"Risk assessment by SARS-CoV-2 and remodulation of the containment measures of the contagion for the National Institute of Infectious Diseases Lazzaro Spallanzani"

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1. Purpose of the document

Following the National Coronavirus emergency on January 31, 2020, it was necessary, in all areas of work, a reshaping of risk analysis and prevention measures to be taken.

The following document is presented as an integral part of the risk assessment prepared for the National Institute of Infectious Diseases - "Lazzaro Spallanzani", located in via Portuense 292, Rome, with the aim of assessing the risk from infection with New Coronavirus SARS-CoV-2 and propose possible containment measures in the hospital.

The Lazzaro Spallanzani hospital, during the Coronavirus emergency, played a fundamental role at the national level. The Institute has been designated as a health reference point for the city of Rome and included in the regional network of infectious diseases of the Lazio Region with a coordinating role with respect to all regional health structures, to ensure that all citizens suspected of acute infectious disease can be admitted wherever they are. Moreover the Institute, since the first moments of the Coronavirus emergency, pursues research objectives on COVID-19.

The document is composed mainly of two parts: in the first one is reported a possible methodology for the assessment of the biological risk COVID-19, operated with the scope of the validity of Legislative Decree no. 81/2008, in order to quantify the dangers arising from the activities carried out by the employees of the Spallanzani hospital; the second part focused on the adoption of prevention, protection and organizational measures to contain the spread of COVID-19 virus in health care environments.

This assessment covers the period from February to May 2020, relating to Phase 1 of the Coronavirus emergency; therefore the data analysed and the results found are limited by the few studies on COVID-19 virus.
2. Generality

2.1 Regulations for COVID-19

With the Ordinance of the Minister of Health of 30 January, Italy blocked all flights to and from China for 90 days, in addition to those from Wuhan, already suspended by the Chinese authorities, following the first cases involving Chinese tourists.

Following the adoption of D.L. No. 6 of 23 February 2020, "Urgent measures in the field of containment and management of the epidemiological emergency by COVID-19", attention was drawn to the importance of adopting correct preventive measures by the general population, stressing the need to ensure the strict application of infection prevention and control measures in all healthcare facilities.

The provisions of Group 2 of Annex XLVI Title "Exposure to biological agents" of Legislative Decree 81/2008 already set out the employer’s obligations with regard to the protection of the health and safety of workers, which include technical measures, organizational, procedural, hygienic, emergency, information and training, health surveillance; such measures shall be taken in relation to the risk assessment. The latter must also take into account (Art. 271, c. 1, e) "any further situations made known by the competent health authority that may affect the risk", as is the current pandemic emergency situation by SARS-CoV-2. Therefore, the existing protection measures for the risk from biological agents should be complemented by the indications identified ad hoc by the reference bodies at national and international level.

Workers must comply with all the prevention measures identified. Chapter 1 of art. 20 of Decree D.Lgs 81/2008, according to which "every worker must take care of his own health and safety and that of other persons present at work, on which fall the effects of his actions or omissions…", applied to the context of the health sector should reflect on the close relationship between health protection, occupational safety and clinical risk management, even more specific and critical in pandemic management situations.

Therefore, an integrated approach is desirable, including risk assessment and management, training, information, awareness raising, communication and
monitoring over time, including with a view to continuous improvement of work organisation.

Among the measures adopted was the order of 22 March 2020, signed jointly by the Minister of Health and the Minister of the Interior, which prohibited all natural persons to move or move by public or private means of transport a municipality other than the one in which they are located, except for proven work requirements, of absolute urgency or for health reasons. The measure also provided for the closure of non-essential or strategic production activities. Groceries, pharmacies, grocery stores and essential services remain open. The same provisions apply, cumulatively to the Dpcm 11 March 2020 as well as to those provided by the order of the Minister of Health of 20 March 2020 whose terms of effectiveness, already fixed on 25 March 2020, are both extended to 3 April 2020.

With the April 2020 DPCM 1, all measures to combat the spread of coronavirus infection have been extended until 13 April 2020. The DPCM 1 will be extended until April 2020. The decree entered into force on 4 April also suspends the training sessions of athletes, professionals and non-professionals, within the sports facilities of all types.

Then with the DPCM 10 April 2020 all measures were extended until 3 May. The Dpcm has allowed the reopening from April 14 of shops for babies and children, bookstores and bookcase.

With the DPCM 26 April 2020 the measures for the containment of the emergency Covid-19 of the so-called "phase two" are specified.

The provisions of the Decree shall apply from 4 May 2020 in place of those of the DPCM 10 April 2020 and shall be effective until 17 May 2020, except as provided for the activities of companies, which shall apply from 27 April 2020 cumulatively. Lastly, Decree-Law 33 of 2020 regulates the end of travel restrictions and the reopening of productive, commercial and social activities from 18 May to 31 July. With the DPCM 17 May 2020 have been defined the prevention and containment measures for cohabitation with coronavirus.
2.2 What is COVID-19?

On 31 December 2019, the Chinese health authorities reported an outbreak of febrile syndrome, associated with pneumonia of unknown origin, among the inhabitants of Wuhan, in central-southern China. The starting point of the infection has been identified in the "wet market" of Huanan, in the center of the city of Wuhan, which was closed on January 1, 2020. On 7 January the pathogen responsible for the epidemic was isolated: it is a new betacoronavirus, which the World Health Organization (WHO) called SARS-CoV-2, to indicate similarity with the SARS virus, which in 2002-2003 caused a global epidemic with 8,096 confirmed cases and 774 deaths. The disease has been called COVID-19 (acronym for Coronavirus disease), as announced in February 2020 by the Director General of the World Health Organization, Tedros Adhanom Ghebreyesus.

The virus belongs to the more general Coronavirus family. To date, 7 human coronaviruses are known:

1. Human Coronavirus 229E (Coronavirus alpha).
2. Human Coronavirus NL63 (Coronavirus alpha).
3. Human Coronavirus OC43 (Coronavirus beta).
4. Human Coronavirus HKU1 (Coronavirus beta).
5. SARS-CoV (Coronavirus beta that caused the Severe Acute Respiratory Syndrome of 2002, epidemic started from China that infected about 8,100 people, among which it caused a mortality of 9.5%).
6. MERS-CoV (Coronavirus beta that caused the Middle East Respiratory Syndrome of 2012, epidemic started by Saudi Arabia that infected about 2,500 people including caused a mortality of 35%).

The first 4 of the list are very common and are also called "cold virus", while the last 3 have been identified in these last few years.
The name "coronavirus" comes from their appearance under the electron microscope, where the proteins placed on their outer surface create an image of a crown. These proteins are precisely those that allow the virus to attach itself to the cell membrane of the cells that will then infect.

At first, the infection was confined almost exclusively to China, but by mid-February it had spread rapidly throughout the world. The global numbers are growing steadily: based on the data provided daily by the European Agency for Disease Prevention and Control, integrated with those that for Italy provides the National Civil Protection.

The COVID-19 has been defined as a "pandemic" by the Director General of the WHO, as it is an epidemic disease that, spreading rapidly among people, expands in vast geographical areas, therefore involving a large part of the world population, in the disease itself or in the simple risk of contracting it. Such a situation presupposes the lack of immunization of the man towards a highly virulent pathogen.
2.2.1 How did the infection happen?

Coronaviruses are carried to humans by intermediate hosts. The contagion from COVID-19 has been of zoonotic type, that is caused from the transmission of the virus from animal to man, in this case, through a phenomenon defined jump of species (or spill over).

In this case, the severity of the condition depends on the fact that, if the virus is new, our immune system does not know it because it has never come into contact with him, does not know how to defend itself and suffers the attack that becomes particularly violent and dangerous in immunologically weak or immunodepressed subjects, especially the elderly carriers of important chronic diseases or other subjects particularly weak at the immune level, cardiopulmonary, renal or metabolic.

WHO pointed to the close analogy between the viral sequence of the isolated pathogen in Wuhan and, believed to be responsible for the epidemic, with that of two coronaviruses that cause severe acute respiratory syndrome similar to bat SARS. From the research it seems therefore to emerge that the SARS-CoV-2 originates from bats and that it has developed mutations that have made it capable of infecting man. However, the passage from bat to man does not appear to have been direct.

We still do not know exactly what was the animal that transmitted the virus to man: it seems likely, however, even in the light of what happened in the epidemics that have occurred to date, that the tank of coronaviruses was a mammal, which could be among those sold at the Wuhan market.

The mutation of the antigenic order is one of the most vigorous weapons available to microorganisms.

2.3 Characteristics of the virus

The characteristics that delineate viruses are transmissibility and lethality.

*Transmissibility* is defined as the propensity of a microorganism to spread within a natural receptive population (by direct or indirect contact).
Transmissibility depends on:

1. from the total length of the time interval in which the host is contagious, the longer the period and the greater the number of people who may be infected;
2. from the amount of pathogen excreted by the host, the higher the number of sneezes and coughs emitted, the higher the possibility of contagion;
3. the possibility of contagion in the absence of symptoms, which is contact with asymptomatic individuals.

The diffusion capacity of a micro-organism is expressed by its basic reproductive rate, the $R_0$ index.

$R_0$ is defined as the average number of secondary cases produced by a primary infection in an entirely susceptible population. It indicates how many people can infect every single patient infected with a specific pathogen, so the higher its value, the greater the chance of spreading in the population.

The susceptibility, or receptivity, of the host to a microbial agent is its ability to host and permit its development. This parameter is affected by some factors, including immunization to that disease. If the population that is exposed to the germ has already been affected in the past or if it has been vaccinated for that disease, the susceptibility will be low, otherwise, as is happening for SARS-CoV-2 and as always occurs in the case of a new virus, the impact of this factor is maximum.

Another factor to be evaluated regarding the contagiousness, is the phenomenon of the superdiffusers, that is, some individuals are able to bear, in front of a very light symptomatology, relatively high viral charges. This resistance allows them to work and perform all normal daily activities, contributing to the circulation of the virus.

The spread of the disease leads to a progressive increase in the number of immune individuals, that is, they have contracted the infection and produced specific antibodies. When subjects no longer susceptible to infection reach a significant percentage in the population, herd immunity is achieved. It is clear that, if the protection guaranteed by the acquisition of the infection is not definitive, for example because the virus mutates, the immunity of the flock cannot be reached definitively. This is why flu vaccination must be repeated every year.
The death rate is equal to the ratio of the number of deaths caused by the infection to the number of people infected in the same period of time. This value therefore represents the probability that an infected person dies due to the infection itself. SARS-CoV-2, at least according to the numbers available today, has an average lethality of about 2%, which reaches its maximum in people aged 80 and over and its minimum in the group under 39 years. The lethality of the new coronavirus grows in patients with cardiovascular disease, diabetics and people already affected by chronic respiratory diseases and hypertension.

The incubation period is defined as the time interval between contagion and the development of clinical symptoms. Its duration varies depending on the type of pathogen, host characteristics and numerous other factors. For SARS-CoV-2, the incubation period may be from a minimum of 1 to a maximum of 15 days.

Below is a graph of the Rt index that is the transmissibility index for each Italian region, data taken on 27/04/2020.

![Graph of Rt index for Italian regions](image)

**Figure 2** Summary estimate of net reproduction number Rt of regions as at 27/04/2020

2.3.1 How COVID-19 is transmitted

SARS-CoV-2 may be transmitted from person to person after close contact with an infected person. The close contact of a confirmed possible case is defined, according to the indications of the European Center for Disease Control and prevention (ECDC), as:
- a person living in the same house as a COVID-19 case;
- a person who had direct physical contact with a COVID-19 case (such as a handshake);
- a person who has had unprotected direct contact with the secretions of a case of COVID-19 (for example, touching bare hands used paper handkerchiefs)
- a person who had a direct face-to-face contact with a case of COVID-19, at a distance of less than 2 m and longer than 15 minutes;
- a person who has been in a closed environment (e.g., classroom, meeting room, hospital waiting room, office) with a COVID-19 case for at least 15 minutes at a distance less than two meters;
- a health professional or other person providing direct assistance to a case of COVID-19 or laboratory personnel handling samples from a case of COVID-19 without the use of recommended PPE or by the use of unsuitable PPE;
- a person who has been seated in an airplane in the two adjacent seats in any direction of a COVID-19 case, travelling companions or carers and crew members assigned to the section of the aircraft where the case index was seated (where the index case has a serious symptomatology or has travelled within the aircraft resulting in increased exposure of passengers, all passengers seated in the same section of the aircraft or throughout the aircraft should be treated as close contact).

The epidemiological link may have taken place within a period of 14 days prior to the occurrence of the disease in the present case.

Interhuman transmission occurs through the droplets of the breath (droplets) of the infected person, which are expelled by coughing, sneezing or normal breathing, and which are deposited on objects and surfaces around the person. The entrance doors of the virus are the mouth, the nose and the eyes: the contagion happens inhaling through the breath the droplets emitted from a sick person, or through personal direct contact, or touching contaminated surfaces and then touching the mouth, your nose or your eyes with your hands.
Even tears can spread the contagion: the researchers of the National Institute of Infectious Diseases "Lazzaro Spallanzani" have in fact isolated the virus in the eye swabs of a patient.

Based on the information gathered so far, it appears that the virus survives on the surface for a few hours. Cleansing with disinfectants containing 75% ethanol (common alcohol for floors) or 1% chlorine (bleach) allows to neutralize the virus. However, contamination by contact with contaminated surfaces in public environments (such as subways and trains) is considered highly unlikely.

Transmission in the absence of symptoms has already been observed. Social distancing measures are therefore the only possibility of protection against this specific risk.

The danger of gold-fecal transmission appears to be low. While it is true that the presence of the virus has been confirmed in the faeces of some infected individuals this does not appear to be the hallmark of this epidemic.

While we are waiting for the research to clarify this route of transmission, it is appropriate to observe the common hygienic norms, including the careful washing of the hands after having used the bath and before eating.

### 2.4 Symptoms

The most common symptoms of COVID-19, which include fever, dry coughing and fatigue, appear gradually and in an initially mild form. Some patients may experience symptoms such as joint pain, nasal congestion, throat pain, or dysentery. The first contact of the host with the virus identifies the infection; only when the infection generates clinical symptoms the infected person is defined sick.

In 80% of cases the infection is asymptomatic, paucisintomatic (accompanied by symptoms not relevant) or generates a disease characterized by manifestations similar to those of the flu. Differential diagnosis is difficult and is only allowed with certainty by microbiological examination of a sample taken with the pharyngeal swab and using the technique of PCR (Polymerase Chain Reaction), an examination that provides the result in only 2-3 hours. This 80% of patients recover without the need for specific care. The presence of numerous asymptomatic or paucisintomatic
cases is of dual value: on the one hand, an obvious advantage, on the other hand, one of the reasons why contagion is so widespread.

With the passing of the days, in some individuals breathing difficulties may appear, about 20% of the patients. Fever, coughing and breathing difficulties are the symptoms that must be directed towards the medical consultation.

In the most serious cases, the virus can trigger pneumonia, severe acute respiratory syndrome, kidney failure and, in some cases, death, which occurs in 2% of those infected.

In cases with more serious symptoms, the indications of the Ministry of Health are not to go to the ER, but to call the general practitioner, the free-choice pediatrician, the medical guard or regional emergency numbers, available on the website of the Ministry of Health.

If, on the other hand, the symptoms are mild and have not been recently in epidemiological risk areas and there has been no contact with confirmed or probable cases, The board of the Ministry of Health is to stay at home until the resolution of symptoms by applying the usual measures of hygiene of the hands and respiratory tract.

### 2.5 Case definition of COVID-19 for reporting

The case definition shall be based on currently available information and may be reviewed in the light of developments in the epidemiological situation and available scientific knowledge.

**Suspected case of COVID-19 requiring diagnostic testing**

The diagnostic test must be performed, necessarily, when one of the following cases is present:

1. A person with acute respiratory infection with sudden onset of at least one of the following signs and symptoms: fever, coughing and difficulty breathing, and without another etiology that fully explains the clinical presentation and history of travel or residence in a country/area where local transmission is reported during the 14 days preceding the onset of symptoms;
2. A person with any acute respiratory infection and who has been in close contact with a likely or confirmed case of COVID-19 during the 14 days preceding the onset of symptoms;

3. A person with severe acute respiratory infection, fever and at least one sign/symptom of respiratory disease, and requiring hospitalization (SARI) and without another aetiology fully explaining the clinical presentation.

As part of primary care or in the hospital emergency room, all patients with symptoms of acute respiratory infection should be considered as suspect cases if local transmission has been reported in that area or country.

For Italy, where a case-by-case assessment is necessary, the national epidemiological situation updated daily on the website of the Ministry of Health can be taken into account and, for the performance of the test, the application of "Document on criteria for clinically asymptomatic subjects to be tested for SARS-CoV-2 infection by oral swab and diagnostic testing" prepared by the Permanent Working Group of the Higher Health Council (LII session).

**Probable case**

A suspect case whose test result for SARS-CoV-2 is doubtful or inconclusive using specific Real Time PCR protocols for SARS-CoV-2 at the identified Regional Reference Laboratories or is positive using a pan-coronavirus test.

**Confirmed case**

A case with laboratory confirmation for infection with SARS-CoV-2 carried out at the National Reference Laboratory of the Higher Institute of Health (ISS) or by Regional Reference Laboratories meeting the criteria listed in Annex 3, regardless of clinical signs and symptoms.

### 2.6 Covid-19 Mortality

It is said that in Italy the mortality from ordinary seasonal flu syndrome is about 7,000 people per year. According to Influnet (the national system of epidemiological and virological surveillance of influenza, coordinated by our
Ministry of Health with the collaboration of the Higher Institute of Health), every year the influenza infects about 6-8 million people, or 9% of the population.

In Italy flu viruses cause directly about 300-400 deaths every year, with about 200 deaths due to primary viral pneumonia, but to these deaths, depending on the estimates of the different studies, must be added 4-8,000 "indirect" deaths caused by lung complications (bacterial pneumonia) or cardiovascular (heart failure) flu.

Flu viruses can in fact create complications especially in the elderly or in any case in all people who before getting flu were already suffering from serious diseases or immunodeficiencies.

Therefore, it is estimated that our mortality rate of seasonal flu (i.e. the ratio of deaths to infected) is below one per thousand, or 0.1%.

Therefore, the new Coronavirus Covid-19, when compared with the ordinary seasonal flu, at the present state of knowledge seems to have to be more lethal, because the provisional data indicate a mortality of around 3%.

This value, however, is affected by the incomplete information on the number of infected: where the next knowledge, as it is possible, should confirm the number of deaths but greatly increase the number of infected, there would clearly be a lower mortality.

The substantial difference between these infections is that, while normal viruses that cause seasonal flu syndrome are known to our organism and cannot infect the entire population because many people are already immunized (because vaccinated or because already protected by natural antibodies formed by previous contacts), since this new Coronavirus is unknown to our immune system, finds people immunologically unprepared and therefore could infect many more people and could spread even faster.
According to data available on 8 May, relating to a total of 28,274 deaths, the surveillance system of the Istituto Superiore di Sanità found, compared to an overall average of 13.1%, a lethality rate of 0.2% for cases between 0 and 9 years old, 0.1% between 20 and 29 years, 0.3% between 30 and 39 years, 0.9% between 40 and 49 years, 2.6% between 50 and 59 years, 10.2% between 60 and 69 years, 24.9% between 70 and 79, 30.2% between 80 and 89 years, 26.3% for those over 80 years. Overall, 84.7% of deaths occur among people over the age of 70.

2.7 People particularly at risk

The first risk factor that can make the effects of the infection severe, critical or fatal is that of age. The latest report of the Istituto Superiore di Sanità on 27,955 patients who died on May 7 shows an average age of 80 years, for 60.9% of men. The infection also affects with greater severity patients who have some co-morbidity, or the coexistence of several different diseases in the same individual: analysis of a sample of 2,621 deceased persons for which it was possible to analyse the medical records shows that 3.9% had no pre-existing pathology at the time of diagnosis of positivity; 15% had a pathology, 21.3% had two...
pathologies, 59.9% had three or more pathologies.

Among previous diseases most frequently observed in deceased patients, 68.2% suffered from hypertension, 31.1% type 2 diabetes, 28.4% ischemic heart disease, 22.3% atrial fibrillation, 20.3% chronic kidney failure, 16.6% COPD (Chronic obstructive pulmonary disease). Among the 27,955 patients who died on 29 April, 312 (1.1%) were under 50 years of age, 66 (0.2%) under 40 years of age. Of these, 40 had serious pre-existing diseases, 14 had no clinical information, and 12 had no major diseases.

![Figure 5](image)

Figure 5 Elaborations Istituto Superiore di Sanità on a sample of 2,621 deaths as of 7 May 2020

Finally, thanks to the data available so far, a table is provided indicating the risk factors that this infection may cause related to other diseases. The real and concrete risk depends on the condition of the immune system.

### 2.8 Risks to health professionals

In relation to the COVID-19 epidemic there are some categories of workers at greater risk of exposure, such as health professionals (OS), laboratory staff, airport and flight staff, operators of services or shops in contact with the public.
In particular, this document aims to be an informative contribution to the protection of health and safety of health workers, category of workers who, due to the peculiarity of their professional activity, have a greater chance of coming into contact with potentially infected persons, as confirmed by the data emerging from the current epidemic and the previous epidemics of SARS and MERS. This is done not only in hospitals (DEA, hospital wards, intensive care and resuscitation departments) but also in the context of medical clinics and diagnostic centres as well as in facilities providing other health services.

Healthcare professionals shall mean all persons who, in whatever capacity, serve in health settings where direct or indirect biological risk exposure may occur through contact with infected patients or materials, including body fluids, medical equipment and contaminated devices, environmental surfaces or contaminated air.

Major international organisations, such as the WHO, the European Centre for Disease Control (ECDC), the US Centre for Disease Control and Prevention (CDC), issue continuously updated documents based on the evolution of the epidemiological situation to provide specific procedures for the control of infections (including technical controls, environmental hygiene measures, good working practices, use of personal protective equipment and administrative provisions) to prevent the spread of the current pandemic.

### 2.9 COVID-19 in Italy

The first two cases of Coronavirus in Italy, a couple of Chinese tourists, were confirmed on 30 January by the Spallanzani Institute, where they were hospitalized in isolation since 29 January.

Subsequently, an Italian researcher positive to the virus and coming from China and a seventeen-year-old, remained stuck for a long time in Wuhan because of flu symptoms, not positive to the coronavirus but equally kept under observation and hospitalized to the Spallanzani.

All of these people recovered and were discharged in February, the last, the couple’s Chinese patient healed on February 26.
Since then, our country has been activated, under the coordination of the ministerial task force, through a surveillance network on the new coronavirus and controls and screening have been activated.

Italy blocked all flights to and from China for 90 days, in addition to those from Wuhan, already suspended by the Chinese authorities, on 30 January with an Ordinance of the Minister of Health.

The Italian Government declared a state of emergency on 31 January, allocating the first funds and appointing the Head of Civil Protection Angelo Borrelli as Extraordinary Commissioner for the emergency.

With the decree of the Head of the Department of Civil Protection of 5 February 2020 a Technical-Scientific Committee was established to deal with emergency.

On 18 February 2020, a man was admitted to the hospital in Codogno, in the province of Lodi, with severe respiratory failure, positive for the coronavirus test, was immediately transferred to the hospital Sacco in Milan, identified, together with the Spallanzani hospital in Rome, as the reference center for dealing with cases of bioemergence. It is the first case of secondary transmission, as he was not in China, but would have had contact with a friend returned from the country.

On 21 February 2020, several cases of coronavirus emerged in Lodigiano, a symptom of a new outbreak of which the extent is not yet known. Some of the affected countries such as Codogno, Castiglione d'Adda and Casalpusterlengo and others, have been effectively closed and declared "red zone".

The Council of Ministers passed a first decree-law on 23 February 2020 with measures for the prohibition of access and removal in municipalities where there were outbreaks and the suspension of demonstrations and events.

As of 4 March, the health monitoring related to the spread of the new Coronavirus on the national territory by the civil protection counted 2706 positive to the virus, 276 people are healed, 1346 patients hospitalized with symptoms, 295 in intensive care, 1065 are in house isolation and 107 are deceased.

The virus was widespread in our country, especially in the north, but it was expanding in all Italian regions (Lombardy 1820, Emilia-Romagna 544, Veneto 360, Piedmont 82, Marche 84, Campania 31, Liguria 26, Tuscany 38, Lazio 30, Friuli-Venezia Giulia 18, Sicily 18, Umbria 9, Puglia 9, Abruzzo 7, Autonomous
Province of Trento 5, Molise 3, Sardinia 2, Basilicata 1, Calabria 1, Autonomous Province of Bolzano 1).

For this reason, on Wednesday, March 4, the government declared the closure of schools and universities throughout Italy until March 15.

While Sunday, March 8 comes the decree that provides for the isolation of Lombardy, absolutely the most affected, and other 14 provinces, which become "red zone".

On Monday, March 9, at about 10 pm, Conte announced on television that he had extended to the whole country the measures already taken for Lombardy and the other 14 provinces, so that all of Italy would become a "protected zone".

The new rules are contained in the new decree Dpcm 9 March 2020, followed by the Dpcm 11 March 2020 that closes commercial activities not of first necessity.

Figure 6 Contagion trends in Italy February - May

2.10 COVID-19 at the institute "Lazzaro Spallanzani"

Rome, January 29, 2020 - At the Spallanzani Institute, a couple of Chinese tourists who had had flu symptoms for several days were hospitalized, then subjected to tests, as usual, were confirmed positive at COVID-19 on January 30.

Since then the Spallanzani, and all the research institutes of Italy, have been involved in the study of this virus for a better knowledge and for the development of new diagnostic and therapeutic strategies.

On 2 February 2020, the virologists of the National Institute of Infectious Diseases "Lazzaro Spallanzani", less than 48 hours after the diagnosis of positivity for the
first two patients in Italy, were able, among the first in Europe, to isolate the virus responsible for the infection.

Having available in laboratories the new pathogen has also allowed to study the mechanisms of the disease for the development of care and the development of the vaccine. The partial sequence of the virus isolated in the laboratories of Spallanzani has been made available to the international scientific community.

Having the virus available is a fundamental step, which will allow to improve the existing diagnostic methods and to set up new ones. In fact, the researchers of the National Institute of Infectious Diseases "Lazzaro Spallanzani", starting from an ocular swab of a patient positive to the virus, hospitalized at the Spallanzani hospital at the end of January and presenting a bilateral conjunctivitis, have been able to isolate the virus, thus demonstrating that it, as well as in the respiratory system, is able to replicate also in conjunctives, and therefore that the virus is also active in the eye secretions of patients positive at COVID-19.

At the Spallanzani are active programs for testing the vaccine.
2.10.1 Hospital structure

The "Lazzaro Spallanzani" Hospital was inaugurated in 1936 as a garrison for the prevention, diagnosis and treatment of infectious diseases, with an endowment of 296 beds in 15 different pavilions, in an area of 134,000 square meters. Over the years its field of interest has gradually transformed, with the evolution of the prevalent infectious diseases.

To date the structure has a total of 169 beds, 152 of which are intended for ordinary hospitalization in acuities of adult patients suffering from infectious diseases, 12 to resuscitation, 8 for the Hospice for the provision of palliative care to terminal patients and 6 day beds.

It has become the main center for health emergencies such as cholera epidemic, that of Salmonella Wien, Hepatitis B, particularly related to the problems of drug addiction, research and treatment on HIV/AIDS infection, SARS (Severe Acute Respiratory Syndrome) and clinical and diagnostic management of hemorrhagic fevers such as Ebola virus disease.

The National Institute for Infectious Diseases "Lazzaro Spallanzani", (briefly called INMI) has legal personality under public law and is recognized as IRCCS by effect of the D.M. 19 December 1996, subsequently confirmed with D.M. 15 February 2005, in the disciplinary specialization "AIDS, other infectious diseases and immunocompromised host".

The L.R. 2/2006 configures the Institute public employee of the Region to national importance, as well as the Health Companies.

The Institute shall pursue research, prevention, diagnosis, treatment and rehabilitation of infectious diseases and immunocompromised host, diagnostic and therapeutic technological innovation, including organ transplantation and cell infusion, with full respect for the personality, dignity and rights of the person.

Currently the Institute holds the only Italian laboratory of biosafety level 4 and five laboratories of level 3.

It is also included in the Regional Network of Infectious Diseases of the Lazio Region, with central role of coordination with respect to all regional health facilities equipped with beds of infectious diseases and infectious specialists, to ensure that all citizens suspected of acute infectious disease can be taken over wherever they
are, including in emergency rooms and local medical studies where infectious specialists are present within 24 hours, and to be able to receive adequate diagnosis and treatment and, if necessary, a bed for infectious diseases, as well as the necessary preventive and isolation measures in cases of contagious diseases, to protect public health.

**Figure 8** Front view of the hospital building (left) and map of the Spallanzani (right)
3. Standards and definitions

3.1 Normative references

<table>
<thead>
<tr>
<th>Reference to the law</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreto Legislativo 81/2008</td>
<td>Single text on the protection of health and safety at work,</td>
</tr>
<tr>
<td>Regio Decreto 27 luglio 1934, n. 1265</td>
<td>Consolidated text of health laws</td>
</tr>
<tr>
<td>Decreto Legislativo N° 81/08 - Allegato XLVI</td>
<td>List of classified biological agents</td>
</tr>
<tr>
<td>Decreto-legge 23 febbraio 2020, n. 6</td>
<td>Urgent measures on containment and management of epidemiological emergency by COVID-19.</td>
</tr>
<tr>
<td>Legge 5 marzo 2020, n. 13</td>
<td>Conversion into law, with modifications, of decree-law n. 6 of 23 February 2020, on urgent measures in the field of containment and management of the epidemiological emergency by COVID-19.</td>
</tr>
<tr>
<td>Document</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Decreto-legge 16 maggio 2020, n. 33</td>
<td>Further urgent measures to address the epidemiological emergency by COVID-19.</td>
</tr>
<tr>
<td>Decreto-legge 17 marzo 2020, n. 18</td>
<td>Decree &quot;Cura Italia&quot; - Measures to strengthen the National Health Service and economic support for families, workers and businesses related to the epidemiological emergency by COVID-19.</td>
</tr>
<tr>
<td>Decreto del Presidente della Repubblica 14 gennaio 1997</td>
<td>Approval of the act of guidance and coordination to the regions and autonomous provinces of Trento and Bolzano, on minimum structural, technological and organizational requirements for the exercise of health activities by public and private structures.</td>
</tr>
<tr>
<td>Decreto-legge 17 marzo 2020, n. 18, Titolo I, art. 3</td>
<td>Reinforcement of territorial assistance networks, to increase the provision of beds in intensive care and operational units of pneumology and infectious diseases, isolated and set up in</td>
</tr>
</tbody>
</table>
accordance with the indications provided by the Minister of Health.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNI EN ISO 9001:2088</td>
<td>The standard specifies the requirements of a quality management system for an organisation.</td>
</tr>
<tr>
<td>EN 374</td>
<td>Classification of chemical protection gloves.</td>
</tr>
<tr>
<td>EN 340:2004</td>
<td>Protective clothing – General requirements</td>
</tr>
<tr>
<td>EN 14126:2006</td>
<td>Protective clothing against infectious agents.</td>
</tr>
<tr>
<td>Decreto del Presidente della Repubblica 327/04</td>
<td>Duties and responsibilities of the Health Director.</td>
</tr>
<tr>
<td>Decreto Ministeriale 17 gennaio 1997, n. 58</td>
<td>Regulation on the identification and professional profile of prevention technician in the environment and in the workplace.</td>
</tr>
<tr>
<td>Decreto Ministeriale 17 gennaio 1997, n. 69</td>
<td>Regulation on the identification of the health care assistant and his professional profile.</td>
</tr>
<tr>
<td>Decreto Ministeriale 14 settembre 1994, n. 739</td>
<td>Regulation on the identification of the figure and the relative professional profile of the nurse.</td>
</tr>
</tbody>
</table>

*Table 1* Regulatory references used for the following document
3.2 Definitions

Room with patients COVID-19

- **Doctor**: In the COVID-19 department, the required medical figure is that of the pneumologist, who deals with the diagnosis and therapy of diseases that can affect the structures of the respiratory system. The pneumologist in contact with patient COVID-19 deals with:
  - Direct care for patients COVID-19.
  - Blood tests/Haematogas.
  - Insertion of CPAP/NIV fan support to COVID-19 patients, if required.
  - Environment at risk from aerosol generation.

Sometimes, external advice is requested to cardiologists and anaesthetists, but they are not continuously present in a department COVID-19. The medical/environment/patient contact is from 2/3 hours per shift.

- **Nurses** (minimum reduction of the number of exposed operators is recommended): it is the health professional responsible for nursing care, namely, therapeutic, palliative, rehabilitative, educational and preventive activity aimed at the individual, in order to recover an adequate state of health. Nurse, in contact with patient COVID-19, takes care of:
  - Direct care for patients COVID-19;
  - Gold swab and rhinopharyngeal execution;
  - Collection of other biological samples;
  - ECG examination shall be carried out;
  - Care contexts where many COVID-19 patients undergoing CPAP/NIV are concentrated;
  - Patient hygiene COVID-19;
  - Environment at risk from aerosol generation;
  - Nursing/patient/environment contact is from 4-6 hours per shift. In addition, shift nurses enter the room one at a time, alternating.
- **Anesthesiologist**: intervenes when the patient is in serious condition, evaluated by the pneumologist, and proceeds to the administration of pharmaceuticals and then intubation of the patient.

- **Medical technician**: is in charge of making chest X-rays to the bed, to perform diagnostic tests, at the request of the department doctor.

- **Social and Health Care Worker**: is the assistant to the nurse and deals with:
  - Feeding of the patient;
  - Hygienic care and patient handling with the assistance and supervision of the nurse.

- **Cleaning staff** (It is recommended to minimize the number of exposed workers): Access in patients' rooms COVID-19, for the sanitization of the environment. Before proceeding to the sanitization of the room, the cleaner is required to perform preventive measures as per standard.

**Other patient transit and internal transport areas (for example wards, corridors):**

- **Health Manager**: the medical manager who must ensure the guidance, supervision and quality of the health facility. It deals with the evaluation of the organization, the information and any structural changes of department. In the department no PPE is required in compliance with the spacing measures.

- **Doctor**: Primary Physician, that is a second level manager/ head of operations unit, is a doctor who has the responsibility of the department. This figure is covered in COVID-19 by the pulmonologist. In the ward he does not carry out any activity involving direct contact with COVID-19 patients, but stops in the ward while waiting for the visit to the patient. There is no need for PPE in compliance with the measures of , it is possible to have in the medical department of transit for consultations requested by the primary.

- **Nurse**: in the ward we can find the figure of the coordinator, in the ward COVID-19, takes care of the management and information of the staff of the ward, the nurse, general, who is in charge of preparing the therapy,
alternating to the patient’s room entrance. Even for the nurse there is no need for PPE in compliance with the distance measurements.

- **Auxiliary/OSS**: In the ward, she refills the tables, containing medicines and medical kits, to be taken to the patient’s rooms COVID-19. It also carries out documentation and analyses. It is recommended to wear surgical mask and disposable gloves only in case of prolonged transport (time over 15 minutes).

- **Desk operator**: person in charge of the secretariat responsible for communication between departments and any clarification to the public.

- **Cleaning staff**: they take care of the sanitization of the rooms common to the sanitary staff (for example kitchen, guardiola and room of the doctors). For the sanitization of such environments is not necessary the dressing, while the PPE are obligatory for the ordinary performance of the activity, as indicated in the risks of the job, or FFP2 masks.

- **Vigilance**: figure that regulates the flows of entry and exits inside the hospital, and is in the ward, on call from the head of the department, only in case of problems.

**Other general definitions found in the health care structure:**

- **Department**: the departmental organization is the ordinary model of operational management of business activities. Where the Department is aimed at integrating welfare activities with those of teaching and research, it is called Department of Integrated Activities (DAI). Each department contains at least 4 UOC and 2 UOSD.

- **Complex Organizational Unit**: the Complex Organizational Unit (UOC) has a significant qualitative and quantitative dimension of the activity and of the professional resources used, it has budget responsibilities and operates, for the specific skills, in technical autonomy-professional and organizational management with full responsibility for the use of resources in relation to the objectives assigned.

- **Departmental Simple Operating Unit**: the Departmental Simple Operating Unit (UOSD) is an organizational articulation, not included in the UOC,
characterized by an adequate qualitative-quantitative dimension of the activity and the professional resources used, directly pertaining to the Department, or to the Functional Area, or to the staff areas of the Management. It has budget responsibilities and operates, for specific skills, in professional technical autonomy and organizational management, with full responsibility for the use of resources in relation to the objectives assigned.

- **Operational Unit**: the Operational Unit (U.U.O.O.) is a multidisciplinary functional entity assigned in the context of a specific structure, which, starting from resources already available, brings together and coordinates the expertise of several specialists involved in the management of a path inherent in a single process across multiple structures.

- **Health Director**: the Health Department supports the activities of the departments paying particular attention to the quality of care, in terms of appropriateness, effectiveness and efficiency of the organizational and welfare processes. It ensures the transposition and compliance of activities with hygiene and health legislation and promotes the technical-professional quality of operators. It ensures multi-specialist integration in line with the needs and expectations of users, including social and psychological. The Health Director is personally responsible for the technical-functional organization of the services and for the possession of the required professional qualifications by the staff who work there. Among the tasks of the Health Director there is the personal responsibility of a general nature on the overall functioning of the garrison with obligations that relate primarily to the supervision of hygiene requirements and the suitability of technical equipment, as well as on the fulfilment by staff of the required professional requirements, but also on the monitoring of the quality of individual diagnostic and therapeutic services provided to patients, on the basis of the Code of Ethics. In addition, the application of DPR 327/04, which requires physical presence in the structure for at least half of the opening hours to the public
• **Administrative Director:** the Administrative Directorate, which is responsible for the coordination and supervision of all administrative activities of the Institute, collaborates with the Director General in the decisions that make direct reference to its area of competence and participates in the process of strategic planning concurring, with the formulation of proposals and opinions, to the definition of the policies of business government.

• **Prevention Technician in the Environment and in the workplace:** according to the D.M. 17.01.1997, n. 58 is identified the professional figure of prevention technician in the environment and workplaces, with the following profile: the prevention technician in the environment and in the workplace is the health care professional who, in possession of the qualifying university diploma, is responsible, within the scope of his skills, for all prevention activities, verification and monitoring of environmental health and safety at the places of life and work, food and drink hygiene, public health hygiene and veterinary hygiene. The prevention technician in the environment and in the workplace, working in the services with inspection and surveillance tasks, shall, within the limits of his duties, be a judicial police officer and carry out preparatory work, for the issue of health authorizations or technical clearances for controlled activities.

• **Health Care Assistant:** the Health Care Assistant is the health care professional who, in possession of the qualifying university diploma and the registration in the professional register, is in charge of prevention, promotion and education for health. The D.M. 17.01.1997, n. 69, denotes the activities proper to the professional, that is those to characterize need of health and priority of the educational/preventive intervention/of recovery turned to the person, the family and the collectivity.

• **Nursing Coordinator:** The Nursing Coordinator plays a very important role within health organizations, as it embodies the link between organizational needs, clinical-welfare needs and business objectives. Following the transposition of art. 6, comma1, letter b) of Law 43/2006 which regulates and distinguishes the graduated health staff, recognizing the obligatory
possession of the Master in coordination by the graduate nurse, Certified to the Functions Directives" (AFD).

- **Nurses:** the Ministerial Decree of 14 September 1994, n. 739 and the Law of 18 December 1980, n. 905 define the figure of the nurse as a health professional responsible for the planning and management of nursing care, i.e., therapeutic activity, palliative, rehabilitative, educational and preventive addressed to the individual, the community or the population, carried out on healthy or sick subjects, in order to recover an adequate state of health and/or to prevent the onset of morpho-alterations functional for both the individual and the community.

- **Socio-sanitary Operator:** the Socio-sanitary Operator (O.S.S.) is the operator who, following the certificate of qualification obtained at the end of specific professional training, carries out activities aimed at satisfying the primary needs of the person, within their areas of competence, in a social and health context.

- **Risk Prevention and Protection Service,** takes care of:
  - Provide support to the Directorate-General in relations with the Representatives of Workers for Safety (RLS) through the preparation of acts and regular participation in meetings on prevention and protection;
  - Safety information and training, developing information and training programmes for the Institute’s employees, coordinating safety training courses;
  - Identification and evaluation of risk factors, updating the Risk Assessment Document, through the collection of information on accidents at work;
  - Internal and external informative debt management, and transmission of information data to the various institutional entities within the time set by the rules;
  - Collaboration for the elaboration of the Single Documents of Assessment of the risks of interference (DUVRI) for the activities entrusted to external firms;
Head of Prevention and Protection Service: as established by Legislative Decree no. 81/2008 within a company/structure is necessary the presence of a Head of Prevention and Protection Service (RSPP). This figure, appointed by the employer, must have the skills and requirements appropriate to the nature of the risks present at the workplace, to take on and demonstrate that he has those responsibilities that enable him to organize and manage the entire system of risk prevention and protection.

U.O.S.D. Risk management and biosecurity, deals with:
- Establishment of protocols and procedures for clinical risk reduction and monitoring of their application, including, as a priority, ministerial recommendations;
- Assessment of risks related to biological agents and prevention interventions to reduce the risk of occupational and accidental exposure for operators, users, patients;
- Internal and external informative debt management, with the sending of information data to the various institutional entities within the time set by the rules;
- acts of a binding nature arising from legal provisions or in pursuance of decisions adopted by the Director-General;
- Organization of audits to verify and promote clinical risk reduction;
- Risk management functions.

U.O.S.D. Planning Programming and Management Control, deals with:
- Internal and external informative debt management and transmission of information data to the various institutional entities within the time set by the rules;
- Classification and management of costs and revenues, with parameterisation of activities and use of the methodology for reversing overheads;
- Development of control systems, analysis of results and deviations for compliance with business strategies;
- Preparation Model LA and related Report;
- Quarterly budget audits with analysis of deviations;
- Drafting of the management reporting system;
- Information flows relevant to the management planning and control system;
- Indicators for monitoring the objectives linked to business planning;
- Preparation of the Performance Plan and support to the OIV for evaluation; - Preparation of a Strategic Plan;
- Preparation of budget sheets for operational units (UU.OO);
- Updating of the plan for Cdicc, Cdir and inputs;
- Analytical Accounting System.
4. Risk assessment by SARS-CoV-2

4.1 Purpose of the analysis

The hospitalization and care facilities, hospitals and not only, both public and private, fall within the scope of the legislation concerning workplaces and must therefore be in compliance with the requirements defined in Chapter I of Title II (Art 62-64) of the Consolidated Law on Safety. Institutions of hospitalization and care are rather complex workplaces and cover a wide range of cases of workplace risk. One of the main characteristics of the hospital environment is the interaction between man and environment, which conditions the way in which it is exposed to biological agents: the sources of infection are represented by the patients themselves or by the environment (air, medical or surgical instruments). All the different tasks, although at different levels, involve contact with potentially infected patients, with biological fluids, with tools or needles. The biological risk therefore characterizes all hospital activities because it derives mainly from the unavoidable interhuman contact.

This analysis focuses entirely on biological risk from New Coronavirus COVID-19 with the aim of:

- identify the main hazards arising from health activities, assess their severity and probability of occurrence;
- identify and assess the risks to which health professionals are exposed;
- assess the risk of Coronavirus related to the hospital environment;
- define the measures to be taken, which will be preventive, protective and organizational.

This risk assessment was carried out for the National Institute of Infectious Diseases - "Lazzaro Spallanzani".
4.2 Reference legislation – D.lgs. n. 81/2008

Following the outbreak of the pandemic, the problem related to the obligation to update the risk assessment, which, as provided for in art. 29, comma 3, del D.lgs. n. 81/2008, "must be immediately reworked on the occasion of changes in the production process or work organization significant for the health and safety of workers [...]. As a result of this reworking, prevention measures must be updated".

The reference context in the case of the New Coronavirus is defined in Title X of Legislative Decree no. 81/2008, whose rules of this Title "apply to all work activities in which there is a risk of exposure to biological agents" in accordance with art. 266, paragraph 1, where it means biological risk "any micro-organism even if genetically modified, cell culture and human endoparasite that could cause infections, allergies or intoxications" according to art. 267.

However, in the case of the New Coronavirus some considerations must be made; the risk of infection always exists until the vaccine is found and this risk does not burden one or more organizations but the whole world. Faced with the emergence of such a biological risk that threatens public health, it is up to the public authorities to indicate the preventive measures and ensure that they are observed. The employer will have to adapt to them. In addition, the contagiousness and danger of this new virus, which according to the definition of art. 268, paragraph 1, letter d, of D.lgs. n. 28/2008, seems to have to be counted among the biological agents of the "group 4", being a biological agent "which may cause serious diseases in human beings and is a serious risk to workers and may present a high risk of propagation in the community, as effective prophylactic or therapeutic measures are not available", even if, in Annex XLVI, the family of this virus ("Coronaviridae") is classified in group 2. However, the characteristics of COVID-19 do not appear to correspond to this classification

Finally, it is recalled that the risk assessment is carried out within the scope of Legislative Decree no. 81/2008, and therefore concerns the risk assessment for workers and not for patients.
4.3 Methodology proposed

The risk analysis and assessment phase requires knowledge of the system and the adoption of different survey criteria; the final result is the production of a list of dangerous situations to which the correct risk value must be associated. In analytical terms, the risk \( R \) can be defined according to the probability \( P \) of the occurrence of the harmful event and the severity/magnitude of damage \( D \) that such an event causes:

\[
R = f(P, D)
\]

Once the dangerous situation and the associated harmful event have been determined, the evaluation can be carried out with the help of one of the methods proposed by the scientific and technical community.

The choice of methodology for the analysis and assessment of the risks associated with a given system shall take into account:

- or the characteristics of the system under study;
- or the availability of information and data;
- or the availability of specific methodologies for the system under consideration;
- or the skills of the assessment team.

The method used for this risk assessment is the AISS-ISPESL. It is a method whose semi-quantitative nature allows its application even if it is difficult to obtain quantitative data. The main benefits of using this methodology are:

- simplicity of application;
- completeness, since it considers and analyses multiple different risk factors (it is one of the few methods to consider the risk factor related to the working environment) providing a complete picture of the subject under investigation;
- effective planning of corrective measures (both preventive and protective) based on a priority of intervention established by a detailed quantified risk index.
4.3.1 Implementing rules

At the basis of this method is the consideration that the occurrence of an accident at work is caused by several factors. These factors can be attributed to three main categories:

1. work tools or equipments
2. the environment
3. man or work organization

The approach of this method involves a quantitative assessment of the risk of accident, carried out by assigning numerical values to the factors falling into the 3 categories considered. It is therefore necessary to assess:

- the overall risk of the workplace $R_g$, depending on both the risks related to the material and the risks related to the working environment;
- the personal abilities of the individual to master the risk $P$;
- the risk of accident $R_{inf}$, function of the two previous parameters.

Assigned the values to the different parameters and quantified the accident risk, we evaluate the perception of the risk or we must place the risk in the sphere of acceptability.

4.3.2 Assessment of overall workplace risk

The overall job risk $R_g$ is calculated as

\[ R_g = Ma \times Amb \]

where:

- **Ma** represents the risk related to the material (in our case COVID-19) and can be expressed as a product of 4 factors:

\[ Ma = Pd \times Ex \times Po \times Ev \]

- $Pd = dangerous\ events$ and expresses the severity of the event;
- $Ex = frequency\ or\ duration\ of\ exposure\ to\ the\ biological\ agent$;
- \( Po = \) probability of occurrence of the dangerous event related to the material factor and depends on exposure to biological risk and protection devices;
- \( Ev = \) probability of avoiding or limiting injury depending on whether the hazard event is perceptible or sudden.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Scale</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pd</td>
<td>low-impact events (impacts, cuts…)</td>
<td>1 ÷ 10</td>
</tr>
<tr>
<td></td>
<td>serious events (fractures, injuries…)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>very serious and irreversible events</td>
<td></td>
</tr>
<tr>
<td>Ex</td>
<td>exposure reduced opportunity</td>
<td>1 ÷ 2</td>
</tr>
<tr>
<td></td>
<td>cyclical exposure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>frequent or continuous exposure</td>
<td></td>
</tr>
<tr>
<td>Po</td>
<td>low (complete inaccessibility to hazardous elements)</td>
<td>0,5 ÷ 1,5</td>
</tr>
<tr>
<td></td>
<td>medium (integral protection devices)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>high (incomplete protection)</td>
<td></td>
</tr>
<tr>
<td>Ev</td>
<td>the dangerous event is clearly perceptible</td>
<td>0,5 ÷ 1</td>
</tr>
<tr>
<td></td>
<td>sudden occurrence of the dangerous event</td>
<td></td>
</tr>
</tbody>
</table>

Table 2 Classification of parameters constituting material risk \( Ma \)

- **Amb** represents the incidence of the working environment and can be expressed as the sum of 3 parameters:

\[
Amb = Qa + Qb + Qc
\]

- \( Qa = \) location of workplace;
- \( Qb = \) working environment;
- \( Qc = \) various situations that can be a source of hyperstress.
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Scale</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qa</td>
<td>clear and spacious workspaces and workplaces at the same level &lt;br&gt;confined and cluttered workspaces and passageways, working areas at different accessible levels using equipment and accessories</td>
<td>0,5 ÷ 1</td>
</tr>
<tr>
<td>Qb</td>
<td>proper lighting, noise-free, good microclimate &lt;br&gt;insufficient lighting, noise disturbing, microclimate bothering</td>
<td>0,3 ÷ 0,6</td>
</tr>
<tr>
<td>Qc</td>
<td>good arrangement of controls, signaling devices and indicators; slight physical stresses &lt;br&gt;inadequate arrangement of controls, signaling devices and indicators; heavy physical stresses</td>
<td>0,2 ÷ 0,4</td>
</tr>
</tbody>
</table>

Table 3 Classification of the parameters constituting the risk linked to the working environment

4.3.3 **Assessment of the individual’s ability to master risk**

The ability of the individual to master the \( P \) risk is assessed through the following formula:

\[
P = Q + \Phi + O
\]

- \( Q \) = *qualification of personnel in relation to the applied task* assessed both on the basis of personal training and on specific workplace training;
- \( \Phi \) = *physiological factors* and concerns the physical and mental adaptation of the worker to the assigned task;
- \( O \) = *work organization*. 
Table 4 Classification of parameters constituting the capacities of the individual P

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Scale</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q</td>
<td>- unqualified and inexperienced person</td>
<td>0 ÷ 10</td>
</tr>
<tr>
<td></td>
<td>- qualified or experienced person</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- qualified and experienced person (with vocational training and specific training in the workplace)</td>
<td></td>
</tr>
<tr>
<td>φ</td>
<td>- poor physical and mental adaptation of the subject to the assigned task</td>
<td>0 ÷ 3</td>
</tr>
<tr>
<td></td>
<td>- good physical and mental adaptation of the subject to the assigned task</td>
<td></td>
</tr>
<tr>
<td>O</td>
<td>- procedures and operating procedures neither codified nor respected</td>
<td>0 ÷ 5</td>
</tr>
<tr>
<td></td>
<td>- procedures and operating procedures codified but not systematically respected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- codified and strictly adhered to procedures and operating procedures</td>
<td></td>
</tr>
</tbody>
</table>

4.3.4 Assessment of accident risk

By assigning the values to the overall risk at the workplace $R_g$ and to the individual skills $P$, it is possible to determine the value of the accident risk $R_{inf}$ as:

$$R_{inf} = R_g - k \cdot P = (Ma \times Amb) - k \cdot P$$

where the weighting coefficient $k$ takes account of the fact that personal factors $P$ become more relevant the higher the material risk. In our analysis will be placed:

$$k = \frac{Ma}{120}$$

Depending on the value assumed by the accident risk $R_{inf}$, calculated for all possible dangerous situations, it is possible to establish how much the risk is acceptable or not. Table 5 will be used in our risk assessment to determine the risk class of the
considered hazardous event, the level of acceptability and the corrective actions required.

<table>
<thead>
<tr>
<th>Accident Risk Values</th>
<th>Risk Category</th>
<th>Acceptability Level</th>
<th>Corrective Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>$R_{\text{inf}} &gt; 28$</td>
<td>Critic</td>
<td>Unacceptable, urgent</td>
<td>Take preventive and protective measures with operational procedures, high frequency training, training and monitoring</td>
</tr>
<tr>
<td>$20 &lt; R_{\text{inf}} \leq 28$</td>
<td>Elevated</td>
<td>Unacceptable</td>
<td>Adoption of preventive and protective measures with operational procedures, high frequency training, training and monitoring</td>
</tr>
<tr>
<td>$12 &lt; R_{\text{inf}} \leq 20$</td>
<td>Middle</td>
<td>Acceptable, control</td>
<td>Adoption of preventive and protective measures, training, training and monitoring with medium frequency</td>
</tr>
<tr>
<td>$R_{\text{inf}} \leq 12$</td>
<td>Low</td>
<td>Acceptable</td>
<td>Adoption of preventive and protective measures, ordinary training, training and monitoring</td>
</tr>
</tbody>
</table>

*Table 5* Risk index and level of acceptability

**4.4 Description and general assessment of the criteria**

The methodology illustrated here will be used to analyze the risk conditions arising from hospital activities carried out by employees of the Infectious Diseases Institute "Lazzaro Spallanzani". A risk analysis will therefore be carried out for each category of Spallanzani worker, on the basis of his duties and the risk conditions to which he is subject.
Reference will be made to the following list of employees

<table>
<thead>
<tr>
<th>Doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
</tr>
<tr>
<td>Anaesthetist</td>
</tr>
<tr>
<td>Health physicist</td>
</tr>
<tr>
<td>Health technician</td>
</tr>
<tr>
<td>Auxiliary, OSS</td>
</tr>
<tr>
<td>Desk operator</td>
</tr>
<tr>
<td>Cleaning staff</td>
</tr>
<tr>
<td>Vigilance</td>
</tr>
</tbody>
</table>

and the following list of assets and risk conditions

a) Direct contact with person with symptomatic infection confirmed in the laboratory;
b) Direct contact with person with symptoms from COVID-19 (not confirmed in laboratory);
c) Procedures performed on the patient generating aerosols (tracheal intubation, cardiorespiratory resuscitation, swab);
d) Direct contact with the environment where the confirmed COVID-19 patient has been assisted;
e) Contact with persons who have interacted with COVID-19 patients confirmed in the healthcare and non-health environment;
f) Direct contact with tools and objects used to assist persons with COVID-19;
g) Contact with a person with COVID 19 during which the correct procedures for hand hygiene were not followed;
h) Direct contact with a person affected by COVID-19 without the use of appropriate personal protective equipment or equipment which is defective;
i) Contact with people who have travelled to China in the last 14 days;
l) Employees who operate in contact with people who have travelled to countries identified by the regional lists and the Ministry of Health as places at risk, but do not present any symptoms of infection;
m) Contact with body fluids and/or respiratory secretions;
n) Assistance to positive people COVID-19 keeping the safety distance of 2 meters;
o) Operating procedures for the treatment of biological samples (swab analysis, transport of samples).

On the basis of the following risk conditions, the following assessments shall apply:

- **Critical/high risk**

Activities involving the following:

- direct contact (or with a stay of less than 2 meters) with COVID-19 patients;
- assistance to positive persons without the use of adequate protective equipment or not following the codified operating procedures;
- COVID-19 positive patient care procedures that generate aerosols

- **Medium risk**

Activities involving the following:

- health care to positive people COVID-19 maintaining a safe distance of 2 meters;
- contact with the hospitalized environment of the patients admitted and with the tools used to assist them;
- gatherings in the same internal environment of healthcare professionals who came into contact with patients suffering from COVID-19

- **Low risk**

Activities involving the following:

- the treatment of biological samples;
The risk categories listed above depend mainly on the severity of the Pd hazard event and the frequency with which the health care provider assists the positive patient at COVID-19 Ex. However, in the present risk assessment, the worst case scenario of adverse effects has been taken into account, or

\[ Pd = 10 \]

for all the tasks considered. This choice derives both from the danger of the New Coronavirus and from the fact that an individual, once contracted the virus, can remain positive even for more than 2 weeks and in some cases, suffer worsening of the clinical picture resulting in death.

Therefore, to place the risk in the sphere of acceptability it is necessary to focus on the time of exposure of the health professional to the aeriform secretions of positive patients. This time depends on:

- by the task performed;
- from care activities (antiviral therapy, swab, intubation, resuscitation)
- from monitoring carried out on patients.

From this point of view the categories of doctors, nurses and anaesthetists are more at risk than the others; generally, for these health professionals it has been considered a frequency of exposure Ex:

\[ Ex = 1,8 \div 2 \]

while it is lower for other workers.

The probability of occurrence of contracting the Po virus and the ability to perceive the dangerous event Ev instead depend on the risk conditions under consideration.

As for the organizational structure and working environments, the Spallanzani Institute is one of the largest reference centers at national level for the diagnosis, treatment, assistance and research on HIV/AIDS infection and Ebola virus. The hospital complex has been designed in accordance with the most advanced standards and with characteristics suitable for the isolation of patients with highly diffusible diseases. The benefits of this innovation consisted not only in increasing
the level of operator safety, but also in ensuring a more comfortable atmosphere for patients. For these reasons, the parameters regarding the risks related to the working environment Amb tend to be low or minimal. Similar considerations can be made for the research centers of Spallanzani; the laboratories present in the structure, are certified according to UNI EN ISO 9001:2008 and adopt strategies and operational solutions aimed at providing organizational support models, guidelines and definitions of clinical-welfare processes for the benefit of the Institute’s users and external persons. The instrumentation used for diagnostic tasks allows high automation, high processivity and complete traceability. Classical studies based on virus cultivation, such as viral isolation and serum neutralisation tests, are also carried out in laboratories. The repertoire of classical and molecular virological analysis dedicated to emerging viruses is among the most complete in Italy.

Finally, the values of the descriptive parameters of individual P capacities vary depending on the job of the health care provider. However, account has been taken of the emergent situation that has arisen; in the face of this biological risk, even the most experienced and qualified personnel have been unprepared. Moreover, due to the limited information and studies concerning COVID-19, considerable uncertainties weigh on both prevention and protection measures to be taken and on the clinical management of the patient. All this means that every person can be in a state of risk from COVID-19. Intermediate values were therefore considered for the qualification of Q staff and for the organization of work O.

4.5 Application of the methodology

Therefore, taking into account the previous assessments, they will now be quantified, based on the activities and the associated risk conditions:

- the risk associated with COVID-19 Ma;
- the risk associated with the Amb work environment;
- the individual capabilities of employees to master biological risk from Coronavirus P.
<table>
<thead>
<tr>
<th>Employee</th>
<th>Activity</th>
<th>Parameters</th>
<th>Class of Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>a) Direct contact with person with symptomatic infection confirms in laboratory;</td>
<td>Pd = 10, Ex = 2, Po = 1.5, Ev = 1</td>
<td>Critical</td>
</tr>
<tr>
<td></td>
<td>c) Aerosol-generating procedures performed on the patient (tracheal intubation, buffering)</td>
<td>Ma = 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>e) Contact with persons who have interacted with confirmed COVID-19 patients in a healthcare and non-health environment;</td>
<td>Qa = 0.6, Qb = 0.3, Qc = 0.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>g) Contact with a person with COVID-19 during which the correct procedures for hand hygiene have not been followed.</td>
<td>Amb = 1.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>h) Direct contact with a person with COVID-19 without the use of individual devices or with defective devices;</td>
<td>Q = 7, φ = 1.5, O = 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>m) Contact with body fluids and/or respiratory secretions;</td>
<td>P = 11.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$R_{inf} = (M_a \times Amb) - k \times P$</td>
<td>$R_{inf} = 33.1$</td>
<td></td>
</tr>
<tr>
<td>Doctor</td>
<td>d) Direct contact with the confirmed COVID-19 patient environment;</td>
<td>Pd = 10, Ex = 2, Po = 1, Ev = 0.7</td>
<td>Middle</td>
</tr>
<tr>
<td></td>
<td>f) Direct contact with tools and objects used to assist people with COVID-19;</td>
<td>Ma = 14</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n) Assistance per person with COVID-19 (confirmed in the laboratory) keeping the safe distance of two meters.</td>
<td>Qa = 0.6, Qb = 0.3, Qc = 0.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Amb = 1.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Q = 7</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>φ = 1.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>O = 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P = 11.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$R_{inf} = (M_a \times Amb) - k \times P$</td>
<td>$R_{inf} = 15.4$</td>
</tr>
<tr>
<td>Employee</td>
<td>Activity</td>
<td>Parameters</td>
<td>Class of Risk</td>
</tr>
<tr>
<td>----------</td>
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<td>------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Doctor</td>
<td>b) Direct contact with person with symptoms from COVID-19 (not yet confirmed in the laboratory); i) Contact with people who have travelled to China in the last 14 days;</td>
<td>Pd = 10 &lt;br&gt; Ex = 1,8 &lt;br&gt; Po = 1,3 &lt;br&gt; Ev = 1 &lt;br&gt; Ma = 23,4 &lt;br&gt; Qa = 0,6 &lt;br&gt; Qb = 0,3 &lt;br&gt; Qc = 0,3 &lt;br&gt; Amb = 1,2 &lt;br&gt; Q = 7 &lt;br&gt; φ = 1,5 &lt;br&gt; O = 3 &lt;br&gt; P = 11,5</td>
<td>Elevated</td>
</tr>
<tr>
<td>Doctor</td>
<td>l) Employees working in contact with people who have travelled to the countries identified by the regional lists and the Ministry of Health as being at risk, but do not present any symptoms of infection;</td>
<td>Pd = 10 &lt;br&gt; Ex = 1,8 &lt;br&gt; Po = 0,7 &lt;br&gt; Ev = 0,7 &lt;br&gt; Ma = 8,8 &lt;br&gt; Qa = 0,6 &lt;br&gt; Qb = 0,3 &lt;br&gt; Qc = 0,3 &lt;br&gt; Amb = 1,2 &lt;br&gt; Q = 7 &lt;br&gt; φ = 1,5 &lt;br&gt; O = 3 &lt;br&gt; P = 11,5</td>
<td>Low</td>
</tr>
</tbody>
</table>

\[ R_{inf} = (M_a \times Amb) - k \times P \]

R_{inf} = 25,8<br> R_{inf} = 9,7
<table>
<thead>
<tr>
<th>Employee</th>
<th>Activity</th>
<th>Parameters</th>
<th>Class of Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
<td>a) Direct contact with person with symptomatic infection confirms in laboratory; c) Aerosol-generating procedures performed on the patient (tracheal intubation, buffering) e) Contact with persons who have interacted with confirmed COVID-19 patients in a healthcare and non-health environment; g) Contact with a person with COVID-19 during which the correct procedures for hand hygiene have not been followed. h) Direct contact with a person with COVID-19 without the use of individual devices or with defective devices; m) Contact with body fluids and/or respiratory secretions;</td>
<td>Pd = 10 Ex = 2 Po = 1,5 Ev = 1 Ma = 30 Qa = 0,6 Qb = 0,3 Qc = 0,3 Amb = 1,2 Q = 5 ϕ = 1,5 O = 2 P = 8,5</td>
<td>Critical</td>
</tr>
<tr>
<td>Nurse</td>
<td>d) Direct contact with the confirmed COVID-19 patient environment; f) Direct contact with tools and objects used to assist people with COVID-19; n) Assistance per person with COVID-19 (confirmed in the laboratory) keeping the safe distance of two meters.</td>
<td>Pd = 10 Ex = 2 Po = 1,2 Ev = 0,7 Ma = 16,8 Qa = 0,6 Qb = 0,3 Qc = 0,3 Amb = 1,2 Q = 5 ϕ = 1,5 O = 2 P = 8,5</td>
<td>Middle</td>
</tr>
</tbody>
</table>

\[ R_{inf} = (M_a \times Amb) - k \times P \]
<table>
<thead>
<tr>
<th>Employee</th>
<th>Activity</th>
<th>Parameters</th>
<th>Class of Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
<td>b) Direct contact with person with symptoms from COVID-19 (not yet confirmed in the laboratory); i) Contact with people who have travelled to China in the last 14 days;</td>
<td>Pd = 10 &lt;br&gt; Ex = 1,8 &lt;br&gt; Po = 1,3 &lt;br&gt; Ev = 1 &lt;br&gt; Ma = 23,4 &lt;br&gt; Qa = 0,6 &lt;br&gt; Qb =0,3 &lt;br&gt; Qc =0,3 &lt;br&gt; Amb = 1,2 &lt;br&gt; Q = 5 &lt;br&gt; ϕ = 1,5 &lt;br&gt; O = 2 &lt;br&gt; P = 8,5</td>
<td>Elevated</td>
</tr>
<tr>
<td>Nurse</td>
<td>l) Employees working in contact with people who have travelled to the countries identified by the regional lists and the Ministry of Health as being at risk, but do not present any symptoms of infection</td>
<td>Pd = 10 &lt;br&gt; Ex = 1,8 &lt;br&gt; Po = 0,7 &lt;br&gt; Ev = 0,7 &lt;br&gt; Ma = 8,8 &lt;br&gt; Qa = 0,6 &lt;br&gt; Qb = 0,3 &lt;br&gt; Qc = 0,3 &lt;br&gt; Amb = 1,2 &lt;br&gt; Q = 5 &lt;br&gt; ϕ = 1,5 &lt;br&gt; O = 2 &lt;br&gt; P = 8,5</td>
<td>Low</td>
</tr>
</tbody>
</table>
### Anaesthetist

<table>
<thead>
<tr>
<th>Employee</th>
<th>Activity</th>
<th>Parameters</th>
<th>Class of Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a) Direct contact with person with symptomatic infection confirms in laboratory;</td>
<td>Pd = 10</td>
<td>Critical</td>
</tr>
<tr>
<td></td>
<td>c) Aerosol-generating procedures performed on the patient (tracheal intubation, buffering)</td>
<td>Ex = 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>e) Contact with persons who have interacted with confirmed COVID-19 patients in a healthcare and non-health environment;</td>
<td>Po = 1,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>g) Contact with a person with COVID-19 during which the correct procedures for hand hygiene have not been followed.</td>
<td>Ev = 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>h) Direct contact with a person with COVID-19 without the use of individual devices or with defective devices;</td>
<td>Ma = 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>m) Contact with body fluids and/or respiratory secretions;</td>
<td>Qa = 0,6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Qb = 0,3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Qc = 0,3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Amb = 1,2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Q = 8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>φ = 2,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>O = 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P = 14,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>R_{inf} = (M_a \times Amb) - k \times P</strong></td>
<td><strong>R_{inf} = 32,4</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>d) Direct contact with the confirmed COVID-19 patient environment;</td>
<td>Pd = 10</td>
<td>Middle</td>
</tr>
<tr>
<td></td>
<td>f) Direct contact with tools and objects used to assist people with COVID-19;</td>
<td>Ex = 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>P</td>
<td>Po = 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ev</td>
<td>Ev = 0,7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ma</td>
<td>Ma = 14</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Qa</td>
<td>Qa = 0,6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Qb</td>
<td>Qb = 0,3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Qc</td>
<td>Qc = 0,3</td>
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<tr>
<td></td>
<td>Amb</td>
<td>Amb = 1,2</td>
<td></td>
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<tr>
<td></td>
<td>Q</td>
<td>Q = 8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>φ</td>
<td>φ = 2,5</td>
<td></td>
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<tr>
<td></td>
<td>O</td>
<td>O = 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>P</td>
<td>P = 14,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>R_{inf} = (M_a \times Amb) - k \times P</strong></td>
<td><strong>R_{inf} = 15,1</strong></td>
<td></td>
</tr>
<tr>
<td>Employee</td>
<td>Activity</td>
<td>Parameters</td>
<td>Class of Risk</td>
</tr>
<tr>
<td>-------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Health physicist</td>
<td>e) Contact with persons who have interacted with confirmed COVID-19 patients in a healthcare and non-health environment;</td>
<td>Pd = 10 Ex = 1,8 Po = 1,4 Ev = 0,8 Ma = 20,2 Qa = 0,7 Qb = 0,3 Qc = 0,3 Amb = 1,2 Q = 8 $\varphi = 1,5$ O = 4</td>
<td>Elevated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$R_{inf} = (M_a \times Amb) - k \times P$</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$R_{inf} = 22$</td>
<td></td>
</tr>
<tr>
<td>Health physicist</td>
<td>o) Operational procedures for the treatment of biological samples (swab analysis, transport of samples)</td>
<td>Pd = 10 Ex = 2 Po = 1 Ev = 0,5 Ma = 10 Qa = 0,6 Qb = 0,3 Qc = 0,3 Amb = 1,1 Q = 8 $\varphi = 1,5$ O = 4</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$R_{inf} = (M_a \times Amb) - k \times P$</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$R_{inf} = 9,9$</td>
<td></td>
</tr>
<tr>
<td>Employee</td>
<td>Activity</td>
<td>Parameters</td>
<td>Class of Risk</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------------------------------------------------------------</td>
<td>------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Health technician</td>
<td>o) Operational procedures for the treatment of biological samples (swab analysis, transport of samples)</td>
<td>Pd = 10, Ex = 2, Po = 1, Ev = 0,5, Ma = 10, Qa = 0.6, Qb = 0.3, Qc = 0.3, Amb = 1.2, Q = 8, ϕ = 1.5, O = 2.5, P = 12</td>
<td>Low</td>
</tr>
<tr>
<td>Health technician</td>
<td>e) Contact with persons who have interacted with confirmed COVID-19 patients in a healthcare and non-health environment; n) Assistance per person with COVID-19 (confirmed in the laboratory) keeping the safe distance of two meters.</td>
<td>Pd = 10, Ex = 2, Po = 1.2, Ev = 1, Ma = 24, Qa = 0.6, Qb = 0.3, Qc = 0.3, Amb = 1.2, Q = 8, ϕ = 1.5, O = 2.5, P = 12</td>
<td>Elevated</td>
</tr>
</tbody>
</table>

\[ R_{\text{inf}} = (M_a \times \text{Amb}) - k \times P \]
<table>
<thead>
<tr>
<th>Employee</th>
<th>Activity</th>
<th>Parameters</th>
<th>Class of Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Auxiliary, OSS</strong></td>
<td>e) Contact with persons who have interacted with confirmed COVID-19 patients in a healthcare and non-health environment;</td>
<td>Pd = 10, Ex = 2, Po = 1.2, Ev = 1, Ma = 24, Qa = 0.6, Qb = 0.3, Qc = 0.3, Amb = 1.2, Q = 5, φ = 1.5, O = 3, P = 9.5</td>
<td>Elevated</td>
</tr>
<tr>
<td></td>
<td>R_{inf} = (M_a \times Amb) − k \times P</td>
<td>R_{inf} = 26.9</td>
<td></td>
</tr>
<tr>
<td><strong>Auxiliary, OSS</strong></td>
<td>d) Direct contact with the confirmed COVID-19 patient environment; f) Direct contact with tools and objects used to assist people with COVID-19;</td>
<td>Pd = 10, Ex = 2, Po = 1.2, Ev = 0.7, Ma = 16.8, Qa = 0.6, Qb = 0.3, Qc = 0.3, Amb = 1.2, Q = 5, φ = 1.5, O = 3, P = 9.5</td>
<td>Middle</td>
</tr>
<tr>
<td></td>
<td>R_{inf} = (M_a \times Amb) − k \times P</td>
<td>R_{inf} = 18.8</td>
<td></td>
</tr>
<tr>
<td>Employee</td>
<td>Activity</td>
<td>Parameters</td>
<td>Class of Risk</td>
</tr>
<tr>
<td>----------------</td>
<td>--------------------------------------------------------------------------</td>
<td>------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Auxiliary, OSS</td>
<td>o) Operational procedures for the treatment of biological samples (swab analysis, transport of samples)</td>
<td>Pd = 10</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ex = 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Po = 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ev = 0,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ma = 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Qa = 0,6</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Qb = 0,3</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Qc = 0,3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Amb = 1,2</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Q = 5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>φ = 1,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>O = 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P = 9,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>R_{inf} = (M_a \times \text{Amb}) - k \times P</td>
<td>11,2</td>
</tr>
<tr>
<td>Desk operator</td>
<td>e) Contact with persons who have interacted with confirmed COVID-19 patients in a healthcare and non-health environment;</td>
<td>Pd = 10</td>
<td>Critical</td>
</tr>
<tr>
<td></td>
<td>h) Direct contact with person with COVID-19 without the use of individual devices or with defective devices;</td>
<td>Ex = 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Po = 1,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ev = 0,8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ma = 24</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Qa = 0,6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Qb = 0,4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Qc = 0,3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Amb = 1,3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Q = 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>φ = 1,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>O = 2,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P = 8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>R_{inf} = (M_a \times \text{Amb}) - k \times P</td>
<td>29,6</td>
</tr>
<tr>
<td>Employee</td>
<td>Activity</td>
<td>Parameters</td>
<td>Class of Risk</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>---------------</td>
</tr>
</tbody>
</table>
| Desk operator | n) Assistance per person with COVID-19 (confirmed in the laboratory) keeping the safe distance of two meters. | Pd = 10
Ex = 1.8
Po = 1.2
Ev = 0.7
Ma = 15.1
Qa = 0.6
Qb = 0.4
Qc = 0.3
Amb = 1.3
Q = 4
ϕ = 1.5
O = 2.5
P = 8
\( R_{inf} = (M_a \times Amb) - k \times P \)
\( R_{inf} = 18.6 \) Middle |
| Cleaning staff| e) Contact with persons who have interacted with confirmed COVID-19 patients in a healthcare environment and not h) Direct contact with a person with COVID-19 without the use of individual devices or with defective devices; | Pd = 10
Ex = 1.4
Po = 1.3
Ev = 0.8
Ma = 14.6
Qa = 0.7
Qb = 0.3
Qc = 0.3
Amb = 1.4
Q = 3.5
ϕ = 1.5
O = 2.5
P = 7.5
\( R_{inf} = (M_a \times Amb) - k \times P \)
\( R_{inf} = 18 \) Middle |
<table>
<thead>
<tr>
<th>Employee</th>
<th>Activity</th>
<th>Parameters</th>
<th>Class of Risk</th>
</tr>
</thead>
</table>
| Cleaning staff | d) Direct contact with the confirmed COVID-19 patient environment; | $P_d = 10$
 $Ex = 2$
 $Po = 1,3$
 $Ev = 0,5$
 $Ma = 13$
 $Q_a = 0,7$
 $Q_b = 0,3$
 $Q_c = 0,3$
 $Amb = 1,3$
 $Q = 3,5$
 $\varphi = 1,5$
 $O = 2,5$
 $P = 7,5$ | Middle |
| Vigilance | b) Direct contact with person with symptoms from COVID-19 (not yet confirmed in the laboratory); | $P_d = 10$
 $Ex = 1,2$
 $Po = 1,4$
 $Ev = 0,8$
 $Ma = 13,4$
 $Q_a = 0,8$
 $Q_b = 0,4$
 $Q_c = 0,3$
 $Amb = 1,5$
 $Q = 4$
 $\varphi = 1,5$
 $O = 3$
 $P = 8,5$ | Middle |
<table>
<thead>
<tr>
<th>Employee</th>
<th>Activity</th>
<th>Parameters</th>
<th>Class of Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vigilance</td>
<td>e) Contact with persons who have interacted with confirmed COVID-19 patients in a healthcare and non-health environment;</td>
<td>Pd = 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>h) Direct contact with a person with COVID-19 without the use of individual devices or with defective devices;</td>
<td>Ex = 1,7</td>
<td>Ma = 19</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Po = 1,4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ev = 0,8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ma = 19</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Qa = 0,8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Qb = 0,4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Qc = 0,3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Amb = 1,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Q = 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>φ = 1,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>O = 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P = 8,5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>R_{inf} = (M_a \times \text{Amb}) - k \times P</td>
<td>R_{inf} = 27,2</td>
<td>Elevated</td>
</tr>
</tbody>
</table>
5. Prevention measures

Routine measures already implemented for biohazard prevention in general:

- The well-separated paths for clean/dirty material must be followed with technical measures to minimize the exposure of operators and environments to possible contamination.
- All horizontal surfaces (furniture, furniture, worktops, trolleys) present are washable, disinfectable and waterproof. Checks on washing, disinfection and sanitation procedures should be stepped up.
- Adequate air exchange (natural and artificial ventilation) is mandatory in the environment.
- Periodic maintenance and replacement of air conditioning filters is mandatory.
- Workers shall carefully check the possible presence of organic materials which must be handled or removed ALWAYS with suitable gloves.
- Workers are obliged to clean equipment which is always used with the PPE worn.
- It has been provided to equip the various departments of manual tools that need taking care that these are suitable for the type of processing carried out and always sterilized or disposed of after each intervention.
- It is mandatory to replace tools in poor condition with reliable and good quality tools.
- Illumination shall be provided to eliminate the risk of non-optimal perception of danger situations.
- During the activity it is not allowed to bring rings, bracelets or other jewelry avoid eating, smoking, bringing hands to mouth or eyes during work.
- Working and protective clothing which is contaminated with biological agents shall be removed when the worker leaves the working area, stored separately from other clothing, disinfected, cleaned and, if necessary, destroyed.
- Workers pay the utmost attention to the cleaning of the hands and in particular: before touching a patient, before an aseptic maneuver, after
exposure to a biological fluid, after contact with the patient, after contact with what is around the patient.

- The number of workers present during the specific activity who are exposed or, who may be potentially exposed, to biological agents is the minimum according to the need of the processing in compliance with the health and safety conditions of workers in order to eliminate or, in any case, to minimize the resulting risks.

- Activities which expose or may potentially expose to biological agents shall be adequately designed in accordance with the health and safety conditions of workers in order to eliminate or, in any case, minimize the risks arising.

5.1 Measures to prevent contact with viruses

The most common tips to try to avoid direct contact with Coronavirus Covid-19 are mainly these:

- Avoid direct or close contact (less than 1.5-2 meters) with sick people or with suspicious respiratory symptoms or even simply with people at risk of disease (that is, people who in the last 15-20 days may have been in contact with people who then fell ill).

- Wash hands often with water and soap with antiseptic solutions applying the protocol issued by the CIO
Hospital Infections Committee and subject of special deliberation.

- Gargle with adequate mouthwash when it is assumed that they have come into inhalation and oral contact with pathogenic viruses.
- Avoid touching your eyes, nose or mouth with unwashed hands (obviously if your hands have touched people or objects contaminated by a short time ago).
- Protect hands using disposable gloves.
- Clean surfaces that may have been infected using chemical disinfectants capable of killing Coronavirus (bleach products [sodium hypochlorite] or other chlorinated solutions, peracetic acid or 75% ethanol).

Figure 9 Correct procedures for washing hands
- It is mandatory to avoid gatherings.
- Minimize immunoimbalance actions (such as voluntary or involuntary stress and toxic substances) and encourage immunostrengthening actions (such as maintaining a proper lifestyle and taking any supplements). In any case, if in the last 15-20 days there have been close contact with people who then fell ill with COVID-19 or with suspicious people to get sick in the future and now you start to accuse of mild respiratory symptoms similar flu, in addition to following all the advice listed in the previous points, it is recommended to:
  - Inform the IRCCS of such occurrence; Stay at home and contact your doctor who will assess the clinical situation and the therapeutic measures to be taken.
  - Sneeze or cough in a handkerchief or elbow with a flexed arm (so as not to contaminate the environment or your hands).
  - Do not touch your nose and mouth with your hands (so as not to self-medicate and facilitate the spread of the virus).
  - Use a surgical mask and throw the used handkerchiefs into a basket that must be closed immediately after use.

5.2 SARS-CoV-2 transmission and surface survival

According to the World Health Organization (WHO), the transmission of coronavirus infections, including SARS-CoV-2, occurs through droplets, 5 μm diameter droplets that originate from the acts of breathing, talking, coughing and sneezing. Due to their size the droplets travel in the air for short distances, usually less than one meter, and can directly reach susceptible subjects in the immediate vicinity, as well as depositing on objects or surfaces that thus become a source of spread of the virus. In fact, in this case, hands that have come into contact with objects so contaminated can be a vehicle for transmission by indirect contact when they touch the mouth, nose and eyes. Given that hand washing is always the cornerstone of proper prevention, regular cleaning followed by disinfection of
surfaces and indoor environments play a crucial role in the prevention and containment of the spread of the virus.

Studies on coronaviruses, not SARS-CoV-2, such as SARS and MERS virus, suggest that the survival time of these pathogens on surfaces, under experimental conditions, varies from a few hours to a few days depending on the material concerned, concentration, temperature and humidity. It should be noted that this data refers to the detection of RNA of the virus and not to its isolation in a viable form, and therefore not related to its actual infectivity.

More recent data on the persistence of SARS-CoV-2 virus confirm its persistence on plastic and stainless steel which, under experimental conditions, is comparable to that of SARS virus (SARS-CoV-1), also showing an analogous exponential decay over time. On plastics and stainless steel, the virus can withstand up to 72 hours, although the infectious charge on these materials is halved after about 6 hours and 7 hours respectively. The surfaces with the lowest persistence are copper and cardboard, where a complete reduction of infectivity has been observed after 4 hours for copper and 24 hours for cardboard.

A recent study evaluated the stability of the SARS-CoV-2 virus at different temperatures, showing that the virus is highly stable at 4 μC, but sensitive to heat. By increasing the temperature to 70 °C, the virus was no longer detectable after 5 minutes. The stability of SARS-CoV-2 virus on different surfaces was also assessed in the same study, as shown in Table 6.

<table>
<thead>
<tr>
<th>Surfaces</th>
<th>Infectious viral particles detected up to</th>
<th>Infecting viral particles not detected after</th>
</tr>
</thead>
<tbody>
<tr>
<td>printing paper and tissue</td>
<td>30 minutes</td>
<td>3 hours</td>
</tr>
<tr>
<td>fabric</td>
<td>1 day</td>
<td>2 day</td>
</tr>
<tr>
<td>wood</td>
<td>1 day</td>
<td>2 day</td>
</tr>
<tr>
<td>banknotes</td>
<td>2 day</td>
<td>4 day</td>
</tr>
<tr>
<td>glass</td>
<td>2 day</td>
<td>4 day</td>
</tr>
</tbody>
</table>
Table 6 Permanence of the New Coronavirus on different surfaces

<table>
<thead>
<tr>
<th>Material</th>
<th>4 day</th>
<th>7 day</th>
</tr>
</thead>
<tbody>
<tr>
<td>plastic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>stainless steel</td>
<td>4 day</td>
<td>7 day</td>
</tr>
<tr>
<td>surgical masks inner layer</td>
<td>4 day</td>
<td>7 day</td>
</tr>
<tr>
<td>surgical masks outer layer</td>
<td>7 day</td>
<td>not determined</td>
</tr>
</tbody>
</table>

The SARS-CoV-2 virus would therefore appear to be more stable on smooth surfaces and extremely stable in a wide range of pH values (pH 3-10) at room temperature (20 °C).

5.3 Training and training of personnel for the correct adoption of prevention, protection and isolation measures

All health and care personnel, including cleaners, must receive specific training on the basic principles of ICA prevention and control. In addition, operators providing direct care to residents of the facility and cleaners must receive specific training on how to prevent the transmission of the infection from SARS-CoV-2.

In particular, the following shall be the subject of training and training programmes for health professionals and carers:

- Characteristics of SARS-CoV-2 infection and COVID-19 disease, with particular attention to the following topics: characteristics of the virus and its mode of transmission, epidemiology, clinical presentation, diagnosis, treatment, procedures to be followed in the event of a suspected or probable/confirmed case. Practical simulations of suspicious case presentation situations COVID-19 can be very helpful;

- It is mandatory for the care of all residents: hand and respiratory hygiene, use of appropriate devices and PPE (in relation to risk assessment), good safety practices in the use of injecting needles, safe disposal of waste, appropriate linen management, environmental cleaning and sterilization of the equipment used for the resident;
- Precautions are required for the prevention of contact-borne diseases and droplets in the assistance of suspected or probable/confirmed cases of COVID-19: gloves, surgical mask, protective glasses/visor, disposable shirts (possibly water-repellent).

- Precautions for the prevention of diseases transmitted by air: when procedures are performed that can generate aerosols and in the assistance of COVID-19 cases based on the risk assessment of the structure: facial filtering (FFP2 or FFP3); isolation room.

- Behaviours to be implemented during breaks and meetings in order to reduce the possible transmission of the virus: It is suggested to foresee appropriate moments, also short, listening and comparison of operators and between operators to help them verbalize feelings of concern, to allow them to suggest "bottom-up" actions to improve and verify the quality of procedures and to share problems, ideas and "best practices" in assistance. At such times, it is essential that the precautionary measures provided for the aggregation of several persons are implemented. Operator training and training should be based on mandatory short-term sessions (no more than 2-3 hours) with practical exercises (for example, on good hand hygiene practices and on the dressing and undressing of devices and PPE) and video presentation. Operators should be recommended to follow specific online courses on COVID-19.

5.4 Organizational measures to prevent the entry of suspected or confirmed cases of COVID-19 into the structure

Preventing the entry of suspected or confirmed cases of COVID-19 is a fundamental aspect of prevention; it is therefore necessary a close governance of access in the structure.

In particular, in each structure:

- It is mandatory for the duration of the emergency, provide for the prohibition of access to the structure by family members and acquaintances
(as indicated in the DPCM of 9 March 2020 art.2, paragraph q); the visit can be authorized in exceptional cases (for example, end-of-life situations) only by the management of the facility, after appropriate risk-benefit assessment. However, the number of authorized persons must be limited and all recommended precautions for the prevention of transmission of the infection by SARS-CoV-2 must be observed. In end-of-life situations, at the request of the dying or family members, consider also authorizing spiritual assistance, where this is not possible through telematic means, with all the recommended precautions for the prevention of transmission of SARS-CoV-2 infection.

- It is absolutely necessary to prevent access to persons with symptoms of acute respiratory infection, even minor ones, or who have had close contact with suspected or confirmed COVID-19 cases within the last 14 days for this purpose, put in place an evaluation system for anyone who needs to enter the social health structure in such a way as to allow the immediate identification of people with flu-like symptoms. It is recommended that this evaluation should also include the measurement of temperature and the compilation of a short questionnaire or interview by an operator. On the same occasion it is important to remember the behavioural rules and the recommended precautions for the prevention of SARS-CoV-2 infection, as well as for the person to perform the hygiene of the hands.

- Keep in mind that the access of new residents in residential social and health facilities is subject to the fact that the facilities provide for the preparation of a temporary reception form dedicated to new guests, or the adoption of appropriate measures to ensure adequate social distance between hosts in order to ensure an additional barrier against the spread of the virus by subjects at a possible incubation stage.

- According to the regional indications and availability, request a swab from residents during a new entry a transfer for resignation protected by the hospital, in addition to the normal assessment, to be carried out by the operators of the facility, health status and possible existence of an exposure risk. Please note that the possible negativity of this buffer does not imply,
however, the safety that this resident cannot develop a disease in the following days. Negative entry swab should be repeated after 14 days before final placement.

- It is mandatory to require the use of surgical mask and accurate hand hygiene to suppliers, maintainers and/or other operators whose stay in the premises must be limited to the time strictly necessary for carrying out specific activities. The delivery of the goods must take place through a single entry for greater control. Staff at the facility shall monitor the temperature of suppliers, maintainers and/or other operators, via remote thermometers or stationary thermoscanners, and investigate the presence of symptoms of acute respiratory infection, prohibiting entry if fever or other symptoms indicative of infection are detected.

5.5 Dressing and Undressing

The dressing and undressing of health professionals requires a precise procedure which protects the operator against the risk of coming into contact with the virus.

The dressing follows the following steps:

1. Remove any jewelry and personal object and practice hand hygiene with soap and water or alcoholic solution for 20/30 seconds.

2. Check the integrity of devices, do not use non-intact devices; wear a first pair of disposable gloves afterwards;
3. Wear disposable shirts over uniform;

4. Wear suitable FFP2/FFP3 facial filter;

5. Wear the second pair of disposable gloves to cover the cuff of the shirt.

6. Place the goggles or visor. Ensure that the devices are positioned well so that they do not move during use.
7. Finish dressing by wearing the cap.

The undressing takes place in the room/anti-filter zone and must follow these behavioural rules:

1. Begin the undressing by removing the first pair of gloves and the gown together by opening it at the back and sliding it upside down to prevent contamination of the clothing below.

2. Dispose of the first pair of gloves and the coat in the container for hazardous waste at infectious risk.
3. Remove the cap and dispose of it in the container for hazardous waste at infectious risk. Remove the protective glasses from the elastic band in a special container.

4. Remove the filter mask by touching only the rubber bands and handling it from the back because the front should be considered contaminated. Dispose of it in an infectious hazardous waste container.

5. Remove the second pair of gloves from the inside without touching the unprotected skin.

6. Practice hand hygiene with soap and water or alcoholic solution for 20/30 seconds
6. Protective measures

Personal protective equipment is equipment used to protect the health and safety of workers; its use is recommended when, despite the application of collective preventive and protective measures, the risks are not eliminated or reduced to acceptable levels.

The new Coronavirus is a respiratory virus that spreads mainly through close contact with a sick person. The primary route is the droplets of the breath of infected people, for example by:

- saliva, coughing and sneezing
- direct personal contacts
- hands, for example, touching with contaminated hands, mouth, nose or eyes

The transmission route to be feared is above all the respiratory one but it is always useful to remember the importance of proper hygiene of the hands and surfaces.

It is therefore necessary to use the specific PPE most suitable to prevent the different modes of infection:

- respiratory protection
- protection of the hands
- eye protection
- body protection

6.1 The masks

PPE for the respiratory tract differs according to the purpose for which it is to be used, but the aim is always to prevent or limit the entry of potentially dangerous agents into the airway. The protection is guaranteed by the filtering capacity of devices able to retain airborne particles mostly dispersed according to size, shape and density, preventing inhalation. There are basically two types of masks:

- surgical
6.1.1 **Surgical masks**

Surgical masks are rectangular, usually green or blue, consisting of some layers of non-woven tissue. They do not filter the inhaled air and hook to the ears with two small elastic bands or with laces. They serve if you are infected to avoid infecting the surrounding people and spilling droplets of saliva. They do not serve to protect themselves from the virus, however, if it is true that there are about 10 times in number of those infected traced that are asymptomatic, they can be an excellent means of containing the contagion.

The Decree-Law of 17 March 2020 n.18, the so called "Decreto Cura Italia", temporarily equates surgical masks with personal protective equipment (PPE) with reference to Legislative Decree 81/2008.

![Surgical mask](image)

**Figure 10** Surgical mask

6.1.2 **Filtering facial masks**

Respiratory protection masks (APVR) are shell masks, better identified as "Filtering Facial Masks", which are used in the world of work to protect themselves from pollutants in the air of the environment. They are composed of a filter paper that by mechanical action stops dangerous particulates: dust, fumes, mists, microorganisms, etc. On the compliant template adopted in Italy, must be present the
reference standard UNI EN 149:2001 and an abbreviation indicating the degree of protection:

a) FFP1
b) FFP2
c) FFP3

The higher the grade, the higher the amount of particulate matter that is blocked between the mesh of the filter paper. The letters "FF" are the acronym of "filtering facial", "P" indicates the protection from dust while the numbers 1,2,3 identify the level of protection (low >80%, average >94%, high >99%). In addition to the protection index, there is another index on masks:

- R stands for Reusable
- NR stands for Not Reusable

The time of use has nothing to do with it, the worker puts them on and when he takes them off he has to throw them away.

**FFP1**

FFP1 class masks provide a first level of respiratory protection in dusty environments and containing suspended particles. They are therefore semi-facial dust masks commonly used in various sectors (textile, food, mining, iron and steel, construction and construction, wood, except hardwood) capable of protecting the respiratory tract from non-volatile solid and liquid particles when their concentration does not exceed 4,5 times the threshold limit value provided for by the legislation. They have a filtering capacity of at least 80% of the particles suspended in the air and a loss to the interior of less than 22%. It is not suitable for protection against airborne pathogens.
FFP2

FFP2 masks offer a second level of respiratory protection and are generally used in the textile, mining, pharmaceutical, iron and steel industry, agricultural and fruit and vegetable industries, automotive bodywork, wood (except hardwood) in testing laboratories and also by health professionals or staff exposed to low-to-moderate risks.

They are able to protect the respiratory tract from dust, mists and fumes of particles with a level of toxicity between the low and medium whose concentration reaches up to 12 times the limit value provided by the legislation. They have a filtering capacity of at least 94% of the particles suspended in the air and a loss to the inside less than 8%.
**FFP3**

FFP3 class masks are an airway protection device commonly used in the textile, mining, pharmaceutical, construction and construction industries, iron and steel industry, waste treatment, in testing laboratories and also by health professionals assisting infected or potentially infected individuals and research staff exposed to high risk.

They are able to protect the respiratory tract from dust, fog and fumes of toxic particles (asbestos, nickel, lead, platinum, rhodium, uranium, pollen, spores and viruses) with a concentration up to 50 times the limit value required by the legislation. They have a filtering capacity of at least 99% of the particles suspended in the air and a loss to the inside less than 2%.

![Figure 13 Mask FFP3](image)

**6.2 Gloves**

The gloves most commonly used in health care, as necessary to prevent contamination with biological materials, are disposable latex or nitrile that have the characteristic of adhering perfectly to the hands and thus allow a perfect manual dexterity. These gloves are classified as PPE category III (complying with EN 374) and protect the user from contact-transmissible pathogens. Gloves are considered suitable for general protection against biological agents in application of standard
precautions. In order for gloves to play their intended role, they must be used and stored in an appropriate manner. In this regard, it should be:

- wear the appropriate size
- gloves must be regularly checked for the absence of defects; if they are defective, they must be replaced immediately
- wash hands when gloves are removed

6.3 **Glasses**

Eye protection can be achieved by using:

- safety glasses with side protection
- protective visors

The reference standard is UNI EN 166 where both equipment is classified in category II.

6.3.1 **Glasses with side protection**

These PPE are limited to protecting against splashing and splashing of blood or other biological fluids (e.g. saliva, urine, amniotic fluid) as they do not fully adhere to the face. There are some limitations/peculiarities of PPE: the simultaneous use of eyeglasses can be a limitation; they do not provide protection to the face and mucous membranes (nose); the reconditioning shall comply with the operating procedures set out in the information document and laid down by the manufacturer.

![Figure 14 Safety goggles](image)
6.3.2  Protective visors

These are splash visors consisting of a wearable support and a transparent protective shield. The wearable support has soft elements to provide comfort to the user and a diameter adjustment system to be worn from different sizes. The protective shield, subjected to scratch-resistant treatment, is made with PET plate, a material with high chemical resistance, with a thickness of less than 1 mm suitable for sterilization and washing with disinfectant substances.

These PPE adequately protect the eyes from splashing and splashing of blood or other biological fluids (e.g. saliva, urine, amniotic fluid) as they adhere completely to the face.

![Protective visor](image)

**Figure 15** Protective visor

6.4  The garments

A protective garment is a protective garment which covers or replaces personal clothing and which is designed to protect against one or more hazards. They are classified in III category with EC type certification for protection against biological agents in accordance with the requirements of technical standard EN 340 and EN 14126/2006. In particular, with these devices the protection against biological agents is determined by the classification in relation to:

- resistance to penetration of synthetic blood;
- resistance to the penetration of pathogens carried by blood;
- resistance to penetration of contaminated solid particles;
- resistance to penetration of contaminated aerosols;
- resistance to penetration of liquids with bacteria.

Among the various devices available to healthcare professionals we have:

- Waterproof shirts: waterproof shirts made of non-woven fabric, very resistant and suitable for pathogens transmissible by contact. It is a disposable device for partial protection of the body from splashing. It has an overlapping rear closure and elastic cuffs in cotton.

- Protective suits: made of non-woven fabric and suitable for pathogens transmissible by contact. It is a disposable device with a cap that protects against splashing and splashing. It has a closing system in the front and footwear equipped with non-slip systems.

6.5 Selection of PPE

The selection of the type of protective device shall take into account the transmission risk of SARS-CoV-2. This depends on:

- Transmission type: by contact or by droplets
- Type of patient: the most contagious patients are symptomatic patients; if such patients would wear a surgical mask or cover their nose and mouth with a handkerchief, the spread of the virus would be greatly reduced
- Type of care contact: the risk increases when
  1. the contact is close
  2. contact is prolonged
  3. the contact is repeated or continuous
  4. procedures or manoeuvres are performed at risk of producing aerosols from the patient’s secretions (such as resuscitation, intubation, testing-tampone)

In addition, a couple of non-negligible remarks need to be made:
1) In the current emergency scenario COVID-19 Italian, the availability of protection devices is not unlimited therefore it is essential to properly manage work in order to reduce improper and excessive consumption of PPE. To prevent their deficiency, it is possible to program the use of the same mask for the care of several patients COVID-19 in continuity, provided that the mask is not damaged, contaminated or damp. In addition, in the absence or lack of availability of filtering faces, they must be insured as a priority for health care professionals engaged in welfare activities; it is therefore necessary to establish a priority order of use for masks:
   1. FFP3: hospitals, intensive care units
   2. FFP2: health care providers, law enforcement agencies
   3. Surgical: cleaning staff

2) In order to ensure maximum protection for health professionals exposed to increased risk, patients admitted to the hospital should also wear surgical masks.

In all health or laboratory activities and in the presence of patients or biological samples infected with airborne transmitted micro-organisms, health care professionals shall wear:

   o Gloves;
   o Water-repellent shirts or protective overalls;
   o Glasses or protective visor;
   o Filter mask FFP3 or, failing this, FFP2

In the absence or lack of protective medical equipment it is possible, in accordance with the report COVID-19 of the Higher Institute of Health "Interim indications for a rational use of protection for infection with SARS-CoV-2 in health and social care activities in the current emergency scenario SARS-CoV-2", specify the PPE and recommended devices for the prevention of infection with SARS-CoV-2 for health professionals depending on work environment, job and type of work activity.
<table>
<thead>
<tr>
<th>Work Context</th>
<th>Recipient of the indication</th>
<th>Activity</th>
<th>Type of PPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 patients’ room</td>
<td>Health workers</td>
<td>Direct assistance to COVID-19 patients</td>
<td>FFP2 or surgical mask; protective suit or disposable shirts; gloves; visor / glasses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aerosol generation risk procedures</td>
<td>FFP3 or FFP2; protective suit or suitable shirts; gloves; visor / glasses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Testing (tampone)</td>
<td>FFP2 or surgical mask in absence; disposable shirts; gloves; visor / glasses</td>
</tr>
<tr>
<td></td>
<td>Cleaners</td>
<td>Access in patients COVID-19 rooms</td>
<td>Surgical mask; disposable shirts; thick gloves; glasses; work shoes</td>
</tr>
<tr>
<td>Patient transit or internal transport areas</td>
<td>All the workers</td>
<td>No activity involving contact with COVID-19 patients</td>
<td>Surgical mask; disposable gloves</td>
</tr>
<tr>
<td>Hospitalization areas without patients COVID-19</td>
<td>Health workers</td>
<td>Direct contact with unsuspecting COVID-19 patients</td>
<td>PPE provided for the ordinary conduct of the activities.</td>
</tr>
<tr>
<td>Triage</td>
<td>Health workers</td>
<td>Screening without direct contact</td>
<td>Surgical mask</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Screening involving direct contact</td>
<td>Surgical mask; suitable shirts; gloves; Visor / glasses</td>
</tr>
<tr>
<td></td>
<td>Patients with respiratory symptoms</td>
<td>Any</td>
<td>Surgical mask</td>
</tr>
</tbody>
</table>
Patients without respiratory symptoms | Any | PPP is not required; Maintain safe distance
---|---|---
Laboratory | Lab technician | Handling of respiratory samples | PPE following the laboratory class

Table 7 Schematization of recommended PPE in relation to the working environment
7. Remodulation of work environments for risk COVID-19

The pandemic situation with New Coronavirus requires a reorganization of health facilities at national level in order to ensure the reception of patients, who need intensive treatment, and safety for health professionals. The Spallanzani Institute in Rome, during the Coronavirus emergency, reorganized the hospital departments and enlarged the hospital center through:

- the installation of a mobile health facility - area of first observation and triage, in collaboration with the Civil Protection, in order to enhance the path of acceptance of suspected cases of infection with COVID-19;
- the preparation of an additional 20 beds intensive care.

The following are the minimum structural, technological and organizational requirements required for the exercise of health activities defined by:

- D.P.R 14 January 1997
- Annex C to DCA 8/2011 e Successive Modifiche e Integrazioni – Regione Lazio

7.1 Advanced Medical Post - PMA

The PMA - Advanced Medical Post - is the fulcrum of the health chain of relief in case of intervention on a limited catastrophe and is located between the collection area and the hospitalization hospitals. When the number of injuries is greater than that manageable by the resources immediately available, the PMA constitutes on the site of the event a medicalized structure in which to continue the triage, that is, the process of dividing patients into severity classes according to the reported injuries and treatment and/or evacuation priorities. It is also the place to administer stabilization treatments for victims and coordinate evacuation to suitable hospitals available.
The function of the PMA allows, among other things, to gain valuable time, during which more ambulances and staff can be mobilized and allows hospitals to prepare for a sudden and high number of victims caused by the extraordinary event.

7.1.1 Location of equipment

It is preferable to set up the PMA inside a building, or in any case inside a masonry structure and, only in the case of unavailability of these structures, to resort to the tents. The advantages are:

- saving time because it is not necessary to set up pitched structures;
- greater safety and security;
- more space available;
- greater comfort for victims and operators - in some cases lighting, heating, running water, telephone lines, etc.

The location of the PMA shall be decided by the Advanced Command Post and shall meet the following criteria:

1. must be close to the location of the event but safe;
2. must be close to the communication routes in order to allow easy access and exit to the different vehicles converging on them;
3. must not be located in an area with unhealthy or muddy soil which hinders the transit of vehicles.

7.1.2 Resources and activation times

The PMA must be completely autonomous in terms of sanitary equipment, electricity, lighting. The material must be stored in ready-made crates, distinguished between logistical and sanitary.

In order for a PMA to arrive and be deployed in a timely manner, it is very important that pre-ordered plans exist and that all equipment can be easily handled and transported with light transport vehicles.
Under ideal conditions, the PMA’s support logistics system must be ready to move to the operating area within 30 minutes of its activation and remain autonomous for at least 12 hours, during which a system of refuelling of medical equipment and of changing of rescue teams must be provided.

7.1.3 **Areas**

The Advanced Medical Post must be divided into 4 areas:

- **triage**: the filter through which all victims pass;
- **related urgencies**: "yellow code" casualty management;
- **absolute urgency**: "code red" casualty management;
- **evacuation**: preparation of the wounded towards the hospital.

The victims in green code are addressed in a space near the area related urgencies, manned by law enforcement and health workers able to assess any worsening of their condition.

Code Green casualties should be assessed in the PMA at the end of the yellow and red evacuation procedures. However, the Health Director of Relief may decide not to evaluate the green codes and to evacuate them from the scene as soon as possible. This is to reduce the psychological stress of the victims, induced by the prolonged stay on the scene, and to make available all pre-hospital health personnel for the treatment of the most serious injured.

The Code Black victims are the people who died after being picked up by health teams. They are placed in a sub-area near the absolute emergency area of the PMA, manned by law enforcement. Even the deceased victims will have to undergo the triage procedure with relative progressive numbering.

The evacuation area is at the exit of the PMA, and from here the victims depart for the destination assigned by Operations Centre 118 with the most suitable means of transport to their clinical situation. Evacuation may be by land by ambulance or by air using helicopters.

The person responsible for the evacuations is usually a nurse of the PMA, who has the task of checking the completion of the PMA card, the transfer operations and the destination of the vehicles.
7.1.4 The tasks of operators

The operators of the PMA are 118 doctors and nurses who can be assisted by other rescuers. Their task is:

- acceptance and registration of injured persons;
- triage;
- stabilization treatments;
- definition of evacuation priorities.

The head of the PMA is a medical 118 expert designated by the operations center; his duties are:

- ensure the best possible quality of treatment for victims, taking into account the resources and resources available;
- maintain contact with the Director of Health Relief - Dss to organize the influx of victims and their evacuation.

7.2 The Intensive Care Unit (ICU)

7.2.1 Spatial planning and design

Space planning and design of a general EUCI shall be based on:

- on the admission criteria for patients;
- patterns of movement of staff and visitors;
- the need to support services, such as nursing areas, department supply areas, office areas, areas for administrative and educational needs.

The number of beds considered best from a functional perspective ranges from 4 to 12 per unit. The internal configuration can be either single or multiple.

In addition:
Each ICU should be a geographically distinct area within the hospital and, where possible, with controlled access.

There should be no crossings leading to other departments.

The movement of personnel and supplies should be separated from the public and visitor movement.

The location of the ICU should be chosen in such a way that the unit is adjacent to, or connected by elevator, the Emergency Department, the operating complex, the intermediate therapy units, and the Radiology Department.

- **Patient area.** Patients must be positioned in such a way that they can be viewed directly or indirectly (for example, by means of television monitors) by healthcare professionals at all times. This approach allows the control of patients in both routine and emergency conditions. The preferred project allows a direct line of vision between the patient and the nursing station. Sliding glass doors and other similar solutions facilitate this management and increase access to the sleeping place in emergency situations. Signals from patient call systems, alarms from monitoring instruments and telephone systems add a sensory overload in intensive care units. Without wanting to reduce their importance or their significance of urgency, such signals should be modulated to the level that will alert the medical staff without being unnecessarily annoying.

- **Nursing station.** A central nursing station should be provided as a comfortable area of sufficient size to suit the needs of the staff. In a modular design ICU, each nursing station should provide most, if not all, of the functional performance of a central location. There must be adequate communication systems and lighting sources and there should be a wall clock. Adequate space for computer terminals and printers is essential when automated data collection systems are in use. Patient data should be readily accessible. Adequate areas and locations for the medical documentation of patients should be provided to both medical and nursing staff. Racks, files
and other containers should be arranged in such a way as to be readily accessible to all staff.

- **Radiological area.** A separate room or a separate area close to each ICU or department sector shall be designated for the display and storage of radiological examinations of patients. Multiple viewers should be available to allow simultaneous display of serial radiographs. A white light source shall also be available for optimum display.

- **Work and supply areas.** Work and supply areas should be located within or immediately in the vicinity of each ICU. Areas should be provided for the storage and rapid recovery of emergency trolleys and monitors/portable defibrillators. There should be a medical area containing a medicine fridge, a drug safe and a sink with hot and cold running water. There must be an area for medical preparations and a room for storing medicines and other supplies. If these areas are closed, glass walls shall be used to allow visualization of patients and ICU activities during medical preparations and to allow monitoring of the area from the outside in such a way as to ensure that only staff authorized is inside.

- **Reception area.** Each ICU and each critical area sector must have an acceptance area to control the access of visitors. It should ideally be allocated in such a way that all visitors have to pass through this area before entering. The acceptance officer should be connected to the ICU by telephone or other communication system. It would be desirable to have a separate entrance for visitors from the one used by health professionals.

- **Environments for special procedures.** If a special procedure environment is desired, it should be located within or in the immediate vicinity of ICU. An environment for special procedures can serve several intensive care units that are in close proximity. Attention should be paid to facilitating access to the ward for patients transported from areas outside the ICU. Room sizes should be sufficient to accommodate equipment and staff. Monitoring tools, equipment, support services and security systems should be consistent with
the specific services provided by ICU. Working surfaces and refuelling areas should be sufficiently adequate to contain all the necessary material and to allow all the procedures required to be carried out without the need for health professionals to leave the working environment.

- **Service environments for clean materials and dirty materials.** Service environments for clean materials and dirty materials shall be separate, interconnected spaces. They must be kept at a controlled temperature and the air supply to the room for dirty materials must be adequately eliminated. Floors must be covered with materials without orders to facilitate cleaning. Systems shall be designed for the disposal of materials contaminated by secretions or body fluids. Special containers must be provided for the removal of needles or other sharp objects.

- **Conservation of equipment.** A safe area must be provided for the storage of the different patient care equipment, which is not in active use. Spaces must be large enough to ensure easy access, easy installation of the equipment and, if necessary, an easy operation. The electrical sockets inside the refuelling area should be supplied in sufficient number to allow the recharge of the batteries of the devices.

- **Area of preparation of nutritional mixtures.** A patient food preparation area should be identified and equipped with suitable food preparation surfaces, an ice maker, a sink with hot and cold running water, a kitchenette and/or a microwave oven, and a refrigerator. Washing equipment should be allocated within or near the same area.

- **Room for the staff.** A staff room should be available within or near each ICU or intensive group to provide a private, comfortable and relaxing environment for the staff. Lockers with secure closures, showers and toilets should also be available. The room should be connected to the ICU by telephone or other communication system and emergency alarms for cardiac arrest should be audible inside.
- **Conference room.** A conference room should be conveniently located for the use of doctors and all department staff. This room must be adequately connected to the ICU by telephone or other communication system, and here too emergency alarms for cardiac arrest should be audible. The conference room can have multiple purposes including continuing training, teaching for internal staff, or multidisciplinary health conferences.

- **Room for visitors / Waiting room.** A visitor’s room or waiting room should be provided in the vicinity of each ICU or ICU facility. Visitor access should be controlled by the receptionist. We recommend 1/1,5 to 2 seats per intensive bed. Public telephones (preferably with locking systems) and supplies for refreshment must be made available to visitors. Sanitation and drinking supply systems should also be available within the room or in its immediate vicinity.

- **Transportation routes for patients.** Patients transported to ICU and ICU should be transported through corridors separate from those used by visitors. Patients' privacy should be preserved and their transport should be rapid and unhindered. When it is necessary to use a transport lift, there should be a large key lift separate from public access.

- **Service and supply corridors.** A perimeter corridor with easy access to entrances and exits should be designed for refueling and the various services required for each ICU. This approach helps to minimize any interruption of care activities to the patient and reduces unnecessary noise pollution.

### 7.2.2 Patient module

Patient modules must be designed to support all necessary health equipment.

- The JCAHO (Joint Commission on Accreditation of Healthcare Organizations) requires that the space between each bed is sufficient to accommodate all the equipment and staff needed for patient care. Each state department of Public Health must be consulted for specific guidelines related to the size of the beds or the space required between the beds.
The alarm button for emergency / cardiac arrest must be present in every bed inside the ICU. The alarm shall be automatically sounded in the hospital telecommunications center, the central nursing station, the ICU conference room, the staff refreshment room, and the on-call doctors' rooms. The origin of the warning signal must be discernible.

Spaces and surfaces for computer terminals and clinical patient documentation should be incorporated into the design of each patient module.

Supplies must be provided for the different personal needs of each patient, as well as care materials, linen and personal hygiene items. Lockable drawers and lockable lockers must be used if medicines and syringes are stored near the beds of patients. Valuable personal items should not be held in ICU. Rather, they should be detained by hospital security personnel until the patient is discharged.

Every effort should be made to provide an environment that minimizes stress to the patient and the team.

Other comfort considerations should include solutions to maintain patient privacy.

7.2.3 Services

Each ICU shall have electricity, water, oxygen, compressed air, vacuum, lighting and environmental control systems that support the needs of patients and the intensive care team under both normal and emergency conditions.

- **Electric current.** The electrical supply for each ICU should be provided by a separate power supply system connected to the main circuit control panel serving the ICU power lines. The main panel should be connected to an emergency electrical supply that should work in case of power failure. Each socket or group of sockets within the ICU should have a specific switch at the level of the main panel. It is essential that ICU staff have easy access to the main panel in case the emergency power supply has to be cut off.
The ideal number of sockets for each bed is 16. The sockets at the head of the bed should be placed at an approximate height of at least 1 meter above the ground in order to facilitate the connection of the electric cables and to discourage disconnection by tearing the electric cable rather than unplugging the plug. The sockets placed on the side of the bed and at the foot of the bed should be placed close to the floor to avoid tripping over the electric cables.

- **Water supply.** The water supply must have a certified origin especially if hemodialysis is practiced. Stop valves must be installed on the pipes that arrive in ICU to allow closing the supply if necessary. Wash-basins must be wide and deep enough to avoid splashing outside water, preferably fitted with taps operated by the operator by means of a photocell or operated by the operator with the elbow, the knee or foot, and shall be placed near the entrance to the patients' playpens or, in the multiple-chamber wards of hospitalization, placed in the middle between 2 beds. When a toilet is included in the patient’s module, it shall be provided with materials for the personal hygiene of the patient, including hot and cold water and a spray nozzle type pedal operated. In addition, where there are toilets, environmental control systems shall be appropriately modified.

- **Oxygen, compressed air and vacuum.** Oxygen and compressed air supplied centrally shall be supplied at 50-55 psi from the main and reserve tanks and their facilities shall follow the NFPA standards. At least two oxygen reserves per patient are required. A compressed air tank per bed is required but two would be desirable. Connections for the supply of oxygen and compressed air must be made with specific key connections to avoid accidental gas exchange. Audible and visible high- and low-pressure alarms shall be installed in each ICU and in the hospital technical center. Manual shut-off valves shall be present in both areas to interrupt gas delivery in the event of fire, excessive pressure or during maintenance.
- **Illumination.** General overhead lighting, plus other ambient lights, should be adapted to different nursing activities, including the compilation of patient documentation, but also adjusted to achieve soft ambient lighting for better patient comfort. Total lighting should not exceed 30 foot-candles (30 foot-candles (fc)). It is preferable to place light intensity regulators with variable dimming control immediately outside the chambers. This system allows to vary during the night the lighting from outside the room, with a minimal sleep disturbance of the patient during his observation. Night lighting should not exceed 6.5 fc for continuous use or 19 fc for short periods of time. Separate light sources for emergency use or other procedures should be fixed to the ceiling directly above the patient and should be fully illuminated with at least 150 fc without shadows.

- **Environmental control systems.** Air quality must be kept adequate and safe at all times. An environmental conditioning system shall be in place to ensure that:

  - a winter and summer indoor temperature of between 20 and 26 °C;
  - a relative humidity in summer and winter of 40-60%;
  - a minimum of 6 total air exchanges per room per hour, with 2 air exchanges per hour filtered by outside air. For rooms with toilets it is necessary a replacement of 2 cubic meters per minute of air filtered from the outside.
  - high efficiency air filtration and 99.95% absolute filtration in the insulation rooms.

Air conditioning and heating must be treated with great care for the comfort of patients. In ICU structured with modular system (patient box), the temperature should be independently adjustable within each box.

7.2.4 **Physiological monitoring**

Each patient box must have monitoring equipment that includes analysis and visualization of one or more electrocardiographic derivations, at least 3 pressure
monitoring lines, and systems of direct or indirect measurements of arterial oxygenation. These parameters must be displayed both in analog and digital format, showing the ultrasound track and curves, numerical frequency interpretation and numerical values of maximum / minimum and average of the pressure data. Each monitoring apparatus shall be provided with the possibility of recording on paper at least two paths simultaneously in two different channels. Alarms should indicate critical values with visual and audible signal.

Patient bedside monitoring equipment should be positioned so as to allow easy access and easy visibility, without interfering with the visualization or access to the patient. The bed nurse and/or the monitor technician must be able to examine the patient’s monitoring status at a glance. This can be achieved either with a central monitoring station or with a bed monitor for patients that allows simultaneous observation of more than one patient. It is understood that none of these systems replace the bedside observation of the patient.

- **Electrocardiogram.** One or more electrocardiographic derivations should be displayed simultaneously. The computerized frequency and wave analysis shall at least recognize and trigger the alarm for tachycardia and ventricular fibrillation, and select the maximum and minimum heart rates chosen. Operator-callable memory functions would be desirable.

- **Pressure lines.** Monitoring equipment shall have the ability to simultaneously display two or more pressure curves in analogue format. In addition, they should display the maximum, minimum and average values in digital form. Alarms shall report critical values for all three parameters displayed in digital form.

- **Respiratory parameters.** Each bedside monitoring station of the patient should have the ability to provide continuous measurement of arterial oxygenation levels. Pulse oximetry and transcutaneous measurement of PO$_2$ are now the preferred methods of oxygenation monitoring. End-tidal CO$_2$ or transcutaneous measurements of PCO$_2$ may be used for monitoring carbon dioxide if necessary.
• **Other Physiological Parameters.** The latest monitoring systems give the possibility to record and display: body temperature, respiratory rate, ST segment amplitude, non-invasive heart rate, mixed venous oxygen saturation, continuous electroencephalogram and other physiological parameters. If necessary, monitoring of these parameters may be added to existing monitoring systems.

7.2.5 **Computerized documentation**

Computerized patient documentation is becoming increasingly popular in ICU. These systems provide data management, admission authorization, medical documentation and nursing "without paper". It is important to fully integrate this technology with all ICU activities. Bedside terminals of the patient facilitate patient management by allowing nurses and doctors to stay in the patient’s bed during compilation processes. To minimize errors, the monitored data must be recorded automatically. Furthermore, when these systems are properly interfaced with other hospital computerized systems, the consultation of the data (laboratory results, radiological reports, etc.) can be carried out in the bed of the patient. The possibility of remote data transmission (to offices, on-call doctors, etc.) is desirable to facilitate the continuity of patient management.

7.2.6 **Voice intercommunication systems**

All ICU should have intercommunication systems that ensure voice connections between the central nursing station, patient modules, on-call rooms, the conference room, and the staff dining room. The refueling areas and the visitor’s lounge or waiting room must be included in this system.

Other types of communication such as how to trace personnel or non-emergency calls can be made using display displays (such as digital or colored lights) that eliminate unnecessary sources of noise.

In addition to the standard telephony services for each ICU, which should be enabled for communications throughout the hospital and outside, there should be internal and external emergency communication systems when normal systems do not work (for example during power outages).
### 7.3 Hospital staff

At national level, Ministerial Decree 13/9/1988 - "Determination of hospital staff standards" - is a useful reference document for the definition of staff standards. Article 3 defines the medical and nursing units required for the total number of beds.

<table>
<thead>
<tr>
<th>Hospital unit</th>
<th>Welfare activities</th>
<th>Units</th>
</tr>
</thead>
</table>
| **Intensive care**                     | Resuscitation; large burns; ICU; Post-transplant intensive care unit; neonatal intensive care | For a type module of 8 beds:  
- 12 medical personnel units  
- 24 nursing staff units  
For each subsequent module of 8 beds:  
- 5 medical personnel units  
- 24 nursing staff units |
| **Sub-intensive therapy**              | cardiosurgery; haematology with transplantation; nephrology with transplantation and haemodialysis | For a type module of 8 beds:  
- 3 medical personnel units  
- 12 nursing staff units |
| **Speciality with high assistance**   |                                                        | For a type module of 20 beds:  
- 11 medical personnel units  
- 22 nursing staff units |
<table>
<thead>
<tr>
<th>field</th>
<th>value</th>
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</thead>
</table>
| neurosurgery; neonatology; infectious diseases; psychiatry; spinal units | For each subsequent module of 20 beds:  
- 5 medical personnel units  
- 22 nursing staff |
|                                                                      | For a type module of 40 beds in Infectious Diseases:  
- 11 medical personnel units  
- 35 nursing staff |

**Table 8** Definition of medical and nursing units according to working environment
8. Clinical management of the patient

The indications shown here are intended to define the operating standards to be followed and the criteria for patient management in order to constitute a reference document for charitable activities.

The procedures and recommendations that will be described are based on the circular of the Ministry of Health of 29/02/2020 "Lines of care of critical patient affected by Covid-19".

8.1 Classification based on respiratory severity

A confirmed case is defined as a case with laboratory confirmation for infection with SARS-CoV-2 carried out at the reference laboratory of the Istituto Superiore di Sanità or at the regional reference laboratories, regardless of the clinical symptoms presented.

According to the WHO Directive (Interim Guidance 20 January 2020) it is possible to define the following clinical syndromes associated with COVID-19:

1) Uncomplicated disease: non-specific symptoms such as fever, malaise, cough, nasal congestion.
2) Mild pneumonia: clinical and radiological diagnosis without signs of severity
3) Severe pneumonia: respiratory failure of any degree
4) ARDS: acute respiratory distress syndrome

To assess the severity of the clinical syndrome of patients with COVID-19, we can refer to some proposed scores to assess the severity of pneumonia. In the following indications, the adoption of the Modified Early Warning Score (MEWS) is proposed. The MEWS is a quick and easy application tool that provides a useful aid in the decision of the correct allocation of the patient, based on the intensity of monitoring and care required. It should be noted that these evaluation scores are only operational support tools and do not replace the doctor’s clinical judgement.
Through the combined use of MEWS and various assessment factors, it is possible to define an algorithm that establishes the most appropriate care setting and care for a positive patient at COVID-19. Therefore, the following shall be taken into account at the same time:

- factors such as age and co-morbidity (cardiovascular disease, respiratory disease, diabetes, kidney disease, smoking, risk pregnancy, obesity, cirrhosis of the liver)
- the presence of characteristic symptoms of the pathology COVID-19 and its complications, which will be identified and evaluated by the doctor responsible
- clinical condition classification score (MEWS)

Figure 16 shows the diagram of the algorithm used in the Infectious Diseases Institute - "Lazzaro Spallanzani" for the decision of the treatments to be attributed to a confirmed case of COVID-19:
8.2 Clinical management based on the severity of the clinical picture

Depending on the severity of the symptoms found in the patient, different hospitalization procedures will be implemented. However, in all cases, the correct procedures must be strictly applied to ensure the safety of health professionals:

a) systematic use of personal protective equipment;

b) application of the correct procedures for wearing and removing PPE (dressing and undressing procedures);

c) implementation of business operational protocols for dedicated care pathways for patients with COVID-19, which avoid putting health professionals at risk;

d) sanitization for droplet transmitted agents;

e) limiting procedures for aerosolizing the respiratory secretions of the infected patient;

f) not to allow visits;

g) have individual rooms with filter area.

In addition, in the most critical cases (MEWS > 1):

- Operators should closely monitor the clinical conditions and vital functions of all patients admitted to COVID-19, including laboratory examinations and instrumental investigations when deemed necessary. The objective of such monitoring is to ensure the rapid transition to a more intensive level of care as soon as a clinical deterioration due to the disease occurs. The frequency of periodic evaluations varies depending on the severity of the patient’s clinical picture, resulting in increased risk for healthcare professionals as well.

- Patients must be subjected to viral therapy. At present, there are no registered antiviral drugs for use in patients with COVID-19. Given the potential severity of this disease, it is proposed that one of three different direct antiviral drugs be used in monotherapy or in combination:

  1) Lopinavir/Ritonavir: already used for the treatment of HIV infection;
2) Chloroquine: drug used for malaria;


8.2.1 Uncomplicated disease (MEWS < 1)

Most patients with these clinical conditions can be managed at home. In this case, the home isolation must be maintained for 14 days until the complete recovery of the patient; at the end of the two weeks must be confirmed the viral clearance obtaining the negativity of 2 virological tests. In addition to the usual hygiene of the hands and surfaces with which it comes into contact, the patient must limit movements in the home - possibly in one room and in a private bathroom - and wear a surgical mask. The assistance of the person will be guaranteed both by telephone every day with a trained health care worker who will have the role of ensuring the evolution of the patient’s clinical conditions, both from an educated caregiver to self-assessment of symptoms.

Hospitalization may be arranged if:

- the age of the patient is over 70 years
- the patient is suffering from other diseases (cardiovascular diseases, respiratory diseases, diabetes, kidney diseases, smoking, pregnancy at risk, obesity, cirrhosis of the liver)

If there is at least one of the conditions described above, the hospital will be provided with direct access (without passing through the emergency room) in acute care facilities, adequately equipped to ensure the required isolation measures. If the clinical criterion is met, but not the virological one, patients may be discharged at home.

8.2.2 Mild pneumonia (MEWS 1-2)

In case of mild pneumonia, the patient will be hospitalized in the Infectious Diseases department. The adult patient with mild pneumonia does not need O₂ therapy, which must be guaranteed if clinical conditions deteriorate.
The patient must be monitored 3 times a day (1 time per shift) with periodic recording of vital parameters (blood pressure, heart rate, respiratory rate) and must be subjected to viral treatment every 12 hours for 10/14 days.

8.2.3 **Severe pneumonia (MEWS 3-4)**

The patient presents:

- severe respiratory failure
- need for non-invasive mechanical ventilation
- cardiovascular shock
- State of confusion
- signs of overload or fatigue of respiratory muscles

In these cases, the patient will be transferred to the Sub-Intensive Therapy Department, equipped with the appropriate equipment and skills for the management of oxygen therapy and non-invasive therapy, and has the appropriate facility to manage patients in combined isolation. In view of the high number of cases of respiratory insufficiency associated with COVID-19, it is necessary to provide an adequate amount of devices for the application of "high-flow nasal oxygen", "continuous positive airway pressure" (cPAP) and non-invasive ventilation (NIV), to ensure maximum safety for patients and healthcare professionals.

The patient should be constantly monitored with both increased frequency in the recording of vital signs, and the use of MEWS for possible transfer to intensive care in case of worsening of the clinical picture. Pulmonary ultrasound may be used as an alternative diagnostic and monitoring tool in patients with acute respiratory insufficiency related to COVID-19. The potential advantages are simplicity of execution, non-invasiveness, the possibility of execution at the hospital or intensive care, avoiding the risks of transport. The main disadvantage is to be an extremely employee operator exam.

The patient must be subjected to:
- Antiviral therapy: Remdesivir intravenously once a day and Chloroquine every 12 hours.
- Supportive therapy: oxygen therapy (the choice of the type of approach will depend on the clinical characteristics of the patient), antibiotic therapy, intravenous rehydration.

8.2.4 ARDS (MEWS > 4)

The patient presents:

- respiratory distress, severe respiratory failure
- need for invasive mechanical ventilation
- cardiovascular shock
- epileptic condition
- severe arrhythmias
- severe neurological history (stroke, brain hemorrhage)

The patient must be transported in the Intensive Care Unit with the possibility of guaranteeing the required isolation measures, in addition to the specific precautionary measures of the patient with COVID-19, treated with invasive mechanical ventilation - the use of "Powered AIR Purifying Respirator" (PAPR). Clinical monitoring should be based:

- the use of invasive and/or non-invasive monitoring and complication prevention protocols;
- performing chest CT;
- the periodic use of MEWS as a clinical instability score or predictive of clinical aggravation;
- on the use of pulmonary ultrasound as an alternative diagnostic tool; the examination can be repeated several times and allows rapid evaluation of the response to therapeutic procedures.
The patient must be subjected to:

- **Antiviral therapy:** Remdesivir once a day intravenously associated with chloroquine every 12 hours for 10 days. In addition, it is necessary to follow an antibiotic therapy based on the results of microbiological tests.

- **Support therapy:** use of non-invasive mechanical ventilation (NIV) for patients with mild ARDS and protective mechanical ventilation for moderate or severe ARDS. In the event of serious deterioration of respiratory and/or cardiocirculatory conditions, such as to put the patient in immediate danger of life, and attributable to a bacterial or fungal infection related to health care, begin, after collecting adequate biological samples necessary for the achievement of etiological diagnosis, an appropriate empirical antimicrobial therapy.
9. Analysis of costs

9.1 Costs of intensive cure

The intensive care unit is a nerve area within a hospital, designed to provide intensive care to patients who are in critical condition. To meet these needs, departments are made available with increasingly specialized personnel and increasingly advanced technologies.

The costs associated with an intensive care unit can be distinguished in:

- costs of medical personnel;
- costs of medicines;
- costs of single-use equipment;
- costs of structure and equipment;
- costs of laboratory activities (such as biological tests);
- costs of blood and blood products;
- costs of other health services (such as physiotherapy).

The percentage composition of the costs just listed is shown in the figure 17, with an average annual cost per department of about 2,400,000 €.

![Figure 17 Percentage composition of the costs of an intensive care unit](image-url)
The Institute Lazzaro Spallanzani responded to the health emergency from COVID-19 by implementing an extension of the intensive care unit of 20 beds. A total location in intensive care costs between 80,000 € and 100,000 €, including:

- bed, with a cost between € 10,000 and € 15,000;
- fan, has a variable cost between € 10,000 and € 25,000 depending on the models and characteristics;
- monitor, for the control of patient parameters - cost between 10,000 € and 20,000 €;
- series of mobile cabinets, cost of 10,000 €;
- infusion pumps, each around 2,000 €, need at least 5 per bed: 10,000€;
- equipment shared among all patients - such as ultrasound, bronchoscope, haematofiltration (emofiltrazione) machines - other 10,000 € per bed.

9.2 Costs of patient stay

The intensity of care is accompanied by a high concentration of resources, both human and material, on a limited number of patients with consequent high unit costs.

The average daily cost of a patient in intensive care is 1,200 €/1,300 €. This cost takes into account:

- the cost of personnel;
- the costs of the equipment;
- the costs of visits, tests and medication.

In general, one specialist doctor is available for every 4 patients and one nurse for every 2 patients in intensive care.
### Personnel cost

<table>
<thead>
<tr>
<th>Healthcare</th>
<th>Monthly amount [€]</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Medical infectious diseases</em></td>
<td>3608</td>
</tr>
<tr>
<td><em>Intensive care doctor and resuscitator</em></td>
<td>13927.55</td>
</tr>
<tr>
<td><em>Anesthesiologist</em></td>
<td>3600</td>
</tr>
<tr>
<td><em>Nurse</em></td>
<td>1200</td>
</tr>
<tr>
<td><em>Health technician</em></td>
<td>13927.55</td>
</tr>
</tbody>
</table>

**Table 9** Monthly cost of Spallanzani staff

A symptomatic COVID-19 patient is subjected to tests and swabs to analyze its positivity; in critical cases, those admitted to intensive care must also be subjected to antiviral treatment.

### Cost of visits, tests and medication

| Visit infectious or hepatological diseases     | 180 €               |
| *Infectious/hepatological disease control visit* | 150 €              |
| *Buffer test*                                  | 50 €                |
| *Serological test*                             | 15.23 €             |
| *Drug "Ritonavir"*                             | 500 €               |
| *Drug "Clorochina"*                            | 75 €                |

**Table 10** Cost of medical examinations, tests and medications submitted to patients COVID-19

Equipment costs were listed in the previous chapter.
9.3 Costs of personal protective equipment

To cope with the Coronavirus emergency, all the necessary protective equipment has been made available to the employees of the facility.

<table>
<thead>
<tr>
<th>Cost of PPE</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical mask</td>
<td>1.50 €</td>
</tr>
<tr>
<td>FFP2 mask</td>
<td>5.75 €</td>
</tr>
<tr>
<td>FFP2 mask with valve</td>
<td>6.50 €</td>
</tr>
<tr>
<td>Mask FFP3</td>
<td>9.50 €</td>
</tr>
<tr>
<td>Disposable gloves</td>
<td>0.30 € (per pair)</td>
</tr>
<tr>
<td>Shirts</td>
<td>6 €</td>
</tr>
</tbody>
</table>

Table 11 Unit cost of PPE provided to Spallanzani employees
Conclusions

This risk analysis has highlighted the main risk conditions to which the health professionals of the Spallanzani Infectious Diseases Institute are subject and the possible corrective measures. The quantification of the parameters showed how the care activities, which provide direct contact with the patient COVID-19 positive, and the health operating procedures, which involve generation of aerosols, are the main sources of risk from SARS-CoV-2 infection. Health care professionals engaged in providing care to patients, even if equipped with appropriate personal protective equipment, are in high-risk conditions because they cannot maintain the minimum safety distance of 2 meters at all times.

The remodeling of healthcare environments, the adoption of preventive measures and the introduction of additional protective measures, allow to reduce the risk of infection with SARS-CoV-2 but not to eliminate it completely, being the persons themselves hospitalized as the sources of transmission of the virus. However, through these corrective measures, it is possible to better protect the health workers in the different departments, and to guarantee reference standards and welfare guidelines to prevent contagion.
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