

Surveillance Epidemiology of Coronavirus (COVID 19) Under Research Exclusion (SECURE)

Inclusion Criteria:

- 1) Chronic liver disease or post-liver transplantation AND

- 2) Laboratory confirmed COVID 19 infection

This form should be completed after the patient has had COVID 19 for a long enough duration to experience partial or complete recovery, hospitalization, or death.

If you have any questions, please reach out to COVID.Cirrhosis@unc.edu

Reporter Information

Name of reporter

Email address of reporter

Name of lead physician providing care for liver
disease/post-liver transplant

Name of center providing care for liver
disease/post-liver transplant

Name of hospital where patient received care for
COVID 19 (enter 'NA' if patient not hospitalized)

Patient Information

Is the patient ≥ 90 years of age?

- Yes
 No

Age

Country of residence

- Not in this country list ---
- Åland Islands
- Afghanistan
- Albania
- Algeria
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia, Plurinational State of
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- Brunei Darussalam
- Bulgaria
- Burkina Faso
- Burundi
- Côte d'Ivoire
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Congo, the Democratic Republic of the
- Cook Islands
- Costa Rica
- Croatia
- Cuba
- Cyprus
- Czech Republic
- Denmark
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Ethiopia

- Falkland Islands (Malvinas)
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern Territories
- Gabon
- Gambia
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Holy See (Vatican City State)
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran, Islamic Republic of
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Korea, Democratic Peoples Republic of
- Korea, Republic of
- Kuwait
- Kyrgyzstan
- Lao Peoples Democratic Republic
- Latvia
- Lebanon
- Lesotho
- Liberia
- Libyan Arab Jamahiriya
- Liechtenstein
- Lithuania
- Luxembourg
- Macao
- Macedonia, the former Yugoslav Republic of
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte

- Mexico
- Micronesia, Federated States of
- Moldova, Republic of
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar
- Namibia
- Nauru
- Nepal
- Netherlands
- Netherlands Antilles
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- Norway
- Oman
- Pakistan
- Palau
- Palestinian Territory, Occupied
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn
- Poland
- Portugal
- Qatar
- Ré union
- Romania
- Russian Federation
- Rwanda
- Saint Barthélemy
- Saint Helena, Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Saint Martin (French part)
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- Sao Tome and Principe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Swaziland
- Sweden
- Switzerland

- Syrian Arab Republic
- Taiwan, Province of China
- Tajikistan
- Tanzania, United Republic of
- Thailand
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- Uruguay
- Uzbekistan
- Vanuatu
- Venezuela, Bolivarian Republic of
- Vietnam
- Virgin Islands, British
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

 State of residence

- ALABAMA ALASKA
 AMERICAN SAMOA ARIZONA
 ARKANSAS CALIFORNIA
 COLORADO CONNECTICUT
 DELAWARE DISTRICT OF COLUMBIA
 FLORIDA GEORGIA
 GUAM HAWAII IDAHO
 ILLINOIS INDIANA
 IOWA KANSAS KENTUCKY
 LOUISIANA MAINE
 MARYLAND MASSACHUSETTS
 MICHIGAN MINNESOTA
 MISSISSIPPI MISSOURI
 MONTANA NEBRASKA
 NEVADA NEW HAMPSHIRE
 NEW JERSEY NEW MEXICO
 NEW YORK NORTH CAROLINA
 NORTH DAKOTA OHIO
 OKLAHOMA OREGON
 PENNSYLVANIA PUERTO RICO
 RHODE ISLAND SOUTH CAROLINA
 SOUTH DAKOTA TENNESSEE
 TEXAS UTAH VERMONT
 VIRGIN ISLANDS VIRGINIA
 WASHINGTON WEST VIRGINIA
 WISCONSIN WYOMING

 Gender

- Female
 Male
 Other

 Race/Ethnicity (may check more than one)

- White
 Black or African American
 American Indian / Native Alaskan
 East Asian (incl. Chinese, Japanese, Korean)
 South / South-East Asian (incl. Bangladeshi, Indian, Pakistani, Sri Lankan)
 Native Hawaiian / Pacific Islander
 Arabic
 Other
 Unknown

 Other race/ethnicity

 Hispanic ethnicity

- Hispanic/Latino
 Not Hispanic/Latino
 Unknown

 Patient BMI category (in kg/m2)

- < 18.5 (Underweight)
 18.5-24.9 (Normal weight)
 25.0-29.9 (Pre-obesity)
 30.0-34.9 (Obesity class I)
 35.0-39.9 (Obesity class II)
 >39.9 (Obesity class III)
 Unknown

Liver transplantation questions

Has the patient had a liver transplantation?

- Yes
- No

What year was the liver transplantation performed?

- Unknown
- 2020
- 2019
- 2018
- 2017
- 2016
- 2015
- 2014
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- 1966
- 1965

Indication for liver transplant (select all that apply)

- Decompensated cirrhosis
- Hepatocellular carcinoma
- Acute liver failure
- Other

Other indication for liver transplantation

Underlying etiology of liver disease (select all that apply)

- Non-alcoholic fatty liver disease (NAFLD)
 - Alcohol-related liver disease (ALD)
 - Hepatitis C virus (HCV)
 - Hepatitis B virus (HBV)
 - Autoimmune hepatitis (AIH)
 - IgG4-related disease
 - Primary biliary cholangitis (PBC)
 - Primary sclerosing cholangitis (PSC)
 - Hemochromatosis
 - Wilson's disease
 - Other
-

Other etiology

Immunosuppression regimen at time of COVID 19 infection (select all that apply)

- Prednisone
 - Tacrolimus
 - Sirolimus
 - Everolimus
 - Cyclosporine
 - Mycophenolate mofetil (MMF)
 - Azathioprine
 - Cyclophosphamide
 - Other
 - Unknown
-

What other immunosuppression medication was used at the time of COVID 19 infection?

Current prophylactic antimicrobial regimen (select all that apply)

- Trimethoprim/sulfamethoxazole or Co-trimoxazole
 - Dapsone
 - Pentamidine
 - Acyclovir/valacyclovir
 - Fluconazole
 - Ganciclovir/valganciclovir
 - Foscarnet
 - Other
 - Unknown
 - None
-

Other prophylactic antimicrobial regimen

Does the patient have any of the following comorbidities (check all that apply)?

- Cardiovascular disease (coronary artery disease, heart failure, arrhythmia, etc.)
- Diabetes
- Asthma
- COPD
- Other Chronic Lung Disease (NOT asthma/COPD)
- Hypertension
- Non-HCC cancer
- History of stroke
- Chronic renal disease (CKD, etc.)
- Human immunodeficiency virus (HIV) infection
- Current cigarette smoker
- Current user of tobacco products other than cigarettes (vaping, etc)
- Current heavy alcohol use (>2 drinks/day for men, >1 drink/day for women)

Chronic liver disease questions

Etiology of liver disease (select all that apply)

- Non-alcoholic fatty liver disease (NAFLD)
- Alcohol-related liver disease (ALD)
- Hepatitis C virus (HCV)
- Hepatitis B virus (HBV)
- Autoimmune hepatitis (AIH)
- IgG4-related disease
- Primary biliary cholangitis (PBC)
- Primary sclerosing cholangitis (PSC)
- Hemochromatosis
- Wilson's disease
- Other

Other etiology

Does the patient have cirrhosis?

- Yes
- No
- Unknown

Child Pugh grade prior to COVID 19 diagnosis?

- A
- B
- C
- Unknown

Did the patient have ascites prior to COVID 19 diagnosis?

- None
- Mild/moderate (diuretic responsive)
- Severe (diuretic refractory)
- Unknown

What was the worst grade of hepatic encephalopathy patient developed prior to COVID 19 diagnosis?

- None
- Grade 1 (trivial lack of awareness, shortened attention span)
- Grade 2 (lethargy, minimal disorientation, subtle personality change)
- Grade 3 (somnolence to semi-stupor but responsive to verbal stimuli, gross disorientation)
- Grade 4 (coma - unresponsive to verbal or noxious stimuli)
- Unknown

Has the patient ever had hepatocellular carcinoma?

Yes
 No
 Unknown

What immunosuppression was the patient taking for IgG4-related disease at time of COVID 19 diagnosis (may check more than one)?

None
 Corticosteroids
 Azathioprine
 Rituximab
 Other
 Unknown

Other immunosuppression for IgG4-related disease

Has the patient received steroids for alcoholic hepatitis recently (within 4 weeks of COVID 19 diagnosis)?

Yes
 No
 Unknown

Treatment for primary biliary cholangitis (PBC) at time of COVID 19 diagnosis

Ursodeoxycholic acid
 Obeticholic acid
 Fibrate
 Other
 No treatment
 Unknown

Other PBC treatments

Does the patient have inflammatory bowel disease (IBD)?

Yes
 No
 Unknown

Immunosuppression medication(s) patient was taking for IBD at time of COVID 19 diagnosis

Prednisone
 Budesonide
 Azathioprine
 Methotrexate
 Mycophenolate
 Infliximab
 Adalimumab
 Ustekinumab
 Vedolizumab
 Other
 None

Other immunosuppression for IBD

Treatment for autoimmune hepatitis (AIH) at time of COVID 19 diagnosis

Prednisone/prednisolone
 Budesonide
 Azathioprine
 Mycophenolate
 Tacrolimus
 Other
 None

Other treatment for AIH

Hepatitis B surface antigen (HBsAg) positive

Yes
 No
 Unknown

Treatment for HBV at the time of COVID 19 diagnosis

Tenofovir
 Entecavir
 Interferon
 None
 Unknown

Did the patient have detectable hepatitis C virus (HCV) RNA at the time of or prior to COVID 19 diagnosis?

Yes
 No
 Unknown

HCV genotype

1
 2
 3
 4
 5
 6
 7
 Unknown

Active treatment for HCV at the time of COVID 19 diagnosis

Yes
 No
 Unknown

Does the patient have any of the following comorbidities (check all that apply)?

Cardiovascular disease (coronary artery disease, heart failure, arrhythmia, etc.)
 Diabetes
 Asthma
 COPD
 Other Chronic Lung Disease (NOT asthma/COPD)
 Hypertension
 Non-HCC cancer
 History of stroke
 Chronic renal disease (CKD, etc.)
 Human immunodeficiency virus (HIV) infection
 Current cigarette smoker
 Current user of tobacco products other than cigarettes (vaping, etc)
 Current heavy alcohol use (>2 drinks/day for men, >1 drink/day for women)

Laboratory data (leave fields blank if unknown)

Baseline serum sodium (mmol/L)

 (Before COVID 19 infection)

Nadir serum sodium (mmol/L)

 (During COVID 19 infection)

Creatinine units

$\mu\text{mol/L}$ mg/dl

Baseline serum creatinine

 (Before COVID 19 infection)

Peak serum creatinine

(During COVID 19 infection)

Baseline prothrombin time (sec)

(Before COVID 19 infection)

Peak prothrombin time (sec)

(During COVID 19 infection)

Albumin units

g/dl g/liter

Baseline albumin

(Before COVID 19 infection)

Nadir albumin

(During COVID 19 infection)

Total bilirubin units

$\mu\text{mol/L}$ mg/dl

Baseline total bilirubin

(Before COVID 19 infection)

Peak total bilirubin

(During COVID 19 infection)

Baseline alanine aminotransferase (ALT) (IU/L)

(Before COVID 19 infection)

Peak alanine aminotransferase (ALT) (IU/L)

(During COVID 19 infection)

Baseline alkaline phosphatase (IU/L)

(Before COVID 19 infection)

Peak alkaline phosphatase (IU/L)

(During COVID 19 infection)

COVID 19 questions

Was this lab confirmed COVID 19 infection?

- Yes
 No
 Unknown

What symptoms did the patient have at the time of COVID 19 diagnosis?

- GI symptoms (abdominal pain, diarrhea, nausea, vomiting)
 Respiratory symptoms (shortness of breath, cough)
 Both GI and respiratory symptoms
 Neither GI or respiratory symptoms
 Unknown

Did patient test positive for influenza at time of COVID 19 infection?

- Yes
 No
 Unknown

What complications did the patient develop during COVID 19 infection?

- New or worsening ascites
 Spontaneous bacterial peritonitis
 Hepatic encephalopathy
 Non-variceal upper GI bleeding
 Variceal upper GI bleeding
 New requirement for renal replacement therapy (e.g. hemodialysis)
 Other

Other complications of COVID 19 infection

What was the grade of ascites during COVID 19 infection?

- Mild/moderate
 Severe
 Unknown

What was the worst grade of hepatic encephalopathy during COVID 19 infection (based on West Haven Criteria)?

- Grade 1 (trivial lack of awareness, shortened attention span)
 Grade 2 (lethargy, minimal disorientation, subtle personality change)
 Grade 3 (somnolence to semi-stupor but responsive to verbal stimuli, gross disorientation)
 Grade 4 (coma - unresponsive to verbal or noxious stimuli)
 Unknown

Did the patient receive specific antiviral treatment for COVID 19 infection?

- Yes
 No
 Unknown

Which of the following treatment(s) did patient receive for COVID 19 (select all that apply)?

- Remdesivir
 Tocilizumab
 Lopinovir/ritonavir
 Chloroquine/hydroxychloroquine
 Ribavirin
 Interferon-alpha
 Other
 Unknown

Other type of antiviral treatment(s) received for COVID-19

What was the reason the patient did not receive COVID 19 antiviral treatment (select all that apply)?

- Elevated liver enzymes
- Underlying liver fibrosis/cirrhosis
- Other contraindication (eg AKI)
- Treatment not available
- Other
- Unknown

What was the reason the patient did not receive COVID 19 antiviral treatment?

Did the patient die?

- Yes
- No
- Unknown

What was the primary cause of death?

- Liver-related complications
- COVID 19-related lung disease
- Cardiogenic shock
- Other

Other cause of death

Has the patient been hospitalized?

- Yes
- No
- Unknown

Has the patient been discharged from the hospital?

- Yes
- No
- Unknown

Length of hospital stay (days)

Did patient require invasive ventilation?

- Yes
- No
- Unknown

Did patient require non-invasive ventilation?

- Yes
- No
- Unknown

Did patient require admission to an intensive care unit?

- Yes
- No
- Unknown