#### What Really Works in Alcohol Monitoring

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### **MADD & NHTSA Statistics**



Every day in America,

another 28 people die as a

result of drunk driving

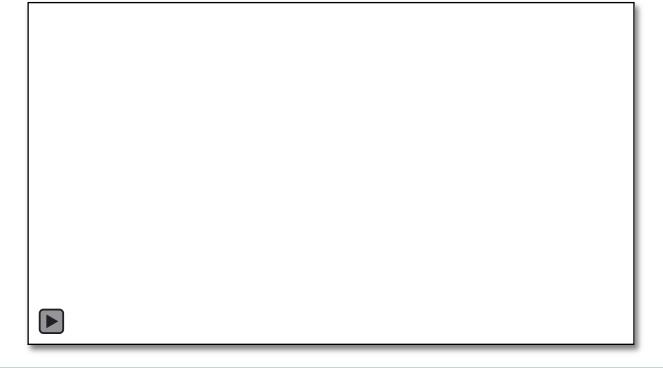
crashes

In 2012, 10,322 people died in drunk driving crashes one every 51 minutes

injured in a drunk driving crash



## Effects of Drugs & Alcohol

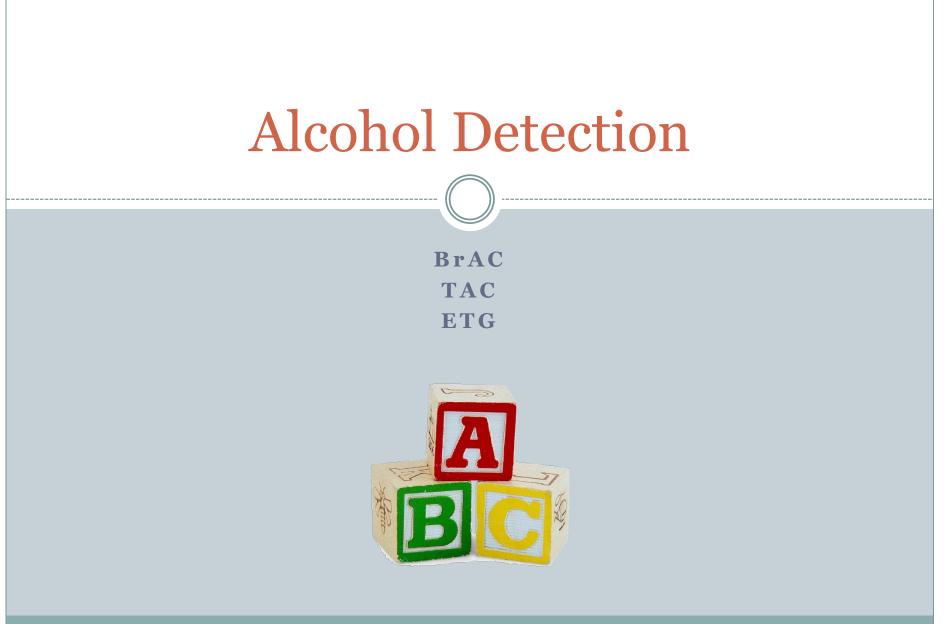


### Agenda

#### Comparison of Alcohol Monitoring Technology

- o BrAC Breath detection
- TAC Sweat detection
- EtG Urine detection "Start with the assumption that the best way to do something is not the way it's being done right now."
   *Aaron Levie, CEO of Box*





### What Are You Looking For?

- Is a drink or two once in a while allowed?
- How soon do you want to know about a drinking event?
- Is differentiating contaminants from consumed alcohol necessary?
- How important is the cost?



## **Breath Alcohol Monitor**

#### ALCOHOL CONSUMPTION WINDOW OF DETECTION CONFIRMATION



Thanks to her new food-breath analyzer, Cheryl could find out what her kids REALLY had for lunch.

### **Blood Alcohol Concentration (BAC)**

#### **Consumption**

- Absorption Rate:
  - Increase for 30 min to 2 hrs.
- Elimination Rate:
  - Average .015 .020% per hour



This illustration is not intended to be used as a scientific BAC measurement, and should not take the place of your own responsible decisions about drinking alcohol, or about whether and when it will be safe for you to drive.



https://www.responsibility.org/end-impaired-driving/solutions/prevention/08-bac-legal-limit/

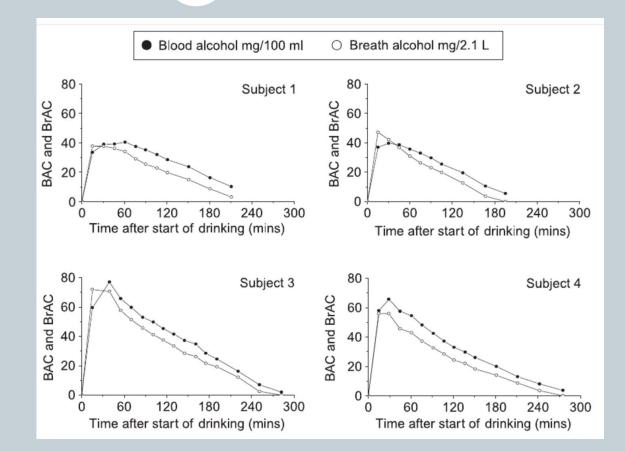
### BAC vs BrAC

#### **Detection**

After 15-30

 min, blood is
 higher than
 breath

 Breath monitors alveolar air





#### Detection

- Fuel Cell
  - BrAC .000 to .600 ≻ +/- 0.005
  - Breath Volume
  - Temperature Humidity





#### Detection

- Features
  - o Battery
  - o Camera
  - Cell modem





#### Detection

### Programming

- Up to 10 tests per day
- Vary test frequency
- Custom settings
  - > Retest
  - > Zero Tolerance





### Contaminants

	Listerine Deeper Clean - Mouthwash	Colgate Total Adv. ALCOHOL FREE - Mouthwash	Listerine Freshburst - Strip	Scope Outlast - Breath Mist	Listerine - Pocketmist	Martinelli Cider - ALCOHOL FREE	Monster - Zero Ultra	Monster - Ultra Blue	Red Bull	5 Hour Xtra Strength Berry	Tresemme Xtra Firm - NON-AEROSOL	Tresemme Xtra Firm - AEROSOL
Wait time after product use	30 sec	0	1 minute	30 sec	30 sec	0	0	0	0	0	0	0
BrAC test result	0.189	0.000	0.000	0.103	0.025	0.000	0.000	0.000	0.000	0.000	0.019	0.015
Rinse mouth	no			no	no						no	no
Time between tests	3 min			3 min	2 min						2 min	3 min
BrAC test result	0.125			0.000	0.000						0.000	0.000
Rinse mouth	no											
BrAC test result	0.000											

## If you rinse & retest, contaminants disappear.

Wait tir			
	1/12	it.	tir

	-			-	-	-	-	-		-	-	
BrAC test result	0.000	0.019	0.000	0.000	0.000	0.000	0.000	0.000	0.009	0.006	0.048	0.189
Rinse mouth		no		no	no	no	no	no	no	no	yes	no
								4 min, 3				
Time between tests		3 min		1 min	1 min	0 min	1 min	swallow	3 min	2 min	2 min	2 min
BrAC test result		0.000		0.000	0.000	0.000	0.000	0.006	0.000	0.000	0.000	0.024
Rinse mouth				no	no	no	no	No				no
retest				1 min	1 min	1 min	< 1 min	2 min				4 min
BrAC test result				0.000	0.000	0.000	0.000	0.000				0.000

#### **Detection Summary**

- Fuel Cell
  - Quantitative

#### • Temp & Humidity Sensor

- Accuracy
- Camera
  - Facial Detection
- Cellular Modem
  - On Board
- Robust Programming
  - Qualitative





### **Breath Alcohol Monitoring**

#### **Confirmation**

#### • BrAC

- Exact reading, closely related to BAC
- Current state of impairment
- Automatic re-test after fail

#### • Zero Tolerance

• 63% of our violations over a 1 week period were consistent with consumed drinking <.020 BAC

• Metabolic Rate

• Consumed vs Contaminant







### **Breath Alcohol Summary**

#### Alcohol Consumption Levels

30 min to 2 hours after consumption
Elimination of .020% per hour

#### Window of Detection

From .000 to .600 with ±.005 accuracy
Multiple tests per day

#### Confirmation

Repeat tests during event
Average fail rate .02, Smart Start Wisconsin is .005



#### ALCOHOL CONSUMPTION WINDOW OF DETECTION CONFIRMATION



### • Fuel Cell

- Monitors perspired alcohol,
- Transdermal Alcohol Concentration (TAC)
- Worn by user
  - No camera or facial detection software needed
- Tests every 30 min
  - No test windows needed
- Pair with base to send data
  Base unit is not portable
- Battery operated
  - Replace 30-60 days







#### **Alcohol Consumption**

		Table 2.	TAC-Based	and AMS C	riteria for the	e Detection (	of Drinking E	vents						
	Males						Females							
Beers (units) consumed	1 (0.92)	2 (1.84)	3 (2.76)	4 (3.68)	5 (4.60)	1 (0.92)	2 (1.84)	3 (2.76)	4 (3.68)	5 (4.60)	Total			
Total n	32	32	32	32	32	29	29	29	29	17	293			
Exceed 0, n (%)	20	30	32	32	32	17	28	29	29	17	266			
	(62.5)	(93.8)	(100)	(100)	(100)	(58.6)	(96.6)	(100)	(100)	(100)	(90.8)			
Exceed 0.02, n(%)	0	8	24	31	32	0	17	23	29	17	181			
	(0)	(25.0)	(75.0)	(96.9)	(100)	(0)	(58.6)	(79.3)	(100)	(100)	(61.8)			
Exceed 0.03, n(%)	0	4	15	29	32	0	11	21	28	17	157			
	(0)	(12.5)	(46.9)	(90.6)	(100)	(0)	(37.9)	(72.4)	(96.6)	(100)	(53.6)			
AMS resolved, n (%)	0	8	19	30	32	0	13	19	29	17	167			
	(0)	(25.0)	(59.4)	(93.8)	(100)	(0)	(44.8)	(65.5)	(100)	(100)	(56.9)			
AMS confirmed, n (%)	0	8	16	27	31	0	11	18	28	17	156			
	(0)	(25.0)	(50.0)	(84.4)	(96.9)	(0)	(37.9)	(62.1)	(96.6)	(100)	(53.2)			

AMS, Alcohol Monitoring Systems; TAC, transdermal alcohol concentration.

Displayed are the number of subjects and the percentage of 32 males and 29 females whose TAC levels were greater than (exceed) various criteria for detection after drinking the designated number of beers (no. beers). Shown also are the number of standard drinks (no. units) contained in each no. beers.

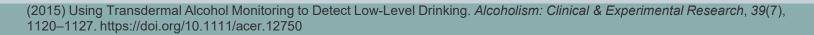


#### Alcohol Consumption

- 1 beer = missed 100%
  - $\times$  TAC for 62.5% of males exceeded zero
  - $\times$  TAC for 58.6% of females exceeded zero
  - 0% Exceeded .02 g/ml & 0% confirmed
- 2 beers = missed 68.5%
  - × TAC for 93.8% of males exceeded zero
  - × TAC for 96.6% of females exceeded zero
  - 41.8% Exceeded .02 g/ml & 31.5% confirmed
- 3 beers = missed 43.9%
  - $\times$  TAC for 100% of all exceeded zero
  - o 77.2% Exceeded .02 g/ml & 56.1% confirmed

## 45.9% of all occasions of drinking 1 to 3 beers were NOT detected.





Clary Clary

### **Alcohol Consumption**

- 4 beer = missed 9.5%
  - × TAC for 100% of all exceeded zero
  - o 98.5% Exceeded .02 g/ml & 90.5% confirmed
- 5 beers = missed 1.5%
  - × TAC for 100% of all exceeded zero
  - o 100% Exceeded .02 g/ml & 98.5% confirmed

Only reliably detects heavy drinking levels of approx. 4 standard drinks for females & 5 for males when consumed in <3 hours.



### **Other Alcohol Consumption Studies:**

- 2014 Predictors of Detection of Alcohol Use Episodes Using a Transdermal Alcohol Sensor
  - The SCRAM sensor is very good at detecting five or more drinks
- 2019 Processing transdermal alcohol concentration (TAC) data to detect lowlevel drinking
  - Reliance upon the AMS criteria for alcohol detection affords a high specificity for detection of heavy drinking but is a poor indicator of abstinence rates.
- 2020 Wearable Transdermal Alcohol Monitors: A Systematic Review of Detection Validity, Relationship Between Transdermal and Breath Alcohol Concentration and Influencing Factors
  - SCRAM seems unable to detect low to moderate drinking levels using the thresholds and criteria set by the manufacturer.



#### Window of Detection

- Approx. 1-2 Hour Delay After Detectable in BAC
- Pairing Required for Data Upload

• Not real time detection





#### Accuracy & Sensitivity

- Water
- Environmental
- Hygiene Products
- Cold Skin (slows vapor loss)
- Hydration Levels
- Individual Characteristics
  - Sweat rate
  - Skin thickness

NHTSA determined that "a TAC reading of 0.02 g/dl produced a 12.34% false-positive rate with SCRAM devices."



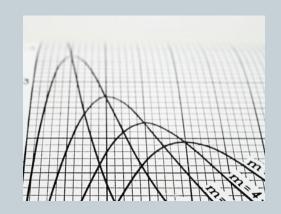
### Confirmation

### • Algorithm

- Confirmed TAC >.02 g/dL
- May require 3 TAC reading of .02 or higher
- Different absorption & elimination rate based on peak TAC
- Avoids contaminates and low BAC events

### • Spiky at Times

- Water affects accuracy
- Misclassify rapid rise in BAC as an external interferent





### **TAC Summary**

#### Alcohol Consumption

- Best for high drinking (5 drinks or more)
- >0.020 BAC

#### • Detection

- o 1 hr after BAC
- o Sample every 30 min
- Sends when paired

#### Confirmation

- Algorithm
- Testimony at .02 or .04 depending on vendor



### Transdermal Vs Breath Alcohol Monitoring

#### Transdermal

#### <u>Accuracy</u>

- .020 g/dL
- Algorithm to Determine BAC
- Contaminants Effect Reading
  - Also Effected by
    - × Water
    - × Cold skin (slows vapor loss

#### **Delayed** Detection

- 1 hr after BAC
- Sample Every 30 Min

#### Pairing Required for Data Upload

#### Breath

#### <u>Accuracy</u>

- .005 BAC
- BrAC Directly Related to BAC
- Retest Clears Contaminants
   Immediate retest after fail

#### **Immediate Detection**

- 30 Min to 2 Hrs Post Drinking
- Scheduled Test Windows

#### <u>All-In-One Unit</u>

- Real-time Reports
  - GPS Location of Tests





#### ALCOHOL CONSUMPTION LEVELS WINDOW OF DETECTION CONFIRMATION



### **Ethyl Glucuronide (EtG)**

- Alcohol Metabolite Found in Urine
- Observed Collection
  - Instant test (POCT) or lab screen
  - Sample can be screened for multiple drugs
- Everyone is Able to Provide
- Lab Confirmation of EtS





### Who May Become A Collector?

Anyone can be a professional collector

A person trained in DOT policies and procedures to collect urine specimens to be used for drug testing programs

• No medical background is necessary



### The Importance of A Professional Collector

- Ensures the integrity and security of the collection process
- Has direct contact with the donor
- Consistently executes every collection
- Collection process is considered "defensible"



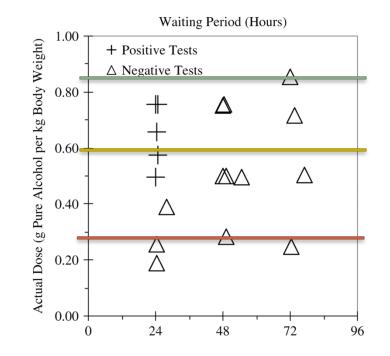


#### OXFORD UNIVERSITY PRESS

#### **Alcohol Consumption**

From: Sensitivity of commercial ethyl glucuronide (ETG) testing in screening for alcohol abstinence

Alcohol Alcohol. 2007;42(4):317-320. doi:10.1093/alcalc/agm014



- Individual test results by actual dosage and actual waiting period.

- 100 ng/ml EtG

High Dose Group Dose 0.66 to 0.85 = <u>up to 6.4 drinks</u> = 0.031 to .109 BAC

Medium Dose Group Dose 0.39 to 0.58 = <u>up to 3.4 drinks</u> = .032 to .087 BAC

#### Low Dose Group

Dose of 0.19 to 0.28 = <u>up to 2.4 drinks</u> =.028 to .034 BAC

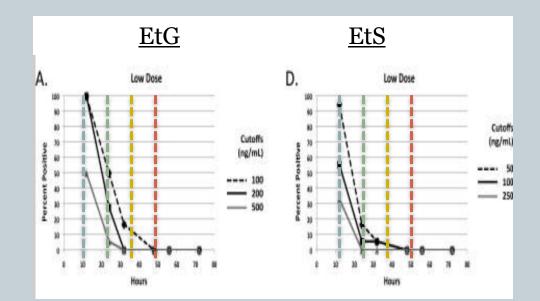
Copyright © The Author 2007. Published by Oxford University Press on behalf of the Medical Council on Alcohol.

### **Ethyl Glucuronide (ETG)**

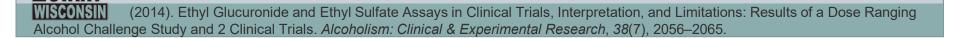
## Alcohol Detection

#### 500 ng/ml

- 0 12 hrs
  - × 50% low dose
- 0 24 hrs
  - $\times$  5% low dose
- o 36 hours
  - $\times$  0% low dose
- 48 hours



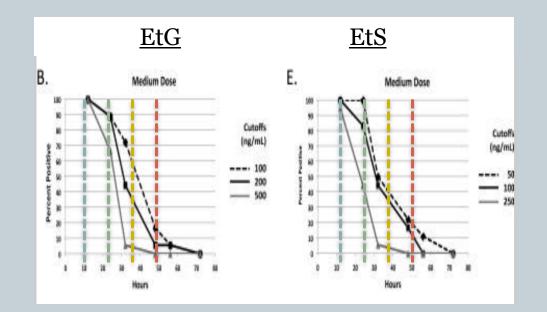
Actual BAC: Low Dose = .028% (20 mg/dl)



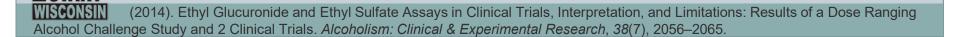
### **Ethyl Glucuronide (ETG)**

### Alcohol Detection 500 ng/ml

- 0 12 hrs
  - × 100% med dose
- 0 24 hrs
  - × 65% med dose
- o 36 hours
  - $\times$  5% med dose
- 48 hours
  - × 0% med dose



Actual BAC: Med Dose = .093% (80 mg/dl)



### **Ethyl Glucuronide (ETG)**

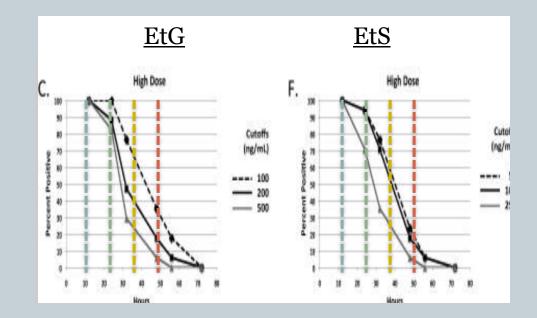
# Alcohol Detection

#### 500 ng/ml

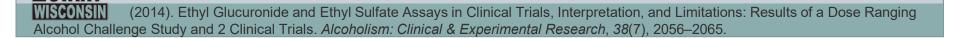
- 0 12 hrs
  - × 100% high dose
- 0 24 hrs
  - × 80% high dose
- o 36 hours
  - × 25% high dose

#### • 48 hours

× 5% high dose



Actual BAC: High Dose = .138% (120 mg/dl)



### **EtG Lowered Sensitivity**

#### **Alcohol Detection**

#### Effected by Contaminants

- Medications
- o Hand Sanitizers
- Hygiene products
- Antiperspirant
- Banana (within 3.5 hrs)
- Sauerkraut (within 5 hrs)
- Bacterial UTI

• False-positive & false-negative results





### **Confirmation with EtS**

#### Alcohol Detection

#### • Few Discrepancies between EtG and EtS

(2014) Ethyl Glucuronide and Ethyl Sulfate Assays in Clinical Trials, Interpretation, and Limitations: Results of a Dose Ranging Alcohol Challenge Study and 2 Clinical Trials



#### • EtS provides a slightly greater sensitivity to alcohol

(2012) The Role of Biomarkers in the Treatment of Alcohol Use Disorders, 2012 Revision





### **EtG Summary**

#### Alcohol Consumption

• Good for medium to high drinking

#### • Detection

• Best within 24 hrs

## • Confirmation

o EtS



### EtG vs Breath Alcohol Monitoring

#### EtG

#### <u>Accuracy</u>

- Detection varies
- EtS needed to confirm
  24-48 hrs to confirm
- Contaminants cannot be cleared

#### Minimal Detection

• 48 hrs or less

#### Limited Availability

• Test at facility

Breath

#### Accuracy

- .005 BAC
- BrAC directly related to BAC
- Repeated test for Confirm
   Immediate provided
- Contaminants can be cleared

#### **Quick Detection**

• 30 min BrAC after drinking

#### Test anywhere, Anytime

- Real-time reports
- GPS Location of tests







### EtG vs TAC vs BrAC Monitoring

#### ЕтG

#### Accuracy

- Detection varies
- EtS needed to confirm
  - 24-48 hrs to confirm
- Contaminants cannot be cleared

#### Minimal Detection

• 48 hrs or less

#### Limited Availability

• Test at facility

#### TRANSDERMAL

#### Accuracy

- .020 g/dL
- Algorithm to determine BAC
- Contaminants effect reading
  - Also Effected by
    - × Water
    - Cold skin (slows vapor loss

#### **Delayed** Detection

- 1 hr after BAC
- Sample every 30 Min

#### <u>Pairing Required for</u> <u>Data Upload</u>

#### BREATH

#### <u>Accuracy</u>

- .005 BAC
- BrAC related to BAC
- Repeat test to confirm
- Clear contaminants

#### **Quick Detection**

- 30 min after drinking
- On Demand or Test Window

#### <u>Test anywhere,</u> <u>Anytime</u>

• Real-time reports

### **Cost of Alcohol Monitoring Program**

#### EtG

- \$4-5 Per Test, Every Other Day
  \$18-25 at a drug testing facility
- EtS/Confirmation is Extra (\$20+)

#### Transdermal

• \$9-12 Per Day + Enrollment

#### Breath

- \$2.50-\$6.50 Per Day + Enrollment
  - o Breath Check \$2.50 Per Day
  - SMART Mobile \$6.50 Per Day
  - o Cellular IID \$4.30 Per Day





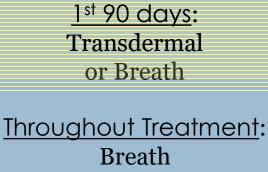
### Suggested Use For Each Technology

#### • Transdermal (TAC)

- Phase 1: when heavy drinking is more likely
- Sanction
- Breath (BrAC)
  - Long term or regular sobriety monitoring
  - o Phase 1-4

#### • Urine (EtG)

- Random or in addition to drug panel
- o Last Phase



<u>Random</u>: Urine



#### What Are You Looking For?



## • Is a drink or two once in a while allowed?

- No? Then a Zero Tolerance program is needed.
- Breath is best technology for this program.
- How soon do you want to know about a drinking event?
  - Now? Then Real-time Alerts are necessary.
  - Breath is best technology for this program.
- Is differentiating contaminants from consumed alcohol necessary?
  - Yes? Then back to back BAC readings are necessary.
  - Breath is best technology for this program.
- How important is the cost?
  - Breath & EtG are lowest cost.
  - EtG require confirmation which can be costly.

## Thank you for your time!



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