Single Centre Retrospective Investigation of the rates and Patterns of screening for hepatocellular carcinoma (HCC) in patients with cirrhosis, or other significant risk factors for the development of HCC, in a regional catchment area of NSW

Short Title: SCRIPT HCC – rates and patterns of screening for HCC in patients in the Hastings Macleay region.

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Abbreviations

AIH	Auto Immune Hepatitis
CLD	Chronic Liver Disease
HARP	HIV and Related Programs
HBV	Hepatitis B Virus
HCC	Hepatocellular Carcinoma
HCV	Hepatitis C Virus
HMLC	Hastings Macleay Liver Clinic
MNCLHD	Mid North Coast Local Health District
NAFLD	Non-alcoholic Fatty Liver Disease
SCRIPT HCC	Single Centre Retrospective Investigation of the rates and Patterns of screening for HepatoCellular Carcinoma
USS	Ultrasound Screen

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Abstract

Background: Hepatocellular Carcinoma is the fifth most common cause of cancer in the world and evidence suggests surveillance can reduce mortality by 37%, even if adherence is poor. Screening for HCC reduces mortality and morbidity in patients with liver disease through early detection and by increasing options for appropriate interventions. Early detection via surveillance have been reported to lead to cost–savings of approximately AUD$68,000 per year of life saved. Integrated care for patients with cirrhosis is necessary to provide a continuum of care between services, thereby decreasing HCC and general liver related deaths (European Association for the Study of the Liver, 2018).

The aim of SCRIPT HCC is to determine the current screening rates and patterns for patients attending the Hastings Macleay Liver Clinic with cirrhosis or with Hepatitis B risk factors for the development of HCC.

Methods: This study was a two-year retrospective descriptive epidemiological investigation of the existing rates and patterns of surveillance for liver cancer by the Hastings Macleay Liver Clinic. Demographic and clinical data were retrieved from patient medical records using an audit tool designed for collection of variables associated with rates and patterns of screening for hepatocellular carcinoma. Data were analysed using descriptive and comparative statistical analysis in Microsoft excel and STATA.

Results: HCC surveillance screening rates in the Hastings Macleay Liver Clinic exceeded recommended timeframes with a significant decrease in number screened from first to fourth recorded ultrasound (31% vs. 2%, p= 0.016). Seventy percent of participants were male, and alcohol (84%) and hepatitis C virus (87%) were the highest aetiological cause of cirrhosis.

Discussion and Implications for practise: Systems to improve HCC surveillance programs are needed to ensure best clinical outcomes for patients living in regional New South Wales. Specific recall systems within the service coupled with national or state registries for people living with cirrhosis could provide a foundation for improving care for this population. A follow-up study investigating barriers to screening in a local context is recommended with the aim of improving existing screening rates. Although the rates are low (31% at first interval) studies have shown that even with adherence rates as low as 33% mortality can be reduced by early detection of HCC.

Keywords: Hepatocellular Carcinoma, Liver Cancer, Ultrasound, Screening.

Executive Summary

SCRIPT HCC is an investigation into existing rates and patterns of screening for liver cancer in people living in the Hastings Macleay region who attend the Hastings Macleay Liver Clinic. The clinic services the lower half of the Mid North Coast Local Health District (MNCLHD) in NSW under the auspices of HIV and Related Programs (HARP) and the North Coast Public Health Unit. Clinicians have developed an integrated model of care called *De**LIVER**ing Integrated Care* with a focus on the prevention, management and screening of liver disease. SCRIPT HCC constitutes the first phase of evaluation for one aspect of this model, 'Cirrhosis Surveillance'. Analysis of the existing rates and patterns of screening of those who are at risk of developing liver cancer (Hepatocellular Carcinoma (HCC)) provides baseline data that will inform future evaluation and interventions aimed at reducing morbidity and mortality due to liver disease in a regional setting .

In 2017 almost 2,000 people died from liver cancer in Australia (Australian Institute of Health and Welfare, 2017; Qian et al., 2010). Six monthly surveillance screening with ultrasound can detect small and potentially curable tumours early, improving survival following cancer diagnosis (Qian et al., 2010). The Cancer Council of Australia state that cancer survival declines with increasing remoteness (Cancer Council Australia, 2018). Surveillance becomes cost-effective when life expectancy is increased by at least three months and when the intervention (e.g. ultrasound) falls below a financial threshold – AUD$68,682 'per year of life saved', (European Association for the Study of the Liver, 2018). Therefore, the approximate cost of an ultrasound twice a year is measured against the potential cost of cancer interventions such as a liver resection, trans-arterial chemo-embolization (TACE) procedure or liver transplant costs.

It is an ongoing challenge to support people living in regional NSW to obtain optimal health care, even when specialist public health services are available. Waiting times for radiological testing and distances required to travel for services are commonly cited barriers to accessing services (Cancer Council Australia, 2018).

Sixty-one participants' clinical files were examined to determine what intervals people in the Hastings Macleay region were receiving ultrasounds for liver cancer screening. The study sample were predominantly male, in their mid-50s, with cirrhosis from alcohol and hepatitis C. Rates and patterns of screening in the Hastings Macleay Liver Clinic did not meet recommended guidelines, with many participants (from 51% at first screen up to 97% by fourth screen) having no recorded ultrasounds within the two year study timeframe. Surveillance ultrasounds allow for early detection of small liver cancers that can be treated with less invasive procedures – resulting in reduced length of stay (LOS) in hospital, decreased morbidity and improved quality of life.

Recommendations

Evaluation of current practice: It is recommended that an evaluation be undertaken of the revised clinic practice of providing radiology requests no more than three months in advance. This altered timeframe provides a 'buffer' of one month for requests and appointment letters is to be established in combination with a database management system that calculates 'due dates' for patients next screening ultrasound. An existing system has been in use since October 2017 and is due for review in October 2018 with the aim of continually improving patient health outcomes.

Access to health educator/counsellor: Increased access to the health educator/counsellor through the service. This service is currently available however in a limited capacity. The recommendation will increase access enabling the Health educator/counsellor to assist patients in making ultrasound bookings, support their attendance at appointments and navigate health system processes, including the Isolated Patients Travel and Accommodation Assistance Scheme (IPTAAS) process and palliative care engagement.

Collaborative and integrated Care: It is recommended that the service investigate the potential collaboration with local Radiology companies to set up appropriate recall and reminder systems for surveillance screening. Text message reminders improve attendance and therefore patient outcomes.

Further Comments:

As the health burden from Non-Alcoholic Fatty Liver Disease (NAFLD) increases in Australia, it has become important that services dealing with liver disease begin developing guidelines for providing surveillance for these patients. This is especially important as NAFLD, with or without cirrhosis, has an ever-increasing risk of developing HCC. The health burden of NAFLD in the Hastings Macleay district is problematic, with a low socio-economic population, increasing obesity in children and adults and an aging population the aim is to make sure that processes can be future proofed, i.e. not dependant on any particular staff member. Multi-systems approaches are needed if we are to improve outcomes for people living with cirrhosis – if we do nothing the health and economic burden will increase due to late diagnosis of HCC and reduced options for positive outcomes.

Introduction

SCRIPT HCC investigates the screening rates and patterns for Hepatocellular Carcinoma (HCC) in people with cirrhosis, or other risk factors for the development of HCC, in people living in the Hastings Macleay region who attend the Hastings Macleay Liver Clinic.

The Hastings Macleay Liver Clinic services the lower half of the Mid North Coast Local Health District (MNCLHD) in NSW from Stuarts Point to Laurieton. It is a rural / regional area and sits under the auspices of Human Immunodeficiency Virus (HIV) and Related Programs (HARP) and the North Coast Public Health Unit. The clinic has been developing an integrated model of care since early 2014, which has evolved into the *De**LIVER**ing Integrated Care Model* with a focus on the prevention, management and screening of liver disease. *The De**LIVER**ing Integrated Care Model* provides a three-pronged framework for providing care for patients with Viral Hepatitis and Chronic Liver Disease (CLD). The first prong is working with local drug and alcohol services to assess, treat and manage clients with viral hepatitis, primarily Hepatitis C Virus (HCV). The second prong provides a systematic approach to cirrhosis surveillance – monitoring patients with cirrhosis for early detection of HCC. Prong three provides case management for patients with CLD and liver failure.

SCRIPT HCC addresses the evaluation process for one aspect of this model, namely 'Cirrhosis Surveillance', through analysis of the existing rates and patterns of screening of those who are at risk of developing HCC. These results will provide baseline data and variables that will inform future evaluation and interventions thus improving morbidity and mortality due to liver disease in a regional setting.

Background and rationale

Hepatocellular Carcinoma is the fifth most common cause of cancer in the world, (Shoreibah, Bloomer, McGuire, & Massoud, 2014). It represents the second highest cause of death from cancer globally (European Association for the Study of the Liver, 2018; Marrero et al., 2018; Patel et al., 2012). Approximately 2-4% of patients with cirrhosis will develop an HCC each year in Australia (McCaughan et al., 2016) with only 15% diagnosed living beyond five years (Heimbach et al., 2018). Nearly 2,000 people died from liver cancer in Australia in 2017 (Australian Institute of Health and Welfare, 2017; Qian et al., 2010). Hepatitis B Virus (HBV) can lead to liver cancer with or without cirrhosis and early detection can prevent thousands of deaths from the disease (NSW Ministry of Health, 2014a).

Surveillance with ultrasound can detect small and potentially curable tumours early in the disease process, improving survival following cancer diagnosis (Qian et al., 2010). Specific population based surveillance is considered appropriate for people living with cirrhosis when the HCC risk exceeds 1.5% per year and 0.2% for people living with HBV (Giannini et al., 2013b) . Surveillance is cost-effective

when life expectancy can be increased by at least three months and the cost of the intervention falls below a 'financial threshold' – which amounts to approximately AUD$68,600 'per year of life saved', (European Association for the Study of the Liver, 2018).

Cirrhosis is a major risk factor for HCC development with an estimated 85-95% of HCC occurring on a background of cirrhosis (Heimbach et al., 2018). Cirrhosis is defined for this study using one or more factors: Fibroscan score >12.5; documented clinical or biochemical results; exam findings or by expert radiological interpretation of ultrasound (Asrani, 2017).

Box 1: Recommendations for HCC surveillance for people living with Cirrhosis or HBV risk factors

- All people with cirrhosis
- Hepatitis B:
  - ⇒ Those with a first-degree family history of HCC
  - ⇒ Asian men aged >40 years, and Asian women aged >50 years
  - ⇒ African people aged >20 years
  - ⇒ Aboriginal or Torres Strait Islander people aged >50 years

Causal agents for cirrhosis include Hepatitis B and Hepatitis C, alcohol abuse, metabolic disease and hereditary haemochromatosis (European Association for the Study of the Liver, 2018). HBV, which is blood born and sexually transmissible, can lead to HCC in the absence of cirrhosis (World Health Organisation, 2018). This subgroup of people considered 'at risk' of developing liver cancer (Box 1) include people from high prevalence countries, Aboriginal and Torres Strait Islander peoples, populations in which the prevalence of the disease is higher (NSW Ministry of Health, 2014a).

Current guidelines (European Association for the Study of the Liver, 2018; Marrero et al., 2018) recommend that *all* people with cirrhosis and those with HBV risk factors have six monthly ultrasounds +/- Alpha Feta Protein (AFP) blood test, as part of an HCC surveillance screening program. Surveillance is differentiated from screening by its application of 'screening tests' in a population identified as 'at risk' (Giannini et al., 2013a). HCC is not reliably detectable by simple pathology and is asymptomatic in the early stages of the disease (Patel et al., 2012; Qian et al., 2010).

Variability exists amongst reported screening adherence rates from as low as 12% amongst a veteran population of 13,002 patients with cirrhosis to as high as 93% in a dedicated chronic liver disease program with 355 participants (Aberra, Essenmacher, Fisher, & Volk, 2013; Qian et al., 2010; Shoreibah et al., 2014). Surveillance provided under the care of a Hepatologist or Gastroenterologist was found to be 51.4% whilst patients seen by a primary health provider were screened less effectively at 16.9% (Shoreibah et al., 2014). These findings suggest that even when service providers are focused on HCC screening there is significant deviation from adherence to recommended guideline

intervals (Allard et al., 2017; Kudo, 2015). However A Chinese surveillance study identified that even with adherence rates as low as 33% a reduction in mortality by 37% has been reported. (European Association for the Study of the Liver, 2018; Kudo, 2015).

This also highlights the potential for improvement in surveillance leading to decrease mortality.

To date, no studies have been published that are specifically aimed at reporting adherence levels of HCC surveillance programs in regional Australia. Where health care associated costs and access to health care facilities and services present barriers to optimal health management. Regional patients face a challenge in access to these curative treatments with patients having to travel to larger metropolitan tertiary hospitals for treatment (Cancer Council Australia, 2018). Transport costs, living away from home expenses, accommodation and associated costs widen the metro – regional divide (Cancer Council Australia, 2018). The ageing patient demographic (patients with liver cirrhosis) of the Hastings Macleay Network increases the likelihood of comorbidities that preclude patients from curative treatments such as resection and transplant (Marrero et al., 2018), true of Port Macquarie where almost 28% of the population are aged 65 years and over (Australian Bureau of Statistics, 2016b). The Australian Cancer Council (2018) have identified that as remoteness increases -> cancer survival rates decline.

Regions of the Hastings Macleay Network have significantly higher proportion of Aboriginal and Torres Strait Islander people – Kempsey for example has 11.6% compared to NSW (2.9%) and Australia (2.8%) (Australian Bureau of Statistics, 2016a). Liver cancer mortality in this population is higher than for non-Aboriginal Australians (Brown, 2017). Regional areas such as Port Macquarie are opening up to refugee resettlement which therefore will increase the demographic at risk (Asian and African descent) of developing HBV associated HCC (Telford, 2018).

Underdiagnoses and subsequent delayed identification of HCC can have devastating consequences for patients living in rural and regional areas, particularly when access to appropriate treatment then requires longer time away from family, support networks and work. Alternately, appropriate screening can lead to the early detection of potentially curable HCC and better survival (NSW Ministry of Health, 2014b). It is therefore important to determine the rates and patterns of screening for HCC in 'at risk' patients in regional NSW, so that these can be compared to existing guidelines and service delivery to patients at risk of developing liver cancer can be improved.

Research Aim and Question

The aim of this study is to determine the current surveillance rates of hepatocellular cancer using six monthly liver ultrasound and alpha feta protein for individuals with cirrhosis, and/or established risk factors for the development of hepatocellular cancer, attend the Liver Clinic within the Hastings Macleay Network in regional NSW.

Short-term objectives include:

1. To determine baseline rates and patterns of screening for HCC in 'at risk' patients over a 2-year period.
2. Compare the results to existing guidelines to assess adherence to surveillance guidelines within the clinic.

SCRIPT HCC aims to answer the question, 'What are the current rates and patterns of screening for HCC in the Hastings Macleay Region?'

It is hypothesised that surveillance rates for HCC in the Hastings Macleay region are below recommended guidelines.

Methods

SCRIPT HCC is a retrospective descriptive epidemiological analysis (Mosby's Medical Dictionary, 2009) of the existing rates and patterns of surveillance for liver cancer occurring within the Liver Clinic within the Hastings Macleay Network.

Disease characteristics

Cirrhosis was determined using an existing Metavir Score >4, Fibroscan score ≥12.5, documented clinical notes from referring physician +/- physical signs noted in the medical record. Cirrhosis occurs when there is significant hepatic injury and scarring that leads to regenerative nodules surrounded by fibrotic tissue. Cirrhosis hinders effective functioning of the liver and leads to portal hypertension and increased risk of developing liver cancer (Tsochatzis, Bosch, & Burroughs, 2014). Chronic Hepatitis B virus (HBV) can lead to cirrhosis and liver cancer (World Health Organisation, 2018), however, HBV can progress to liver cancer without the patient having cirrhosis therefore a subgroup of people living with HBV require routine HCC surveillance (NSW Ministry of Health, 2014a). For the purposes of this study, five categories were used to differentiate the reason for surveillance: HCV, HBV with cirrhosis; HBV without cirrhosis; Alcohol, Non-alcoholic Fatty Liver Disease (NAFLD) and Autoimmune Hepatitis (AIH). Alcohol was considered an aetiological contributor if documented to ever have had 'self-reported' moderate to heavy alcohol intake (Mathurin & Bataller, 2015).

Study location

The Hastings Macleay Liver clinic (HMLC) covers two primary geographic areas with one clinic physically located in Kempsey and the other in Port Macquarie. According to the Australian Statistical Geography Standard Remoteness Structure, Australian states and territories are divided into five Remoteness Areas (RAs) based on resident access to services. Inner cities (0-having greatest access to services), Inner Regional (1), Outer regional (2), Remote (3) and very remote ((4) – representing the poorest access to services). The HMLC sits within two of the five remoteness areas – Clinic 1 in 'Outer Regional' whilst Clinic 2 is considered 'Inner Regional' (Australian Bureau of Statistics, 2018).

Two Private Gastroenterologists provide specialist-consulting services to regional patients via a public clinic that operates under the auspices of North Coast HIV and Related Programs (HARP). There are currently 389 patients registered to these services with patients most commonly attending the clinic within their geographical area. Telehealth has been utilised regularly over the past 12 months as a means of increasing patient contact for specialist consultations.

Participants

Existing lists and current clinical databases (as at August 2017) of HMLC service patients were used to identify potential participant records. Patient records of those on these lists were retrieved, with individuals who had been cited as having cirrhosis, advanced liver disease or HCC surveillance requirements identified as eligible for participation in the study. A list of all identified eligible participants was collated into one list that was transferred to a re-identifiable Excel spreadsheet and

given a SCRIPT study number. This number was used on the audit sheet to ensure confidentiality of patient information during data collection and analysis.

Outcome measures

The primary outcome measured is the 'time between ultrasounds' to determine if participants are screened within the recommended six monthly time frame. The first recorded ultrasound was identified as the baseline ultrasound and the time in months was measured from this date to the next recorded ultrasound and from the second to the third, third to fourth and fourth to fifth if they were recorded. The secondary outcomes were variances that potentially influence rates and patterns of screening for hepatocellular carcinoma including geographic location of the participant in relation to the clinic they attend, gender, aboriginality and aetiology of disease.

Data collection

Retrospective data collection was conducted using Medical Records and Electronic Medical Records – (ultrasound scans and associated indicators) for the period from 31 August 2015 to 31 August 2017. Demographic and clinical characteristics were collected using an audit tool designed by the investigator (Appendix A). Participant first recorded ultrasound became the 'baseline ultrasound' (USSBL) enabling consistent measurement of 'time since last ultrasound' for each consecutive ultrasound – labelled USS#1, USS#2, USS#3 and USS#4. A one month lee-way was provided therefore ultrasounds attended within 0-7months were accepted as within recommended screening timeframe. There was potential for four to five ultrasounds to be documented in this timeframe, based on hepatocellular carcinoma screening recommendations (European Association for the Study of the Liver, 2018; Heimbach et al., 2018).

Ultrasounds were grouped in time since last ultrasound in months in three categories; less than seven months since last ultrasound - indicating adequate screening, Greater than seven months as inadequate screening and not recorded indicated that no ultrasound had been attended. Radiology not recorded in the medical record is considered not attended because under the NSW Health policy directive (New South Wales Ministry of Health, 2012) clinicians are responsible for documenting patient care accurately and adequately to reflect patient care therefore if not documented then the activity 'did not happen'.

Data analysis

Data collation and analysis were performed under the supervision and advice of a Local Health District (LHD) statistician (AH). Microsoft Excel was used to perform the descriptive analysis of demographic data. Analysis of categorical variables were conducted using Pearsons chi square, with a significance level of $p<0.05$ in STATA statistical analysis program (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP.)

Ethics approval was received via North Coast NSW Human Research Ethics Committee (NCNSW HREC) Reference: LNR/17/NCC/90 – LNR168 – 4th of September 2017. Site-specific assessment (SSA) was submitted to the MNCLHD Research Governance Office and was approved on the 2nd of November 2017 (LNRSSA/17/NCC/105).

Results

There were 142 participants identified for auditing (Figure 1). Of these, 39 were excluded due to ineligibility because of: enrolment outside of the study period (OOSP), existing HCC (requires more frequent monitoring), transferred to private Gastroenterology services, not having cirrhosis, referred by GP but 'Did not attend' for assessment or patient deceased. Of the remaining 103 participants, 41% were either lost to follow up, discharged from service or not audited due to time constraint of the study. Therefore 59% (n = 61) of eligible participant files were audited.

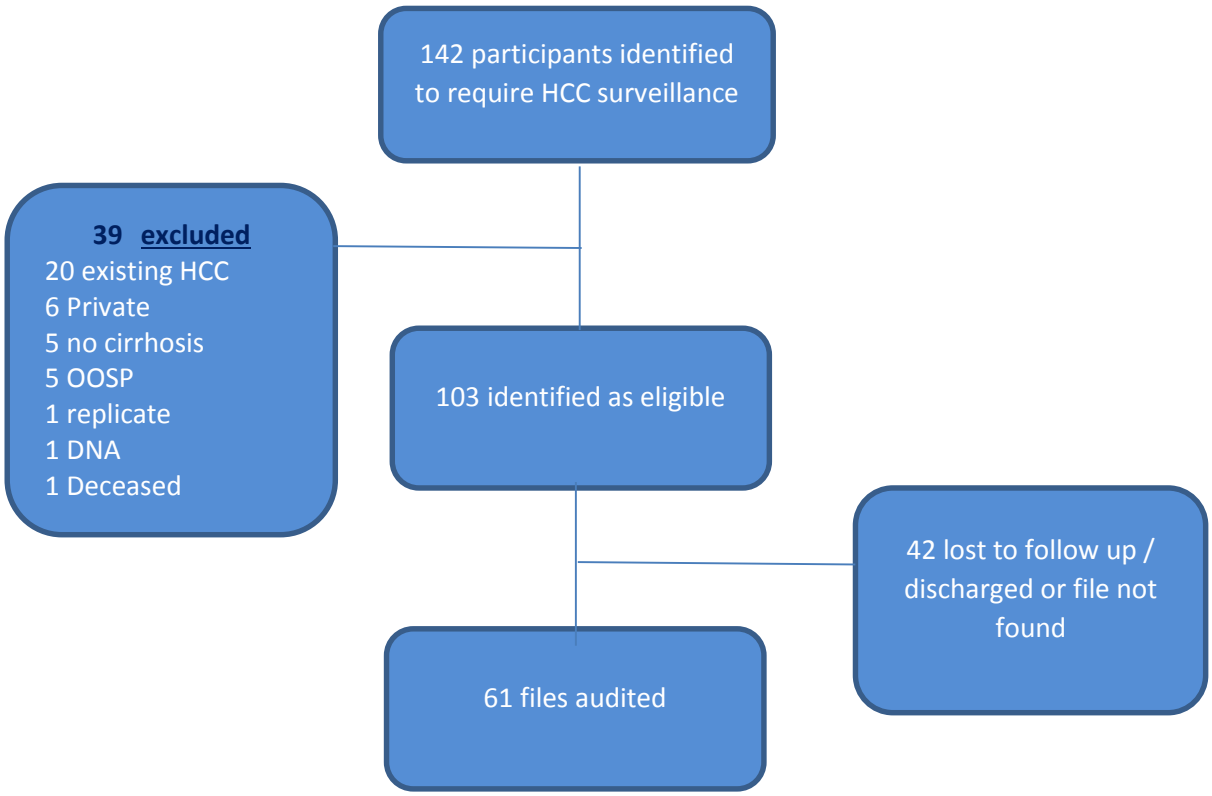

Figure 1: Participant selection process

Demographic and aeteological characteristics of participants

The mean age of participants was 56 years (Table 1). Seventy percent were men and 30 percent women with similar gender ratios observed in Clinic 1 and Clinic 2 (73:27% and 68:32% respectively). Participants travelled on average 21.9 Km to services with the furthest travelled 92.2 kilometres to Clinic 1 and less than one kilometre to Clinic 2.

Alcohol and HCV were the main cause of cirrhosis accounting for 84 and 87% respectively. There were 72% of participants with both HCV and Alcohol as the aetiology of their cirrhosis. Surveillance due to HBV (with or without cirrhosis) accounted for two participants. Auto Immune Hepatitis was not identified in any participants. Eight percent of participants were Aboriginal and 2% of African descent.

TABLE 1: DEMOGRAPHIC DATA: BETWEEN 2 CLINIC LOCATIONS

Characteristics		Combined (n=61)	Clinic 1 (n=30)	Clinic 2 (n=31)
Age in years	(mean ± s.d.)	56 ± 8.2	56 ± 7.7	56 ± 9.0
Gender n (%)				
	Male	43 (70)	22 (73)	21(68)
	Female	18 (30)	8 (27)	10 (32)
Kilometres (Km)	(mean)	21.9	20.3	23.6
	High	92.2	92.2	79.3
	Low	0.8	1.2	0.8
Aetiology n (%)				
	Alcohol §	51(84)	25 (83)	26 (84)
	Viral Hepatitis ¥	53 (87)	24 (80)	29 (94)
	NAFLD	2 (3)	1 (3)	1 (3)
Aboriginality n (%)				
	Aboriginal	5 (8)	2 (7)	3 (9)
	African female >20	1 (2)	0 (0)	1 (3)

§ Alcohol and Viral Hepatitis aetiologies commonly overlap (n=44 (72)

¥ HBV with cirrhosis / no cirrhosis included in viral hepatitis (n=2)

Surveillance Ultrasounds

Adequate surveillance ultrasounds were performed for 31% of participants at the first ultrasound; 16% at the second; 11% at the third and 2% at the fourth ultrasound. The difference in proportion of participants receiving adequate screening at first ultrasound compared to fourth ultrasound was statistically significant (31% vs. 2%, p= 0.016). Ultrasounds were performed, but outside the adequate timeframes for 18% of participants at first recorded follow-up ultrasound; 13% at second; 3% at third and 2% of participants attended their ultrasound within an inadequate time interval at the fourth recorded follow-up ultrasound. The number of participants with no recorded (NR) ultrasound increased at each interval with 51% NR at first ultrasound; 70% at second; 85% at third and 97% of participants having no recorded ultrasound at fourth ultrasound interval (Table 2).

Table 2: Number and percentage of ultrasound scans conducted and reported Adequate or inadequate timeframes in a two year period in the HMLC

Time since last USS	#1 USS n (%*)	#2 USS n (%)	#3 USS n (%)	#4 USS n (%)	*p* value¥
<7mths	19 (31)	10 (16)	7 (11)	1 (2)	0.016
>7mths	11 (18)	8 (13)	2 (3)	1 (2)	0.016
NR	31 (51)	43 (70)	52 (85)	59 (97)	0.968

**percentages rounded to nearest whole number so do not always add to 100%*

¥ difference in proportion of ultrasounds conducted in adherence to screening recommendations from first to fourth follow up ultrasound

Discussion

Surveillance rates of hepatocellular for individuals with cirrhosis, and/or established risk factors for the development of hepatocellular cancer within the Hastings Macleay Network in regional NSW do not achieve NSW Health guidelines.

Demographic data gleaned from SCRIPT HCC about patients living with cirrhosis who attend the HMLC region identified age, gender, distance from clinics and aetiology of disease as contributing factors that influence progression of disease with cirrhosis (Brown, 2017; European Association for the Study of the Liver, 2018).

Age

The mean age of the participants in this study was 56, with 77% born between 1945-1965. Heimbach et al (2018) discuss targeted prevention and screening programs for this age group due to their increasing risk of incidence of HCC partially due to their overrepresentation of infection with HCV (Marrero et al., 2018).

Gender

More men were represented in the study than women, which corresponds to the literature suggesting a greater than 2:1 predominance of men to women for the development of HCC (European Association for the Study of the Liver, 2018; Heimbach et al., 2018). Men are also more likely to die from excessive alcohol consumption than women are. This may be attributable to the fact that men

drink more and therefore progress to liver cirrhosis and develop HCC more (Mathurin & Bataller, 2015).

Distance from Clinic

Although patients were prepared to travel 21.9kms on average to attend services, one participant travelled almost 100kms (92.2km) to continue seeing the Gastroenterologist / Hepatologist who they had been seeing previously at another clinic nearer to their residence. Being closer to services did not appear to make people attend to screening any more frequently. Clinic 1 was the 'outer regional' clinic whilst Clinic 2 was categorised as 'inner regional' (Australian Bureau of Statistics, 2018). This difference in remoteness categorisation did not alter frequency of screening.

Aetiology

Alcohol

Alcohol abuse was identified as a contributed to liver cirrhosis in 84% of all participants and this was reflected fairly evenly in both clinics highlighting the strong correlation between alcohol and the development of cirrhosis (Mathurin & Bataller, 2015). In Europe alcohol is recognised as the most prevalent cause of liver disease with consequential cirrhosis the major cause of alcohol related deaths (European Association for the Study of the Liver, 2018; Mathurin & Bataller, 2015). Current collaboration with Drug and Alcohol services in the Hastings Macleay region is providing a platform for earlier detection of Alcohol related cirrhosis. Improvement could also be found by including an alcohol score within screening assessment process.

Viral Hepatitis

Hepatitis B and Hepatitis C are major risk factors for the development of HCC (NSW Ministry of Health, 2014b)and in Australia HCV is the biggest driver for liver transplantation. Although a slowly progressing disease, Hepatitis C leads to cirrhosis in 20-30% of HCV positive people (Hepatitis C Virus Infection Consensus Statement Working Group, 2018). Eighty-seven percent cirrhosis aetiology in participants was attributable to HCV infection with a higher representation (94% of participants) attending the 'inner regional' clinic.

The Hastings Macleay region only has 2 people with Hepatitis B who fit the criteria for HCC surveillance screening (table 1). This may be due to the low proportion of newly arrived refugees that are currently settled in the area plus undiagnosed disease in Aboriginal and Torres Strait Islander people (NSW Ministry of Health, 2014a). Port Macquarie I, however, targeted for upcoming relocation of newly settled refugees so these numbers may increase (Telford, 2018). One study identified that less than 10% of HBV related HCC occurred in patients without cirrhosis (Chayanupatkul et al., 2016).

Non-Alcoholic Fatty Liver Disease (NAFLD)

NAFLD is defined by the presence of hepatitis steatosis on radiological imaging or biopsy without the presence of any secondary causes such as chronic alcohol intake. There is a close association with metabolic disorder such as obesity and diabetes (Chalasani et al., 2018). In contrast with the current literature that highlights NAFLD as one of the four main causes of cirrhosis and liver disease there

were only two patients in this study that had NAFLD on a background of cirrhosis with chronic HCV infection. This is due to these patients predominantly managed under private Gastroenterologists. The American Association for the Study of Liver Diseases (AASLD) state that NAFLD-related HCC diagnosis has increased by 9% in the United States due to the increasing obesity (Chalasani et al., 2018). Generally an older population, this patient group and are more likely to die from primary HCC than other patients due to comorbidities like heart disease and chronic diabetes (Chalasani et al., 2018). Recent findings show that patients with NAFLD do not necessarily have to have cirrhosis to develop HCC. One study identified 13% of patients with HCC did not have cirrhosis (Mittal et al., 2016).

Port Macquarie as the primary regional centre in the Hastings Macleay reflects these findings with age and gender and lifestyle factors of the retired – self reported high alcohol intake and lack of awareness of physiological consequences. There is likely an underdiagnoses of excess alcohol consumption and a lack of open dialogue about this with their GPs and other health care providers.

Ultrasound intervals

The findings in SCRIPT HCC of 31% optimal adherence to screening intervals at 0-7mths support other literature that highlight the difficulty of engaging and supporting patients to adhere to optimal screening intervals. The optimal interval according to Heimbrach et al (2018) for surveillance is between 4 and 8 months, with six months recommended in the clinical guidelines (European Association for the Study of the Liver, 2018; Marrero et al., 2018). Ultrasound intervals were measured at less than seven months and greater than seven months to identify good or poor adherence to these guidelines. SCRIPT HCC reinforced what other studies have found (Allard et al., 2017; Goldburg et al., 2017; Singal et al., 2012), it is difficult to meet these recommendations for screening even when serviced by a specialist liver clinic setting.

A meta-analysis found that surveillance rates under 30% were common, with single centre tertiary programs having higher rates of adherence, around 60-80% (Selvapatt, House, & Brown, 2016). These were predominantly in metropolitan areas and had programs designed specifically for HCC surveillance (Allard et al., 2017; Selvapatt et al., 2016; Singal et al., 2012).

Observations

In a metropolitan study on adherence to recommended surveillance for liver cancer in patients with hepatitis B it was recognised that adherence to HCC surveillance was difficult to achieve even when an integrated disease specific service was established within the community health centre (Allard et al., 2017). The authors make note that surveillance for HCC in Australia lacks support by any external agencies or media campaigns to promote its value (Allard et al., 2017). Implementation of al population-based cancer screening program such as the Pap-Smear registry or Breast Screening have been effective for other types of cancer. A similar program to improve HCC surveillance has been observed to decrease mortality from HCC (Kudo, 2015). Therefore the development of a population

based screening service for people at risk of developing HCC needs to be developed to provide a multipronged approached to patient support and recall.

Appropriate HCC educational materials are scarce, and those that are available are unsuitable for populations with low health literacy (Allard et al., 2017). Visual guides rather than written materials, use of social medial platforms such as banners and better health messages, use of Hepatitis NSW visual and low literacy material should be more widely available.

Barriers to effective HCC surveillance have been identified, (Farvardin et al., 2017) almost 50% of patients who participated in one survey reporting one or more barrier for them in undertaking appropriate surveillance. Reported barriers included: finding the booking or scheduling of appointments for ultrasounds difficult; associated financial costs of test; not knowing where to go for ultrasound and difficulty with transportation (Farvardin et al., 2017). A long 'lead-time' (greater than three months from when the patient is given forms for ultrasound and pathology) is reported as leading to reduced follow up for screening ultrasounds (Goldburg et al., 2017). Patients of the HMLC are given their screening forms six months out from time of next ultrasound and this may have been a contributing factor of the poor adherence to surveillance screening.

Strengths and limitations

SCRIPT HCC provided the first retrospective epidemiological investigation into rates and patterns of screening for HCC at the HMLC. As such, this study has highlighted areas for improvement and advanced knowledge around this important part of appropriate patient care in rural and regional health districts.

As with any retrospective audit, the research is dependent on the available information and as such there are gaps in data leading to potentially lower rates of adherence.

During the retrospective period of the study, there were multiple staffing changes within the HMLC. A perceived limitation of this study is that this interruption to staffing was an influencing factor in the larger gaps around USS#3 and USS#4 as this time line would have fallen directly during the main transitional period. What this highlights however is that there needs to be systems in place that do not rely on any one particular staff member or position for effective and competent health care provision. A longer study period that included a larger number of participants may have reduced this problem however even with these numbers it is obvious that there needs to be some interventions to improve ongoing patient care.

The design of the audit may not have clearly captured the overall rates of surveillance, as the 'time of initial assessment' (the time at which the participant entered the service) was different for each participant. Therefore, some participants may only have required two ultrasounds within the reporting period – increasing the proportion of participants with no recorded ultrasound at USS#3 and USS#4 as above. The study period would benefit from extension to accommodate the large time intervals between measured interventions (6 monthly ultrasounds) – this may increase statistical accuracy of results. Eligibility criteria could be adjusted to exclude participants who have not had a certain amount of USS within the timeframe noted.

Conclusion and recommendations

SCRIPT HCC has identified rates and patterns of screening in the Hastings Macleay Liver Clinic were below recommended intervals between 31% and 2% and identified that a high proportion of participants have no recorded ultrasounds within the study timeframe. Men with a mean age of 56, with cirrhosis from a combination of alcohol abuse and hepatitis C are the predominant population in these clinics. It is an ongoing challenge to support people living in regional NSW even when specialist public health services are operating with the specific purpose of improving health outcomes.

Recommendations for future practice:

Evaluation of current practice: It is recommended that an evaluation be undertaken of the revised clinic practice of providing radiology requests no more than three months in advance. This altered timeframe provides a 'buffer' of one month for requests and appointment letters is to be established in combination with a database management system that calculates 'due dates' for patients next screening ultrasound. An existing system has been in use since October 2017 and is due for review in October 2018 with the aim of continually improving patient health outcomes.

The clinic revise the existing practice of providing radiology requests more than three months in advance – a buffer of one month for requests and appointment letters is to be established in combination with an electronic data-management system that calculates due dates for patients next screening ultrasound. A similar system has been in use since October 2017 and is due for review in October 2018 with the aim of continually improving patient outcomes.

Access to health educator/counsellor: Increased access to the health educator/counsellor through the service. This service is currently available however in a limited capacity. The recommendation will increase access enabling the Health educator/counsellor to assist patients in making ultrasound bookings, support their attendance at appointments and navigate health system processes, including the Isolated Patients Travel and Accommodation Assistance Scheme (IPTAAS) process and palliative care engagement. This would help support patients with complex needs, many of whom have low literacy levels or come from low socioeconomic background. Increased use of Hepatitis NSW resources and advocacy programs can be utilised.

Collaborative and integrated Care: Collaboration with Radiology companies to set up appropriate recall and reminder systems for surveillance screening intervals. It would be ideal for this collaboration however an alternative would be for Radiology to send SMS to clients when their screening is due and also to contact via either fax or email the local liver clinic or provider caring for the patient to support them in recalling the patients. Studies have shown that the use of SMS reminders improve patient outcomes and attendance (Kannisto, Koivunen, & Välimäki, 2014) therefore this method of recall could be built into both the radiology software and the Liver Clinic processes.

NAFLD cirrhosis and non-cirrhosis management Guidelines: Further development of guidelines around providing surveillance for patients with NAFLD without cirrhosis according to the increasing risk of developing HCC in the absence of cirrhosis in these people. The Australasian Hepatology Association (AHA) are currently developing some nursing guidelines in this area and can be modified for local context once published. This will allow for more informed management of this cohort of patients. As the health burden from Non-Alcoholic Fatty Liver Disease (NAFLD) increases in Australia, it has become important that services dealing with liver disease begin developing guidelines for providing surveillance for these patients. This is especially important as NAFLD, with or without cirrhosis, has an ever-increasing risk of developing HCC. The health burden of NAFLD in the Hastings Macleay district is problematic, with a low socio-economic population, increasing obesity in children and adults and an aging population the aim is to make sure that processes can be future proofed, i.e. not dependant on any particular staff member.

Alcohol education and Awareness: Development of Alcohol cessation programs built in to the management of patients presenting to the Hastings Macleay Liver Clinics to address the risk of alcohol related liver damage. Education to patients and GPs in relation to regional retirees and the identified risk attached to even moderate to high alcohol intake as contributing risk factors in the development of liver damage and cirrhosis.

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Appendices:

Appendix A: Audit sheet

Data item	Data dictionary	Data entry field
Demographic information		
Patient ID	SCRIPT#	SCRIPT#___
Date of Birth (DOB)	DD-MM-YYYY	__-___-____
Date of Death (DOD)	DD-MM-YYYY (00-00-0000 if alive)	__-___-____
Gender	Male = 1 Female = 2 Other = 3	_
Aboriginal or Torres Strait Islander	Aboriginal = 1 TSI = 2 Both = 3 None = 4	_
Country of Birth (COB)	Country where patient was born	_____
Ethnicity	Ethnicity of patient such as Indian decent	_____
Post Code	PC of patient's residence at registration	____
Clinic Location	KPSY = 0 PMQ = 1	_
General Practitioner or Gastroenterologist	GP = 0 Gastro = 1 If Gastro: = LDB / SK / AE / Reg.	_ ___
Date of Initial visit	DD-MM-YYYY *(to establish time of care transition to service)*	__-___-____
Alcohol and other drug history		
Alcohol History *Use of The World Health Organization's Alcohol Use*	ETOH Past Y/N ETOH Current Y/N	_ _

Disorders Identification Test (AUDIT)	AUDIT score if available *see appendix A*	__
Intravenous Drug Use	Past IVDU Y/N Current IVDU Y/N	
Clinical Investigations		
Weight	At initial assessment in kilograms	___kg
Height	At initial assessment in centrie~~e~~metres	___cm
Body Mass Index (BMI) *calculated by dividing weight in kilograms by height in metres squared* *i.e 60kg/1.60² (1.6x1.6 = 2.56)* *60kg/2.56 = BMI 23.44*	Underweight <18.50 = 1 Normal range 18.50-24.99 = 2 Overweight >25 = 3 Pre-Obese 25.00-29.99 = 4 Obese class 1 30.00-34.99 = 5 Obese class 2 35.00-39.99 = 6 Obese class 3 >40.00 = 7	_ _ _ _ _ _ _
Hepatitis and Liver disease assessment		
Hepatitis B Virus (HBV)	HBVag +ve Y/N HBVcAb +ve Y/N HBVsAb +ve Y/N	_ _ _
Hepatitis C Virus (HCV)	HCV ab +ve Y/N HCV RNA PCR +ve Y/N**	_ _
**If HCVRNA PCR +ve	Genotype 1a| 1b| 2| 3| 4| 5| 6| 7|	_
Date of diagnosis	DD-MM-YYYY	__-__-____
HCV Treatment	On Tx Y/N Completed Tx Y/N Failed Tx Y/N	
Fibroscan™ Score (or other fibrosis score)	Measures as kilopascals (kPa) F0 F1 F2 F3 F4	__._kPa

Cirrhosis aetiology	HBV HCV Alcohol NAFLD Auto Immune	Y/N Y/N Y/N Y/N Y/N			_ _ _ _ _
Childs Pugh **see appendix B**	As measured at initial assessment CPA = 1 CPB = 2 CPC = 3				_ _ _
MELD **see appendix C**	Dialysis at least twice in the past week Creatinine	Y/N			
HCC surveillance data					
HCC surveillance indication	HBV HCV Alcohol NAFLD Auto Immune	Y/N Y/N Y/N Y/N Y/N			
Date of ultrasounds DD-MM-YYYY	__-__-___	__-__-___	__-__-___	__-__-___	__-__-___
AlphaFeta Protein (AFP) no.	_	_	_	_	_
Lesions detected Y/N	_	_	_	_	_
HCC confirmed Y/N	_	_	_	_	_
HCC treatment					