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## Letter to the Editor



## Home-based COVID 19 management: A consensus document from Italian general medical practitioners and hospital consultants in the Lombardy region (Italy)

Dear Editor,

The coronavirus disease 2019 (COVID-19) pandemic has infected more than 56,628,581 people causing 1,406,449 deaths worldwide, as of November 24, 2020. [1] Among the 17,131,853 active cases (November 24, 2020), 99% are reported as “mild”, and 1% as “serious or critical”, with the proportion between critical and mild cases remaining substantially unchanged throughout the outbreak.

This data shows the potential for an integrated hospital and home management of COVID-19 patients, thus avoiding saturation of hospital beds with patients with relatively mild symptoms. These patients may not need oxygen therapy, and require surveillance of only a few parameters; yet, if systematically admitted to hospital, they may cause hospital overcrowding, spread the infection among health personnel, and reduce the potential of care for the sickest patients. [2]

An integrated approach is critical in order to avoid a collapse of the health care system and social policies. Safe discharge of low-risk patients from the Emergency Room after initial diagnosis requires: a reliable, evidence-based and publicly endorsed definition of “low-risk”; plans and equipment for home surveillance, to be ready for admission of patients showing an unfavorable evolution; specific treatment, if any proven useful, to prevent complications; follow-up of possible organ damage to prevent any sequelae. [3] This approach can only be successful with a policy strategy based on an early involvement of general practitioners (GPs), a close bidirectional collaboration with the hospital system, and an official endorsement by the health care authorities.

This synergy might serve as a template beyond the COVID-19 outbreak; it could serve for high transmission infectious disease and chronic disorders, improving antibiotic treatment at home (in the setting of national projects against antibiotics resistance), with positive effects on resource allocation, as it has been shown in the context of chronic obstructive pulmonary disease (COPD), diabetes, low-risk pulmonary embolism, [4] and heart failure. [5]

Following this concept and guided by the suggestions of the Steering Group (SG) (NM, SS, MP), we conducted a consensus-building approach based on three main stages, according to a modified nominal group technique [6]: (1) definition of the research question and selection of experts (March–April 2020); (2) conduct of a modified nominal group exercise in six open rounds (April–August 2020); and (3) a final consensus group meeting to achieve the list of features via conference call (October 2020).

On the behalf of the PANDEMIA (ProgrAm for reDuction of clinical Events in COVID-19 patients Managed at home In collaboration with general prActitioners) collaboration group: Chiara Cogliati, Francesca Di Marco, Maria Grazia Manfredi, Antonio Voza, Barbara Omazzi, Filippo Galbiati, Valeria Tombini, Stefano Paglia, Luca Bonacchini, Fabrizio Colombo, Paolo Tarsia, Anna Maria Brambilla, Filippo Ottani, Riccardo Bottelli, Davide Lauri, Marco Magri, Mauro Martini, Michele Marzocchi, Nicolò Minghetti, Cristian Pellegrini, Maddalena Wu, Sergio Leonardi, Stefania Piconi, Carlo La Vecchia, Antonella Bitetto, Paolo Bonfanti, Thea Scognamiglio, Giulio Stefanini, Guido Bertolini, Dario Brunelli, Francesca Cortellaro.

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The primary aim of the PANDEMIA group was to provide a clinical risk stratification tool for patients with suspected SARS-CoV-2 infection. The Steering group recruited panellists which had an established expertise in treating infectious and respiratory disease and within the field of thromboembolism and cardio-vascular disease, based on the complex systemic involvement in patients with COVID-19 disease, along with a group of General Practitioners (GPs) representative of the whole cohort of the Metropolitan area of Milan. Both the SG and panellists had no conflict of interest nor they received personal honoraria and/or consulting fees. A research fund provided by Fondazione Veronesi was received and delivered to the four institutions of the SG in order to implement the territorial elements needed for the early diagnostic phase.

Because insufficient published data were available to provide panellists with an informative systematic review of studies at the time of the first rounds, SG and panellists relied the evolving literature as well as their growing experience for the first decision, along with data drawn from hospitalized patients.

Literature review was updated on October, 2020. In order to set out to produce final recommendations, we used the GRADE (Grades of recommendation, assessment, development and evaluation) system, which provides a definition for the quality of evidence followed by a subsequent judgment about the strength of recommendations. [7,8]

All the available evidence is considered low to moderate, because mainly supported by the current clinical practice, whereas well designed studies are lacking. However, the recommendations provided in this document are considered strong, according to the GRADE's binary classification, because of these key determinants: 1) the favorable balance between desirable and undesirable effect; 2) the limited uncertainty in values and preferences; 3) the more favorable effect in resource allocation compared to a more indiscriminate access to each emergency room; 4) their adoption and integration in official regional regulations by Lombardy policy makers. [9]

- Patients with symptoms suspected for SARS-CoV-2 infection should first contact their GPs.
- The management model requires that upon receiving a patient call, the GP will register symptoms and report them on a specific data-sheet on the Public Health Agency portal dedicated to the insertion of few essential data. The following symptoms will be collected, either

via telephone call or through a dedicated web platform depending on local situation: body temperature; respiratory rate / min (if feasible); chest pain; cough; dyspnoea, at rest or exertional; anosmia or ageusia; headache/dizziness; myalgia; arthralgia; asthenia; vomit/diarrhea; loss of appetite; skin lesions, especially peripheral; conjunctivitis. Furthermore, oxygen saturation will be required (basal and exertional based on patient’s compliance) if the subject already possesses a pulse oximeter, otherwise this data will be obtained after delivering the instrument.

- Comorbidity will be quantified using a *modified Elixhauser model*, [10] which includes age, current cancer or having been treated for cancer in the previous year, known respiratory disease, obesity (BMI>30), ischemic heart disease or history of vasculopathy with treatments in the previous year, diabetes mellitus, eGFR< 60 ml/min or known chronic renal failure, current or previous HIV infection, coagulopathy, history of immune-depression or organ transplantation and falciform anemia.
- Confirmed cases in the neighborhood or household cluster will be considered risk factors too.

The risk stratification approach and the management scenarios are reported in Fig. 1.

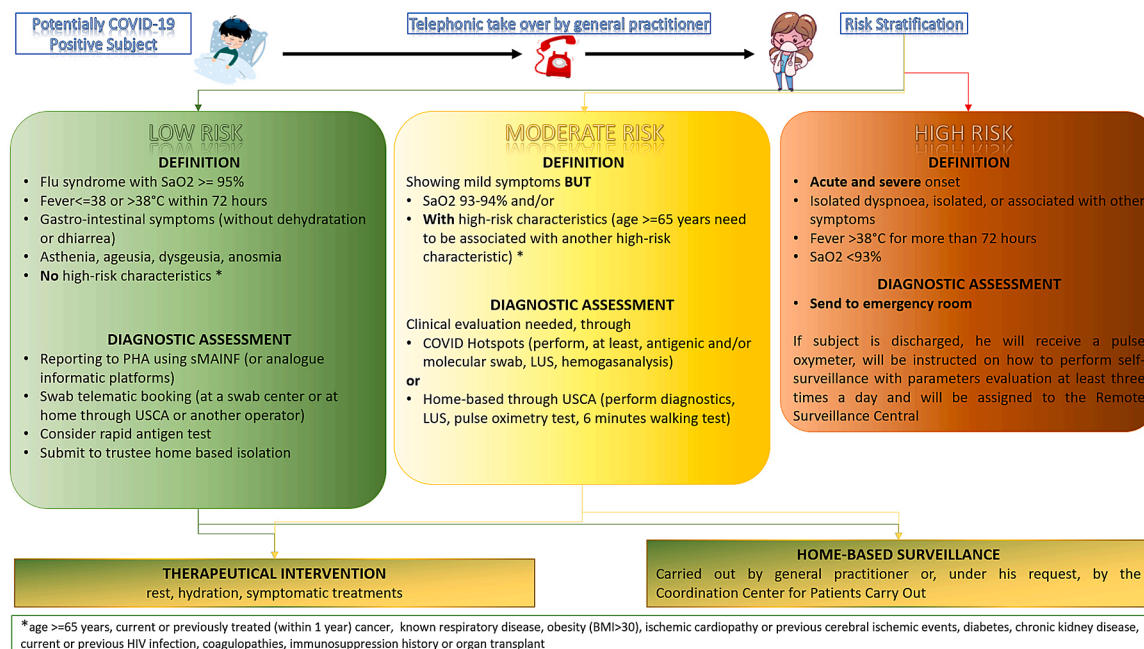
The PANDEMIA Group has introduced a model of temporary patient facility call “Hot Spot” for fast diagnosis and patients’ consultation, strictly related to the GPs activities. Hot spots are located in an area next to the Emergency Room, where physicians involved in taking care of COVID-19 patients do work. These facilities may allow faster diagnosis in patients with *influenza like illness* (ILI) and suspected SARS-CoV-2 infection, throughout clinical visit, biochemical tests and lung ultrasound imaging.

From a diagnostic standpoint a relevant tool is represented by lung ultrasound (LUS), that can be extensively used in this setting. LUS shows many advantages that made it increasingly used over the past few decades, especially in critical care and emergency setting. Compared to Chest X-Ray, LUS is easier to learn and to perform (5 minutes in most cases) and shows higher sensitivity and specificity. Moreover, it has shown a good correlation with CT scan. Unlike computerized

tomography, LUS can be performed at bedside, minimizing the number of operators involved, and has no radiological hazard, which results of particular interest in pregnant and paediatric patients. LUS images of COVID 19 pneumonia are similar to that of other interstitial viral pneumonia and ARDS of different origin. None of the LUS features seems to be COVID specific, even if a “light beam” appearance has been recently suggested as a typical sign of SARS-CoV-2 pneumonia. [11] However, during pandemic outbreaks, high clinical suspicion and high prevalence increase the pre-test probability and LUS can contribute to early diagnosis of COVID 19 pneumonia. This potential benefit of LUS can be relevant for the correct management of infected patients in case RT-PCR swabs are not available or time for processing specimen is considered excessively long. [11] Due to its high negative predictive value LUS can be used to identify patients with low probability of pneumonia, thus furnishing a relevant aid in risk stratification and management. [11]

A specific contribution of this project has been dedicated one-day workshops performed by emergency physicians for GP’ students in the Milan Metropolitan Area. The first edition has been performed in October, 2020.

For patients with mild clinical illness and mild involvement at LUS, providing care at home may be considered, [2] as long as they can be followed up and cared for by family members. An assessment of the social context (general home conditions, caregivers) is an essential part of the initial patient evaluation, mostly by the GP. Patients and household members should be educated about personal hygiene measures that prevent the spread of infection to cohabitants at home. The patient and family members should be provided with ongoing support, adhering to established WHO recommendations. [9] Monitoring should continue for the duration of home care. In addition, sanitary assistance may be provided by the family physician and/or by nursing personnel of the health care system, by home visits and/or using simple tools of remote monitoring: appropriate and cost-effective tools include transcutaneous oxygen saturimetry (delivered by the referral hospital for each city domain); body temperature; heart rate control. According to the published data only about 10 to 15% of such stratified and home-managed cases will subsequently require ER or hospital admission.



**Fig. 1.** Title: Italian general medical practitioners and hospital consultants integrated approach; Caption: Description of the risk stratification and the diagnostic flow since patients ‘call to general practitioner in cases of suspected SARS-Cov-2 infection. sMAINF: “Segnalazione MALattie INFettive e Vaccinazioni”; LUS: Lung UltraSound; PHA: Public Health Agency; USCA: “Unità speciali di continuità assistenziali”.

In conclusion, the present consensus document, resulting from a multispecialty collaboration and communication, provides clinical practice recommendations on patient stratification and management algorithm in patients with SARS-CoV-2 infection. COVID-19 disease has invested several critical aspects of patient's health status, involving the lungs, the cardiovascular system, thromboembolic disease, kidney and neurological function, gastrointestinal disorders and dermatological manifestations. General medical practitioners, infectious disease specialists, pulmonologists, emergency physicians, internal medicine specialists, cardiologists, nephrologists, and anesthesiologists have contributed to its creation. This document represents a bottom-up opportunity to improve care fragmentation and patients' management. The model suggested is being implemented as a pilot project in four hospitals in the Milan Metropolitan Area and Lecco province and has been endorsed by the General Medical Council for the Milan Metropolitan Area and the health authority in Lombardy.

### Funding

Fondazione Umberto Veronesi grant funds will contribute to cover costs for 4 days dedicated to ultrasound imaging training for 100 general practitioners (that will participate in the project). Teachers will be representative physicians of ASST Grande Ospedale Metropolitan Niguarda, FBF Sacco, Lodi.

### Disclosures

None

### Declaration of Competing Interest

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome. We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us. We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property. We further confirm that any aspect of the work covered in this manuscript that has involved either experimental animals or human patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.

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Nuccia Morici<sup>a,b,\*</sup>, Massimo Puoti<sup>a</sup>, Maria Teresa Zocchi<sup>c,e</sup>,  
Carla Brambilla<sup>c</sup>, Andrea Mangiagalli<sup>c</sup>, Stefano Savonitto<sup>d</sup>

<sup>a</sup> ASST Grande Ospedale Metropolitan Niguarda, Milan, Italy

<sup>b</sup> Department of Clinical Sciences and Community Health, Università degli Studi di Milano, Milan, Italy

<sup>c</sup> General Practitioners Group, Azienda Territoriale della Salute, Milan Metropolitan Area, Italy

<sup>d</sup> Ospedale A. Manzoni, Lecco, Italy

<sup>e</sup> Ordine dei Medici Chirurghi e degli Odontoiatri di Milano, Milan, Italy

\* Corresponding author at: Dipartimento Cardioracovascolare, Intensive Coronary Care Unit and De Gasperi Cardio Center, ASST Grande Ospedale Metropolitan Niguarda, Piazza Ospedale Maggiore, 3, Milan 20162, Italy.

E-mail address: [nuccia.morici@ospedaleniguarda.it](mailto:nuccia.morici@ospedaleniguarda.it) (N. Morici).