

ETHOS Cohort

<p>STUDY TITLE:</p>	<p>ETHOS Cohort (Enhanced Treatment for Hepatitis C in Opioid Substitution Settings)</p> <p>The ETHOS Cohort has been developed to examine HCV assessment, treatment uptake, response to therapy and re-infection following successful treatment among people with chronic HCV infection and a history of injection drug use. In addition, this study will evaluate the expected cost-effectiveness of providing assessment and treatment for chronic HCV infection in the opiate pharmacotherapy setting.</p>
<p>STUDY OBJECTIVE:</p>	<p>Among patients with chronic HCV infection and a history of injecting drug use, the specific objectives of this study are to examine:</p> <ol style="list-style-type: none"> 1. Uptake of HCV treatment and associated factors. 2. Response to HCV treatment and associated factors. 3. Incidence of HCV re-infection following sustained virological response. 4. Expected cost-effectiveness of providing HCV assessment and treatment.
<p>STUDY DESIGN:</p>	<p>A prospective observational cohort in patients with chronic HCV and a history of injection drug use.</p> <p>Data collected at enrolment and subsequent follow up visits includes:</p> <ul style="list-style-type: none"> ▪ Practitioner administered questionnaires : <ul style="list-style-type: none"> - Demographics - Injecting drug history and behaviours - Drug use and treatment history - Hepatitis C information - Social functioning - Mental health assessment (MINI & DASS21) ▪ Case note review: <ul style="list-style-type: none"> - Full medical and psychiatric history - Markers of liver disease - History of HCV assessment ▪ Pathology test results ▪ Measure of health status and outcome (EQ-5D) ▪ Resource Usage Form
<p>STUDY DRUGS:</p>	<p>N/A</p>

STUDY COMPLETION DATE:	Recruitment stop date: 31-December 2012 Study closure date: 31-December 2014
IS THE STUDY OPEN TO ENROLLMENT?:	This study is currently open to enrolment at participating sites. <i>Inclusion Criteria:</i> <ul style="list-style-type: none"> ▪ ≥ 18 years of age. ▪ Written informed consent. ▪ Chronic HCV infection as determined by HCV antibody positive and HCV RNA positive. <i>Exclusion Criteria:</i> <ul style="list-style-type: none"> ▪ Acute hepatitis symptoms. ▪ ALT ≥ 10xULN. ▪ Negative or unknown HCV antibody status.
NUMBER OF PATIENTS ENROLLED/TARGET ENROLLMENT:	244/500
SPONSOR:	The National Centre in HIV Epidemiology and Clinical Research
PARTICIPATING SITES:	<ul style="list-style-type: none"> ▪ <i>Clinic 36:</i> outreach hospital for RPAH ▪ <i>Centre for Addiction Medicine:</i> Blacktown Methadone Unit and Fleet Street Opioid Treatment Unit, Sydney West Area Health Service ▪ <i>Kite Street Medical Centre:</i> Orange ▪ <i>Newcastle Pharmacotherapy Service:</i> Hunter New England NSW Health Service ▪ <i>Gateway Clinic and Woodland Clinic:</i> Sydney West Area Health Service ▪ <i>Rankin Court Treatment Centre:</i> St Vincent's Hospital ▪ <i>Regent House:</i> outreach clinic of RPAH ▪ <i>Aboriginal Medical Service:</i> Western Sydney ▪ <i>Kirketon Road Centre:</i> South Eastern Sydney and Illawarra Health Service
CONTACT PERSON:	Michelle Micallef P +61 2 9385 0878

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