Diagnostic Testing for Alzheimer's Disease

Policy Development Group Meeting

September 13, 2012

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

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

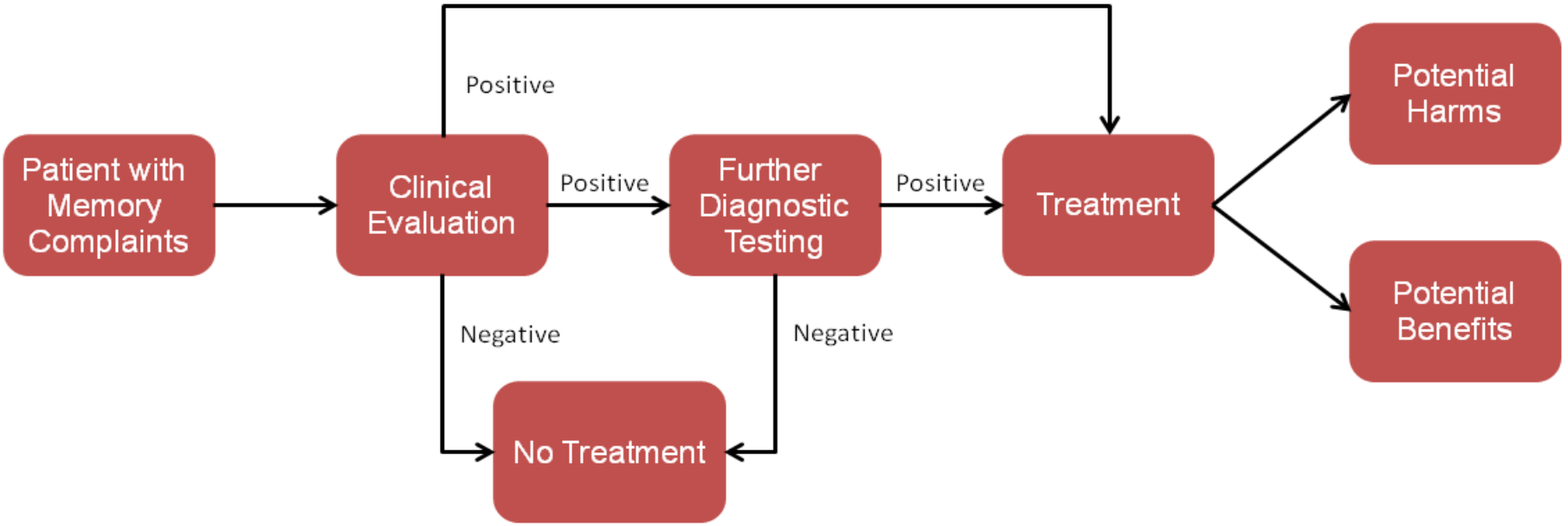
- Bring together leading representatives of clinical researchers, patients, the life science industry, and insurers to share perspectives on how best to generate the evidence needed to guide coverage determinations and the appropriate use of diagnostic tests for Alzheimer's disease
  - Describe a consistent 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



Evidence Hierarchies

Diagnostic Imaging Evidence Hierarchy Level	Genetic Testing Evidence Category	Example of Outcome Measures
1. Technical Efficacy	1. Analytic validity	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
2. Diagnostic Accuracy	2. Clinical validity	Sensitivity/specificity vs. gold standard test or vs. some other standard
3. Diagnostic Impression		Change in presumptive diagnosis following introduction of new test results
4. Diagnostic Action		Initiation or cessation of treatment; impact on use of additional diagnostic studies
5. Patient Outcomes	3. Clinical utility	Cognitive/functional decline, time to institutionalization, side effects of treatment driven by test results, mortality
6. Societal Outcomes		Cost-effectiveness of testing

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?