



Early View

Editorial

Early consensus management for non-ICU ARF SARS-CoV-2 emergency in Italy: from ward to trenches

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Early consensus management for non-ICU ARF SARS-CoV-2 emergency in Italy: from ward to trenches

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The number of people infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is increasing dramatically throughout the world (1), and in Italy (2-3), particularly in the northern region of Lombardy (4). Regional Italian medical and political authorities have implemented extraordinary measures to contain the spread of the virus. This disease may cause massive diffuse alveolar damage resulting in acute respiratory failure (ARF) that requires, in a high percentage of cases, mechanical ventilation (5-8). Based on our general experience so far in dealing with the disease and on the existing knowledge (albeit still limited and evolving) (5-8), Italian respiratory scientific societies proposes here an Early Consensus Statement Management for non-ICU ARF SARS-CoV-2 emergency. It represents the expert opinion of pulmonologists directly involved in the first line of assistance. The Consensus identified two urgent areas for action: a) management, and b) organization. We carried out a search of the published literature in PubMed, Ovid, Embase databases and relevant websites from the construction of the databases to March 20, 2020 in order to retrieve guidelines and recommendations, meta-analyses, systematic reviews, state of the art papers, and randomized trials. The search terms used were: "Coronavirus pneumonia", "ARDS", "Acute Hypoxemic Respiratory Failure", "SARS", "MERS", "Influenza", "Acute Respiratory Failure or Mechanical Ventilation", "Noninvasive ventilation AND Acute hypoxemic respiratory failure". Based on the literature search, a small group of 4 pulmonologists professionals produced a preliminary document, which was then submitted to the consensus group of 10 doctors. Consensus on the final document was achieved through video conference meetings (Conference Call). Using a Delphi-like procedure, we asked the experts to rate the entire document on a 5-point Likert scale (0 = totally disagree; 1=disagree; 2=sufficiently agree; 3=moderately agree; 4=totally agree). Consensus was considered when more than 75% of the respondents rated the document as "totally agree". In this context the proposed paper is a changeable consensus not necessarily totally in line with the WHO documents because the Italian situation was and unfortunately still is continuously in progression

day by day. Below we summarize the recommendations that we consider most appropriate and urgent.

The management-related actions regarded, first, the need to ensure maximum protection of doctors and nurses working in the field (e.g. working at a distance of at least one meter from the suspected or positive patient). Second, the need to create an epidemiological/clinical assessment protocol (triage) to classify patients based on medical history, geographical origin (i.e. inside or outside the cluster zones), and clinical signs such as fever, persisting cough for more than 48-72 hours, dyspnea, $\text{SaO}_2 < 93\%$ when breathing air. Third, the need to develop a diagnostic algorithm to determine which tests to perform when, i.e. pharyngeal swab for SARS-CoV-2, chest X-ray or pulmonary high-resolution CT. The proposed triage led to the identification of four patient categories: green ($\text{SaO}_2 > 94\%$, $\text{RR} < 20$ breaths/min); yellow ($\text{SaO}_2 < 94\%$, $\text{RR} > 20$ but responds to oxygen 10-15 l/min); orange ($\text{SaO}_2 < 94\%$, $\text{RR} 25-30$ but poor response to oxygen 10-15 l/min and needing continuous positive airway pressure [CPAP]/noninvasive ventilation [NIV] with $\text{FiO}_2 < 50\%$; red ($\text{SaO}_2 < 94\%$, $\text{RR} > 30$ but poor response to oxygen 10-15 l/min, CPAP/NIV with $\text{FiO}_2 > 50\%$ or presenting respiratory distress with $\text{PaO}_2/\text{FiO}_2 < 200$ and needing endotracheal intubation [EI] and ICU admission). The actions requested concerned indications for the transfer of suspected or confirmed cases, depending on the local situation, to one of the following: 1) ad-hoc so-called COVID HUB hospitals (i.e. special units inside or outside the hospital dedicated to these patients and developed, on average, within or shortly after the first week from the initial outbreak); 2) infectious disease units, or dedicated areas ready for isolation of confirmed cases and immediate ARF treatment; or 3) ICU for early intubation of compromised patients with low $\text{PaO}_2/\text{FiO}_2$ or patients "not responding" to oxygen/CPAP/NIV. The Consensus focused on a "what to do" management pathway (see flow chart, Fig. 1) stressing the need for close patient monitoring, care of comorbidities, fluid and nutritional prescription, sedation if needed, use of aerosol devices if needed, and monitoring for risk of a sudden deterioration of the patient's clinical conditions. It discussed the indications for high-flow oxygen blender, level of FiO_2 to guarantee just an $\text{SaO}_2 > 90\%$, high-flow nasal cannula oxygen (HFNC) devices, and CPAP/NIV indications as a form of treatment or as ceiling of treatment and palliative care. After extensive discussion, the Consensus set the indication for CPAP between 10 and 12 cmH₂O, without humidification and with helmet (first choice), for CPAP use with a mask (second choice) and for NIV use with an oronasal face mask (third choice), using high performance ventilators or, if these are lacking, dedicated NIV platforms or home ventilators. Due to the non sufficient number of ICU beds, respiratory intermediate units and negative pressure rooms to provide the respiratory support to all the patients, Consensus proposed Emergency Room, medical wards, dedicated units and surgical rooms had to be transformed in locations to provide any form of mechanical ventilation in rooms with possibility of air exchange (big windows to open periodically achieving a change of air of at least 160L/h, as recommended). Clearly when all these environments are unavailable, CPAP/NIV is indicated using the maximum available personnel protection. Indications when to stop CPAP/NIV in case of worsening did not reach a consensus amongst the audit group, nor did standardized indications for when to perform intubation, as this depends on the number of beds of the referral ICU and their actual occupancy. Obviously, the group suggested a regular decontamination of the ventilator and devices used, at the end of the ventilator treatment. Due to uncertainty around the potential for aerosolization, HFO, NIV, including bubble CPAP, we have further stressed the need for airborne precautions. Consensus stressed also that, in the de novo severe critical patients and in patients failing 2 hours of CPAP/NIV,

the GOLD standard remains the ICU admission. Otherwise, in a “war” condition like our with a huge numbers of patients, paucity of ICU beds and ventilators the option of CPAP/NIV administered non invasively remains the unique change. The Consensus was not focused on the role of antiviral, antibiotics, steroids, anticoagulant and others innovative drugs because this topic was not strictly related to the consensus object. Regarding organization, pulmonologists have been involved in identifying: a) hospitals or hospital areas for isolated suspect patients awaiting confirmation of diagnosis; b) specific “contaminated” paths, zones and the team involved; c) transferal procedures for patients into negative aeration rooms (when available) or, as second choice, into one-bed rooms or an area with a distance of at least 2 meters between patients. The work in these days has led to the creation of isolation areas for patient groups (positive and on EI; positive on NIV/CPAP; positive with respiratory failure on oxygen therapy; negative pending the second pharyngeal swab if the clinic and CT scan suggest bilateral and interstitial pneumonia). The respiratory team has had to manage and co-manage patients with other specialists in the multidisciplinary team with maximal flexibility to find discharge routes to “intermediate” units (such as Internal Medicine, Respiratory Rehabilitation, Social Units) for COVID patients with further need of clinical and infective follow-up. The Consensus agreed to abolish visits by family members to COVID patients, offering once a day a face-to-face contact or a telephone call with one family member only. Since the first days of the crisis, our teams have been involved in sharing ceiling treatment decisions for EI and CPAP/NIV use based on the patient’s medical history, age, beds available and numbers of new cases. Finally, all our staff has been strongly exhorted to use adequate personal protective equipment (PPE) according to the WHO document, equipment that, up till now, remains not easy to find due to the huge demand.

Up to day (March 28), in Italy more than 86.000 people are found COVID positive, 40.000 are isolated at home, 4.000 are admitted in ICU, 6.000 have been ventilated non invasively, 9000 died and 11.000 people recovered. A large number of patients are co-managed with mixed teams of pulmonologists and others specialists. Our respiratory teams are living in a constant state of anxiety, anguish, fear, helplessness, panic, despondency, inadequacy, with moments of deafening silence and moments of excited frenzy, but at the same time with courage, firmness, determination, professionalism, solidarity and compassion. As illustrated in **Figure 2**, the general public seems to be well aware and empathize with us in our particular situation.

In conclusion, based on our actual experience and the recent literature, it seems clear that the viral spread is destined to continue growing; hence further extraordinary organizational proposals, detailed protocols and specialized teams are urgently required. We do not know if we are facing something similar to what was experienced by heroic doctors and nurses in the 1950s during the polio epidemic when most hospitals had limited availability of iron lungs for patients unable to breathe independently (9). On that occasion, makeshift respiratory centers were set up to assist the most severe patients, from which the Intensive Care Unit was born (9). Our suggestions for our colleagues and health policy makers are: 1) To develop as soon as possible clear and effective measures to protect health workers 2) To increase immediately and maintain in the next future the beds of ICU and dedicated to NIV and critical care patients in respiratory settings 3) To completely rethink the different European health systems considering a wide range of flexibility and the strong need for the development of home care assistance and of new models of hospital organization 4) To develop a “Marshall plan” to sustain the devastating impact of the COVID 19 pandemic on disability and socio-economic systems.

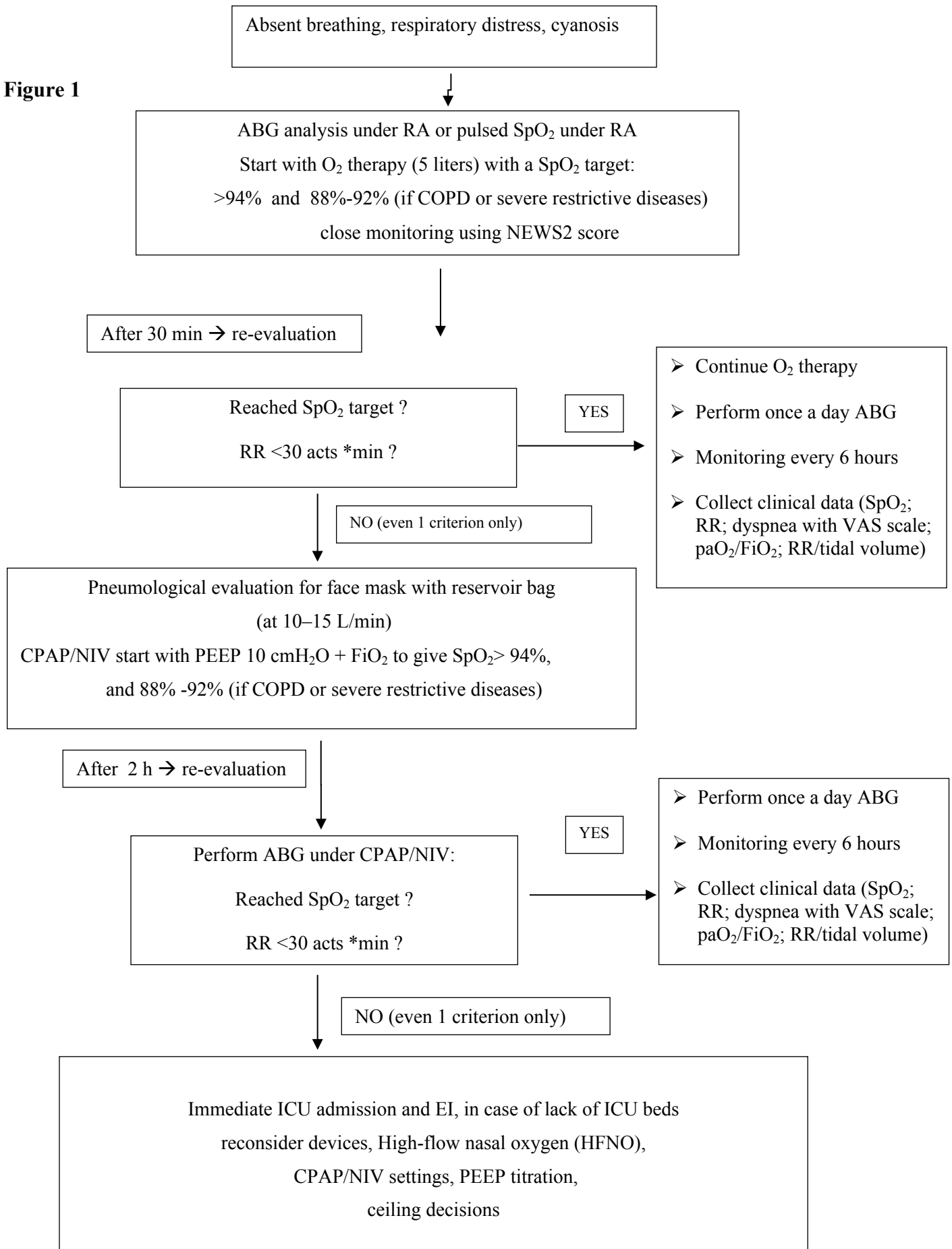
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References

1. WHO. Global surveillance for human infection with coronavirus disease (COVID-2019). Jan 31, 2020. [https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-\(2019-ncov\)](https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-(2019-ncov)) (accessed on 4 march 2020).
2. Istituto Superiore di Sanità. <https://www.epicentro.iss.it/coronavirus/>. Accessed on Centers for Disease Control and Prevention (CDC) 2019 Novel Coronavirus. <https://www.cdc.gov>. Accessed on 04 March 2020.
3. European Centre for Disease Prevention and Control. <https://www.ecdc.europa.eu/en/novel-coronavirus-china>. Accessed on 04 March 2020.
4. Stefano Spina, Francesco Marrazzo, Maurizio Migliari, Riccardo Stucchi, Alessandra Sforza, *Roberto Fumagalli. The response of Milan's Emergency Medical System to the COVID-19 outbreak in Italy. www.thelancet.com. Published online February 28, 2020 [https://doi.org/10.1016/S0140-6736\(20\)30493-1](https://doi.org/10.1016/S0140-6736(20)30493-1).
5. Zhang Y, Xu J, Li H, Cao B. A novel coronavirus (COVID-19) outbreak: a call for action. *Chest*. 2020 Feb 19. pii: S0012-3692(20)30323-8. doi: 10.1016/j.chest.2020.02.014. [Epub ahead of print]
6. Zhu N, Zhang D, Wang W, Li X, Yang B, Song J, Zhao X, Huang B, Shi W, Lu R, Niu P, Zhan F, Ma X, Wang D, Xu W, Wu G, Gao GF, Tan W; China Novel Coronavirus Investigating and Research Team. A Novel Coronavirus from Patients with Pneumonia in China, 2019. *N Engl J Med*. 2020 Jan 24. *N Engl J Med*. 2020;382:727-733. doi: 10.1056/NEJMoa2001017.
7. Huang C, Wang Y, Li X, Ren L, Zhao J, Hu Y, Zhang L, Fan G, Xu J, Gu X, Cheng Z, Yu T, Xia J, Wei Y, Wu W, Xie X, Yin W, Li H, Liu M, Xiao Y, Gao H, Guo L, Xie J, Wang G, Jiang R, Gao Z, Jin Q, Wang J, Cao B. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet*. 2020;395:497-506. doi: 10.1016/S0140-6736(20)30183-5.
8. Wu Z, McGoogan JM. Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in China. *JAMA* 2020; 2020: 25–28.
9. Pincock S, BjørnAage Ibsen. *The Lancet* 2007; 370: 1538. doi:10.1016/s0140-6736(07)61650-x.

Figure 1



Legend: ABG = Arterial Blood Gases; RA = room air; SpO₂ = pulsed arterial saturation of oxygen; COPD= chronic obstructive pulmonary disease; O₂ = oxygen; RR = respiratory rate ; paO₂ = arterial partial pressure of oxygen, FiO₂ = inspiratory fraction of oxygen; RR = respiratory rate; CPAP = continuous positive airway pressure; NIV = non invasive ventilation ; PEEP = positive end expiratory pressure; EI = endotracheal intubation



Figure 2. The Italian population understand health staff situation

("Doctors and nurses, you are our pride, thank you")