Received: 21 September 2021 | Accepted: 28 January 2022

DOI: 10.1111/dme.14799

DIABETIC Medicine

RESEARCH: CARE DELIVERY

An exploration of barriers and facilitators to implementing a nonalcoholic fatty liver disease pathway for people with type 2 diabetes in primary care

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Funding information
Health Innovation, Investment and Research Office (HIIRO) Clinical Research Fellowship; Metro South Health Research Support Scheme Grant

Abstract

Aims: We explored barriers and facilitators to the implementation of nonalcoholic fatty liver disease (NAFLD) pathway for people with diabetes to identify determinants of behaviour surrounding the diagnosis, assessment and management of NAFLD.

Methods: Health practitioners ($n = 24$) recruited from multidisciplinary diabetes clinics in primary care ($n = 3$) and hospital ($n = 1$) settings participated in four focus group discussions, and common themes were identified using thematic analysis.

Results: Lack of knowledge and access to resources were key factors that underpinned an inconsistent approach by clinicians to NAFLD diagnosis and risk stratification and impacted their confidence to discuss the diagnosis with patients. Participants often prioritised other medical issues above NAFLD due to lack of concern about liver-related consequences, reluctance to overburden patients with information, lack of time and perceived absence of accessible fibrosis tests. All participants agreed that implementation of a NAFLD pathway would improve patient care and the general practitioners proposed that screening for NAFLD could be incorporated into routine review cycles for type 2 diabetes. A consistent message from participants was that educating patients about their liver disease needs to be implemented in an integrated care pathway.

Conclusions: From the perspectives of health practitioners, there is a gap in clinical practice for the implementation of clear, evidence-based guidelines for NAFLD in people with T2D. By focusing on comorbidity prevention and integrating NAFLD as a diabetes complication to be addressed during established cycles of care, many barriers to implementing a NAFLD pathway in primary care could be overcome.

Elizabeth E. Powell and Patricia C. Valery contributed equally.

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KEYWORDS
delivery of health care, integrated, diabetes complications, fibrosis, focus groups, General Practitioners, patient care, risk assessment

1 | INTRODUCTION

Nonalcoholic fatty liver disease (NAFLD) is the most common chronic liver disorder in primary care[1] and is highly prevalent (47.3%–63.7%) in people with type 2 diabetes.[2] NAFLD is an overarching term that includes steatosis and the necroinflammatory state termed nonalcoholic steatohepatitis (NASH) which is defined by hepatocyte injury. The diagnosis of NAFLD requires the detection of fatty liver and the exclusion of secondary causes, such as excessive alcohol use and other chronic liver diseases. NAFLD, in particular NASH, may be associated with progressive liver fibrosis that can lead to complications of cirrhosis and hepatocellular carcinoma (HCC) in 5%–10% of affected individuals over 10–20 years.[3,4] Among people with NAFLD, the presence of type 2 diabetes is associated with a more than twofold increased risk of advanced fibrosis, cirrhosis-related complications and liver disease mortality.[5] The presence of advanced fibrosis is the key predictor of liver-related outcomes and mortality.[3] Early identification of people with NAFLD at increased risk of advanced fibrosis is crucial in order to target those who require surveillance for liver cancer and liver decompensation. To date, there is no approved pharmacotherapy for NAFLD, and a healthy lifestyle, weight reduction and management of cardiometabolic risk remain the cornerstone of treatment.[6]

Although NAFLD screening in the community is not endorsed, the American Diabetes Association now recommends an evaluation for NAFLD in people with type 2 diabetes and hepatic steatosis or abnormal liver enzymes.[7] Guidance documents from hepatology associations[8–10] advocate testing for advanced fibrosis in people with a diagnosis of NAFLD, although the specific testing algorithms vary, and include simple fibrosis scores (such as NAFLD Fibrosis score or Fibrosis-4 Index), ultrasound-based elastography or commercial biomarkers (such as the serum Enhanced Liver Fibrosis (ELF) test). The ability to apply recommendations from international bodies varies greatly with the different structures and resourcing of health care systems. The current 'standard of care' considers that people with NAFLD at 'low risk' of advanced fibrosis can remain in primary care with a focus on managing cardiometabolic comorbidities, whilst those at 'increased risk' of advanced fibrosis require referral for hepatology assessment. With a rise in recognition of NAFLD, strategies to reduce pressure on secondary care for assessment of fibrosis will be essential.[11]

What's new?

- There is an inconsistent approach by clinicians to nonalcoholic fatty liver disease (NAFLD) diagnosis and risk stratification in people with type 2 diabetes, and the determinants of behaviour around NAFLD management remain unclear.
- Focus group discussions with diabetes clinicians identified (i) lack of knowledge about liver-related outcomes and (ii) limited access to a structured NAFLD pathway and tools to assess fibrosis risk were key factors contributing to the failure to recognise NAFLD and identify people at risk of advanced fibrosis.
- Integrating NAFLD as a diabetes complication to be addressed during established cycles of care may help to overcome barriers to NAFLD management.

In addition to providing evidence-based pathways, implementing an assessment of liver fibrosis into primary health care requires clinicians to carry out this guidance. Although awareness of NAFLD guidelines has been surveyed,[12,13] few studies[14] have explored clinicians' perceived barriers and facilitators to NAFLD management. Evaluating these factors is an important step to facilitate the implementation of a NAFLD pathway in at-risk populations. We aimed to explore barriers and facilitators to the implementation of a NAFLD pathway for people with diabetes using qualitative analysis to identify determinants of behaviour surrounding the diagnosis, assessment and management of NAFLD among key health practitioners (HPs).

2 | METHODS

2.1 | Participants

Participants were recruited from multidisciplinary diabetes clinics in primary care ($n = 3$) and hospital ($n = 1$)

settings in Brisbane, Australia. All HPs in the clinics were invited to take part. Informed written consent was obtained from each participant and the study was approved by the Metro South Health human research ethics committee (HREC/2021/QMS/722731).

2.2 | Data collection

Using a semi-structured interview guide, four focus group discussions were conducted between April and May 2021. Two senior team members (a clinical hepatologist (EEP) and a medical epidemiologist experienced in qualitative research (PCV)) designed an interview guide (Table 1). The guide enabled discussion of pre-conceived barriers and facilitators to implementation of a NAFLD pathway and further allowed participants to introduce new topics that they felt were relevant. We considered data saturation[15] to be achieved when no new topics were elicited. Focus groups were audio recorded and transcribed verbatim by a team member (LG) who was present at the sessions. Transcripts were re-reviewed alongside the audio for accuracy.

2.3 | Data analysis

Thematic analysis was used to identify common themes using an inductive approach.[16] Transcripts were reviewed independently by three team members (LG, PCV and EEP) for data familiarisation and preliminary coding. A round-table discussion was held to generate initial themes. LG coded the quotations into these initial themes and coding was independently reviewed by PCV and EEP with consideration given to the utility and accuracy of quotations and themes to represent the meaning behind the data. At this stage, some amalgamation of themes occurred.

LG and EEP then independently analysed each interview transcript line-by-line and coded quotations into the agreed themes. The two reviewers compared their codes by looking at each quote and the theme(s) the reviewer had allocated it into. The initial coding by LG and EEP demonstrated 85.1% agreement. The agreement indicated a quotation was either coded or not coded to the same theme by both. Disagreement occurred when one reviewer coded a quotation to a theme and the other did not. Each disagreement was then discussed, and a decision was made by each reviewer as to whether they wanted to change their coding. The final agreement was 98.6%.

2.4 | Data trustworthiness

To ensure the trustworthiness and authenticity of the narrative, a number of approaches were taken. Throughout data collection and analysis, memos were written by LG to record reflections about the interview and the initial analysis. A number of illustrative quotes were used to link data and analysis and to support the breadth and depth of each reported category. Although it was not possible to seek validation of findings by returning to all participants in this study, clarification of key concepts was sought throughout the interview process.

3 | RESULTS

Four focus groups were conducted with a total of 24 HPs. Five participants who only contributed non-verbal responses (e.g. nodding) were excluded from the analysis. The 19 HPs who contributed verbally included general practitioners ($n = 9$), endocrinologists and endocrine advanced trainees ($n = 7$) and diabetes educators ($n = 3$).

TABLE 1 Interview guide

Question	Prompts
Let's start with your understanding about NAFLD in the community. Do you think NAFLD is important? Do you think NAFLD is common?	• Do you think NAFLD can cause serious liver disease? • Do you think young people can get NAFLD? • How do you identify someone who might have NAFLD?
Can we now talk about the diagnosis of NAFLD? How do you diagnose NAFLD?	• Are you comfortable diagnosing NAFLD?
What about assessing the severity of liver disease (assessing the severity of fibrosis)?	• Do you use non-invasive scores (FIB-4, NFS)?
Let's talk about the management of NAFLD. How do you manage NAFLD?	• Are you comfortable managing NAFLD? • How do you decide which patients to investigate and refer?
With regard to education and resources, what support do you need to diagnose, investigate and manage NAFLD?	• Do you use online guidance or pathways such as SpotOnHealth

There were 13 female and 6 male participants, and each focus group interview lasted approximately 40 min.

Eight themes were identified to influence HPs' decisions and behaviours surrounding NAFLD. Themes were grouped to reflect the two key stages of a NAFLD pathway: 'Diagnosis' and 'Assessment and Management'. Quotations that illustrated these two stages are summarized in Tables 2 and 3, and a sample of quotations (displayed in brackets) are used to exemplify each theme.

3.1 | NAFLD diagnosis and assessment

3.1.1 | NAFLD is highly prevalent

Participants identified NAFLD as a prevalent condition in their patients with obesity or diabetes (see Table 2: T1Q1, T1Q2). One participant also noted the general increase in obesity, and, therefore, NAFLD, in the younger population who attend a university medical centre (T1Q4).

As a result of this high prevalence, some participants noted that actively seeking to diagnose and treat NAFLD would result in an overwhelming burden on health services in the absence of a structured pathway (T7Q7, T3Q1).

3.1.2 | Abnormal liver enzymes are the primary trigger to diagnose and/or investigate for NAFLD

None of the participants had a consistent workup that they performed in every suspected case of fatty liver but most used abnormal transaminases to prompt them to suspect the diagnosis in patients with metabolic risk factors (T2Q2, T2Q4, T2Q7, T2Q9–11, T2Q14–15, T2Q18, T2Q19). Some participants were aware, however, of the poor correlation between the presence and severity of NAFLD and abnormal liver enzymes (T2Q6, T2Q8).

After identifying persistently abnormal liver enzymes, some participants stated they would proceed to an ultrasound to confirm their suspicion of fatty liver (T2Q2–5, T2Q13, T2Q16, T2Q17). A few would organise a FibroScan (T2Q3, T2Q15) or used simple scores (T2Q2, T2Q17) to risk-stratify patients, but this was uncommon.

However, several participants voiced concerns about the reliability of NAFLD diagnoses made by other clinicians, particularly regarding the exclusion of secondary causes of steatosis and assessment of liver disease severity (T2Q9, T3Q12, T3Q13).

3.1.3 | There is a need for structured guidance

Uncertainty surrounding diagnosis and risk stratification of NAFLD was often attributed to lack of accessible NAFLD guidelines for primary care providers (T3Q1, T3Q6, T3Q7, T3Q12, T3Q14). This uncertainty led to all four focus groups indicating a preference for structured guidance for the assessment of NAFLD.

During the focus group discussions, participants identified four key characteristics of a NAFLD pathway that would facilitate its implementation into clinical practice. The total number of times each characteristic was mentioned is indicated by (n=) and exemplar quotations are included in Table 4 as well as in Tables 2 and 3:

1. Clear criteria regarding which patients should be on the pathway ($n = 21$).
2. A simple risk-assessment tool, ideally incorporated into GP software, identifies patients who require further investigation ($n = 60$).
3. Provision of guidance on appropriate tests to confirm NAFLD severity ($n = 59$).
4. An explanation for interpretation of the tests and what must be actioned, including appropriate patient management and follow up ($n = 38$).

3.1.4 | Healthcare providers considered long-term liver consequences a rare occurrence

Perceptions surrounding treatment goals and patient outcomes were found to influence HPs' decisions about the priority of NAFLD diagnosis and assessment. Most HPs were aware that only a small proportion of people with NAFLD would develop long-term liver-related complications, and this comprised our fourth theme (T4Q2–3, T4Q4).

The perception that long-term liver consequences were a rare occurrence appeared to influence the clinical markers HPs used to identify patients for investigation. HPs had limited knowledge of the risk factors for advanced liver disease and frequently referred to liver synthetic dysfunction and portal hypertension as the clinical indicators that would trigger further investigation of NAFLD (T2Q1, T2Q11, T2Q12, T2Q16). These features are markers of advanced, often irreversible, liver disease.

Combined with uncertainty about appropriate NAFLD assessment, the perceived absence of an effective treatment contributed to HPs' tendency to prioritise other medical issues above NAFLD (T4Q1, T6Q2, T6Q6).

TABLE 2 Quotations coded into themes 1 to 5, under the topic of NAFLD diagnosis

Theme 1: NAFLD is highly prevalent		
T1Q1	*E1*	*But our type 2 population would have it in one third to fifty per cent of people I would suspect.*
T1Q2	*GP4*	*Yeah, how many do I see. That [NAFLD] would probably correlate with the number of obese people that I see, who are young. In their 30–40s, I would see a reasonable number. But most of mine, some of that is a function of my cohort, but most of mine are going to be older.*
T1Q3	*GP4*	*The reason we NAFLD score all of our diabetics is because the risk of, especially in the poorly controlled diabetics or very fat diabetics, the risk of having a fatty liver disease is so very high, it's almost universal. We thought we could justify then just NAFLD scoring everyone because probably most of them have it [NAFLD].*
T1Q4	*GP7*	*We're starting to see more cases at uni[versity] in the international cohort, so probably in the last 5–6 years. ... there was more, increased education about the diagnosis and we're seeing a lot of international students that are presenting who are gaining weight in the ––4 years that they're doing their studies. We're starting to pick up abnormal liver function tests.*
Theme 2: Abnormal liver enzymes are the primary trigger to diagnose and/or investigate for NAFLD		
T2Q1	*E2*	*Probably abnormal transaminases, low platelets, low albumin.*
T2Q2	*GP1*	*If I've got someone who I think is at risk, whether they're overweight, diabetic, or hypertensive or (with) any risk factors, then I'd do a NAFLD score. And I'd just essentially base my diagnosis on the NAFLD score, as well as I'd do an ultrasound, usually. And usually, they'd correlate like if you see something on ultrasound you'd also see a NAFLD score that's slightly elevated. But not always.*
T2Q3	*GP1*	*If the NAFLD score is a low risk and the US is normal then I'd leave it at that and just continue to check in 12 months. If the NAFLD score is low risk then I might just re-check it in 6 months and continue doing 6 monthly monitoring. If it doesn't correlate - say it's a low NAFLD score but the ultrasound results suggest severe fatty liver, then I might refer. And if it's an elevated NAFLD score I'd refer for a FibroScan.*
T2Q4	*GP2*	*Elevated liver function tests, signs of NAFLD on their US, mostly, sometimes you don't see it on ultrasound though, and I've excluded viral hepatitis and excluded significant alcohol intake.*
T2Q5	*GP4*	*I would write a diagnosis of fatty liver disease if I saw steatosis on the ultrasound.*
T2Q6	*GP4*	*you can have normal LFTs and still have fatty liver.*
T2Q7	*GP4*	*I think if you see quite abnormal LFTs and you've excluded everything it might give you some concern that it's more severe.*
T2Q8	*GP3*	*But you can have normal LFTs and have cirrhosis and hepatocellular cancer.*
T2Q9	*GP2*	*The vast majority of the time the mildly elevated LFTs get ignored as, 'Oh it's just a little bit of fatty liver'. And nobody thinks about which one, out of those mildly elevated liver function tests, is going to have cirrhosis or advanced fibrosis, and we need to worry about it a little bit more.*
T2Q10	*GP5*	*I would tend to [investigate] if someone has got consistently raised LFTs. Often I would send them for a fibrosis assessment - so a FibroScan as I know you can do those in private places or the equivalent, just to get an idea of perhaps what their risk level is at the moment, and then deciding whether they need to be tied in with a specialist clinic for ongoing monitoring.*
T2Q11	*GP5*	*So I would just be saying if they've got, with our patients - weight, persistent LFT derangement, certainly if their synthetic markers should be red-flagged, you know the albumin levels or platelets, but it's not as common to see them.*
T2Q12	*GP5*	*Well, I suppose that if there were signs that they were developing progressive liver disease, cirrhosis.*
T2Q13	*E6*	*I'd say often they come with the diagnosis and I will have high suspicion and sometimes I'll go on to do an ultrasound to confirm that and sometimes I don't.*
T2Q14	*E6*	*Really it would just be the LFTs would be my first flag. And then starting to be more than mildly elevated, I'd start to get more concerned.*
T2Q15	*GP8*	*I pay attention to the AST, ALT ratio, ...[when] AST is greater than the ALT then I start to pay more attention. I tend to organise a FibroScan .... There's those calculators as well you can use, but I have to admit when I'm looking at someone's results if the general picture is not making me worried I might not systemically do that. If sort of all the platelets are normal and some others, I might not go through the rigmarole of doing that, maybe I should be.*

(Continues)

TABLE 2 (Continued)

T2Q16	*GP8*	*Those other signs of problems; the albumin and the platelets and things like that. And sometimes I might use a calculator to justify that worry. And sometimes when you've done the ultrasound that might say there's significant steatohepatitis - that might make me more concerned as well and think about getting an opinion. If there's actually clinical signs of liver failure that makes me worry.*
T2Q17	*GP9*	*I think the liver enzymes and then APRI score and ultrasound. So this basically we do, as a measure of their disease. ... depends on the results of the APRI score - then probably we think if we would refer them to a hepatologist for FibroScan*
T2Q18	*GP9*	*Particularly whenever we see the LFTs are a bit elevated then the first question is "are you drinking alcohol"? Yeah, we do the alcohol drinking questionnaires. ... in terms of metabolic syndrome, if it's not that suspicious, if the LFTs are elevated but not that much and it's the first time, then I tend to do another test in say 4–6 weeks time, just to see whether it is coming down or not. If they're still persisting that same way or increasing up then I go for further tests and things.*
T2Q19	*GP8*	*I would do a liver panel in anyone who's got persistently elevated LFTs, even if it's quite mild.*
Theme 3: There is a need for structured guidance		
T3Q1	*E3*	*... certainly, from my perspective the helpful thing would be a tool that was readily available to non-specialists that would actually guide us for risk. Because I think your clinic would be overwhelmed if you saw every type 2 diabetic, that's not practical. Um, and, what we need is ok –this is the at-risk population, these are the ones we need to FibroScan.*
T3Q2	*E2*	*And I suppose then, giving us criteria above whatever score to refer to you so then you can manage them.*
T3Q3	*EAT*	*I think people would have a good uptake of a risk stratification tool because we do use them in lots of other areas. But it would help that patient and doctor interaction on the day, but then there needs to be something else on a practical level to get the ones you want to see and who needs to do that screening.*
T3Q4	*E3*	*That's the key thing, is having the protocols in place, the means to identify the at-risk group. As you say we're in an enriched population in our clinics, they [GPs in the community] are going to be seeing all comers. So you have to twig, this person might have liver disease, therefore we go down that pathway.*
T3Q5	*GP3*	*So those patients you follow with NAFLD and you're worried they've got [advanced disease] and you're doing 6 monthly hepatocellular cancer screening - Is that all you do, or do you keep doing FibroScanning as well? And how often do you do it? Because that's the bit I get really mixed up with.* *I've read the NICE guidelines to try to understand it, but it was just ELF score and this score and that score and oh my God.*
T3Q6	*GP3*	*I think what you really want is guidance, at least from my perspective, some guidance that you're actually doing the right thing.*
T3Q7	*GP4*	*These are the reasons to suspect, these are the diagnostic criteria, these are the tests you order at the beginning and this is the process. Then I can incorporate that into a stream that works with our chronic disease nurses because such a lot of this is lifestyle related and that's their role - providing lifestyle education and coaching. Then we can ... try to create something that's a bit more holistic for the individual patient. So if you're got NAFLD plus other [chronic diseases], cause they've always got comorbidities, then you have to construct a pathway that's suitable for that individual and our practice nurses, our chronic disease nurses are very good at that. But the problem at the moment is I don't have a structured sort of pathway for NAFLD that I can give to them and go "right, we're going to translate that into something that looks suitable for our practice and suitable for our people", and that we can then incorporate into that "whole individual" management planning.*
T3Q8	*GP4*	*.. we just need a way of identifying people at the highest risk. Cause there's a whole lot of people, even with indeterminate scores, who come back with low-risk FibroScans. And even for doctors I think it's kinda like, what is the yield, you know. I do all this and what is the yield. If we had access to things like ELF testing ... the advantage of ELF would be, that it could just be added [to other blood tests]*
T3Q9	*GP5*	*I suppose a risk assessment saying what their score is and then maybe what their likelihood of progression is.*
T3Q10	*E5*	*Or at least have a pathway from there, for those that have a FibroScan above the threshold or whatever score you are using.*
T3Q11	*E5*	*Yeah, as simple as possible, preferably integrated into our best practices—just sink a few parameters in there*

TABLE 2 (Continued)

T3Q12	*GP8*	*... almost like a checklist would be a really safe thing to do. Because I feel like fatty liver is something where it's so common to have these mild liver function derangements on blood tests. And it's such an alluring label to stamp on someone's chart and not feel the need to do anything else about it.. I've seen people before who've had a fatty liver diagnosis on their chart and nothing else has happened. Not saying I'm perfect at doing these things. But, it is a very tempting thing and I think it would be reassuring even amongst different clinicians to sort of know, that other people have done the same thing as you would have, as well. Because it seems to be completely on the clinician's individual [choice]– what they reckon they should do about fatty liver –and we all use these different calculators and different types of workups.*
T3Q13	*GP8*	*Different levels of workup. And you tend to, when you're jumping between patients. It's also very hard to know what's been done before. They've just got fatty liver written on their chart. You've got no idea if that just means their ALT was up and someone wrote fatty liver on their chart because they're overweight or if they've done everything else. You have no idea.*
T3Q14	*GP7*	*The interesting thing I've found with the Asian students, they don't have elevated BMIs. But they are experiencing fatty liver at a low BMI. And we have this discussion all the time because you want to be careful with over-screening, but every time one of them comes in I think "oh, maybe I should do an e/lfts."*
Theme 4: Healthcare providers considered long-term liver consequences a rare occurrence		
T4Q1	*E1*	*The HCC risk ... again we can't necessarily refer every person here for an annual ultrasound. But we probably could get GPs to do it - but to do that we need to know if they have fibrosis which we don't necessarily know because we don't necessarily have a FibroScan.*
T4Q2	*E3*	*What proportion of NAFLD is that very high-risk group? I've been an endocrinologist for 25 years and I've had one patient that's had NAFLD HCC and died from it, in 25 years and there's been a lot of diabetics along the way.*
T4Q3	*E3*	*But how common is it? Well, I think it's really rare because that's been my experience. But I'm happy to be educated.*
T4Q4	*GP5*	*Well, chronic liver scarring is a problem so that is why I suppose we are doing these assessments like FibroScans to try and get an idea of where they are sitting; if they are likely to be patients that are going to be progressive.*
Theme 5: There are significant challenges of discussing NAFLD with patients		
T5Q1	*EAT*	*Just that I think, armed with a risk stratification tool like you're talking about - access to a scan - I think that would change the shape of the conversation we would have with people about their liver disease. Because I take the point of <other doctor> we all try to improve their glycaemic control, their metabolic profile, but often it gets a bit lumped into one conversation. But if we're got something saying that this patient is at really high risk for having advanced fibrosis, the shape of that conversation might change and you might convert more of the stuff that goes into the ether of "go see your GP" and we put it in a letter and it never happens realistically. You might actually have more of a breakthrough. I'm always too optimistic but you actually might get someone that goes and makes an appointment.*
T5Q2	*GP1*	*... by the time they know about heart disease, they know about diabetes, they're happy to talk to you about that, that, that. And then you get to the liver and they're fading out—I see too many doctors, too many specialists. You don't often get anyone refusing a referral to a specialist except for the liver.*
T5Q3	*DE1*	*We always get resistance - you know we are talking about weight and we have lots and lots of obviously morbidly obese patients that come through and when we start talking about weight loss strategies, all those sort of things, some of them you don't much further than they know that they have to eat better, lose weight, move more. But sometimes the discussion does not progress much better than talking about strategies and motiving and choosing which goals they want to choose to work on between appointments, those sorts of things.*
T5Q4	*E5*	*... there is that disease rejection thing I mean people reject the idea of having diabetes and that they have to change their lifestyle and they start getting scared when you say not only that, but your kidneys are bad, your heart is bad, your liver is not too good, your eyes are just about to start. You know by the time you've come out with that, there is this kind of push back from patients about—don't tell me anymore.*
T5Q5	*GP5*	*... practically the barrier often is not even just the education of GPs it is actually that - is it accessible - because people really resist. They don't like going to tests they don't benefit from, [if] you know there are no complications [of NAFLD].*

(Continues)

TABLE 2 (Continued)

T5Q6	*E6*	*Quite often also, patients don't know that they have that label. And they're not going to really worry about something that no one else has even told them they have first of all. But if your doctor's worried and doing things, then there's going to be a little bit more buy in … that it's something that needs addressing.*
T5Q7	*DE3*	*There's already so much information that we're already giving them just on their diabetes management—whether it's their insulin or lifestyle. To add something extra in there I think they'd just get overloaded and often with what we already do, there's that overload and you have to know when enough is enough and either bring them back for another review. But I guess what we tend to do is write it back into the GP letter—if we're writing one back.*
T5Q8	*DE3*	*Try and relate it to them, something tangible. Because if you just say fatty liver, they have no idea what you're talking about. Same as if you say you know—your triglycerides are up, they have no idea, you've got to break it down. So as an educator it's really time-consuming.*

Abbreviations: DE, diabetes educator; E, endocrinologist; EAT, endocrinology advanced trainee; GP, general practitioner; T1Q1, theme 1, quote 1.

3.1.5 | There are significant challenges of discussing NAFLD with patients

Due to the prevalence of multimorbidity among the patients managed by participants, a diagnosis of NAFLD was rarely the selective focus during the patient review. When discussed, NAFLD tended to be raised in the context of weight. HPs also disclosed reticence to discuss the diagnosis of NAFLD due to perceived information overload or concerns about the patient's ability to process the diagnosis relative to other health concerns. (T5Q2, T5Q3, T5Q4, T5Q7, T6Q9). The challenge of discussing NAFLD with patients formed our fifth theme.

However, one participant observed:

> Quite often, patients don't know that they have that label [NAFLD], and they're not going to worry about something that no one has even told them they have. But if your doctor's worried and doing things, then there's going to be a little bit more buy in; that it's something that needs addressing.—Endocrinologist 7.

Reluctance among patients to follow through with further investigations was also identified as a barrier to diagnosis and assessment (T5Q2, T5Q5, T6Q9). One diabetes educator remarked on the importance of delivering appropriate education relative to patients' health literacy and the additional time required to achieve this (T5Q8).

3.2 | NAFLD management

3.2.1 | Diagnosing NAFLD does not change management

The perceived inability to monitor NAFLD and the belief that patients with the metabolic syndrome with or without NAFLD were not managed any differently was found to influence decision making, and this comprised our sixth theme. Clinician knowledge about managing people with NAFLD centred on weight loss, and most considered specific management of NAFLD superfluous when there were no clinical signs of liver disease (T6Q1, T6Q2, T6Q5, T6Q6, T6Q9).

Endocrinologists were aware of the GLP-1 receptor agonist trials in NAFLD and made use of these medications despite the current limited knowledge of their efficacy in NAFLD (T6Q2, T6Q7).

Clinicians were aware that the leading cause of mortality in NAFLD is cardiovascular disease and actively monitored and managed this aspect of their patients' health. Conversely, participants voiced their anticipated regret regarding the time and effort invested in a NAFLD intervention that may not change patient outcomes, whether that be a lack of response to weight-loss advice or the costs of further investigations (T6Q1, T3Q8).

Despite expectations of failure and wasted effort, participants acknowledged that patient awareness and understanding of liver disease and cancer risk was important to motivate lifestyle changes (T6Q4).

3.2.2 | Time and resource constraints in clinical practice mean other issues are prioritised above NAFLD

Unsurprisingly, time and resource constraints in clinical practice were identified barriers that contributed to the prioritisation of other chronic conditions above NAFLD. This comprised our seventh theme. Whilst the use of chronic disease nurses as 'lifestyle coaches' was an enabling factor in one practice (T3Q7), several HPs expressed difficulties accessing allied health support for lifestyle interventions and management of the metabolic syndrome. That was particularly the case during one focus group consisting only of GPs (T7Q10). Several participants identified difficulties accessing tests to aid risk stratification, further limiting their assessments (T4Q1, T7Q1, T7Q4).

TABLE 3 Quotations coded into themes 6 to 8, under the topic of NAFLD management

Theme 6: Diagnosing NAFLD does not change management		
T6Q1	*E3*	*The issue is how do you treat it, and we treat it the same way we treat everything else, and it usually doesn't work.*
T6Q2	*E3*	*Because I think all of the patients we tell them to lose weight, use metformin, use GLP−1 analogues and SGLT−2 inhibitors and we treat their lipids, we treat their hypertension. So we're kind of doing all the stuff.*
T6Q3	*E1*	*What are you gonna do about it because my thought is, telling the GP to send them to Joe Average down the road to get a FibroScan done with someone who does 2 FibroScans a year on your XL probe-requiring patient is a dead loss. So it's the "what do I do about this at the end" - is this going to change anything?*
T6Q4	*E2*	*I find that things like liver disease and cancer risk are quite triggering for a lot of patients and they may act if they were high risk of those things.. then that may actually be some form of other motivation.*
T6Q5	*GP3*	*We do need a group [lifestyle intervention group]. We make the diagnosis, but it's weight loss, and weight loss, the bariatric surgery, all of those things.*
T6Q6	*GP5*	*Because I suppose from our point of view there's so many things. But the management really is quite similar to the management that we are doing for these other things - the weight loss. I suppose you are wanting to assess who are at higher risk, but the management is not that you would be doing anything particularly different.*
T6Q7	*E6*	*I think, a lot of our treatment for diabetes overlaps with treatment for NAFLD. I think all of us are pretty diet focused and all would give out lots of hand-outs about diet. And I would often favour a GLP−1 agonist if I know or suspect they've got NAFLD.*
T6Q8	*GP7*	*I think in the ones who aren't a type 2 diabetic just yet, it's something they can see. They can see there's an abnormality. Maybe it's not something so dramatic that you have to start treatment, but they can see that things are not right and they've got the ability to improve it. So, I think the diagnosis is important for that reason. That it's telling them that things, you know, there's some damage that will continue if you don't do something about it. And there's an indication with other things as well and correlation with type 2 diabetes and cardiovascular disease and probably other things I should know about but can't remember.*
T6Q9	*GP8*	*You know in terms of, because they're usually going to have metabolic syndrome as well, someone's got metabolic syndrome and fatty liver. So that sort of covers the basis of all of them because really the fatty liver itself is almost the one that there's not much - from the patient's perspective, we don't even, as far as I know, we don't even have a way of monitoring it, to say—hey your fatty liver has gotten way better! Unless we're doing serial ultrasounds or something. I don't know. So, they might not even know it's getting better. Is that true?*
Theme 7: Time and resource constraints in clinical practice mean other issues are prioritised above NAFLD		
T7Q1	*E3*	*I don't even know how to get a FibroScan, I thought it was a research tool that we couldn't actually order.*
T7Q2	*E1*	*That's the thing - they're not transplantable and they're probably going to die of their other metabolic associated bits and pieces first.*
T7Q3	*GP4*	*So I can understand why the NHS has done that (recommended the ELF test). I just think it's easier, it's just another test. And when you've got an ELF that comes back and it says you know this is probably elevated, then there's really this trigger - I must refer now. Whereas the problem with an indeterminate NAFLD score, for example, is you know the vast majority of the indeterminate ones are going to be fine. And it's like, is it just indeterminate or is it nearly at the upper level. So I think being able to do something like an ELF would be helpful. Because the truth is, <Name of doctor> is currently sending you all of hers [NAFLD patients]. I send you some of mine but if every GP starts doing this you'll be completely overwhelmed and you know that and we know that.*
T7Q4	*GP5*	*I don't think it matters so much if it is a radiological or serum test, but one maybe that we could do [in the community]. Because that is the thing- because of the expense of the radiological study at the moment, it is not MediCare rebatable for sure. That is why we end up referring a lot through hepatology... If we could refer to it (fibrosis test) and then do a risk assessment then [we can] decide do they need HCC surveillance.*

(Continues)

TABLE 3 (Continued)

T7Q5	*E5*	*I think probably the liver side of it does not get as much prominence as some of the other routine bits and bobs. Probably it is one of those things that is so common yet only a relatively small number of people would, over a long period of time, would get really sick directly due to this and there is probably more concentration on the cardiovascular side.*
T7Q6	*GP5*	*That is just the things that come up in the shorter term for us- the patients are presenting with heart attacks and bleeds. It is a bigger percentage of our patients, the cardiovascular things, but I mean they are tied in, like I have said, if they've got advanced liver disease then they are much more likely to have advanced cardiovascular disease as well, but I suppose just in terms of that monitoring.*
T7Q7	*E5*	*... so the ones we see are all the worse end of diabetes, so we probably should do more with them but there are a lot of other things to do I think.* *And referring them all to the liver clinic would fairly rapidly overwhelm the liver clinic.*
T7Q8	*GP5*	*Well HCC possibly, but probably more commonly cardiovascular.*
T7Q9	*GP8*	*I think that what you said about the risk of there being another, another in the big, long list of diagnoses that's sort of siloed, I think really applies here. And so, if a lot of the messaging you're giving them, overlaps with the messaging we want to, because really, we're trying to tell them about all the ways that you can undo or reverse this process that's happening in your body through mostly lifestyle changes and also maybe taking the tablets that you've been given. So, I think if it's integrated into something that's more broad that might be more useful to me as a thing to dedicate time to show the patient.*
T7Q10	*GP 1, 2, 3*	*"But they've already got a bad knee, they've already used up all of their GPMP (GP Management Plans*) on all the other things. You know, like the podiatry." - GP3* **[GP Management Plans allow a person with a complex and/or chronic illness to claim a Medicare rebate for up to five visits (in total) to certain allied health professionals within a calendar year.]* *"There's no space for the dietician."- GP2* *"And [the podiatry is] actually a practical thing that [patients] want."—GP1* *"Sure, I'd love to refer everyone to a dietician, but it's not possible."—GP2*
Theme 8: Healthcare providers favour an integrated approach in primary care		
T8Q1	*E4*	*The other issue comes into, say that person moves overseas or interstate or we discharge them from the clinic and they turn up to their FibroScan but they're not following up with anyone - who's going to see the result?*
T8Q2	*E2*	*And it's ordered by a registrar, not copied into a consultant and the registrar no longer works there - I don't know what happens to the result.*
T8Q3	*E3*	*I wanted to talk about the role of primary care. I understand this is a research project so you want as many coming through as we can get and that's great. But in the future, the future isn't going to be in hospital, it's going to be putting this into the primary care setting and having the facilities there. And primary care does a good job - look what they've done with cervical cancer before we had the vaccine. Screening for cancer and chronic consequences is one of the things primary care does really quite well.*
T8Q4	*GP2*	*We really really really do need something in the community that we can access, so we can avoid the referral [to hepatology].*
T8Q5	*GP5*	*I would say it's not rocket science because it's the lifestyle stuff and then, I didn't say it before, but yeah the HCC monitoring. Like anything, it would just be an algorithm we would put into our review, our care plan reviews, that we need to be doing this at this point. So I think most GPs who do chronic disease would be comfortable.*
T8Q6	*GP5*	*We do our set care plan reviews for diabetics in general practice, not so much in the diabetes clinic. Every 3 months we are doing a review of their HbA_{1c}, checking renal function, and just running past have they had their urine albumin check—all those tick box things at our three-month review or on some of them they come up 12 monthly or the eye checks two yearly. At the moment I don't think there is a liver part to that, so that could be added to a typical diabetes clinic disease review that is done at practices.*

TABLE 3 (Continued)

T8Q7	*E5*	*I think the thing that people have not done much is integrated all into one pathway so you don't have your eye pathway, heart pathway and your liver. If you had that as one, you are saying a lot of therapeutic goals are the same, with intensive respect to management.*
T8Q8	*E6*	*Diabetes has changed a lot in the last 10 years with the advent of newer agents which prevent other comorbid conditions, like the SGLT−2 and GLP−1 [agents]. So diabetes isn't about numbers and A1Cs anymore, it's about prevention of other things. You don't die from diabetes you die from heart attacks and cirrhosis... So I think there's good space for it [management of NAFLD].*

Abbreviations: E, endocrinologist; EAT, endocrinology advanced trainee; GP, general practitioner; T1Q1, theme 1, quote 1.

TABLE 4 Exemplar quotations to support the four key characteristics of a NAFLD pathway identified by participants

Key characteristics of a NAFLD pathway		
Clear criteria regarding which patients should be on the pathway	*E3*	*... what we need is ok—this is the at-risk population, these are the ones we need to FibroScan.*
	GP8	*I have to admit when I'm looking at someone's results if the general picture is not making me worried I might not systemically do that. If sort of all the platelets are normal and some others, I might not go through the rigmarole of doing that, maybe I should be*
A simple risk-assessment tool, ideally incorporated into GP software, that identifies patients who require further investigation	*GP5*	*A risk assessment saying what their score is and then maybe what's their likelihood of progression...just like when we calculate cardiovascular risk from best practice—a simple tool.*
	EAT1	*I think people would have a good uptake of a risk stratification tool because we do use them in lots of other areas.*
Provision of guidance on appropriate tests to confirm NAFLD severity	*GP8*	*Yeah, I think it would be; almost like a check-list would be a really safe thing to do. Because I feel like fatty liver is something where it's so common to have these mild liver function derangements on blood tests. And it's such an alluring label to stamp on someone's chart and not feel the need to do anything else about it... I think it would be reassuring even amongst different clinicians to sort of know, that other people have done the same thing as you would have .... Because it seems to be completely on the clinician's individual [choice]– what they reckon they should do about fatty liver—and we all use these different calculators and different types of workups.*
An explanation for interpretation of the tests and what must be actioned, including appropriate patient management and follow up	*E2*	*And I suppose then, giving us criteria above whatever score to refer to you so then you can manage them*
	GP3	*So those patients you follow with NAFLD and you're worried they've go [advanced disease] and you're doing 6 monthly hepatocellular cancer screening - Is that all you do, or do you keep doing FibroScanning as well? And how often do you do it? Because that's the bit I get really mixed up with.*
		I've read the NICE guidelines to try to understand it, but it was just ELF score and this score and that score and oh my God.

3.2.3 | Healthcare providers favour an integrated approach in primary care

Whilst all participants felt they had the skills to target weight loss and lifestyle factors, endocrinologists identified their role as providing specialist advice on diabetes management rather than lifestyle factors or long-term patient follow-up. They felt that in a specialty clinic many patients would be lost to follow up, and NAFLD interventions would be most appropriately implemented in primary care (T8Q1, T8Q2, T8Q3).

The belief that primary care practices were best placed to manage lifestyle diseases was supported by many of the GPs (T8Q4, T8Q5, T8Q6, T3Q7).

GPs were generally confident to manage NAFLD within their clinical paradigm. There was also the belief that if appropriate tests were easily accessible and integrated into usual care for high-risk patients, then there would be a good uptake of a NAFLD pathway in general

practice. A suggestion from clinicians was to ensure clear parameters for management and referral (T3Q2, T3Q3, T3Q4, T3Q5, T3Q6, T3Q7, T3Q9, T3Q10).

Rather than manage each metabolic comorbidity in isolation, HPs consistently recommended including NAFLD management as part of the routine metabolic assessment to reinforce the shared features of these conditions. The need for an integrated approach to NAFLD management in primary care was established as our eighth theme (T8Q6, T8Q7).

A consistent message from participants was that educating patients about their liver disease needs to be implemented in an integrated care pathway. This will allow time-poor clinicians to communicate more efficiently with patients about the overall health consequences of metabolic disease. Increasing clinician confidence in establishing a diagnosis of NAFLD and communicating this to patients may facilitate patient engagement in care and translate to successful lifestyle interventions (T5Q1, T6Q4)).

Clinicians in all focus groups agreed that implementation of a NAFLD pathway and access to appropriate fibrosis tests in the community would improve patient care (T8Q4, T8Q8, T5Q1, T3Q1, T3Q7).

4 | DISCUSSION

Lack of knowledge and access to resources were key factors that underpinned an inconsistent approach by clinicians to NAFLD diagnosis and risk stratification and also impacted their confidence to discuss the diagnosis with patients. Participants often prioritised other medical issues above NAFLD due to lack of concern about liver-related consequences, reluctance to overburden patients with information, lack of time and the absence of accessible fibrosis tests. Our data support findings from an earlier European study that proposed under-diagnosis of NAFLD in primary care was due to under-investigation of abnormal liver enzymes/imaging and lack of confidence to make a diagnosis (particularly if liver enzymes were in the normal range).[17] Whilst the rate of adverse liver-related outcomes in NAFLD is lower than other chronic liver diseases,[18] failure to recognise and risk-stratify NAFLD may lead to future presentation with advanced fibrosis or HCC, and reduced availability and cost-effectiveness of therapies.

All participants agreed that the implementation of a NAFLD pathway would improve patient care. GPs perceived their role to centre on the management of lifestyle factors, and several GP participants proposed that screening for NAFLD could be incorporated into routine review cycles for diabetes. The lack of awareness of the NAFLD information accessible via a local online database for general practice suggests that implementation of a NAFLD pathway will require concurrent delivery of targeted education to facilitate uptake of relevant guidelines and tools. Endocrinologists supported the implementation of a NAFLD pathway in primary care and identified that such a pathway was unlikely to succeed in a specialty clinic due to the loss of patients to follow up.

In order to facilitate pathway use in clinical practice, participants identified the need for clear criteria regarding which patients should be on the pathway. A dedicated screening pathway would provide a standardised approach to evaluating fibrosis in all people with T2D, in contrast to the current situation where NAFLD may be detected incidentally. Although there are limited data regarding the cost-effectiveness of screening for NAFLD in people with T2D,[19,20] there is increasing support for identifying people with NAFLD and advanced fibrosis in at-risk populations.[21,22] Similarly, other key characteristics of a pathway identified by our participants (simple risk-assessment tool, interpretation of tests, provision of guidance) have been recognised or trialled in other centres. In Scotland, a structured algorithm for analysis and subsequent investigation of abnormal liver enzymes was found to correctly (in 91.3% of cases) triage patients to referral for specialist investigation or to ongoing management in primary care.[23] The authors commented that their systematic approach "demystifies liver enzyme derangement for the primary care provider" and could be automated and integrated with GP care pathways and laboratory tests.[23] However, a qualitative study of HPs in northeast England found that, similar to our data, there was a lack of awareness that NAFLD guidelines exist and this contributed to inconsistent referral practice.[14] Whereas the latter study contained a predominance of specialist gastroenterologists and hepatologists ($n = 8$), with fewer diabetologists ($n = 3$) and GPs ($n = 6$),[14] our current study included equivalent numbers of GPs ($n = 9$) and endocrinologists ($n = 7$). However, the relative lack of GPs is a key limitation of our study that may limit the external validity of our findings. An additional limitation is the lack of consumer input, an important consideration as some screening pathways may involve a series of potentially demanding steps for patients. Nevertheless, the findings from both studies highlight the importance of improving knowledge about available guidance and diagnostic tools and also providing appropriate HP training to use and interpret the tools correctly.

The changing paradigm of diabetes management to focus on complication prevention (rather than HbA_{1c} targets) was proposed as a facilitating factor for the integration of a NAFLD pathway in primary care and diabetes clinics. Recent literature also supports the shift away from 'disease silos' towards holistic models of care for

multi-system diseases like NAFLD. Trials of integrated clinics involving multisystem assessment of comorbid conditions (including diabetes and heart disease) have demonstrated substantial patient benefits including improvement in markers of liver disease and cardiovascular risk factors.[24–26]

5 | CONCLUSION

From the perspectives of health professionals, there is a gap in clinical practice for the implementation of clear, evidence-based guidelines for NAFLD in people with diabetes. By focusing on comorbidity prevention and integrating NAFLD as a diabetes complication to be addressed during established cycles of care, many barriers to implementing a NAFLD pathway in primary care could be overcome.

ACKNOWLEDGEMENTS

LG and MA were supported by a Metro South Health Research Support Scheme Grant. KLH was supported by a Health Innovation, Investment and Research Office (HIIRO) Clinical Research Fellowship. Open access publishing facilitated by The University of Queensland, as part of the Wiley - The University of Queensland agreement via the Council of Australian University Librarians.

CONFLICT OF INTEREST

None.

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How to cite this article: Gracen L, Hayward KL, Aikebuse M, et al. An exploration of barriers and facilitators to implementing a nonalcoholic fatty liver disease pathway for people with type 2 diabetes in primary care. *Diabet Med*. 2022;39:e14799. doi:10.1111/dme.14799