

Smart Patients Get Smart Care™

Performing a COVID-19
Risk Assessment:
Understanding What
Has Changed Now That
the Government
Response Has Scaled
Down

June 27, 2023

10:30 AM PT, 11:30 AM MT, 12:30 PM CT, 1:30 PM ET

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Speakers

Speaker





Moderator
Brian Koffman, MDCM (retired), MS Ed
Co-Founder, Executive Vice President, and Chief Medical Officer
CLL Society



Ghady Haidar, MDInfectious Disease Specialist, Assistant Professor of Medicine Director of Research, Bone Marrow Transplant and Hematological Malignancy Infectious Diseases, Program Director of the Transplant Infectious Diseases Fellowship Program, University of Pittsburgh



Speaker
Robyn Brumble, MSN, RN
Director of Scientific Affairs and Research
CLL Society



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COVID-19 and Immunocompromised Individuals in 2023

Ghady Haidar, MD
Assistant Professor of Medicine
Transplant Infectious Diseases
Program, University of Pittsburgh
and UPMC

June 27, 2023

Outline

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- Brief COVID-19 update
- Vaccine guidance
- COVID-19 therapies
- Protracted SARS-CoV-2 infection
- Available clinical trials for immunocompromised individuals

COVID-19 in Spring 2023

COVID-19 hospital admissions levels in US by county

Based on new COVID-19 hospital admissions per 100,000 population

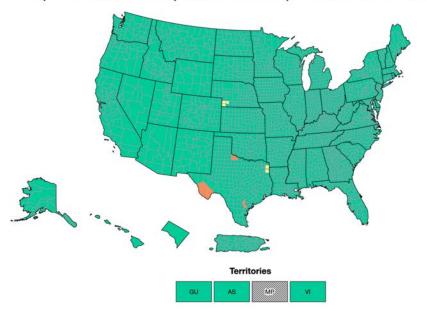
		Total	Percent	% Change	
	≥ 20.0	8	0.25%	-0.03%	
	10.0 - 19.9	6	0.19%	-0.9%	
	<10.0	3209	99.69%	0.93%	

Time Period: New COVID-19 hospital admissions per 100,000 population (7-day total) are calculated using data from the MMWR week (Sun-Sat) ending May 20, 2023.

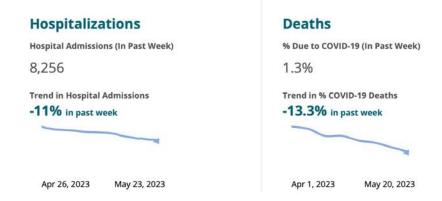
Green is good! (low # of hospitalizations)

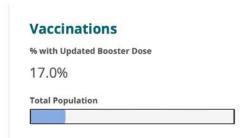


US Reported COVID-19 New Hospital Admissions Rate per 100,000 in the Past Week, by County



Weekly Update for the United States





New COVID-19 hospital admissions per 100,000 population, past week (total)

Low (<10.0)</p>

Medium (10.0 to 19.9) ● High (≥20.0) 🦓 Insufficient data

Burden of COVID-19 in the Immunocompromised



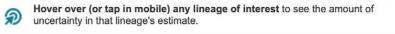
- ~ 3% of the US population are considered immunocompromised, including all of those with CLL/SLL
- According to the CDC: In 2022 <u>12.2%</u> of COVID-19 <u>hospitalizations</u> were immunocompromised individuals
 - More **ICU admissions** vs immunocompetent
 - More inpatient <u>deaths</u> vs immunocompetent
 - Regardless of vaccination
- Difficult to track numbers

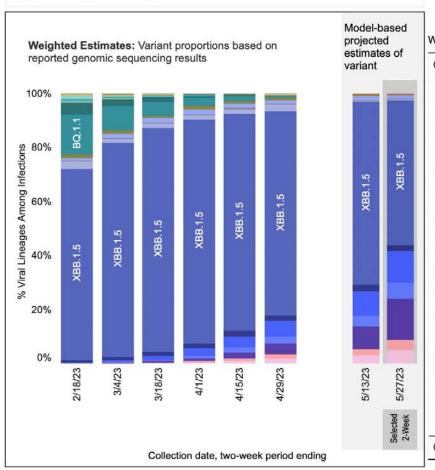
COVID-19 in 2023

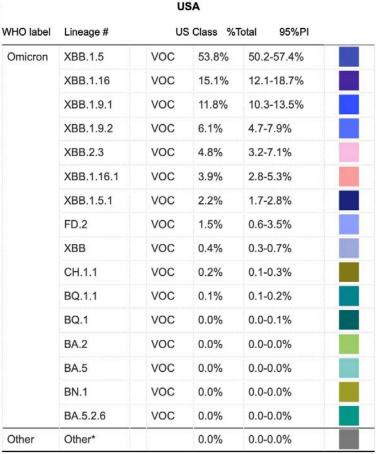
Weighted and Nowcast Estimates in United States for 2-Week Periods in 2/5/2023 – 5/27/2023

Nowcast Estimates in United States for 5/14/2023 – 5/27/2023









- XBB era
 - Mostly XBB1.5, others (e.g., Arcturus, XBB1.16)
- On a practical basis, no real differences for management

COVID-19 Symptoms

- Cough
- Fever
- Myalgias
- Headache
- Dyspnea (new or worsening over baseline)
- Sore throat
- Diarrhea
- Nausea/vomiting
- Anosmia or other smell abnormalities
- Ageusia or other taste abnormalities
- Rhinorrhea and/or nasal congestion
- Chills/rigors
- Fatigue
- Confusion
- Chest pain or pressure

Most patients with confirmed COVID-19 have fever and/or symptoms of acute respiratory illness. However, various other symptoms have been associated with COVID-19; this list is not inclusive of all reported symptoms. These symptoms are also not specific for COVID-19, and the predictive value of a single symptom in the diagnosis of COVID-19 is uncertain.

COVID-19: coronavirus disease 2019.

Reference:



- Does not include all symptoms
- Symptoms may change with new COVID-19 variants and can vary depending on vaccination status
 - E.g., conjunctivitis with XBB1.16
- No symptom can rule in/out COVID-19
- Low threshold to get tested



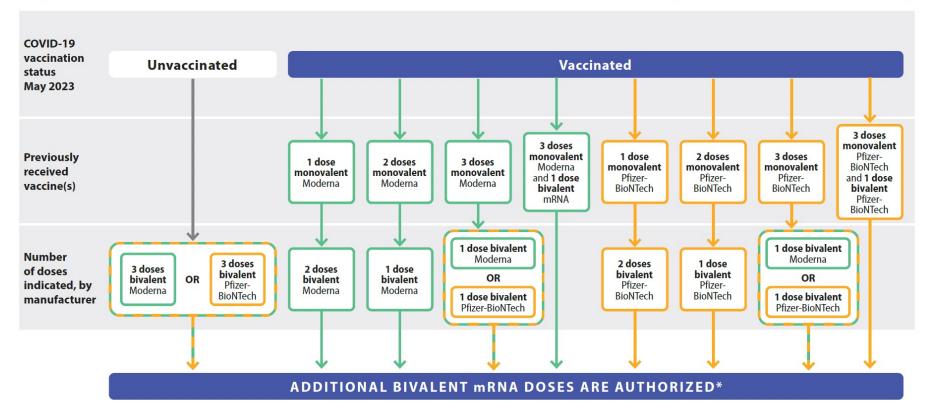
Centers for Disease Control and Prevention. Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19). Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html.

Vaccination Recommendations in 2023

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 6 years and older,** mRNA vaccines, May 2023*







^{*}For product-specific dosages, administration intervals, additional dose information, and options for heterologous dosing, see <u>Table 2</u> in the Interim Clinical Considerations for Use of COVID-19 Vaccines.



Updated Vaccine Guidance



- Overall, shift to bivalent vaccines
- Immunocompromised individuals may receive 1 additional bivalent vaccine dose at least 2 months following the last recommended bivalent COVID-19 vaccine dose
 - Open-ended > 2 months after that (guidance unclear)
- Vaccinate the "bubble"
 - Individuals > 65 years old may receive an additional bivalent vaccine > 4 months after their last one

Outpatient COVID-19 Therapies in 2023



Drug	Nirmatrelvir/r (Paxlovid)	Remdesivir	Molnupiravir	Convalescent plasma*
Efficacy	///	///	✓	?
Ease of delivery	√√√ (oral) !!**XXX**!!	XXX (IV)	√√√ (oral)	XXX (IV)
Drug Interactions		///	///	\ \ \ \
Safe during pregnancy	? (RTV safe)	//	XXX	√ √
NIH recommendation	Alla	Blla	Clla	Insufficient evidence in IC; some may use

Test early, treat early!

Protracted SARS-CoV-2 Infection



- Not the same as "long COVID-19" because there is an active infection where individuals are still shedding the virus
- Prolonged SARS-CoV-2 replication in immunocompromised individuals
 - Cancer, solid organ transplant, AIDS, and other
 - Case reports/case series
- Intra-host evolution → how new variants emerge within immunocompromised individuals
- Limited antiviral arsenal available to treat

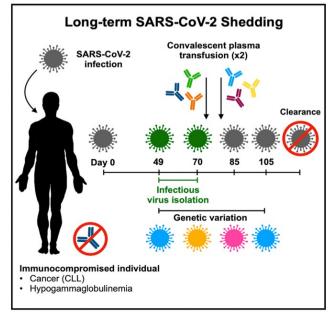
Protracted Infections For Up to 268 Days!

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Cell

Case Study: Prolonged Infectious SARS-CoV-2 Shedding from an Asymptomatic Immunocompromised Individual with Cancer

Graphical Abstract



Highlights

 Persistent SARS-CoV-2 infection and shedding in immunocompromised individual

Authors

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In Brief

This case study describes a female immunocompromised individual with chronic lymphocytic leukemia and acquired hypogammaglobulinemia who became persistently infected with SARS-CoV-2. Although asymptomatic throughout the course of infection, she demonstrated prolonged shedding of infectious SARS-CoV-2 virus and RNA. This study demonstrates that certain individuals may remain infectious for prolonged periods of time and highlights the need for further studies to understand risk factors for prolonged infectious SARS-CoV-2 shedding.

- Why do we think this occurs?
- Not the same as "paxlovid rebound"
- How should an immunocompromised individual be monitoring for this?
 - Home antigen testing-how often and for how long?
- What if symptoms persist or re-occur?
 - Continue to isolate/mask
 - When to consult with an infectious disease doctor

Recommendations for Treating Protracted COVID-19





- Use the same antivirals as other patients, with "fine print"
- Use a combination of antivirals? \rightarrow insufficient evidence
- Give antivirals longer than standard duration? → insufficient evidence
- Non-committal about the use of convalescent plasma

How to Manage Protracted Infection: Unconventional Approaches



Open Forum Infectious Diseases

BRIEF REPORT

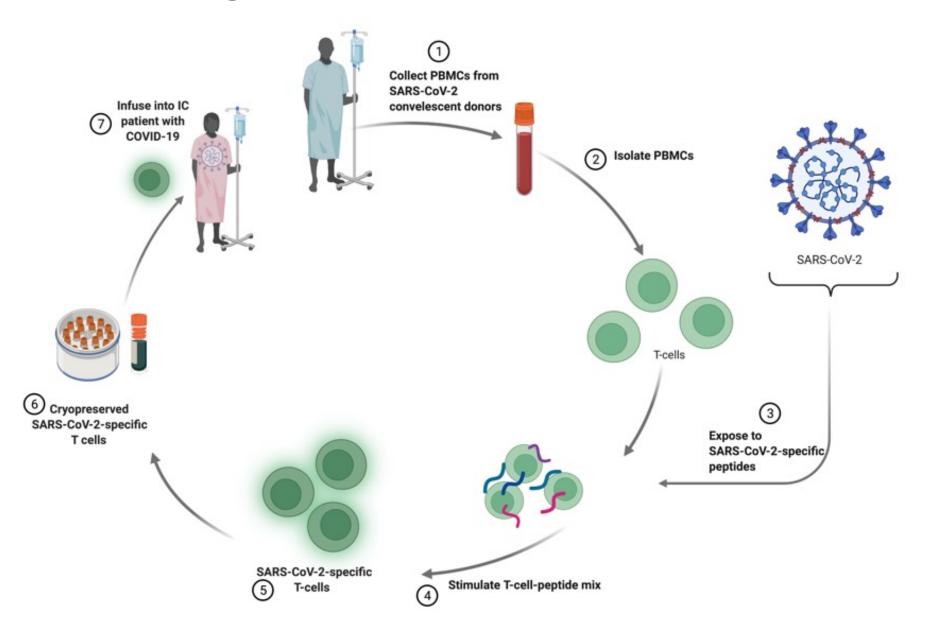
Successful Treatment of Prolonged Severe Acute Respiratory Syndrome Coronavirus 2 Infection in Patients With Immunodeficiency With Extended Nirmatrelvir/Ritonavir: Case Series

Madison Breeden,^{1,0} Samuel L. Aitken,^{2,3} Ji Hoon Baang,¹ Misty Gravelin,⁴ Daniel R. Kaul,¹ Adam S. Lauring,^{1,0} Lindsay A. Petty,¹ and Kevin S. Gregg¹

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- We don't know
- No clinical trials
- Have been using trial and error
 - 4 B-cell malignancy patients
 - 2-8 months of illness
 - All previously received remdesivir
 - 2/4 previously received paxlovid
 - 2/4, previously received the monoclonal antibody bebtelovimab
 - Success with giving a longer course of paxlovid (up to 21 days vs the standard 5 days)

Treating with Viral-Specific T-Cells?





Treating with Viral-Specific T-Cells?

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- SARS-CoV-2 viral-specific T-cells (VSTs) were given to 6 immunocompromised patients with protracted COVID-19 infection
 - 4 had blood cancer, 2 had lung transplants
 - 3 patients had <u>partial responses</u> after failing other therapies but then died
 - 2 patients completely recovered, but the role of VSTs in recovery was <u>unclear</u> due to the concomitant use of other antivirals
 - 1 patient had not responded to 2 courses of remdesivir and experienced <u>sustained recovery</u> <u>after VST administration</u>
- Not currently available
- Needs further study

Clinical Infectious Diseases

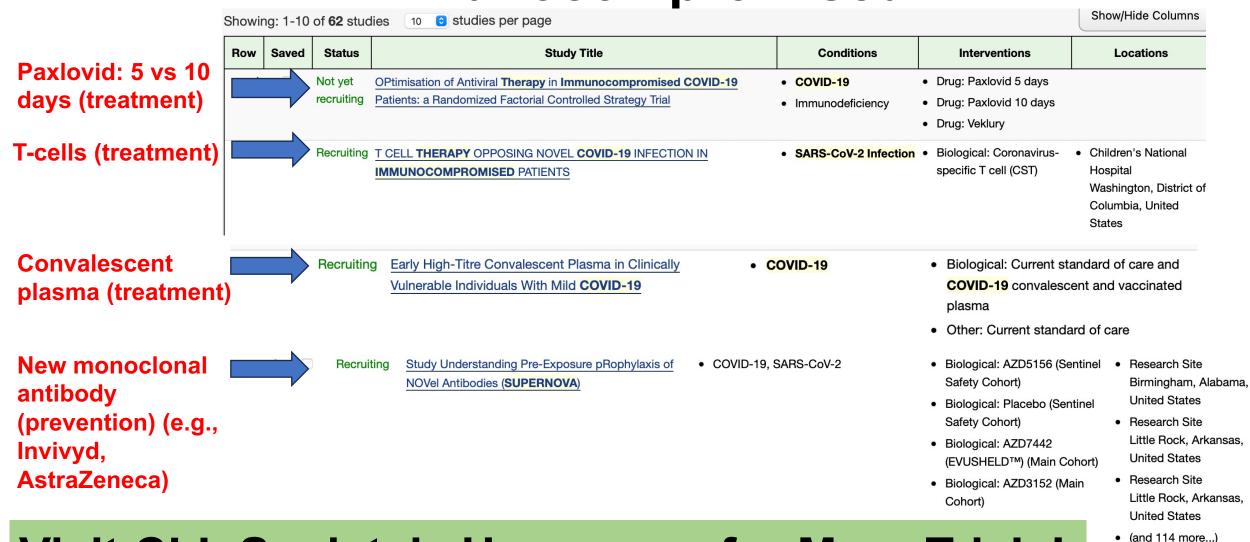
BRIEF REPORT

Therapy With Allogeneic Severe Acute Respiratory Syndrome Coronavirus-2–Specific T Cells for Persistent Coronavirus Disease 2019 (COVID-19) in Immunocompromised Patients

Ghady Haidar, ^{1,0} Jana L. Jacobs, ¹ Kailey Hughes Kramer, ¹ Asma Naqvi, ¹ Amy Heaps, ¹ Urvi Parikh, ¹ Kevin D. McCormick, ¹ Michele D. Sobolewski, ¹ Mounzer Agha, ² Tatiana Bogdanovich, ¹ Vasilii Bushunow, ² Rafic Farah, ² Matthew Hensley, ³ Yen-Michael S. Hsu, ² Bruce Johnson, ³ Cynthia Klamar-Blain, ¹ Jennifer Kozar, ⁴ Elizabeth Lendermon, ³ Bernard J. C. Macatangay, ¹ Christopher C. Marino, ² Anastasios Raptis, ² Erin Salese, ¹ Fernanda P. Silveira, ¹ Ann M. Leen, ⁵ William L. Marshall, ⁶ Michael Miller, ⁷ Badrish Patel, ⁷ Ercem Atillasoy, ⁷ and John W. Mellors ¹

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COVID-19 Clinical Trials for the Immunocompromised



Visit CLL Society's Homepage for More Trials!

In Summary



- COVID-19 burden for the general public right now is lower compared to before, but immunocompromised patients remain at higher risk
- Vaccination guidance has shifted to bivalent vaccines, please get boosted!
- Outpatient COVID-19 therapies do work → tested early and let your provider know you tested positive
 - Be aware that drug interactions exist with Paxlovid-work with your CLL healthcare provider
- Protracted SARS-CoV-2 infection in immunocompromised patients is a real concern and research is needed
- There are several clinical trials ongoing, so additional help is on the horizon!



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COVID-19 Personal Risk Assessment & Action Plan

Robyn Brumble, MSN, RN
Director of Scientific Affairs & Research
CLL Society

June 27, 2023

Outline



- COVID-19 personal risk assessment
- Changes in light of the Public Health Emergency (PHE) ending
- Where to find the most accurate COVID-19 information
- Advocating for your best (and safest) care
- CLL Society's COVID-19 Action Plan

COVID-19 Risk Assessment

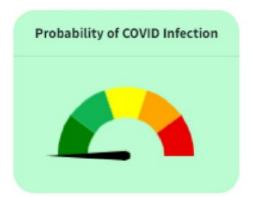
<u>Definition</u>: Using a framework to help assess the *personal* risk that COVID-19 poses to our *personal* health, implementing tools to mitigate those risks, and then making a *personal* decision as to whether the risk of the activity is worth taking.



Your COVID-19 Risk Assessment Result!!









Assessing Risks of the Environment

- Knowing the rate of transmission in the community
- What is the setting of the activity (social distancing, indoors, outdoors, is there good ventilation)
- What is the size of the gathering
- Is anyone else going to be masked
- Are any of the individuals you are gathering with ideally willing to test and isolate for several days prior to meeting
- What is the vaccination status of others in attendance

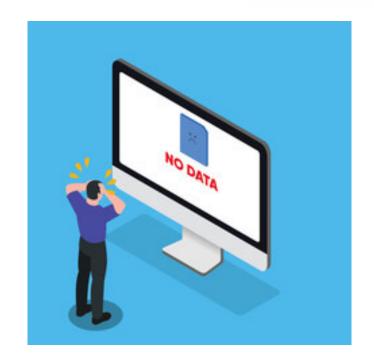




Changes Since the End of the PHE



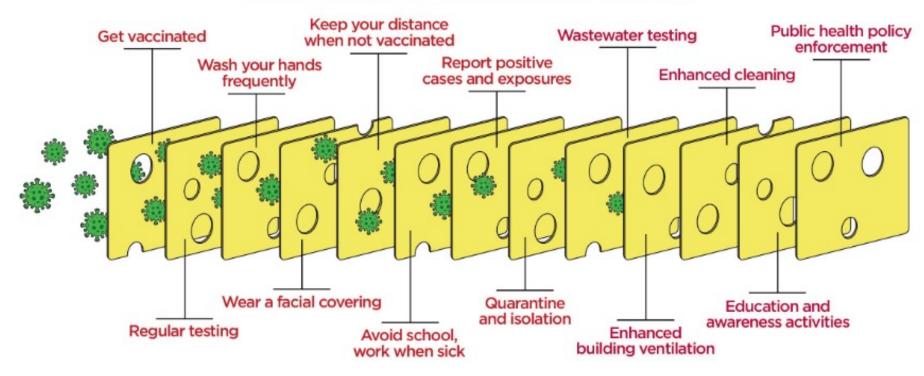
- CDC's ability to collect and share certain data are very limited and there is a longer lag in reporting
- COVID-19 death counts will remain, but the source of the data has changed
- Case numbers are no longer being highlighted by the CDC's COVID Data Tracker
- At-home tests are no longer required to be provided free of charge by insurance providers



What Remains the Same

- CLL SOCIETY
- Hospitals are still required to report data through the end of 2024.
- Test positivity numbers will remain, but the source of information has changed and lag about a week behind when they are reported
- Vaccines remain mostly free available (for now)
- Treatments for COVID-19 remain available for free while the government's stockpile lasts
- Wastewater surveillance and genomic sequencing for the type of variants that are present will remain in place through 2024.
- Telehealth coverage
- FDA's Emergency Use Authorization

Shared Responsibilities and Interventions

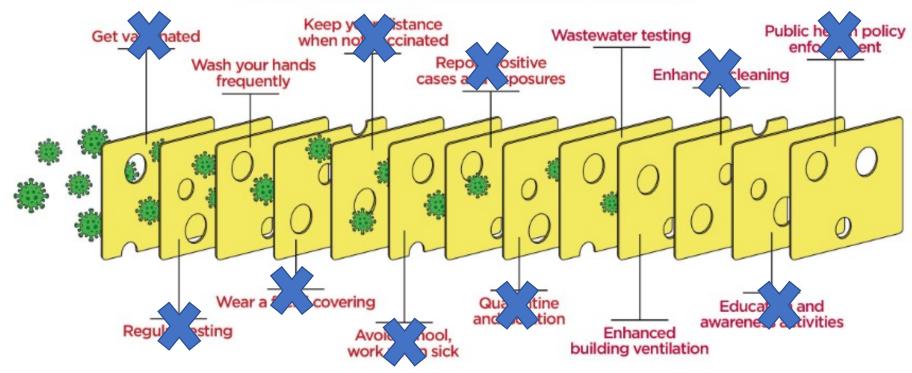




This illustration was adapted from the Swiss Cheese Model developed by James Reason, Ph.D.

Remember to continue the basics of infection control for yourself!

Shared Responsibilities and Interventions





This illustration was adapted from the Swiss Cheese Model developed by James Reason, Ph.D.

Remember to continue the basics of infection control for yourself!

Paradigm Shift to the Individual

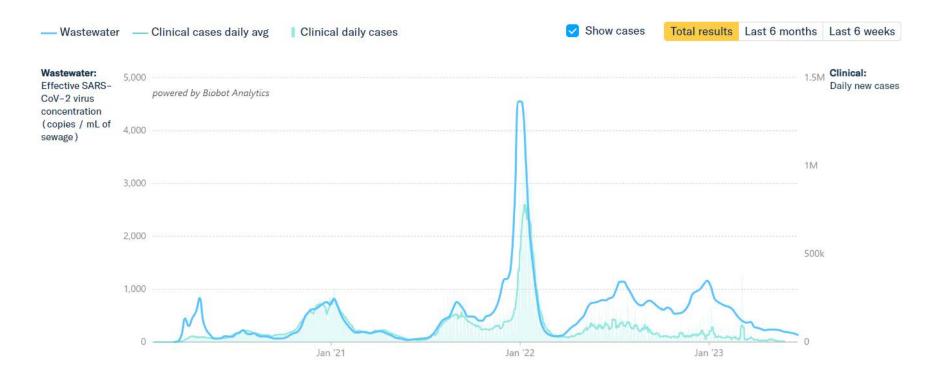
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- How many risk factors do <u>you</u> have that would make you at higher risk for poorer outcomes?
- Will you be wearing a high quality KN95 or N95 facemask?
- Are you fully vaccinated?
- When available, have you received your COVID-19 preexposure prophylaxis monoclonal antibody therapy?
- Can you distance yourself from others at the gathering?
- Do you have your COVID-19 Action Plan up-to-date and know what to do to act fast if you should test positive?
- What is the benefit to you of participating in the activity?

Where to Find Timely and the Most Accurate COVID-19 Statistics



- Wastewater data doesn't lie and is not dependent upon how many people take a COVID-19 test or states reporting!
 - ➤ Biobot Analytics
 - ➤ National Wastewater Surveillance System



Managing Your Risks As Masks Are Disappearing in Healthcare Settings



- Wear a well-fitted quality N95 mask
- Utilize telehealth options when appropriate
- Request appointments early in the morning before the waiting areas become full
- When scheduling an appointment ask them to put a note in your chart that you are immunocompromised and requests masks be worn by healthcare staff
- If urgent care or emergency care is needed, request to be placed in an isolated area while you wait
- You have the right to safe healthcare! Never hesitate to ask staff that will be in contact with you to please wear a mask.



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How can we help you?

CLL SOCIETY The World's Leading Authority for Chronic Lymphocytic Leukemia Patients

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Living With CLL V About Us V Research V Advocacy V



COVID-19 Action Plan

Be Prepared to Fight Back Against COVID-19

Complete Prior to COVID-19 Exposure



Directions for Completing the COVID-19 Planning Checklist

CLL Society highly encourages individuals living with CLL to prepare ahead of time and have a comprehensive COVID-19 Plan already in place just in case you have either a known exposure or receive a positive test result. The following are guidelines to assist you in completing your personalized COVID-19 Planning Checklist. Please keep all printed information in a designated COVID-19 Planning Folder that can be easily accessed if needed.

- 1) Obtain an oxygen (O2) pulse oximeter (O2 saturation monitoring device) and have it readily available in your home. Inexpensive O2 pulse oximeters can be purchased on Amazon or from your local drug store.
- 2) Have a reliable digital thermometer available. If you only have oral thermometers in your home, consider purchasing one for each member of the household to prevent spreading the virus to other family members.
- 3) Know ahead of time where you will go to get tested for COVID-19, and confirm they will perform the necessary testing:
 - . The location you choose should be willing to offer you BOTH the rapid test and the PCR test at the same time. Remember, the Rapid test can indicate evidence of COVID-19 infection, but the PCR is typically more accurate. (Please also note, some rapid tests will not detect variants).
 - · Always err on the side of caution and get tested right away should you experience any respiratory symptoms, or if you have known exposure to COVID-19. Do not dismiss allergy or cold symptoms!
 - . The earlier you know, the earlier you can receive treatment, which is of utmost
- 4) High titer convalescent plasma should be administered early after diagnosis and is authorized under the EUA (Emergency Use Authorization) for the treatment of hospitalized patients with COVID-19 and impaired immunity. That would include CLL patients. It is not used in severe COVID-19. Convalescent plasma may need to be administered more than once.
- 5) Monoclonal antibodies directed against the COVID-19 spike protein have proven to help high-risk patients and should be given within 10 days of diagnosis and can be given outpatient. The earlier the better! You must investigate ahead of time which hospitals in your area provide rapid access to this critical COVID-19 treatment! COVID-19 monoclonal antibody therapies are not available everywhere and are most likely not available at your local small community hospital. So please spend time finding out exactly where you can access them quickly should you need them. It is also important to understand the criteria that make you eligible for receiving this critical COVID-19 treatment should there be any pushback when you advocate for receiving it:
 - Search this map to find the hospitals in your area that have monoclonal antibody therapy available, and make it part of your plan to visit their emergency room if COVID-19 treatment becomes necessary.



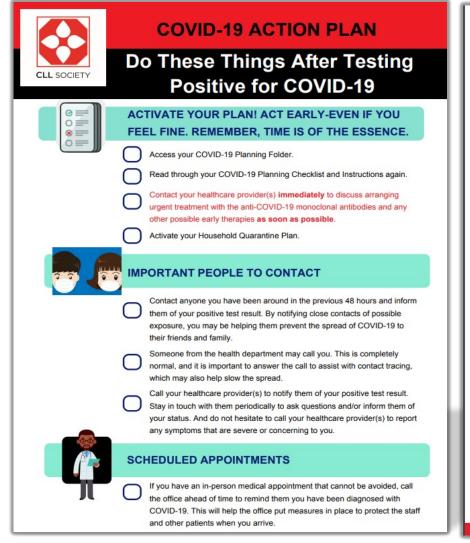


How to Quarantine Appropriately



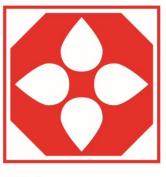


What Do I Do If I Do Get COVID-19?





COVID-19 and may remain contagious after symptoms resolve.



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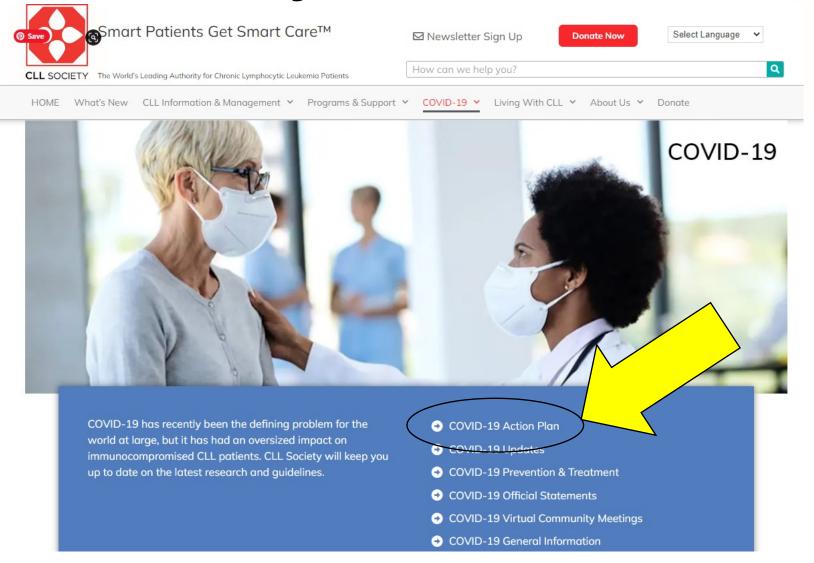
Where to Find the COVID-19 Action Plan On CLL Society's Website



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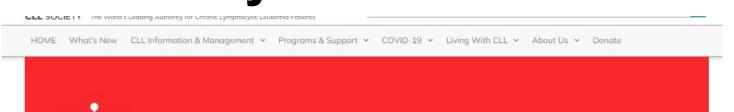


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Where to Find the COVID-19 Action Plan On CLL Society's Website



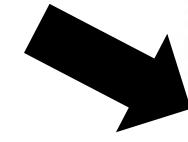




Checklists for Chronic Lymphocytic Leukemia (CLL)
Preparing for Pre- and Post-COVID-19 Exposure

Downloading and completing the CLL Society's COVID-19 Action Plan could save your life.

Complete and print this action plan, which will help you prepare in advance for possible exposure, testing positive, time sensitive therapies, and home management, including what you need for safe isolation, and much more. Preparing in advance can minimize the panic that many experience when exposed or diagnosed because you will have a written plan to guide you. If you do only one thing to protect yourself and your loved ones during the pandemic, please complete your family's COVID-19 Action Plan. The life you save might be your own.









COVID-19 Action Plan
COVID-19 Updates
COVID-19 Prevention & Treatment
COVID-19 Official Statements
COVID-19 Virtual Community
Meetings
COVID-19 General Information

RECENT NEWS

When appropriate, the CLL Society will be posting updates and background information on the present Coronavirus pandemic

In Summary

- Performing a COVID-19 personal risk assessment is still important.
- Continue to have situational awareness and know where to obtain the most accurate COVID-19 statistics for your area.
- Keep up-to-date on vaccines, continue to mask, and take all other infection control measures.
- Revisit your COVID-19 Action Plan from time to time to make sure the information within it is still correct.
- Discuss your COVID-19 Action Plan with others in the household.





Poll Question







Audience Questions & Answers

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Thank You for Attending!



Please take a moment to complete our **post-event survey**, your feedback is important to us

If you're question was not answered, please feel free to email asktheexpert@cllsociety.org

Join us on July 12th for our next "Ask Me Anything" event on Facebook Live and Zoom

CLL Society is invested in your long life. Please invest in the long life of the CLL Society by supporting our work

cllsociety.org/donate-to-cll-society/