Diagnostic Testing for Alzheimer’s Disease

Policy Development Group Meeting

September 13, 2012
Agenda for the Day

• Introductions and declaration of interests
• Overview of goals of project
• Review of white paper (structure, organization, perspectives, etc.)
• Lunch break
• Review of recommendations (framing, utility for multiple audiences, etc.)
• Dissemination plan
• Next steps
Project Goals

- Bring together leading representatives of clinical researchers, patients, the life science industry, and insurers to share perspectives on how best to generate the evidence needed to guide coverage determinations and the appropriate use of diagnostic tests for Alzheimer’s disease
  - Describe a consistent framework for the assessment of evidence on diagnostic tests for AD
  - Evaluate the current literature to identify the types of studies still needed
  - Recommend study types and key elements of study design to provide suitable evidence base
Review of Draft
White Paper Structure
White Paper Structure

- Introductory sections
  - Evolving diagnostic paradigm for AD
  - Overview of diagnostic testing methods
- Conceptual approach to evaluating evidence on AD diagnostic tests
- Review of current evidence
- Clinical guidelines/coverage policies
- Key ongoing/planned AD diagnostic studies
- Overview of biomarker validation study designs
- Recommendations for future research
Simplified analytic framework: Diagnostic testing for Alzheimer’s Disease

Patient with Memory Complaints → Clinical Evaluation → Further Diagnostic Testing → Treatment

Positive

Positive

Negative

Negative

No Treatment

Potential Harms

Potential Benefits
# Evidence Hierarchies

<table>
<thead>
<tr>
<th>Diagnostic Imaging Evidence Hierarchy Level</th>
<th>Genetic Testing Evidence Category</th>
<th>Example of Outcome Measures</th>
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<tbody>
<tr>
<td>1. Technical Efficacy</td>
<td>1. Analytic validity</td>
<td>Interpretable scan resolution, accuracy and reliability of tests of CSF proteins to measure CSF protein levels, inter-reader and inter-laboratory reliability of test results</td>
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<tr>
<td>2. Diagnostic Accuracy</td>
<td>2. Clinical validity</td>
<td>Sensitivity/specificity vs. gold standard test or vs. some other standard</td>
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<td>3. Diagnostic Impression</td>
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<td>Change in presumptive diagnosis following introduction of new test results</td>
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<td>4. Diagnostic Action</td>
<td></td>
<td>Initiation or cessation of treatment; impact on use of additional diagnostic studies</td>
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<tr>
<td>5. Patient Outcomes</td>
<td>3. Clinical utility</td>
<td>Cognitive/functional decline, time to institutionalization, side effects of treatment driven by test results, mortality</td>
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<td>6. Societal Outcomes</td>
<td></td>
<td>Cost-effectiveness of testing</td>
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Key Issues

• **Overall white paper structure and flow**
  – Does the conceptual approach to evidence assessment seem “right”?

• **Unnecessary sections?**

• **Missing sections or under-represented issues?**
  – FDA issues covered adequately?
  – European issues covered adequately?
  – Biomarker validation research designs section – helpful?

• **Appropriate balance of insurer vs. other perspectives?**
  – Will the analysis/discussion help insurers?
Review of Recommendations for Future Research
Research Recommendations

• Structure
  – What insurers will be looking for
  – Broad research recommendations
  – Trial design recommendations

• Are the recommendations valid and useful?
  – Clinical researchers
  – Life science industry
  – Do they reflect what insurers think will help produce “good” evidence on AD diagnostics?
Next step: Revision and comment cycle
Then: Dissemination
Dissemination Plan

• Target audiences

• Methods/versions
  – Target journals and other media

• Authorship considerations for possible academic or other versions
Conclusion

• Revision and comment cycle: target date?
• Final thoughts on meeting
• Questions?