Drug Chemists are Getting the Right Answers: Assessing Drug Analysis Error Rates in Municipal, County and Federal Laboratories

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Disclaimer:
The views expressed during this presentation are those of the authors alone and do not represent the views of the Oakland Police Department, Kern County Regional Laboratory, the Drug Enforcement Administration, the United States Department of Justice, or the United States Federal Government.
Error Rate

Addresses:

- Accuracy
- Reliability
- Validity

of methods to produce test outcomes

- Vernacular
  - How often you are wrong

- Statistical
  - Type I and Type II
  - False Positive and False Negative

- Scientific / Forensic
  - Proportion of test reports issued with the incorrect/incomplete answer

- Judicial
  - How much reliance should be placed on the results to determine trial outcome
NAS Report, 2009

- **Recommendation # 3**
- **Quantify measurement of uncertainty**
- **Demonstration of validity of forensic methods**
- **Research into accuracy, reliability of forensic analyses**
  - “Studies…should reflect actual practice on realistic case scenarios averaged across a representative sample of forensic scientists and laboratories."
- **These argue for the establishment of error rate**
Assessment of Error can be accomplished in several ways:

- Determining how often analysts correctly identify samples unknown to them, but known to the system (competency and proficiency tests; PT)
- Using Quality Assurance (QA) data obtained from Quality Control (QC) samples to quantify agreement
- Reanalyzing (RA) casework to assess correctness
Error Assessment

- **Proficiency Test (PT)**
  - **PRO**
    - Maps laboratory process
  - **CON**
    - Unless blind, analyst aware

- **Quality Control (QC)**

- **Reanalysis (RA)**
Error Assessment

**PRO**

- Casework reflects street samples—not pristine
- QC removal is routine not treated different by analyst

**CON**

- Liquids/plants excluded
- QA program ≠ entire laboratory process
- Other errors introduced
Error Assessment

- **Proficiency Test (PT)**
  - **PRO**: Reflective of actual street samples
  - **PRO/CON**: May (or may not) map entire laboratory process
  - **CON**: Adjudicated cases only
  - Labor intensive to rework analyses already completed

- **Quality Control (QC)**

- **Reanalysis (RA)**
DEA System

**Background:**
- DEA laboratory system (8 labs; > 270 chemists)
- Tens of thousands reports per year

**Objective:**
- Quantitative assessment of the reliability of the *overall* laboratory process
- Quality of laboratory results
- Confidence (or uncertainty) of reported identifications
DEA Laboratory Analytical Scheme:

- Requires analysts to test, at minimum:
  - Two portions
  - Two different and independent techniques
  - Use negative controls
  - Use positive controls (traceable reference materials)

- SWGDRUG Recommendations

- ASTM E2329
  - Standard Practice for Identification of Seized Drugs
DEA Drug Identification Process:
DEA Drug Identification Process:

- Where can errors occur?
- Phase I
  - Sample swapping, wrong barcoding, etc.
- Phase II
  - Analysis, sample swapping, contamination, etc.
- Phase III
  - Report preparation, dissemination, etc.
Uncertainty in Qualitative Analysis:

- Limited studies

- Past emphasis on quantitative analysis:
  - Measurement uncertainty

References:

DEA PTP Historical Data:

- 2005-2016
- 4794 test results
- 2392 inter-laboratory (24-27 PT rounds/year)
- 2058 intra-laboratory
- 216 external
- 128 blind
Classification of PT Results:

- **All PTP Results**
  - **CS Present?**
    - **YES**
      - **CS Reported?**
        - **YES** True Positive
        - **NO** False Negative
    - **NO** False Positive
  - **NO** True Negative
Calculating Response Rates:

\[ TPR \ (\text{sensitivity}) = \frac{\text{True Positives}}{\text{All Positives}} = \frac{TP}{(TP + FN)} \]

\[ TNR \ (\text{specificity}) = \frac{\text{True Negatives}}{\text{All Negatives}} = \frac{TN}{(TN + FP)} \]

\[ FPR \ (\text{Type I error}) = \frac{\text{False Positives}}{\text{All Negatives}} = \frac{FP}{(TN + FP)} = 1 - \text{specificity} \]

\[ FNR \ (\text{Type II error}) = \frac{\text{False Negatives}}{\text{All Positives}} = \frac{FN}{(TP + FN)} = 1 - \text{sensitivity} \]
# DEA Results Matrix:

<table>
<thead>
<tr>
<th></th>
<th>CS Reported</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>YES</td>
<td>NO</td>
<td>Total:</td>
</tr>
<tr>
<td>CS Present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>YES</td>
<td>4333</td>
<td>4</td>
<td></td>
<td>4337</td>
</tr>
<tr>
<td>NO</td>
<td>4</td>
<td>453</td>
<td></td>
<td>457</td>
</tr>
<tr>
<td>Total:</td>
<td>4337</td>
<td>457</td>
<td></td>
<td>4794</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.00092</td>
<td>0.99124</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>FNR (type II error)</td>
<td>TNR (specificity)</td>
<td></td>
</tr>
</tbody>
</table>
About the False Results:

- **4 False Positives:**
  - Sample swapping
  - Low-level secondary CS reported w/o fulfilling QA and documentation requirements
  - 2 incorrect CS reported (LIMS)

- **4 False Negatives:**
  - Sample swapping
  - Low concentration of target CS
  - 2 cases of low-level secondary CS
Using Bayesian Inference:

\[ P(A|B) = \frac{P(B|A) \cdot P(A)}{P(B)} \]

\[ P(CS|+) = \frac{P(+|CS) \cdot P(CS)}{P(+)} \]

\[ P(nCS|+) = \frac{P(+|nCS) \cdot P(nCS)}{P(+)} \]

Confidence in the Positive ID:

\[ P(CS|+) = \frac{P(+|CS) \cdot P(CS)}{P(+|CS) \cdot P(CS) + P(+|nCS) \cdot P(nCS)} \]

- **Prior probabilities**
- **True Positive Rate**
- **False Positive Rate**
- **Posterior probability**

- **Probability CS is present, given a reported result**
- **Confidence in the positive identification result**
# DEA Submissions & Reports:

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
<th>Laboratory Results</th>
<th>CS (%)</th>
<th>NCS (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>CS</td>
<td>NCS</td>
<td></td>
</tr>
<tr>
<td>1994</td>
<td>37,115</td>
<td>32,779</td>
<td>4,336</td>
<td>88.32</td>
</tr>
<tr>
<td>1995</td>
<td>38,668</td>
<td>34,645</td>
<td>4,023</td>
<td>89.60</td>
</tr>
<tr>
<td>1996</td>
<td>43,662</td>
<td>38,836</td>
<td>4,826</td>
<td>88.95</td>
</tr>
<tr>
<td>1997</td>
<td>49,156</td>
<td>43,965</td>
<td>5,191</td>
<td>89.44</td>
</tr>
<tr>
<td>1998</td>
<td>55,946</td>
<td>49,919</td>
<td>6,027</td>
<td>89.23</td>
</tr>
<tr>
<td>1999</td>
<td>60,093</td>
<td>53,869</td>
<td>6,224</td>
<td>89.64</td>
</tr>
<tr>
<td>2000</td>
<td>64,608</td>
<td>57,840</td>
<td>6,768</td>
<td>89.52</td>
</tr>
<tr>
<td>2001</td>
<td>66,235</td>
<td>59,776</td>
<td>6,459</td>
<td>90.25</td>
</tr>
<tr>
<td>2002</td>
<td>64,504</td>
<td>58,065</td>
<td>6,439</td>
<td>90.02</td>
</tr>
<tr>
<td>2003</td>
<td>59,793</td>
<td>54,148</td>
<td>5,645</td>
<td>90.56</td>
</tr>
<tr>
<td>2004</td>
<td>56,709</td>
<td>50,973</td>
<td>5,736</td>
<td>89.89</td>
</tr>
<tr>
<td>Total</td>
<td>596,489</td>
<td>534,815</td>
<td>61,674</td>
<td><strong>88.2 – 90.9</strong></td>
</tr>
</tbody>
</table>
Population: DEA Lab Submissions

- $P(\text{CS}) = 0.90$
- $P(\text{nCS}) = 0.10$

Confidence = $P(\text{CS}|+) = \frac{P(+|\text{CS}) \cdot P(\text{CS})}{P(+|\text{CS}) \cdot P(\text{CS}) + P(+|\text{nCS}) \cdot P(\text{nCS})}$

$P(\text{CS}|+) = \frac{(0.99907)(0.90)}{(0.99907)(0.90) + (0.00875)(0.10)}$

$P(\text{CS}|+) = 0.99902 = 99.90\%$
Population: DEA Lab Submissions

- \( P(CS) = 0.90 \)
- \( P(nCS) = 0.10 \)

\[
\text{Uncertainty} = P(nCS|+) = \frac{P(+|nCS) \cdot P(nCS)}{P(+|nCS) \cdot P(nCS) + P(+|CS) \cdot P(CS)}
\]

\[
P(nCS|+) = \frac{(0.00875)(0.10)}{(0.00875)(0.10) + (0.99907)(0.90)}
\]

\[
P(nCS|+) = 0.00097 = 0.097\%
\]
OPD Proficiency Tests

- Proficiency Test results
  - Shows that OPD analysts get the right answer
  - 20 years, averaging 2-3 analysts per year, n=87
  - All proficiency test answers submitted were correct
  - No failures occurred

- As a small population, not statistically significant

- Potential to lead to incorrect conclusion of “0% error”
OPD QA Program/QC samples

- Another treasure trove
- In 1996, ASCLD/LAB assessment, team of assessors wanted more information regarding microcrystalline testing
- OPD opted to start a QA program
  - In 2000, SWGDRUG recommendations suggested contemporaneous peer review, OPD instead elected to continue QA Program
OPD QA Program/QC samples

- All powders > 0.06 g sampled and set aside
- Analyst conducts testing; sometime throughout analysis, collects QC sample into ziplock
  - No mandate to do so before or after test sample is collected
  - No mandate to ensure homogeneity
    - May not know this until after testing is complete
- Liquids and plant material excluded
QA Program

- At least 10% QC samples randomly selected and tested

- In the first year, 1996, original analysis reconfirmed by retesting using the same method
  - If the submission had been tested by microcrystals, it was retested by microcrystals

- In the second year, 1997, the selected samples were run by GC/MS

- For 20 years from 1997 – 2016 this has continued

- 4459 samples analyzed in this time
Analysis

Submission

Evidence

Analysis

ASTM E2329 / SWGDRUG recommendations

Result

Write report
Analysis and QA Program

Submission
- Evidence

Analysis
- ASTM E2329 / SWGDRUG recommendations
- QC

Result
- Write report
- TR/AR
- Publish Report
- QC result from GC/MS
Archived Data
Classification of QC Results:

- **Original Report**
  - CS Present?
    - Yes
    - No

- **QC**
  - Yes
    - True Positive
  - No
    - False Positive
    - False Negative (low coc not ID)
    - True Negative
OPD Results

- 4459 QC samples
- 4445 Agreement after investigation (99.6%)
- 7 False Positives
- 7 False Negatives

False Positives
- Isomer indistinguishability
- Unexplained trace cocaine in QC, need to retest
- 3 cases of meth+MDA where meth not observed in QC

False Negatives
- Isomer indistinguishability
- 4 cases of method limitation: microcrystal and trace cocaine
- Threshold – analyst did not call
## OPD Results Matrix

<table>
<thead>
<tr>
<th>CS reported</th>
<th>CS Present QC</th>
<th>TPR (sensitivity)</th>
<th>FPR (type I error)</th>
<th>FNR (type II error)</th>
<th>TNR (specificity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>4218</td>
<td>0.99834</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NO</td>
<td>7</td>
<td>0.02991</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total:</strong></td>
<td><strong>4225</strong></td>
<td><strong>234</strong></td>
<td><strong>4459</strong></td>
<td><strong>0.00166</strong></td>
<td><strong>0.97009</strong></td>
</tr>
</tbody>
</table>
OPD Methods in Casework

- 4459 QC samples (89.2%)
- 3977 microcrystals (6.7%)
- 299 instrument (3.88%)
- 173 micro+inst (5.1%)
- 227 negative samples (0.22%)

Proportion of Cases Analyzed by Method

- Color & Crystal Tests Only: 3.88%
- Instrumentation Only: 6.71%
- All Three Techniques: 89.19%
- Undetermined (mislabel or unable to locate case folder): 0.22%
Population: OPD Lab Submissions

- $P(\text{CS}) = 0.95$
- $P(\text{nCS}) = 0.05$

Confidence = $P(\text{CS} | +) = \frac{P(+ | \text{CS}) \cdot P(\text{CS})}{P(+ | \text{CS}) \cdot P(\text{CS}) + P(+ | \text{nCS}) \cdot P(\text{nCS})}$

$P(\text{CS} | +) = \frac{(0.99834)(0.95)}{(0.99834)(0.95) + (0.02991)(0.05)}$

$P(\text{CS} | +) = 0.99728 = 99.84\%$
Population: OPD Lab Submissions

- $P(CS) = 0.95$
- $P(nCS) = 0.05$

Uncertainty = $P(nCS|+) = \frac{P(+)nCS \cdot P(nCS)}{P(+)nCS \cdot P(nCS) + P(+)CS \cdot P(CS)}$

$$P(nCS|+) = \frac{(0.02991)(0.05)}{(0.02991)(0.05) + (0.99834)(0.95)}$$

$$P(nCS|+) = 0.00272 = 0.16\%$$
Microcrystalline Tests

- **Positive Aspects**
  - Fast
  - Cheap
  - Intuitive
  - Used in forensic science for over 100 years

- **Negative Aspects**
  - ‘Techniquey’
  - Not good for mixtures
  - Few tests for emerging drugs; more for established ones
Microscope for Microcrystals
Methamphetamine Microcrystals
Kern Regional Crime Lab

- Two microcrystalline tests conducted
  - Cocaine base 113
  - Cocaine salt 27
  - Methamphetamine 510
  - Amphetamine 3

- GC/MS confirmation
  - Cocaine base 113
  - Cocaine salt 27
  - Methamphetamine 511
  - Amphetamine 5

653 out of 656 correctly identified = 99.5%
Conclusion

- Drug Chemists are doing an excellent job identifying controlled substances

- Error rates were effectively assessed by using:
  - PTs, QA Program/QC samples and Reanalysis
  - All demonstrated to be less than 0.5%

- This study addresses NAS Report Rec #3 by assessing error “… on realistic case scenarios averaged across a representative sample of forensic scientists and laboratories”
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Questions?

Thank You!

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