

Urine Drug Monitoring: A Review of the Clinical Evidence

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Outline

- Why use UDM in clinical care?
- What is the evidence?
- What types of tests are appropriate?
- From a clinical perspective, what is appropriate payer policy?

Why use UDM?

- Physicians are poor at detecting misuse
 - Low disclosure by patients
 - Nonspecific signs/symptoms
- Provides objective data
- Complements self-report and behavioral monitoring

Why use UDM?

- Confirms adherence to prescribed medications
- Identifies undisclosed use of non-prescribed drugs
- Helps identify opioid misuse
 - including diversion
- May prevent addiction and overdose

UDM is recommended

- American Pain Society
- American Academy of Pain Management
- American Society of Interventional Pain Physicians
- American Society of Addiction Medicine
- Federation of State Medical Boards
- Department of Veterans Affairs

UDM identifies aberrant drug use

Author, Year	Setting	N	Results
Passik, 2007	Cancer center	215	44% positive for illicit drug or negative for prescribed medication
Michna, 2007	Pain	470	20% positive for illicit drug 12% negative for prescribed medication
Fleming, 2007	Primary care	801	24% positive for illicit drug
Cone, 2008	Pain	10,922	11% positive for illicit drug (9% marijuana, 3% cocaine)
Couto, 2009	Diverse	938,586	11% positive for illicit drug 29% positive for nonprescribed medication 38% negative for prescribed medication

UDM identifies aberrant drug use

≥11% positive for illicit drugs
≥ 12% negative for prescribed medications

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UDM vs. self-report

Author, Year	Setting	N	Results
Berndt, 1993	Pain	109	6% positive for unreported codeine
Fishbain, 1999	Pain	226	0.4% positive for unreported opioid 12% negative for prescribed opioid
Schuckman, 2008	ED	248	32% positive for unreported drugs of abuse
Schneider, 2008	Pain	188	4% positive for unreported opioid 10% positive for illicit drug (8% MJ only) 2% negative for prescribed opioid*

*Using immunoassay techniques

UDM vs. behavioral monitoring

Author, Year	Setting	N	Results
			<i>Among patients without behavioral issues,</i>
Belgrade, 2001	Pain	94	30% had unexpected result: 13% positive for non-prescribed opioids 7% positive for illicit drugs 7% negative for prescribed opioids 6% refused or gave insufficient sample
Katz, 2003	Pain	122	21% positive for non-prescribed opioid or illicit drug
Manchikanti, 2003	Pain	100	14% positive for illicit drug: 10% marijuana 4% cocaine

UDM vs. behavioral monitoring

14% to 30% of urine results were aberrant

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Katz, 2003	Pain	122	21% positive for non-prescribed opioid or illicit drug 49% of aberrant use would be missed
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Outcome studies

- Does routine UDM reduce opioid misuse, addiction, or overdose?
- Systematic review in this week's *Annals of Internal Medicine*
- Broadly defined UDM and outcomes

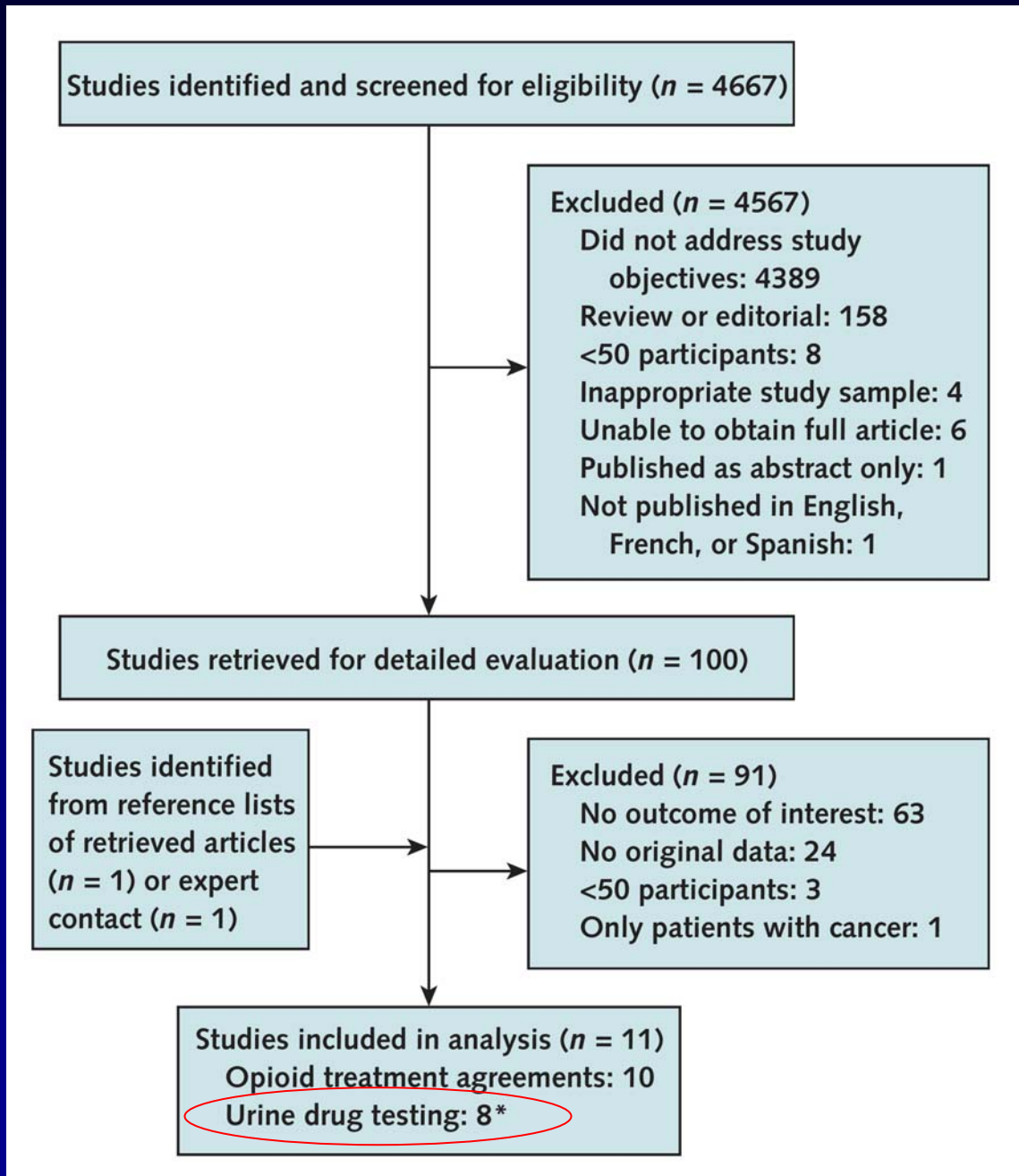
Search strategy

- MEDLINE, PsycINFO, EMBASE, Cochrane (through 6/09)
 - Combining 3 topic areas (with “AND”)
 1. Opioid medications
 2. Chronic pain
 3. Urine drug testing
- References from selected articles, relevant reviews, and expert contacts

Inclusion criteria

- English, French, or Spanish
- Published as full manuscript (not abstract)
- Original research (not review or editorial)
- Outpatient setting (not ED or post-op)
- ≥ 50 participants
- Adults with chronic noncancer pain
- UDM had to be a clinical intervention, not a one-time event for research purposes

Study flow diagram



Study description

- 8 studies evaluated UDM
- 4 in primary care, 4 in pain clinics
- 7 evaluated multi-component interventions
 - Included treatment agreements, monthly visits, other supports
- No studies assessed outcomes of addiction or overdose

Study quality

- No randomized, controlled trials
- All observational
- 3 had comparison condition
 - 1 was pre-post
 - 2 used historical controls
- Quality rating: 5 fair, 3 poor

Studies with control groups

Study, year	N	Design	Strategy	Change in Opioid Misuse
Wiedemer, 2007	335	RCS, Pre-post	Routine UDM, OTA, regular monitoring with clinical pharmacist	51% before → 28% after ARR, 22.9% (95% CI, 17.3-28.7) in AMTB
Manchikanti, 2006	500	PCS, historical controls	Routine UDM and OTA	18% before → 9% after ARR, 8.6% (CI, 4.4-12.8) in multiple sources
Manchikanti, 2005	500	PCS, historical controls	Routine UDM and OTA	23% before → 16% after ARR, 6.5% (CI, 1.3-11.7) in illicit drug use

PCS= prospective cohort study, RCS= retrospective cohort study, OTA= opioid treatment agreement (contract), ARR= absolute risk reduction, AMTB= aberrant medication-taking behavior

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7% to 23% reduction in misuse

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Chelminski, 2005	85	PCS	Routine UDM, OTA, monthly visits, interdisciplinary program	32% with misuse
Ives, 2006	196	PCS	Routine UDM, OTA, monthly visits, interdisciplinary program	32% with misuse
Hariharan, 2007	330	RCS	Routine UDM and OTA	17% with any misuse, 4% with prescription drug misuse, 16% with illicit drug use
Vaglianti, 2003	780	RCS	Monthly UDM and OTA	24% with misuse
Katz, 2003	122	RCS	Routine UDM	43% with misuse

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Studies without control groups

17% to 43% with misuse following UDM

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Review conclusions

- Limited, low quality evidence
- Modest reduction in misuse (7% to 23%) after routine UDM, when implemented within a multi-component intervention
- Need more research
 - Tease out component effects
 - Compare UDM strategies
 - Evaluate clinical outcomes (addiction and overdose)

State of the evidence

- UDM is effective at identifying aberrant drug use, beyond relying on patient self-report or behavioral monitoring
- UDM, when used as part of a comprehensive management program, may reduce misuse
- Data insufficient to determine best protocol or schedule for UDM

Payer issues

- Which patients?
 - Risk stratify?
- When and how often?
 - At initiation, randomly, regularly, when misuse is suspected?
- For which drugs?
- Which type(s) of test?

Types of UDT

- Screening tests
 - Immunoassay (qualitative)
 - Can be performed at point of care
 - Inexpensive
 - For opiates and benzodiazepines, detect drug class
 - Not reliable for semi-synthetic and synthetic opioids
- Confirmatory tests
 - Gas or thin-layer liquid chromatography and mass spectrometry (quantitative)
 - More sensitive and specific

Appropriate payer policy

- For all patients with chronic noncancer pain who are treated with long-term opioid medications
 - Not only when illicit drug use suspected
 - Medicare local coverage determinations
 - Won't catch diversion, will miss abuse
 - Without frequency limits
 - For screening and confirmatory tests
 - May be ways to reduce use of GC/MS
 - Panels should include main drugs of abuse and all opioids

Cost and codes

- Screening (immunoassay): \$40 to \$200
- Confirmatory (GC/MS): \$100 to \$500
- Appropriate ICD-9-CM codes should include:
 - Chronic pain (338.2), Other (338.29)
 - Specific pain conditions
 - Long-term use of high risk medications (v58.69)
- CPT code for drug screen: 80101

Other payer issues

- Too early to use as a quality indicator in pay-for-performance initiatives
- Fund research to determine best use
 - Effective testing protocol to reduce misuse
 - Cost-effectiveness of drugs on panel, which assays, in which circumstances

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