The Ethical Dimensions of Outcome Research

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Issue #1. The **Cultural Assumptions** that Make Outcome Studies Possible

Three Traditional/Historical Assumptions That Inform Contemporary Western Science

- There exists a material “substrate” or lots of substrates (depending on your theory level—subatomic, atomic, molecular, cellular, organ, systemic, etc.) that account for or explain diseases, illness, pain, etc.; “physical-materialist reductionism”
- These material substrates can be observed, measured and known—especially in terms of how they react with one another
- That these substrates and their molecular interactions follow law-like regulatory patterns that are essentially the same from person to person, so that what is discovered in research with relatively small populations can be generalized to many others

Challenges these Assumptions Present

- But even if we accept “material reductionism,” it can be maddeningly difficult to know which of the involved “materialisms” or their synergies account for the phenomena being studied, e.g., protein interactions at the gene level, neural networks, etc.
- Other causal/metaphysical factors might be present that affect that affect interactions but that are not explained very well by contemporary western models, e.g., emergent properties, “dark matter,” other dimensions (string theory), etc.
- Human response to drugs and interventions can vary enormously, e.g., opioids, psychotropics, etc. What works in one person or population can be quite ineffective in another.
Suppose, though, that a culture didn’t entertain the belief in materialistic-reductionism as we do in the West. Then what?

Point: The West’s penchant for outcomes studies derives from and is made possible by the metaphysical beliefs and commitments of our culture. Not all cultures share these explanatory models, and so not all of them would resonate with our take on outcomes.

Issue #2: The Ethical Dimensions of Prognostic Outcome Studies
Example

Results from somatosensory evoked potential testing could predict the likelihood of nonawakening from coma with a very high level of certainty. Adults in coma from hypoxic-ischemic encephalopathy and with absent somatosensory evoked potential responses have less than a 1 percent chance of awakening. (Robinson, et al., *Critical Care Medicine*, March 2003.)

So, now what?

- Do we continue to care for such persons?
- Is a less than 1 percent but more than 0 percent chance of awakening from coma good enough to encourage aggressive treatment? (This is a very common problem presenting to hospital ethics committees, where patients are "probably" terminal.)
- Is living a life in coma or a persistent vegetative state a life worth living?

Point: Many outcome studies that have considerable prognostic value will only stir the ethical debate. We will not view these kinds of outcome studies in a moral vacuum.

Issue #3: How should we allocate treatments in a time of limited resources? What is the most rational way to spend insurance dollars? Which outcomes are the important ones to secure?
Examples

- Reimburse Viagra but not birth control pills
- Reimburse hospital stays for diabetic coma but not insulin supplies
- Poor funding for behavioral health and cognitive functioning in contrast to physical functioning
- Preserving life with little quality versus allocating dollars for better nutrition and other preventive services

In fact, all treatment decisions bearing on outcomes look to values

- How desirable is the outcome we are seeking? (Superior erections, longer life, neuroenhancement!!!!)
- How likely is it that the intervention will result in achieving the desired outcome and with what degree of success? (e.g., an 80 percent likelihood of a 50 percent decrease in your current pain: genetic profiling/predictive health/risk assessment)
- How much is this going to cost?
- How long will the outcome last or endure?

Issue #4: What outcome measures and methodological designs to use?

Lots of Outcome Measures

- QOL and Patient satisfaction measures
- Mortality
- Expenditures
- QALYs
- Employability/Return to work
- LOS
- FIMs

All these measures look to a certain life condition or situation and so each one reveals a particular value. And not only that....
Your Research Methodology Might Be Biased or Questionable

• Ask too narrow a question (mortality v. QOL)
• Administer a low dose of the control drug
• Always use a placebo as the control
• Invent your own scale (e.g., omit side-effects)
• “First shoot the arrow, then draw the target”
• “Creative” statistics, e.g., not stating confidence interval

Issue #5: On a macro level, which outcomes do we finally decide we want when we can’t have them all?
Point: On the deepest of levels, “outcomes” speak directly to what we value most. And because we do not have a universally adopted template of values in the United States, our disagreements about “outcomes” will be determined democratically with an eye to our economic resources.

Issue #6: Outcome as Evidence Based or Hype?

Huge EVB Practice Problem in Rehabilitation
- Tremendous difficulty in controlling variables that might affect outcome, e.g., severity/type/location of injury, educational level, age, family support, coping mechanisms, financial resources, etc.
- Methodologically weak studies are the norm in rehabilitation
- Controlling for the “dynamic interplay” of therapist and client (John Whyte)

The Allure of Hype: Bobath
- “The most popular treatment approach in stroke rehabilitation.” (Kollen et al 2009)
- Two meta-analyses of Bobath outcomes research over 40 years found no evidence that Bobath was superior to any other approaches
Implications

- Rehabilitation curriculum needs to teach students to become knowledgeable about and pay keen attention to the methodology and design of outcome studies
- Disseminators of rehabilitation “knowledge” need to relate their findings as objectively as possible
- Critical forums—through professional organizations, at national conferences, at training programs—need to be formally established to maintain evidential soundness and credibility for rehabilitation outcome studies
What to learn from this?

- Placebo? Take seriously!
- “Relational” healing? Suspicion or frustration with 20th century Western medicine? Why?
- Better public relations among “metaphysical healers”?

Issue #8: Provability in General

The Decline Effect

(Jonah Lehrer, The New Yorker, December 13, 2010)

- In 1991, Danish zoologist Anders Moller discovers that female barn swallows are more likely to mate with males who have long symmetrical feathers, suggesting that symmetry might be a proxy for genetic fitness.
- Over the next 3 years, 9 out of 10 studies on sexual selection and symmetry confirm the finding.

In fact, other findings during 91 - 94

- Women prefer the smell of symmetrical men, but only during their fertile phase during the month.
- Women had more orgasms with symmetrical men.
- Symmetrical men are consistently rated better dancers in Jamaican dance routines.
But in 1994 that started to change

- In 1994, 8 of 14 publications on sexual selection and symmetry confirm the finding
- 1995: 4 of 8 studies confirm the finding
- 1998: 4 of 12 studies confirm the finding
- Later: Questions over PSA testing; 2nd generation antipsychotics; hormone replacement therapy in women

So, why is that?

- Publication bias: Positive results are attractive, leading to selective reporting
- Subtle omissions and unconscious misperceptions might be more common than we think, e.g., ACCUPUNCTURE
  - 47 studies between 1966 and 1995 in China, Taiwan, and Japan: All confirmed acupuncture's therapeutic effectiveness
  - 94 studies in U.S., Sweden and UK during that period: 56% found therapeutic benefit
- Motivated reasoning: If you want something to be true, you'll find a way to prove it!

Might it be?????

- Sheer randomness exists and is caused by invisible variables we don't understand?
- Consider the sheer difficulty of proving anything: Just because an idea is true doesn't mean it's provable; and just because an idea is provable doesn't mean it's true.

Nevertheless, let us hope………..

- That outcome studies from Western scientists will maintain an objective platform by which they are discussed and disseminated;
- That purchasers will be knowledgeable about what these studies say;
- That clinical and scientific discussions of outcomes will not deteriorate to the intellectual level of our political talk shows;
- Rehabilitationists will be able to demonstrate their outcome claims with as much compelling and persuasive data that are available—assuming such exists anywhere!