policy

Health
Justice Health &
Forensic Mental Health Network

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Management of Advanced Liver Disease and Hepatocellular Carcinoma

Policy Number	1.175
Policy Function	Continuum of Care
Issue Date	15 January 2018
Summary	This policy provides guidance for the screening, assessment, treatment and monitoring of patients who are at risk of, or who are living with, advanced liver disease and/or hepatocellular carcinoma.
Responsible Officer	ED Clinical Operations
Applicable Sites	☐ Administration Centres ☐ Community Sites (e.g. Court Liaison Service, Community Integration Team, etc.) ☒ Health Centres (Adult Correctional Centres or Police Cells) ☒ Health Centres (Juvenile Justice Centres) ☒ Long Bay Hospital ☒ Forensic Hospital
Previous Issue(s)	Policy Number 1.175 (March 2014) Policy Number 1.241 (16 December 2013) Policy 2.023 (August 2010)
Change Summary	• Incorporation of advanced liver disease and hepatocellular carcinoma assessment and management
TRIM Reference	POLJH/1175
Authorised by	Chief Executive, Justice Health & Forensic Mental Health Network

1. Preface

Advanced Liver Disease (ALD) is a disease process of the liver that involves progressive destruction and regeneration of the liver parenchyma from bridging fibrosis to cirrhosis. Venous flow into the liver decreases due to this cirrhosis, leading to elevated portal pressures (portal hypertension). Portal hypertension then leads to splenomegaly, causing anaemia and thrombocytopenia. Recognised complications of ALD include ascites, hepatorenal syndrome, hepatopulmonary syndrome, variceal bleeding, liver failure and hepatic encephalopathy.

Cirrhotic patients may have stable liver functions for long periods of time, and an acute insult in the presence of advanced fibrosis and decreased functional reserve may lead to development of hepatic decompensation as a result of a progressive clinical course of ALD or they may develop acute liver decompensation rapidly due to an acute precipitating event such as variceal bleeding or sepsis.

This policy describes an integrated approach to screening, assessment and management of patients with chronic (ALD) and hepatocellular carcinoma (HCC).

There is a close nexus between chronic HBV, chronic HCV and imprisonment, as injecting drug use is a key risk factor for transmission of both of these viruses, and also a major driver of criminal activity. Although unrestricted access to testing and highly effective antiviral therapy is available for both of these chronic viral infections, only a small minority of those diagnosed in Australia are currently receiving treatment. Left undiagnosed and untreated, these infections will continue to drive a rapidly growing disease burden on the Australian Health Care System via the insidious progression of hepatic fibrosis leading to cirrhosis, ALD and culminating in, liver failure and HCC.

The NSW Ministry of Health (The Ministry) has committed to at least doubling the number of people on treatment for chronic HCV and tripling the number of people on treatment for chronic HBV, in order to avert the personal, social and health care costs of the burgeoning epidemic of ALD and its complications. The Ministry goals and the supporting targets and priorities for NSW are articulated in the *NSW HCV Strategy 2014 - 2020* and the *NSW HBV Strategy 2014 - 2020*.

Data collected during 2012-2014 in JH&FMHN from staging the degree of hepatic fibrosis by Transient Elastography (Fibroscan™) revealed that 11% of patients with chronic HCV have cirrhosis (fibrosis stage 4, or F4), indicating the substantive burden of ALD due to HCV alone in the NSW custodial system.

Cirrhosis of the liver is the greatest risk factor for Hepatocellular Carcinoma, (HCC) in Australia. HCC is the most rapidly rising cause of cancer death in Australia (Strasser 2013). Other causes of ALD include alcohol, fatty liver disease (steatohepatitis), non-alcoholic steatosis (NASH), primary sclerosing cholangitis, primary biliary cirrhosis, autoimmune hepatitis and Metabolic and or genetic causes for example Wilsons disease and Haemochromatosis.

2. Policy Content

2.1 Mandatory requirements

Staff must comply with this policy which:

- provides guidance for the holistic management of patients who have ALD and HCC;
- ensures patients affected by ALD and HCC receive appropriate information relating to the condition;

- provides clinical guidelines for management of new patients with ALD and HCC;
- provides clinical guidelines for monitoring of patients with ALD and HCC;
- provides guidelines for accommodation requirements for people living with ALD or HCC
- ensures patients living with ALD or HCC receive ongoing clinical care including antiviral therapy if appropriate; and
- ensures continuation of treatment when patients ALD or HCC enter the correctional system, move within the correctional system, or are released from the correctional system.

2.2 Implementation - roles & responsibilities

It is the responsibility of all clinical staff within JH&FMHN to provide care and treatment to patients living with ALD or HCC. It is the role of the Nurse Practitioner (NP), Transitional Nurse Practitioner (TNP) and Clinical Nurse Consultant (CNC) Hepatology to coordinate and support primary prevention (baseline endoscopy, symptoms of portal pressure and monitoring and surveillance regime) and secondary prevention (endoscopy surveillance, medication adherence and therapeutic response to medication)

Patients who are living with hepatitis, ALD or HCC must be referred to the JH&FMHN Hepatitis Nurse Led Model of Care (NLMC). They must be regularly monitored and managed by the Primary Health Care Nurses (PHN) and the public sexual health nurses (PSHN) in consultation with the Hepatology NP , TNP or CNC, including those with cirrhosis (F4) detected by FibroScan and also those with an increased risk of HCC without cirrhosis.

Further detail on staff roles and responsibilities and the processes for each of the above is provided in this policy in Section 3. Procedure content.

3. Procedure content

3.1 Identification of patients with ALD and HCC

The identification component of the clinical pathway for ALD and HCC must be commenced by the PHNs at the Reception Screening Assessment (RSA) or at the Early Detection Program Screening (EDP). Those patients who report, or are known or suspected to have ALD, must be referred through the Patient Administration System (PAS) / iPM to the PSHN who must undertake an initial ALD assessment including laboratory investigations and other clinical observations and measurements as per the *JH&FMHN Protocol for Management of ALD and HCC*. The patients must then be referred to the JH&FMHN Hepatitis Nurse Led Model of Care (NLMC).

There is an increased likelihood of fulminant hepatitis (due to reduced reserve of hepatic synthetic function) in patients with cirrhosis. Therefore as per the JH&FMHN Policy 1.245 *Immunisation of Patients*, a two dose hepatitis A immunisation (0, 6-12 months) must be offered to these patients, either as a monovalent vaccine, or combined with HBV immunisation (Twinrix 720/20) if the patient is non-immune to HBV, in accordance with the *Australian Immunisation Handbook*.

3.2 Laboratory Monitoring

Laboratory monitoring must be consistent with the *JH&FMHN Protocol for Management of ALD and HCC*.

3.3 History and clinical assessment for ALD and HCC

The NLMC NP / TNP / CNC Hepatology will undertake a further history, clinical assessment and Fibroscan using the *NLMC Advanced Liver Disease (ALD) Clinical Assessment Form* JUS060.340. For those patients with ALD or HCC who are also living with chronic HCV or chronic HBV, the NLMC NP / TNP / CNC will also undertake further targeted assessment and complete the *NLMC Hepatitis C Clinical Assessment Form* JUS060.342 or the *NLMC Hepatitis B Clinical Assessment Form* JUS060.341. Upon completion of the form or forms, a specialist consultation should be undertaken (by discussion only or face-to-face) to determine whether a person to person consultation with the patient is required and to designate ongoing monitoring, management and treatment requirements.

Patients with stable ALD may then be managed in a shared care arrangement with the General Practitioner (GP) and the NLMC NP / TNP / CNC Hepatology and the Infectious Diseases (ID) Specialist or Hepatologist and ID Registrar. Establishment and ongoing management of this shared care arrangement is communicated by the relevant waitlist entries. The recommended review intervals for the NP / TNP / CNC, GP and the Specialists as well as the clinical and laboratory monitoring parameters will be directed by the NP / TNP / CNC in consultation with the Specialists. Suggested medical interventions for patients with ALD, but with relatively stable liver function, are outlined in the *JH&FMHN Protocol for Management of ALD and HCC*. The frequency and recording of clinical monitoring must be documented in the patient's health record and the next consultation waitlisted. Patients with stable ALD including compensated cirrhosis can be housed in a Centre with or without 24 hour Nursing presence.

The specialist consultation is undertaken by discussion only, by telehealth, by telephone or face-to-face and the consultation is documented in the patients' health record. If the consultation is not face to face, the documentation will be faxed by secure fax or emailed to the relevant centre. The originals will be mailed to the patient's clinic by the RN working with the specialist during the consultation.

Patients with unstable ALD requiring immediate intervention must be transferred to the local hospital's Emergency Department. Refer to JH&FMHN policy 1.252 *Access to Local Public Health Services*. Patients with unstable ALD, including decompensated cirrhosis that are not requiring transfer to hospital, must be housed in a Centre where there is 24 hour nursing presence.

Resuscitation of patients with proven or suspected variceal bleeding must be done in accordance with JH&FMHN *Adult Emergency Response Guidelines* and the *JH&FMHN Protocol for Management of ALD and HCC*. Proven or suspected spontaneous bacterial peritonitis (SBP) must be managed according to the *JH&FMHN Protocol for Management of ALD and HCC*.

3.4 Screening for HCC

Regular screening for HCC is facilitated by the PSHNs in consultation with the NLMC NP / TNP / CNC, for all those identified with cirrhosis (F4) detected by FibroScan, and also those with an increased risk of HCC without cirrhosis (Asian males with chronic HBV over 40 years, Asian females with chronic HBV over 50 years, African males with chronic HBV over age 20 years, a family history of HCC). In addition to those with chronic HBV or HCV, those with cirrhosis due to alcohol, haemochromatosis, and auto-immune liver diseases are at an increased risk for HCC and must be screened.

This screening consists of six monthly upper abdominal ultrasound. A suspicious lesion found on ultrasound must trigger a referral by the NLMC TNP / CNC for urgent triple phase CT or MRI scan, followed by specialist review.

3.5 Monitoring of ALD

Monitoring of patients on HCV and HBV treatments is the responsibility of the health centre where the patient is located. Staff should liaise with the PSHN or CNC/TNP Hepatology for any questions or concerns.

Regular monitoring of ALD must be undertaken in all those with cirrhosis (F4) detected by FibroScan or suspected on the basis of clinical or laboratory findings. The *NLMC Advanced Liver Disease (ALD) Clinical Assessment Form* JUS060.340 must be completed for these patients. Upon completion of the Form, a specialist consultation should be undertaken (by discussion only or face-to-face) to determine whether a face-to-face consultation with the patient is required and to designate ongoing management and monitoring requirements.

Clinical or laboratory evidence of liver failure (decompensated cirrhosis) may include:

- ascites
- peripheral oedema
- encephalopathy
- portal hypertension
- subacute bacterial peritonitis
- gastro-oesophageal varices
- coagulopathy, jaundice
- hepato-renal syndrome

For these patients the PSHN or PCN will undertake more frequent monitoring – as determined by CNC/NP/TNP and the specialist. This monitoring will also generally include:

- temperature, pulse, blood pressure, handwriting and star charts, in addition to weight and girth;
- FBC, LFTs, UECs, and INR testing;
- at least six monthly HCC screening by ultrasound

For those without clinical or laboratory evidence of liver failure (compensated cirrhosis), this monitoring will be undertaken by the PSHN or PCN, at a frequency determined in consultation with the CNC/NP/TNP and the specialist:

- temperature, pulse, blood pressure, handwriting and star charts, in addition to weight and girth;
- FBC, LFTs, UECs, and INR testing;
- at least six monthly HCC screening by ultrasound.

Endoscopic screening for varices should be performed in all patients once the diagnosis of cirrhosis is established. In patients with compensated cirrhosis who have no varices on screening endoscopy, endoscopic screening should be repeated in 2-3 years. In those who have small varices, the endoscopy should be repeated in 1-2 years. In the presence of decompensated cirrhosis, the endoscopy should be repeated at yearly intervals.

3.6 Lifestyle

Patients must be given information regarding management of their ALD, an explanation of what cirrhosis is, why it is a problem, what the signs and symptoms are and what the signs and symptoms of decompensation are. Information needs to be given about appropriate dietary management and fluid intake, exercise and sleep patterns and requirements and medication management.

3.7 Continuity of care

Ensuring continuity of care is a high priority for patients who are released to freedom whilst living with ALD or HCC. Patients must continue their treatment in the community without interruption due to the clinical risks associated with missing medications and regular review and support.

Prior to the patient's departure, health centre staff must liaise with JH&FMHN Pharmacy regarding discharge medications. Staff must also ensure the patient is provided with all appropriate follow up information including but not limited to JHeHS Release Summary and Transfer of Care summary (including medications and follow up appointments) and FibroScan report.

Staff handing over care of the patient must endeavour to connect the patient with a GP, specialist MO and make arrangements with the patient for the required information below to be sent to the nominated service/address or to be provided to the patient upon release, or both. The Hepatitis NSW Directory provides a listing of available services by postcode. Staff must obtain contact details in the community for the patient and record this information in the patient's health record. All clinical staff should liaise with a PSHN for clarification of this process as required.

3.8 Palliative Care and End of Life Choices

Appropriate palliative care measures must be considered for patients with ALD. The ID Specialist or Hepatologist will consult with the patient regarding if and when to be referred to Palliative Care Services. These should include, but not be limited to, a referral by the ID Specialist or Hepatologist to a palliative care specialist, a pain management team, the CNS 2 Cancer Care Coordinator, Integrated Care and about hospital or hospice placement. Early release for health-related reasons should be considered and managed according to JH&FMHN policy 1.170 *Early Release for Health-Related Reasons*. End of life treatment decisions must be made in consultation with the patient, his/her family, the treating medical team and the Legal Advisor, Governance Unit in accordance with the Ministry Guidelines GL2005_057 *End of Life Care and Decision Making Guidelines*, and PD2014_030 *Using Resuscitation Plans in End of Life Decisions* and JH&FMHN policy 1.174 *End of Life Care, Not for Cardio-Pulmonary Resuscitation Orders and Advance Care Directives – Adult Centres Only*. Deaths associated with ALD must be managed in accordance with JH&FMHN policy 1.120 *Management of a Death*.

3.9 Documentation and Alerts

Information relating to patient care is to be documented in the patient's Health Record and an alert must be placed in iPM PAS

e.g. Clinical/Gastrointestinal/Advanced Liver Disease

4. Definitions

Must

Indicates a mandatory action to be complied with.

Should

Indicates a recommended action to be complied with unless there are sound reasons for taking a different course of action.

5. Legislation and Related Documents

JH&FMHN Policies and Procedures and Guidelines	1.034 *Admission and Assessment - Medical and Surgical Unit Long Bay Hospital* 1.120 *Management of a Death* 1.170 *Early Release for Health-Related Reasons* 1.141 *Release Planning and Transfer of Care Policy - Adult Ambulatory Setting* 1.142 *Discharge Planning - Medical Subacute and Aged Care Rehabilitation Unit* 1.174 *End of Life Care, Not for Cardio-Pulmonary Resuscitation Orders and Advance Care Directives – Adult Centres Only* 1.231 *Health Problem Notification Form (Adults)* 1.235 *Health Problem Notification and Escorts Form (Adolescents)* 1.241 *Hepatitis C and B Care Management and Treatment* 1.245 *Immunisation of Patients* 1.252 *Access to Local Public Health* *Adult Emergency Response Guidelines* *Protocol for Management of Advanced Liver Disease and Hepatocellular Carcinoma*
JH&FMHN Forms	JUS005.001 *Health Problem Notification Form* JUS005.002 *Health Problem Notification and Escort form (Adolescents)* JUS030.303 *NLMC HEPATITIS INITIAL ASSESSMENT FORM* JUS060.341 *NLMC HEPATITIS B CLINICAL ASSESSMENT FORM* JUS060.342 *NLMC HEPATITIS C CLINICAL ASSESSMENT FORM* JUS060.340 *NLMC ADVANCED LIVER DISEASE (ALD) CLINICAL ASSESSMENT FORM* JUS110.306 *Star and Handwriting Chart*
NSW MoH Policy Directives, and	*NSW HCV Strategy 2014 - 2020* *NSW HBV Strategy 2014 - 2020*

Guidelines	GL2005_057 *End of Life Care and Decision Making Guidelines* PD2014_030 *Using Resuscitation Plans in End of Life Decisions*
Other Guidelines	Hepatitis NSW Directory *Gastroenterological Society of Australia: Clinical Guidelines and Updates:* *American Association for The Study of Liver Diseases: Practice Guidelines* *European Association for the Study of The Liver: Clinical Practice Guidelines*Australasian Hepatology Association Consensus- Based Guidelines: www.hepatologyassociation.com.au