Drug Early Warning Signals: Methodology Overview

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Notice

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Study Overview

The Drug Early Warning Signals (DEWS) project uses the methodology developed as part of the earlier Community Drug Early Warning System (CDEWS) project. The CDEWS methodology is based on the national Drug Use Forecasting (DUF) program, launched in 1987, and its modified versions, the Arrestee Drug Abuse Monitoring (ADAM) and ADAM II programs which ended in 2013. These programs sent researchers into booking facilities across the country to interview arrestees and obtain a voluntary urine specimen for analysis. An independent laboratory then tested the specimens for ten drugs (ADAM II). The results provided information about the drugs present and served as an early warning indicator of emerging drugs in the general community. The Center for Substance Abuse Research (CESAR) at the University of Maryland, College Park, with funding from the Office of National Drug Control Policy (ONDCP), then piloted CDEWS to test the feasibility of a new, less costly and more rapid, drug surveillance system which retests urine specimens already collected by existing drug testing programs. The CDEWS methodology is designed to achieve two primary objectives: 1) to identify and describe the use of emerging drugs in populations at high risk for recent drug use; and 2) to specify any important drugs that the current local testing program may be missing.

CESAR staff work with testing programs at criminal justice agencies and health care facilities to obtain a sample of urine specimens that are ready to be discarded. These de-identified specimens are sent to the collaborating CDEWS laboratory to test each specimen for an expanded panel of approximately 240 licit and illicit drugs, including opioids, benzodiazepines, antidepressants, synthetic cannabinoids (SC), fentanyls, and other new psychoactive substances (NPS). The results are especially important for detecting emerging drugs because prior epidemics in the use of illegal drugs have often shown up in urinalysis results from criminal justice populations before they became evident in the larger community (DuPont & Wish, 1992; Wish, 1997). In addition, local testing programs typically can test for only a small number (often 6-12) of different drugs and the DEWS results for approximately 240 substances can be used by the local testing programs to gain some insight into whether their standard limited test panel is adequate to identify most of the drugs being used by their testing population. DEWS provides an indication of drugs locally available, but is not designed to compute prevalence estimates of use and cannot determine if a person testing positive for a licit drug used it under a physician's supervision.

The CDEWS methodology has now been piloted in nineteen sites and the results are provided in nine reports already released by the Office of National Drug Control Policy (NDEWS, 2018).

CDEWS Methodology

The following is a description of the standard methodology utilized in most participating sites. It is sometimes necessary to deviate from this methodology for our site collections. In these cases, such deviations have been specified in our individual site reports. This methodology has been repeated in multiple sites across the United States.

Collection of Urine Specimens

Prior to collecting the urine specimens for retesting, CESAR researchers talk with staff from the participating programs by phone to determine their policies regarding required specimen holding periods, testing protocols, detection limits and other relevant site details. Specimens are then accumulated by each program using the specific CDEWS guidelines provided by CESAR as to how specimens are to be handled and stored. Specimens are obtained directly from the participating program following completion of the program's onsite testing and prior to urine specimen disposal. Only one specimen per person is included in the study sample. Only specimens with a minimum volume of 5mL are included in the study. Designated program staff ship the selected specimens directly to the CDEWS collaborating laboratory for expanded drug testing. Prior to data collection, CESAR submits applications for the necessary approvals and obtains approval for each collection from University of Maryland's Institutional Review Board (IRB).

Collection of Demographic Information

Specimens selected for the study are de-identified and labeled with a non-identifiable study ID and the site location. Basic demographic elements, such as: overall initial test result (positive/negative), specimen collection date, age, gender, race, ethnicity, zip code, and toxicology results for specific drugs from the program's instant testing are also collected and transferred to CESAR by the participating program using an electronic database linked by the assigned study ID.

Selecting Substances for Inclusion on the Testing Panel

In the prior studies, we learned that both the chemical composition of synthetic drugs available and patterns of use can vary widely even within a brief period of time. It is a recognized challenge for both laboratories and law enforcement agencies to keep up with the rapid changes in specific synthetic drugs. The chemists producing these drugs modify the chemical structures of the substances as existing formulations are scheduled by the DEA and made illegal.

To ensure that the drug test panel for each study is as current as possible and includes the most relevant drugs or metabolites, CESAR staff review data on emerging drug trends and

conduct interviews with toxicologists to identify substances for inclusion on the panel. We also work collaboratively with the CDEWS testing laboratory to identify substances of relevance to the test panel. Selecting substances to include in the study test panel is critical to CDEWS' ability to detect emerging drugs, particularly as related to NPS, an area of fast-paced change in terms of availability and use.

Interviews with Toxicologists to Develop the CDEWS Testing Panel

We interviewed 10 chemists at 4 labs prior to finalizing the test panel (Table 1). These interviews help us to identify new psychoactive substances (NPS) to consider adding to our panel and to assess the availability of tests for these drugs. The persons interviewed were selected from existing networks of toxicologists with expertise in the area of NPS and/or urine testing that we have identified from past CDEWS studies, as well as through other professional networks. A standard set of questions was asked including:

- What specific substances do you think are most important for us to include in our testing panel?
- Are there any new or emerging synthetic drugs that we should include?
- What synthetic drugs do you test for at your agency?
- What synthetic cannabinoid metabolites have you been finding in your most recent specimens? fentanyl analytes? cathinones? other synthetic drugs?
- To your knowledge, are there tests available for each of these drugs? What would be the recommended test (EIA, LC/MS, etc.)?

Table 1: Toxicologists Interviewed for CDEWS

NAME	TITLE/AFFILIATION
Dr. Gregory Endres; Dr. Donna Iula	Cayman Chemical
Dr. Felix Adatsi	Office of Forensic Toxicology Services, Pretrial Services Agency for the District of Columbia
Jill Head; Emily Dye	Special Testing and Research Laboratory, Drug Enforcement Administration
Dr. Jeffrey Walterscheid; LCDR Pedro Ortiz; Major Lynn Wagner; Theresa Hippolyte; Dr. Paul Kaiser	Division of Forensic Toxicology, Armed Forces Medical Examiner System

Review of Relevant Data Sources

To plan our test panel, we also review data and information from a number of national and international data sources. For the current studies, these included a review of the 2016 National data from the Drug Enforcement Administration's (DEA) National Forensic Laboratory Information System (NFLIS) (U.S. DEA, Office of Diversion Control, 2016), emerging threat

assessment reports for 2016 from the DEA's Special Testing and Research Laboratory (Head, 2017; U.S. DEA, Special Testing and Research Laboratory, Emerging Trends Program, 2016a, 2016b, 2016c, 2016d, 2016e), as well as reports from the United Nations Office on Drugs and Crime (UNODC) Early Warning Advisories (UNODC, 2016a, 2016b), and other sources (Iula, 2017; U.S. DEA, Federal Register, 2017; U.S. DEA, Public Affairs, 2016).

Updates to the Testing Panel

Based on the information learned from these efforts, we added 85 additional new drugs to the testing panel used as part of the previous iteration of the CDEWS methodology (see Table 2 below for the full panel). Several additional NPS were identified as relevant to the study but were not included due to non-availability of a test for the drug and cost. The following drugs were added to the panel:

- 20 synthetic cannabinoids: 5F-AB-PINACA N-OH, 5F-ADB metabolite 7, 5F-AMB, 5F-AMB metabolite 7, 5F-APINACA, AB-FUBINACA (metab 2), FUB-144, FUB-AKB-48, FUB-JWH-018, FUB-PB-22, FUB-PB-22 3-carboxyindole metabolite, JWH-210-N-COOH, JWH-250-N-COOH, MA-CHMINACA, MAB-CHMINACA metabolite M2, MDMB-CHMICA, MDMB-FUBICA metabolite 3, MDMB-FUBINACA metabolite M1, MMB-CHMICA and MMB-FUBINACA.
- 11 fentanyl analytes: 3-Methylfentanyl (3-MF), Acetyl NorFentanyl, Benzylfentanyl (R-4129), Cyclopropyl fentanyl, FIBF (p-fluoroisobutyryl fentanyl), Methoxyacetyl fentanyl, Norsufentanil, Ocfentanil (A-3217), ortho-Fluorofentanyl, Tetrahydrofuran fentanyl (THF-F), and Valeryl fentanyl (TCE).
- 51 other new psychoactive substances: α-PBP, α-PVT, 1-(3-TFMPP), 2-AI (2-Aminoindane), 2C-E, 2C-I, 2-DPMP (Desoxypipradrol), 25-C-NBOH, 25I-NBF, 25I-NBMD, 25I-NBOH, 30C-NBOMe, 3,4-diMeO-PVP, 3,4-DMMC, 3,4,5-trimethoxycocaine, 4F-PVP, 4-MBC (Benzedrone), 4-MeO-PV8, 4-MeO-PV9, 4-MPBP, 5-MAPB, 5-MeO-AMT, 5-MeO-DALT, 5-MeO-DiPT, 5-MeO-DMT, 7-Hydroxy-Mitragynine, AMT, Bufotenine, D2PM, DBZP, Diphenidine, DiPT, DMAA, DOB, DOC, DOET, DOI, DOM, Escaline, MDAI, Mescaline, MOPPP, MPHP, NM-2AI, N,N-DPT, Norketamine, Noscapine, PV8, PV9, Pyrovalerone, and TMA (Trimethoxyamphetamine).
- 3 prescription drugs: Diphenhydramine, Gabapentin, and Naltrexone

Table 2: The CDEWS Laboratory Expanded Drug Screening Panel and Limits of Detection

GENERAL PANEL

	COMPOUND	LOD (ng/mL)		COMPOUND	LOD (ng/mL)
1	α-Hydroxyalprazolam	25	39	Hydrocodone	25
2	α-Hydroxymidazolam	5	40	Hydromorphone	25
3	α-Hydroxytriazolam	25	41	Hydroxyzine	25
4	6-Monoacetylmorphine (6-MAM)	5	42	Lorazepam	25
5	7-Aminoclonazepam	25	43	MDA	25
6	Alprazolam	25	44	MDEA	5
7	Amitriptyline	25	45	MDMA (Ecstasy)	5
8	Amphetamine	25	46	Meperidine	25
9	Atomoxetine	25	47	Methadone	25
10	Benzoylecgonine (Cocaine)	25	48	Methamphetamine	5
11	Bupropion	25	49	Methylphenidate	25
12	Carisoprodol	50	50	Morphine	25
13	Cetirizine	25	51	Naltrexone	25
14	Chlorpromazine	25	52	Nordiazepam	25
15	Citalopram	25	53	Normeperidine	25
16	Clonazepam	25	54	Nortriptyline	25
17	Codeine	25	55	Oxazepam	25
18	Cyclobenzaprine	25	56	Oxycodone	25
19	Demoxepam	25	57	Oxymorphone	25
20	Desalkflurazepam	25	58	Paroxetine	25
21	Desmethylvenlafaxine/Desvenlafaxine	25	59	PCP	0.25
22	Desomorphine	5	60	Phenmetrazine	25
23	Dextromethorphan	0.25	61	Prazepam	25
24	Diazepam	25	62	Promethazine	25
25	Diclazepam	25	63	Pseudoephedrine	25
26	Diphenhydramine	25	64	Pyrazolam	25
27	Doxepin	25	65	Quinine	25
28	Duloxetine	25	66	Sertraline	25
29	EDDP	25	67	Temazepam	25
30	Ephedrine	25	68	Thioridazine	25
31	Estazolam	25	69	Tramadol	25
32	Etizolam	25	70	Venlafaxine	25
33	Flubromazepam	25	71	Zaleplon	5
34	Flunitrazepam	25	72	Zolpidem	5
35	Fluoxetine	25	73	Zopiclone	5
36	Flurazepam	25			
37	Gabapentin	25			
38	Haloperidol	25			

Table 2 (Cont'd): The CDEWS Laboratory Expanded Drug Screening Panel and Limits of Detection

THC/BUPRENORPHINE/LSD PANEL

	COMPOUND	LOD (ng/mL)
1	Buprenorphine	1
2	LSD/Metabolite (2-oxo-3-hyroxy-LSD)	0.05/0.25
3	Naloxone	1
4	Norbuprenorphine	1
5	THC-COOH	5

SYNTHETIC CANNABINOID PANEL

	COMPOUND	LOD (ng/mL)		COMPOUND	LOD (ng/mL)
1	5F-AB-PINACA	0.2	26	JWH-018-N-COOH	0.2
2	5F-AB-PINACA N-OH	0.2	27	JWH-019-N-OH	0.2
3	5F-ADB (metab 7)	0.2	28	JWH-073-N-COOH	0.2
4	5F-AKB-48 N-OH	0.2	29	JWH-081-N-OH	0.2
5	5F-AMB	0.2	30	JWH-122-N-OH	0.2
6	5F-AMB (metab 7)	0.2	31	JWH-210-N-OH	0.2
7	5F-APINACA	0.2	32	JWH-210-N-COOH	0.2
8	5F-PB-22 3-carboxyindole	0.2	33	JWH-250-N-OH	0.2
9	AB-CHMINACA (Parent)	0.2	34	JWH-250-N-COOH	0.2
10	AB-CHMINACA (metab 4)	0.2	35	MA-CHMINACA	0.2
11	AB-CHMINACA (metab 6)	0.2	36	MAB-CHMINACA (metab M2)	0.2
12	AB-FUBINACA (Parent)	0.2	37	MAM-2201-N-COOH/JWH-122-COOH	0.2
13	AB-FUBINACA (metab 2)	0.2	38	MDMB-CHMICA	0.2
14	AB-PINACA N-COOH	0.2	39	MDMB-FUBICA (metab 3)	0.2
15	ADB-FUBINACA (Parent)	0.2	40	MDMB-FUBINACA (metab M1)	0.2
16	ADBICA-N-COOH	0.2	41	MMB-CHMICA	0.2
17	ADB-PINACA-N-COOH	0.2	42	MMB-FUBINACA	0.2
18	AKB-48-N-COOH	0.2	43	PB-22 3-carboxyindole	0.2
19	AM-2201-N-OH	0.2	44	RCS-4-N-COOH	0.2
20	BB-22 3-carboxyindole	0.2	45	UR-144-N-COOH	0.2
21	FUB-144	0.2	46	XLR-11-N-OH	0.2
22	FUB-AKB-48	0.2			
23	FUB-JWH-018	0.2			
24	FUB-PB-22	0.2			
25	FUB-PB-22 3-carboxyindole metabolite	0.2			

Table 2 (Cont'd): The CDEWS Laboratory Expanded Drug Screening Panel and Limits of Detection

DESIGNER DRUG PANEL

	COMPOUND	LOD (ng/mL)		COMPOUND	LOD (ng/mL)
1	α-PBP	5	49	Diphenidine	5
2	α-PVP	5	50	DiPT	0.25
3	α-PVT	5	51	DMAA	1000
4	β-Methylphenethylamine (β-MPEA)	5	52	DMT	0.25
5	1-(3-TFMPP)	0.25	53	DOB	0.25
6	2-AI (2-Aminoindane)	5	54	DOC	0.25
7	2C-B	0.25	55	DOET	0.25
8	2C-E	0.25	56	DOI	0.25
9	2C-I	0.25	57	DOM	0.25
10	2C-T-7	0.25	58	Escaline	0.25
11	2-DPMP (Desoxypipradrol)	5	59	Ethylone	5
12	25B-NBOMe	0.25	60	Eutylone	5
13	25-C-NBOH	0.25	61	Flephedrone	5
14	25C-NBOMe	0.25	62	Ketamine	0.25
15	25I-NBF	0.25	63	Loperamide	5
16	25I-NBMD	0.25	64	MBDB	5
17	25I-NBOH	0.25	65	mCPP	0.25
18	25I-NBOMe	0.25	66	MDAI	5
19	30C-NBOMe	0.25	67	MDPV	5
20	3,4-diMeO-PVP	5	68	Mephedrone	5
21	3,4-DMMC	5	69	Mescaline	0.25
22	3,4,5-trimethoxycocaine	5	70	Methcathinone/Ephedrone	5
23	4-Fluoroamphetamine (4-FA)	5	71	Methedrone	5
24	4-Fluoromethamphetamine (4-FMA)	5	72	Methiopropamine (MPA)	5
25	4F-PVP	5	73	Methoxetamine (MXE)	0.25
26	4-MBC (Benzedrone)	5	74	Methylone	5
27	4-MeO-PV8	5	75	Mitragynine (Kratom)	0.25
28	4-MeO-PV9	5	76	MOPPP	5
29	4-Methylethcathinone (4-MEC)	5	77	MPHP	5
30	4-MPBP	5	78	MT-45	5
31	5-APDB/6-APDB	5	79	Naphyrone	5
32	5-MAPB	0.25	80	NM-2AI	5
33	5-MeO-AMT	0.25	81	N,N-DPT	0.25
34	5-MeO-DALT	0.25	82	Norketamine	0.25
35	5-MeO-DiPT	0.25	83	Noscapine	1
36	5-MeO-DMT	0.25	84	Pentedrone	5
37	5-MeO-MiPT	0.25	85	Pentylone	5
38	7-Hydroxy-Mitragynine	5	86	Phentermine	100
39	AMT	0.25	87	Psilocin	0.25
40	Benzylpiperazine (1-BZP)	0.25	88	PV8	5
41	Bromo-DragonFLY	0.25	89	PV9	5
42	Bufotenine	0.25	90	Pyrovalerone	5
43	Butylone	5	91	TMA (Trimethoxyamphetamine)	0.25
44	Cathinone	5	92	Trazodone	0.25
45	D2PM	5	93	U-47700	5
46	DBZP	5	94	W-15	5
47	Dibutylone	5	95	W-18	5
48	Dimethylone	5			

Table 2 (Cont'd): The CDEWS Laboratory Expanded Drug Screening Panel and Limits of Detection

FENTANYL PANEL

	COMPOUND	LOD (ng/mL)
1	β-hydroxythiofentanyl	1
2	3-Methylfentanyl (3-MF)	1
3	4-ANPP (Despropionyl fentanyl)	5
4	Acetylfentanyl	1
5	Acetyl NorFentanyl	1
6	Benzylfentanyl (R-4129)	1
7	Butyryl Fentanyl	1
8	Carfentanil	1
9	Cyclopropyl Fentanyl	1
10	Fentanyl	1
11	FIBF (p-fluoroisobutyryl fentanyl)	1
12	Furanylfentanyl (Fu-F)	1
13	Methoxyacetyl Fentanyl	1
14	Norfentanyl	1
15	Norsufentanil	1
16	Ocfentanil (A-3217)	1
17	ortho-Fluorofentanyl	1
18	Para-Fluorobutyryl Fentanyl	1
19	Para-Fluorofentanyl (p-FF)	1
20	Tetrahydrofuran Fentanyl (THF-F)	1
21	Valeryl Fentanyl (TCE)	1

Testing of Urine Specimens by the CDEWS Collaborating Laboratory

All specimens are sent to the CDEWS collaborating laboratory, the Division of Forensic Toxicology of the Armed Forces Medical Examiner System (AFMES) located in Dover, Delaware, for an expanded drug testing panel. All specimens are held in cold or frozen storage for the duration of the study. Approximately 240 drugs were tested for using Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS) in our current study. This panel includes 46 SC metabolites and 95 designer stimulants, 21 fentanyl analytes, and 78 other illicit and prescription drugs (see Table 2). The test results, labeled by study ID, are sent electronically to CESAR.

Constructing and Cleaning of the Database

At the completion of each data collection effort, the participating program sends an electronic database containing the relevant demographic information, linked by Study ID. Upon completion of the testing, AFMES sends an electronic database containing the urine test results,

also containing the study ID. These files are then linked and merged into a final data file. The data are then checked to ensure the accuracy of this linkage. Additional cleaning is done to verify that there are no missing data. Any questions regarding the findings are addressed with the laboratory. The database is then analyzed using SPSS and the findings presented in a site-specific report.

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