Joint statement on the current coronavirus pandemic
SARS-CoV-2 — COVID-19 in children and adult patients with
Primary Immunodeficiencies (PID)

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Recent updates are highlighted in yellow.
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Coronavirus

In December 2019, a cluster of pneumonia cases was reported in Wuhan, Hubei Province, China, linked to a novel coronavirus (SARS-CoV-2, leading to COVID-19 disease).\(^1\) Coronaviruses are common in many different animal species and it is rare that they infect people and spread between them, but it happens. Recent examples include Severe Acute Respiratory Syndrome (SARS-CoV-1—CoV, for coronavirus), and Middle East Respiratory Syndrome (MERS-CoV). The SARS-CoV-2 is distinct from the previous two coronaviruses and causes COVID-19 disease.\(^2\)

**Current situation**

The situation is constantly changing, and we encourage you to monitor the latest advice applicable to your area.

As of 28-05-2020, over 5,710,393 cases of COVID-19 have been reported worldwide (188 countries). The countries with the highest number of reported cases are the United States of America, Brazil, Russia, the United Kingdom, Spain, Italy, France, Germany, Turkey, India and Iran.\(^3\)

The spread and severity of this viral outbreak has demonstrated the need for a fast and comprehensive response from the public health sector. Beside the virus itself, one of the biggest threats is the overwhelming of the healthcare systems/hospitals due to the rapid spread and the lack of herd immunity in the general population.

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Transmission

The transmission mode of COVID-19 is similar to previous coronavirus outbreaks, spreading from person to person through:

- Respiratory droplets spreading when coughing or sneezing
- Close personal contact with an infected person (shaking hands or touching)
- Touching contaminated surfaces and then touching eyes, nose or mouth with unwashed hands.⁴

SARS-CoV-2 RNA has been detected in faeces, blood, serum, saliva, nasopharyngeal specimens, urine and ocular fluid.⁵ Findings have also demonstrated that children may release virus in the stools up to 15 days after recovering from COVID-19. This means that keeping distance and frequent hand washing should be applied even after clinical recovery.

The incubation period for COVID-19 is currently estimated to range from one to fourteen days, with a median incubation period of five to six days. The onset and the duration of viral shedding is not yet fully established, but reports show that the virus has been identified in respiratory specimens up to two days before demonstrated symptoms (pre-symptomatic), peaking in the second week after infection. A high viral load close to symptom onset points to SARS-CoV-2 being easily transmissible early in the infection. So far, reports do not demonstrate a significant difference in viral load in asymptomatic and symptomatic patients, indicating the potential virus transmission from asymptomatic patients.⁶ Further studies are needed to establish their role in transmission.

There are some reports of animals testing positive to COVID-19 after contact with infected humans. It is recommended that people who are sick with COVID-19 and people who are at risk limit contact with animals. When handling and caring for animals, basic hygiene measures should always be implemented.⁷

Clinical symptoms due to COVID-19 infection

Human coronaviruses commonly cause mild to moderate illness in the general population. So far, the main clinical signs and symptoms reported in this outbreak vary from no symptoms at all to fever, fatigue, dry cough and runny nose. Some patients also experience aches and pains, myalgias, nasal congestion, sore throat and/or diarrhea. Reports also demonstrate transient loss of taste and smell. These symptoms are usually mild and begin gradually. Approximately 80% of the affected people recover from the disease without needing any special treatment.⁸

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⁶ Ibid.
⁸ Ibid.
A SARS-CoV-2 infection is often divided into three phases (I: Early infection, II: Pulmonary phase, III: Hyperinflammation phase), with a minority of the patients transitioning to the third phase. Severe COVID-19 cases may progress to acute respiratory distress syndrome (ARDS) as a result of an aggressive inflammatory response, a cytokine storm, (mimicking hemophagocytic syndrome) during phase III, for which transfer to intensive care unit (ICU) for non-invasive (face respiratory mask) or invasive (mechanical artificial ventilation) might be needed. Thus, the severity of the disease is not only due to the virus itself, but to the hyperinflammatory response to the infection.\(^9\) This usually occurs after 6 to 10 days.

It has been reported that evolution to a more severe stage of the disease, requiring urgent medical care, can be very rapid (within a few hours).

Some patients suffering from a more severe course of the infection have also developed thrombotic complications. In addition to this, cardiac damage (cardiomyopathy), acute kidney injury (AKI) and encephalitis have been reported.\(^10\)

Recent studies have showed that specific antibodies against SARS-CoV-2 are generated after a COVID-19 infection, but further research is needed to establish if this will result in long-term immunity.\(^11\) However, based on experiences from MERS-CoV and SARS-CoV-1 (previous coronaviruses), it is possible that patients who recover from SARS-CoV-2 will develop long-term, but not life-long, antibodies.

**Paediatric inflammatory multisystem syndrome and SARS-CoV-2 infection in children**

Several countries have reported cases (15-05-2020, 230 suspected cases in EU/EEA countries) of children in need of intensive care due to a rare paediatric inflammatory multisystem syndrome (PIMS). The presenting symptoms are fever, abdominal pain, conjunctivitis, rash, irritability and in some cases cardiac involvement. The syndrome has features similar to both Kawasaki disease (KD) and toxic shock syndrome (TSS). A possible link between PIMS and SARS-CoV-2 (PIMS-TS) is being investigated as some of the children tested positive for the virus, while others were tested positive for SARS-CoV-2-specific antibodies. The potential link with COVID-19 is neither established nor well understood, but the importance of prompt contact with a doctor if a child presents symptoms should be stressed.\(^12\)

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Tests for COVID-19

The test for active SARS-CoV-2 infection usually consists of a nasal (nasopharyngeal) swab, possibly more sensitive than an oral (oropharyngeal) swab, that is sent to a dedicated microbiology laboratory for detection of the virus (by polymerase chain reaction (PCR) method, within a few hours). However, in some cases, a negative PCR does not rule out infection ("false negative").

Serology tests, i.e. testing through detecting antibodies (IgG and IgM) against SARS-CoV-2 in the blood, are becoming increasingly available. Such tests will reveal whether a person has made a detectable antibody response after being infected with the virus. There are currently various serology tests including some rapid tests being made available online for people to do in their homes, but many of these tests have not been carefully validated and may not be reliable to the highest standards.

Should PID patients get systematically tested for COVID-19?

The situation is constantly changing, and we advise you to follow the latest advice applicable to your area.

As the result of limited testing capacity, most national guidelines do not recommend that patients with different chronic diseases, including PID, be managed differently than other patients regarding screening. At this stage, it is not recommended that PID patients with no or atypical symptoms be tested.

For patients with PID who are not able to produce antibodies (such as patients with agammaglobulinemia), serology tests will not be useful. For other forms of PID (including those treated with Ig replacement therapy), this test might be of help, as current Ig preparations do not contain anti-SARS-CoV-2 IgG yet and do not contain any IgM at all.

In general, it is advised to adhere to local and national guidelines for testing.

For PID patients who have tested positive for COVID-19, it is recommended to perform a second screening after the patient has clinically recovered, as it may be that some PID patients, especially patients with a Combined Immune Deficiency (CID), might struggle with clearing the infection. These patients may remain positive longer and risk remaining a source of infection to their environment.

On the other hand, it is not clear if PID patients have been tested positive for COVID-19 are able to build a sufficient memory response to protect themselves from recurrent infections.
Treatments (vaccines & anti-viral medicines)

There is currently no anti-viral drug solely developed for SARS-CoV-2 available, but there are anti-viral medications that were previously used for other viruses that have shown some efficacy. In the beginning of May, the U.S Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the investigational antiviral drug remdesivir for the treatment of COVID-19 in adults and children hospitalized with severe disease. An EUA is different than FDA approval and may be revised or revoked during the emergency.

The antiviral combination lopinavir/ritonavir, and the immunomodulatory/antiparasitic drugs chloroquine and hydroxychloroquine, used with or without antibiotics (such as azithromycin) did not prove to be efficient and trials have been withdrawn, indefinitely or temporarily.

Different drugs and drug combinations are currently being investigated in randomized controlled clinical trials (RCCTs). Results of these RCCTs should be awaited before a treatment could be recommended.

There is currently no vaccine available for COVID-19. One or several vaccines could be available in 2021, but it is not guaranteed.

Plasma derived COVID-19 treatments

Convalescent plasma (plasma with antibodies from recovered COVID-19 patients) is being investigated as a treatment option for seriously ill patients. It is important to note that although scarce promising reports, further research is needed to establish if convalescent plasma is a safe and effective treatment for COVID-19.14

Efforts by the plasma industry to fast track the development of COVID-19 treatments (hyperimmune globulins) should also be noted. A group of 10 world-leading global pharmaceutical companies active in the plasma industry have joined together in an attempt to accelerate the development of an unbranded anti-SARS-CoV-2 polyclonal hyperimmune immunoglobulin medicine. This alliance now also includes global organisations from outside the plasma industry who are providing support to encourage increased plasma donation.15 In addition, other plasma industry companies are also working on similar research programmes.16

There are also clinical trials that have started, or will soon start, studying intravenous immunoglobulin (IVIG) as a potential treatment for COVID-19. So far there is no evidence that IVIG is an effective treatment for patients infected with SARS-CoV-2 and more research is

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14 Kai Duan, Bende Liu, Cesheng Li et al. Effectiveness of convalescent plasma therapy in severe COVID-19 patients. PNAS 28 April 2020. Available at: https://www.pnas.org/content/117/17/8490
needed. Regardless of the outcomes of clinical trials, we emphasize the importance of continuity of Ig replacement therapy for PID patients whose life relies on a continuous life-long and stable supply of immunoglobulins.

**COVID-19 clinical trials at a glance**

- COVID-19 clinical trials listed on TranspariMED.
- COVID-19 NIH clinical trials registry.
- Living mapping and living network meta-analysis of COVID-19 studies.
- **Anticovid**

**Precautions**

Any respiratory virus that can be spread from person-to-person may be a risk for PID patients. Therefore, PID patients should be cautious and keep track of developments of COVID-19 in their region. Whilst immunoglobulin (Ig) replacement therapy provides protection against a wide range of infections, it does not guarantee immunity against coronavirus. The World Health Organization’s (WHO)\(^\text{17}\) and the Centers for Disease Control and Prevention’s (CDC)\(^\text{18}\) recommendations to reduce exposure to and transmission of COVID-19 include, but are not limited to, the list below.

- The MOST IMPORTANT means to prevent infection are:
  - Wash hands frequently (every hour) with hand rub or soap and water for 20 seconds, (if not possible use alcohol-based hand rub), especially after direct contact with ill people or their environment
  - Avoid touching eyes, nose and mouth
  - Avoid close contact (at least 1 meter) with people suffering from acute respiratory infections
  - Avoid close contact (at least 1 meter) with anyone who has fever and cough
  - For extra precaution, avoid close contact (at least 1 meter) with other people when leaving your home
  - Avoid greeting people by shaking hands, kissing or hugging
  - Respect the confinement measures wherever these are applicable

- People with symptoms of acute respiratory infection should practice cough etiquette (maintain distance, cover coughs and sneezes with disposable tissues or clothing, and wash hands) and wear a respiratory mask if instructed by their local health care provider.

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Additional measures

Masks can be effective if the person wearing one has the appropriate training for a good fitting mask, but if not used appropriately they can pose a risk for contamination. The mask needs to be replaced regularly. Guidance from the WHO\textsuperscript{19} on the appropriate way of wearing masks includes:

- Before putting on a mask, wash your hands (with alcohol-based hand rub or soap and water).
- Cover mouth and nose with mask and make sure there are no gaps between your face and the mask.
- Avoid touching the mask while using it; if you do, clean your hands with alcohol-based hand rub or soap and water.
- Replace the mask with a new one as soon as it is damp and do not re-use single-use masks.
- To remove the mask: remove it from behind (do not touch the front of mask)
- Discard immediately in a closed bin; clean hands with alcohol-based hand rub or soap and water.

Some countries have taken measures for citizens to wear masks when spending time outside their homes and we advise that national guidelines be followed. If you are not able to wear a facemask (for example, because it causes trouble breathing), then you should do your best to cover your coughs and sneezes, and people who are caring for you should wear a facemask if they enter your room. If a shortage occurs, masks should be reserved for hospital staff and people experiencing symptoms.

For extra precaution, clean and disinfect frequently touched surfaces daily, including tables, doorknobs, light switches, countertops, handles, desks, phones, keyboards, toilets, faucets, and sinks.

Questions regarding daily life (school attendance, work, travel…) depend on the local epidemiological situation and the underlying PID and needs to be discussed with the PID expert physician. This becomes especially relevant during the time of moving out of confinement (see below) when decisions regarding returning to work, school, or living with people in the same household who are returning to normal life become immediately relevant. For patients with higher risk for a severe course of the disease it may be considered to continue working from home, to not send the children back to school and to wear special masks (FFP2) for increased personal protection. However, many of these measures present a strong confinement to life and the cost and benefit needs to be balanced.

If you feel unwell and experience symptoms such as fever, cough and/or difficulty in breathing, stay home and seek prompt medical assistance from your health care provider.

Moving out of confinement

Due to strong confinement measures, several countries have now reached a plateau in the number of cases. Whilst some other countries are still facing a high number of new cases each day, when reaching the plateau phase there should be no significant increase in reported cases for an extended period of time. Depending on the confinement exit strategies put in place, this may be followed by a decline in infections.

It is important to understand that de-confinement measures do not mean that the virus has been extinguished. Confinement has been the strategy in many countries to "flatten the curve" of infections and to avoid overwhelming the health care systems. In many of these countries there is still only a small proportion of the population that has been exposed to the virus so far and de-confinement may lead to a further increase in infections.\(^\text{20}\) Hygiene measures and social distancing are still key to protect PID patients after de-confinement.

COVID-19 in PID patients

To date (28-05-2020), global surveys aimed at collecting data on COVID-19 in PID patients do not point to an increased risk of COVID-19, especially not in its severe form, although some cases have been reported. However, certain PID patients might be at higher risk than others to catch this infection or a more severe course of the disease. In the absence of more precise data, patients with PIDs need to take extra care to avoid getting this infection.

Mapping of COVID-19 in PID patients

Research efforts are underway in order to monitor the cases of COVID-19 in patients with PID at a global scale.

Since the launch of the first survey, 57 cases have been reported.

Typical presentation symptoms: upper respiratory symptoms, cough, shortness of breath, fever.

7 patients had diarrhea and vomiting. 7 patients had myalgia. 32 necessitating admission, 15 evolving into respiratory insufficiency, 5 succumbed. 5 patients required non-invasive ventilation, 10 invasive ventilation and 1 ECMO. Complications: 4 hemophagocytic lymphohistiocytosis (HLH), 5 sepsis (1 Candida), 4 bacterial pneumonia, 4 hypotension/shock with kidney failure, 1 severe autoimmune haemolytic anemia (AIHA), 1 anemia, 1 neutropenia.

Full survey summary available here.

A second-tier survey aimed at collecting more data is also open for entering cases. “\text{COPID19}” is the more detailed second phase of the worldwide survey of COVID-19 in PID patients and is directed to physicians who manage PID patients.

Recommendations for PID patients

Patients with PID living in areas of high prevalence should take every precaution and adhere to local, regional and national recommendations (staying at home, teleconsultation, work from home, etc.).

Beyond the precautions mentioned above, we advise prompt phone contact with a doctor if an infection is suspected (should it be your PID expert, or your GP who should let your PID expert know about your condition in order to provide the best advice for each PID patient’s specific condition). Patients should always keep the details of their PID diagnosis and medical charts, medications, PID expert doctor and next of kin at hand, in case urgent medical care is needed.

PID patients with lung and/or heart complications, solid organ transplant recipients, recent recipients of hematopoietic stem cell transplantation or gene therapy, PID patients undergoing treatment for a cancer (malignancy), as well as patients under immunosuppressive or immunomodulatory drugs (for autoimmune, inflammatory, or autoinflammatory conditions complicating the PID course) should remain on their specific therapy until recommended otherwise by their PID expert physician. Immunosuppressive drugs (in particular corticosteroids), might limit signs of infections (fever and other clinical symptoms). It is thus recommended to contact your PID expert physician in case of any unexplained changes in clinical status including your well-being.

PID patients with overweight, old age, cardiovascular disease, diabetes mellitus and/or significant respiratory issues (severe asthma, bronchiectasis or chronic respiratory failure) should receive special attention (as for any risk of respiratory infection).

Keep in mind that it is always essential to continue the regular treatment for your PID.

Plasma Derived Medicinal Products (PDMPs), such as immunoglobulins (IVIG or SCIG) are safe and will protect you from many other infections.

For everyone, including PID patients, we strongly recommend you to keep up with the latest information on the COVID-19 outbreak in your region, for example provided by the World Health Organization (WHO), the European Centre for Disease Prevention and Control (ECDC) and by your national and local public health authorities.

National guidelines provided by national health authorities should be followed (the epidemiological situation and the management might differ from one country to another).

We want to stress that your PID expert can give you the best personalized advice.

Patients can also visit the IPOPI website to have full access to the FAQ.
COVID-19 and influenza season

Some regions of the world are entering the seasonal flu period. To ensure protection against influenza viruses, it is recommended that most PID patients and their families be vaccinated against seasonal flu by inactivated vaccines.

Please note that recommendations will vary between PID patients and specialist advice should always be sought before receiving vaccinations.

More info on PID and vaccination available here.

Plasma Derived Medicinal Products (PDMPs), including Immunoglobulins

According to a statement from the Plasma Protein Therapeutics Association (PPTA) there is no risk of transmission of SARS-CoV-2 by PDMPs.21

A study in China has demonstrated the detection of SARS-CoV-2 RNA in blood donations22, but it should be noted that this does not pose a risk to PID patients in terms of transmission via immunoglobulin therapies. The virus inactivation and removal steps during the manufacturing process of PDMPs ensure the safety of IG therapies.

For PID patients who are on Ig replacement therapy, there is no evidence to date that more frequent dosing of Ig will offer more protection. Whilst Ig replacement therapy provides protection against a range of infections, it does not guarantee immunity against coronavirus.

For PID patients whose condition does not require them to be under regular Ig replacement therapy, there is no need to start Ig replacement therapy since no antibodies targeting COVID-19 are expected to be contained in the existing preparations.

Decline in plasma supply

The COVID-19 outbreak and associated confinement and movement restriction measures will impact supply of blood and plasma collection and may affect medicinal product circulation and supply.

National guidelines on masks may also pose a potential risk for plasma collection as donation centres may not be able to fully operate if they face mask shortages.

As the plasma necessary to produce PDMPs is either collected from plasma donors (apheresis plasma) and from blood donations (recovered plasma), this will almost inevitably impact access to these life-saving therapies, although it may take a few months before PDMPs shortages start

to be observed (it usually takes 7-10 months from the time plasma is collected from a human donor to reach the patients).

Numerous countries have reported significant drops in blood collection and a similar development is expected for plasma collection.

Various PID stakeholders are currently taking measures to react to this development on both national and regional levels so that PID patients are prioritized in case of any supply tensions or shortages associated with the COVID-19 outbreak.
Supporting organisations

About IPOPI
IPOPI is the leading advocate for primary immunodeficiencies’ patients worldwide working in collaboration with patients, doctors, politicians, regulators, pharmaceutical industry and other relevant stakeholders. IPOPI is the Association of national PID patient organisations currently representing 68 countries. More info: [http://www.ipopi.org](http://www.ipopi.org), [Facebook](https://www.facebook.com), [Twitter](https://twitter.com)

About ESID
The European Society for Immunodeficiencies (ESID) is a non-profit organization whose main objectives are to facilitate the exchange of ideas and information among doctors, nurses, biomedical investigators, patients and their families concerned with primary immunodeficiency diseases and to promote research on causes, mechanisms and treatment of these disorders. ESID was established as an informal group in 1983 and became a society in 1994. More info: [www.esid.org](http://www.esid.org), [Twitter](https://twitter.com)

About INGID
The aims of INGID are to improve and extend the quality of nursing care of patients with primary immune deficiencies, and to increase the awareness and understanding of primary immunodeficiencies amongst nurses. More info: [www.ingid.org](http://www.ingid.org)

About APSID
The Asia Pacific Society for Immunodeficiencies (APSID) works to provide PID care, education and research for PID patients, through collaborative infrastructure and various APSID Working Parties. A group of over 60 Asian paediatricians and scientists interested in Primary Immunodeficiency met in Osaka, April 2015 and pledged to establish APSID with the following missions: To care and cure patients with primary immunodeficiency (PID), To share PID experience so as to promote collaboration & education, To improve PID management through understanding its genetics & pathogenesis and To advocate and advance the care of PID patients through engaging governments, patient organizations & industry. More info: [https://paed.hku.hk/apsid/](https://paed.hku.hk/apsid/)

About ARAPID
ARAPID is the Arab Society for PID. Its purpose is to bring together the English-speaking east region of the Arab world, closer to the French-speaking west region, to better serve PID patients from the Arab world who are united by consanguinity, etiological profile of PIDs and culture (awareness). More info: [www.arapid.org/en/](http://www.arapid.org/en/)
About ASID

The African Society for Immunodeficiency (ASID) is a PID focused scientific society. Its main objectives are to improve PID awareness and care within Africa and has been working on addressing continental African PID peculiarities. ASID strives to support African patients through collaborating with national and international patient groups and works with national societies and other relevant authorities to achieve its objectives. ASID also collaborates with international PID societies and alliances, and the industry to promote better PID care and research. More info: www.asid-africa.org

About CIS

The Clinical Immunology Society (CIS) is based in the United States but has members from around the globe. The mission of CIS is to facilitate education, translational research and novel approaches to therapy in clinical immunology and to promote excellence in the care of patients with immunologic/inflammatory disorders. More info: www.clinimmsoc.org

About LASID

The Latin American Society for Immunodeficiencies (LASID) is a vibrant and inclusive international society. This is the home of all professionals dedicated to the field of Primary Immunodeficiencies aiming to develop and perfect the education, scientific research, and health care within this medical specialty. LASID’s mission comprises the following: To increase awareness in Primary Immunodeficiency Diseases (PIDD) at all levels all over the continent, to develop diagnostic capabilities to reach as many as possible patients and to favor the development of centers providing appropriate treatments for PIDD patients. More info: www.lasid.org

About SEAPID

South East Asia Primary Immunodeficiency Network or “SEAPID” is a regional NGO - the South East Asian network of Primary Immunodeficiency Experts. It was established in Bangkok, Thailand on 26th January 2015, following an accord reached by experts from the six South East Asian founding countries, namely, Indonesia, Malaysia, the Philippines, Singapore, Thailand and Vietnam.

About IUIS Inborn Errors of Immunity Committee (IEI)

The IEI Committee consists of experts in all aspects of primary immunodeficiencies. Its missions are: to provide an up-to-date classification of all primary immunodeficiency diseases (IEIs), to assist with the identification, diagnosis and management of patients with these uncommon conditions, to support diagnostic and therapeutic guidelines developed by national societies and others, to assist healthcare providers, to promote awareness, diagnosis and treatment of IEIs in all regions of the world, to produce ad hoc reports on any aspect of IEIs, to assist in the welfare of patients with these conditions. More info: www.iuis.org/committees/iei/
More resources:

Videos

Short educational videos by Prof. Kate Sullivan, member of the medical board of the Immune Deficiency Foundation (IDF).

- Video from 3 March 2020.
- Video from 10 March 2020.
- Video from 18 March 2020.
- Video from 10 April 2020.
- Video from 8 May 2020.

Websites

- Adiós Corona (content curated by physicians and scientists and available in many different languages)