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The First Seven Years (1991-1998) Of the FAA's Postmortem Forensic Toxicology Proficiency-Testing Program

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16. Abstract

Postmortem biosamples from the victims of aviation accidents are submitted to the Civil Aeromedical Institute (CAMI) for forensic toxicology, wherein acquiring accurate and authentic analytical data is the primary objective. Adherence to quality assurance/quality control (QA/QC) procedures is essential to achieve that objective, and proficiency-testing (PT) is an integral part of QA/QC of laboratories. However, there was previously no suitable PT program that could address the complexity of forensic toxicology. Existing PT programs do not include decomposed samples and solid tissues, and the majority of aviation (and to some extent, even medical examiner and coroner) case samples are putrid and of multiple types. Therefore, CAMI in July 1991 started such a needed PT program. This program is used to (i) professionally develop and maintain technical currency on a voluntary, interlaboratory, and self-evaluation basis and (ii) quantifiably assess methods in the absence and presence of interfering substances. There are currently about 30 laboratories in the program, including CAMI's Toxicology and Accident Research Laboratory. Functioning under various governmental/non-governmental agencies and academic institutions, these laboratories represent a broad cross-section of the country. PT samples are distributed quarterly, and result summaries are sent to the participants, while maintaining their anonymity. Since the inception of the program, 28 PT samples encompassing whole blood, plasma, urine, kidney, or liver, with (or without) drugs and common chemicals (nicotine, caffeine, ß-phenylethylamine, etc.) have been evaluated by the participants. Analytical findings were generally consistent with the anticipated values, but they were dependent on the nature and conditions of the specimens and types of the added analytes. Some incidences of false positives of concern were noted, as well. This is a nationally recognized PT program: It is one of the few programs recommended by the American Board of Forensic Toxicology in which laboratories may participate for their accreditation by the Board. Although participation in this program is currently free of charge, it has a potential for commercialization through the private sector. Whether the program is in the private or public sector, it will continue to play a critical part in supporting the QA/QC component of forensic toxicology, thereby enhancing operational performance.

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The First Seven Years (1991-1998) of the FAA's Postmortem Forensic Toxicology Proficiency-Testing Program

INTRODUCTION

During fatal aircraft accident investigations, postmortem biosamples collected from the victims at autopsy are submitted to the Federal Aviation Administration's (FAA's) Civil Aeromedical Institute (CAMI) for forensic toxicological evaluation (Public Law, 1988). In forensic toxicology, acquiring accurate analytical data is the main objective to seek the chemical basis for the cause of accident (or death). Strict adherence to quality assurance/quality control (QA/QC) procedures is essential to achieve that objective, and external proficiency-testing (PT) programs are independent, effective ways to authenticate such internal QA/QC procedures of laboratories (Sohn, 1977; Walberg, 1977; Field, 1981; Schaller et al., 1991). These PT programs are instrumental for the laboratories to scientifically achieve their primary objective of acquiring accurate analytical data on biological evidence. Participation in such programs allows laboratories to withstand the professional and judicial scrutiny of analytical results, and thus, be able to validate their performance. Although there have been several external proficiency programs for drug analysis, none of them was specifically designed for postmortem forensic toxicology. They mainly focus on clinical toxicology and forensic testing of drugs of abuse, including alcohol (Boone et al., 1977; Flores and Moulden, 1977; Sohn, 1977; Walberg, 1977; NIDA 1988; Osselton et al., 1990). These programs have been utilizing preserved plasma, serum, urine, and/or occasionally, blood samples: They do not include tissues and/or putrid samples. The majority of those programs encompass only specific groups of certain drugs, or volatiles, in only one type of biological fluid. Therefore, there was a critical scientific need for a program that could realistically address analytical issues and accommodate challenges encountered in postmortem forensic toxicology situations (Bost, 1990).

The principal function of a forensic toxicology laboratory is to analyze any available postmortem tissue samples or bodily fluids, but many such samples are in an advanced stage of decomposition. Decomposed biosamples are common not only with aviation accident cases but also with medical examiner/coroner cases. Being primarily responsible for the toxicological analysis of postmortem aviation specimens (Public Law, 1988), CAMI initiated the needed PT program in 1991. This program is tailored for drug analysis in different types of preserved and decomposed biological samples. This initiative was taken with a view that the PT program will permit CAMI and the participating laboratories to evaluate proficiency of postmortem forensic toxicology testing and, thereby, assess methods of analysis applicable to the discipline. Initially, laboratories that had prior professional contacts with CAMI were invited to participate in the program. Later, this program was announced in two toxicology newsletters (Chaturvedi, 1991a, b) and in the 1991 Meeting of the American Academy of Forensic Sciences in Anaheim, CA. Consequently, additional laboratories joined the program, making it fully functional in July 1991. Since then, about 30 laboratories, including CAMI's Toxicology and Accident Research Laboratory, have been participating in this program. In this report, details of the FAA's Civil Aeromedical Institute (CAMI) postmortem forensic toxicology PT program and findings of the PT surveys during its first seven years are summarized.

GENERAL DESCRIPTION

In the program, biological samples containing (or not containing) drug(s) are submitted to the participating laboratories for analysis on a quarterly basis, i.e., in January, April, July, and October. These samples may also contain possible primary metabolite(s) of the drug(s) and/or other chemical entities—for example, caffeine, nicotine, β-phenylethylamine, tryptamine, etc.—frequently encountered in postmortem forensic samples to give an appearance of a "true" specimen. However, there are not more than 5 analytes in any given survey specimen. Analytes included in the program are volatiles, controlled substances—such as amphetamines,

cannabinoids, cocaine, opiates, and phencyclidine—and prevalently used prescription/nonprescription medications. Types of biological samples intended for inclusion in this program are serum, plasma, whole blood, urine, and tissues, though the former 2 types are not generally preferred. As is the situation with the majority of the aviation accident fatalities and medical examiner/coroner cases, serum/plasma cannot be easily obtained from decomposed bodies. To represent PT samples as "true" blind postmortem specimens, case histories are not provided with their submissions. A particular PT sample consists of only a single type of biological specimen, and the turnaround for reporting the analytical results is 4-5 weeks. It is anticipated that participants take routine necessary precautions during the handling of biological specimens and properly discard the samples after the completion of the analysis. Types of specimens and of analytes and their concentrations for a particular PT sample are selected on the basis of (i) current analytical and toxicological issues, (ii) problematic topics and analytes mentioned in the literature, (iii) inputs from the participants and other forensic toxicologists, (iv) CAMI forensic toxicology analytical and aircraft accident research findings, (v) drugs prevalent in the general population and their relevance to aviation, and (vi) general trends of the use of various categories/types of drugs.

Participating laboratories have an option to conduct qualitative or quantitative analysis, using their standard analytical procedures for the presence of only those analytes routinely identified in a given specimen type in their setups or to defer the analysis of a particular sample because of any other reasons. However, it was anticipated that the analytical report sheets would be received from the participants, regardless of the inclusion or exclusion of analysis results. Receiving responses from them assures that they received, and responded to, a particular PT sample. The anonymity of participating laboratories is strictly maintained.

In the shipping carton along with the specimen, there are an instruction sheet, a blank analytical report sheet, an inner confidential-report envelope, an outer mailing return-envelope, and an attention sheet with a business reply label. The participants are requested to send the empty shipping box back, using the enclosed business reply label. Analytical report enclosures have no identification code numbers related to the participants. After completing the analysis, the participants record the analytical findings on the analytical report sheet, place the sheet in the inner envelope, and seal it. They then return the inner envelope in the pre-addressed, postage-paid outer envelope. The outer envelopes are opened by a different, assigned person than the inner envelopes. Furthermore, the inner, as well as the outer, envelopes are discarded and, thus, are not retained in the records. Such a methodical process ensures minimizing the establishment of a possible link between the analytical report (data) and its originating laboratory.

Participation in this program is on a voluntary basis and is presently free of charge. Participation can be discontinued at any time if a participant chooses to do so; however, at least a 4-week notice is desired. Commitment to the activities under this program does not imply endorsement of any functions or capabilities of either the participating laboratories or CAMI's Laboratory.

MATERIALS AND METHODS

Materials

Human urine is either obtained from commercial sources or collected from volunteers; human whole blood, plasma, and serum are supplied by a local blood bank. Commercial human urine is drug-free. It is determined and certified by the supplier to be "drug-free," based on immunoassay screening techniques. Other matrices are screened in CAMI's Laboratory to rule out the presence of commonly used drugs, and those determined to contain drugs are not used for the preparation of PT challenges. Tissues are purchased from local slaughterhouses. Tissue homogenates are not subjected to drug screening. Drugs, metabolites, and chemicals are obtained from Sigma Chemical Co., St. Louis, MO; Alltech-Applied Sciences, State College, PA; and/or any other suitable commercial sources.

Sample Preparation

Urine, plasma, serum, and blood need no initial preparation prior to adding measured amounts of analytes. However, tissues are weighed, cut into small pieces, homogenized in deionized water in a large Waring blender, and then analytes are added, mixed, and allowed to equilibrate for at least 24 hours. The final tissue homogenate mixture generally contains 1 g of tissue per 3 mL of homogenate (1:3 w/v). Sometimes, putrefaction processes are initiated in the

samples by keeping them at ambient temperature for selected periods. To some specimens, putrefactive agents are added. Stock solutions of analytes in desired concentrations are prepared in appropriate solvents.

Sample Distribution

Blood (plasma or serum) samples in 2 (or 3) x ≈7.5-mL portions are shipped in 10-mL glass tubes. Tubes are placed into Styrofoam holders (2 or 3 tubes/holder). Urine or homogenate samples in ≈70-mL quantities are sent in 100-mL plastic bottles. Each sample is shipped with frozen gel bags in an insulated box to every participant by an air courier service for next-day delivery; samples are hand-delivered to CAMI's Laboratory on the day following shipment.

Result Summaries

After receiving the analytical report sheets from the participants, the results are compiled, tabulated, and statistically analyzed; summaries are prepared and distributed to all participants. This process takes approximately 4 weeks. Each summary provides the participants with the information related to the results of a particular PT survey. The summary includes analyte weighed-in amounts; qualitative and quantitative analytical respondent percentages; individual results of all participants, along with types of analytical methods used; and range of the reported quantitative results for analytes of interest, with mean and standard deviation (SD_x) values. If sufficient data are available, related histograms and Shewhart charts are also included. Analytical values that are clearly determined to be outliers are excluded from the statistical analysis. Results in the summary are without identification of their specific laboratories of origin. If necessary, participants' remarks, a brief description of the sample preparation method, and relevant comments, are incorporated in the summary.

RESULTS

The PT program participants represent a broad cross-section of the country, and consist of laboratories functioning under various county, city, state, and federal governmental agencies. Non-governmental commercial organizations and educational institutions are also included in the participating laboratories (Fig. 1). Two federal, 22 other governmental

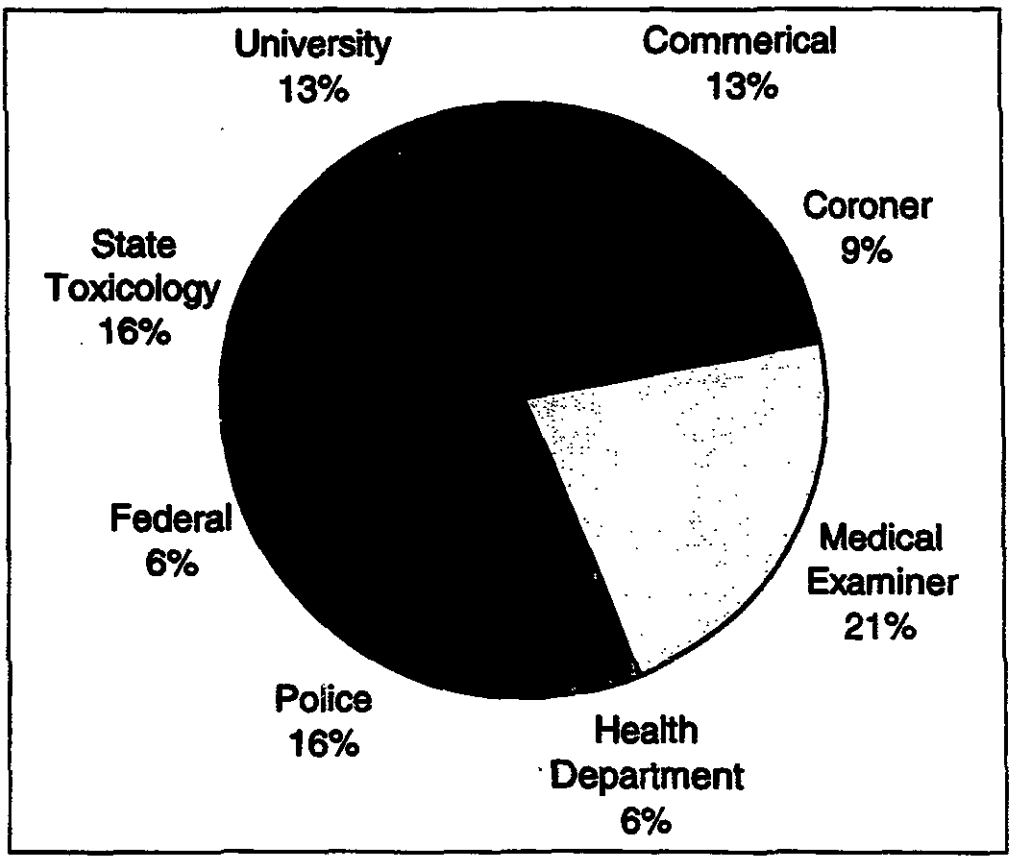

FIG. 1—*Types of laboratories participating in CAMI's PT program.*

entity, 5 commercial, and 3 university laboratories are now part of the PT program. Out of these, 16% do only antemortem toxicology; the remaining laboratories also perform postmortem toxicology. At the program's inception, there were only 21 participants, but this number subsequently increased to 34, and it is now 32 (Fig. 2). Two laboratories discontinued their participation because of an increase in workload and/or change in mission. No attempts were made to enlist more laboratories in the program. During the 1991-1998 covered period, the average of the number of participants was 33.

As is summarized in Table 1, various types of specimens with or without exogenous analytes were submitted to the participating laboratories. Analytes included in the surveys were abused drugs, prescription and non-prescription drugs, and common substances (e.g., caffeine, nicotine, and ethanol), covering a wide range of pharmacological agents, from mood altering to those used to cure diseases and to lose weight. Other substances, like putrefactive bases and methanol, were also included. Out of the total of 28 samples, there were 1 plasma, 8 whole blood, 13 urine, 1 kidney, and 5 liver specimens submitted for the surveys. Twenty-one percent of the samples were without added analytes and/or contained only non-reportable analytes, such as low amounts of caffeine or nicotine.

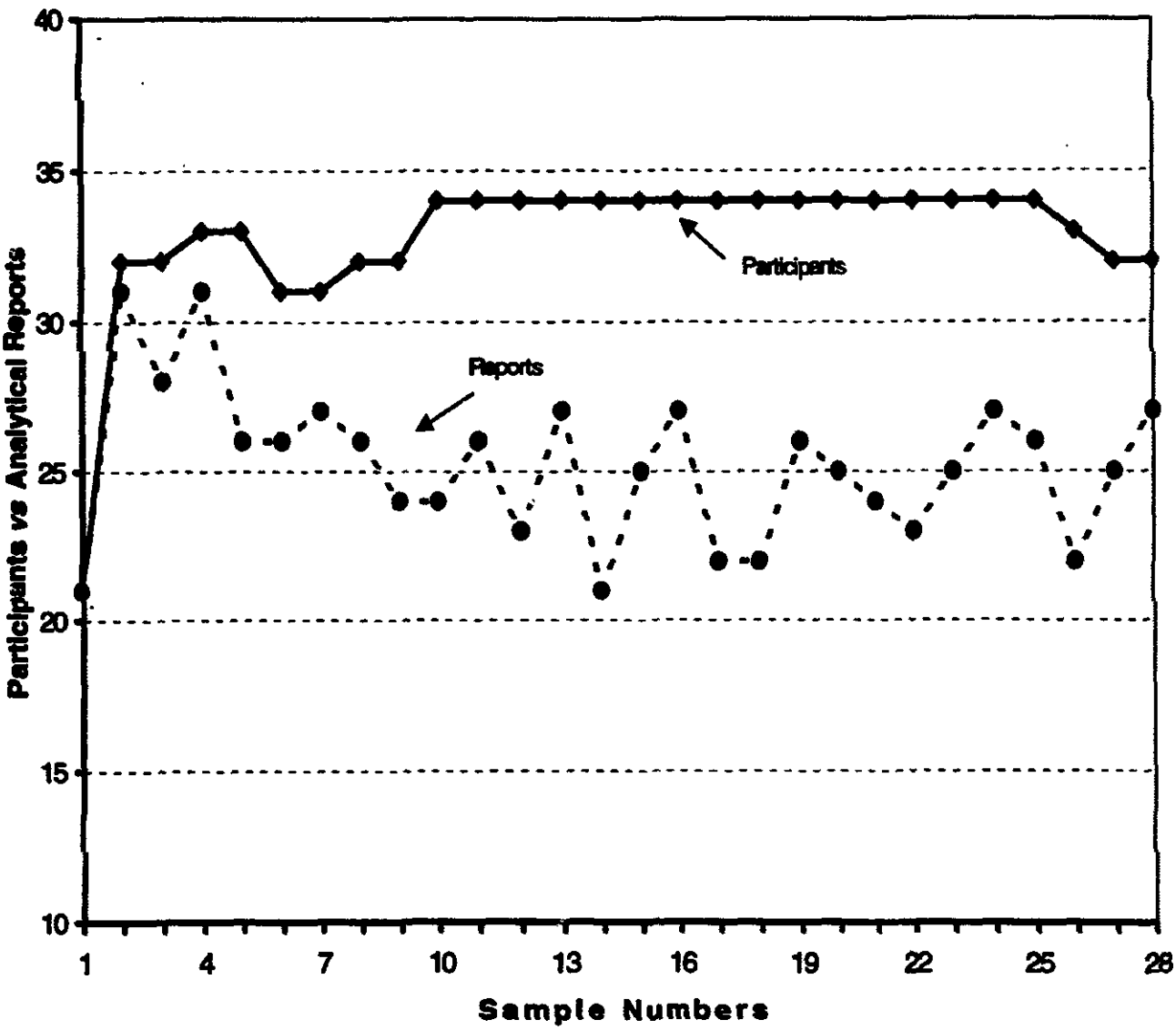

FIG. 2—*Numbers of participants and of analytical reports received from the participating laboratories during the first 7 years of the PT program.*

TABLE 1—*PT sample description and participants' analytical responses.*

Sample No.	Specimen Type	Analytes' Weighed-in Concentration	Respondents' Analyses Details			Participants/ Analytical Reports Received	False Positives of Concern (Number of Laboratories)
			Mean (SD_R) Concentration*	% Values within $2SD_R$	Qualitative (only)/ Quantitative		
1	Human Urine	*d*-Amphetamine (1.44 µg/mL)	1.28 (0.23)	90.9	10/11	21/21	
		Phencyclidine (59.1 ng/mL)	61.3 (13.1)	90.9	6/11		
2	Human Plasma	Codeine (800 ng/mL)	831 (197)	94.4	9/18	32/31	
		Morphine (68 ng/mL)	68.3 (14.3)	93.8	2/16		
		Ethanol (amount undetermined)	58.7 (4.8)	100	0/20		
3	Putrefied Human Blood	*d*-Amphetamine (0.58 µg/mL)	0.47 (0.28)	100	1/5	32/28	
		β-Phenylethylamine† (12.4 µg/mL)	---	---	---		
4	Human Urine	THC-COOH (61 ng/mL)	62 (16)	100	9/9	33/31	
		Phencyclidine (21 ng/mL)	25 (4)	87.5	6/8		
		Methanol (47.9 mg/dL)	46.2 (4.1)	100	4/6		
		Pseudoephedrine (0.89 µg/mL)	0.98§	---	9/1		
5	Putrefied Swine Liver Homogenate	Caffeine‡ (1.6 µg/mL)	---	---	---	33/26	Cocaine & Phencyclidine (1)
		Cotinine‡ (0.23 µg/mL)	---	---	---		
		Nicotine‡ (2.1 µg/mL)	---	---	---		
		β-Phenylethylamine† (3.3 µg/mL)	---	---	---		
6	Human Blood	THC (10.0 ng/mL)	9.0; 10.6§	---	1/2	31/26	
		THC-COOH (30.6 ng/mL)	32.3 (3.3)	100	0/4		
		Ethanol (79.0 mg/dL)	76.8 (4.3)	100	0/20		
		Methanol (24.0 mg/dL)	24.2 (3.0)	85.7	2/7		

TABLE 1—*PT sample description and participants' analytical responses (Continued).*

Sample No.	Specimen Type	Analytes' Weighed-in Concentration	Respondents' Analyses Details			Participants/ Analytical Reports Received	False Positives of Concern (Number of Laboratories)
			Mean (SD_n) Concentration*	% Values within $2SD_n$	Qualitative (only)/ Quantitative		
7	Human Urine	Morph. . (71.1 ng/mL)	128.3 (72.6)	100	2/3	31/27	
		Cocaine (49.5 ng/mL)	60.3 (24.1)	100	8/8		
		Benzoylecgonine (197.9 ng/mL)	206.9 (28.9)	90.9	4/11		
		Ethanol (63.1 mg/dL)	61.2 (5.0)	89.5	2/19		
8	Swine Kidney Homogenate	*d*-Amphetamine (1.1 µg/mL)	1.9 (1.5)	100	3/5	32/26	
		Phencyclidine (0.24 µg/mL)	0.24 (0.21)	91.7	4/12		
9	Human Urine	Quinidine (65.2 µg/mL)	63.7 (8.5)	100	9/6	32/24	
		Salicylic Acid (199.9 µg/mL)	242.0 (35.4)	100	4/5		
10	Human Blood	Procainamide (10.1 µg/mL)	9.5 (2.0)	100	7/6	34/24	
		N-Acetylprocainamide (15.6 µg/mL)	14.1 (3.3)	100	2/6		
		Ethanol (110.0 mg/dL)	102.7 (11.5)	95.7	0/23		
11	Human Urine	Ephedrine (1.02 µg/mL)	1.1§	---	11/1	34/26	Phenobarbital (1)
		Phenytoin (5.14 µg/mL)	5.8 (1.0)	100	15/5		
		β-Phenylethylamine† (0.13 µg/mL)	---	---	---		
12	Human Blood	Acetaminophen (15.0 µg/mL)	14.5 (0.7)	100	3/3	34/23	
		Ethanol (160.0 mg/dL)	150.4 (5.2)	100	1/21		
		d-Propoxyphene (270 ng/mL)	260 (80)	100	3/6		
		d-Norpropoxyphene (330 ng/mL)	320 (100)	100	7/10		
13	Human Urine	No Substance	---	---	---	34/27	
14	Swine Liver Homogenate	No Substance	---	---	---	34/21	Phenobarbital (1)

TABLE 1—*PT sample description and participants' analytical responses (Continued).*

Sample No.	Specimen Type	Analytes' Weighed-in Concentration	Respondents' Analyses Details			Participants/ Analytical Reports Received	False Positives of Concern (Number of Laboratories)
			Mean (SD_n) Concentration*	% Values within $2SD_n$	Qualitative (only)/ Quantitative		
15	Human Urine	Ethanol (50.0 mg/dL)	46.3 (9.7)	100	1/14	34/25	Benzodiazepines (1)
		Morphine (7.9 µg/mL)	8.1 (1.1)	100	17/6		Cocaine (1)
		Morphine-3-glucuronide (20.2 µg/mL)	---	---	---		
		Total Morphine (20.4 µg/mL)	20.0 (1.4)	100	0/6		
16	Human Blood	Cocaine (464 ng/mL)	332 (73)	100	11/14	34/27	
		Benzoylecgonine (743 ng/mL)	788 (124)	100	5/13		
		Phencyclidine (96 ng/mL)	83 (12)	91.7	7/12		
		Ethanol (50.6 mg/dL)	49.1 (4.3)	85.7	1/21		
17	Human Urine	Cotinine‡ (0.27 µg/mL)	---	---	---	34/22	Lidocaine & Ketamine
		Nicotine‡ (2.09 µg/mL)	---	---	---		
		Methanol (47.2 mg/dL)	49.4 (4.6)	90	1/10		
		Salicylic Acid (145.9 µg/mL)	176.6 (14.3)	100	3/3		
		THC-COOH (61 ng/mL)	61 (2.3)	88.9	5/9		
18	Swine Liver Homogenate	Quinidine (3.9 µg/mL)	0.73; 1.4; 0.96§	---	2/3	34/22	Barbital (1)
		β-Phenylethylamine† (6.0 µg/mL)	---	---	---		Cocaine (1)
19	Human Urine	Ethanol (31.6 mg/dL)	32.5 (5.8)	88.3	2/17	34/26	
		Methanol (111.4 mg/dL)	113.8 (9.7)	92.3	1/13		
		Quinidine (59.2 µg/mL)	65.0 (21.9)	100	14/5		
		THC-COOH (102 ng/mL)	78 (20)	87.5	6/8		
20	Human Blood	Isopropanol† (70.0 mg/dL)	62.4 (4.7)	92.3	6/13	34/25	THC (1)
		Phenobarbital (24.9 µg/mL)	24.1 (7.0)	100	9/13		Mephobarbital (2)
		Phenytoin (19.7 µg/mL)	16.0 (3.9)	100	8/11		

TABLE 1—*PT sample description and participants' analytical responses (Continued).*

Sample No.	Specimen Type	Analytes' Weighed-in Concentration	Respondents' Analyses Details			Participants/ Analytical Reports Received	False Positives of Concern (Number of Laboratories)
			Mean (SD_n) Concentration*	% Values within $2SD_n$	Qualitative (only)/ Quantitative		
21	Human Urine	Caffeine‡ (5.16 µg/mL)	---	---	---	34/24	Phenytoin (1)
		Cotinine‡ (0.39 µg/mL)	---	---	---		
		Nicotine‡ (2.89 µg/mL)	---	---	---		
		β-Phenylethylamine† (3.0 µg/mL)	---	---	---		
22	Swine Liver Homogenate	Verapamil (0.34 µg/mL)	0.27 (0.07)	100	2/6	34/23	
		Norverapamil (0.48 µg/mL)	0.49 (0.08)	100	3/3		
23	Human Urine	Fenfluramine (49.1 µg/mL)	34.4 (7.7)	100	12/5	34/2.	LSD (1)
		Phentermine (49.6 µg/mL)	44.6 (8.3)	100	18/5		
24	Human Blood	No substance	---	---	---	34/27	
25	Human Urine	Ethanol (63.2 mg/dL)	66.1 (6.2)	95	0/20	34/26	
		Oxazepam (79.2 ng/mL)	90§	---	1/1		
		THC (15 ng/mL)	1§	---	2/1		
		THC-COOH (100 ng/mL)	76.1 (22.7)	100	7/11		
26	Swine Liver Homogenate	No substance	---	---	---	33/22	p-Methoxy-amphetamine & Nitrazepam (1) Phentermine (1)
27	Human Blood	*d*-Amphetamine (10 ng/mL)	10§	---	1/1	32/25	Phentermine (2)
		l-Methamphetamine (104 ng/mL)	80; 110§	---	2/2		Methaqualone (1)
		β-Phenylethylamine† (10.0 µg/mL)	---	---	---		

TABLE 1—*PT sample description and participants' analytical responses (Continued).*

Sample No.	Specimen Type	Analytes' Weighed-in Concentration	Respondents' Analyses Details			Participants/ Analytical Reports Received	False Positives of Concern (Number of Laboratories)
			Mean (SD_a) Concentration*	% Values within $2SD_a$	Qualitative (only)/ Quantitative		
28	Human Urine	Atenolol (100.8 µg/mL)	---	---	6/0	32/27	
		Ethanol (70.8 mg/dL)	62.7 (5.9)	88	0/17		
		Fentanyl (25.0 ng/mL)	23.9 (1.6)	100	5/3		
		Oxazepam (30.0 ng/mL)	37.0§	---	2/1		

*Concentration units are the same, as are listed in the corresponding rows of the table's preceding column (No. 3).

†A putrefactive base not commonly reported in postmortem toxicology cases.

§No statistical calculation—single or limited value(s).

‡At this concentration, not considered of toxicological significance. Therefore, laboratories generally do not report this substance.

†Fifteen laboratories reported the presence of acetone, which could have been attributed to the *in vitro* biotransformation of isopropanol to acetone.

In general, analytical reports were returned within the window of the given time frame, but reports were not received from all participants. Average response for the analytical report-return was 77% (SD_n: 10). With the initial 4 PT surveys, report-return response was close to 95%, but it subsequently decreased and stabilized at around 70% with some degree of fluctuation (Fig. 2). Since anonymity of the participants and of their results is strictly maintained, it was not possible to determine whether the remaining reports were or were not received from the same participants every time, or from different participants. Analytical responses were dependent on the nature and conditions of the specimens and types of analytes—for example, ethanol in urine was correctly quantitated by the majority of participants, whereas amphetamine and methamphetamine levels in blood were reported by only a few of the participants. Some incidences of false positives of concern were noted: They were primarily associated with drugs of abuse. In relation to the qualitative analysis, more participants quantitatively analyzed those analytes whose analysis is routinely carried out in toxicology setups—for example, ethanol, cocaine, morphine, and THC-COOH.

DISCUSSION

PT programs play a critical part in the QA/QC component of laboratories (Sohn, 1977; Walberg, 1977; Field, 1981; Suro and Thomas, 1997), and the CAMI PT program is a timely, suitable program for the field of postmortem toxicology. The suitability of this program is clearly evident by its acceptance as one of the recommended programs by the American Board of Forensic Toxicology (ABFT) Laboratory Accreditation Program, wherein successful participation in a PT program is required for the laboratories to be accredited by the Board (ABFT, 1996). Such inclusion of the PT program is based on the report of the joint Forensic Laboratory Guidelines Committee of the Society of Forensic Toxicologists, Inc., and the American Academy of Forensic Sciences, Inc., and on the additional recommendations of the Guidelines and ABFT's Accreditation committees. The national nature of the CAMI program is further supported by the fact that its participants are from different parts of the country, having a broad national geographic coverage and representing a wide spectrum of the nation's laboratory system.

The CAMI's PT program is currently the only program that addresses the postmortem laboratory practice and entails the analysis of "true" postmortem samples. It routinely provides materials of postmortem nature as a challenge—for example, tissue homogenates are not simple matrices and do require a specific and appropriate analytical approach. Because postmortem toxicology services need such types of challenges as a means of measuring their performance, it is essential that such a program continue to provide these challenges, to which the postmortem forensic industry has access.

Findings from the PT surveys further supported the fact that qualitative and quantitative analytical responses are dependent on the nature and conditions of specimens and the types of analytes. Naturally, they are also dependent upon the common usage of the drugs and related medicolegal implications. Quantitative values were in remarkably good agreement with the respective target concentrations. In the majority of the cases, the values were within 20% of the weighed-in amounts of the analytes and/or within 2 SD_n of the means of the reported values, excluding any evident outliers, such as values with decimal errors. On a few occasions, the presence of some analytes not added in a particular sample was reported. Those analytes could be construed as false positives and be of concern, particularly if they are controlled substances; however, finding those chemical substances might be genuine, as they might be originally present in the matrix used for the preparation of a PT challenge. Although blood and urine used for the sample preparation are initially screened for the presence of commonly used drugs, the screening methods may not rule out the presence of those drugs if they are present in amounts below the detectable limits of the assays. Other drugs, which cannot be screened by the employed methods, may also be present in the blood and urine, and veterinary drugs might be present in the animal tissue homogenate samples. In addition, macromolecules of animal origin in the tissue homogenates might interfere with antibody-based screening methods, thereby leading to false positives. Therefore, laboratories may occasionally, and even correctly, find analytes other than those added during the preparation of the PT samples. Of course, such findings should be correctly supported by the analytical results obtained following the participating laboratories' standard operating

procedures, including the possible re-analysis of the sample. The genuine presence of those analytes can also be deduced by the evaluation of the analytical results of other participants tabulated in the analytical summary reports. Obviously, if several participants found the particular analyte(s), then it could be concluded as "true positive(s)," otherwise it may be viewed as an isolated incidence.

This program permits the FAA and the participating laboratories to evaluate proficiency for forensic toxicology testing and assess methods of analysis applicable to the field. This PT program does not fulfill any regulatory and/or certification requirements, but it allows for (i) the professional development and maintenance of technical currency on a voluntary, interlaboratory, and self-evaluative basis, and (ii) the quantifiable assessment of methods in the presence and absence of interfering postmortem substances. Indeed, it serves as an independent tool for the FAA to monitor its internal forensic toxicology proficiency in relation to the outside forensic toxicology laboratories. Although the laboratories are presently not charged any fee for their participation in the PT program, all participants, including the FAA, mutually and effectively share scientific and technical information that reflects the proficiency in bioanalytical practices.

In view of its origin, nature, field, and scope, this program can be referred to as the FAA's Postmortem Forensic Toxicology Proficiency-Testing Program. Administered by the FAA's Civil Aeromedical Institute (CAMI), this program has two components: goods and service. The preparation of samples and their distribution, including necessary instructions, come under the goods category, while the collection of analytical report sheets, compilation, tabulation, and analyzation of results, and preparation and distribution of result summaries fall under the service category. Having a potential for being registered under both of the categories, this program could be registered as "FAA's CAMI PFT-PT Program" with the trademark (™) to cover the goods activity, as well as with the service mark (℠) to cover the service activity. The registration would be achieved following the agency's proper procedures in coordination with the FAA's Office of Research and Technology Applications. After the registration, the program could be turned over to a qualified licensee in the private sector, with some degree of the FAA's oversight to guarantee and maintain the program's quality; or, it may continue to be administered by CAMI. Whether the program is in the private or public sector, it will remain an effective, flexible, practical, and applicable instrument for measuring the performance of forensic toxicology operations and enhancing efficiency. A QA/QC program must be effectively implemented and maintained in order to withstand professional and judicial scrutiny of analytical results. To achieve that goal, PT programs are crucial.

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