



Predictors for more severe course of COVID-19

In order to provide adequate intensive care beds for severely ill patients, patient care can be provided either on an outpatient or inpatient basis, subject to the necessary strict isolation measures and depending on the clinical severity of the disease. In the case of outpatient care, the isolation of infected persons from non-infected persons and regular clinical follow-up must be ensured in order to identify clinical predictors of a more severe course with necessary hospitalization of the patient.

Predictors for a MORE SEVERE COURSE appear to be (1):

- Age (>50 years)
- Male sex
- Pre-existing conditions
- Immunosuppression

- Respiratory frequency > 30/min, severe shortness of breath or SpO2 <90% with room air
- Persistence of fever with hardly no influence of anti-pyretics
- A marked lymphopenia
- · Elevation of LDH and troponin

Oxigen Saturation is one of the parameters mentioned to detect a worsening of a COVID patient, mentioned both by WHO and national and local recommendations (ITA), for example WHO (2,3): "...SpO2 \leq 93% on room air..."; SIAARTI (4) (Italian association Intensive Care); SIMG (5) Indications for GP remote monitoring patients in their houses b: "in range if BP systolic >100 mmHg, Sat > 93 %"

SOURCES

- 1) https://www.rki.de/DE/Content/Kommissionen/Stakob/Stellungnahmen/Stellungnahmen-Covid-19 Therapie Diagnose.pdf? blob=publicationFile
- 2) WHO, China Joint Mission on Coronavirus Disease 2019 (COVID-19)
- 3) WHO, Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected
- 4) http://www.siaarti.it/SiteAssets/News/COVID19%20-%20documenti%20SIAARTI/Percorso%20COVID-19%20-%20Sezione%201%20%20-%20Procedura%20Area%20Critica.pdf
- 5) https://www.simg.it/coronavirus-indicazioni-per-assistenza-domiciliare-ai-pazienti-affetti-da-sars-cov-2/



Practical implementations happening in Italy

1) Self measurement at home + communication over the phone. In order to respect quarantine and avoid risk of infection for healthcare professionals, healthcare providers tend to adopt protocols where the patient take the measurement by himself, in his setting and then communicate the result over the phone

In Trento area "patients have to call 2 times per day the nurse to monitor temperature and Oxigen" (source: newspapers, 5)

"The Ats of Bergamo has already distributed the saturimeters to GP, together with five thousand masks, even if the president of the local Order of Doctors Guido Marinoni suggests to give them directly "to every patient at home with pneumonia", because the one from Bergamo (3,993 infected yesterday) is "an apocalypse scenario" and "out of about 600 family doctors, 118 are sick or in quarantine and one is dead (newspapers, 6)

2) Self measurement at home + data transfer (Telemedicine). This approach, due to its obvious benefits (quarantine, efficiency, data reporting) is emerging, also for fragile patient in general...

"Early oxygen therapy, pulse oximeters, and nutrition can be delivered to the homes of mildly ill and convalescent patients, setting up a broad surveillance system with adequate isolation and leveraging innovative telemedicine instruments. This approach would limit hospitalization to a focused target of disease severity, thereby decreasing contagion, protecting patients and health care workers, and minimizing consumption of protective equipment" (6)

"People are left at home, and I wouldn't want to end up dead in the house unrecognized. We need to be close to them... telemedicine must be used. In this way you would have the ability to intervene when you see the evil parade and to decide who goes further quarantined" (7)

SOURCES

5) TV News: https://www.rainews.it/tgr/trento/video/2020/03/tnt-coronavirus-assistenza-domiciliare-infermieri-3d66e7e2-9f63-4c68-a7fc-4cfdbbf8d690.html

6) Clinicians at a hospital at the epicenter of the crisis (Bergamo) At the Epicenter of the Covid-19 Pandemic and Humanitarian Crises in Italy: Changing Perspectives on Preparation and Mitigation. https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0080#.XncKDCUU8M8.twitter

7) M. Gallo, infectious disease Director at Sacco hospital (ITA)

 $https://rep.repubblica.it/pwa/intervista/2020/03/19/news/coronavirus_galli_numeri_spaventosi_ma_continueranno_a_salire_c_e_troppa_gente_in_giro_-251743895/\#success=true$



Supporting COVID-19 emergency: USE CASES

USE CASES:

- Patient COVID positive managed at home in order to enable healthcare providers to remote monitor their situation, and act accordingly in case of a worsening of the condition e.g. hospitalize patients
- Patient COVID discharged in early stage of recovery in order to free up spaces in the hospital and keep them monitored in their houses, with frequent measurements
- Population at high risk (e.g.: elderly, Diabetes, ...) to remote monitor their situation, avoiding contacts that could be very dangerous for them, in different context (e.g.: homes, nursing homes)

KEY HEALTHCARE PROVIDERS *:

- · Hospitals this is today the "bottle-neck" of the crisis
- · Local Health Authorities who cares about patient at home
- Homecare provides to avoid contact with fragile/elderly

* This is based on the Italian experience. Please refer to your country' COVID organization and plan in order to support in tackling the bottle-neck.



COVID-19: Solution

CGM Solution:

- Patient Data
- Data Monitoring
- Alarm Generation (SMS + eMail)
- ClickDoc Teleconsultation

1:1 Telemonitoring Kit:

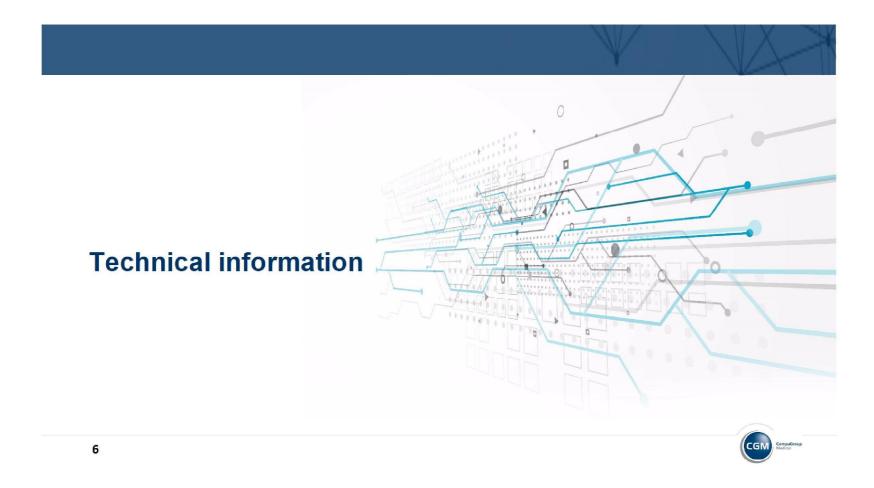
- Locked SmartPhone with M2M SIM and App: reminders, data view, receive information
- PulseOx (Saturation + HeartBeat)
- Temperature can be added manually in the App
- Opt. Blood Pressure
- Opt. Glucosemeter

All Medical Device Class II A

When the kit is not needed any more, the provider can re-allocate the kit after sanitize it. CGM can remotely associate the kit to a different new patient



5



H&S, a CGM company, certifications

- From January 2020 H&S is a 100% CompuGroup Medical company;
- · H&S has 20 years experience in Telemedicine technologies;
- H&S certifications set includes ISO 13485 "Medical devices -- Quality management systems -- Requirements for regulatory purposes" to design and manage Medical Device data"







ISO 27017 & 27018 IN PROGRESS

• All the products (hardware and software) are full compliant to GDPR rules and CE Medical Device class IIA.





H&S Health Platform ecosystem



WEB PLATFORM (SaaS)

H&S Health Platform (CE mark Class IIA) Export Reporting, Print



- Mobile Health Gate: 1:1 App, dedicated smartphone (Class IIA)
- Mobile App



- Medical devices (Class IIA)
- · Environmental sensors
- Specific diagnostic







COVID PATIENT/ AT RISK







Web Platform



WEB PLATFORM (SaaS)

H&S Health Platform (CE mark Class IIA)

- Patient medical record
- Receives and analyses medical data from up to 50 remote devices and data from environmental sensors (Telemedicine, Telemonitoring, AAL)
- Configurable account profile (i.e. operator, supervisor, doctor, nurse,...)
- Enables:
 - 24/7 patients monitoring;
 - · Treatment plan definition for chronic patient (using template)
 - · Personalized patient treatment plan and monitoring scheduling;
 - · Range settings for each patient to generate alert;
 - · Pharmacological reminders;
 - Generate medical report and examination description;
 - · Personalized questionnaires and educational materials;
 - Direct connection with patient and family (SMS, mail, chat) also sending empowerment contents;
- Reporting



Next Steps & Project Plan

5.1.1c

