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AASLD EXPERT PANEL CONSENSUS STATEMENT: COVID-19 CLINICAL BEST PRACTICE ADVICE FOR HEPATOLOGY AND LIVER TRANSPLANT PROVIDERS

Overview

Coronavirus disease 2019 (COVID-19), the illness caused by the SARS-CoV-2 virus, has impacted every aspect of life and health care since 2020 and this impact is likely to continue for the foreseeable future. Patients with chronic liver disease (CLD) including cirrhosis are at higher risk of death from COVID-19, but clinical risk factors in specific liver diseases, such as autoimmune hepatitis (AIH) or liver cancer, or in transplant recipients, are not clearly defined. With rapid advancement in the field, there has been a need for guidance on the prevention and management of COVID-19 in those with CLD and liver transplantation (LT). This version is a distillation and update of guidances from two larger documents, *"Clinical best practice advice for hepatology and liver transplant providers during the COVID-19 pandemic: AASLD expert panel consensus statement"*, which was first published online in March 2020 and in print in *Hepatology* in April 2020, and "*AASLD expert panel consensus statement: Vaccines to prevent COVID-19 in patients with liver disease*", first published online in February 2021 and in print in *Hepatology* in August 2021. These online documents have been updated regularly to include the rapidly evolving changes in information relevant for the hepatology workforce. Our aim is to provide a template for developing clinical recommendations and policies to mitigate the impact of the COVID-19 pandemic on liver patients and health care providers.

Evaluation of COVID-19 Patients with Elevated Liver Biochemistries

- Serum aminotransferase levels are commonly elevated (in up to 50% of patients) in hospitalized patients with COVID-19, but are usually only mildly abnormal without jaundice. These elevations may be caused by a virus-induced cytopathic effect and/or immune damage from the provoked inflammatory response. It can be difficult to differentiate whether increases in liver biochemistries are due to SARS-CoV-2 infection itself, its complications, and/or drug-induced liver injury (DILI).
- A large global series noted that DILI caused by one or more drugs used to treat COVID-19 was infrequent and there are usually confounders causing elevated liver biochemistries. Aminotransferase elevations were more often seen than a cholestatic pattern. Outcome was favorable in most patients and death attributable to a drug was rare.
- In children and adults, consider etiologies unrelated to COVID-19, including other viruses such as hepatitis A, B, and C, DILI, and pancreaticobiliary disease when assessing patients with COVID-19 and elevated liver biochemistries.
- Consider other causes of elevated liver biochemistries, including myositis, cardiac injury, ischemia, DILI, and cytokine release syndrome.
- Consider cholangiopathy or secondary sclerosing cholangitis of critically ill patients (SSC-CIP) in patients with severe COVID-19 and prolonged hospitalization with worsening cholestasis and jaundice. Cases of chronic cholangiopathy have infrequently required LT.
- The presence of elevated liver biochemistries should not be a contraindication to using investigational or off-label therapeutics for COVID-19, although AST or ALT levels >5x ULN may exclude patients from consideration of some investigational agents.

AASLD COVID-19 Task Force Clinical Oversight and Education Subcommittee

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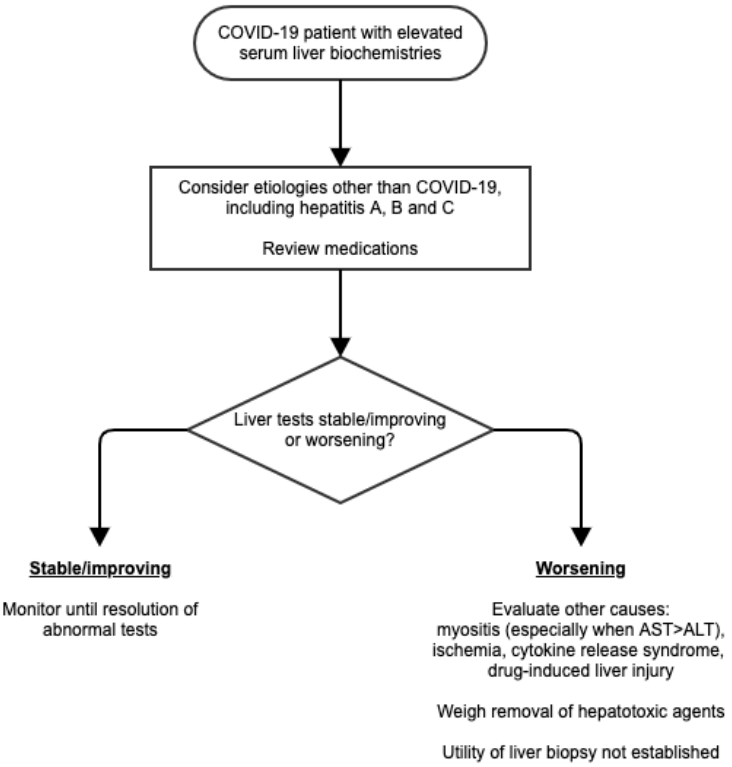
- Regular monitoring of liver biochemistries should be performed in all hospitalized COVID-19 patients (**Figure 1**), particularly those treated with remdesivir or tocilizumab, regardless of baseline values.
- Sinusoidal microthrombi have been described in autopsy series. Budd-Chiari syndrome and splanchnic venous thrombosis have been rarely described as complications of COVID-19, and an increased awareness of such thrombotic events is essential.
- Do not presume disease flare or acute cellular rejection without biopsy confirmation in patients with AIH or LT recipients with active COVID-19 and elevated liver biochemistries.
- COVID-19 vaccination-related liver injury with immune-mediated features or severe hepatitis has been reported in some individuals where corticosteroid therapy has been of some benefit. Outcomes have been generally favorable.

Figure 1. Approach to the Patient with COVID-19 and Elevated Serum Liver Biochemistries



Management of Chronic Liver Disease

- CLD is associated with COVID-19-related severity and mortality, particularly in patients with decompensated cirrhosis, alcohol-associated liver disease, and/or hepatocellular carcinoma (HCC).
- Consider COVID-19 in patients with new complications of cirrhosis and test patients with unexplained acute hepatic decompensation for SARS-CoV-2.
- Features of coagulopathy (low platelet count, increased prothrombin time, increased D-dimer) can be seen in COVID-19 as well as CLD, leading to bleeding or micro/macrothrombotic events.
- Optimize the use of telemedicine services for managing stable outpatients with CLD.

Alcohol-Associated Liver Disease

- Alcohol consumption and alcohol-associated liver disease have significantly increased during the COVID-19 pandemic, which have led to significant increases in liver transplant listings and transplantation for alcohol-associated liver disease.
- Inquire about alcohol use and recommend counseling or other interventions when alcohol use disorder is identified.

Hepatitis B, Hepatitis C, Autoimmune Hepatitis, and Primary Biliary Cholangitis

- Continue treatment for hepatitis B, hepatitis C, AIH, or primary biliary cholangitis (PBC) if already on treatment.
- There is no contraindication to initiating treatment of hepatitis B, hepatitis C, AIH, or PBC in patients without COVID-19 as clinically warranted.
- Initiating treatment of hepatitis B in a patient with COVID-19 is not contraindicated and should be considered if there is clinical suspicion of a hepatitis B flare. Potential reactivation of HBV while on dexamethasone or drugs such as tocilizumab is a concern. Consider HBV prophylaxis in HBsAg-positive patients on such therapies.
- Initiating treatment of hepatitis C or PBC in a patient with COVID-19 is not routinely warranted and can be deferred until recovery from COVID-19.

Hepatocellular Carcinoma

- Continue monitoring in those on or off therapy for HCC and continue radiological surveillance in those at risk for HCC.
- Avoid HCC surveillance in patients with COVID-19 until infection is resolved.
- Avoid liver cancer treatments or surgical resection in patients with COVID-19 until infection is resolved, if able based on urgency of the individual patient.
- Avoid initiating immunotherapy in individuals with HCC and COVID-19 until infection resolves.

Liver Transplantation

Potential Donors

Screen all donors for history of symptoms and signs of COVID-19	Yes
Test all donors for SARS-CoV-2	Yes
Transmission of SARS-CoV-2 reported from liver donor to recipient	No
Transplant livers from donors with incidental finding of SARS-CoV-2*	Yes, obtain recipient consent

*Findings that favor the safety of donation include lack of infiltrates consistent with COVID-19 on chest imaging and SARS-CoV-2 infection diagnosed in the previous 90 days, high cycle threshold because this suggests ongoing shedding of viral nucleic acid often without viable virus. Consider the impact of COVID-19 on donor organ quality.

Potential Recipients

Recommend vaccination	Yes, including close contacts of recipient
Screen for COVID-19 symptoms prior to transplant	Yes
Transplant recipient with active COVID-19	Not recommended**

**Repeat testing is reasonable 14 or more days after diagnosis (or 21 days for those hospitalized for COVID-19 or immunocompromised individuals). If symptoms have resolved, repeat positive testing may not be a contraindication to transplantation. In many cases, SARS-CoV-2 PCR may continue to be positive and cycle threshold values, clinical assessment, and consideration of recipient need can inform the decision to proceed with transplantation.

Management of Patients on Immunosuppressive Agents (Including LT Recipients)

- Tacrolimus is associated with better survival, while mycophenolate is an independent predictor of severe COVID-19 in LT recipients with COVID-19.
- Oral corticosteroid therapy used prior to a COVID-19 diagnosis for another underlying condition should not be discontinued.

Immunosuppressed Patients *Without* COVID-19

- Do not adjust current immunosuppressive drugs or dosages in anticipation of infection or vaccination.
- Encourage vaccination with an initial 3-dose series of an mRNA COVID-19 vaccine.
- Encourage up-to-date vaccination including boosters for all individuals.
- Patients who received incomplete vaccination pretransplantation should ideally complete the vaccination series posttransplantation; consider waiting 1 month posttransplant to continue vaccinating recipients.
- Initiate immunosuppressive therapy in patients with liver disease with or without COVID-19 who have strong indications for treatment (e.g., AIH, graft rejection).

Immunosuppressed Patients *With* COVID-19

- Consider lowering the overall level of chronic immunosuppression based on general principles for managing infections in immunosuppressed patients and to decrease the risk of superinfection.
    - Avoid decreasing or holding calcineurin inhibitors.
    - Decreasing or holding antimetabolites (e.g., azathioprine or mycophenolate) is commonly done but data are limited.

Outpatient Prevention and Treatment of COVID-19

- Clinicians should educate patients with CLD and LT recipients that early testing is indicated if signs or symptoms of COVID-19 develop and about the availability of pre-exposure prophylaxis and early treatment with antiviral therapies or monoclonal antibodies (**Table 1**).
- Clinicians and patients can find available COVID-19 therapies by visiting the Department of Health and Human Services COVID-19 test-to-treat locator at https://covid-19-test-to-treat-locator-dhhs.hub.arcgis.com.
- Liver clinics should be aware of local options for the administration of monoclonal antibodies.
- Prescribe COVID-19 antiviral therapies or monoclonal antibodies as early as possible for those who test positive for SARS-CoV-2.
- The use of new or increased doses of corticosteroids should be avoided in the outpatient setting.

- Hydroxychloroquine with or without azithromycin, azithromycin alone, lopinavir/ritonavir, and ivermectin have been shown to be ineffective or harmful and should not be used to treat or prevent COVID-19.

Table 1. Outpatient Prevention and Treatment of COVID-19

Agent	Mechanism	Route	Target Population	Issues Related to Liver Disease	Approval Status
Prevention					
Tixagevimab/ cilgavimab (Evusheld)	Monoclonal antibody	IM	Pre-exposure prophylaxis (not treatment) in immune-compromised individuals ≥12 years and ≥40 kg or those who cannot receive any approved or authorized COVID-19 vaccine due to a history of severe adverse reaction to a COVID-19 vaccine or component Repeat every 6 months	No known hepatotoxicity	FDA EUA
Treatment					
Nirmatrelvir/ ritonavir (Paxlovid)	Protease inhibitor	Oral	Outpatients ≥12 years old and ≥40 kg with COVID-19 at high risk of progression to severe COVID-19	Not recommended in patients with severe liver (Child-Pugh C) or renal impairment (eGFR ≤30 mL/min) Significant drug interactions due to ritonavir (e.g, CNI, mTORI) Significant drug interactions with some HCV direct-acting antivirals	FDA EUA
Molnupiravir (Lagevrio)	Nucleoside analog	Oral	Outpatients ≥18 at high risk for progression who cannot access or use other approved treatments	No known hepatic toxicity and not hepatically cleared Avoid in pregnant and breastfeeding women	FDA EUA
Remdesivir (Veklury)	Nucleotide analog prodrug	IV	Mild to moderate COVID-19 in high-risk, nonhospitalized patients (3-day course)	Potential for hepatotoxicity Monitor liver biochemistries	FDA approved
Bebtelovimab	Monoclonal antibody	IV	High-risk outpatients ≥12 years old and ≥40 kg with mild to moderate COVID-19 Preferred for most LT recipients because of lack of drug interactions		FDA EUA

Pre-Exposure Prophylaxis

- *Tixagevimab/Cilgavimab (Evusheld)* is a monoclonal IgG1 antibody given by IM injection.
    - Reduces the incidence of SARS-CoV-2 infection in immunosuppressed individuals at risk for severe COVID-19.

- Authorized (EUA) for pre-exposure prophylaxis in immunocompromised individuals ≥12 years and weighing ≥40 kg who have been vaccinated.
- Also authorized for those who cannot receive any approved or authorized COVID-19 vaccine due to a history of severe adverse reaction to a COVID-19 vaccine or component.
- Not a treatment for COVID-19 and not authorized for post-exposure prophylaxis.
- Likely remains active against most Omicron variants identified, but does not provide any T cell immunity; therefore, COVID-19 vaccination remains the optimal strategy for prevention.
- Should not be used in place of vaccination.
- Should be delayed for 2 weeks after COVID-19 vaccination to allow for improved vaccine response.
- Use caution with use of Evusheld in patients with heart disease because of an increased risk of cardiac adverse events in one of two randomized controlled trials.
- A repeat dose should be administered every 6 months.

Antiviral Therapies

- *Nirmatrelvir/Ritonavir (Paxlovid)* is an oral antiviral that significantly reduces the risk of COVID-19 related hospitalization or death in patients treated within 5 days of symptom onset.
  - FDA EUA for patients ≥12 years and weighing ≥40 kg with COVID-19 who are at high risk of progression to severe COVID-19 and within 5 days of symptom onset.
  - Not recommended in patients with severe renal impairment (eGFR ≤30 mL/min) as the appropriate dose has not been determined.
  - Not recommended in patients with severe liver impairment (Child-Pugh class C) as no pharmacokinetic or safety data are available in these subjects.
  - No dosage adjustment is needed for patients with either mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment.
  - Significant drug interactions with drugs metabolized by CYP3A4 because of the ritonavir component (e.g., calcineurin inhibitors and mTOR inhibitors).
    - Use extreme caution in transplant recipients because of these significant drug interactions, which may lead to dangerously high levels of drugs metabolized by this pathway, especially calcineurin inhibitors.
    - There are also significant drug interactions with some HCV direct-acting antiviral regimens (e.g., glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir).
    - It is mandatory to check for drug interactions in all patients prescribed Paxlovid prior to initiation of this treatment.
    - See patient eligibility screening checklist and drug interaction tool.
- *Molnupiravir (Lagevrio)* is an oral nucleoside analog that inhibits SARS-CoV-2 replication.
  - Associated with a 30%-50% reduction in hospitalization or death compared to placebo.
  - Authorized (EUA) for the treatment of mild-to-moderate COVID-19 in adults at high risk for progression to severe COVID-19 who are not candidates for other proven therapies for mild to moderate COVID-19 and should be initiated within 5 days of symptom onset.
  - Contraindicated in pregnancy and breastfeeding; use caution in individuals of reproductive potential because of the risk of teratogenicity.
  - Not recommended for those <18 years old.
- *Remdesivir (Veklury)* is approved for the treatment of mild-to-moderate COVID-19 in high-risk, nonhospitalized patients within 7 days of symptom onset.
  - 87% reduction in risk of hospitalization or death.
  - Requires 3 daily IV infusions.

Monoclonal Antibodies

- *Bebtelovimab* is authorized (EUA) for the treatment of high-risk outpatients aged ≥12 years and weighing ≥40 kg with mild-to-moderate COVID-19.
    - Preferred for most LT patients because of lack of drug interactions.
- Bamlanivimab + etesevimab and casirivimab + imdevimab (REGEN-COV) are not expected to provide clinical benefit against Omicron variants and are no longer authorized in the US for treatment or post-exposure prophylaxis of COVID-19.
- Sotrovimab is not expected to provide clinical benefit against currently circulating strains and is no longer authorized in the US for treatment of COVID-19.

Inpatient Management of COVID-19

- *Remdesivir (Veklury)* should be offered for a 5-day duration to hospitalized patients with liver disease or liver transplant recipients hospitalized with COVID-19 and requiring supplemental oxygen.
    - Appears to work best when given early (e.g., patients requiring low flow oxygen).
    - Benefit uncertain in patient requiring non-invasive mechanical ventilation or high-flow oxygen.
    - No benefit shown in patients with liver disease or LT recipients requiring mechanical ventilation.
    - Baseline testing of liver biochemistries should be performed prior to initiating remdesivir and testing should be repeated frequently during treatment with drug discontinuation for elevations >10x ULN or signs or symptoms of liver inflammation.
- *Dexamethasone* 6 mg daily for up to 10 days should be given to patients with liver disease and LT recipients hospitalized with COVID-19 and requiring significant supplemental oxygen above baseline or mechanical ventilation if there is no contraindication (e.g., severe non-SARS-CoV-2 infection, uncontrolled hyperglycemia).
    - If already receiving corticosteroids at lower than an equivalent dose of 6 mg daily of dexamethasone (prednisone 40 mg), the dose should be increased to equivalent of 6 mg daily of dexamethasone.
    - If dexamethasone is not available, an alternative corticosteroid at equivalent doses may be substituted.
- *Tocilizumab (IL-6 inhibitor)* or *Baricitinab (JAK inhibitor)* may benefit a subset of deteriorating critically ill patients already receiving corticosteroids and should be considered for patients with liver disease or solid organ transplantation with close monitoring for superinfection.

COVID-19 Vaccinations

- We strongly recommend that patients with CLD and LT recipients receive COVID-19 vaccinations and boosters (**Table 2**).
- All patients with CLD and LT recipients, including vaccine recipients, should continue to mitigate their risk of SARS-CoV-2 exposure (e.g., masking, social distancing, hand washing, etc.).
- Reports of a rare autoimmune hepatitis-like syndrome following COVID-19 vaccination should not discourage COVID-19 vaccination.
- In patients whose liver biochemistries increase after vaccination and do not immediately return to baseline on repeat testing, a thorough evaluation should follow to exclude acute cellular rejection (ACR) or viral infection of the liver.
- Family members and caregivers of LT recipients should be vaccinated against SARS-CoV-2.
- Rare serious adverse events have been reported with all of the available COVID-19 vaccines (**Table 3**).

- Serological testing for evidence of prior SARS-CoV-2 infection (anti-nucleocapsid antibodies) is not recommended prior to COVID-19 vaccination and testing for anti-Spike glycoprotein antibodies prior to or after vaccination is not recommended.
- Other vaccines such as influenza, pneumococcus, and other inactivated vaccines can be administered at the same time as COVID-19 vaccines.
- Any instances of suspected adverse events to COVID-19 vaccines should be reported to the VAERS website at https://vaers.hhs.gov.
- As of September 2022, the only authorized booster is one dose of bivalent vaccine (Moderna or Pfizer) ≥2 months after the primary series or most recent booster.

Table 2. COVID-19 Vaccine Schedule for Children and Adults in the United States

	Pfizer-BioNTech mRNA			Moderna mRNA		Novavax Adjuvanted	J&J/Janssen Adenoviral vector*
	6 mo-4 yrs	**5-11 yrs**	**≥12 yrs**	**6 mo-11 yrs**	**≥12 yrs**	**≥12 yrs**	**≥18 yrs**
Primary series							
Immunocompetent e.g., CLD not on immunosuppressive medications	3 doses	2 doses		2 doses		2 doses	1 dose
Immunocompromised e.g., CLD or LT recipients on immunosuppressive medications	3 doses	3 doses		3 doses		2 doses	1 dose J&J followed by mRNA vaccine
Booster**							
	NA	Monovalent ≥3 mo after primary series	Bivalent ≥2 mo after primary series	NA	Bivalent ≥2 mo after primary series	Bivalent ≥2 mo after primary series	Bivalent ≥2 mo after primary series

NA = not authorized
*Janssen COVID-19 vaccine should only be used in certain limited situations; mRNA primary vaccine series preferred whenever possible
**Pfizer-BioNTech bivalent booster recommended for ages 12-17 years; Moderna or Pfizer-BioNTech bivalent booster recommended for ages ≥18 years

Recommendations are changing frequently. Visit the CDC website for up-to-date recommendations regarding vaccines and schedules.

Table 3. Severe Adverse Events Associated with COVID-19 Vaccines

Adverse event	Vaccine association	Incidence (per million)	Time to onset	Management
Anaphylactic reaction	mRNA Adenoviral Recombinant protein	2-5 overall	Up to 1 hour	Immediate anti-histamine, epinephrine/steroids Hospitalize if severe
Guillain-Barré Syndrome	Adenoviral	7.8 overall and up to 15.6 in males 50-64 years 100 cases reviewed	Median 13 days (r: 0 to 75 days) 98% within 6-week window	Hospitalize IVIG if progressive Intubation and plasmapheresis if severe
Thrombosis and thrombocytopenia syndrome	Adenoviral	3.0 overall and 8.8 in women 30-49 years	Within 15 days	Anti-PF4 antibodies Avoid heparin
Myocarditis/ pericarditis	mRNA Recombinant protein	10.6 overall and 70.7 in males 12-25 years	Median 2 days	Supportive care NSAIDs Steroids if severe

Chronic Liver Disease and Hepatocellular Carcinoma

- Patients with CLD who are receiving antiviral therapy for HBV or HCV or medical therapy for PBC or AIH should NOT withhold their medications while receiving the COVID-19 vaccines.
- It is not recommended to withhold immunosuppression prior to or after COVID-19 vaccine administration for the purposes of increasing the likelihood of vaccine efficacy.
- Patients with HCC undergoing locoregional or systemic therapy should also be considered for vaccination without interruption of their treatment. However, patients with recent infections or fever should NOT receive the COVID-19 vaccine until they are medically stable.

Liver Transplant Candidates

- Some transplant centers have developed medically and ethically justified policies that require COVID-19 vaccination to be listed for transplantation.
- Potential live liver donors and recipients of live donor livers should be vaccinated at least two weeks before transplantation when feasible. However, a lack of COVID-19 vaccination should not delay emergent living donor LT.

Liver Transplant Recipients

- To optimize response, COVID-19 vaccination should be avoided in LT recipients with active ACR, those being treated for ACR, or those on high daily doses of corticosteroids, until the episode is resolved and their baseline immunosuppression reestablished.
- LT candidates should receive a COVID-19 vaccine prior to transplantation whenever possible to help ensure an adequate immune response.
- If a COVID-19 vaccine is not administered prior to transplantation, the optimal time to administer the COVID-19 vaccine is likely at least three months post-LT when immunosuppression is lower and other prophylactic medications are stopped or minimized. However, given the ongoing community spread of SARS-CoV-2, immunization may be initiated as early as four weeks posttransplant, especially for the highest-risk individuals with other comorbid factors associated with severe COVID-19.
- LT recipients who recover from COVID-19 infection should still receive a complete series of COVID-19 vaccines. Some recommend waiting 3 months after a recent SARS-CoV-2 infection before getting the bivalent booster.

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