SAMHSA Scientific and Technical Review – Hair Testing
May 11-13, 2016
Meeting Report

Narrative Summary

Background

Since the inception of urine workplace drug testing in the mid-1980s, the Department of Health and Human Services (HHS) has maintained an ongoing interest in improving and expanding the Federal Workplace Drug Testing Program by incorporating promising technologies and considering alternate specimens for testing. The Substance Abuse and Mental Health Services Administration (SAMHSA), an HHS agency, has maintained an open dialogue with the scientific and drug-testing communities resulting in periodic technical modifications to the program and the proposed incorporation of alternative testing specimens such as oral fluids and hair. In August of 2015, SAMHSA's Drug Testing Advisory Board (DTAB) recommended that SAMHSA pursue hair as an alternative testing specimen with the caveats that "…performance standards that sufficiently address external contamination and hair color impact…" be established before use of the specimen in Federal programs. In December of 2015, Congress passed, and the President signed, the Fix America's Surface Transportation (FAST) Act. Provisions of that Act permit the use of hair as a testing specimen for commercial motor vehicle operators regulated by the Department of Transportation. Additionally, the FAST Act requires the Secretary of DHHS to issue "scientific and technical guidelines for hair testing as a method of detecting the use of controlled substances for purposes of section 31306 of title 49, United States Code" [The DOT drug/alcohol program regulations for Commercial Motor Vehicles].

Consistent with on-going interests to improve the program, and to comply with FAST Act and DTAB recommendations, SAMHSA convened a Scientific and Technical Review Meeting (2016 S&T Meeting) of 20 scientists with expertise in hair testing on May 11-13, 2016. The group included hair testing researchers, laboratory practitioners and laboratory directors; a Medical Review Officer (MRO); and toxicologists familiar with workplace drug testing regulations, programs, technologies, specimens, and policies.

The purpose of the 2016 S&T meeting was to critically review the current state-of-the-science and technology concerning hair drug testing and the utility of hair as a specimen for use in Federal programs. Favorable opinions were reached on a number of programmatic, scientific, and technical testing issues that are essential elements of an effective workplace drug testing program using hair. These issues included:

- Basic collection parameters
- Chain of custody
- A requirement that specimens be both screened and, if positive, confirmed
- The need to embrace new screening technologies
- The need for MRO review of results
- The need for laboratory certification
- The need for an ongoing performance testing (PT) program
- The need for SAMHSA oversight.

However, there were also a number of unresolved issues among the experts that currently limit the appropriateness of hair testing for federally regulated programs.

This review highlights the areas of concern expressed in the 2015 DTAB recommendation and those identified in the 2016 S&T meeting. A summary of the meeting conclusions regarding critical issues in hair testing is presented below.

Hair Color and Hair Treatments

The impact of hair color on hair drug testing results was identified in SAMHSA'S 2004 Guidelines for Proposed Alternative Specimens as "a major concern." The impact of hair color was also identified by the DTAB in their recommendation as an unresolved issue in hair drug testing. It has been shown that both natural hair color and hair treatments may affect drug disposition in hair. A donor's natural hair color cannot be reliably determined by simple observation because of the use of hair coloring, bleaching, and other treatment products. An individual's natural hair color is determined by its melanin content. There are two types of melanin: eumelanin and pheomelanin. Eumelanin concentrations are higher in black hair and lower in red hair. Conversely, pheomelanin concentrations are highest in red hair and lower in black hair. Melanin is absent in white hair.

Historically, controlled clinical and animal studies have established that hair color influences the amount of drug incorporation into hair especially those drugs that maybe

classified "chemically" as weakly basic (e.g. codeine, cocaine, amphetamine). Also, *in vitro* studies in which black, brown, and blond hair were placed in a solution of cocaine showed the highest concentration in black hair and the least in blond. In contrast, population studies have not demonstrated a significant association between hair color, or race, and drug presence.

During the 2016 S&T meeting, experts reached certain conclusions about the impact of hair color and treatments on drug concentrations in hair. The use of chemical products such as bleach, straighteners, and relaxers confound the assessment of natural color, damage the hair, and impact the incorporation of drugs, metabolites, and other target markers into the hair. These treatments also affect the decontamination and removal of drugs, metabolites, and other target markers when deposited on the hair. Even lifestyle choices and common hygiene (e.g., frequency of brushing and washing) may reduce incorporation and concentrations of detected drugs, metabolites, and other target markers. Further, experts concluded that hair morphology varies based on ethnicity and that hair morphology may have effects during decontamination procedures (discussed below). They also expressed concern that there are only limited studies in this area. Importantly, they concluded that melanin content and hair treatments affect the incorporation and retention of basic drugs into the hair, that the effects are not well understood, and that the effects are related to both the drug used and the drug-testing cutoff concentration(s). Although melanin content and speciation can be determined in some specialized laboratories, the methods currently in use are not readily automated and are not practical for use in production testing settings.

Contamination and Decontamination

Drug contamination of the hair is a distinct possibility for individuals in any environment where drugs are being handled, ingested, or smoked. These individuals may involuntarily have drug deposited on their hair and also have involuntarily ingested them. Similarly, those handling drugs (e.g., law enforcement agents, crime scene investigators and evidence technicians) risk ingestion and direct transfer of drugs to their hair. Children, adolescents, and other non-users are also subject to exposure by ingestion and environmental contamination if drugs are smoked or otherwise present in their homes or environment.

Both the SAMHSA'S 2004 Guidelines for Proposed Alternative Specimens and the 2015 DTAB recommendation recognized external contamination as a major issue in hair testing. It is essential that hair testing procedures be able to distinguish environmental

exposure from deliberate use or inadvertent ingestion. Many laboratories use "washing procedures" designed to remove environmentally deposited drugs from the hair. However, these procedures are not standardized and vary widely across laboratories. Some laboratories do not attempt to remove drug contamination, while others have devised various "washing" procedures, the efficacy of which is argued in the literature without agreement.

Scientists at the 2016 S&T meeting concluded that there is currently no definitive mechanism to distinguish use from external contamination and that the efficacy of washing procedures likely varies with the extent of contamination and integrity of hair specimen. They noted that depending on the condition of the hair and type of wash procedure, false positive tests might be generated by facilitating uptake of externally contaminated drug into the hair. Concern was also expressed that washing protocols may remove incorporated drug from the hair and extensive washing might actually result in false negative tests.

Scientists at the 2016 S&T meeting concluded that to establish a scientifically sound testing Federal program 1) "…that an effective decontamination procedure that could readily distinguish drug use from external contamination would have to be in place in the absence of unique drug biomarkers (e.g. Carboxy-THC) detectable in the hair", and 2) at this time there are no such procedure(s).

Additional Critical Issues

The issue of contamination/decontamination of drugs deposited on hair could be resolved without the uncertainties of washing procedures if unique markers of drug ingestion were available. Such a "drug use biomarker" could confirm drug use as opposed to environmental contamination by drugs deposited on the hair. Drugs entering the body by all routes of administration undergo biotransformation (metabolism). This process results in the drug and/or its biotransformation products entering the circulation and being incorporated into the hair much like drugs and drug metabolites may enter urine or other body fluids. Therefore, the detection of a unique biotransformation product, or profile of the drug and its metabolites in the hair, could provide convincing evidence that the drug was actively ingested and not merely deposited on the hair from an external source.

However, the scientists concluded that unique marker(s) of use have only conclusively been identified for marijuana (i.e., detection of the carboxy-metabolite of tetrahydrocannabinol). In earlier studies of other drugs, the potential biomarkers proposed

were later found not to be unique and were present in illicit drug preparations (e.g. cocaine, methamphetamine, and heroin). Even regulated pharmaceutical products may contain small amounts of chemically related drugs that are also potential biomarkers of use, and some drug metabolites are available as drugs (e.g. methamphetamine-amphetamine). Of the proposed list of drugs for inclusion in a Federal hair-testing program (amphetamine, methamphetamine, MDA, MDMA, morphine, codeine, 6-acetylmorphine, oxycodone, oxymorphone, hydrocodone, hydromorphone, cocaine, marijuana and PCP), only marijuana and potentially PCP have currently identified unique biomarkers. Potential biomarkers have been identified for cocaine and some opioids, but more research is needed to establish their utility for hair testing. At this time, the use of unique drug biomarkers to distinguish ingestion from contamination remains speculative in nature with the exception of marijuana.

Specific gravity (SG), pH, and creatinine concentration provide objective and measurable markers of urine specimen validity. Dilute specimens have a low SG and creatinine concentration, while higher SG and creatinine concentrations are found in concentrated urine specimens. Adulterated specimens may show pH values outside of those consistent with physiological urine. Analogous markers have not been identified to ensure that a suitable and representative hair specimen has been collected for testing. Scientists at the 2016 S&T meeting identified this as a significant limitation to developing a hair testing program, and an issue needing further research.

Conclusions

Many of the necessary components for use of hair as a testing specimen in Federal Workplace Drug Testing Programs can be accommodated given adequate time for incorporation and sufficient financial and human resources. The program can be modeled after the existing Federal testing programs for urine and adding oral fluid.

Scientists at the S&T 2016 meeting concluded that the effect(s) of hair "color" on hair drug tests results remains controversial and unresolved. Although often referred to as a potential "hair color" bias, melanin content is the underlying issue. Epidemiological studies remain at odds with clinical, *in vitro* and animal studies as to the effect on hair color/melanin content/type on the incorporation of drugs, metabolites, and other target markers. Additional research was recommended before pursuing implementation of a hair testing program in the Federal workplace.

Scientists at the meeting also concluded that treatments such as bleaching, straightening, relaxing, frequent washing, and vigorous brushing may 1) decrease the hair concentrations of incorporated drug, 2) have effects that are drugs, metabolites, and other target markers and profile dependent, and 3) because of the physical and chemical damage caused by these processes, they may also increase the susceptibility of the hair to external contamination. Therefore, it was concluded that additional research is needed before pursuing implementation of a hair testing program in the Federal workplace.

S&T Meeting participants also concluded that despite a wealth of literature and more than three decades of research and debate, the ability to differentiate drug-use or ingestion from environmental exposure remains problematic. The efficacy of laboratory washing and its effect(s) on hair drug tests results also remains controversial. Washing procedures vary by laboratory and there is no agreement among the major hair testing laboratories on which procedure(s) effectively distinguish ingestion from contamination. Vigorous and extensive washing procedures may remove incorporated drugs, metabolites, and other target markers from the hair and increase the risk of false negative test results. They may also damage the hair, facilitating the incorporation of drugs, metabolites, and other target markers into the hair and risking false positive results. Mild washing procedures may be ineffective at removing drugs, metabolites, and other target markers deposited on the hair and also risk false positive test results.

Expert committees at the 2016 S&T meeting could not recommend a decontamination procedure for use in Federal workplace testing and concluded that additional research is needed and there was not a defined marker of specimen validity for hair specimens except for porosity.

Critically, experts could not identify unique drugs, metabolites, and other target markers or profile(s) to distinguish use from external contamination for amphetamine, methamphetamine, MDA, MDMA, morphine, codeine, 6-acetylmorphine, oxycodone, oxymorphone, hydrocodone, hydromorphone, and cocaine. Given the deficiencies of the decontamination procedures, additional research was recommended to identify unique marker(s) of use before accepting hair as a testing specimen in the Federal workplace.