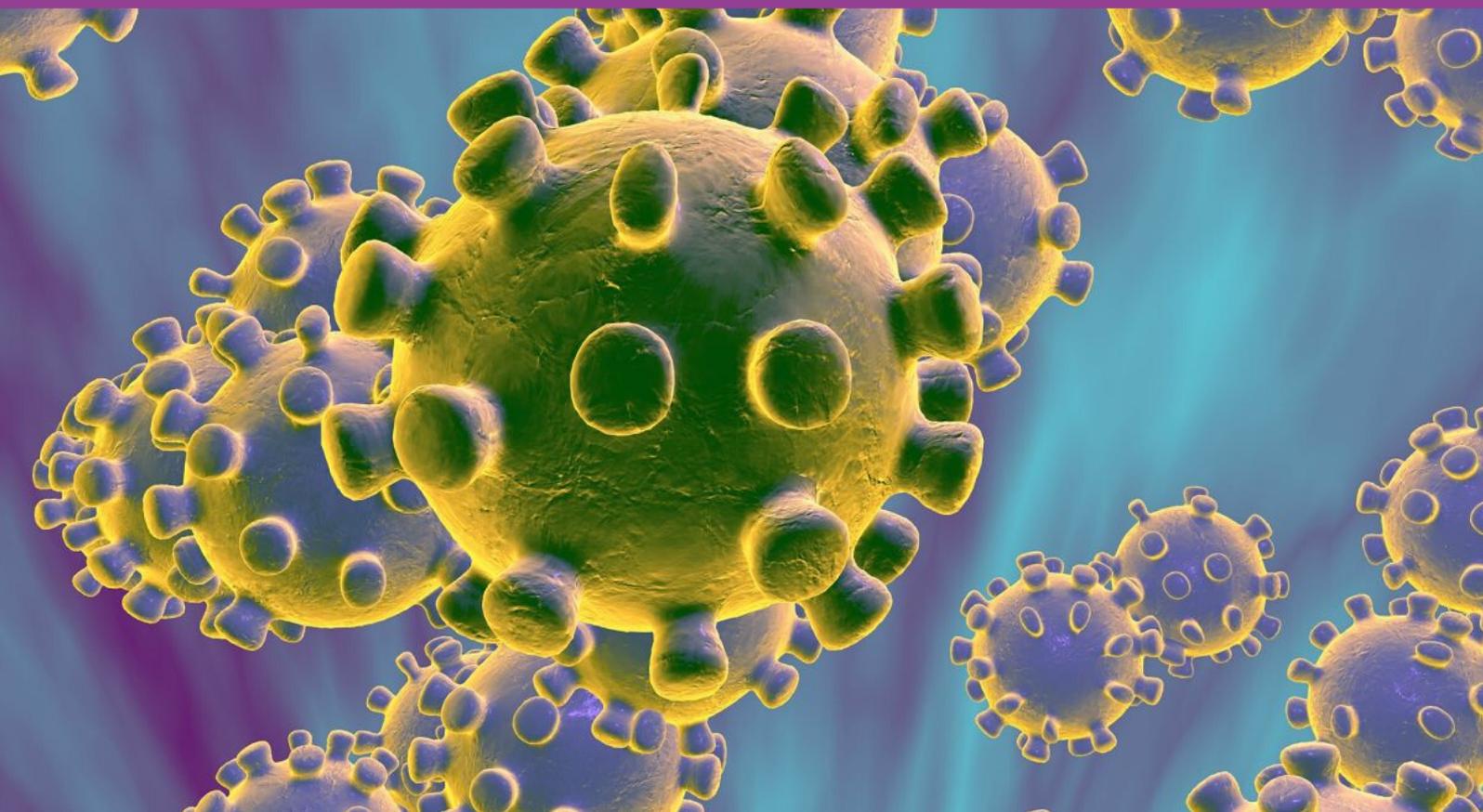




IgNS Immunoglobulin
National Society

Advancing Ig Therapy Practice

COVID-19 Resource Guide and FAQ





IgNS COVID-19 Resource Guide and FAQ

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IgNS places the utmost importance on maintaining the health and safety of patients and healthcare providers during this COVID-19 global pandemic. We have compiled relevant guidance to support clinicians and patients through the complexities of managing Ig patients during this crisis.

The information provided within this document does not replace clinical judgement and patient-specific decisions, established clinical guidelines, or policies set in place by individual organizations. The COVID-19 Resource Guide and FAQ is intended to be used as a supplement to making clinical decisions during the current situation.

Please note that this is a rapidly developing and changing situation. Monitor guidance from your local health department and the CDC regularly.

Interim Guidance Regarding COVID-19

Health officials are still learning how a newly discovered respiratory virus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV2), spreads and how severe the infection can be. SARS-CoV2 is the virus that causes COVID-19 illness. Important Information About How COVID-19 Spreads:

- 1) The virus is thought to spread mainly from person to person. As in between people who are in close contact with one another (within 6 feet).
- 2) Through respiratory droplets produced when an infected person coughs or sneezes. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.
- 3) It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes.
- 4) People are thought to be most contagious when they are most symptomatic (the sickest).
- 5) Spread before people show symptoms may be possible.



General Care Considerations for COVID-19

1. Is it critical that this service be provided now, can it be postponed until the risk of COVID-19 is lower, or can this service be done remotely by other mechanisms (e.g., phone call, video conference)?
2. General Infection Prevention Strategies Organizations should encourage staff to routinely employ infection prevention strategies to reduce transmission of common respiratory viruses (e.g., influenza or “flu” or “the common cold”).
3. Stay home if you are sick.
4. Cover your mouth and nose with a tissue when coughing or sneezing (in the absence of a tissue, cough or sneeze into your shirt sleeve or bent arm).
5. Keep your hands clean (wash your hands often with soap and water for at least 20 seconds). Use an alcohol-based hand sanitizer, if soap and water are not available.
6. Avoid touching your eyes, nose, or mouth with unwashed hands.
7. Regarding Facemasks: In line with the Centers for Disease Control and Prevention (CDC), IgNS does not recommend the routine use of masks if you are healthy. Facemasks are not warranted for general/routine tasks by staff – even those who have frequent interaction with the general public.
8. Guard Against Stigma Organizations should work to prevent actions that could perpetuate stigma attached to COVID-19 or appear to be targeted at one group of people. There is absolutely no excuse for using the outbreak as a way to spread racism and discrimination. Organizations should encourage that staff stay informed, remain vigilant, and take care.



Frequently Asked Questions Regarding COVID-19 for Healthcare Providers

I. What screening procedures should be in place prior to treating patients in the home or infusion center?

During the COVID-19 crisis, all patients receiving care in the home or infusion center environment should be screened via phone within 24 hours prior to each infusion. The goal of pre-screening is to identify any potential risk of an airborne transmissible disease, like COVID-19, before any contact with the patient.

Any patient with any of the symptoms listed below, should not be treated in the home or infusion clinic setting:

- i. ***fever > than 100 F***
- ii. ***dry cough***
- iii. ***difficulty breathing***



IgNS COVID-19 Patient Screening Questionnaire

Listed below are examples of relevant screening questions that may be used in conjunction with the individual organizations' policies and procedures for Infection and Exposure Control.

If the patient responds "YES" to any of the questions below, refer to individual organization policy and procedure for guidance on treatment of the patient. Decisions related to whether or not to treat a patient based on the screening questions below should be made with the patient's healthcare team and prescriber.

This tool may also be used for healthcare professionals to "self-screen". Please refer to [CDC Guidance for Healthcare Professionals with Potential Exposure](#) for guidance.

Healthcare professionals who suspect a COVID-19 infection should contact local or state health departments to report infection.

1. In the last 14 days, have you or any member of your household:
 - a. Traveled to or from a country outside of the United States?
 - i. *If YES, follow organizational policy in place for treatment of patients with possible exposure.*
 - ii. *If NO, continue to Question 1b*
 - b. Had close contact with a person under investigation for COVID-19?
 - i. *If YES, refer to the [CDC risk assessment](#) for guidance*
 - ii. *If NO, continue to Question 1c*
 - c. Had close contact with a person with confirmed COVID-19?
 - i. *If YES, refer to the [CDC risk assessment](#) for guidance*
 - ii. *If NO, continue to Question 2*



2. Are you sick today with anything other than a common cold or allergies?
 - a. If YES
 - i. What is the illness?
 - ii. Have you been told they have an illness that can be spread by coughing, sneezing, or talking?
 - *If YES*
 - *Contact pharmacy and/or prescriber to notify of symptoms.*
 - *Determine need for COVID-19 evaluation*
 - *Request prescriber to contact the local or state health agency to report potential infection and determine next steps for testing.*
 - *Obtain order to either proceed or hold infusion pending COVID-19 testing results.*
 - *If NO, continue to Question 3.*
 - b. If NO, continue to Question 3.
3. Are you experiencing a fever > 100 degrees, dry cough, or difficulty breathing?
 - a. If YES, inform provider in order to determine if COVID-19 evaluation is needed, as well as potential reporting to local or state health agencies to determine next steps for testing.
 - b. If NO, continue to Question 4.
4. Has the patient been required to wear a mask when leaving the house?
 - a. If YES, determine why the patient was required to wear a mask
 - b. If NO, continue to Question 5.
5. Is anyone in your household currently sick with any illness that can be spread to visitors?
 - a. If YES, follow organizational procedure for guidance
 - b. If NO, make a final determination regarding patient's treatment

Refer to **symptoms of COVID-19** from the CDC for more information.

Refer to CDC guidance for implementing home care of the patient with COVID-19 not requiring hospitalization.



II. Should personal protective equipment (PPE) be worn while caring for ALL patients during the COVID-19 crisis?

Wearing a mask

1. If you are healthy, you only need to wear a mask if you are caring for a person with a suspected COVID-19 infection
2. Wear a mask if you are coughing or sneezing
3. Masks are effective only when used in combination with proper and frequent hand-washing
4. If you wear a mask, you must know how to use it and dispose of it. Please refer to [WHO guidance regarding the use of masks](#) for more information.

PPE should *only* be worn by healthcare professionals caring for a patient with a known or suspected case of COVID-19. Eye protection, masks, gowns, and gloves should be worn when caring for these patients. Patients should also wear a facemask while being evaluated for COVID-19. It is critical to use N95 masks only when necessary due to the current supply shortage. Information regarding the route of transmission of COVID-19 is fluid. Please refer to [CDC Infection and Prevention Control](#) for recommendations and updates.

Alleviating the anxiety of patients during this time is critical. Patients may request that a healthcare professional wear a mask at all times, however it is important that patients understand the reasons and situations where PPE is required. Please use the resources provided in this document as well as organizational policies to educate patients.



III. What happens if there is a shortage of PPE?

The global outbreak of COVID-19 has caused disruptions to overseas manufacturing, supply chains and delivery schedules. Additionally, public concern about transmission of COVID-19 has resulted in an unusually high volume of consumer purchases which are impacting supply. Healthcare facilities are also increasing purchase volumes in preparing to care for large numbers of infected patients. The decrease in supply coupled with a tenfold increase in demand has resulted in supply shortages which are estimated to last 3-4 months. Strategies to combat this shortage are underway, including plans for global surge manufacturing, and consideration of releasing stockpiles of N95 respirators that have exceeded their shelf-life. The following actions are recommended during the PPE supply shortage:

1. Review [CDC guidance regarding conventional, contingency and crisis alternative strategies for optimizing the supply of N95 respirators](#)
2. Conserve available supplies and maximize efficacy by providing ongoing staff training regarding when PPE is needed, what type of PPE is needed, and how to properly [put on and take off PPE](#).
3. Monitor inventory of PPE closely, and employ strategies to prevent losses by theft, damage, or accidental loss.
4. Monitor inventory of patients receiving therapy at home to ensure they have the minimum amount needed to safely receive care.
5. Instruct patients and caregivers on the proper and appropriate use of PPE.



IV. Should patients continue to receive prescribed immunoglobulin (Ig) during the COVID-19 pandemic?

If the patient is suspected of COVID-19 exposure or illness, or another febrile illness, please follow guidance outlined in the Screening Questionnaire in Section I of this FAQ. Always consult with the patient’s prescriber and healthcare team to make a final determination.

Patients who are not under evaluation for a possible COVID-19 infection or exposure, and who are not symptomatic of another febrile illness, should be receiving their Ig doses as prescribed. Depending on the diagnosis, the patient’s disease progression, and other factors that must be discussed with the prescriber, the dosing and interval of treatment may or may not be altered. This information, combined with COVID-19 activity data and guidance from local and state public health officials, should inform plan of care decisions made by healthcare providers for patients.

Prudent usage of Ig for indications where a robust level of evidence for efficacy and safety exists is critical in this time. Ig has not been studied for the treatment of COVID-19 or similar, systemic viral infections to date.

V. Are there over-the-counter (OTC) medications that can be used to treat COVID-19?

During this time, it is critical that patients get information from reliable sources like the CDC, the WHO, and their physicians. Aside from standard fever- and other symptom-reducing OTC drugs, currently no FDA-approved options exist for the treatment of COVID-19. Patients should refrain from experimenting with medication regimens obtained from the internet or social media. This is dangerous and can cause harm to patients. Talk to patients frequently about what medications they are taking, and warn of “social media cures”. Encourage patients to speak with their physicians regarding what medications they may take for symptom relief.

VI. Is there research to support the use of Ig therapy to treat or prevent COVID-19?

At this time, there is no evidence that Ig is effective in the treatment or prevention of COVID-19.



VII. Will there be shortage of Ig during the COVID-19 crisis?

Because Ig therapy is not a treatment for COVID-19, there is no reason to believe this pandemic would have an effect on the current supply of Ig therapy. Patients should not “ration” their products by increasing the dose intervals (especially with SCIG). This is a dangerous practice that can put their health, disease progression, and ability to fight infections at risk. Patients should not stockpile Ig, since supply interruptions are not expected to be caused by COVID-19; however, due to a tightening in Ig supply for the past 18 months, stockpiling Ig may negatively impact other patients’ access to this lifesaving therapy

Because plasma supply, and the supply plasma-derived biologics (including Ig) is finite, it is critical that Ig therapy is utilized in a judicious manner, to treat indications where efficacy and safety have been established in clinical trials.

VIII. Is there a concern over the safety of the plasma supply due to COVID-19?

Because of its morphology (lipid enveloped virus, of approximately 120nm in diameter), COVID-19 is highly susceptible to viral inactivation and removal processes currently in place in Ig manufacturing for all brands available in the US, Canada, and Europe. These processes include the use of solvent/detergent treatment, caprylate, nanofiltration, pasteurization, and exposure to low pH.

Manufacturing time from initial donation to final product is approximately nine to twelve months. Therefore, current Ig products were manufactured utilizing plasma collected months before the COVID-19 situation developed. In the US, Ig products are manufactured using US plasma donors only. Additionally, strict screening processes and ongoing monitoring of qualified plasma donors in the US provides an important layer of safety around plasma used to manufacture plasma protein therapies. Please see [IgNS’ statement on the safety of plasma-derived therapies](#).



IX. What can patients do to protect themselves?

The best way to protect yourself from COVID-19 is to use the same everyday strategies recommended to prevent the spread of similar illnesses like the common cold or the flu:

1. Wash your hands frequently
2. Stay home if you are sick.
3. Practice social distancing
4. Cover your cough or sneeze with a tissue and immediately throw it away. If a tissue is
5. unavailable, use your bent elbow.
6. Avoid touching your face.
7. Clean frequently touched surfaces in your home with a household disinfectant
8. Wash your hands. Yes, we've listed this twice! Handwashing is the very best way to prevent the spread of infection.

X. What is the proper technique for hand washing?

1. Wet hands with clean running water (hot or cold), turn off tap and apply soap.
2. Lather hands by rubbing together with soap. Lather the backs of hands, between fingers, and under nails.
3. Scrub for at least 20 seconds. How do you know you are done? Sing Happy Birthday two times through.
4. Turn on water using forearm or elbow
5. Rinse hands well.
6. Turn off tap with forearm or elbow to avoid recontamination
7. Dry hands using a clean towel or air-dry.

Note: If soap and water are not readily available, alcohol-based hand sanitizer with at least 60% alcohol may be used.

In addition to proper handwashing techniques, follow existing aseptic technique standards per organizational policy during preparation of medications and administration.

Visit [CDC Handwashing Guidelines](https://www.cdc.gov/hand/handwashing/index.html) for more information.



Resources

1. CDC 2019 Novel Coronavirus Situation Summary, available at:
<https://www.cdc.gov/coronavirus/2019-nCoV/summary.html>
2. Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission, available at: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/community-mitigation-strategy.pdf>
3. Guidance on Preparing Workplaces for COVID-19, available at:
<https://www.osha.gov/Publications/OSHA3990.pdf>
4. Healthcare Personnel Preparedness Checklist for COVID-19 available at:
<https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp-preparedness-checklist.pdf>
5. Steps Healthcare Facilities Can Take Now to Prepare for Coronavirus Disease 2019 available at: <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/steps-to-prepare.html>
6. IgNS Ig Therapy Standards of Practice. Edition 2.1, 2019. www.ig-ns.org