

# How Should Remote Clinical Monitoring Be Used to Treat Alcohol Use Disorders?: Initial Findings From an Expert Round Table Discussion

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Scientific evidence combined with new health insurance coverage now enable a chronic illness management approach to the treatment of alcohol use disorders (AUDs), including regular monitoring of blood alcohol content (BAC), as a useful indicator of disease control. Recent technical advances now permit many different types of remote, real-time monitoring of BAC. However, there is no body of research to empirically guide clinicians in how to maximize the clinical potential of remote BAC monitoring.

As an initial step in guiding and supporting such research, the manufacturer of one remote BAC monitoring system sponsored a group of experienced clinicians and clinical researchers to discuss 8 issues that generally affect remote, clinical BAC monitoring of “adults in outpatient AUD treatment.”

The expert panel unanimously agreed that remote BAC monitoring for at least 12 months during and after the outpatient treatment of AUD was a clinically viable deterrent to relapse. There was also consensus that positive test results (ie, recent alcohol use) should lead to intensified care and monitoring. However, there was no agreement on specific types of clinical intensification after a positive test. The panel agreed that sharing positive and negative test results with members of the patient support group was helpful in reinforcing abstinence, yet they noted many practical issues regarding information sharing that remain concerning. Significant differences within the panel on several important clinical issues underline the need for more clinical and implementation research to produce empirically-supported guidelines for the use of remote BAC monitoring in AUD treatment.

**Key Words:** addiction, alcohol use disorder, breathalyzer, remote monitoring, treatment

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Despite the fact that the medical costs associated with alcohol use disorders (AUDs) are over \$120 billion per year, until very recently, there has been relatively little involvement of physicians or other general healthcare providers in the treatment of AUDs (Sacks et al., 2015). By convention, most contemporary AUD treatment has been delivered outside mainstream healthcare by specialty “treatment programs” that are time-limited by insurance restrictions and highly structured to deliver a standardized “program” of care (McLellan et al., 2005; Foll et al., 2009). Within these programs, care has predominantly consisted of various types of counseling and behavioral therapies to achieve patient acceptance of their alcohol use problem, promote understanding of relapse triggers, and promote a commitment to new attitudes, friends, and behaviors to promote a sober lifestyle. Outcome research has typically concentrated upon program “graduation” rates and “post-treatment” abstinence as standard measures of treatment “success” or “failure” (McLellan et al., 2005).

Despite these longstanding conventions, there is increasing movement towards a different approach to managing AUDs. First, there is now clear scientific evidence of genetic vulnerability to alcohol, opioid, and other substance use disorders (Volkow and Li, 2005; Foll et al., 2009). In addition, there is evidence that persistent brain changes occur with heavy use of alcohol and many other addictive substances (Mayfield et al., 2002; Coleman et al., 2011). This neurobiological evidence suggests that alcohol and other substance use disorders are best considered acquired chronic illnesses, similar in onset, progression, management, and outcomes to other chronic illnesses such as asthma, hypertension, or diabetes (McLellan et al., 2000). Finally, recent legislative changes in health care require essentially all health plans to offer generally the same type, duration, range of care options for treatment of mental and substance use disorders as is currently available for comparable physical illnesses (Mental Health Parity and Addiction Equity Act, 2008; Affordable Care Act, 2010). However, most physicians have

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very little understanding about AUDs and even less training in treatment management for the illness.

### **Programmatic Versus Personalized Disease Management**

The modern management of chronic physical illnesses is quite different from contemporary management of AUD. Whereas most AUD treatment is time-limited, the management of other chronic illnesses consists of continuing “disease management,” achieved through long-term care and monitoring (Bodenheimer et al., 2002). Also, whereas most contemporary AUD treatment occurs in programs with relatively standardized protocols, chronic illness management assumes that evidence-based “personalized care” is necessary to enhance patient engagement and improve outcomes (Hamburg and Collins, 2010). Personalized care regimens use the results of recurrent clinical monitoring of key disease progression indicators to adjust the nature and intensity of the treatment regimen to meet the individual needs of the patient (Hamburg and Collins, 2010). This monitoring usually includes remote, real-time measurement of these indicators using electronic devices such as blood pressure monitors, blood glucose monitors, and more (Abernethy et al., 2010; Herzer et al., 2012). The monitoring serves the dual purposes of measuring symptom improvement and also providing support for decisions on whether and how to adjust subsequent care to reduce the likelihood of relapse (Hamburg and Collins, 2010).

### **How Should Remote Clinical Monitoring Be Used in the Treatment of Alcohol Use Disorders?**

There are conceptual (McKay and Hiller-Sturmhöfel, 2011; McLellan et al., 2014) and some methodological indications (Kim et al., 2011; Oslin et al., 2014) that AUDs may be better managed using a chronic illness approach. However, for the reasons described above, there is not yet the evidence-base needed to guide a personalized, chronic care approach to the treatment of AUDs, or even to guide the use of monitoring technology within that treatment approach. Indeed, outpatient monitoring protocols have not been standardized or even practiced in any consistent manner.

In an effort to stimulate and give clinical guidance to monitoring research, the manufacturer of a wireless, real-time blood alcohol content (BAC) monitoring system (Soberlink) sponsored a day-long meeting of 9 clinicians and clinical researchers with extensive experience in the treatment of AUDs, hereafter referred to as the “expert panel.” Most of the panel had used the Soberlink monitoring system in the course of their research and practice, but most had also used other types of monitoring procedures and technologies. The purpose of the meeting was to draw upon that clinical experience of the panel to inform the design of future research studies of remote BAC monitoring in the context of a clinically relevant format.

In this context, 2 points are emphasized. First, the discussion and guidelines that follow do not derive from a systematic review of available evidence. That body of evidence does not yet exist, in part, because there has been no

agreed-upon starting point for that research. Second, whereas the discussion and guidelines were derived from common experience with 1 type of monitoring (remote, wireless BAC monitoring), the issues discussed and the clinical experience of the panel were broadly relevant to many different types of monitoring in this field.

## **METHODS AND PROCEDURES**

### **The BAC Monitoring System**

The Soberlink system that served as the focal example for the consensus discussion was an appropriate model from which to discuss the broader topic of clinical monitoring in the treatment of substance use disorders. This is because the system uses a standard breathalyzer, allows real-time monitoring of BAC at virtually any time and any location; provides real-time notifications to the treating clinician(s) and to an approved list of patient support contacts; and has been in operation since 2011, with more than 55,000 individuals.

### **BAC Collection Procedures**

An important first step in using any BAC monitoring system is a negotiated and signed agreement between the clinician and patient on the number and timing of tests each day, the list of approved contacts who will be notified of the test results, and any positive or negative consequences from noncompliance or from repeated positive test results. Patients are usually encouraged to approve several of their family, friends, or other supportive individuals to receive the results of all testing. This is seen as an opportunity to increase the patient’s social support resources and personal commitment to maintaining behavioral change.

Accuracy and sensitivity are also important features of any BAC monitoring technology. The Soberlink system uses the same standard fuel cell technology employed by virtually all hand-held breathalyzer units and is able to detect 2 standard drinks (12 oz beer; 6 oz of wine; 1.5 oz of spirits) 2 to 5 hours after ingestion, or binge drinking (5 or more drinks) up to 12 hours after ingestion (Wigmore and Langille, 2009). The system uses facial recognition software to verify the identity of the patient. Efforts to cover the camera, cover the face, or any other attempt to tamper with the system sends a message, indicating tampering immediately to the clinician, the patient, and the contact group. The sample collection system also records the temperature of the breath specimen: temperatures significantly below 98.6 degrees are also an indication of tampering.

In a typical day, a monitored patient will voluntarily submit a breath test 2-4 times or more within two-hours of a previously agreed upon time by blowing into the breathalyzer as the system simultaneously verifies his/her identity using the facial recognition software. Failure to submit within the 2-hour timeframe is considered a missed test. If a scheduled test is missed, if there is not a positive identity, or if the system detects tampering, the system automatically messages the clinician, the patient, and all approved contacts of the patient. The system can provide any frequency of tests, but is typically scheduled for 3 tests per day to permit effective monitoring with little intrusion on the patient’s day-to-day schedule.

Monitoring is usually more frequent at periods of greatest risk for relapse and can be tapered over time with clinical progress.

The system reports all positive tests within 15 minutes. However, because the system is quite sensitive, it may detect alcohol in mouthwash or cologne that might produce a false-positive reading. Thus, after every presumptive positive result, the patients are asked to remove everything from their mouth, rinse and swallow water, then submit a retest in 15 minutes. This procedure has reduced the rates of false-positive results to less than 1/10 of 1% of all presumptive positive tests.

### The Expert Panel

The expert panel was comprised of 9 individuals with significant clinical and research experience in the treatment of AUDs. The group was primarily comprised of individuals who had used the Soberlink alcohol monitoring system ( $n = 6$ ) in their clinical practices, but the panel also included 3 who had not. Seven of the 9 panel members had significant experience in the use of other alcohol and drug-monitoring devices in the course of clinical research projects. Effort was also made to represent a wide range of clinical populations and monitoring situations. For example, 4 of the panel had experience treating physicians, lawyers, airline pilots, and nurses required to receive AUD treatment including continuous monitoring as part of a professional rehabilitation program (McLellan et al., 2008; DuPont and Skipper, 2012).

### The Role of the Sponsor

The sponsor provided travel, accommodations, and a \$500 honorarium to each participant for their attendance at the meeting, but the sponsor did not support the preparation of this manuscript. Several members of the sponsoring organization attended the consensus discussion, but beyond an opening presentation about the history of the company and the development of the monitoring system, no member of the sponsoring organization had input into the consensus discussion. The sponsoring organization was shown preliminary copies of this manuscript to assure accuracy about technical elements of the monitoring system, but no member of the sponsoring organization participated in the interpretation of the discussion findings, the writing, or the editing of the manuscript.

### The Consensus Process

The consensus meeting consisted of a premeeting dinner followed by a day-long meeting to discuss, and, where possible, come to consensus on fundamental issues associated with the during and posttreatment monitoring of adults with AUD. During the premeeting dinner, the corresponding author introduced the consensus process and explained the rationale for all decisions regarding the clinical issues and discussion parameters for the following day (see below).

Because the purpose of the meeting was to use clinical experience to inform subsequent research studies, failure to come to consensus on a clinical issue was considered useful for stimulating hypothesis-testing studies. Thus, it was agreed from the outset that there would be no attempt to force a consensus on any clinical issue discussed. Even when consensus was achieved on an issue, this was not considered a

final disposition, but an indication for future confirmatory research studies. During the consensus discussion, the corresponding author served as the monitor, facilitating discussion on each of the 8 issues until consensus either was achieved, or until it was clear that the panel had divided views.

### The Example Clinical Situation

The discussion focused upon a common and highly representative clinical situation upon which to discuss the role of BAC monitoring: adult outpatient AUD treatment delivered within a specialty care outpatient program, a hospital-based clinic, or a private practice setting. The rationale for this decision was that BAC monitoring, especially remote monitoring, was much more critical in these outpatient settings than in hospital or residential care settings, because outpatient care represented over 85% of all care for AUDs (Department of Health and Human Services, 2013) and because monitoring procedures during outpatient AUD care was thought to be quite similar to monitoring after residential care. For example, a positive test result (ie, recent alcohol use) might lead to increased monitoring and/or a recommendation for more intensive care regardless of whether the finding came while the patient was actively involved in outpatient alcohol treatment or the patient had recently been discharged from residential treatment.

Whereas monitoring of adolescents with AUD was recognized as very important, the consensus process purposely focused on adult treatment because the great majority of individuals in alcohol treatment are adults (Department of Health and Human Services, 2013), because there are not as many clinical options for treating adolescents (ie, some restrictions on use of medications, fewer evidence-based therapies) (Mericle et al., 2015), and because there are special considerations regarding information sharing among adolescent populations.

To set the general context for the consensus discussion, the panel was asked to consider the following hypothetical case:

*“A recently abstinent adult patient with a severe alcohol use disorder (but no other serious substance use, mental or physical health problems) who had been referred to continuing outpatient treatment immediately following discharge from residential treatment at a local program. The patient’s stated goal is to remain abstinent and in recovery from alcohol use.*

*In this context, and assuming that you would have the authorization and ability to conduct the kind of care you consider optimal – how would you utilize remote monitoring in the care plan?”*

The patient was assumed to be employed, not legally mandated to treatment (eg, justice system or employer), covered by health insurance, and to have some reliable, supportive personal contacts willing and able to serve as part of the patient’s “recovery network.”

### Rationale

This hypothetical patient was purposely designed as a “best case,” who had relatively few of the clinical and social

complications that often complicate treatment and monitoring, such as no insurance, co-occurring physical and mental health problems, court-ordered care, and/or deteriorated family and social relationships. Further, the panel was purposely directed to assume that they would have the authority and ability to provide what they judged to be a very sound treatment plan. Whereas all of the typical complicating clinical, social, and insurance issues were discussed throughout the consensus discussion, and are also described here, it was agreed that focusing on these many vexing impediments could stymie productive discussion, and that virtually all those complications would significantly increase the clinical need for monitoring.

## RESULTS

### What Is the Recommended Frequency of Clinical Monitoring at Initiation?

#### *Recommendation*

The panel came to consensus on a recommendation of 3 tests per day at the start of outpatient programmatic or office-based care.

#### *Rationale*

This was the issue that required the least amount of discussion among the panel due to the empirical evidence available on relapse rates after discharge from residential and outpatient alcohol treatments (Witkiewitz and Marlatt, 2004), and the consistency of shared clinical experience among the panel.

The monitoring system described here is capable of detecting alcohol for 2 to 5 hours after a drinking event (Wigmore and Langille, 2009; Jones, 2010). Thus, 3 tests per day cover more than half a 24-hour day. In this case, a patient agreement stipulating 3 scheduled tests per day should serve as a deterrent to alcohol use that could occur in the interim periods. Finally, those panel members who had experience with the system suggested that a 3-per-day schedule did not pose a significant level of intrusion for most patients.

#### *Mitigating Circumstances*

It was recognized that systems with different detection thresholds would require different rates and schedules of testing. It was agreed that the initial monitoring schedule might be increased to 4 times per day for patients whose personal circumstances required exposure to environmental triggers for drinking relapse. It was also agreed that the monitoring schedule could be reduced to twice per day in most patients after approximately 4 weeks of favorable results, but that missed tests, tampering, or positive findings would lead to both extension of the 3-per-day monitoring schedule, and also other clinical interventions (discussed below).

### How Long Is It Clinically Advisable to Monitor?

#### *Recommendation*

The panel ultimately came to consensus that 1 year of monitoring was considered the minimum period necessary to

assure stabilization of the clinical condition. However, many panel members did not favor a recommendation for any fixed period of monitoring time, and most members emphasized that many patients require infrequent monitoring for longer periods of time, or more frequent monitoring during high relapse risk periods (eg, holidays, stressful work periods, stressful family/social situations, etc). Several panel members noted that clinical monitoring of key markers is a core feature of care in other chronic illnesses [eg, hemoglobin (HgA1C) monitoring in diabetes] with no finite time frame.

#### *Rationale*

The rationale for the recommendation involved both the clinical experience of the panel, and also published research. Most panel members agreed that with the establishment and maintenance of abstinence, it is common for many aspects of the clinical picture to change, sometimes even the diagnosis. Moreover, it is common for a recovering patient's motivation and confidence levels to wax and wane substantially for many months. For both these reasons, it was considered clinically prudent to establish an agreed upon monitoring contract for not less than 1 year, but to maintain the option of extending monitoring as needed.

This suggestion is generally supported by available longitudinal research showing a marked decrease in risk of relapse after 12 months of sustained abstinence (Kaskutas et al., 2005; Moos and Moos, 2007). In addition, brain imaging studies of alcohol-dependent individuals during the course of their recovery have shown that many structural and functional changes in brain motivation, inhibition, and cognitive centers continue to show recovery for 12 months after initiation of abstinence (Pfefferbaum et al., 1995; Volkow and Li, 2005).

#### *Mitigating Circumstances*

Panel members agreed that under conditions of court or other authority-mandated treatment, required periods of monitoring supersede clinical judgment. It was also unanimously agreed that regardless of the particular type of monitoring system used, monitoring served both as a "check-up" on the effectiveness of the treatment plan and also as a salient reminder to patients that re-use of alcohol would be shared with their family and other important social contacts. Because of the deterrent effects of monitoring, many of the panel felt it clinically unwise to create a formal "end of monitoring" time point. These panel members favored ending the first year of regular monitoring with an extended, indefinite period of infrequent monitoring. This recommendation was also supported by research with groups such as physicians and airline pilots who have shown very favorable longer-term outcomes when infrequent monitoring continues through a 5-year period (McLellan et al., 2008; DuPont and Skipper, 2012).

### Should Monitoring Be Based on a Prescheduled or Random Schedule?

#### *Recommendation*

The panel came to consensus on a recommendation of scheduled testing at agreed upon time points. However, the panel also agreed that the patient contract should stipulate that

“there may be circumstances where additional, unscheduled testing is required.” Additionally, the contract should clearly delineate any consequences associated with a positive test or with evidence of tampering (see below.) Those consequences should be very patient-specific and will depend on a number of clinical factors, regardless of the type of monitoring system used. These contracts should be developed jointly between the therapist, patient, and support system members.

### **Rationale**

Although random testing of biological samples has been a mainstay of research or court monitoring, the panel agreed that this is neither desirable nor necessary for remote monitoring in most clinical situations. Because a monitoring system can usually detect alcohol use for 3 to 5 hours, an agreed upon schedule of 3 tests per day was considered very adequate for monitoring purposes (Skipper et al., 2013). The panel also emphasized that BAC monitoring for clinical purposes should be used in the same way that HgA1c or blood pressure monitoring is used to track the course of the illness and the effectiveness of the level of care provided, not as a way of “catching” the patient in a transgression. In this regard, the clinical priority is to create a monitoring situation that provides adequate ability to evaluate the clinical course without being intrusive to the patient’s schedule or privacy.

### **Mitigating Circumstances**

Three sets of circumstances were considered important exceptions to the general recommendation. First, and for the reasons specified, the panel agreed that scheduled 3-per-day testing was important from the start of monitoring, but that with a significant period of favorable results, the frequency of testing could be decreased. However, with a reduction in frequency, there is greater rationale for unscheduled, on-demand testing. Again, it was emphasized that the purpose of testing was not to “catch” the patient, but to both evaluate the continued effectiveness of the treatment plan and to provide the patient a motivational deterrent to a resumption of drinking. In particular, most panel members strongly recommended a morning test scheduled shortly after waking, as this test should be able to record heavy drinking during the prior night.

A second and important mitigating circumstance to scheduled testing was a patient request for either additional or random testing. Such requests were not uncommon in the experience of most panel members who felt such patient requests signaled important changes in a patient’s motivation to remain sober and their ability to foresee challenging social situations (eg, holidays, stressful work periods, stressful family/social situations, etc).

A final mitigating circumstance that would signal additional testing was evidence of a tampered or positive test (see below).

### **What Is the Recommended Clinical Response to a Tampered or Falsified Test?**

#### **Recommendation**

The panel unanimously agreed that efforts to circumvent monitoring or to provide a false sample, though rare,

were serious issues that should occasion immediate clinical intervention. The consensus was that the patient’s support group should be notified, and the clinician should contact the patient and request an in-person appointment which would include additional testing (most recommended urine EtG testing) and perhaps a re-assessment of recent clinical status.

#### **Rationale**

Regardless of the type of clinical monitoring used, purposeful tampering or attempted falsification is a serious challenge to successful treatment because it suggests a lack of reciprocal commitment and engagement in treatment. This was the basis for the recommended re-evaluation of the clinical relationship. The panel felt that the re-evaluation should start with a biological sample (urine EtG, hair, etc) that would be tested for the presence of all potentially addictive substances. Four of the panel suggested a full re-assessment of patient status and a face-to-face meeting with members of the approved contacts.

All panel members agreed that falsification or tampering should not be considered grounds for treatment discharge. Indeed, most panel members indicated that tampering or falsification was an important indication of the need for intensified treatment and monitoring. Because most of the panel believed there were a myriad of complicating individual circumstances surrounding attempts to tamper or falsify a test, there was no consensus on any specific clinical intervention after tampering.

#### **Mitigating Circumstances**

There were no suggested mitigating circumstances that would substantially modify the above recommendations.

### **What Is the Recommended Clinical Response to a Missed Test: a Test That Was Not Submitted Within the Agreed Upon Time Period?**

#### **Recommendation**

The panel did not come to full consensus on a comprehensive response to this issue, largely because most panel members felt there were many legitimate reasons for a single missed test, but not multiple missed tests. What follows are 3 elements that 3 or more panel members agreed upon, but there was not a majority agreement for all of these. If the patient has not submitted a verified test within the scheduled time limit, the patient’s support contact group should be contacted; the clinician should contact the patient by telephone or in-person; and an additional test should be scheduled (some recommended urine EtG testing).

#### **Rationale**

The panel members varied substantially in their reported rates of missing tests. One panel member suggested that there had been no missed tests in a sample of over 100 patients monitored over a 2-year period. In contrast, another panel member suggested that in a normal day, approximately 30% of scheduled tests may be missed.

Despite the variability in rates of missed tests, all panel members agreed that any missed test was cause for some concern, but that a missed test was not the same as a positive test. A majority agreed that a missed test did not reliably predict subsequent dropout or poor performance. This is because many work, family, and social circumstances may lead to difficulties in submitting a sample within the agreed upon 2-hour time window.

It was widely agreed that missed testing was more common in the first week of monitoring and that the frequency of continued missed tests was likely to depend upon the consequences after the early misses. Four panel members favored clear consequences for any deviation from the agreed upon contingencies of the clinical contract to maintain confidence in the system. At the same time, most panel members felt the consequences should be adjusted to be appropriate to the circumstances (eg, missing a test by 5 minutes versus ignoring a test entirely). One panel member reported requiring the patient to come in (and pay) for a confirmatory urine EtG after a missed test, which resulted in very minimal repeated missed tests.

Because of general agreement that a single missed test was not indicative of imminent treatment dropout, many of the panel members voiced concerns over the level of effort that might be required to respond, and the level of legal liability that might be incurred over a single missed test. These concerns were enhanced by the often unnecessary levels of worry among the patient's support group surrounding a missed test.

### **Mitigating Circumstances**

There was no agreement on the type or even the level of clinical intervention considered appropriate after an initial missed test. Whereas notification of the missed test to the clinician and to the list of approved patient contacts is a standard part of the monitoring system, there was no full agreement that these features were clinically useful. The model case under consideration was designed to have no binding legal or professional society contingencies. It was recognized that an externally imposed requirement for monitoring (eg, physician health plan, family court, etc) with mandatory consequences could significantly modify clinical procedures.

### **What Is the Recommended Clinical Response to the First Positive Test Result?**

#### **Recommendation**

The panel unanimously agreed that even 1 positive test result was a clinically significant event and that it had to be dealt with in a manner that included at least the following elements:

1. the patient's support contact group should be contacted;
2. the clinician should contact the patient by telephone or in person, and request a face-to-face meeting; and
3. the frequency of monitoring should be increased.

However, the panel did not come to consensus on specific changes to the clinical plan. Indeed, there was no

consensus that any clinical change should be instituted after 1 positive test result.

#### **Rationale**

Lack of consensus was based upon different levels of experience with remote monitoring. All panel members who had used a monitoring system suggested that most patients who had had a positive test result were able to return to abstinence by sharing their results with their contact group and by increasing monitoring frequency (usually for a month). In contrast, all panel members who had not used a monitoring system were skeptical that simply continued monitoring would have beneficial effects.

#### **Mitigating Circumstances**

Many panel members suggested that whether, and in what way a change to the treatment plan should be made, was tied to situation-dependent variables such as the severity of the relapse detected (eg, a single drink at a wedding or a binge drinking and driving episode), the prior history of the patient, the point during treatment at which the positive result occurred (early in care monitoring or after a significant period of sustained sobriety), and whether the patient self-disclosed their drinking.

### **What Is the Recommended Clinical Response to a Second Positive Test Result?**

#### **Recommendation**

Again, the panel unanimously agreed that every positive test result, especially a repeated positive result, was a clinically significant event that required clinical intervention. Again, there was agreement that at a minimum, this intervention should include the following elements:

1. the patient's support contact group should be contacted;
2. the clinician should contact the patient by telephone or in person, and request a face-to-face meeting;
3. the frequency of monitoring should be increased; and
4. there should be intensification of treatment (type not specified).

The panel unanimously agreed that a repeated positive test should occasion the same responses to the first positive test, and also some type of treatment intensification. However, there was no agreement on the specific type or frequency of care that should be recommended.

Members of the panel who were involved with treatment of licensed, safety-sensitive professionals suggested that a second positive result required removal from work and likely referral for reevaluation and consideration for residential or day treatment. The remaining members of the panel representing a very wide range of clinical populations felt it was not possible to identify any specific intensification recommendation, feeling that that choice was best negotiated among patient, clinician, family, and any involved referral source (eg, referring physician, family court, etc). Viable intensification options included encouragement to attend additional mutual support group (eg, AA meetings), more frequent office visits, individual counseling, family therapy,

intensive outpatient treatment, residential treatment, and/or a prescribed medication.

### **Rationale**

The panel unanimously agreed that there was need for focused research on whether repeated positive findings predicted dropout or a full relapse, and on what types of therapeutic changes were most likely to reduce the likelihood of dropout and relapse. Three panel members suggested that a good starting point for such research would be a review of similar situations in the management of other chronic illnesses (eg, what clinical changes are recommended when monitoring of diabetic patients reveals repeated elevations of HgA1c testing).

### **Mitigating Circumstances**

Three panel members noted that a second positive result might not occasion significant clinical change if that second positive result had occurred many months after the first positive result, and/or if that event appeared to be associated with unusual circumstances.

### **How Should Monitoring Results Be Shared With Approved Patient Contacts, and What Training or Guidance Should They Be Given With Regard to Their Reactions Toward the Patient?**

#### **Recommendation**

This was the most controversial topic of the consensus discussion and the panel did not come to consensus on:

1. whether it was a uniformly good idea to share any information with the patient contacts; or
2. whether, or how, to train or instruct the patient contacts in responses to negative and positive test results; or
3. what types of responses from the contacts would be clinically helpful.

#### **Rationale**

As indicated previously, the monitoring system currently sends all positive responses to the clinician, and also all approved contacts. The rationale for this is that making the results public to those in a position to support the patient is expected to serve as a deterrent to drinking, and in the event of a drinking lapse, the patient's contact group could serve as a support network to help the patient regain motivation and sobriety.

Virtually all panel members agreed with the premises behind information sharing, but several practical concerns were also raised. First, many panel members voiced that managing the contact group could incur significant time requirements (eg, requests for guidance and worried discussions). Second, a majority of the panel members suggested that they would be more positive about information sharing with the contact group if only confirmed positive results were shared, and not missed or unconfirmed positive results. It was agreed that, regardless of the monitoring system used, false-positive test results could

produce unnecessary worry, conflict, and frustration within the contact group.

A third concern voiced by most panel members was violation of patient confidentiality by members of the support group. Unlike the treating clinician, patient support groups are not legally bound to confidentiality. Inappropriate sharing could result in significant social harms to the patient and potential legal consequences for the clinician. For example, an exasperated spouse might choose to report a positive test result to the patient's employer, leading to serious consequences and potential legal liability. Finally, whereas all panel members agreed that there was a need for instruction or training of contact members, most panel members said they had neither the staff nor the time available to perform such training. Again, virtually all panel members agreed this was an area for additional research.

### **Mitigating Circumstances**

No suggested mitigating circumstances would substantially modify the above discussion.

## **DISCUSSION**

At this writing, there are many political, financial, scientific, and technological forces pressing for change in the treatment of AUD. Basic science discoveries are increasing acceptance that severe AUD is best considered a chronic illness (McLellan et al., 2000; Mayfield et al., 2002; Volkow and Li, 2005; Coleman et al., 2011). New healthcare legislation and insurance regulations require most healthcare organizations to provide AUD treatment comparable with the management of other chronic illnesses, including all evidence-based behavioral therapies, medications, support services, and monitoring (Mental Health Parity and Addiction Equity Act, 2008; Affordable Care Act, 2010). Finally, emerging technology now enables an increasing number and types of affordable, real-time, remote monitoring of BAC that should improve and extend the effectiveness and efficiency of a "chronic disease management" approach to the treatment of AUD (Bodenheimer et al., 2002; Hamburg and Collins, 2010).

However, these changes are quite new and there is need for research to inform clinicians on how to safely and sensibly incorporate an individualized disease management approach including key indicator (BAC) monitoring and management into regular care. To provide initial clinical guidance to promote relevant, hypothesis-testing research in this emerging area, a manufacturer of a wireless, real-time BAC monitoring system (Soberlink) sponsored a day-long meeting of 9 clinicians with extensive experience in the treatment of patients with AUD to draw upon their experience regarding the remote clinical monitoring of BAC during outpatient AUD treatment.

It must be emphasized that this discussion focused upon clinically-oriented monitoring such as might be used in the management of other chronic illnesses, not sanction-oriented monitoring that is often used to detect and punish illicit behavior (eg, driving while impaired). Whereas both clinical and sanction-oriented monitoring share a goal of deterring relapse to drinking, the primary purpose of clinical monitoring is to track BAC as 1 important indicator of patient

adjustment during ongoing care, and to use that indicator to adjust the intensity and composition of care to optimize patient benefit. Because recovery from AUD involves significant behavioral change, a third and important purpose of remote monitoring is to share the positive and negative results from the monitoring with the clinical team and (when indicated) patient family and close friends as an important source of support for positive behavioral change.

### Consensus Issues

The expert clinical panel showed unanimous agreement on only 2 issues. All agreed that remote BAC monitoring is currently feasible, practical, and valuable in managing patient recovery and deterring relapse in the outpatient treatment of adult AUD. Monitoring of adolescents with AUD was not discussed and could be quite different. All panel members also agreed that monitoring should continue for at least 1 year during and following outpatient treatment to optimize stabilization (many members favored longer periods of monitoring), and that 2 to 4 scheduled samples per day generally provides good coverage with minimal patient intrusion.

Three other areas of consensus, but not unanimity, included the following:

- A single missed test (failure to submit a breath sample within agreed upon time frame) was considered clinically concerning but not a reliable indicator of future dropout or relapse. Modest clinical consequences were suggested (eg, patient contact, discussion, possibly an inperson appointment), but a single missed test was not thought to require a more significant clinical response. Multiple missed tests were considered more serious and likely to require a more significant response.
- Evidence of tampering or falsification of a clinical test was considered more severe and was considered to warrant a more aggressive clinical response including a face-to-face re-assessment of patient status, and also intensification of the monitoring schedule and likely the treatment plan. There was agreement that tampering or falsification was not by itself a reason to discharge a patient. Rather, all agreed these behaviors signaled need for more and/or different treatment.
- A positive result (alcohol use) was also considered concerning and might (but not always) require intensification or change in treatment. Multiple positive results were broadly considered indicative of need for more intensive treatment.

Whereas there was often consensus among the panel that a particular event or finding (eg, missed test, tampered test, positive specimen) should result in some type of intensified clinical care and/or monitoring, there was usually little agreement on specific corrective actions. Lack of consensus was typically due to 2 issues. First, it was recognized that the personal and situational issues surrounding any of the above events might be idiosyncratic and thus inappropriate for any fixed clinical response. Relatedly, most of these experienced clinicians favored situation-specific evaluations and negotiations, and did not wish to be constrained by any general recommendation.

The area of greatest debate and concern was the sharing of monitoring results with the patient support group. Whereas most panel members agreed that there was significant potential for relapse deterrence and general clinical benefit from a properly constituted and trained support group, issues of training and management, and particularly the potential for patient harm through sharing of clinically sensitive information by the support group were major concerns.

## CONCLUSION

### Need For Additional Research

The most basic area of agreement among the panel was the need for more practical clinical and implementation research in the area of patient monitoring. At this writing, there is no doubt about the viability and potential value of BAC and possibly other key indicator monitoring; the technology is now readily available to support remote clinical monitoring. However, the results from this experienced, expert panel make clear that there are important, fundamental areas of disagreement and clinical confusion on how best to use clinical monitoring to promote patient recovery. Some of these are highlighted below to promote new research.

### Adolescent AUD Treatment

It is important to emphasize that the panel discussion was purposely confined to adult patients in outpatient care, who were not mandated into care. Adolescent patterns of problematic alcohol use are often quite different and potentially more dangerous than adult drinking patterns. Moreover, there are fewer evidence-based components of care available to treat adolescent AUD, thus somewhat reducing the potential clinical information value of monitoring for adolescents. Thus, it is not yet possible to generalize even these broad recommendations to adolescent patients. This is a critical area for research.

### Role of Clinical Relationship

Perhaps the most basic question is whether, and under what circumstances, is monitoring by itself—without clinical involvement—useful in preventing relapse and promoting recovery. The premise for the consensus meeting and for all the recommendations is the presence of some level of ongoing clinical involvement, either in an outpatient program and/or in office-based care. But the monitoring technology is not restricted to healthcare settings and could be used in workplace, school, or family settings. Indeed, there is growing interest in adaptive and self-care models of treatment in chronic addiction (McKay, 2009). Under these circumstances, self-monitoring could be used in a constructive manner as a means of sustained engagement in a recovery-oriented lifestyle in coordination with a trusted health care provider.

### Role of Abstinence As a Clinical Goal

The panel discussion purposely focused on a rather severe clinical case and a clinical goal of sustained abstinence. However, because most monitoring systems can (or soon will be able to) detect any level of alcohol use, it is reasonable to question whether the same monitoring technology could be



paired with common alcohol use screening instruments to not only identify at risk drinking, but allow more precise measurement of drinking behavior in patients who wish to moderate their drinking in lieu of total abstinence. Such monitoring might reasonably occur within primary care, college campus health clinic, or other settings for individuals who believe that with some assistance they can control the frequency and amount of their alcohol use.

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