable procedures and tools to tackle that calamity. On the basis of this experience, authors might identify some core do's and don'ts learnt through this initiative.

The first issue is related to the swift identification of the key priority to be addressed, among the different urgent issues to cope with. In our case, the monitoring COVID-19 home quarantined patients has been immediately considered a key component in the management of the epidemic, particularly in the first phase of the outbreak, also with a view of preventing overflowing of patients to the intensive care wards. Even if it has represented a challenging action considering the relative uncertainty about the clinical manifestations and related indicators in the early stage of the epidemic, developing a dedicated telemedicine system appeared to be a vital action to support health care staff in delivering efficient healthcare service despite the huge increase of infected patients. This prompt identification of a list of priorities to be addressed (in this case, telemonitoring) could occur only if previous teamwork

and well-organised collaboration among key stakeholders are in place.

The second issue is related to the ability to select pre-existing infrastructures, to adapt them in light of the new contextual factors and to deliver the service within a reasonable timeframe. The provision of a telemonitoring system was essential if provided in the shortest timeframe possible, considering the rapid increase of the COVID-19 epidemic that was putting the healthcare provincial institutions under enormous pressure. Developing from scratch a new tool for monitoring COVID-19 positive patients would have resulted in an impossible and detrimental task.

In other words, the result achieved in the Province of Trento could be linked to specific contextual dynamics, that authors consider even more essential factors in the framework of sudden outbreaks and public health calamities: availability of former collaboration, pre-existing technological infrastructures, and a multidisciplinary approach.

First and foremost, an essential factor was the availability of a former collaboration in place among the key health organizations within the Province (APSS, APT, FBK). This was likely to be the key factor of success of this very initiative. Within a scenario of a pressing pandemic, this previous teamwork and the availability of pre-existing tools and technological infrastructures have represented a solid foundation for coordinating a complex task as the swift delivery of an ad-hoc telemonitoring system to tackle a relatively unknown epidemic. The TrentinoSalute4.0 alliance has also enabled a rapid adaptation of already available eHealth platforms, that have been speedily converted as a ready-to-use tool to tackle the sudden COVID-19 outbreak.

An additional factor of success was the multidisciplinary approach adopted. The harmonization between technological assets and organizational procedures, as well as putting together clinical know-how, public health expertise and IT knowledge, was possible only because of a multifaceted and integrative working method. The fact that medical doctors, nurses, project managers, IT technicians were already exposed to long-term cooperation in the field of digital health resulted in a prompt and smooth cooperation within quite a critical context due to the COVID-19 pandemic.

Finally, authors would like to further stress the importance of the abovementioned factors also in view of potential future scenarios similar to the COVID-19 outbreak. First and foremost, this experience has underlined the clear need for building up solid collaboration among the key health, policy and research organizations at local level, ideally by establishing specific joint centre for digital health. If already present, these alliances must be strengthened considering their potential pivotal role in case of tsunamis in the field of public health. In fact, this could guarantee the availability of an organisational asset for a prompt and swift reaction to emergencies. Furthermore, promoting multidisciplinary collaboration and mutual inspiration among IT experts, public health managers and healthcare staff could represent a vital long-term investment to ensure smooth convergence of different stakeholders in emergency circumstances. Lastly, the design of technological and digital health infrastructures with high levels of flexibility and adaptability could also be a strategy to pursue, to make these infrastructures flexible in case of emergency.

Lessons learnt: evaluation and assessment

Parallel to this, authors can also list here a number of lessons learnt through this initiative in terms of evaluation and assessment, albeit time constraint led to the lack of a robust methodological asset for evaluating and testing the system.

First of all, there is a clear need for developing an approach for assessing and validating technological tools developed in a strict period of time for emergency purposes, like the one described in the present paper. Evaluating to what extent the harmonization between technological assets and organizational procedures is put in place should be a key action, even when a rapid reaction to the emergency leads to a swift adaptation and implementation of available technologies to address the containment of the healthcare crisis.

Secondly, in ideal conditions, the adoption of a robust study designs should be considered, even within a context of emergency like the one experienced. Setting up a clear study design (e.g. case-control design) within this first phase of the project could have further improved the interpretation of outcome and results of this initiative. For instance, the idea of including a control group was discussed, but the emergency prevented the project team to design a suitable research plan, as the core objective was to deliver a ready-to-use system to support healthcare staff, in the very early phase of the epidemic outbreak. More advanced strategies for implementing robust study designs for reacting to emergencies should be considered in future crisis scenarios.

Thirdly, the opportunity of a broader psychological-sociological assessment of the experiences of family members and patients monitored at home, as well as the experience of the healthcare staff adopting the technological tool, could have represented an added value in evaluating the initiative. Attached to this, a cost-effectiveness analysis of the entire initiative would be a critical, albeit complex, task to further assess the viability and sustainability of the technological-organizational asset.

To conclude, we might underline that the rapid onset of the COVID-19 pandemic urgently called upon the need of swift changes in the healthcare provisioning, as well as the need for a rapid “design-to-deliver” approach to made immediately available to healthcare staff specific solutions that can support management of a rapidly increasing number of patients. Within this scenario, monitoring of COVID-19 home quarantined patients was a key component, as it constituted a challenging but important action to deliver efficient healthcare service and to control patients’ status and related hospitalization levels.

This paper describes how we managed to develop and deliver in short time an eHealth tool to assist healthcare staff in coping with a flood of COVID-19 home-quarantined patients, even in the period of a severe and unpredictable outbreak.

The TreCovid19 system has provided useful insights of possible viability and impact of a technological-organizational asset to manage a potentially critical workload for healthcare staff involved in the periodic monitoring of a relevant number of quarantined patients, notwithstanding its limitations due to the rapid implementation of the whole initiative. TreCovid19 presents high potential to further support the local healthcare system when facing higher peaks of COVID-19 epidemic or future healthcare emergencies: in this perspective, further optimization of the system, its potential extension to larger groups of home-quarantined patients in the Province of Trento, and a robust validation assessment of the entire

model might further increase its applicability.

ACKNOWLEDGEMENTS

The authors would like to thank all the TreCovid19 users, including patients and healthcare staff, as well as all the colleagues from the different institutions and departments contributing to the TreCovid19 project in such a difficult period as the one we all faced during the first COVID-19 outbreak.

CONFLICTS OF INTEREST

Authors declare that they have no competing interests.

References

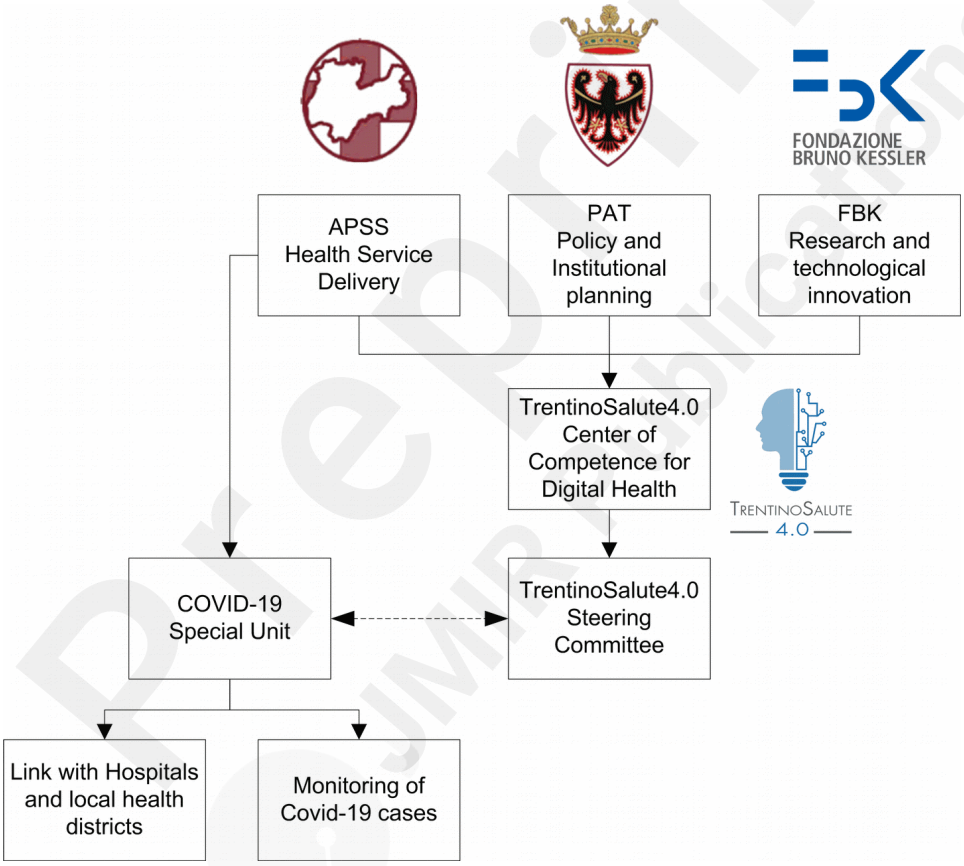
CITATION Ols20 \l 1033 : , (1),
CITATION Hol20 \l 1033 : , (2),
CITATION Wor20 \l 1033 : , (3),
CITATION Wor201 \l 1033 : , (4),
CITATION Guz21 \l 1033 : , (5),
CITATION Rem20 \l 1033 : , (6),
CITATION Acu20 \l 1033 : , (7),
CITATION XuH20 \l 1033 : , (8),
CITATION Tim20 \l 1033 : , (9),
CITATION Rem20 \l 1033 : , (6),
CITATION Omb20 \l 1033 : , (10),
CITATION May19 \l 1033 : , (11),
CITATION Ecc201 \l 1033 : , (12),
CITATION Fon19 \l 1033 : , (13),
CITATION Man17 \l 1033 : , (14),
CITATION Kar18 \l 1033 : , (15),
CITATION Osm17 \l 1033 : , (16),

SUPPLEMENTARY MATERIALS

Supplementary material: organisational diagram

The organisational diagram visually represents the structural asset and relations among the different institutions involved in the initiative.

Supplementary graph 1: organisational diagram



Supplementary material: detailed items (Italian version with translation into English)

Table 1 of the manuscript details the key pieces of information that have been identified by the team of medical doctors and nurses in charge of monitoring the disease progression, and that was used to develop the automated alarming system. The detailed questionnaire used through the App is provided here as supplementary material. The questionnaire was designed and used in Italian. In the following table an English translation is provided.

Supplementary Table 1: detailed items adopted in the App questionnaire

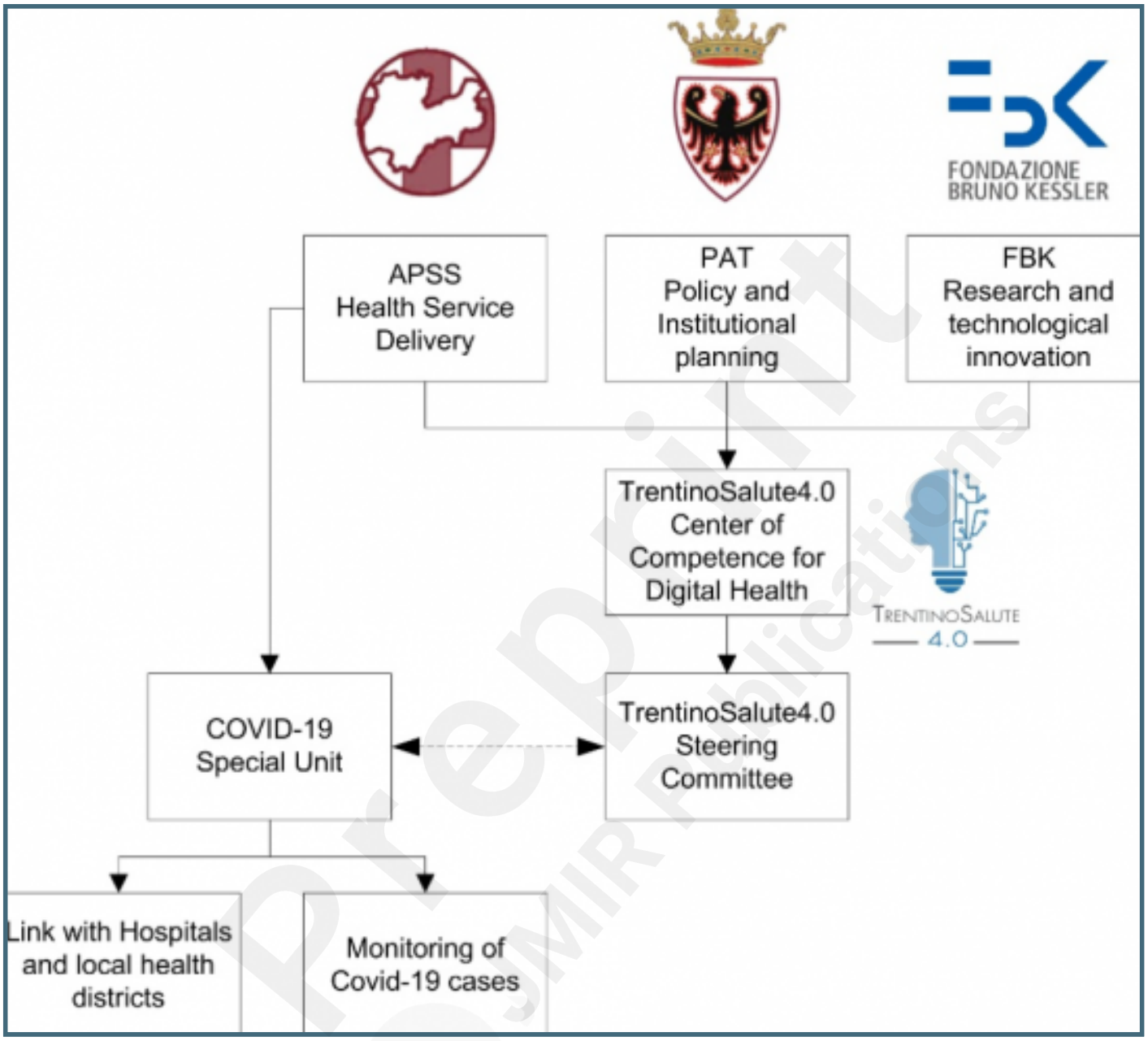
Item number	Question (original version in Italian)	Question (English translation)
1	Se sei in grado di rispondere come ti senti in questo momento? Vigile; Confuso-disorientato; Non risvegliabile	If you are able to answer how do you feel right now? Alert and oriented; Confused-disoriented; Not awakened
2	Qual è il valore della tua temperatura corporea (febbre)? (>34, <44)	What is your body temperature (fever)? (> 34, <44 C)
3	Assumi farmaci per la febbre? (SI/NO)	Are you taking fever medications? (YES / NO)
4	Mangi e bevi come al solito? (SI/NO)	Do you eat and drink as usual? (YES / NO)
5	Quanto ti senti stanco? Inserisci un valore da zero (per nulla) a 10 (moltissimo) (0–10)	How tired do you get? Enter a value from zero (not at all) to 10 (a lot) (0-10)
6	Hai la tosse? Se sì indica se è la prima volta o come si presenta rispetto a ieri? a) Non ho la tosse b) Sì è la prima volta c) Sì è migliorata d) Sì è stazionaria e) Sì è peggiorata	Do you have cough? If so, indicate if it is the first time or how it looks compared to the cough you had yesterday? a) I don't have cough b) Yes, it is the first time c) Yes, it has improved d) Yes, it is stationary/stable e) Yes, it got worse
7	Qual è il grado da zero (per nulla) a dieci (moltissimo) di difficoltà respiratoria che percepisci? (0–10)	From zero (not at all) to ten (very much), what is the level of breathing difficulty that you have? (0-10)
8	Se hai il saturimetro indica il valore percentuale di saturazione (SpO2) misurato attraverso il saturimetro, altrimenti inserisci zero. (0 - 100%)	If you have an oximeter with you, please indicate the percentage/value of saturation (SpO2) measured through the oximeter; otherwise enter zero. (0 - 100%)
9	Se hai il saturimetro inserisci il numero di battiti cardiaci rilevati,	If you have an oximeter with you, please indicate the number of

	altrimenti inserisci zero	heartbeats detected; otherwise enter zero
10	Qual è la frequenza respiratoria? Indica il numero di respiri che fai al minuto (per sapere come fare questa misurazione vai nella sezione “Video Tutorial” della Home e guarda il video “l’autocontrollo della frequenza respiratoria”. La persona che ti assiste può guardare il video “il controllo della frequenza respiratoria”) (0-100)	What is the respiratory rate? Please indicate the number of breaths you take per minute (to find out how to do this measurement go to the "Video Tutorial" section of the Home and watch the video "self-monitoring of the respiratory rate". The person/caregiver assisting you can also watch the video "respiratory rate ") (0-100)
11	A livello del polpaccio presenti dolore, gonfiore, calore o rossore? Rispondi sì in presenza di uno o più dei disturbi elencati (SI/NO)	Do you have pain, swelling, warmth or redness in your calf? Answer yes in case of one or more of the following symptoms (YES / NO)
12	E per finire se hai misurato la pressione arteriosa, inserisci il valore della pressione minima (diastolica) (0-300). E ora il valore della pressione massima (sistolica) (0-300)	And finally, if you have measured your blood pressure, enter the value of the minimum (diastolic) pressure (0-300). And now the value of the maximum (systolic) pressure (0-300)
13	Confermi che ad oggi hai rispettato le norme di isolamento? (SI/NO)	Do you confirm that today you have followed the isolation regulations? (YES / NO)
14	Confermi i seguenti valori? Riepilogo dei valori (SI/NO) - Se non corrispondono vengono riproposti per la correzione	Do you confirm the following values? Summary of values (YES / NO). Patient is in the position of amending/correcting the values
Messag e	*I tuoi dati sono stati inviati correttamente. Ti ricordo di inserire le prossime rilevazioni: una alla mattina tra le 10 e le 12 e una al pomeriggio tra le 16 e le 18. Grazie per il tempo dedicato, buona giornata e a presto.*	*Your data has been sent successfully. Let me remind you to enter the next measurements according to the agreed timeline: once in the morning between 10 and 12, and once in the afternoon between 16 and 18. Thank you and have a good day.*
Note	*Sta all’operatore decidere se aumentare la frequenza di inserimento dati. Nel caso di 3 inserimenti giornalieri:* - *8.30 / 10.30* - *12.30 / 14.30* - *16 / 18*	*It is up to the healthcare staff to decide whether to increase the data entry frequency. In case of 3 daily entries, the slots are as follows:* - *8.30 / 10.30* - *12.30 / 14.30* - *16 / 18*

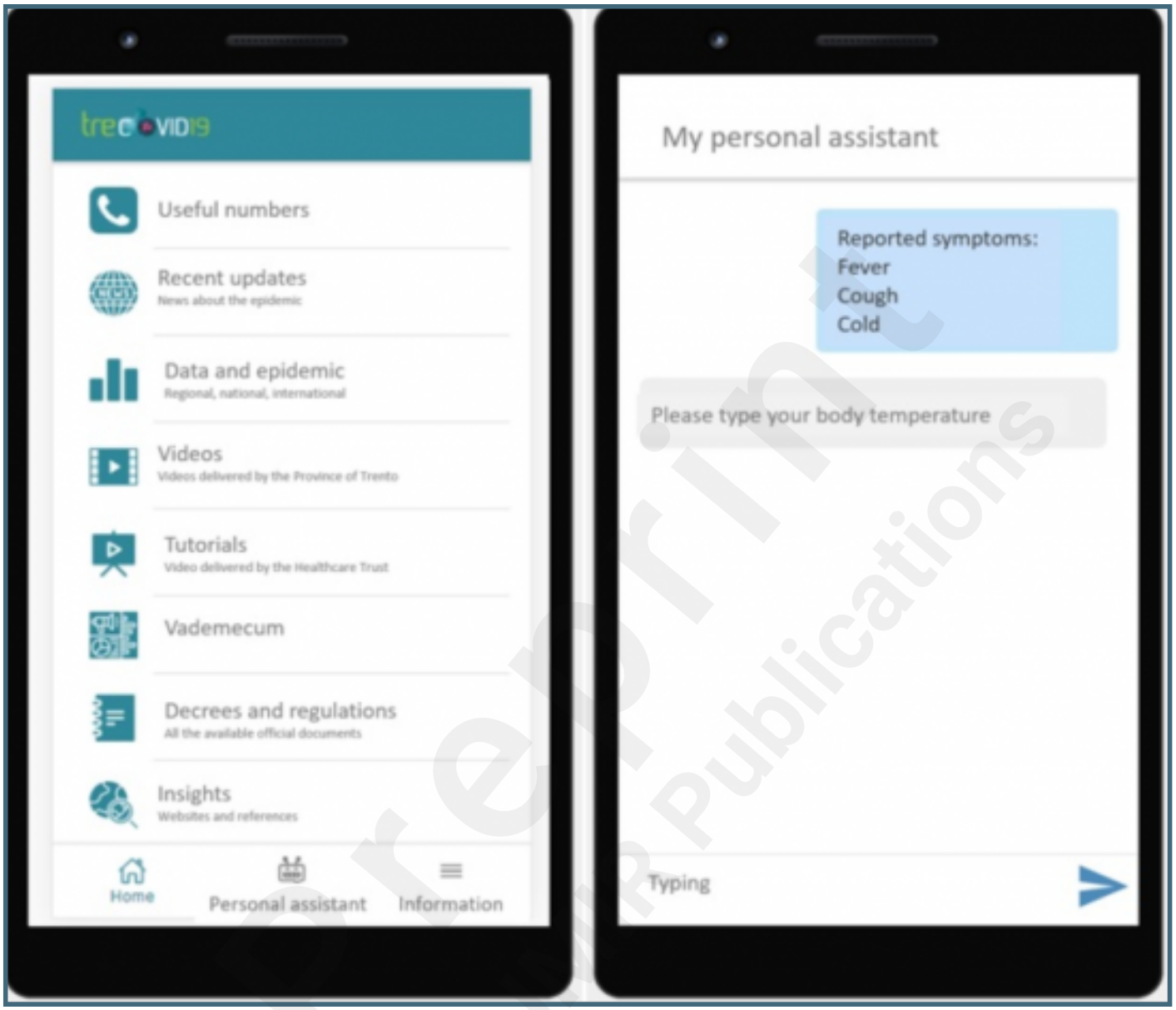
Supplementary Files

Figures

Supplementary graph: organisational diagram.



Layout of the TreCovid19 App.



Timeline of project piloting and enrolment.