FAA EXPERIENCE WITH NEUROPSYCHOLOGICAL TESTING FOR AIRMEN WITH DEPRESSION ON SSRI MEDICATIONS

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Disclosure Information
James R. DeVoll, M.D.

• I have no financial relationships to disclose.

• I will not discuss off-label use and/or investigational use in my presentation

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• Opinions expressed do not necessarily represent the position of the FAA
Introduction


However...

• Psychiatric disorders manifested by depression or other affective symptoms may impair cognitive function

• Selective Serotonin-Reuptake Inhibitor (SSRI) medications may also impair cognitive function
Introduction

Requirements of the SSRI Policy

- Limited to: depression (not bipolar)
- Acceptable medications:
  - Fluoxetine (Prozac)
  - Escitalopram (Lexapro)
  - Sertraline (Zoloft)
  - Citalopram (Celexa)
- Treatment: 12 months documented stability
- And: no evidence of aeromedically significant neurocognitive deficiencies
Introduction

So… How to identify significant aeromedical deficiencies?

Require submission of:

• Full battery of neuropsychological testing
• An aeromedical NP screening test
  (CogScreen-AE)
Introduction

Seemed simple enough…

But, when actually put into a process, things became a bit more complicated.
**Introduction**

**SSRI Decision Path**

- **Airman is on:**
  - Fluoxetine (Prozac)
  - Escitalopram (Lexapro)
  - Sertraline (Zoloft)
  - Citalopram (Celexa)

- **Nature of Diagnosis**
  - Depression and/or Other Diagnosis

- **Airman must contact HIMS AME**
  - On SSRI more than 12 months? **No**
    - • Advise must be on SSRI at least 12 months before SI consideration
      • If airman elects to discontinue use of SSRI at this point, see SSRI Decision Path I

- **Currently on multiple psychiatric medications and/or history of unacceptable diagnosis or symptoms**
  - • Advise NOT Acceptable
    - • Defer
    - • Forward all material and exam to AMCD for FAA decision

- **Airman MUST provide statement, evaluation reports, records, tests, and letters as outlined PER SPECIFICATION SHEET**

- **HIMS AME to:**
  - Review all material, conduct detailed evaluation, make recommendation regarding SI, agree to continued monitoring per FAA Policy, send package to AMCD for review

- **FAA Issues SI**

- **DENIED**
  - (Depending on reason, airman may be able to re-enter flow-chart process)
Introduction

SSRI Follow Up Path

Airman with SSRI Special Issuance

First and Second Class

Third Class

Airman must send to HIMS AME:
• Current status report from treating physician
• Psychiatric consultation status report every 6 months

Letter From airline management every 3 months for those flying under FAR Part 121 or 135

Review by HIMS AME

Neurocognitive testing annually

Forward to FAA Chief Psychiatrist for issuance approval

Concerns or abnormalities: defer to FAA Chief Psychiatrist

Neurocognitive testing every 2 years
Introduction

Full Neuropsychological Battery (NP-battery)

• The Wechsler Adult Intelligence Scales
• Trail Making Test, Parts A and B
• Executive function tests
  – Category Test or Wisconsin Card Sorting Test; and Stroop Color-Word Test
• Paced Auditory Serial Addition Test (PASAT)
• A continuous performance test
  – Test of Variables of Attention [TOVA], Conners’ Continuous Performance Test [CCPT], or Integrated Visual and Auditory Continuous Performance Test [IVA]
• Test of verbal memory
  – WMS-IV subtests, Rey Auditory Verbal Learning Test, or California Verbal Learning Test-II
• Test of visual memory
  – WMS-IV subtests, Brief Visuospatial Memory Test-Revised, or Rey Complex Figure Test
• Tests of Language
  – Boston Naming Test and testing for verbal fluency (i.e., the COWAT and a semantic fluency task)
• Psychomotor testing (Finger Tapping, and either Grooved Pegboard or Purdue Pegboard)
• Personality testing to include Minnesota Multiphasic Personality Inventory (MMPI-2)
Introduction

SSRI Cases Opened in System

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<th>Month and Year</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010 7</td>
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</tr>
<tr>
<td>2010 8</td>
<td>2</td>
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<td>2011 5</td>
<td>2</td>
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<tr>
<td>2011 6</td>
<td>2</td>
</tr>
</tbody>
</table>
Introduction

Concerns evident from the first 24 months:

1. Complexity of process for initial consideration and continuation in the program for airmen and HIMS AMEs
2. Complexity faced by FAA AAM personnel in the processing chain
3. Costs: both for the airman and in person-hours required for FAA processing
4. Ethical and privacy concerns over release of testing results and data
Introduction

So with these issues in mind…

… what is the “right” NP testing data needed for:

• Initial SSRI program certification decision?

• Follow-on certification decisions?
Introduction

Objectives of this study:

• Evaluate CogScreen-AE vs. Full NP-battery for assessing eligibility for medical certification under the SSRI protocol

• Examine data for other CogScreen-AE metrics that might further refine qualification predictions (e.g., LRPV scores, processing speed scores, etc.)
Methods

• **Case Identification:**
  Queried the Medical Appeals Branch database for all cases evaluated under the SSRI protocol from 4/2010 through 6/2012

• **Sources of information:**
  – Medical Appeals Branch Database: Case status and final certification determination
  – FAA electronic medical records (DIWS) and hardcopy records: results of CogScreen-AE and NP-battery testing and other supplementary information
Methods

Data Elements for each case

• NP Testing Performance Summary
  
  CogScreen-AE deficiency: Yes / No
  NP-battery deficiency: Yes / No

• Issued a Medical Certificate: Yes / No

• Disqualified due to NP deficits: Yes / No

• CogScreen-AE: LRPV score; subtest scores <5th & 15th p-tile

• NP-battery: significant subtests
Methods

Selection Criteria:
• The most recent record (if reviewed >1)
• Both CogScreen-AE and NP-battery results available for review
• Final determination made regarding certification

Analysis
• Sensitivity, Specificity, Positive Predictive Value (PPV) and Negative Predictive Value
Results

For the period April 2010 – June 2012:

• Total individual airmen: 128
• Total meeting selection criteria: 98

• Issued: 79

• Denied: 19
  • Neurocognitive deficiencies 11
  • Other disqualification* 8

* Other medical condition; did not meet SSRI policy requirements due to type of psychiatric diagnosis, suicide history, inadequate treatment duration or stability, or unacceptable medication usage (multiple medications, use of unapproved SSRI, etc.)
## Results

<table>
<thead>
<tr>
<th></th>
<th>Cognitive Deficiency on Full NP Test Battery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>CogScreen-AE: Weak/Deficient Performance</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Total NP Determinations</td>
<td>11 (Disqualified)</td>
</tr>
</tbody>
</table>

- CogScreen-AE identified 25.2 % as potentially impaired
- NP-battery: impairment confirmed in 12.6 %
- Overall: 87.4% neurocognitively eligible, and 12.6% disqualified.
## Results

<table>
<thead>
<tr>
<th>CogScreen-AE performance:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>100.0%</td>
</tr>
<tr>
<td>Specificity</td>
<td>87.4%</td>
</tr>
<tr>
<td>PPV</td>
<td>50.0%</td>
</tr>
<tr>
<td>NPV</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
## Results

Relationship of LRPV “probability for brain dysfunction” to determinations:

<table>
<thead>
<tr>
<th>CogScreen-AE: LRPV Score*</th>
<th>Cognitive Deficiency on Full NP Test Battery</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td></td>
<td>4</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td>Low</td>
<td></td>
<td>7</td>
<td>76</td>
<td>83</td>
</tr>
<tr>
<td>Total NP Determinations</td>
<td></td>
<td>11</td>
<td>87</td>
<td>98</td>
</tr>
</tbody>
</table>

Odd’s Ratio = 3.95

* “High” if >= 0.8
## Results

**Relationship of LRPV “probability for brain dysfunction” to determinations:**

<table>
<thead>
<tr>
<th></th>
<th>Cognitive Deficiency on Full NP Test Battery</th>
<th>Fisher Test p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>CogScreen-AE:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean LRPV Score</td>
<td>High</td>
<td>0.9672</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>0.5333</td>
</tr>
<tr>
<td></td>
<td>Fisher Test p-value</td>
<td>0.02</td>
</tr>
</tbody>
</table>

**Other potential metrics: inadequate number of data points for analysis.**
Discussion

• Limitations
  – Relatively small sample size (n = 98)
  – Low counts in some cells

• Potential Biases
  – Retrospective or post hoc analysis
  – Testing done by a variety of neuropsychologists
  – No standardized “study protocol” for reviewers’ interpretations or determinations
  – Reviewers not blinded to clinical history
  – Unable to assess potential impact of cases excluded from analysis due to missing CogScreen-AE data
Discussion

Strengths of the study

• “Real world” data = representative of the actual testing and reports that we can expect to be submitted by airmen in the future and consistent with past experience
Discussion

• Interpretation: CogScreen-AE performed well as a screening test by identifying all airmen with significant cognitive deficiencies diagnosed by full NP battery testing.

• The positive predictive value was only 50%, suggesting that half of individuals undergoing full NP battery testing on the basis of CogScreen-AE will not have deficits.
Discussion

However, based on the findings of this study, over 75% of airmen tested by CogScreen-AE may be spared full NP battery testing!!!
Discussion

Conclusions:
1. Current data compelling for eliminating full NP-battery testing as a requirement for initial consideration, unless deficiencies are suggested by CogScreen-AE
2. Follow-on NP testing requires only CogScreen-AE, except where clinically indicated on a case-by-case basis
Discussion

• High LRPV score may increase odds of finding deficiencies on full NP-battery testing, these data not sufficient to draw any other inferences.

• Insufficient numbers for further analysis of potential importance of subtest results.
Discussion

Future questions:

• Can we further refine interpretation of CogScreen-AE to reduce the number of airmen required to undergo further “non diagnostic” full NP battery testing?
• Can we further reduce the frequency of follow-on testing from current requirements (annual for first-/second-class and every 2 years for third-class)?
Thank You