

Covid, Long Covid and Fragility. Let's keep the attention high!



CITTADINANZ TTIVA



Index	
Foreword	4
1. Why a guide for frail patients?	6
2. Cittadinanzattiva's initiatives during the pandemic	8
3. Is the pandemic over? Towards a new 'normality	8
4. Vaccination against COVID-19: let's look at the facts	10
5. The impact of COVID-19 on frail patients	11
6. Risk factors	12
7. Vaccination against COVID-19 in pregnancy and lactation	15
8. Vaccination against COVID-19 in pediatric age	17
9. When vaccination is not enough: prophylactic measures for frail patients	18
10. The Long Covid	19
11. How do citizens orient themselves? Our useful tips	20

Foreword

The spread of the coronavirus in Italy began in late February 2020, with the outbreak discovered in Codogno. Italy was the first European country to be widely affected by the pandemic and had to take action to prepare health and political responses to an unparalleled emergency in contemporary history, without any previous experience and consolidated procedures to refer to, in conditions of severe shortage of health resources to deploy.

The pandemic crisis and the containment measures adopted have highlighted multiple **needs and emergencies to deal with**, both in the strictly health-related sphere and in a broader sense, affecting multiple aspects of the lives of all citizens, especially the most vulnerable and exposed.

- -> The most critical issues were immediately identified in the health sector. In particular:
- · lack of protective equipment for general practitioners;
- · lack of precise hygienic and therapeutic guidelines;
- · shortage of beds in intensive care units;
- high exposure to infections in hospitals for cancer patients during courses of treatment;
- suspension of services for chronic and rare disease patients, immunocompromised and non-hospitalised acute patients and non-self-sufficient people with disabilities;
- shortcomings in the territorial care system;
- spread of outbreaks in nursing homes;
- need to reduce complications from COVID-19 related to classical influenza diseases and to enable differential analysis.
- -> On the **citizen protection** side, among the social and care needs that emerged was the lack of clear and reliable information on the coronavirus.

The institutions have applied the rules of public and political communication to crisis communication, contributing to generating an overload of information from multiple and often contradictory sources. These factors amplified the climate of apprehension and uncertainty, generated by the fear of a health emergency, and contributed to the proliferation of **fake news** in the absence of an unambiguous, authoritative and reliable channel of information.

Today, three years later, the scenario has changed dramatically. On Friday, 5 May 2023, the World Health Organisation decreed that **COVID-19 no longer constitutes a public health emergency** of **international** concern (PHEIC)¹.

It is important to know!

COVID remains and will remain with 'us' for a long time.

From this moment on, the international protocols that are triggered in the event of an international public health emergency lapse.

COVID will be treated like other influenza and endemic viruses.

¹https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic

While it is true that even an endemic virus can constitute a public health emergency, it is undeniable that Sars-CoV-2 has lost the characteristics that technically configure an epidemic as 'pandemic': a pandemic occurs when a new virus, for which there are no drugs, finds the population immunologically uncovered, and is therefore able to spread globally .. Today, we have vaccines to prevent COVID-19 and specific therapies to treat it.

COVID-19 is increasingly taking on the contours of an endemic virus, which spreads seasonally, losing vigour. The data² for the first months of 2023 show that in Italy the number of new cases and deaths from COVID continues to decrease. In the rest of Europe, pandemic data³ also confirm a decreasing trend.

There is, however, a large segment of the population for whom COVID-19 still poses a strong **threat**: these are **frail patients** exposed to higher **risk factors** for whom it is important to provide specific prevention plans as well as adequate and timely prophylaxis and treatment.

In this ever-changing scenario, Cittadinanzattiva's **Be A.W.A.R.E.**⁴ initiative takes place. The guide **Covid**, **Long Covid and Frailty. Let's keep the attention high!** was created with the aim of providing information to increase the knowledge and awareness of the general population on the risks, for people with frailty or specific conditions, of developing severe forms of COVID-19.



² www.governo.it/it/cscovid19/report-vaccini/ - www.salute.gov.it/portale/nuovocoronavirus/

³ www.ecdc.europa.eu/en/COVID-19/country-overviews

⁴ Be A.W.A.R.E. (Be Active citizens for Widespread Awareness, infoRmation and Education)

1. Cittadinanzattiva's initiatives during the pandemic

Since February 2020, Cittadinanzattiva has been strongly committed to dealing with the social emergencies caused by the COVID-19 epidemic and continues its activities in support of citizens. By connecting all stakeholders and actors who contribute to supporting public health, it contributes to ensuring the protection of people, especially the most vulnerable and exposed.

Cittadinanzattivais present throughout
the country

20 regional offices21 Citizen Advisory Centres245 territorial assembliesaround 30,000 associates

Thanks to its articulation, each activity was undertaken in a capillary manner throughout the country. The activities⁵ unfolded along five main lines: information, advocacy, distance training, and partnership.

Cittadinanzattiva's activities during the COVID-19 emergency

1. Information activities

- -> **Desi (virtual assistant)**: an artificial intelligence tool that can be consulted 24 hours a day on the homepage of Cittadinanzattiva website www.cittadinanzattiva.it. It is a service available free of charge to citizens that has responded to all requests for information on the coronavirus (measures, recommendations, health regulations and all updates shared by the government and the various Ministries).
- -> **Online guide** on the coronavirus emergency: dedicated to citizens with sections on specific topics (health, transport, taxation, school), with links to official websites, expert video clips and various other information.
- -> **#Insiemesenzapaura** (#Togetherwithoutfear): national information and communication campaign on the coronavirus emergency aimed at citizens, promoted together with the FIMMG (Italian Federation of General Practitioners).
- -> **Torniamo a curarci** (Let's take care of ourselves again): a campaign by Cittadinanzattiva in collaboration with FIMMG aimed at emphasising the indispensable role of healthcare professionals in providing diagnosis and treatment and highlighting the extraordinary value of the relationship between doctor and patient.
- -> **Vademecum dedicated to nursing homes (RSAs):** a practical guide to support and assist people housed in **nursing homes** (RSAs) and their families in times of coronavirus emergency.

2. Protection initiatives

- -> Front line for reporting inefficiencies and information requests: a dedicated e-mail address (coronavirus@cittadinanzattiva.it) and a national back office service for activists in the territories to ensure coordination between regional, local and national levels.
- -> **Dedicated information and listening service for nursing homes RSAs**: to support and assist the relatives of guests and **nursing homes** RSA operators.
- -> **Provision of personal safety equipment for general practitioners**: to support and make their role as territorial care providers possible and effective, to overcome the shortage of supplies during the acute phases of the pandemic.
- -> 'Reconnected': campaign to provide data subscriptions, satellite web connections and devices.
- -> "Annual report of our Citizens' Health Advisory Centre (PiT salute)": presented in December 2020 The Pit salute report in which all the requests of information and complains received by Cittadinan-zattiva's Citizen Advisory Centres(PIT) in 2020 were analysed, in the midst of the emergency phase.
- -> 'Civic survey on vaccines': through the right to civic access to public documents, it has been realized a monitoring of the regional actions regarding the influenza vaccination campaign. The information obtained was made available to citizens through a monitoring report.

⁵ All activities are available on <u>www·cittadinanzattiva·it</u>

3. Advocacy

- -> Socio-medical and home care assistance for chronic and rare patients: it has been proposed an amendment to the so-called 'Cura Italia' to strengthen socio-medical and home care assistance for the chronic and rare patients, immunocompromised, non-hospitalised acute patients and non-self-sufficient people with disabilities through a three-year funding plan displayed by the regions.
- -> **Chronic diseases and emergencies:** FADOI internists and Cittadinanzattiva launched an appeal to AIFA (Italian Medicines Agency) requesting a three-month extension of the treatment plans drawn up by specialists, without which 10 million chronic patients would be left without life-saving medicines.
- -> Nursing homes (RSAs), an emergency within an emergency: letter appealing to the Ministry of Health, the Presidents of the Regions and the Regional Health Councillors to adopt extraordinary emergency plans for the prevention, care and control of COVID-19 infection in RSAs.
- -> **Distribution of drugs for patients suffering from chronic or rare diseases**: a joint appeal by Federfarma and Cittadinanzattiva to the Regions to request the maximum simplification of procedures and to ensure that patients suffering from chronic or rare diseases can also obtain drugs and medical aids, usually distributed in public hospitals, directly in territorial pharmacies⁶, in line with the Civil Protection ordinance aimed at limiting travel.
- -> Appeal to the Ministry of Health, jointly signed with the FIMMG, asking to: anticipate the start of influenza and anti-pneumococcal vaccination campaign, to lower the target of at-risk individuals to 60 years of age, and to call for the timely launch of procurement tenders for increased vaccine doses for the 2020/21 season.

4. Distance learning activities

-> **Webinars in times of emergency**: a "distance" training and information programme promoted by Cittadinanzattiva's SCAF (Scuola Civica di Alta Formazione di Cittadinanzattiva - <u>www.scuolacivica.it</u>). The webinars, available on the website www.scuolacivica.it, were realised thanks to the contribution of experts in different subjects and aimed at providing useful advice to face everyday problemsduring the coronavirus outbreak. The topics covered by the webinars were: taxation and suspension of payments, mortgages and financing, welfare and work, social bonus and electricity, gas and water bills, school, health and environment.

5. Partnership

- -> "nobody should be excluded": social campaign in 11 languages by Equivalenti.it and EGUALIA in collaboration with Cittadinanzattiva, with the aim of providing all communities in our country with information in their mother tongue on how to avoid dangerous behaviour and thus contribute to stopping the spread of the coronavirus.
- -> Cittadinanzattiva and the National Order of Psychologists: collaboration on the sensitive issue of psychological support in times of emergency by COVID-19 and dissemination of guides and vade-mecum #psicologicontrolapaura and #psicologionline.
- -> Cittadinanzattiva and Chronic patients' Associations: through the National Coordination of Chronic and Rare patients' Associations (CnAMC) of Cittadinanzattiva, a letter was sent to the Presidents of the Regions, the Regional Health Councillors and the Ministry of Health to request a nationwide extension of at least 90 days for the supply of essential medical devices for patients with chronic diseases, due in March and April 2020.
- -> Adhesion to the Italian Red Cross **project 'Il tempo della gentilezza'**: a national home delivery service of food and medicines for the elderly, frail and immunocompromised people.
- -> Supporting pharmacies in **delivering medicines**, **disinfectants**, **hospital supplies**, **masks and meals to the needy** through the network of volunteers in the area. The initiative was implemented in collaboration with Federfarma.

⁶ This is a particular method of direct drug distribution, called "Distribuzione Per Conto" (literally "Distribution on their behalf") based on an agreement between the Regions/Local Health Authorities/intermediate distributors and contracted pharmacies: in this case, the drugs are purchased by the Local Health Authority/Region but distributed to the patient, on their behalf, by territorial pharmacies open to the public.

2. Why a guide for frail patients?

Official globalpandemicdata showed that, from the very beginning, the **elderly population was** most affected by the infection, with the average age of deceased patients being 80 years old and many having **previous** chronic diseases.

The data⁷, available in Italy seem to confirm that heart diseases, diabetes and chronic renal insufficiency are significantly more frequent and numerically greater among COVID-19 patients who die, compared to the general population. There are also additional risk factors that may lead to a **more severe course of the disease**.

Today we have much more information on this disease and we are able to prevent it with vaccination (or at least mitigate its effects) but also to treat it and to provide specific plans that focus on early diagnosis and on taking care of fragile patients and allowing timely access to treatment throughout the territory. Cittadinanzattiva, through its **Citizen Advisory Centres(PIT)** and **Help Desk**⁸, collects requests for information and protection from frail patients and their caregivers who need guidance and information about their rights. The direct testimonies of patients that reach us, through the Associations that are part of the National Coordination of Chronic patients'Associations (CnAMC), confirm the great need for direct, simple and specific communication. We encounter requests that denote a lack of information and a lack of specific communication dedicated to frail patients also with respect to the actions that need to be taken against COVID-19.

In fact, several **preventive** (such as vaccines) and **therapeutic** (such as monoclonal antibodies and antivirals) **strategies** are now available to counter the COVID-19 pandemic, which need to be adequately communicated to the public, defining the precise indications for use, particularly for frail patients and their families and caregivers.

Hence the idea of a guide that aims to provide useful information for the general public and raise the level of awareness of the general population and people with frailty and special conditions about the risks of developing severe forms of COVID-19.

3. Is the pandemic over? Towards a new normality

The World Health Organisation has declared that COVID-19 is no longer a global health emergency. COVID-19 has not disappeared but the virus has become **endemic** like other forms of influenza. This means that we will have to learn to **live with** the virus and manage any peak phases that reoccur by paying close attention to 'fragile' groups.

The WHO itself called on all countries not to '**let their guard down**', to continue monitoring the evolution of COVID-19, not to dismantle the health services built up over the past three years, and not to pass the message that the COVID danger is behind them.

From a formal point of view, having emerged from the global health emergency phase, it will no longer be mandatory for countries to report the number of cases and positivity rates to the WHO, although it is possible that many nations will decide to do so anyway. Individual states will have the authority to decide whether to treat COVID-19 as a public health emergency in their territory.

From a social point of view in Italy, it seems that the pandemic has been over for a long time. The situation¹⁰ of the variants is under control, the incidence of cases is very low, and we have very high immunisation. Many people have had the anti-Covid vaccines and have been infected with Sars-CoV-2. The restrictive measures to contain the infection have been lifted, with the exception of special cases. In

⁷ Epicentre, ISS, The role of past chronic diseases in the prognosis of COVID-19 patients - https://www-epicentro-iss-it/coronavirus/sarscov-2-flussi-dati-confronto-patologie-croniche-pregresse

⁸ The Pit (Integrated Protection Project) is an orientation, information and protection service for citizens who have suffered inefficiencies in the areas of health, public services and justice. It is not simply a listening desk: the objective is the protection of rights through citizen participation. www.cittadinanzattiva-it

⁹ Since 1996, the activities coordinated by Cittadinanzattiva include the National Coordination

of the Associations of the Chronically III (CNAMC), a network representing an example of a transversal alliance of about 110 associations and federations of people suffering from chronic and rare diseases, for the protection of their rights.

¹⁰ Istituto Superiore di Sanità Integrated surveillance Covid-19 main national data: https://www-epicentro-iss-it/coronavirus/sars-co-v2-sorveglianza-dati

short, a phase of '**coexistence' with the virus** has begun, which is associated with an increased ability to manage the disease.

At this stage, it becomes crucial to 'keep the attention high' and to focus not only on preventing the disease with vaccination plans aimed at the entire population, but also on specific programmes and protocols for those who fall within the 'targets' most at risk in the event of COVID- 19 infection. The behaviour of all people and fragile individuals will make the difference.

It remains essential to continue to adopt the planned and/or recommended individual and collective behavioural measuressuch as: mask use, room ventilation, hand hygiene and to pay attention to crowded situations.

Watch out for the rules on masks!!

The Order¹⁰ of the Ministry of Health of 28 April 2023 changed the rules on personal protective equipment in hospitals, RSAs and other healthcare facilities.

- -> From 1 May until 31 December 2023, the **mask requirement** inside hospitals will remain in force in those wards housing frail, elderly or immunocompromised patients, especially those with a high intensity of care. The obligation is extended to workers, users and visitors of socio-medical and socio-assistance facilities, including hospitality and long-term care facilities, nursing homes, hospices, rehabilitation facilities, residential facilities for the elderly, including non-self-sufficient ones.
- -> Health Directorates may order the use of respiratory protective equipment by health workers and visitors in other hospital wards and waiting rooms. Directorates may also order the use of respiratory protective equipment for all those with respiratory symptoms.
- -> In medical practices, the decision on the use of respiratory protective devices remains at the discretion of general practitioners and paediatricians.
- -> The decision on the performance of diagnostic swabbing for Sars-CoV-2 infection for the purpose of emergency room access is left to the discretion of Health Directorates and Regional Authorities.
- -> The following subjects are not required to wear respiratory protective equipment:
 - a: children under six years of age
 - b: persons with a pathology or disability that is incompatible with the use of the mask, as well as persons who have to communicate with a disabled person in such a way that they cannot use the device.



¹¹ www-gazzettaufficiale-it/eli/id/2023/04/29/23A02592/SG

4. Vaccination against COVID-19: let's take stock!

High vaccination coverage, the completion of vaccination cycles and the maintenance of a high immune response through the **booster dose**, with particular regard to the categories indicated by the ministerial provisions, are necessary tools to mitigate the clinical impact of the epidemic and the most effective weapon to combat COVID-19.

Vaccination recalls in the **elderly and** in the more **fragile** population groups are essential, also considering the progressive reduction of the protective effect against Sars-CoV-2 infection as time passes, both from previous infection and from vaccination.

Starting on 27 December 2020, the so-called 'Vaccine Day', the vaccination campaign against COVID-19 began in Italy and throughout Europe. In Italy, several Circulars of the Ministry of Health followed one another, gradually identifying the vaccination methods and the priority categories to be vaccinated, as well as the methods for booster doses.

Let's take stock:

-> Primary Cycle

The primary vaccination cycle is planned for all individuals from the age of 5. For the age group **6 months - 4 years** (inclusive), the vaccine is recommended for children with fragile conditions that may expose them to the development of more severe forms of SARS-Cov2 infection and it is also available, at the request of the parent or parental guardian, for the vaccination of all other children in this age group.

-> First dose of Recall

Bivalent vaccination is **recommended** for:

- all persons **aged 12 years** or older still waiting to receive their **first booster dose** regardless of the vaccine used to complete the primary cycle
- children aged **5-11 years** (inclusive) with frail conditions that expose them to the development of more severe forms of Sars-CoV-2 infection (vaccine with specific formulation).

-> Second dose of Recall

Bivalent vaccination is **recommended** for those who are still waiting for their **second booster dose**:

- people aged 60 and over
- health workers
- operators and guests of residential facilities for the elderly
- pregnant women
- persons (12 years and over) with high frailty due to concomitant/pre-existing pathologies

-> Further booster doses after the second one

An additional booster dose with m-RNA vaccine in the bivalent formulation is recommended to the following persons who have already received a second booster dose with monovalent mRNA vaccine, at least 120 days after itor the last Sars-CoV-2 infection (date of positive diagnostic test):

- people aged 80 and over
- guests of residential facilities for the elderly
- persons aged 60 and over with frailty due to concomitant/pre-existing illnesses (see annex to the Circular of 17 October 2022).

 $^{{\}color{red}^{12}} \ \underline{www\cdot salute\cdot gov\cdot it/portale/nuovocoronavirus/dettaglioContenutiNuovoCoronavirus}$

¹³ Circular 9 December 2022 - Ministry of Health <u>www.salute.gov.it/portale/nuovocoronavirus/dettaglioContenutiNuovoCoronavirus</u>

ATTENTION: Upon request, all other persons over the age of 60 who have already received a second booster may still receive an additional vaccine dose.

5. The impact of COVID on frail patients

Frailty is defined as a 'clinical condition with multiple causes and factors, characterised by reduced strength and endurance, reduced physiological functionality and increased vulnerability¹⁴.

The results of the first epidemiological observations on patients with COVID-¹⁹ immediately underlined that there was a close association between advanced age and increased mortality and that risk factors had a negative influence on disease outcome.

In the context of the COVID-19 pandemic, frailty acts synergistically with factors such as age and co-morbidities and determines the complexity of a patient's care, as it negatively influences the ability to tolerate highly invasive treatments such as mechanical ventilation, extracorporeal circulation or drugs with important risks of adverse events and interactions.

Data from several studies confirm that heart disease, diabetes and chronic renal failure are significantly more frequent and numerically more numerous among COVID-19 patients who died, compared to the general population¹⁴.

Frail individuals have a higher rate of adverse disease outcomes: frailty assessment at an early stage is important to identify the most vulnerable patients.

In other words, some people have a higher risk than others of becoming severely ill with COVID-19, which means they are more likely to:

- · going to hospital
- · being admitted to intensive care
- needing the ventilator to breathe
- · die
 - -> It is therefore crucial to define those who are fragile patients or those who are more prone to contract 'severe' forms of COVID-19 in order to ensure that action can be taken in time for the available treatments to be effective.
 - -> Today we have vaccines and specific treatments, but it is essential that there is maximum information for patients and their families and caregivers and that synergy is created between the general practitioner, the patient and the other specialists treating them.

¹⁴ Hewitt J et al., The effect of frailty on survival in patients with COVID-19 (COPE): a multicentre, European, observational cohort study. Lancet Public Health 2020; 5: e444–51

¹⁵ Pranata R et al., Clinical frailty scale and mortality in COVID-19: A systematic review and dose-response meta-analysis. Archives of Gerontology and Geriatrics. 2021; 93: 104324

Comorbidity, fragility and vulnerability: let's define them!16

- -> **Comorbidity** is the simultaneous **presence** in the same subject of **two or more illnesses**, **which in** itself cannot be regarded as synonymous with frailty.
- -> **Multi-morbidity** is the presence of two or more long-term medical conditions in a single patient, taking into account the influence of each condition on the other. It is a condition usually more frequent among the elderly.
- -> **Frailty** is defined as a condition of latent vulnerability with the possibility of a risk of adverse outcomes of either a general type (death, loss of autonomy in activities of daily living, institutionalisation) or of a particular type and which in any case increase the risk of hospitalisation.
- -> **Vulnerability** is a concept that must refer to a condition of risk for a specific disease.

6. Risk factors

It is essential that at-risk patients and their relatives and caregivers are properly informed and adopt appropriate behaviour to prevent COVID-19 infection, and in the event of illness, it becomes important to immediately alert one's general practitioner so that he or she can quickly activate the protocol with the specific therapies.

- -> The first step is the awareness of being an individual who is potentially more exposed to risk factors than others.
- -> Which conditions and diseases increase the risk of becoming seriously ill.

Remember!!

Studies on COVID-19 are still ongoing, the list of diseases and conditions is therefore likely to expand to other diseases or conditions.

Always refer to your doctor and follow the instructions of your general practitioner or specialist.

¹⁶ Istituto Superiore di Sanità, in <u>www·iss·it</u> and Società italiana Medici di Medicina Generale, in <u>www·simg·it/COVID-19-le-lezioni-ap-prese/</u>

Who is most at risk of contracting COVID-19 in severe forms:

-> People aged > 65 years

The immune system's defences decline with advancing years. People over 65 are more likely to develop severe disease. In many cases, these are people who have more than one disease (comorbidity).

-> Oncological patients

In general, certain pharmacological treatments used to fight cancer may diminish the very capacity of the immune system and, as a result, the latter may not efficiently counteract the entry of microorganisms (such as Sars-CoV-2). For some types of cancer (e.g. haematological tumours), it is often necessary to use therapies that result in immunosuppression, even in anticipation of bone marrow or stem cell transplantation.

-> Patients suffering from immunodeficiency caused by congenital or acquired disease (hiv) or as a result of the use of drugs used after transplantation

Such patients have a compromised immune system and may not be protected by the vaccine even if they have followed the vaccine schedule and should continue to take all precautions, including wearing a mask. In these cases, it is crucial to activate antiviral therapies in good time.

-> Patients suffering from chronic diseases

The immune system of patients with chronic diseases often does not function optimally and such diseases can cause inflammation. Both factors constitute an increased risk in the case of COVID-19 infection.

- PATIENTS SUFFERING FROM CHRONIC LUNG DISEASE

Such diseases impair basic pulmonary function, they include:

- · asthma (moderate to severe)
- bronchiectasis (abnormal and irreversible dilatation of the bronchial tree)
- bronchopulmonary dysplasia (chronic lung disease of premature infants)
- chronic obstructive pulmonary disease (COPD)
- emphysema
- interstitial lung diseases (accumulation of inflammatory cells in the lungs)
- pulmonary embolism
- pulmonary hypertension

The presence of Sars-CoV-2 can aggravate the situation and lead to ARDS (acute respiratory distress syndrome).

- PATIENTS SUFFERING FROM DIABETES

Diabetes is a disease that involves high baseline inflammation, a condition that promotes insulin resistance and damage to pancreatic cells (responsible for insulin secretion itself). Sars-CoV-2 can exacerbate chronic inflammation, activate blood clotting processes and cause further damage to the pancreas.

- PATIENTS SUFFERING FROM CHRONIC HEART DISEASE

Patients with chronic heart disease are more likely to become severely ill when infected with COVID-19 and also more likely to experience acute cardiovascular events.

They are among the chronic heart diseases:

- heart failure
- cardiomyopathies
- hypertension
- coronary diseases

- CHRONIC KIDNEY DISEASE PATIENTS

People on dialysis may have a weaker immune system, a condition that results in a lower response to infections. People with a kidney transplant must take immunosuppressive drugs on a daily basis, which decrease the activity of the immune system. It is important to continue to follow the instructions of the general practitioner or specialist and not to discontinue drug therapies or dialysis on one's own initiative.

- PATIENTS WITH CHRONIC LIVER DISEASE

Chronic liver diseases (e.g. alcohol-related liver disease, non-alcoholic hepatic steatosis, autoimmune hepatitis and cirrhosis) are also risk factors for COVID-19.

- STROKE PATIENTS

Stroke, a disease that alters the blood supply to the brain, is a risk factor for COVID-19.

-> PATIENTS SUFFERING FROM GENETIC DISEASESE

Even in the presence of certain genetic diseases, there is a risk of contracting the disease in a more severe form when infected with COVID-19.

- CYSTIC FIBROSIS

Cystic fibrosis is a serious genetic disease that mainly affects the respiratory and digestive systems. It is caused by a mutation in a gene that results in the production of excessively dense mucus, leading to several conditions, including recurrence of respiratory infections.

- HAEMOGLOBINOPATHIES

Patients with haemoglobinopathies, particularly \(\Dagger\)-thalassaemia or sickle-cell anaemia or combined forms, are defined as individuals at high risk of developing more severe complications of COVID-19.

-> PEOPLE WITH DISABILITIES

People with certain types of disabilities may be more likely to suffer from severe COVID-19 due to various causes, such as suffering from previous illnesses, living in the community or living in unfavourable conditions.

-> DEMENTIAS AND OTHER NEUROLOGICAL CONDITIONS

Dementia does not increase the risk of COVID-19, but behaviours dependent on it are behind the higher probability of contracting the infection. Patients may forget to wash their hands or follow prophylactic recommendations. Moreover, infectious diseases such as COVID-19 and influenza can further worsen cognitive impairment. There are currently no data on how Sars-CoV-2 can infect more people with neuromuscular diseases. There is no known predisposition for neuromuscular patients to contract the virus but, as most of them have respiratory problems, there is concern that if they contract the infection they may develop severe forms or complications¹⁷.

-> OBESITY

The risk of contracting COVID-19 in severe forms increases significantly in the presence of obesity.

-> OTHER CONDITIONS THAT INCREASE RISK FACTORS

- ADDICTIONS TO SMOKING, ALCOHOL OR DRUGS (OPIOIDS, COCAINE).

¹⁷ COVID-19 recommendations and neuromuscular diseases, by the UILDM Medical and Scientific Commission at https://disabilita-governo-it/it/notizie/uildm-raccomandazioni-COVID-19-e-malattie-neuromuscolari/

Remember!!

Previous chronic conditions may increase the risk of becoming ill with CO-VID-19 and developing severe forms.

The elderly, and therefore more fragile population (more prone to falling ill and contracting diseases), is the one to be protected most from the risk of infection.

Oncological or chronic patients run a higher risk of becoming ill with symptomatic COVID-19 than the general population.

Among chronic patients, people with heart failure, neurological or rheumatic diseases are at greatest risk.

7. Vaccination against Covid -19 in pregnancy and breastfeeding

Women who are pregnant or have recently given birth (up to 42 days after the end of pregnancy) are more likely to be ill than non-pregnant women.

Those who contract **COVID-19** during **pregnancy** have no particular problems; these may occur if the mother becomes seriously ill because the likelihood of preterm delivery (before 37 weeks' gestation) increases.

As in the general population, mRNA vaccines were particularly effective in preventing severe COVID-19 disease in pregnant women.

Due to the current availability of numerically consistent data, international public health agencies (e.g., EMA and FDA)¹⁷ argue that vaccination, with a primary and booster (third and fourth dose) cycle, is the safest and most effective way to protect pregnant women and their babies from COVID-19.

Despite the available data on the advisability and effectiveness of vaccination against COVID-19 in pregnancy, many women remain sceptical and have doubts about vaccination.

The Italian National Institute of Health (Istituto Superiore di Sanità)¹⁸ has updated the recommentations on vaccination against COVID-19 in pregnancy and breastfeeding.

The document²⁰ follows on from a ministerial circular and differs from previous versions as it incorporates new data from the international scientific literature: it considers the new vaccines available against the most recent versions of the Sars-CoV-2 virus and includes the extension of the fourth dose (or second booster dose) to all individuals over the age of 12, including pregnant women or new mothers breastfeeding their children.

¹⁸ https://www-ema-europa-eu/en; https://www-fda-gov/

¹⁹ https://www-epicentro-iss-it/vaccini/COVID-19-target-gravidanza-allattamento

²⁰ https://www-epicentro-iss-it/vaccini/pdf/indicazioni-vaccini-covid-gravidanza-allattamento-pdf

Summary of covid-19 vaccination indications for pregnant and breastfeeding women²¹

- -> Primary vaccination against COVID-19 and booster doses (third and fourth doses) with mRNA vaccines are recommended for all pregnant women at any time during gestation, especially if there is an increased risk of developing severe COVID-19 disease:
 - · women aged 30 or over
 - · with a body mass index (kg/m2) greater than 30
 - with other pathologies
 - · with citizenship of countries with high migration pressure
- -> Primary vaccination and booster doses (third and fourth doses) can be administered at the same time as the recommended vaccinations against whooping cough and influenza during pregnancy.
- -> Primary vaccination against COVID-19 and booster doses (third and fourth dose) with mRNA vaccines are recommended for all breast-feeding women, without the need to stop breast-feeding.
- -> Primary vaccination and booster doses (third and fourth doses) with mRNA vaccines do not expose the infant to risk and allow him or her to acquire antibodies against Sars-CoV-2 via milk.
- -> The vaccination schedule of an infant breastfed by a vaccinated mother does not provide for any change in the milk.



²⁰ Istituto Superiore di Sanità, in <u>www:iss:it</u> and Società italiana Medici di Medicina Generale, in <u>https://www:simg:it/COVID-19-le-lezioni-apprese/</u>

8. Vaccination against COVID-19 in paediatric age

The COVID-19 vaccine is also suitable for all children, even very young ones, from 6 months of age. Children **between 6 months and 4 years** of age can be vaccinated against COVID-19 because the available data document its safety and efficacy. With regard to this age group, more than 4,500 children between 6 months and 4 years of age have participated in the clinical safety studies carried out so far, and it has been shown that the side effects are similar to those observed in older children.

Clinical studies²² have also documented **over 75 per cent efficacy** in preventing COVID-19 in this age group. Like adults, after vaccination against COVID-19, children and young people may experience some local (pain, swelling) or general (fever, discomfort) side effects, which are short-lived (one to two days).

The safety of COVID-19 vaccines has also been closely monitored in studies conducted **in the age group 5-11 years and 12 years and older**. Several million doses have been administered worldwide. The Ministry of Health has extended the recommendation for the vaccination against COVID-19 to children in the **6 months-4 years** (inclusive) **range**²³ who have **fragile conditions**, **which are** indicated in the circular. The vaccine may also be available for children who do not have these conditions **at the request of the parent** (there is therefore no recommendation for the healthy). Three doses (0.2 ml) are planned, with the second dose 3 weeks after the first and the third dose 8 weeks after the second one.

Summary of covid-19 vaccination indications for paediatric children

-> From 6 months to 4 years of age

Vaccination, as specified in the Ministry of Health circular, is recommended for children with fragile conditions that expose them to the development of more severe forms of SARS-Cov2 infection such as:

- immunodeficiencies
- oncological pathologies
- certain haematological pathologies
- cardiology and respiratory
- · chronic kidney disease
- severe pictures of obesity
- type 1 diabetes
- neurological and muscular pathologies
- trisomy 21 and other chromosomal and syndromic diseases
- prematurity in the first 2 years of life
- severe disability

The vaccine may also be made available for the vaccination of **children without risk conditions**, at the request of the parent.

-> From 5 to 11 years of age

Recommended for all children (except in specific cases) and recommended for those in fragile situations.

²² https://www-aifa-gov-it//ema-raccomanda-l-approvazione-dei-vaccini-anti-COVID-19-comirnaty

²³ https://sip·it/wp-content/uploads/2022/12/Circolare-Comirnaty-pediatrico-3mcg-pdf

9. When vaccination is not enough: prophylactic measures for frail patients

There are people who do not respond effectively to vaccination against **COVID-19**. This is the case with **fragile patients** such as immunocompromised individuals or cancer patients undergoing chemotherapy treatment. For them, the solution is the use of **monoclonal antibodies** in the form of **prophylaxis**. In the fight against **COVID-19**, **antibodies** play a crucial role. Since the early months of the pandemic, the isolation of the most effective antibodies from patients' plasma and subsequent large-scale production appeared to be one of the main solutions to **neutralise coronaviruses**.

Until a few months ago, we had only heard about monoclonal antibodies being used to treat patients with COVID-19. Now, however, there is talk of their use in prophylaxis.

The use of monoclonal antibodies in prophylaxis, unlike that in treatment, is unrelated to the incidence of the disease and is more easily programmable by centres that are in charge of patients who fall into the **eligible categories** identified in the Italian Medicines Agency (AIFA) registry²⁴.

- -> Monoclonal antibodies are antibodies that are reproduced in the laboratory in unlimited quantities and for an infinite number of times, representing a concentration of the immune system's best weapons to target the virus. Although they are not 'drugs' capable of acting by blocking virus replication, the use of effective monoclonal antibodies is designed to minimise the damage caused by the virus. To date, several monoclonal antibody combinations have been approved in the treatment of individuals with COVID-19²⁵.
- -> Antivirals²⁶ are together with vaccines and monoclonal antibodies one of the strategies deployed by international health teams to counter the COVID-19 pandemic. These drugs, to be taken early, have the main purpose of inhibiting the replication and maturation of viral particles, as well as the complications of infection.

The administration of current **antiviral drugs** is strictly indicated for frail patients at high risk of contracting serious forms of the disease (having neoplasia, renal insufficiency, immunodeficiency, obesity or cardiovascular diseases, etc.). Such individuals must be expressly indicated by the doctor, who, having been alerted in good time to the onset of symptoms attributable to COVID-19, will manage the patient appropriately.

Important!!

If you are a frail patient, family member or caregiver, remember to pay close attention to possible symptoms of COVID-19 infection, take the swab and in case of a positive result immediately inform your general practitioner and specialist.

Constantly update your doctor about your state of health and the onset of any symptoms.

Antiviral therapy in cases where it is indicated is all the more effective if administered promptly within the first five days of the onset of symptoms.

²⁴ https://www-aifa-gov-it//aggiornamento-registro-anticorpi-monoclonali-COVID-19

²⁵ <u>https://www-aifa-gov-it/uso-degli-anticorpi-monoclonali</u>

²⁶ https://www-aifa-gov-it/uso-degli-antivirali-orali-per-COVID-19

10. The long COVID

More than three years after the start of the COVID-19 pandemic, many studies have been conducted on the different symptoms, variants and effects of the virus on the population. Among the effects that the disease can leave behind is 'Long COVID', a condition that results in the persistence of symptoms attributable to the infection despite the fact that the subject is actually considered negatively infected following the swab result.

-> The term 'Long COVID' refers to the condition of patients who, more than four weeks after the illness and despite a negative swab result, continue to report symptoms attributable to the infection.

The symptoms most frequently reported by people with 'Long COVID' are as follows:

- excessive and persistent tiredness
- muscle weakness and pain
- sarcopenia (i.e. the progressive decline in muscle mass and strength)
- reduced appetite

Some patients also reported long-term consequences at the level:

- neurological: headache, memory problems, concentration difficulties, dizziness, sleep disorders
- · cardiology: tachycardia, arrhythmia, chest pain, changes in blood pressure
- pneumological: dyspnoea and persistent coughing
- gastrointestinal: abdominal pain, nausea and diarrhoea
- dermatological: chilblains and skin rashes
- psychological: anxiety, stress and depression

The Istituto Superiore di Sanità²⁷ has drawn up **guidelines** for the management of patients with long COVID, which contains good practices to be followed for their care, and has also set up a **national surveillance** system for the disease. This system will make it possible to produce periodic reports, updated monthly.

To assist patients with this particular condition, several outpatient clinics have been set up throughout the country, with different distribution from region to region.

->There are currently a total of **113 outpatient clinics in the country**, officially surveyed by the Istituto Superiore di Sanità (ISS). The national map of long COVID outpatient clinics is public and can be consulted on the Institute's website²⁸.

Important!!

If you continue to have symptoms after you have been negatively affected by COVID-19, talk to your general practitioner who can check whether it is long COVID.

There are referral centres throughout the country specialised in the management of patients with long COVID.

²⁷ https://www·iss·it/long-covid-linee-guida

²⁸ https://www·iss·it

11. How the Citizen Navigates: Our Useful Tips

- -> Remember: only your family doctor, your paediatrician or your specialist are able to make a specific diagnosis and direct you in the best way possible, knowing your condition. Don't rely on do-it-your-self or word of mouth, don't spontaneously stop taking treatment and don't take over-the-counter medicines without first consulting your doctor. You are entitled to personalised care!
- -> Ask your doctor or paediatrician for advice on vaccination against Covid-19: they will be able to give you all the information and give you the best orientation!
- -> If you are a frail patient, caregiver or family member pay close attention to hand and surface hygiene, use a mask, avoid crowded places and maintain social distancing
- -> Notify your general practitioner, paediatrician or specialist as soon as possible if you have contracted COVID-19. Antivirals must be administered within 5 days of the onset of symptoms
- -> If you think you have long COVID, don't procrastinate! Talk to your doctor, there are protocols for symptom management and regional reference centres.

No to FAKE news!!

Always consult your doctor or other health professionals if in doubt.

Consult accredited and official information sources.

For further information: www.cittadinanzattiva.it



The Be A.W.A.R.E. project is supported by a grant from **Pfizer Inc.**