University of California San Diego / School of Medicine / Division of Infectious Diseases

Baseline Urine Methamphetamine (UTOXM) Predicts ART Adherence and Poor Retention in Care Attributes

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BACKGROUND

Early initiation of treatment is highly recommended for persons living with HIV infection, but objective baseline tests with predictive ability to distinguish persons at risk of poor ARV adherence and characteristics associated with poor retention in care are lacking.

Highly accurate estimates of adherence can be obtained FDA approved & CE marked Digital Health Feedback System (DHFS) consisting of an edible ingestion sensor (IS), external wearable patch and paired mobile device, can detect and record the timing of ingested ARVs .Encrypted data are automatically uploaded to a secure Internet server, allowing near-real time remote confirmation

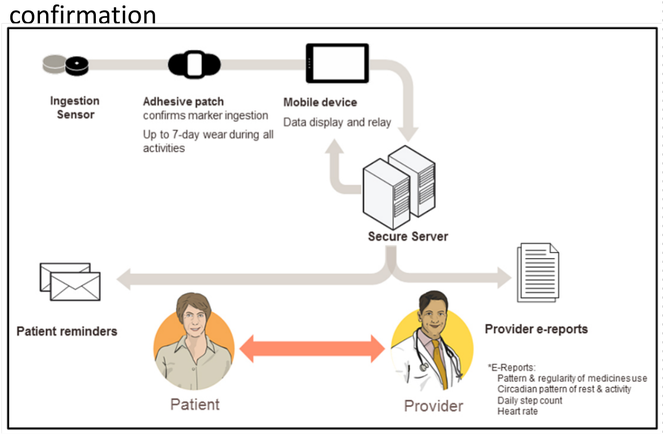


Figure 1. Digital Health Feedback System - how it works.

We developed Digital ARVs by co-encapsulating ARVs with an IS to generate precise ingestion records. Prior to clinical use, equivalence of IS-ARVs & parent ARVs was confirmed.



Figure 2. Co-encapsulation of ARVs with ingestible sensor

OBJECTIVES

- Evaluate the utility of baseline urine toxicology testing for methamphetamine (UTOXM) in persons starting oral ARVs
- Evaluate characteristics associated with positive UTOXM results
- Prospectively follow adherence to evaluate if UTOXM at baseline predicts ART adherence

METHODS

- PWH were prescribed ingestible-sensor-enabled ARV (IS-ARVs) technology to observe medication taking in the natural setting (West Coast of USA) for the first 16 weeks of treatment
- Baseline UTOX was performed
- Baseline demographics & self-report questionnaires were obtained
- Analysis of participant demographics, confirmed doses (taking and timing), persistence on study, and self-report questionnaires
- Mixed-effects logistic regression analysis for UTOXM association performed

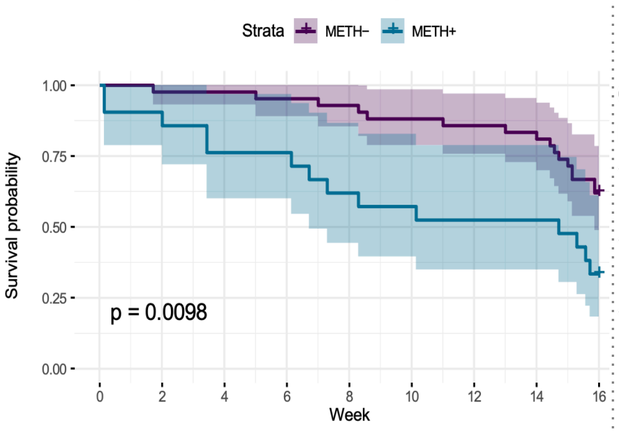
RESULTS

Demographic characteristics of study participants (N=68)	
Mean Age	37 years (IQR 30-46)
Male	82.5%
Race/Ethnicity	33.3% White; 34.9% Hispanic
	22.2% African American; 3.2% Asian

RESULTS CONTINUED

- UTOXM was negative in 42, positive in 21 (5 no UTOXM due to COVID).
- 6049 combined observation days
- Baseline NEGATIVE UTOXM (vs positive):
  - Daily confirmed dose OR = 3.12 (CI 1.71-5.71), P<0.001
  - Regularity of dose timing OR = 5.05 (CL 2.43-10.6), P<0.001.

Figure 4: Study survival curves by Methamphetamine Status



- 16-week persistence on study for UTOXM positive was 0.333 (0.182-0.610) vs negative 0.619 (95% CI 0.488-0.785) P=0.0098
- Baseline POSITIVE UTOXM (vs negative) associated with:
  - Higher homelessness/transient housing rate (52.4% vs 21.4% P=0.028)
  - Higher Life Chaos score 14.2 vs 9.0, P=0.001
  - More depression as measured by Mood PHQ8 11.8 vs 6.9, P=0.001
  - Lower mean income $7,400 vs $31,500, P=0.042

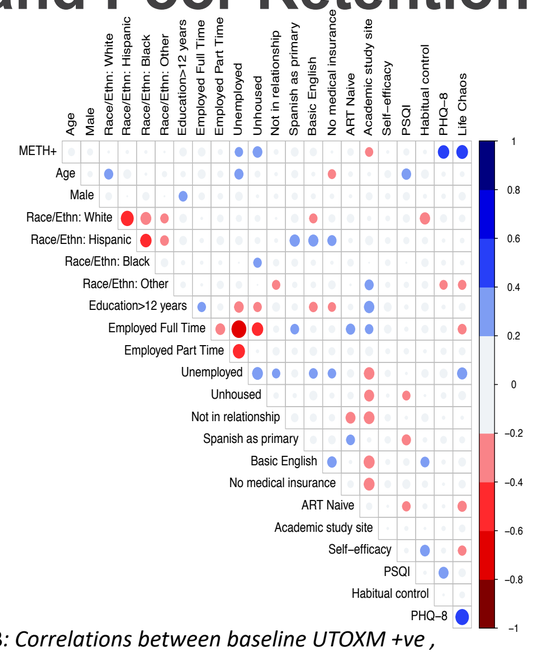


Figure 3: *Correlations between baseline UTOXM +ve , demographics and self-report questionnaires. (Positive correlation=blue, negative correlation=red)*

CONCLUSION

Baseline UTOXM in PWH starting oral ART identified:

- Highly significant differences in treatment adherence
- Persistence on study (a surrogate for care retention)
- Distinctive subpopulation with attributes associated with poor care engagement:
  - Life chaos
  - Depression
  - Homelessness

Baseline UTOX, simple screening tool to identify PWH requiring **differentiated care**

- Easily employed in mobile testing sites offering quick start care.
- Initial oral generic ART Regimens → $36,000-$48, 000 per year
- Cost of UTOXM → <$1

"Everybody gets so much information all day long that they lose their common sense"
Gertrude Stein

ACKNOWLEDGEMENTS

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