Field Performance of Current Generation Breath-Alcohol Simulators

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Abstract

The between-run accuracy and reproducibility of vapor-alcohol control tests associated with quantitative evidential breath-alcohol testing in the field were evaluated. Control samples were generated at six separate sites with 34°C TOXITEST™ II breath-alcohol simulators and analyzed by infrared spectrometry with Model 5000-D Intoxilyzers in the recirculation mode. Control test results at target alcohol concentrations of 0.060, 0.080, 0.090, 0.100, 0.110, and 0.120 g/210 L ($n = 779$) were combined and analyzed by standard statistical methods. Results were correlated with target values, and the signed and absolute differences were calculated and analyzed. Data treatment included ANOVA, linear regression analysis, t statistics, and relative and cumulative frequency distributions of the differences. We found the performance of these current generation simulators in the field to be similarly satisfactory to that obtained in our laboratory evaluation. We further found that vapor-alcohol control samples generated with these devices conformed to established formal requirements and that they can serve as an effective quality assurance measure in evidential breath-alcohol analysis.

Introduction

The use of control samples is a well established practice in the quality assurance of chemical measurements (1). Use of control tests accompanying every subject test in quantitative evidential breath-alcohol testing was recommended in 1960 by Dubowski (2) and is one of the procedural controls recommended in 1968 by the National Safety Council's Committee on Alcohol and Other Drugs (3). State regulations governing evidential breath-alcohol testing for air and ground traffic law enforcement in Oklahoma (4) and many other jurisdictions also mandate performance of control tests in association with every subject test.

The vapor produced by equilibration of alcohol[1] between water and air at controlled temperature, using a breath-alcohol simulator, is an appropriate sample for control tests with breath-alcohol analyzers (5). The characteristics and performance of simulators and the validity of control test results are, therefore,

of widespread interest and import. We recently reported results of a laboratory evaluation of current generation commercial breath-alcohol simulators and concluded that these devices can be satisfactorily used to calibrate breath-alcohol analyzers and for control tests (6). We now present findings and conclusions from field experience in the use of such simulators in association with current generation automated quantitative evidential breath-alcohol analyzers for traffic law enforcement purposes in Oklahoma. This information is also pertinent for other jurisdictions which use the same or comparable apparatus.

Experimental

Vapor-alcohol analysis. The alcohol concentration of vapor-alcohol control samples was measured by infrared spectrometry at six locations with six Model 5000-D Intoxilyzers (CMI, Inc.) with the Oklahoma software package. The analyzers were calibrated to indicate alcohol concentrations in g/210 L and were operated in the recirculating simulator mode. Control test results to three decimal places were stored in the respective instrument memories. The analyzers were linked to a central location by telephone lines and modem devices. Data were periodically collected from the instruments by computerized data retrieval using the ADAMS program (CMI, Inc.) and were verified by comparison with the written entries on logs of tests at each testing site. Prior to their field placement, all analyzers and simulators were extensively bench-tested in our laboratory and were found to be acceptably calibrated and to perform within established tolerances.

The evidential breath-alcohol analysis protocol in use in Oklahoma with the Model 5000-D Intoxilyzer includes the following steps: air blank, breath test 1, air blank, 2-minute interval, air blank, breath test 2, air blank, control test, air blank. For forensic purposes in Oklahoma, breath and vapor-alcohol analysis results are reported to two decimal places, truncated.

Vapor-alcohol control samples. Vapor-alcohol samples were generated with production models of the 34°C TOXITEST™ II Alcoholic Breath Simulator (CMI, Inc.) used in association with each alcohol analyzer. These simulators are designed for and were used with a 0.5-L alcohol solution volume and at 34°C operating temperature, with verified factory settings. Under Oklahoma State

Table I. Simulator Control Test Results

Target value, g/210 L	Number of		Control Test Result, g/210 L					
	Tests	Sites	Mean	SD	CV (%)	Median	Mode	Span
0.060	21	1	0.064	0.0018	2.81	0.064	0.064	0.061–0.069
0.080	49	3	0.080	0.0032	4.00	0.080	0.082	0.075–0.089
0.090	183	4	0.091	0.0026	2.89	0.091	0.091	0.082–0.098
0.100	306	6	0.100	0.0027	2.70	0.100	0.100	0.094–0.110
0.110	71	1	0.110	0.0018	1.63	0.110	0.110	0.103–0.113
0.120	149	4	0.118	0.0045	3.87	0.118	0.116	0.110–0.130

Table II. Paired Sample Differences* for the Combined Simulator Alcohol Control Tests (n = 779)

Parameter	Difference, g/210 L				
	Mean	SD	Median	Mode	Span
Signed difference	0	0.0032	0	0	–0.010 to +0.010
Absolute difference	0.002	0.0021	0.002	0.001	0 to 0.010

*Control Test Target Value minus Result

Figure 1. Relative frequency distribution of signed vapor-alcohol concentration differences (target value minus control test result).

Simulator solutions. Simulators were charged with 0.5 L of alcohol solutions prepared and verified to yield vapor-alcohol concentrations of 0.060, 0.080, 0.090, 0.100, 0.110, or 0.120 g/210 L at 34°C as previously described (6). Control test target values were established by independent gas chromatographic headspace analysis of the ethanol solutions in two separate forensic laboratories. Such verified simulator solutions are distributed to points of use in Oklahoma in ready-to-use form in sealed containers labeled with the certified nominal control test value.

Statistical analyses. Statistical examination and data analysis were carried out by standard statistical methods (8,9) by using STATGRAPHICS Version 5 (1991) software (Statistical Graphics Corp.) with a microcomputer for both descriptive statistics and significance testing.

Results

Accuracy and precision of control tests on simulator-generated vapor samples.

The principal underlying experimental data yielded by the study are summarized in Table I for each of the six control test target values, along with their descriptive statistics. The data shown are the combined results from analyzer-simulator combinations at several separate sites, except for those at the 0.060 and 0.110 g/210 L target values which were obtained from single sites.

Best fit linear regression analysis of the six simulator control test results *means* upon their respective control test target values yielded the following equation, where x = control test target value, g/210 L, y = control test result, g/210 L, and r = Pearson correlation coefficient for the regression:

$$y = 0.984x + 0.0015 \tag{1}$$
$$r = 0.999$$

Differences between simulator test target values and vapor-alcohol measurements

The paired-sample differences (control test target concentration minus result) for the combined simulator alcohol control tests (n = 779) are summarized in Table II for both signed and absolute differences, together with the corresponding descriptive statistics. The sign test for the 779 differences yielded 308 positive differences, 352 negative differences, and 119 tied pairs.

Figure 1 is a histogram of relative frequency distributions of the 779 signed differences with normal curve overlay, and Figure 2 shows the cumulative frequency distribution of those differences. For the data shown in Figure 1, skewness = 0.037 and kurtosis = 0.407, both small departures from a perfectly symmetrical distribution. The span for 90% of the actual signed differences was –0.005 to 0.005 g/210 L and for 99% was –0.009 to 0.009 g/210L.

One-sample statistical analysis (ANOVA) of the difference between the paired alcohol-vapor target values and results yielded a computed t statistic of –1.58 (778 d.f.). At $p = 0.05$, the null hypothesis that the analytical bias of the control analyses equals zero was, therefore, retained.
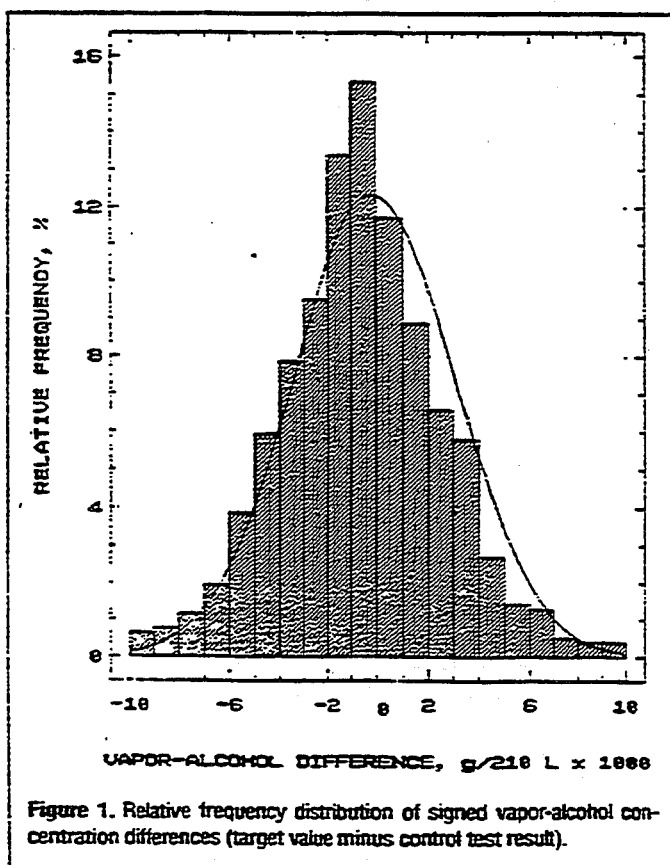
regulations, analyzers and simulators are required to be inspected and serviced by a state-licensed breath-alcohol test supervisor, after the earlier of 25 evidential breath-alcohol analyses or 30 days, at which time new alcohol solution is installed.

Gas chromatography. Alcohol in simulator solutions was analyzed by automated gas chromatographic headspace analysis with a model F-45 vapor space chromatograph (Perkin-Elmer Corp.) as previously described (7).
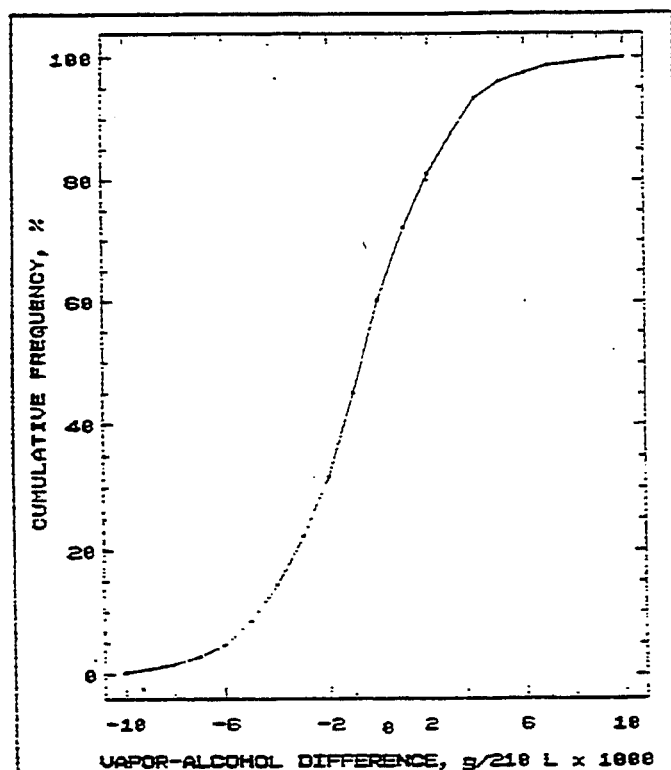
Figure 2. Cumulative frequency distribution of signed vapor-alcohol concentration differences (target value minus control test result).

alcohol control tests performed in the field with TOXITEST™ II simulators were as a class highly accurate and had good reproducibility. The results summarized in Table II are pertinent to the ±0.01 g/210 L maximum acceptable difference between target value and control test result mentioned above. Every experimental result conformed to that criterion. Further. the mean. median. and mode of the signed differences were close to zero. and these differences are essentially Gaussian in distribution. as shown in Figure 1 and by the small negative skewness and kurtosis values. The mean. median. and mode of the absolute differences were also close to zero. and the differences were positively skewed (skewness = 1.08) with a preponderance of lower values.

We conclude from these findings that the field performance of current generation commercial breath-alcohol simulators as control-test devices parallels and approximates that found in our laboratory studies and that these devices can amply meet control-test requirements for quantitative evidential breath-alcohol testing.

Acknowledgments

Discussion

To be useful and valid for quality assurance in the present context. control tests must yield consistent. predictable results when properly carried out on validated control specimens and must allow ready determination of whether the tested analyzer is performing within preestablished specifications. The results reported herein demonstrate that the underlying simulator control tests meet those requirements. The National Safety Council's Committee on Alcohol and Other Drugs has recommended that the results of control analyses for vapor-alcohol should agree with the sample value within ±0.01 g/210 L (3). Oklahoma State regulations governing evidential breath-alcohol testing also require the results of a control analysis to be within ±0.01 g/210 L of the corresponding vapor-alcohol concentration target value (4). Every simulator control test result for alcohol in this series met both of those acceptability criteria.

The control test results reported herein are. of course. pooled between-run results obtained in the field over a period of several months with six different simulators and six different alcohol analyzers. In contrast. the accuracy (systematic error limit) and precision requirements of the federal NHTSA model specifications for calibrating units for breath-alcohol testers. i.e.. target-test agreement within 2% and a CV not exceeding 2% at a target alcohol concentration of 0.10 g/210 L. apply only to within-run results for a single tested device (10). In our prior laboratory evaluation. the TOXITEST II simulator met those NHTSA model specifications criteria (6). The simulators used in this study also met that NHTSA accuracy requirement. even with these between-run field test results. at the only NHTSA-specified target vapor-alcohol concentration occurring in this study. 0.10 g/210L.

The data summarized in the tables document that the vapor-

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