## LETTER TO THE EDITOR

A new paradigm of hospital care for SARS-COV-2 patients in the post-emergency phase in Italy

Un nuovo modello di assistenza ospedaliera per i pazienti SARS-COV-2 nella fase post-emergenziale in Italia

Key words: Healthcare workers, health care model, nosocomial infection, COVID

## Abstract

In Italy, at the beginning of the SARS-CoV-2 pandemic, the main organizational model of hospital care was represented by the physical or functional division of hospitals and wards into COVID and non-COVID areas, in order to separate SARS-CoV-2-infected patients from the others. Now that the emergency phase has reached its long-awaited end, it is necessary to develop a new hospital care paradigm that may deal with SARS-CoV-2-positive patients discriminating between those who are hospitalized because of COVID-19 and those who are diagnosed with SARS-CoV-2 infection immediately before or after the first access to healthcare facilities.

## Dear Editor.

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is a novel coronavirus which was identified following reports of a cluster of pneumonia cases of unknown etiology in the city of Wuhan (Hubei province of China). Following the unprecedentedly fast spread of the SARS-CoV-2 disease (COVID-19) worldwide, the World Health Organization (WHO) declared that the infection had reached pandemic state on March 11th, 2020 (1). Following this development, countries all over the world enforced policies aimed at limiting the contagion's spread, with special attention to hospitals and other settings which were identified as high-risk scenarios for SARS-CoV-2 epidemics (2, 3).

Available evidence shows that SARS-CoV-2 can act as a healthcare-associated pathogen. Hospitalized patients are at risk of contracting SARS-CoV-2 infection from other subjects located in the same facility or from healthcare workers (HCWs). Several SARS-CoV-2 outbreaks in hospitals have been described, among both hospital patients and subjects living in long-term assistance or rehabilitation facilities (4).

In Italy, at the beginning of the pandemic, hospitals were strengthened by applying the Ministry of Health guidelines for COVID-19 patients. Temporary facilities were therefore activated both inside and outside public and private hospitals in order to address the increasing demand for COVID-19-dedicated assistance. For these subsidiary healthcare structures, neither authorization nor accreditation were required for the duration of the national emergency status (expected until 31st July, then extended until 31st December 2021 by art. 1 of Law Decree No. 105 of 2021) (5).

Hospital care was therefore rearranged by separating hospitals into areas dedicated to SARS-CoV-2-positive patients and areas reserved to subjects SARS-CoV-2-negative subjects. These sectors were separated from one another either functionally or physically. Existing hospitals were sometimes entirely converted into SARS-COV-2-only facilities,

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while additional COVID-dedicated settings were obtained in the form of emergency facilities. Such structures were often located in fair centers, such as the so-called Large Emergency Unit in Bari's Eastern Fair exhibition space.

This care model was necessary to guarantee the best possible assistance during the emergency phase. Nevertheless, it currently (September 2022) needs an update in consideration of the followings:

- SARS-CoV-2 patients' characteristics changed over time. While respiratory life support was often needed by SARS-CoV-2 patients during the first pandemic phases, the appearance and predominance of low-virulence variants currently makes it generally unnecessary. On the other hand, SARS-CoV-2 patients with asymptomatic or paucisymptomatic infection often require other forms of assistance due to their background diseases.
- Mathematical models suggest that SARS-CoV-2 will keep on circulating for several years. The virus' persistence may lead to the selection of new variants, some of which might be vaccine-resistant. It is therefore necessary to identify logistic solutions for hospitals that are sustainable over time, in relation to currently available human and instrumental resources.
- Organizational models must guarantee the safety of HCWs. Indeed, the organizational model of COVID and non-COVID areas did not eliminate occupational risk, and several outbreaks have been observed among hospital operators of both sectors (6, 7).

Moreover, compared to previously circulating variants, Omicron infections are less likely to lead to a severe clinical outcome, and rarely require hospitalization and Intensive Care Unit (ICU) admission. In fact, despite a three-fold increase of SARS-CoV-2 notification rates having been reported in July 2022 since the beginning of the pandemic, hospitalization and mortality rates are currently lower than the ones observed in previous pandemic waves (8). Moreover, vaccine effectiveness studies have shown that currently available anti-SARS-CoV-2 vaccines are protective against severe clinical outcomes of Omicron infection. Vaccination with at least three doses of anti-SARS-CoV-2 vaccine furtherly increases protection, and new Omicron-specific products have been recently approved for administration in HCWs and vulnerable patients (9).

As SARS-CoV-2 gets closer and closer to an endemic circulation status, a new paradigm of hospital care is required in order to optimize our response to this new phase of the pandemic. This model must allow a gradual "return to normality", thus addressing the choices adopted by the Italian Government with Law Decree 24<sup>th</sup> March 2022, n. 24.

This new paradigm should respect a few key concepts:

- Specialized healthcare must be guaranteed for patients suffering from all forms of SARS-CoV-2 infection, including asymptomatic and paucisymptomatic ones.
- HCWs must be adequately trained to perform procedures and protocols for the management of SARS-CoV-2 patients, especially during high-contagiousness phases.
- The swab-based approach to contagiousness determination should be surpassed in favor of a multifactorial analysis of the risk of contagiousness. Precaution should always be maintained, but available evidence should be kept into consideration during the decision process.

In January 2022, the Italian Federation of Healthcare and Hospitals' (FIASO) Study Center launched a survey on an 18-sentinel-hospital sample aiming to monitor the progress of the pandemic, especially as far as its impact on hospitals was concerned. In this survey, hospitalized SARS-CoV-2-positive patients were divided into two groups:

- Hospitalized for COVID: patients with clinical, laboratory and radiographic signs of lower airway involvement.
- Hospitalized with COVID: patients without clinical, radiographic and laboratory signs of lung involvement, whose hospitalization was determined by other causes.

The FIASO data show the progressive change in the care paradigm, as specialized care was requested more and more as the pandemic progressed, while respiratory assistance and infectious diseases' specialized consultation became a secondary asset in COVID-dedicated facilities. The analysis showed that, from January 2022 to July 2022, hospitalizations FOR COVID dropped from 76% of all COVID hospitalization to 49%, while hospitalizations WITH COVID rose from 24% to 51% (10).

In the new organizational model, the approach to hospitalized patients must change according to their COVID status

Hospital model for patients who were hospitalized "FOR COVID" (FC-Ps). Assistance to FC-Ps must be guaranteed mainly in Infectious Disease Departments. Dedicated facilities should be equipped with rooms set up for isolation and with negative pressure ventilation systems, and might be located inside Infectious Disease Wards, Respiratory Disease Wards or ICUs. Beds in these facilities could then be managed according to contingent necessities.

Hospital model for patients who were hospitalized "WITH COVID" (WC-Ps). WC-Ps should be assisted within the ordinary wards, in order to effectively heal the conditions which led to hospitalization. During the contagiousness phase, subjects should be functionally isolated to reduce the risk of the virus circulating among other patients. Isolation rooms should be equipped with negative pressure ventilation systems and should be located in an area of

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the ward not intended for ordinary transit and, if possible, should be in close proximity to an outflow route (entrance, exit) and an elevator dedicated to stretcher-bound patients. In the absence of negative pressure rooms, patients may be placed in ordinary rooms with adequate ventilation and internal procedures that guarantee 3 to 5 air changes per hour. Locations intended for isolation should be marked appropriately by standardized signs indicating biological danger, and non-healthcare personnel should not be allowed to approach these sites, as well as visitors. In case of non-self-sufficient patients, minors and other peculiar categories, a supporting subject could be allowed to enter the isolation zone with appropriate personal protective equipment (PPE). The correct functioning of the negative pressure ventilation systems must be verified with periodic checks. COVID isolation rooms should be as far as possible from rooms dedicated to patients with immune system deficiencies or to subjects who have not completed the anti-SARS-CoV-2 vaccination cycle.

In each department, a suitable path must be identified to allow the patients to be mobilized for diagnostic or surgical procedures. Isolated subjects must not leave the hospital room except for undelayable diagnostic or therapeutic purposes. During mobilization, patients should wear respiratory PPEs in the form of face masks, preferably FFP2/NK95 models. If the patient is unable to use the mask correctly, exit and entrance paths should be sanitized immediately after transit, with special attention to elevators. Transport for diagnostic purposes should be planned beforehand in order to avoid the patient's contact with other subjects. During transfer, HCWs should also be instructed to wear PPEs in order to avoid contact with potentially infectious biological substances. These operations should be scheduled at the end of the so-called "clean" procedures and diagnostic environments or operating room should be adequately sanitized at the end of the procedures themselves. Specialist consultations should be carried out within the hospital and, if possible, physical movement of patients should be avoided.

Food should be administered by HCWs or catering operators with adequate PPE training; in any case, direct contact with the patient should be avoided and contact with surfaces should be limited to a minimum.

Evaluation of the actual contagiousness period. The evaluation of the actual contagiousness period of hospitalized patients should follow a multifactorial approach, which combines clinical and laboratory criteria and is not excessively simplified solely relying on the result of laboratory tests. The interpretation of the test results for SARS-COV-2 (be they antigenic tests or molecular tests) should not prescind from an appropriate clinical evaluation. Therefore, in line with what is reported by the international public health institutions and scientific literature, and considering the latest recommendations of the Italian Ministry of Health (11), a maximum isolation of 14 days since the first positive swab should be enforced, regardless of the results of third generation molecular or antigenic swabs.

Nasopharyngeal swab sampling. In-hospital search for SARS-COV-2 using a molecular or third generation antigenic swab is recommended: 1) within 72 hours prior to admission to hospital in case of scheduled hospitalization (ordinary hospitalization, day surgery, day hospital); 2) upon accessing emergency room, waiting for the report in a special dedicated area, except in urgent cases that cannot be postponed; 3) every 72 hours since admission for all hospitalized patients.

In the event of a positive screening test prior to scheduled hospitalization, hospitalization may still take place in areas reserved to WC-Ps.

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