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Pilot Test of New Roadside Survey Methodology for Impaired Driving

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16. Abstract

This study developed and tested procedures to enhance roadside survey procedures to include collecting and analyzing oral fluid and blood samples from the nighttime weekend driving population. Roadside surveys involve collecting information from a random sample of drivers. In the past, they have been used to measure the extent of alcohol use in the nighttime driving population in order to establish regular measures of that activity, which is a measure of progress in reducing impaired driving. This study developed and tested techniques to extend the scope of that measurement to drugs other than alcohol. Breath and oral fluid samples were successfully collected from over 600 drivers at 6 locations across the United States. Blood samples were obtained from approximately half of those subjects. Laboratory analyses for alcohol and other drugs were conducted on the oral fluid and blood samples. Procedures and results are described in this report. The findings indicate that this form of expanded roadside survey is practicable in the United States. The intent of this Pilot Test was to develop and test procedures that would be used in the next full-scale national roadside survey. It was not designed to yield a nationally-representative sample of the nighttime weekend driving population; thus the results are not representative of the United States as a whole.

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Executive Summary

The Pacific Institute for Research and Evaluation (PIRE) worked with the National Highway Traffic Safety Administration (NHTSA) to develop and conduct a "Pilot Test of New Roadside Survey Methodology for Impaired Driving." This final report presents the results of the two phases of the project:

(1) The feasibility study, in which the procedure to collect survey data and biological samples at the roadside was developed and refined; and

(2) The pilot test, in which the developed procedure was tested in six States.

This study lays the groundwork for the next decennial national roadside survey of impaired driving, which will estimate the incidence of alcohol- and drug-positive drivers on U.S. roads.

Background

Three prior national roadside surveys of drivers have been conducted. The first, sponsored by NHTSA, was in 1973 (Wolfe, 1974). The second, sponsored by the Insurance Institute for Highway Safety (IIHS), was in 1986 (Lund & Wolfe, 1991). The most recent, in 1996, was funded by NHTSA and IIHS (Voas et al., 1998). These surveys were taken of a national probability sample from the 48 contiguous States.

New to this pilot test was to develop and test the collection of additional types of biological samples which could be used to determine the extent of the presence of drugs other than alcohol in the nighttime driving population. These data are essential to developing more precise estimates of the crash risk associated with the presence of alcohol and other drugs in drivers and measuring the national progress in reducing the prevalence of alcohol- and drug-impaired driving. The full-scale roadside survey will be more extensive than any previous project, and will provide a much broader perspective on which drugs are detected in the nighttime driving population than previously known.

Methodology

In the feasibility study, PIRE developed and tested a roadside survey protocol for (1) subject sampling, (2) sample collection and analysis, and (3) data presentation. We collected data (survey, breath, oral fluid, and blood) from approximately 50 drivers in Delaware. This provided preliminary indications of the potential ability to assess the incidence of alcohol- and other drug-positive drivers in the nighttime driving population, and provided data on alcohol use from breath samples, and alcohol and other drug use from oral fluid (saliva) samples. Additionally, we examined the feasibility of obtaining blood samples from drivers. We also developed and tested a screening instrument designed to detect alcohol use disorders (AUDs) among the nighttime driving population. This activity was funded through a grant from the National Institute of Alcohol Abuse and Alcoholism (NIAAA).

After the feasibility test and procedure development, PIRE conducted a pilot test to refine data collection procedures and test analytic procedures. In the pilot study, we collected data (breath, oral fluid, and blood) from approximately 100 drivers at each of six sites across the country (for a target total of at least 600 subjects providing oral fluid samples). These sites were selected from the primary sampling units of the National Analysis Sampling System (NASS) of NHTSA. Thus, the pilot test was 1/10 of the contemplated sample size of the next national roadside survey (6,000 subjects), which will be used to estimate the incidence of alcohol and drugged driving on our Nation's roadways. The intent of this Pilot Test was to develop and test

procedures that would be used in the next full-scale national roadside survey. It was not designed to yield a nationally-representative sample of the nighttime weekend driving population; thus the results are not representative of the United States as a whole.

Conclusion

One use of the national roadside survey is to track trends in alcohol levels of the nighttime driving population. Though this study is a pilot test and the sample size is relatively small, it is of interest to examine the general results in relation to previous national roadside surveys. These are presented in the figure below (Figure 1) and are generally quite encouraging. The long-term trend has been for an ever increasing proportion of survey respondents to have zero blood alcohol concentration (BAC) readings and for fewer to have positive readings at each level of BAC reading. That seems to have held true in this pilot test, conducted nearly a decade after the most recent national roadside survey. However, because of the small sample size in the pilot study, one cannot say definitively that that is the true trend. Such conclusions are best left for the next full-scale national roadside survey.

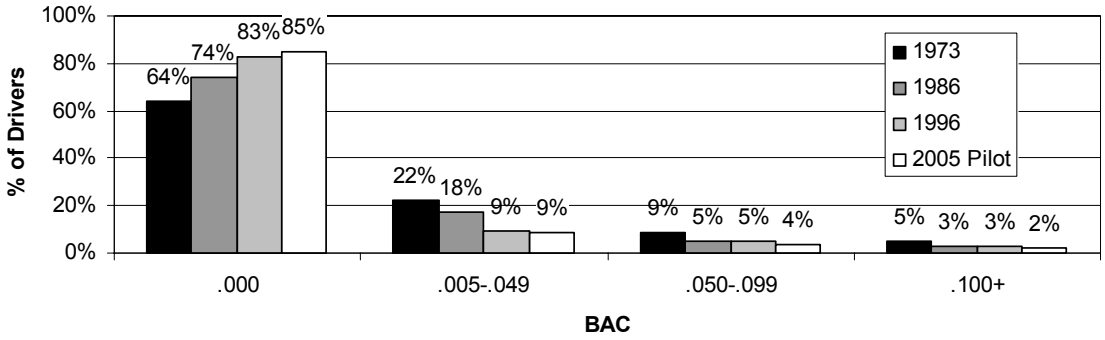

Figure 1. BACs of Drivers in National Surveys

The major focus of this study was to determine whether it is feasible and practical to collect oral fluid and blood from the nighttime driving population and analyze them for drugs. We determined that it is feasible to do so, with a lower response rate than that achieved for breath tests of alcohol. However, one should bear in mind that the overall response rates achieved (67% for oral fluid and 42% for blood) are in line with many telephone and mail surveys, which of course are based on self-report. Results of the analyses of the specimens obtained indicated that approximately 16 percent of these nighttime drivers tested positive for drugs other than alcohol. Additionally, the results of the chemical analyses indicated a much higher use rate than that obtained for the same subjects based on self-report. The most frequently encountered drug was marijuana and its metabolites, followed by cocaine and amphetamines. Another area examined was whether it was feasible and practical to administer a brief alcohol use disorder (AUD) self-report screening instrument at the roadside. Again we found that this was feasible and meaningful results could be obtained.

In summary, the results of this pilot test indicate that it is practical to expand the traditional roadside survey to include self-report based measures of AUD and biological measures of drug use. The objective biological measures, either through oral fluid or blood, are much to be desired over reliance on self-report of drug use.

Introduction

Purpose

This report summarizes the results of a feasibility study and pilot study conducted by the Pacific Institute for Research and Evaluation (PIRE) under the National Highway Traffic Safety Administration (NHTSA) Task Order "Pilot Test of New Roadside Survey Methodology for Impaired Driving" under Contract DTNH22-02-D-95121.

Background

Three prior national roadside surveys of drivers have been conducted in the United States. The first, sponsored by NHTSA, was in 1973 (Wolfe, 1974). The second, sponsored by the Insurance Institute for Highway Safety (IIHS), was in 1986 (Lund & Wolfe, 1991). The most recent, in 1996, was funded by NHTSA and IIHS (Voas et al., 1998). These surveys were taken of a national probability sample from the 48 contiguous States.

Historically, a roadside survey in the context of this study has been a survey conducted during weekend nights where drivers are stopped at random, a brief interview is conducted and a breath sample is requested in order to determine the drivers' blood alcohol concentration (BAC). These surveys have been used to track progress in the Nation's effort to reduce alcohol-impaired driving.

In 1996, breath samples were requested from 6,298 drivers, of which 95.7 percent provided a valid breath sample. In 1986, 93.7 percent of 3,043 drivers provided a breath sample and in 1973, 86.3 percent of 3,698 drivers did so. In the 1996 survey, 17 percent of nighttime weekend drivers had a positive breath alcohol concentration (BAC), compared to 26 percent in 1986, and 36 percent in 1973. In 1996, there was a significant decrease in drivers with BACs of .05 or below compared to 1986, but little or no change in drivers with higher BACs. There was also a significant decrease in drivers under the age of 21 who had been drinking heavily (greater than .10 BAC) in 1996 compared to the previous surveys (4% in 1973 to .3% in 1996) (see Table 1).

Table 1. Trends From Prior National Roadside Surveys

	1973	1986	1996
Participants	3,698	3,043	6,298
Breath Samples	86.3%	93.7%	95.7%
Positive BAC	36%	26%	17%
<21 Yrs. BAC ≥.10	4.1%	2.7%	0.3%

New to this pilot test was to develop and test the collection of additional types of biological samples which could be used to determine the extent of the presence of drugs other than alcohol in the nighttime driving population. These additional data are essential to estimating the national progress in reducing the prevalence of alcohol- and drug-impaired driving. Another aspect of this pilot study was to develop and pilot test a self-report screening instrument to determine alcohol use disorder (AUD) prevalence in the nighttime driving population. This activity was funded through a grant from the National Institute of Alcohol Abuse and Alcoholism (NIAAA). The full-scale roadside survey will be more extensive than any previous project, and will provide a much broader perspective on which drugs are detected in the nighttime driving population than previously known. This pilot study is intended to both

develop data collection and analysis techniques for biological samples other than breath and to test the viability of those techniques in the context of previous roadside survey sampling procedures.

Drug Testing Opportunities

Typically, previous national roadside surveys used an off-duty police officer to randomly stop nighttime weekend drivers so that researchers could ask them a few questions about their driving and drinking, and then obtain a breath test as an objective measure of their BAC. However, since the first national roadside survey was conducted, the technology for collecting and analyzing oral fluid or saliva to detect drugs (including alcohol) has greatly improved. Oral fluid testing for recent use of alcohol and other drugs of interest appears to be a promising method for testing drivers for drugs other than alcohol in the upcoming full-scale national roadside survey.

In a recent study conducted by Cone et al. (2002), oral fluid testing of 77,218 subjects in private industry showed a 5 percent positive rate for any the five Substance Abuse and Mental Health Services Administration (SAMHSA) drug categories (marijuana, cocaine, opiates, phencyclidine, and amphetamines). The pattern and frequency of drug positives was remarkably similar to urine drug prevalence rates in the general workplace from other surveys (Cone et al., 2002). Further, in a study of 180 drivers given blood, urine, and oral fluid tests which were analyzed using quantitative Gas Chromatography/Mass Spectrometry (GC/MS), the positive predictive value of oral fluids was 98 percent for amphetamines, 92 percent for cocaine, and 90 percent for cannabinoids (Samyn et al., 2002).

However, in an analysis of blood, urine, saliva, and sweat from 198 injured drivers admitted to a hospital, saliva detected only 14 positives for cannabinoids, while 22 positives were detected in the urine. The amount of matrix (body fluid) collected in saliva appears to be smaller when compared to urine, and the levels of drugs are typically higher in urine than in saliva, according to the authors (Kintz et al., 2000). In a study of saliva and sweat, Samyn and van Haeren (2000) concluded that saliva should be considered a useful analytical matrix for the detection of drugs of abuse after "recent use" when analyzed using GC/MS. This finding is most desirable in the roadside testing of drivers.

Yacoubian et al. (2001), tested 114 adult arrestees using saliva and urine and concluded that saliva testing may have certain advantages over urine testing for drugs, including (1) ease of sample collection, (2) subject preference for giving saliva over urine, (3) less vulnerability of adulteration in saliva, (4) little concern for subjects producing an adequate sample with saliva, and (5) saliva storage is easier than urine. The authors found a sensitivity of 100 percent and a specificity[1] of 99 percent for cocaine in saliva and a sensitivity of 88 percent and specificity of 100 percent for heroin. However, saliva results only had a sensitivity of 5 percent for marijuana,

[1] **Sensitivity:** Sensitivity is ability of a test to measure what it purports to measure or in this case the ability of the oral fluid tests to correctly identify active drug users. It is operationalized as a proportion represented by the true positives (i.e., those who are drug positive and actually test positive) divided by all persons who are drug positive [i.e., those who are positive and test positive (i.e., true positives) plus those who are positive and test negative (false negatives)]. The formula for sensitivity is Sn = TP / (TP + FN) where TP and FN are the number of true positive and false negative results, respectively. You can think of sensitivity as 1 minus the false negative rate. Notice that the denominator for sensitivity is the number of drug positive persons.
Specificity: Specificity is the ability of a test to correctly identify non-cases of disease or in this case the ability of the oral fluid tests to correctly identify non-drug users. It is operationalized as a proportion represented by the true negatives (i.e., those who are drug negative and test negative) divided by all persons who are drug negative [i.e., those who are negative and test negative (i.e., true negatives) plus those who are negative, but falsely test positive (false positives)]. The formula for specificity is Sp = TN / (TN + FP) where TN and FP and the number of true negative and false positive results, respectively. You can think of specificity as 1 minus the false positive rate. Notice that the denominator for specificity is the number of non drug users.

likely reflecting only detection of very recent smoking, in that marijuana does not migrate from the blood supply to the oral fluid. Thus, positives in oral fluid are an indication of residual marijuana remaining in the mouth after ingestion. This may well be a positive factor for the current study in that when marijuana is detected in saliva, it is more likely to be in its active phase in the body rather than simply evidence the marijuana has been consumed during a look-back period which may be as long as two weeks and may no longer have a potential impairing effect.

Hold et al. (1999) conducted a review of the literature of using saliva for drug testing; the review included 135 references and provided guidelines for techniques for collecting and measuring drugs in saliva. In an earlier review of drugs of abuse found in saliva, Schramm et al. (1992) concluded that initial studies with cocaine and phencyclidine suggested a correlation between saliva and blood concentration, but that tetrahydrocannabinol (THC) does not appear to be transferred from blood to saliva. Recent marijuana smoking, however, can be detected in saliva from the buccal cavity.[2]

With regard to saliva and BAC, Bates et al. (1993), found that saliva strips and breath tester results for alcohol correlated very highly (r=.89-.90) with each other. Blood sample analyses, however, still remain the "gold standard" in terms of measurement of alcohol and other drugs in the human body, because they are the form of analysis which has been most established.

Project Objectives

This study was composed of two main components—a feasibility study and a pilot study.

In the feasibility study, PIRE developed and tested the protocol for (1) driver sampling, (2) sample collection and analysis, and (3) data presentation for a roadside survey incorporating collection of oral fluid and blood.

After the feasibility test and procedure development, PIRE conducted a pilot test to refine data collection procedures and test analytic procedures. In the pilot study, we collected data (breath, oral fluid, and blood) from approximately 100 drivers at each of six sites across the country (600 subjects). These sites were selected from the primary sampling units of the National Automotive Sampling System/Crashworthiness Data System (NASS/CDS) of NHTSA. Thus, the pilot test was 1/10 of the contemplated sample size of the next national roadside survey (6,000 subjects), which will be used to estimate the incidence of alcohol and drugged driving on our Nation's roadways. On the following pages we describe the activities undertaken to conduct the pilot test, present the results of that endeavor and discuss issues that should be addressed in preparation for the full-scale national roadside survey.

Survey Sampling Procedures

It is obviously impossible to conduct surveys on all the roads in America. It is, therefore, necessary to construct a sampling system that is representative of the United States but requires interviewing only a few thousand of the more than 196 million drivers using American roads (NHTSA, 1978; Lunn et al., 1979). All three prior national roadside surveys limited the area

[2] The buccal cavity includes that part of the mouth bounded anteriorly and laterally by the lips and the cheeks, posteriorly and medially by the teeth and/or gums, and above and below by the reflections of the mucosa from the lips and cheeks to the gums.

covered to the 48 contiguous States. All three surveys were conducted between 10 p.m. and midnight and between 1 a.m. and 3 a.m. on both Friday and Saturday nights, when heavy drinking is most likely to occur and alcohol-involved crashes are most frequent (NHTSA, 2004). From a practical standpoint, these national surveys had to limit survey locations to roadways with sufficient traffic to provide enough interviews to justify the expense of employing a survey crew. Thus, counties with populations of less than 20,000 were not surveyed. In counties with larger populations, only roadways with 2,000 to 4,000 average daily traffic counts were included in the survey. Finally, commercial operators could not be asked to take time from their employment to be interviewed. In the past, motorcycles were excluded; in our pilot test, motorcycles would have been included, if any had presented themselves when vehicles were being selected to participate. This means that in the past three national roadside surveys, information was provided on private four-wheel vehicle operators at locations and during periods when drinking and driving is most prevalent. Therefore, these results were not typical of all drivers at all times or on all roadways in the United States.

The 1973 and 1996 national surveys made use of multi-staged samples developed to be representative of the 48 contiguous States in the year data were collected. The 1986 survey attempted to use the same locations used in 1973. In 1996, the initial sample structure was taken from the National Automotive Sampling System/Crashworthiness Data System (NASS/CDS, 1995). The first stage of the 1973 and 1996 sample designs was the selection of primary sampling units (PSUs) made up of cities, large counties, or groups of counties from within four regions of the United States and three levels of population density. The second step was to select from a list of the police jurisdictions (PJs) within each of the selected PSUs that would be invited to participate in the survey. The third step was to select survey sites within the geographical area of the selected PJs by placing a grid over a map of the area and randomly selecting 1-square-mile cells within which the survey sites would be located. Finally, drivers to be interviewed were selected at random from the traffic passing through the survey site.

These sampling procedures were followed to ensure that the probability of selecting a PSU and a PJ survey location and driver was known at each of these stages in the sample design. Knowing these probabilities allowed the computation of the probability that each individual driver would be interviewed in the survey. This was done by multiplying the sampling probabilities at each of the four stages to obtain the final overall probability of being sampled. The weight given to each case in the final totals (sampling weight) was then computed as the inverse of the sampling probability- that is, data from drivers who were unlikely to be interviewed based on the sampling procedure used were given more weight than data from drivers who were more likely to be interviewed. This ensured that the basic requirement of the sampling theory – that is, every driver has an equal chance of being interviewed – was met by adjusting for the biases inherent in the selection of locations within the sampling frame. A more detailed description of the sampling procedure is provided in Lestina, Greene, Wells, and Voas (1999).

The major barrier to carrying out this staged sampling scheme was obtaining police department support for the survey. In some localities, city attorneys or the police leadership believed that legal limitations to stopping vehicles or potential liability prevented their participation in the surveys. In other cases, the police departments reported that they lacked the personnel resources to support the effort. This resulted in the requirement to make substitutions in all three national surveys and in this pilot test for initially selected PSUs and PJs where enforcement assistance was not available. Substitutions were required for 5 PSUs in the 1973 survey, 9 PSUs in the 1986 survey, and 5 PSUs in the 1996 survey. The effect of these departures

from the original structure of the sample was minimized by ensuring that the substitute was selected from the same geographical and population stratum.

Selection of Primary Sampling Units (PSUs)

The primary sampling units (PSUs) in the National Automotive Sampling System (NASS/CDS, 1995) consist of two parts: (1) the General Estimates System (GES) (NHTSA, 1991) collects data on an annual sample of approximately 54,000 police-reported motor vehicle traffic crashes occurring in 60 PSUs across the United States; and (2) the Crashworthiness Data System (CDS) collects detailed information on an annual sample of approximately 5,000 traffic crashes involving at least one vehicle that is towed from the crash scene in 24 PSUs across the nation.

The pilot test sampling began with the 24 PSUs employed by the CDS (NASS/CDS, 1995). The CDS sampling frame was used in the 2005 pilot test for two reasons: (1) use of the CDS offered the possibility of weighting the sample by crash frequency rather than population which has the advantage of producing a smaller sampling variance (NASS/CDS, 1995) and (2) use of the CDS list of police jurisdictions potentially provided easier access to police departments because they were already cooperating with NHTSA. The multi-stage sampling system used in the three prior national roadside surveys will produce a valid comparable estimate of the national level of drinking and driving for the next national roadside survey as long as the sampling plan is carefully implemented. In this pilot study, we adhered, to a large extent, to that sampling procedure in order to test our ability to obtain cooperation for the more complex survey (involving collecting oral fluid and blood samples in addition to breath samples) from both police agencies and the driving public.

Selection of Counties

In the first two stages of the sample, counties and police departments were selected using a probability proportional to size (PPS) scheme, where the number of fatal and serious injury crashes served as the measure of size. The survey used the NASS/CDS (1995) sample for parts of the first two stages. Initially, the 24 PSUs that were selected from the CDS came from a frame of 1,195 PSUs, which then formed the set of selected PSUs for the national survey.

We stratified the 24 CDS PSUs by east and west of the Mississippi to insure that we would have geographic dispersion within our six sites. We then conducted a simple random sample to identify three PSUs in each of the two regions. A backup sample of three PSUs in each of the regions was also taken so that we would have replacement PSUs should we be unable to obtain cooperation in any of those initially sampled. We were able to obtain cooperation in five of the six sites initially selected. State-level administrators for the other site were reluctant to endorse the survey activity so a replacement site was recruited from the same region of the country. The six PSUs used in this pilot test are shown in Figure 2.

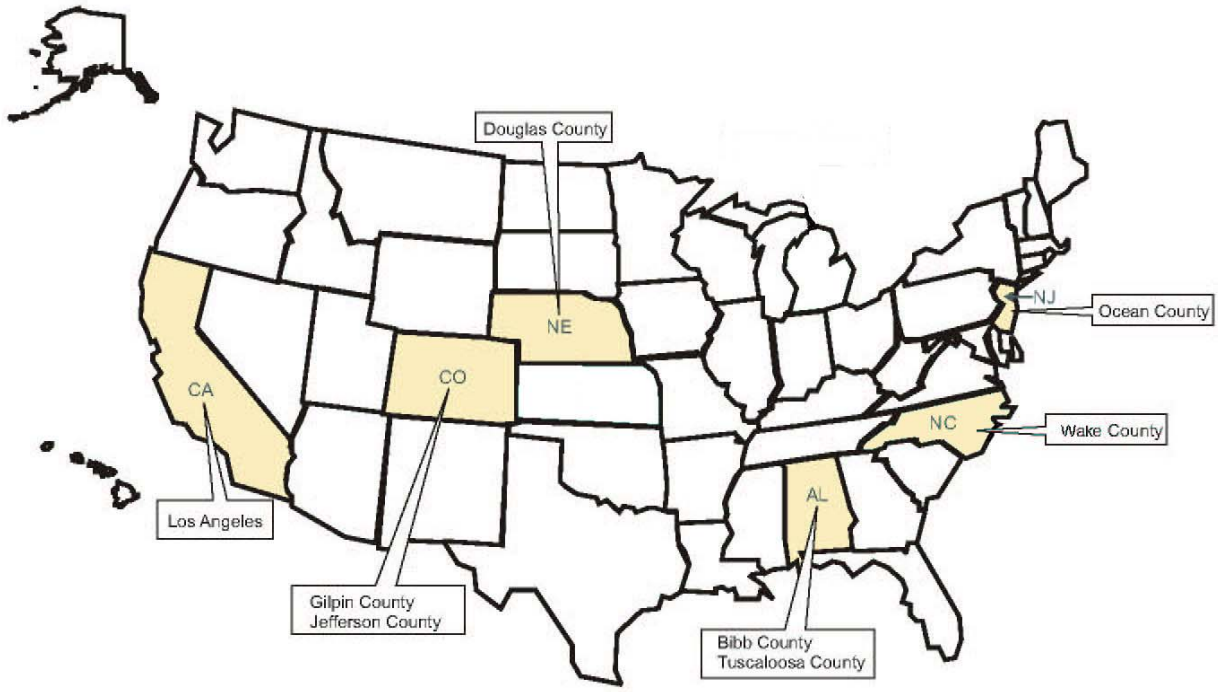

Figure 2. National Roadside Survey Pilot Test Primary Sampling Unit Locations

Selection of Police Jurisdictions

The same general procedure as in the three previous national surveys was employed in selecting and recruiting police departments for this pilot study. Initially, using the CDS frame, departments were selected from those chosen for the CDS using simple random sampling. This preserved the underlying PPS scheme. Police departments electing not to participate were replaced by other departments from the same PSU.

Departments were excluded where it would be difficult to install survey sites (for example, departments patrolling Native American reservations, airports, hospitals, and harbor jurisdictions). State police units were also excluded because their jurisdictions were limited to interstate and arterial highways. Because vehicles could not be safely stopped at these locations they would be inappropriate for survey sites. Table 2 presents a summary of the police jurisdictions participating in the study.

Table 2. National Roadside Survey Pilot Test Sites

EAST COAST	WEST COAST
ALABAMA	**CALIFORNIA**
Bibb County PD* – 4 sites	Torrance PD - 4 sites
NEW JERSEY	**COLORADO**
Dover Township PD – 1 site	Gilpin County PD – 2 sites
Manchester PD – 1 site	City of Golden PD – 2 sites
South Tom's River PD – 1 site	
Berkeley Township PD – 1 site	
NORTH CAROLINA	**NEBRASKA**
Cary PD – 4 sites	Omaha PD – 4 sites

* Police Department

Selection of Survey Locations

Once police departments were selected and recruited, survey locations were determined in conjunction with the departments. A map of the area was divided into squares of approximately 1-square mile each. Squares containing few or no road segments such as fields or parks were not included in the sampling frame. From those available, squares were selected, using simple random sampling, as possible sites for a survey location with no more than one survey location permitted in a square.

The site supervisor and police officer were instructed to find a safe and effective site within the selected square. To be considered safe, the site had to provide enough viewing distance of the roadway to permit an officer to signal oncoming vehicles to stop. This distance varied with the typical speed of the traffic on the roadway. The best locations were lighted, off-road parking areas into which selected drivers could be directed. In all cases, it was necessary to have the police department approval of the survey site. Table 3 presents the sites where survey activities were conducted.

Table 3. NRS Pilot Test Sites

STATE	COUNTY	DATE	FRIDAY SITE 1	FRIDAY SITE 2	SATURDAY SITE 1	SATURDAY SITE 2
NJ	Ocean	8/5-6/2005	Rte. 35 in Seaside Park	Pinewald Keswick in Manchester	Fisher Blvd. in Dover	Rte. 166 in South Tom's River
AL	Bibb	8/19-20/2005	Rte. 82 South in Brent	CR219 in Centreville	CR97 near CR12 crossing in Woodstock	Rte. 11 in Woodstock
CA	Los Angeles	9/9-10/2005	Sepulveda Blvd. in Torrance	Crenshaw Blvd. in Torrance	Torrance Blvd. in Torrance	Pacific Coast Hwy. in Torrance
CO	Gilpin	9/16-17/2005	Mile 1.5, Rte. 119 in Black Hawk	Mile 12, Rte. 119 in Dury Hill	N/A	N/A
	Jefferson		N/A	N/A	S. Golden Rd. at Johnson in Golden	Rte. 58 at Briarwood in Golden
NC	Wake	9/23-24/2005	High House Rd. in Cary	N. Harrison Ave. in Cary	Maynard Rd. in Cary	Tryon Rd. in Cary
NE	Douglas	10/7-8/2005	132nd St. in Omaha	Pacific St. in Omaha	Pacific St. in Omaha	84th St. in Omaha

Survey Administration

Procedures

Overview

The roadside survey procedures implemented in the pilot test followed, as closely as possible, those used in the three prior national roadside surveys (Lestina et al., 1999). This involved: (1) identifying a safe, well-lit location to conduct the survey, and (2) an off-duty police officer directing traffic into interview bays marked off by cones. However, adding procedures such as the collection of oral fluid and blood necessitated some variations on the prior procedures (e.g., a blood-draw van), while maintaining a safe, efficient, and cost-effective data collection protocol for collecting the desired specimens (breath, saliva, and blood) and information from the nighttime driving population.

Our goal for the pilot phase was to obtain at least 600 oral fluid samples (100 in each State), which was accomplished. For the pilot test phase, we refined the protocol developed in the feasibility phase and then continued to further refine it through the pilot testing. The following protocol reflects these changes, and the protocol used in the pilot test sites.

General Survey Procedures

The site supervisor arrived at the PSU on Thursday before the survey and visited the proposed survey sites with the liaison officers from the cooperating police departments. Three different sites with off-road parking were identified for each of the two survey periods for both Friday and Saturday nights for a total of 12 sites in each of the 6 States, in order to have spare sites. The sites were chosen for safety of the public, the police, and the researchers. Desired attributes included an adequate off-road area to conduct the interviews, easy access from the roadway, good lighting, and traffic volume. The site supervisor planned the layout of car entry, exit, position of bays for data collection, and site of blood draw van with law enforcement prior to the data collection activities (see Figure 3 for samples of site layout sketches).

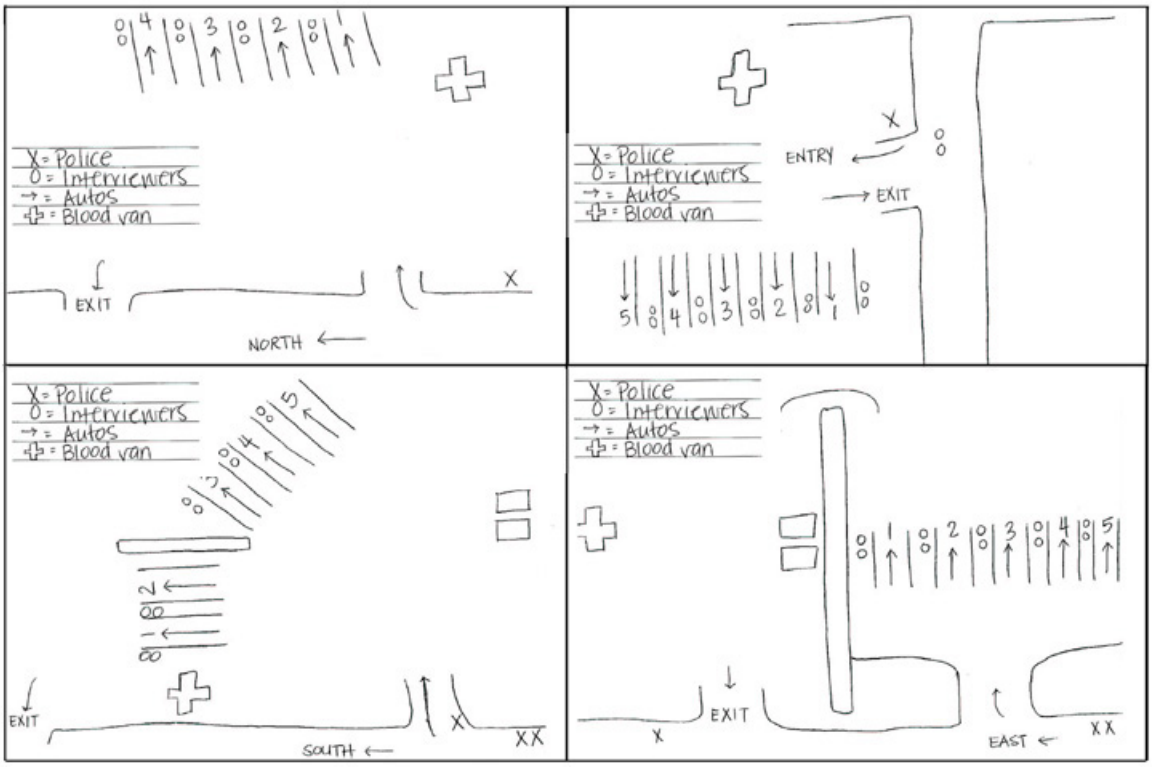

Figure 3. Site Supervisor's Sketches of Site Layouts

Data collectors and a phlebotomist arrived in time to meet the officers at the site prior to the data collection. Surveys were conducted between 10 p.m. and midnight and between 1 a.m. and 3 a.m. on both Friday and Saturday nights, for one weekend in each of the six selected States.

Once all parties were present at a site, an officer positioned a police vehicle at the side of the road with its overhead lights flashing so that approaching traffic could see it and with the vehicle's headlights illuminating the officer. Data collectors, working in an off-road parking lot, set up the activity with bays marked off by orange traffic cones, borrowed from the police agency. Data collectors unpacked their suitcases of supplies in preparation for vehicles. When ready, the site supervisor signaled the officer who flagged down the next vehicle that could be safely stopped, and then directed the driver into the interview site. After the vehicle entered the site, the driver had no further contact with the police officer. Commercial vehicles were excluded from the survey, but motorcycles were not.

Driver Selection

At the sites, drivers were selected from the traffic flow by an officer, who would signal the next car approaching the survey site after a data collector had completed a survey. This procedure is typically used in roadside surveys and results in a random selection of eligible vehicles that is not biased toward any particular class of driver. To insure unbiased selection of the first vehicle at each interview site, the third vehicle passing the site after initiation of the survey was chosen by an officer for the first interview. Police officers were provided with handheld counters to record all vehicles passing the site during an interview period so that driver selection probabilities could be estimated.

To ensure that a random sample of motorists was selected for the survey, it was necessary to bring the next available vehicle into the survey site when a data collector was ready for a subject. In practice, a few of the selected motorists were missed because they turned away from

the site or the officer was unable to signal them in time, or, having spoken with the motorist, the officer allowed the individual to proceed without entering the site, often because the driver indicated they were in a hurry. Few drivers refused to enter the site.

Basic Survey Sequence

As the motorist came to a safe stop in the bay, the data collector recorded basic demographics based on observation (e.g., the number of passengers, use of a safety belt by the driver, and the gender and ethnicity of the driver). These data were recorded so that we would have descriptive information of potential subjects who refused. The data collector then approached the vehicle and initiated contact with the driver using basic protocol, including an introduction explaining that participation is anonymous, voluntary, and can be ended at any time. Once oral consent for an interview (see Appendix A) was obtained, the subjects answered questions covering topics such as the subject's annual mileage, the origin and destination of that trip, drinking, drinking and driving, demographics, and whether they were acting as a designated driver (the survey appears in Appendix B). (Note: If subjects objected to answering survey items, we asked them to provide a breath sample before they exited the survey bay.)

During the interview, the data collector also obtained a passive alcohol sensor (PAS) reading on each subject (for more detail, see Appendix C). After the interview was complete, the data collector requested a breath test.

The data collector then requested an oral fluid sample, offering a $10 incentive to the respondent to participate. (During the feasibility phase of the study, a variety of monetary incentives were experimented with for obtaining oral fluid and blood specimens and for obtaining participation in the AUD screener data collection. It was determined that the optimum, fiscally feasible, incentive schedule was $10 for oral fluid, $50 for blood, and $5 for the AUD screen.) If the subjects agreed, a collection device was provided and they were asked to place the tab under their tongue. While the device was in their mouth, we presented them with a paper and pencil drug use questionnaire (Appendix D) for them to fill out. When that was completed, we asked them if they would answer a questionnaire about alcohol use (Alcohol Use Disorder [AUD] screener Appendix E) offering them an additional $5.00. After the conclusion of the oral fluid collection, subjects were requested to provide a blood sample for an incentive of $50. If they agreed, they were escorted to a phlebotomist a few feet away, who drew the blood sample. At the conclusion of the survey procedure they were escorted back to their vehicles and asked a few questions about their survey experience and how we could improve the survey procedures. They were then safety directed on their way. Incentive levels were determined during the feasibility phase of the study where a variety of incentive levels were tested. This combination of incentives was determined to be optimal within a reasonable cost frame.

Field Data Recording

Observational data, responses to the questions replicating the previous national roadside survey, AUD screener questions, questions about the survey procedure, and results from the PAS were recorded electronically in the field on a Personal Digital Assistant (PDA). We used the Sony Clié J2 model. Screen shots of the data entry pages in the PDA appear in Appendix F. Results of the breath test on the Portable Breath Test Device (PBT) were not displayed on the device but rather stored within the device and downloaded to a computer and merged with other data about the subject at a later date, so that no one in the field knew the BAC reading at the time, because the samples were anonymous and confidential.

Breath Sample Collection Procedure

The data collector obtained breath samples using a portable breath alcohol test (PBT) device (Intoxilyzer SD-400, for more detail, see Appendix G) (Figure 4). Because some subjects refuse to provide a breath test and others are not able to blow sufficient air to provide a valid sample, a PAS that can detect alcohol in the expired air around the face (Kiger, Lestina, & Lund, 1993) was also used. The PAS unit has the same fuel cell alcohol detector as the SD-400 unit. Rather than requiring a mouthpiece, however, it has a small electrical pump that pulls in air from in front of the subject's face (Cammisa, Ferguson, & Wells, 1996; Fiorentio, 1997). When the PAS is held within six inches of the face and the pump is activated, it provides a rough indication of the individual's BAC. We used the PAS Vr. for this purpose. It is a low cost, portable passive sensor (we did not use the more commonly known flashlight model which uses the same fuel cell technology), and has single-button control. The PAS displays a color-coded 9-element LED bar-graph and numeric display of the approximate alcohol level. After viewing the PAS level, the data collector enters the number of colored bars indicated into the handheld PDA.

Figure 4. Portable Breath Alcohol Test (PBT) Device, Intoxilyzer S-400

If a driver appeared impaired, the data collector signaled the site supervisor who administered a breath test with a PBT which displayed the result. If the driver had a BAC of .05 or above we attempted to arrange a ride home for the driver from another occupant of the vehicle if that person passed a BAC test, from a friend or relative of the driver, or by taxi. The need for the research team to provide transportation was infrequent.[3]

Oral Fluid Collection Procedure

We obtained saliva samples from the subjects using the *Quantisal* device, offering a monetary incentive of $10. During the oral fluid collection, the data collector asked the subject to complete a brief paper and pencil questionnaire regarding over-the-counter, prescription, and

[3] During the pilot study, four subjects were found to be impaired; one in New Jersey, one in North Carolina, and two in Nebraska. Field supervisors and data collectors followed protocol for all incidents to ensure that subjects arrived at their destinations safely. In the first incident, the data collector smelled alcohol on the subject and got a high PAS reading; she then called for a supervisor. The supervisor talked to the subject and took a BAC reading with an unmasked PBT. As the subject did not have anyone to call for a ride and his home was only five miles from the site, one researcher drove him home in the subject's car while another followed in a rental car. The subject was very appreciative and said that he did not have any friends that would have done this for him. The researchers drove back together. In the second incident, the phlebotomist smelled alcohol on the subject and alerted a supervisor. The supervisor took an unmasked PBT reading of both the subject and her passenger, to determine if the passenger could drive the subject home; however, both exceeded the BAC limit. The supervisor drove the two women home, with another researcher following, and the researchers drove back together. In the third incident, a subject pulled her vehicle into a bay and the data collector, who found that the subject was visibly impaired, alerted the site supervisor. The subject agreed to call for a ride, but no one was available, so research staff gave her a ride home in her car with another supervisor following; again the researchers drove back together. In the last incident, as the officer directing traffic waved a subject in she had difficulty understanding the directions. The officer notified a supervisor, who took an unmasked PBT reading. The subject was given a choice of calling someone for a ride, or being driven home. She called someone and took the survey while waiting for her ride. She left her car in the private school parking lot that was being used for the site, to be retrieved later.

recreational drug use (see Appendix D). Subjects were assured that their answers were completely anonymous and confidential. The *Quantisal* device (see Appendix H), with the color change pad indicating sufficient fluid volume, reliably indicated when a sufficient sample had been collected.

Blood Collection Procedure

After the oral fluid collection, we then requested a blood sample with an additional $50 incentive. If the subject agreed to give a blood sample, the vehicle was moved forward to clear the interview bay and to permit another interview to begin, and the subject exited the vehicle and was escorted to a van for the blood draw.

When available, we used a police command vehicle outfitted for blood drawing, including a well-lit interior, appropriate seating, and arm rest. We engaged a licensed phlebotomist to conduct the blood draws. However, when command vehicles were not available, the phlebotomist worked out of a rental van, setting up the blood collection area so that the donor sat in the van and the phlebotomist stood just outside the van with supplies. The phlebotomist was also trained to conduct interviews and participate in data collection when not involved with blood draws. During blood draws, one gray top tube of the subject's blood was drawn (5 mL). A gray top tube is a glass test-tube type container which holds a volume of up to 5 mL of blood and also contains a preservative of potassium oxalate/sodium fluoride that reduces the need for refrigeration but does not affect the ability to detect and quantify drugs.

We were not able to draw a full tube for all subjects because of small and difficult-to-locate veins. In those cases, the laboratory was able to conduct an initial screening test, but was not able to conduct a confirmatory analysis by GC/MS, due to the insufficient volume.

In summary, the following are the steps in the roadside survey pilot test (drivers could leave the survey at any time):

- Officer motions vehicle into research bay
- Researcher receives verbal consent from subject
- Researcher:
    - Collects observational data – entered into PDA by researcher
    - Asks basic roadside survey questions – entered into PDA by researcher
    - Reads PAS test
    - Requests breath test
        - Takes BAC with PBT
    - Requests oral fluid sample
        - Collects oral fluid sample taken
        - Gives subject incentive
    - Gives written drug questions – self-reported on paper by participant
    - Asks AUD questions – entered into PDA by researcher
        - Gives subject incentive for AUD
    - Requests blood sample
        - Collects blood sample
        - Gives subject incentive
- Subject directed back onto the roadway

Oral Fluid and Blood Analyses

Selection of Drugs

PIRE staff and NHTSA staff developed an initial list of drugs to be screened for, based on the literature (Jones, R., Shinar, D., & Walsh, J., 2003; Couper, F., & Logan, B., 2004) and experience with drugged-driving research. The drugs were selected because of a combination of their potential impaired-driving effects, their likelihood of appearing in drivers, a cost-responsible number of potential positive screens (each positive result followed by a GC/MS confirmation test adds cost to the analyses), and in the case of oral fluid, the availability of scientific techniques to analyze oral fluid to detect and quantify the drug. NHTSA then provided this list to experts (both in the United States and internationally) in the field of epidemiology of drug use, driving, and toxicology. The experts responded to the list with additions and deletions, resulting in the entries in Table 4.

Table 4. Drugs of Interest for the National Roadside Survey Pilot Test

Cocaine (including Benzoylecgonine and cocaethylene metabolites)
Opiates (Heroin**,** 6-acetylmorphine; Morphine, codeine, morphine, hydrocodone, hydromorphone, and oxycodone)
Amphetamines (including confirmatory tests for methamphetamine, MDA, MDEA, and MDMA)
Cannabanoids (THC metabolite)
Phencyclidine (PCP)
Benzodiazepines (array of options for drug-specific confirmatory tests, e.g., rohypnol, diazepam)
Barbiturates
Methadone
Ethyl Alcohol
GHB
Propoxyphene
Tramadol
Sertraline (Zoloft) Fluoxetine (Prozac)
Zolpidem
Tricyclics (amitryptiline, nortryptiline, etc)
Carisoprodol and metabolite, meprobamate

Drug categories in bold constitute the National Institute of Drug Abuse (NIDA) five drug categories of abuse.

Oral Fluid

The tubes from each data collection weekend were packaged and sent together overnight to a laboratory for analysis. Upon receipt of the specimens to the testing facility, screening analysis was carried out using enzyme linked immunosorbent assays (ELISA) at the cut-off concentrations described in Table 5. Screen positive specimens were then reanalyzed, using a separate sample of the fluid, using gas chromatography-mass spectrometry (GC/MS), according to standard operating procedures. All methods were fully validated according to good laboratory practices, and all standard operating procedures are on file at Immunalysis Corporation (Pomona, CA).

Instrumentation:

- *Agilent Technologies* 6890 gas chromatography - 5973 mass selective detector (GC/MSD); electron impact (EI) mode

Extraction:

- Oral fluid (1 mL) of diluted specimen (1:3 buffer) was extracted using mixed mode solid phase methods with drug specific column phases

Derivatization:

- Drug specific derivatives used for maximum detectability and stability
- Drugs included in the confirmation profile are shown in Table 6

Blood

Upon receipt of the specimens to the testing facility, screening analysis was carried out using enzyme linked immunosorbent assays (ELISA) at the cut-off concentrations described in Table 5. Screen positive specimens were then sent to BioTox Laboratories, Riverside, California for confirmation using liquid chromatography- mass spectrometry – mass spectrometry (LC/MS/MS). All methods were fully validated according to good laboratory practices, and all standard operating procedures are on file at BioTox Laboratories (Riverside, CA).

Drugs

Instrumentation:

- Applied Biosystems: LC/MS/MS System, Model API 2000 Triple Quadropole
- Shimadzu: System Controller Model SCL-10A VP
- Liquid Chromatograph Pumps Model 10AD VP
- Degasser Model D-G4-11A Degasser/Autosampler Model SIL-20A
- Thermo Electron: 3 µm Hypersil GOLD, 50 mm x 2.1 mm HPLC column

Gradient HPLC system:

- Mobile Phase A: double deionized water + 0.01% Formic Acid
- Mobile Phase B: acetonitrile + 0.01% Formic Acid

Extraction:

- Oral fluid (1 mL of buffer) and blood samples (1 mL) were confirmed for drugs using LC/MS/MS
- Mixed mode solid phase extraction using drug specific column phases

Ethanol (Oral Fluid and Blood)

Instrumentation:

- Perkin-Elmer: Model F-45 Gas Chromatograph
- Flame ionization detector (FID)
- 0.2% Carbowax 1500 Graphpac-GC, 80/100 column (6 ft. x 1/8 in. ID)

Extraction:

- Whole blood or 3:1 buffered oral fluid (0.1 mL), add 1 mL double deionized water containing 0.1% propanol
- Analyzed using headspace GC/FID

More detailed descriptions of the oral fluid and blood analytic procedures appear in Appendix I.

Table 5. Concentrations (ng/mL) used for Analysis in Oral Fluid and Blood

Drug Class	Cut-off Values (ng/mL) Oral fluid Screening	Confirmation	Blood Screening	Confirmation
Cocaine, BZE	20	8	25	5
Opiates	40	10	25	5
Oxycodone	25	10	25	5
Methamphetamine	50	50	25	5
Amphetamine	50	50	25	5
Cannabinoids	4	2	10	0.5
Phencyclidine	10	10	5	5
Benzodiazepines	20	10	20	1
Barbiturates	50	50	500	500
Methadone	50	25	50	5
Ethyl alcohol	.02%	.02%	.02%	.02%
Tramadol	50	25	50	5
Sertraline	50	25	50	5
Fluoxetine	50	25	50	5
Zolpidem	10	10	10	5
Tricyclic anti-depressants	25	25	25	5
Methylphenidate	10	10	10	5
Carisoprodol	100	50	500	500

Table 6. Drugs Included in Confirmation Profile in Oral Fluid and Blood

Drug class	Oral fluid	Blood
Cocaine	Cocaine, benzoylecgonine	Cocaine, benzoylecgonine, cocaethylene
Opiates	6-acetylmorphine, codeine, morphine, hydrocodone, hydromorphone	6-acetylmorphine, codeine, morphine, hydrocodone, hydromorphone, oxycodone
Amphetamines	Methamphetamine, amphetamine, MDMA, MDA, MDEA, pseudoephedrine, phentermine	Methamphetamine, amphetamine, MDMA, MDA, phenylpropanolamine, phentermine, fenfluramine, pseudoephedrine, phendimetrazine
Cannabinoids	THC	THC, 11-OH-THC, THC-COOH
Benzodiazepines	Oxazepam, nordiazepam, lorazepam, chlordiazepoxide, temazepam, diazepam, alprazolam, triazolam	Oxazepam, nordiazepam, lorazepam, chlordiazepoxide, norchlordiazepoxide, flurazepam, desalkylflurazepam, estazolam, temazepam, diazepam, alprazolam, alpha-hydroxyalprazolam clonazepam, flunitrazepam, 7-aminoflunitrazepaṃmidazolam, triazolaṃ,alpha-hydroxytriazolam, methylclonazepam
Barbiturates	Phenobarbital, pentobarbital, secobarbital, butalbital	Phenobarbital, pentobarbital, secobarbital, butalbital
Methadone	Methadone	Methadone, EDDP
Tramadol	Tramadol	Tramadol, Desmethyltramadol
Sertraline	Sertraline	Sertraline, Desmethylsertraline
Fluoxetine	Fluoxetine	Fluoxetine, Norfluoxetine
Tricyclic antidepressants	Amitryptiline, nortriptyline	Amitryptiline, nortriptyline, doxepin, desmethyldoxepin, imipramine, desipramine, trimipramine, clomipramine, amoxapine, protriptyline, maprotiline
Carisoprodol	Carisoprodol, meprobamate	Carisoprodol, meprobamate

Results

Data Collection and Management

Overall, the data collection procedures developed during the feasibility phase of this project went quite smoothly. There are essentially three stages to the data collection site recruitment. Once sites had been randomly selected from the NASS-CDS primary sampling units, queries were made to the NHTSA regional offices soliciting help in obtaining cooperation from the States. Then, in turn, we asked the States for assistance in gaining the cooperation of local law enforcement agencies in the selected jurisdiction. One State was reluctant to have the survey activity occur in their State and thus, we had to resample to identify an additional site for potential recruitment. Once we had State agreement and assistance, we were successful in obtaining cooperation in every jurisdiction.

There was a learning curve involved in implementing this larger scale data collection activity as well as further development of dealing with logistical issues as we expanded the realm of data collection sites throughout the rest of the country, often involving air travel to the sites. Participation rates for each of the sites appear in Table 7. Additionally, there were some regional variations in the receptivity of the motoring public to the data collection requests. The most receptive population was that encountered in Alabama. The least receptive was the first jurisdiction in which we collected data in New Jersey.

Pilot Study Subject Recruitment Patterns

Table 7 presents information on subject participation rates by jurisdiction. The lowest participation rate was in New Jersey, the first site where we collected data. We fared somewhat better in subsequent sites, probably because the survey team became more proficient. However, we also sensed a more general willingness to cooperate with the research activities in some areas. This was particularly true in the Alabama site where the public was very willing to "help out."

Table 7. Response Rates by Site and Survey Element

	NJ	AL	CA	CO	NC	NE	Total	% (Out of Vehicles Entering Bays)	% (Out of Participants)
Vehicles Entering Bays	170	116	163	158	165	187	959		
# Participants	136 (80.0%)	108 (93.1%)	138 (84.7%)	141 (89.2%)	142 (86.1%)	153 (81.8%)	818	85.30%	
# Breath Samples Provided	120 (70.6%)	105 (90.5%)	131 (80.4%)	137 (86.7%)	128 (77.6%)	140 (74.9%)	761	79.35%	93.03%
# AUD Surveys	88 (51.8%)	62 (53.4%)	78 (47.9%)	95 (60.1%)	90 (54.5%)	103 (55.1%)	516	53.81%	63.08%
# Oral Fluid Samples Provided	103 (60.6%)	100 (86.3%)	99 (60.7%)	116 (73.4%)	119 (72.1%)	105 (56.1%)	642	66.94%	78.48%
# Blood Samples Provided	54 (31.8%)	78 (67.2%)	59 (36.2%)	79 (50.0%)	69 (41.8%)	67 (35.8%)	406	42.34%	49.63%

From Table 7 above, in the last two columns, we indicate the participation rate both in terms of the percentage of individuals initially recruited who participated in each of the main elements

of the survey and then the percentage of persons who initially agreed to participate who completed subsequent elements of the survey. Thus, 79.35 percent of the subjects we initially attempted to recruit provided a breath sample. However, 93.03 percent of those who had at least answered some of the initial questions agreed to provide a breath sample. The corresponding refusal rates for these two examples are 20.65 percent and 6.97 percent. Of interest is once a person has agreed to participate in the survey, nearly 80 percent provided an oral fluid sample and nearly 50 percent provided a blood sample.

This entire procedure (survey, BAC, oral fluid sample, and blood sample) took approximately 20-25 minutes (see Table 8). The survey and BAC test alone averaged approximately 5-7 minutes. The survey with BAC and oral fluid test averaged approximately 10-12 minutes; adding the blood test increased the data collection time to 20-25 minutes.

Table 8. Time Required per Subject for Roadside Data Collection

Test	Combined Time
Survey and BAC	5-7 minutes
Survey, BAC and one Oral Fluid Sample	10-12 minutes
Survey, BAC, Oral Fluid Sample, and Blood Sample	20-25 minutes

As mentioned earlier, taking this survey on the road involved a good deal of logistical planning in that not only was it necessary to obtain cooperation from participating law enforcement agencies and identify suitable data collection sites, but it also required transporting a data collection team and equipment to the data collection sites. A listing of the equipment required appears in Table 9.

Table 9. List of Equipment used in the National Roadside Survey Pilot Test

Outfits	Lab coats Reflecting safety vests "Research Team" hats	
Equipment	PDAs with survey PBTs (no display of BAC) 1 PBT with display of BAC PASs Breath tubes Extra supply of batteries Saliva collection devices	
Incentives	Cash/Money orders	
Paper documents to bring	Paper surveys (as backup, in case PDAs fail) Blood consent forms Drug questionnaires Numbered labels for blood, saliva, bags for tracking Supervisor Report Form Consultant Agreement forms Consultant Invoices Chain of Consent forms for saliva Chain of Consent forms for blood	
Also need	Signs for side of blood draw van Traffic sign Orange traffic cones (if not provided by police) TV-tray tables Battery-operated table lamps Garbage bags Car counters	Stapler, scissors, tape Velcro tape Duct tape First aid kit Extra batteries (AA, AAA, 9-V) Gloves Hand warmers Headbands

	Stopwatches Pens, styli, golf pencils Clipboards Index Cards	Paper towels Rain ponchos Flashlights w/traffic wands
Blood Sample and Oral Fluid Sample Supplies	Quantisal oral fluid tests Needles (ask the lab what gage they prefer for adequate test results) A few butterfly needles Vacutainers (the plastic connector) Gloves (powder-free latex may be preferred) Gray-top tubes Pre-wrapped alcohol pads Pre-wrapped sterile 2X2's gauze pads Band-aids Sharps container (for needles) First aid kit Tourniquets Absorbent shipping pads (for blood specimens) Cooler and blue ice Specified cardboard container for shipping	

The process of merging the data was one of the more complex parts of this study. There were potentially six forms of data collected for each subject:

- PDA survey entered by the interviewer
- PAS sample
- PBT breath sample
- self-reported drug use survey filled out on paper by the participant
- oral sample
- blood sample

The PDA and self-report surveys were matched together based on a unique identifier created from the date, interviewer number, and case number. The PBT data were matched based on sample number, and the biological specimens were matched based on laboratory Chain of Custody (COC) numbers that were recorded in the PDA. (COC numbers are assigned by the laboratory and are used to maintain a documented link between sample collection and the laboratory, showing who has possession of the samples.)

The success of the data merging depended on the interviewers recording the identifying information (case, sample, and COC numbers) correctly. We were very successful in this respect. The data from the first few collections had some problems that we were able to resolve. These problems included the interviewers leaving some of the answers blank, or forgetting to enter the demographic observations about subjects who refused to do any part of the survey. These problems occurred less often at each successive collection.

Sample Characteristics

Of the 754 drivers who entered the survey site and at minimum provided a BAC test, 62 percent were male. The majority of drivers (40.1%) were in the age category of 21–34 years of age, followed by 45 years and older (26.4%). See Table 10 for details. The total N's in this series of tables varies by table because of missing data on some data elements.

Table 10. Gender and Age Group - NRS Pilot Study

	N	%
Gender		
Male	468	62.1%
Female	286	37.9%
Count	**754**	
Age group		
≤ 20	120	17.9%
21 – 34	269	40.1%
35 – 44	104	15.5%
45 – 54	114	17.0%
55 – 64	44	6.6%
65+	19	2.8%
Count	**670**	

As Table 11 shows, our interviewers' observations of race were highly accurate. The interviewers were able to correctly observe the race Black/African American 98.4 percent of the time, and the race White 99.2 percent of the time. They observed the race Asian correctly 89.2 percent of the time, but only observed the ethnicity Hispanic correctly 66.7 percent of the time. As these observations are fairly reliable, we will use observed race to fill in the self-reported race/ethnicity if it is missing. This could be useful in the full-scale study

Table 11. Crosstabs of Observed Race/Ethnicity (Columns) Versus Self-Reported Race/Ethnicity (Rows)

			Observed Race/Ethnicity						
			Asian	Black / African American	Hispanic	Other	Unknown	White	Total
Self-Report Race/ Ethnicity	Asian	Count	33	0	1	0	0	3	37
		% within Self-Reported Race	89.2%	.0%	2.7%	.0%	.0%	8.1%	100%
	Black / African American	Count	0	61	0	0	0	1	62
		% within Self Reported Race	.0%	98.4%	.0%	.0%	.0%	1.6%	100%
	Hispanic	Count	2	2	50	0	0	21	75
		% within Self Reported Race	2.7%	2.7%	66.7%	.0%	.0%	28.0%	100%
	Other	Count	3	2	2	15	3	7	32
		% within Self Reported Race	9.4%	6.3%	6.3%	46.9%	9.4%	21.9%	100%
	White	Count	0	1	1	2	0	489	493
		% within Self Reported Race	.0%	.2%	.2%	.4%	.0%	99.2%	100%
Total		Count	38	66	54	17	3	521	699
		% within Self Reported Race	5.4%	9.4%	7.7%	2.4%	.4%	74.5%	100%

Trends

The following tables compare the 2005 pilot study results with the prior three year surveys (1973, 1986, and 1996). In some instances data were not available for comparison.

The number of interview and breath tests provided by drivers is shown in Table 12. As can be seen, in this 2005 pilot study, 959 motorists entered the site. Of these, 79.2 percent of drivers provided a valid breath measure. This is lower than previous years. Possible explanations to this difference are discussed in the summary conclusions.

Table 12. Drivers Entering the Survey Sites

	1973	1986	1996	2005 Pilot
Vehicles entering site	3,698	3,043	6,298	959
Entered site and interviewed	3,353 (90.7%)	2,971 (97.6%)	6,045 (96.0%)	731 (76.2%)
Entered site, valid breath sample	3,192 (86.3%)	2,850 (93.7%)	6,028 (95.7%)	761 (79.4%)
Entered site, no breath sample	506 (13.7%)	193 (6.3%)	270 (4.3%)	198 (20.6%)

Table 13 presents the BACs of drivers in the four surveys by the time of night and weekend night. Note that the pilot study data assessed BACs at both the .10 and .08 levels in order to allow comparison between survey years. As was the case in the past three survey years, the greatest percentage of high BACs is in the 1 a.m.–3 a.m. time period and on Saturdays. When assessing total cases across each survey year, average BAC levels (at both ≥.05 and ≥.10 levels) are lowest in 2005.

Table 13. Comparison of High BAC Drivers in Relation to Time of Night and Weekend Night and Overall for Samples in 1973, 1986, 1996, and 2005

	1973			1986			1996			2005			
	N	≥.05	≥.10	N	≥.05	≥.10	N	≥.05	≥.10	N	≥.05	≥.10	≥.08
Friday													
10 p.m.–midnight	845	9.5%	3.0%	750	4.7%	1.6%	1,842	4.2%	1.0%	209	1.9%	0.5%	0.5%
1 a.m.–3 a.m.	755	20.6%	7.3%	648	11.9%	5.0%	1,492	13.1%	4.0%	175	9.1%	3.4%	4.0%
Saturday													
10 p.m.–midnight	841	9.5%	3.4%	833	6.7%	2.8%	1,865	5.3%	2.4%	203	1.0%	0.0%	0.0%
1 a.m.–3 a.m.	751	21.6%	10.1%	619	15.0%	5.5%	1,281	16.4%	6.7%	174	12.1%	5.2%	6.9%
All Cases	**3,192**	**13.7%**	**5.1%**	**2,850**	**8.4%**	**3.2%**	**6,480**	**7.7%**	**2.8%**	**761**	**5.6%**	**2.1%**	**2.6%**

Table 14 provides a comparison between the four surveys on driver demographic characteristics including gender, ethnicity and age by BAC level. The percentage of female drivers participating in the study has steady increased from 17 percent in 1973, 26 percent in 1986, and 32 percent in 1996 to 38 percent in 2006. Further, the number of females in 2005 testing at the .10 BAC level or greater has increased since 1996. Male drivers testing at the .10 or greater level, however, have decreased from past years. In fact, females at this level even surpass males in 2006. This finding warrants further investigation during the full-scale survey.

Motorists identified as Hispanic have also grown in percentage at 11 percent in the 2005 pilot study, compared to 10 percent in 1996, 5 percent in 1986 and 1 percent in 1973. By age group, the percentage of 2005 participants age 20 and younger is similar to 1996 and 1986. There was a slight decrease in participants ages 21–34 and those in the 35-44 categories in the 2005 study as compared to previous years. In 2005, we recorded the age of older drivers in greater detail as illustrated at the bottom of Table 14. Examination of that portion of the table indicates that all high-BAC drivers over the age of 45 fell between the ages of 45-64, and were in the range of .05-.08.

Table 14. Comparison of High BAC Drivers in Relation to Demographic Characteristics

	1973			1986			1996			2005			
	N	≥.05	≥.10	N	≥.05	≥.10	N	≥.05	≥.10	N	≥.05	≥.08	≥.10
Gender													
Male	2,648	14.7%	5.5%	2,114	9.9%	3.9%	4,229	8.7%	3.5%	468	6.4%	2.8%	1.9%
Female	526	8.8%	3.0%	728	3.9%	1.3%	1,984	5.8%	1.5%	286	4.5%	2.4%	2.4%
Race/Ethnicity													
White	2803	13.3%	5.1%	2352	7.4%	2.7%	4362	7.1%	2.3%	493	4.7%	2.6%	2.0%
African American	256	16.5%	6.0%	328	13.5%	5.9%	947	9.4%	3.6%	62	4.8%	3.2%	3.2%
Hispanic	43	22.0%	3.3%	124	13.0%	4.4%	612	14.9%	7.5%	75	0%	0%	0%
Asian										37	8.1%	5.4%	5.4
Other										32	6.3%	0%	0%
Age Group													
≤ 20	767	10.9%	4.1%	506	4.6%	2.7%	977	2.8%	0.3%	120	1.6%	.8%	.8%
21 – 34	1,393	15.4%	5.7%	1,341	9.9%	3.3%	2,634	11.3%	3.8%	269	9.2%	5.9%	4.8%
35 – 44	419	15.9%	5.8%	497	9.4%	4.7%	1,215	6.9%	3.7%	104	3.9%	1.0%	1.0%
45+	559	12.1%	4.1%	489	6.8%	1.8%	1,219	5.2%	1.7%	177	1.7%	0%	0%
Further Age Breakdown										**N**	**≥.05**	**≥.08**	**≥.10**
45-54										114	1.8%	0%	0%
55-64										44	2.3%	0%	0%
65-74										16	0%	0%	0%
75+										3	0%	0%	0%

Figure 5 provides a graphic illustration of how BAC levels have changed across the four decades. Of course, one should not overstate the findings from 2005 because the sample size is so much smaller. However, it is notable that the trend is to lower percentages over time in all categories of positive BAC drivers. Conversely, the proportion of drivers who are alcohol negative has been increasing, going from 64.0 percent in 1973, to 74 percent in 1986, to 82.8 percent in 1996, to 85.5 percent in 2005.

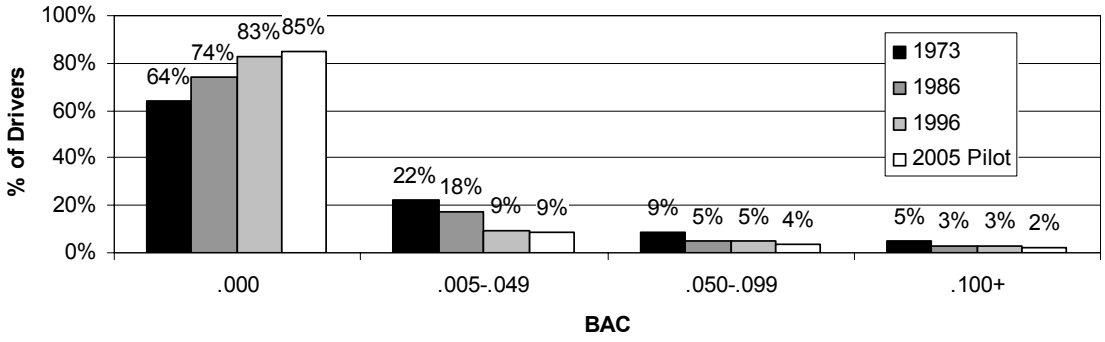

Figure 5. BACs of Drivers in National Surveys

Pilot Study

Breath Test Alcohol Results

As illustrated in Table 15-16 and Figure 6, BAC of drivers in 2005 reveal the greatest percentage of BAC-positive drivers under .05 levels, at 8.9 percent and the least in the .08 or higher category, at 2.6 percent. Of course the predominant category is the BAC-negative group (85.5%). We used a cutoff of .005 to identify BAC negative in order to provide a slight margin to reduce the possibility of false positives.

Table 15. Breath Test Results

	N	%
< 0.005	650	85.5%
≥ 0.005 and < .05	68	8.9%
≥ .05 and < .08	23	3.0%
≥ .08	20	2.6%
Total # samples	**761**	**100%**

Table 16 presents the BAC distribution of drivers testing at or above .08. The majority of these 20 cases were at BACs from .100 to .149. The three highest BACs as measured in breath are .150, .154, and .183.

Table 16. Breath Test Results: Distribution of BACs above .08

BAC Category	Frequency	Percent
.080 - .099	4	20%
.100 - .149	13	65%
.150 and above	3	15%
Total	**20**	**100%**

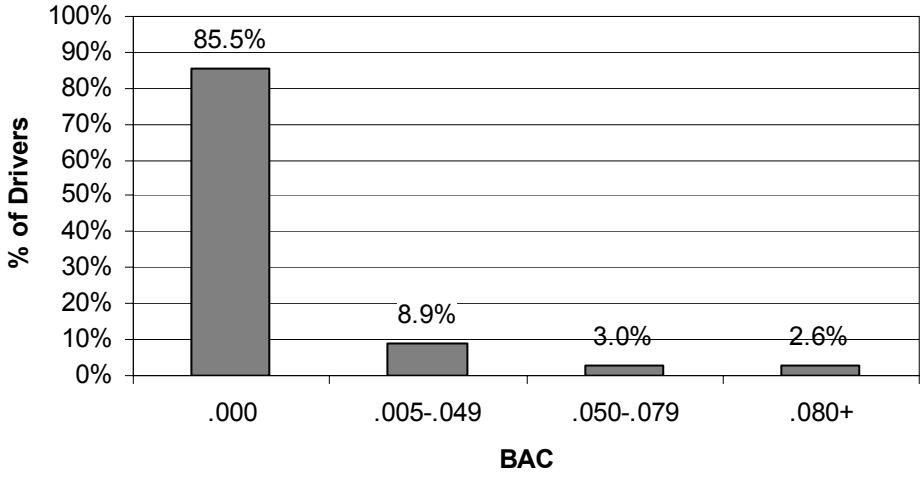

Figure 6. 2005 Pilot BACs with New Categories

Tables 17 and 18 look at the BAC categories by race and ethnicity (including observational race/ethnicity where self reported race/ethnicity is missing). The first table uses the new BAC categories; the second table uses the BAC categories from the previous three studies.

Table 17. Race/Ethnicity by BAC Categories

			BAC Categories					
			< .005	.005 - .049	.050 - .079	.080+	Missing	Total
Race/ Ethnicity	Asian	Count	30	2	1	2	2	37
		% within Race	81.1%	5.4%	2.7%	5.4%	5.4%	100%
	Black / African American	Count	49	7	1	2	3	62
		% within Race	79.0%	11.3%	1.6%	3.2%	4.8%	100%
	Hispanic	Count	62	10	0	0	3	75
		% within Race	82.7%	13.3%	.0%	.0%	4.0%	100%
	Other	Count	24	0	2	0	6	32
		% within Race	75.0%	.0%	6.3%	.0%	18.8%	100%
	White	Count	391	43	10	13	36	493
		% within Race	79.3%	8.7%	2.0%	2.6%	7.3%	100%
Total		Count	556	62	14	17	50	699
		% within Race	79.5%	8.9%	2.0%	2.4%	7.2%	100%

Table 18. Race/Ethnicity by Previous BAC Categories

			BAC Categories					
			< .005	.005 - .049	.050 - .099	.100+	Missing	Total
Race/ Ethnicity	Asian	Count	30	2	1	2	2	37
		% within Race	81.1%	5.4%	2.7%	5.4%	5.4%	100%
	Black / African American	Count	49	7	1	2	3	62
		% within Race	79.0%	11.3%	1.6%	3.2%	4.8%	100%
	Hispanic	Count	62	10	0	0	3	75
		% within Race	82.7%	13.3%	.0%	.0%	4.0%	100%
	Other	Count	24	0	2	0	6	32
		% within Race	75.0%	.0%	6.3%	.0%	18.8%	100%
	White	Count	391	43	13	10	36	493
		% within Race	79.3%	8.7%	2.6%	2.0%	7.3%	100%
Total		Count	556	62	17	14	50	699
		% within Race	79.5%	8.9%	2.4%	2.0%	7.2%	100%

Assessment of PAS readings by BAC category indicates the greatest correspondence between devices (PAS and PBT) at the < .005 and .005 – 049 ranges. Unfortunately, due to administration difficulties, the PAS device was not used in 12 percent of the cases in our pilot test. Cases in the 050 - .079 and .080+ range showed the least correspondence. The PAS requires the surveyors to be fairly close to the driver in order to get an accurate reading. We suspect the discrepancy between the device results is due to surveyors not properly handling the PAS device. This needs further investigation. The results of this comparison appear in Table 19. The shaded areas highlight the subjects for which the two readings were fairly concordant. Given the sensitivity of the instruments we show .01 and 0 on the PAS tube concordant with the PBT.

Table 19. PAS Reading by BAC Categories – NRS Pilot Study

		BAC Categories from PBT				
		< .005	.005 –.049	.050 - .079	.080+	Total
PAS Reading	0	312	29	7	8	356
	.01	167	21	3	0	191
	.02	8	2	1	0	11
	.03	2	2	1	0	5
	.04	0	0	0	1	1
	.05	2	1	0	0	3
	.06	0	0	0	1	1
	.08	0	0	0	1	1
	.10	1	0	0	0	1
	Not used	64	7	2	6	79
Total		**556**	**62**	**14**	**17**	**649**

Drug Results

Six hundred thirty-nine oral fluid samples were analyzed for drugs. Though 642 oral fluid samples were collected, 3 containers leaked during transport and sufficient volume to conduct analyses was available only for the remaining 639. Of these 639, there were also 394 blood samples available for analysis. Blood samples were provided by 406 subjects; however, 12 were unable to provide sufficient volume to permit analysis. Every subject who provided a blood sample also provided an oral fluid sample.

Table 20 provides a description of the number and percentage of positive drug and alcohol results as determined by oral fluid and blood specimens[4]. Of the 639 drivers who provided samples tested for drugs, 22.7 percent tested positive for drugs, alcohol, or drugs and alcohol combined. Interestingly, the majority were positive only for drugs. The lowest percentage had a combination of alcohol and drugs.

Table 20. Oral and Blood Specimen Results

	N	%
Drug Only	85	13.3%
Alcohol Only	49	7.7%
Drug & Alcohol	11	1.7%
Negative	494	77.3%
Total # Samples	**639**	**100%**

Table 21 presents summary oral fluid and blood results by racial/ethnic group. The groups were quite similar in terms of the proportion testing negative. Because of small sample size, one should not draw any firm conclusions from these data.

Table 21. Oral and Blood Specimen Results by Racial/Ethnic Group

Race/Ethnicity	Negative	Drugs Only	Alcohol Only	Drugs & Alcohol
Asian	26 (78.8%)	3 (9.1%)	4 (12.1%)	0
Black/African American	46 (86.8%)	3 (5.7%)	3 (5.7%)	1 (1.9%)

[4] It is important to note that within this report, drug-positive refers only to the drugs examined (screened for) in this study. Participating drivers may have been positive for other drugs not covered within the scope of this project.

Hispanic	61 (79.2%)	10 (13.0%)	6 (7.8%)	0
Other	23 (92.2%)	1 (4.0%)	1 (4.0%)	0
White	338 (74.9%)	68 (15.1%)	35 (7.8%)	10 (2.2%)
Total	**494**	**85**	**49**	**11**

Tables 22 and 23 show the results of cross tabs conducted to assess self-reported use of any drugs that "may have affected driving in last year" (Table 22) and "tonight" (Table 23) versus the results of drivers who tested positive for drugs in oral fluid or blood. As can be seen in Table 22, approximately 5 percent of the respondents self-reported use in the past year of drugs they thought might impair their driving and also had a positive drug test result. Almost 10 percent did not self-report such drug use, but had a positive drug result on either the oral fluid or blood test. Thus, approximately two-thirds of those who tested positive for drugs on the night of the survey did not admit using impairing drugs during the previous year.[5]

Table 22. Have you taken any meds or drugs in the past year that you think may have affected your driving? by Drug Test Positive (DRUGPOS)

		DRUGPOS		
		No	**Yes**	**Total**
Have you taken any meds or drugs in the past year that you think may have affected your driving?	**Yes**	107	32	139
	No	418	62	480
Total		**525**	**94**	**619**

For both Table 22 and 23 the total number of positive drug tests is 94 rather than the 96 reported earlier. That is because two of the subjects who took a drug test did not answer the self-report question on the survey. Table 23 displays the results of the question about drug use the evening of the survey compared with the oral fluid and blood tests. Here the disparity between self-report and results of analyses of biological samples is even more dramatic. Of the 15.2 percent who tested positive for drugs, only 2 of 94 admitted having consumed impairing drugs that evening. Though many of the positive drug test results could have resulted from use in the prior day or days, the disparity of self report for the past year and evening from objective test results may speak to a limited accuracy of self-report of drug use for accurate measurement of actual drug use in situations such as these. This concern should be tempered by the understanding that some respondents may have felt that the drugs they were taking did not have an impairing effect. Additionally, self-report does have its merits when one is trying to measure changes over time in response patterns.

Table 23. Have you taken any meds or drugs tonight that you think may affect your driving? by Drug Test Positive (DRUGPOS)

		DRUGPOS		
		No	**Yes**	**Total**
Have you taken any meds or drugs tonight that you think may affect your driving?	**Yes**	7	2	9
	No	518	92	610
Total		**525**	**94**	**619**

[5] Note that respondents were responding to a question on drugs that they thought might "have affected your driving." It is possible that some drivers, for some of the drugs, may not have considered the drugs they took to have an impairing effect on driving.

Tables 24–29 compare drivers self-report drug use versus drug test results for four of the NIDA 5 drugs of abuse and diazepam. There were no positive test results for Phencyclidine (PCP) and thus we did not create a table for that drug. The same general pattern observed in the summary tables above appear when individual drug classes are the subject of the question. Marijuana was the most frequently identified drug in the biological samples and most frequently having self-reported use. However, self-report remained drastically lower than the objective results for this individual drug as well. Recent use of amphetamines including dietary supplements was more frequently reported than amphetamines alone, but again, dramatically underreported, when compared to the objective test results.

Table 24. Tested Positive for Cocaine by Self-Report Used Cocaine

			Self Report Used Cocaine						
			Never	1+ Years	Past Year	Past Month	Past 2 Days	Tonight	Total
Tested Positive for Cocaine	No	Count	565	29	3	0	1	0	598
		% within Tested Positive for Cocaine	94.5%	4.8%	.5%	0	.2%	0	100%
	Yes	Count	11	3	0	0	0	0	14
		% within Tested Positive for Cocaine	78.6%	21.4%	.0%	0	.0%	0	100%
Total		Count	576	32	3	0	1	0	612
		% within Tested Positive for Cocaine	94.1%	5.2%	.5%	0	.2%	0	100%

Table 25. Tested Positive for Opiates by Self-Report Used Heroin, Morphine, or Codeine

			Self Report Used Heroine, Morphine or Codeine						
			Never	1+ Years	Past Year	Past Month	Past 2 Days	Tonight	Total
Tested Positive for Opiates	No	Count	557	38	7	5	0	0	607
		% within Tested Positive for Opiates	91.8%	6.3%	1.2%	.8%	0	0	100%
	Yes	Count	6	0	1	0	0	0	7
		% within Tested Positive for Opiates	85.7%	.0%	14.3%	.0%	0	0	100%
Total		Count	563	38	8	5	0	0	614
		% within Tested Positive for Opiates	91.7%	6.2%	1.3%	.8%	0	0	100%

Table 26. Tested Positive for Amphetamines by Self-Report Used Amphetamines

			Self Report Used Amphetamines						
			Never	1+ Years	Past Year	Past Month	Past 2 Days	Tonight	Total
Tested Positive for Amphetamines	No	Count	530	50	12	6	4	2	604
		% within Tested Positive for Amphetamines	87.7%	8.3%	2.0%	1.0%	.7%	.3%	100%
	Yes	Count	11	0	0	0	0	1	12
		% within Tested Positive for Amphetamines	91.7%	.0%	.0%	.0%	.0%	8.3%	100%
Total		Count	541	50	12	6	4	3	616
		% within Tested Positive for Amphetamines	87.8%	8.1%	1.9%	1.0%	.6%	.5%	100%

Table 27. Tested Positive for Amphetamines by Self-Report Used Amphetamines

			Self Report used Amphetamines including Dietary Supplements						
			Never	1+ Years	Past Year	Past Month	Past 2 Days	Tonight	Total
Tested Positive for Amphetamines	No	Count	335	84	74	41	44	26	604
		% within Tested Positive for Amphetamines	55.5%	13.9%	12.3%	6.8%	7.3%	4.3%	100%
	Yes	Count	7	0	0	1	3	1	12
		% within Tested Positive for Amphetamines	58.3%	.0%	.0%	8.3%	25.0%	8.3%	100%
Total		Count	342	84	74	42	47	27	616
		% within Tested Positive for Amphetamines	55.5%	13.6%	12.0%	6.8%	7.6%	4.4%	100%

Table 28. Tested Positive for Cannabinoids by Self-Report Used Marijuana

			Self-Report Used Marijuana						
			Never	1+ Years	Past Year	Past Month	Past 2 Days	Tonight	Total
Tested Positive for Cannabinoids	No	Count	445	94	19	9	2	1	570
		% within Tested Positive for Cannabinoids	78.1%	16.5%	3.3%	1.6%	.4%	.2%	100%
	Yes	Count	15	11	2	7	6	3	44
		% within Tested Positive for Cannabinoids	34.1%	25.0%	4.5%	15.9%	13.6%	6.8%	100%
Total		Count	460	105	21	16	8	4	614
		% within Tested Positive for Cannabinoids	74.9%	17.1%	3.4%	2.6%	1.3%	.7%	100%

Table 29. Tested Positive for Benzodiazepines by Self-Report Used Benzodiazepines

			Self-Report Used Benzo						
			Never	1+ Years	Past Year	Past Month	Past 2 Days	Tonight	Total
Tested Positive for Benzodiazepines	No	Count	546	37	12	4	2	1	602
		% within Tested Positive for Benzodiazepines	90.7%	6.1%	2.0%	.7%	.3%	.2%	100%
	Yes	Count	5	3	1	0	1	0	10
		% within Tested Positive for Benzodiazepines	50.0%	30.0%	10.0%	.0%	10.0%	.0%	100%
Total		Count	551	40	13	4	3	1	612
		% within Tested Positive for Benzodiazepines	90.0%	6.5%	2.1%	.7%	.5%	.2%	100%

Objective Measures of Drug Use

Summary

As noted earlier, 639 oral fluid samples were analyzed for drugs. Though 642 oral fluid samples were collected, 3 containers leaked during transport and sufficient volume to conduct analyses was available only for the remaining 639. Of these 639, there were also 394 blood samples available for analysis. Blood samples were provided by 406 subjects; however, 12 were unable to provide sufficient volume to permit analysis. Every subject who provided a blood sample also provided an oral fluid sample.

Drugs were detected in 96 cases:

- 33 paired samples (34.4%) were positive via oral fluid and blood
- 28 (29.2%) were positive via oral fluid where blood was refused
- 29 (30.2%) were positive via blood only
- 6 (6.2%) were positive via oral fluid only

In the subjects where blood only was positive for therapeutic drugs, the concentrations detected were all in the therapeutic range and would not be considered at a high enough level to cause impairment.

Drugs known to cause impairment were detected in many of the specimens and included marijuana, benzodiazepines (diazepam, alprazolam), carisoprodol, the narcotics (oxycodone, codeine, hydrocodone), methadone, tramadol, and cocaine.

Antidepressants

The antidepressants/selective serotonin uptake inhibitors (SSRIs) such as fluoxetine and sertraline can cause impairment in rare circumstances where extremely high blood concentrations are measured. The data reviewed does not suggest that the concentrations found would have a significant effect on one's ability to operate a motor vehicle. Fluoxetine and its metabolite norfluoxetine were found in four blood samples with corresponding oral fluid negative samples; and in four paired samples. Sertraline was found in five blood samples with

correspondingly negative oral fluid specimens; and in five pairs of samples both were positive for the drug.

Benzodiazepines

Benzodiazepines are known to cause impairment in traffic cases when present at high level. There were four cases in which alprazolam was reported, however, in two of the subjects, the concentrations were so low (1 ng/mL and 4 ng/mL) it is highly unlikely that the direct pharmacological effects of the drug would cause impairment. In the other two cases (27 ng/mL and 19 ng/mL in the presence of THC), while the concentrations were within the therapeutic concentration range, it should be noted that the desired/therapeutic effect of alprazolam is sedation - which would have a detrimental effect on driving a motor vehicle.

In both of these subjects, corresponding oral fluid analysis did not detect alprazolam and it is likely that the cross-reactivity on immunoassay tests for alprazolam is low. However, it is known that benzodiazepines do not appear in the oral fluid in very high quantity due to their high level of protein binding.

The most common benzodiazepine, diazepam (Valium™) and/or its metabolites nordiazepam, oxazepam and temazepam were detected in 4 blood samples and not in the corresponding oral fluid specimens. Diazepam and nordiazepam were found in one oral fluid sample, the corresponding blood sample was refused.

Carisoprodol

In one case, carisoprodol (Soma™) and its metabolite meprobamate were detected in both blood and oral fluid. Even at therapeutic concentrations, this may cause driving impairment as the desired effect is sedation.

Marijuana

The most prevalent drug detected was marijuana. There appeared to be a strong positive correlation between the oral fluid and blood tests, the only discrepancies (negative oral fluid and a positive blood) are from 10 cases where the inactive metabolites were detected in blood, and not the active tetrahydrocannabinol (THC).

A positive metabolite result (THCA) with a negative parent compound (THC) is consistent with remote use - in these cases a negative oral fluid would not miss an impaired driver.

THC or its metabolites were detected in 37 oral fluid cases and in 23 blood specimens. Thirteen had corresponding positive oral fluid samples; 10 contained only inactive THC metabolites, as described above.

In oral fluid, the active parent compound, tetrahydrocannabinol (THC) was detected in all cases where marijuana use was determined. In 22 samples where THC was detected in oral fluid, a blood collection was refused.

Cocaine

Cocaine or its metabolites were detected in 14 oral fluid samples and only 4 blood samples, hence oral fluid appears to be a better specimen type for the detection of recent cocaine use. Of the other 10 oral fluid positive samples, 5 had corresponding blood samples which were negative, and 5 subjects refused to give blood.

There was only one blood sample containing parent cocaine, whereas oral fluid detected 13 positives. The presence of parent drug, (cocaine) in either specimen indicated the presence of active drug in the system.

Other Stimulants

Methamphetamine, amphetamine, pseudoephedrine, phenylpropanolamine and phentermine are members of the same sympathomimetic stimulant group of drugs. They were detected in a small number of cases.

Other Drugs

The other drugs detected (butalbital, amitryptiline) were only present in one or two cases, and given the reported concentrations, none at a concentration to cause impairment. Overall:

- oral fluid specimen collection compliance was considerably better than blood
- oral fluid accounted for more total drug positives than blood
- there were significantly more positive results for the impairing drugs cocaine and THC in oral fluid compared to blood
- low saliva:plasma ratio continues to cause difficulty in oral fluid detection of benzodiazepines

Table 30 presents each of the drug positive results for both oral fluid and blood, and Table 31 summarizes those results.

Table 30. Specimens Positive for Drugs*

Specimen ID	Oral Fluid	Blood
1	Negative	THC-COOH 5
2	Negative	Sertraline 31
3	Negative	Alprazolam 1
4	Negative	Alprazolam 4
5	Negative	Diazepam 15; Nordiazepam 9
6	Negative	Diazepam 582, Nordiazepam 881, Oxazepam 140, Temazepam 31
7	Negative	Fluoxetine 14; Norfluoxetine 13
8	Negative	Fluoxetine 17; Norfluoxetine 14
9	Negative	Oxycodone 10; Pseudoephedrine 87
10	Negative	Oxycodone 7
11	Negative	Sertraline 19
12	Negative	Fluoxetine 88, NorFluoxetine 178
13	Negative	Phentermine 19 ; THC-COOH 14
14	Negative	Pseudoephedrine 340; Phenylpropanolamine 16
15	Negative	Pseudoephedrine 46
16	Negative	Alprazolam 27
17	Negative	Hydrocodone 11
18	Negative	Pseudoephedrine 19
19	Negative	Pseudoephedrine 19
20	Negative	Pseudoephedrine 160; Phenylpropanolamine 12
21	Negative	THC-COOH 17
22	Negative	THC-COOH 18
23	Negative	THC-COOH 9
24	Negative	THC-COOH 11

25	Negative	THC-COOH 12; Sertraline 158
26	Negative	THC-COOH 26
27	Negative	Fluoxetine 39; Norfluoxetine 40
28	Negative	Sertraline 17
29	Negative	THC-COOH 5
30	Amitriptyline 23; Nortriptyline 12	Amitryptyline 15; Nortriptyline 6
31	Amphetamine 23, Methamphetamine 37	Negative
32	Amphetamine 122	Amphetamine 48
33	Butalbital 446; Codeine 86	Refused
34	Butalbital 456	Refused
35	BZE 3.5; COC 12.1	Refused
36	BZE 56	Negative
37	Carisoprodol 18; Meprobamate >1000	Carisoprodol 100; Meprobamate 2000
38	COC > 1000 ; BZE >1000; THC 11	Refused
39	COC > 500; BZE 303	COC 54; BZE 132; Cocaethylene 10
40	COC 22; BZE 20	BZE 65
41	COC 23; BZE 97	BZE 157; THC-COOH 29
42	COC 4	Negative
43	COC 87; BZE 19	Negative
44	COC 9.4	Negative
45	COC 9; BZE 3	Negative
46	Fluoxetine 35	Fluoxetine 71; Norfluoxetine 148
47	Fluoxetine 40, THC 82	Fluoxetine 36; Norfluoxetine 89
48	Fluoxetine 51; Norfluoxetine 55	Fluoxetine 54; Norfluoxetine 99
49	Fluoxetine 71	Fluoxetine 211; Norfluoxetine 169
50	Hydrocodone 20, Oxycodone 4	Hydrocodone 14
51	Hydrocodone 36	Refused
52	Hydrocodone 88	Hydrocodone 7
53	Methadone > 1000	Refused
54	Methamp 677, Amp 71, THC 420	Refused
55	Methamphetamine 4876; Amphetamine 541	Methamphetamine 942; Amphetamine 117
56	Nordiazepam 9; Diazepam 8	Refused
57	Phentermine > 100; THC 1.3	Phentermine 129
58	Pseudoephedrine > 100; THC 72.6	Pseudoephedrine 50; THC 2; OH-THC 0.8; THC-COOH 30
59	Sertraline 18.4	Sertraline 79; Diazepam 34, Nordiazepam 45, Oxazepam 8
60	Sertraline 22	Sertraline 18
61	Sertraline 24	Sertraline 112
62	Sertraline 62	Sertraline 203
63	THC 6.6	Refused
64	THC > 100	Refused
65	THC > 100	THC 3.8; 11-OH-THC 1.2; THC-COOH 144
66	THC > 400	Refused
67	THC > 500	THC 27; 11-OH-THC 13; THC-COOH 247
68	THC 0.9	Refused
69	THC 1.3	THC 1.4; 11-OH-THC 1; THC-COOH 89
70	THC 1.7	THC-COOH 12

71	THC 10.6	THC 0.5; 11-OH-THC 0.6; THC-COOH 29
72	THC 10.6	Refused
73	THC 10.8	Refused
74	THC 11.5; Meth >500, AMP >500	Methamp 175; Amp 59; THC-COOH 29
75	THC 13.7	Refused
76	THC 14.1; COC 8; BZE 25	Refused
77	THC 15.6	Refused
78	THC 168; COC 9	Refused
79	THC 19	Refused
80	THC 2.3	Refused
81	THC 21.2	THC 0.8; THC-COOH 41
82	THC 21.2; COC 75, BZE 10	BZE 104; THC 3.8; 11-OH-THC 2.2; THC-COOH 209
83	THC 23.4; Sertraline 8	THC 1.6; 11-OH-THC 0.6; THC-COOH 61; Sertraline 17
84	THC 24.7	Refused
85	THC 3.8	THC 0.5; THC-COOH 13
86	THC 37.9	Refused
87	THC 4.4	Refused
88	THC 53.9; COC >500; BZE 422	Refused
89	THC 6.7	Refused
90	THC 62.2	Refused
91	THC 65	Refused
92	THC 7.4	Refused
93	THC 7.8	THC 0.8; THC-COOH 31
94	THC 9.8	Alprazolam 19, THC 3.6; 11-OH-THC 6.1; THC-COOH 124
95	Tramadol 160.4	Diazepam 6, Tramadol 19; Desmethyltramadol 28, Sertraline 32
96	Tramadol 1724	Tramadol 130; Desmethyltramadol 22

*See color key in Table 31.

Table 31. Summary of Total Drug Positive Results by Matrix Tested

Color Key	
Both Oral Fluid & Blood Positive	33
Oral Fluid Positive	6
Blood Positive	29
Oral Fluid Positive; Blood Refused	28
Total	**96**

In Table 32, the overall results for drug positives are summarized by drug and sample type.

Table 32. Overall Drug Results (Includes Specimens Positive for Multiple Drugs)

Drug Class	Positive Samples	
	Oral Fluid	Blood
Amitriptyline/nortriptyline	1	1
Amphetamine/methamphetamine	4	3
Barbiturates	2	0
Benzodiazepines	1	6
Carisoprodol/meprobamate	1	1
Cocaine and metabolites	14	1
Fluoxetine	4	8
Methadone	1	0

Opiates (hydrocodone, oxycodone, codeine)	4	4
Pseudoephedrine/phentermine/phenylpropanolamine	2	8
Sertraline	5	9
THC	37	20
Tramadol	2	2
Total	**78**	**66**

In Table 33, we summarize the combined results of the oral fluid and blood tests for drugs other than alcohol. Successful laboratory analyses were conducted on 639 drivers. Oral fluid was analyzed for all of these drivers and blood for 394 of them. All drivers who provided blood also provided oral fluid. Thus, 14 of these 639 drivers, or 2.2 percent tested positive for cocaine. The most frequently encountered drug was cannabinoids, with 47 or 7.4 percent of drivers having THC or a metabolite of that substance on board. One must bear in mind that metabolites of THC appear in blood well after the active phase of its potentially impairing effect. Cannabinoids were followed in frequency of appearance by two stimulants, cocaine and amphetamines, each of which presented 2.2 percent of the time in tested drivers. Benzodiazepines (Valium and its relatives) 1.6 percent, Sertraline (Zoloft) 1.6 percent, Fluoxetine (Prozac) 1.3 percent were the next most frequently encountered drugs. Opiates were encountered in 1.1 percent of the tested drivers. Other drugs appeared much less frequently. As indicated in Table 33, many drivers tested positive for more than one drug. Thus we provide as the last line of this table the number of drivers who tested positive for any drug, 96. This constitutes 15.0 percent of the total group who provided oral fluid or oral fluid and blood.

Table 33. Drivers Testing Positive for Drugs other than Alcohol in either Oral Fluid or Blood

Drug	N	% (Out of Valid Drug Tests = 639)
Cocaine	14	2.2%
Opiates	7	1.1%
Amphetamines	14	2.2%
Cannabanoids	47	7.4%
Benzodiazepines	10	1.6%
Barbiturates	2	0.3%
Methadone	1	0.2%
Tramadol	2	0.3%
Sertraline	10	1.6%
Fluoxetine	8	1.3%
Tricyclic Antidepressants	1	0.2%
Carisoprodol	1	0.2%
Driver tested positive for any of above drugs	96	15.0%

Ethanol

The results for ethanol are given in Tables 34 and 35. Some specimens correlate well between the breath, oral fluid, and blood samples, while others are difficult to explain.

Saliva has been shown to equilibrate rapidly with blood in terms of its alcohol content, being slightly higher on average than whole blood. Saliva/whole blood ethanol concentration ratios have been reported on average to be 1.08 for male subjects (n=48) within the first six hours after drinking (range: 0.84-1.36) (Jones, 1979). Other studies have reported similar ratios:

- 1.10 (n=13; range 0.97-1.31) (Jones, 1993)
- 1.20+/-0.13 (n=6; range 1.10-1.40) (Ferrara et al., 1994)
- 1.12 (n=244])and 1.10 (n=21) (Haeckel & Bucklitsch, 1987)

On the whole, the data appear to correlate well with the paired blood/breath, with some outliers. There were three cases where breath was negative, yet blood was positive at .03, .04 and .08 (oral fluid negative in all these cases).

In seven subjects, the breath was negative, and oral fluid was positive between .02 and .28. In these seven cases, blood was refused four times, and three paired breath and blood samples were negative. Such discrepancies are difficult to explain, as breath/blood correlation in particular is widely studied.

Issues

These discrepancies could be related to possible collection issues particularly for oral fluid. In the early part of the study, the volatility of ethanol was not addressed. In the later location collections, the specimens were frozen as soon as possible after collection, and sent to the laboratory on dry ice. At the laboratory, improved sampling processes were implemented involving recapping and freezing the specimens as soon as sufficient sample volume was removed for testing. In this way, the loss of ethanol was minimized and correlation between the breath/blood and oral fluid improved as the study progressed.

When oral fluid is collected, the swab is placed into a transportation buffer; the device is capped, and sent to the laboratory for testing. The volume of the transportation buffer is 3 mL, therefore when one milliliter (1 mL) of saliva is placed into the tube, the total amount of sample volume for testing is 4 mL, and the drug and ethanol content in the sample is diluted by four. In the ethanol testing, it is possible when correcting for the dilution, a value below the limit of quantitation (LOQ) of the assay was multiplied by four, to give the final result. At the low end of the range (.005–.02), the correlation to the breath test was 17.3 percent; in the range above .02, the correlation to the breath test improved to 35/87 = 40.2 percent. This was also true with the blood samples, with 8.6 percent correlation at the low end of the testing range, improving to 19/87 (21.8%) above .02.

Table 34 presents, for those subjects who were positive for any alcohol in any matrix, the results for breath alcohol (%), oral fluid ethanol (%), and blood ethanol (%). Table 35 summarizes those data.

Table 34. Specimens Positive for Ethanol in at Least One Matrix

Breath Alcohol (%)	Oral Fluid Ethanol (%)	Blood Ethanol (%)
0	0	.03
0	0	.04
0	0	.08
0	.02	0
0	.02	0
0	.04	Refused
0	.05	Refused
0	.09	Refused
0	.16	0
0	.28	Refused
.005	0	0
.005	Refused	Refused
.006	0	0
.007	0	0
.008	0	Refused
.008	0	Refused
.009	0	0
.011	0	Refused
.012	0	0
.012	0	Refused
.012	.02	Refused
.013	0	0
.013	0	Refused
.014	0	0
.014	.03	Refused
.015	.05	0.14
.016	Refused	Refused
.017	Refused	Refused
.018	0	0
.018	0	Refused
.019	0	.03
.019	.03	Refused
.019	Refused	Refused
.02	0	0
.02	Refused	Refused
.021	0	0
.021	0	Refused
.021	0	Refused
.022	0	0
.022	0	Refused
.023	.05	0
.024	0	0
.024	.03	0
.024	.03	Refused
.025	0	0

.025	.03	Refused
.025	.10	.08
.026	0	.03
.026	.05	Refused
.027	0	Refused
.028	.02	Refused
.029	0	0
.03	.03	.04
.03	Refused	Refused
.03	Refused	Refused
.032	.09	0
.033	Refused	Refused
.033	Refused	Refused
.034	0	0
.034	0	.03
.035	.07	.06
.036	0	Refused
.037	.06	.07
.037	Refused	Refused
.038	0.04	Refused
.039	0	Refused
.039	0	Refused
.039	.06	.04
.039	.06	Refused
.039	.06	Refused
.041	0	Refused
.041	Refused	Refused
.043	0	Refused
.044	0	Refused
.044	.07	.06
.045	Refused	Refused
.05	0	.05
.052	.07	Refused
.052	0.1	.06
.052	Refused	Refused
.052	Refused	Refused
.053	.05	.05
.053	Refused	Refused
.056	Refused	Refused
.058	.04	.07
.059	0	0
.059	.07	Refused
.062	Refused	Refused
.064	0	.09
.065	0	.10
.066	0	0
.067	.03	Refused
.067	.13	Refused

.069	Refused	Refused
.072	Refused	Refused
.074	Refused	Refused
.075	0	Refused
.078	.05	.09
.078	Refused	Refused
.081	.13	Refused
.081	Refused	Refused
.093	0	Refused
.099	Refused	Refused
.103	Refused	Refused
.108	.11	Refused
.11	.11	.17
.112	0	.13
.118	.15	Refused
.122	.09	0.10
.128	.14	Missing
.128	Refused	Refused
.132	.21	Refused
.133	.27	Refused
.134	Refused	Refused
.143	.21	Refused
.146	Refused	Refused
.15	Refused	Refused
.15	Refused	Refused
.154	.07	Refused
.183	.26	.23
N/A	.06	Refused
N/A	.12	Refused

Table 35. Specimens Positive for Ethanol in at Least One Matrix

Breath Result	# Breath Samples	Oral Fluid			Blood		
		Positive	Negative	Refused	Positive	Negative	Refused/Missing
N/A	2	2	0	0	0	0	2
0	10	7	3	0	3	3	4
.005–.019	23	4	15	4	2	8	13
.02–.079	66	24	25	17	15	12	39
≥ .08	21	11	2	8	4	0	17
Total	**122**	**48**	**45**	**29**	**24**	**23**	**75**

When breath was positive over the legal limit (.08), oral fluid was positive in 11 cases (11/21 = 52.3%); negative in 2 cases (9.5%) and 8 subjects refused to give a specimen (38%). Blood was positive in 4 cases (4/21 =19%) and subjects refused to give blood in all the other 17 cases.

The total refusal rate for blood was much higher than in oral fluid. From 110 subjects testing positively for alcohol via breath (>0.005), 68 (61.8%) refused to donate a blood sample (one blood sample was missing). In contrast, only 29 (26.4%) refused to give oral fluid.

Fourteen subjects were positive via all matrices (Figure 7).

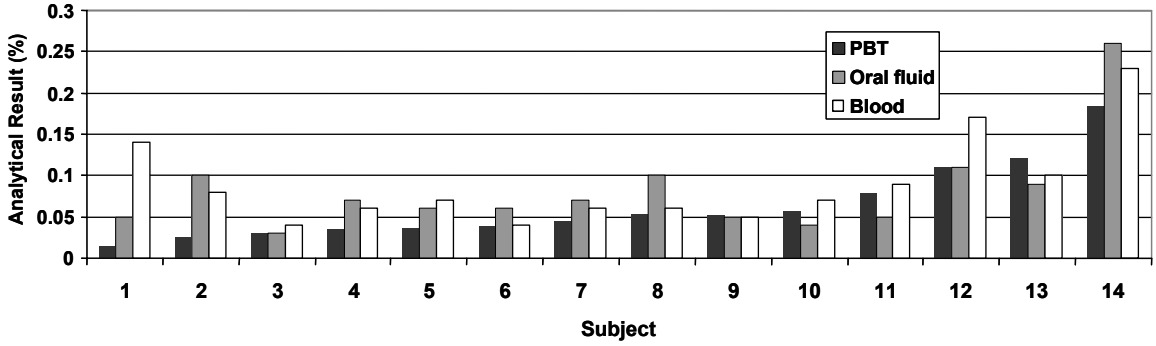

Figure 7. Pattern of BAC Test Results by Biological Matrix

The collection rate for oral fluid was higher than blood. Initial problems with ethanol volatility during collection and storage have been addressed, and correlation between breath and oral fluid results should improve in future studies.

Alcohol Use Disorder Results

While subjects were providing an oral fluid sample, a screening instrument was administered to those who were over 18 years of age. To determine whether it was appropriate to administer the screening instrument to the subjects, they were first asked if they had had a drink in the past year. Five hundred and sixteen people met that criterion. Those persons were administered the remainder of the screener.

To assess alcohol use disorders, a 15-item screener was constructed. The first three items were derived from the Alcohol Use Disorders Identification Test (AUDIT) and represent the AUDIT consumption subscale, also known as the AUDIT-C (Chung et al., 2002; Conley, 2001; Babor, de la Fuente, Saunders, & Grant, 1992). Scores of 6 or more signal heavy drinking for men and scores of 5 or more signal heavy drinking for women using the AUDIT-C. The values that correspond to AUDIT-C response options are included on the AUDIT-C Screener (See Appendix E, attached).

Items 4-7 on the screener are derived from the Alcohol Use Disorders and Associated Disabilities Diagnostic Interview Schedule (AUDADIS; Grant & Dawson, 1997; Cottler et al., 1997; Pull et al., 1997). The way the AUDADIS is constructed, there is one item per DSM-IV symptom. A positive response to any of these items signals alcohol abuse.

Items 8-15 on the screener are also derived from the AUDADDIS. Items 8 and 9 both tap into the domain of tolerance. Items 10-15 are each representative of one DSM-IV diagnostic symptom. A total therefore of 7 diagnostic symptoms are represented across the 8 items. A positive response to 3 of any of the 7 symptoms signals alcohol dependence.

Response Rates and Sample Size

As a first step in determining eligibility for applying the AUD screening instrument, English-speaking roadside survey participants aged 18+ were asked if they had consumed alcohol in the previous year. Of the 959 drivers who entered the survey sites, 530 met these preliminary eligibility criteria and answered that they had consumed alcohol in the last year. 516 of those individuals then answered the 15-item AUD screener. Thus, of those who met the selection

criteria, there was a 97.4 percent response rate. These data are presented in tabular form in Table 36.

Table 36. AUD 15-item Screener Response Rates

Vehicles Entering Site	Number of Drivers Ineligible	Number of Past Year Drivers/Drinkers Eligible for AUD Screener	AUD Sample Size	Response Rate*
959	429 (44.7%)	530 (55.3%)	516 (53.8%)	516/530 = 97.4%

*Response rate calculated based on number of respondents eligible. Eligibility criteria included being English speaking, aged 18 and older, and reporting past year consumption of alcohol.

Alcohol Use Disorder Estimates

As summarized in Table 37, based on the 15-item screener data obtained at the roadside, binge drinking within the past year was the most prevalent alcohol-related diagnosis with 35.7 percent of all respondents reporting binge drinking in the past year (n=184/516). Alcohol abuse was the second most reported problem drinking behavior with 8.3 percent of respondents meeting criteria for non-dependent alcohol abuse (n=43). An estimated 6.8 percent of respondents met criteria for alcohol dependence (n=35). These AUD estimates, based on self-report from a stratified random sample of the nighttime driving population, converge with other estimates from the general population derived from national household surveys (SAMHSA, 2004); they are also based on symptoms occurring and co-occurring in the past year.

The AUD results, including information on the BACs of drivers, are discussed separately in an article in preparation for submission to the Journal of Studies on Alcohol.

Table 37. AUD Screener Prevalence Estimates. n= 516

AUD	N	Prevalence
Binge Drinking	184	35.7%
Alcohol Abuse	43	8.3%
Alcohol Dependence	35	6.8%

Discussion and Recommendations

The primary goal of this study was to develop and test data collection and biological sampling and analysis procedures to determine whether it was practical to conduct a full-scale national roadside survey in the United States which would include testing for the presence of drugs other than alcohol in the nighttime driving population. The general conclusion is that such an endeavor is feasible.

However, based on the experience in this study, certain observations should be made. Most salient is that the response rate for this pilot study was lower than that achieved in previous national roadside surveys. We believe that this is partly due to the fact that the collection of the additional information and biological samples for this study made the survey much longer for individual subjects and the setting more intimidating. We attempted to mitigate this effect some by administering the basic roadside survey and breath test at the beginning of the interview. In some of the previous national roadside surveys, a single data collector was sometimes paired with an individual officer and motorists were simply flagged down, a few questions were asked, a breath sample was requested, and then the subjects were sent on their way. In this study, the survey sites typically involved eight researchers and two law enforcement officers, the survey itself required 15–20 minutes, and additionally, biological samples (oral fluid and blood) were requested. Thus, even though monetary incentives were offered, subjects may have felt that the survey would take too long. The sheer size of the operation may have been intimidating to some potential respondents. And the public may just be more wary of such activities than they were a decade ago. For example, some potential respondents asked us if we were going to be testing for their DNA. Nonetheless, the response rate for the BAC testing was higher than many telephone surveys, and that for blood was comparable to many mail surveys.

It is important for comparison with previous national roadside surveys that we obtain as high a percentage of alcohol tests as possible. One way to accomplish this, even if the active breath test is refused, is through a reading on the Passive Alcohol Sensor (PAS). For this study, we used a smaller PAS (using the same basic technology) which was in a small black box we could attach to the PDA. We did this because we thought it would be less obvious and intimidating than the larger flashlight-based passive sensors. However, in practice, we did not obtain as many PAS readings as in the past. This was partly due to the fact that it was more awkward to put the PDA and PAS close to the face of the respondent when a sample was being taken by activating the pump, and partly because the PAS was not only less obtrusive to the subject but to the data collector as well. This resulted in a number of cases in which the interviewer failed to activate the PAS, even though there was a prompt on the PDA screen. Thus, we recommend that, for future roadside surveys, the researchers revert back to the flashlight type device for passive sensor measures.

Approximately two-thirds of the drivers we approached to participate in the survey provided oral fluid samples and, of those, approximately two-thirds provided a blood sample. Thus there is a sizeable fraction of drivers that we have both types of biological samples and for which toxicological test results may be compared between the two matrixes. This comparison on a larger sample of drivers than obtained in the pilot study could provide insight on the relative values obtained from blood and oral fluid in a naturally occurring sample of the driving population. This information would be useful for a variety of reasons. For example, blood remains the ”gold standard” and additional information relating oral fluid results to blood results would make oral fluid results more relevant to those who wish to relate them to blood results. Additionally, if NHTSA or others were to undertake a crash risk study relating drug use

patterns in the population at risk to those in crashes, one approach would be to use fatally injured drivers as the crash population. In that case, the driver biological samples would likely be blood, and, in all likelihood, that in the population at risk would be oral fluid. Data relating oral fluid and blood results in the same person obtained from the national roadside survey would provide information useful in conducting comparisons between case and control test results used to develop risk estimates in the hypothetical study. For these reasons, we recommend that NHTSA consider obtaining both blood and oral fluid in a sizeable subsample of the next national roadside survey.

We believe that it is important NHTSA retain breath testing as a measure of BAC in future national roadside survey activities. The first reason is because the response rate is highest for breath testing. Second, with a sufficient sample size, estimates of BAC for persons who refuse the PBT but for whom a PAS reading was obtained could be developed. Third, as discussed earlier, because of a variety of factors, mostly involving the logistics of field collection (including the possibility of residual mouth alcohol from recently ingested drinks), sample storage and shipment and laboratory procedures, there is not a one-to-one relationship between BAC levels determined by the three mechanisms for samples collected in the field. Thus, when one wishes to compare results from previous roadside surveys with future ones it would be best to have used the same breath testing approach and biological matrix.

Another component of this pilot test was to examine the feasibility of using a brief screening survey to assess the extent to which persons with alcohol use disorders (AUDs) presented in the nighttime driving population. This is important because little is known about that specific issue and much of the policy debate has focused on whether problem drinkers are significantly overrepresented in the drinking and driving and alcohol-related crash-involved population. Our study indicates that it is indeed feasible to conduct such a screening at the roadside. The preliminary results obtained from this pilot study indicate that the nighttime driving population is quite similar to the population as a whole in terms of AUDs (SAMSA, 2004). Of course, this remains to be confirmed from the more comprehensive sample which would be obtained from a full scale national roadside survey. This brief screening tool would also be useful in comparing AUD profiles between the population at risk, impaired driving arrestees, and crash-involved drivers.

Though this study is just a pilot test and the sample size is relatively small, it is of interest to examine the general results in relation to previous national roadside surveys. These are presented in Figure 8 below and are generally quite encouraging. The long term trend has been for an ever-increasing proportion of survey respondents to have zero BAC readings and for fewer to have positive readings at each level of BAC reading. That seems to have held true in this pilot test, conducted nearly a decade after the most recent national roadside survey. However, because of the small sample size in the pilot study, one cannot say definitively that that is the true trend. Such a conclusion is best left for the next full-scale national roadside survey. To reiterate, the intent of this Pilot Test was to develop and test procedures that would be used in the next full-scale national roadside survey. It was not designed to yield a nationally-representative sample of the nighttime weekend driving population; thus the results are not representative of the United States as a whole.

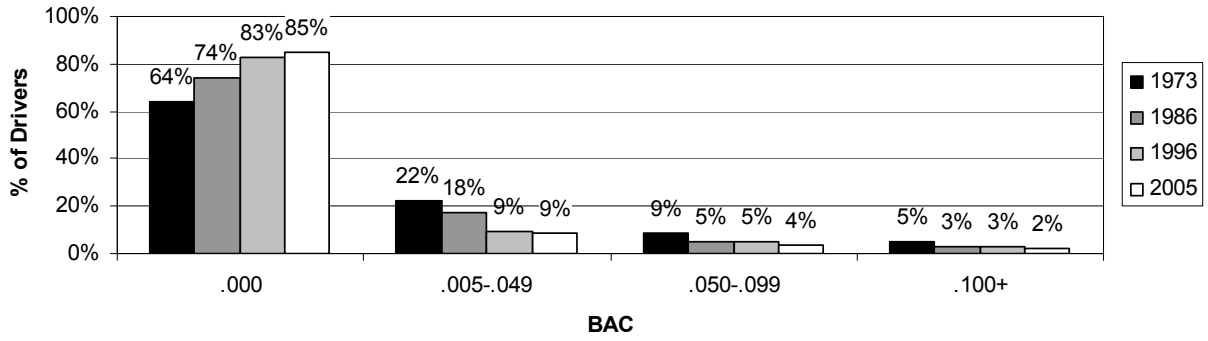

Figure 8. Blood Alcohol Concentrations of Drivers in National Surveys

The major focus of this study was to determine whether is was feasible and practical to collect oral fluid and blood from the nighttime driving population and analyze them for drugs. We determined that it is feasible to do so, with a lower response rate than that achieved for breath tests of alcohol. However, one should bear in mind that the overall response rates achieved (67% for oral fluid and 42% for blood) are in line with many telephone and mail surveys, which of course are based on self-report. Results of the analyses of the specimens obtained indicated that approximately 16 percent of these nighttime drivers tested positive for drugs other than alcohol. Additionally, the results of the chemical analyses indicated a much higher use rate than that obtained for the same subjects based on self-report. The most frequently encountered drug was marijuana and its metabolites, followed by cocaine and amphetamines.

In summary, the results of this pilot test indicate that it is practical to expand the traditional roadside survey to include self-report based measures of alcohol use disorder and biological measures of drug use. The objective biological measures, either through oral fluid or blood, are much to be desired over reliance on self-report of alcohol and/or drug use, which is often contextually illegal.

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Appendix A
National Roadside Survey Pilot Test
Verbal Interview Consent

Hi! My name is _____. We are conducting a paid survey on nighttime driving and you were selected at random. You have not committed any violation. Your responses are voluntary and anonymous. The survey takes just a few minutes and consists of some questions and a breath sample. In addition, you will have the opportunity to earn up to $65 for completing some other components of the survey if you chose to do so. You are free to leave at any time.

Appendix B
National Roadside Survey Pilot Test Instrument

Time: __ __ : __ __

Selected Vehicle:

- ☐ Failed to stop for police officer
- ☐ Stopped but police officer let it go
- ☐ Turned off before reaching officer
- ☐ Turned around before reaching officer

Vehicle Type:

- ☐ Car
- ☐ SUV
- ☐ Minivan
- ☐ Van
- ☐ Pickup
- ☐ Other

Driver's Age:

- ☐ 16-20
- ☐ 21-34
- ☐ 35+
- ☐ Unknown

Driver's Sex:

- ☐ Male
- ☐ Female
- ☐ Unknown

Driver's ethnicity:

- ☐ White
- ☐ Black
- ☐ Hispanic
- ☐ Native American
- ☐ Asian/Pacific Islander
- ☐ Other

Safety Belts

Driver	Passenger	
☐	☐	Lap and shoulder belts
☐	☐	Shoulder belt only
☐	☐	Lap belt only
☐	☐	None
☐	☐	Unknown
	☐	Not applicable

Number of Passengers:

0 1 2 3 4 5 6+

Passengers under age 18 present:

- ☐ Yes
- ☐ No
- ☐ Unknown

Intro: Hi! My name is _____. We are conducting a paid survey on nighttime driving and you were selected at random. You have not committed any violation. Your responses are voluntary and anonymous. The survey takes just a few minutes and consists of some questions and a breath sample. In addition, you will have the opportunity to earn up to $65 for completing some other components of the survey if you chose to do so. You are free to leave at any time.

1. **The average driver drives about 12,000 miles a year. Would you say you drive:**
   - ☐ More than average
   - ☐ Average
   - ☐ Less than average
   - ☐ No answer
2. **About what percent of your total driving takes place at night?**
   - ☐ 0-20%
   - ☐ 21-40%
   - ☐ 41-60%
   - ☐ 61-80%
   - ☐ 81-100%
   - ☐ No answer

[ASSESS INTOXICATION LEVEL]

- ☐ Highly intoxicated
- ☐ Moderately intoxicated
- ☐ Slightly intoxicated
- ☐ Not intoxicated
- ☐ Unknown

3. **About how many miles away are you now from where you live?**
   - ☐ 0-5
   - ☐ 6-10
   - ☐ 11-20
   - ☐ More than 20
   - ☐ No answer

[ACTIVATE PAS]

4. **Where are you coming from?**

	Where are you going to?	
From	To	Place
☐	☐	Own home
☐	☐	Someone else's home
☐	☐	Work
☐	☐	Restaurant/eating place
☐	☐	Bar, tavern, club
☐	☐	School/church
☐	☐	Sport or rec facility/park
☐	☐	Store or gas station
☐	☐	Hotel/motel
☐	☐	Other
☐	☐	No answer

5. **About how many miles is it between those two places?**
   - ☐ 0-5
   - ☐ 6-10
   - ☐ 11-20
   - ☐ More than 20

☐ No answer

6. **Now I have a question about your use of alcohol. Do you ever drink alcoholic beverages such as beer, wine, or liquor?**
   - ☐ Yes
   - ☐ No ***[GO TO Q. 13]***

7. **About how many alcoholic beverages do you consume in an average week?**
   - ☐ 0
   - ☐ 1-2
   - ☐ 3-4
   - ☐ 5-7
   - ☐ 8-14
   - ☐ More than 14
   - ☐ No answer

8. **Have you had anything to drink today?**
   - ☐ Yes
   - ☐ No ***[GO TO Q. 12]***
   - ☐ No answer ***[GO TO Q. 12]***

9. **How long ago did you finish your last drink? _____Hours _____Minutes**

10. **Was that beer, wine, liquor, or a combination?**
    - ☐ Beer
    - ☐ Wine
    - ☐ Liquor
    - ☐ Combination
    - ☐ Other Malt beverage
    - ☐ Wine cooler
    - ☐ Hard cider
    - ☐ Other
    - ☐ No answer

11. **Could you estimate your breath alcohol level?**

    _____

12. **In the past 12 months, did you ever drive after drinking enough that you might be considered to legally have had too much to drink and drive?**

#8>>
   - ☐ Yes--> How many times did that happen would you say? ____ times
   - ☐ No

13. **Tonight, are you, or have you been, a designated driver?**

#6>>
   - ☐ Yes
   - ☐ No
   - ☐ Unknown
   - ☐ No answer

[PASSIVE SENSOR READING]
   - ☐ Red 3
   - ☐ Red 2
   - ☐ Red 1
   - ☐ Yellow 4
   - ☐ Yellow 3
   - ☐ Yellow 2
   - ☐ Yellow 1
   - ☐ Green 2
   - ☐ Green 1

- ☐ 00
- ☐ Not used

14. Compared to a year ago, is enforcement of impaired driving laws in _____ County:

- ☐ Much stronger
- ☐ A little stronger
- ☐ About the same
- ☐ A little weaker
- ☐ Much weaker
- ☐ No answer

Now I have a few background questions for statistical purposes:

15. What is your age? _____ years

16. What is your zip code? _____

17. How far have you gone in school?

- ☐ Less than high school graduation
- ☐ High school grad
- ☐ Some college
- ☐ College grad
- ☐ Some graduate work
- ☐ No answer

18. Are you currently employed, unemployed, retired, on disability, a homemaker, a student, or other?

- ☐ Employed
- ☐ Unemployed
- ☐ Retired
- ☐ On disability
- ☐ Homemaker
- ☐ Student
- ☐ Other
- ☐ No answer

19. Are you Hispanic or Latino?

- ☐ Yes
- ☐ No
- ☐ No answer

20. To which racial group would you say you belong? (all that apply)

- ☐ White
- ☐ Black or African American
- ☐ Indian or Alaska Native
- ☐ Asian
- ☐ Native Hawaiian or other Pacific Islander
- ☐ Other
- ☐ NA

Thank you for participating in this survey

Appendix C
National Roadside Survey Pilot Test
Passive Alcohol Sensor (PAS) Specifications

FEATURES AND BENEFITS

- D.O.T. Approved Omnibus Bill CFR 49, part 40 for workplace testing
- Active, Direct or Passive Sampling Mode --- The flexible sampling design allows the operator to switch between passive (non-invasive), or active alcohol detection, to direct alcohol breath testing using a mouthpiece with the flip of a switch
- Ideal for Zero Tolerance applications
- Single-button control
- Heated electrochemical fuel cell
- Visual prompts
- Pocketsize, lightweight, and rugged
- Color-coded display and numeric readout in % BAC
- Approximately 600 tests per alkaline battery (9 volt)
- Passive Mode: Turn it on, set to the passive mode. Press control button and quickly release; sample is automatically collected and processed
- Active Direct Mode: Turn it on, set active mode. Attach mouthpiece, subject blows; press control button, sample automatically collected and processed
- "Sniffs" breath and open containers or enclosed spaces for the presence of alcohol

TECHNICAL SPECIFICATIONS

Product Name	P.A.S. Vr. Alcohol Screening & Verification System
Function	Combines both direct and passive testing for detecting low levels of alcohol in exhaled breath or the environment
Alcohol Sensor	Electrochemical fuel cell generates an electrical current in response to alcohol vapor
Cell Heater	Built-in heater regulates fuel cell temperature at 104 (40 C)
Calibration	Performed at the factory. Calibration checks are recommended every six months or more frequently if the unit appears to be losing sensitivity
Accuracy	Meets D.O.T. requirements at 0.020% BAC (± .005)
Specificity	Fuel cell detects only alcohol. It is unaffected by acetone, paint and glue fumes, foods, confectionery, methane, and practically any other substance likely to be found in the breath

Breath Sample	Pump runs for 5 seconds and draws in a 1 cu. in. (15ml) air sample (nominal figures)
Display	Color-coded 9-element LED bar-graph and numeric display of alcohol level
Peak Reading	05-20 sec's at 104 F (40 C); longer at low temperatures unless fuel cell heater on
Recovery Time	1-2 minutes after a positive reading; longer if fuel cell overloaded or heater off
Power Supply	9 volt alkaline battery
Battery Capacity	Approximately 600 tests without heater
Environmental Operating temperature range	0 to 104 F (-18 to +40 C). The P.A.S. Vr. housing is weather resistant
Dimensions	2.75" (6.8cm) w x 4.60" (11.5cm) h x 1.50" (3.8cm)
Weight	6.5oz (0.2kg) with battery
Accessories	Disposable mouthpieces for sanitary direct testing 9 volt alkaline batteries Wet bath simulator w/cal-pump

GENERAL INFORMATION

Description

- The P.A.S. Vr. is a hand-held, rapid alcohol detection and screening instrument which uses a platinum electrochemical fuel cell sensor of high alcohol specificity, accuracy, and stability.
- Designed to satisfy DOT and zero-tolerance specifications.
- The operator-controlled sampling system guarantees accurate detection of alcohol, and is especially suited for quick subsequent measurements.

Technology

- Platinum electrochemical fuel cell with integrated heater.
- Specificity - detector is unaffected by acetone, confections, methane, and all other substances likely to be found in the human breath which would distort test results.
- Accuracy - The P.A.S. Vr. Is accurate to ± 0.005 BAC. Meets DOT requirements at 0.020 BAC.
- Detects low breath alcohol levels from 0.01 BAC and up.
- Custom calibration levels available for medical or other applications.
- Response time - seconds from sampling.

Sampling

- Breath sample automatically taken during 4-8 second blow (reaching deep lung air).
- Passive, active, or mouthpiece sampling with single push of button.
- Sanitary - disposable mouthpieces for sanitary testing.
- Non-intrusive passive sampling.

Physical Characteristics

- Display - color coded LEDs and numeric readout
- Instrument Status - five LEDs indicate current status
- Dimensions - 2.75" (6.8 cm) W x 4.60" (11.5cm) H x 1.50" (3.8 cm) D
- Weight - approximately 6.5 oz. (.2 kg)

Operating Temperature

- Warm-up time approximately 30 seconds after initial turn on at temperatures of 59°F (15°C) or more
- Heated Fuel Cell approximately 0°F (-18°C) to 105°F (40°C)
- Use outside or inside

Power Supply

- 9-volt alkaline battery
- Battery life approximately 1,000 samples

P.A.S. System and Warranty

The P.A.S. Vr. is available in a convenient, protective case containing several disposable mouthpieces and a 9-volt alkaline battery is installed. Additional batteries and mouthpieces may be purchased separately; please see accessories. Warranty covers one year parts and labor with the exception of the proprietary platinum electrochemical fuel cell which carries a full two-year warranty.

Sensitivity Check and Calibration

Our Quality Assurance Plan calls for a sensitivity check to be performed once every month (minimum) and full calibration once every six months (minimum) or if a sensitivity check shows the unit out of calibration. The P.A.S. Vr. may be calibrated with a NHTSA approved Wet Simulator.

Manufactured in the United States

USE EXAMPLES

LAW ENFORCEMENT

How Used

The P.A.S. Vr. Alcohol Screening and Verification System is an advanced portable breath alcohol tester (PBT) that features both passive alcohol screening and direct measurements to verify alcohol concentration (deep lung) with the flip of a switch. This hand-held analyzer provides both color coded LEDs and numeric readout.

The P.A.S. Vr. is used to check breath alcohol levels with or without a subject's direct participation. When used without the subject's direct participation it is known as passive sampling, as opposed to active or direct testing where the subject blows directly into a mouthpiece or the intake port.

Where Used

The P.A.S. Vr is designed specifically for use by law enforcement, correctional officers, security personnel and school officials. It can be operated with one hand, leaving the other completely free. The instrument is easy to use, and has been designed to withstand the physical conditions experienced in operational situations. It is resistant to adverse weather conditions and mechanical shocks.

What advantage does the P.A.S. Vr. have over other PBTs?

Standard PBTs are strictly direct testing devices, which require the use of expensive disposable mouthpieces. The P.A.S. Vr. offers direct testing (using a mouthpiece to obtain an exact BrAC with DOT approved accuracy); and the additional flexibility of passive sampling, or active sampling (which do not require the use of mouthpieces). The P.A.S. Vr. may be used as a rapid screening device to detect alcohol in human breath or in the environment, such as in the case of open containers or spilled liquids. The sensitivity of the P.A.S. Vr. allows it to detect background levels of alcohol in enclosed spaces such as vehicles, rooms, lockers, etc. This is useful for detecting drinking by minors in cars or at social gatherings, without sampling each individual's breath, or in work-release programs and treatment centers.

The passive sampling mode (used without the subject's direct participation) is also ideal for use in emergency situations. For example when a crash victim is unconscious, it can be important to know whether he or she has been drinking. This will often determine the best course of emergency medical treatment. It is also important to know whether alcohol might have contributed to the accident. PBTs require the crash victim to blow into a mouthpiece; with the P.A.S. Vr. even an unconscious subject could be sampled using the passive sampling mode's proprietary sample pump to draw in the sample.

SCHOOLS

How Used

The P.A.S. Vr. Alcohol Screening and Verification System is an advanced portable breath alcohol tester (PBT) that features both passive alcohol screening and direct measurements to verify alcohol concentration (deep lung) with the flip of a switch. This hand-held analyzer provides both color coded LED's and numeric readout.

The P.A.S. Vr. is used to check breath alcohol levels with or without a subject's direct participation. When used without the subject's direct participation it is known as passive sampling, as opposed to active or direct testing where the subject blows directly into a mouthpiece or the intake port.

Where Used

Every school system has an interest in preventing drug and alcohol abuse in its student populations. The school years are the time when the physical, psychological, and addictive effects of drugs and alcohol are most severe. Children grow chemically dependent faster than adults and their record of successful recovery is extremely poor. Children's lost educational opportunities will affect the rest of their lives. The effect of drug and alcohol abuse is not limited to the abuser; the student body, the faculty, and the entire educational process are all victims.

A proven important benefit to any alcohol awareness program, the Vr. provides "real time" evidence that alcohol is present. Whenever alcohol use or the presence of alcohol is suspected, this instrument, with the push of a button, will sample and measure the presence and concentration of alcohol. The product may be used in any situation where alcohol use or presence is not allowed, e.g., zero tolerance. For example, introducing passive alcohol testing (P.A.S.) in schools has resulted in a marked decrease in alcohol use at school activities, such as dances, sporting events, proms and verification testing in "reasonable suspicion" cases during school hours. The use of this testing capability has clearly influenced student behavior in many schools and universities. (Specific school references are available upon request.)

What advantage does the P.A.S. Vr. have over other PBTs?

The use of P.A.S. test systems in a school's "alcohol awareness" program reduces classroom disruptions and disruptions at school functions, saving untold amounts of teacher/supervisor time, injury, property damage, insurance claims and loss of lives. These savings may amount to hundreds of millions of dollars, according to the National Highway Traffic Administration (NHTSA) and the Insurance Institute for Highway Safety (IIHS).

Standard PBTs are strictly direct testing devices, which require the use of expensive disposable mouthpieces. The P.A.S. Vr. offers direct testing (using a mouthpiece to obtain an exact BrAC with DOT approved accuracy); and the additional flexibility of passive sampling, or active sampling (which do not require the use of mouthpieces). The P.A.S. Vr. may be used as a rapid screening device to detect alcohol in human breath or in the environment, such as in the case of open containers or spilled liquids. The sensitivity of the P.A.S. Vr. allows it to detect background levels of alcohol in enclosed spaces such as vehicles, rooms, lockers, etc. This is useful for detecting drinking by minors in cars or at social gatherings, without sampling each individual's breath.

DOT

How Used

The P.A.S. Vr. Alcohol Screening and Verification System is a DOT-approved alcohol screener. The P.A.S. Vr. is an advanced portable breath alcohol tester (PBT) that features both passive alcohol screening and direct measurements to verify alcohol concentration (deep lung) with the flip of a switch. This hand-held analyzer provides both color coded LEDs and numeric readout.

The P.A.S. Vr. is used to check breath alcohol levels with or without a subject's direct participation. When used without the subject's direct participation it is known as passive

sampling, as opposed to active or direct testing where the subject blows directly into a mouthpiece or the intake port.

Where Used

The American Medical Association has demonstrated that a blood alcohol concentration (BAC) of 0.040% impairs any individual to some degree. Impairment can occur at even lower levels in some individuals. As a result, industries that test for alcohol have chose to use either 0.04 or zero BAC as maximum acceptable levels in the workplace.

The P.A.S. Vr. has been used very successfully as a deterrent in industry. When used as a rapid screening device to detect alcohol in human breath the P.A.S. Vr. will help you decide whether to use an evidential breath tester (EBT) in individual employee cases. The P.A.S. Vr. designed for industry and transportation agencies complies with the U.S. Department of Transportation requirements for workplace testing regulations according to 49 CFR, Part 40.

What advantage does the P.A.S. Vr. have over other PBTs?

Standard DOT approved PBTs are strictly direct testing devices, which require the use of expensive disposable mouthpieces. The P.A.S. Vr. offers direct testing (using a mouthpiece to obtain an exact BrAC with DOT approved accuracy); and the additional flexibility of passive sampling, or active sampling (which do not require the use of mouthpieces). The P.A.S. Vr. may be used as a rapid screening device to detect alcohol in human breath or in the environment, such as in the case of open containers or spilled liquids. The sensitivity of the P.A.S. Vr. allows it to detect background levels of alcohol in enclosed spaces such as vehicles, rooms, lockers, etc. This is useful for detecting drinking by minors in cars or at social gatherings, without sampling each individual's breath.

DRUG TREATMENT AND MEDICAL FACILITIES

How Used

The P.A.S. Vr. Alcohol Screening and Verification System is an advanced portable breath alcohol tester (PBT) that features both passive alcohol screening and direct measurements to verify alcohol concentration (deep lung) with the flip of a switch. This hand-held analyzer provides both color coded LED's and numeric readout.

The P.A.S. Vr. is used to check breath alcohol levels with or without a subject's direct participation. When used without the subject's direct participation it is known as passive sampling, as opposed to active or direct testing where the subject blows directly into a mouthpiece or the intake port.

Where Used

This design has often been selected by Alcohol Safety Action Program (ASAP) Directors, (or similar private programs) to monitor the court referred subjects. By checking each subject, each time they enter for counseling the behavioral impact is much greater than random checking. The passive mode allows much more cost-effective screening than the typical portable breath tester (PBT).

Without this cost-effective device, the centers usually are limited to random testing. That is often insufficient to influence behavior because the odds of being the random subject is so infrequent, many habitual drinkers are more than willing to take the risk.

What advantage does the P.A.S. Vr. have over other PBTs?

Standard PBTs are strictly direct testing devices, which require the use of expensive disposable mouthpieces. The P.A.S. Vr. offers direct testing (using a mouthpiece to obtain an exact BrAC with DOT approved accuracy); and the additional flexibility of passive sampling, or active sampling (which do not require the use of mouthpieces). The P.A.S. Vr. may be used as a rapid screening device to detect alcohol in human breath or in the environment, such as in the case of open containers or liquids. The sensitivity of the P.A.S. Vr. allows it to detect background levels of alcohol in enclosed spaces such as vehicles, rooms, lockers, etc. This is useful for detecting drinking by minors in cars or at social gatherings, without sampling each individual's breath, or in work-release programs and treatment centers.

The passive sampling mode (used without the subject's direct participation) is also ideal for use in emergency situations. For example when a crash victim is unconscious, it can be important to know whether he or she has been drinking. This will often determine the best course of emergency medical treatment. It is also important to know whether alcohol might have contributed to the accident. PBTs require the crash victim to blow into a mouthpiece; with the P.A.S. Vr. even an unconscious subject could be sampled using the passive sampling mode's proprietary sample pump to draw in the sample.

MANUFACTURED BY:

PAS Systems International, Inc.
P.O. Box 330
Fredericksburg, Virginia 22404
Telephone: 540-372-3431 | 800-660-SNIF
FAX: 540-372-7647

Appendix D
National Roadside Survey Pilot Test
Drug Questionnaire

The following questions ask about use of medications and drugs and driving.
This is for research purposes only. All of your responses are completely anonymous.

Have you ever taken any of the following medications/drugs? (please check all that apply)

- Over-the-counter medications (cough medicines, dietary supplements, etc.)
- Prescription drugs (anti-biotics, muscle relaxant, anti-depressant, etc.)
- Recreational drugs

Do you believe any of the medications/drugs you have taken (or are taking) could effect your driving?

- Yes
- No

Have you taken any medications or drugs in the past **YEAR** that you think may effected your driving?

- Yes
- No

Have you taken and medications or drugs **TONIGHT** that you think may effect your driving?

- Yes
- No

Have you ever **NOT** driven because you were on a medication/drug?

- Yes
- No

The following is a list of medications/drugs or types of drugs people may use. Please indicate when was the last time you used that particular medication/drug.

	Never	1 Plus years	Past year	Past month	Past 2 days	Tonight
Cough Medicines (Robitussin, Benadryl, etc.)	•	•	•	•	•	•
Amphetamines (Ritalin, Aderall, etc.)	•	•	•	•	•	•
Muscle relaxants (Somo, Miltown, etc.)	•	•	•	•	•	•
Dietary supplements	•	•	•	•	•	•
Anti-depressant (zertek, prozac, etc.)	•	•	•	•	•	•
Marijuana (dope, bomb, weed, pot, hash)	•	•	•	•	•	•
Cocaine (crack or coke)	•	•	•	•	•	•
Ecstasy (“E”, Extc, MDMA, “X)”	•	•	•	•	•	•
GHB	•	•	•	•	•	•
Phencyclidine (PCP)	•	•	•	•	•	•
Diazepam (valium, etc.)	•	•	•	•	•	•
Rohypnol (Ruffies)	•	•	•	•	•	•
Methamphetamine (meth)	•	•	•	•	•	•
Heroin, Morphine, codeine	•	•	•	•	•	•
Ketamine (Special K)	•	•	•	•	•	•

Appendix E
National Roadside Survey Pilot Test
Alcohol Use Disorder (AUD) Survey Instrument

AUD Screener

ASK: I'd like to ask you a question about your use of alcohol in the past year. Just to be sure, have you had a drink of any type of alcoholic beverage in the past year? Please do not include times when you only had a sip or two from a drink. (PAUSE and clarify if respondent hesitates) By a "drink," I mean a can or bottle of beer, a glass of wine or a wine cooler, a shot of liquor, or a mixed drink with liquor in it.

[IF ANSWERED NO] That ends the survey portion of the interview. (Proceed to Drug Questionnaire).

[IF ANSWERED YES] ASK: I can offer you an additional $5 to answer a few more questions about your use of alcohol in the past year. Your answering these questions is completely voluntary and you can end the interview at any time. This will take approximately five more minutes of your time. There is no risk to you from answering these questions. Unless you have any questions I'd like to continue. (PAUSE) [If no, thank and proceed to Drug Questionnaire).

1. In the past year, how often did you have a drink containing alcohol?
   - ☐ Never
   - ☐ Monthly or less
   - ☐ 2-4 times/month
   - ☐ 2-3 times/week
   - ☐ 4 or more times/week

2. In the past year, how many drinks containing alcohol did you have on a typical day when you were drinking?
   - ☐ 1-2
   - ☐ 2-4
   - ☐ 5 or 6
   - ☐ 7-9
   - ☐ 10 or more

3. In the past year, how often did you have six (five for a woman) or more drinks on one occasion?
   - ☐ never
   - ☐ less than monthly
   - ☐ monthly
   - ☐ weekly
   - ☐ daily/almost daily

4. Did your drinking often interfere with taking care of your home or family or cause you problems at work or school?
   - ☐ yes
   - ☐ no
   - ☐ no answer

5. Did you more than once get into a situation while drinking or after drinking that increased your chances of getting hurt—like driving a car or other vehicle or using heavy machinery after having had too much to drink?
   - ☐ yes
   - ☐ no
   - ☐ no answer

6. Did you get arrested, held at a police station, or have legal problems because of your drinking?
   - ☐ yes
   - ☐ no
   - ☐ no answer

7. Did you continue to drink even though it was causing you trouble with your family or friends?
   - ☐ yes
   - ☐ no
   - ☐ no answer

8. Have you found that you have to drink more than you once did to get the effect you want?
   - ☐ yes
   - ☐ no
   - ☐ no answer

9. Did you find that your usual number of drinks had less effect on you than it once did?
   - ☐ yes
   - ☐ no
   - ☐ no answer

10. Did you more than once want to try to stop or cut down on your drinking, but you couldn't do it?
    - ☐ yes
    - ☐ no
    - ☐ no answer

11. Did you end up drinking more or drinking for a longer period than you intended?
    - ☐ yes
    - ☐ no
    - ☐ no answer

12. Did you give up or cut down on activities that were important to you or gave you pleasure in order to drink?
    - ☐ yes
    - ☐ no
    - ☐ no answer

13. When the effects of alcohol were wearing off, did you experience some of the bad after-effects of drinking – like trouble sleeping, feeling nervous, restless, anxious, sweating or shaking, or did you have seizures or sense things that weren't really there?
    - ☐ yes
    - ☐ no
    - ☐ no answer

14. Did you spend a lot of time drinking or getting over the bad after effects of drinking?
    - ☐ yes
    - ☐ no
    - ☐ no answer

15. Did you continue to drink even though it was causing you to feel depressed or anxious or causing a health problem or making one worse?
    - ☐ yes
    - ☐ no
    - ☐ no answer

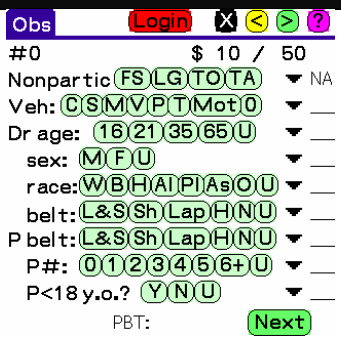
Appendix F:

National Roadside Survey Pilot Test: Screenshot

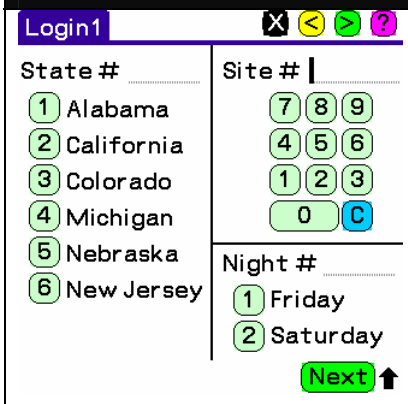
Appendix F

National Roadside Survey Pilot Test Screenshots

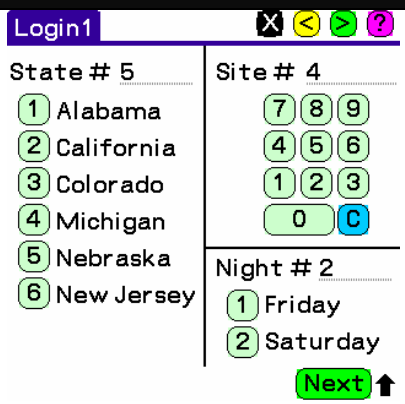
The initial screen of the database may be in table view. Because no records are in the database, the table is empty. To start data entry, tap on the New button at the bottom of the screen to open a new record.



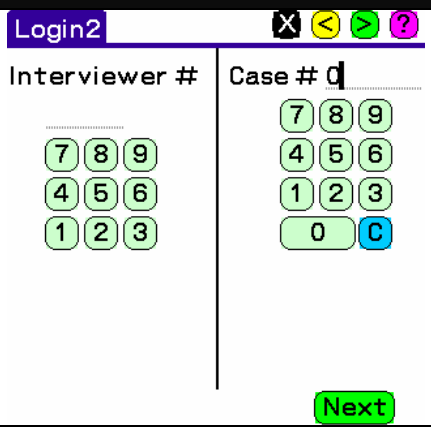
The Obs screen will be the first screen viewed at the beginning of each record. Because this is the first record, the first step is to Login by tapping on the button at the top of the screen.



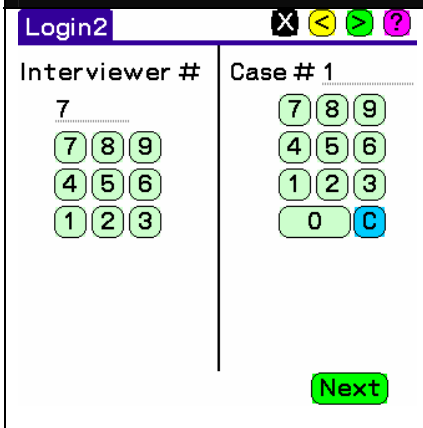
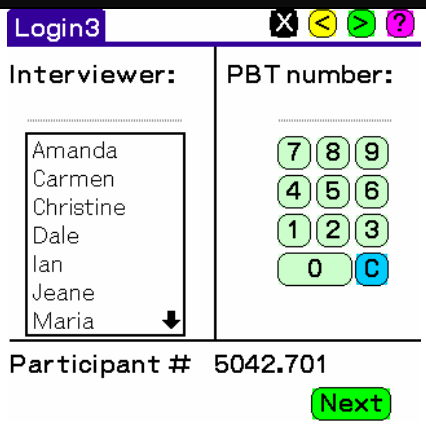
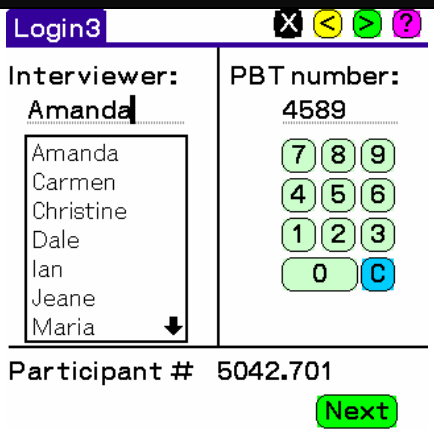
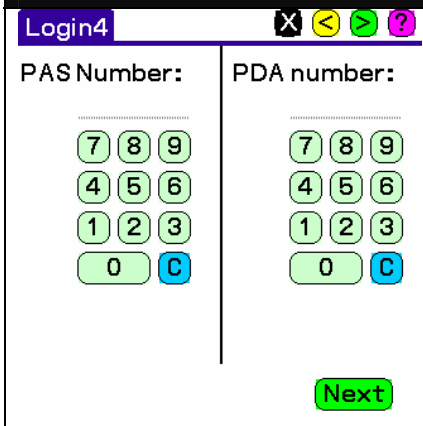
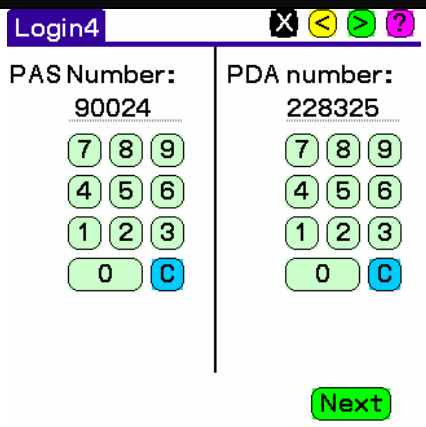
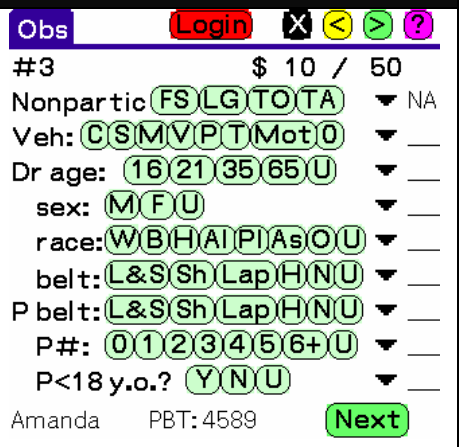
The Login1 screen is used to enter the elements of the location ID—State, Site #, and Night #. Tap on the light green buttons to enter the information as instructed by the site supervisor. Tapping on the buttons for State and Night will replace the information in the respective fields; for Site, however, the buttons append to what is in the field. Use the blue C button to clear the Site field if necessary

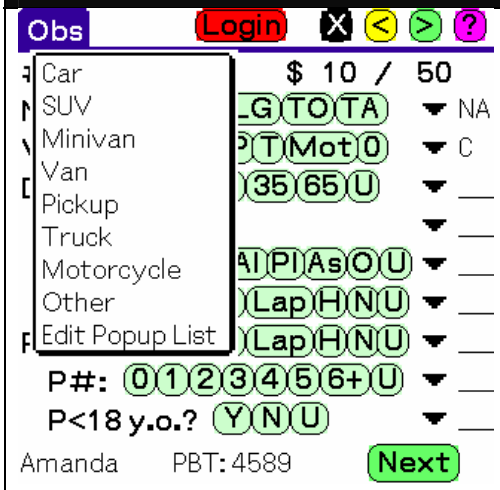


An example of the Login1 screen filled in.

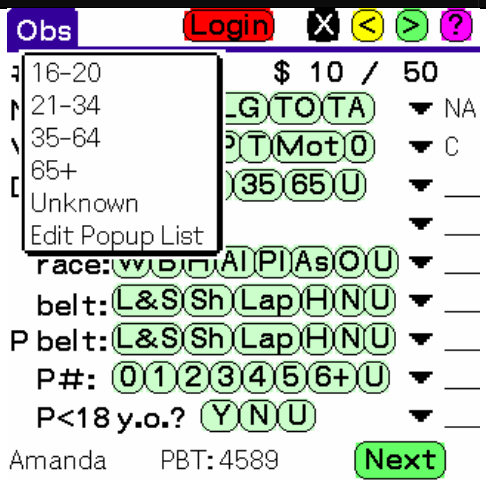


Each night of data collection, each interviewer will be assigned a number by the supervisor., which is entered on Login2. The beginning Case # is also set on this screen. Case # will autotmatically increment for each new record until reset to a different number. For the first record for a night of data collection, set the Case # to 1. As a general rule, when changing to a different PDA during the night, use the same interviewer number and set the Case # to 1 greater than the last Case # on the previously used PDA.

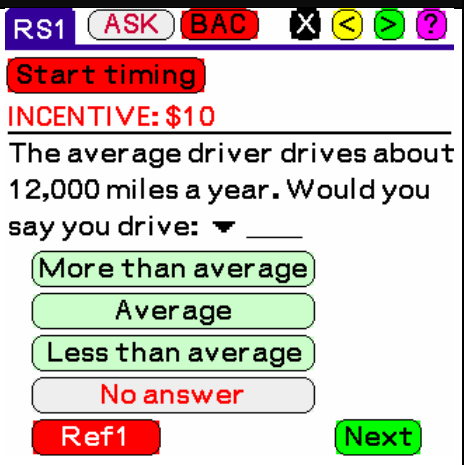
		
An example of the Login2 screen filled in.	At the bottom of Login3 is the Participant # created from the fields entered on Login1 and Login2. The first digit is the State (5=Nebraska), the second and third digits are the site (04), the fourth digit is the night (2=Saturday). The first digit to the right of the decimal point is the interviewer number. On a night of data collection, these first five digits will stay constant and only the last 2 digits, which are based on the Case #, will vary.	Select your name from the list in the box at the left. If your name is not in the box, enter your name by using Grafitti or with an onscreen keyboard (tap on the "a" in the lower left of the Grafitti screen to get the keyboard to appear). The number from the label on the PBT sensor is entered by tapping on the appropriate numbers in the keypad. The blue C button will clear the PBT number and you can start over. Above is an example of the Login3 screen filled in.
		
The Login4 screen works similarly—tap the appropriate numbers from your passive sensor (PAS) and the PDA.	An example of the Login4 screen filled in.	The information recorded during Login will be copied to all following records. Login should always be done at the beginning of data collection or whenever equipment or interviewer changes. After Login, the name of the data collector and the PBT being used will appear at the bottom of the Obs screen. At this point, data collection is ready to begin.



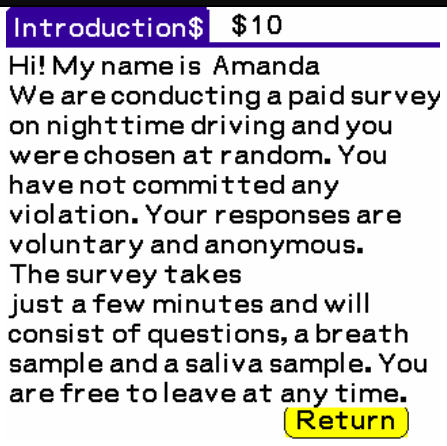
There are of methods of entering data: Method 1 is to tap on a button which enters the caption into the field and Method 2 is to bring up the popup menu by tapping on the downward arrow and selecting the desired option from the list. To cram as much information into one screen, the captions on the buttons are abbreviated, but the captions do correspond with the possible selections in the popup menu. Here the popup menu for Vehicle is displayed and you can see how the C S M V P T Mot O buttons match up. Tapping the buttons is preferred because that method will be much faster once you have become familiar with the abbreviations.



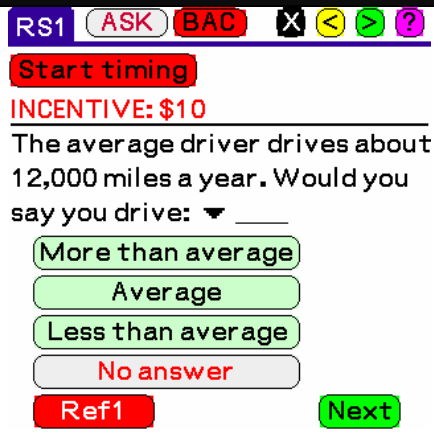
For driver age, only the first number in the range is in the button, as shown in the popup menu below. Tap on the Next button to go to the next screen and start the survey.



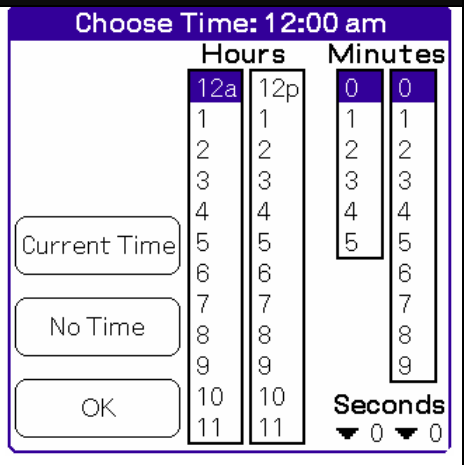
The RS1 screen has the first question of the survey. Before reading it, introduce yourself and tell something about the survey itself. A suggested spiel is available by tapping the ASK button at the top.



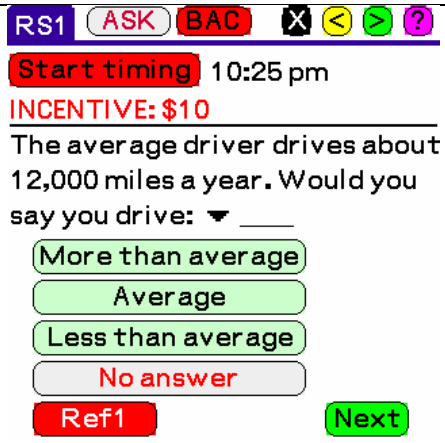
The Intro is personalized with the interviewer's name. Tap on the Return button to go back to RS1 screen.



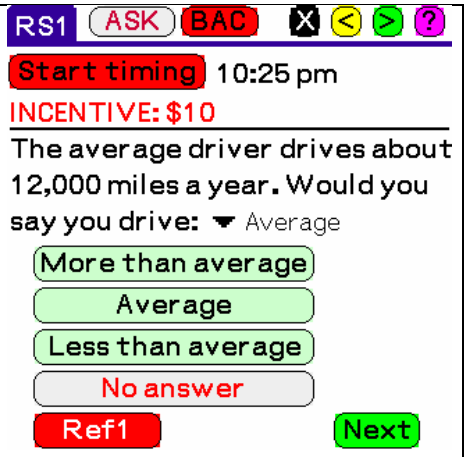
To record how long the survey takes tap the "Start timing" button, which will bring up...



... the Choose Time screen. Tap on Current Time to return to the RS1 screen.

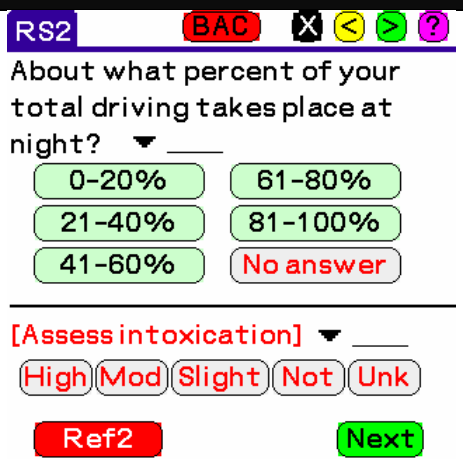


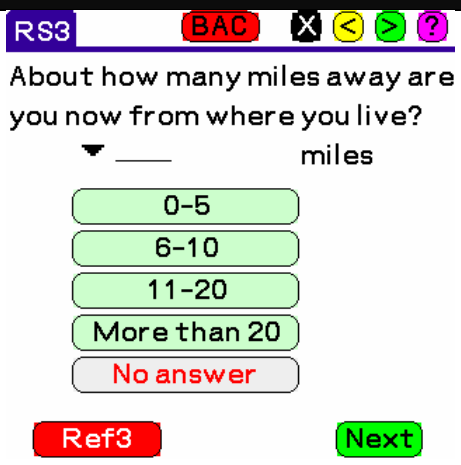
Some explanation about the other buttons on this screen that reappear on many other screens:
BAC—jumps to PBT2 screen. If a driver refuses to continue with the survey at any time, ask them for a breath sample.
X—jumps to Options screen
<—goes back to previous screen
>—goes to next screen in sequence
?—goes to Help screen
Ref1—tap on this button when driver refuses to answer any more questions (not just a refusal or don't know for a single question)
Next—goes to next screen in sequence



Upon return to RS1, the current time appears to the right of the button. After you get proficient with the survey, you will probably be able to say your spiel and enter the start time simultaneously.

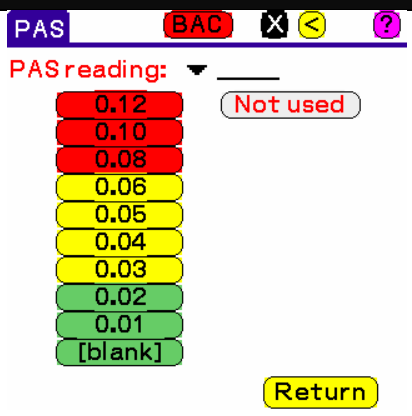
The procedure is to read the question and then the possible answers in the light green buttons. Don't read any answers in red text and gray background. Record the answer by tapping on the desired button or selecting the appropriate answer from the popup menu. After entering the answer, tap on the Next button to go to the RS2 screen.



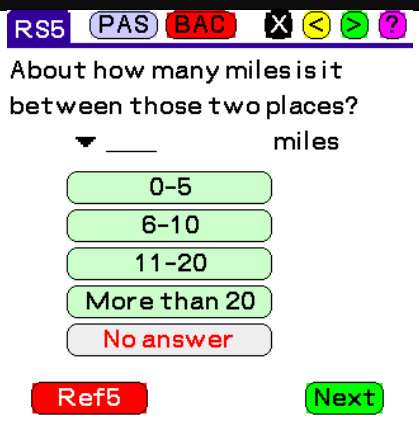


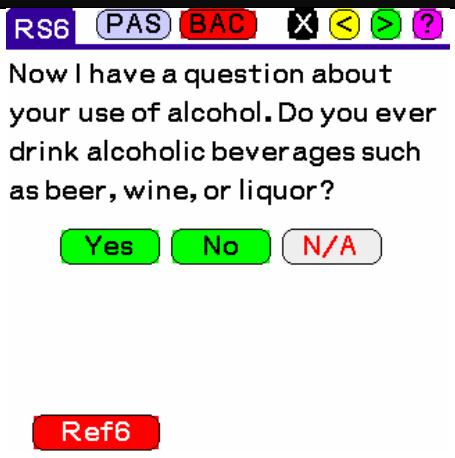
The RS2 screen has a question to be asked of the driver as well as an observation by the data collector concerning the driver's intoxication level. Text in red is not to be read to the driver.

The RS4a screen has a cue to turn the Passive Sensor on. This question is used for the PAS because it is more likely to elicit a longer reply. Also starting on this screen is the PAS button, which will jump to a screen to record the PAS reading.

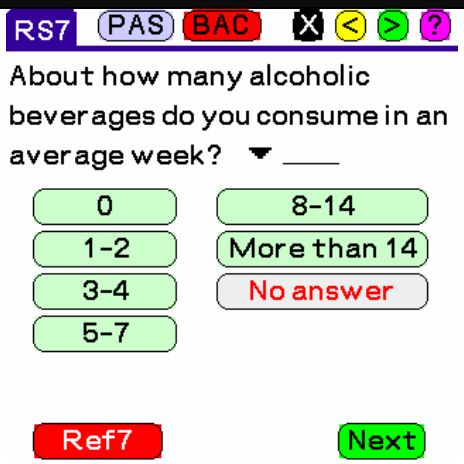


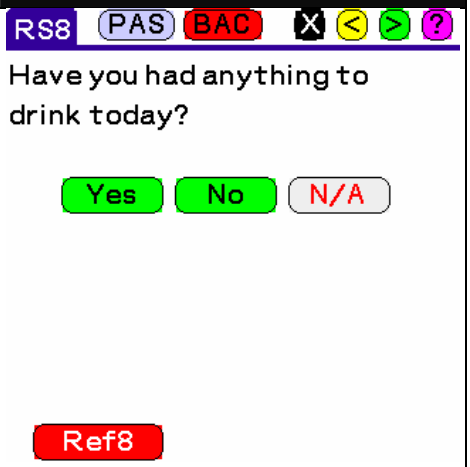
The PAS screen can be displayed by tapping on the PAS button from many of the survey screens. After recording the reading, tap on the Return button to go back to the previous screen.



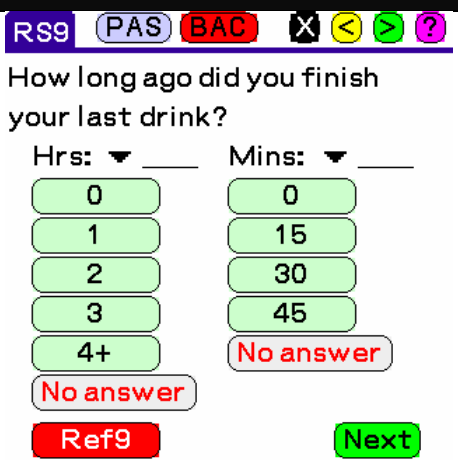


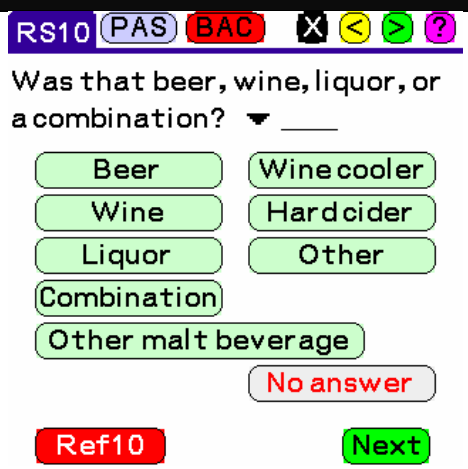
On RS6, the answer buttons are bright green like a Next button and there is no Next button. If a driver answers No to this question, there's no point in asking more questions about drinking. Tap on the No button for the No answer and jump to RS13. Similarly, the Yes button records Yes answer jumps to RS7.

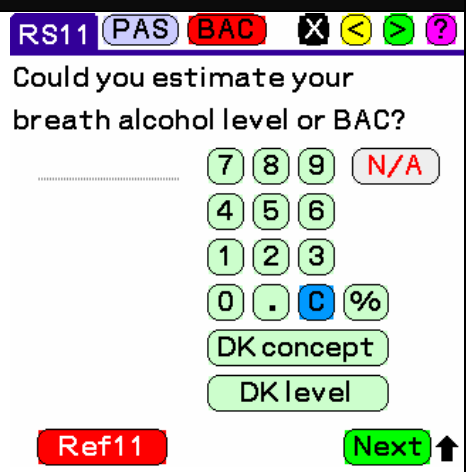




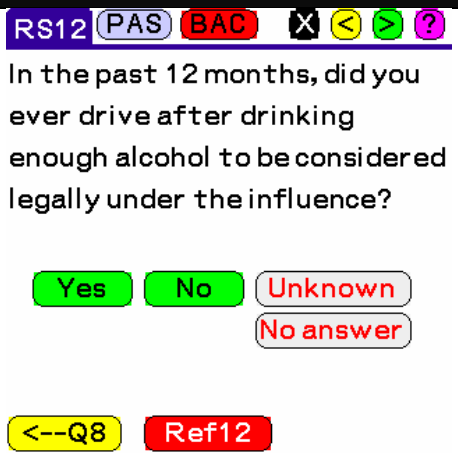
As on RS6, the Yes and No buttons on RS8 record the answer and jump to the appropriate screen (RS9 or RS12).

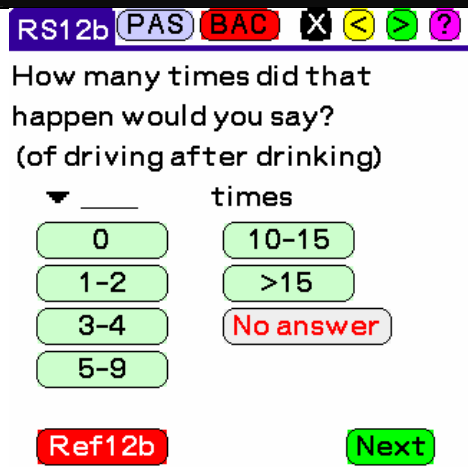


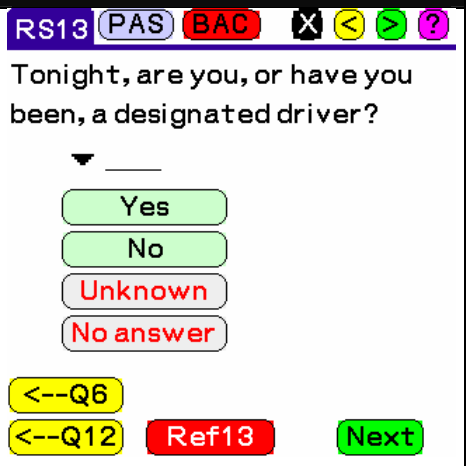




In response to the question on RS11, drivers may say they don't know. The two buttons below the number pad distinguish between those who don't know the concept of BAC and those who don't know their level of BAC.

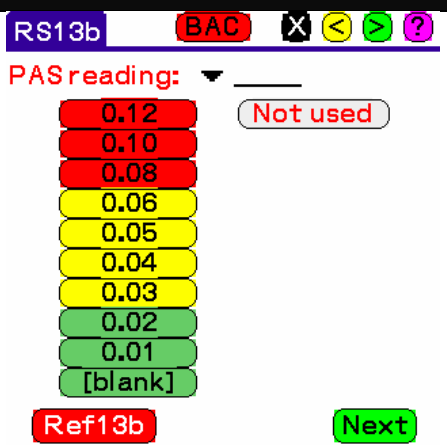




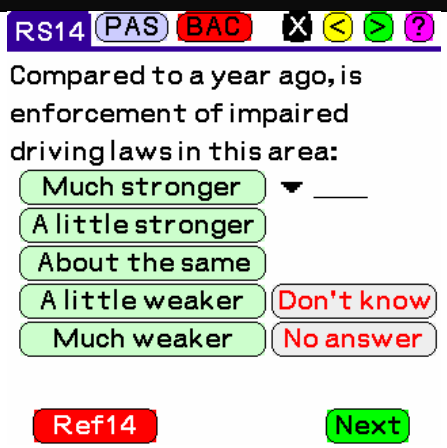


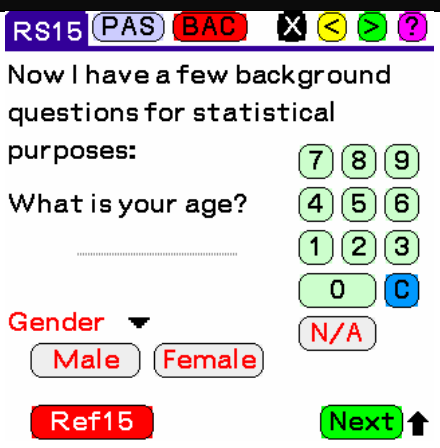
As on previous screens, the Yes and No buttons record the answer and jump to the appropriate screen. In addition, this screen is the target of the No button on RS8. If the driver changes his answer or the wrong button was tapped, use the yellow <--Q8 button to go back to RS8.

RS13 is the target of the No buttons on RS6 and RS12. You can use the yellow buttons in the lower left to go back to those questions as needed.

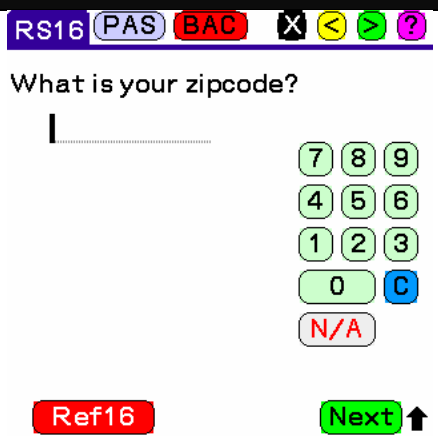


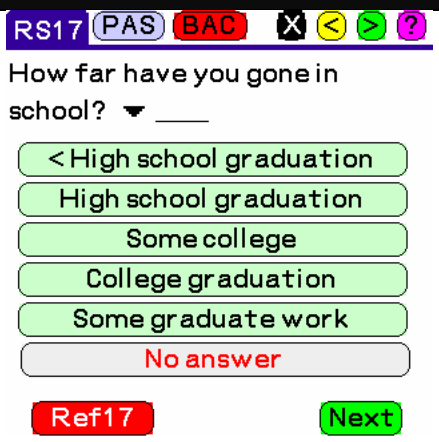
Although the PAS reading may already be recorded, this screen appears in the sequence as a reminder in case the PAS malfunctioned earlier or was not used.

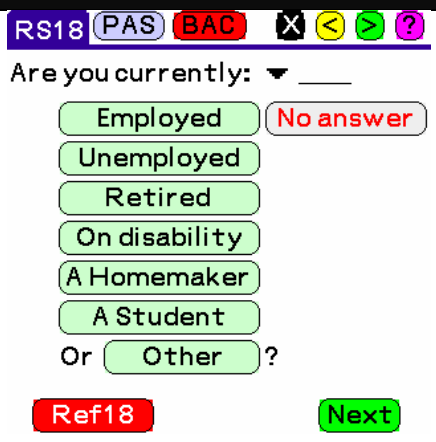




Record age and gender information again and don't go back to correct the information from the Obs screen.

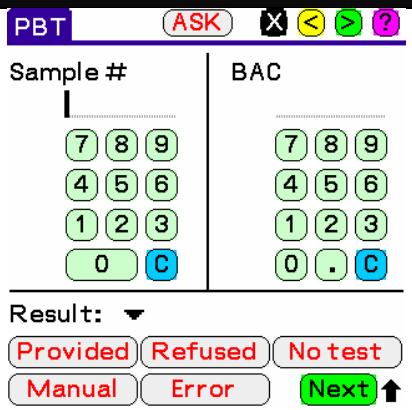
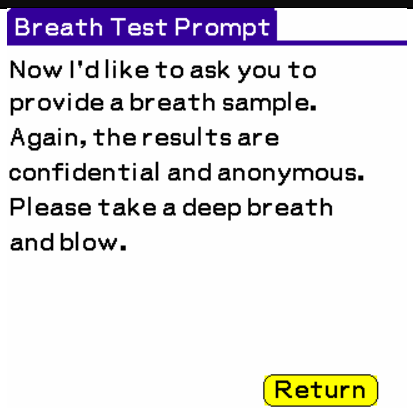
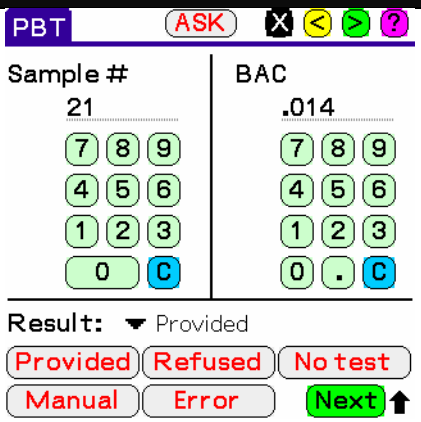
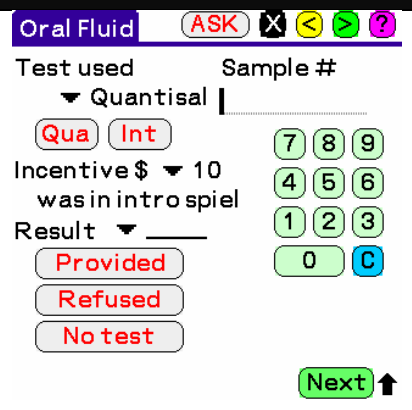
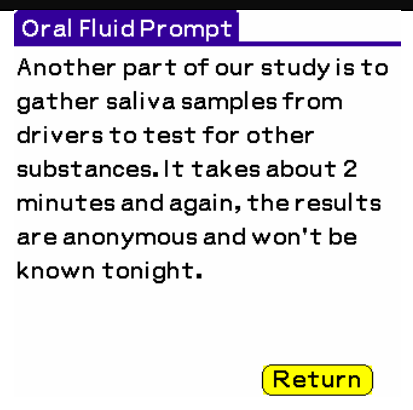
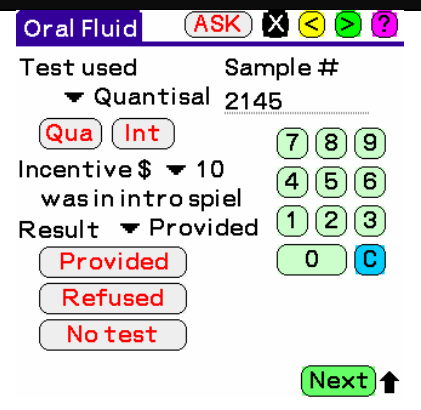


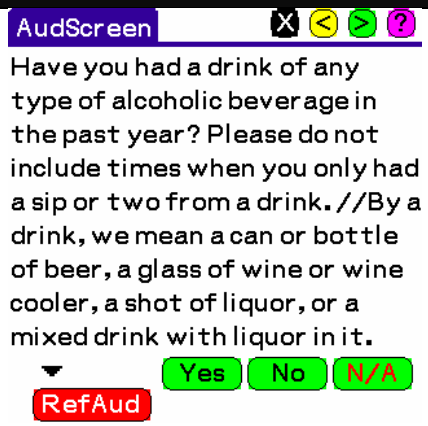




The RS20 question allows multiple responses. Tapping on a light green button will append the caption to the field.

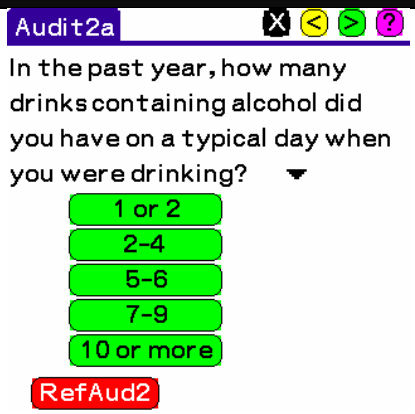
An example of how RS20 might appear if the driver mentions several races.

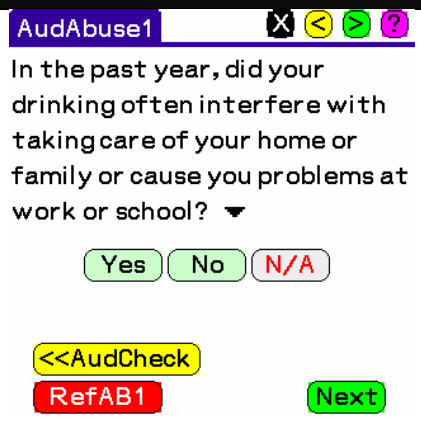
		
Tell the driver something about what to expect when giving a breath sample. Tap on the ASK button for a sample spiel.	Sample spiel for introducing the breath test.	After the driver has given a breath sample, record the sample number (review on the PBT if needed) and enter the PBT reading if it appears. At the bottom of the screen, indicate whether the driver provided a breath sample or explicitly refused to give one. In cases where a driver does not provide sufficient air for a valid sample, ask them to try again and at their peak blowing, press the Manual button on the PBT. Use the Error button when the PBT gives an error message. Use the "No test" button to indicate that the PBT was not used for some reason (out of tubes, not turned on, overlooked, etc.).
		
Tap on ASK button for a spiel about the oral fluid sample. The standard device used for oral fluid samples is the Quantisal, but the Intercept device can be used. The default for the incentive is $10, but can be changed.		The Sample # is taken from the preprinted labels and will also be used for the paper-and-pencil drug survey and for the blood sample. Once entered, it will reappear at the appropriate places on following screens.

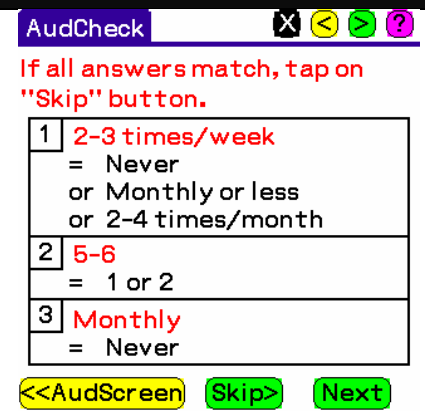


After the Oral Fluid sample come the Audit questions. (This section may be revised.) If the driver answers No on AudScreen, the rest of the Audit questions are skipped.

Drivers who admit drinking are asked a series of 3 screening questions. Depending on their responses to those questions, they may be asked more questions.

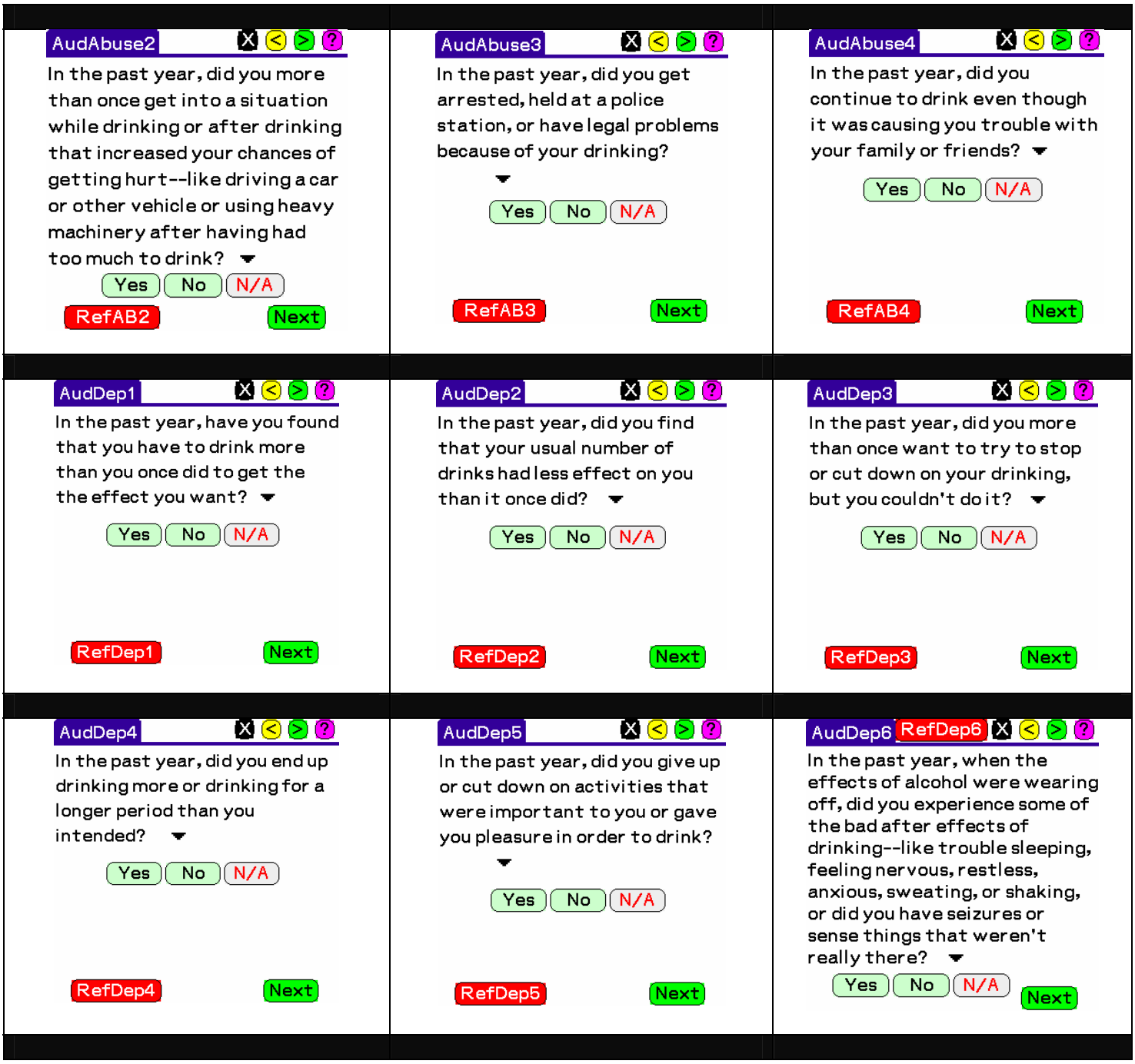


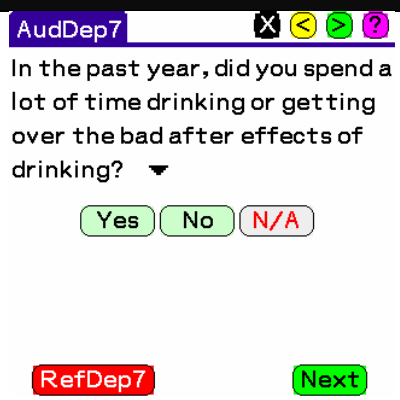
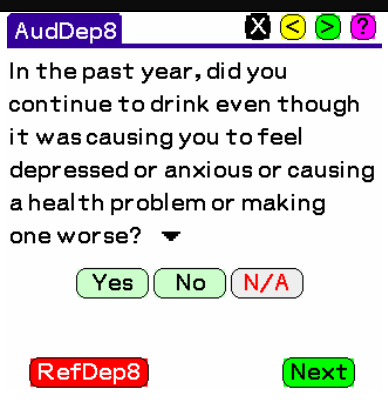
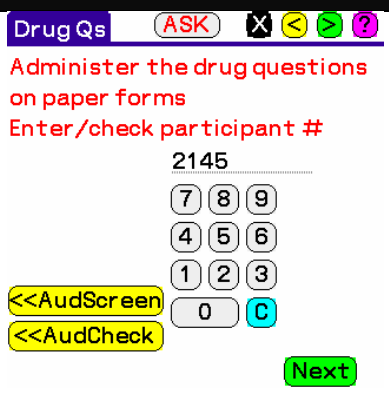
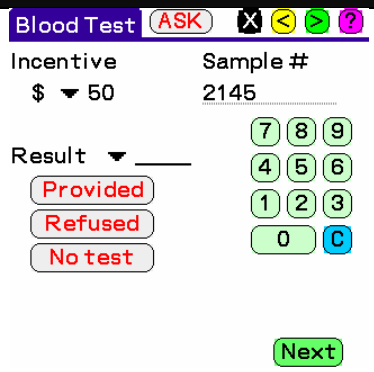
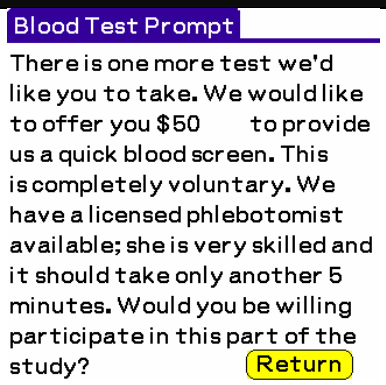
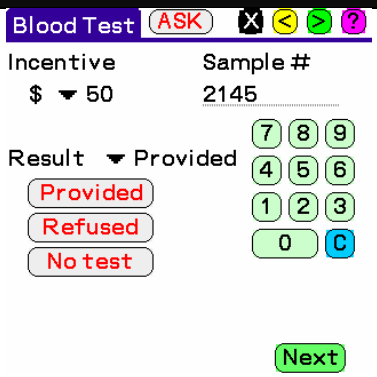


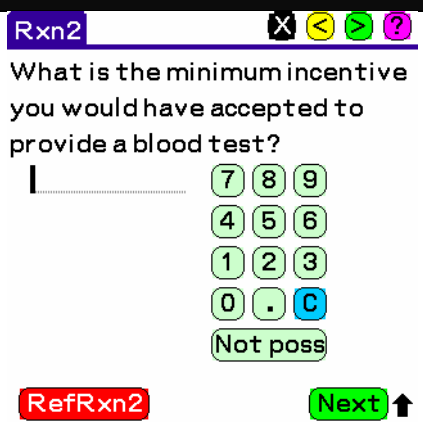


The <<AudCheck button on the AudAbuse1 screen allows you to review the answers to the three screening questions.

The AudCheck screen (accessible from the AudAbuse1 and Drug Qs screens) shows the combinations of answers that result in skipping the rest of the Audit questions. With this set of responses (drinks 2-3 times/week, 5-6 drinks per typical episode, and Monthly episodes of 6 or more drinks), the full Audit would be asked. The Skip> button will go to the Drug Qs screen and the Next button will go to the AudAbuse1 screen.


AudAbuse2
In the past year, did you more than once get into a situation while drinking or after drinking that increased your chances of getting hurt--like driving a car or other vehicle or using heavy machinery after having had too much to drink?
Yes
No
N/A
RefAB2
Next
AudAbuse3
In the past year, did you get arrested, held at a police station, or have legal problems because of your drinking?
Yes
No
N/A
RefAB3
Next
AudAbuse4
In the past year, did you continue to drink even though it was causing you trouble with your family or friends?
Yes
No
N/A
RefAB4
Next
AudDep1
In the past year, have you found that you have to drink more than you once did to get the the effect you want?
Yes
No
N/A
RefDep1
Next
AudDep2
In the past year, did you find that your usual number of drinks had less effect on you than it once did?
Yes
No
N/A
RefDep2
Next
AudDep3
In the past year, did you more than once want to try to stop or cut down on your drinking, but you couldn't do it?
Yes
No
N/A
RefDep3
Next
AudDep4
In the past year, did you end up drinking more or drinking for a longer period than you intended?
Yes
No
N/A
RefDep4
Next
AudDep5
In the past year, did you give up or cut down on activities that were important to you or gave you pleasure in order to drink?
Yes
No
N/A
RefDep5
Next
AudDep6
RefDep6
In the past year, when the effects of alcohol were wearing off, did you experience some of the bad after effects of drinking--like trouble sleeping, feeling nervous, restless, anxious, sweating, or shaking, or did you have seizures or sense things that weren't really there?
Yes
No
N/A
Next

		
		After the Audit questions, administer the paper and pencil survey about drug use. If the Sample # was entered on the Oral Fluid screen, it will reappear here as the participant #. Because this screen is the target after skipping the Audit questions, the yellow buttons in the lower left can be used to jump back.
		
If the Sample #/Participant # was entered on the Oral Fluid screen or the Drug Qs screen, it will reappear on the Blood Test screen. The default incentive for the Blood Test is $50, but can be changed.	When asking the driver about the blood test, be clear that you are asking for a sample. A suggestion that we are asking them to donate blood, which implies a pint of blood, is likely to evoke a refusal.	In most cases, if you get to the point of asking for a blood sample, the only answer on the Blood Test screen that needs to be filled in is the Result—Provided, Refused, or No test.

<table>
<tr>
<td> 
</td>
<td> 
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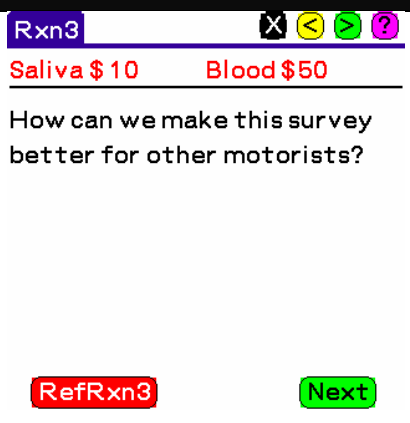
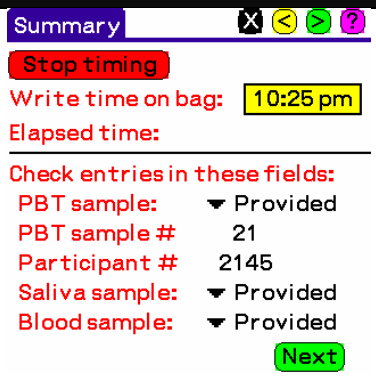
<td> 
</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Most people will not have anything to suggest in response to this question. If they do, write it on a piece of paper and identify it with a participant number.</td>
</tr>
<tr>
<td> 
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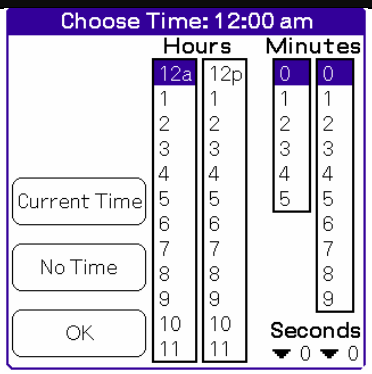
<td> 
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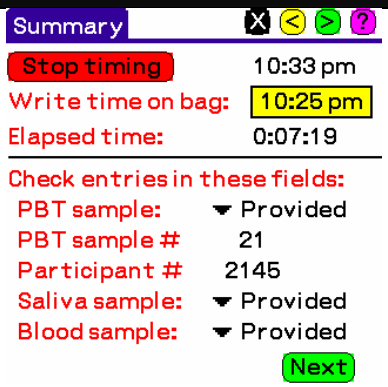
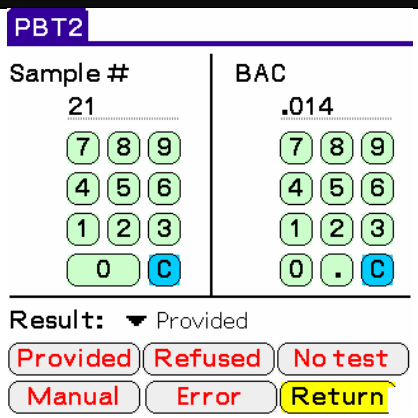
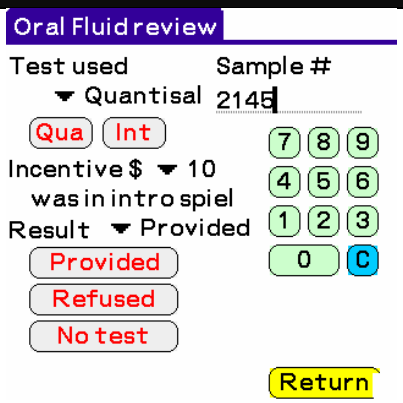
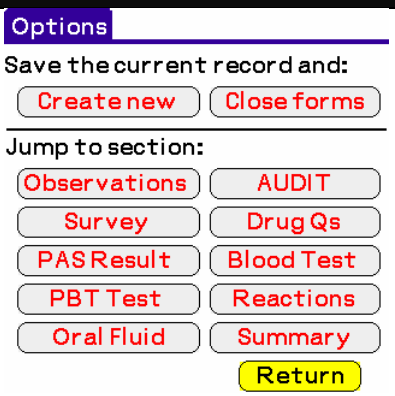
<td> 
</td>
</tr>
<tr>
<td>After finishing Rxn3, release the driver. On the summary screen, tap the Stop timing button and ...</td>
<td>...then the Current Time button on the Choose Time screen.</td>
<td>The ending time will then appear on the screen as well as the elapsed time of the survey. If any data is missing from the 5 fields below the line, it should be entered now. Three fields have options for popup menus; tapping on the answers for PBT sample # or Participant # will bring up the PBT2 screen or the Oral Fluid review screen, respectively.</td>
</tr>
</table>

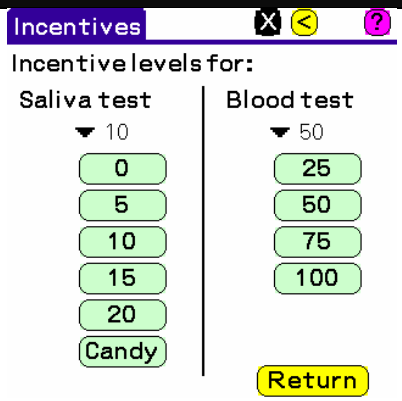






The PBT2 screen is also used as the target of the BAC button on the RSx screens. Tapping on the Return button will go back to the previous screen.

The Options screen is the last screen in the survey. It is also available from any other screen by tapping the white X button. When data entry on a driver is complete, save the record and create a new record or go back to table view by closing the forms. To access a section of the record, tap on the appropriate button. Tapping on the Return button will take you back to whatever screen this was accessed from.



Defaults for monetary incentives are set at $10 for the oral fluid sample, and $50 for the blood test. The defaults can be adjusted on the Oral Fluid and Blood Test screen respectively.; as well as by tapping on the default values appearing at the top of the Obs screen and displaying the Incentives screen. Changing the defaults works only for the current record and needs to be done for each record.

Appendix G
National Roadside Survey Pilot Test
Portable Breath Alcohol Tester (PBT) Specifications

FEATURES AND BENEFITS

The PA-400 uses an ethanol specific electrochemical sensor that operates in conjunction with a precision, electronically controlled pump. The pump draws a breath sample into the sample chamber where it is read by an electrochemical sensor that analyzes the sample for ethanol. A microprocessor controls all internal aspects of the sampling process. The sensors sample at a point where the deepest lung air is being blown out. The deep lung air best correlates to the person's actual blood alcohol concentration. Thus, this is why the sensors take the sample upon a drop in blow volume (the subject is running out of air).

The PA-400 sensors record the date, time, sample number, and the BAC results of all samples in an internal memory computer chip. With the configuration software that comes with these breath test devices, one can either allow the BAC result to display or the display can be turned off. In most research surveys, the BAC is not displayed so as to keep this information out of the hands of any law enforcement in the area where the survey is being conducted. Only the Field Supervisor has the authority and ability to turn the display on or off. The roadside surveys to take place in Tennessee will have the display turned on since the researchers are working with the police who have agreed to allow the researchers find safe transportation home for any driver who has a BAC of .050 or higher.

TECHNICAL SPECIFICATIONS

Product Name	Intoxilyzer 400PA
Function	On-the-spot measurement of breath alcohol concentration.
Alcohol Sensor	Electrochemical fuel cell
Instrument Control	By microcontroller
RF Interference	Case is impregnated with RFI shielding material for RFI protection
Calibration	Secure calibration using either dry gas or wet bath simulator
Accuracy	±.005 BrAC up to .100 BrAC and ±5% above .100 BrAC, which meets DOT specifications
Specificity	Fuel cell sensor is unaffected by acetone, paint and glue fumes, foods, confections, methane, and practically any other substance found in the human breath
Breath Sample	Automatic after the subject blows for 4-6 seconds.
Display	Four-digit LCD
Visual Indicator	Four LED lights indicate status (Wait, Ready, Flow, Analyzing)
Audible Indicator	Beeper signals fault conditions and changes in instrument status
Communications Port	Two-channel, RS-232 serial interface to printer or PC
Reset Time	Immediate at zero alcohol reading, up to two minutes after a positive breath test. Within five seconds of sampling, depending on alcohol concentration
Power Supply	Five AA alkaline batteries (included)
Memory Function	Stores 500 test results including date and time. Recalls last breath test even if instrument has been switched off and back on. Stored tests can be downloaded to the printer or a PC
Recommended Operating Temperature	23° to 104°F (-5° to 40°C)
Dimensions	3¼" wide x 1¾" deep x 6¾" high (sensor) (8.3 cm wide x 4.4 cm deep x 17.1 cm high)
Weight	One pound (.45 kg)
Accessories	Data 400 software for downloading of results to a PC for data management and/or printing Online 400 software allows for factory customization to a wide range of testing protocols thermal or impact printer expanded memory to store up to 10,000 test results reusable sample cups rechargeable power unit 12-volt power supply
Included	Storage case Illustrated operator's manual Five mouthpieces
Warranty	One year, parts and labor

To Use the Portable Breath Tester (PBT):

1. Turn on the instrument using the large button on the upper left front of the instrument. The instrument performs a diagnostic test and displays the time and date. The sensor's WAIT (red) light will stay on briefly, and then the READY (green) light will come on. The sensor is now ready for the respondent to blow. The sample number

is displayed on the LED briefly after the last sample clears—the display will show the time, the date, and then the sample number (example: 0001)—and then the display will go blank. To recall the upcoming sample number simply press turn the unit off and on and watch for the sample number (the unit will take about 20 seconds to go through the diagnostic sequence and then display the sample number for a split second). Keep the sample number in mind.

2. Record the sample number on the questionnaire or into your PDA.

3. Prepare to take the sample by taking a sterile mouthpiece and opening it so as not to touch the end the respondent's lips will touch, leaving the plastic wrapper on. Insert the tiny "T" appendage into the sensor.

4. Instruct the respondent to take a deep breath and blow out slowly and steadily—as if blowing out candles on a birthday cake or blowing up a balloon.

5. Position the PA-400 so that the respondent can blow into the mouthpiece so that the breath will not strike you in the face. Ask the respondent to remove the plastic wrapper and place his/her lips around the end of the tube. Have the respondent take deep breath and blow, as stated above in #4.

6. The sensor will take the sample automatically, providing the subject blows correctly. The sample is taken when the subject's flow rate begins to drop; approximately 5 seconds.

7. When the respondent blows correctly, the FLOW (yellow) light will come on and you will hear a soft whining sound as the pump takes in the sample. Data Collectors must position the sensor so as to see the lights. When the sample is taken, the sensor's WAIT (red) along with the ANALYZING (orange) lights come on and you will hear a double beep (beep, beep). You must watch for these lights.

8. The display will begin to register a sample and if alcohol is present it should peak in about 20 seconds.

9. If the driver fails to blow long and steady enough, or blows in two or more different ways (such as blowing lightly followed by sucking in), the PA-400 should beep and go back to the READY (green) mode or it may stick and make a continuous beep. Pull the sensor away and re-instruct the driver on how to blow and again attempt to gather his/her breath sample.

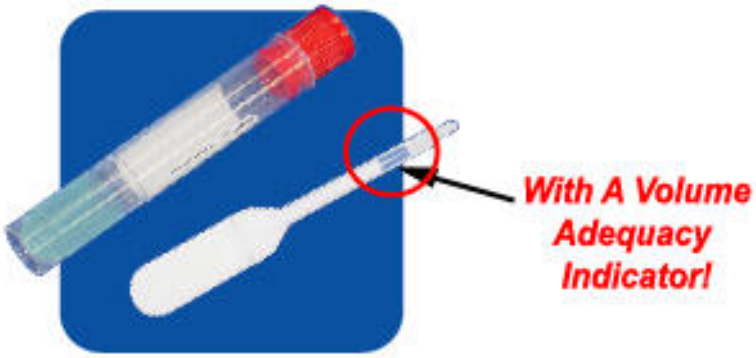
10. If the driver has asthma, a cold, or other respiratory problems that prevents providing enough breath for the PA-400 to sample automatically, you should attempt one, or maybe two, more times to take the sample automatically. Otherwise, ask the driver to blow one more time and take the sample manually. To take a manual sample, have the driver again blow into the tube and as the FLOW (yellow) light registers, hit the button labeled "Man." You must indicate if the sample was taken manually since such a sample does not reflect the deep lung air and likewise does not reflect the person's actual BAC level.

11. **Warning Indicators and Error Messages:** please refer to your owner's manual. The Data Collectors must tell the Field Supervisor if any warning sounds, lights or messages appear while using their PA-400

Appendix H
National Roadside Survey Pilot Test
Quantisal Oral Fluid Specifications

FEATURES AND BENEFITS

Quantisal™



The saliva sampler is intended for the collection and the transport of oral fluid for forensic and research purposes.

Collection: A saliva specimen is collected by placing a cellulose pad affixed to a polypropylene stem (Collector) under the tongue of an individual until a define volume of saliva has saturated the cellulose pad. The defined volume taken up by the cellulose pad is indicated by coloration (blue) in a window on the stem (volume adequacy).

Preservation: The collector is transferred into a provided polypropylene tube containing a preservative buffer. The tube is stopped with a provided cap. The specimen is ready for storage or transport.

Volume adequacy: The cellulose pad placed under the tongue for collection is extended into a cellulose tail accommodated in the interior of the polypropylene stem. Blue dye is placed on the cellulose tail below the window in the stem. Upon saturating the cellulose pad with specimen, aqueous medium migrates along the cellulose tail by capillary action and dissolves the dye. Upon further migration of liquid, the dye becomes visible in the window of the stem.

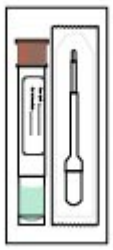
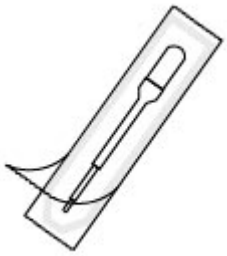
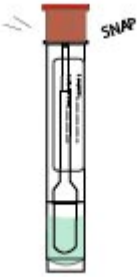
Materials provided:
a) Saliva collector with volume adequacy indicator.
b) Transport tube with snap cap. The tube contains 3 mL of buffer with non azide preservative.

INSTRUCTIONS
Warning do not put buffer fluid of transport tube into mouth.

1) Do not use device beyond expiration date printed on package.
2) Record patient information and collection date on tube label.
3) Remove collector from pouch.
4) Position collector under tongue. Close mouth. DO NOT CHEW OR SUCK ON PAD! Do not move pad during collection.
5) The collector should remain under tongue until indicator turns completely blue. Blue color indicates collector is saturated with 1 ml of saliva. The collection time may take from 2 - 10 minutes. If the indicator has not turned blue within 15 minutes the pad should be removed from the mouth and discarded. Recollection with a new device may begin immediately but only after saliva has accumulated in the mouth. The collector may be place in the same position.
6) Open mouth and lift tongue. Remove collector from mouth.
7) Remove cap from transport tube. Insert the saturated collector into the tube. Do not place collector into mouth after it has been in the buffer liquid.
8) Carefully place cap over the top of the collector stem in tube. FORCEFULLY PUSH CAP DOWNWARD UNTIL CAP "SNAPS" FLUSH WITH TOP OF TUBE.
9) Mix saturated collector with buffer by gently shaking tube.
10) Ship saliva specimen to laboratory as soon as possible.

PERFORMANCE CHARACTERISTICS:

Saliva collection volume and collection time: The collection volume is 1 mL., with a variation of about 10 percent. It takes on an average about 3 minutes to collect this volume (n=302; first time users) The individual collection time may exceed 10 minutes (2 cases in 302)

INSTRUCTIONS FOR QUANTISAL		
		
	Peel open package and remove collector.	Place collector under the tongue and close mouth. When indicator window turns blue, remove collector from mouth.
		
Uncap transport tube in upright position and hold tube in hand. DO NOT STAND TUBE ON TABLE.	Insert collector into the uncapped transport tube.	SNAP CAP firmly for transport.

Appendix I
National Roadside Survey Pilot Test
Oral Fluid and Blood Analytic Procedures

Introduction

Within the criminal justice system, urine has traditionally been used as the biological specimen for analysis. However, there are numerous products available which are designed to render a urine drug test inaccurate (gluteraldehyde, oxidants, nitrites etc.) as well as simple dilution of the specimen by the donor, with tap or toilet water. Unless a collection is observed, the possibility of a diluted, adulterated or substituted urine specimen is increased. While laboratories are able to test for some of these adulterants, obviously further testing increases overall costs.

As a result, interest in an alternative specimen for testing has increased. Advancing technology has allowed laboratories to measure lower amounts of drug in biological specimens, allowing drug testing programs to incorporate the unique benefits offered by alternative biological fluids, at a comparable cost.

When drugs are ingested, smoked, or injected, they travel through the body, and over time, convert into drug metabolites, which are subsequently excreted from the body. The highest concentrations of these drugs and metabolites is in the urine, but they are also present in measurable quantities in blood, saliva, sweat, tears, hair and even finger and toenails. Improved instrumentation has allowed laboratories to measure drugs in these "alternative" matrices.

Due to its ease of collection, oral fluid has emerged as the specimen of choice to replace urine in many applications of testing for drugs of abuse

Advantages of Oral Fluid Testing

1. **Collection**
   Saliva is easy to collect, handle, transport and store. Since the collection is observed, the chance of adulteration or substitution of the sample is minimized, and there is no embarrassment or requirement for a same sex observer as there is with urine. The entire collection process is rapid, taking perhaps 2-3 minutes.

   Applications specifically based on ease of collection include:
   a) Criminal justice, parole and probation testing where often observed urine collection is required. There is no same sex observation requirement using saliva, and the dignity of the donor is preserved.
   b) Drug court, where a high number of specimens are often required to be collected, handled, and shipped in a short space of time.
   c) Staffing agencies, requiring a rapid specimen collection for pre-employment purposes.

2. **Adulteration**
   Since collection is observed, there is a limited opportunity for the donor to adulterate or substitute the sample. It is difficult to hold in the mouth anything which may affect the test for any length of time, particularly if engaged in conversation when filling out drug testing forms, providing personal information and interacting with the collector.
   In contrast to urine, the drug concentration in saliva is unaffected by liquid intake.

3. **Window of detection**

For most drugs, the detection time after use, using urine as the specimen, is approximately 2-4 days. *(Note: An exception is marijuana, where in some cases, chronic marijuana smokers can be detected up to 2-3 weeks after last use).*

For oral fluid, the detection window is generally shorter, although for some drugs it can approach 2 days, overlapping the urine window. The advantage of this is that very recent drug use can be detected by employing saliva as the test specimen. Since saliva is thought to reflect blood levels at a given time point, the presence of a parent drug (for example, cocaine) can be interpreted as an indication of being "under the influence" of cocaine at that specific time. It is generally not possible to interpret a urine test result as being "under the influence" of a drug, and this critical information would be lost using urine as the test specimen.

Applications specifically based on the ability of saliva to show a person to be "under the influence" of a drug include:

a) Probation and Parole settings, where using illegal drugs is a violation of parole
b) "Reasonable suspicion", "For cause" or "Post accident" testing, when there is an incident or a suspicious activity in the workplace, which may be due to drug or alcohol use
c) Methadone maintenance and pain management centers, requiring a rapid answer as to whether the individual recently ingested the prescription drug

4. **Profile of drugs**

The profile of drugs analyzed using saliva is somewhat wider, and considerably more useful than those in the standard urine panel.

- *Opiates:* Recent data has shown a very high prevalence of 6-acetylmorphine (a metabolite of heroin) in saliva specimens testing positively for morphine. The selection of oral fluid as the test specimen increases the opportunity of identifying heroin users. Under the urine program, 6-AM is not even tested for unless over 2000 ng/ml of morphine are present, severely reducing the number of heroin users identified by urinalysis.

- *Marijuana:* Marijuana metabolites take 3-6 hours after smoking to be detectable in urine. However, the active compound, tetrahydrocannabinol (THC) will be present almost immediately in saliva, likely due to its presence in the mouth following marijuana smoking, therefore very recent use can be identified.

- *Cocaine:* In urine testing, only a metabolite, benzoylecgonine is detectable using the SAMHSA guidelines. A positive urine finding gives no information on the state of the individual donor. In contrast, for oral fluid analysis, both parent cocaine and benzoylecgonine are identified. The presence of cocaine in the sample can be interpreted as very recent use of cocaine and possibly "under the influence" of the drug. The detection of benzoyecgonine lengthens the window of detection for cocaine use in saliva.

- *Amphetamines*: Under proposed guidelines for both urine and oral fluid, the inclusion of Ecstasy and its metabolite will be allowed in the amphetamine panel.

5. **Cost savings:**

The major cost saving in converting from urinalysis to oral fluid testing is in the collection:

- No same sex observers are required
- No special facilities or conditions are needed (for example, "blueing" agent in toilet water)
- The cost of specimen transport and storage is significantly reduced
- There are no added costs to determine "adulteration" of the specimen

- In workplace settings, there is a significant reduction in time wasted travelling to and from the collection site, since collections can be performed anywhere

6. "**On-site" tests**
   Oral fluid lends itself very well to "on-site" testing, in terms of obtaining a rapid result, with no requirement for skilled personnel or special facilities. Rapid tests have been reported to perform well for opiates, methadone, amphetamines, and to some extent, cocaine. However, the main problem with all "on-site" oral fluid tests at this time, is the difficulty of achieving the required sensitivity for marijuana testing.

   The proposed "cut-off" levels can be achieved using laboratory based testing, which also has the added advantages of improved quality control, confirmed results using GC/MS or MS/MS techniques and formal reporting.

Disadvantages of Oral Fluid Testing

Of course, nothing is perfect, and there are disadvantages to using oral fluid as a test specimen.

a) Collection Devices:

There are several variations in collection device and it has been reported that the method of collection influences the test result. Some devices consist of a pad attached to a stick (like a popsicle) which is placed into the mouth for a given time (e.g. Intercept ™). The saliva absorbs onto the pad and is then placed into a buffer for transport to the laboratory. The problem with this is that it is not known exactly how much oral fluid was actually collected, so there is a potential for erroneous results, most likely false negatives based on insufficient sample volume. Cut-off concentrations based on such a device are not relevant or applicable to other types of collectors.

Other devices (e.g. Quantisal™) have a blue volume indicator on the collector showing when 1 mL has been collected. This is an improvement over the Intercept™ collection system, however, both of these devices are then placed into a buffer for transportation, and it is difficult to determine precisely how much drug is eluted from the pad into the buffer.

Some manufacturers are now requiring donors to "spit in a cup" which is often not too pretty to observe!

b) Specimen Volume

A problem related to the type of device is the collection of adequate volume for screening and confirmation, particularly if more than one drug confirmation is required.
Generally, a much lower volume of saliva than urine is provided by a donor. This brings up the issues of re-testing of the specimen (in the event of a batch failure) and "split-sample" testing (when another laboratory is required to confirm the first result). An adequate volume of specimen is critical for a valid test. In some collection devices, drugs may absorb onto the collection pad, and it is not clear how much drug is removed from the pad by the buffer.

Some "on-site" screening tests require the collection of an additional specimen to be sent to the laboratory for confirmation, but the same issues regarding collection device are valid.

c) Federal Workplace Testing

The Division of Workplace Programs, within the Substance Abuse and Mental Health Service Administration (SAMHSA), has yet to approve any alternative specimens for federal workplace testing, but saliva, hair and sweat are currently under consideration for approval in workplace programs. Guidelines have been drafted and are in the process of implementation.

However, certified laboratories are currently offering oral fluid testing and carrying out its analysis under good laboratory practice conditions, including chain-of-custody, quality control, batch review and formal reporting requirements. There are accrediting agencies specifically inspecting oral fluid procedures, so that the quality of the result is ensured.

Summary

Oral fluid offers a simple, dignified, observed collection. It provides a relatively short history of drug use, therefore is an excellent specimen choice for **"reasonable suspicion**", "**post-accident**" or "**for cause**" testing, where identification of the parent drug shows that the donor was "under the influence" of the drug at the time the sample was taken. It is particularly useful for the identification of heroin users, and those under the influence of marijuana.

As oral fluid testing becomes more popular, the costs associated with its analysis are approaching those of urine, providing an excellent opportunity for drug testing programs to benefit from the analysis of alternate specimens.

Matrix	Advantages	Disadvantages
URINE	1) Most widely tested specimen 2) Drugs are generally in high concentration 3) Adequate volume for testing and re-testing by a second laboratory 4) Federal standard cut-offs, testing protocols and laboratory procedures exist	1) Easy to adulterate 2) Collection not observed 3) More costly for shipping and storage 4) No relationship between drug concentration and impairment
SALIVA	1) Easy to collect 2) Difficult to adulterate since collection is observed 3) Presence of parent drug shows "under the influence" 4) Useful for the detection of recent drug use 5) Useful for the identification of heroin users	1) Short drug history 2) Marijuana levels are low, and likely due to THC in the mouth following smoking 3) Specimen volume may be device dependent and is generally low 4) No standard cut-offs, testing or collection protocols, or laboratory procedures (yet !)

Standard Drug Confirmation Panel

Urine Profile	**Oral Fluid Profile**
Cocaine: Benzoylecgonine	**Cocaine**: Cocaine **and** benzoylecgonine
Opiates: • codeine • morphine (Note: Over 2000 ng/ml morphine then requires further testing for 6-acetylmorphine)	**Opiates**: • codeine • morphine • 6-acetylmorphine (heroin metabolite) • hydrocodone • hydromorphone • oxycodone
Amphetamines: • methamphetamine • amphetamine	Amphetamines: • methamphetamine • amphetamine • MDMA (Ecstasy) • MDA
Marijuana: Carboxy-THC	**Marijuana:** THC
Phencyclidine	**Phencyclidine**

Screening Assays

Oral Fluid

Sample Preparation

The oral fluid specimens were collected using a Quantisal™ collection device (Immunalysis, Pomona CA). When the absorbent collection pad had absorbed 1 mL of neat oral fluid (+-10%), a blue dye was visible in the indicator window on the plastic stem of the collection pad. The pad was placed in a polypropylene transport tube containing 3 mL of extraction buffer solution, capped and sent to the laboratory.

The sample volume of oral fluid used for screening was analyte dependent. The desired concentration range is shown below. An aliquot of the oral fluid + buffer was added to the micro-plate wells for analysis according to the manufacturer's instructions in the package insert (representative insert included). A specimen was considered to be presumptively positive if it screened higher than the cut-off concentrations.

Blood

Sample Preparation

The blood specimens were collected into gray top tubes and transported to the laboratory. Upon receipt the specimens were diluted 1:10 with bovine serum albumin.

The sample volume of diluted blood used for screening was analyte dependent. The desired concentration range is shown below. An aliquot of the diluted blood was added to the micro-plate wells for analysis according to the manufacturer's instructions in the package insert (representative insert included). A specimen was considered to be presumptively positive if it screened higher than the cut-off concentrations.

DOSE RESPONSE IN CONCENTRATION PER MICRO-WELL FOR ELISA

KIT	*Picograms / well*	*Analyte*
Amphetamine 209	50-150	d-amphetamine
Barbiturates 210	40-80	Secobarbital
Carisoprodol 231	5000	Carisoprodol
Benzodiazepines 214	40-80	Oxazepam
Benzoylecgonine 206	150-300	Benzoylecgonine
Cocaine/benzoylecgonine 212	200-300	Benzoylecgonine
Methamphetamine 211	50-150	d-methamphetamine
Morphine Specific 213	80-120	Morphine
Oxycodone 221B	150-250	Oxycodone
PCP 208	7.5-15	PCP
Cannabinoids 224	40 - 60	Carboxy-THC (l)
Cannabinoids 205	40-60	Carboxy-THC (l)
Methadone 232	100-200	Methadone (d,l)
Fluoxetine 234	750-1200	Fluoxetine
Sertraline 235	500 -1000	Sertraline
Tramadol 225	700-1200	Tramadol
Zolpidem 233	40-60	Zolpidem

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