

Getting to “Yes”

When do we know (what is the minimal threshold) when we have “just enough” evidence for a real world (read, coverage decision maker; clinical guideline committee) decision?

Bryan R. Luce, PhD, MBA

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Solving Surfing Techniques**

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Is “Getting to Yes” a VOI Problem?

Theoretically yes, but not necessarily from a manufacturers point of view and in the CER framework!

- Deft: If and only if the value of obtaining additional evidence (VOI) exceeds the cost, then more evidence should be obtained.
 - “VOI analysis evaluates the extent to which new evidence might improve expected benefits by reducing the chance for error and compares that improvement with the cost of the information”. (Claxton, Neumann, Health Affairs, 2005)

.....Why?

Take “Coverage with Evidence Development (CED)”

- The party (e.g. Medicare) who is demanding the evidence (to accrue the benefits) does not pay the price of the research.

.....Thus...

- Medicare’s “willingness to pay” (except for ethical, mission or political constraints) is, theoretically, infinite.

The CER Evidence Generation Scenario for, say, New Innovative, FDA-approved Drug/Medical Technology

- Sufficient evidence to clear FDA hurdle, but...
- Insufficient “comparative” evidence for Medicare
 - Typically, evidence is promising, not conclusive, not sufficient, not fully addressing, e.g. the “Medicare” population, so...
 - Medicare, in essence, asks for additional evidence, possibly within CED context
 - So, question to manufacturer should be “if I generate more evidence, e.g. a CER trial, at exactly what point will Medicare say: “Got it!”
- (Now, manufacturer may need to do “ROI” analysis: Anirban’s problem)
- But Medicare’s decision process is *not* VOI process.

Is “Getting to Yes” a “Satisficing” Problem?

Satisficing (a portmanteau of "satisfy" and "suffice") is a decision-making strategy which attempts to meet criteria for adequacy, rather than to identify an optimal solution. A satisficing strategy may often be (near) optimal if the costs of the decision-making process itself, such as the cost of obtaining complete information, are considered in the outcome calculus.

“Satisficing” is *Bounded Rationality*

Herbert Simon pointed out that human beings lack the cognitive resources to maximize: we usually do not know the relevant probabilities of outcomes, we can rarely evaluate all outcomes with sufficient precision, and our memories are weak and unreliable. A more realistic approach to rationality takes into account these limitations: This is called bounded rationality. Simon, H. A. (1978). *Rationality as a process and product of thought*. *American Economic Review*, 68, 1-16

*Wikipedia

Satisficing in Decision Making

Satisficing explains the tendency to select the first option that meets a given need or select the option that seems to address most needs rather than the “optimal” solution.

- Example: A task is to sew a patch onto a pair of jeans. The best needle to do the threading is a 4 inch long needle with a 3 millimeter eye. This needle is hidden in a haystack along with 1000 other needles varying in size from 1 inch to 6 inches. Satisficing claims that the first needle that can sew on the patch is the one that should be used. Spending time searching for that one specific needle in the haystack is a waste of energy and resources.

What's needed for understanding “Getting to Yes?”

- A situational & empirical approach?
- Situational due to factors e.g.
 - risk (disease, intervention)
 - available alternative therapies
 - seriousness of disease
 - expected benefit of intervention

Empirical Thought Experiment

- Build off a Bayesian meta-analysis
- Simulate new evidence generation
- Update decision-maker in “real time” until...
- A “subjective” evidence threshold is met:
aka: “Just Enough” new evidence.
(Have we “satisficed” Medicare?)

Please contribute ideas to our blog

www.PACEInitiative.org



The screenshot shows a Mozilla Firefox browser window displaying the PACE Initiative website. The browser title is "The PACE Initiative - Mozilla Firefox". The website header features the text "THE PACE INITIATIVE" in large, white, serif font, with the subtitle "PRAGMATIC APPROACHES TO COMPARATIVE EFFECTIVENESS" in a smaller, white, sans-serif font below it. A red navigation bar contains the following links: [HOME](#), [ABOUT US](#), [ANNOUNCEMENTS & ACTIVITIES](#), [RESOURCE CENTER](#), [BLOG](#), and [CONTACT US](#). The main content area has a light blue background and contains a paragraph of text about the PACE Initiative's mission. Below this is a red banner with the text "NEW DEVELOPMENTS!". Underneath the banner are three blue links: [PACE Initiative Announces Stage Two!](#), ["New Approaches to Clinical Trials: Implications for Comparative Effectiveness" National Invitational Forum scheduled for May 6, 2009](#), and [Dr. Bryan R. Luce speaks to the Institute of Medicine on the need for "true transformational clinical trial design"](#). A fourth link is also present: ["The Comparative Effectiveness Research Wave: Solving Surfing Techniques" Symposium set for ISPOR Annual Meeting in Orlando, FL, on May 18, 2009](#). The footer of the website is a dark blue bar with the text "© 2009 United BioSource Corporation, Inc."

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THE PACE INITIATIVE

PRAGMATIC APPROACHES TO COMPARATIVE EFFECTIVENESS

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The PACE Initiative was launched by the United BioSource Corporation (UBC) in January 2008. The focus of this collaborative effort is to improve the practicality and efficiency of comparative clinical studies to address mounting "real-world" evidentiary demands by payers, clinicians, and policy makers. It was created in the belief that whereas the comparative effectiveness national agenda must include comparative and pragmatic trials, traditional approaches to designing and conducting such trials are too costly, take too much time and are commonly not answering real world needs. PACE investigators are exploring the challenges and opportunities, in particular, of Bayesian and adaptive trial techniques as applied to real world comparative effectiveness applications.

Use the links above to learn more about the PACE Initiative, become a "Friend of PACE," or join in the PACE Blog conversations.

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