# Integrated Liver Toolkit and Education Program for the Management of Liver Cancer in Primary Care Pilot: Summary of the Evaluation Report

**M Williamson, C O'Callaghan, K Meikle, A Kabir, F Haigh and M Barr,**

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## Background

The Integrated Liver Toolkit Education Program for the Management of Liver Cancer in Primary Care Pilot (ILTE Program) was developed by the Central and Eastern Sydney Primary Health Network (CESPHN), Royal Prince Alfred Hospital and St George Hospital in consultation with the HIV and Related Programs in South Eastern Sydney Local Health District and Sydney Local Health District, and Hepatitis NSW and was funded by the Cancer Institute NSW. The ILTE Program was developed in response to increasing incidence rates of hepatocellular carcinoma (HCC) and poor survival rates, and evidence that early detection of HCC in high-risk populations and its appropriate management will improve survival.

The ILTE Program aimed to:

- Test a model for facilitating early detection of HCC, via timely surveillance of primary care patients with a cirrhosis diagnosis or with pathology results suggesting potential cirrhosis (confirmed via Fibroscan).
- Strengthen management of patients diagnosed with cirrhosis and HCC via appropriate referrals to specialist hospital-based liver clinics.

The Centre for Primary Health Care and Equity at the University of New South Wales were engaged to conduct a qualitative and data evaluation of the ILTE Program to understand the impact, acceptability and feasibility of wider implementation.

## Methods

### Evaluation questions

A. What is the potential of the model presented in the ILTE Program to improve clinical outcomes for patients who are at risk of developing HCC?
B. How acceptable is the model for those stakeholders involved?
C. Should broader implementation of the model be supported across general practices in the CESPHN region?

## Evaluation methods

1. To understand the potential of the model and assess its impact on clinical outcomes of patients who are at risk of developing HCC, a data review of the following information, provided by CESPHN, was reviewed by the evaluators:
    - Two draft journal articles prepared by the researchers, detailing the qualitative results of the ILTE Program. One about screening patients in general practice for undiagnosed cirrhosis, and the other about examining patients with cirrhosis in general practice.
    - Information about the POpulation Level Analysis & Reporting (POLAR) Liver toolkit (LTK). POLAR metrics for each practice over the life of the ILTE Program, screen shots, CESPHN POLAR data portal report (dummy data), and monthly reports to practices (dummy data).
    - Information about the Clinical Hospital Liaison (CHL) visits, REDCap data sheets (which showed what variables were collected on the CHL visits to general practices), output from the LTK, recall information, visits at the hospital liver clinic, patient tests results and education, and assessment of patients with known cirrhosis.
    - In-depth interview with one of the CESPHN project co-ordinators.
2. To understand the acceptability of the model, semi-structured interviews were conducted with staff from the participating general practices and hospital-based liver clinics, using interview guides modified for each of the roles. The interview guides focussed on the key features of the ILTE Program. Respondents were asked questions related to the benefits, challenges and preferences to continue using that feature (where relevant), and respondents' suggestions for improvements were sought. The interviews also explored the outcomes of the ILTE Program on patients, general practice staff and hospital liaison staff.
3. To understand the potential of the ILTE Program for broader implementation:
    - We examined the processes and outputs of the ILTE Program (including the three-stage screening process to identify patients with cirrhosis and HCC) and resource use.
    - We conducted a brief review of the literature on the evidence related to the methods and outcomes of the ILTE Program.
    - We synthesised the quantitative and qualitative results for the three evaluation questions and made recommendations about:
        - The potential for a broader implementation of the ILTE Program.
        - Areas that would benefit from further development if there was a decision to extend the program across CESPHN.

# Results

## A. Impact on clinical outcomes for patients at risk of developing HCC

Of the 114,640 active patients aged 18-79 years of age in the nine participating practices, no patients with a new HCC diagnosis were detected, and 15 patients with undiagnosed cirrhosis were identified. Of the population with relevant results available, 0.07% of patients were found to have advanced fibrosis or cirrhosis. *The positive predictive value of the ILTE Program was 8.4% for cirrhosis and 12.3% for advanced fibrosis or cirrhosis.*

We also explored the other data that might indicate improvements to the integrated management of patients at risk of or with cirrhosis and HCC. We found:

- Fibroscans were conducted on all patients who were found to be at high risk of liver cirrhosis.
- Patients with Fibroscan results suggestive of cirrhosis were referred to hospital-based liver clinics, where further tests, (such as ultrasounds) were conducted to assess for HCC and were booked for six monthly reviews. (A few patients were referred to other hospitals and we do not have information about ongoing management on these patients).
- Individuals with Fibroscan results suggestive of advanced fibrosis were booked for six monthly reviews.

- 96% of patients seen at the CHL Fibroscan clinics in general practice, Royal Prince Alfred Hospital or St George Hospital had information had diagnosis and a management plan communicated back to the general practitioner (GP), 31% also received education about their condition and how to prevent further disease progression.

General practice staff also reported improved knowledge about liver disease and screening for cirrhosis and HCC, and a number also reported feeling more confident in the management of the condition.

There were a number of unintended consequences:

- Some high-risk patients who may have benefited from further assessment, were not identified by the LTK or did not respond to recall. Inability to identify patients may have been due to relevant data, such as pathology tests results, not being available, or tests not having been conducted in the previous two years. Only one in four at-risk patients agreed to return for further assessment, and in one general practice this was only one in seven patients. Further analysis comparing these patients to those that returned, showed that some had results suggestive of significant liver disease.
- A number of interview respondents highlighted that the patient recall process had allowed them additional opportunities to educate patients about how to prevent the progression of their liver disease, as well as an opportunity to review other conditions for which patients had not accessed the general practice for care because of COVID-19.

## B. The acceptability of the model - interview study

Using an interview guide modified for the different roles, we interviewed five representatives from general practice (four GPs and one practice manager; we aimed to recruit at least one representative from each of the 9 general practices) and five representatives of the CHL teams (two medical staff and three nursing staff). We asked questions about the benefits and challenges of each of the project phases, and the impact of the project on patient and staff outcomes. To understand the acceptability of the ILTE Program, we applied the theoretical framework of acceptability for healthcare intervention developed by Sekhon et al., (2017)[1]. This framework had the following constructs: burden of participating, perceived usefulness or effectiveness, intervention coherence and complexity, user experience, and intention and capability to continue participation. We added an addition construct, external environment, which played a significant role in the delivery and acceptability of the ILTE program.

### *Perceived usefulness or effectiveness of the Program*

Most participants reported that the ILTE Program allowed for at-risk patients to be screened for significant liver disease. General practice staff also acknowledged that the ILTE Program had improved confidence and knowledge of general practice staff about liver disease, screening and management, while hospital staff reported improved knowledge and use of non-invasive tests to screen for liver disease. Concerns were raised about the oversensitivity of the LTK in identifying at-risk patients: "*It probably oversampled people. So, we had a lot of people on there that, in after looking at their files, didn't need to be on there."*

### *Burden of participating*

Respondents from both the CHL team and the general practice staff, reported that there was considerable work organising and conducting the CHL visits and organising patient recall. They also

[1] Sekhon M, Cartwright M, Francis, JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC Health Services Research 2017;17(1):1-3.

stated that the process of the clinical audits, which required the CHL team to manage the extraction of data from the LTK and the review of patients to identify high risk patients for recall, was burdensome in terms of time and costs.

### *Intervention coherence and complexity*

The respondents stated that the intervention was complex and required considerable input from the CHL team to ensure the steps of the ILTE Program worked effectively. The steps included using the LTK to identify patients at risk of serious liver disease, recalling patients and referring patients for further assessment.

Most respondents from general practice reported that the tool was difficult to use: "*I can't see GP's using this of their own initiative because of how finicky and time consuming [it is].*"

A number of respondents reported that significant support was needed to run the LTK and interpret the findings: *"It needs a lot of coaxing and services wrapped around the actual tool, so the tool does its job. You need more than just the tool."*

Different practices used recall processes, some more successfully than others, success rates ranging between 9.8% and 38.9%.

### *User experience*

Respondents from general practices that had previous experience with similar projects, and/or had teams available to conduct recalls and follow-up patients, found the project more acceptable.

### *Intention to continue using the Liver Toolkit*

Some respondents felt it was not feasible to continue to use the LTK unless there were improvements to the specificity and streamlining of the patient recall and the assessment processes. One respondent summed it up: *"I think, as it stands right now, without a staff member from the hospital or the PHN [Primary Health Network] assisting us with the tool, no, I think it would be hard to do. I think it's an excellent idea, but it requires either support or simplifying because it's too much for your run-of-the-mill practice to really use on their own right now."*

However, two general practices with more patients at higher risk of cirrhosis, reported having mechanisms and staff to support quality improvement or research activities, and were more willing to continuing with the use of the LTK.

### *The external environment*

Although not mentioned by Sekhon et al., (2017), the environment played an important role in the acceptability of the project. The COVID-19 pandemic and associated lockdowns in 2020-2022 had a significant impact on some practices, which meant that they dropped out of the ILTE Program. There were extra demands on staff in the general practice and the CHL teams during this time, which also had a significant impact on response rates for patient recall and the capacity of practices to engage with the ILTE Program and the LTK. Staff turnover at the general practices and the hospital clinics also made it difficult to develop ongoing processes and communication between the general practices and the CHL team.

## C. Understanding the potential of the ILTE Program to have broader implementation

### *Broader implementation*

Overall, the respondents felt this was an important project and should be continued in some form, and they recommended a number of improvements. There was strong support for continuing Fibroscan clinics in general practices where there were higher numbers of at-risk patients.

It did seem that the use of the three criteria to identify patients by the LTK was more successful than by clinical judgement alone, so it would be important to ensure that similar measures were incorporated into any future implementations.

There is also growing international evidence of the benefits of similar screening programs using non-invasive methods in a three-stage approach: (1) excluding low-risk patients using validated algorithms based on pathology tests, (2) using Fibroscans to identify patients with cirrhosis, and (3) screening patients with cirrhosis for HCC.

Before broader implementation, it will be important to improve the completeness and accuracy of methods used to identify and recall patients at risk of severe liver disease.

### *Areas that would benefit from further development or consideration before broader implementation*

If broader implementation is to be considered, we suggest that the following areas would require further development:

- Improving the specificity and simplifying the interface of the LTK or similar data extraction tool.
- Improving the patient recall methods.
- Ensuring ongoing expert advice about the tests, cut-offs and screening procedures used to identify patients with cirrhosis and HCC.
- Consideration of incorporating scores to identify high-risk patients, such as aspartate aminotransferase to Platelet Ratio Index into the GP clinical software products or through pathology laboratories to calculate these measures for relevant patients.
- Use of specialist liver nurses to run Fibroscan clinics at the general practice.
- Improvements to the monitoring of the impact of the ILTE Program (ensuring relevant information can be extracted to check the ILTE Program is working effectively).
- Estimation of possible costs and consideration of comparative benefits with other programs.

## Strengths and limitations of the evaluation

We were able to synthesise a range of quantitative and qualitative evidence about the impact, acceptability and potential for wider implementation of the ILTE Program. This enabled us to understand the experiences and challenges faced by stakeholders, including GPs, general practice staff, CHL staff and CESPHN staff, in developing and implementing the ILTE Program. This also enabled us to understand its impact on patients, (including their management and experiences) and stakeholders (including their increased knowledge and changed practices).

### *Limitations of qualitative interview study*

A list of potential participants for the key informant interviews was provided by the CESPHN. As required by the ethics committee, potential participants were initially contacted by the CESPHN staff and the CHL. This may have influenced participation in the interviews. Our intention was to interview around 12 stakeholders, including at least one representative from each of the nine practices involved in the ILTE Program. However, only four GPs and one practice manager agreed to participate from five of the nine participating practices, so we may have missed interviewing some stakeholders, who could have had very different views to those interviewed. However, similar themes emerged across the different stakeholders, suggesting that we were capturing most of the important issues.

### *Limitations of the data review*

We were only able to access a limited amount of quantitative data and were dependent on using sources of information prepared by the ILTE Program researchers for information about the impact of the ILTE Program. Our analysis of the impact on patient management was based on extracts of data from the LTK, draft journal articles about the screening of patients for undiagnosed cirrhosis and HCC, the audit of patients with cirrhosis, and some information extracted from the REDCap database.