

## SARS-COV-2 pandemic: establishing three risk levels for 19 Italian regions and two autonomous provinces

In Italy, there are 19 regions and two autonomous provinces, and each of these 21 jurisdictions has local responsibility for health care. As regards the COVID-19 pandemic, these 21 jurisdictions have been classified into three classes of risk (mild, moderate, and high) associated with three colours (green/yellow, orange, and red).

More than 20 indicators are routinely collected in these jurisdictions, and this information determines, every 2 weeks, the colour assigned and the consequent restrictions in everyday life. The replicability index (Rt according to the Italian notation) is the main parameter influencing this decision.

In November 2020, a number of health care professionals began a collaboration (based on a Facebook group named PIFO including 446 people) specifically aimed at discussing topics and controversies in the field of COVID-19.<sup>1</sup> A total of 34 professionals participated in the experience described herein: 14 of these were invited to share their views through an ad hoc questionnaire.

Our purpose was to build a consensus on the following question: how can the 21 monitoring parameters established by national institutions be translated into the three risk classes? Reference 1 (Italian) reports in detail on the questions of our survey.

The criterion for agreeing the final consensus from individual responses was to select the most voted response for categorical variables, the median for numerical ones. The consensus statement was

designed to, first, select a limited number of parameters (restricted to three) and to, consequently, determine the risk levels with the respective colours.

Three main parameters were identified in our survey: (1) replicability index; (2) incidence of new cases over 14 days (normalised to 100 000 people); and (3) percentage of intensive care unit (ICU) beds occupied by COVID-19 patients. These three parameters were prioritised in the above order.

In the decision model adopted by the group, the first parameter provisionally determines the colour assignment. Thereafter, the initial colour assignment can remain unchanged or, alternatively, can be worsened by one level if parameters (2) and/or (3) rise above a predetermined alarm threshold (table 1). This approach resembles the one currently adopted by the frameworks of ASCO and ESMO in evaluating innovative anti-cancer treatments.<sup>2-5</sup> For each of the three parameters, our survey identified the cut-off values that separate individual risk levels. Rt was confirmed as the leading parameter to guide colour assignment, but the two co-primary parameters mentioned above were evaluated as well (table 1).

In summary, our experience has shown that, in managing the COVID-19 epidemic, adopting a set of ranked risk levels according to a fully transparent approach is feasible. In our view, the decision process can better rely on three parameters rather than on one single parameter (Rt) (or, alternatively, 21 which are too many). In the perspective of further developments, one hypothesis could be to embed in the decision an outlook at 14 days (namely, the incidence projected at 14 days based on Rt) so that prospective projections rather than retrospective

data determine the decision which is made every 2 weeks.

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**Table 1** Description of the algorithm that converts three parameters included in the national COVID monitoring framework into the risk levels associated with the three pre-determined colours (green/yellow, orange, and red)

Replicability index* (or Rt according to the Italian notation)	Initial colour assignment†	Additional parameters*			Process of colour assignment revision	Final colour assignment†
		Number of new cases over 14 days normalised to 100 000 subjects	Percentage of ICU beds occupied by COVID-19 patients			
>1.20	red	ininfluent	–	ininfluent	n.a.	red
between 1.00 and 1.20	orange	>400	and/or	>30%	yes	red
		≤400	and	≤30%	no	orange
<1.00	green/yellow	>400	and/or	>30%	yes	orange
		≤400	and	≤30%	no	green/yellow

\*The official information on these indexes recorded on a daily basis is available at the following internet addresses: <https://github.com/pcm-dpc/COVID-19/tree/master/dati-andamento-nazionale> (nationwide information) <https://github.com/pcm-dpc/COVID-19/tree/master/dati-regioni> (region-specific data) <https://github.com/pcm-dpc/COVID-19/tree/master/dati-province> (data for individual provinces).

†According to the present algorithm.

ICU, intensive care unit; n.a., not applicable.

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