Urine Drug Monitoring: Indiana Council of Community Mental Health Centers

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Overview and Conclusions

- Urine Drug Monitoring (UDM) is a new and useful tool that supports medication adherence
- Extensive data demonstrate its utility in clinical practice
The Problem

• While treatment of people with Serious and Persistent Mental Illness has improved dramatically, medication compliance remains a vexing problem
• Few tools are available to clinicians to assess adherence levels
  – Self-report interviewing is notoriously unreliable
  – Medication Possession Ratios (MPRs) and other measures are good, but insufficient
Measuring Medication Adherence

• Until now, there have been no direct measures of compliance that are available to clinical practitioners

![Clinical Assessment of Medication Compliance in Schizophrenia](image)

Current tools for medication adherence are not reliable enough to aid consistently in treatment decision-making

Poor Adherence is a Major Driver of Adverse Outcomes Among People with Serious Mental Illness

• Antipsychotic medications are the primary and critical treatment modality for patients with serious and persistent mental illnesses\(^1\)

• **Compliance rates are especially poor within short periods of time**

![Bar chart showing estimated percentage of schizophrenic patients only partially adherent](image)

- 7-10 Days: 25%
- 1 Year: 50%
- 2 Years: 75%

• Non-adherence to antipsychotics may be the single most important **modifiable** factor contributing to psychotic relapse and hospitalization\(^2\)

• Patient relapse results in healthcare costs 2.8x more than patients who do not relapse in the 1-year follow up period

**Providers need reliable, objective data to aid in assessing patients’ adherence to prescribed antipsychotics**


Antipsychotic UDM: Scientific Highlights

• Research supporting urine drug monitoring as an effective tool
  – Appropriate cutoffs to detect urine excretion
  – Monitor for relevant metabolites
• Research to support the development of reference ranges
  – Aripiprazole (McEvoy et al)
  – Risperidone
  – Quetiapine extended release
  – Lurasidone
Antipsychotic UDM: Aripiprazole

- Metabolite OPC3373 was detected more frequently than aripiprazole and dehydroaripiprazole
  - Aripiprazole detected: 50% of samples
  - Dehydroaripiprazole detected: 8% of samples
  - OPC3373 detected: all samples

- **SUMMARY: The detection of OPC3373 should be considered the most reliable indicator of aripiprazole medication use; high false negative rates when not using OPC3373**
Abilify®, Seroquel XR®, Risperdal®, and Lurasidone

Normalized laboratory results are compared to a database of results from patients who have been clinically assessed as adherent, providing additional information about the likelihood of adherence.
Urine Drug Monitoring Represents a Major Advance for Clinicians

- Rapidly available, valid data about adherence
- Insight into prescribed medication compliance and the presence of other medications or illicit drugs
- Information to communicate productively with patients, their family and other supports

Abnormalities found in patient samples

- Illicit Medication Found: 40.2%
- Prescribed Medication Not Found: 37.6%
- No Abnormalities Found: 21.9%

Ingenuity Health data on file; N=1,224
Prescribers of antipsychotics were asked to rate patients on the prescriber’s expectation of medication presence (N=59)

- 63% Expect Presence of Medication
- 37% Unsure, or Expect Non-Presence
- 57% ATP Detected
- 43% ATP Not Found

Provider Predictions of Adherence vs. Results

Ingenuity Health data on file
What is Available?

- Common psychoactive medications
  - Antipsychotic medications critically important, with reference ranges
- Common illicit drugs
  - Continually evolving set, including K2/spice, methamphetamine
- Opioids and related
  - All those commonly prescribed, with reference ranges for many
- Genetic Testing is provided by Ingenuity Health
  - Targeted use
Adherence Monitoring: Elements

Monitor the most commonly prescribed antipsychotic medications:

- Aripiprazole (Abilify®)
- Clozapine (Clozaril®)
- Haloperidol (Haldol®)
- Olanzapine (Zyprexa)
- Lurasidone (Latuda)
- Paliperidone (Invega®)
- Quetiapine (Seroquel®)
- Risperidone (Risperdal®)
- Ziprasidone (Geodon®)
Also detects:

- Antidepressants
- Benzodiazepines
- Stimulants
- Sedatives/hypnotics
- Opioids/synthetic opiates
- Illicit drugs
  - Bath Salts, Synthetic Marijuana
- Alcohol
  - EtG/EtS biomarkers
## Genesis™ Summary Report

**CLINIC INFORMATION**
- Name: Mental Health
- Provider: Doctor Test 4

**PATIENT INFORMATION**
- Name: Test, Patient 4
- DOB: 11/06/1975

**SPECIMEN INFORMATION**
- Requisition Number: M1000085
- Report Version: 1
- Date Collected: 09/17/2013
- Date Reported: 09/19/2013 3.59 PM

### 1. Illicit Drugs
- Marijuana Metabolite (THCA)

### 2. Medications Or Metabolites Detected But Not Listed On Requisition
- Oxycodeine
- Oxymorphone
- Noroxycodone
- Norfentanyl

### 3. Medication Monitoring Results

<table>
<thead>
<tr>
<th>Medication Prescribed</th>
<th>Test Result (Medication or metabolite)</th>
</tr>
</thead>
<tbody>
<tr>
<td>METHADONE TABLET</td>
<td>Positive</td>
</tr>
<tr>
<td>RISPERDAL</td>
<td>Positive</td>
</tr>
</tbody>
</table>

### 4. Rx Guardian CD Standard Scores (Current)

Genesis Summary Report displays Standard Scores and Historical Trends for the following prescribed drugs: Morphine (extended release formulations and Kadian), Hydrocodone, Oxycodeine (immediate and extended release formulations), Oxymorphone (immediate and extended release formulations) and Methadone.

### 5. Rx Guardian CD Historical Trend

Less than 5% of patients clinically assessed as adherent in the Rx Guardian CD database have Standard Scores less than -2.0 or greater than +2.0.

Less than 1% of patients clinically assessed as adherent in the Rx Guardian CD database have Standard Scores less than -3.0 or greater than +3.0.
Sample Clinics and Results

- NC CMHC Consortium
  - Almost two years’ experience
  - Strong patient education component with virtually no “opt-outs” and significantly reduced non-adherence
  - Protocol for ongoing use adopted

- Texas CMHC
  - Large, multi-site enterprise
  - Implemented testing system-wide
  - Education efforts → halving of non-adherence rates
  - Protocol for ongoing use adopted
Early Results: Sample Texas CMHC

- Adult Behavioral Health patients positive for illicit drugs

<table>
<thead>
<tr>
<th>Month</th>
<th>Clinic A</th>
<th>Clinic B</th>
<th>Clinic C</th>
</tr>
</thead>
<tbody>
<tr>
<td>August</td>
<td>20%</td>
<td>22%</td>
<td>21%</td>
</tr>
<tr>
<td>September</td>
<td>20%</td>
<td>19%</td>
<td>17%</td>
</tr>
<tr>
<td>October</td>
<td>18%</td>
<td>22%</td>
<td>17%</td>
</tr>
</tbody>
</table>

- Clinic A: Average 300 patients/mth
- Clinic B: Average 600 patients/mth
- Clinic C: Average 300 patients/mth
Current Progress: Use and Results

- Use of UDM growing rapidly
- Provider satisfaction high
  - Process data indicate effects on treatment planning, patient education
- Studies planned or underway
  - Process and Clinical outcomes including treatment changes/ augmentations, symptom improvement
  - Reductions in IP and ER use
Current Progress: Reactions and Direction

• Scientific Advisory Panel exceptionally positive
• Protocols/guidelines being studied
  – Stratification by acuity and risk
• Pilot studies to examine impact in the context of comprehensive programs (e.g., PACT)