

What are the knowledge gaps in affordable care?

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Outcomes of chronic conditions: An important knowledge gap

Common conditions associated with uncommon but fearful outcomes—
two examples, ancient and recent:

- Diagnostic evaluation of headache: 12-19% consult a physician; 16 million visits vs. 10,700 new cases of brain tumor (1975) with only 1/3 having headache as an early symptom; CT, then a new technology, over utilized as r/o strategy.
(Diagnostic evaluation of headache: impact of computerized tomography and cost-effectiveness *JAMA* 1980;243;35362)
- Heartburn and Barrett's esophagus both risk factors for esophageal adenocarcinoma. 7.3 million persons have frequent symptoms with 5-15% having Barrett's. 8,000 new cases of esophageal carcinoma in 2004 of whom 40% report no history of frequent heartburn. (Incidence of adenocarcinoma among patients with Barrett's esophagus *NEJM* 2011;365 1375-83)

Common features: Population at risk for dreaded outcome is large, but absolute risk is small. Both CT and endoscopy can be effective in detecting dreaded outcome.

Gap: Knowledge through empiric observation to address issue of whether widespread use of avoidable care was occurring.

Common Conditions where there is a strong impetus to “do something”: Dementia and Alzheimer's disease

History littered with examples of drugs advanced for this purpose:

- Vasodilan (1970's), Hydergine, brain foods

Research then identified cholinergic deficit as characteristic of Alzheimer's disease

- Great hope for drug development: Analogy was to Parkinson's disease and L-dopa replacement therapy

Special efforts to find scales that would distinguish active drug effects: FDA, pharma and scientists

- One scale is ADAS-COG* and agreement that efficacy defined as "reduce rate of decline"

Clearly the public and investigators were aligned in goal to find effective treatment

*Alzheimer's Disease Assessment Scale – Cognitive subscale

Development of current treatments to 2012

From THA* to donepezil and similar agents:

- Typical study design: Open label test for responders; then enroll and randomize only responders
- Use ADAS-COG, a scale geared to detect small differences in measured cognition
- Mean differences between treatment and control not likely detectable to clinicians
- Few, if any, experience functionally significant improvement

One observation: Improvement on ADAS-COG scale for an RCT of community exercise intervention was greater than typical effects of donepezil and other widely used medications

Biology of late life dementias: AD deficits involved multiple neurotransmitters; late-life dementias, not “pure AD”, involve vascular Lewy Body and other degenerative processes.

*Tetrahydroaminoacridine

What is the gap here?

In clinical research: We aim to find a difference so we use scales based on surrogate measures (so called intermediate outcomes) or scales that are not aligned to patient-valued outcomes.

When there is an intense desire to "do something" this kind of knowledge gap will almost inevitably lead to overtreatment.

The challenge to remedy the gap:

- Balance outcomes designed to find treatment effect with assessment of patient-valued outcomes and functional measures in research.
- Develop methods to align patient values and utilities with treatments; think beyond short-term decisions for surgery and diagnostic tests to consider chronic-disease treatments, which typically end up being life-long.

Thank you.