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What hepatology clinicians and their patients with alcohol-related liver disease think of wearable alcohol biosensors to aid abstinence from alcohol: A qualitative study

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Abstract

Introduction: We aimed to determine acceptability and feasibility of innovative wearable alcohol biosensor monitors (ABM) for patients with alcohol-related liver disease (ALD) and their clinicians.

Methods: Patients and clinicians at a tertiary care centre participated in qualitative interviews on usability, acceptability, feasibility, efficiency/effectiveness, impact of device on behaviour/clinical practice and preferences/barriers. Interviews were audiotaped, transcribed and coded using a constant comparison method for category themes.

Results: Patients ($n = 23$) were 56% female, mean 44 years old, 87% White, with moderate–severe liver disease. Some felt the ABMs appearance was unappealing; others felt it provided an opportunity for openness and education of others. While some found it feasible to wear, others felt it was unrealistic to wear 24/7. Importantly, there were many positive themes on effectiveness/efficiency—participants felt the ABM could better record their alcohol use and patterns of use than they could remember. Patients felt wearing the ABM motivated abstinence, gave accountability and was a source of security.

Clinicians ($n = 13$) were mostly hepatologists (77%), seeing on average 38 ALD patients/month. Clinicians felt seeing patterns and amounts of alcohol use could inform clinical decision making and treatments but expressed concern over the volume and complexity of data.

Discussion and Conclusions: Perspectives on ABMs for managing ALD were mixed among patients and providers. Future device designs may overcome acceptability barriers due to device appearance. However, for clinicians, the logistics of data gathering plus the complexity and volume of data produced by the ABM device requires considerable thought to make this an efficient tool for clinical use. Clinicaltrials.gov identifier NCT03533660: Alcohol biosensor monitoring for alcohol liver disease.

KEYWORDS
acceptability, alcohol-related liver disease, feasibility, wearable alcohol biosensors

1 | INTRODUCTION

Wearable alcohol biosensor monitors (ABM) are electrochemical devices that measure alcohol vapour secreted transdermally in perspiration indirectly measuring the blood alcohol content, and thus, by inference, alcohol consumption [1]. Compared to self-report, ABMs can improve on inaccuracies in self-report, provide continuous estimations of alcohol use (e.g., including peak and duration of alcohol levels) not obtainable with self-report, and could reduce user burden [2]. In treatment settings such accuracy could improve the monitoring of outcomes and appropriateness of treatment planning.

Working with patients with alcohol-related liver disease (ALD), we recognise successful treatment and prevention of liver decompensation depends primarily on total abstinence from alcohol. In contrast to addiction treatment where abstinence or even harm reduction may be eventual goals with less need for immediate adherence, the complete abstinence requirement in the ALD patient population makes it a useful group in which to test new strategies for efficient monitoring of patient behaviour. In particular, patients with decompensated ALD are an especially compelling group for identifying real-time monitoring approaches to alcohol use. Currently, these ALD patients are monitored through clinical interview and (ideally) random laboratory alcohol testing, although in real world clinical settings these practices are often inconsistently applied. In fact, our prior work [3, 4] showed most discoveries of alcohol use in patients with ALD were not made until months after the initiation of consumption and were largely captured through prospective repeated research surveys not routinely employed in clinical settings. We believed the key characteristics of ABMs, namely continuous monitoring and improved accuracy, could be especially useful in a medical population such as patients with ALD for whom a more accurate appraisal of alcohol use when combined with feedback may motivate them to change their drinking habits and engage in appropriate treatment. Early detection of use could also inform quicker intervention to prevent further harm.

Previous research on ABMs initially involved laboratory and field-testing studies focused on sensitivity and accuracy of alcohol measurement [5–8]. A 2022 review of the acceptability and feasibility of wearable alcohol biosensors showed that, 45% of 22 published studies that used or investigated experiences of people using an ABM focused on laboratory or ambulatory participants to examine how to measure alcohol consumption with the ABM technology [9]. Most (82%) studies, were conducted in persons in good health, were of short duration of wear (several days to several weeks) [6, 10–18] and only 18% included participants with an alcohol use disorder. None were conducted in medically ill populations—in fact medical illness was often an exclusion criterion. Few studies considered acceptability [11–13, 19, 20] or feasibility [20] using quantitative questions [9]. Feasibility was mostly determined not from the participant's perspective but from measures of adherence to wearing or tampering with the device [11, 19–22]. A quantitative survey of alcohol use disorder patients who had never worn an ABM device found an overall favourable opinion of ABMs with anticipated advantages of helping them accomplish treatment goals and prevent relapse [23]. Alessi et al. examined the acceptability and feasibility of ABM in an alcohol treatment cohort using a quantitative survey measure after 12 weeks of wear [19]. While some were willing to wear it longer and felt it helped them to cut down on drinking, issues with physical and social comfort of wear were common. Richards et al., in a single qualitative study of 20 heavy drinking adults (<50% had any experience with ABMs), found participants felt that potentially helpful features would include real-time data

with alerts and the ability to share data with family/friends and health care clinicians to support their recovery [24].

While these studies have revealed basic issues with ABMs in healthy individuals or alcohol treatment seeking cohorts, there has been no examination of ABMs in a medical cohort specifically to enhance their medical treatment. Thus, we felt an investigation of ABM in a medical cohort, over a duration to approximate actual clinical needs and usage, was required to evaluate feasibility and acceptability of these devices in an actual clinical scenario. Whether biosensor devices would facilitate identification beyond self-reports, be integrated into the clinical workflow, accepted by patients and clinicians, and improve outcomes requires investigation. Although it is possible that monitoring with a biosensor would be viewed by clinicians (and perhaps even patients) as more convenient and more desirable, there could also be disadvantages. Patients may feel uncomfortable using the device or feel it is an intrusion. Clinicians may be concerned about additional time and staffing needs resulting from ABM use.

Thus, the feasibility of integrating ABMs into routine clinical care requires examining both patients with ALD and their clinicians' perceived potential benefits (e.g., convenience and acceptability, potential improvement in care delivery, facilitation of developing/adjusting treatment plans) and possible barriers (e.g., resistance to adoption, problems with use, interference in patient-clinician relationship). We collected qualitative data from outpatient participants with ALD who wore an ABM device for 3 months and hepatology clinicians who worked with outpatients with ALD. Qualitative methods are especially useful for understanding patient and clinician cultures and perspectives to determine the perceived needs, barriers and preferences for monitoring alcohol use and are essential for future translation of this technology into clinical practice [9, 25, 26].

2 | METHODS

2.1 | Ethics statement

This study was approved by the University of Pittsburgh Human Research Protections Office (PRO 18010209). All participants signed written informed consent prior to study participation.

2.2 | Overall study design and primary aim

The present data were collected in the context of a 3-month randomised control trial (RCT). Patients with ALD who intended to stop drinking wore the ABM and were randomised to receive monthly ABM personalised feedback on the data retrieved from the device versus an enhanced usual care group that wore the ABM device but did not receive information about device data. While our primary study aim was to examine acceptability and feasibility of ABM for patients with ALD, the RCT design also allowed testing of feedback on the device data. In this paper we report findings from our directed qualitative content analysis using a constant comparison approach [27] to determine usability, acceptability, feasibility and efficiency of biosensor use. Qualitative interviews were conducted for both ALD patients and hepatology clinicians. We followed the consolidated criteria for reporting qualitative research guidelines for conducting and reporting qualitative data [28].

2.3 | Patient participants

Eligible patients for the RCT (and therefore for the qualitative interviews at the end of the trial) had decompensated ALD, were drinking within the past 3 months and followed at our liver specialty clinic. Between September 2018 and February 2020 potential participants were first approached by treating clinician for permission to allow research staff to discuss the study with them. If they agreed to this discussion research staff would discuss the study, perform screening and, if eligible, recruit them if they were interested. Potential participants were excluded if they scored poorly (i.e., <21) on the Montreal Cognitive Assessment [29] or had current hepatic encephalopathy. They were also screened out using the Stages of Change Readiness and Treatment Eagerness Scale problem recognition subscale. A score ≤26 in the face of ALD complications indicates very low recognition of an alcohol problem, possibly pathologic denial, and these individuals are unlikely to stop use or be interested in help for their drinking [30]. Participants had to be willing to wear the ABM device for 3 months.

For the RCT 54 potential participants were approached and 36 (67%) agreed to be screened for eligibility. Of those found eligible ($n = 34$), 97% were enrolled ($n = 33$). Of 18 patients who declined screening for the RTC, the primary reason was the device appearance ($n = 5$), 4 would not commit to study participation, 3 were too ill, 3 did not have transportation to return for the study, 1 was interested but too busy, 1 was afraid wearing the device would trigger thoughts to drink and 1 felt their active lifestyle would damage the device. There were no significant differences between those enrolled in the RCT and those who declined screening or enrolment on sex or race/ethnicity, but enrolees were

significantly younger (45 ± 11 vs. 55 ± 19, $t = 2.3$, $p = 0.026$). Twenty-seven completed the intake interview (four withdrew before starting: two were lost to follow up at the beginning of the COVID-19 shut down and two became too ill or died).

As we wanted patient perspectives on the ABM after wearing it for several months, we conducted the qualitative interview at the end of the 3-month RCT. Twenty-three were interviewed at the RCT end for the qualitative study (four participants died of their ALD during the study). We judged that this sample size would be more than sufficient to reach thematic saturation [26].

2.4 | Clinician participants

Hepatology specialty clinicians (physicians and physician assistants) practicing at the University of Pittsburgh Medical Center, Center for Liver Diseases were approached for participation in a qualitative interview to gain their perspectives on the ABM device and its potential usefulness after being shown the device and how it is used (see below). To reach thematic saturation [26] we planned to recruit at least 10 clinicians. We achieved thematic saturation (described below) with the first 13 approached who all agreed to participate.

2.5 | ABM device and monitoring of alcohol use

We used the wrist transdermal alcohol sensor (WrisTAS™ Giner/SmartStart, Newton, MA, USA) for its more discreet appearance like a wristwatch, ultra-lightweight design, location of wearing on the wrist and the ability to remove it in an emergency (see Figure 1). The validity, precision and accuracy of WrisTAS was favourably evaluated by the National Highway Traffic Safety Administration under laboratory testing and meets law enforcement and justice system standards [1, 18, 31]. The validity, precision and accuracy of WrisTAS was evaluated by the National Highway Traffic Safety Administration under laboratory testing demonstrating a high rate of true positives, >82%, across a range of BAC and had accuracy down to 0.02 g/dL BAC [1, 18, 31], specificity from 67.5% to 92.94% [32] with virtually no false positives, even in liver disease [1, 33]. The WrisTAS can be programmed to have a near continuous sampling interval. There are no visible sensors or displays on the device—participants cannot 'see' any data nor can they download the data. The device captured data for 1 month on a single battery. Research staff retrieved the devices monthly for a battery change and to download device data.

The device provides a database of continuous estimated blood alcohol levels. For clinical purposes a post-processing software algorithm provides the data in graphical form along with temperature and proximity sensor data (see Figure 2). Additionally, the software can transform the blood alcohol content over a specific period of time (i.e., a drinking episode) into standard alcohol drinks per episode (see Figure 3). These data were adjusted for sex.

The device was worn on the wrist with an adjustable Velcro strap. Participants were fitted with the ABM and instructed on its use, with demonstration of how to put it on, remove it and adjust it to make sure it was snug and the sensor was flat on the skin. A brochure on wearing instructions was provided with photos showing proper wearing of the device (location on arm and orientation) as well as restrictions (e.g., not wearing during showering/swimming as the device is not waterproof). They were also told not to use alcohol hand sanitizer or cosmetics with alcohol (e.g., perfume/cologne) near or under the device sensor. They were told to wear it at all times,

FIGURE 1 Pictures of alcohol biosensor monitor device WrisTAS™ showing black electronic box with battery and data storage and sensor (round clear disc).

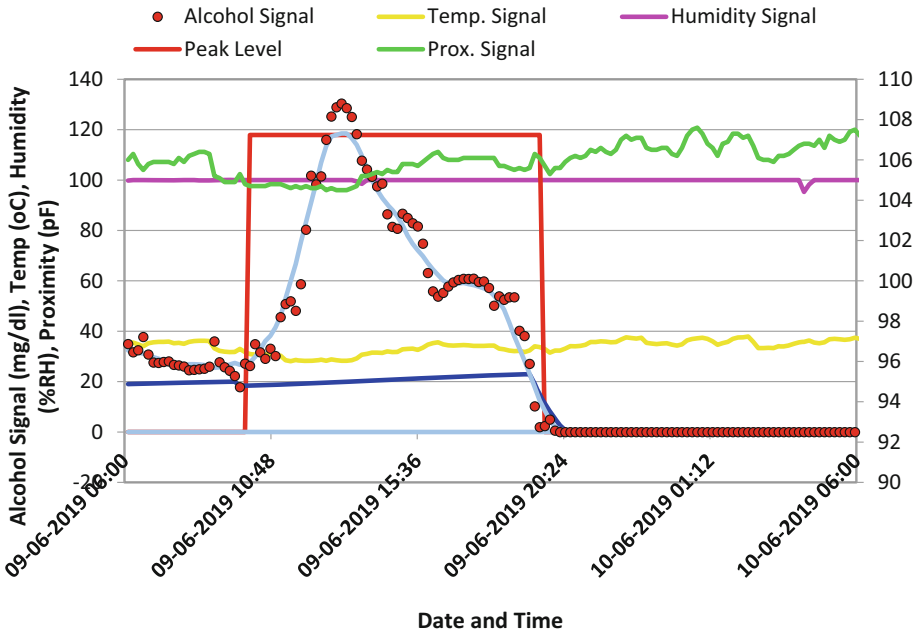

FIGURE 2 Alcohol biosensor monitor data graph demonstrating a participant's single drinking episode.

Total # of Drinking Events:	13
Average # of Drinks (per event):	11.8
Days of Binge Drinking:	12
Longest Time Not Drinking:	3 day(s) 7 hrs 0 mins
Total Time Not Worn:	9 day(s) 20 hrs 11 mins

Analysis Report - Drinking Events:

Starting Time:	Ending Time:	Peak Alcohol Value (mg/dL):	# of Drinks:
6/6/2019 15:17	6/7/2019 11:47	42	9
6/7/2019 14:17	6/7/2019 20:17	36	8
6/8/2019 11:17	6/8/2019 23:37	31	9
6/9/2019 10:07	6/9/2019 19:37	98	10
6/10/2019 11:47	6/10/2019 16:47	29	2
6/12/2019 6:27	6/12/2019 16:27	136	18
6/15/2019 23:27	6/16/2019 8:07	103	23
6/18/2019 10:07	6/19/2019 2:57	143	19
6/19/2019 13:47	6/19/2019 19:07	150	12
6/21/2019 0:17	6/21/2019 7:07	104	6
6/23/2019 8:37	6/23/2019 19:57	119	16
6/23/2019 22:07	6/24/2019 6:47	34	8
6/24/2019 18:17	6/25/2019 4:47	158	14

FIGURE 3 Alcohol biosensor monitor table summarising data from 1 month of participant wear.

even while sleeping. Participants received $25 for each month of wear.

2.6 | Assessments

2.6.1 | Baseline characteristics

Patient baseline demographics were collected during an intake interview in addition to detailed information on self-reported alcohol consumption over the prior 3 months, related health problems/health care utilisation, and days in addiction treatment using Project Match Form 90 AI [34]. The M.I.N.I. Neuropsychiatric Interview for DSM5 Alcohol Use Disorders (AUD) module (a validated diagnostic interview) [35] was used to categorise the severity of their AUD. Medical record reviews determined the liver disease severity rated by the Model for End-Stage Liver disease (MELD) score.

Demographic and clinical practice information was collected from clinician participants during their interview.

2.6.2 | Qualitative interviews and data analyses

After 3 months of ABM wear, patient participants underwent a qualitative interview about their experience.

Clinician participants' qualitative interviews included showing them the ABM device and providing copies of graphical data and a table representing 1 month of device wear from a participant in the study (see Figures 2 and 3). All participants completed by telephone an audiotaped interview lasting 30–50 min, depending on the length of their answers. Participants were told their responses would be transcribed and de-identified before review by researchers. A trained research interviewer, who was not involved in the patient's clinical care and did not work with the clinicians, used a semi-structured qualitative interview script of open-ended questions with prompts as needed to explore participants' perceptions of ABM use. The patient interview questions were organised around six a priori categories for patients: usability, acceptability, feasibility, efficiency/effectiveness (improve care, ability to capture amounts and patterns of drinking), impact of device on behaviour, and preferences or barriers to use. Clinician interviews were organised around seven a priori categories: usability/usefulness, acceptability, feasibility, efficiency/effectiveness (time/cost savings, more effective care), potential impact on health care and health care delivery, utility and preferences or barriers to use. Topic areas were chosen based on our prior experience and knowledge of the subject area and issues related to the use of technology in health care.

Three of the authors (Andrea DiMartini, Mary Amanda Dew and Jon Punzi) reviewed the de-identified fully transcribed interviews and coded them using a directed approach to content analysis with the key concepts [36] being the a priori categories of the interview. A codebook was developed [26] organised around these initial coding categories and using constant comparison techniques (i.e., assuring all data are systematically compared to all other data in the data set) [37] in which data were examined for similarities and differences to previously coded data and themes. Specifically using the main categories as a starting point, transcripts were read and reread as deductive subcategories emerged. Preliminary codes were grouped and categorised according to their meanings, similarities and differences as the subcategories emerged and were developed [27]. As coding progressed, we determined thematic saturation by redundancy in themes and lack of emergence of new themes. Coding was done independently, and coding discrepancies were resolved through consensus between two coders (Andrea DiMartini and Mary Amanda Dew for patient interviews and Andrea DiMartini and Jon Punzi for clinician interviews). Responses were additionally categorised as positive or negative within the specific content area (e.g., 'the device was uncomfortable to wear' would be a negative usability comment). As our goal was to explore and gain insight into the viewpoints of participants, rather than assigning objective characteristics such as numbers, we did not count the number who endorsed specific themes [38, 39].

3 | RESULTS

3.1 | Demographic data

3.1.1 | Patient participants

Our ALD cohort characteristics (Table 1) are similar to characteristics of the general ALD population in demographics [40], AUD severity and participation in addiction counselling [40, 41]. However, over half of our cohort were women whereas the ALD population is predominantly male (60%–70%) [40]. Most had a severe AUD (>5 of the DSM5 criteria) [35]; endorsing on average 8 of the criteria. They had an average MELD score of 21, indicating severe end-stage liver disease. Less than a quarter were in formal addiction counselling (four in outpatient alcohol counselling and one in outpatient alcohol counselling following a residential treatment program).

From the proximity sensors on the devices we determined, on average, participants wore their devices 70% of the time. Fifty percent of patients wore it approximately 90% of the time or more and only two wore it infrequently (7% and 13% of the time).

3.1.2 | Clinician participants

We had significant diversity among our clinician participants with respect to age, sex, racial/ethnic characteristics, years of practice and number of patients with ALD seen per month (Table 1).

3.2 | Qualitative results

3.2.1 | Patient participants

See Table 2 for positive/negative themes and representative quotes.

Usability

A variety of positive and negative comments were made about wearing the device, with a focus on comfort,

TABLE 1 Cohort characteristics: patients and clinicians.

Patient participants ($N = 23$)	
Demographics	
Sex, % (n) women	56 (13)
Age in years, mean (SD), range	44 (10), range 30–64
Race, % (n) White[a]	87 (20)
Hispanic, % (n) yes	4 (1)
Occupation, % (n) clerical/semi-technical/unskilled	52 (12)
Marital status, % (n) married or with partner	26 (6)
Medical variables	
Days in the medical hospital in past 90 days, mean (SD), range	15 (16), range 0–66
Model end stage liver disease score (MELD), mean (SD) range	21 (9), range 6–35
Alcohol history variables	
Alcohol use disorder severity, mean (SD), range	8 (3), range 3–11
When last drinking, average drinks per drinking day, mean (SD), range	11 (5), range 4–20
Number of drinking days in the past 3 months, mean (SD), range	44 (29), range 8–90
Currently participating in formal addiction treatment, % (n) yes	22 (5)
Participating in 12-step meetings attendance, % (n) yes	39 (9)
Clinician participants ($N = 13$)	
Demographics	
Sex, % (n) women	46 (6)
Age in years, mean (SD), range	43 (12), range 27–72
	85 (11)
Race, % (n) White	46 (6)
Hispanic, % (n) yes	15 (2)
Occupation, % (n) MD or MD PhD (hepatologists)	77 (10)
% (n) Physician assistants in hepatology	23 (3)
Years in clinical practice, M (SD), range	15 (11), range 2–40
Number of patients with ALD seen per month, M (SD), range	38 (26), range 5–100

[a]Participants selected their race from five categories. A white person is defined as anyone having origins in any of the original peoples of Europe, the Middle East or North Africa.

wearability and ease of use in daily activities. Some participants reported they had no interference with daily activities or discomfort not even during sleep and that they forgot they were wearing it. For example, one participant noted that:

> 'It didn't interfere with my activities. I play basketball, I play some tennis and it did not interfere with those activities either'.
>
> (White, male, age 58)

Other participants, in contrast, reported it was at times uncomfortable, and interfered with daily activities and some could not sleep with the device due to uncomfortableness. One participant noted:

> 'It's bulky and would knock into things. I work at a desk so I had keyboard and mouse and I would tend to hit it into things'.
>
> (White, male, age 39)

A few participants also reported taking it off to give their skin time to breathe or loosening the strap to improve comfort. Some worried about accidentally damaging the device during normal activities or forgetting to take it off for activities involving water.

Acceptability

Acceptability themes focused on the appearance of the ABM device. Some felt the appearance was inconspicuous, that people are used to seeing others wear devices, or that no one noticed it. One participant felt that:

> '... it looked kind of like an older version of a Fitbit so it wasn't something anyone ever questioned or looked twice at'.
>
> (White, female age 32)

Some noted not only did they not mind the appearance or did not hide its purpose, but also they felt the appearance of the device provided opportunities to educate others about alcohol use or to discuss their health issues. One participant explained:

> '... for me it made things more out in the open, that, "yes you are battling a disease." And this is here to help'.
>
> (White, male, age 59)

However, others felt it had an unappealing appearance, was bulky or had an odd shape that drew attention to it. The most negative comments focused on the device appearing as though it was a law enforcement device, implying that the wearer was on house arrest. For example, one participant reported:

TABLE 2 ALD patient positive and negative themes from qualitative interviews with representative quotes.

Category	Sub-category	Representative comments
Usability		
Positives	• Comfortable not cumbersome	"I'd just totally forget about having it on and think nothing of it."
	• No interference with activities/lifestyle/sleep	"It didn't interfere with my activities. I play basketball, I play some tennis and it did not interfere with those activities either."
	• Easy to use	"The device was relatively easy to wear. It felt more like a watch than anything else."
Negatives	• Uncomfortable/cumbersome/annoying	"... you notice it moving, the bulkiness of it, it snagging on something, then you notice it more and it gets annoying."
	• Interfered with sleep and other activities	"It's bulky and would knock into things. I work at a desk so I had keyboard and mouse and I would tend to hit it into things."
	• Worried about care of device, damaging or cleaning it	"I was always worried that, one day I'm going to, reach into a bucket of water without thinking because, I'm out watering plants or, I'm fishing, or I'm this, or I'm that."
Acceptability		
Positives	• Appearance did not bother, inconspicuous, no one noticed	"I thought it looked kind of like an older version of a Fitbit so it wasn't something anyone ever questioned or looked twice at."; "People are used to the idea that people have devices on their bodies and it doesn't seem peculiar."
	• Did not hide its purpose/privacy not broken/provided opportunity for openness	"It kind of, for me anyway, made things more out in the open, that, "yes you are battling a disease." And this is here to help."
		"I volunteered it. I said "hey look what I have...." They were interested. I'm like, it tracks if I have any alcohol in my system."
	• Others (medical professionals/family) had positive reactions and supported its use	"It also reassured my family too. They see me wearing it, and they knew I wasn't drinking."
	• Gives a sense of security, willing to wear longer for stability/security	"Having a device gives you some sense of security that maybe if your willpower isn't strong enough, or you know just life happens as it does, then there's some recourse."; "I would wear it longer, especially if I had issues trying to stay sober."
Negatives	• Felt self-conscious, stigmatized, hid its purpose	"Sometimes when I wore it, was out with it on, I would be embarrassed and my family thought it was for house arrest..."
	• Appearance not optimal/could be improved	"You don't see a lot of big, square, black, flat, faceless watches."
	• Disappointed/offended in doctor for asking them to wear, doctor did not trust them	"I think there would need to be a very specific way to bring it up without coming across as offensive."
	• Visual reminder could be negative	"Sometimes, wearing that device, can make you feel as if there are things, that are out of control in your life."
Feasibility		
Positives	• Not a problem for lifestyle/routine/practical to wear daily even long term	"Once I made it part of my routine, it was easy. I put it on the counter and brush teeth, shave, or whatever. Then it would be sitting there with my stuff and I'd just put it back on."
	• Have to be able to take it off (not locked on)	"If I had to or wanted to I could take it off... not like a house arrest ankle bracelet, so that settled my mind."
Negatives	• Somewhat impractical to wear 24/7 esp long term	"It wouldn't really bother anyone who wears a watch, but I'm not real sure if somebody wears watches at nighttime."
	• Can be difficult to take it off for a lot of activities esp. multiple times a day, easy to forget to put back on	"I think it would be burdensome if you worked, especially in an environment where you have to frequently wash your hands, you know, if you were like a nurse or something like that."
	• Being able to remove is a problem - could take off to drink and say you forgot to wear it/cheat the system	" If I really wanted to, I could've taken this off, had a few beers, let it get through my system, put it back on, and say I forgot. But the downside is, what are you gaining?"; "I took it off because I was afraid alcohol was going to show up on my report."
	• Would be prohibitive if insurance did not cover	"I think it can be a little difficult to get people to do it if it's not covered by some insurance..."

(Continues)

TABLE 2 (Continued)

Category	Sub-category	Representative comments
Efficiency Positives	• Better data, more accurate and quicker than verbal report	"Sometimes I blacked out and don't even know this stuff."; "Sometimes I don't know how many I put down, to tell the truth." "I think I minimize sometimes to them [doctors] what I'm drinking and to myself too."
	• Depth of data (drinking patterns, timing, amounts) can better inform treatment and therapy considerations, may help doctor interpret labs/change medications or intervene more quickly	"The doctor would be able to see trends or patterns, or such. Like, when you drank or what time you drank. Like, what you guys use: "reconstruct." What made you drink? What led you to drink, etc.?" "If you are able to pinpoint certain times of the day, like if you're consistently slipping up, like evenings, you could come up with a different kind of plan or maybe increase a medication to help curb the (my) cravings and then take it at that time of day."
	• Wearing helps to establish, show proof of sobriety	"I can walk in there and tell my doctor till I'm blue in the face anything he wants to hear. But where's the proof?" "It made me feel good. I was comforted in that I had proof [of not drinking]..."
	• Improves clinical collaborative care	"I think they [the doctors] try a little harder when they know you're trying." "The liver doctor can reach out to the therapist or psychologist and get help out in that way. Everyone can work together. It's better to have a team of people focused on your health, rather than just one person."
	• Time and cost savings having the device data	"It would save a lot of time and money to not have to go to the doctor's frequently, because they see I haven' been drinking."
Negatives	• Would not necessarily improve medical care, already honest with doctor about alcohol use	"When I said I wouldn't drink, I just didn't drink. So I don't think that I could ask for better care than I got from my doctor." "I know [my doctor] is going to ask me if I drink, I will say "yes...I don't lie [about drinking]."
	• Worry it could record non-drinking alcohol exposures -mouthwash/hand sanitizer/ or inaccurate readings	"...certain things can spike your alcohol level that are not necessarily drinking, like sanitizer, perfumes and what not..."; "I kind of freaked out that mouthwash I put in my mouth would set it off."
Impact of device on behavior Positives	• Improved motivation, reinforced abstinence	"That's the first time I've been sober that long. I've been struggling with not drinking so it was very helpful to stay sober." "I was still taking my medicine and going to AA and doing other things, but this is one of the items that I had also been doing which I hadn't in the past. It was something new and I think it added to the things that were part of my recovery." "Trust me, there's several times I did think about going and drinking and that device was a big factor as to why I didn't."
	• More accountability to self and others	" I'm not saying that would stop you from drinking because if you want to really drink, you're going to drink—but I think there would be a small voice inside your head saying, you know, "oh when I go back to the doctor he's going to read this, and I'm going to get chewed out—lectured by the doctor, you know, that I can't drink alcohol."
	• Changed behavior could last after stopped using device	"I think that it helped me to get over the hump, you know, sitting there serving as a constant reminder of the cause of my illness. And I think that that's going to have a lasting effect."
	• For those who received feedback: showed progress, confirmation they had not drank, positive reinforcement	"Even though I know I didn't consume any alcohol, just to be able to at the end of the day, to look at it and be like, "all right, I did this today, let's do another day." This is what they're getting; "good job," kind of like pat yourself on the back."
	• It reminds you that you are not on your own	"You're not on your own and it is a serious thing that needs to be dealt with and other people are taking it seriously as well."

TABLE 2 (Continued)

Category	Sub-category	Representative comments
	• Would be best to use in early months of sobriety when it is more of a struggle	"Now is the crucial state because you feel better, you think you can go and drink and you can't."; I think wearing it for a year is more suitable."; "I thought it might be helpful for me to be aware in those first few months after my last episode with alcohol."
Negatives	• Need real time feedback on drinking and positive reinforcement to help change behavior	"...if you're not going to be able to track yourself on a daily basis...and then it kind of made you feel a little, not so much in control."
	• Individual has to be ready to stop/buy into monitoring	"If you want to drink, you're going to drink, regardless of if you have a bracelet on your hand."; In my case, it was a positive thing. I could see other people would be like 'who cares about this watch."
	• No impact - too sick/had liver disease/ already made up mind not to drink	"I was so sick at the time the furthest thing from my mind was drinking and it still is."
	• Not 100% effective in preventing drinking as drinking had to do with other factors not just the device	"Some days when my days were bad I would drink more. I don't think it had to do with the device. It was how I was feeling."
	• Impact only while wearing it	"... sometimes when I put it on, it's like I've got this on I need quit drinking a little bit and I slow myself down a little bit. But then I'd take it off and I pick up heavier. So the device helped remind me that 'you have this on and you're drinking a lot."
Preferences, facilitators, or barriers	• No problem with doctor having the device data – same as other health information/dr should know	"Your doctor has you do a stress test, and they're like 'you have some heart issues and we want you to wear this device, so we can see what's going on in your everyday activity.' They have all that stuff. This should be the same thing."
Positives	• Would wear if doctor prescribed, would not change relationship esp. if had open trusting relationship	" If he [dr] prescribed it and thought that it would be beneficial to me, then, I would try to do anything I could to stay on the right track. To me that would be no different than a doctor prescribing you medication."
	• Provider having data from device avoids having to repeat their drinking (humiliating) and lessens feelings of shame/ guilt/and potential for lying about drinking	"It's humiliating to repeat the story again and again. I think if you have empirical evidence to that, because there are a number of caregivers involved in all this, I have this that tells them what's going on... it lessens the feelings of guilt amongst the user."; "I just don't like to talk about it."
	• Payment was an incentive to wear it	"At first I did it to help with the research study and the incentive of the money"
	• Wearing it/telling others can lead to pride	"It gave you a sense of pride. Like, look what I'm doing, I am going the extra step... I am serious about quitting drinking."
	• Bracelet or watch is best of wearable devices	"Something around your ankle wouldn't be very practical because that's obviously very noticeable. So as far as practicality, the bracelet or watch would be best."
	• Better/preferable choice than other therapies	"I understand there are drugs that you can take, that if you do consume any alcohol it makes you incredibly ill. And I think something like this (device), is incredibly more preferable than that."
Negatives	• Wearing it can lead to negative feelings for patient and family members	"I think it made my wife uncomfortable, because it was constantly reminding her whenever she saw it... there's definitely a real negative stigma attached to alcoholism and no one likes to be reminded that their spouse is, you know, is an alcoholic."
	• Would prefer some other type of monitoring	"I would rather have to take a breathalyzer every now and again than wear the bracelet."
	• Negative reminder you are not in control/ you are ill	"Wearing that device can make you feel as if there are things that are out of control in your life."

> 'Sometimes when I wore it, was out with it on, I would be embarrassed and my family thought it was for house arrest ...'
>
> (Black, female, age 36)

This caused embarrassment or self-consciousness for some wearers, who stated that they would not want to wear such a device unless it could be camouflaged or hidden under clothing.

Participants largely agreed they would use the device if their doctors prescribed it for them. Some felt wearing it gave them a sense of security that their doctor would know of their drinking, especially at their advanced stage of liver disease where quick intervention could prevent further liver injury. On participant described wearing the device as reassuring:

> 'Having a device gives you some sense of security that maybe if your willpower isn't strong enough, or you know just life happens as it does, then there's some recourse'.
>
> (White, female, age 31)

Others felt it could remind them they were not in control. For example:

> 'Sometimes, wearing that device, can make you feel as if there are things, that are out of control in your life'.
>
> (White, male, age 59)

Feasibility

Most stated that it would be reasonable to wear such a device for months but not years. For example:

> 'Once I made it part of my routine, it was easy. I put it on the counter and brush teeth, shave, or whatever. Then it would be sitting there with my stuff and I'd just put it back on'.
>
> (White, male 48)

Some comments noted its use would be impractical if an individual participated in activities or a job that required frequent removal, or did not typically wear a watch, or did not receive any real-time feedback from the device. One participant noted wearing it continuous could be challenging:

> 'It wouldn't really bother anyone who wears a watch, but I'm not real sure if somebody wears watches at nighttime'.
>
> (White, male, age 49)

Although the need for it to be removable was seen as a necessity, this was also noted to be a disadvantage as it could be removed to drink. However, one participant conceded this would only hurt the patient:

> 'If I really wanted to, I could've taken this off, had a few beers, let it get through my system, put it back on, and say I forgot. But the downside is, what are you gaining?'
>
> (White, male, age 49)

Some wondered if the cost of using such a device could be prohibitive if insurance did not cover it.

Effectiveness/efficiency

The majority of comments on effectiveness indicated participants believed the device would be more accurate than self-report at capturing alcohol consumption patterns (including quantity, frequency, timing and duration of use) because it would not rely on patient memory for such details, or because patients may minimise any drinking. One participant stated once they started drinking it was difficult to recall or admit how much they drank:

> 'Sometimes I don't know how many I put down, to tell the truth'.
>
> (Black, female, age 36)

> 'I think I minimise sometimes to them [doctors] what I'm drinking and to myself too'.
>
> (Black, female, age 36)

An advantage noted was that the device could provide evidence of abstinence in situations where alcohol abstinence was required (e.g., liver transplant candidate). Some felt not wearing the device would be informative because it could signal that patients were drinking. The only negative comments regarding device effectiveness came from participants who felt they were already honest with their doctor about their use.

Additionally, many positive themes were noted on how the accuracy and detail of device data could improve medical care by identifying times and possible patterns of drinking, and helping patients to reconstruct circumstances around which they might drink. One participant explained:

> 'The doctor would be able to see trends or patterns, or such. Like, when you drank or what time you drank. Like, what you guys use: "reconstruct." What made you drink?

What led you to drink, etc.?'

(White, male, age 48)

Another described the data as being helpful to treatment planning:

> 'If you are able to pinpoint certain times of the day, like if you're consistently slipping up, like evenings, you could come up with a different kind of plan or maybe increase a medication to help curb the (my) cravings and then take it at that time of day'.
>
> (Multiracial, female, age 39)

The data were seen as likely to be beneficial both to a medical doctor and mental health professional or addiction therapist by, for example, helping clinicians to interpret lab results and prescribe or change medications. As one participant described it could facilitate collaborative care:

> 'The liver doctor can reach out to the therapist or psychologist and get help out in that way. Everyone can work together. It's better to have a team of people focused on your health, rather than just one person'.
>
> (White, female, age 32)

Others noted if the device data demonstrated the patient was stable, they would require fewer doctor's appointments resulting in time and cost savings. As stated by one participant:

> 'It would save a lot of time and money to not have to go to the doctor's frequently, because they see I haven't been drinking'.
>
> (White, female, age 32)

Potential impact of device on behaviour

Patients described the ABM as 'another tool in their toolbox' that added to their recovery and stability in addition to their therapy and other treatments. One participant noted:

> 'I was still taking my medicine and going to AA and doing other things, but this is one of the items that I had also been doing which I hadn't in the past. It was something new and I think it added to the things that were part of my recovery'.
>
> (White, male, age 58)

Some noted the device helped them to achieve and sustain abstinence, for example, by providing accountability to self and others or providing positive reinforcement. One participant described it as:

> 'Even though I know I didn't consume any alcohol, just to be able to at the end of the day, to look at it and be like, "all right, I did this today, let's do another day."'
>
> (White, male, age 49)

Others noted that it would be a comfort to know that their doctors cared so much about their well-being that they would prescribe such a device. As one participant explained:

> 'You're not on your own and it is a serious thing that needs to be dealt with and other people are taking it seriously as well'.
>
> (White, male, age 59)

The impact of the ABM on alcohol use was felt to be greatest at the beginning of recovery when the effort to stay sober would be most challenging. Some felt wearing it for months if not the first year would be beneficial to sustained behaviour change but that the decision to continue wearing and length of wear should be up to the patient and their therapists/doctors. Participants believed the effects of wearing the ABM could continue long after they stopped wearing it although some felt the device only helped as a reminder while they wore it. As one participant explained it only helped her while she was wearing it:

> '... sometimes when I put it on, it's like I've got this on I need quit drinking a little bit and I slow myself down a little bit. But then I'd take it off and I pick up heavier. So the device helped remind me that "you have this on and you're drinking a lot."'
>
> (Black, female, age 36)

Nonetheless participants noted a patient had to be trying to achieve sobriety, be willing to wear the ABM and actually wear it for it to be useful. One participant described the effect as:

> 'Trust me, there's several times I did think about going and drinking and that device was a big factor as to why I didn't'.
>
> (White, female, age 49)

Even then it would not be completely effective as described by participants:

> 'If you want to drink, you're going to drink, regardless of if you have a bracelet on your hand'.
>
> (White, male, age 49)

> 'Some days when my days were bad I would drink more. I don't think it had to do with the device. It was how I was feeling'.
>
> (Black, female, age 36)

Those who felt they had already strongly committed to sobriety and were not having difficult staying sober did not see the advantage of wearing an ABM. For these participants the severity of their liver disease already sufficiently motivated them to remain abstinent. As explained by one participant:

> 'I was so sick at the time the furthest thing from my mind was drinking and it still is'.
>
> (White, female, age 48)

Preferences, facilitators or barriers

The ABM data were felt to be similar to other types of medical data and should be available to patients' doctors and other clinicians. As two participants described:

> 'Your doctor has you do a stress test, and they're like "you have some heart issues and we want you to wear this device, so we can see what's going on in your everyday activity." They have all that stuff. This should be the same thing'.
>
> (White, male, age 49)

> 'If he [dr] prescribed it and thought that it would be beneficial to me, then, I would try to do anything I could to stay on the right track. To me that would be no different than a doctor prescribing you medication'.
>
> (White, female, age 41)

Others noted the device would obviate the potentially humiliating experience of having to recount drinking to a care provider, could lessen feelings of shame and guilt around disclosure, and reduce the potential for lying.

Some felt wearing it could lead to feelings of pride while others felt wearing the ABM could cause negative feelings for patients and family members as a reminder of their problem or lead to thoughts that the patient was not in control. For example, one participant felt positively:

> 'It gave you a sense of pride. Like, look what I'm doing, I am going the extra step ... I am serious about quitting drinking'.
>
> (White, male, age 49)

while another expressed an undesirable effect:

> 'I think it made my wife uncomfortable, because it was constantly reminding her whenever she saw it ... there's definitely a real negative stigma attached to alcoholism and no one likes to be reminded that their spouse is, you know, is an alcoholic'.
>
> (White, male, age 59)

3.2.2 | Clinician participants

See Table 3 for positive/negative themes and representative quotes.

Usability/usefulness

Clinicians felt the ABM went beyond patient self-report to objective, comprehensive data on quantity, frequency, and patterns of use. The ability to see blood alcohol concentrations and peak alcohol levels—information that would not otherwise be available—was felt to be potentially transformative to understanding alcohol use. Some made an analogy of the ABM to continuous glucose monitors. Two clinicians describe the potential benefits as:

> 'It will help monitor patients better. Right now we have so few tools and medications, it would be helpful'.
>
> (Asian, male age 51)

> 'Biomarkers don't give the pattern or progression, just one time, only that they were drinking in the past. But this (device) is a real time, dynamic test'.
>
> (Asian, female age 45)

However, concerns were also noted regarding how such complex data could be best displayed, and whether it would truly be clinically useful. Some clinicians felt that the volume of information generated would be overwhelming. Some felt the data had to be available in real time for it to be useful in clinical practice. One clinician felt the device provided too much data:

TABLE 3 Clinician positive and negative themes with representative quotes.

Category	Sub-category	Representative comments
Usability/ usefulness		
Positives	• Data easy to understand, graphs add useful visual picture	"I love the graph. I think [the data] are very easy to understand and follow."
	• Adds objective data to subjective self-report	"Patient reported data and history is subjective. Obviously, the biosensor is lending objectivity to the alcohol history."
	• Great resource, adds to the few tools clinicians have available	"It will help monitor patients better. Right now we have so few tools and medications, it would be helpful."
	• Adds dynamic data to biomarkers, may replace biomarkers	"Biomarkers don't give the pattern or progression, just one time, only that they were drinking in the past. But this (device) is a real time, dynamic test."; "Ethanol and EtG metabolite levels could be negative, but they are drinking."
Negatives	• Too much data and detail, needs to be summarized into clinically relevant, actionable information	"From a clinical perspective there's no reason to have this degree of detail, it doesn't really matter."; "There's more information than is useful. [This] clutter gets in the way of the thought and decision processes."
	• This precision only needed for certain clinicians; any drinking is against medical advice	"Having the numbers is not going to change my care plan. From a behavioral health standpoint this information might be more useful."; "You don't need to know when they are drinking or how much, it's a 'yes' or 'no' answer."
	• Needs to be real time data to help patients/clinicians	"To be useful the data needs to be coming in, in real time, then allowing access to be able to act on it."
Acceptability		
Positives	• Patient reassured that clinician cares, is invested in their care, going beyond standard care, improves the relationship	"Patient might feel his doctor is really interested in helping him and this might improve the relationship."; "Patients will feel their doctors are trying to help them and actually care about them and their potential for alcohol use."
	• Acceptability and adoption would be enhanced with education about device and purpose	"If the patient is educated in the right way I'm sure they will understand the benefits."
Negatives	• Patients react negatively; appearance embarrassing/ stigmatizing, could feel not trusted by their doctor, offended, guilty	"Basically you're policing someone at home... there could be apprehension, what the data is used for, why are you doing this to me, I told you what I do, you don't believe me."; "It could definitely turn away people who feel guilty about their drinking and don't want anybody monitoring how much they actually drink."
	• Need to use data with sensitivity, not judgmental, clinician would need to be trained, can't be punitive	"Providers should be trained how to be motivational without being confrontational. If used in a confrontational manner it can really backfire and make the patient reluctant to come back."
	• Patient has to be willing to wear it; those willing to wear may be different that typical ALD patient, those who could benefit most not likely to use it	"A patient who is denying alcohol, they're not going to wear this device because its going to completely unmask everything they're doing."; "The question is would somebody who's fallen a little bit off the rails or out of care would they really be wearing this?"
Feasibility		
Positives	• Even patients who drink heavily could wear responsibly	"There are a lot of people who are functioning alcoholics that have quite a bit of consumption but do a lot of things, go to work and do all of these other things. So yeah I think it's feasible."
Negatives	• Not practical for long term wear	"I can't see people wearing it for months or years, kind of like a constant thing, just what people have told me."
	• Other methods more practical	"It's so much simpler to simply do a phosphatidylethanol which has really changed how I practice now."
	• Patient could be unreliable, or intentionally circumvent detection, take it off, lose it	"You could easily let someone else wear the device for you."; "I'm trying to figure out when a patient wore it and whether episodes of drinking were missed because of not wearing...."; 'It's a very unreliable population you might lose your devices."
	• Cost may be prohibitive if not covered by insurance	"I understand the device is pretty expensive. So if it was covered by insurance it could be helpful."

(Continues)

TABLE 3 (Continued)

Category	Sub-category	Representative comments
Effectiveness/ efficiency	• Avoids missing/inadequate interview data, patient diverting or directing the discussion	"We have a powerful tool to reveal reality."; "Some patients are very savvy, they know how to drive the discussion, so you get so focused on something, that they don't even allow you to ask the question "Are you drinking"?"
Positives	• Quick, accurate, saves time/costs; negligible time to review, saves unnecessary tests looking for other causes, saves time by facilitating discussion getting to the point, avoids defensiveness	"We spend a lot of time and money looking for other causes of worsening liver function because our patients are telling us they are not drinking...it avoids unnecessary testing looking for other causes of hepatic decompensation"; "You could broach the discussion much more easily to say "I had a chance to review your biosensor data" and you could start the discussion on "What are the triggers for your alcohol use?" And that also saves time."; "We wouldn't need to spend as much time interrogating their alcohol use"
	• Staff could be trained to introduce device, its use and analyze data much like getting patient vitals/doing fibroscans	"Having a dedicated person to do it would be feasible, like we have a dedicated nurse who does the fibroscans."
Negatives	• Would increase time and effort of staff and clinicians	"If you take the time to review some information together with a patient, you're taking more time than you would otherwise."; "The logistics must be considered, like a technician to upload and digest data reaching the MD."
	• Alcohol data would not necessarily prompt faster action or intervention, rather liver injury prompts action	"The amount a patient is drinking doesn't necessarily correlate with the severity of the injury or whether they warrant medical therapy or hospitalization." "The data may prolong our conversation due to spending more time on alcohol use as part of our clinical visit."
	• Limited time in medical encounter, need to focus on medical management, may prolong the interview	"We have a limited amount of time with patients, and we just medically manage their liver disease symptoms."
Potential impact improving health care and delivery	• May aid diagnosis especially in low level/undisclosed drinking or with coexisting liver disease	"When you are trying to parse out the differences between multiple etiologies [of liver disease in a given patient] it would be quite helpful."; " The amount of alcohol consumed may be mild, but consistent and chronic and that may explain a decompensation, that's something that a lot of times goes undetected."; "If you have liver function tests, on a particular day or week, correlating with a pattern of drinking then you see how powerful it becomes."
Positives	• Potential to help ALD/AUD treatment and testing decisions, help in decisions on treatment intensity	"It would be very helpful to find the pattern of drinking to prescribe either medications or therapy at particular times based on their patterns."
	• Clinician could act more quickly to prevent disease progression	"If you know the patient is drinking very heavily, I will see them more often, do procedures more often to be sure we get any decompensation on time."; "For alcohol associated hepatitis patients having these devices would be super important. It has high mortality. So these devices would be offered to all of them, for early detection of relapses and early interventions."; "You are monitoring somebody you're not seeing in clinic and seeing them drinking so it's as timely as you can get in calling someone and saying, "I saw you're back to drinking. How can I help you?"
	• Improves care collaboration between patient and clinician, gives provider more confidence in discussion, more informed discussion, similar to use/ discussions of other biomarkers	"I see the displays and graphics as ...an interactive display that allows a patient and provider to look together at the same data and assist in making our decisions about future care."; "Alcohol history questioning is a very sensitive difficult topic, even for the most experienced medical provider. This good objective data allows you to initiate a discussion about patterns of drinking."; "You can use the data to talk confidently about their alcohol use."

TABLE 3 (Continued)

Category	Sub-category	Representative comments
	• Could create better patient self-awareness of their drinking, its impact on their liver and improve understanding of amounts, patterns and triggers of drinking, increase readiness and motivate change	"We have a whole array of motivational tools to help patients arrive at a decision to stop or minimize their alcohol consumption. I would use this as just one more tool in my toolkit."; "With this data you can get the patient to buy in to the fact that the drinking is problematic."; "This shows real connection with their behavior and a physiologic process that happens in real time in the body."; "This could be used for early identification and helping them stay sober and prevent relapse."; "We try to tell our patients and sometimes it doesn't sink but if you could show them in real time with the visuals, it really reinforces the message of alcohol consumption on liver disease."
Negatives	• Disrupt clinician-patient relationship, feel attacked, lose trust, could lead to confrontation	"I think there's potential that it could interfere with the patient provider relationship and trust and rapport."
	• Data wouldn't inform diagnosis, treatment plan, there are better tools for disease progression, won't change prognosis	"If I had a tool like this, it would be more objective. But on the very broad question about it improving prognosis, I think, you need lots of data, long-term data to be able to make a claim like that." "I don't think medically-speaking the device data would help...we see them more regularly anyway if they are drinking more so to manage the complications of their liver disease not necessarily to discuss just the alcohol because patients who are more actively drinking tend to be seen more often."
	• Only helpful for certain patients, data of any type won't necessarily change their behavior	"A patient that's willing to participate already has a degree of insight so I think those patients probably would be set up to do better."; "Sometimes we biopsy patients to prove that they're drinking and they're still lying to you."; "I think there are barriers like getting people to comply with it, because people that are actively drinking often don't want to tell you or don't want to change their behavior."
Utility Positives	• Blood alcohol concentrations as provided by ABM can add to concept of alcohol use in terms of standard drinks	"Blood alcohol concentrations [as ABM provides] could change our concept of alcohol use or add to what we already use because we do not use peak alcohol or measure alcohol concentrations in real practice."
	• Patient gains better awareness and control over their health	"A benefit of this technology is patient empowerment, patient self-awareness."
	• Could be used to prove abstinence especially in situations that demand it (e.g., pre- and post-LT)	"I'd think there are implications for who to refer for liver transplantation, we generally take them at their word but if we have alcohol data that suggests that they are not adhering to abstinence, then we wouldn't go down that path."
Negatives	• Patient has to have buy in	"Wearables of all kinds are trendy and their staying power, their sustainability will depend on how the wearer perceives the value to themselves."
	• Big data complicated to analyze and manage	"I think it's going to be very complicated to analyze and to combine these big data in a way you can make sense of it associated with disease progression."
	• Security and sensitivity of data critical and should be protected – not for everyone to use in the medical record	"[There are] issues about confidentially of access to this data by providers, it should not be available to everybody and anybody."; "The risk will be with employers and insurance, it must be protected on the Informatics side..."
	• Need to have confidence in the data	"Clinician needs confidence the data have been accurately calibrated to standard drinks."
Preferences or barriers Positives	• To be equitable implementation must be uniform across providers	"The set up has to be uniform across the board on how we implement it and consistent amongst providers..."
	• Confirmation of wearing device is important feature	"It's good to know you can tell they're wearing it, my biggest concern is people find ways to hide their alcohol use."

(Continues)

TABLE 3 (Continued)

Category	Sub-category	Representative comments
Negatives	• Should address patient needs, need evidence it helps patients	"Firstly, it should be evidenced-based and we should know that it actually improves patient outcomes."; "if this is not going to help someone manage their addiction, it's not going to help me."
	• Could be unethical if used to deny care, could be coercive	"To catch somebody drinking and deny them care because of it I think that's unethical and not how I see my role."
	• Could give false sense of reassurance	"If the patient's getting real time data and using their blood alcohol level to decide if they can drive or if they can drink more than one, that could be a potential unintended consequence."

> 'There's more information than is useful. [This] clutter gets in the way of the thought and decision processes'.
>
> (White, male age 72)

and another felt only a simple binary answer was needed:

> 'You don't need to know when they are drinking or how much, it's a "yes" or "no" answer'.
>
> (Asian, male, age 51)

Acceptability

Some clinicians felt a patient who had good rapport with their doctor would see the request for ABM use as evidence of the clinician's genuine concern for the patient. Many clinicians felt patients would see its benefits and agree to use it if its purpose and usefulness were explained. One clinician described it as facilitating care:

> '[The] patient might feel his doctor is really interested in helping him and this might improve the relationship'.
>
> (Asian, male, age 57)

Others felt the request could be offensive, stigmatising and turn the patient away from care. All clinicians felt the patient had to be willing to wear the device. One clinician cautioned:

> 'Basically you're policing someone at home ... there could be apprehension, what the data is used for, why are you doing this to me, I told you what I do, you don't believe me'.
>
> (Asian, male, age 57)

Another clinician felt it would not help those unable to be forthcoming about their drinking:

> 'A patient who is denying alcohol, they're not going to wear this device because its going to completely unmask everything they're doing'.
>
> (Asian, male age 42)

Feasibility

Clinicians felt it would be feasible for short term use (several months) especially for patients early in recovery, but not long term. Some felt certain patients with ALD would not be able to adhere to the degree of responsibility and participation required for the devices to be effective. As one clinician noted patients

who did not wear the device consistently would not have accurate data:

> 'I'm trying to figure out when a patient wore it and whether episodes of drinking were missed because of not wearing ...'
>
> (White Hispanic, male age 44)

Other biomarkers or patient self-diary entries were felt to be more practical in capturing alcohol use relevant to clinical work. Using ABMs would not be feasible if the expense and monitoring of the devices was not covered by insurance. One clinician noted current blood sample biomarkers are easier to use:

> 'It's so much simpler to simply do a phosphatidylethanol which has really changed how I practice now'.
>
> (Asian, male age 51)

Efficiency/effectiveness

While most agreed that ABM use in clinical practice would require extra time from staff and clinicians, some felt the extra time would be offset by less time wasted on unnecessary tests or more time-consuming interviews on alcohol use. As one clinician described:

> 'We spend a lot of time and money looking for other causes of worsening liver function because our patients are telling us they are not drinking ... it avoids unnecessary testing looking for other causes of hepatic decompensation'.
>
> (White, male, age 40)

Many noted they already ask all patients about alcohol use so the device would not overcome barriers to asking about use. However, overcoming inaccurate or missing data could be time saving. As one clinician perceived device data could improve shortcomings in the patient interview:

> 'Some patients are very savvy, they know how to drive the discussion, so you get so focused on something, that they don't even allow you to ask the question "Are you drinking?"'
>
> (White, Hispanic, male age 44)

Other clinicians felt it could save time either providing a gentle introduction into the discussion of alcohol use or spending less time asking about use:

> 'You could broach the discussion much more easily to say "I had a chance to review your biosensor data" and you could start the discussion on "What are the triggers for your alcohol use?" And that also saves time'.
>
> (White, male, age 40)

> 'We wouldn't need to spend as much time interrogating their alcohol use'.
>
> (White, female, age 27)

Clinicians uniformly agreed that, for the device to be efficiently used by clinicians, a technician or nurse in the clinic (rather than the clinician themselves), would need to be dedicated to device deployment and monitoring. For example, clinicians felt:

> 'We have a limited amount of time with patients, and we just medically manage their liver disease symptoms'.
>
> (White, female, age 33)

> 'The logistics must be considered, like a technician to upload and digest data reaching the MD'.
>
> (White, Hispanic, male age 44)

Potential impact on improving health care

Some felt the quantitative data could aid understanding the course and prognosis of liver disease especially in low level drinkers or those with coexisting liver diseases. As one clinician explained:

> 'If you have liver function tests, on a particular day or week, correlating with a pattern of drinking then you see how powerful it becomes'.
>
> (Asian, male, age 47)

Some felt the greatest benefit would be to identify undisclosed drinkers earlier in their disease course where it could have greatest impact on prognosis. As one clinician noted without device data the impact of low-level drinking may not be appreciated:

> 'The amount of alcohol consumed may be mild, but consistent and chronic and that may explain a decompensation, that's something that a lot of times goes undetected'.
>
> (Asian, male, age 42)

Similar to patient views, some clinicians felt ABM devices would be best earlier in recovery when a patient might be struggling with sobriety or if they needed better motivation or understanding of their illness. This information could aid decisions on the intensity and type of treatment needed both for ALD and an AUD. Two clinicians describe how device data could inform sooner intervention:

> 'If you know the patient is drinking very heavily, I will see them more often, do procedures more often to be sure we get any decompensation on time'.
>
> (White, Hispanic, male age 44)

> 'You are monitoring somebody you're not seeing in clinic and seeing them drinking so it's as timely as you can get in calling someone and saying, "I saw you're back to drinking. How can I help you?"'
>
> (White, Hispanic, male age 44)

While others acknowledged the potential of understanding disease progression and response to treatment, they did not feel having these data would necessarily improve prognosis. Having objective data could facilitate a discussion of alcohol use in a non-judgmental way. However, sensitivity in the discussion would be important to avoid leading patients to feel ashamed or judged. Two clinicians describe the possible drawbacks:

> 'A patient that's willing to participate already has a degree of insight so I think those patients probably would be set up to do better'.
>
> (Asian, male, age 42)

> 'I think there's potential that it could interfere with the patient provider relationship and trust and rapport'.
>
> (White, female, age 41)

Utility of the technology

The ability of the ABM to provide real-time blood alcohol levels was felt to be very informative and novel although some clinicians felt they would need confidence the devices were accurately calibrated into standard drinks to be interpretable for clinical work. Aside from the issue of usefulness of so much data, the sheer magnitude of the data, could be difficult to analyse and interpret for clinical purposes. Data security was felt to be critical, especially if they were to be entered into a patient's medical record where access may be open to other non-clinical entities such as insurance companies. Thus, while one clinician believed this technology could benefit patients:

> 'A benefit of this technology is patient empowerment, patient self-awareness'.
>
> (White, male, age 72)

another felt the data may not facilitate clinicians' understanding of liver disease:

> 'I think it's going to be very complicated to analyse and to combine these big data in a way you can make sense of it associated with disease progression'.
>
> (White, Hispanic, male age 44)

Preferences, facilitators, barriers

Although clinicians felt using ABM devices would increase time and effort in the clinic, they felt the offset in improved data and better ability to care for patients was worth the extra time. Some were concerned these data could be used to deny care, believing this would be unethical. In order to maintain equity the implementation would need to be consistent across all providers. As one clinician described:

> 'Firstly, it should be evidenced-based and we should know that it actually improves patient outcomes'. 'If this is not going to help someone manage their addiction, it's not going to help me'.
>
> (White, female, age 41)

4 | DISCUSSION

Few ABM devices are commercially available, several are underdevelopment/field testing and others discontinued after field testing (see Davis-Martin and Brobbin for reviews) [32, 42]. Developers recognising the bulky size of devices, high cost and short battery life are deterrents to acceptability are addressing these features in newer models [43]. At the time of our study only two companies had commercially available products both using fuel-cell technology (SCRAM and WrisTAS); both are still available. Both were tested by the National Highway Traffic Safety Administration under laboratory testing and meet law enforcement and justice system standards [1, 31]. The WrisTAS has been upgraded to the BARE™ and the newer sleeker ORBIS™ (SmartStart Grapevine, TX, USA) which according to the company uses newer transdermal technology consistently more accurate than existing

devices [43]. Of the two available devices we chose the WrisTAS (Giner/SmartStart, Newton MA, USA) for reasons described above. However, our study was not to evaluate the accuracy and reliability of ABMs in clinical practice rather to determine the feasibility and acceptability in a clinical population and with clinicians caring for these patients. The accuracy and validity of ABMs is evolving as new companies enter the field and develop new models of sensors and new casings [32].

We envisioned ABM devices could have great clinical potential for patients to motivate abstinence and to aid clinicians in providing clinical care. As these devices are not being used in clinical settings, we sought to characterise patient and clinician perspectives on these devices. Our qualitative interviews from patient and hepatology clinician stakeholders identify positive and negative perspectives of ABM devices and the potential benefits and pitfalls of using this emerging technology.

With respect to usability and acceptability, issues that detracted from the device were felt by patients and clinicians to be easily remedied by design and appearance improvements. In fact, many gave helpful and creative suggestions on how to improve the appearance (e.g., making it look like a piece of jewellery or making the casing look like an exercise monitor) and usability (e.g., allow real time monitoring by participant or provide other functions) rather than outright rejection of the device or the concept. Similar perspectives were identified in a survey of AUD patients provided pictures of devices but not having worn them [23]. Perceived stigma was the main disadvantage to wearing such a device and features that increased device discretion would enhance its acceptability [23].

With ongoing efforts at minimization of technology, newer iterations of ABM devices since we deployed our version are overcoming the unappealing appearance barriers and have sleeker, more watch like designs [10]. A newer iteration of the WrisTAS, (the BARE SmartStart, Newton MA), developed after our study concluded, has both sensor and electronics in a single casing that appears more like a watch, although this device is not yet available for clinical or research use. Another ABM device developed, the BACtrack Skyn®, which has a very slim appearance like a Fitbit®, measures alcohol use over a 1-week period but is still in beta testing [10, 44]. However, the sleeker design is at the expense of usability/feasibility features as the wearer is responsible for downloading the data weekly and charging the device for 4 h. A recent newer sleek appearing device, the ION®, has a 72-h memory, requires a battery charge every 3–4 days, and a cartridge replacement daily [45]. Devices requiring weekly or daily maintenance by the user are much less feasible in clinical practice. In our study some clinicians speculated many patients with ALD could have difficulties using the current ABM device and felt the more complicated the responsibilities, the less likely a patient would adequately adhere. Additionally, devices need to be waterproof to be practical for daily use. Finally, while the ability to adjust and remove non-law enforcement devices is important to patient safety and comfort, if the device is not properly worn, snug against the skin, it could result in erroneous or missed readings.

Both patients and clinicians felt real-time data would be extremely useful for immediate reaction by treating clinicians if a patient was discovered to be drinking. In fact, some clinicians felt data reviewed after the fact would not be as clinically useful. Patients also felt they needed real-time feedback for the device to be helpful. Real-time data collection and uploading to internet databases continues to present a challenge to miniaturising technology. Such an ABM device would need to house both sensors for alcohol detection as well as some type of short-range wireless technology or internet connection capability. Wearable devices that currently combine these technologies are law enforcement devices (e.g., SCRAM®, ORBIS®) which serve specific deterrence functions but lack sensitivity to the wearers' needs such as comfort or appearance. These newer devices remain large, bulky and heavy.

Importantly, both patients and clinicians agreed with the concept of using ABM for monitoring, providing data to clinicians, and potentially improving clinical decision making and care. Both saw the value in motivating abstinence and providing accountability. However, the use of an ABM device was seen as necessarily remaining voluntary, which might limit it to only motivated and insightful patients. Nevertheless, many patients felt the extra information ABM could provide would be motivating and could provide them with greater insight into the quantity and frequency of their drinking. Although several participants responded that they would already be open and honest with their clinicians about alcohol use, no participant felt their recollection would be better than a continuous monitor or that the information would not be helpful to clinical care. Additionally, patients noted having another 'tool for their sobriety toolbox' was a value added by the ABM device.

In smoking cessation interventions biosensor feedback has been successfully used to increase insight, awareness and readiness to stop smoking [24]. Even months after the intervention quit rates increased and abstinence continued. These studies suggest receiving real-time biometric data from sensors can be educational and motivational, and lead to positive changes in substance use attitudes and behaviours [24].

In an expert consensus statement on how remote ABM monitoring should be used to treat AUD, experts recommended a one-year duration of monitoring for those early in recovery due to likelihood of relapse in first year [46]. One year is in keeping with the definition of sustained abstinence, and several of our patient participants felt long-term monitoring would be best. However, most patients and clinicians felt short term use (over several months) would be optimal especially when a patient was early in their recovery.

4.1 | Limitations

The patient participants who agreed to participate may have been more insightful and interested in stopping alcohol use. Although we do not know the characteristics of those who declined screening (e.g., they may have had poor insight or less interested in stopping alcohol use), of those who were screened none had poor insight that would have precluded participation. While we did have a higher proportion of women participants compared to a typical cohort of ALD patients (~75% male) [32, 40] we believe this provided a better understanding of women's issues with ABM use.

It is possible that the research team (including the study interviewer) were biased towards finding support of the use of ABMs. To limit potential bias, we used scripted interview questions that inquired about both risks and benefits of ABM use and used non-leading prompts (e.g., 'Can you tell me more about that?'). We were careful to catalogue all clinician and patient participant comments, positive and negative, and used two reviewers to analyse and reconcile all comments. The wide array of supportive and non-supportive comments suggests we adequately covered both sides of the issue.

5 | CONCLUSIONS

Hepatology clinicians treating patients with ALD are challenged with managing two diseases: ALD and AUD. While their focus is on treating ALD, the need to be aware of the amount and frequency of ongoing alcohol use is an essential part of their care provision. It is possible that ABM data by identifying unrealised or underreported alcohol use will aid prognosis and facilitate treatment planning but this requires demonstration. In this study biosensor use was seen as an important tool to be used by the hepatologist but especially by mental health clinicians who would address the AUD. Hepatology clinicians did not feel they had the time or expertise to deal with addiction treatment. Given hepatology clinicians may be the patients entry into medical care and the stability of the AUD directly affects the course and prognosis of ALD suggests ABM data may be best used in an integrated care setting to comanage these two diseases.

Participants and clinicians agreed the possibility of ABM data could be very beneficial to patient care. Participants, all of whom had severe liver disease, realised continued drinking could result in morbidity and mortality. Clinicians felt the ability to identify alcohol use early on and intervene could improve care and possibly save lives. Importantly, clinicians and patients alike felt the use of ABM devices must be carefully and thoughtfully integrated into a patient centred approach to AUD management. It should be designed for and by patients to address their needs. The data we present here are the first step in understanding clinician and patient stakeholder needs with respect to the translation of ABM into clinical care.

AUTHOR CONTRIBUTIONS

Conceptualization: DiMartini, Dew, Bataller, Behari, Jakicic, Dunn, McNulty; Data Curation: DiMartini, Dew, Punzi, Bataller, Behari, Dunn, McNulty, Young; Formal Analysis: DiMartini, Dew, Punzi, McNulty, Young; Funding Acquisition: DiMartini, Dew, Bataller, Behari, Jakicic, Dunn, McNulty; Investigation: DiMartini, Dew, Punzi, Bataller, Behari, Dunn, McNulty, Young; Project Administration: DiMartini, Dew, McNulty; Writing, Review & Editing manuscript: DiMartini, Dew, Punzi, Bataller, Behari, Dunn, McNulty, Young, Jakicic.

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CONFLICT OF INTEREST STATEMENT

No relevant conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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