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

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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**

<table>
<thead>
<tr>
<th>Type of Visit</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Reactions*</td>
<td>1,569,377</td>
<td>1,520,010</td>
<td>1,585,320</td>
<td>2,132,760</td>
<td>2,267,273</td>
<td></td>
</tr>
<tr>
<td>Misuse or Abuse of Pharmaceuticals</td>
<td>867,300</td>
<td>766,330</td>
<td>860,103</td>
<td>953,316</td>
<td>1,127,631</td>
<td>1,244,879</td>
</tr>
<tr>
<td>Misuse or Abuse of Illicit Drugs</td>
<td>991,365</td>
<td>921,127</td>
<td>958,164</td>
<td>974,272</td>
<td>993,379</td>
<td>973,591</td>
</tr>
</tbody>
</table>

* Data for ED visits involving adverse reactions to pharmaceuticals are not available for 2004.
Study Set Up

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

<table>
<thead>
<tr>
<th>Site</th>
<th>Initial Sampling Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>West Virginia University Emergency Department</td>
<td>Electronic medical record system (MERLIN)</td>
</tr>
<tr>
<td>University of New Mexico Emergency Department</td>
<td>University Hospital patient tracking system &quot;FirstNet.&quot;</td>
</tr>
<tr>
<td>Massachusetts General Health Emergency Department</td>
<td>Hospital ED Information System (EDIS)</td>
</tr>
<tr>
<td>Jackson Memorial ED</td>
<td>Access Corner/Powderchart</td>
</tr>
<tr>
<td>University of Cincinnati Emergency Department</td>
<td>LastWord</td>
</tr>
<tr>
<td>Bellevue Emergency Department</td>
<td>Electronic Whiteboard</td>
</tr>
</tbody>
</table>
## Synopsis of the Pre-Screening and Screening Process

<table>
<thead>
<tr>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampling Procedure</td>
</tr>
<tr>
<td>Brief Intervention Tool (BIT)</td>
</tr>
<tr>
<td>Verbal Consent</td>
</tr>
<tr>
<td>Tobacco Alcohol and Drug (TAD)</td>
</tr>
<tr>
<td>Secondary Screening Form (SSF)</td>
</tr>
</tbody>
</table>

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

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 addiction 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: 70%
- Female: 30%

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: 7%
- GED/12 Years Education: 32%
- Some College: 26%
- College Degree: 32%
- Some Graduate: 7%
- Graduate Degree: 32%
- Post Graduate Degree: Not Specified

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

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**BITs, TADs and Randomizations (HOW)**

<table>
<thead>
<tr>
<th>Site</th>
<th>Number of Bits</th>
<th>Number of Verbal Consents to Study</th>
<th>Number Agreed to Complete TAD</th>
<th>Number of TADs</th>
<th>Number of Written Consents</th>
<th>Number Randomized</th>
<th>Percentage of BITs Randomized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>5787</td>
<td>3626</td>
<td>3600</td>
<td>3550</td>
<td>259</td>
<td>255</td>
<td>4%</td>
</tr>
<tr>
<td>Site 2</td>
<td>3226</td>
<td>2314</td>
<td>2304</td>
<td>2262</td>
<td>289</td>
<td>287</td>
<td>9%</td>
</tr>
<tr>
<td>Site 3</td>
<td>4256</td>
<td>3688</td>
<td>3503</td>
<td>3389</td>
<td>137</td>
<td>135</td>
<td>3%</td>
</tr>
<tr>
<td>Site 4</td>
<td>4043</td>
<td>2844</td>
<td>2643</td>
<td>2383</td>
<td>179</td>
<td>179</td>
<td>4%</td>
</tr>
<tr>
<td>Site 5</td>
<td>2880</td>
<td>2268</td>
<td>2250</td>
<td>2231</td>
<td>195</td>
<td>194</td>
<td>7%</td>
</tr>
<tr>
<td>Site 6*</td>
<td>770</td>
<td>769</td>
<td>724</td>
<td>709</td>
<td>236</td>
<td>234</td>
<td>30%</td>
</tr>
<tr>
<td>Total</td>
<td>20762</td>
<td>15509</td>
<td>15224</td>
<td>14972</td>
<td>1295</td>
<td>1286</td>
<td>6%</td>
</tr>
</tbody>
</table>

* 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.

**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.
### Summary of TAD

#### Results of Randomized Participants

<table>
<thead>
<tr>
<th>Site</th>
<th>Cannabis</th>
<th>Cocaine</th>
<th>Amph</th>
<th>Meth</th>
<th>Inhalants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N(%)</td>
<td>Avg Days</td>
<td>N(%)</td>
<td>Avg Days</td>
<td>N(%)</td>
</tr>
<tr>
<td>Site 1</td>
<td>256</td>
<td>42(16%)</td>
<td>19</td>
<td>39(15%)</td>
<td>11</td>
</tr>
<tr>
<td>Site 2</td>
<td>267</td>
<td>142(49%)</td>
<td>18</td>
<td>86(30%)</td>
<td>10</td>
</tr>
<tr>
<td>Site 3</td>
<td>135</td>
<td>64(47%)</td>
<td>17</td>
<td>29(21%)</td>
<td>9</td>
</tr>
<tr>
<td>Site 4</td>
<td>179</td>
<td>89(50%)</td>
<td>20</td>
<td>66(36%)</td>
<td>10</td>
</tr>
<tr>
<td>Site 5</td>
<td>194</td>
<td>145(75%)</td>
<td>15</td>
<td>21(11%)</td>
<td>8</td>
</tr>
<tr>
<td>Site 6</td>
<td>234</td>
<td>86(36%)</td>
<td>19</td>
<td>109(47%)</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>1265</td>
<td>567(44%)</td>
<td>18</td>
<td>349(27%)</td>
<td>11</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sedatives or sleeping pills</th>
<th>Halluc</th>
<th>Street opioids</th>
<th>Prescribed opioids</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>N(%)</td>
<td>Avg Days</td>
<td>N(%)</td>
<td>Avg Days</td>
<td>N(%)</td>
</tr>
<tr>
<td>Site 1</td>
<td>2(1%)</td>
<td>27</td>
<td>1(0%)</td>
<td>5</td>
</tr>
<tr>
<td>Site 2</td>
<td>2(1%)</td>
<td>16</td>
<td>2(1%)</td>
<td>4</td>
</tr>
<tr>
<td>Site 3</td>
<td>4(3%)</td>
<td>19</td>
<td>3(2%)</td>
<td>3</td>
</tr>
<tr>
<td>Site 4</td>
<td>3(2%)</td>
<td>17</td>
<td>1(1%)</td>
<td>13(7%)</td>
</tr>
<tr>
<td>Site 5</td>
<td>4(2%)</td>
<td>6</td>
<td>1(1%)</td>
<td>12</td>
</tr>
<tr>
<td>Site 6</td>
<td>5(2%)</td>
<td>23</td>
<td>2(1%)</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>20(2%)</td>
<td>17</td>
<td>9(1%)</td>
<td>4</td>
</tr>
</tbody>
</table>
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

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Data and Statistics Center 2

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