

What should be behind a quality toxicology report?

Outline of content

Presented: December 3, 2013 by Peter Stout, Ph.D., D-ABFT

Introduction –

Peter Stout

Dr. Peter Stout, a senior research forensic scientist in the Center for Forensic Sciences (CFS) at RTI International, has more than 15 years of experience in forensic urine drug testing, postmortem toxicology, and human performance testing laboratories. Dr. Stout earned a Ph.D in Toxicology from the University of Colorado and is a Diplomate of the American Board of Forensic Toxicology (ABFT). He began his career as a Navy officer and technical director of one of the Navy's drug testing laboratories. After separating from active duty, he became a laboratory director for a commercial laboratory providing full service forensic toxicology and forensic chemistry services. At RTI, he has served as the project leader for the Pilot Oral Fluid Performance Testing Program and as key personnel for the National Laboratory Certification Program (NLCP). He is currently a senior scientist and key staff member for the National Institute of Justice (NIJ)-funded Forensic Technology Center of Excellence. The purpose of the center is to facilitate technology transfer and adoption in the forensic sciences. Dr. Stout is a laboratory inspector for the NLCP; and for the ABFT. He serves on the North Carolina Forensic Science Advisory Board and is currently the president elect of the Society of Forensic Toxicologists.

Goals

Understanding that recent changes in the interpretation of rule 702 in North Carolina have created potential challenges in the determination of quality scientific evidence and expertise, the goal of this presentation is to provide the perspective of a forensic toxicologist about what we as scientists view as the nature of forensic toxicology. It is too complex in a short presentation to address what are the specific methods and processes acceptable in the forensic toxicology community and how error rates and maintenance and control programs should function. Rather, the presentation will focus on those institutions and resources specific to forensic toxicology that help define acceptable credentialing and best practices.

Three basic areas will be covered:

1. The tools viewed as current and archaic.
2. Issues of credentialing specific to forensic toxicology. Specifically, issues of accreditation and certification and what are the programs and institutions specific to forensic toxicology.
3. Where best practice information originates in forensic toxicology.

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Forensic Toxicology as a discipline and its tools

Toxicology is the study of the adverse effects of drugs and chemicals on biological systems. **Forensic toxicology** deals with the application of toxicology to cases and issues where those adverse effects have administrative or medicolegal consequences, and where the results are likely to be used in court.

Forensic toxicology is a modern science, based on published and widely accepted scientific methods and practices, for both analysis of drugs in biological materials, and interpretation of those results.

Forensic Toxicology typically is viewed to encompass three major areas

1. **Workplace drug testing** – such as urine based drug screening for illicit drug use. Though, this area has come to also involve testing of medical personnel and more complicated testing. This is largely testing conducted by commercial companies. For scale in 2009, about 5.5 million samples were run under Federal guidelines and an estimated 50 million workplace samples in total.
2. **Human performance testing** – is largely the testing and interpretation alcohol and its involvement in driving. Drugs and other potentially impairing substances have become an increasing part of this testing. This is the testing that is most dominant in the classical crime laboratory institution. For scale, in 2009, about 700,000 toxicology requests were reported nationally in the 411 publically funded crime laboratories
3. **Postmortem toxicology** – is the testing and interpretation of drugs and toxicants involved in deaths. This type of testing is conducted in a variety of laboratory types, but is largely in association with medicolegal death investigation institutions (medical examiners and coroners). For scale, in 2004 about 1 million cases were referred to ME's and coroners of that probably about 700,000 had toxicology work done.

Forensic Toxicology most typically involves testing conducted as a two stage workflow. Classically, this has been referred to as a **Screen**, a low cost, easily automated, less specific test to isolate potentially positive samples from negatives and a **Confirmation**, a more specific, complex sensitive test to specifically identify and quantify target analytes. Newer, more specific, sensitive and rapid instrumentation has altered the workflow concept, but the essential nature of two separate tests from the original sample material is still relevant for ensuring proper sample identification.

The major analytical tools used in forensic toxicology are in three major categories:

1. **Immunoassays** – many different technologies are used, but all are based on competitive binding and interaction with antibody based recognition mechanisms. They are classically used as screening techniques and provide useful identification of classes of compounds.
2. **Chromatography** – Gas chromatography and liquid chromatography are the workhorses. These techniques are based on the separation of chemical components in a sample based on physical

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characteristics of the target analytes. Rarely now are chromatographic techniques used in isolation except for headspace alcohol analysis and occasionally as a screening technique. Almost always chromatography is used in association with a mass spectrometry method.

3. **Mass spectrometry** – these techniques allow for the specific identification of molecular structures based on the measurement of molecular mass. Some techniques allow for unique fragmentation and additional structural information to be identified. MS is almost always used in conjunction with a chromatographic method (e.g. GC-MS or LC-MS). Multiple stage MS is becoming ever more dominant (MS/MS) and allows for greater sensitivity and specificity.

While not necessarily incorrect, a variety of technologies that have been historically used are not viewed as sufficient technologies currently. These are techniques that may be seen in analyses and may be appropriate in some circumstances, but should be viewed more critically.

1. Thin Layer Chromatography (TLC)
2. Chromatography without mass spectrometry (e.g. GC with flame ionization detection, or nitrogen-phosphorous detection, LC with a diode array detector). The most notable exception to this is the common use of GC-FID for headspace alcohol testing.
3. UV and visible light spectrometry. A notable exception here is the common use of this for the determination of Carbon Monoxide.
4. Color spot tests or color reaction tests.

Credentialing

As with all professions, forensic toxicology has accreditation and certification issues specific to the discipline. As with all forensic disciplines, the lack of a national framework for accreditation of laboratories and certification of personnel has created a patchwork landscape of voluntary credentialing. While most publically funded crime laboratories are accredited, the appropriateness and completeness of this accreditation for forensic toxicology is mixed. A substantial portion of forensic toxicology work is conducted outside of the classical crime laboratory making the accreditation and certification landscape additionally complex.

Certification

Certification in forensic toxicology is almost entirely voluntary. There are a few state licensure programs nationally and in North Carolina, analysts in the state crime laboratory are required to be certified.

The dominant board for forensic toxicology certification is the American Board of Forensic Toxicology. Diplomates are PhD level practitioners with experience that sit for the board exam. This board distinction does not distinguish sub specialties. The Board has begun more specialized levels and certification for non-PhD personnel.

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Due to questionable practices by some boards such as the American Board of Forensic Examiners (an Advisory Board under the American College of Forensic Examiners Institute (ACFEI)), the Forensic Specialties Accreditation Board (FSAB) was formed to accredit the boards. This is much like the Medical Specialties Accreditation Board. ABFT is recognized under this accreditation system. There is currently a push among certification boards to seek recognition under ISO 17024.

Unique to North Carolina, the analysts in the state crime lab system are largely certified by the Forensic Toxicology Certification Board (FTCB). This board is not recognized under the FSAB. Within the last few weeks, ABFT and FTCB have announced signing a letter of intention to merge the two boards and consolidate the FTCB with ABFT. This would presumably bring individuals certified by FTCB under the recognition of FSAB.

Accreditation

Multiple accreditation efforts apply within toxicology and depending on the type of testing being conducted some accreditations are more appropriate than others.

Workplace drug testing: The National Laboratory Certification Program (or NLCP) oversees Federally regulated workplace testing (approximately 10% of the total testing). Various state programs cover some components outside of this. Parole and probation testing, which often looks much like workplace testing may fall under CLIA accreditation depending on the reimbursement by Medicare/Medicaid for this testing.

Crime laboratory accreditations: (ASCLD-LAB legacy program, ASCLD-LAB International program, A2LA, ANSI-FQS are the dominant entities) Various groups offer ISO 17025 recognition which is the closest ISO guidance pertinent to crime lab testing. There is a push currently to have accrediting entities seek recognition under ISO 17011.

Post mortem and human performance testing:

1. ABFT has a laboratory accreditation program covering this type of testing.
2. Clinical Laboratory Improvement Act (CLIA) accreditation is often seen in commercial, hospital and university labs that conduct toxicology work. It has some bearing on forensic work but is also an imperfect fit. This is a Federal Act, but authority is delegated to the States and is managed at the State level. As mentioned above, parole and probation testing has some impacts in some states from this accreditation.
3. College of American Pathologists (CAP) Some laboratories, particularly more post mortem oriented laboratories choose this program. Like CLIA it is more clinically oriented, CAP work with the ISO 15189 standard (a clinical relative of ISO 17025) and some laboratories see this as a better fit for toxicology laboratories than ISO 17025.

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Proficiency testing

Proficiency testing is the practice of subjecting laboratories to constructed test samples with the goal of comparing laboratory performance between laboratories and against the ideal targets for the test material. The vast majority of proficiency testing is referred to as “open”, or the laboratory know the samples are a test, but not what the results should be. Some programs also include “blind” tests, or samples that are submitted to the laboratory in a manner identical to unknown samples. In other words the laboratory is blind to both the result and the identity.

Proficiency testing is perhaps the single most powerful tool to assess a laboratory’s proficiency. Ideally, a laboratory should have a regular PT for every compound and matrix being reported. Realistically, these are very difficult programs to run and participate in.

Best Practices

Forensic Toxicology benefits over other forensic disciplines from its roots being in the wider community of toxicology and analytical chemistry. As such, there is a **vast** literature fed by the pharmaceutical industry, medical practice and environmental industry. There are quite literally thousands of journals pertinent to this discipline and tens of thousands of relevant journal articles. However there is a drawback. Because the practice of Forensic Toxicology is applied and specialized, those articles that are most pertinent to the direct practice are not as attractive to the larger, higher impact journals. The journals that are the most relevant to forensic toxicology are much lower impact. For instance, the Journal of Forensic Sciences, the official journal of the American Academy of Forensic Sciences typically has an impact factor <2. Clinical Chemistry, more focused on clinical rather than forensic, has among the highest ratings (at ~6) of relevant journals.

Probably the most relevant Journals to Forensic Toxicology are:

1. Journal of Analytical Toxicology
2. Forensic Science International
3. Journal of Forensic Sciences
4. Journal of Legal Medicine
5. Clinical Chemistry
6. Journal of Chromatography B

The **Scientific Working Group on Forensic Toxicology (SWGTOX)** is perhaps the most pertinent group for promulgation of best practice standards. While SWGTOX is a relatively new organization, the functions it has been doing have been performed as committees within the Society of Forensic Toxicologists (SOFT) for many years.

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Part of best practices in forensic toxicology and much of what SWGTOX has been working on are practices that address the Daubert prongs of error rate and maintenance and control. "Validation" in forensic toxicology refers to the evaluation of methods prior to their being used in production. The goal is to understand general aspects of a methodology appropriate for its use. Things such as limits of detection and linearity, potential interference, sources of error and carryover should be understood prior to implementation of a method.

Strong quality assurance and quality control programs are essential to the ongoing understanding of the performance of a method. This should include continuous evaluation of control performance and programs designed to recognize potential problems at a level prior to their affecting reported results.

Summary

Forensic Toxicology is a complex discipline. Unfortunately the current circumstance of inconsistent standards and oversight systems complicates the assessment of quality scientific information. Because a laboratory is accredited, does not mean that the accreditation is relevant to the type of testing being reported. Because a laboratory is not accredited does not necessarily mean the results are inappropriate. Similarly for certification of individuals the presence or lack of certification does not guarantee appropriateness of the individual.

Having some understanding of the institutions and resources that are accepted by the forensic toxicology scientific community can help to provide a framework for critical examination of specific circumstances.