

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

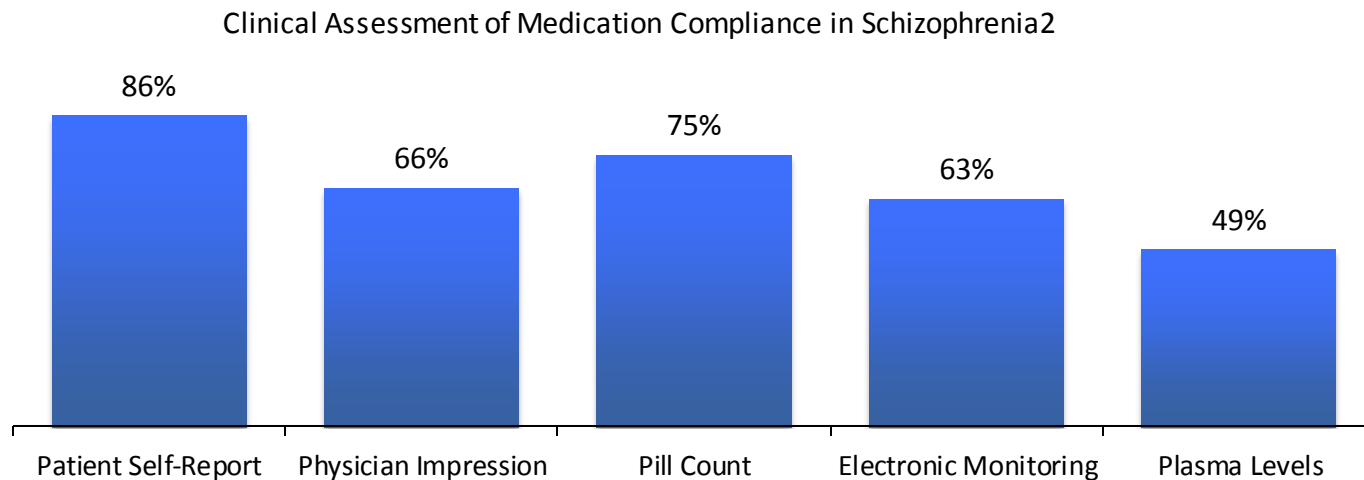


The Problem

- 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



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

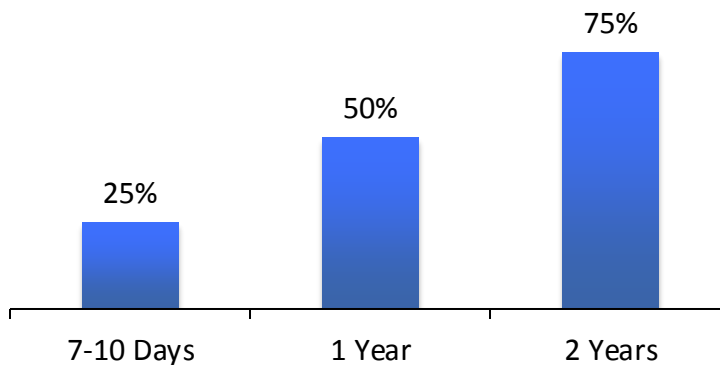
¹Dolder, CR, et al., *J Clin Psychopharmacology* 2003;23(4): 389-399



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 illnesses¹
- ***Compliance rates are especially poor within short periods of time***

Estimated Percentage of Schizophrenic Patients Only Partially Adherent¹



- Non-adherence to antipsychotics may be the single most important **modifiable** factor contributing to psychotic relapse and hospitalization²
- 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

¹Dolder, CR, et al., *J Clin Psychopharmacology* 2003;23(4): 389-399

²Ascher-Svanum, H., et al *BMC Psych.* 2010;10:2



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

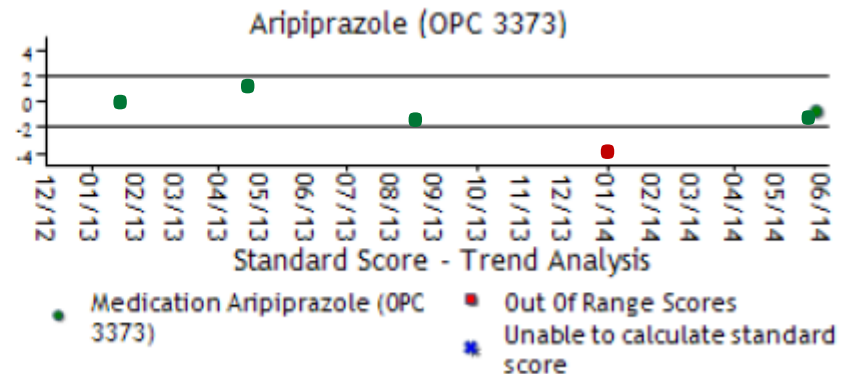
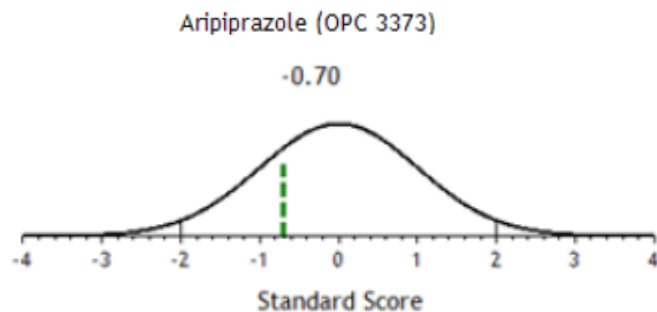


Antipsychotic UDM: Aripiprazole

- 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***

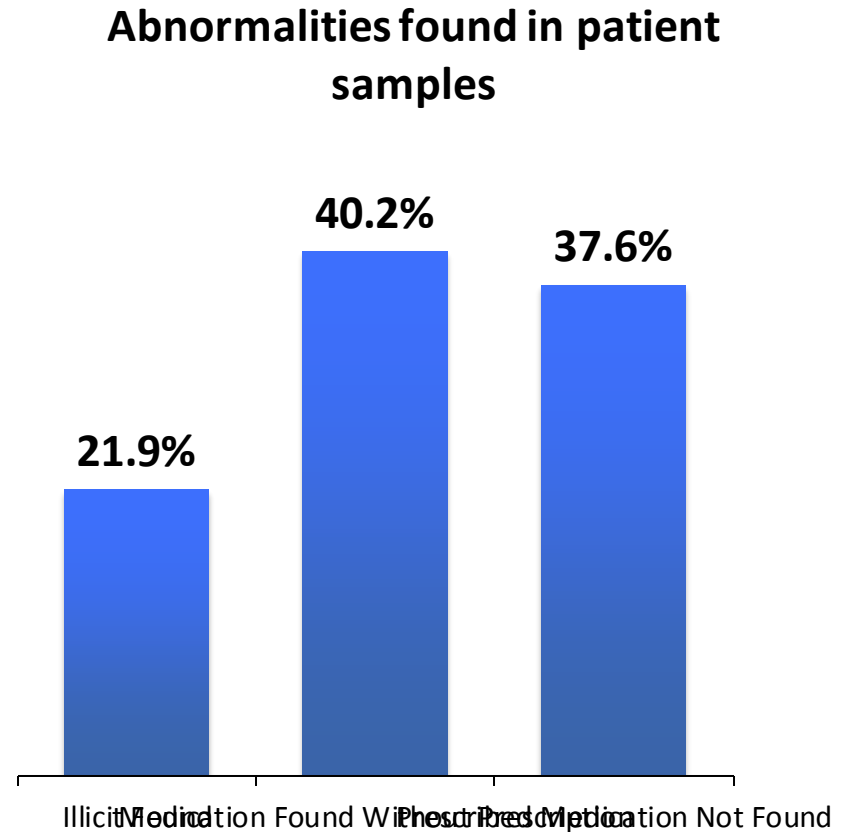
Abilify[®], Seroquel XR[®], Risperdal[®], and Lurasidone

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

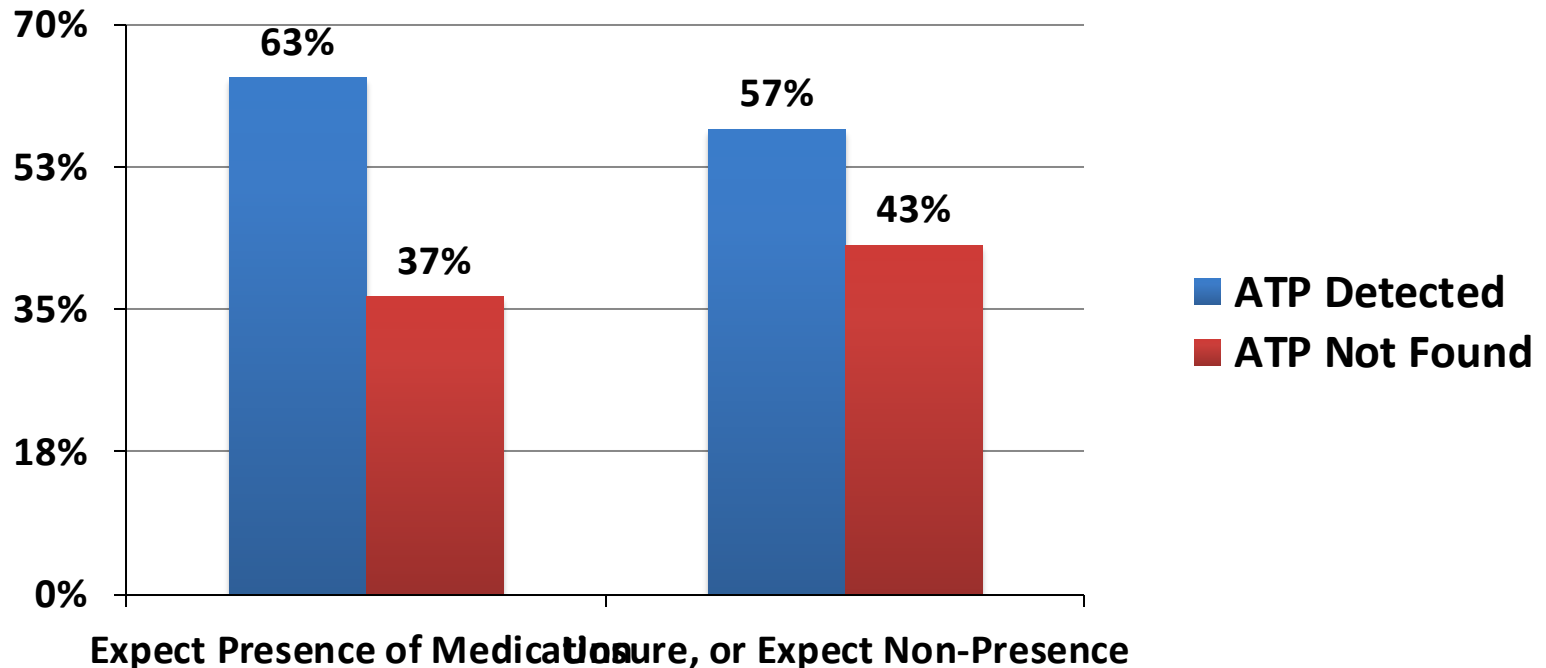
- Rapidly available, valid data about adherence
- Insight into prescribed medication compliance and the presence of other medications or illicit drugs
- Information to communicate productively with patients, their family and other supports



Ingenuity Health data on file; N=1,224

Provider Predictions of Adherence vs. Results

Prescribers of antipsychotics were asked to rate patients on the prescriber's expectation of medication presence (N=59)



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®)



Ingenuity Health Monitoring

Also detects:

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



GenesisSM Results Report

486 Gallimore Dairy Rd
Greensboro, NC 27409
Phone: 877-854-8150
Fax: (336) 387-7691

CLINIC INFORMATION	PATIENT INFORMATION	SPECIMEN INFORMATION
Name: MentalHealth	Name: Test, Patient07	Requestion Number: W3319007
Account: 235109	DOB: 08/15/1969	Lab Accession Number: 8130900544
Address: 7090 SAMUEL MORSE DRIVE ABERDEEN, MD 21001	Height: 62 in. Weight: 142 lbs. Gender: Female	Date Collected: 09/13/2013 Date Received by Lab: 09/17/2013 2:37 PM Date Reported: 09/18/2013 3:17 PM Report Version: 1
Fac: Doctor Test 7	ID:	

Test Performed	Lab Result (Qualitative)	Lab Result (ng/mL)	Assay Cutoff (ng/mL)	Normalized Value	Standard Score	95% Database Reference Range*	Range Comparison	Medication Comparison
ILLICIT DRUGS								
Cocaine Metabolite								
Benzoylcegonine (IA)	Negative	17	150					
MDMA								
MDMA (IA)	Negative	30	500					
Phencyclidine								
Phencyclidine (IA)	Negative	1	25					
OPIATES								
Opiates								
Opiates (IA)	Positive	375	50					See MS Results
Codeine (MS)	Negative		100					Consistent
Morphine (MS)	Negative		100					Consistent
Hydrocodone (MS)	Negative		100					Consistent
Hydromorphone (MS)	Negative		100					Consistent
Norhydrocodone (MS)	Negative		100					Consistent
Oxycodone/Oxymorphone								
Oxycodone/Oxymorphone (IA)	Positive	1640	100					See MS Results
Oxycodone (MS)	Positive	8377	100					REVIEW
Oxymorphone (MS)	Positive	2416	100					REVIEW
Noroxycodone (MS)	Positive	14330	100					REVIEW
RESULTS EXPLANATION								
The presence of oxycodone, oxymorphone, and noroxycodone (a metabolite of oxycodone) has been confirmed. This indicates recent oxycodone or oxycodone/oxymorphone usage. A prescription for oxycodone/oxymorphone was not reported. Typical detection time is up to 3 days.								
Heroin Metabolite								
6-acetylmorphine (IA)	Negative		10					

Clinic Name: MentalHealth	Patient Name: Test, Patient07	Requisition Number: W3319007
Toxicology Specialists: 855-287-8293	Ingenuity Health is a service of Ameritox Ltd.	Page: 2 of 5



GenesisSM Summary Report

486 Gallimore Dairy Rd
Greensboro, NC 27409
Phone: 877-654-6150
Fax: (432) 561-8450

CLINIC INFORMATION

Name: MentalHealth
Provider: Doctor Test 4

PATIENT INFORMATION

Name: Test, Patient 4
DOB: 11/06/1976

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

Oxycodone
Norfentanyl

Oxymorphone

Noroxycodone

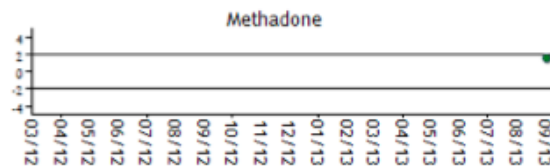
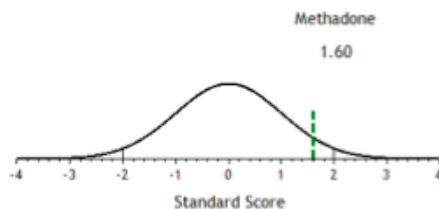
3. Medication Monitoring Results

Medication Prescribed	Test Result (Medication or metabolite)
METHADONE TABLET	Positive
RISPERDAL	Positive

4. Rx Guardian CD Standard Scores (Current)

5. Rx Guardian CD Historical Trend

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



Standard Score - Trend Analysis

- Medication Methadone
- Out Of Range Scores
- Unable to calculate standard score

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.

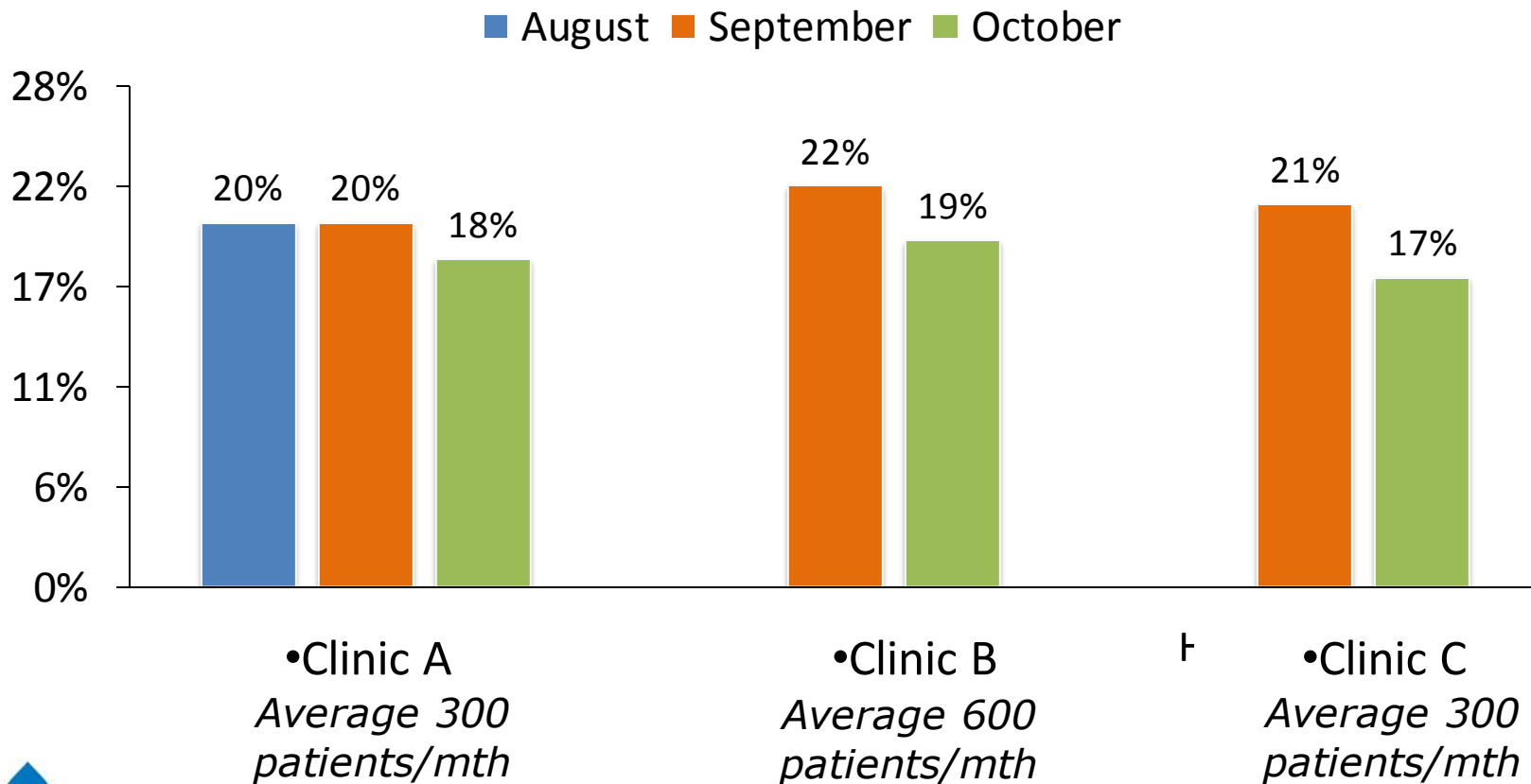
Sample Clinics and Results

- 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



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)