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May 20, 2022

SECTION 77.6 HEALTH PROTECTION AND PROMOTION ACT

CHIEF MEDICAL OFFICER OF HEALTH ORDER

**(Order to Public Hospitals to provide information relating to severe acute
hepatitis of unknown origin among children)**

ONTARIO MINISTRY OF HEALTH

**ORDER OF THE CHIEF MEDICAL OFFICER OF HEALTH UNDER SECTION 77.6 OF
THE HEALTH PROTECTION AND PROMOTION ACT,**

R.S.O. 1990, c. H.2 (The Act)

WHEREAS under section 77.6 of the Act, the Chief Medical Officer of Health, where he is of the opinion that there exists an immediate and serious risk to the health of persons anywhere in Ontario, may issue an order directing any health information custodian, as defined in the *Personal Health Information Protection Act, 2004* to provide to the Chief Medical Officer of Health or his or her delegate with any information provided in the order;

AND WHEREAS, under section 77.6(2), the Chief Medical Officer of Health is of the opinion, based on reasonable and probable grounds, that the information is necessary to investigate, eliminate or reduce the immediate and serious risk to the health of persons in Ontario presented by severe acute hepatitis of unknown origin among children;

AND WHEREAS, under section 77.6(3), the information requested in this order is to be used or disclosed only to investigate, eliminate, or reduce the risk and for no other purpose;

AND WHEREAS, under section 77.6(1), the Chief Medical Officer of Health may require health information custodians named in the order to disclose information, including personal health information, to a delegate;

AND HAVING REGARD TO severe acute hepatitis of unknown origin in children observed internationally as follows: Since October 2021, there have been, as of the date of this Order, at least 348 probable cases of acute hepatitis of unknown origin reported among children aged one month up to 16 years of age in 21 countries.

These cases are negative for hepatitis viruses A, B, C, D and E and have aspartate transaminase (AST) or alanine transaminase (ALT) levels over 500 U/L. The aetiology is considered unknown and active investigation continues; however, SARS-CoV-2 and adenovirus have been identified in some cases.

AND HAVING REGARD TO some cases having required transfers to specialist children's liver units, some having required liver transplantation, and there being at least one death reported as a result of infection.

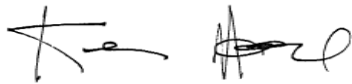
THE CHIEF MEDICAL OFFICER OF HEALTH THEREFORE ORDERS pursuant to the provisions of section 77.6 of the Act that:

1. Every person or entity who operates a hospital within the meaning of the *Public Hospitals Act* ("Public Hospital"), any institution, building or other premises or place that is established for the purposes of the treatment of patients and that is approved under the *Public Hospitals Act* as a Public Hospital, must provide to the Chief Medical Officer of Health's delegate, the Ontario Agency for Health Protection and Promotion ("Public Health Ontario"), the information as outlined in Appendix B ("Case Report Form") respecting any cases of severe acute hepatitis of unknown origin among patients who are children ("Patients") and who meet the probable case definition in Appendix A (the "Information"). The Public Hospital must make best efforts to obtain the information from the parent or guardian (or child, where applicable) noted in sections 7 to 11 of the Case Report Form (Appendix B).

2. Every Public Hospital must disclose the Information to Public Health Ontario within one (1) business day after the Public Hospital learns that it has a Patient who meets the probable case definition in Appendix A.
3. Every Public Hospital must disclose the Information to Public Health Ontario. If a Public Hospital has a Patient that meets the probable case definition in Appendix A, the Public Hospital must contact Public Health Ontario at 647 260-7619 and provide the name and contact information for a representative of the Public Hospital that can be contacted by Public Health Ontario to report the information in the Case Report Form. Outside of business hours, a Public Hospital representative can call the above telephone number and leave a message, absent of personal health information.

This Order takes effect immediately and shall remain in force until revoked.

Dated at Toronto this 20 day of May, 2022

A handwritten signature in black ink, appearing to read 'K. Moore', with a stylized flourish at the end.

Dr. Kieran Moore

Chief Medical Officer of Health

For more information on acute hepatitis and communications released by the Office of the Chief Medical Officer of Health, please visit

https://www.health.gov.on.ca/en/pro/programs/publichealth/acute_hepatitis/default.aspx.

APPENDIX A

CASE DEFINITIONS for severe acute hepatitis of unknown origin in children.

Confirmed case

- N/A at present.

Probable case

- A person who is 16 years and younger presenting with clinical evidence¹ of severe acute hepatitis since October 2021 and requiring hospitalization,

AND

- With elevated serum transaminase >500 IU/L (AST or ALT) or INR>2.0,

AND

- Excluding hepatitis caused or attributed to a hepatitis virus (A, B, C, D, E²) or a known or expected presentation of a drug or medication; a genetic, congenital, or metabolic condition; an oncologic, vascular, or ischemia related condition; or an acute worsening of chronic hepatitis.

¹ Clinical evidence of hepatitis may include jaundice, dark urine, pale stools, or non-specific symptoms (e.g., nausea, vomiting, diarrhea, abdominal pain).

² If hepatitis D or E serology results are pending or test was not done, but other criteria met, these can be reported as probable cases.

APPENDIX B

This case report form will require information from both the clinical team and the parent/guardian of the case (or the case themselves if they are an adult).

Date reported to PHAC (dd/mm/yyyy):		Initial report Updated report	<input type="checkbox"/> <input type="checkbox"/>
Section 1: Reporter details			
Public health authority			
Name:		Title:	
Cell phone:		Email address:	
Province or Territory			
Clinician			
Name:		Title:	
Cell phone:		Email address:	
Organization:		Date of interview (dd/mm/yyyy):	

PART A: CLINICAL INFORMATION

Section 2: Case information

First name:		Last name:	
Date of birth (dd/mm/yyyy):		Personal health identifier:	
Sex	Female <input type="checkbox"/> Male <input type="checkbox"/> Other <input type="checkbox"/>	Address during the 5 months prior to diagnosis Specify if there was another address during the period	

Section 3: Current case status

Alive, recovered and discharged	<input type="checkbox"/>
Alive, discharged and recovering	<input type="checkbox"/>
Alive, in hospital	<input type="checkbox"/>
Alive, in intensive care (ICU/CCU)	<input type="checkbox"/>
Deceased	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
More information:	
Name of hospital where diagnosis of acute hepatitis was made:	----- Unknown <input type="checkbox"/>

Was liver transplant required?	Yes <input type="checkbox"/>	Name of hospital and date of liver transplant if applicable:	Hospital
	No <input type="checkbox"/>		-----
	Unknown <input type="checkbox"/>		Unknown <input type="checkbox"/>
			Date

			Unknown <input type="checkbox"/>

Section 4: Presenting illness of case

Please provide a summary of the symptoms and signs of the presenting illness (including prodromal symptoms) and dates of onset if known:

Symptom	Symptom present	Symptom onset date (dd/mm/yyyy)
Jaundice	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Nausea	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Abdominal pain/ cramping	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Diarrhea	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Bloody stool	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Pale stool	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Dark urine	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Rash	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Vomiting	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Respiratory Symptoms – shortness of breath, cough	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Upper Respiratory Symptoms – runny nose, congestion, sore throat	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /

Section 4: Presenting illness of case

Please provide a summary of the symptoms and signs of the presenting illness (including prodromal symptoms) and dates of onset if known:

Symptom	Symptom present	Symptom onset date (dd/mm/yyyy)
Fever	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Malaise/ tiredness	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Conjunctivitis	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /
Other (please specify below):	Yes <input type="checkbox"/> No <input type="checkbox"/>	/ /

Please provide clinical contact details of this presentation:

Clinical contact	Clinical contacts during this presentation	Admission date – Discharge date (dd/mm/yyyy)
Visited Family doctor or pediatrician	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Visited ER	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Admission to hospital (for at least 1 night)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
ICU/CCU admission	Yes <input type="checkbox"/> No <input type="checkbox"/>	

Section 5: Laboratory results / Toxicology / Investigations

NOTE: Please follow provincial guidelines/directives for laboratory testing. Please provide results of all tests performed.

Laboratory marker	Result	Not tested	Pending	Date sample collected (dd/mm/yyyy)
Highest ALT				/ /
Highest AST				/ /
Highest Bilirubin				/ /
Highest INR				/ /
Highest Ferritin				/ /

Section 5: Laboratory results / Toxicology / Investigations

NOTE: Please follow provincial guidelines/directives for laboratory testing. Please provide results of all tests performed.

Infectious diseases	Detected	Not detected	Not tested	Pending	Date sample collected (dd/mm/yyyy)
CMV PCR in blood (indicate viral load if available)					/ /
EBV PCR in blood (indicate viral load if available)					/ /

Section 5: Laboratory results / Toxicology / Investigations

NOTE: Please follow provincial guidelines/directives for laboratory testing. Please provide results of all tests performed.

Infectious diseases	Detected	Not detected	Not tested	Pending	Date sample collected (dd/mm/yyyy)
Enterovirus PCR in blood (indicate viral load if available)					/ /
HSV – 1 PCR in blood (indicate viral load if available)					/ /
HSV – 2 PCR in blood (indicate viral load if available)					/ /
HAV: PCR in blood if done, or stool (please specify)					/ /
HAV: IgG					/ /
HAV: IgM					/ /
HBV (HBsAg)					/ /
HBV DNA					/ /
Hepatitis B antibody tests (please specify)					/ /
HCV (Ab)					/ /

Section 5: Laboratory results / Toxicology / Investigations

NOTE: Please follow provincial guidelines/directives for laboratory testing. Please provide results of all tests performed.

Infectious diseases	Detected	Not detected	Not tested	Pending	Date sample collected (dd/mm/yyyy)
HCV RNA					/ /
HEV: IgM					/ /
HEV: IgG					/ /
HEV PCR in blood (or stool)- please specify					/ /
Adenovirus – stool sample					/ /
Adenovirus – respiratory sample					/ /
Adenovirus – blood sample (indicate viral load)					/ /
Adenovirus – other sample					/ /
Adenovirus genotyping (indicate sample used)					/ /
SARS-CoV-2 PCR – respiratory sample					/ /
SARS-CoV-2 anti-spike and/or anti-N antibody					/ /

Section 5: Laboratory results / Toxicology / Investigations

NOTE: Please follow provincial guidelines/directives for laboratory testing. Please provide results of all tests performed.

Infectious diseases	Detected	Not detected	Not tested	Pending	Date sample collected (dd/mm/yyyy)
RSV PCR – respiratory sample					/ /
Influenza PCR – respiratory sample					/ /
Enterovirus PCR – respiratory sample					/ /
Varicella PCR in blood					/ /
Parvovirus B19 IgM or IgG or PCR, please indicate					/ /
EBV serology (IgG and IgM)					/ /
CMV serology (IgG and IgM)					/ /
Stool PCR for norovirus and/or enterovirus (select those included if not all available)					/ /
Other (please specify):					/ /

Section 5: Laboratory results / Toxicology / Investigations

NOTE: Please follow provincial guidelines/directives for laboratory testing. Please provide results of all tests performed.

Toxicology	Detected	Not detected	Not tested	Pending	Date sample collected (dd/mm/yyyy)
Heavy metal screen: Lead					/ /
Heavy metal screen: Arsenic					/ /
Heavy metal screen: Mercury					/ /
Drug screen: Peak acetaminophen concentration					/ /
Urine toxicology (please provide details of any positive tox results)					/ /

Section 5: Laboratory results / Toxicology / Investigations

NOTE: Please follow provincial guidelines/directives for laboratory testing. Please provide results of all tests performed.

Investigations	Performed	If yes, please summarise findings:	Date of test
Radiology:			
Liver biopsy* (summarise histopathology report, including whether damage starting at portal tracts or diffuse)	Yes <input type="checkbox"/> No <input type="checkbox"/>		/ /
List immunohistochemistry stains performed* (adenovirus/CMV/EBV etc)	Yes <input type="checkbox"/> No <input type="checkbox"/>		/ /

*Not be considered a recommended / mandatory test, based on clinical need.

Section 6: Case medical and health history

Did the case have COVID-19? Yes ☐ Suspected ☐ Unknown ☐ No ☐

Was it confirmed by a test (most recent episode)? Yes ☐ [PCR ☐; Rapid antigen test ☐]
No ☐

Date of onset (most recent episode) (dd/mm/yyyy):

Please summarize any other previous illnesses requiring treatment/care in the 5 months prior to diagnosis:

Illness type (e.g., gastrointestinal illness, injury)	Hospitalisation required (yes/no)	Date of onset/ days to resolution	Primary Symptoms	Over the counter or prescribed medication taken

Please describe any other medication the case has been prescribed in the 5 months prior to diagnosis	
Does the case have any underlying medical condition? Including liver related/metabolic/autoimmune/ischaemic	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, details: (diagnosis, date of diagnosis, medication)	/ /
Is the case immunosuppressed?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, details: [condition (include if primary, secondary, medication related), date of diagnosis, medication]	/ /
Does or has the case take(n) any supplements or medicines acquired, over the counter, purchased over the internet or accessed by any other methods? (Including herbal, alternative medicines, vitamins, or other supplements); specifically, prompt acetaminophen/ anti-inflammatory drugs (e.g., aspirin, ibuprofen)/anticonvulsants in the 5 months prior to diagnosis?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, details: (product, dose and frequency, where purchased)	/ /
Has the patient received any vaccine in the 5 months prior to diagnosis?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, details: (type, date of administration)	/ /
Has the patient received a COVID-19 vaccine?	Yes <input type="checkbox"/> No <input type="checkbox"/> Date:
Does the patient have autoimmune hepatitis? Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	If yes, details:

Does the patient have HLH (Hemophagocytic Lymphohistiocytosis)? Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	If yes, details:
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Section 7: Interviewee details (case or parent/guardian)			
Interviewee name:		Relationship to the case (if not interviewing the case):	
Cell phone:		Email address:	

PART B: EXPOSURE INFORMATION

Section 8: Exposure to ill contacts		
Does the case regularly go to daycare or school? Yes <input type="checkbox"/> No <input type="checkbox"/>		
Provide recent details of illnesses or infections among close contacts ³ , including group settings (e.g., outbreak in classroom), in the 5 months prior to diagnosis of the case if known:		
Nature of contact (household, daycare, etc.)	Illness type (e.g., Gastro, COVID-19)	Date of symptom onset or test result (if asymptomatic)
		/ /
		/ /
		/ /
		/ /

³ Close contacts are defined as having cared for, lived with, spent significant time within close quarters (e.g., co-worker, daycare) or had direct contact with respiratory secretions and other body fluids (e.g., feces) in the 5 months prior to case onset.

Have any close contacts been jaundiced or had a similar condition (gastrointestinal symptoms, etc.) in the 5 months prior to diagnosis of the case?

Yes ☐ No ☐

Section 9: Exposure to animals

Has the case had contact with animals? Yes ☐ No ☐

If yes, specify type of animal (e.g., dog, cat, guinea pig, livestock, backyard poultry, petting zoo, etc.):

Section 10: Travel History

In the 5 months prior to diagnosis of acute hepatitis, has the case had any day trips, travel and/or overnight visits to other households or locations? Please ensure to include any travel/trips to another province within Canada and outside Canada.

Yes ☐ No ☐

If yes, specify province, territory (circle) or country:

BC AB SK MB ON QC NB NS PE NL YK
NT NU

Has any household contact travelled or has the case been in close contact with visitors in the 5 months prior to diagnosis? Please ensure to include any travel to or visitors from another province within Canada and outside Canada.

Yes ☐ No ☐

If yes, specify province, territory (circle) or country:

BC AB SK MB ON QC NB NS PE NL YK
NT NU

Section 11: Any other information

Are there any other remarkable events, interactions, or experiences in the 5 months prior to diagnosis that have not been discussed so far that might be important or that you suspect may have caused or contributed to the illness? This may include parties or functions.

END OF QUESTIONNAIRE