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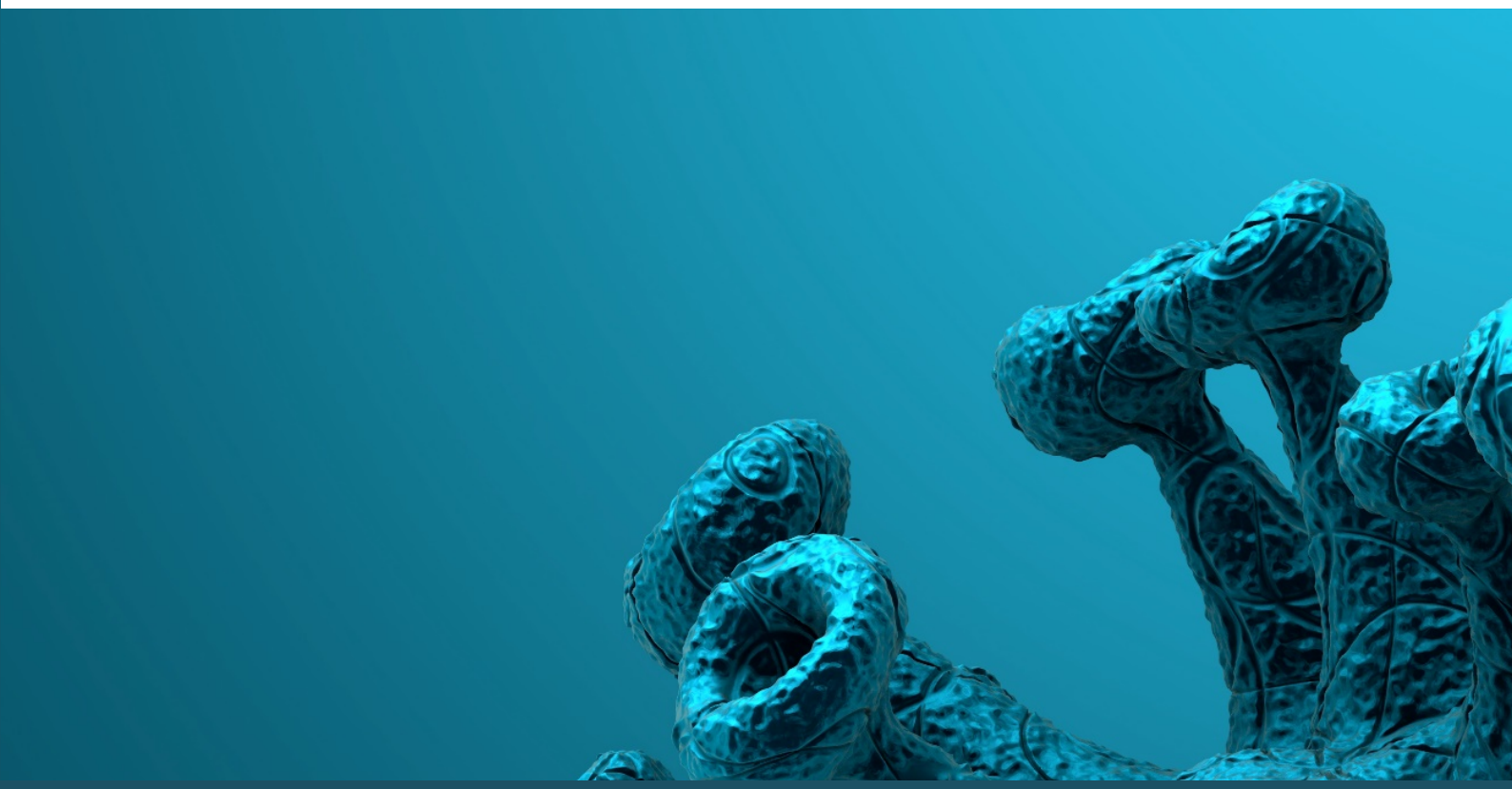
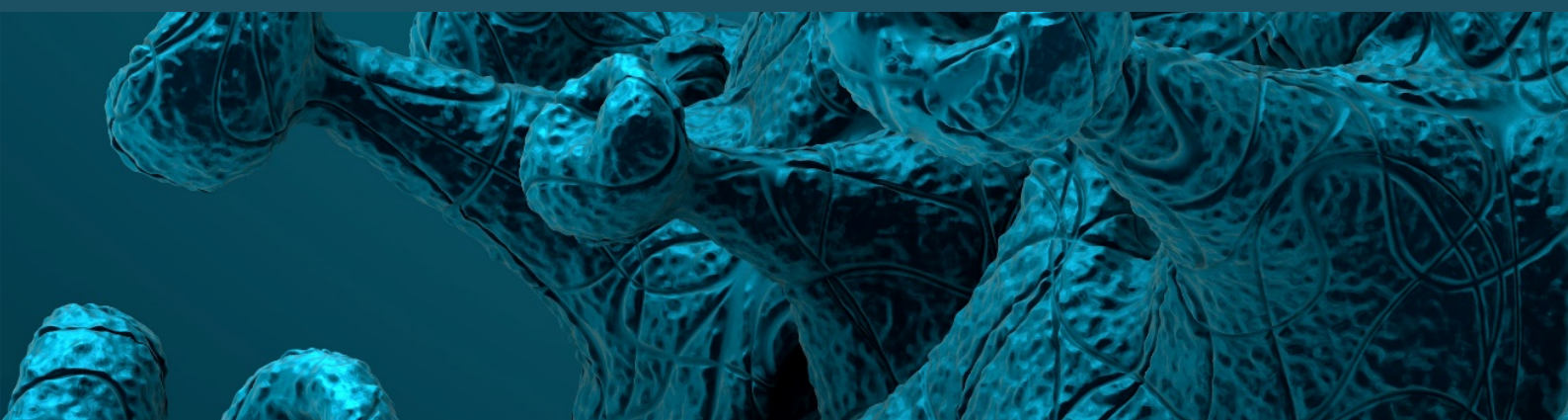


Prevention and response to COVID-19: evolution of strategy and planning in the transition phase for the autumn-winter season

Complementary insight into existing general documents on preparedness, planning and specific contexts



Prevention and response to COVID-19: evolution of strategy and planning in the transition phase for the autumn-winter season

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With the beginning of the autumn-winter season, Italy, as other European countries, is experiencing a slow and progressive worsening of the SARS-CoV-2 epidemic at a time when increased co-circulation of other respiratory pathogens (such as influenza viruses) is expected. Although, as of the end of summer, the increase in the number of cases has been more contained in Italy compared with other European countries, it is critical to strengthen preparedness against all possible epidemic scenarios. This document, based on the 8 WHO Strategic Pillars of COVID-19 response, is a "Toolbox" for Public Health Authorities responding to the SARS-CoV-2 outbreak in Italy. After reconstructing the activities performed from the start of this pandemic event, this document describes for each of the 8 WHO Strategic Pillars, the national initiatives performed and currently available during the transition phase and the activities conducted to enhance preparedness to face the autumn-winter season. The document provides the list of available operational tools and documents as well as a section proposing a shared approach to escalation and de-escalation of mitigation/control measures for each scenario and possible level of risk assessed at regional level.

Original Italian version

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The responsibility for scientific and technical data lies with the authors, who declare that they do not have any conflict of interest.

Editing and graphics: ISS Scientific Communication Unit (Sandra Salinetti and Paola De Castro)

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Acronyms

ADA	Aid Distribution Analysis
AGENAS	*Agenzia Nazionale per i Servizi Sanitari Regionali* (National Agency for Regional Healthcare Services)
AIFA	*Agenzia Italiana del Farmaco* (Italian Medicines Agency)
AP	Autonomous Province
ARDS	Adult Respiratory Distress Syndrome
AREU	*Azienda Regionale Emergenza Urgenza* (General Directorate of the Regional Emergency)
CNOP	*Consiglio Nazionale Ordine Psicologi* (National Council of Psychologists)
COVID-19	Corona Virus Disease - 2019
CSG	Coronavirus Study Group
CTS	*Comitato Tecnico Scientifico* (Technical Scientific Committee)
DM Health	Decree of Minister of Health
DPC	*Dipartimento della Protezione Civile della Presidenza del Consiglio dei Ministri* (Italian Department of Civil Protection of the Presidency of the Council of Ministers)
DPCM	Decree of the President of the Council of Ministers
ECDC	European Centre for Disease Prevention and Control
ECMO	ExtraCorporeal Membrane Oxygenation
EMA	European Medicines Agency
EU/EEA	European Union / European Economic Area
EUA	Emergency Use Authorization
EWRS	Early Warning Response System
FBK	Fondazione Bruno Kessler
FDA	Food and Drug Administration
HFOT	High Flow Oxygen Therapy
HLH	Hemophagocytic LymphoHistiocytosis
ICU	Intensive Care Unit
IDSA	Infectious Diseases Society of America
ILI	Influenza-Like Illness
IMO	International Maritime Organization
INAIL	*Istituto Nazionale Assicurazione Infortuni sul Lavoro* (Italian National Institute for Insurance against Accidents at Work)
INMI	*Istituto Nazionale Malattie Infettive* (National Institute of Infectious Diseases)
IPC	Infection Prevention and Control
IRCCS	*Istituto di Ricovero e Cura a Carattere Scientifico* (Scientific Institute for Research, Hospitalization and Healthcare
ISS	*Istituto Superiore di Sanità* (Italian National Institute of Health)
ISTAT	*Istituto Nazionale di Statistica* (Italian National Institute of Statistics)
LMWH	Low Molecular Weight Heparin
LTCF	Long-Term Care Facilities
MD	Medical Device
NAS	*Nuclei Antisofisticazioni e Sanità dell'arma dei Carabinieri* (Unit responsible for food safety and health related issues)
NIC/ISS	National Influenza Centre/Istituto Superiore di Sanità
PEEP	Positive End-Expiratory Pressure
PH	Public Health
PHEIC	Public Health Emergency of International Concern

PPE	Personal Protective Equipment
RCCE	Risk Communication and Community Engagement
REACT	WHO Rapid Evidence Appraisal for COVID-19 Therapies
RECOVERY	Randomized Evaluation of COVID-19 Therapy
R0	Basic reproduction number
R_t	Effective reproduction number
SARS-CoV-2	Severe Acute Respiratory Syndrome CoronaVirus 2
SIC	Sepsis Induced Coagulopathy
USMAF	*Uffici di Sanità Marittima, Aerea e di Frontiera* (Maritime, Aviation and Border Health Office)
WHO	World Health Organization

Glossary

De-escalation
Re-modulation of activities with less stringent measures

Escalation
Re-modulation of activities with more stringent measures

Inter-pandemic phase
Period between pandemics

Lockdown
Implementation of measures on a variable scale aimed at drastically reducing the risk of gatherings and inter-personal contact such as the closure of shops, the prohibition of events and exhibitions, the limitation of individual mobility, the closure of schools of all levels, and the large scale implementation of home-based work

National epidemic in acute phase
New cases nationwide are clearly increasing with high numbers and signs of overburdening of health services

National epidemic in post-acute phase
New cases nationwide have peaked and, although still in high numbers, have a decreasing trend

National epidemic in transition phase
New cases at national level are stable or with small variations, incidence is low and there is no overload of health services. In other words, the epidemic is controlled nationally

Pandemic alert phase
Identification of a new virus emerging in humans

Pandemic phase
Period characterized by the worldwide spread of the new pathogen

Pandemic Transition phase
Global risk decrease

R_0: Basic reproduction number
Transmissibility of a pathogen in the absence of intervention

R_t: Effective reproduction number
Transmissibility of a pathogen calculated over time in the presence of interventions

Preface

Preparedness in public health emergencies includes all activities aimed at minimizing the risks posed by infectious diseases and mitigating their impact, regardless of the extent of the event (local, regional, national, international). During a public health emergency, planning, coordination, timely diagnosis, evaluation, investigation, response and communication are required.

This document is an evolution of existing national preparedness activities to support the assessment, and, if necessary, the enhancement of health system preparedness in the Regions/Autonomous Provinces in order to cope better with a possible increase in the number of new infections of SARS-CoV-2 and with the possible scenarios for the autumn-winter season 2020-2021. Following the analysis of the critical issues found in the first phase of the epidemic, the elaboration of possible epidemic scenarios and the development of a self-assessment tool for the preparedness of health services (Circular of the Ministry of Health "Elements of preparedness and response to COVID-19 in the autumn-winter season" published on August 11, 2020), this document, developed by multiple international, national and regional institutions, aims to strengthen national coordination and planning in the short term by making initiatives, tools and measures developed since the beginning of this pandemic and operational at this stage readily available.

The structure of the document follows the 8 key strategic pillars identified by the World Health Organization for the response to the COVID-19 pandemic: Country-level coordination, planning, and monitoring; Risk communication and community engagement; Surveillance, rapid response teams and case investigation; Points of entry; National laboratories; Infection Prevention and Control (IPC); Case management; and Operational support and logistics. Elements transversal to these pillars, such as training and scientific research, are mentioned when relevant to the short-term operational response, within the mentioned 8 pillars.

In summary, this document provides a "toolbox" for public health authorities engaged in the response to the SARS-CoV-2 outbreak in Italy. After reconstructing the activities carried out since the beginning of this pandemic event, the document provides for each strategic pillar the national initiatives put in place and operational during the transition phase and the preparedness activities carried out in anticipation of the autumn-winter season. The document also provides a shared approach to the escalation/de-escalation of containment/mitigation measures, consistent with what was defined in law DPCM No.108 of 27 April 2020, based each possible scenario and on the level of risk classification in each Region/Autonomous Province provided each week according to the Decree of the Minister of Health issued on the 30th April 2020. In the Appendix all the tools and operational measures for each strategic pillar are provided.

Introduction

The COVID-19 pandemic is a global emergency linked to the onset of a new virus (SARS-CoV-2). In a short time, this pathogen has caused a pandemic to which the World Health Organization (WHO) assigns three specific characteristics (1):

- **Speed and scale:** The disease has spread rapidly around the world and was able to overload even the most resilient health systems;
- **Severity:** overall 20% of cases are severe or critical, with a crude clinical case fatality rate currently of over 3%, increasing in older age groups and in those with certain underlying conditions;
- **Societal and economic disruption:** shocks to health and social care systems and measures taken to control transmission have had broad and deep socio-economic consequences.

In the absence of effective drugs and a vaccine, in a fully susceptible population, SARS-CoV-2 from December 31, 2019 to September 18, 2020 resulted in more than 30 million confirmed cases of infection worldwide and over 900,000 deaths (2). According to data published by the European Centre for Disease Prevention and Control (ECDC), in the EU/EEA countries (European Union/European Economic Area), there were more than 2 million confirmed cases and more than 185,000 deaths (3). In Italy, more than 290,000 confirmed cases of SARS-CoV-2 infection and more than 35,000 deaths (4) had been reported.

The Coronavirus Study Group (CSG) of the International Committee on Taxonomy of Viruses has officially classified as SARS-CoV-2 the virus provisionally named by the international health authorities as 2019-nCoV and responsible for COVID-19 (CoronaVirus Disease 2019) cases. After evaluating the novelty of the human pathogen and on the basis of phylogeny, taxonomy and established practice, the CSG formally associated this virus with the coronavirus that causes severe acute respiratory syndrome (SARS-CoVs, Severe Acute Respiratory Syndrome Coronaviruses), classifying it, precisely, as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).

Due to its relatively long incubation period (median 5-6 days, range 1-14 days) (5), a viral shedding pattern documented from 1-2 days before the onset of symptoms (6) that can continue for weeks after the onset of symptoms (7), which can be initially mild and nonspecific, and the presence of asymptomatic and mildly symptomatic cases capable of transmitting the infection (8), SARS-CoV-2 seems more adapted to humans than the SARS-CoV virus that emerged in 2002 and more efficient in its transmission.

Chapter 1

Preparing and responding to the COVID-19 pandemic

The WHO (9) and the ECDC (10) identify the following *continuum* of phases in the response to a pandemic from emerging viruses:

- **Inter-pandemic phase:** period between pandemics.
- **Alert phase:** identification of a new emerging pathogen in humans (e.g., new influenza sub-type). At this stage it is necessary to increase the level of attention and carry out risk assessments at local, national and global level. If the risk assessments indicate that the new pathogen does not have the potential to evolve into a pandemic strain, proceed towards de-escalation, i.e. adjusting activities towards less stringent measures, i.e. corresponding to those of the inter-pandemic phase.
- **Pandemic phase:** period characterized by the spread of the new pathogen globally that is globally monitored through surveillance. The transition between the inter-pandemic phase, the alert phase and the pandemic phase can occur rapidly or gradually, mainly on the basis of virological, epidemiological and clinical data.

  Within the pandemic phase, each country can observe different stages of the **epidemic at the national level** with:

  - **acute phases** in which cases are evidently increasing, with high numbers and signs of health service overload;
  - **post-acute phases** in which the new cases found per day have reached a peak and, although still in high numbers, have a decreasing trend;
  - **epidemic transition phases** in which cases are stable or with limited variations, the incidence is low and there is no overload of health services. In other words, they are phases in which the epidemic is controlled nationally.
- **Pandemic transition phase:** as the risk decreases globally, de-escalation of actions may occur, with a reduction of epidemic response activities at national level and a shift towards recovery actions, based on country specific risk assessments.

The *continuum* of the phases of a pandemic is shown in Figure 1.

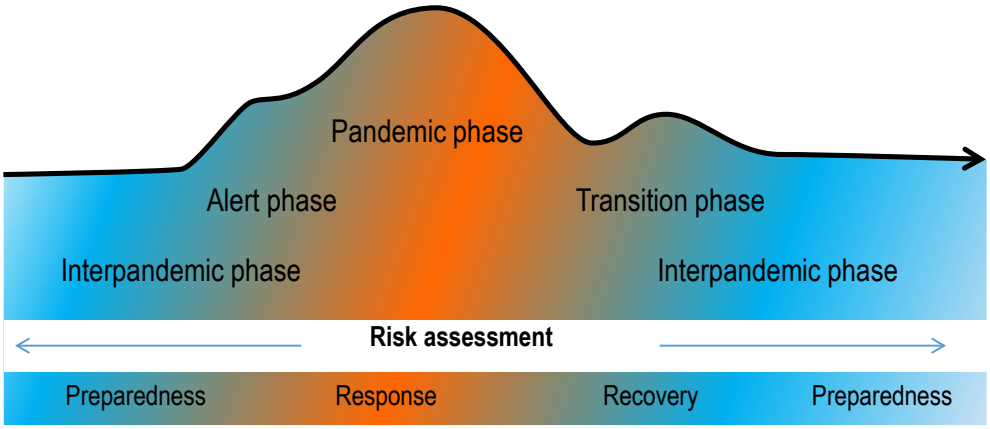

Figure 1. *Continuum* of the phases of a pandemic (source WHO)

During an epidemic due to emerging pathogens, for which a population is fully susceptible, and in the absence of effective drugs and vaccines, the risk associated with uncontrolled spread lies in the fact that it

is possible to observe many cases of the disease in a short time with overload of all the structures and services dedicated to their management.

For this reason, non-pharmacological measures should be implemented to reduce the risk of infection, such as increasing hygiene levels and performing large-scale physical distancing. These measures will have the effect of slowing the spread of infection by "flattening the curve" and allowing the management of fewer concurrent infections over a longer period of time (Figure 2).

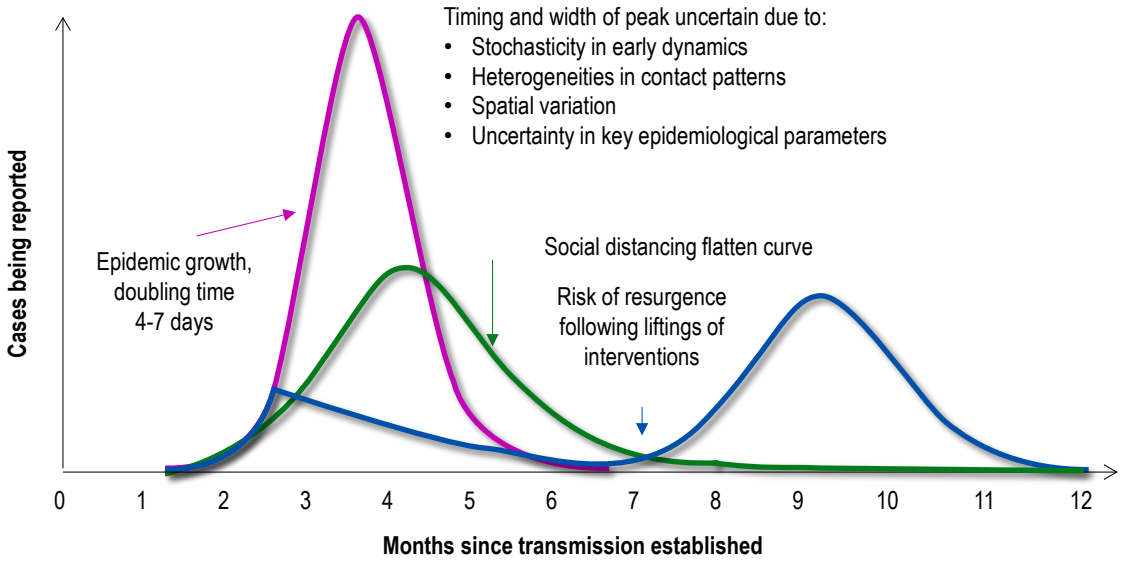

Figure 2. Illustrated simulation of a COVID-19 transmission model (11)

Numerous non-pharmacological measures have been described to slow the transmission of SARS-CoV-2 (11) which should be implemented in combination for better efficacy (12). **Four phases were also identified in the response to a COVID-19 outbreak** (13):

i) Phase 1: slowing the spread with containment measures;

ii) Phase 2: transition with remodulation of containment measures;

iii) Phase 3: development of immunity and suspension of physical distance measures;

iv) Phase 4: reconstruction and preparation of systems.

Of these, the first two fall into the pandemic phase.

Chapter 2

Phases of the COVID-19 pandemic in Italy (December 2019 – September 2020)

This section shows the timeline of preparation and response to the pandemic from COVID-19, with particular attention to the measures taken in Italy as of the 30th of September 2020.

2.1. End of the inter-pandemic phase

On December 31st, 2019, Chinese health authorities reported an outbreak of pneumonia of unknown aetiology in the city of Wuhan (Hubei Province), China. Since many of the initial cases reported an exposure to Wuhan's South China Seafood City market, a possible transmission mechanism from live animals was initially suspected.

On January 9th, 2020, the China CDC (China's Centres for Disease Control and Prevention) identified a new coronavirus (provisionally called 2019-nCoV) as an etiological agent of this disease.

2.2. Alert phase

On the 14th of January 2020, the WHO reported in its communications that the evidence of a possible human to human transmission of the new virus was limited. However, on the 22nd of January after a mission to China, the WHO stated that there was evidence of human to human transmission, but that further studies would be needed to verify its extent. This led to the start of the alert phase.

On the 22nd of January 2020, a national task force to counter COVID-19 was set up in Italy by the Minister of Health. The task force is coordinated by the Ministry of Health (General Directorate of Prevention and Planning).

The participating institutions included the Istituto Superiore di Sanità (ISS, the National Institute of Health in Italy), the Dipartimento della Protezione Civile (DPC, the Italian Department of Civil Protection of the Presidency of the Council of Ministers), the IRCSS Istituto Nazionale Malattie Infettive (INMI, National Institute of Infectious Diseases) L. Spallanzani, the Network of the Uffici di Sanità Marittima, Aerea e di Frontiera (USMAF, the Maritime, Aviation and Border Health Offices), the NAS of the Armed Force Carabinieri (Unit responsible for food safety and health related issues), the Agenzia nazionale per i servizi sanitari regionali (AGENAS, the National Agency for Regional Healthcare Services), the Agenzia Italiana del Farmaco (AIFA, the Italian Medicines Agency) and Armed Forces and the Regions/Autonomous Provinces (APs). The aim of the task force was to:

- alert the relevant health facilities;
- enable airport controls;
- safely repatriate compatriots from contexts of high transmission of SARS-CoV-2;
- issue operational guidelines for prevention and restrictions of people's mobility in the event of an epidemic;
- verify implementation of response actions and their compliance with international guidelines (WHO, ECDC);
- manage confirmed cases in Italy in collaboration with all regional health services, Local Health Units (LHU), hospitals and IRCCSs.

Direct flights from China to Italy were suspended on the 30th of January 2020 (Figure 3). On the same day, the WHO Director General declared the novel SARS CoV-2 coronavirus a Public Health Emergency of International Concern (PHEIC) (15). The Italian Council of Ministers met on the 31st of January and declared a state of national health emergency, initially for a period of six months, then extended. This included the allocation of funds necessary for the implementation prevention measures as a follow-up to the PHEIC declaration by the WHO and for the needed DPC ordinances.

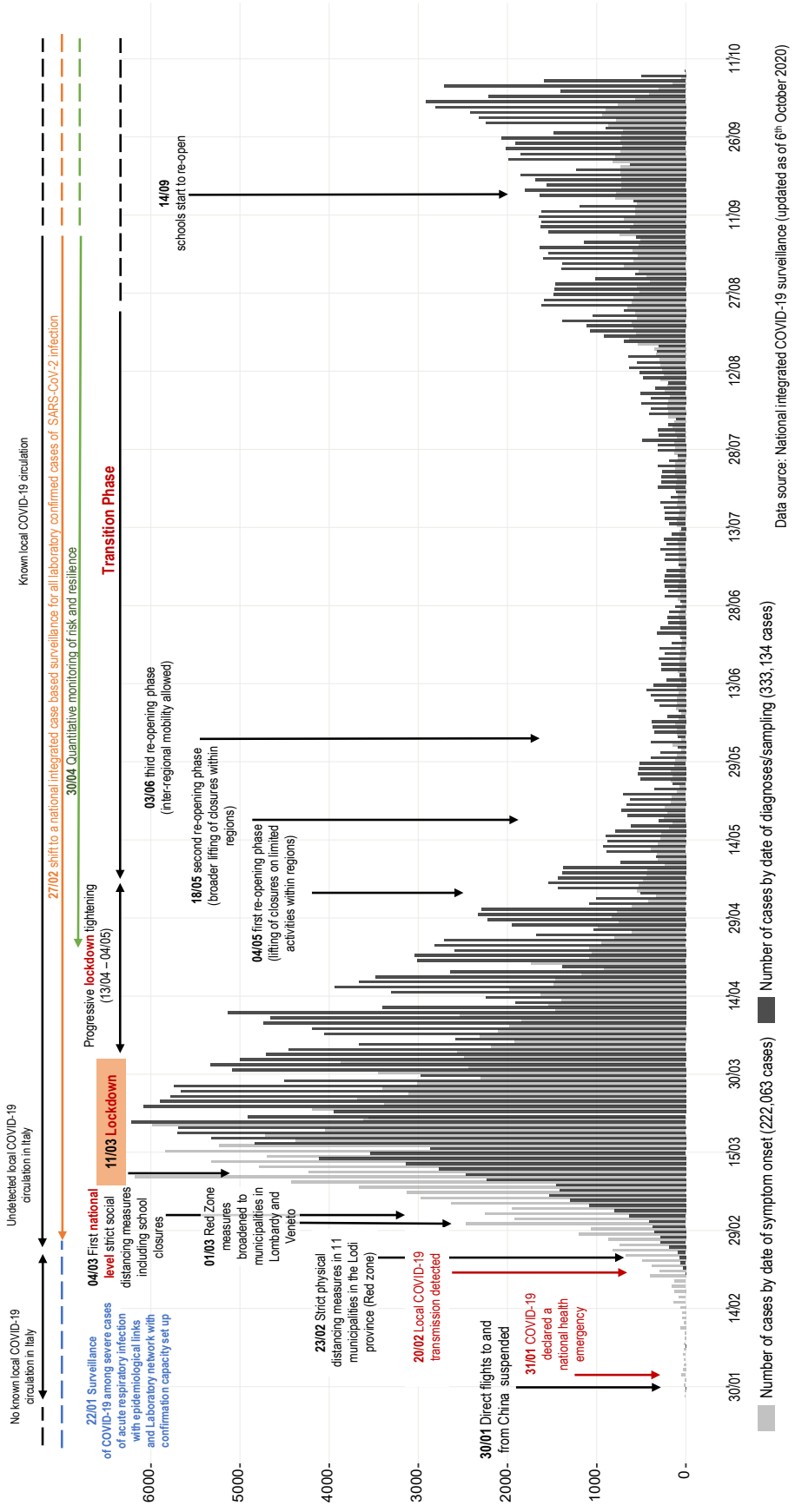

Figure 3. Phases in the management of COVID-19 in Italy. Epidemic curve by date of diagnosis and symptom onset, main containment measures and reopening interventions, 30 January – 6 October 2020

On the 3rd of February 2020, with the order of the head of DPC n. 630, the Technical Scientific Committee (Comitato Tecnico-Scientifico, CTS) was established with the mandate to technically advise and support coordination activities to overcome the epidemiological emergency due to the spread of SARS-CoV-2. In February 2020, as recommended by the CTS, preparedness studies were carried out aimed at risk classification and health planning through an inter-institutional collaboration involving the Directorate General of Health Planning of the Ministry of Health, the ISS, the General Directorate of the Regional Emergency (AREU) of Lombardy and INMI L. Spallanzani, representing the State-Regions Conference, with the multidisciplinary involvement of the Bruno Kessler Foundation (FBK).

During this phase, activities were carried out to strengthen the ability to identify cases of COVID-19 in Italy. In particular, with the Ministerial Circular "New Coronavirus pneumonia (2019-nCoV) in China" of the 22nd of January 2020 (16), epidemiological surveillance on severe cases of acute respiratory disease with a history of travel to areas of COVID-19 transmission or contact with confirmed cases of SARS-CoV-2 infection was established, based on the WHO case definitions and the ECDC technical specifications to EU/EEA countries and the UK. All cases corresponding to the case definition in Italy were notified within 24 hours to the Ministry of Health, Directorate General of Health Prevention (Office 5 – Prevention of Transmissible Diseases and International Prophylaxis) and to the ISS (Department of Infectious Diseases), through a dedicated online surveillance platform. With the onset of the national COVID-19 outbreak, this surveillance system was adapted to the epidemiological context of local transmission.

A network of 31 laboratories with diagnostic capabilities to carry out laboratory analyses for suspected cases of SARS-CoV-2 infection according to the protocols indicated by the WHO, was established by the same Circular. At the same time, the national reference laboratory for confirming and reporting to the WHO all cases of SARS-CoV-2 infection identified in Italy, was nominated at the ISS (WHO National Influenza Centre – NIC/ISS). With the Ministerial Circular n. 9774 of the 20th of March 2020 (17) and n. 11715 of 3rd of April 2020 (18), more than 70 Regional Laboratories were authorized to provide COVID-19 diagnoses. Those in turn authorized additional laboratories identified in the Regions themselves, according to arrangements agreed with the ISS. Laboratory confirmation is necessary to define a positive COVID-19 case in Italy. For this reason, the activity of laboratories, and in particular of the reference laboratories, is one of the bases for monitoring the epidemic. Centrally coordinated networks are a guarantee of consistency and quality (Figure 4).

On the 20th of February 2020, with the identification of the first case of locally transmitted COVID-19 (19-21), Italy passed from a preparedness to an epidemic response phase, with rapid and continuous risk re-assessments and the activation of the measures envisaged in the previous planning phase. On the 24th of February 2020, a WHO-led team with experts from the WHO and the ECDC arrived in Italy to support national authorities in assessing the situation.

Since the 27th of February, with Ordinance n. 640 of the Presidency of the Council of Ministers-Department of Civil Protection (23), epidemiological and microbiological surveillance of the SARS-CoV-2 virus and surveillance of the clinical characteristics of COVID-19 were defined. The first two were entrusted to the ISS, the third to INMI L. Spallanzani in Rome, as a WHO Collaborating Centre for clinical management, diagnosis, response and training on highly contagious diseases, in collaboration with the ISS. The strengthening of epidemiological and microbiological surveillance with the establishment of an integrated national system of surveillance of all confirmed cases of SARS-CoV-2 virus infection in Italy, in addition to a parallel surveillance system of aggregated data collected by the Ministry of Health and published by the Civil Protection, allowed to monitor the progress of the epidemic at national and sub-national level (*see* Figure 3).

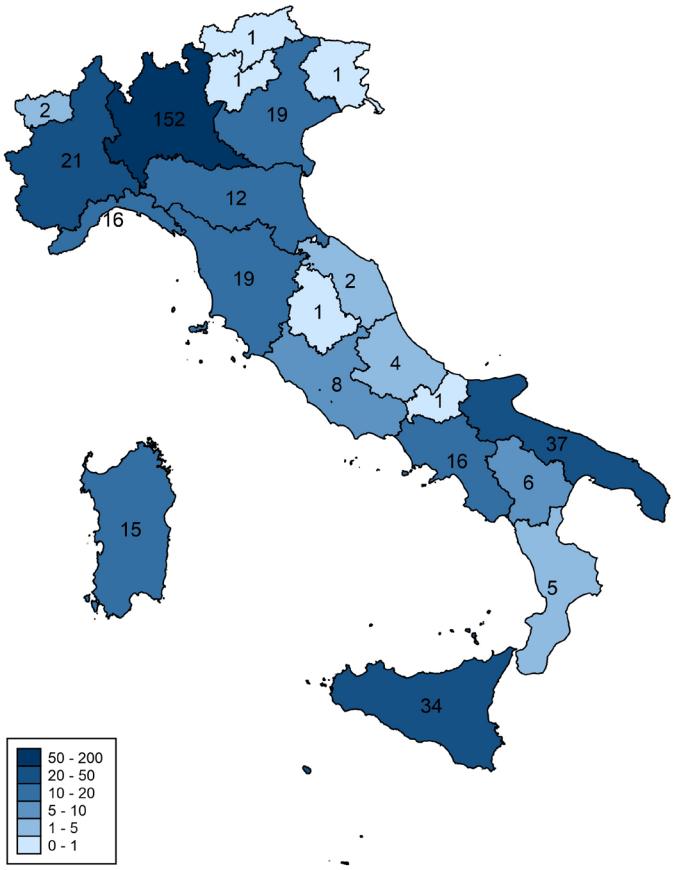

Figure 4. Number and geographical distribution of the laboratories identified by the Regions/APs for the diagnostic confirmation of SARS-CoV-2 infection and registered in the data collection platform of the national reference laboratory in ISS, 23 September 2020

2.3. Pandemic phase

On the 11th of March 2020, as Italy faced the acute phase of the SARS-CoV-2 outbreak by declaring a national lockdown (24), the WHO declared COVID-19 a pandemic and triggered the beginning of the pandemic phase. At this stage, all countries had begun to activate measures to contain, delay and mitigate the transmission and impact of SARS-CoV-2. On the same day, an institutional collaboration was established between the WHO and the Italian Government with a residential presence of a WHO expert in the CTS.

The national outbreak of COVID-19 in Italy as of September 30th 2020 can be divided into the following phases:

- **Acute phase:** February 20 to March 20, 2020 (peak) with a rapid increase in the number of cases, particularly in elderly populations with co-morbidities. The number of cases had rapidly exceeded territorial contact-tracing and isolation/quarantine capabilities in the epicentre of the epidemic. There was a high mortality and a rapid overload of healthcare services (in particular hospitals) in the most affected parts of the country.

  From the 23rd of February, with the introduction of the first measures of physical distancing, and from the 4th of March with the first closures on a national scale, **phase 1 of the response to the epidemic**

began in Italy (slowing down the spread with measures containment), which culminated on the 11th of March 2020 with a national lockdown, i.e. with the implementation of measures aimed at drastically reducing the risk of gatherings and person to person interaction. This included closure of commercial establishments, the prohibition of events and exhibitions, the limitation of individual mobility, the closure of schools at all levels, the large-scale institution of home-based work. This phase was therefore characterized by a **re-modulation of mitigation and control activities towards more stringent measures** (escalation) with the adoption of extraordinary measures throughout the country. The purpose of phase 1 was to slow the spread of the virus.

The daily analysis of data from the COVID-19 integrated surveillance system, coordinated by the ISS (26) and of the aggregated data collected by the Ministry of Health and by the Civil Protection (27), allowed to monitor the progress of the epidemic at a national (*see* Figure 3) and sub-national level.

Extraordinary measures have also been taken to rapidly strengthen healthcare services, responding to the emergency by recruiting health staff, supplying equipment and consumables, and implementing measures to contain the socioeconomic consequences of the national lockdown.

In terms of epidemiological effectiveness, the national lockdown have been successful in achieving a major slowdown in the spread of the virus, as reported by national surveillance systems (*see* Figure 3).

Before the 11th of March 2020 (national lockdown), the estimated R0 for SARS-CoV-2 was around 3 in all Regions with sustained transmission, with some local variation due to localised and targeted interventions. This is the transmission rate of SARS-CoV-2 in the absence of interventions (R0: basic reproduction number). From the lockdown date to March 25th, transmissibility decreased in all Regions to Rt values between 0.5 and 0.7. In this case, the transmission was calculated over time in the presence of interventions (Rt: effective reproduction number).

- **Post-acute phase:** from March 21st to May 4th 2020, in the context of the national lockdown with extraordinary control and mitigation measures, the integrated ISS COVID-19 surveillance system registered a stabilization followed by a decrease in the number of new COVID-19 cases, with the gradual recovery of hospital and PH services.

  At this stage, measures have been implemented to strengthen health services at national level and to further expand the healthcare network, ensuring an extraordinary supply of equipment and consumables.

  According to Annex 10 "Principles for Health Risk Monitoring" (28) of the Decree of the President of the Council of Ministers (DPCM) of April 26th, 2020 (*Gazzetta Ufficiale* n.108 of 27/4/2020) and according to the Decree of the Minister of Health (DM Health) issued on April 30th, 2020 (29), in the month of May 2020, a weekly monitoring system developed and implemented by the ISS was launched and coordinated by the Ministry of Health. The system provides each week to every Region/AP a quantitative classification of epidemic risk and of the resilience of their hospital and PH services in order to respond promptly with adequate interventions.

  In terms of transmissibility, from March 25th until approximately the end of May (end of the national lockdown) the Rt remained almost constantly within the range Rt = 0.5 and Rt = 0.7 in all Regions/APs.

  At this stage, the need for a gradual restoration of production activities, compatibly with the epidemic curve and with the aim to protect the health and safety of all workers, led INAIL to develop a methodological approach for estimating occupational risk by sector of economic activity. This model, which allowed the creation of 4 risk categories (low, medium-low, medium-high, high) according to three parameters (exposure, proximity and aggregation), was adopted by the CTS in order to plan

the reopening phases (30). The need for a gradual reopening also led to the reorganisation of the ground public transport system (31).

- **Epidemic transition phase:** from the 4th of May 2020 until the date of publication of this document, although the pandemic phase is still active globally, Italy has entered **phase 2 of the response to the epidemic (transition with re-modulation with less stringent containment measures - de-escalation)**. This entailed the gradual reopening (4th and 18th of May and 3rd of June 2020) of work, commercial and recreational activities, the gradual restoration of intra-regional, inter-regional and international mobility, as well as the reopening of secondary schools to allow state examinations to take place face to face. In this phase, based on the model developed by INAIL in the previous phase, the CTS provided specific guidance for the conduction of sports and recreational activities.

  At this stage, infection control activities at primary care level were strengthened, for example by increasing diagnostic tests to include cases with mild symptoms and enhancing contact tracing. The weekly monitoring system was implemented fully, allowing a classification of the risk and resilience of the PH services in each Region/AP. A national seroprevalence survey was carried out between the 25th of May and the 15th of July 2020, and estimated that on average 2.5 % of Italians had been exposed to the virus (32).

  This phase was characterized in Italy and in other European countries, by an initial decrease followed by a substantial stabilization of cases in low incidence contexts (as in Italy until the end of July 2020) followed by a slow and gradual increase in the number of cases with epidemic transition characteristics compared to previous phases and no signs of healthcare service overload. This was partly due to the circulation of infection mainly in younger aged populations within transmission contexts also associated with travel and recreational activities.

  In Italy, since June 2020, there has been a slight but steady increase in Rt that has exceeded the threshold of 1 in its average value around the 16th of August 2020 with subsequent weekly fluctuations around the average value of 1 and marked interregional variability due to the presence of outbreaks.

  During the epidemic transition phase, activities were focused on preparedness for the autumn-winter 2020 season. During this phase, the weekly monitoring system was operational on an ongoing basis, guidelines and documents were issued and adopted (33) for the reopening of schools (since September 14, 2020) and to support the preparedness of health services for a possible increase in the number of cases and hospitalizations due to COVID-19 in Italy (34). In line with international evidence (35), Italy has given extreme importance to the preparation for the reopening of schools and, later, to the monitoring of its impact on epidemic trends. In order to assess the evidence and target public health actions, on the 31st of August 2020 Italy, together with the WHO's European office, proposed and hosted the "High-level virtual meeting on schooling during the COVID-19 pandemic", addressed to the Health Ministers of the WHO European Region (36).

Chapter 3

Possible epidemic scenarios in the autumn-winter period in Italy

The scenarios for autumn, in terms of the impact on the health system, will greatly depend on some unknowns:

1) **Transmissibility of SARS-CoV-2 in late summer.** It is not yet clear whether the increase in transmissibility (Rt) observed from June in some Regions/APs will stabilize around the values observed during September or if it will continue to increase over time. It is quite clear that the scenarios will change considerably depending on whether or not it is possible to maintain Rt at values close to 1 in the autumn-winter season.

2) **Transmissibility of SARS-CoV-2 in schools.** The true transmissibility of SARS-CoV-2 in schools is not yet known, although outbreaks in school settings have been described in countries where schools reopened for longer periods. Furthermore, the impact of school reorganization measures has not been quantified. Although there is evidence that the viral load of symptomatic and asymptomatic cases, and therefore the transmission potential, is not statistically different, more generally, it is not known how much children, more often asymptomatic, are able to transmit SARS-CoV-2 compared with adults. All this makes the role of transmission in schools from September on the overall epidemiology of SARS-CoV-2 in Italy very uncertain.

3) **Transmissibility of SARS-CoV-2 in the workplace.** Workplaces have proved to be an important reservoir of infections since the acute phase, not only in specific risk environments, such as healthcare, but also in the agri-food sector (farms, meat processing, markets) and courier services that, in Italy and in other countries, have experienced clusters of considerable size. Furthermore, the resumption of in-person work activities, even if in varying percentages depending on the sector, could contribute to the generation of additional epidemic clusters.

4) **Impact of population mobility on SARS-CoV-2 transmission.** The resumption of in-person school and work activities tends to put the public transport system at full capacity. This inevitably would increase in the occasions in which exposure to the virus could occur.

5) **Contribution of the occupational health and safety management system in the workplace.** The system, which has been implemented over time, has already proved itself as a natural infrastructure capable of contributing to the mitigation of risk. This occurs thanks of the integration of existing organizational measures for prevention and protection, starting from the "Shared protocol of regulation measures to contrast and contain the spread of COVID-19 virus in the workplace" issued on March 14th and further integrated on April 24th, and of sector-specific Protocols which favour the protection of health and safety of 23 million implicated workers with inevitable positive effects also on the larger community. Health surveillance continues to be of particular importance including its activities aimed at providing information on risks as well as protecting "fragile" workers.

6) **General population acceptance of hygiene and behavioural measures for the prevention of SARS-CoV-2 transmission**. It is possible that already encountered critical issues, such as the degree of collaboration of infected people in supporting the epidemiological investigation and contact tracing activities and the degree of compliance with / adherence to isolation measures among cases with confirmed infection and their close contacts could worsen.

7) **Response capacity of prevention and control systems**. The improved ability of PH systems to quickly identify outbreaks, isolate cases and apply quarantine measures to close contacts is evident and contributes significantly to keeping transmission under control. However, it is not known at the moment what level of transmission, for example in terms of the number of outbreaks, PH systems can effectively manage. It should be noted that the beginning of the flu season could make these activities more complex and demanding.

Another important aspect to consider, related more to the resilience of the health system than to the transmission of SARS-CoV-2, concerns the average age of cases. In the summer months, a significant decrease in the average age of cases was observed with relatively few new COVID-19 hospitalizations. However, this was followed by a new increase in the median age in cases diagnosed between the end of August and the beginning of September. It is currently unclear whether this trend will continue over time and whether it will be possible to effectively protect at-risk categories such as the elderly.

In light of these uncertainties, the possible scenarios for autumn in the different Regions can thus be summarized:

- **SCENARIO 1**
  Situation of localized transmission (clusters) largely similar to what was observed in the period July-August 2020, with regional Rt above the threshold for limited periods (less than 1 month) and low incidence. In the event that transmissibility does not systematically increase in early autumn, schools have a modest impact on transmissibility and regional health systems are able to track and control new outbreaks, including school outbreaks.

- **SCENARIO 2**
  Situation of sustained and widespread transmission manageable by the health system in the short/medium-term, with regional Rt values systematically and significantly between Rt = 1 and Rt = 1.25 (with estimates of the 95%CI of Rt between 1 and 1.25). New outbreaks, including school ones, cannot be fully tracked, but PH services still manage to greatly limit the transmission potential of SARS-CoV-2 with ordinary and extraordinary containment/mitigation measures. An epidemic with these features of transmissibility could be characterized by the impossibility of containing all the outbreaks and by a constant increase in the number of cases: at least symptomatic ones. It is possible to observe a reduction in the percentage of asymptomatic cases over the total, due to the inability to conduct an epidemiological investigation on all cases. This would correspond to an increase in hospitalization rates and admissions to intensive care units. However, the growth in the number of cases could be relatively slow, without leading to a significant overload of healthcare services for at least 2-4 months.

- **SCENARIO 3**
  Situation of sustained and widespread transmission with risks in the ability of the health system to cope in the medium-term, with regional Rt values systematically and significantly between Rt = 1.25 and Rt = 1.5 (i.e. with estimates of the 95%CI of Rt between 1.25 and 1.5), and in which the transmission potential of SARS-CoV-2 can be limited only modestly with ordinary and extraordinary mitigation measures. An epidemic with these characteristics is expected to have a faster growth in the number of cases than in scenario 2, evidence of a failure to track chains of transmission, and initial signs of healthcare system overload due to the increase of more severe cases (increase in the occupancy rate of hospital beds – medical area and intensive care). This is expected to correspond to a high or very high level of risk according to the monitoring system defined in the decree of the Minister of Health issued on 30 April 2020. The growth in the number of cases could lead to an overload of healthcare services within 2-3 months. However, it is important to note that if the epidemic were to spread predominantly among younger age groups, as observed in the July-August 2020 period, with the most fragile groups (e.g., the elderly) being protected, the time-frame for intervention could be considerably longer.

- **SCENARIO 4**
  Situation of uncontrolled transmission with short-term critical issues in the ability of the health system to cope, with regional Rt values systematically and significantly higher than 1.5 (with estimates of the 95%CI of Rt higher than 1.5). Although a scenario of this type would lead to more aggressive mitigation and containment measures in the affected territories, it would also quickly lead

to a high number of cases and clear signs of an overload of healthcare services without the possibility of tracing the origin of new cases. The increased case load could overwhelm healthcare services within 1-1.5 months, unless the epidemic spreads predominantly among the younger age groups, as observed in the period July-August 2020, with the most fragile groups (e.g., the elderly) being protected. However, it should be noted that achieving an effective protection of the most fragile categories seems rather unlikely in an epidemic characterized by this level of transmission.

Chapter 4

Policies adopted in Italy to address autumn-winter 2020 season in reference to WHO strategic pillars

The WHO strategy in the document "COVID-19 strategic preparedness and response plan operational planning guidelines to support country preparedness and response" (SPRP) published in February 2020 (37), and in the document "2019 Novel coronavirus (2019 nCoV): strategic preparedness and response plan" updated in April 2020 (1) identifies 8 key strategic pillars in the response to the COVID-19 pandemic (Figure 5):

- Pillar 1. Country-level coordination, planning, and monitoring
- Pillar 2. Risk communication and community engagement
- Pillar 3. Surveillance, rapid response teams and case investigation
- Pillar 4. Points of entry
- Pillar 5. National laboratories
- Pillar 6. Infection Prevention and Control (IPC)
- Pillar 7. Case management
- Pillar 8. Operational support and logistics.

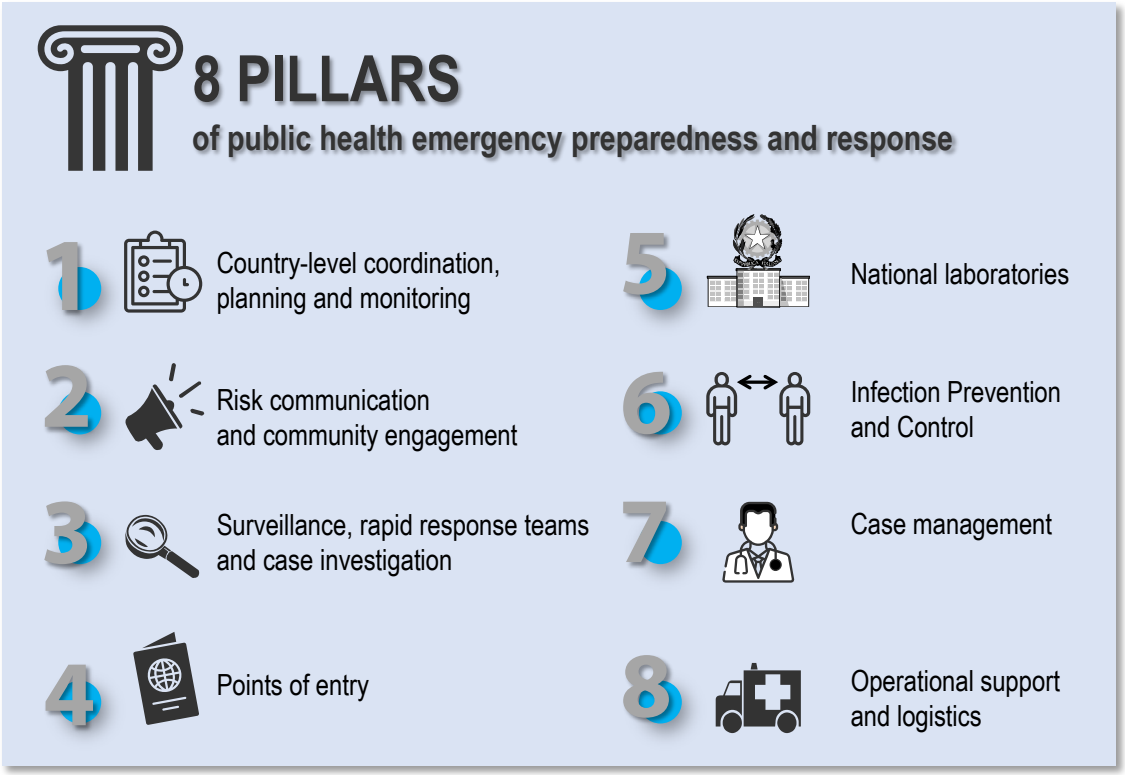

Figure 5. The 8 WHO strategic pillars for public health emergency preparedness and response to COVID-19

In Italy, actions to respond to the SARS-CoV-2 virus outbreak were carried out in line with the strategic indications provided by the WHO (1, 37, 38), demonstrating a high level of preparedness (39). The following paragraphs provide a description for each strategic pillar of the activities carried out during the transition phase and the operational preparedness activities to face the autumn-winter 2020 season. An inventory of operational tools in force is also provided for each pillar.

Pillar 1. Country-level coordination, planning, and monitoring

Activities during the transition phase

In Italy, during the period of epidemic transition, all mechanisms of coordination and multi-sector and inter-institutional interface are still active for the definition of national programming decisions and to draft policy, organization, planning and technical-scientific documents.

These documents, together with those already produced in the earlier stages of the pandemic, are the regulatory and technical basis to support operational interventions and a tool that can be used in the event that the epidemic worsens in the coming months. The level of response of regional systems to national planning measures continues to be monitored, and training courses in FAD (*Formazione a Distanza*, Distance Learning) are being carried out by the ISS targeting health professionals. For example, the "SARS-CoV-2 Preparation and Contrast" course, aims to encourage the creation of a common language and shared procedures among health professionals on this new emerging problem that had never been addressed before, as well as to disseminate in a coordinated way the guidance provided by the national and regional institutions also at the local level. Since the beginning of training activities, the ISS has ensured the availability of the EDUISS distance learning platform, which is used to transmit existing consensus-based national guidance to be adapted according to specific regional and local needs.

Regulations supporting public health measures potentially needed for epidemic containment have been periodically updated to ensure their legitimacy (latest update: DPCM issued September 7th, 2020, "Additional implementation provisions of the Decree-Law of the 25th of March 2020, n 19, bearing urgent measures to deal with the epidemiological emergency caused by COVID-19, and the Decree-Law of the 16th of May 2020, n. 33, bearing further urgent measures to deal with the epidemiological emergency caused by COVID-19").

A **weekly monitoring system has been implemented for the quantitative classification of the risk and resilience of regional PH and healthcare systems**, implemented by the ISS and coordinated by the Ministry of Health (28, 29). The system includes regular consultation mechanisms with technical contacts within regional health systems and with a national coordination committee ("Cabina di Regia"). In order to monitor the quality and completeness of the information reported by the Regions/APs and to provide them with a tool to check their data quality, automatic reports are produced weekly and sent to each Region/AP reporting missing/inconsistent data for each indicator being evaluated and possible discrepancies in the number of cases of SARS-CoV-2 virus infection reported to the integrated COVID-19 surveillance coordinated by the ISS and to the system managed by the Ministry of Health/Civil Protection.

With regards to the protection against accidents, INAIL has provided operational guidance for the protection of workers insured with the Institute who have contracted the infection at work since the beginning of the emergency due to the epidemic spread of the new Coronavirus SARS-CoV-2, also by means of specific regulatory provisions. It provided explanations aimed at clarifying the procedure to report illness-injury complaints and the related medical certification and favoured a proactive role of its local structures to allow the acquisition of those complaints. This monitoring, as of 31 August 2020, detected 52,209 accident complaints as a result of COVID-19 reported to INAIL, of which 71.2% are in the health and social care sector.

In view of the involvement of the health sector in the management of the pandemic, INAIL, in collaboration with the *Consiglio Nazionale Ordine Psicologi* (CNOP, the National Council of Psychologists), has activated a national initiative to promote psychological support services aimed at health professionals. The aim is to provide all health facilities with procedural guidance and useful tools for the activation of psychosocial support services, established locally with task forces of psychologists.

Initiatives to strengthen preparation for the autumn-winter season

Regional planning activities aimed at strengthening the endowments and organisation of hospital health care and PH services for the management of the COVID-19 emergency have been planned, directed and financed with specific rules, and the national arrangements for monitoring have been defined, aimed at verifying the state of implementation of the activities and any critical situations.

Specifically, a legislative measure has been adopted, The Decree-Law 34/2020 converted into Law 77/2020 ("Rilancio" Decree), which in Article 1 provided for the adoption by the Regions/APs, of plans to strengthen and reorganize territorial healthcare with the aim of ensuring that infected patients, their contacts and people in isolation, as well as frail people and people affected by chronic and invalidating illnesses are taken charge of in a timely way.

Specifically the measure defines the strengthening of the local functions involved in the diagnostic ascertainment system and in the monitoring and surveillance of COVID-19 and the enhancement of home care for infected patients and for those suffering from chronic illnesses, disability, mental health issues and addictions, that are not self-sufficient, who need palliative care and pain therapy. The activation of regional operational centres is also defined to ensure the coordination of the implemented healthcare and social-health activities. These activities are supported by specific funding. The system in place to monitor cases and clusters of SARS-CoV-2 in schools and kindergartens has also been strengthened, through the close collaboration of local PH services and schools in order to adopt evidence and/or PH good-practice based operational approaches that are rational, consensus-based and consistent across the country, thus avoiding fragmented and dissimilar approaches.

The same law, in art. 2, decrees the adoption of hospital reorganization plans, aimed at making structural expansions of the intensive care hospital bed capacity, with an overall increase of 3,500 hospital beds, and of the sub-intensive care hospital bed capacity, with an increase of 4,225 hospital beds (of which 50%, that is 2,112, that can be transformed into intensive care hospital beds in the event of an emergency), with the aim of guaranteeing adequate levels of assistance also in case of significant increases in demand.

At present, all hospital reorganization plans submitted by the Regions and APs under art. 2 of the Decree-Law 34/2020 and according to the indications made in the Circular of the Ministry of Health No.11254 of 29.05.2020, have been approved by the Ministry of Health and implementation procedures have been launched by the Extraordinary Commissioner, as stated in paragraph 11 of the decree (*see also* Pillar 8).

Both of these plans (for hospital services and primary services) have been included in the COVID-19 operational programmes as per art. 18 of the Decree-Law 18/2020 and are jointly monitored by the Ministry of Health and the Ministry of Economy.

In order to support the preparedness of health services to a possible further increase in the number of cases and hospitalizations for COVID-19 in Italy in the autumn-winter 2020 season, the document "Elements preparedness and response elements to COVID-19 in the autumn-winter season" has been prepared (34). Further a monthly mechanism to exchange on the resilience of healthcare and PH services was also set up, coordinated by the Ministry of Health and implemented by the ISS, with regular updates (preparedness reports) for each Region/AP and video-conference meetings with regional health system representatives to ensure continuous coordination for timely responses and collaborative decision-making.

Table A1 of the Appendix includes the body of national standards, circulars, ordinances and instruments produced in the field of programming, coordination and monitoring of activities aimed at addressing the SARS-CoV-2 pandemic and in force for the autumn-winter 2020 season organized by topic.

Pillar 2. Risk communication and community engagement

Activities during the transition phase

In the new epidemic phase, communication aims to maintain the results achieved during the lockdown period and to promote further containment of the epidemic. At this stage, the production of scientifically rigorous content is vital.

In view of the main targets (media, health professionals and citizens) it is necessary to use a simple and clear communication.

To involve the entire population in adopting correct behaviours to contrast the epidemic, it is essential to acquire the imperative of transparency, also sharing the margins of uncertainty that characterize scientific knowledge in all times of emergency.

At this stage, it is crucial to conduct constant, coherent and coordinated communication with the other institutions, in order to develop trust in the public and represent a constant, authoritative and reliable reference.

The Press Offices of the institutions involved are a liaison for the coordination of communication. In ISS, in particular, the Risk Communication and Community Engagement (RCCE) coordination mechanism, started in the first emergency phase with the establishment of the Communication Group (Press Office, Scientific Communication Unit with the integration of some reference experts), continues to be active.

Initiatives to strengthen preparation for the autumn-winter season

To strengthen the preparation for the autumn-winter season at this stage, the communication of the institutions involved continues to ensure:

- constant production of content aimed at increasing population awareness and at contrasting fake news through the main institutional channels (press releases, web sites and social media, infographics and videos);
- support for the dissemination of surveillance data and of information on the epidemiological situation through social channels and the web;
- management of interviews and the identification of institutional spokes-people;
- communication actions aimed at prevention for more fragile population groups;
- activation of inter-institutional synergies to promote stakeholder training;
- la dissemination of technical content and related updates on the management of this phase of the emergency to stakeholders (school, supermarkets, etc.).

The Communication area is also conducting a preparedness activity to address increased transmission scenarios including:

- constant monitoring of population sentiment through research, surveys and focus groups;
- adaptation of the communication strategy to the different epidemiological scenarios by preparing where necessary media briefings and press conferences, with the presence of representatives of the institutions involved;
- adaptation of the strategy and possible enhancement of activities on social channels;
- timely information on new diagnostic and prevention tools.

Table A2 of the Appendix contains the body of national standards, circulars, ordinances and tools produced in the field of risk communication and population engagement, aimed at addressing the SARS-CoV-2 pandemic and in force for the autumn-winter 2020 season organized by topic.

Pillar 3. Surveillance, rapid response teams and case investigation

Activities during the transition phase

During the transition phase, the integrated epidemiological and microbiological COVID-19 surveillance system established with Ordinance n. 640 of the Presidency of the Council of Ministers - Department of Civil Protection issued on 27/2/2020, coordinated by the ISS, continues. The Integrated Surveillance System collects, through a web platform, individual data on people who tested positive for SARS-CoV-2 using molecular testing through rhinopharyngeal swabs. This system allows not only to monitor the progress of the epidemic in the country, but to carry out specific analyses for population subgroups, including vulnerable population groups.

The national reference laboratory at the ISS is tasked with carrying out viral genomic surveillance in order to monitor the molecular epidemiology of SARS-CoV-2, in a defined number of clinical samples for each Region/AP, which are sent monthly to the ISS (17) – *see* Pillar 5.

As the outbreak progresses and with it the need to gather additional information on confirmed cases, the surveillance form has been integrated with new information, such as the variable "origin of the case (native, imported from another region or abroad)", and the variable "setting" that allows to describe the place/community where the disease was likely contracted.

Since June 2020, the ISS has integrated the data collection form of the Ministry/Civil Protection's daily aggregated surveillance of COVID-19 into the Integrated Surveillance System's Web platform. The Ministry of Health, after checking and validating the data, publishes the automatically generated summary table on its portal. The system also automatically sends the data to a Civil Protection repository to update their online dashboard.

The identification and management of contacts of probable or confirmed cases of COVID-19, through quarantine and active surveillance, is aimed at identifying and isolating secondary cases in a timely manner, in order to interrupt transmission chains. During the transition period, characterised by widespread transmission of the virus throughout the country, with outbreaks of considerable size, there has been a gradual increase in these activities, both nationally and locally, after the re-openings that followed the national lockdown. The identification and management of close contacts was carried out at the local level by local health authorities.

At the national level, the prevailing activities were:

- request for passenger lists of aircrafts, ships, coaches and trains, with identification of passengers-close contacts and communication of information;
- reporting to the regional health authorities for the activation of health surveillance;
- exchange of selective messages between EU countries / IHR National Focal Point.

To conduct these activities, a multidisciplinary team of prevention and health assistants and medical doctors was set up and a database containing the COVID-19 Contact Tracing carried out nationwide was established.

In June 2020, the ISS published a guide outlining the key stages of the contact tracing process, providing a set of standard forms for data collection, with the aim of providing a tool to make the approach to this

activity consistent across the country (40) and developed a distance learning course (FAD) "COVID-19 Epidemiological Emergency: elements for contact tracing", for public health workers who carry out these activities in the context of COVID-19. The course is being delivered and an updated edition, which will be enriched by the real life experiences collected in the last months of outbreak-control, is planned from mid-October. Finally, the ISS has made the Italian version of the Go.Data software, a web platform developed by the WHO to facilitate the collection of data during public health emergencies, available.

In the context of digital health, the Extraordinary Commissioner for the COVID-19 Emergency (Presidency of the Council of Ministers), in collaboration with the Ministry of Health and the Ministry for Technological Innovation and Digitalization, has issued a mobile phone application aimed at proximity tracking ("Immuni" App) as a tool to assist traditional contact tracing. Other activities in this area have been:

- an inter-institutional technological assessment of solutions to contrast the COVID-19 epidemic;
- a fact-finding survey of the technologies used by fragile and disabled citizens;
- the study of data protection issues in order to promote data policies in favour of the establishment of EU and national portals for COVID-19 Open Data;
- the promotion of technological innovation in relation to the interoperability of electronic medical records, the creation of tools for the management of digital health at sea and reliable Artificial Intelligence applications;
- the development of open source teleconsultation software that can be automatically audited for operational continuity (ISO 27000) and protected with innovative tools for cyber security, currently in trial operation and awaiting authorization.

Initiatives to strengthen preparation for the autumn-winter season

In the 2020-2021 flu season in Italy, surveillance of the SARS-CoV-2 virus will also be incorporated into the sentinel surveillance of influenza viruses (InfluNet). The InfluNet system is based on a network of sentinel general practitioners and primary care paediatricians, recruited from the Regions, who report the cases of Influenza Like Illnesses (ILI) they observe among their patients. Sentinel doctors and other doctors working in primary and secondary care also collaborate in the collection of biological samples for the identification of circulating viruses. Virological surveys of the biological samples collected are carried out by laboratories that are part of the InfluNet network. In the context of the InfluNet network, a specific distance learning (FAD) course is planned for the entire network of social-health workers aimed at contrasting both influenza and COVID-19.

Environmental surveillance of SARS-CoV-2 (41-43) through urban wastewater is also planned in order to acquire indications on the epidemic trend and develop early warning through the national project SARI ("Sorveglianza Ambientale Reflue in Italia") coordinated by the ISS through the Interregional Coordination of Prevention, the Health Commission, the Conference of the Regions and the APs of the State-Regions Conference, in line with the recent European recommendations of health preparedness for COVID-19 outbreaks (44, 45).

A fact-finding survey will be carried out to define the current situation of contact tracing activities carried out at regional and local level, in order to improve and make the process more efficient and consistent and to identify the areas to be strengthened.

The document "Operational guidance for the Management of SARS-CoV-2 Cases and Outbreaks in Schools and Kindergartens" (46), was produced, aimed at giving a rational and uniform approach to contact investigation and tracing procedures following the school reopening. This was followed by the implementation by ISS of the distance learning (FAD) course "Operational Guidance for the Management

of SARS-CoV-2 Cases and Outbreaks in Schools and Kindergartens", for health professionals and school operators.

A platform is being designed to manage the national rapid alert network - along the lines of the European Commission's Early Warning Response System (EWRS) – in which Central Regions and Authorities have the possibility to exchange communications promptly and, over all, with the guarantee that sensitive data is adequately protected. The purpose of this tool is to improve the communication flow between all the actors involved.

Table A3 of the Appendix contains the body of national standards, circulars, ordinances and instruments produced in the field of surveillance, rapid response teams and case investigation aimed at addressing the SARS-CoV-2 pandemic and in force for the autumn-winter 2020 season organized by topic.

Pillar 4. Points of entry

Activities during the transition phase

During the epidemic transition period, the USMAF continued to ensure the monitoring activities imposed since the beginning of the pandemic. The number of points of entry enabled to international traffic, especially in the maritime sector, has imposed the need to increase by tenfold the human resources assigned to the maritime and air health offices.

The USMAF Coordination Office of the Ministry of Health's Directorate General of Prevention coordinated the integration of human resources and the distribution to peripheral offices of the materials needed for the pandemic emergency, from Personal Protective Equipment (PPE) to thermometers, to information technology (IT) instruments. It also drafted health protocols, with European colleagues from the Joint Action Healthy GateWays and with the cooperation of trade associations and the General Command of the Port Authorities. With the resumption of cruise activity in the Mediterranean Sea, an *ad hoc* protocol was transmitted to the International Maritime Organization (IMO).

With the cooperation of regional health authorities and the Civil Protection, temperature monitoring was implemented for all travellers, initially only for international arrivals, then from all destinations and finally also for departures. Together with port and airport operators, a number of measures have been implemented to prevent the spread of SARS-CoV-2: from training workers in sanitization of environments, to verifying passenger distancing and the correct compilation of self-declarations.

In parallel with the validation and availability of rapid antigenic testing, the USMAF began monitoring incoming passengers from European destinations for which restrictive measures had been imposed. The need to comply, with the cooperation of the Border Police, with the DPCMs that followed that identified a number of countries from which an access ban to Italy was imposed, led to the obligation to identify facilities where to accommodate travellers while conducting the mandatory quarantine.

Initiatives to strengthen preparation for the autumn-winter season

In compliance with the DPCM issued on the 7th of September 2020 (47), the USMAF Coordination Office is in charge of drafting and authorizing health protocols (including mandatory swabs and self-isolation) in order to grant exemptions to the access ban to Italy (for sporting events, fairs, other).

A Health Biosafety Training tool was developed that simulates, through a docufilm, the management of patients with a suspected contagious infectious disease in a critical infrastructure (ports and airports), in compliance with the 2005 International Health Regulations. The tool was developed by the Medical Council of Palermo as the leader of the Medical Councils of Sicily, together with the Ministry of Health and aims to

describe the procedures for the management of a suspected contagious infectious disease case with the involvement of multiple actors; to implement prevention and control measures through the functions of the Provincial Health Services and, over all, to train a pool of qualified people, defined as focal points, that are capable of working in teams and who have specific biocontainment know-how, in particular on the use of PPE and transport systems.

Table A4 in Appendix shows the body of national standards, circulars, ordinances and instruments produced in the field of cross-border entry/health points aimed at addressing the SARS-CoV-2 pandemic and in force for the autumn-winter 2020 season organized by topic.

Pillar 5. National laboratories

Activities during the transition phase

On July 16th, 2020, the "Rilancio" Decree was approved, converted into law n. 34 issued on May 19th 2020, containing urgent measures in the field of health, support for work and the economy, as well as social policies related to the epidemiological emergency from COVID-19. The approved text recognizes for the first time in ordinary law the role of the network of Microbiology and Virology laboratories in the strategy to contrast the pandemic. The text reads:

> "The Regions and the Autonomous Provinces establish the laboratory networks of microbiology for the diagnosis of SARS-CoV-2 infection, identifying them among the laboratories equipped with suitable infrastructural requirements and adequate specialist staff skills, to cover the needs of services generated by the epidemiological emergency […]. The Regions and Autonomous Provinces [...] identify a public regional reference laboratory that operates in connection with the Istituto Superiore di Sanità and identifies, with coordination tasks at the regional level, for the purposes of accreditation, the public and private laboratories operating in the reference territory, that comply with the prescribed requirements "(48).

The need to formally recognise the laboratory networks that perform the molecular diagnosis of COVID-19 lies in the importance of the specialist tasks carried out by laboratories in contrasting the spread of the epidemic. In Italy, the model of laboratory networks is well established, and has long been applied at national level for all major infectious diseases that can cause epidemics (e.g., influenza) and that require very advanced surveillance systems with a strong laboratory component (e.g., the network for the surveillance of invasive bacterial diseases).

In the transition phase, the authorized Regional Laboratories performed diagnostic functions with reference molecular methods or diagnostic kits, on samples (oral-nasal-pharyngeal swabs) from symptomatic, asymptomatic subjects or from patients previously positive for SARS-CoV-2 to document the end of the infection (re-testing) with a progressive increase in diagnostic capacity (Figure 6).

The Regional Reference Laboratory at INMI L. Spallanzani has been entrusted with the task of validating the new rapid molecular and antigenic diagnostic tests. The laboratory also focused on characterising strains of SARS-CoV-2 of regional clusters, the sequences shared with the scientific community.

Having been designated national reference laboratory in the TSUNAMI study, for the coordination and standardization of the neutralizing capacity of the plasma of convalescent COVID-19 patients, in collaboration with the laboratory of the S. Matteo Polyclinic in Pavia, the INMI assessed the possibly different neutralizing capacity of patient antibodies using different and well characterized viral strains, using a single reference strain that was distributed to the laboratories involved together with a pool of sera with known neutralizing titre.

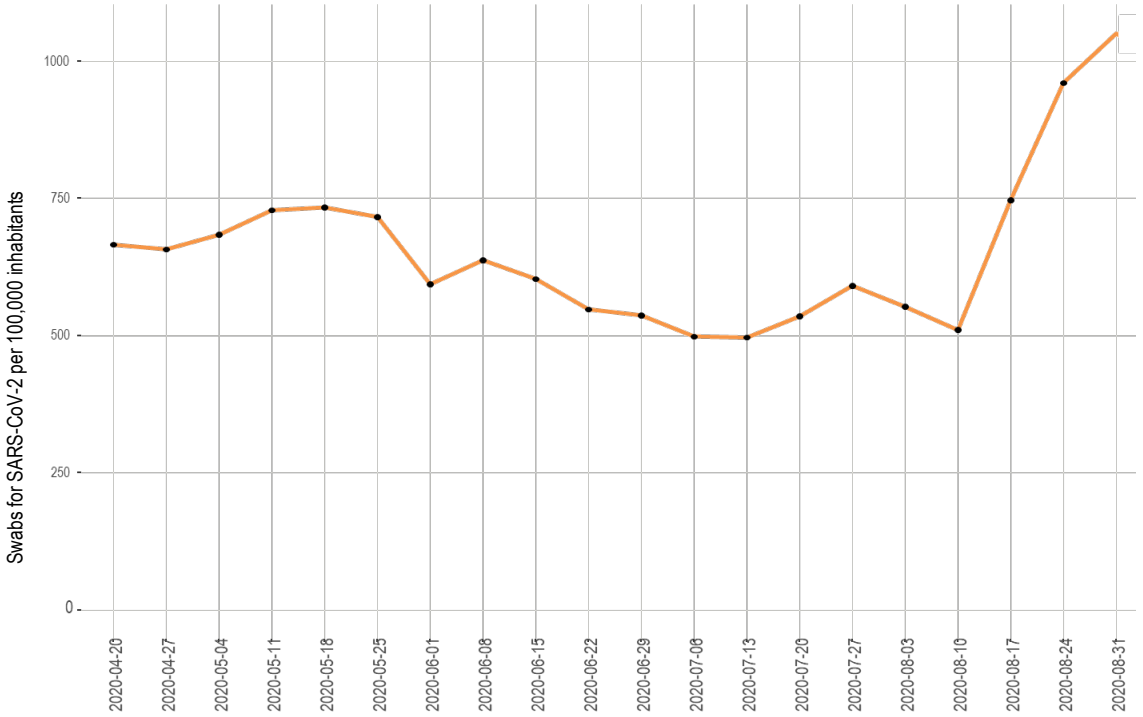

Figure 6. Weekly assessment rate (per 100,000 inhabitants), 20 February – 31 August 2020 (source Italian Ministry of Health)

The COVID-19 National Reference Laboratory at the ISS performed all molecular confirmations positive swabs from all Italian Regions (50) in the first phase and in particular between the end of February and March to ensure an accurate and comparable diagnostic capacity on the national territory. Subsequently, in addition to continuing its support to the peripheral laboratories in the InfluNet network throughout the country, it began the molecular monitoring of the SARS-CoV-2 virus circulating in Italy, through viral isolation and / or genomic sequencing directly from the oral nasopharyngeal swabs. The analysis of mutations in viral genomes from a sub-set from each Region/AP to characterize the virus causing epidemic clusters, to share them with the national and international scientific community, and to monitor the predominance of certain strains in in different Italian Regions. The study will take into consideration the whole national territory both in the lockdown phase and in the transition phase following the restart of the various activities. This monitoring in the pre-introduction phase of the vaccine will allow to take a snapshot of viral changes without vaccine pressure.

In addition, the National Reference Laboratory at the ISS isolated and titred strains of SARS-CoV-2 virus. This activity has enabled serum-neutralisation tests to be developed on cells and to provide different ISS research groups with the virus for in vitro infection studies.

Initiatives to strengthen preparation for the autumn-winter season

In the autumn-winter season, the SARS-CoV-2 virus and seasonal influenza viruses are expected to co-circulate, with similar symptoms, requiring a laboratory confirmation to ascertain differential diagnosis. With this in mind, concurrent monitoring of cases of infection due to SARS-CoV-2 and to influenza viruses, including the detection of possible co-infections in the community, becomes extremely important through the implementation of multiple molecular diagnostic tests (51).

To this end, the ISS began the integration of COVID-19 surveillance with the InfluNet system, with a request to the laboratories of the InfluNet network to systematically test the swabs received for influenza viruses also for the SARS-CoV-2 virus (*see* Pillar 3).

In addition, the National Reference Laboratory at the ISS will be operational:

- providing laboratory support for the development of molecular protocols for multiplex rt-Real time PCR for the simultaneous detection and differentiation of SARS-CoV-2 and influenza viruses. Recently the Food and Drug Administration (FDA) authorized a Real Time PCR multiplex rt kit, developed and perfected by the CDC, for the simultaneous detection and differentiation of influenza A/B viruses under the Emergency Use Authorization (EUA) and SARS-CoV-2 (https://www.fda.gov/media/139744/download). This kit is intended primarily for Influenza / COVID-19 International Reference Laboratories and Authorized Laboratories (CLIA) and is indicated for the differential diagnosis in upper and lower respiratory tract specimens from patients with flu-like symptoms. Protocols developed by the ISS are also available (51);
- providing support for the production of in-house reagents;
- strengthening laboratory capacities also through pool-testing methodologies (52) to be evaluated and shared with peripheral laboratories;
- evaluating protocols and methodologies for rapid point-of-care diagnosis with antigenic or molecular tests that have the ability of offering results on site very quickly (30-60 minutes), with lower cost and without the need for highly specialized personnel. These tests could be strategic to control possible outbreaks in schools or closed communities (prisons, LTCF).

Table A5 in the Appendix includes the body of national standards, circulars, ordinances and instruments produced in the field of national laboratories aimed at addressing the SARS-CoV-2 pandemic and in force for the autumn-winter 2020 season, organized by topic.

Pillar 6. Infection prevention and control (IPC)

Activities during the transition phase

During the transition phase, technical documents were updated to support various activities related to infection prevention and control through inter-institutional collaboration and with the support of WHO experts.

These documents update the regulatory references and information on scientific knowledge available in that area and provide appropriate guidance both in the context of the remodulation phase of containment measures and in the re-establishment of non-emergency healthcare activities.

The most widely used tools were the Ministry of Health Circulars, ISS COVID-19 reports, INAIL technical documents, CTS and Regional documents, for which consensus on content was carefully and widely sought during their writing and definition phases. These documents were made available to national, regional and local decision-makers. In particular, guidance on the management of quarantine and home isolation (53), the use of protective equipment in healthcare activities (54), prevention and control in social and long-term care residential facilities (55), management of indoor environments (56), disinfection of healthcare and non-healthcare environments (58) have been updated. These documents were disseminated through institutional and non-institutional websites, Ministerial circulars and regulatory acts. Other technical indications have been provided for the prevention of infections related to the restart of commercial/productive, recreational activities, sports and transport. In particular, in addition to the aforementioned technical document for the planning of reopening (30) and technical document on the reorganisation of the public transport system (31), additional documents have been drawn up, focussed on

the resumption of recreational bathing activities (59), catering (60) and personal care services (61). INAIL-ISS working groups developed additional technical documents and opinions that supported the CTS in drawing decisions or indications of specific activities, such as the restart of sport, cultural activities and mass events.

The provision of the obligation to use airway protection (whether a surgical mask or a cloth mask) in all indoor environments open to the public and also outdoors when it is not possible to maintain the distance of at least one meter between people, decreed since DPCM of the 26th of April 2020, has been one of the cornerstones of the strategy for containing the circulation of the virus in the general population.

Pursuant to art. 122 of the Decree-Law of the 17th of March 2020, n. 18, by decree of the President of the Council of Ministers of the 18th of March 2020, the current Extraordinary Commissioner was appointed for the implementation and coordination of the necessary measures for the containment and contrast of the COVID-19 epidemiological emergency (*Gazzetta Ufficiale Serie Generale* n.73 of 20-03-2020) (62). The Extraordinary Commissioner for the COVID-19 emergency manages all useful interventions to deal with the health emergency including planning and organizing activities, identifying needs, directing human and instrumental resources and launching the acquisition and distribution of drugs, equipment and medical and personal protection devices, in liaison with the Head of the Civil Protection Department (63). On the basis of this provision, from the point of view of health planning, the Civil Protection continued its work for the procurement and distribution of PPE to the Regions/APs in the healthcare and residential sectors (*see* Pillar 8).

Support for infection prevention and control has also been provided through the ongoing training of healthcare professionals through courses, webinars and training materials, including the following distance learning (FAD) courses produced by the ISS: Prevention and control of infections in the context of the COVID emergency, COVID-19 health emergency: management of patients on dialysis, COVID-19 health emergency: Dental patient management, COVID-19 Health Emergency: nutritional and food risk management.

Initiatives to strengthen preparation for the autumn-winter season

For the school sector, that was identified as a possible critical point, the CTS produced documents for the reopening of schools that were attached to the School Plan 2020-2021. In order to contain the risks of an inappropriate response to cases and outbreaks in schools, a document with technical guidance for the management of such cases was produced. The document was adopted by the Unified Conference of Regions and APs. In addition, in agreement with the Ministry of Education, among the preventive measures to be taken for the safe reopening of schools, individual workstations were purchased by the Structure of the Commissioner at the Civil Protection to facilitate the maintenance of distancing between students in classrooms. In addition, the daily provision of surgical masks has been ensured for school staff and students of all schools.

Table A6 in the Appendix includes the body of national regulations, circulars, ordinances and instruments produced in the field of Infection Prevention and Control (IPC) aimed at addressing the SARS-CoV-2 pandemic and in force for the autumn-winter 2020 season, organized by topic.

Pillar 7. Case management

Activities during the transition phase

During the transition phase, based also on national and international experience of the clinical management of COVID-19 patients, therapeutic and clinical management protocols have been defined that are described in this section.

Clinical management of COVID-19 patients

SARS-CoV-2 was, for all intents and purposes, an unknown pathogen to the international scientific community until the end of December 2019 and the clinical management of patients with COVID-19 has progressively evolved over time, reflecting the progressive accumulation of information relating to the pathogenic determinism of the disease, patient symptoms and the knowledge that has gradually accumulated on efficacy and toxicities associated to different therapies. In particular, the treatment focused on differentiated approaches that involved:

- drugs with potential antiviral activity against SARS-CoV-2;
- drugs with prophylactic / therapeutic activity against thrombotic manifestations;
- drugs capable of modulating the immune response;
- plasma infusions aimed at transferring antibodies that neutralize the binding between the novel coronavirus and its receptor expressed on human cells (ACE2).

It is noteworthy to recall that, even today, there are wide margins of uncertainty with respect to the effectiveness of some of the aforementioned therapeutic agents and the use of the different therapies vs. not using them depend on the severity of the clinical manifestations presented in the patients. Not coincidentally, there is a strong recommendation that patients with the most severe symptoms (hospitalised patients) in particular should be included in clinical trials whose conduct is aimed at defining conclusively the role of different treatment options.

This document summarizes the evidence available to date, presenting the role of patient management approaches with particular emphasis on inpatients in intensive care units (TI). As this study area is constantly evolving, it is widely possible that what is proposed in the text may be subject to significant changes in the weeks and months ahead.

Emerging drug therapies in the treatment of SARS-CoV-2 in critical patients

As mentioned above, SARS-CoV-2 infection is an extremely complex condition due to the related physio-pathogenic mechanisms, the multiplicity of clinical manifestations and for the role played by the immune response of the subjects.

The clinical course of the infection can be summarized in the following 3 stages:

1. an initial phase during which SARS-CoV-2 begins its replication after binding to ACE2 and penetrating inside the host's cells. This phase is usually characterized clinically by the presence of general malaise, fever and dry cough. In this stage, the cases in which the host's immune system is able to block the infection have an absolutely benign course;
2. the disease can then evolve into a second phase, characterized by morpho-functional alterations in the lungs caused both by the cytopathic effects of the virus and by the host's immune response. This phase is characterized very often by bilateral interstitial pneumonia associated with respiratory symptoms that are stable in the early phase and without hypoxemia, but which can subsequently lead to progressive clinical instability;
3. this scenario, in a limited number of people, can evolve towards a worsening clinical picture dominated by a cytokine storm and the consequent hyperinflammatory state that determines local and systemic consequences, and represents a negative prognostic factor producing at the pulmonary level arterial and venous vasculopathy, with thrombosis of small vessels and evolution towards severe and sometimes permanent lung lesions (pulmonary fibrosis). The final stages of this very serious clinical picture lead to severe ARDS (Adult Respiratory Distress Syndrome) and, in some cases, can trigger disseminated intravascular coagulation. In this phase, a progressive alteration of

some inflammatory parameters such as CRP, ferritin, and pro-inflammatory cytokines (IL2, IL6, IL7, IL10, GSCF, IP10, MCP1, MIP1A and TNFα) and of coagulation such as increased levels of fibrin breakdown products such as D-dimer, consumption of coagulation factors, thrombocytopenia, etc.

Based on these three pathogenic phases, 5 clinical stages of COVID-19 disease (Table 1) are identified based on the classification of the US National Institutes of Health (NIH) (64).

Table 1. Clinical stages of COVID-19 disease by NIH classification (64)

Stage	Characteristics
Asymptomatic or pre-symptomatic infection	Diagnosis of SARS-CoV-2 in complete absence of symptoms
Mild illness	Presence of mild symptoms (e.g., fever, cough, loss of taste and smell, malaise, headache, muscle pain), but in absence of shortness of breath, dyspnoea, or abnormal chest imaging
Moderate illness	$SpO_2 \geq 94\%$ clinical or radiological evidence of pneumonia
Severe illness	$SpO_2 < 94\%$, $PaO_2/FiO_2 < 300$ mmHg, respiratory frequency >30 breaths per minute (adult), or lung infiltrates
Critical illness	Respiratory failure, septic shock, and/or multiple organ dysfunction.

A further classification of the severity of clinical manifestations from COVID-19, which has the advantage of including assessments that pertain to the paediatric field, has been published by the WHO (65) (Table 2).

Table 2. WHO classification of the severity of clinical manifestations of COVID-19

Severity classification	Main clinical events	Description
Mild disease	-	Symptomatic patients meeting the case definition for COVID-19 without evidence of viral pneumonia or hypoxia.
Moderate disease	Pneumonia	**Adolescent or adult** with clinical signs of pneumonia (fever, cough, dyspnoea, fast breathing) but no signs of severe pneumonia, including $SpO_2 \geq 90\%$ on room air. **Child** with clinical signs of non-severe pneumonia (cough or difficulty breathing + fast breathing and/or chest indrawing) and no signs of severe pneumonia. Fast breathing (in breaths/min): < 2 months: ≥ 60; 2-11 months: ≥ 50; 1-5 years: ≥ 40 While the diagnosis can be made on clinical grounds; chest imaging (radiograph, CT scan, ultrasound) may assist in diagnosis and identify or exclude pulmonary complications.
Severe disease	Severe pneumonia	**Adolescent or adult** with clinical signs of pneumonia (fever, cough, dyspnoea, fast breathing) plus one of the following: respiratory rate > 30 breaths/min; severe respiratory distress; or $SpO_2 < 90\%$ on room air **Child** with clinical signs of pneumonia (cough or difficulty in breathing) + at least one of the following: - central cyanosis or $SpO_2 < 90\%$; severe respiratory distress (e.g. fast breathing, grunting, very severe chest indrawing); general danger sign: inability to breastfeed or drink, lethargy or unconsciousness, or convulsions. - fast breathing (in breaths/min): < 2 months: ≥ 60; 2-11 months: ≥ 50; 1-5 years: ≥ 40.

Severity classification	Main clinical events	Description
		While the diagnosis can be made on clinical grounds; chest imaging (radiograph, CT scan, ultrasound) may assist in diagnosis and identify or exclude pulmonary complications.
Critical disease	Acute respiratory distress syndrome (ARDS)	**Onset**: within 1 week of a known clinical insult (i.e. pneumonia) or new or worsening respiratory symptoms. **Chest imaging:** (radiograph, CT scan, or lung ultrasound): bilateral opacities, not fully explained by volume overload, lobar or lung collapse, or nodules. **Origin of pulmonary infiltrates:** respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assessment (e.g. echocardiography) to exclude hydrostatic cause of infiltrates/oedema if no risk factor present. **Oxygenation impairment in adults:** - Mild ARDS: 200 mmHg < PaO_2/FiO_2 ≤ 300 mmHg (with PEEP or CPAP ≥ 5 cm H_2O) - Moderate ARDS: 100 mmHg < PaO_2/FiO_2 ≤ 200 mmHg (with PEEP ≥ 5 cm H_2O) - Severe ARDS: PaO_2/FiO_2 ≤ 100 mmHg (with PEEP ≥ 5 cm H_2O) **Oxygenation impairment in children:** note OI and OSI. Use OI when available. If PaO_2 not available, wean FiO_2 to maintain SpO_2 ≤ 97% to calculate OSI or SpO_2/FiO_2 ratio: - Bilevel (NIV or CPAP) ≥ 5 cm H_2O via full face mask: PaO_2/FiO_2 ≤ 300 mmHg or SpO_2/FiO_2 ≤ 264. - Mild ARDS (invasively ventilated): 4 ≤ OI < 8 or 5 ≤ OSI < 7.5. - Moderate ARDS (invasively ventilated): 8 ≤ OI < 16 or 7.5 ≤ OSI < 12.3. - Severe ARDS (invasively ventilated): OI ≥ 16 or OSI ≥ 12.3.
Critical disease	Sepsis	**Adults:** acute life-threatening organ dysfunction caused by a dysregulated host response to suspected or proven infection. Signs of organ dysfunction include: altered mental status, difficult or fast breathing, low oxygen saturation, reduced urine output, fast heart rate, weak pulse, cold extremities or low blood pressure, skin mottling, laboratory evidence of coagulopathy, thrombocytopenia, acidosis, high lactate, or hyperbilirubinemia. **Children:** suspected or proven infection and ≥ 2 age-based systemic inflammatory response syndrome (SIRS) criteria, of which one must be abnormal temperature or white blood cell count.
	Septic Shock	**Adults:** persistent hypotension despite volume resuscitation, requiring vasopressors to maintain MAP ≥ 65 mmHg and serum lactate level > 2 mmol/L. **Children:** any hypotension (SBP < 5th centile or > 2 SD below normal for age) or two or three of the following: altered mental status; bradycardia or tachycardia (HR < 90 bpm or > 160 bpm in infants and heart rate < 70 bpm or > 150 bpm in children); prolonged capillary refill (> 2 sec) or weak pulse; fast breathing; mottled or cool skin or petechial or purpuric rash; high lactate; reduced urine output; hyperthermia or hypothermia.

Different stages of the disease are matched by different therapeutic approaches (66) (Figure 7). Finally, it is useful to recall that SARS-CoV-2 can cause damage to other organs besides the lung. Among these it is worthwhile to mention damage observed to the heart, kidney and central and peripheral nervous system.

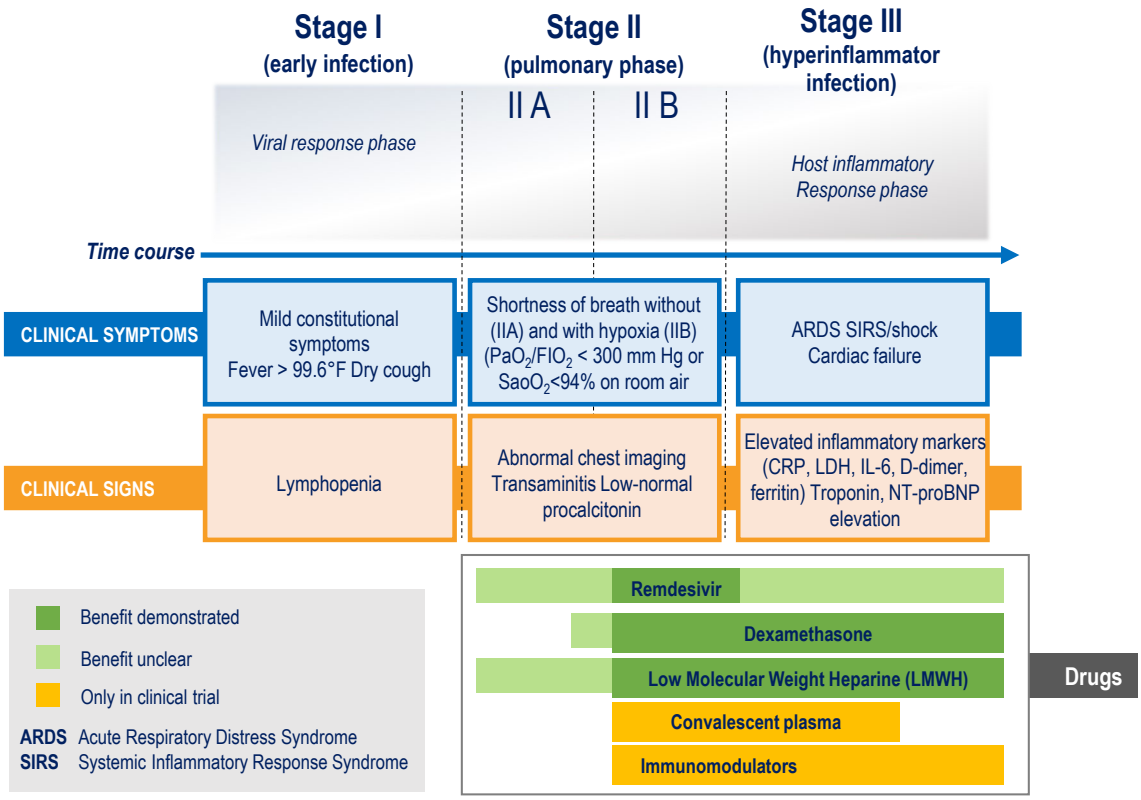

Figure 7. Therapies considered effective by clinical stage of COVID-19 disease - modified from (66)

Corticosteroids

The use of corticosteroids is recommended by the main international guidelines, in the absence of specific contraindications, in subjects hospitalized with severe COVID-19 disease who require oxygen supplementation (including subjects in invasive and non-invasive mechanical ventilation). According to the evidence available to date, glucocorticoids represent the only class of drugs that has demonstrated a benefit in terms of mortality reduction.

Rationale

Due to their powerful anti-inflammatory effect, corticosteroids have been used in pathologies closely related to COVID-19, including SARS, MERS, severe influenza, community-acquired pneumonia, ARDS or cytokine release syndrome. However, evidence to support the use of corticosteroids in these conditions has always been controversial due to various reasons, including the lack of sufficiently robust randomized studies in terms of sample size, the heterogeneity of the populations studied and the often inadequate ways of collecting data regarding dosages, the severity of the underlying disease, and side effects.

Key evidence

The main evidence to support the use of dexamethasone in COVID-19 stems from the RECOVERY (Randomized Evaluation of COVID-19 Therapy) study, a randomized open controlled study conducted in the UK under the auspices of the Randomized Evaluation of COVID-19 Therapy, which compared different treatments in hospitalised subjects with COVID-19 (67). Analysis of 6,425 randomized subjects (2,104 in the arm with dexamethasone and 4,321 in the usual care arm) showed, in the general population, a statistically lower mortality in the dexamethasone treatment arm than in the control arm (22.9% vs 25.7%;

RR 0.83; 95%CI 0.75-0.93; p<0.001). In the subgroup analysis, the reduction of the mortality rate in the dexamethasone treated arm compared to the control group was observed also in the subgroup of subjects in invasive mechanical ventilation (29.3% vs 41.4%; RR 0.64; 95%CI 0.51-0.81), while it was not found in the subgroup of subjects who did not receive any oxygen supplementation (17.8% vs 14.0%; RR 1.19; 95%CI 0.91-1.55).

Other randomized clinical trials, some of which were discontinued early after the disclosure of recovery trial results, were published (68-71) and a recent meta-analysis of the WHO Rapid Evidence Appraisal for COVID-19 The (REACT) Working Group confirmed the benefit of steroid drugs in reducing mortality (OR 0.66; 95%CI 0.53-0.82; p<0.001) (72).

The effectiveness is reported to be similar between dexamethasone and hydrocortisone, suggesting that the benefit is generally due to the class of steroid drugs and not to a specific steroid, without a clear superiority between low doses (6 mg/die dexamethasone) and higher doses (20 mg dexamethasone for 5 days plus 10 mg for an additional 5 days or until discharge from the intensive care unit). Based on the data from the meta-analysis, the WHO issued specific recommendations for the use of corticosteroids (73):

- **Recommendation 1**. Systemic corticosteroids are recommended in the treatment of patients with severe or critical manifestations of COVID-19 (strong recommendation with moderate certainty of evidence)
- **Recommendation 2.** It is suggested not to use steroid drugs in the treatment of patients with non-severe manifestations of COVID-19 (conditional recommendation based on low certainty of evidence).

The AIFA guidelines are soon to be published, according to which the use of corticosteroids is recommended in hospitalized patients with severe COVID-19 disease who need oxygen supplementation (including those on invasive and non-invasive mechanical ventilation).

Remdesivir

The use of remdesivir can be considered, in hospitalized patients with severe COVID-19 disease, who require standard oxygen supplementation, but who do not require high flow oxygen and mechanical ventilation

The recommended dosage of remdesivir in patients 12 years of age and older and weighing at least 40 kg is:

• day 1: single loading dose of remdesivir 200 mg administered by intravenous infusion
• from day 2 onwards: 100 mg administered once daily by intravenous infusion

The total duration of the treatment must be at least 5 days and must not exceed 10 days.

Studies conducted so far have not shown a difference in efficacy between the 5-day treatment and the 10-day treatment, either in patients with moderate disease or in the severe disease cohort.

Rationale

Remdesivir is a nucleotide analogue of adenosine that has demonstrated clinical efficacy by inhibiting SARS-CoV-2 replication at the RNA dependent RNA polymerase level (74). Initially used for Ebola Virus Disease, remdesivir is the first antiviral drug to have been approved by the European Medicines Agency (EMA) with specific indication for the "treatment of coronavirus disease 2019 (COVID-19) in adults and adolescents (aged 12 years and weighing at least 40 kg) with pneumonia requiring additional oxygen therapy". Remdesivir has been authorised in Europe with the "conditional approval" procedure.

At the moment, in Italy, remdesivir can only be provided under the Emergency Support Instrument according to the protocols reported on the website of AIFA (75).

Key evidence

The main study that evaluated the efficacy and safety of remdesivir was the ACTT-1 study, a randomized, double-blind, multinational clinical trial sponsored by the National Health Institutes in the United States on the effectiveness of remdesivir *vs* placebo (both administered for 10 days) in a population that included hospitalized subjects, largely with oxygen therapy (74). The data showed, in the general population of patients hospitalized with COVID-19, a statistically significant superiority of remdesivir in clinical recovery time (4 days) in patients in the remdesivir group compared to those in the placebo group (11 vs 15 days: 1.32, 95%CI 1.12-1.55; p<0.001). In the population layer that had pneumonia and additional oxygen need, the difference in the median recovery time was 12 days in the remdesivir group compared to 18 in the placebo group (RR 1.36; 95%CI 1,143–1,623; p<0.001). No difference was observed in the subgroup of patients with 'mild-moderate' disease (stage 4; RR 1.38; 0.94-2.03). There were also no differences, compared to placebo, in hospitalised patients on ventilator support (non-invasive ventilation and high-flow oxygen therapy; RR 1.20; 95%CI 0.79-1.81) and mechanical ventilation (invasive mechanical ventilation and ECMO; RR 0.95; 95%CI 0.64-1.42). In the general population being treated with remdesivir, a more favourable trend in terms of mortality was observed at 14 than in the placebo group without achieving statistical significance; HR 0.70; 95%CI 0.47-1.04).

A previous double-blind randomised clinical trial, conducted in China, but prematurely suspended due to difficulties in completing recruitment, had not shown any benefit in terms of mortality (77). Finally, the two "SIMPLE" studies conducted in populations with moderate (78) or severe disease (79) were published.

Based on the data available to date (although derived from studies with significant methodological issues), the clinical benefit of remdesivir appears to be demonstrated only in the population under supplemental oxygen therapy treatment that does not require the provision of high flow oxygen, non-invasive ventilation, invasive mechanical ventilation or ExtraCorporeal Membrane Oxygenation (ECMO). In addition, studies so far have shown no difference in effectiveness between 5-day treatment and 10-day treatment, both in patients with moderate illness and in patients with severe disease.

Low Molecular Weight Heparin (LMWH)

The use of low molecular weight heparin (LMWH) in the prophylaxis of thrombo-embolic events in patients with acute respiratory infection and reduced mobility is recommended by the main guidelines and must continue for the entire period of immobility.

In severe cases of COVID-19, the use of LMWHs at therapeutic dosages may be considered in patients who have D-dimer levels much higher than normal (4-6 times) and / or a high score on a scale of Sepsis Induced Coagulopathy (SIC) (score> 4) which considers laboratory and clinical parameters.

Rationale

In view of the involvement of the micro-vascular system and the presence of venous and pulmonary thromboembolism observed in the autopsy on patients who died of COVID-19 (80, 81), there is a biological and clinical rationale for LMWH therapy (82). The impact of this treatment in Intensive Care (ICU) is difficult to assess as all patients admitted to ICU receive, as per guidelines, prophylaxis against deep vein thrombosis, based on LMWH, and already have a basic "protection".

Numerous studies have confirmed the importance of the thrombotic events associated with COVID (83-87).

In the complex physio-pathogenic framework that characterizes COVID-19 disease, two scenarios of use of LMWHs can be identified:

- in the initial phase of the disease when pneumonia is present and a hypo-mobility of the patient with bed rest is determined. In this phase, LMWH must be used at a prophylactic dose in order to prevent venous thromboembolism;
- in the most advanced phase in patients hospitalized to contain thrombotic phenomena starting from the pulmonary circulation as a result of the hyperinflammation that characterizes COVID-19. In this case, LMWHs should be used at therapeutic doses.

Key evidence

The first data to assess the impact of anticoagulant therapy on the course of COVID relate to a retrospective analysis of 415 consecutive cases of COVID-19 severe pneumonia in the Wuhan hospital in China (82). The study suggested that, in patients who demonstrated clotting activation, administration of heparin (non-fractional or LMWH) for at least 7 days could determine a survival advantage. The positive therapeutic effect was only evident in those patients who show a very high level of D-dimer (6 times the upper maximum values) or a high score on a SIC scale (score ≥ 4). Subsequent retrospective studies provided further support for a mortality benefit related to the use of anti-coagulants at therapeutic doses (88, 89).

Immunomodulators

There are currently no results from randomised immunotherapy studies (anti-IL-6 monoclonal antibodies, anti-IL-1, tyrosin-kinase inhibitors) confirming the effectiveness of immunotherapy in COVID-19 treatment. For this reason, the use of these drugs should be prioritised in randomised clinical trials that assess their effectiveness.

Rationale

Subjects with COVID-19 observe a cytokine profile similar to the one documented in hemophagocytic lymphistiocytosis (HLH), a condition characterized by a hyper-inflammatory syndrome and an often-fatal hypercytokinemia, which is generally associated with the severity of the disease.

In light of these observations, the use of drugs modulating the cytokine and inflammatory response in COVID-19 should be preferentially intended for patients with evidence of hyper-inflammatory response (a marker or more among lymphocytopenia, elevated levels of D-dimer, ferritin, CRP and LDH).

Key evidence

The role of immunomodulators (particularly monoclonal antibodies that inhibit IL-6, IL-1 and various tyrosine-kinases) in the treatment of COVID-19 disease stages with increased immune activation remains controversial in the literature. In particular, although observational studies or uncontrolled studies have suggested a clinical benefit associated with the use of these drugs (90, 91), the absence of results from randomized clinical controlled trials makes their therapeutic value difficult to assess. Preliminary reports of two studies on the use of Tocilizumab and Sarilumab respectively appear to indicate a lack of treatment benefit in the populations studied (91, 93), while data from the PHASE III EMPACTA study were recently released which would demonstrate an advantage of Tocilizumab over the standard of care in terms of progression to mechanical ventilation or death (94). For the time being, these results are not yet published and, overall, the available evidence does not allow to assess their effectiveness in an incontrovertible way. The use of these drugs should therefore be considered only within randomized controlled clinical trials.

Convalescent plasma

The literature data available at the moment does not allow us to support recommendations regarding the routine use of convalescent plasma for the treatment of COVID-19; its use should be occur exclusively within randomized studies that evaluate its effectiveness.

Rationale

The use of convalescent plasma or hyperimmune immunoglobulins is based on the hypothesis that an increase in humoral immunity achieved through the infusion of antibodies directed against SARS-CoV-2 is an effective strategy in the therapy of new coronavirus infection. This therapeutic approach finds its origins in other epidemic situations and has been used for the treatment of Ebola virus disease, in MERS, and in influenza A and H1N1.

Key evidence

A clinical trial conducted in China in the period February-April 2020, but terminated early due to the difficulties of enrolment due to the epidemiological evolution of the epidemic, in which 103 subjects with severe or critical stage COVID were enrolled, demonstrated a benefit in the use of convalescent plasma versus standard of care in terms of time to clinical improvement in the subgroup of subjects with severe disease (95). On the contrary, there was no efficacy related to plasma infusion in subjects with less severe manifestations attributable to COVID-19 as well as in patients in a critical / advanced situation. In light of the data available at the moment, the main international guidelines concur that convalescent plasma cannot considered as a standard of care and that its possible efficacy needs to be documented by conducting additional controlled clinical studies (96). In this perspective, it should be emphasized that in Italy the TSUNAMI multicentre randomized clinical trial has been activated (see Pillar 5), aimed at documenting in a solid and incontrovertible way the efficacy of therapies with plasma of cured / convalescent subjects in patients suffering from of COVID-19 characterized by respiratory failure.

Drugs in clinical development

Thanks to their selective the mechanism of action and the potential for great efficacy, it must finally be remembered that the use of monoclonal antibodies that could neutralize the virus and represent an important therapeutic option for COVID-19 patients is being tested.

Drugs not currently recommended

AIFA has suspended authorization for off-label use of certain drugs for COVID-19 patients used during the first phase of the epidemic, such as chloroquine and hydroxychloroquine (May 29, 2020), lopinavir/ritonavir and darunavir/cobicistat (July 17, 2020), which are currently only expected to be used in clinical trials.

With regard to azithromycin, the lack of a solid rational and the absence of evidence of efficacy in the treatment of COVID-19 patients, does not allow for recommendation of its use, alone or associated with other drugs, with particular reference to hydroxychloroquine, aside for possible bacterial superinfections.

To further and fully define the role of the different treatment options, the recommendations of the Infectious Diseases Society of America (IDSA) for the treatment and management of COVID-19 patients certainly serve as a reference. In fact, in March 2020, the IDSA set up a panel of experts to identify recommendations useful for the treatment and management of COVID-19 patients. After an initial publication of recommendations on 11 April 2020, the panel continued to work, updating knowledge on existing literature and producing updates on the topic. In particular, the last update was on **September 25, 2020**.

In this last document, several recommendations are identified, supported by evidence-based medicine, in line with the above and with respect to the determinations made by AIFA and thus summarized:

- **Recommendation 1.** IDSA recommends NOT to use hydroxychloroquine (or equivalent drug classes, such as chloroquine) in patients with COVID-19 (strong recommendation, moderate certainty of evidence).
- **Recommendation 2.** In hospitalized patients with COVID-19, IDSA recommends NOT to use the hydroxychloroquine (or equivalent) / azithromycin combination (strong recommendation, low certainty of evidence).
- **Recommendation 3.** In hospitalized patients with COVID-19, IDSA recommends the lopinavir / ritonavir combination only within a clinical trial (gap in knowledge available to date).
- **Recommendation 4.** In hospitalized patients with non-severe SARS-CoV-2 disease (patients with SpO2> 94% in ambient air who do not require oxygen supplementation), ISDA does NOT recommend the use of glucocorticoids (conditional recommendation, low certainty of evidence).
- **Recommendation 5.** In patients admitted to hospital with COVID-19, IDSA does NOT recommend the routine use of tocilizumab, a monoclonal antibody that inhibits Interleukin-6 (conditional recommendation, low certainty of evidence).
- **Recommendation 6.** In patients admitted to hospital with COVID-19, IDSA recommends the use of convalescent plasma only in the context of a clinical trial (gap in knowledge currently available).
- **Recommendation 7.** In hospitalized patients with severe SARS-CoV-2 disease (defined as an SpO2 ≤94% in ambient air, including patients on oxygen supplementation and patients on mechanical ventilation or ECMO) IDSA suggests the use of remdesivir without other antiviral treatments (conditional recommendation, moderate certainty of evidence).

  In situations characterized by limited drug stocks, it should be considered that remdesivir has been shown to be more effective in patients who have severe illness on oxygen supplementation than in those on mechanical ventilation and / or ECMO (*see above*).
- **Recommendation 8.** In patients with severe SARS-CoV-2 disease on oxygen supplementation but not on mechanical ventilation or ECMO, IDSA suggests treatment with the antiviral drug remdesivir in a 5-day and not a 10-day schedule (conditional recommendation, low certainty of evidence). Note that in patients on mechanical ventilation or ECMO the treatment duration is 10 days.
- **Recommendation 9.** In critically ill hospitalized patients mechanically ventilated or ECMO patients (Critical stage disease includes conditions of marked organ dysfunction secondary to sepsis / septic shock. In COVID-19 patients the most common form of organ failure is represented by respiratory failure due to ARDS), IDSA recommends the use of dexamethasone (strong recommendation, moderate certainty of evidence).
- **Recommendation 10.** In hospitalized patients with severe but non-critical SARS-CoV-2 disease (defined as an SpO_2 ≤94% in ambient air, including patients on oxygen supplementation), ISDA recommends the use of dexamethasone (strong recommendation, certainty of moderate evidence). As regards recommendations 9 and 10, it should be emphasized that if dexamethasone is not available an equivalent dose of another glucocorticoid should be used. The recommended dose of dexamethasone is 6 mg intravenously or orally for 10 days (or until discharge) or an equivalent dose of another glucocorticoid if dexamethasone is not available. Examples of equivalent / alternative doses to dexamethasone 6 mg / day are: methylprednisolone 32 mg and prednisone 40 mg.
- **Recommendation 11.** in hospitalized patients with severe SARS-CoV-2 disease, IDSA does NOT recommend the use of famotidine outside a clinical trial (conditional recommendation, very low certainty of evidence).

Capacity of Intensive Care Units and planned response to the pandemic

During the acute phase of the SARS-CoV-2 pandemic, one of the crucial elements was the strong pressure on the National Health Service and in particular on the management of patients in Italian Intensive Care Units (ICUs).

In the period between the beginning of March and April 2020, Italian ICUs came to saturation, despite the installation of new beds dedicated to intensive management in areas of the hospital outside the ICUs. A report well illustrated the situation in Bergamo's ICU, with full saturation of the new intensive care beds, although they increased by 200% compared to the usual capacity (97).

As a result of this situation, the Ministry of Health (98) under the Circular of the Ministry of Health (DGPROG) of the 29th of February and 1st of March 2020 and then Article 2 of the Decree-Law of the 19th of May 2020 n. 34, carried out a census of the beds available in the period before the COVID-19 pandemic, and then highlighted the need for an increase in order to offer resuscitation treatment appropriate to the number of patients in need of intensive care. This upgrade was put in place during the emergency, creating hundreds of additional beds, also equipped in non-ICU departments and for which the afore cited Decree-Law sanctioned consolidation. From the original 5,179 beds in the ICU, an increase of up to 8,679 beds has been established, which resulted in an expansion of IC beds from 12 to 14 per 100,000 inhabitants, thus meeting the standards recommended by the international societies of the sector (*see* Pillar 1).

The supply of mechanical ventilators was a problem in the early stages, given the high number of critical patients admitted to ICU at the same time. The COVID-19 emergency response system was tasked with procuring the ventilators needed for the emergency, now part of the consolidated ICU armament. In March alone, the Structure of the Commissioner delivered 1,231 ventilators and 6,831 CPAP (*see* Pillar 8).

To confirm the needs and correct decisions taken at the government level, a recently published European study (99) highlighted considerable unevenness in European countries concerning the levels of access to ICU during the pandemic, calculated on the basis of the number of beds per 100,000 inhabitants and other factors such as the time required to transport a patient from the place of residence to ICU.

The highest accessibility index was shown for Germany (35,5), and one of the lowest for Italy (8.1). This study also showed a negative correlation between the ICU accessibility index and the fatality index of SARS-CoV-2-related cases. The conclusions underlined the possibility of using the results of the study to develop a national logistical plan proportionate to epidemiological needs, this was done in Italy.

Therapy and techniques to support vital functions in ICU

The picture of respiratory failure in SARS-CoV-2 substantially matches the one described by the Berlin international definitions for ARDS (Adult Respiratory Distress Syndrome) (100-102) (Table 3).

Table 3. Berlin's Definition of ARDS (100)

Timing	Within one week of a clinical insult or new or worsening respiratory symptoms
Radiological images	Diffuse bilateral nodular opacities not fully explained by suffusions, lung / lobar collapse, or nodules
Origins of oedema	Respiratory failure not fully explained by heart failure or fluid overload with the need for objective confirmation (e.g., echocardiography, aimed at excluding hydrostatic oedema)
Oxygenation	
Mild	200 mmHg < PaO_2/FiO_2 < 300 mmHg with PEEP or CPAP > 5 cm H_2O
Moderate	100 mmHg < PaO_2/FiO_2 ≤ 200 mmHg with PEEP or CPAP ≥ 5 cm H_2O
Severe	$PaO_2/Fi\ O_2$ ≤ 100 mmHg with PEEP or CPAP ≥ 5 cm H_2O

ARDS: *Adult Respiratory Distress Syndrome*; **PEEP**: *Positive End-Expiratory Pressure*

Like all ARDS treated so far, also severe respiratory failure from COVID-19 has seen the application of traditional humidified and heated High Flow Oxygen Therapy (HFOTs), non-invasive and invasive protective ventilation (low current volumes, moderate levels of Positive End-Expiratory Pressure - PEEP adjusted to respiratory response, as well as the use of drugs with neuromuscular blocking action in the first 24-48 hours, of pronation techniques up to the use of ECMO - extracorporeal oxygenation) (103). In accordance with the recommendations, the use of the various techniques is modulated, as usual, according to severity.

The reference technical and therapeutic algorithm was developed for the Surviving Sepsis Campaign by the Society of Critical Care Medicine and the European Society of Intensive Care Medicine (Figure 8) (104).

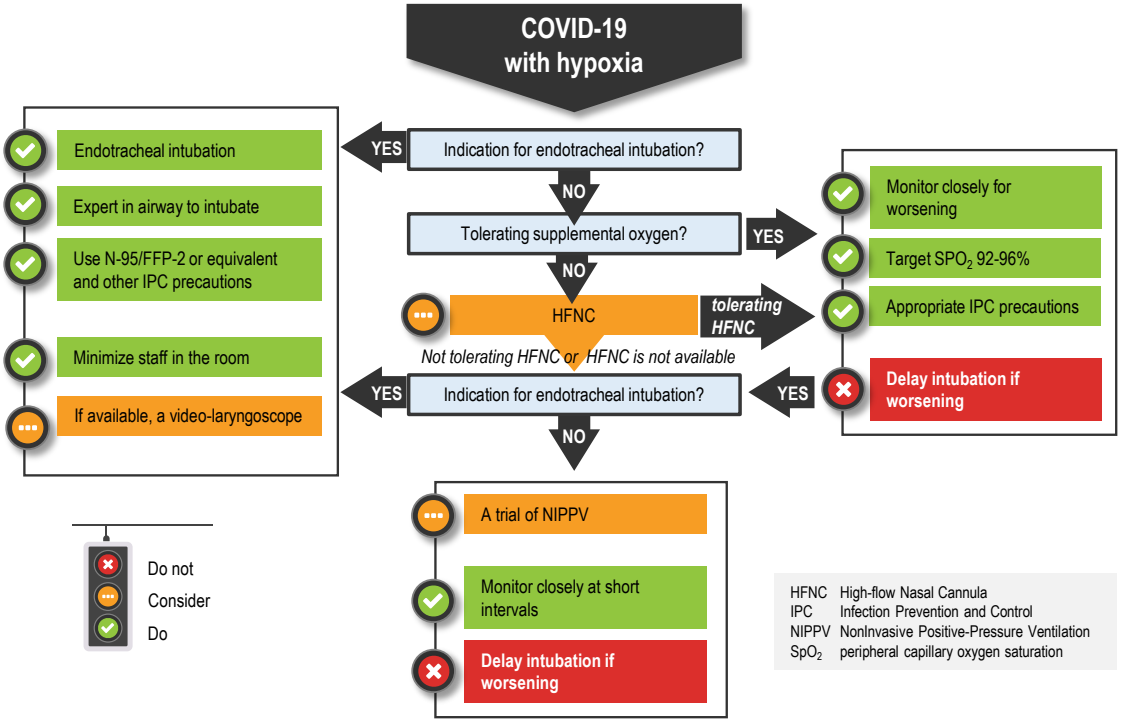

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Figure 8. A technical-therapeutical algorithm for the clinical management of hypoxemic COVID-19 patients

Many patients were treated initially or throughout the course of the disease using a CPAP helmet or Pressure Support dispensing system in non-invasive ventilation (105, 106), in some cases achieving good results by placing the sick with the CPAP helmet (107) in prone position.

Those who, despite these aids, did not improve their oxygenation (as determined by the Ratio PaO_2/FiO_2) were then intubated and treated invasively as described. The ventilator treatments therefore adhered to the existing recommendations and guidelines, to those published by the WHO on 13th of March 2020 in the document entitled "Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected" and updated in the version published on 27th of May 2020 (108,109).

These recommendations were applied in the treatment of patients with ARDS from COVID-19 during a pandemic, as they were in the pre-COVID-19 era for other forms of ARDS.

The sample of the first 1,500 patients treated in ICU in the Lombardy region shows that these criteria have been met (88-90% of invasively ventilated patients with endotracheal intubation, 12% with non-invasive ventilation or high-flow oxygen therapy, 30% with the use of pronation and about 1-2% in ECMO) (110).

The use of non-invasive ventilation, in the various frameworks of respiratory failure, even outside of ICU has translated into mortality rates in line with the data reported in the literature (21% for mild forms, 28% in moderate forms and 40% in severe forms (111, 112).

In support of multi-organ function deficits, the recommendations currently applied under these conditions are and were followed even before the pandemic, using dialysis or circulatory support with vasoactive and inotropic drugs (104, 113).

Initiatives to strengthen preparation for the autumn-winter season

If there is a significant increase in the number of cases again in the autumn-winter months, the demand for ordinary or ICU hospital care by patients for severe clinical conditions and/or acute respiratory failure may once again increase. This would add to the usual access to hospital services in a season when other respiratory pathogens such as influenza viruses are expected to co-circulate for a period that can extend over time.

The health planning elements described in Pillar 1 are aimed specifically at modulating the hospital offer in Italy. The Infection Prevention and Control activities described in Pillar 6 are also aimed at reducing the risk of infection of healthcare professionals and preventing the onset of care-related infections.

In order to optimize the management of patients in ICU, an increase in the number of grants for specialization schools in anaesthesiology and resuscitation was also decided for the current academic year, with increases ranging from 30 to 50%, compared to the previous year.

Finally, the concerted action of the European Society of Intensive Care (ESICM) and the EU under the European Community C 19 SPACE program is of interest for training healthcare professionals who do not normally work in intensive care, in order to offer ICU support during the SARS-CoV-2 pandemic. The aim of the program is to increase the skills and number of healthcare professionals who can be engaged in basic intensive care if there is again a need for a new rapid, temporary increase in intensive care capacity (https://www.esicm.org/european-commission-c19-space-information-webinar/)

Table A7 in Appendix shows the body of national standards, circulars, ordinances and instruments produced in the field of clinical case management aimed at addressing the SARS-CoV-2 pandemic and in force for the autumn-winter 2020 season, organized by topic.

Pillar 8. Operational support and logistics

Implementation of the plan to strengthen hospital wards on the national territory provided for by the “Rilancio” Decree

In the “Rilancio” Decree, the intensive care and sub-intensive care facilities are planned to be upgraded, with an increase of 5,612 beds for the former (3,500 permanent and 2,112 sub-intensive care beds that can be converted, in an emergency, in intensive care beds) and 4,225 for the second.

There are two types of interventions for the implementation of the upgrade:

- Infrastructure interventions for the adaptation of hospitals
- Procurement of the equipment necessary to equip the bed units.

The “Rilancio” Decree identifies the Commissioner as the actuator of the Plans, once the following requirements have been met: drafting the plans by the Regions, approval by the Ministry of Health and registration by the Court of Auditors.

The approval process for the Regional Plans ended with the registration of them by the Court of Auditors, which ended on 28 July 2020.

It was only after that date that the Commissioner was able to start the work aimed at implementing the planned upgrades, including, if necessary, using the possibility provided by Article 2 to delegate this activity to the individual Regional Presidents.

The Commissioner, meanwhile, has initiated the procedures for acquiring materials and carrying out the necessary work. The procedures apply throughout the country and ensure efficiency and transparency to the process:

- ***Procedures for carrying out infrastructural interventions to upgrade hospitals***
  - Procedures are envisaged that allow construction interventions through the use of framework agreements stipulated by the Commissioner or through public award procedures activated by the Regions, in the event of delegation of the Commissioner’s powers;
  - Mobile facilities: 4 mobile facilities will be hired, each with 75 intensive care beds, to be activated in case of need.
- ***Supply of equipment necessary for the preparation of beds in Intensive and Sub-Intensive Care Units***
  - Definition of framework agreements with suppliers by September, considering that the provision of equipment will be necessary when the infrastructure interventions in the hospitals are completed.
  - On the basis of the framework agreements, the equipment will be acquired directly from the implementing bodies.
  - Verification with Regions and Autonomous Provinces completed, for the precise identification of the necessary equipment in the individual hospitals. The Regions have sent their needs.

In general, it should be noted that:

- At the start of the emergency, 5,179 intensive care beds were active in Italy. The decree sets the goal of increasing them by 5,612 units (3,500 stable beds and 2,112 sub-intensive care beds that can be transformed, in an emergency, into intensive care beds). During the emergency, the Commissioner distributed 3,125 intensive care ventilators and has availability for an additional 1,354 ventilators.
- To date, 15,755 beds in sub-intensive care are active (+ 9,230 compared to the start of the emergency). The objective of the decree is to make 4,225 beds stable among those already built. Therefore, no further ventilators are required than those already supplied.

Procurement of tests, swabs and personal protective equipment

The Structure of the Commissioner provides daily free of charge Medical Devices (MDs), PPE and the remaining material, whose requirements are communicated twice a week by the administrations.

Since the beginning of the emergency, Regions/APs have received over **900.4 million products** including PPE, MDs and electromedical equipment – a curve that is constantly increasing. Stocks that are available as tracked by the above mentioned system in the regional warehouses, suggest that at the moment availability is higher than current requirements also considering distributions to citizens.

All data on the distribution of devices and equipment for the containment and contrast of the epidemic can be accessed on the system "Aid Distribution Analysis" (ADA), on the websites of the Presidency of the Council, the Ministry of Health and Civil Protection. The data is updated daily.

The quantities and types of products distributed over time take into account the epidemiological trend and product stocks in regional warehouses. Every day, the Structure of the Commissioner notifies the Administrations of the imminent arrival of products and the Regions, and then in the following 24 / 48h, it checks the actual quantities that have arrived and the availability. This allows a transparent and updated real-time mapping of devices and equipment dedicated to the fight against Coronavirus, that are distributed every day to Regions/APs in order to deal with the emergency. This system can be consulted as mentioned on the ADA system.

Molecular tests and swabs

The Structure of the Commissioner has initiated an additional supply of molecular tests. More than 9 million stand-alone kits and reagents were distributed to the Regions, as well as 44 machines to process these tests. This supply has allowed the Regions to potentially increase their capacity to administer swabs (about 60,000 per day) and to be able to carry out, until the 31st of December 2020, more than 106,000 molecular tests per day.

Rapid antigen testing

The Extraordinary Commissioner has published a public bid request for the provision of 5 million rapid tests for the qualitative detection of SARS-CoV-2-specific antigens on nasopharyngeal or saliva swabs.

The request was published on the institutional websites of the Presidency of the Council of Ministers - Special Commissioner for Emergency COVID-19 - and the Ministry of Health.

The tests will be transported throughout the country with suitable vehicles and, in addition, there is the availability to provide on loan for free use, if necessary, a sufficient number of vehicles, at the distribution sites indicated by the Extraordinary Commissioner, for the administration of the tests once they are delivered.

The demand for a supply of rapid testing is an important step in further intensifying the prevention activities already put in place by the Government to contrast the epidemic. The aim is to meet the needs associated with international movements of passengers from higher-incidence areas and the needs arising from the reopening of schools, especially at a time such as the autumn period, of ascertained, increased circulation of all respiratory viruses.

Lastly, the Structure of the Commissioner, due to the extreme necessity and urgency of carrying out rapid tests for the SARS-CoV-2 antigen, in order to contain the risk due to entry into the country of subjects from the States indicated in the ordinance of the Minister of Health of the 12th of August 2020, on the recommendation of the Ministry of Health, proceeded with the purchase of 255,000 tests intended for airports and ports.

Serological tests

Following a tender, the Structure of the Commissioner acquired 2 million rapid serological kits to be used for the preventive screening campaign on teaching and non-teaching staff, to be carried out before schools start. The kits have already been distributed to the Regions which are currently administering them.

Face masks

To date, the Structure of the Commissioner has a stock of about 746 million masks.

These stocks must be added on the one hand to the national production, which is progressively making an additional 30 million face masks available per day, and on the other hand to the number of masks

currently in stock in the Regions, amounting to about 150 million. Considering a total daily requirement of about 16.5 million, the availability of the Structure of the Commissioner (until the 31st of December 2020) would allow to meet the requirements until August 2021.

Other devices

To date, a number of other devices are available and contracted, such as 32 million shirts and overalls, 905 million gloves, 8 million glasses and visors and 21 million litres of sanitizing gel. This sum of devices can ensure the supply for at least the remaining part of the year, if not, until the first quarter of 2021.

Initiatives to combat drug shortages

In the first phase of the pandemic, AIFA had set up an operational network with the representatives of the Regions and associations of pharmaceutical companies (Assogenerici and Farmindustria), to ensure the real-time supply of critical products to hospitals (resuscitation drugs, antivirals) and to provide logistical support with respect to all specific issues related to drugs (for example, oxygen production, territorial distribution of products subject to donation or seizure).

The main initiatives implemented are:

- establishment of a single point of contact for business continuity;
- operational simplifications to create coordinated public-private actions with evident results in terms of speed of response to requests from the Regions;
- streamlining of the methods of importing medicines from non-EU countries;
- management of the distribution of drugs to support Civil Protection and the government Structure of the Commissioner;
- preparation, in agreement with industrial associations, of the collection of drug needs related to the COVID-19 emergency, through the “community of experts” of the Regions.

The AIFA/Regions/Companies operational network, which had avoided stock ruptures during the March-April crisis, has been kept active, and is currently collecting data on expected medicinal requirements and on already established stocks, to optimize the distribution of critical drugs to local structures.

Table A8 in the Appendix includes the body of national standards, circulars, ordinances and instruments produced in operational and logistical support aimed at addressing the SARS-CoV-2 pandemic and in force for the autumn-winter 2020 season, organized by topic.

Chapter 5

Approach to adjust containment / mitigation measures at the Regional/AP level in the context of hypothetical national SARS-CoV-2 virus transmission scenarios in the autumn-winter period

According to the DPCM No.126 of 17-05-2020, Regions and APs are given the authority to define how and when various activities should be re-started during the post-lockdown reopening period:

> "provided that they have previously ascertained that these activities are compatible with the evolution of the epidemiological situation in their territories and that they identify the protocols or guidelines that apply to prevent or reduce the risk of contagion in accordance with the principles contained in the national protocols or guidelines." (114).

In order to support the assessment of the regional epidemiological situation, the Ministry of Health in collaboration with the ISS established a system to monitor risk and resilience of health services on a weekly basis. The monitoring of the situation is shared with the Regions/APs, and evaluated by a committee called in Italian "Cabina di Regia" (i.e. a direction cabin) consisting of experts from the Ministry of Health, the ISS and representatives of the Regions/AP (29).

This section proposes a common approach to the escalation/de-escalation of measures on the basis of different transmission scenarios described in the document, hypothesized at national level, keeping in mind that very different epidemiological conditions can occur in each Region/AP that require specific and non-uniform control/mitigation measures across the country.

The interventions described for each scenario aim to support and direct decision-making process in each Region and AP on the basis of its specific epidemiological scenario. Consistently with their orientation-aimed function, **they are not considered binding**.

For each national scenario, this section proposes measures that can be escalated/de-escalated according to a likely level of **risk that could be identified during the weekly classification** of each Region/AP based on the monitoring system that is defined in the Decree of the Minister Health issued on the 30th of April 2020 (e.g., very low risk levels are not considered likely in critical transmission scenarios such as the scenario 4).

The proposed adjustment, both in a restrictive and in a permissive sense (escalation and de-escalation), is consistent with the content of Annex 10 (28) "Principles for monitoring health risk" of the DPCM issued on the 26th of April 2020 "Further implementing provisions of the Decree-Law of 23 February 2020, n. 6, containing urgent measures regarding the containment and management of the epidemiological emergency from COVID-19, applicable throughout the national territory" (Figure 9) and is now defined in more detail on the basis of the transmission scenarios described in this document.

For the escalation and de-escalation of the measures, temporal criteria account for a delay of at least 3 weeks in observing epidemiological changes in the surveillance data due to the incubation period and the timing of notification/data transmission. Further delays were considered in scenarios with higher transmission to account for increase in reporting delay adequate levels of timeliness and completeness of the surveillance data cannot be maintained.

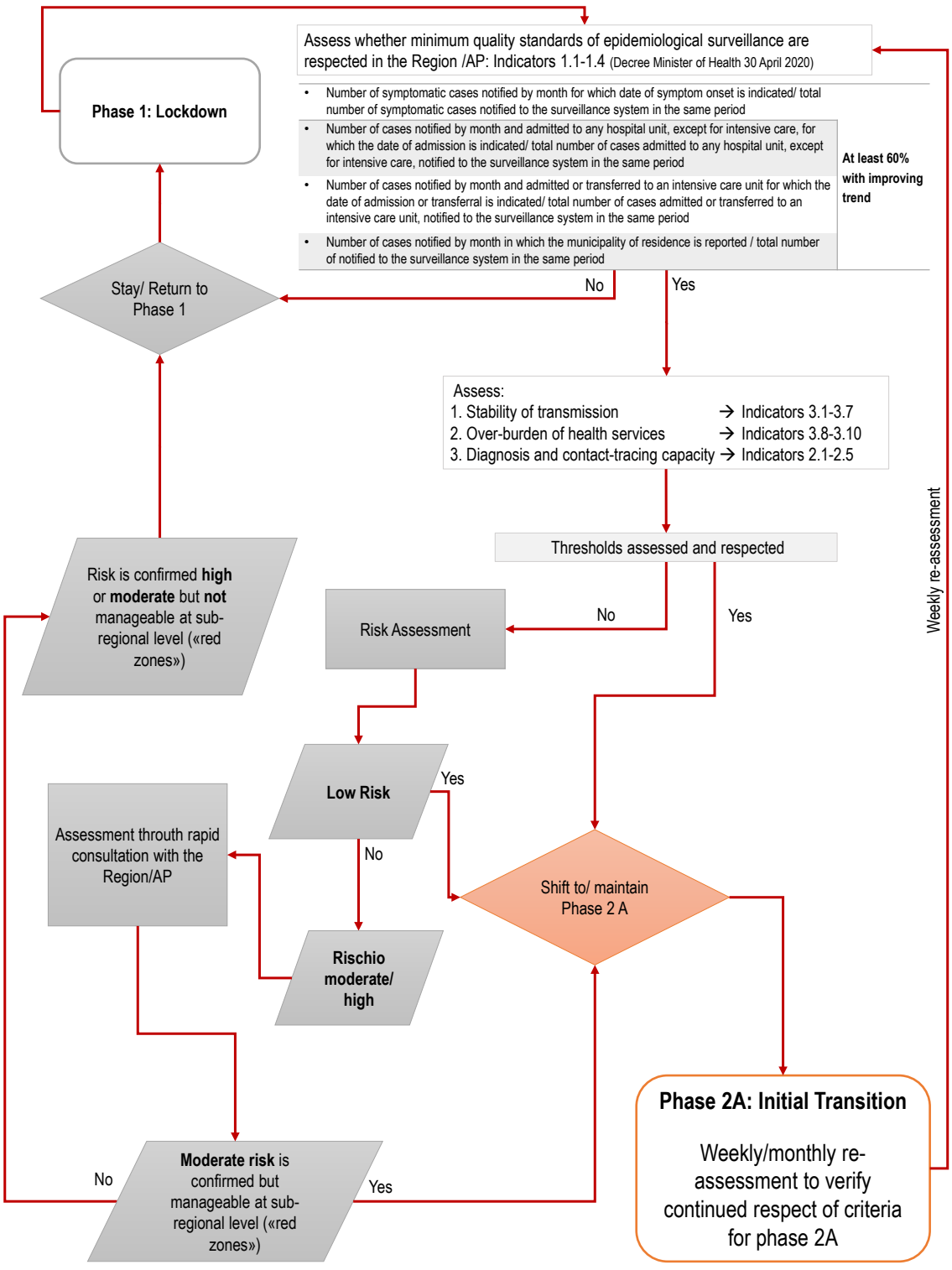

Figure 9. Principles for health risk monitoring.
Translated from Annex 10 of the DPCM n.108 27-04-2020 (28), the indicators here mentioned are described in detail in the Decree of the Minister of Health issued 30-04-2020 (29)

SCENARIO 1. Situation of localized transmission (clusters) largely similar to what was observed in the period July-August 2020

Description of scenario 1

Regional Rt above threshold for limited periods (less than 1 month) and low incidence, with transmission predominantly associated with already identified outbreaks, schools have a modest impact on transmissibility and regional health systems are able to track and monitor new outbreaks, including school ones.

In a national scenario of this kind, it is likely that many Regions/AP are classified as low or moderate risk, although high risk situations are possible, perhaps at the sub-regional level.

1. Weekly risk classification: VERY LOW/LOW

Action: de-escalation of activities towards less stringent measures or maintenance

Intervention: ordinary, such as

- Isolation of cases
- Quarantine of contacts
- Standard precautions (PPE, physical distancing, individual/environmental hygiene) defined by the competent institutions (CTS, Ministries, ISS, INAIL etc.).

2. Weekly risk classification: MODERATE

Action: consider escalation of activities towards more stringent measures or maintenance

Assess risk in the Region/AP to define sub-regional higher risk situations (circulation in provinces/municipalities; school clusters)

Intervention: ordinary + extra-ordinary interventions in institutions (e.g., schools) or limited geographical areas

- Increased control of the actual implementation of the measures already adopted on the territory (see minimum criteria)
- Scaled-up precautions where indicated in the documents produced for specific areas and contexts (e.g., schools) only in areas with greater risk of exposure
- Possible closure of activities, suspension of events and limitation of population mobility in sub-regional geographical areas (municipalities/provinces)

Figure 10 shows a flow chart for the re-modulation of measures based on the weekly classification of risk in a Region/AP.

Table 4 shows the same re-modulation with greater detail focussed on territorial measures at regional level and considers the difference in expected incidence of flu-like syndromes - ILI (Influenza-Like Illnesses) that will impact health services at the same time. The table indicates the actors involved, where **N:** National (Central) Level; **R**: Regional Level; **L**: Local Level.

SCENARIO 1
Localized transmission (clusters) largely similar to what was observed in the period July- August 2020

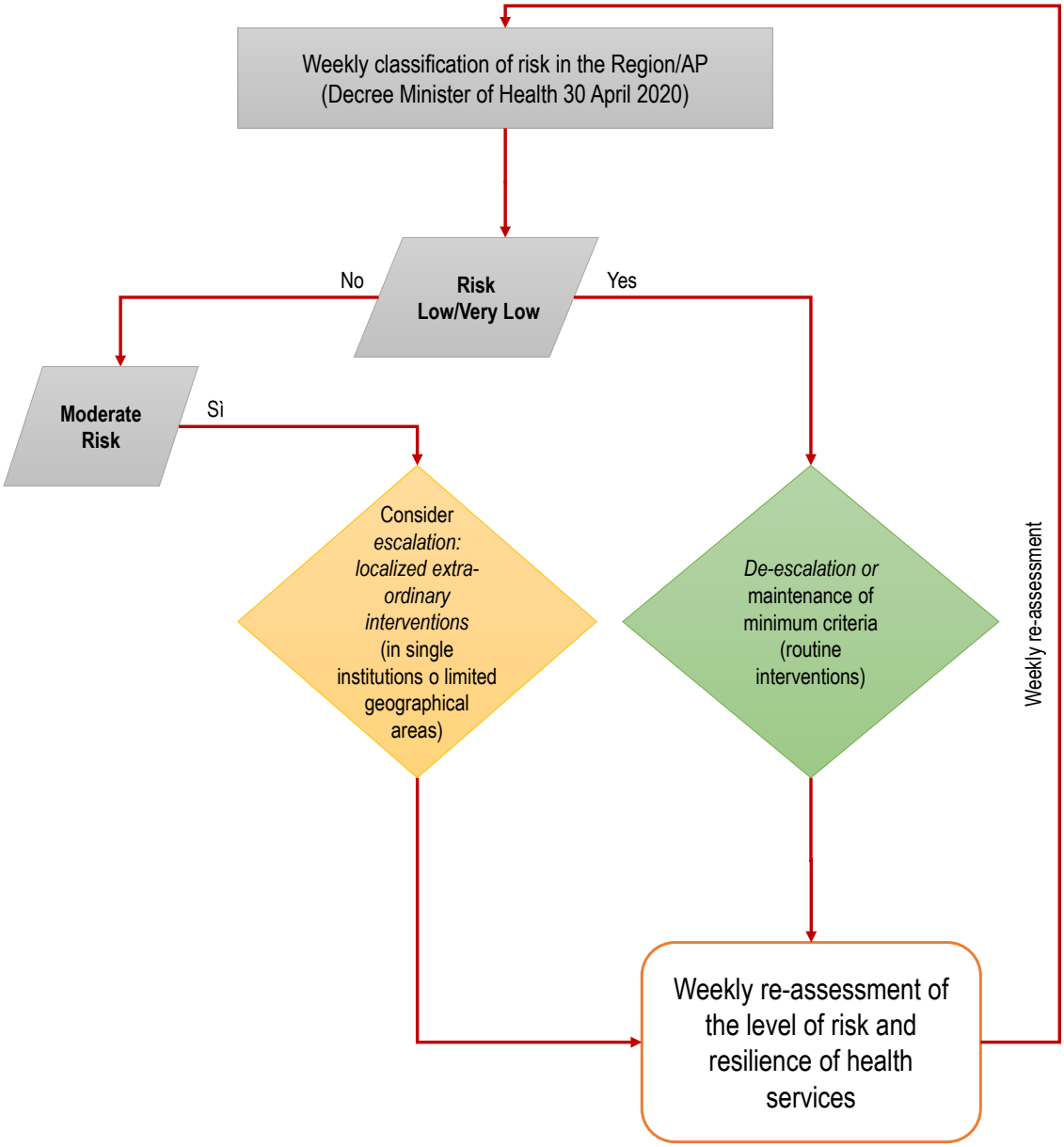

Figure 10. Adjustment of measures (escalation/de-escalation) based on the weekly risk classification in a Region/AP in a national localized transmission context (scenario 1)

Table 4. SCENARIO 1: situation of localized transmission (clusters) largely similar to what was observed in the period July-August 2020

Weekly risk classification in the Region/AP	
LOW/VERY LOW	**MODERATE**
SARS-CoV-2 transmission is limited to clusters with known transmission chains	**Increasing number of SARS-CoV-2 infections, local transmission (not imported), not all transmission chains are known**
OBJECTIVE: *containment and control of clusters* ***Intervention:*** *minimum criteria (routine interventions)*	***OBJECTIVE:*** *containment and control of clusters* ***Intervention:*** *ordinary + extra-ordinary interventions in institutions (e.g., schools) or limited geographical areas*
SEPT. - OCT. 2020 (expected ILI incidence LOW)	
Testing and management of suspected, confirmed cases and contacts	
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts ▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ possible simplification of active surveillance [**N, R, L**] ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks [**R, L**] ▪ activation of rapid training paths of additional staff to support Public Health - PH services (Dipartimenti di Prevenzione, DdP) **[R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened [**R, L**]
Community	
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure **[N, R]**	▪ social distancing is strengthened [**R, L**] ▪ local red zones **[R, L]** ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) **[R, L]** ▪ home-based work is encouraged to reduce public transport and workplace crowding **[N, R]**
School/Universities	
▪ face to face lessons ▪ required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people ▪ limit activities that cause mixing of different classes and groups	▪ possibility of introducing the obligation, also on a local basis, to wear face masks also in static situations including when a minimum distance of 1 meter between people is present [**L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L]** ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L]** ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**]
NOV. - DEC. 2020 (expected ILI incidence MODERATE)	
Testing and management of suspected, confirmed cases and contacts	
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts ▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activat**ion of** additional staff to support COVID-related tasks [**R, L**] ▪ activation of rapid training paths of additional staff to support PH services (Dipartimenti di Prevenzione, DdP) **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened [R, L] ▪ activation of hotels as isolation premises [**R, L**]
Community	
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure [**R, L**] ▪ possible interruption, on a local basis, of social/cultural activities/events at greater risk of generating in-person gatherings **[N, R]**	▪ social distancing is strengthened [**R, L**] ▪ local red zones **[R, L]** ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) **[R, L]** ▪ home-based work is encouraged to reduce public transport and workplace crowding **[N, R]** ▪ possible limitation of population mobility in sub-regional geographic areas [**R, L**]
Schools/Universities	
▪ face to face lessons ▪ required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people ▪ limit activities that cause mixing of different classes and groups	▪ possibility of introducing the obligation, also on a local basis, to wear face masks also in static situations including when a minimum distance of 1 meter between people is present [**L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L]** ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L]** ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**]

Weekly risk classification in the Region/AP	
LOW/VERY LOW	**MODERATE**
JAN. - MAR. 2021 (Expected ILI incidence MODERATE/HIGH)	
Testing and management of suspected, confirmed cases and contacts	
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts ▪ activation of additional staff to support COVID-related tasks **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ simplification of contact tracing [**N, R, L**] ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks [**R, L**] ▪ activation of rapid training paths of additional staff to support PH services (Dipartimenti di Prevenzione, DdP) **[R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened [R, L] ▪ activation of hotels as isolation premises [**R, L**]
Community	
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure [**R, L**] ▪ possible interruption, on a local basis, of social/cultural activities/events at greater risk of generating in-person gatherings [**N, R**]	▪ social distancing is strengthened [**R, L**] ▪ local red zones [**R, L**] ▪ consider introducing the obligation to wear face masks to protect airways also out-doors (e.g., on a time or place basis) [**N, R, L**] ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) **[R, L**] ▪ home-based work is encouraged to reduce public transport and workplace crowding [**N, R**] ▪ possible limitation of population mobility in sub-regional geographic areas [**R, L**]
Schools/Universities	
▪ face to face lessons ▪ required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people ▪ limit activities that cause mixing of different classes and groups ▪ possibility of introducing the obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present **[R, L]** ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) **[R, L]**	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present on a local [**L**] or regional [**R**] basis ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L]** ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ consider with higher priority the possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L]** ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**]

SCENARIO 2. Situation of sustained and widespread transmission manageable by the health system in the short/medium-term

Description of scenario 2

Prevalent regional Rt values between Rt = 1 and Rt = 1.25 (with estimates of the 95%CI of Rt between 1 and 1.25). It is not possible to fully track new clusters, including school ones, but it is still possible to greatly limit the transmission potential of SARS-CoV-2 with ordinary and extra-ordinary containment/mitigation measures. An epidemic with these characteristics of transmissibility could be characterized by a constant increase in the incidence of cases (at least symptomatic ones as it is possible that a reduction in the percentage of asymptomatic cases is observed inability to conduct an epidemiological investigation on all cases) and corresponding hospitalizations and admissions to intensive care units. **However, the growth in the number of cases could be relatively slow, without significantly overloading healthcare services for at least 2-4 months.**

In a national scenario of this kind, it is likely that many regions/AP are classified as at risk from moderate to high, although low-risk situations are possible, at least if transmissibility in areas with sustained transmission were to be restricted in a short period, thus limiting cross-regional transmission.

1. Weekly risk classification: LOW/VERY LOW for at least 3 consecutive weeks following a higher risk assessment

Action: de-escalation of activities towards less stringent measures or maintenance

Intervention: ordinary, such as

- Isolation of cases
- Quarantine of contacts
- Standard precautions (PPE, physical distancing, individual/environmental hygiene) defined by the competent institutions (CTS, Ministries, ISS, INAIL, etc.).

2. Weekly risk classification: MODERATE

Action: consider escalation of activities towards more stringent measures or maintenance

Assess risk in the Region/AP to define sub-regional higher risk situations (circulation in provinces/municipalities; school clusters)

Intervention: ordinary + extra-ordinary interventions in institutions (e.g., schools) or limited geographical areas

- Increased control of the actual implementation of the measures already adopted on the territory (see minimum criteria)
- Scaled-up precautions where indicated in the documents produced for specific areas and contexts (e.g., schools) only in areas with greater risk of exposure
- Possible closure of activities, suspension of events and limitation of population mobility in sub-regional geographical areas (municipalities/provinces)

3. Weekly risk classification: HIGH/VERY HIGH for less than 3 consecutive weeks

Action: consider escalation of activities towards more stringent measures

Intervention: extra-ordinary extended (temporary local restrictions on a sub-provincial scale)

- Physical distance: e.g., closing night clubs, bars, restaurants (initially potentially only at specific times - for example in the evening/night in order to avoid "movida" activities)
- School/university closures (incremental: class, campus, on a geographical basis based on the epidemiological situation)
- Mobility restrictions (from/to high transmission areas and possible restoration of home-based work in specific areas).
- Temporary local restrictions on a sub-provincial scale (red zones) for at least 3 weeks with careful monitoring during the reopening phase. If a relatively low incidence is not maintained and Rt <1.2 in the mean value for at least 3 weeks after reopening, assess the need for restoration of restrictions with possible geographical extension.

Should a classification of high/very high risk persist for over 3 consecutive weeks in a context not manageable with the extra-ordinary measures already in place, assess the response options in sub-sequent scenarios.

Figure 11 shows a flow chart for the re-modulation of measures based on the weekly classification of risk in a Region/AP.

Table 5 shows the same re-modulation with a declination from territorial measures at the regional level and considers the difference in expected incidence of flu-like syndromes - ILI (Influenza-Like Illnesses) that will impact health services at the same time. The table indicates the actors involved, where **N**: National (Central) Level; **R**: Regional Level; **L:** Local Level.

SCENARIO 2
Sustained and widespread transmission manageable by the health system in the short/medium-term

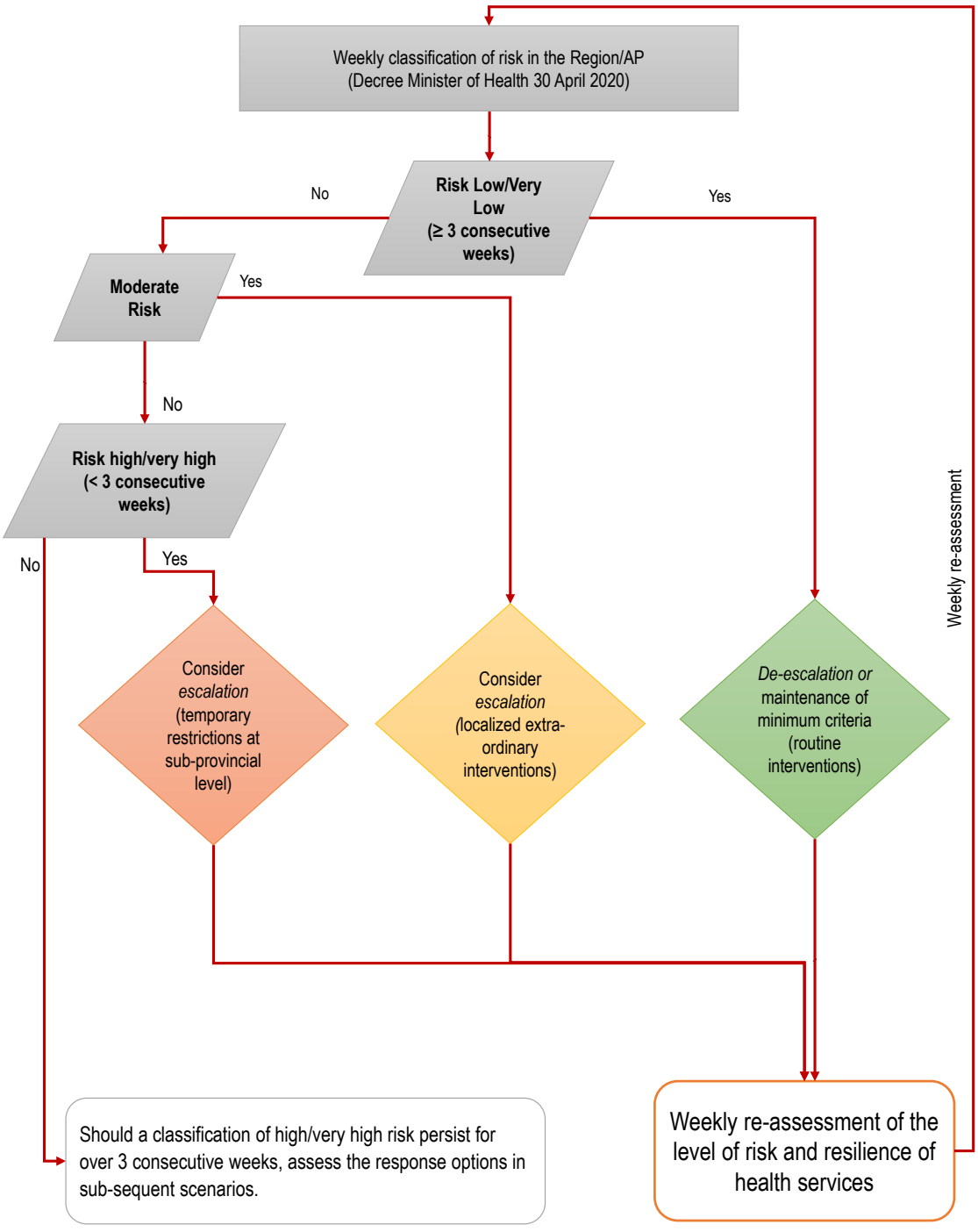

Figure 11. Adjustment of measures (escalation/de-escalation) based on the weekly risk classification in a Region/AP in a national context of sustained and widespread transmission manageable by the health system in the short-medium term (scenario 2)

Table 5. SCENARIO 2: situation of sustained and widespread transmission manageable by the health system in the short/medium-term

Weekly risk classification in the Region/AP		
LOW/VERY LOW for at least 3 consecutive weeks from a higher risk assessment	**MODERATE**	**HIGH/VERY HIGH (for less than 3 consecutive weeks)**
SARS-CoV-2 transmission is limited to clusters with known transmission chains	**Increasing number of SARS-CoV-2 infections, local transmission (not imported), not all transmission chains are known**	**Clusters no longer distinct from each other, new cases unrelated to known transmission chains, gradual increase in pressure for Prevention Departments**
OBJECTIVE: *containment and control of clusters* ***Intervention:*** *minimum* ***criteria (routine interventions)***	***OBJECTIVE:*** *containment and control of clusters* ***Intervention:*** *Ordinary + Extra-ordinary interventions in institutions (e.g., schools) or limited geographical areas*	***OBJECTIVE:*** *Mitigation of viral spread* ***Intervention:*** *extra-ordinary extended (temporary local restrictions on a sub-provincial scale)*
SEPT - OCT. 2020 (expected ILI incidence LOW)		
Testing and management of suspected, confirmed cases and contacts		
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts ▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ possible simplification of active surveillance [**N, R, L**] ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks [**R, L**] ▪ activation of rapid training paths of additional staff to support Public Health - PH services (Dipartimenti di Prevenzione, DdP) **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened [R, L]	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities [**R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g., healthcare workers) [R, L] ▪ hotels to be used as isolation premises are strengthened [**R, L**]
Community		
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure **[N, R]**	▪ social distancing is strengthened [**R, L**] ▪ local red zones **[R, L]** ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) **[R, L]** ▪ home-based work is encouraged to reduce public transport and workplace crowding **[N, R]**	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ possibility of introducing the obligation, also on a local basis, to wear face masks outdoors [**L**] ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities [**N, R, L**] ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**
School/University		
▪ face to face lessons ▪ required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people ▪ limit activities that cause mixing of different classes and groups	▪ possibility of introducing the obligation, also on a local basis, to wear face masks also in static situations including when a minimum distance of 1 meter between people is present [**L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**]	▪ obligation to wear a face mask (> 6 years) also in static situations including when a minimum distance of 1 meter between people is present **[R, L]** ▪ suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the local (e.g., a single educational structure [**R, L**] or more structures in an area) [R, L]
NOV. - DEC. 2020 (expected ILI incidence - MODERATE)		
Testing and management of suspected, confirmed cases and contacts		
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) [**R, L**]

Weekly risk classification in the Region/AP		
LOW/VERY LOW for at least 3 consecutive weeks from a higher risk assessment	**MODERATE**	**HIGH/VERY HIGH (for less than 3 consecutive weeks)**
▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ activation of additional staff to support COVID-related tasks [**R, L**] ▪ activation of rapid training paths of additional staff to support PH services (Dipartimenti di Prevenzione, DdP) **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened [R, L] ▪ activation of hotels as isolation premises [**R, L**]	▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g., healthcare workers) [**R, L**] ▪ hotels to be used as isolation premises are strengthened [**R, L**]
Community		
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure [**R, L**] ▪ possible interruption, on a local basis, of social/cultural activities/events at greater risk of generating in-person gatherings **[N, R]**	▪ social distancing is strengthened [**R, L**] ▪ local red zones **[R, L]** ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) **[R, L]** ▪ home-based work is encouraged to reduce public transport and workplace crowding **[N, R]** ▪ possible limitation of population mobility in sub-regional geographic areas [**R, L**]	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ consider introducing the obligation to wear face masks to protect airways also out-doors (e.g., on a time or place basis) [**N, R, L**] ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities [**N, R, L**] ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**
School/Universities		
▪ face to face lessons ▪ required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people ▪ limit activities that cause mixing of different classes and groups	▪ possibility of introducing the obligation, also on a local basis, to wear face masks also in static situations including when a minimum distance of 1 meter between people is present [**L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**]	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present [**L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ reduce the number of face to face class hours integrating distance learning for students of all school levels, in particular for middle-high school and university students [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**] ▪ consider temporary closures (2-3 weeks) of schools/universities with a scale and duration to be defined on the basis of the epidemiological situation activating distance learning where possible **[N, R]**
JAN. - MAR. 2021 (expected ILI incidence – MODERATE/HIGH)		
Testing and management of suspected, confirmed cases and contacts		
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts ▪ activation of additional staff to support COVID-related tasks **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ simplification of contact tracing [**N, R, L**] ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks [**R, L**] ▪ activation of rapid training paths of additional staff to support PH services (Dipartimenti di Prevenzione, DdP) **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened [**R, L**] ▪ activation of hotels as isolation premises [**R, L**]	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities [**R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ consider possible additional re-modulation of SARS-CoV-2 screening activities prioritizing target categories [R, L] ▪ hotels to be used as isolation premises are strengthened [**R, L**]

Weekly risk classification in the Region/AP		
LOW/VERY LOW for at least 3 consecutive weeks from a higher risk assessment	**MODERATE**	**HIGH/VERY HIGH (for less than 3 consecutive weeks)**
Community		
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure [**R, L**] ▪ possible interruption, on a local basis, of social/cultural activities/events at greater risk of generating in-person gatherings [**N, R**]	▪ social distancing is strengthened [**R, L**] ▪ local red zones [**R, L**] ▪ consider introducing the obligation to wear face masks to protect airways also out-doors (e.g., on a time or place basis) [**N, R, L**] ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) **[R, L]** ▪ home-based work is encouraged to reduce public transport and workplace crowding [**N, R**] ▪ possible limitation of population mobility in sub-regional geographic areas [**R, L**]	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ obligation to wear face masks to protect airways also out-doors is introduced [**N, R, L]** ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities [**N, R, L**] ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**
Scuole/Università		
▪ face to face lessons ▪ required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people ▪ limit activities that cause mixing of different classes and groups ▪ possibility of introducing the obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present **[R, L]** ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) **[R, L]**	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present on a local [**L**] or regional [**R**] basis ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L]** ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ consider with higher priority the possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L]** ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**]	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present on a local[**L**] or regional [**R**] basis ▪ alternate lessons wherever possible, with morning and afternoon rotations [**R, L**] ▪ suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ reduce the number of face to face class hours integrating distance learning for students of all school levels, in particular for middle-high school and university students [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**] ▪ consider temporary closures (2-3 weeks) of schools/universities with a scale and duration to be defined on the basis of the epidemiological situation activating distance learning where possible **[N, R]**

SCENARIO 3. Situation of sustained and widespread transmission with risks in the ability of the health system to cope in the medium-term

Description of scenario 3

Prevalent regional Rt values are between Rt = 1.25 and Rt = 1.5 (with estimates of the 95%CI of Rt between 1.25 and 1.5), and transmission potential can only modestly be limited with ordinary and extraordinary containment/mitigation measures. An epidemic at this level should be characterized by a faster increase in positive cases than scenario 2, failure to track transmission chains, and initial signs of overload of healthcare services due to the increase in critically severe cases (with increased occupancy rates of hospital beds – medical area and intensive care). This is expected to correspond to a high or very high level of risk according to the monitoring system defined in the decree of the Minister of Health issued on 30 April 2020. The increase in the number of cases could lead to an overload of healthcare services within 2-3 months. However, it is important to note that if the epidemic were to spread predominantly among younger age groups, as observed in the July-August 2020 period, with the most fragile groups (e.g., the elderly) being protected, the time-frame for intervention could be considerably longer.

In a national scenario of this kind, it is likely that many Regions/APs would be classified as high risk, although lower risk situations are possible, at least if transmissibility were to be limited in areas with sustained transmission for a short time, thus limiting interregional transmission. If high-risk persists for more than three weeks, it is likely that more aggressive containment measures would be needed.

1. **Weekly risk classification: LOW/VERY LOW for at least 4 consecutive weeks, based on a reassessment of consolidated data to rule out an underestimation of risk due to a delay in the notification of surveillance data**

   Action: carefully de-escalate activities towards less stringent measures if conditionally increased or maintenance

   Intervention: ordinary, such as
   - Isolation of cases
   - Quarantine of contacts
   - Standard precautions (PPE, physical distancing, individual/environmental hygiene) defined by the competent institutions (CTS, Ministries, ISS, INAIL, etc.).

2. **Weekly risk classification: persistently MODERATE or for at least 4 consecutive weeks, based on a reassessment of consolidated data to rule out an underestimation of risk due to a delay in the notification of surveillance data**

   Action: consider escalation of activities towards more stringent measures or maintenance

   Assess risk in the Region/AP to define sub-regional higher risk situations (circulation in provinces/municipalities; school clusters)

   Intervention: ordinary + extra-ordinary interventions in institutions (e.g., schools) or limited geographical areas

   - Increased control of the actual implementation of the measures already adopted on the territory (see minimum criteria)

- Scaled-up precautions where indicated in the documents produced for specific areas and contexts (e.g., schools) only in areas with greater risk of exposure
- Possible closure of activities, suspension of events and limitation of population mobility in sub-regional geographical areas (municipalities/provinces)

3. Weekly risk classification: HIGH/VERY HIGH for less than 3 consecutive weeks

Action: consider escalation of activities towards more stringent measures

Intervention: extra-ordinary, extended (temporary local restrictions on a sub-provincial scale)

- Physical distance: e.g., closing night clubs, bars, restaurants (initially potentially only at specific times - for example in the evening/night in order to avoid "movida" activities)
- School/university closures (incremental: class, campus, on a geographical basis based on the epidemiological situation)
- Mobility restrictions (from/to high transmission areas and possible restoration of home-based work in specific areas).
- Temporary local restrictions on a sub-provincial scale (red zones) for at least 3 weeks with careful monitoring during the reopening phase. If a relatively low incidence is not maintained and Rt <1.2 in the mean value for at least 3 weeks after reopening, assess the need for restoration of restrictions with possible geographical extension.

4. Weekly risk classification: HIGH/VERY HIGH for 3 or more consecutive weeks and evidence of a situation that cannot be managed with the extraordinary measures already in place

Action: Consider regional/provincial restrictions

- Define a form of more extensive restriction on a provincial or regional scale based on the epidemiological situation
- Large-scale restoration of home-based work and limitations of individual mobility

Intervention: extra-ordinary (Table 6)

Figure 12 shows a flow chart for the re-modulation of measures based on the weekly classification of risk in a Region/AP.

Table 6 shows the same re-modulation with a declination from territorial measures at the regional level and considers the difference in expected incidence of flu-like syndromes - ILI (Influenza-Like Illnesses) that will impact health services at the same time. The table indicates the actors involved, where **N**: National (Central) Level; **R**: Regional Level; **L**: Local Level.

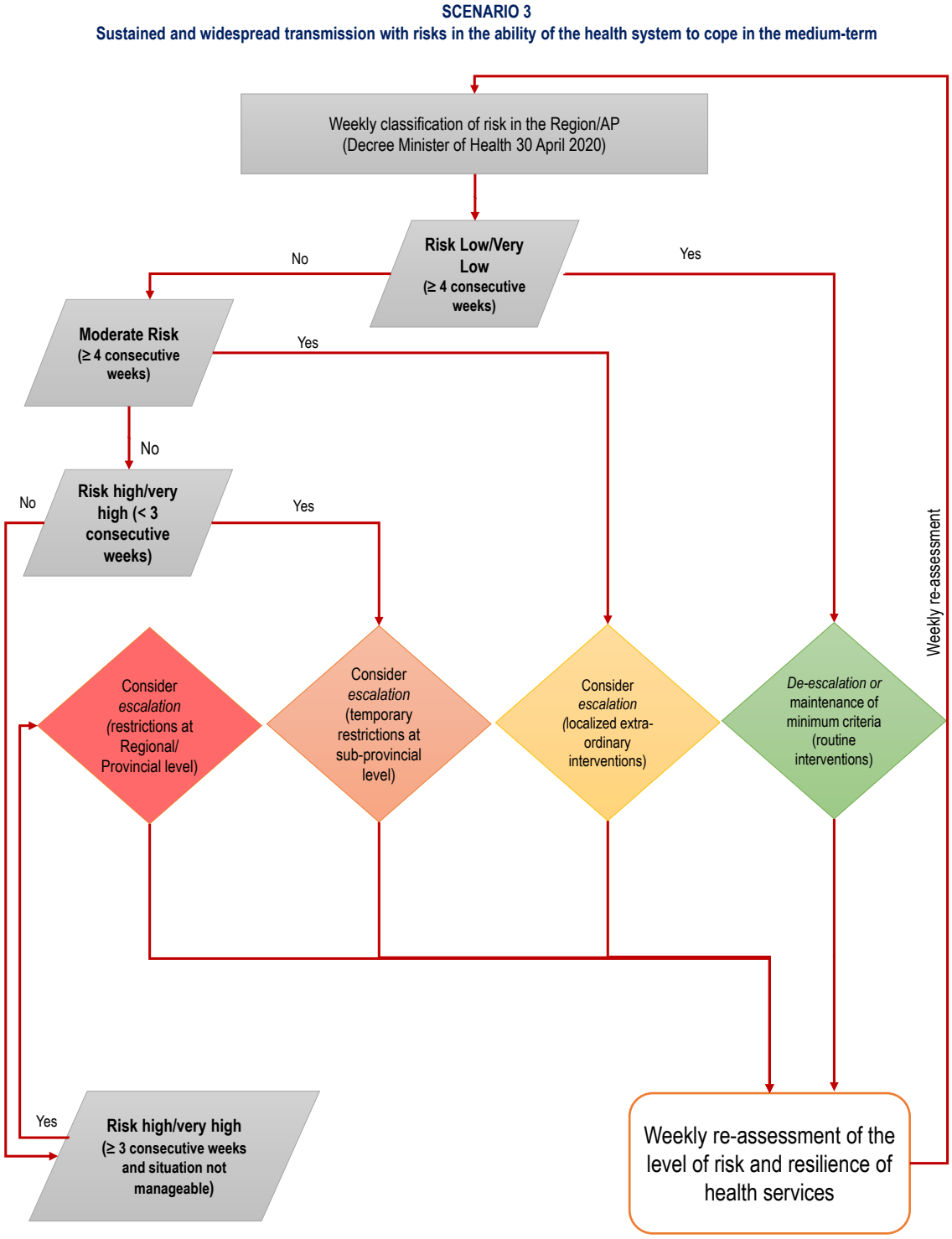

Figure 12. Adjustment of measures (escalation/de-escalation) based on the weekly risk classification in a Region/AP in a national context of sustained and widespread transmission with risks in the ability of the health system to cope in the medium-term (scenario 3)

Table 6. SCENARIO 3: situation of sustained and widespread transmission with risks in the ability of the health system to cope in the medium-term

Weekly risk classification in the Region/AP			
LOW/VERY LOW for at least 4 consecutive weeks from a higher risk assessment	**MODERATE for at least 4 consecutive weeks from a higher risk assessment**	**HIGH/VERY HIGH (for less than 3 consecutive weeks)**	**HIGH/VERY HIGH (for 3 or more consecutive weeks and situation not manageable)**
SARS-CoV-2 transmission limited to clusters with known transmission chains	**Increasing number of SARS-CoV-2 infections, local transmission (not imported), not all transmission chains known**	**Clusters no longer distinct from each other, new cases unrelated to known transmission chains, gradual increase in pressure for Prevention Departments**	**Widespread community transmission, clusters no longer distinct, new cases unrelated to known transmission chains, gradual increase in pressure for Public Health services**
OBJECTIVE: *containment and control of clusters* ***Intervention: minimum criteria (routine interventions)***	***OBJECTIVE:*** *containment and control of clusters* ***Intervention:*** *ordinary + extra-ordinary interventions in institutions (e.g., schools) or limited geographical areas*	***OBJECTIVE:*** *Mitigation of viral spread* ***Intervention:*** *extra-ordinary extended (temporary local restrictions on a sub-provincial scale)*	***OBJECTIVE:*** *Mitigation of the viral spread, reduction in case load, end widespread community transmission* ***Intervention:*** *possible regional/provincial restrictions*
SEPT. - OCT. 2020 (expected ILI incidence LOW)			
Testing and management of suspected, confirmed cases and contacts			
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts ▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ possible simplification of active surveillance [**N, R, L**] ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks [**R, L**] ▪ activation of rapid training paths of additional staff to support Public Health - PH services (Dipartimenti di Prevenzione, DdP) **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened [**R, L**]	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g., healthcare workers) [**R, L**] ▪ hotels to be used as isolation premises are strengthened [**R, L**]	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g., healthcare workers) [R, L] ▪ hotels to be used as isolation premises are strengthened [**R, L**]
Community			
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure **[N, R]**	▪ social distancing is strengthened [**R, L**] ▪ local red zones **[R, L]** ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) **[R, L]** ▪ home-based work is encouraged to reduce public transport and workplace crowding **[N, R]**	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ possibility of introducing the obligation, also on a local basis, to wear face masks outdoors [**L**] ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities [**N, R, L**] ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**	▪ general restrictions with scope and duration to be defined on the basis of the epidemiological situation; in case of localized restrictions, limitation of mobility to/from affected areas **[N]**
School/University			
▪ face to face lessons ▪ required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people limit activities that cause mixing of different classes and groups	▪ possibility of introducing the obligation, also on a local basis, to wear face masks also in static situations including when a minimum distance of 1 meter between people is present [**L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding,	▪ obligation to wear a face mask (> 6 years) also in static situations including when a minimum distance of 1 meter between people is present **[R, L]** ▪ suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible activation of distance learning for part of the classes of high	▪ closures of schools/universities the scope and duration of which are to be defined on the basis of the epidemiological situation activating distance learning where possible **[N]**

Weekly risk classification in the Region/AP			
LOW/VERY LOW for at least 4 consecutive weeks from a higher risk assessment	**MODERATE for at least 4 consecutive weeks from a higher risk assessment**	**HIGH/VERY HIGH (for less than 3 consecutive weeks)**	**HIGH/VERY HIGH (for 3 or more consecutive weeks and situation not manageable)**
	depending on viral circulation in each local context [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**]	school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the local (e.g., a single educational structure [**R, L**] or more structures in an area) [**R, L**]	
NOV. - DEC. 2020 (expected ILI incidence MODERATE)			
Testing and management of suspected, confirmed cases and contacts			
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts ▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks [**R, L**] ▪ activation of rapid training paths of additional staff to support PH services (Dipartimenti di Prevenzione, DdP) [**R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened [**R, L**] ▪ activation of hotels as isolation premises [**R, L**]	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) [**R, L**] ▪ activation of additional external staff to support PH services (DdP) and COVID related activities [**R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g., healthcare workers) [**R, L**] ▪ hotels to be used as isolation premises are strengthened [**R, L**]	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) [**R, L**] ▪ activation of additional external staff to support PH services (DdP) and COVID related activities [**R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g., healthcare workers) [R, L] ▪ hotels to be used as isolation premises are strengthened [**R, L**]
Community			
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure [**R, L**] possible interruption, on a local basis, of social/cultural activities/events at greater risk of generating in-person gatherings **[N, R]**	▪ social distancing is strengthened [**R, L**] ▪ local red zones **[R, L]** ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) **[R, L]** ▪ home-based work is encouraged to reduce public transport and workplace crowding **[N, R]** ▪ possible limitation of population mobility in sub-regional geographic areas [**R, L**]	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ consider introducing the obligation to wear face masks to protect airways also out-doors (e.g., on a time or place basis) [**N, R, L**] ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities [**N, R, L**] ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**	▪ general restrictions with scope and duration to be defined on the basis of the epidemiological situation; in case of localized restrictions, limitation of mobility to/from affected areas **[N]**
School/University			
▪ face to face lessons ▪ required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people ▪ limit activities that cause mixing of different classes and groups	▪ possibility of introducing the obligation, also on a local basis, to wear face masks also in static situations including when a minimum distance of 1 meter between people is present [**L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ possible activation of distance learning for part of the classes	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present [**L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ reduce the number of face to face class hours integrating distance learning for students of all school	▪ closures of schools/universities the scope and duration of which are to be defined on the basis of the epidemiological situation activating distance learning where possible **[N]**

Weekly risk classification in the Region/AP			
LOW/VERY LOW for at least 4 consecutive weeks from a higher risk assessment	**MODERATE for at least 4 consecutive weeks from a higher risk assessment**	**HIGH/VERY HIGH (for less than 3 consecutive weeks)**	**HIGH/VERY HIGH (for 3 or more consecutive weeks and situation not manageable)**
	of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context **[N, R, L]** ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) **[L]**	levels, in particular for middle-high school and university students **[N, R, L]** ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) **[L]** consider temporary closures (2-3 weeks) of schools/universities with a scale and duration to be defined on the basis of the epidemiological situation activating distance learning where possible **[N, R]**	
JAN. - MAR. 2021 (expected ILI incidence MODERATE/HIGH)			
Testing and management of suspected, confirmed cases and contacts			
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts ▪ activation of additional staff to support COVID-related tasks **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ simplification of contact tracing **[N, R, L]** ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks **[R, L]** ▪ activation of rapid training paths of additional staff to support PH services (Dipartimenti di Prevenzione, DdP) **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened [R, L] ▪ activation of hotels as isolation premises **[R, L]**	▪ simplification of contact tracing **[N, R, L]** ▪ simplification of active surveillance **[N, R, L]** ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ consider possible additional re-modulation of SARS-CoV-2 screening activities prioritizing target categories [R, L] ▪ hotels to be used as isolation premises are strengthened **[R, L]**	▪ simplification of contact tracing **[N, R, L]** ▪ simplification of active surveillance **[N, R, L]** ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ consider possible additional re-modulation of SARS-CoV-2 screening activities prioritizing target categories [R, L] ▪ hotels to be used as isolation premises are strengthened **[R, L]**
Community			
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure **[R, L]** ▪ possible interruption, on a local basis, of social/cultural activities/events at greater risk of generating in-person gatherings **[N, R]**	▪ social distancing is strengthened **[R, L]** ▪ local red zones **[R, L]** ▪ consider introducing the obligation to wear face masks to protect airways also out-doors (e.g., on a time or place basis) **[N, R, L]** ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) **[R, L]** ▪ home-based work is encouraged to reduce public transport and workplace crowding **[N, R]** ▪ possible limitation of population mobility in sub-regional geographic areas **[R, L]**	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ obligation to wear face masks to protect airways also out-doors is introduced **[N, R, L]** ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities **[N, R, L]** ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**	▪ general restrictions with scope and duration to be defined on the basis of the epidemiological situation; in case of localized restrictions, limitation of mobility to/from affected areas **[N]**
School/University			
• face to face lessons • required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people • limit activities that cause mixing of different classes and groups • possibility of introducing the obligation to wear face	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present on a local **[L]** or regional **[R]** basis ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available **[R, L]**	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present on a local**[L]** or regional **[R]** basis ▪ alternate lessons wherever possible, with morning and afternoon rotations **[R, L]** ▪ suspension of higher risk lessons (e.g., physical education, singing,	▪ closures of schools/universities the scope and duration of which are to be defined on the basis of the epidemiological situation activating distance learning where possible **[N]**

Weekly risk classification in the Region/AP			
LOW/VERY LOW for at least 4 consecutive weeks from a higher risk assessment	**MODERATE for at least 4 consecutive weeks from a higher risk assessment**	**HIGH/VERY HIGH (for less than 3 consecutive weeks)**	**HIGH/VERY HIGH (for 3 or more consecutive weeks and situation not manageable)**
masks also in static situations including when a minimum distance of 1 meter between people is present **[R, L]** possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) **[R, L]**	▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ consider with higher priority the possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L]** ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**]	wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ reduce the number of face to face class hours integrating distance learning for students of all school levels, in particular for middle-high school and university students [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**] ▪ consider temporary closures (2-3 weeks) of schools/universities with a scale and duration to be defined on the basis of the epidemiological situation activating distance learning where possible **[N, R]**	

SCENARIO 4. Uncontrolled transmission with short-term critical issues in the ability of the health system to cope

Description of scenario 4

Prevalent regional Rt values higher than 1.5 (with estimates of the 95%CI of Rt higher than 1.5). A scenario of this type could quickly lead to a high number of cases and clear signs of an overload of healthcare services without the possibility of tracing the origin of new cases. The increased case load could overwhelm healthcare services within 1-1.5 months, unless the epidemic spreads predominantly among the younger age groups, as observed in the period July-August 2020, with the most fragile groups (e.g., the elderly) being protected. However, it should be noted that achieving an effective protection of the most fragile categories seems rather unlikely to in an epidemic characterized by this level of transmission.

In a national scenario of this kind, many Regions/AP would likely be classified as at high risk and, given the speed of transmission and the interconnection between the Regions/AP, it is unlikely that there will be lower than moderate risk classifications. If the high risk situation persists for longer than three weeks, it is very likely that very aggressive containment measures would be needed.

1. Weekly risk classification: MODERATE for at least 4 consecutive weeks, based on a reassessment of consolidated data to rule out an underestimation of risk due to a delay in the notification of surveillance data

Action: consider escalation of activities towards more stringent measures or maintenance or consider with caution de-escalation of activities towards less stringent measures if previously escalated in the context of high/very high risk classifications

Assess risk in the Region/AP to define sub-regional higher risk situations (circulation in provinces/municipalities; school clusters)

Interventions: ordinary + extra-ordinary interventions in institutions (e.g., schools) or limited geographical areas

- Increased control of the actual implementation of the measures already adopted on the territory (see minimum criteria)
- Scaled-up precautions where indicated in the documents produced for specific areas and contexts (e.g., schools) only in areas with greater risk of exposure
- Possible closure of activities, suspension of events and limitation of population mobility in sub-regional geographical areas (municipalities/provinces)

2. Weekly risk classification: HIGH/VERY HIGH for less than 3 consecutive weeks

Action: consider escalation of activities towards more stringent measures

Interventions: extra-ordinary extended (temporary local restrictions on a sub-provincial scale)

- Physical distance: e.g., closing night clubs, bars, restaurants (initially potentially only at specific times - for example in the evening/night in order to avoid “movida” activities)
- School/university closures (incremental: class, campus, on a geographical basis based on the epidemiological situation)
- Mobility restrictions (from/to high transmission areas and possible restoration of home-based work in specific areas).

- Temporary local restrictions on a sub-provincial scale (red zones) for at least 3 weeks with careful monitoring during the reopening phase. If a relatively low incidence is not maintained and Rt <1.2 in the mean value for at least 3 weeks after reopening, assess the need for restoration of restrictions with possible geographical extension.

3. Weekly risk classification: HIGH/VERY HIGH for 3 or more consecutive weeks and evidence of a situation that cannot be managed with the extraordinary measures already in place

Action: Consider regional/provincial restrictions

- Define a form of more extensive restriction on a provincial or regional scale based on the epidemiological situation
- Large-scale restoration of home-based work and limitations of individual mobility

Interventions: extra-ordinary (Table 7)

Figure 12 shows a flow chart for the re-modulation of measures based on the weekly classification of risk in a Region/AP.

Table 7 shows the same re-modulation with a declination from territorial measures at the regional level and considers the difference in expected incidence of flu-like syndromes - ILI (Influenza-Like Illnesses) that will impact health services at the same time. The table indicates the actors involved, where **N:** National (Central) Level; **R**: Regional Level; **L**: Local Level.

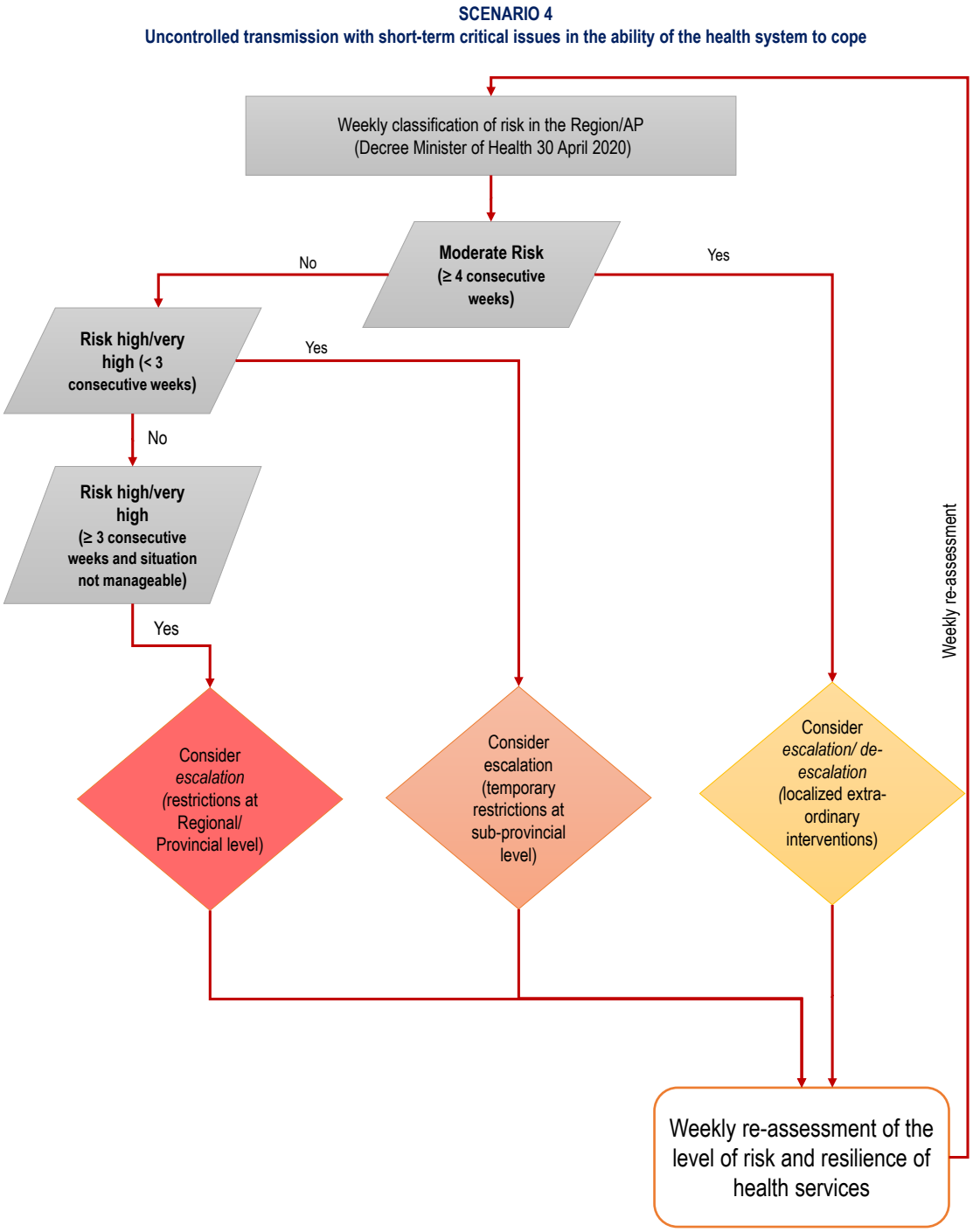

Figure 12. Adjustment of measures (escalation/de-escalation) based on the weekly risk classification in a Region/AP in a national context of uncontrolled transmission with short-term critical issues in the ability of the health system to cope (scenario 4)

Table 7. SCENARIO 4: uncontrolled transmission with short-term critical issues in the ability of the health system to cope

Weekly risk classification in the Region/AP		
MODERATE **for at least 4 consecutive weeks from a higher risk assessment**	**HIGH/VERY HIGH** **(for less than 3 consecutive weeks)**	**HIGH/VERY HIGH** **(for 3 or more consecutive weeks and the situation is not manageable)**
Increasing number of SARS-CoV-2 infections, local transmission (not imported), not all transmission chains known	Clusters no longer distinct from each other, new cases unrelated to known transmission chains, gradual increase in pressure for Prevention Departments	Widespread community transmission, clusters no longer distinct, new cases unrelated to known transmission chains, gradual increase in pressure for Public Health services
OBJECTIVE: *containment and control of clusters* ***Intervention:*** *ordinary + extra-ordinary interventions in institutions (e.g., schools) or limited geographical areas*	***OBJECTIVE:*** *Mitigation of viral spread* ***Intervention:*** *extra-ordinary extended (temporary local restrictions on a sub-provincial scale)*	***OBJECTIVE:*** *Mitigation of the viral spread, reduction in case load, end widespread community transmission* ***Intervention:*** *possible regional/provincial restrictions*
SEPT. - OCT. 2020 (expected ILI incidence LOW)		
Testing and management of suspected, confirmed cases and contacts		
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ possible simplification of active surveillance **[N, R, L]** ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks[**R, L**] ▪ activation of rapid training paths of additional staff to support Public Health - PH services (Dipartimenti di Prevenzione, DdP) [**R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened [R, L]	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g., healthcare workers) [R, L] ▪ hotels to be used as isolation premises are strengthened [**R, L**]	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g., healthcare workers) [R, L] ▪ hotels to be used as isolation premises are strengthened [**R, L**]
Community		
▪ social distancing is strengthened [**R, L**] ▪ local red zones [**R, L**] ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) [**R, L**] ▪ home-based work is encouraged to reduce public transport and workplace crowding [**N, R**]	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ possibility of introducing the obligation, also on a local basis, to wear face masks outdoors [**L**] ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities [**N, R, L**] ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**	▪ general restrictions with scope and duration to be defined on the basis of the epidemiological situation; in case of localized restrictions, limitation of mobility to/from affected areas **[N]**
School/University		
▪ possibility of introducing the obligation, also on a local basis, to wear face masks also in static situations including when a minimum distance of 1 meter between people is present [**L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**]	▪ obligation to wear a face mask (> 6 years) also in static situations including when a minimum distance of 1 meter between people is present **[R, L]** ▪ suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L]** ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L]** ▪ temporary closure of schools/universities on the basis of the local (e.g., a single educational structure [**R, L]** or more structures in an area) [R, L]	▪ closures of schools/universities the scope and duration of which are to be defined on the basis of the epidemiological situation activating distance learning where possible **[N]**
NOV. - DEC. 2020 (expected ILI incidence MODERATE)		
Testing and management of suspected, confirmed cases and contacts		
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients

Weekly risk classification in the Region/AP		
MODERATE **for at least 4 consecutive weeks from a higher risk assessment**	**HIGH/VERY HIGH** **(for less than 3 consecutive weeks)**	**HIGH/VERY HIGH** **(for 3 or more consecutive weeks and the situation is not manageable)**
▪ activation of additional staff to support COVID-related tasks [**R, L**] ▪ activation of rapid training paths of additional staff to support PH services (Dipartimenti di Prevenzione, DdP) [**R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened [R, L] ▪ activation of hotels as isolation premises [**R, L**]	▪ priority is given to COVID-related activities in PH services (DdP) [**R, L**] ▪ activation of additional external staff to support PH services (DdP) and COVID related activities [**R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g., healthcare workers) [R, L] ▪ hotels to be used as isolation premises are strengthened [**R, L**]	▪ priority is given to COVID-related activities in PH services (DdP) [**R, L**] ▪ activation of additional external staff to support PH services (DdP) and COVID related activities) [**R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g., healthcare workers) [**R, L**] ▪ hotels to be used as isolation premises are strengthened [**R, L**]
Community		
▪ social distancing is strengthened [**R, L**] ▪ local red zones [**R, L**] ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) [**R, L**] ▪ home-based work is encouraged to reduce public transport and workplace crowding **[N, R**] ▪ possible limitation of population mobility in sub-regional geographic areas [**R, L**]	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ consider introducing the obligation to wear face masks to protect airways also out-doors (e.g., on a time or place basis) [**N, R, L**] ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities [**N, R, L**] ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**	• general restrictions with scope and duration to be defined on the basis of the epidemiological situation; in case of localized restrictions, limitation of mobility to/from affected areas **[N**]
School/University		
▪ possibility of introducing the obligation, also on a local basis, to wear face masks also in static situations including when a minimum distance of 1 meter between people is present **[L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**]	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present [**L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ reduce the number of face to face class hours integrating distance learning for students of all school levels, in particular for middle-high school and university students [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**] ▪ consider temporary closures (2-3 weeks) of schools/universities with a scale and duration to be defined on the basis of the epidemiological situation activating distance learning where possible **[N, R]**	▪ closures of schools/universities the scope and duration of which are to be defined on the basis of the epidemiological situation activating distance learning where possible **[N]**
JAN. - MAR. 2021 (expected ILI incidence MODERATE/HIGH)		
Testing and management of suspected, confirmed cases and contacts		
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ simplification of contact tracing [**N, R, L**] ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks **[R, L**] ▪ activation of rapid training paths of additional staff to support PH services (Dipartimenti di Prevenzione, DdP) [**R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) [**R, L**] ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) [**R, L**] ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L**] ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases

Weekly risk classification in the Region/AP		
MODERATE **for at least 4 consecutive weeks from a higher risk assessment**	**HIGH/VERY HIGH** **(for less than 3 consecutive weeks)**	**HIGH/VERY HIGH** **(for 3 or more consecutive weeks and the situation is not manageable)**
▪ active-search for SARS-CoV-2 with screening of target populations is strengthened **[R, L]** ▪ activation of hotels as isolation premises [**R, L**]	▪ consider possible additional re-modulation of SARS-CoV-2 screening activities prioritizing target categories [R, L] ▪ hotels to be used as isolation premises are strengthened [**R, L**]	▪ consider possible additional re-modulation of SARS-CoV-2 screening activities prioritizing target categories [R, L] ▪ hotels to be used as isolation premises are strengthened [**R, L**]
Community		
▪ social distancing is strengthened [**R, L**] ▪ local red zones **[R, L**] ▪ consider introducing the obligation to wear face masks to protect airways also out-doors (e.g., on a time or place basis) **[N, R, L**] ▪ possible interruption of higher risk social/cultural activities (e.g., discos, bars – also on a time basis) [**R, L**] ▪ home-based work is encouraged to reduce public transport and workplace crowding [**N, R**] ▪ possible limitation of population mobility in sub-regional geographic areas [**R, L**]	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ obligation to wear face masks to protect airways also out-doors is introduced [**N, R, L]** ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities [**N, R, L**] ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**	▪ general restrictions with scope and duration to be defined on the basis of the epidemiological situation; in case of localized restrictions, limitation of mobility to/from affected areas **[N**]
School/University		
▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present on a local [**L**] or regional **[R**] basis ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available [**R, L**] ▪ possible suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ consider with higher priority the possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context **[N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**]	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present on a local[**L**] or regional [**R**] basis ▪ alternate lessons wherever possible, with morning and afternoon rotations [**R, L**] ▪ suspension of higher risk lessons (e.g., physical education, singing, wind instruments, laboratories used by multiple classes, etc.) [**R, L**] ▪ reduce the number of face to face class hours integrating distance learning for students of all school levels, in particular for middle-high school and university students [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g., preventive suspension campuses/class groups or of individual schools/universities) [**L**] ▪ consider temporary closures (2-3 weeks) of schools/universities with a scale and duration to be defined on the basis of the epidemiological situation activating distance learning where possible **[N, R]**	▪ closures of schools/universities the scope and duration of which are to be defined on the basis of the epidemiological situation activating distance learning where possible **[N]**

TRANSMISSION AND SPREAD OF COVID-19			
SCENARIO 1 **Localized transmission (clusters) largely similar to what was observed in the period July- August 2020**	**SCENARIO 2** **Sustained and widespread transmission manageable by the health system in the short/medium-term**	**SCENARIO 3** **Sustained and widespread transmission with risks in the ability of the health system to cope in the medium-term**	**SCENARIO 4** **Uncontrolled transmission with short-term critical issues in the ability of the health system to cope**
Description: *Rt above threshold for limited periods (<1 month), also assessing percentage of positive swabs/total swabs excluding screening and re-testing; low incidence, transmission limited to clusters with known transmission chains* ***Objective:*** *containment and control of clusters* ***Intervention****: minimum criteria (routine interventions)*	***Description:*** *regional Rt between 1 and 1.25, also assessing percentage of positive swabs/total swabs excluding screening and re-testing; increasing incidence with reduction in percentage of asymptomatic cases; few unknown chains of transmission, good limitation of transmission potential* ***Objective****: containment and control of clusters* ***Intervention:*** *ordinary + extra-ordinary interventions in institutions (e.g. schools) or limited geographical areas*	***Description:*** *regional Rt between 1.25 e 1.5, also assessing percentage of positive swabs/total swabs excluding screening and re-testing; rapid increase in incidence and clinical severity; clusters are no longer distinguished; new cases often not linked to known chains of transmission; progressive increase in pressure for PH and healthcare services; limited reduction of transmission potential* ***Objective:*** *mitigation of viral spread* ***Intervention****: extra-ordinary extended (temporary local restrictions on a sub-provincial scale)*	***Description:*** *regional Rt >1.5 also assessing percentage of positive swabs/total swabs excluding screening and re-testing; high incidence and clinical severity; widespread community transmission with no cluster distinction; relevant pressure on PH and healthcare services* ***Objective:*** *mitigation of the viral spread, reduction in case load, end widespread community transmission* ***Intervention****: possible regional/provincial restrictions*
SEPT. - OCT. 2020 (expected ILI incidence LOW)			
Testing and management of suspected, confirmed cases and contacts	**Testing and management of suspected, confirmed cases and contacts**	**Testing and management of suspected, confirmed cases and contacts**	**Testing and management of suspected, confirmed cases and contacts**
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts ▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ possible simplification of active surveillance **[N, R, L]** ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks **[R, L]** ▪ activation of rapid training paths of additional staff to support Public Health - PH services (Dipartimenti di Prevenzione – DdP) **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened **[R, L]**	▪ simplification of contact tracing **[N, R, L]** ▪ simplification of active surveillance **[N, R, L]** ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g. healthcare workers) **[R, L]** ▪ hotels to be used as isolation premises are strengthened **[R, L]**	▪ simplification of contact tracing **[N, R, L]** ▪ simplification of active surveillance **[N, R, L]** ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g. healthcare workers) **[R, L]** ▪ hotels to be used as isolation premises are strengthened **[R, L]**
Community	**Community**	**Community**	**Community**
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure **[N, R]**	▪ social distancing is strengthened **[R, L]** ▪ local red zones **[R, L]** ▪ possible interruption of higher risk social/cultural activities (e.g. discos, bars - also on a time basis) **[R, L]** ▪ home-based work is encouraged to reduce public transport and workplace crowding **[N, R]**	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ possibility of introducing the obligation, also on a local basis, to wear face masks outdoors **[L]** ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities **[N, R, L]** ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**	▪ general restrictions with scope and duration to be defined on the basis of the epidemiological situation; in case of localized restrictions, limitation of mobility to/from affected areas **[N]**
School/University	**School/University**	**School/University**	**School/University**
▪ face to face lessons ▪ required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people ▪ limit activities that cause mixing of different classes and groups	▪ possibility of introducing the obligation, also on a local basis, to wear face masks also in static situations including when a minimum distance of 1 meter between people is present **[L]** ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available **[R, L]** ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context **[N, R, L]** ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g. preventive suspension campuses/class groups or of individual schools/universities) **[L]**	▪ obligation to wear a face mask (> 6 years) also in static situations including when a minimum distance of 1 meter between people is present **[R, L]** ▪ suspension of higher risk lessons (e.g. physical education, singing, wind instruments, laboratories used by multiple classes, etc.) **[R, L]** ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available **[R, L]** ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context **[N, R, L]** ▪ temporary closure of schools/universities on the basis of the local (e.g. a single educational structure **[R, L]** or more structures in an area) **[R, L]**	▪ closures of schools/universities the scope and duration of which are to be defined on the basis of the epidemiological situation activating distance learning where possible **[N]**

TRANSMISSION AND SPREAD OF COVID-19			
SCENARIO 1 **Localized transmission (clusters) largely similar to what was observed in the period July- August 2020**	**SCENARIO 2** **Sustained and widespread transmission manageable by the health system in the short/medium-term**	**SCENARIO 3** **Sustained and widespread transmission with risks in the ability of the health system to cope in the medium-term**	**SCENARIO 4** **Uncontrolled transmission with short-term critical issues in the ability of the health system to cope**
***Intervention**: minimum criteria (routine interventions)*	***Intervention:** ordinary + extra-ordinary interventions in institutions (e.g. schools) or limited geographical areas*	***Intervention**: extra-ordinary extended (temporary local restrictions on a sub-provincial scale)*	***Intervention**: possible regional/provincial restrictions*
NOV. - DEC. 2020 (expected ILI incidence MODERATE)			
Testing and management of suspected, confirmed cases and contacts	**Testing and management of suspected, confirmed cases and contacts**	**Testing and management of suspected, confirmed cases and contacts**	**Testing and management of suspected, confirmed cases and contacts**
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts ▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks **[R, L]** ▪ activation of rapid training paths of additional staff to support PH services (Dipartimenti di Prevenzione – DdP) **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened **[R, L]** ▪ activation of hotels as isolation premises **[R, L]**	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g. healthcare workers) **[R, L]** ▪ hotels to be used as isolation premises are strengthened **[R, L]**	▪ simplification of contact tracing [**N, R, L**] ▪ simplification of active surveillance [**N, R, L**] ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ re-modulation of SARS-CoV-2 screening activities prioritizing target categories (e.g. healthcare workers) **[R, L]** ▪ hotels to be used as isolation premises are strengthened **[R, L]**
Community	**Community**	**Community**	**Community**
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure **[R, L]** ▪ possible interruption, on a local basis, of social/cultural activities/events at greater risk of generating in-person gatherings **[N, R]**	▪ social distancing is strengthened **[R, L]** ▪ local red zones **[R, L]** ▪ possible interruption of higher risk social/cultural activities (e.g. discos, bars – also on a time basis) **[R, L]** ▪ home-based work is encouraged to reduce public transport and workplace crowding [**N, R**] ▪ possible limitation of population mobility in sub-regional geographic areas **[R, L]**	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ consider introducing the obligation to wear face masks to protect airways also out-doors (e.g. on a time or place basis) **[N, R, L]** ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities [**N, R, L**] ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**	▪ general restrictions with scope and duration to be defined on the basis of the epidemiological situation; in case of localized restrictions, limitation of mobility to/from affected areas **[N]**
School/University	**School/University**	**School/University**	**School/University**
▪ face to face lessons ▪ required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people ▪ limit activities that cause mixing of different classes and groups	▪ possibility of introducing the obligation, also on a local basis, to wear face masks also in static situations including when a minimum distance of 1 meter between people is present [**L**] ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available **[R, L]** ▪ possible suspension of higher risk lessons (e.g. physical education, singing, wind instruments, laboratories used by multiple classes, etc.) **[R, L]** ▪ possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context [**N, R, L**] ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g. preventive suspension campuses/class groups or of individual schools/universities) **[L]**	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present **[L]** ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available **[R, L]** ▪ possible suspension of higher risk lessons (e.g. physical education, singing, wind instruments, laboratories used by multiple classes, etc.) **[R, L]** ▪ reduce the number of face to face class hours integrating distance learning for students of all school levels, in particular for middle-high school and university students **[N, R, L]** ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g. preventive suspension campuses/class groups or of individual schools/universities) **[L]** ▪ consider temporary closures (2-3 weeks) of schools/universities with a scale and duration to be defined on the basis of the epidemiological situation activating distance learning where possible **[N, R]**	▪ closures of schools/universities the scope and duration of which are to be defined on the basis of the epidemiological situation activating distance learning where possible **[N]**

TRANSMISSION AND SPREAD OF COVID-19			
SCENARIO 1 **Localized transmission (clusters) largely similar to what was observed in the period July- August 2020**	**SCENARIO 2** **Sustained and widespread transmission manageable by the health system in the short/medium-term**	**SCENARIO 3** **Sustained and widespread transmission with risks in the ability of the health system to cope in the medium-term**	**SCENARIO 4** **Uncontrolled transmission with short-term critical issues in the ability of the health system to cope**
***Intervention**: minimum criteria (routine interventions)*	***Intervention:** ordinary + extra-ordinary interventions in institutions (e.g. school/s) or limited geographical areas*	***Intervention**: extra-ordinary extended (temporary local restrictions on a sub-provincial scale)*	***Intervention**: possible regional/provincial restrictions*
JAN. - MAR. 2021 (expected ILI incidence MODERATE/HIGH)			
Testing and management of suspected, confirmed cases and contacts	**Testing and management of suspected, confirmed cases and contacts**	**Testing and management of suspected, confirmed cases and contacts**	**Testing and management of suspected, confirmed cases and contacts**
▪ diagnostic ascertainment and confirmation of all suspected cases ▪ isolation of close and at-risk contacts ▪ contact tracing, swab-testing and quarantine of close and at-risk contacts ▪ activation of additional staff to support COVID-related tasks **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts ▪ epidemiological exploratory actions ▪ screening of target populations ▪ timely monitoring of all cases and clusters ▪ monitoring for community viral transmission indicators ▪ early warning systems	▪ diagnostic ascertainment and confirmation of all suspected cases ▪ simplification of contact tracing **[N, R, L]** ▪ isolation of close and at-risk contacts ▪ cohort isolation of patients ▪ activation of additional staff to support COVID-related tasks **[R, L]** ▪ activation of rapid training paths of additional staff to support PH services (Dipartimenti di Prevenzione – DdP) **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ active-search for SARS-CoV-2 with screening of target populations is strengthened **[R, L]** ▪ activation of hotels as isolation premises **[R, L]**	▪ simplification of contact tracing **[N, R, L]** ▪ simplification of active surveillance **[N, R, L]** ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ consider possible additional re-modulation of SARS-CoV-2 screening activities prioritizing target categories **[R, L]** ▪ hotels to be used as isolation premises are strengthened **[R, L]**	▪ simplification of contact tracing **[N, R, L]** ▪ simplification of active surveillance **[N, R, L]** ▪ cohort isolation of patients ▪ priority is given to COVID-related activities in PH services (DdP) **[R, L]** ▪ activation of additional external staff to support PH services (DdP) and COVID related activities **[R, L]** ▪ swab-testing offered to suspected cases, close and at-risk contacts, with priority given to symptomatic cases ▪ consider possible additional re-modulation of SARS-CoV-2 screening activities prioritizing target categories **[R, L]** ▪ hotels to be used as isolation premises are strengthened **[R, L]**
Community	**Community**	**Community**	**Community**
▪ standard precautions (face masks to protect airways, social distance, hand and respiratory hygiene, environmental hygiene) ▪ scaled-up precautions where indicated in documents for specific contexts in areas with higher risk of exposure **[R, L]** ▪ possible interruption, on a local basis, of social/cultural activities/events at greater risk of generating in-person gatherings **[N, R]**	▪ social distancing is strengthened **[R, L]** ▪ local red zones **[R, L]** ▪ consider introducing the obligation to wear face masks to protect airways also out-doors (e.g. on a time or place basis) **[N, R, L]** ▪ possible interruption of higher risk social/cultural activities (e.g. discos, bars – also on a time basis) **[R, L]** ▪ home-based work is encouraged to reduce public transport and workplace crowding **[N, R]** ▪ possible limitation of population mobility in sub-regional geographic areas **[R, L]**	▪ local/provincial/regional actions to increase social distancing **[R, L]** ▪ obligation to wear face masks to protect airways also out-doors is introduced **[N, R, L]** ▪ temporary restrictions -red zones (<2-3 weeks) with reopening possible only after Rt and incidence assessments **[R, L]** ▪ interruption of social/cultural/sport activities at greater risk of generating in-person gatherings **[R, L]** ▪ consider the interruption of some at-risk productive activities **[N, R, L]** ▪ possible limitation of mobility between Regions or within the same Region (from/to high transmission areas: defined area, single locality, municipality, province, etc.) **[N, R]**	▪ general restrictions with scope and duration to be defined on the basis of the epidemiological situation; in case of localized restrictions, limitation of mobility to/from affected areas **[N]**
School/University	**School/University**	**School/University**	**School/University**
▪ face to face lessons ▪ required use of face masks in dynamic situations and in the absence of a minimum distance of 1 meter between people ▪ limit activities that cause mixing of different classes and groups ▪ possibility of introducing the obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present **[R, L]** ▪ possible suspension of higher risk lessons (e.g. physical education, singing, wind instruments, laboratories used by multiple classes, etc.) **[R, L]**	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present on a local **[L]** or regional **[R]** basis ▪ possibility of alternating lessons with morning and afternoon rotations, if needed increase the space available **[R, L]** ▪ possible suspension of higher risk lessons (e.g. physical education, singing, wind instruments, laboratories used by multiple classes, etc.) **[R, L]** ▪ consider with higher priority the possible activation of distance learning for part of the classes of high school and university students to guarantee physical distancing and avoid crowding, depending on viral circulation in each local context **[N, R, L]** ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g. preventive suspension campuses/class groups or of individual schools/universities) **[L]**	▪ possible obligation to wear face masks also in static situations including when a minimum distance of 1 meter between people is present on a local**[L]** or regional **[R]** basis ▪ alternate lessons wherever possible, with morning and afternoon rotations **[R, L]** ▪ suspension of higher risk lessons (e.g. physical education, singing, wind instruments, laboratories used by multiple classes, etc.) **[R, L]** ▪ reduce the number of face to face class hours integrating distance learning for students of all school levels, in particular for middle-high school and university students **[N, R, L]** ▪ temporary closure of schools/universities on the basis of the number of suspected/confirmed cases within each school community and/or of the level of community viral circulation at local level (e.g. preventive suspension campuses/class groups or of individual schools/universities) **[L]** ▪ consider temporary closures (2-3 weeks) of schools/universities with a scale and duration to be defined on the basis of the epidemiological situation activating distance learning where possible **[N, R]**	▪ closures of schools/universities the scope and duration of which are to be defined on the basis of the epidemiological situation activating distance learning where possible **[N]**

Appendix A
Operational tools and measures in response to COVID-19 in the autumn-winter 2020 season in Italy by main topic

Table A1. Pillar 1: operational tools and measures in response to COVID-19 in the autumn-winter 2020 season in Italy by main topic

Main topic	Document title	Author	Date of issue
20-21 September 2020 Italian electoral consultations/constitutional referendum	Circular of the Italian Ministry of Health. Subject: Indications on prevention measures against the risk of SARS-CoV-2 infection during September 2020 electoral consultations/constitutional referendum, with particular reference to the training of personnel dedicated to collecting the vote at the homes of voters undergoing home treatment or in quarantine or fiduciary isolation for COVID-19, as well as in health facilities with COVID-19 Departments with less than 100 beds. n. 0029600-11/09/2020-DGPRE-DGPRE-P	Italian Ministry of Health - General Directorate for health prevention	11/09/2020
20-21 September 2020 Italian electoral consultations/constitutional referendum	Circular of the Italian Ministry of Health. Subject: Indications on prevention measures against the risk of SARS-CoV-2 infection during September 2020 electoral consultations/constitutional referendum, with particular reference to voting in long-term care facilities. n. 0029601-11/09/2020-DGPRE-DGPRE-P	Italian Ministry of Health - General Directorate for health prevention	11/09/2020
20-21 September 2020 Italian electoral consultations/constitutional referendum	Circular of the Italian Ministry of Health. Subject: Indications on prevention measures against the risk of SARS-CoV-2 infection during September 2020 electoral consultations/constitutional referendum, with particular reference to voting of people in quarantine and in home isolation. n.27319 14/08/2020 DGPRE 0027319-P	Italian Ministry of Health - General Directorate for health prevention	14/08/2020
Aggregated health data flow transmission	Circular of the Italian Ministry of Health. Subject: Extension to July 31 of the terms related to the obligations foreseen by art. 40 (1) of the Decree Law 81/2008 n. 011056-31/03/2020-DGPRE	Italian Ministry of Health- General Directorate for health prevention	31/03/2020
Analysis of Ministerial Decree (DPCM) July 14, 2020; how to conduct September 20-21, 2020 electoral consultations ensuring safety; other topics	CTS minutes N. 95 - July 16-20, 2020	CTS - Italian Civil Protection Department	20/07/2020
Autism Spectrum Disorder	Rapporto ISS COVID-19 n. 8/2020 Rev. Interim guidance for the appropriate support of people with Autism Spectrum Disorder and/or with intellectual disability in the current SARS-CoV-2 emergency scenario. Version April 30, 2020	ISS	30/04/2020
Celiac disease	Rapporto ISS COVID-19 n. 38/2020. Interim guidance on the assistance to individuals affected by celiac disease in the SARS-CoV-2 emergence. Version of May 29, 2020	ISS	29/05/2020
Compulsory insurance	Data on complaints related to COVID-19 (VIII National Report - monitoring as of August 31, 2020)	INAIL	21/09/2020
COVID-19 containment measures	Decree-Law July 30, 2020, n. 83. Urgent measures related to the expiry of the COVID-19 epidemiological emergency declaration approved on January 31, 2020. (20G00112) (*GU Serie Generale* n.190, 30/7/2020)	Italian Government	30/07/2020
Data protection	Rapporto ISS COVID-19 n. 42/2020. Data protection in COVID-19 emergency. Version of May 28, 2020.	ISS	28/05/2020
Definition, certification and coding of deaths due to COVID-19; Italian Football Federation (FIGC): resumption of the Serie A football championship; other topics	CTS Minutes N. 88, June 12, 2020	CTS - Italian Civil Protection Department	12/06/2020

Main topic	Document title	Author	Date of issue
Epidemiological aspects; gradual lifting of COVID-19 containment measures; other topics	CTS minutes N. 40 - March 31, 2020	CTS - Italian Civil Protection Department	31/03/2020
Epidemiological data analysis; rapid molecular diagnostic tests for the detection of SARS-CoV-2	CTS minutes N. 35 - March 24, 2020	CTS - Italian Civil Protection Department	24/03/2020
Epidemiological data update, as of March 9, 2020 at 400 pm	CTS minutes N. 23 - March 14, 2020	CTS - Italian Civil Protection Department	10/03/2020
Phase 2: Monitoring indicators	Circular of the Italian Ministry of Health. Subject: 26/4/2020 COVID-19 Emergency: health risk monitoring activities related to transition from Phase 1 to Phase 2 as reported in Annex 10 of Ministerial Decree (DPCM) April 26, 2020. n. 0015279-30/04/2020-DGPRE-DGPRE-P	Italian Ministry of Health- General Directorate for health prevention, General Directorate of health planning	30/04/2020
First-aid procedures and training of professional rescuers	Circular of the Italian Ministry of Health. Subject: prevention and control measures against SARS-CoV-2 spreading in first aid procedures and for training of rescuers Updating. n. 021859-23/06/2020-DGPRE	Italian Ministry of Health- General Directorate for health prevention	23/06/2020
Guidelines for management of critically ill patients with COVID-19 and the use of PPE	CTS minutes N. 13, March 29, 2020	CTS - Italian Civil Protection Department	29/02/2020
Health care delivery	Circular of the Italian Ministry of Health. Subject: Updating of guidelines for the organisation of hospital and territorial services during COVID 19 emergency. n.007865-25/03/2020-DGPROGS.	Italian Ministry of Health- General Directorate of health planning	25/03/2020
Heat Health Watch Warning System	Circular of the Italian Ministry of Health. Subject: Heat Health Watch Warning System and prevention of heating impact on health during COVID19 emergency - Activities 2020. n. 20278-11/06/2020-DGPRE.	Italian Ministry of Health- General Directorate for health prevention	11/06/2020
Hospital network management	Circular of the Italian Ministry of Health. Subject: Organisational guidelines for increasing hospital network during COVID-19 emergency. n. 0011254-29/05/2020-DGPROGS-MDS-P	Italian Ministry of Health- General Directorate of health planning	29/05/2020
Hospital network management	Circular of the Italian Ministry of Health. Subject: Guidelines for the progressive reactivation of scheduled activities deemed deferrable during COVD-19 emergency. n. 0011408-01/06/2020-DGPROGS-MDS-P	Italian Ministry of Health- General Directorate of health planning	01/06/2020
Hospital network management	Law July 17 2020, n. 77. Conversion into law of Law Decree May 19 2020, n.34 on urgent measures on health sector, support to work and economic activities, social policies during COVID-19 emergency (*Gazzetta Ufficiale* n. 180 18/7/2020)	Italian Government	19/09/2020
Hospital network management	Law April 24 2020, n. 27. Convertion into law of Decree-Law March 17 2020, n.18 on measures to increase Italian National Health Service and economic support for families, workers and enterpries related to COVID -19 Emergency (20G00045) (*GU Serie Generale* n.110 29/4/2020 - Suppl. Ordinario n. 16)	Italian Government	30/04/2020
Hospital network management	Guidelines for remodelling of the deferrable planned activity during COVID-19, March 16 n. 2020 0007422-16/03/2020-DGPROGS-MDS-P - Annex 1 (A01)	Italian Ministry of Health- General Directorate of health planning	16/03/2020
ICU bed capacity	Circular of the Italian Ministry of Health. Subject: Increasing bed capacity of national health system and further indications on COVID-19 emergency management. n. 002627-01/03/2020-DGPROGS	Italian Ministry of Health- General Directorate of health planning	01/03/2020
ICU bed capacity	Circular of the Italian Ministry of Health. Subject: guidelines for management of critically ill patient with COVID-19 n. 002619-29/02/2020-DGPROGS	Italian Ministry of Health- General Directorate of health planning	29/02/2020

Main topic	Document title	Author	Date of issue
Increasing hospital bed capacity at national level; transport of critically ill patients and use of PPE	CTS minutes N. 14, March 1, 2020	CTS - Italian Civil Protection Department	01/03/2020
Increasing hospital network capacity; organisational plan	Circular of the Italian Ministry of Health. Subject: Organisational guidelines for increasing hospital network capacity duringCOVID-19 emergency n. 011254-29/05/2020-DGPROGS.	Italian Ministry of Health-General Directorate of health planning	29/05/2020
IPC	Circular of the Italian Ministry of Health. Subject: Measures to prevent the risk of infection from SARS-CoV-2 during 20-21 September 2020 elections and referendum, with focus on voters in quarantine and isolation. - Updating n. 0029599-11/09/2020-DGPRE-DGPRE-P	Italian Ministry of Health-General Directorate for health prevention	12/09/2020
Management of suspected/confirmed cases and cluster of SARS-CoV-2 at schools and childhood education services	Circular of the Italian Ministry of Health. Subject: Indications for management of cases and clusters of SARS-CoV-2 at schools and childhood educational services n.017167-21/08/2020-DGPROGS	Italian Ministry of Health-General Directorate for health prevention, General Directorate of health planning	21/08/2020
Mental health	Rapporto ISS COVID-19 n. 41/2020. Indications for caring for relatives' difficulties and needs of inpatients with COVID-19. Version of May, 29, 2020.	ISS	29/05/2020
Ministry of Health Guidelines for remodelling of the deferrable planned activity during COVID-19; other topics	CTS minutes N. 25, March 12, 2020	CTS - Italian Civil Protection Department	12/03/2020
Monitoring and surveillance of elederly and vulnerable people; Italian National Blood Centre; CT diagnostics and artificial intelligence	CTS minutes N. 36, March 25, 2020	CTS - Italian Civil Protection Department	25/03/2020
Nationwide containment/mitigation measures against the spread of SARS-CoV-2 (DPCM 25/02/2020)	CTS minutes N. 12, February 28, 2020	CTS - Italian Civil Protection Department	28/02/2020
Open data ISS, genomic sequencing of SARS-CoV-2	CTS minutes N. 86, June 5, 2020	CTS - Italian Civil Protection Department	05/06/2020
Organization teaching activities at university level; national network for the development of randomised controlled studies on the effectiveness of new therapies against emerging infectious pathogens	CTS minutes N. 53 April 16, 2020	CTS - Italian Civil Protection Department	16/04/2020
Pandemic scenarios update following the Ministerial Decree (DPCM) - April 10, 2020; preventing the spread of COVID-19 in long-term care facilities; other topics	CTS minutes N. 50 - April 11, 2020	CTS - Italian Civil Protection Department	11/04/2020
Phase 2 in Italy: approach for integrated management of SARS-CoV2 emergency to allow return to normality; PPE; other topics	CTS minutes N. 39, March 30, 2020	CTS - Italian Civil Protection Department	30/03/2020
Preparedness and response	Circular of the Italian Ministry of Health. Subject: Element of preparedness and response to the COVID 19 in the autumn-winter season. n. 0027007-11/08/2020-DGPRE-MDS-P	Italian Ministry of Health-General Directorate for health prevention, General Directorate of health planning	11/08/2020
Preparedness for a COVID-19 in the autumn-winter season	Circular of the Italian Ministry of Health. Subject: Preparedness to COVID-19 in the autumn-winter season, n.027007-11/08/2020-DGPRE	Italian Ministry of Health-General Directorate for health prevention, General Directorate of health planning	11/08/2020
Primary care emergency activity in Lombardy and tailoring interventions to infectious and respiratory diseases; gradual lifting of coronavirus containment measures	CTS minutes N. 43 - April 3, 2020	CTS - Italian Civil Protection Department	03/04/2020
Rare Diseases	Rapporto ISS COVID-19 n. 24/2020. Interim guidelines for the appropriate support of children with adrenal insufficiency during the	ISS	10/05/2020

Main topic	Document title	Author	Date of issue
	current SARS-CoV-2 pandemic emergency. Version May 10, 2020		
Rare Diseases	Rapporto ISS COVID-19 n. 39/2020. Census of needs (March 23 - April 5, 2020) of people with rare diseases in the current SARS-CoV-2 emergency scenario. Version of May 30, 2020	ISS	30/05/2020
Redefining COVID-19 containment measures according to epidemiological data; other topics	CTS minutes N. 57 - April 22, 2020	CTS - Italian Civil Protection Department	22/04/2020
Redefinition of containment measures: Phase 2 approach for integrated management of SARS-CoV2 emergency to allow return to normality	CTS Minutes N. 49, April 2020	CTS - Italian Civil Protection Department	09/04/2020
Reorganising essential health services delivery	Circular of the Italian Ministry of Health. Subject: Clarifications on guidelines for redesigning scheduled activities deemed deferrable during COVID-19 emergency. n.008076-30/03/2020-DGPROGS	Italian Ministry of Health- General Directorate of health planning	30/03/2020
Reorganising essential health services delivery	Circular of the Italian Ministry of Health. Subject: Clarifications on guidelines for redesignig scheduled activities deemed deferrable during COVID-19 emergency n.007422-16/03/2020-DGPROGS	Italian Ministry of Health- General Directorate of health planning	16/03/2020
Request from ministries: redefinition of containment measures against spread of SARS-CoV2	CTS minutes N. 59, April 24 and 25, 2020	CTS - Italian Civil Protection Department	25/04/2020
Research	Rapporto ISS COVID-19 n. 47/2020. Research ethics during the COVID-19 pandemics. Considerations on observational and in particular epidemiologic studies. Version of May 29, 2020.	ISS	29/05/2020
Response to request of Ministry of Health on school closure	CTS minutes N. 18, March 4, 2020.	CTS - Italian Civil Protection Department	04/03/2020
Restarting elective outpatient activities; serological tests for SARS-CoV-2 Ab detection	CTS minutes N. 80 May 25, 2020.	CTS - Italian Civil Protection Department	25/05/2020
School	Decree-Law September 8, 2020, n. 111. Urgent measures to face economic non-deferrable needs and to support the return to school during COVID 19 emergency. (20G00134) *(GU Serie Generale*, n. 223, 8/9/2020).	Italian Government	09/09/2020
Serological tests for SARS-CoV-2 Ab detection	Circular of the Italian Ministry of Health. Subject: Screening and diagnostic tests. n. 016106-09/05/2020-DGPRE	Italian Ministry of Health- General Directorate for health prevention	09/05/2020
Substances/devices use	Rapporto ISS COVID-19 n. 56/2020. Focus on professional use of ozone also in reference to COVID-19. Version of July 23, 2020.	ISS - INAIL	23/07/2020
Teachers and students coming from areas at risk for COVID-19	Circular of the Italian Ministry of Health. Subject: Indications for the management of students and teacher moving from and to China affected regions.	Italian Ministry of Health- General Directorate for health prevention	01/02/2020
Training	Rapporto ISS COVID-19 n. 57/2020. Training for preparedness in the COVID-19 emergency: the case report of the Istituto Superiore di Sanità. Version of May 31, 2020	ISS	31/05/2020
Transport by train, airplane and public bus; vaccination in children and adolescents	CTS minutes N. 63, April 30, 2020	CTS - Italian Civil Protection Department	30/04/2020
Vaccination coverage during COVID-19 Emergency	Circular of the Italian Ministry of Health. Subject: impact of COVID-19 emergency on vaccination activities - analysis of phenomenon and operational recommendations n. 025631-30/07/2020-DGPRE	Italian Ministry of Health - General Directorate for health prevention	30/07/2020
Worker protection	Circular of INAIL. n. 22, May 20 2020. Insurance coverage of confirmed cases of COVID-19 during working activities. Law Decree March 17 2020, n. 18 “Measure to	INAIL	20/05/2020

Main topic	Document title	Author	Date of issue
	strengthen national health services capacity and economic support for families, workers and enterprises during COVID-19" - Article 42 paragraph 2, converted into to the Law 24 April 2020. Clarifications.		
Worker protection	Stress management and burnout prevention among health care workers during COVID-19 emergency.	INAIL-CNOP	11/04/2020
Worker protection	Rapporto ISS COVID-19 n. 22/2020 Rev. Interim guidance for the appropriate support of the health workers in the SARS-CoV-2 emergency scenario. Version of May 28, 2020.	ISS	28/05/2020
Worker protection	Circular of the Italian Ministry of Health April 29, 2020. Subject: "Operational indications to prevent and contain SARS-CoV-2 spreading in the working places and in the community. Updating and clarifications with focus on vulnerable workers	Italian Ministry of Health-General Directorate for health prevention; Italian Ministry of Labour and Social Policies	04/09/2020

Table A2. Pillar 2: operational tools and measures in response to COVID-19 in the autumn-winter 2020 season in Italy by main topic

Main topic	Document title	Author	Date of issue
Companion animals	Rapporto ISS COVID-19 n. 16/2020. Companion animals and SARS-CoV-2: what do we need to know, how should we behave? Version April 19, 2020.	ISS	19/04/2020
Ethics	Rapporto ISS COVID-19 n. 40/2020. Emergency communication in the COVID-19 units. Ethical aspects. Version of May 25, 2020.	ISS	25/05/2020
Free psychological listening service	Circular of the Italian Ministry of Health. Subject: Activation of the free psychological listening service of the Ministry of Health n. 0001165-06/05/2020-DGCOREI-DGPRE	Italian Ministry of Health - General Directorate for health prevention	06/05/2020
Risk communication	Coronavirus - A practical guide for carers of older people	ISS-INAIL- Gemelli Research Centre for the promotion and the development of geriatric care	24/04/2020
Risk communication	COVID-19 e protezione degli operatori sanitari - seconda edizione	INAIL	24/03/2020
Risk communication	Rapporto ISS COVID-19 n. 15/2020. Recommendations on risks related to the online purchase of drugs for prevention and therapy of COVID-19 infection and to the dissemination of fake news about therapies on social networks. Version April 16, 2020.	ISS	16/04/2020
Worker protection	Video on “Common regulatory protocol for measures to combat and contain the spread of the COVID-19 virus in the workplace – 24 April 2020”	INAIL	28/05/2020

Table A3. Pillar 3: operational tools and measures in response to COVID-19 in the autumn-winter 2020 season in Italy by main topic

Main topic	Document title	Author	Date of issue
Contact tracing and the"Immuni" App	Circular of the Italian Ministry of Health. Subject: Tracing and management of the contacts of COVID-19 cases and App Immuni. n. 018584-29/05/2020-DGPRE	Italian Ministry of Health - General Directorate for health prevention and General Directorate of health planning	29/05/2020
Contact tracing and Isolation	Rapporto ISS COVID-19 n. 53/2020. Guide to contact tracing for COVID-19. Version of June 25, 2020.	ISS	25/06/2020
Contact tracing and Isolation	Rapporto ISS COVID-19 n. 54/2020. Technologies supporting proximity detection: reflections for citizens, professionals and stakeholders in COVID-19 era. Version of May 31, 2020	ISS	31/05/2020
COVID-19 case and close contact definition	Circular of the Italian Ministry of Health. Subject: COVID-2019. New indications and clarifications. n. 005443-22/02/2020-DGPRE	Italian Ministry of Health - General Directorate for health prevention	22/02/2020
COVID-19 case definition	Circular of the Italian Ministry of Health. Subject: Updating COVID-19 case definition. n. 007922-09/03/2020-DGPRE	Italian Ministry of Health - General Directorate for health prevention	09/03/2020
COVID-19 case definition	Circular of the Italian Ministry of Health. Subject: COVID-19 updating. n. 006360-27/02/2020-DGPRE	Italian Ministry of Health - General Directorate for health prevention	27/02/2020
COVID-19 case definition and collecting clinical samples	Circular of the Italian Ministry of Health. Subject: Novel coronavirus (2019-nCoV) pneumonia in China. n. 002302-27/01/2020-DGPRE.	Italian Ministry of Health - General Directorate for health prevention	27/01/2020
Definition of patient recovered from COVID-19	Circular of the Italian Ministry of Health. Subject: Opinion of the Higher Health Council: Definition of patient recovered from COVID-19. n. 006607-29/02/2020-DGPRE	Italian Ministry of Health - General Directorate for health prevention	29/02/2020
Definitions of cases to undergo swabbing	Circular of the Italian Ministry of Health. Subject: Reference to the information provided in the Circular of February 22, 2020	Italian Ministry of Health - General Directorate for health prevention	25/02/2020
Diagnostic tests for asymptomatic individuals	Circular of the Italian Ministry of Health. Subject: Document on criteria for testing clinically asymptomatic individuals for SARS-CoV-2 infection through rhino-pharyngeal swab. n. 006337-27/02/2020-DGPRE	Italian Ministry of Health - General Directorate for health prevention	27/02/2020
Epidemiological and clinical surveillance	Rapporto ISS COVID-19 n. 18/2020. Recommendations for the collection and analysis of data disaggregated by sex related to incidence, manifestations, response to therapies and outcomes in COVID-19 patients. Version April 26, 2020	ISS	26/04/2020
Epidemiological surveillance	Circular of the Italian Ministry of Health. Subject: Case definition update. n. 0007922-09/03/2020-DGPRE-DGPRE-P	Italian Ministry of Health- General Directorate for health prevention	09/03/2020
Epidemiological surveillance	COVID-19: instructions for completing death certificate (ISTAT D4 model).	ISTAT	16/04/2020
Epidemiological surveillance	Rapporto ISS COVID-19 n. 34/2020. Territorial surveillance and protection of public health: some ethical and legal issues. Version of May 25, 2020.	ISS	25/05/2020
Epidemiological surveillance	CTS minutes N. 38, March 27, 2020	CTS - Italian Civil Protection Department	27/03/2020
Laboratory diagnosis	Circular of the Italian Ministry of Health. Subject: Cancellation and replacement of the Circular of the Ministry of Health n. 0009480 March 19, 2020 "COVID-19: contact tracing in the field of health surveillance and updating of indications for laboratory diagnosis of SARS-CoV-2 infection." n. 009774-20/03/2020-DGPRE.	Italian Ministry of Health - General Directorate for health prevention	20/03/2020
Microbiological surveillance	CTS minutes N. 69, May 11, 2020	CTS - Italian Civil Protection Department	11/05/2020
Miscellaneous	CTS minutes N. 93, July 3, 2020.	CTS - Italian Civil Protection Department	03/07/2020

Main topic	Document title	Author	Date of issue
Nationwide seroprevalence survey; experimental therapies; other topics	CTS minutes N. 44, April 4, 2020	CTS - Italian Civil Protection Department	04/09/2020
Novel coronavirus identification (2019-nCoV)	Circular of the Italian Ministry of Health. Subject: Novel coronavirus (2019-nCoV) pneumonia in China. n. 001997-22/01/2020-DGPRE	Italian Ministry of Health - General Directorate for health prevention	22/01/2020
School	Rapporto ISS COVID-19 n. 58/2020 Rev. - Operational guidance for the management of SARS-CoV-2 cases and outbreak in schools and kindergartens. Version of August 28, 2020.	ISS; Italian Ministry of Health; Italian Ministry of Education; INAIL; Bruno Kessler Foundation; Emilia-Romagna Region; Veneto Region	28/08/2020
Students from risk areas	Circular of the Italian Ministry of Health. Subject: Updates to the ministerial circular 01.02.2020 regarding measure related to the management of students returning from cities at risk in China. n. 004001-08/02/2020-DGPRE	Italian Ministry of Health - General Directorate for health prevention	08/02/2020

Table A4. Pillar 4: operational tools and measures in response to COVID-19 in the autumn-winter 2020 season in Italy by main topic

Main topic	Document title	Author	Date of issue
Airport sanitation channel	Circular of the Italian Ministry of Health. Subject: COVID-2019: indications for the management of athletes coming from affected areas.n. 005257-20/02/2020-DGPRE.	Italian Ministry of Health - General Directorate for health prevention	20/02/2020
Management of possible COVID-19 cases	Circular of the Italian Ministry of Health. Subject: Possible coronavirus (nCoV) cases and related management. n. 002993-31/01/2020-DGPRE.	Italian Ministry of Health - General Directorate for health prevention	31/01/2020
Monitoring of passengers from China	Circular of the Italian Ministry of Health. Subject: 2019 nCov: Operational indications for monitoring the health status of passengers on flights from China. n. 002265-24/01/2020-DGPRE.	Italian Ministry of Health - General Directorate for health prevention	24/01/2020
Preventive measures at airports	Circular of the Italian Ministry of Health. Subject: Chinese nCoV coronavirus epidemic: Urgent measures to protect public health. Prohibition of landing of all flights from China at the airports of Ciampino, Roma Urbe, Perugia, Ancona. n. 2.31.152/165- 27/01/2020 DGPRE.	Italian Ministry of Health - General Directorate for health prevention	27/01/2020

Table A5. Pillar 5: operational tools and measures in response to COVID-19 in the autumn-winter 2020 season in Italy by main topic

Main topic	Document title	Author	Date of issue
Laboratory diagnostics/testing strategies	Ordinance of the Italian Ministry of Health. Subject: COVID-19 Pandemic - Update of indications on diagnostic tests and on the criteria to be adopted in priority setting. Update of indications on laboratory diagnosis. n. 0011715-03/04/2020-DGPRE-DGPRE-P	Italian Ministry of Health - General Directorate of Health Planning	03/04/2020
Laboratory diagnostics/testing strategies	Rapporto ISS COVID-19 n. 11/2020 Rev. 2. Recommendations for sampling, storing and analysis of oro/nasopharyngeal swab for COVID-19 diagnosis. Version of May 29, 2020	ISS	29/05/2020
Laboratory diagnostics/testing strategies	Rapporto ISS COVID-19 n. 13/2020. Recommendations for collection, transport and storage of COVID-19 biological samples. Version of April 15, 2020	ISS	15/04/2020
Laboratory diagnostics/testing strategies	Rapporto ISS COVID-19 n. 28/2020. COVID-19 in vitro diagnostic devices. Part 1: regulations and types. Version of 18 May, 2020	ISS	18/05/2020
Laboratory diagnostics/testing strategies	Rapporto ISS COVID-19 n. 46/2020. COVID-19 in vitro diagnostic devices. Part 2: market development and information to stakeholders. Version of May 23, 2020	ISS	23/05/2020

Table A6. Pillar 6: operational tools and measures in response to COVID-19 in the autumn-winter 2020 season in Italy by main topic

Main topic	Document title	Author	Date of issue
Deferrable activities	CTS minutes N. 83, May 29, 2020. Opinion on Guidelines for the progressive reactivation of scheduled activities deemed deferrable during COVID -19 emergency.	CTS - Italian Civil Protection Department	29/05/2020
Catering	Technical document on the proposal for remodelling COVID-19 containment measures in the catering sector	INAIL; ISS	12/05/2020
Commercial establishments	Ministerial Decree (DPCM) April 26, 2020 - Further provisions implementing the Decree-Law of 23 February 2020, n. 6, containing urgent measures regarding the containment and management of the epidemiological emergency from COVID-19, applicable nationwide. (*GU Serie Generale*, n. 108, 27/4/2020). Annex 5 - Measures for commercial establishments	Italian Presidency of the Council of Ministers	27/04/2020
Community protection	Ministerial Decree (DPCM) April 26, 2020. Further provisions implementing the Decree-Law of 23 February 2020, n. 6, containing urgent measures regarding the containment and management of the epidemiological emergency from COVID-19, applicable nationwide. (*GU Serie Generale*, n. 108, 27/4/2020). Art. 3 - Information and prevention measures throughout the national territory; paragraphs 2, 3 and 4 community masks	Italian Presidency of the Council of Ministers	27/04/2020
Conferences / Churches / Communities	Ministerial Decree (DPCM) May 17, 2020 - Further provisions implementing the Decree-Law March 25, 2020, n. 19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n. 126, 17/5/2020). Annex 1 - Protocol with the Italian Episcopal Conference regarding the resumption of celebrations with the people. Annex 2 - Protocol with the Italian Jewish Communities Annex 3 - Protocol with the Protestant, Evangelical, Anglican Churches Annex 4 - Protocol with the Orthodox Communities Annex 5 - Protocol with the Hindu, Buddhist (Buddhist Union and Soka Gakkai), Baa'i and Sikh communities Annex 6 - Protocol with the Islamic Communities Annex 7 - Protocol with the Community of the Church of Jesus Christ of Latter-day Saints.	Italian Presidency of the Council of Ministers	17/05/2020
Construction sites	Ministerial Decree (DPCM) April 26, 2020 - Further provisions implementing the Decree-Law of 23 February 2020, n. 6, containing urgent measures regarding the containment and management of the epidemiological emergency from COVID-19, applicable nationwide. (*GU Serie Generale*, n. 108, 27/4/2020). Annex 7 – Shared protocol for containing the spread of COVID-19 on construction sites.	Italian Presidency of the Council of Ministers	27/04/2020
Contact tracing and isolation	Rapporto ISS COVID-19 n. 1/2020 Rev. - Interim guidance for the implementation of isolation and home health care in the current COVID-19 context. Version of July 24, 2020	ISS	24/07/2020
Containment and management	Ordinance of the Italian Ministry of Health August 16, 2020. (20A04564). Further urgent measures regarding the containment and management of the epidemiological emergency from COVID-19. (*GU Serie Generale*, n. 204, 17/8/2020).	Italian Ministry of Health	17/08/2020
Containment measures in workplace; other topics	CTS minutes N. 48 April 8, 2020	CTS - Italian Civil Protection Department	08/04/2020
Containment of SARS-CoV-2 spread (Ministry for Cultural and	CTS minutes N. 62 April 29, 2020	CTS - Italian Civil Protection Department	29/04/2020

Main topic	Document title	Author	Date of issue
Environmental Heritage activities), State Police exposure risks; other topics			
Cruise ships	Ministerial Decree (DPCM) August 7, 2020 - Further provisions implementing the Decree-Law March 25, 2020, n. 19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n.198, 8/8/2020). Annex 17 – Measures for the management of COVID-19 emergency on cruise ships.	Italian Presidency of the Council of Ministers	08/08/2020
Cycling events	CTS minutes N. 94 July 7, 2020. Opinion on safety procedures for the resumption of cycling events.	CTS - Italian Civil Protection Department	07/07/2020
Dental activity	CTS minutes N. 72 May 13, 2020. Opinion on operational indications for dental activities during phase 2 of the COVID-19 pandemic.	CTS - Italian Civil Protection Department	13/05/2020
Disinfection of outdoor environments	Circular of the Italian Ministry of Health. Subject: Disinfection of outdoor environments and use of disinfectants (sodium hypochlorite) on road surfaces and urban pavements for the prevention SARS-CoV-2 infection transmission. n. 0009361-18/03/2020-DGPRE-DGPRE-P.	Italian Ministry of Health-General Directorate for health prevention	18/03/2020
Economic and productive activities	Ministerial Decree (DPCM) June 11, 2020 - Further provisions implementing the Decree-Law March 25, 2020, n. 19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. Annex 9 - Guidelines for the reopening of the economic and productive activities of the Conference of Regions and Autonomous Provinces, June 11, 2020. 20/95 / CR1 / COV19.	Italian Presidency of the Council of Ministers	11/06/2020
Economic and productive activities	Ministerial Decree (DPCM) July 14, 2020 - Further provisions implementing the Decree-Law March 25, 2020, n. 19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n. 176, 14/7/2020). Annex 1 - Guidelines for the reopening of the economic and productive and recreational activities of the Conference of Regions and Autonomous Provinces, July 14, 2020. 20/127/CR7ter-a/COV19.	Italian Presidency of the Council of Ministers	14/07/2020
Economic and productive activities	Ministerial Decree (DPCM) May 17, 2020 - Further provisions implementing the Decree-Law March 25, 2020, n. 19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n. 126, 17/5/2020). Annex 17 - Guidelines for the reopening of the economic and productive activities of the Conference of Regions and Autonomous Provinces, May 16, 2020.20/81/CR01/COV19.	Italian Presidency of the Council of Ministers	17/05/2020
Electoral/referendum consultations	Health and safety protocol for the conduct of the September 2020 electoral and referendum consultations	Italian Ministry of Interior-Italian Ministry of Health	07/08/2020
Entertainment shows	Ministerial Decree (DPCM) May 17 2020 - Provisions implementing the Decree-Law 25 March 2020, n. 19 and the Decree Law 16 May 2020 n.33, on urgent measures to face with COVID-19 emergency. (*GU Serie Generale* n. 126, 17/5/2020). Annex 9- Live entertainment/shows and cinema.	Italian Presidency of the Council of Ministers	17/05/2020
Environmental hygiene	Rapporto ISS COVID-19 n. 19/2020 Rev.- Interim recommendations on disinfectants products during COVID-19 health emergency: medical surgical devices and biocidal products. Version of July 13, 2020	ISS	13/07/2020
Environmental hygiene	Rapporto ISS COVID-19 n. 20/2020 Rev. 2 - Interim provisions on disinfection and cleaning of indoor environments in healthcare settings to prevent transmission of SARS-CoV-2. Version of July 7, 2020	ISS	07/07/2020

Main topic	Document title	Author	Date of issue
Environmental hygiene	Rapporto ISS COVID-19 n. 21/2020 - Guide for the prevention of Legionella contamination in the water systems of tourist accommodation facilities and other buildings for civil and industrial use, not used during the COVID-19 pandemic. Version May 5, 2020	ISS	03/05/2020
Environmental hygiene	Rapporto ISS COVID-19 n. 25/2020 - Interim recommendations on cleaning and disinfection of non-healthcare settings during COVID-19 health emergency: surfaces, indoor environments and clothing. Version of May 15, 2020	ISS	15/05/2020
Environmental hygiene	Rapporto ISS COVID-19 n. 26/2020 - Interim guidance to manage disposable facial masks and gloves coming from household and non-household sources. Version May 18, 2020	ISS	18/05/2020
Environmental hygiene	Rapporto ISS COVID-19 n. 27/2020 - Indications for the prevention of Legionella risk in dental unit waterline during COVID-19 pandemic. Version May 17, 2020	ISS	17/04/2020
Environmental hygiene	Rapporto ISS COVID-19 n. 33/2020 - Guidance on ventilation/air-conditioning facilities in non-medical community facilities and in domestic environments in relation to the spread of SARS-CoV-2 virus. Version of May 25, 2020.	ISS	25/05/2020
Environmental hygiene	Rapporto ISS COVID-19 n. 36/2020 - Provisions on bathing activities in relation to the spread of the SARS-CoV-2 virus. Version May 31, 2020.	ISS	31/05/2020
Environmental hygiene	Rapporto ISS COVID-19 n. 37/2020 - Directions on swimming pools, as referred to the Agreement of January 16, 2003 between the Ministry of Health, the Regions and the Autonomous Provinces of Trento and Bolzano, in relation to the spread of the SARS-CoV-2	ISS	31/05/2020
Environmental hygiene	Rapporto ISS COVID-19 n. 5/2020 Rev. 2 - Ad interim provisions to prevent and manage the indoor environment in relation to the transmission of the infection by the SARS-CoV-2 virus. Version of May 25, 2020.	ISS	25/05/2020
Environmental hygiene	Rapporto ISS COVID-19 n. 7/2020 - Recommendations for disinfection of outdoor environments and road surfaces as to prevent the spread of SARS-CoV-2 infection. Version March 29, 2020	ISS	29/03/2020
Environmental hygiene	Rapporto ISS COVID-19 n. 9/2020 - Interim provisions on the management of sewage sludge to prevent the SARS-CoV-2 virus diffusion. Version April 3, 2020.	ISS	03/04/2020
Food hygiene and safety	Rapporto ISS COVID-19 n. 17/2020 - Interim provisions on food hygiene during the SARS-CoV-2 epidemic. Version April 19, 2020.	ISS	19/04/2020
General criteria for the elaboration of sector protocols	Ministerial Decree (DPCM) June 11, 2020 - Further provisions implementing the Decree-Law March 25, 2020, n. 19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n. 147,11/6/2020). Annex 10 - General criteria for the elaboration of sector protocols.	Italian Presidency of the Council of Ministers	11/06/2020
Guidelines for the activities of summer educational services for children (0-3 years); other topics	CTS minutes N. 84 June 3, 2020.	CTS - Italian Civil Protection Department	03/06/2020
Health workers protection	Rapporto ISS COVID-19 n. 2/2020 - Version May 10, 2020. Interim guidance for rational use of SARS-COV-2 infection protections in health and socio-health activities in the current SARSCOV-2 emergency scenario. Version May 10, 2020.	ISS	10/05/2020
IPC	Ordinance of the Italian Ministry of Health August 12, 2020. Further urgent measures regarding the containment and management of the	Italian Ministry of Health	13/08/2020

Main topic	Document title	Author	Date of issue
	epidemiological emergency from COVID-19. (20A04514). *GU Serie Generale*, n. 202, 13/8/2020		
IPC	Update of the measures to prevent the transmission of the new Coronavirus infection (SARS-CoV-2) through the transfusion of labile blood components, March 9, 2020. Integrated by the Circular March 16, 2020.	ISS-National Blood Centre	09/03/2020
IPC	Integration to the circular N. 0653.CNS.2020 March 9, 2020 "Update of measures to prevent the transmission of the new Coronavirus infection (SARS-CoV-2) through the transfusion of labile blood components".	ISS-National transplant Centre	16/03/2020
IPC	Coronavirus & Dialysis Protocol, February 27, 2020.	Italian Society of Nephrology	27/02/2020
Imaging	Rapporto ISS COVID-19 n. 50/2020 Rev. - Contribution of technological innovation to the safety of diabetic patients undergoing ocular fundus examination in COVID-19 times. Version of June 24, 2020.	AUSL Pescara; ISS; University of Turin; International Agency for the Prevention of Blindness; Vita-Salute San Raffaele University; University of Chieti-Pescara	24/06/2020
Interim indications for isolation and home care in the context of COVID-19	CTS minutes N. 22 March 9, 2020.	CTS - Italian Civil Protection Department	09/03/2020
IPC in funeral services	Circular of the Italian Ministry of Health. Subject: Emergency indications related to the COVID-19 epidemic concerning the funeral, cemetery and cremation sector - Update in light of the changed legal and epidemiological situation (pdf, 0.07 Mb). n. 018457-28/05/2020-DGPRE	Italian Ministry of Health-General Directorate for health prevention	28/05/2020
IPC in funeral services	Circular of the Italian Ministry of Health. Subject: Emergency indications related to the COVID-19 epidemic concerning the funeral, cemetery and cremation sector (Revision after DPCM April 26, 2020). n. 015280-02/05/2020-DGPRE	Italian Ministry of Health-General Directorate for health prevention	02/05/2020
IPC in funeral services	Circular of the Italian Ministry of Health. Subject: Emergency indications related to the COVID-19 epidemic concerning the funeral, cemetery and cremation sector. n. 012302-08/04/2020-DGPRE	Italian Ministry of Health-General Directorate for health prevention	08/04/2020
IPC in residential health and social care facilities	Circular of the Italian Ministry of Health. Subject: Interim indications for the prevention and control of SARS-CoV-2 infection in residential health and social acre facilities. n. 0013468-18/04/2020-DGPRE-DGPRE-P	Italian Ministry of Health-General Directorate for health prevention and General Directorate of health planning	18/04/2020
Management of fragile and marginalised people	CTS minutes N. 96 July 27, 2020 Management of fragile and marginalised people in the context of the COVID-19 epidemic	ISS	24/07/2020
Mass Gathering	VCTS minutes N. 66 May 4-5-6, 2020. Actions and modalities for the reopening of the Museums	CTS - Italian Civil Protection Department	06/05/2020
Mass Gathering	CTS minutes N. 98 August 5, 2020; N. 96 July 24, 2020 and N 95 July 20, 2020. Opinion on mass gatherings.	CTS - Italian Civil Protection Department	luglio-agosto 2020
Miscellaneous	CTS minutes N. 68 May 8-18, 2020. Opinion on the National Protocol for a Safe Reception. Opinion on the use of eye and face protection for the controllers on board public transport. Opinion on the management and use of aeraulic systems and on the provision of PPE to be provided for all staff of the Prime Minister	CTS - Italian Civil Protection Department	10/05/2020
Miscellaneous	CTS minutes N. 77 May 19, 2020. Evaluation of the resumption of training of Serie A football teams. September 2020 regional and administrative elections.	CTS - Italian Civil Protection Department	21/05/2020
Miscellaneous	CTS minutes N. 82 May 28, 2020. Considerations on air transport. Opinion on resumption of elective surgical activities.	CTS - Italian Civil Protection Department	28/05/2020

Main topic	Document title	Author	Date of issue
	Brief criteria and technical references for the acquisition of PPE and for the evaluation of their preliminary safety features. Answer to the question from the Ministry of Labor and Social Policies on training activities in the field of health and safety at work.		
Miscellaneous	CTS minutes N. 92 July 1-2, 2020. Response to the request of the Extraordinary Commissioner for finding single-seat benches to be distributed to schools. Opinion on the Protocol on the regulation of measures to combat and contain the spread of the COVID-19 during public competitions under the competence of the 'RIPAM' commission.	CTS - Italian Civil Protection Department	1-2/07/2020
Miscellaneous	TCS minutes N. 97 July 30, 2020 Technical document on SARS-CoV-2 infection preventive measures during September 2020 electoral consultations. Opinion on methods of resuming teaching activities for the Academic Year 2020-2021 in Universities.	CTS - Italian Civil Protection Department	30/07/2020
Personal care	Technical document on hypotheses of remodulation of the measures containing the contagion of SARS-CoV-2 in the field of personal care: services of hairdressers and other aesthetic treatments	INAIL-ISS	13/05/2020
Personal care	Technical document on risk analysis and measures to contain SARS-CoV-2 infection in recreational bathing and beach activities	INAIL-ISS	12/05/2020
Personal Protective Equipment (PPE)	Circular of the Italian Ministry of Health. Subject: Novel coronavirus COVID-19 pneumonia - further information, precautions and operational indications on PPE use	Italian Ministry of Health-General Directorate for health prevention	18/03/2020
Personal Protective Equipment (PPE)	Circular of the Italian Ministry of Health. Subject: Novel coronavirus COVID-19 pneumonia - further details on the use of PPE by local police personnel. n. 011392-01/04/2020-DGPRE	Italian Ministry of Health-General Directorate for health prevention	01/04/2020
PPE disposal management; other topics	CTS minutes N. 27 March 14, 2020	CTS - Italian Civil Protection Department	14/03/2020
PPE in health and social health activities	Circular of the Italian Ministry of Health. Subject: Interim indications for a rational use of protections from SARS-CoV-2 infection in health and social-health activities (care for COVID-19 patients) in the current SARS-COV-2 emergency scenario. Updated March 28, 2020. n. 010736-29/03/2020-DGPRE	Italian Ministry of Health-General Directorate for health prevention	29/03/2020
PPE; medical devices	CTS minutes N. 65 May 3, 2020	CTS - Italian Civil Protection Department	03/05/2020
PPE; nasopharyngeal swabs for the detection of SARS-Cov-2	CTS minutes N. 45 April 6, 2020	CTS - Italian Civil Protection Department	06/04/2020
PPE; other topics	CTS minutes N. 28 March 15, 2020	CTS - Italian Civil Protection Department	15/03/2020
Procedures for front-line workers in contact with the public	Circular of the Italian Ministry of Health. Subject: Indications for front-line workers in contact with the public. n. 003190-03/02/2020-DGPRE.	Italian Ministry of Health General Directorate for health prevention	03/02/2020
Procedures for Verification Technicians	Circular of the Italian Ministry of Health. Subject: COVID-19. Operational Recommendations for Verification Technicians. n. 009268-18/03/2020-DGPRE.	Italian Ministry of Health General Directorate for health prevention	18/03/2020
Prophylactic measures for repatriated compatriots	Circular of the Italian Ministry of Health. Subject: Clarifications regarding the Ordinance of the Minister of Health February 21, 2020 containing "Further prophylactic measures against the spread of the infectious disease COVID19". n. 006144-27 / 02/2020-DGPRE	Italian Ministry of Health General Directorate for health prevention	27/02/2020
Protection of oncological and onco-haematological patients	CTS minutes N. 19 March 5, 2020	CTS - Italian Civil Protection Department	05/03/2020
Protocols for religious ceremonies; conducting upper secondary final exams; resumption of teaching activities for the 2020-2021 school year	CTS Minutes N. 73, May 14, 2020	CTS - Italian Civil Protection Department	14/05/2020

Main topic	Document title	Author	Date of issue
Public gaming shops	CTS minutes N. 87 June 8, 2020. Opinion on reopening of casinos, bingo halls, gaming halls and other regulated public gaming shops	CTS - Italian Civil Protection Department	08/06/2020
Questions from Italian Ministry of Justice	CTS Minutes N. 70, May 11, 2020	CTS - Italian Civil Protection Department	11/05/2020
Recommendations for elderly people	CTS Minutes N. 58, April 23, 2020	CTS - Italian Civil Protection Department	23/04/2020
Redefinition of quarantine and isolation modalities, restarting school activities, other topics	CTS Minutes N. 90, June 22, 2020	CTS - Italian Civil Protection Department	22/06/2020
Adjusting COVID-19 containment measures thermal baths and Spas facilities; influenza vaccination campaign 2020-21, other topics	CTS Minutes N. 78, May 21, 2020	CTS - Italian Civil Protection Department	21/05/2020
Resuming close contact sports; other issues related to risk containment measures from SARS-CoV2	CTS minutes N. 91 June 23, 2020	CTS - Italian Civil Protection Department	23/06/2020
Resuming teaching activities for the next school year	CTS minutes N. 81 May 26, 2020	CTS - Italian Civil Protection Department	26/05/2020
Rhino-pharyngeal swabs; management of suspected COVID-19 cases in developmental age	CTS minutes N. 30 March 17, 2020	CTS - Italian Civil Protection Department	17/03/2020
SARS-CoV-2 infection containment measures	Circular of the Italian Ministry of Health. Subject: Indications for the implementation of SARS-CoV-2 containment measures through sanitation procedures of non-sanitary structures (surfaces, internal environments) and clothing. n. 017644 - 22/05/2020-DGPRE	Italian Ministry of Health General Directorate for health prevention	22/05/2020
School	Updating of Technical document on the proposal for remodelling COVID-19 containment measures in the school sector. Approved on the CTS meeting minutes n.90, June 22 2020	CTS - Italian Civil Protection Department	23/06/2020
School	Updating of Technical document on the proposal for remodelling COVID-19 containment measures in the school sector for conducting upper secondary final exam. Approved on the CTS meeting minutes n.73, May 14 2020	CTS - Italian Civil Protection Department	14/05/2020
School	Updating of Technical document on the proposal for remodeling COVID-19 containment measures in the school sector. Approved on the CTS meeting minutes n.82, May 28 2020	CTS - Italian Civil Protection Department	28/05/2020
School	Preventing measures and recommendations for every school students regarding the restart of 20-21 school year. Approved on the CTS meeting minutes n.104, August 31 2020	CTS - Italian Civil Protection Department	31/08/2020
School	Response to the question of Ministry of Education concerning the beginning of 2020-2021 school year. Approved on the CTS meeting minutes n.94, July 7 2020	CTS - Italian Civil Protection Department	07/07/2020
School	Response to the question of Ministry of Education concerning the use of face mask. Approved on the CTS meeting minutes n.100, August 10 2020	CTS - Italian Civil Protection Department	10/08/2020
School	Decree of Ministry of Education n. 80, August 3 2020. Guidance document on the resuming of residential school and educational activities for children aged 0-6	Italian Ministry of Education	03/08/2020
School	Decree of Ministry of Education n. 87, August 6 2020. Agreement protocol for ensuring safety precautions to prevent COVID 19 in reopening schools	Italian Ministry of Education and Unions	06/08/2020
School	Decree of Ministry of Education n. 39, June 26 2020. Adoption of the Document for planning training and educational activities in every institution within the National System of Education for the 2020-2021 school year	Italian Ministry of Education	26/06/2020
School	Ministerial Decree (DPCM), September 7 2020. Annex D. Further provisions implementing the Decree-Law 25 March 2020, n. 19 and the Decree Law 16 May 2020 n.33, on urgent measures to face	Italian Presidency of the Council of Ministers	07/09/2020

Main topic	Document title	Author	Date of issue
	with COVID-19 emergency. (20A04814). *GU Serie Generale*, n. 222, 7/9/2020		
School	Agreement protocol for restarting of residential childhood educational activities ensuring safety precautions to prevent COVID 19	Italian Ministry of Education	ND
School transport	Ministerial Decree (DPCM) August 7, 2020 - Further provisions implementing the Decree-Law March 25, 2020, n. 19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n.198, 8/8/2020). Annex 16 - Guidelines for dedicated school transport	Italian Presidency of the Council of Ministers	08/08/2020
Shopping centres	CTS minutes N. 74 May 15, 2020 Technical document on the hypothesis of remodelling SARS-CoV-2 infection containment measures in the retail sector: shopping centres, shopping parks, factory outlets and markets	CTS - Italian Civil Protection Department	15/05/2020
Social interactions and playing for children and adolescents	Ministerial Decree (DPCM) May 17 2020 - Provisions implementing the Decree-Law 25 March 2020, n. 19 and the Decree Law 16 May 2020 n.33, on urgent measures to face with COVID-19 emergency. (*GU Serie Generale* n. 126, 17/5/2020). Annex 8 – Guildelines for safety management of structured social interations and playing initiatives for children and adolescents during Phase 2 of COVID- 19 emergency	Italian Presidency of the Council of Ministers	17/05/2020
Sport	Circular of the Italian Ministry of Health. Subject: Implementing modalities of quarantine for close contacts of COVID-19 cases, in specific context, such as competitive games of professional team. 0021463-18/06/2020-DGPRE-DGPRE-P	Italian Ministry of Health-General Directorate of health planning	18/06/2020
Sport	CTS minutes N. 65, May 3, 2020.	CTS - Italian Civil Protection Department	03/05/2020
Suspected COVID cases in cruise ships	CTS minutes N. 3 February 12, 2020	CTS - Italian Civil Protection Department	12/02/2020
Thermal and balneal-thermal facilities	CTS minutes N. 78, May 21, 2020. Remoduling containment measures against 19 spreading within balneal-thermal facilities	CTS - Italian Civil Protection Department	21/05/2020
Transport	Circular of the Italian Ministry of Health. Subject: Indications for the remodeling of phase 2 containment measures in relation to collective public transport by land, with a view to resuming commuting, in the context of the SARS-COV-2 emergency. n. 0014916-29/04/2020-DGPRE-DGPRE-P	Italian Ministry of Health	29/04/2020
Transport	Technical document on the hypothesis of remodeling the containment measures in relation to collective public transport by land, with a view to resuming commuting, in the context of the SARS-CoV-2 emergency	INAIL; ISS	27/04/2020
Transport	Ministerial Decree (DPCM) April 26, 2020 - Further provisions implementing the Decree-Law of 23 February 2020, n. 6, containing urgent measures regarding the containment and management of the epidemiological emergency from COVID-19, applicable nationwide. (*GU Serie Generale*, n. 108, 27/4/2020). Annex 8 - Shared protocol for the containment of the spread of COVID-19 in the transport and logistics sector	Italian Presidency of the Council of Ministers	27/04/2020
Transport	Ministerial Decree (DPCM) August 7, 2020 - Further provisions implementing the Decree-Law March 25, 2020, n. 19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n.198, 8/8/2020). Annex 15 - Guidelines for information to users and organizational modalities for limiting the spread of COVID-19 in the field of public transport.	Italian Presidency of the Council of Ministers	08/08/2020

Main topic	Document title	Author	Date of issue
Transport	Ministerial Decree (DPCM) September 7, 2020. Further provisions implementing the Decree-Law March 25, 2020, n. 19, containing urgent measures to face the epidemiological emergency from COVID-19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n. 222 7/9/2020). Annex A	Italian Presidency of the Council of Ministers	07/09/2020
Transport	Ministerial Decree (DPCM) September 7, 2020. Further provisions implementing the Decree-Law March 25, 2020, n. 19, containing urgent measures to face the epidemiological emergency from COVID-19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n. 222 7/9/2020). Annex B.	Italian Presidency of the Council of Ministers	07/09/2020
Transport	Ministerial Decree (DPCM) September 7, 2020. Further provisions implementing the Decree-Law March 25, 2020, n. 19, containing urgent measures to face the epidemiological emergency from COVID-19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n. 222 7/9/2020). Annex C.	Italian Presidency of the Council of Ministers	07/09/2020
Transport	CTS minutes N. 61 April 28, 2020	CTS - Italian Civil Protection Department	28/04/2020
Transport; other topics	CTS minutes N. 55 April 18, 2020	CTS - Italian Civil Protection Department	18/04/2020
Universities	Ministerial Decree (DPCM) September 7, 2020. Further provisions implementing the Decree-Law March 25, 2020, n. 19, containing urgent measures to face the epidemiological emergency from COVID-19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n. 222 7/9/2020) Annex E.	Italian Presidency of the Council of Ministers	07/09/2020
Upper secondary school final exam; other topics	CTS minutes N. 67 May 7, 2020	CTS - Italian Civil Protection Department	18/05/2020
Vaccinations; urgent problems regarding developmental age; other topics	CTS minutes N. 52 April 15, 2020.	CTS - Italian Civil Protection Department	15/04/2020
Waste management	Rapporto ISS COVID-19 n. 3/2020 Rev. 2 - Interim guidance to manage urban waste related to the transmission of the SARS-CoV-2 virus infection. Version of May 31, 2020	ISS	31/05/2020
Worker protection	Framework protocol for the prevention and safety of public employees in the workplace in relation to the health emergency from “COVID-19”. Approved in CTS minutes N. 95, July 16, 2020	Italian Ministry of Public Administration – Unions Rome	24/07/2020
Worker protection	CTS minutes N. 24, March 11, 2020	CTS - Italian Civil Protection Department	11/03/2020
Worker protection	CTS minutes N. 26, March 13, 2020	CTS - Italian Civil Protection Department	13/03/2020
Worker protection	CTS minutes N. 37, March 26, 2020.	CTS - Italian Civil Protection Department	26/03/2020
Worker protection	Circular September 4, 2020 - Indications and clarifications to the circular April 29, 2020 with particular regard to “fragile” workers. n. 00028877-04 / 09/2020-DGPRE-DGPRE-P and n. 13 - 04/09/2020 Ministry of Labor and Social Policies.	Italian Ministry of Health; Italian Ministry of Labour and Social Policies	04/09/2020
Worker protection	Circular of the Italian Ministry of Health. Subject: Operational indications relating to the activities of the occupational health physician in the context of measures to combat and contain the spread of the SARS-CoV-2 virus in the workplace and in the	Italian Ministry of Health	04/09/2020

Main topic	Document title	Author	Date of issue
	community. n 0014915 - 29/04/2020-DGPRE-DGPRE-P.		
Worker protection	Circular no. 1585 September 11, 2020. Interministerial circular of the Ministry of Health and the Ministry of Labor and Social Policies September 4, 2020, n. 13 - Operational indications regarding the procedures for fragile workers with permanent and fixed-term contracts for which the school director is responsible.	Italian Ministry of Education	11/09/2020
Worker protection	Decree-Law March 17, 2020, n. 18 Measures to strengthen the National Health Service and economic support for families, workers and companies connected to the epidemiological emergency from COVID-19 - converted into Law April 24, 2020, n. 27. Art. 15 - (Extraordinary provisions for the production of surgical masks and PPE)	Italian Government	17/03/2020
Worker protection	DPCM August 7, 2020. Further provisions implementing the Decree-Law March 25, 2020, n. 19, and the Decree-Law May 16, 2020, n. 33, containing further urgent measures to deal with the epidemiological emergency from COVID-19. (*GU Serie Generale* n.198 8/8/2020). Art2; Annex 9; Annex 13.	Italian Presidency of the Council of Ministers	08/08/2020
Worker protection	Rapporto ISS COVID-19 n. 32/2020 - Interim guidance on SARS-CoV-2 infection containment and food hygiene in the food service industry. Version of May 27, 2020	ISS	27/05/2020
Worker protection	Rapporto ISS COVID-19 n. 4/2020 Rev. 2 - Interim indications for the prevention and control of SARS-CoV-2 infection in residential social and health facilities. Version of August 24, 2020	ISS	24/08/2020
Worker protection	Rapporto ISS COVID-19 n. 52/2020 - Management of the epidemiological emergency from SARS-CoV-2 in the veterinary university structure. Version of June 11, 2020	ISS	11/06/2020
Worker protection	Rapporto ISS COVID-19 n. 52/2020 - Management of the epidemiological emergency from SARS-CoV-2 in the veterinary university structure. Version of June 11, 2020.	ISS	11/06/2020
Worker protection	Operational instruction March 19, 2020. Covid Emergency - 19. Implementation of art. 15 Decree-Law March 17, 2020, n. 18. Extraordinary PPE validation	INAIL	19/03/2020
Worker protection	Shared protocol for the protection of workers in the cine-audiovisual sector	Italian Ministry of Labour and Social Policies and Unions	07/07/2020
Worker protection	Rapporto ISS COVID-19 n. 25/2020 - Interim recommendations on cleaning and disinfection of non-healthcare settings during COVID-19 health emergency: surfaces, indoor environments and clothing. Version of May 15, 2020	ISS	15/05/2020
Workplace	Technical document on the possible remodeling of the measures to contain the infection from SARS-CoV-2 in the workplace and preventive strategies.	INAIL	23/04/2020
Workplace	Ministerial Decree (DPCM) April 26, 2020 - Further provisions implementing the Decree-Law of 23 February 2020, n. 6, containing urgent measures regarding the containment and management of the epidemiological emergency from COVID-19, applicable nationwide. (*GU Serie Generale*, n. 108 April 27, 2020). Annex 6 - Shared protocol on measures to combat and contain the spread of COVID-19 in the workplace April 24, 2020.	Italian Presidency of the Council of Ministers	27/04/2020

Table A7. Pillar 7: operational tools and measures in response to COVID-19 in the autumn-winter 2020 season in Italy by main topic

Main topic	Document title	Author	Date of issue
Birth pathway	Circular of the Italian Ministry of Health. Subject: Indications for pregnant-parturient, puerperia, newborn and breastfeeding. n.011257-31/03/2020-DGPRE	Italian Ministry of Health-General Directorate for health prevention, General Directorate of health planning	31/03/2020
Clinical and organisational management	Circular of the Italian Ministry of Health. Subject: Emergency indications for healthcare activities and prevention and control measures in Mental Health Departments and in the Infantile Neuropsychiatry Services of Childhood and Adolescence. n. 0014314-23/04/2020-DGPRE-DGPRE-P	Italian Ministry of Health-General Directorate for health prevention, General Directorate of health planning	23/04/2020
Clinical management	Rapporto ISS COVID-19 n. 29/2020 - Interim guidance on Kawasaki disease and acute multisystem inflammatory syndrome in children and adolescents in the current emergency scenario from SARS-CoV-2 infection. Version of May 21, 2020	ISS	21/05/2020
Clinical management	Rapporto ISS COVID-19 n. 48/2020 -Interim immunological strategies for COVID-19 therapy and prevention. Version of June 4, 2020.	ISS	04/06/2020
Clinical management	Rapporto ISS COVID-19 n. 6/2020 - Recommendations to perform autopsies in patients with SARS-CoV-2 infection	ISS	23/03/2020
Clinical management of Rare Diseases	Rapporto ISS COVID-19 n. 14/2020 - Interim guidance for the appropriate support of people with enzymopenia G6PD (favism) in the current SARS-CoV-2 emergency scenario. Version April 14, 2020	ISS	14/04/2020
Clinical surveillance	Rapporto ISS COVID-19 n. 49/2020 - COVID-19: Interim report on definition, certification and classification of causes of death. Version of June 8, 2020	ISS; INAIL; ISTAT	08/06/2020
Clinical surveillance	Healthcare guidelines for critically ill patient affected by COVID-19, February, 28 2020	Expert group: M Antonelli, L Richeldi, R Bernabei, A Villani	29/02/2020
Evaluation of the document on the criteria for the use of invasive and non-invasive systems for the management of acute respiratory failure in adults and related costs	CTS minutes N. 11, February 27, 2020	CTS-Italian Civil Protection Department	27/02/2020
Hospital network management	Rapporto ISS COVID-19 n. 12/2020 - Interim provisions on telemedicine healthcare services during COVID-19 health emergency. Version of April 13, 2020	ISS	13/04/2020
Hospital network management	Rapporto ISS COVID-19 n. 35/2020 - The General Practitioner and the COVID-19 pandemic: some ethical and organizational issues. Version of May 25, 2020.	ISS	25/05/2020
Imaging	Rapporto ISS COVID-19 n. 55/2020 - Current situation on the use of imaging for COVID-19. Version of July 7, 2020.	ISS; University of Tor Vergata	07/07/2020
Laboratory diagnostics/testing strategies	Indications on collecting swabs for SARS-CoV-2 in organ transplant recipients from living and deceased donors, March 16, 2020.	ISS-National transplant Centre; Italian Ministry of Health	16/03/2020
Management of cancer patient	Circular of the Italian Ministry of Health. Subject: Recommendations for the management of cancer and onco-hematology patients during COVID-19 emergency. n.007023-10/03/2020-DGPROGS.	Italian Ministry of Health-General Directorate of health planning	10/03/2020
Management of immunosuppressed patients	Circular of the Italian Ministry of Health. Subject: Recommendations for the management of immunosuppressed patients residing in Italy during the COVID-19 emergency. n.007942-27/03/2020-DGPROGS.	Italian Ministry of Health-General Directorate of health planning	27/03/2020
Maternal and child health	Rapporto ISS COVID-19 n. 44/2020 - Indications of an intervention plan for the management of perinatal anxiety and depression in COVID-19 emergency and post-emergency phase. Version of May 31, 2020	ISS	31/05/2020

Main topic	Document title	Author	Date of issue
Maternal and child health	Rapporto ISS COVID-19 n. 45/2020 - Interim indications for pregnancy, childbirth, breastfeeding and the care of very young children 0-2 years in response to the COVID-19 emergency.	ISS	31/05/2020
Mental health	Rapporto ISS COVID-19 n. 30/2020 - Guidance for the first level telephone intervention aimed at personalized information and empowerment of the general population within the COVID-19 emergency. Version of May 24, 2020.	ISS	24/05/2020
Mental health	Rapporto ISS COVID-19 n. 31/2020 - Interim indications for second level telephone psychological support in the healthcare system in the COVID-19 emergency scenario. Version of May 26, 2020.	ISS	26/05/2020
Mental health/childhood	Rapporto ISS COVID-19 n. 43/2020 - Interim indications for the appropriate support of the children/adolescents' mental health during the pandemic COVID-19. Version of May 31, 2020.	ISS	31/05/2020
Plasma from seroconverted patients for therapeutic use; other topics	CTS minutes N. 4, April 7, 2020	CTS-Italian Civil Protection Department	07/04/2020
Recommendations for the management of immunosuppressed patients	CTS minutes N. 31, March 18, 2020	CTS-Italian Civil Protection Department	18/03/2020
Recovery criteria, antihypertensive drugs	CTS minutes N. 32, March 19, 2020	CTS-Italian Civil Protection Department	19/03/2020
Substance use/devices	Rapporto ISS COVID-19 n. 51/2020 - Food supplements or drugs? Regulations and recommendations for conscious use in time of COVID-19. Version of May 31, 2020	ISS	31/05/2020
Treatments with convalescent plasma or hyperimmune immunoglobulins	CTS minutes N. 51, April 14, 2020	CTS-Italian Civil Protection Department	14/04/2020

Table A8. Pillar 8: operational tools and measures in response to COVID-19 in the autumn-winter 2020 season in Italy by main topic

Main topic	Document title	Author	Date of issue
Blood donations and blood components	Circular of the Italian Ministry of Health. Subject: Epidemiological emergency from COVID-19: blood donations and blood components. n. 0008138-10/03/2020-DGPRE-MDS-P	Italian Ministry of Health General Directorate for health prevention	10/03/2020
Diagnostic devices	Circular of the Italian Ministry of Health. Subject: COVID-19: Diagnostic devices list update n. 012413-08/04/2020-DGPRE.	Italian Ministry of Health- General Directorate for health prevention	08/04/2020
Drugs	Donations of drugs for the COVID-19 emergency, Coordinated by AIFA	AIFA	18/05/2020
Drugs	Procedures for importing lacking drugs and support to regions for the COVID emergency	AIFA	21/05/2020
Operational and logistic support	CTS minutes N. 54, April 17, 2020	CTS-Italian Civil Protection Department	17/04/2020
Worker protection	Circular of the Italian Ministry of Health. Subject: Face masks for medical use and personal protective equipment (PPE) quality and safety requirements verification. n. 0003572 - 18/03/2020-GAB-GAB-P	Italian Ministry of Health	18/03/2020

References

1. World Health Organization. *COVID-19 Strategy Update, 14 April 2020*. Geneva: WHO; 2020. https://www.who.int/docs/default-source/coronaviruse/covid-strategy-update-14april2020.pdf?sfvrsn=29da3ba0_19
2. World Health Organization. *WHO Coronavirus Disease (COVID-19) Dashboard*. Ultima consultazione 18/9/2020. https://covid19.who.int/
3. European Centre for Disease Prevention and Control. *COVID-19 pandemic.* Ultima consultazione 18/9/2020. https://www.ecdc.europa.eu/en/covid-19-pandemic
4. Istituto Superiore di Sanità. *Dati della Sorveglianza integrata COVID-19 in Italia.* Ultima consultazione 18/9/2020. https://www.epicentro.iss.it/coronavirus/sars-cov-2-dashboard
5. European Centre for Disease Prevention and Control. *Rapid Risk Assessment. Outbreak of acute respiratory syndrome associated with a novel coronavirus, China: first local transmission in the EU/EEA – eighth update*. ECDC: Stockholm; 2020. https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-rapid-risk-assessment-coronavirus-disease-2019-eighth-update-8-april-2020.pdf
6. He X, Lau EHY, Wu P, Deng X, Wang J, Hao X, *et al.* Temporal dynamics in viral shedding and transmissibility of COVID-19. *Nat Med* 15 April 2020;1-4.
7. Liu Y, Yan L-M, Wan L, Xiang T-X, Le A, Liu J-M, *et al.* Viral dynamics in mild and severe cases of COVID-19. *Lancet Infect Dis* 2020;20(6)656-7. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30232-2/abstract
8. Li R, Pei S, Chen B, Song Y, Zhang T, Yang W, *et al.* Substantial undocumented infection facilitates the rapid dissemination of novel coronavirus (SARS-CoV-2). *Science* 2020;368(6490):489-93. https://science.sciencemag.org/content/early/2020/03/13/science.abb3221
9. World Health Organization. *Pandemic Influenza Risk Management. A WHO guide to inform & harmonize national & international pandemic preparedness and response*. Geneva: WHO; 2017. (WHO/WHE/IHM/GIP/2017.1) http://www.who.int/influenza/preparedness/pandemic/influenza_risk_management/en/
10. European Centre for Disease Prevention and Control. *Guide to revision of national pandemic influenza preparedness plans - Lessons learned from the 2009 A(H1N1) pandemic.* Stockholm: ECDC; 2017. https://www.ecdc.europa.eu/sites/default/files/documents/Guide-to-pandemic-preparedness-revised.pdf
11. Anderson RM, Heesterbeek H, Klinkenberg D, Hollingsworth TD. How will country-based mitigation measures influence the course of the COVID-19 epidemic? *The Lancet* 2020;395(10228):931-4.
12. Ferguson NM, *et al.* on behalf of the Imperial College COVID-19 Response Team. *Impact of non-pharmaceutical interventions (NPIs) to reduce COVID19 mortality and healthcare demand*. London: Imperial College; 2020. https://www.imperial.ac.uk/media/imperial-college/medicine/sph/ide/gida-fellowships/Imperial-College-COVID19-NPI-modelling-16-03-2020.pdf
13. Gottlieb S, Caitlin Rivers C, McClellan MB, Lauren Silvis L, Watson C. *National Coronavirus Response: a road to reopening.* Washington, DC: American Enterprise Institute; 2020. https://www.aei.org/wp-content/uploads/2020/03/National-Coronavirus-Response-a-Road-Map-to-Recovering-2.pdf
14. World Health Organization. *Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV). 30 January 2020 Statement.* Geneva: WHO; 2020. https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)
15. World Health Organization. *Timeline: WHO's COVID-19 response.* Geneva: WHO; 2020. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/interactive-timeline
16. Ministero della Salute. Circolare n. 1997 del 22 gennaio 2020 "Polmonite da nuovo coronavirus (2019-nCoV) in Cina". https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2020&codLeg=72796&parte=1%20&serie=null

17. Ministero della Salute. *Circolare n. 9774 del 20 marzo 2020. Annullamento e sostituzione della Circolare del Ministero della Salute n. 00*09480 del 19 marzo 2020 "COVID-19: rintraccio dei contatti in ambito di sorveglianza sanitaria e aggiornamento delle indicazioni relative alla diagnosi di laboratorio di casi di infezione da SARS-CoV-2". https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2020&codLeg=73714&parte=1%20&serie=null

18. Ministero della Salute. *Circolare n. 11715 del 3 aprile 2020. Pandemia di COVID-19 – Aggiornamento delle indicazioni sui test diagnostici e sui criteri da adottare nella determinazione delle priorità. Aggiornamento delle indicazioni relative alla diagnosi di laboratorio*. https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2020&codLeg=73799&parte=1%20&serie=null

19. Cereda D, Tirani M, Rovida F, Demicheli V, Ajelli M, Poletti P, *et al.* The early phase of the COVID-19 outbreak in Lombardy, Italy. *ArXiv200309320 Q-Bio* 20 marzo 2020 http://arxiv.org/abs/2003.09320

20. Guzzetta G, Poletti P, Ajelli M, Trentini F, Marziano V, Cereda D, *et al.* Potential short-term outcome of an uncontrolled COVID-19 epidemic in Lombardy, Italy, February to March 2020. *Eurosurveillance* 2020;25(12):2000293.

21. Riccardo F, Ajelli M, Andrianou X, Bella A, Manso MD, Fabiani M, *et al.* Epidemiological characteristics of COVID-19 cases in Italy and estimates of the reproductive numbers one month into the epidemic. *medRxiv*. 11 aprile 2020;2020.04.08.20056861.

22. World Health Organization. Joint WHO and ECDC mission in Italy to support COVID-19 control and prevention efforts. Geneva: WHO; 2020. https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/2/joint-who-and-ecdc-mission-in-italy-to-support-covid-19-control-and-prevention-efforts

23. Italia. Presidenza del Consiglio dei Ministri, Dipartimento della Protezione Civile. Ordinanza 27 febbraio 2020 Ulteriori interventi urgenti di protezione civile in relazione all'emergenza relativa al rischio sanitario connesso all'insorgenza di patologie derivanti da agenti virali trasmissibili. (Ordinanza n. 640). (20A01348). *Gazzetta Ufficiale Serie Generale*, n. 50 del 28 febbraio 2020. http://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=73469

24. Italia. Decreto del Presidente del Consiglio dei Ministri 11 marzo 2020. Ulteriori disposizioni attuative del decreto-legge 23 febbraio 2020, n. 6, recante misure urgenti in materia di contenimento e gestione dell'emergenza epidemiologica da COVID-19, applicabili sull'intero territorio nazionale. (20A01605). *Gazzetta Ufficiale Serie Generale* n. 64 del 11 marzo 2020. http://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=73643

25. World Health Organization. *WHO characterizes COVID-19 as a pandemic*. Geneva: WHO; 2020. https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020#:~:text=WHO%20has%20been%20assessing%20this,to%20use%20lightly%20or%20carelessly

26. Istituto Superiore di Sanità. *Sistema di sorveglianza integrata COVID-19.* https://www.epicentro.iss.it/coronavirus/sars-cov-2-sorveglianza

27. Dipartimento Protezione Civile. *COVID-19 Situazione Italia.* Roma: Presidenza del Consiglio dei Ministri; 2020. http://opendatadpc.maps.arcgis.com/apps/opsdashboard/index.html#/b0c68bce2cce478eaac82fe38d4138b1

28. Presidenza del Consiglio dei Ministri. Allegato 10 "Principi per il monitoraggio del rischio sanitario" al DPCM del 26 aprile 2020 "Ulteriori disposizioni attuative del decreto-legge 23 febbraio 2020, n. 6, recante misure urgenti in materia di contenimento e gestione dell'emergenza epidemiologica da COVID-19, applicabili sull'intero territorio nazionale. (20A02352). *Gazzetta Ufficiale Serie Generale* n. 108 del 27-04-2020. https://www.gazzettaufficiale.it/do/atto/serie_generale/caricaPdf?cdimg=20A02352010000101100 01&dgu=2020-04-27&art.dataPubblicazioneGazzetta=2020-04-27&art.codiceRedazionale=20A02352&art.num=1&art.tiposerie=SG

29. Ministero della Salute. *Decreto del 30 aprile 2020. Emergenza COVID-19: attività di monitoraggio del rischio sanitario connesse al passaggio dalla fase 1 alla fase 2A di cui all'allegato 10 del DPCM 26/4/2020*. https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2020&codLeg=73981&parte=1%20&serie=null

30. INAIL. *Documento tecnico sulla possibile rimodulazione delle misure di contenimento del contagio da SARS-CoV-2 nei luoghi di lavoro e strategie di prevenzione*. Roma: Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro; 2020. https://www.inail.it/cs/internet/docs/alg-pubbl-rimodulazione-contenimento-covid19-sicurezza-lavoro.pdf

31. INAIL-ISS. *Documento tecnico sull'ipotesi di rimodulazione delle misure contenitive in relazione al trasporto pubblico collettivo terrestre, nell'ottica della ripresa del pendolarismo, nel contesto dell'emergenza da SARS-CoV-2.* Roma: Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro, Istituto Superiore di Sanità; 2020. https://www.inail.it/cs/internet/docs/alg-pubbl-documento-tecnico-trasporto-pubblico-covid-2_6443146338089.pdf

32. Ministero della Salute. *COVID-19, illustrati i risultati dell'indagine di sieroprevalenza.* Roma: Ministero della Salute; 2020. http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=4998

33. Ministero della Salute. *Indicazioni operative per la gestione di casi e focolai di SARS-CoV-2 nelle scuole e nei servizi educativi dell'infanzia.* Roma: Ministero della Salute; 2020. http://www.salute.gov.it/portale/documentazione/p6_2_2_1.jsp?lingua=italiano&id=2944

34. Ministero della Salute. Circolare dell'11 agosto 2020. Elementi di preparazione e risposta a COVID-19 nella stagione autunno-invernale. Roma: Ministero della Salute; 2020. https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2020&codLeg=75670&parte=1%20&serie=null

35. Leeb RT, Price S, Sliwa S, *et al.* COVID-19 Trends Among School-Aged Children — United States, March 1–September 19, 2020. *MMWR Morb Mortal Wkly Rep.* 2020;69(39);1410-5 DOI: http://dx.doi.org/10.15585/mmwr.mm6939e2

36. World Health Organization. *High-level virtual meeting on schooling during the COVID-19 pandemic.* Geneva: WHO; 2020. https://www.euro.who.int/en/media-centre/events/events/2020/08/high-level-virtual-meeting-on-schooling-during-the-covid-19-pandemic

37. World Health Organization. *COVID-19 Strategic preparedness and response plan operational planning guidelines to support country preparedness and response.* Geneva: WHO; 2020. https://www.who.int/docs/default-source/coronaviruse/covid-19-sprp-unct-guidelines.pdf?sfvrsn=81ff43d8_4

38. World Health Organization. *COVID-19 operationalization of the global response strategy in the WHO European Region. August 2020.* Copenhagen: WHO Regional Office for Europe; 2020. https://apps.who.int/iris/bitstream/handle/10665/334167/WHO-EURO-2020-1073-408190-55167-eng.pdf

39. World Health Organization. *Updated country preparedness and response status for COVID-19 as of 9 June 2020*. Geneva: WHO; 2020. https://www.who.int/publications/i/item/updated-country-preparedness-and-response-status-for-covid-19-as-of-9-june-2020

40. Filia A, Urdiales AM, Rota MC*. Guida per la ricerca e gestione dei contatti (contact tracing) dei casi di COVID-19. Versione del 25 giugno 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 53/2020)

41. La Rosa G, Mancini P, Bonanno Ferraro G, Veneri C, Iaconelli M, Bonadonna L, Lucentini L, Suffredini E. SARS-CoV-2 has been circulating in Northern Italy since December 2019: Evidence from environmental monitoring. *Sci Total Environ* 2020;750:141711. DOI: 10.1016/j.scitotenv.2020.141711

42. La Rosa G, Iaconelli M, Mancini P, Bonanno Ferraro G, Veneri C, Bonadonna L, Lucentini L, Suffredini E. First detection of SARS-CoV-2 in untreated wastewaters in Italy. *Sci Total Environ.* 2020;736:139652. DOI: https://doi.org/10.1016/j.scitotenv.2020.139652

43. Hart OE, Halden RU. Computational analysis of SARS-CoV-2/COVID-19 surveillance by wastewater-based epidemiology locally and globally: Feasibility, economy, opportunities and challenges. *Sci Total Environ.* 2020;730:138875. DOI: 10.1016/j.scitotenv.2020.138875

44. European Commission. *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Short-term EU health preparedness for COVID-19 outbreaks.* Brussels: European Commission, 2020. https://ec.europa.eu/info/sites/info/files/communication_-_short-term_eu_health_preparedness.pdf

45. World Health Organization. *Status of environmental surveillance for SARS-CoV-2 virus.* Geneva: WHO; 2020. https://www.who.int/news-room/commentaries/detail/status-of-environmental-surveillance-for-sars-cov-2-virus

46. Gruppo di Lavoro ISS, Ministero della Salute, Ministero dell'Istruzione, INAIL, Fondazione Bruno Kessler, Regione Emilia-Romagna, Regione Veneto. *Indicazioni operative per la gestione di casi e focolai di SARS-CoV-2 nelle scuole e nei servizi educativi dell'infanzia. Versione del 28 agosto 2020*. Roma: Istituto Superiore

di Sanità; 2020. (Rapporto ISS COVID-19 n. 58/2020 Rev.). https://www.iss.it/rapporti-covid-19/-/asset_publisher/btw1J82wtYzH/content/id/5470148?

47. Italia. Decreto del Presidente del Consiglio dei Ministri. Ulteriori disposizioni attuative del decreto-legge 25 marzo 2020, n. 19, recante misure urgenti per fronteggiare l'emergenza epidemiologica da COVID-19, e del decreto-legge 16 maggio 2020, n. 33, recante ulteriori misure urgenti per fronteggiare l'emergenza epidemiologica da COVID-19. *Gazzetta Ufficiale Serie Generale* n. 222 del 7 settembre 2020. https://www.gazzettaufficiale.it/eli/id/2020/09/07/20A04814/sg

48. Italia. Legge del 17/07/2020 n. 77. Conversione in legge, con modificazioni, del decreto-legge 19 maggio 2020, n. 34, recante misure urgenti in materia di salute, sostegno al lavoro e all'economia, nonche' di politiche sociali connesse all'emergenza epidemiologica da COVID-19. *Gazzetta Ufficiale* n. 180 del 18 luglio 2020 - Allegato. https://def.finanze.it/DocTribFrontend/getAttoNormativoDetail.do?ACTION=getArticolo&id=%7BBD9BD795-8B0D-43A3-B02A-27121FB87DED%7D&codiceOrdinamento=600000000000000&articolo=Allegato

49. GISAID Iniziative [Homepage]. https://www.gisaid.org/

50. Ministero della Salute. Circolare n. 5443 del 22 febbraio 2020. COVID-2019. Nuove indicazioni e chiarimenti. https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2020&codLeg=73195&parte=1%20&serie=null

51. Mancini F, Barbanti F, Scaturro M, Fontana S, di Martino A, Marsili G, Puzelli S, Calzoletti L, Facchini M, Di Mario G, Fabiani C, Bella A, Riccardo F, Pezzotti P, Stefanelli P, Rezza G, Ciervo A. Multiplex rt-Real Time PCR assays for diagnostic testing of SARS-CoV-2 and seasonal influenza viruses. A challenge of the phase 3 pandemic setting. Submitted

52. Lohse S, Pfuhl T, Berkó-Göttel B, Rissland J, Geißler T, Gärtner B, Becker SL, Schneitler S, Smola S. Pooling of samples for testing for SARS-CoV-2 in asymptomatic people. *Lancet Infect Dis.* 2020; (published online April 28.) DOI: https://doi.org/10.1016/S1473-3099(20)30362-5

53. Gruppo di lavoro ISS Prevenzione e controllo delle Infezioni. *Indicazioni ad interim per l'effettuazione dell'isolamento e della assistenza sanitaria domiciliare nell'attuale contesto COVID-19. Versione del 24 luglio 2020*. Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n.1/ 2020 Rev.)

54. Gruppo di lavoro ISS Prevenzione e controllo delle Infezioni. *Indicazioni ad interim per un utilizzo razionale delle protezioni per infezione da SARS-CoV-2 nelle attività sanitarie e sociosanitarie (assistenza a soggetti affetti da covid-19) nell'attuale scenario emergenziale SARS-CoV-2 . Versione del 10 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n. 2/ 2020 Rev. 2).

55. Gruppo di lavoro ISS Prevenzione e controllo delle Infezioni – COVID-19. *Indicazioni ad interim per la prevenzione e il controllo dell'infezione da SARS-CoV-2 in strutture residenziali sociosanitarie e socioassistenziali. Versione del 24 agosto 2020.* Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n. 4/ 2020 Rev 2.).

56. Gruppo di lavoro ISS Ambiente e Qualità dell'aria indoor. *Indicazioni ad interim per la prevenzione e gestione degli ambienti indoor in relazione alla trasmissione dell'infezione da virus SARS-CoV-2. Versione del 25 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 5/ 2020 Rev. 2).

57. Gruppo di Lavoro ISS Prevenzione e Controllo delle Infezioni COVID-19. *Indicazioni ad interim per la sanificazione degli ambienti interni nel contesto sanitario e assistenziale per prevenire la trasmissione di SARS-CoV 2. Versione del 7 luglio 2020*. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 20/2020 Rev. 2).

58. Gruppo di Lavoro ISS Biocidi COVID-19. *Raccomandazioni ad interim sulla sanificazione di strutture non sanitarie nell'attuale emergenza COVID-19: superfici, ambienti interni e abbigliamento. Versione del 15 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 25/2020)

59. INAIL-ISS. *Documento tecnico sull'analisi di rischio e le misure di contenimento del contagio da SARS-CoV-2 nelle attività ricreative di balneazione e in spiaggia.* Roma: Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro, Istituto Superiore di Sanità; 2020. https://www.inail.it/cs/internet/docs/alg-pubbl-doc-tencico-att-ricr-balenzione-spiaggia-covid-2.pdf

60. INAIL-ISS. *Documento tecnico su ipotesi di rimodulazione delle misure contenitive del contagio da SARS-CoV-2 nel settore della cura della persona: servizi dei parrucchieri e di altri trattamenti estetici.* Roma: Istituto

Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro, Istituto Superiore di Sanità; 2020. https://www.inail.it/cs/internet/docs/alg-pubbl-doc-tecn-ipotesi-rimod-parrucchieri-trat-estetici.pdf

61. INAIL-ISS. *Documento tecnico su ipotesi di rimodulazione delle misure contenitive del contagio da SARS-CoV-2 nel settore della ristorazione*. Roma: Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro, Istituto Superiore di Sanità; 2020. https://www.inail.it/cs/internet/docs/alg-pubbl-doc-tec-ipotesi-rimod-misure-cont-ristoraz-covid-2_6443147014458.pdf
62. Governo Italiano - Presidenza del Consiglio dei Ministri. *Commissario straordinario per l'emergenza COVID-19.* Roma: Governo Italiano; 2020. http://www.governo.it/it/cscovid19
63. Governo Italiano Presidenza del Consiglio dei Ministri. *Attività*. Roma: Governo Italiano; 2020. http://www.governo.it/it/dipartimenti/commissario-straordinario-lemergenza-covid-19/cscovid19-attivita/14420
64. National Institutes of Health. *COVID-19 Treatment Guidelines. Management of persons with COVID-19*. Bethesda, MD NIH; 2020. https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf
65. World Health Organization. *Clinical management of COVID-19; Interim guidance 27 May 2020*. Geneva: WHO; 2020. https://apps.who.int/iris/bitstream/handle/10665/332196/WHO-2019-nCoV-clinical-2020.5-eng.pdf?sequence=1&isAllowed=y
66. Siddiqi HK, Mehra MR. COVID-19 illness in native and immunosuppressed states: A clinical-therapeutic staging proposal. *J Heart Lung Transplant* 2020;39(5):405-7. DOI: 10.1016/j.healun.2020.03.012
67. The RECOVERY Collaborative Group, Horby P, Lim WS, *et al.* Dexamethasone in hospitalized patients with COVID-19 - Preliminary Report. *N Engl J Med.* 2020 Jul 17;NEJMoa2021436. doi: 10.1056/NEJMoa2021436
68. Dequin PF, Heming N, Meziani F, *et al.* Effect of hydrocortisone on 21-day mortality or respiratory support among critically Ill patients with COVID-19: a randomized clinical trial *JAMA* 2020;324(13):1298-306. doi:10.1001/jama.2020.16761
69. Prescott HC, Rice TW. Corticosteroids in COVID-19 ARDS: evidence and hope during the pandemic. *JAMA* 2020;324(13):1292-5. doi:10.1001/jama.2020.16747
70. Tomazini BM, Maia IS, Cavalcanti AB, *et al.* Effect of Dexamethasone on days alive and ventilator-free in patients with moderate or severe acute respiratory distress syndrome and COVID-19: The CoDEX Randomized Clinical Trial. *JAMA* 2020;324(13):1307-16. doi:10.1001/jama.2020.17021
71. Writing Committee for the REMAP-CAP Investigators, Angus DC, Derde L, *et al.* Effect of Hydrocortisone on mortality and organ support in patients with severe COVID-19: The REMAP-CAP COVID-19 Corticosteroid Domain Randomized Clinical Trial. *JAMA* 2020;324(13):1317-29. doi:10.1001/jama.2020.17022 [
72. WHO Rapid Evidence Appraisal for COVID-19 Therapies (REACT) Working Group, Sterne JAC, Murthy S, *et al.* Association between administration of systemic corticosteroids and mortality among critically Ill patients with COVID-19: A Meta-analysis. *JAMA* 2020;324(13):1330-41. doi:10.1001/jama.2020.17023
73. World Health Organization. *Corticosteroids for COVID-19. Living Guidance.* Geneva: WHO; 2020. https://www.who.int/publications/i/item/WHO-2019-nCoV-Corticosteroids-2020.1
74. Beigel JH, Tomashek KM, Dodd LE, *et al.* Remdesivir for the treatment of COVID-19 - Preliminary Report [published online ahead of print, 2020 May 22]. *N Engl J Med.* 2020
75. Agenzia Italiana del Farmaco. *Procedura di richiesta per il farmaco Veklury® (remdesivir).* Roma: AIFA; 2020. https://www.aifa.gov.it/-/procedura-di-richiesta-per-il-farmaco-veklury-remdesivir-
76. Wang Y, Zhang D, Du G, *et al.* Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial. *Lancet* 2020;395:1569-78
77. Spinner CD, Gottlieb RL, Criner GJ, *et al.* Effect of remdesivir vs standard care on clinical status at 11 days in patients with moderate COVID-19: a randomized clinical trial. *JAMA* 2020;324(11):1048-57
78. Goldman JD, Lye DCB, Hui DS, *et al.* Remdesivir for 5 or 10 Days in Patients with Severe COVID-19. *N Engl J Med*. 2020 May 27;NEJMoa2015301
79. Wichmann D, Sperhake JP, Lütgehetmann M, *et al.* Autopsy Findings and Venous Thromboembolism in Patients With COVID-19: A Prospective Cohort Study. *Ann Intern Med.* 2020;173(4):268-77

80. Carsana L, Sonzogni A, Nasr A, *et al.* Pulmonary post-mortem findings in a series of COVID-19 cases from northern Italy: a two-centre descriptive study. *Lancet Infect Dis*. 2020;20(10):1135-40

81. Tang N, Bai H, Chen X, *et al.* Anticoagulant treatment is associated with decreased mortality in severe coronavirus disease 2019 patients with coagulopathy. *J Thromb Haemost*. 2020;18(5):1094-9

82. Helms J, Tacquard C, Severac F, *et al.*; CRICS TRIGGERSEP Group (Clinical Research in Intensive Care and Sepsis Trial Group for Global Evaluation and Research in Sepsis). High risk of thrombosis in patients with severe SARS-CoV-2 infection: a multiCentre prospective cohort study. *Intensive Care Med* 2020;46(6):1089-98

83. Llitjos JF, Leclerc M, Chochois C, *et al.* High incidence of venous thromboembolic events in anticoagulated severe COVID-19 patients. *J Thromb Haemost* 2020;18(7):1743-6

84. Poissy J, Goutay J, Caplan M, *et al.*; Lille ICU Haemostasis COVID-19 Group. Pulmonary embolism in patients with COVID-19: Awareness of an increased prevalence. *Circulation* 2020;142(2):184-6

85. Klok FA, Kruip MJHA, van der Meer NJM, *et al.* Incidence of thrombotic complications in critically ill ICU patients with COVID-19. *Thromb Res* 2020;191:145-7

86. Lodigiani C, Iapichino G, Carenzo L, *et al.*; Humanitas COVID-19 Task Force. Venous and arterial thromboembolic complications in COVID-19 patients admitted to an academic hospital in Milan, Italy. *Thromb Res* 2020;191:9-14

87. Thomas W, Varley J, Johnston A, *et al.* Thrombotic complications of patients admitted to intensive care with COVID-19 at a teaching hospital in the United Kingdom. *Thromb Res* 2020;191:76-7

88. Paranjpe I, Fuster V, Lala A, *et al.* Association of treatment dose anticoagulation with in-hospital survival among hospitalized patients with COVID-19. *J Am Coll Cardiol* 2020;76(1):122-4

89. Motta JK, Ogunnaike RO, Shah R, *et al.* Clinical outcomes with the use of prophylactic versus therapeutic anticoagulation in COVID-19. *medRxiv* 2020.07.20.20147769; DOI: https://doi.org/10.1101/2020.07.20.20147769 [pre-print]

90. Guaraldi G, Meschiari M, Cozzi-Lepri A, *et al.* Tocilizumab in patients with severe COVID-19: a retrospective cohort study. *Lancet Rheumatol* 2020;2(8):e474-e484

91. Biran N, Ip A, Ahn J, *et al.* Tocilizumab among patients with COVID-19 in the intensive care unit: a multicentre observational study. *Lancet Rheumatol* 2020;2(10):e603-e612

92. Sanofi Media Relations. *Sanofi provides update on Kevzara® (sarilumab) Phase 3 trial in severe and critically ill COVID-19 patients outside the U.S.* Paris: SANOFI; 2020. https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/media-room/press-releases/2020/2020-09-01-07-00-00-2086564-en.pdf

93. Roche Group Media Relations. *Roche provides an update on the phase III COVACTA trial of Actemra/RoActemra in hospitalised patients with severe COVID-19 associated pneumonia*. July 29, 2020. https://www.roche.com/investors/updates/inv-update-2020-07-29.htm

94. Indiana Pharmacists. *Phase 3 EMPACTA Study: Tocilizumab shows efficacy in COVID-19 associated pneumonia*. Greensburg, IN: Indiana Pharmacists Association; 2020. https://www.indianapharmacists.org/news/phase-3-empacta-study-tocilizumab-shows-efficacy-in-covid-19-associated-pneumonia/

95. Li L, Zhang W, Hu Y, *et al.* Effect of Convalescent plasma therapy on time to clinical improvement in patients with severe and life-threatening COVID-19: a randomized clinical trial. *JAMA*. 2020;324(5):460-70

96. Paul AK, *et al.* for the National Institutes of Health COVID-19 Treatment Guidelines Panel. *Ann Intern Med.* 2020 Sep 25. doi: 10.7326/M20-6448

97. Fagiuoli S, Lorini FL, Remuzzi G. Adaptations and lessons in the province of Bergamo. *N Engl J Med* 2020;382(21):e71

98. Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri. *Linee di indirizzo organizzative per il potenziamento della rete ospedaliera per emergenza COVID-19, art 2 decreto-legge 19 maggio 2020 n. 34.* Roma: FNOMCEO; 2020. https://portale.fnomceo.it/wp-content/uploads/2020/05/Copia_DocPrincipale_Circolare_Rete_Ospedaliera_-_28.5.2020.pdf

99. Bauer J, Brüggmannet D, Klingelhöfer D, *et al.* Access to intensive care in 14 European countries: a spatial analysis of intensive care need and capacity in the light of COVID-19. *Intensive Care Med* 2020 Sep 4;1-9.

100. ARDS Definition Task Force; V Marco Ranieri, Gordon D Rubenfeld, B Taylor Thompson, *et al.* Acute respiratory distress syndrome: the Berlin Definition. *JAMA* 2012;307(23):2526-33

101. Grasselli G, Tonetti T, Protti A, *et al.* Pathophysiology of COVID-19-associated acute respiratory distress syndrome: a multicentre prospective observational study. *Lancet Respir Med.* 2020:S2213-2600(20)30370-2

102. Grieco DL, Bongiovanni F, Chen L, *et al.* Respiratory physiology of COVID-19-induced respiratory failure compared to ARDS of other etiologies. *Crit Care* 2020;24(1):529

103. Ramanathan K, Antognini D, Combes A, *et al.* Planning and provision of ECMO services for severe ARDS during the COVID-19 pandemic and other outbreaks of emerging infectious diseases. *Lancet Respir Med* 2020;8(5):518-26

104. Alhazzani W, Hylander Møller M, Arabi YM, *et al.* Surviving Sepsis Campaign: guidelines on the management of critically ill adults with Coronavirus Disease 2019 (COVID-19). *Intensive Care Med.* 2020;48(6):e440-e469

105. Antonelli M, Conti G, Pelosi P *et al.* New treatment of acute hypoxemic respiratory failure: noninvasive pressure support ventilation delivered by helmet--a pilot controlled trial. *Crit Care Med.* 2002;30(3):602-8

106. Patel BK, Wolfe KS, Pohlman AS, *et al.* Effect of noninvasive ventilation delivered by helmet vs face mask on the rate of endotracheal intubation in patients with Acute Respiratory Distress Syndrome. A randomized clinical trial. *JAMA* 2016;315(22):2435-2441

107. Coppo A, Bellani G, Winterton D, *et al.* Feasibility and physiological effects of prone positioning in non-intubated patients with acute respiratory failure due to COVID-19 (PRON-COVID): a prospective cohort study. *Lancet Respir Med* 2020;8(8):765-774

108. World Health Organization. *Coronavirus disease (COVID-19) technical guidance: Patient management.* Geneva: WHO; 2020. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management

109. Petrucci N, De Feo C. Lung protective ventilation strategy for the acute respiratory distress syndrome. *Cochrane Database Syst Rev* 2013;2013(2):CD003844

110. Grasselli G, Zangrillo A, Zanella A, *et al.* Baseline characteristics and outcomes of 1591 patients infected with SARS-CoV-2 admitted to ICUs of the Lombardy Region, Italy. *JAMA* 2020;323(16):1574-81

111. Bellani G, Laffey JG, Pham T, *et al.* Noninvasive ventilation of patients with Acute Respiratory Distress Syndrome. Insights from the LUNG SAFE Study. *Respir Crit Care Med* 2017;195(1):67-77

112. Grasselli G, Greco M, Zanella A, *et al.* Risk factors associated with mortality among patients with COVID-19 in Intensive Care Units in Lombardy, Italy. *JAMA Intern Med* 2020 Jul 15:e203539

113. Stevens PE, Levin A, Kidney Disease: Improving Global Outcomes Chronic Kidney Disease. Guideline Development Work Group Members. Evaluation and management of chronic kidney disease: synopsis of the kidney disease: improving global outcomes 2012 clinical practice guideline. *Ann Intern Med.* 2013;158(11):825-30

114. Italia. Decreto del Presidente del Consiglio dei Ministri 17 maggio 2020 Disposizioni attuative del decreto-legge 25 marzo 2020, n. 19, recante misure urgenti per fronteggiare l'emergenza epidemiologica da COVID-19, e del decreto-legge 16 maggio 2020, n. 33, recante ulteriori misure urgenti per fronteggiare l'emergenza epidemiologica da COVID-19. (20A02717). *Gazzetta Ufficiale Serie Generale* n.126 del 17 magio 2020. https://www.gazzettaufficiale.it/eli/id/2020/05/17/20A02717/sg

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