DTAB Future Direction

SAMHSA's Center for Substance Abuse Prevention

Drug Testing Advisory Board

Ron Flegel, B.S., MT(ASCP), M.S.
Chair DTAB

August 6-7, 2015
Drug Testing Advisory Board

• Discussion Points
  • Goals
  • Milestones
  • Objectives
  • Updates
Division of Workplace Programs

- Director: Ron Flegel, B.S., MT(ASCP), M.S.
- CDR Sean Belouin, Pharm.D.
- Janine Denis Cook, Ph.D., DABCC, FACB
- CAPT Jennifer Fan, Pharm.D., J.D.
- Deborah Galvin, Ph.D.
- Eugene D. Hayes, Ph.D., M.B.A.
- Charles LoDico, M.S., F-ABFT
- Coleen Sanderson
- Hyden Shen, J.D.
- Program Assistant: Giselle Hersh
DTAB Goals

• To assist SAMHSA in:
  • Implementation of Mandatory Guidelines for Urine (URMG)
  • Implementation of Mandatory Guidelines for Oral Fluid (OFMG)
  • Evaluation of hair as an alternate specimen
Publications:


Publications:

Publications:


Publications in submission or preparation:

Presentations:

Presentations:

- Brandi L. Puet, Julie Knight, Anne DePriest, Rebecca Heltsley, David L. Black, Timothy Robert, Yale H. Caplan, and Edward J. Cone, Disposition of Oxycodone and Hydrocodone in Oral Fluid. SOFT 2013, October 28 – November 1, 2013, Orlando, FL.
- Cone, E.J., Bigelow, G., Herrmann, E.S., Mitchell, J.M., LoDico, C., Flegel, R., and Vandrey, R., Passive Inhalation of Cannabis Smoke is Drug Administration. TIAFT meeting, October 30, 2015, Florence, Italy.
Presentations:

- Flegel, R., SAMHSA’s Role in Establishing Drug Testing Standards for Contemporary Drugs, SOFT meeting, October 18-23, 2015.
Special Studies

• **Cannabis vaporization** followed by inhalation
  • NIDA/SAMHSA collaboration
  • This study evaluated cannabis pharmacodynamics and pharmacokinetics in occasional and frequent smokers after vaporized administration (eCigarettes)
  • Occasional and frequent cannabis smokers were in a double blind, randomized, crossover, placebo-controlled design where participants consumed smoked vaporized cannabis (6.9% Δ9-tetrahydrocannabinol [THC])
  • Whole blood, oral fluid, urine, dried blood spots, and breath are collected throughout the study
Special Studies, cont’d

- Pharmacokinetic and pharmacodynamic effects of oral cannabis
  - 3 doses
    - 10 mg, 25 mg, or 50 mg THC doses of orally consumed intact cannabis (e.g., cannabis-containing brownies)
  - Collected oral fluid, plasma, hair and urine for up to 9 days post consumption
  - Conducted subjective, behavioral, and cognitive performance assessments to evaluate the time course of the consequences of oral cannabis ingestion among study participants
Publications


• Cone, E.J., Bigelow, G.E., Herrmann, E.S., Mitchell, J.M., LoDico, C.P., Flegel, R and Vandrey, R. **Non-smoker exposure to secondhand cannabis smoke. I. Urine screening and confirmation results.**

• Herrmann, E.S., Cone, E.J., Mitchell, J.M., Bigelow, G.E., LoDico, C., Flegel, R. and Vandrey, R. **Non-smoker exposure to secondhand cannabis smoke. II: Effect of room ventilation on the physiological, subjective, and behavioral/cognitive effects.**

DTAB Hair Testing Milestones

- Milestones
  - Two year review of technical and scientific issues
  - Hair testing industry input
  - Review of public comments in response to Request for Information (RFI)
MRO Manual Update

- Subject Matter Expert (SME): Dr. Richard Hilderbrand
  - Spearheading the Medical Review Officer (MRO) Manual revisions
    - Consistency with the proposed revisions for Urine Mandatory Guidelines
    - Place holder for proposed Oral Fluid Mandatory Guidelines
MRO Manual Update

• MRO Manual Working Group
  • 12 Members
    • Sean Belouin, Rich Hilderbrand, Yale Caplan, Donna Smith, Lawrence Brown, Ted Shults, Jim Ferguson, Susan Crumpton, Robert Swotinsky, David Kuntz, David Nahin, Nicholas Lomangino
  • DWP staff
MRO Manual Update

• Major issues
  • Addressing the addition of prescription opioid drugs to drug testing panel:
    • Oxycodone, oxymorphone, hydrocodone, hydromorphone
  • Hydrocodone combination drugs rescheduled to Schedule II
  • “What is considered a valid prescription under the Drug-Free Workplace Programs (DFWP) and how will it be interpreted by the MRO?”
MRO Manual Update

• Major Issues continued . . .
  • Addition of the electronic Federal Custody and Control Form (eCCF)
  • Mandatory Guidelines allow “transmitting a scanned image of the completed MRO copy of the Federal CCF”
  • Addressing when lab reports “insufficient volume” to the MRO
• Case notes
  • Whether to be included or kept separate from MRO Manual
DTAB Objectives

- Objectives
  - URMG - public comments
  - OFMG - public comments
  - Preparation of the final UrMG and OFMG
  - Evaluation of the scientific supportability of hair
  - Implementation of MRO Manual
DTAB Short Term Objectives

- Short Term Objectives
  - Review RFI Comments for Hair (August)
  - Review URMG public comments (August)
  - Review OFMG public comments (August)
  - Review URMG changes to proposed URMG (October)
  - Review OFMG changes to proposed OFMG (October)
Future Goals

- Development of a DFWP database
  - SAMHSA working with the a federal agency / contractor to create a real-time database for federally regulated drug tests
  - Federal agency and federally regulated drug tests (DOT and NRC) – Phase II
  - Data contained in the database: specimen number, federal agency, type of test, collection site, drug test result, quantitative data, demographic information by zip code, reason for test, reporting reason, etc.
Database Goals

• Generate reports that:
  • Provide data for federal agencies to incorporate into their annual survey report (ASR)
  • Provide true total and non-negative data for individual and combined federal agencies
  • Provide geographical distributions of dilute and non-negative specimens for individual and combined federal agencies
Database Advantages

• The advantages of establishing a regulated drug testing database for participating federal agencies
  • Increased data reporting accuracy through federal agency collaboration
  • Near real-time reporting
  • Consolidation of drug testing result data
  • Potential 80% reduction in agency burden when generating the ASR
Long Term Database Goals

Potential long range opportunities

• eCCF transmission of data
• Standard variables across laboratory reporting
• Replacement of the non-negative specimen list
• Other federal agency participation (DOT/NRC)
• Real time data – within hours to days
• Detect federal agency trends – drug test results
• Single reporting method for laboratories
Other Program Goals

- Complete the training course modules for inspectors/lab responsible persons and staff
- Continue to research alternative specimens for inclusion in the MG
- Develop supporting guidance documents for alternative matrices in the MG
- Revise the current urine MG to include the DTAB recommendation
Time Line: Step 1

- Timeline for the publication of final revisions to the Mandatory Guidelines to include Schedule II drugs in urine and oral fluids as an alternate specimen

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<th>Step 1</th>
<th>Tentative Date</th>
<th>Urine</th>
<th>Oral fluids</th>
<th>Hair</th>
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Time Line: Step 2

- Timeline for the publication of final revisions to the Mandatory Guidelines to include Schedule II drugs in urine and oral fluids as an alternate specimen

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Routing Process

Mandatory Guidelines Routing Process
FOR INTERNAL USE ONLY

1. DWP, DOJ, OGC and DTAB (Concept and Recommendations)
   Timeframe: Approximately 12-18 Months

2. SAMHSA ADMINISTRATOR (Reviews Recommendations)
   Timeframe: Approximately 5 Months

3. HHS SECRETARY & BEHAVIORAL HEALTH COORDINATING COMMITTEE
   (Reviews and approves recommendations)
   Timeframe: Allow 60 days

4. DWP SUBMITS PROPOSED MANDATORY GUIDELINES

5. SAMHSA REVIEW OF DRAFT MANDATORY GUIDELINES

6. DEPARTMENT OF HEALTH AND HUMAN SERVICES/OPDIVs REVIEW
   (Urine and Oral Fluid MG approved 2/28/14)

7. OMB DISTRIBUTES TO EXECUTIVE BRANCH FEDERAL AGENCIES FOR REVIEW
   Timeframe: Allow 60 days
   Period starts from 3/3/14.
   Agencies received 7/11/14.

8. RECOMMENDATIONS SENT TO DWP FOR SAMHSA FINAL REVIEW AND ACTION.
   REVISIONS ARE RE-ROUTED THROUGH HHS.
   Timeframe: 2 weeks
   DWP received approx. 8/19/14

9. REVISIONS ARE FORWARDED BACK TO FEDERAL AGENCIES FOR CONCURRENCE.
   OMB will give agencies 2 weeks to reply/resubmit additional comments/ recommendations. If needed, OMB will be decision maker or set up meeting between federal agency and HHS.
   Timeframe: 2 weeks
   DWP sent to OMB to send to federal agencies approx. 11/18/14
Routing Process

10. Once OMB receives all comments, the MG will be returned to HHS for final notices with Administrator’s signature.
   Timeframe: _______

11. OMB review and approval of proposed mandatory guidelines.
   Reviewed by OMB, COP office and federal agencies – comments are consolidated.
   Timeframe: 90 day period, sometimes longer. (Period started 4/10/14)

12. Federal Register Notice posted for public comment.
   Timeframe: 60-90 days, optional?

13. Public comments and recommendations reviewed by DWP.
   Timeframe: _______

   Timeframe: _______

15. Route final guidelines through SAMHSA for approval by SAMHSA administrator.
   Timeframe: _______

16. SAMHSA administrator signs final notice for federal register.
   Timeframe: _______

17. Post final notice of mandatory guidelines and implementation date in Federal Register.

March 2014
Summary

- Continue to partner with DOT and NRC to harmonize the MG for urine and oral fluid
- Communicate with the laboratories on program issues
- Continue to advance the technology and science in the Program
- Address emerging drug testing issues and trends
- Program oversight and review
- Studies / tasks regarding alternate matrices
- Marijuana issues/reclassification/rescheduling
- Synthetic opiates / prescription drug use
Thank You
Division of Workplace Programs