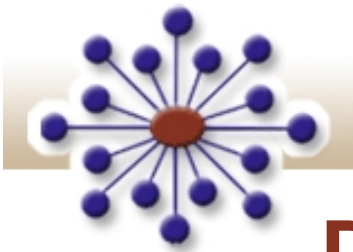


# Screening, Enrollment, and Assessment in the SMART-ED study

Robert Lindblad, MD

Ro Shauna S. Rothwell, PhD





# Need for SMART-ED: Drug Related ED visits are on the rise

Figure 3. Drug-Related Emergency Department (ED) Visits, by Type of Visit: 2004 to 2009\*

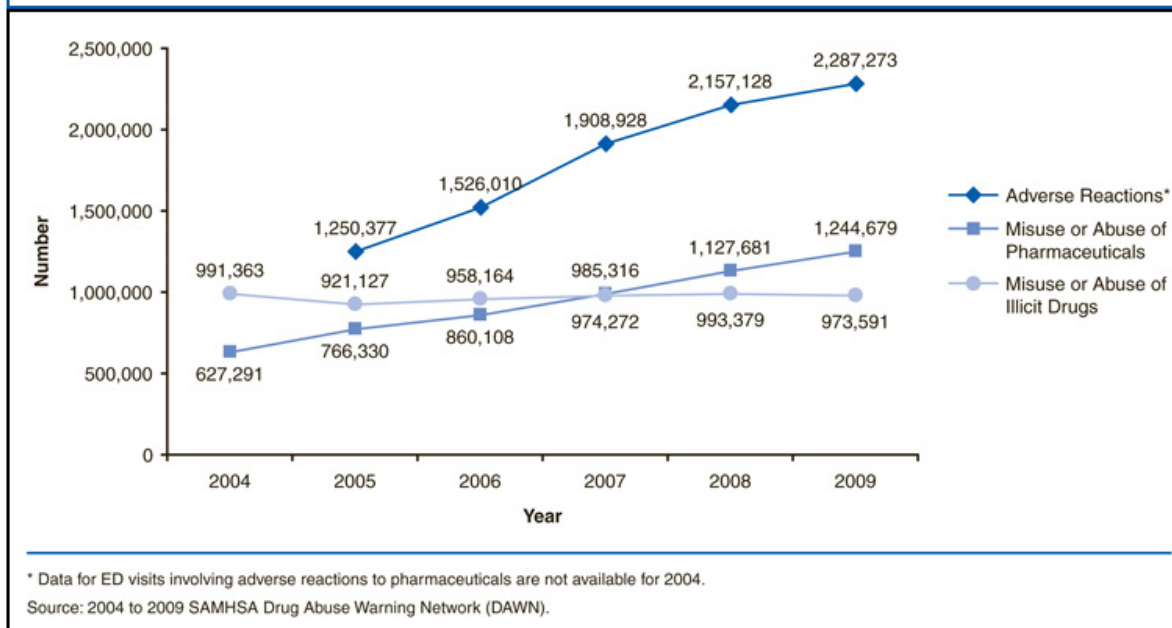


Figure 3 Table. Drug-Related Emergency Department (ED) Visits, by Type of Visit: 2004 to 2009\*

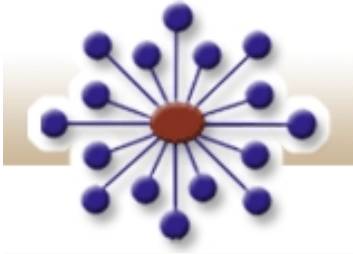
Type of Visit	2004	2005	2006	2007	2008	2009
Adverse Reactions*	†	1,250,377	1,526,010	1,908,928	2,157,128	2,287,273
Misuse or Abuse of Pharmaceuticals	627,291	766,330	860,108	985,316	1,127,681	1,244,679
Misuse or Abuse of Illicit Drugs	991,363	921,127	958,164	974,272	993,379	973,591

\* Data for ED visits involving adverse reactions to pharmaceuticals are not available for 2004.  
Source: 2004 to 2009 SAMHSA Drug Abuse Warning Network (DAWN).



## Study Set Up

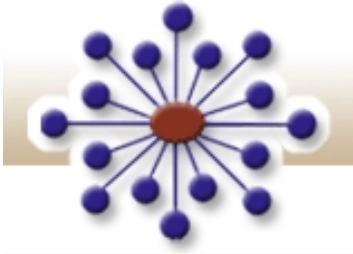
- Emergency Department (ED) selection
- Integration into the ED - **communication**
- Flexibility
- Recruitment
- Study flow
- Results



# SMART ED Emergency Department Selection

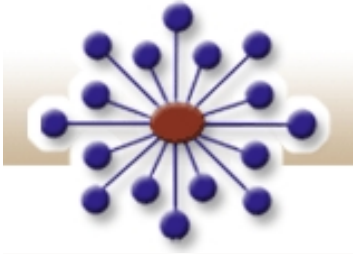
- Emergency Department Issues
  - Chaotic environment providing clinical care to a geographically limited population, SBIRT part of practice, research naive
  - Large study with potential for many screen failures
  - Limited staff to perform research assessments





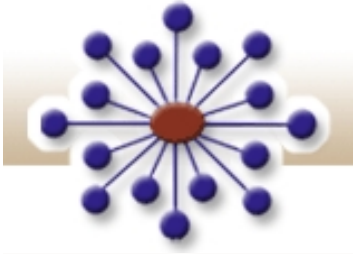
# SMART ED Emergency Department Selection, *continued*

- Study solutions
  - No current routine use of the SBIRT model for drug users
  - Research experience
  - Large volume of patients who use drugs
  - Ability to present a convincing plan for patient flow and space utilization
  - Have or are able to hire appropriate research staff to conduct the study (in conjunction with the NIDA CTN)
  - Have sufficient referral network for patients needing specialty addiction treatment
  - Population representative of US population (in aggregate)



# Integration of SMART-ED into Emergency Departments

- Principal Investigator had to be a ED Physician
- Hire staff to conduct research
- All EDs that participated had a **communication** plan
- Study Staff timed intervention to minimize interference with medical treatment
- Depending on level of acuity, some participants were approached prior to the initial evaluation by a physician, and some after
- Research assistant/interventionist worked closely with ED staff to identify potential participants, determine eligibility and to determine acuity



# Integration of SMART-ED into Emergency Departments

- Data Collection

- The HP-EliteBook 2730P was the Tablet PC used for the study

- Benefits

- facilitate rapid screening
- electronic data capture
- mobility within the busy ED setting

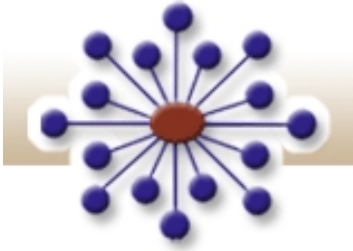


- Web based data entry with no data residing on the tablet

- None of the SMART-ED tablet PCs were stolen or misplaced

- Sites kept tablet logs

- To maximize confidentiality, the screening Tobacco Alcohol and Drug assessment (TAD) was completed by the participants unless the participant was not comfortable with this technology



# Flexibility: One size does not fit all

## Emergency Department Logistics Issues

- Variable recruitment hours and procedures
- Variable ED logistics
- Variable handling of medical and psychiatric events

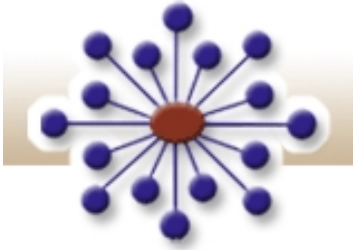
## Study Solution

- Each site developed site specific SOPs to address specific needs
  - All were reviewed centrally
- SMART-ED Study was initiated in two waves (2 sites followed by 4 sites)
- Issues discovered during wave 1 implementation were addressed during wave 2 training



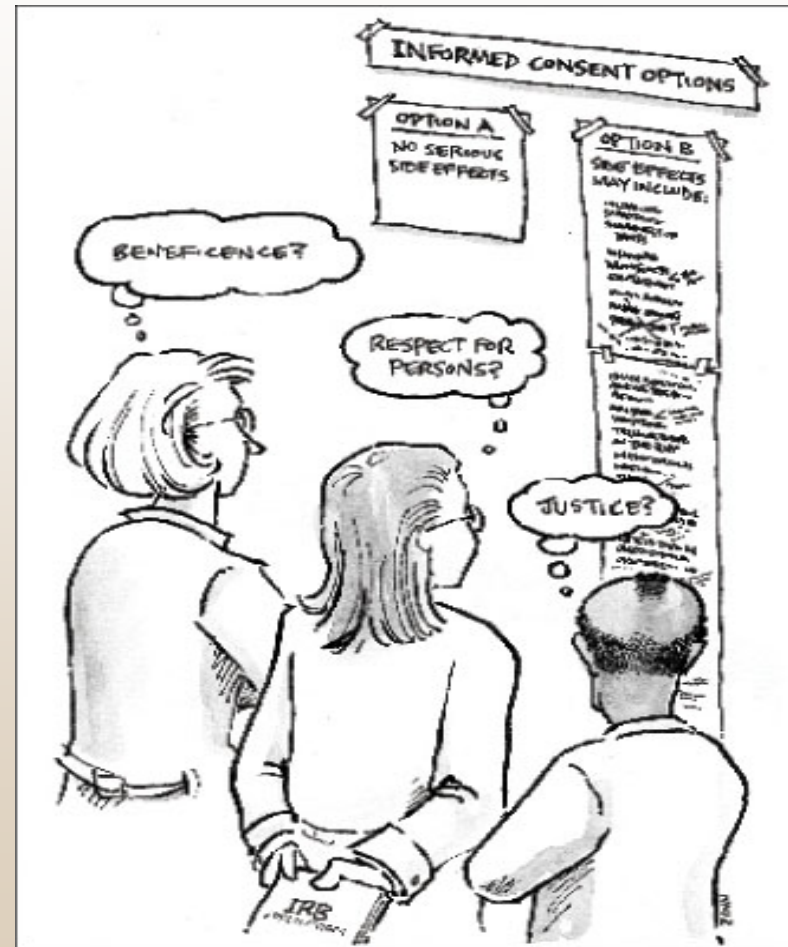
Emergency Departments

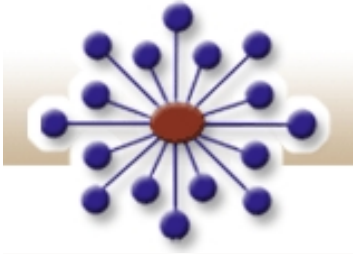




# Flexibility: Consenting Process

- Issue
  - Consent process had to be brief
- Solution
  - Participants provided verbal consent for the anonymous collection of screening data, using a brief IRB-approved script
  - Refusals and inability to participate were recorded on the BIT
  - After completing two screening forms (TAD and SSF) the participant received written informed consent



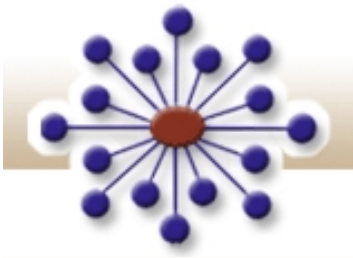


# Recruitment

ISSUE: Needed to ensure that the each site had a sampling procedure to ensure that the patients screened are broadly representative of the ED population

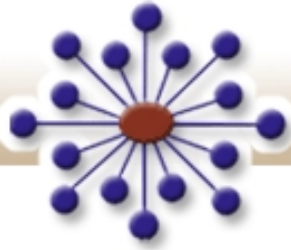
Solution:

- Most RA Interventionist assessed triage level by Patient Chart and/or consultation with ED staff such as a charge nurse or physician
- Next, the RA consulted various electronic systems to complete the Brief Intervention Tool assessment

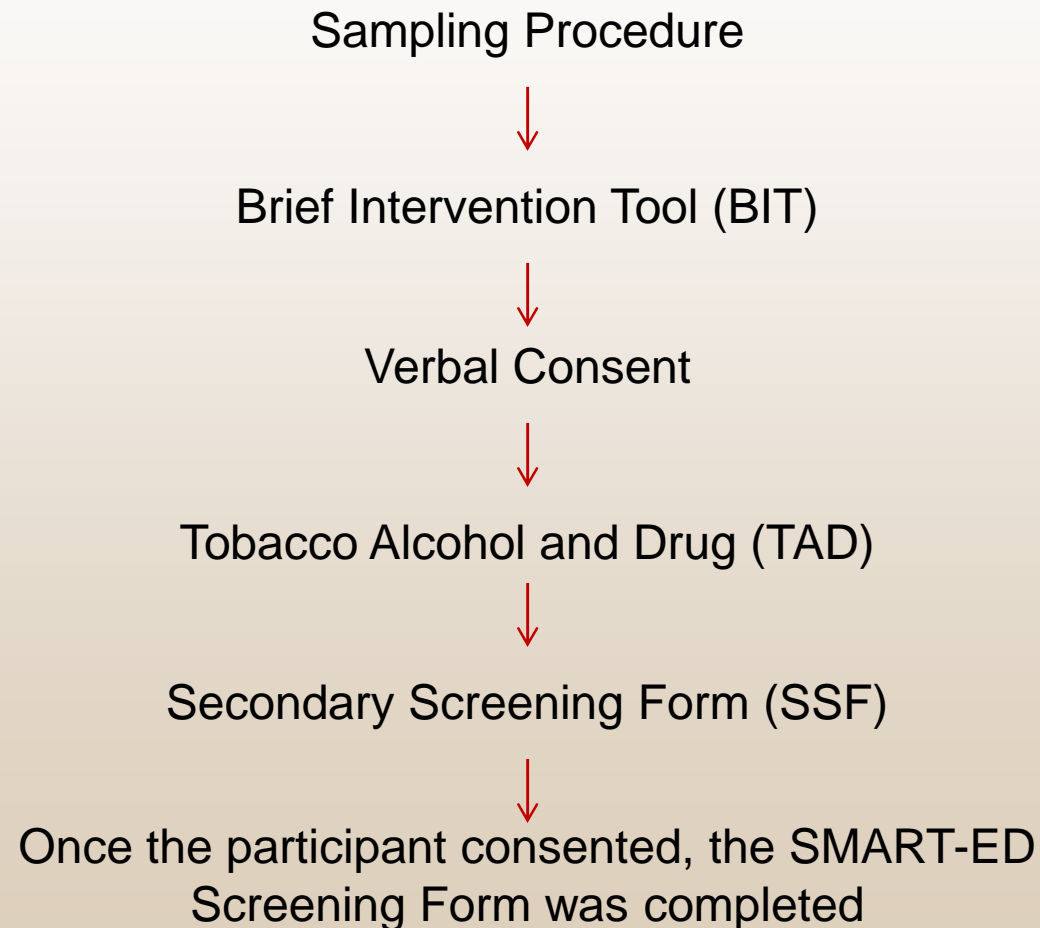


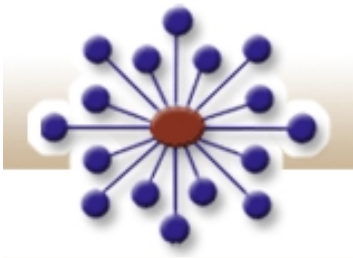
## Recruitment, *continued*

Site	Initial Sampling Procedure
West Virginia University Emergency Department	Electronic medical record system (MERLIN)
University of New Mexico Emergency Department	University Hospital patient tracking system "FirstNet."
Massachusetts General Health Emergency Department	Hospital ED Information System (EDIS)
Jackson Memorial ED	Access Corner/Powerchart
University of Cincinnati Emergency Department	LastWord
Bellevue Emergency Department	Electronic Whiteboard



# Synopsis of the Pre-Screening and Screening Process





# Synopsis of the Pre-Screening and Screening Process

Sampling Procedure



Brief Intervention Tool (BIT)



Verbal Consent



Tobacco Alcohol and Drug (TAD)



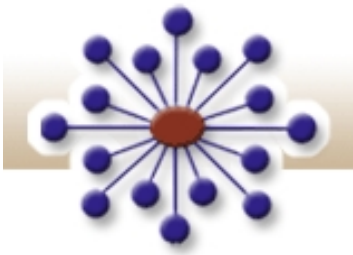
Secondary Screening Form (SSF)



Once the participant consented, the SMART-ED Screening Form was completed

Date, Age, Gender,  
Presenting complaint,  
Triage level





# Synopsis of the Pre-Screening and Screening Process

Sampling Procedure



Brief Intervention Tool (BIT)



Verbal Consent



**Tobacco Alcohol and Drug (TAD)**



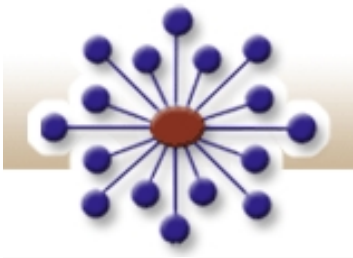
Secondary Screening Form (SSF)



Once the participant consented, the SMART-ED screening Form was completed

Heavy Smoking Index  
The AUDIT C  
DAST 10

If the DAST score is  $\geq 3$ , follow-up questions identified the primary drug of abuse (patient report) and the number of days of use of this substance in the past 30 days.



# Synopsis of the Pre-Screening and Screening Process

Sampling Procedure



Brief Intervention Tool (BIT)



Verbal Consent



Tobacco Alcohol and Drug (TAD)

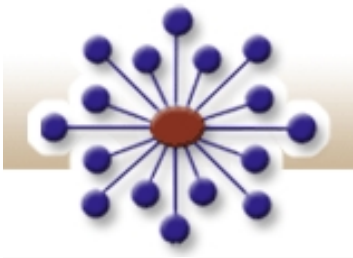


Secondary Screening Form (SSF)



Once the participant consented, the SMART-ED Screening Form was completed

In addition  
treatment  
Resides more than  
50 miles  
At least two locators  
Access to a phone  
Status as a prisoner



# Synopsis of the Pre-Screening and Screening Process

Sampling Procedure



Brief Intervention Tool (BIT)



Verbal Consent



Tobacco Alcohol and Drug (TAD)

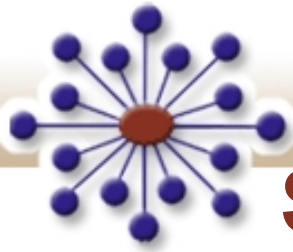


Secondary Screening Form (SSF)



Once the participant consented, the SMART-ED Screening Form was completed





# SMART-ED Biological Measure of Substance Abuse: Drug Hair Analysis

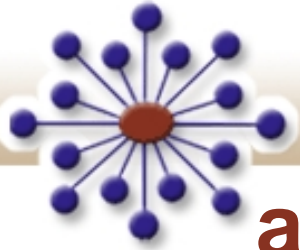
No sir, I don't think we'll have any difficulty gathering a sufficient sample.

*Clearly, I have no hair to spare!*



Cocaine  
Opiates  
PCP  
Amphetamines  
Marijuana

Hair grows 1.3  
cm/month  
4 cm – 3 mo  
detection



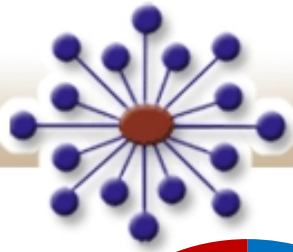
# The Results of Selection, Integration and Flexibility in the SMART-ED Study

## Success!

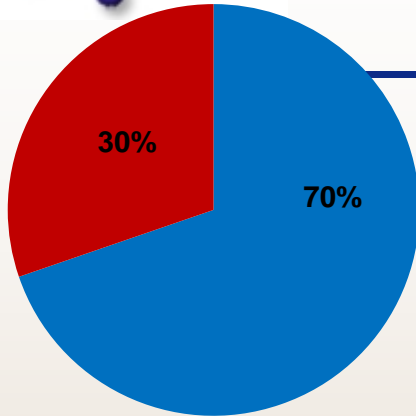


Who

How



# SMART-ED Participant Demographics and Socioeconomics (Who)



Gender

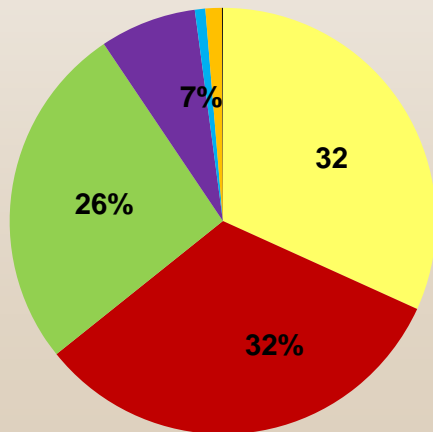
■ Male

■ Female

→ **Age** → 50% 25-45 Years old  
Mean Age was 36+/-

→ **Race** → 50% White  
34% Black  
4% Mixed Race  
5% Other

→ **Ethnicity** → 76% Not Hispanic/Latino  
24% Hispanic or Latino



Education

■ 1-11 Years Education

■ GED/12 Years Education

■ Some College

■ College Degree

■ Some Graduate

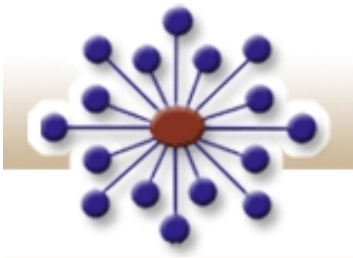
■ Graduate Degree

■ Post Graduate Degree

→ **Income** → 63% earned <15,000  
14% earned <30,000  
12% Declined to Answer

**Employment Past**

→ **30 Days** → 42% Unemployed  
19% Full time employment  
15% Retired  
6% Part time regular hours  
9% Part time irregular hours

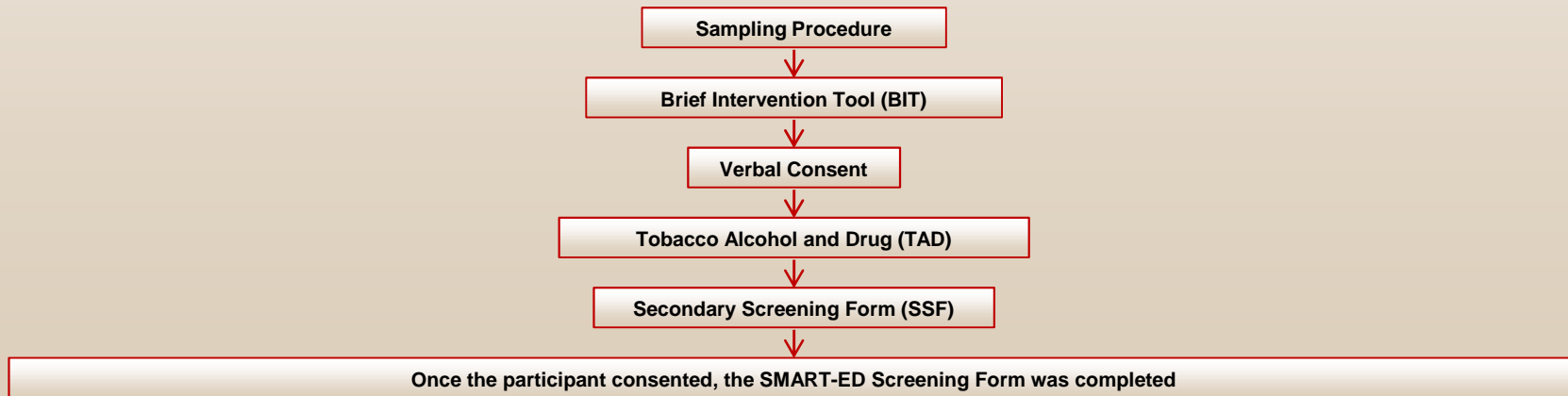


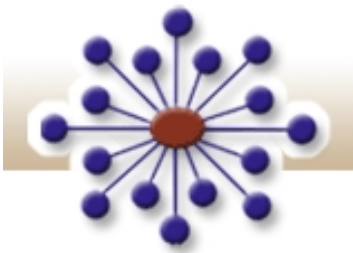
# BITs, TADs and Randomizations (HOW)

	Number of BITs	Number of Verbal Consents to Study	Number Agreed to Complete TAD	Number of TADs	Number of Written Consents	Number Randomized	Percentage of BITs Randomized
Site 1	5787	3626	3600	3550	259	256	4%
Site 2	3226	2314	2304	2262	289	287	9%
Site 3	4256	3688	3503	3389	137	135	3%
Site 4	4043	2844	2843	2831	179	179	4%
Site 5	2680	2268	2250	2231	195	194	7%
Site 6*	770	769	724	709	236	234	30%
Total	20762	15509	15224	14972	1295	1285	6%

\* Hospital uses a research consent for all patients that are admitted.

By signing this consent, the future SMART-ED participant agreed to research prior to consenting to a particular study. This process decreases the rate of screen fails thus increasing the percentage of BITs randomized compared to other sites.

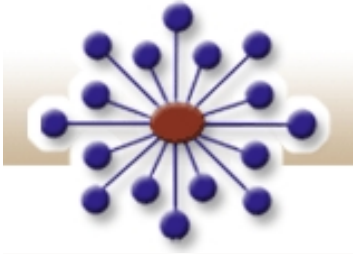




# Summary of TAD Results of Randomized Participants

	Cannabis		Cocaine		Amph		Meth		Inhalants		
	Number of Participants Randomized	N(%)	Avg Days*	N(%)	Avg Days*	N(%)	Avg Days*	N(%)	Avg Days*	N(%)	Avg Days*
Site 1	256	42(16%)	19	39(15%)	11	1(0%)	3	40(16%)	10		.
Site 2	287	142(49%)	18	86(30%)	10		.		.		.
Site 3	135	64(47%)	17	29(21%)	9		.	2(1%)	10		.
Site 4	179	89(50%)	20	65(36%)	10	1(1%)	3	5(3%)	16		.
Site 5	194	145(75%)	15	21(11%)	8	1(1%)	15	1(1%)	27		.
Site 6	234	85(36%)	19	109(47%)	15		.	1(0%)	1		.
Total	1285	567(44%)	18	349(27%)	11	3(0%)	7	49(4%)	11		.

	Sedatives or sleeping pills		Halluc		Street opioids		Prescribed opioids		Other	
	N(%)	Avg Days*	N(%)	Avg Days*	N(%)	Avg Days*	N(%)	Avg Days*	N(%)	Avg Days*
Site 1	2(1%)	27	1(0%)	5	112(44%)	21	19(7%)	19		.
Site 2	2(1%)	16	2(1%)	4	41(14%)	18	14(5%)	18		.
Site 3	4(3%)	19	3(2%)	3	22(16%)	19	10(7%)	11	1(1%)	18
Site 4	3(2%)	17		.	13(7%)	29	3(2%)	21		.
Site 5	4(2%)	6	1(1%)	12	7(4%)	19	14(7%)	17		.
Site 6	5(2%)	23	2(1%)	2	23(10%)	24	9(4%)	26		.
Total	20(2%)	17	9(1%)	4	218(17%)	21	69(5%)	18	1(0%)	18



## Conclusions

- Implementing a study in different Emergency Departments requires flexibility, constant communication and time efficiency
- Sample was diverse with respect to substance of abuse and ethnicity, used drugs frequently and had a very low socioeconomic status



# Acknowledgements

## NIDA Clinical Coordinating Center (CCC)



### Data and Statistics Center 2

Alex Borbely  
Neal Oden  
Gaurav Sharma  
Colleen Allen