

Modeling in AD: An Industry Perspective

Trent McLaughlin, Ph.D.
Elan Pharmaceuticals, plc

Societal Impact of AD

- ◆ Introduction of new therapies in AD has the potential to increase drug expenditures
- ◆ Aging population = increased number of persons with / at risk for AD
- ◆ Combination = significant challenges to healthcares systems already struggling to contain costs and provide adequate care

Societal Impact of Treatment

- ◆ Delay progression to higher states of dependency (I.e. nursing home admission)
 - Potential cost savings (to whom?)
 - Policy / planning implications
- ◆ Alter the pattern of service provisions
 - Longer time at home may mean need for additional supportive social services
 - Shift from inpatient care to outpatient / day care for treatment or respite

Planning for Impact of New Therapies: Responsibilities

◆ Governments & Policy-makers:

- Direct healthcare resource use to those areas with greatest practical need.

◆ Research community:

- Educate decision makers about burden of AD
- Place role, cost, of treatment in true perspective

◆ Pharmaceutical Industry:

- Provide evidence regarding value for money of treatment using scientifically valid, ethical, methods

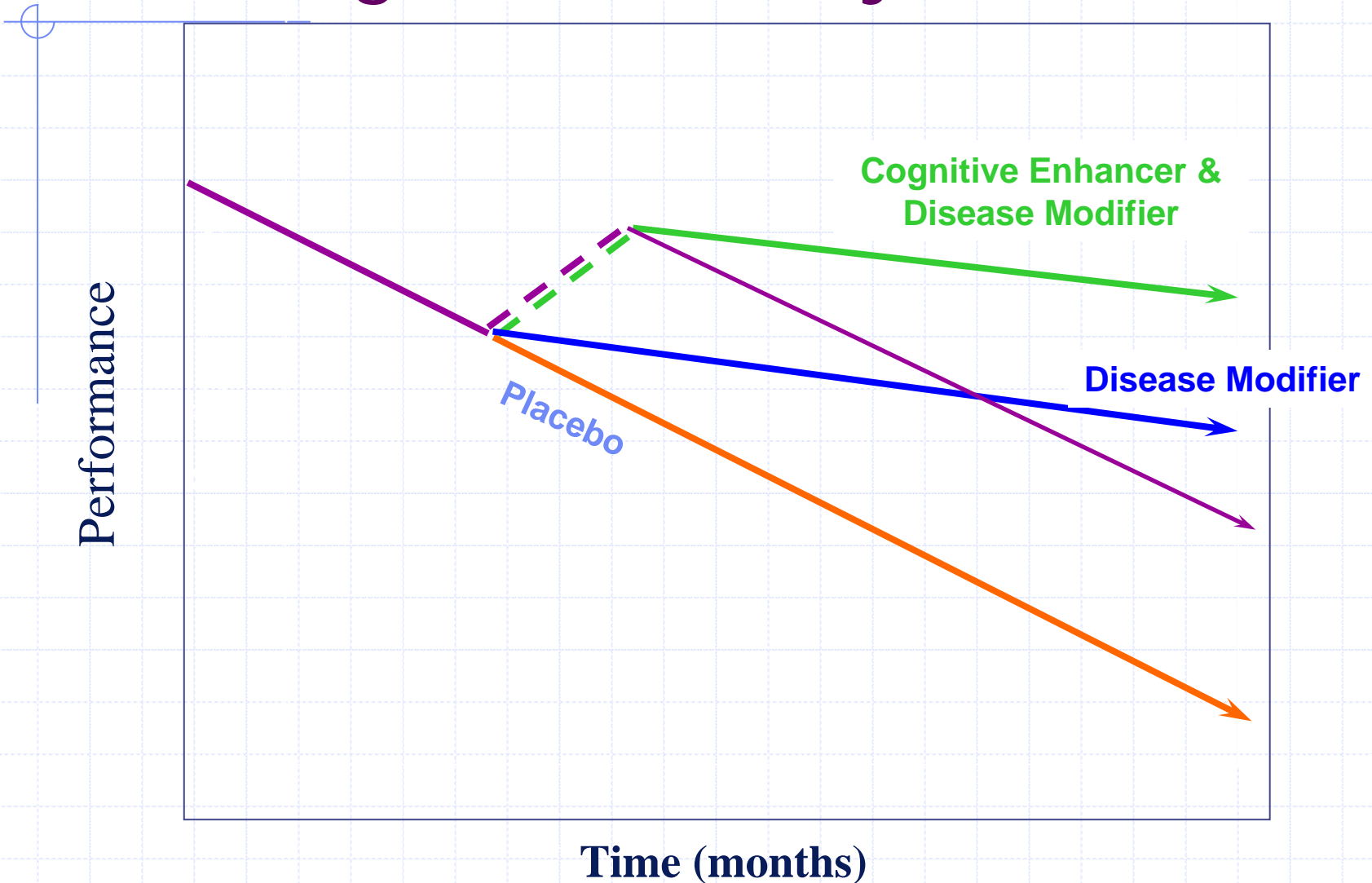
Planning for New Therapies

- ◆ Translating efficacy data to actual practice:
 - Longer time periods
 - Potentially different populations
- ◆ Collecting / Organizing information from multiple sources
 - RCT's
 - Other research
 - Literature
 - Local knowledge

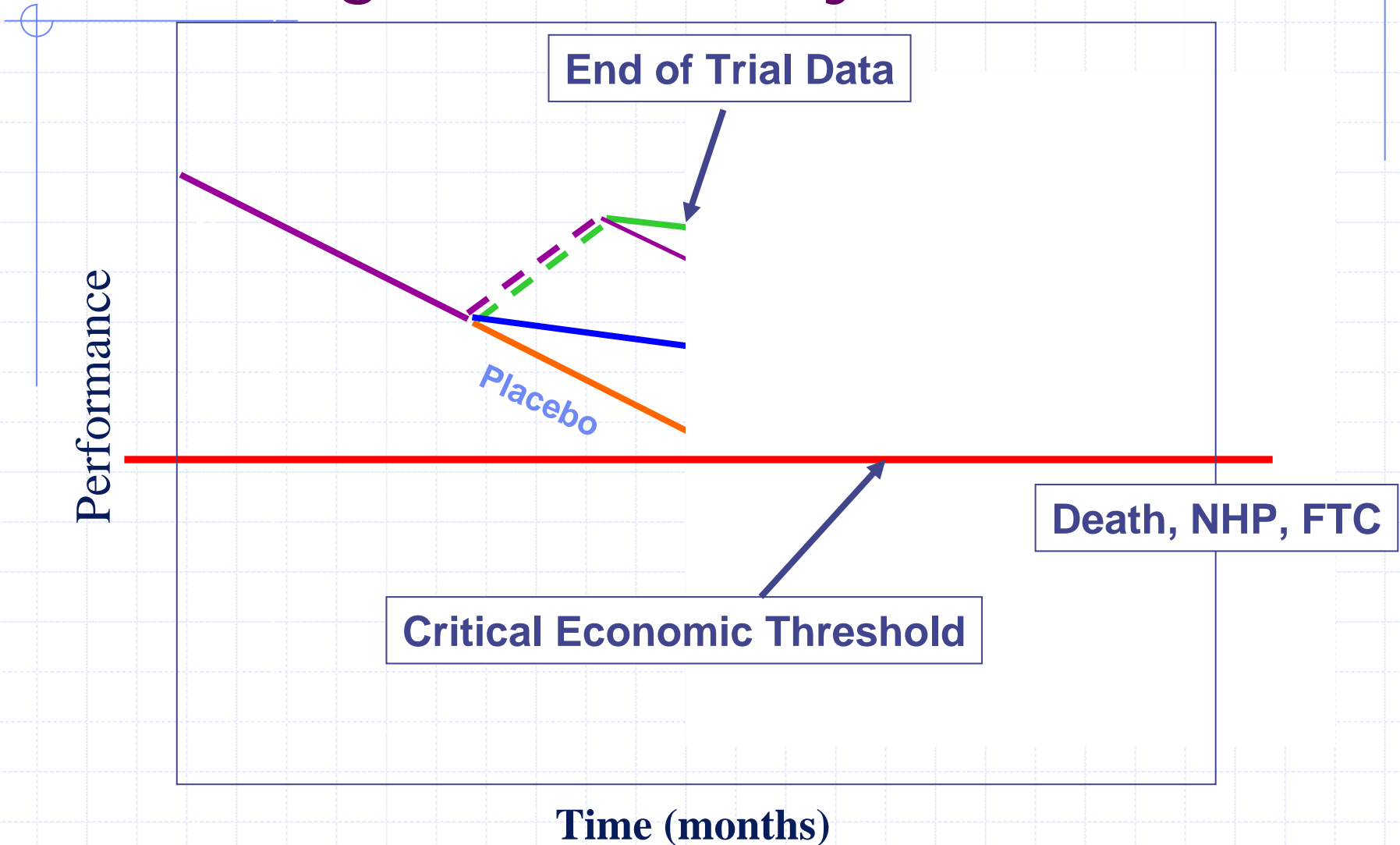
Economic Modeling in AD

- ◆ A tool to assist **a wide variety** of decision makers for evaluating the value of new treatments:
 - Absence of information on long term impacts
 - Other (non-trial) populations
 - Country / population specific resources and costs

Modeling in AD – Why?



Modeling in AD – Why?



Challenges

◆ Variety of users

- Levels of expertise
- Needs for information
- Perspectives

◆ Lack of belief in industry-sponsored models

- 'Launch' model at same time as product
- Created with minimal / no outside involvement
- Methods / Assumptions not always clear
- Outcomes often described in manner not 'relevant' to users

Requirements

- ◆ Transparency
- ◆ Realistic Representation of AD
- ◆ Flexibility / Incorporation of multiple view points, perspectives
- ◆ Adequate granularity to capture short- and long- term impacts of treatment

Transparency

◆ Face validity

- **Multiple audiences** from power users to those with minimal / no modeling expertise
- Describe disease process in terms that are relevant to decision makers, can be tied to clinical practice

◆ Transparency Standards*

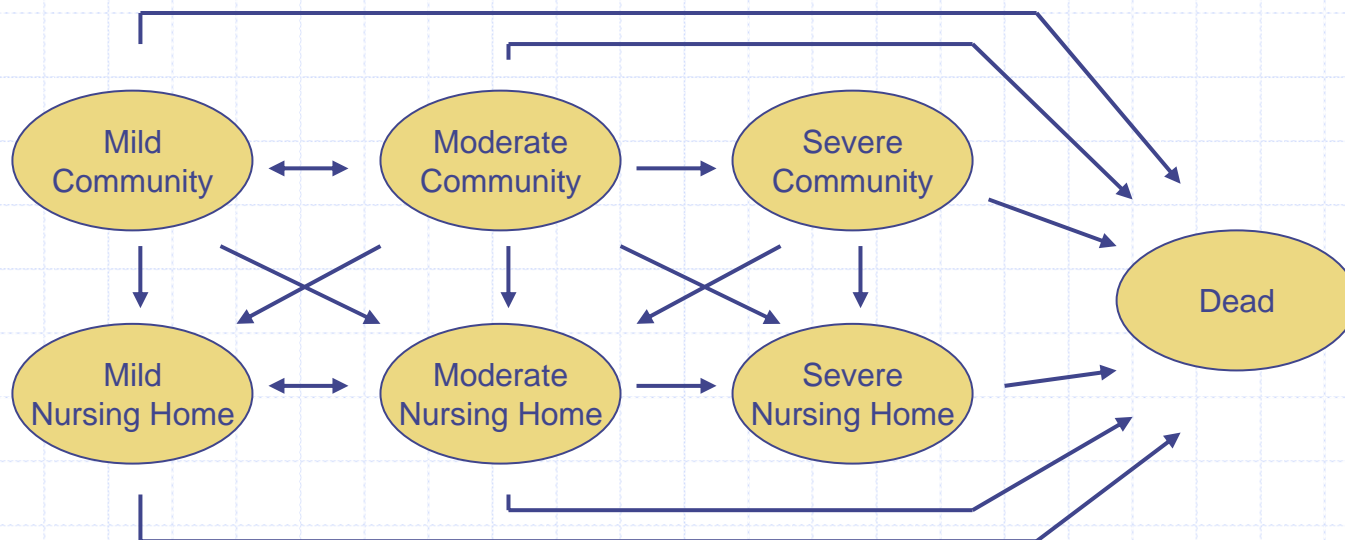
- Description of model and chance to examine algorithms
- Written documentation and training manual
- Clear description, justification of methods, data sources
- Sensitivity analyses capability in model / included in written materials

◆ Additional requirements

- Process was public, inclusive of external clinical experts
- Ability to 'lift the hood' with minimal transaction cost

Realistic Representation

- ◆ In order for decision makers to trust the results, imperative that model's representation of the disease / treatment process meshes with their expectations

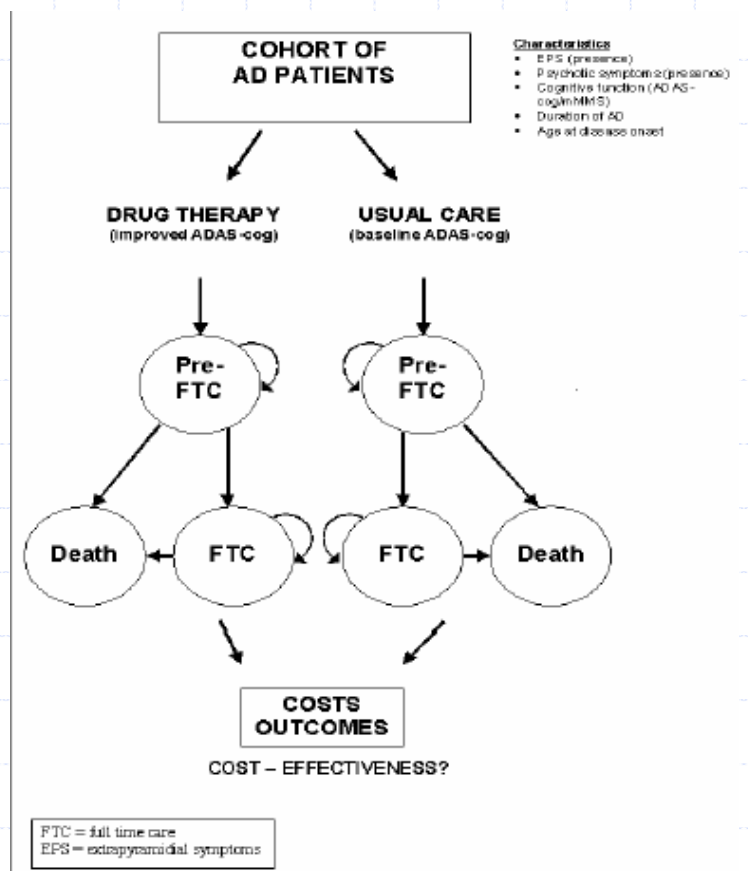


Flexibility

- ◆ Ability for model to provide answers to multiple audiences
- ◆ Incorporate impacts of different healthcare systems
- ◆ 'Easy' to make changes to inputs and see the impact of those changes in terms that are meaningful to decision makers

Granularity

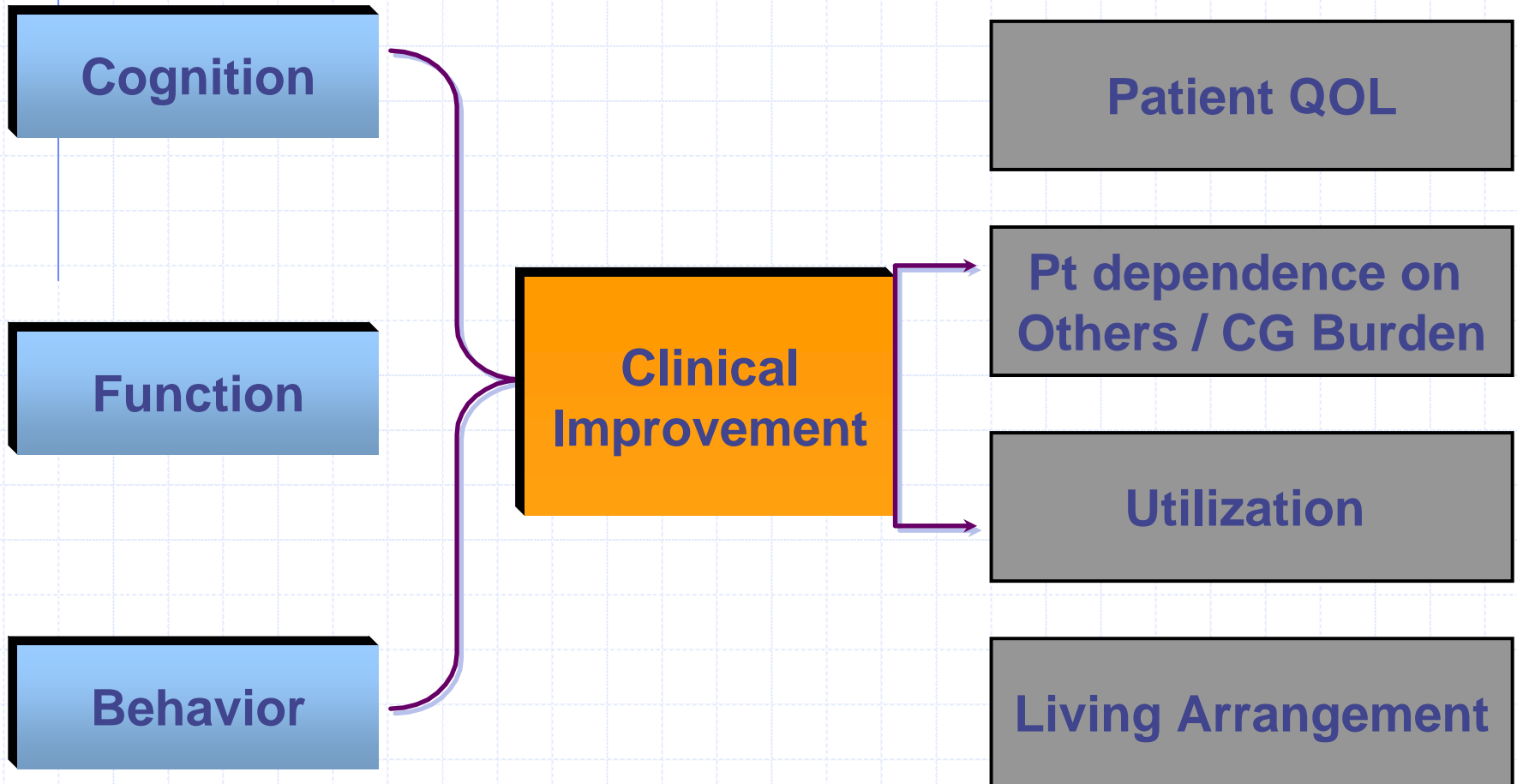
- ◆ Balance ease of use / presentation and ability to adequately describe impacts of the disease and treatment



Ward A, Caro J, et al. *Int J Geriatr Psychiatry* 2003; 18:740-747

Measuring Value of AD Treatment

- ◆ Need to **translate** data into meaningful endpoints for various perspectives (ie. payers, providers, patients)



Translating Clinical Endpoints

◆ Nursing Home Placement

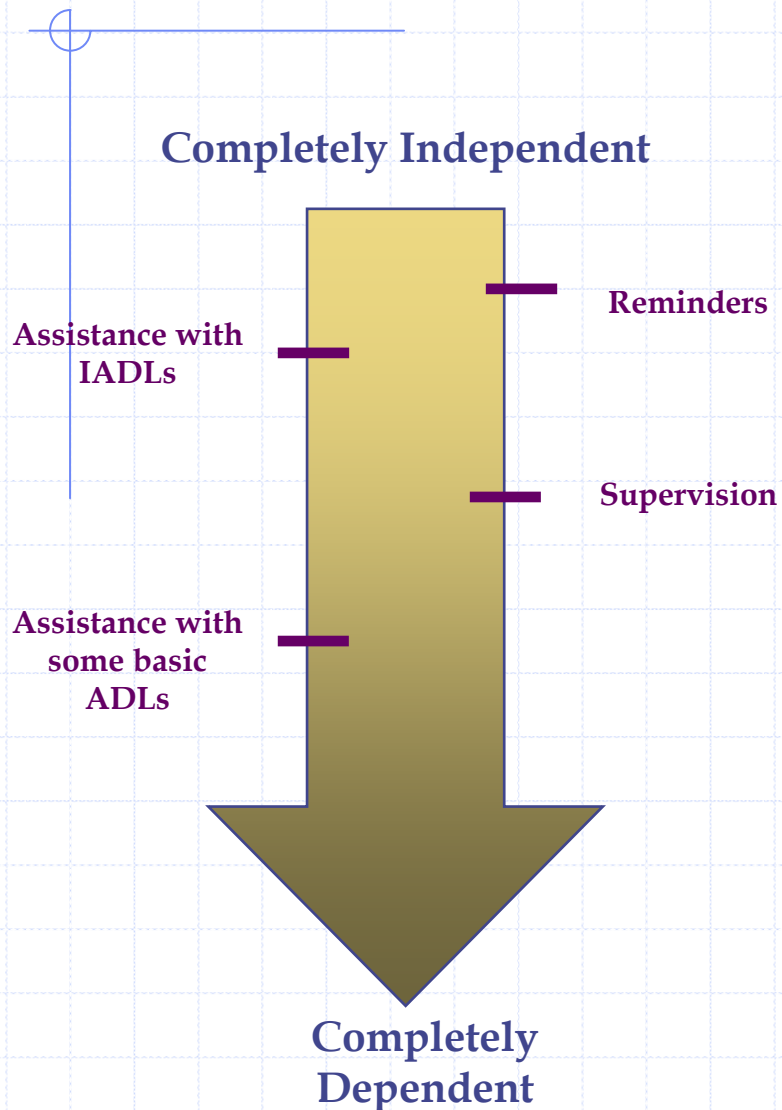
- Focus on key economic threshold – transition from home care to professional care in institution
- Transparent
- Lack of Precision
- NHP not always due to AD progression
- Not always relevant to all audiences

Translating Clinical Endpoints

◆ Reliance / Dependence on Others

- AD is associated with increasing assistance needs due to changes in
 - ◆ Cognition (memory, executive function)
 - ◆ Function (ADL loss)
 - ◆ Behavior (risk to self, others)
- Describe progression as continuum of Independent ----> Dependent

Continuum of Assistance Needs



◆ Quantify relationship between cognition, function, behavior and level of care need?

◆ Other factors?

◆ Economic impact of changing care needs?

Discussion

- ◆ Need for translating current clinical measures of AD progression, and impact of treatment, into a language that is meaningful to a broad audience.
- ◆ Different decision makers will require different information; need for transparency when sifting through data.

Discussion (continued)

◆ Previous attempts at assessing treatment value

- Focused primarily on cognition as measure of AD progression
- Translated cognitive changes into living situation (at home vs. institutionalized)

◆ Possible Future directions

- Broader measure of disease, treatment impacts
- More granularity re: short term changes, outcomes

Thank you!

